PEER REVIEW REPORT ON **CAPTAN** 21.03.2006

TABLE OF CONTENTS

	Document	**File Name**
00	Cover page	00 captancover.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

List of all reports from EPCO Expert Meetings

Date	Name	Section
11 - 14.04.2005	EPCO Expert Meeting 21	Environmental Fate and Behaviour
11 - 15.04.2005	EPCO Expert Meeting 22	Ecotoxicology
10 - 13.05.2005	EPCO Expert Meeting 23	Mammalian Toxicology
11 - 13.05.2005	EPCO Expert Meeting 24	Residues
24 - 26.05.2005	EPCO Expert Meeting 25	Physical and Chemical Properties
10 – 13.12.2007	PRAPeR Expert Meeting 39	Mammailian Toxicology
12 – 13.12.2007	PRAPeR Expert Meeting 40	Residues
08 – 11.04.2008	PRAPeR Expert Meeting 44	Mammalian Toxicology
11 – 11.04.2008	PRAPeR Expert Meeting 45	Residues

REPORT OF EPCO EXPERT MEETING 21

CAPTAN

Rapporteur Member State: Italy

Specific comments on the active substance in the section

4. Environmental Fate and Behaviour

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	**Supplier**	**File Name**
29 October 2004	Germany	Captan com01 DE

2. Documents submitted for meeting:

Date	**Supplier**	**File Name**
15 October 2004	RMS/Italy	Captan consultation report
17 January 2005	RMS/Italy	Captan reporting table rev1-3
January 2005	RMS/Italy	Captan addendum vol3 B8 (numbering of open points corrected)
17 March 2005	RMS/Italy	Captan list of end points
17 March 2005	RMS/Italy	Captan evaluation table rev0-1 (numbering of open points corrected)

3. Documents tabled at the meeting:

Date	**Supplier**	**File Name**
06 April 2005	RMS/Italy	Captan summary of representative uses

The conclusions of the meeting were as follows:

4. **Data on preparations:** Merpan 80WDG, Malvin WDG.

5. **Classification and labelling:** R53.

6. **Recommended restrictions/conditions for use:** None at the stage.

7. **Reference List**

Areas of concern: Groundwater contamination by metabolites

Appendix 1: EPCO discussion table: CAPTAN

Appendix 2: Evaluation table

Appendix 1: Discussion Table, CAPTAN (Fu)

4. Environmental Fate and Behaviour

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 4.1: RMS to update list of end points with respect to PEC gw. (see reporting table 4(2))	The RMS expert gave a brief introduction on the active substance and stated that the list of endpoints was amended. It was deemed appropriate to include the names of the respective FOCUS scenarios.	Open point fulfilled. The experts agreed to set a new open point (see new open point 4.21): RMS to amend list of endpoints and include names of FOCUS scenarios.
	Open point 4.2: RMS to amend the list of end points. For PEC soil method of calculation it is sufficient to indicate that first order kinetic was assumed. (see reporting table 4(5)9	RMS stated that the list of endpoints was amended accordingly. The meeting annotated an inconsistency between the sections PECsoil (method of calculation) and route of degradation in soil (major metabolites) concerning the DT50 of metabolite THPAM. See new open point 4.19	Open point fulfilled. The experts agreed to set a new open point 4.19: RMS to clarify the inconsistency in the list of endpoints between sections PECsoil and route of degradation concerning the DT50 of metabolite THPAM.
	New open point: 4.19: RMS to clarify the inconsistency in the list of endpoints between sections PECsoil and route of degradation concerning the DT50 of metabolite THPAM.	This open point was proposed at EPCO 21.	Open point still open.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 4.3: RMS to amend the list of end points to include individual values of DT_{50} with the mean. (see reporting table 4(7))	The RMS stated that this was done. Additionally, the meeting asked to include the individual values in the list of endpoints as the THPAM degradation is pH-dependent. Also the means should be removed because only three single values are available.	Open point fulfilled. The experts agreed to set a new open point (see open point 4.21): RMS to amend the list of end points, to include the individual values as the THPAM degradation is pH-dependent and also to remove the means.
	Open point 4.4: RMS to amend list of end points to include individual values for sorption Koc together with the mean and to clearly indicate the pH dependence on the adsorption of THPAM. (see reporting table 4(8))	Individual values are not given but the range. Individual values should be included in the list of end points. EFSA expert suggested to additionally remove the mean K_{oc} for THPAM as it is confusing as there is dependence with pH. The meeting agreed on this proposal.	Open point fulfilled. The experts agreed to set a new open point (see open point 4.21): RMS to amend the list of end points to add individual Koc values and to remove the mean K_{oc}.
	Open point 4.5: PEC sed for THPI should be included in the list of end points. (see reporting table 4(9))	RMS stated that this was done. However PEC sed should be calculated with a sediment density of 1.3 g / mL (see data requirement 4.14.	Open point fulfilled.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 4.6: RMS to report main hydrolysis products in the end points list. (see reporting table 4(13))	RMS stated that this was done. Additionally, the meeting asked to include the percentages of formation for the hydrolysis products in the list of endpoints	Open point fulfilled The experts agreed to set a new open point (see new open point 4.21): RMS to include percentages of formation of the main hydrolysis products in the list of endpoints.
	Open point 4.7: RMS to report the max. amounts of metabolites in water and in sediment and DT_{50} if available. (see reporting table 4(14))	RMS stated that this was done. Additionally, the meeting asked to also include available DT50 for metabolites in the water phase and the total system.	Open point fulfilled. The experts agreed to set a new open point (see new open point 4.21): RMS to amend the list of end points and to include available DT50 of the metabolites for the water phase and the total system.
	Open point 4.8: RMS to include input parameters of the FOCUS PEC gw calculations in the end points list. (see reporting table 4(15))	RMS stated that this was done.	Open point fulfilled.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
4.1	Two new laboratory aerobic soil degradation studies. These studies should cover the ranges of pH 4.5 to 5 and pH 8. Metabolites THCY and THPAI should be addressed as well with separate studies if necessary. (see reporting table 4(16))	The RMS expert reported, that captan degrades very rapidly in soil. No problem is seen with a possible pH dependency of degradation rate. Additionally it was stated that the metabolite THCY occurs only under anaerobic conditions and is therefore not considered relevant for the representative uses proposed. The meeting discussed this data requirement also in connexion with data requirements 4.2, 4.3 and 4.4. The meeting followed the proposal of the RMS, taking into account the reported data on degradation, to agree that the available data are sufficient to characterise the fate of the active substance in soil. The RMS was asked to add the percentage of metabolites formed under aerobic conditions to the list of endpoints. In addition, the results of the anaerobic soil degradation study (formation of metabolites, DT50) should be included in the endpoint list.	Data requirement fulfilled. The experts agreed to set a new open point (see open point 4.21): RMS to include in the list of end points the percentage of metabolites formed under aerobic conditions as well as the results of the anaerobic soil degradation study (formation of metabolites, DT50).
4.2	Adequate kinetic analysis of degradation data should be provided for the soil degradation studies (kinetic model employed, goodness of fitting). (see reporting table 4(16))	The meeting agreed to the data presented by the RMS in the addendum and with the conclusions that were drawn.	Data requirement fulfilled.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
4.3	Relevance of field USA study with respect to EU conditions should be assessed. (see reporting table 4(16))	The RMS expert explained the arguments of the notifier with regard to the representativity of the US study sites for the European evaluation. It was noted that field studies are not triggered due to the rapid degradation of the active substance. The RMS accepted the proposal of the notifier to use the worst case DT50f obtained at Waterloo, New York for the calculation of PEC soil. The conditions at this site correspond to northern European conditions and therefore this approach is considered conservative. It was noted that no field data is available for locations corresponding to central European conditions but the meeting agreed on the approach proposed by the RMS.	Data requirement fulfilled.
4.4	DT_{50} values estimated in the laboratory studies for the metabolites THPI and THPAM using first order kinetics should be provided for modelling purposes. (see reporting table 4(21))	The meeting agreed that this data requirement is covered by the discussion on data requirement 4.2.	Data requirement fulfilled. See also data requirement 4.2
4.5	Notifier to provide clarification on deviations of the anaerobic degradation studies(Lay (1992) and Pack et al. (1988b)). (see reporting table 4(28))	The original comment of one Member State challenged the acceptability of the studies. The RMS expert stated that they did not evaluate the quality of the study again as anaerobic degradation studies are considered not relevant for the risk assessment. Also no new information was submitted by notifier. The discussion on this data requirement is also related to open point 4.9. The meeting agreed that anaerobic conditions are not relevant for the assessment of the representative uses proposed for captan.	Data requirement fulfilled. See also open point 4.9.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 4.9: RMS to assess if the anaerobic degradation studies (Lay (1992) and Pack et al. (1988b) are acceptable and essential for the risk assessment. If anaerobic studies are finally considered not acceptable and not essential this information should be removed from the end points list. (see reporting table 4(28) and 4(29)	The RMS concluded that the studies are not essential for risk assessment and that at least for one of the anaerobic soil degradation study the data are acceptable. The meeting agreed on this proposal and decided that the data for anaerobic degradation should be included in list of endpoints. This open point also refers to data requirement 4.5	Open point fulfilled. The experts agreed to set a new open point (see open point 4.21): RMS to amend the list of end points and include data on anaerobic degradation. See also data requirement 4.5
4.6	Literature data and references to support Captan Koc must be provided and assessed. (see reporting table 4(41))	The RMS has presented the data in the addendum. The meeting accepts the data but data from scientific literature but data referred to as personal communication will be neglected. A new open point is proposed to amend the list of end points to include new data provided. It was noted that the mean Koc obtained form literature data (Koc = 110.66 mL / g) is lower and worst case than the value used for FOCUS gw modelling (Koc = 200 mL / g). See data requirement 4.15.	Data requirement fulfilled. Mean Koc = 110.66 mL / g from literature data (see D.R 4.15) The experts agreed to set a new open point 4.20: RMS to amend the list of end points with regard to K_{OC} values for captan. The selected values from open literature should not comprise data from personal communications.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	New open point 4.20: RMS to amend the list of end points with regard to K_{OC} values for captan. The selected values from open literature should not comprise data from personal communications.	This open point results from data requirement 4.6 and was proposed at EPCO 21.	Open point still open.
	Open point 4.10: RMS to consider relevance of leaching studies with respect to soil degradation. Also to consider if a reliable Koc may be obtained from column leaching studies. (see reporting table 4(46))	The RMS stated that the notifier had submitted a new evaluation of the degradation studies performed with captan. It is suggested that the degradation data obtained from the aged residue column leaching study should be considered atypical rather than the data from soil degradation studies. The meeting concluded that in this case the literature dat may be accepted due to the rapid degradation. However, it was noted that determination of adsorption constants from leaching studies might be an appropriate way to derive K_{OC} values for rather unstable substances. The open point is also related to data requirement 4.6.	Open point fulfilled.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 4.11: RMS to clarify on the information available on the degradation of anaerobic metabolite THCY under aerobic conditions. (see reporting table 4(30) and 4(48))	The meeting discussed the issue of the relevance of anaerobic degradation under data requirement 4.5 and open point 4.9. It was agreed that aerobic data for metabolite THCY from the study Pack, 1979 should be included in the list of endpoints.	Open point fulfilled. The experts agreed to set a new open point (see open point 4.21): RMS to amend the list of end points. Aerobic data (Pack 1979) for anaerobic metabolite THCY should be included in the list of endpoints.
	Open point 4.12: RMS to clarify which DT_{50} are relevant for the risk assessment of metabolite THPI. (see reporting table 4(49))	The meeting agreed that this open point was covered by the data requirements 4.2 and 4.4. and that the RMS has chosen appropriate DT50 from new evaluated data.	Open point fulfilled.
4.7	Report Verharr, H.J.M. (1999) “Relevance and leaching behaviour of THPI and THPAM, two degradation products of captan” must be provided and assessed by the RMS in an addendum. (see reporting table 4(50))	The RMS agreed with the notifier that this report is no longer relevant for the risk assessment as a new evaluation has been submitted. The meeting took note and affirmed that the leaching behaviour of the metabolites must be addressed anyway (see data requirement 4.15).	Data requirement fulfilled.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
4.8	New PEC soil with worst case field DT_{50} should be calculated in the lack of more reliable data (see data requirements 4.1, 4.2 and 4.3 (in comment 4(16) of the reporting table)). (see reporting table 4(55))	The RMS has reported new PEC soil calculations in the addendum on page 27 and 28. The PEC calculation was based on worst case field DT50 for the active substance and on laboratory data for the metabolites which was adjusted to 15 °C. The list of endpoints has been amended accordingly. The discussion on this data requirement is related to data requirement 4.3. The meeting agreed to the calculation presented by the RMS.	Data requirement fulfilled.
4.9	New initial PEC sw, taking into account multiple applications must be provided for metabolites THPI and THPAM. (see reporting table 4(60))	The RMS stated that a new report was submitted by the notifier. New PECsw and PECsed have been calculated and the list of endpoints has been updated accordingly. The data are presented in the addendum. The meeting discussed the DT50 values used for the PEC calculation. The RMS expert explained that the value of 17.8 d for the water phase was used representing the worst case derived from an assumed DT90 of 59 d as there were no residues detectable after 59 d of study duration for both metabolites (Tab.8.6.24 in the addendum). The experts agreed on this approach and concluded that the data requirement was fulfilled. The RMS is asked to include an explanation with regard to the derivation of the DT50 values for the metabolites in the list of endpoints. This data requirement is also related to the data requirements 4.13, 4.14 and 4.16.	Data requirement fulfilled. The experts agreed to set a new open point (see open point 4.21): RMS to include an explanation with regard to the derivation of the DT50 values for the metabolites in water used for PEC_{SW} calculations in the list of endpoints.
4.10	Notifier to calculate the hydrolysis rate from the ring labelled captan (Lee, K.S. 1989b.) (see reporting table 4(62))	RMS stated that the values are reported in the addendum and were included in list of endpoints.	Data requirement fulfilled.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
4.11	Hydrolysis of metabolites THPI, THPC and THPAM should be provided according EEC guidelines. Metabolites should be reported. (see reporting table 4(64))	The RMS accepted the argument of the notifier that the studies with the main hydrolysis products THPI and THPAM are valid although they were conducted at elevated temperatures. With regard to THPC a new kinetic analysis of the hydrolysis study conducted with the active substance was provided which shows the transient nature of this degradation product. The RMS concluded that sufficient information concerning the hydrolysis products is available. The meeting followed the conclusion of the RMS and agreed on the derivation of DT50 values for THPI and THPAM at 25 °C from studies performed at higher temperatures by extrapolation with the Arrhenius equation.	Data requirement fulfilled.
4.12	Nofitier to provide readily biodegradability test. (see reporting table 4(66))	The RMS expert explained that new data have not been provided. The active substance will rapidly degrade by hydrolysis anyway. After a discussion the meeting agreed that it can not be concluded from the hydrolysis data that mineralisation will occur comparably rapid. The experts, however, came to the conclusion that a study on ready biodegradability is not deemed essential and therefore the data requirement was removed. The active substance should be regarded as not readily biodegradable unless proven by an appropriate study.	Data requirement not fulfilled Data requirement removed. The active substance should be regarded as not readily biodegradable.
4.13	Notifier to provide calculation of DT_{50} value of the metabolite THPI in the water sediment system. (see reporting table 4(69))	Data provided by the notifier shows that in one water/sediment system the decline of THPI could be analysed and a DT50 of 4.8 d could be derived. The RMS has accepted this new evaluation. The experts agreed; the derivation of reasonable worst case estimates for DT50 of metabolites was already discussed with data requirement 4.9.	Data requirement fulfilled.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point ~~4.12~~ 4.18: Due to the lack of water sediment study at alkaline pH, a worst case assessment may be performed for alkaline conditions using results of hydrolysis study to make the risk assessment for surface water contamination by metabolite THPC. (see reporting table 4(70)) (Numbering of open point has been corrected. Reference in addendum vol3 B8 has also been amended accordingly)	The meeting agreed that this was already discussed in the context of data requirement 4.11. Due to the fact that in the water sediment study the water phase is alkaline and to the transient nature of THPC shown in the hydrolysis study the experts concluded that this degradation product will not significantly contribute to the residue in surface water and therefore this open point can be considered as fulfilled.	Open point fulfilled.
4.14	PEC sed for metabolites THPI and THPAI must be provided. (see reporting table 4(78))	The RMS stated that the data for THPI have been provided and were evaluated (cf. data requirement 4.9) but the data for PECsed for THPAI are still missing. The RMS expert explained that THPAI may have been formed from THPAM during exhaustive extraction as an artefact. The meeting concluded that the data requirement with regard to THPAI is not fulfilled and agreed that PEC sediment should be recalculated with a density of 1.3 g/ml.	Data requirement still open, a data gap identified. PEC values for THPAI to be provided and PEC sediment to be recalculated with density of 1.3 g/mL.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 4.13: RMS to assess relevance of ground water metabolite THPAM if enough data available or identify data gaps. (see reporting table 4(79))	This open point is covered by the discussion on data requirement 4.15.	Open point covered by data requirement 4.15.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
4.15	Notifier to provide new PEC GW modelling consistent with GAPs and reliable input parameters. Metabolites should be assessed according SANCO/221/2000-rev 10. (see reporting table 4(80))	The discussion on this data requirement also covers the open points 4.13 and 4.14. The new PEC_{GW} calculations provided by the notifier have been presented in the addendum. The meeting discussed the input parameters for the modelling. With regard to the DT50 of the active substance it was noted that laboratory data have been used for the calculation. In the field studies, which were not triggered due to rapid degradation but were submitted supporting the laboratory data, the DT50 were higher than in the laboratory studies. The experts concluded that the use of field data would not change significantly the results for the active substance. Regarding the metabolites a worst case situation is covered by assuming rapid degradation of the active substance. Considering the K_{OC} assumed for captan the experts referred to the discussion on data requirement 4.6 where it was agreed not to include the values referred to as personal communication in the average (Mean Koc = 110.66 mL / g from literature data). However experts agreed that the results for the active substance will not change with respect to the calculated with Koc = 200 mL /g. Due to the pH dependency of the sorption of metabolite THPAM and the fact that K_{OC} values are available only for rather acidic and alkaline soils the notifier proposed to interpolate the K_{OC} of THPAM from a correlation of measured K_{OC} versus soil pH. By this means input data fitting to the pH value of the soil in the respective FOCUS scenario could be derived. The experts agreed to accept this approach although it is not exactly in accordance with the FOCUS guidance. It was noted that a similar approach has also been discussed and accepted in EPCO 16 expert meeting. The experts agreed that the correlation K_{OC} versus pH should be added in the list of endpoints. It was noted that, in particular for the northern European use in pome fruit, the PEC_{GW} for the metabolites exceed 0.1 µg/l. It is stated in the addendum that the fungicidal activity of the metabolites has been verified. The meeting concluded that this is not sufficient to address the possible relevance of these metabolites. Toxicological and ecotoxicological relevance have to assessed, at least considering the northern European use. It should be noted that for this use PEC_{GW} of the metabolites (THPI and THPAM) exceed the threshold of 0.75 µg/l.	Data requirement fulfilled. Relevance of metabolites in groundwater THPI and THPAM should be addressed by ecotox and toxiclogy meetings. It should be noted that for this use PEC_{GW} of the metabolites (THPI and THPAM) exceed the threshold of 0.75 µg/l.. The experts agreed to set a new open point (see open point 4.21): RMS to amend the list of end points and include correlation K_{OC} versus pH for metabolite THPAM.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Message from EPCO 21 to EPCO 22 and EPCO 23 Relevance of metabolites in groundwater THPI and THPAM should be addressed by ecotox and toxiclogy meetings. It should be noted that for this use PEC_{GW} of the metabolites (THPI and THPAM) exceed the threshold of 0.75 µg/l.		
	Open point 4.14: RMS to prepare new addendum with new information of potential groundwater contamination. (see reporting table 4(80))	This open point is covered by the discussion on data requirement 4.15.	Data requirement fulfilled. See open point 4.13

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 4.15: RMS to revise the residue definition in ground water. Monitoring analytical methods will need to be provided for the new metabolites if they will be added to the residue defintion. (see reporting table 4(81))	The RMS had accepted the proposal of the notifier to consider only captan in the residue definition. The experts agreed that the active substance should be included in the residue definition by default although it is not expected to occur due to very rapid degradation. With regard to the metabolites the possible relevance is not yet sufficiently assessed. The meeting agreed to include the metabolites THPI and THPAM in the residue definition pending further assessment. Residue analytical methods should be available for these metabolites.	Open point still open. The experts agreed to set a new open point (see open point 4.21): RMS to include metabolites THPI and THPAM in the residue definition for groundwater in the list of endpoints.
4.16	PEC FOCUS sw taking into account run off and drainage must be provided. Input parameters should be clearly justified. (see reporting table 4(82))	This data requirement is related to data requirement 4.9. The RMS had accepted the new PEC_{SW} calculation submitted by the notifier taking into account only the entry via spray drift. The meeting discussed the relevance of entry pathways into surface waters. It was noted that, in this case, addressing run-off and drainage needs not necessarily be done by calculations according to FOCUS. The experts also saw problems regarding the consistency in handling different active substances. The experts concluded that with regard to drainage the situation may be very different in the MS. At least for the northern European use scenarios entry into surface water via drainage may not be excluded. It was noted that entry via drainage may be particularly relevant for the metabolites which are mobile in soil. In conclusion, the meeting agreed that the data requirement may be considered as fulfilled for southern European uses. For northern European use scenariosa proper assessment will be necessary to address possible entry routes other than spray drift. It was noted that the list of endpoints only contains the PEC_{SW} values for the southern European uses. The RMS is asked to include PEC_{SW} values for northern European use scenarios.	Data requirement still open, a data gap identified. For northern European use scenarios entry routes other than spray drift need to be addressed. The experts agreed to set a new open point (see open point 4.21): RMS to include PEC_{SW} for northern European use scenarios in the list of endpoints.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
4.17	Relevance of depleted thiophosgen in air should be assessed. An analytical method for monitoring thiophosgen may be needed if it is finally included in the residue definition in air. (see reporting table 4(87))	The RMS had accepted the argument of the notifier that considering the studies with captan labelled in the CCl_3 side chain, it can be concluded that degradation proceeds via THPC and thiocarbonic acid. The experts noted that it is unknown whether the radioactivity recovered from the volatiles traps consisted of thiophosgene or other compounds (e.g. thiocarbonic acid). The meeting agreed on the explanation of the RMS and concluded that only traces of thiophosgene may be present in air. Message addressed to EPCO 23: It cannot be excluded that traces of thiophosgene occur in the air.	Data requirement fulfilled. <u>Message from EPCO 21 to EPCO 23 (tox section)</u>: It cannot be excluded that traces of thiophosgene occur in the air.
	Message from EPCO 21 to EPCO 23 (tox section): It cannot be excluded that traces of thiophosgene occur in the air.		
4.18	Rate of degradation in air must be provided. (see reporting table 4(88))	The RMS presented in the addendum the new data submitted by the notifier. The meeting agreed and asked the RMS to add in the list of endpoints that the calculations are based on the average concentrations of hydroxyl radicals and ozone for a 12 h day.	Data requirement fulfilled. The experts agreed to set a new open point (see open point 4.21): RMS to add in the list of endpoints that the calculations are based on the average concentrations of hydroxyl radicals and ozone for a 12 h day.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
4.19	Report with the monitoring data should be provided and assessed in an addendum by RMS. (see reporting table 4(90))	The report of a 2 year surface water monitoring in the Netherlands was submitted and summarised in the addendum. The RMS said that captan was only detected in one sample at 0.08 µg/l during the monitoring programme. The meeting agreed that the monitoring results will not influence the assessment. The results were included in the list of endpoints.	Data requirement fulfilled.
	Open point 4.16: The request of a lysimeter study to be discussed in an expert meeting. (see reporting table 4(92))	The meeting discussed possible leaching and modelling of PECgw already with open points 4.13 – 4.15 and data requirement 4.15. The experts did not consider a lysimeter study necessary in this case. General comment: The meeting was of the opinion that guidance is needed on how to decide on the necessity of a lysimeter study in the framework of groundwater risk assessment. It was noted that additional information can be derived from these studies (e.g. metabolites which have not been detected in soil metabolism studies).	Open point fulfilled.
	Open point 4.17: DT_{90} in water < 3 days needs to be confirmed in an expert meeting and to communicate to the experts of the phys-chem section. (see reporting table 4(93) and 1(65))	Question from phys.-chem section: The meeting confirmed for captan DT90 in water below three days.	Open point fulfilled.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
4.20	New data gap: Notifier to assess soil photolysis metabolite THCY with regard to occurrence under field conditions and possibility of leaching into groundwater.	The meeting discussed the major metabolite THCY observed during the soil photolysis study with up to 15 % AR. It was concluded that the notifier has to assess the metabolite THCY with regard to occurrence under field conditions and possible leaching to groundwater.	New data gap identified by EPCO 21.
	New open point 4.21: RMS to revise the list of end points according to the amendments proposed by EPCO 21	RMS to include the individual DT_{50} values for THPAM in soil as the degradation is pH-dependent and also to remove the means. RMS to include data on anaerobic degradation. RMS to include aerobic data (Pack 1979) for anaerobic metabolite THCY in the list of endpoints. RMS to remove the mean K_{OC} for THPAM. RMS to include percentages of formation of the main hydrolysis products in the list of endpoints. RMS to include available DT50 of the metabolites for the water phase and the total system derived from the water/sediment study. RMS to include an explanation with regard to the derivation of the DT50 values for the metabolites in water used for PEC_{SW} calculations in the list of endpoints. RMS to include all PECsw relevant for the risk assessment in the list of endpoints (northern European use scenarios). RMS to include names of FOCUS scenarios of PEC_{GW} calculations. RMS to add in the list of endpoints that the calculations regarding photochemical oxidative degradation are based on the average concentrations of hydroxyl radicals and ozone for a 12 h day. RMS to include the percentage of metabolites formed under aerobic conditions as well as the results of the anaerobic soil degradation study (formation of metabolites, DT50). (see data requirement 4.1)	Open point still open.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
		Residue definition: Soil: Captan, THPI , THPAM, THCY(anaerobic and photolysis, pending further assessment), TPAI (anaerobic, not relevant foe representative uses proposed) Groundwater: Captan, THPI , THPAM, THCY(pending further assessment) Surface Water: Captan, THPI, THPAM sed: Captan, THPI, THPAI (PEC sed need to be calculated) Air: Captan	
	Message EPCO 22 to EPCO 21: Argumentation of the Notifier on open point 5.17 is forwarded to EPCO 21.	Open point 5.17 NOT from ET: Revised PECsoil values have been provided (*Terry, A. (2005). Predicted environmental concentrations of captan and its major degradation products in soil in the European Union*). These can be used in the risk assessment for earthworms. In addition, a justification on why the EPPO (2002) correction factor of 2 is not relevant for earthworm endpoints for captan has been submitted (*ref: Norman, 2005*). A low risk to earthworms can be demonstrated for all uses.	Answer of EPCO 21: EPCO 21 is happy with the PEC soil values provided in the new list of end points.
		The German comments of 29 October 2004 were submitted to the Joint EFSA/COM Evaluation Meeting on 8-10 November 2004 and it has to be assumed that they were discussed during the Evaluation Meeting. Therefore the experts concluded that a further discussion in this meeting is not necessary.	

Appendix 2: Evaluation table

4. Environmental Fate and Behaviour

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Section 4 Data requirements: ***19*** Open points: ***18***			Section 4 Data gaps: ***3*** Open points: ***4***
	Open point 4.1: RMS to update list of end points with respect to PEC gw. (see reporting table 4(2))	The new report: *Terry, A. and Price, O. (2005). Predicted Environmental Concentrations of captan and its major degradation products in groundwater in the European Union using the FOCUS groundwater scenarios* has been made available to the RMS.	list of end point updated	EPCO 21 (11. – 14.04.2005): Open point fulfilled. The experts agreed to set a new open point (see new open point 4.21): RMS to amend list of endpoints and include names of FOCUS scenarios.
	Open point 4.2: RMS to amend the list of end points. For PEC soil method of calculation it is sufficient to indicate that first order kinetic was assumed. (see reporting table 4(5)9		list of end point updated	EPCO 21 (11. – 14.04.2005): Open point fulfilled. The experts agreed to set a new open point 4.19: RMS to clarify the inconsistency in the list of endpoints between sections PECsoil and route of degradation concerning the DT50 of metabolite THPAM.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	New open point: 4.19: RMS to clarify the inconsistency in the list of endpoints between sections PECsoil and route of degradation concerning the DT50 of metabolite THPAM. This open point was proposed at EPCO 21.			EPCO 21 (11. – 14.04.2005): Open point still open.
	Open point 4.3: RMS to amend the list of end points to include individual values of DT_{50} with the mean. (see reporting table 4(7))		list of end point updated	EPCO 21 (11. – 14.04.2005): Open point fulfilled. The experts agreed to set a new open point (see open point 4.21): RMS to amend the list of end points, to include the individual values as the THPAM degradation is pH-dependent and also to remove the means.

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

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
		Further laboratory studies on THCY and THPAI are not required.		
4.2	Adequate kinetic analysis of degradation data should be provided for the soil degradation studies (kinetic model employed, goodness of fitting). (see reporting table 4(16))	Re-calculation of DT50 values has been conducted and reported (together with goodness of fit) in new report: '*Terry, A. and Price, O. (2005). Fate of captan in soil under aerobic conditions: A Review*.	See comment 4.3	EPCO 21 (11. – 14.04.2005): Data requirement fulfilled.
4.3	Relevance of field USA study with respect to EU conditions should be assessed. (see reporting table 4(16))	The relevance of the USA field studies has been examined and reported in new report: '*Terry, A. and Price, O. (2005). Fate of captan in soil under aerobic conditions: A Review*. 5 of the 6 studies were found to be conducted under climatic conditions with relevance to the EU.	The new report submitted show the field dissipation studies conducted in the USA were very useful for confirming the fate of captan in soil. It should be noted that the undertaking of field studies is not triggered by the laboratory degradation studies for captan nor for the major soil metabolites (DT_{50} <60 days). Hence, field studies are not strictly necessary for the risk assessment process. However, the Notifier has re-calculated the DT_{50} values for captan and THPI and analysed for correspondence of climatic conditions at the field locations with locations in the EU. Five of the six field studies were conducted under conditions similar to those at locations in the EU, with one corresponding to a location in Northern Europe (the study conducted at Waterloo, New York	EPCO 21 (11. – 14.04.2005): Data requirement fulfilled.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
4.5	Notifier to provide clarification on deviations of the anaerobic degradation studies(Lay (1992) and Pack et al. (1988b)). (see reporting table 4(28))	Captan is only used in the spring and summer and not in the autumn and winter. In addition, captan and its major soil metabolites degrade with laboratory DT50 values of between 0.4 and 14 days. Therefore, it is very unlikely that significant amounts of these substances will be present in soil during times when anaerobic conditions might be experienced (autumn/winter) following use according to the GAP. Therefore, the anaerobic degradation studies are not required for risk assessment purposes.	we agree	EPCO 21 (11. – 14.04.2005): Data requirement fulfilled. See also open point 4.9.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	New open point 4.20: RMS to amend the list of end points with regard to K_{OC} values for captan. The selected values from open literature should not comprise data from personal communications. This open point results from data requirement 4.6 and was proposed at EPCO 21.			EPCO 21 (11. – 14.04.2005): Open point still open.
	Open point 4.10: RMS to consider relevance of leaching studies with respect to soil degradation. Also to consider if a reliable Koc may be obtained from column leaching studies. (see reporting table 4(46))	A new evaluation of the hydrolysis, soil degradation and field dissipation studies for captan and its major soil metabolites has been conducted and is reported in the new report: '*Terry, A. and Price, O. (2005). Fate of captan in soil under aerobic conditions: A Review*. The fate and behaviour of captan in soil is clear and has been derived from studies designed to investigate the fate in soil of captan, including the generation of representative DT50 values. The aged column leaching study was designed to investigate the leaching potential of captan degradation products rather than the rate of degradation of captan; and the incubation of captan in soil would have been carried out in a way that would have allowed the best opportunity to	The Notifier has submitted a new appropriate report . See the NOT comment	EPCO 21 (11. – 14.04.2005): Open point fulfilled.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Open point 4.11: RMS to clarify on the information available on the degradation of anaerobic metabolite THCY under aerobic conditions. (see reporting table 4(30) and 4(48))	Captan is only used in the spring and summer and not in the autumn and winter. In addition, captan and its major soil metabolites degrade with laboratory DT50 values of between 0.4 and 14 days. Therefore, it is very unlikely that significant amounts of these substances will be present in soil during times when anaerobic conditions might be experienced (autumn/winter) following use according to the GAP. Therefore, the aerobic fate of the anaerobic metabolite THCY is not relevant.	Agree	EPCO 21 (11. – 14.04.2005): Open point fulfilled. The experts agreed to set a new open point (see open point 4.21): RMS to amend the list of end points. Aerobic data (Pack 1979) for anaerobic metabolite THCY should be included in the list of endpoints.
	Open point 4.12: RMS to clarify which DT_{50} are relevant ofr the risk assessment of metabolite THPI. (see reporting table 4(49))	A new evaluation of the hydrolysis, soil degradation and field dissipation studies for captan and its major soil metabolites has been conducted and is reported in the new report: '*Terry, A. and Price, O. (2005). Fate of captan in soil under aerobic conditions: A Review*. This includes clarification of the DT50 values relevant for the risk assessment of THPI.	See comment 4.3	EPCO 21 (11. – 14.04.2005): Open point fulfilled.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
4.10	Notifier to calculate the hydrolysis rate from the ring labelled captan (Lee, K.S. 1989b.) (see reporting table 4(62))	The requested values were, in fact, reported in the study but, by oversight, were not included in the DAR. The calculated hydrolysis DT_{50} values were determined to be 11.7 hours, 4.7 hours and 8.1 minutes at pH values of 5, 7 and 9 respectively.		EPCO 21 (11. – 14.04.2005): Data requirement fulfilled.
4.11	Hydrolysis of metabolites THPI, THPC and THPAM should be provided according EEC guidelines. Metabolites should be reported. (see reporting table 4(64))	The hydrolysis studies conducted with THPI and THPAM were reasonable and sufficient to derive the rate of hydrolysis of these two metabolites at 25°C, as the rate constants for the hydrolyses had been determined at three temperatures allowing appropriate extrapolation to 25°C. Only THPI, THPAM and THPC were detected above 10% in the parent hydrolysis study. Therefore, although it is agreed that the rate of degradation of these metabolites should be provided, it is not considered necessary that the nature of their transformation products be determined. The rate of transformation of THPC can be calculated from the parent study using a multicompartment modelling package (new report: *Terry, A. (2005). Kinetic analysis of the degradation of THPC generated in hydrolysis studies on captan at pH9*). This demonstrates that THPC is a very transient intermediate with a calculated DT50 of 15.7 minutes	we agree	EPCO 21 (11. – 14.04.2005): Data requirement fulfilled.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Open point ~~4.12~~ 4.18: Due to the lack of water sediment study at alkaline pH, a worst case assessment may be performed for alkaline conditions using results of hydrolysis study to make the risk assessment for surface water contamination by metabolite THPC. (see reporting table 4(70)) (Numbering of open point has been corrected. Reference in addendum vol3 B8 has also been amended accordingly)	The water/sediment studies were conducted at ALKALINE pH. Given that THPC was formed/detected at neutral to alkaline pH values in the hydrolysis studies it follows that IF THPC was a significant transformation product in natural water systems then it would have been detected in the water/sediment studies. It is, though, not surprising that THPC does not feature in the water/sediment studies because it was a very transient intermediate even at pH9 (calculated DT50 maximum of 15.7 minutes; new report: *Terry, A. (2005). Kinetic analysis of the degradation of THPC generated in hydrolysis studies on captan at pH9*) under sterile conditions. Therefore, THPC is not relevant for the risk assessment process.	agree	EPCO 21 (11. – 14.04.2005): Open point fulfilled.
4.14	PEC sed for metabolites THPI and THPAI must be provided. (see reporting table 4(78))	A new report: *Terry, A. (2005). Predicted Environmental Concentrations of THPI and THPAM in surface water and sediment arising from spray drift, in the European Union*, has been provided to the RMS.	The Notifier has submitted a new report in which appropriate PEC values have been calculated	EPCO 21 (11. – 14.04.2005): Data requirement still open, a data gap identified. PEC values for THPAI to be provided and PEC sediment to be recalculated with density of 1.3 g/mL.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Open point 4.13: RMS to assess relevance of ground water metabolite THPAM if enough data available or identify data gaps. (see reporting table 4(79))	New PEC groundwater calculations (new report: *Terry, A. and Price, O. (2005). Predicted Environmental Concentrations of captan and its major degradation products in groundwater in the European Union using the FOCUS groundwater* scenarios) show that safe uses are indicated for captan in the EU. A study on pesticidal (fungicidal) activity of THPI and THPAM shows them to be non-relevant in this context.	Agree	EPCO 21 (11. – 14.04.2005): Open point covered by data requirement 4.15.
4.15	Notifier to provide new PEC GW modelling consistent with GAPs and reliable input parameters. Metabolites should be assessed according SANCO/221/2000-rev 10. (see reporting table 4(80))	The new report: *Terry, A. and Price, O. (2005). Predicted Environmental Concentrations of captan and its major degradation products in groundwater in the European Union using the FOCUS groundwater scenarios* has been made available to the RMS. This contains the input parameters for use in FOCUS PEC gw modelling. For many scenarios PECgw values for captan and metabolites are <0.1 µg/L. Hence, 'safe uses' in the context of Annex 1 listing have been established. In addition, a study on pesticidal (fungicidal) activity of THPI and THPAM shows them to be non-relevant in this context.		EPCO 21 (11. – 14.04.2005): Data requirement fulfilled. Relevance of metabolites in groundwater THPI and THPAM should be addressed by ecotox and toxiclogy meetings. It should be noted that for this use PEC_{GW} of the metabolites (THPI and THPAM) exceed the threshold of 0.75 µg/l.. The experts agreed to set a new open point (see open point 4.21): RMS to amend the list of end points and include correlation K_{OC} versus pH for metabolite THPAM.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Message from EPCO 21 to EPCO 22 and EPCO 23 Relevance of metabolites in groundwater THPI and THPAM should be addressed by ecotox and toxiclogy meetings. It should be noted that for this use PEC_{GW} of the metabolites (THPI and THPAM) exceed the threshold of 0.75 µg/l.			
	Open point 4.14: RMS to prepare new addendum with new information of potential groundwater contamination. (see reporting table 4(80))	The new report: *Terry, A. and Price, O. (2005). Predicted Environmental Concentrations of captan and its major degradation products in groundwater in the European Union using the FOCUS groundwater scenarios* has been made available to the RMS.	The Notifier has submitted a new report in which appropriate values have been calculated	EPCO 21 (11. – 14.04.2005): Data requirement fulfilled. See open point 4.13

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Open point 4.15: RMS to revise the residue definition in ground water. Monitoring analytical methods will need to be provided for the new metabolites if they will be added to the residue defintion. (see reporting table 4(81))	The PEC_{GW} calculations indicate that there are many use scenarios where captan, THPI and THPAM do not exceed 0.1 μg/L. Hence, 'safe uses' in the context of Annex 1 listing have been established. In those scenarios where THPI and THPAM do exceed 0.1 μg/L, the concentrations are not predicted to reach 10 μg/L. A study on pesticidal (fungicidal) activity of THPI and THPAM shows them to be non-relevant in this context. As such, it is proposed that the residue in groundwater should be considered to be captan only (although based on modelling captan is very unlikely to be found in groundwater).	The new report: *Terry, A. and Price, O. (2005). Predicted Environmental Concentrations of captan and its major degradation products in groundwater in the European Union using the FOCUS groundwater scenarios* has been made available to the RMS. The PEC_{GW} calculations indicate that there are some use scenarios THPI and THPAM exceed 0.1 μg/L Where THPI and THPAM do exceed 0.1 μg/L, the concentrations are not predicted to reach 10 μg/L. A study on pesticidal (fungicidal) activity of THPI and THPAM shows them to be non-relevant in this context.	EPCO 21 (11. – 14.04.2005): Open point still open. The experts agreed to set a new open point (see open point 4.21): RMS to include metabolites THPI and THPAM in the residue definition for groundwater in the list of endpoints.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
4.16	PEC FOCUS sw taking into account run off and drainage must be provided. Input parameters should be clearly justified. (see reporting table 4(82))	It is not considered necessary to conduct FOCUS surface water evaluations for Annex 1 listing as when the dossier was submitted this was not a requirement. In addition, an assessment of risk to surface waters has been included in the DAR for run-off and for captan for spray drift. A new report: *Terry, A. (2005). Predicted Environmental Concentrations of THPI and THPAM in surface water and sediment arising from spray drift, in the European Union* has been submitted giving PECs for THPI and THPAM. Drainage is not an exposure route of relevance for captan as products are only used late spring/summer and soil DT50 values for captan and its metabolites are between 0.4 and 14 days, only. In any case, the growing of pome fruit, peaches/ nectarines, and tomatoes would not be expected on artificially drained soil.	agree	EPCO 21 (11. – 14.04.2005): Data requirement still open, a data gap identified. For northern European use scenarios entry routes other than spray drift need to be addressed. The experts agreed to set a new open point (see open point 4.21): RMS to include PEC_{SW} for northern European use scenarios in the list of endpoints.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
4.17	Relevance of depleted thiophosgen in air should be assessed. An analytical method for monitoring thiophosgene may be needed if it is finally included in the residue definition in air. (see reporting table 4(87))	The amount of trichloromethyl –^{14}C captan derived radioactivity volatilised from the soil surface amounted to 0.4% per day averaged over the 9 day study. As a worst-case, on the first day the amount volatilised comprised < 1%. This would lead to negligible concentrations of thiophosgene in air, even assuming that all the material lost was thiophosgene, and therefore this metabolite need not be considered further.	agree	EPCO 21 (11. – 14.04.2005): Data requirement fulfilled. Message from EPCO 21 to EPCO 23 (tox section): It cannot be excluded that traces of thiophosgene occur in the air.
	Message from EPCO 21 to EPCO 23 (tox section): It cannot be excluded that traces of thiophosgene occur in the air.			
4.18	Rate of degradation in air must be provided. (see reporting table 4(88))	A new report: *Curl, M.G. (2004).The Estimation of Photochemical Oxidative Degradation of Captan*, has been made available to the RMS.	The Notifier has submitted a new report in which appropriate values have been calculated	EPCO 21 (11. – 14.04.2005): Data requirement fulfilled. The experts agreed to set a new open point (see open point 4.21): RMS to add in the list of endpoints that the calculations are based on the average concentrations of hydroxyl radicals and ozone for a 12 h day.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Open point 4.17: DT_{90} in water < 3 days needs to be confirmed in an expert meeting and to communicate to the experts of the phys-chem section. (see reporting table 4(93) and 1(65))	The rate of hydrolysis of captan was found to be extremely rapid in water at all pH values. The longest DT50 was at pH 5 (18.8 hours) which corresponds to a DT90 of 62 hours (2.6 days). Therefore, DT90 in water <3 days.	agree	EPCO 21 (11. – 14.04.2005): Open point fulfilled.
4.20	New data gap: Notifier to assess soil photolysis metabolite THCY with regard to occurrence under field conditions and possibility of leaching into groundwater.			EPCO 21 (11. – 14.04.2005): New data gap identified by EPCO 21.
	New open point 4.21: RMS to revise the list of end points according to the amendments proposed by EPCO 21.			EPCO 21 (11. – 14.04.2005): Open point still open.
	Message EPCO 22 to EPCO 21: Argumentation of the Notifier on open point 5.17 is forwarded to EPCO 21.			EPCO 21 (11. – 14.04.2005): Answer of EPCO 21: EPCO 21 is happy with the PEC soil values provided in the new list of end points.

REPORT OF EPCO EXPERT MEETING 22

CAPTAN

Rapporteur Member State: Italy

Specific comments on the active substance in the section

5. Ecotoxicology

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
29 October 2004	Germany	Captan com01 DE

2. Documents submitted for meeting:

Date	Supplier	File Name
15 October 2004	RMS/Italy	Captan consultation report
17 January 2005	RMS/Italy	Captan reporting table rev1-3
January 2005	RMS/Italy	Captan addendum vol3 B9
March 2005	RMS/Italy	Captan list of end points ecotox
17 March 2005	RMS/Italy	Captan evaluation table rev0-1
March 2005	Notifier	Captan notifier response to comments ecotox

3. Documents tabled at the meeting:

Date	Supplier	File Name
06 April 2005	Denmark	Captan comment DK (06-04-2005)
06 April 2005	Denmark	Captan summary of representative uses

The conclusions of the meeting were as follows:

4. **Data on preparations:** Merpan' 80 WDG, 'Malvin' WDG.

5. **Classification and labelling:** N., R50/53.

6. **Recommended restrictions/conditions for use:** buffer zones

7. **Reference List**

Areas of concern:

Appendix 1: EPCO discussion table: CAPTAN

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Captan (Fu)

5. Ecotoxicology

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 5.1: RMS to amend the list of endpoints regarding the toxicity values for bees. (see reporting table 5(1))	RMS informed that the list of endpoints have been amended. MS stated that the presentation of the trigger value is confusing therefore an open point was set to delete the higher than symbol.	EPCO 22 (11.04.-15.04.2005): Open point still open. RMS to amend the higher than symbol before the trigger value for bees in the list of endpoints.
	Open point 5.2: RMS to amend the list of endpoints regarding NTA (indicating exact effect percentages and study type). (see reporting table 5(2))	Done. The meeting accepted this amendment.	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.
	Open point 5.3: RMS to amend the list of endpoints regarding the acute toxicity to earthworms. (see reporting table 5(4))	RMS: We amended everything?! The Meeting accepted the amendment.	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 5.4: RMS to amend the list of endpoints regarding the data on toxicity to aquatic organisms. (see reporting table 5(5))	Done. The meeting accepted the amendment.	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.
	Open point 5.5: RMS to amend the list of endpoints regarding the LC_{50} and NOEC for birds. (see reporting table 5(7))	Done. The recalculation of the NOEC of the reproduction study was discussed. Mean food intake of bobwhite was miscalculated. 17 g has to be used instead of 15.3 g. This will not change the outcome of the risk assessment but has to be amended.	EPCO 22 (11.04.-15.04.2005): Open point still open. RMS should verify the recalculation to daily dose of the NOEC for bobwhite quail.
	Open point 5.6: RMS is proposed to prepare an addendum with a revised risk assessment for birds and mammals according to SANCO/4145/2000. (see reporting table 5(10))	Acute risk to birds: MS commented that the interception factor hasn't been used. The meeting agreed that the acute risk to birds is addressed as they are higher than values and above or very close to the trigger. Short-term risk to birds: The meeting agrees that the short term risk to birds is addressed because tomato plants are not attractive to herbivorous birds. RMS offered to make scientific references available on the content of solanin in tomato plants at different growth stages. RMS will make references to studies to support the unpalatability of Solanaceae available. Long-term risk to birds:	EPCO 22 (11.04.-15.04.2005): Open point closed.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
		RMS: For the herbivorous birds the risk is regarded as addressed because tomato plants are not attractive to herbivorous birds (see above). For the insectivorous birds the risk is acceptable after refinement. 1) RUD for insects MS: The RUD value of 5.1 is appropriate for the large insects but not for the small insects. To refine PT blue tits are used as focal species and they feed on aphids. Meeting agreed that this value is in this case not acceptable and therefore an open points was set for the RMS to review the RA for birds based on the default RUD of 29 for insectivorous birds. In relation to this the notifier will be asked to present an argumentation on the residue decline in insects. 2) PT value RMS: Blue tits are representative for small birds eating insects. This is following the guidance. The study was conducted by Crocker, in UK. The methods to follow the birds has been radio tracking. The study is one of the most extensive available at the moment: several fields, 3 years of observations and the use of radiotracking. Meeting agreed to use the 95th percentile from this study leading to a PT of 0.6 until other studies become available. The meeting agreed that this PT of 0.6 could also be used for the representative use in peaches/nectarines. In general MS feel a need for more guidance on the setting for PT and PD values (see also general report EPCO 22). Has a deposition factor for the risk assessment for birds been used? Answer: Not for the residue calculations in insects. The averaging period may not be longer than the interval between the applications. <u>Acute risk to mammals:</u> The meeting agreed that the acute risk to mammals is addressed as they are higher than	New open point: RMS to recalculate the long term risk to birds with the default RUD value. <u>Data gap identified:</u> Notifier to present an argumentation on the residue decline in insects.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
		values and above or very close to the trigger. <u>Long-term risk to mammals</u>: Refinement was presented from the Notifier. The proposed refinement step is about the PT value. The NOEC has been changed. Now the risk was calculated with the new NOEC. 1) NOEC The RMS considered a NOEC of 250 mg as/kg bw/day from the multigeneration studies. It is questioned that the rabbit is an appropriate species as indicator species for the refinement of the risk. There are teratological effects visible which have to be considered too. Comment of FR 5(34) related to the dermal study. In the three generation rat reproduction study there is a discrepancy in the toxicological endpoint. The NOEL of 100 mg is ecotoxicologically relevant. MS: Regarding the NOEC from the teratology study the NOEL was low and the endpoint of the 100 from the rat study will be the relevant. One MS disagreed. EFSA: the reduction on the litter in the developmental toxicity study in the rabbit is high and an effect of the substance is clearly visible. There was a concern with the endpoint for mammals. Meeting agreed on a NOEC of 100 mg a.s /kg bw and MSs have two weeks after the meeting to react on this. EFSA will then make a post meeting note in the report. Post meeting EFSA Note: 8 participants of the meeting reacted after the meeting. The RMS remains with their original proposal for a NOEC of 250 mg as/kg bw. One expert proposed a NOEL of 40 mg as/kg bw. The other 6 experts reconfirmed the NOEC of 100 mg as/kg bw.	Still to be discussed: MS experts have two weeks after the meeting to react on the long-term risk assessment. Especially comments on 100 mg a.s /kg bw are welcome. Post meeting EFSA Note: 8 participants to the meeting reacted after the meeting. The RMS remains with their original proposal for a NOEC of 250 mg as/kg bw. One expert proposed a NOEL of 40 mg as/kg bw. The other 6 experts reconfirmed the NOEC of 100 mg as/kg bw.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
		2) The assumption of the PT value of 0.5. MS presented also a concern on the PT value assumption. Ground vegetation under the trees could be treated as well. In southern Europe the soil is vegetation free and the risk to herbivorous mammals could hence be regarded as addressed. Southern MS were asked to confirm this after the EPCO meeting to EFSA. Post meeting EFSA Note: the participant from Spain let EFSA know after the EPCO meeting that it is common practice in Spain to have the soil completely free of weeds. The participant of Greece let EFSA know that in the 50% of the orchards where herbicides are applied, they leave a grass/weedzone between the tree rows and a plant free zone below the trees (as in Northern Europe). The grass/weed zone is then (ca one week later) destroyed by tractors (mechanicaly), so the orchard is finally weed free. there is still a 50% of orchards where herbicides are applied in all area of the field. Open point depending on the outcome of the relevance of insect mammals in southern European orchards a risk has to be calculated. Meeting agreed that in northern Europe the PT assumption is not acceptable. As it is expected that due to the new NOEC the TER will be below the trigger value a data requirement for the notifier to submit an argumentation on the use of an pt-value of 0.5 for the use in orchards was set.	New open point Open point pending on the outcome of the relevance of insectivorous mammals in southern European orchards a risk has to be calculated. <u>Data gap identified:</u> Notifier to submit an argumentation on the PT assumption of 0.5 for the use in orchards.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 5.7: MS to discuss the acceptability of the acute toxicity study to mallards in an expert meeting. (see reporting table 5(11))	The LD50 was considered as unreliable from one MS. For the risk assessment this is not regarded as very relevant. No toxicity was measured. It is a draw back of this study but due to low toxicity it is accepted in this case.	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.
	Open point 5.8: Pending on the outcome of the discussion on the PECsw and water sediment study in the section on Fate and behaviour, a revision of the aquatic risk assessment may be necessary. (see reporting table 5(21))	Done. This point is addressed.	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.
	Open point 5.9: MS to discuss the aquatic risk assessment in an expert meeting taking into account the written comments from DE (29-10-2004).	German late comment: to discuss the need of an fish early life stage study. RMS stated that the compound is too short persistent in the test for a long life study. The DT_{50} is lower than two days in the water. No chronic testing is necessary. 12 applications should have been taken into consideration in the acute risk assessment but a semi-static study is available. The meeting agreed that no early life stage study is necessary. - DT_{50} far less than spraying interval.	EPCO 22 (11.04.-15.04.2005): See also open point 5.10 Open point closed.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	(see reporting table 5(22))	- Pulsed exposure addressed with the fish semi static study. - The triggers for the need for such as study are only borderline met (bioconcentration factor and toxicity) - The acute/chronic risk ratio is close to 1. The trigger value for the BCF was discussed. The meeting agreed on 1000 in this case because of the very short DT50-value.	
	Open point 5.10: RMS to prepare an addendum with a revised risk assessment to fish (based on the LC_{50} of 98 µg/L). (see reporting table 5(24))	Three options were discussed: a) Based on the LC_{50} the endpoint of 98 µg a.s./L for brown trout should be presented with an uncertainty factor between ten and 100. The trigger will be decided after the Scientific Panel has discussed this. b)HC5 is 65 µg a.s./L. The meeting discussed the use of an HC5 approach. It is regarded in general as acceptable. The uncertainty factor has to be discussed in addition to the HC5 approach. The HC5 based on an LC50 together with a safety factor should be used. c) One MS is using an approach on the base of the HC5 based on NOEC without an uncertainty factor of 1. The uncertainty factor of 1 is not accepted by the majority of the meeting. A safety factor was regarded as necessary for the probabilistic approach. EFSA: The scientific panel is discussing at the moment on how much the safety factor can be lowered depending on how many test species were tested in the dossier. The opinion is still awaited. And thus this shouldn't be discussed now.	<u>EPCO 22 (11.04.-15.04.2005)</u>: Open point closed. Open point for EFSA: To include the results of the opinion of the Scientific Panel in the conclusion.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
		Meeting agreed to use a deterministic approach based on the LC_{50} of 98 µg as/L of the brown trout to do the risk assessment for Annex I inclusion. The expert meeting discussed the use of a probabilistic HC5 approach and decided that this could be used at MS level due to the limited experience at the moment and because the meeting could not come to an appropriate uncertainty factor for the probabilistic approach. EFSA will highlight this in the conclusion. New open point raised from the folpet discussions: this approach can be used here too. EFSA stated that the long term risk assessment could be conducted with help of the NOEC value from the rainbow trout (28 d semi static study). This value can be compared with the initial PEC value.	New open point: RMS to conduct the long-term risk assessment for aquatic organisms with proposal made by EFSA.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 5.11: RMS to prepare an addendum to revise the endpoints for aquatic organisms (based on measured concentrations if appropriate) and revise the aquatic risk assessment if necessary. (see reporting table 5(29))	The test concentration hasn't been clear. The test has been repeated. See p. 22ff of the addendum. New and old study did lead to very similar results of the LC50. Thus RMS accepted the position of the Notifier. Meeting accepted new studies. Two new studies were provided. With rainbow trout and stickleback. RMS presented the assessment. EFSA: 5(29): the assessment should be based on the measured concentration at the start of the test otherwise the risk could be underestimated. RMS: common problems with compounds which are highly soluble in water. But RMS agreed to use the initially measured concentration. After checking the DAR at 0 hours the risk with the formulation seems acceptable. The question is when the first measurements were taken. MS asked if the opinion can be based on the new studies. But the new studies are undertaken with the active but here problem occurred with the formulation. Two formulations were tested. One is no lead formulation. Some studies weren't valid but they are not undertaken with the lead formulation and thus the studies are not needed.	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
5.1	Notifier to submit the composition of the tested formulations to proof their comparability to the lead formulations. (see reporting table 5(31))	Notifier supplied the information. For reasons of transparency the RMS is asked to put this information into an addendum to the confidential section to be discussed in EPCO 25.	EPCO 22 (11.04.-15.04.2005): Data requirement fulfilled. New open point RMS to add the information to the confidential section of the DAR to be discussed at EPCO 25.
	Open point 5.12: RMS to prepare an addendum regarding the risk of the metabolite THPAI to sediment dwelling organisms (THPAI was not tested on aquatic invertebrates) to be discussed in an expert meeting. (see reporting table 5(32))	RMS: This metabolite was only found once in the sediment. RMS can not identify a danger of this metabolite. EFSA: This should be forwarded to fate section. There has no ecotoxicological risk been identified. RMS didn't agree. This point can be closed because the fate experts didn't expected this metabolite neither in water nor in sediment. One metabolite (THPAI) might be relevant. The argumentation is still the low toxicity. THPAI and THPAM: What is the difference between these metabolites? If one functional group is different between the metabolites than the toxicity can be very different. RMS assumes that the toxicity is similar. This was accepted by the meeting.	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.
	Open point 5.13: RMS to prepare an addendum to revise the risk assessment for NTA (see reporting table 5(38))	Two news studies were presented. And the addendum was presented. Which dose is needed to be tested? 6.75 kg a.s/ha is the highest in-field dose rate to be expected. MS: The dose rate should follow ESCORT 2. In ESCORT 2 after 8 applications it may not be higher than 3.5 kg a.s./ha.	EPCO 22 (11.04.-15.04.2005): Open point closed

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
		DT50 on vegetation of captan is 11 ?. This is not fast degradable. The new studies include four application with a factor of 2.7. The 6.75 values seems to cover the in-field risk. It is questioned how the sum of all applications can be calculated. For the uses in northern Europe 6.75 kg a.s/ha is the worst case. The peaches and nectarines have the highest dose rates. The infield rate as presented is confirmed. The risk is presented in the addendum on p 50. Meeting agreed that the indicator species have been addressed. Are there enough leaf dwelling species tested with the high enough dose rates? No, because *Chrysoperla carnea* as second species hasn't been tested at high enough dose rates. *Aphidius* as most sensitive species is covering the concern.	
	Open point 5.14: MS to discuss the acceptability of the laboratory toxicity test with *T. pyri* in an expert meeting. (see reporting table 5(39))	Only the mortality part of the study can be considered as valid.	EPCO 22 (11.04.-15.04.2005): Open point closed.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 5.15: RMS to amend the list of endpoints regarding the list of representative uses (spray interval should be included). (see reporting table 5(41))	RMS regards this as done. This point is left open for technical reasons as the part of the list of endpoints containing the list of representative uses was not available to the participants of this meeting and hence they were unable to say they agree with the changes made.	EPCO 22 (11.04.-15.04.2005): Open point still open.
	Open point 5.16: Pending on the discussion of the PECs in the section on Fate and behaviour, a revision of the risk to earthworms may be necessary. (see reporting table 5(46))	Fate hasn't had any problems with the PEC values.	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.
	Open point 5.17: RMS to prepare an addendum to revise the risk assessment for earthworms. (see reporting table 5(47))	RMS presented the assessment in the addendum. The argumentation of the RMS is questioned. The Koc value of captan is 200ml/g. This is low. The absorption in reality of such a compound is unclear because degradation might be fast. The DT50 in the field is much longer than in the laboratory. This is very unusual. Are the lab studies underestimating the risk in the field? Problem to be forwarded to fate meeting.	EPCO 22 (11.04.-15.04.2005): Argumentation of the Notifier on open point 5.17 is forwarded to EPCO 21. Open point still open. Waiting for the answer from EPCO 21. Answer from EPCO 21: Answer EPCO 21:

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
			EPCO 21 is happy with the PEC soil values provided in the new list of end points.
5.2	Notifier to address the risk to other non-target fauna and flora. (see reporting table 5(54))	Notifier didn't regard this as necessary, because this is no herbicide. At least screening data should have been provided.	EPCO 22 (11.04.-15.04.2005): Data requirement still open.
	Open point 5.18: Pending on the discussion of the PECgw values in the section on Fate and behaviour, data on pesticidal activity of the major ground water metabolites may be necessary (see reporting table 5(54))	Message from EPCO 21 to EPCO 22 and EPCO 23: Relevance of groundwater metabolites THPI and THPAM should be addressed. The level of 0.1 µg/l is exceeded for some scenarios. Table 30 and 31 of the addendum. The activity of the metabolite THPI and THPAM are less than half of the activity of the compound at 25 mg/L. Thus the biological activity of both metabolites is not regarded as comparable with the active. MSs agreed that THPAI and THPAM are less toxic than the parent. From ecotoxicological point of view these metabolites are not relevant.	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 5.19: MS to discuss the need for further data to address the risk to sewage treatment in an expert meeting. (see reporting table 5(56))	RMS: The substance has a low probability to reach the water treatment plants. . The meeting agreed that the availability of the *Pseudomonas* study and the very short DT_{50}-value is addressing this point. .	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.
	Message from EPCO 21 to EPCO 22 PEC sediment needs to be recalculated with a sediment density of 1.3 g/ml. Only slight changes are expected		Answer to EPCO 21: This is not an issue for the active substance as the NOEC for Daphnia is above 0.1 mg/L. No studies from sediment dwellers are considered necessary.
	Residue definitions	Soil: THPI and THPAM are regarded as less relevant as the parent. Water compartment: not relevant THPAI is a major metabolite in the sediment. Open point 5.12. regarded the metabolite as not relevant. THPAI and THPI are a groundwater metabolites. THPI is not relevant. THPAI data on the pesticidal activity are missing. EFSA will clarify after the meeting.	

Appendix 2: Evaluation table

5. Ecotoxicology

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Section 5 Data requirements: ***2*** Open points: ***19***			Section 5 Data requirements: ***1*** Open points: ***8*** Data gaps: ***2***
	Open point 5.1: RMS to amend the list of endpoints regarding the toxicity values for bees. (see reporting table 5(1))		List of end points amended	EPCO 22 (11.04.-15.04.2005): Open point still open. RMS to amend the higher than symbol before the trigger value for bees in the list of endpoints.
	Open point 5.2: RMS to amend the list of endpoints regarding NTA (indicating exact effect percentages and study type). (see reporting table 5(2))		List of end points amended	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.
	Open point 5.3: RMS to amend the list of endpoints regarding the acute toxicity to earthworms. (see reporting table 5(4))		List of end points amended (values are reported both in original and corrected by dividing endpoint by 2)	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.

section 5 – Ecotoxicology (B9)

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Open point 5.4: RMS to amend the list of endpoints regarding the data on toxicity to aquatic organisms. (see reporting table 5(5))		List of end points amended (lowest endpoint for each aquatic group and metabolites were included)	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.
	Open point 5.5: RMS to amend the list of endpoints regarding the LC_{50} and NOEC for birds. (see reporting table 5(7))		List of end points amended	EPCO 22 (11.04.-15.04.2005): Open point still open. RMS should verify the recalculation to daily dose of the NOEC for bobwhite quail.
	Open point 5.6: RMS is proposed to prepare an addendum with a revised risk assessment for birds and mammals according to SANCO/4145/2000. (see reporting table 5(10))	A risk assessment according to SANCO/4145/2000 has been provided to the RMS (*Ref: Norman and Wyness, 2003*). Addition comments from Member States have also been addressed (*ref: Norman, 2005, EU Review of captan: Notifier responses to various comments on ecotoxicology raised in the official Reporting Table*)	Endpoints for birds risk assessment were: >2000 mg/kg/bw (acute), > 800 mg /kg/bw/day (short term), 74.4 mg/kg/bw (long term). For mammals toxicity endpoints were: >2000 mg/kg bw/day (acute), 250 mg /kg bw/day (long term). Tier 1 risk assessment Acute and short term TERs were acceptable while the long term TERs for insectivorous birds (all uses) and small herbivorous mammals in South EU (pome, peaches/nectarines) were less than 5 indicating further refinement. Tier 1 short term TER for medium herbivorous bird was>5 but this scenario is unrealistic since the foliage of tomato plants is not attractive to	EPCO 22 (11.04.-15.04.2005): Open point closed. New open point (5.20) Data gap identified (5.3): Still to be discussed: MS experts have two weeks after the meeting to react on the long-term risk assessment. Especially comments on 100 mg a.s /kg bw are welcome. Post meeting EFSA Note: 8 participants to the meeting reacted after

section 5 – Ecotoxicology (B9)

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	continued Open point 5.6: RMS is proposed to prepare an addendum with a revised risk assessment for birds and mammals according to SANCO/4145/2000. (see reporting table 5(10))		birds. Tier 2 risk assessment. The following assumptions were used: for insectivorous birds RUD on insects was 5.1 mg/kg.; PT= 0.61 (based on blue tits behaviour in orchards) . For mammals the ecological relevant endpoint was 250 mg/kg bw (based on a rat multigeneration study); the PT value was set at 0.5 assuming that a field vole would get half of the diet with the grass growing under the trees which is reasonable and still conservative since the grass under the trees is often managed and its growth is restricted by shading. Under these assumptions all the calculated TERs are above the triggers. Captan is of low toxicity to birds and mammals and its degradation rate is rapid. TERs long term values are moreover based on no effect of the highest dose tested in reproduction studies, the risk to birds and mammals is considered acceptable.	the meeting. The RMS remains with their original proposal for a NOEC of 250 mg as/kg bw. One expert proposed a NOEL of 40 mg as/kg bw. The other 6 experts reconfirmed the NOEC of 100 mg as/kg bw. New open point (5.21) Data gap identified (5.4):
	New open point 5.20: RMS to recalculate the long term risk to birds with the default RUD value. See open point 5.6 This open point was proposed at EPCO 22.			EPCO 22 (11.04.-15.04.2005): Open point still open.

section 5 – Ecotoxicology (B9)

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
5.3	New data gap: Notifier to present an argumentation on the residue decline in insects. See open point 5.6. This data gap was identified at EPCO 22.			EPCO 22 (11.04.-15.04.2005): Data gap identified.
	New open point 5.21: Open point pending on the outcome of the relevance of insectivorous mammals in southern European orchards a risk has to be calculated. See open point 5.6 This open point was proposed at EPCO 22.			EPCO 22 (11.04.-15.04.2005): Open point still open.
5.4	New data gap: Notifier to submit an argumentation on the PT assumption of 0.5 for the use in orchards. See open point 5.6. This data gap was identified at EPCO 22.			EPCO 22 (11.04.-15.04.2005): Data gap identified.

section 5 – Ecotoxicology (B9)

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Open point 5.7: MS to discuss the acceptability of the acute toxicity study to mallards in an expert meeting. (see reporting table 5(11))	The Notifier supports the statement from the RMS in the Reporting Table (5(11): Sept 04). This issue is not important for the risk assessment. Captan is clearly of low acute toxicity, as also shown in the study on bobwhite quail (LD50 >2000 mg/kg bw).	See RMS response in reporting table (5.11)	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.
	Open point 5.8: Pending on the outcome of the discussion on the PECsw and water sediment study in the section on Fate and behaviour, a revision of the aquatic risk assessment may be necessary. (see reporting table 5(21))	With respect to the sediment water fate study, a revision of the aquatic risk assessment is not required (please see Notifer comment on Open Point 4.12). PECsw values following multiple applications have been provided for THPAM and THPI (*ref: Terry, A. (2005). Predicted Environmental Concentrations of THPI and THPAM in surface water and sediment arising from spray drift, in the European Union*.). These can be used in the aquatic risk assessment.	See new risk assessment (addendum)	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.

section 5 – Ecotoxicology (B9)

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Open point 5.9: MS to discuss the aquatic risk assessment in an expert meeting taking into account the written comments from DE (29-10-2004). (see reporting table 5(22))	Responses to comments from DE have been provided (*ref: Norman, 2005, EU Review of captan: Notifier responses to various comments on ecotoxicology raised in the official Reporting Table*). It should be noted that two new static acute toxicity studies have been submitted on rainbow trout (Jenkins, 2004a) and stickleback (Jenkins, 2004b) which included chemical analysis of the test media. LC50 values in terms of mean measured initial concentrations were similar to those based on nominal concentrations for previous studies on the same species, using the same study design. Hence, this confirms the validity of the previous static acute toxicity studies on fish (6 species).	See new risk assessment (addendum)	EPCO 22 (11.04.-15.04.2005): See also open point 5.10 Open point closed.
	Open point 5.10: RMS to prepare an addendum with a revised risk assessment to fish (based on the LC_{50} of 98 µg/L). (see reporting table 5(24))	Notifier agrees with use of the LC50 of 98 µg a.s./L for brown trout as the basis of the risk assessment. Six species of fish were tested, and the range of sensitivity is narrow. Hence, uncertainty over inter-species variation in sensitivity has been minimised (this approach was agreed at HARAP). Therefore, as agreed by RMS in their comment (Sept 04) and as supported by some other Member States (NL, UK) a TER trigger of 10 is appropriate.	See new risk assessment (addendum)	EPCO 22 (11.04.-15.04.2005): Open point closed. Open point for EFSA: To include the results of the opinion of the Scientific Panel in the conclusion. New open point (5.22):

section 5 – Ecotoxicology (B9)

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	New open point 5.22: RMS to conduct the long-term risk assessment for aquatic organisms with proposal made by EFSA. See open point 5.10. This open point was proposed at EPCO 22			EPCO 22 (11.04.-15.04.2005): Open point still open.
	Open point 5.11: RMS to prepare an addendum to revise the endpoints for aquatic organisms (based on measured concentrations if appropriate) and revise the aquatic risk assessment if necessary. (see reporting table 5(29))	Validity of previous static acute tests on fish has been confirmed by two new acute studies with analysis of test media (please see comment on Open Point 5.9). Hence, risk assessment only requires revision in terms of choice of acute toxicity endpoint for fish (LC50 for brown trout).	The addendum include a new risk assessment based on the static acute LC50 for the most sensitive fish species (brown trout) of 98 µg a.s./l. Two new acute toxicity test on fish have been performed to confirm the results of previous tests were the concentrations of the a.s. during the test were not measured. The measured concentrations are in agreement with the nominal concentrations used in the previous test supported by measurement of the applied stock solution.	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.
5.1	Notifier to submit the composition of the tested formulations to proof their comparability to the lead formulations. (see reporting table 5(31))	Some ecotoxicology studies used an 83%w/w WP formulation. Formulation details have been supplied to the RMS in MCW confidential DOC J. The formulation is comparable to the 80 %w/w WG lead formulations. Where equivalent studies on the WG are not available, the WP results are relevant.	Agreed	EPCO 22 (11.04.-15.04.2005): Data requirement fulfilled. New open point (5.23) RMS to add the information to the confidential section of the DAR to be discussed at EPCO 25.

section 5 – Ecotoxicology (B9)

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	New open point 5.23: RMS to add the information to the confidential section of the DAR to be discussed at EPCO 25. See data requirement 5.1. New open point was proposed in the EPCO 22.			EPCO 22 (11.04.-15.04.2005): Open point still open.
	Open point 5.12: RMS to prepare an addendum regarding the risk of the metabolite THPAI to sediment dwelling organisms (THPAI was not tested on aquatic invertebrates) to be discussed in an expert meeting. (see reporting table 5(32))	A full response has been provided by the Notifier (*ref: Norman, 2005, EU Review of captan: Notifier responses to various comments on ecotoxicology raised in the official Reporting Table*). In the sediment water fate study THPAI was only greater than 10% applied radioactivity in sediment (= 11.3%) on one sampling occasion. In addition, the sample extraction method was found to result in breakdown of THPAM to THPAI. Hence, the one detection at >10% was probably an artefact of the method. The focus of the assessment should be on acute risk to fish from captan itself.	RMS agrees with the notifier argumentation (see reporting table 5.32) that the low toxicity of THPI for invertebrates can be indirectly arguedby the results of the chronic semistatic toxicity study on Daphnia were the rapid hydrolysis of captan in water leads to the THPAI formation during the test. Moreover the structure of THPAI is similar to THPAM which has an EC50 of 220 mg/l in a 48 h test with Daphnia magna.	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.

section 5 – Ecotoxicology (B9)

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

section 5 – Ecotoxicology (B9)

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Open point 5.15: RMS to amend the list of endpoints regarding the list of representative uses (spray interval should be included). (see reporting table 5(41))			EPCO 22 (11.04.-15.04.2005): Open point still open.
	Open point 5.16: Pending on the discussion of the PECs in the section on Fate and behaviour, a revision of the risk to earthworms may be necessary. (see reporting table 5(46))	Revised PECsoil values have been provided (*Terry, A. (2005). Predicted environmental concentrations of captan and its major degradation products in soil in the European Union*). These can be used in the risk assessment for earthworms. In addition, a justification on why the EPPO (2002) correction factor of 2 is not relevant for earthworm endpoints for captan has been submitted (*ref: Norman, 2005*). A low risk to earthworms can be demonstrated for all uses.		EPCO 22 (11.04.-15.04.2005): Open point fulfilled.

section 5 – Ecotoxicology (B9)

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Open point 5.17: RMS to prepare an addendum to revise the risk assessment for earthworms. (see reporting table 5(47))	Please refer to comment on Open Point 5.16.	A new risk assessment has been provided by the notifier (see addendum) based on PEC soil values calculated after the last application (70% foliar interception) . For North EU pome fruit TERs are above the trigger indicating an acceptable risk. For peaches and nectarines and South EU pome fruit the acute TERs values are higher than the trigger indicating a low risk while this is not true for the long term risk which requires a refinement. Notifier propose not to use e correction factor of 2 as indicated by the Guidance document based on the rapid hydrolysis of captan during the test (DT50 and DT90 < 1day) to give degradation products which have not a strong affinity for organic matter. RMS thinks this reasoning is acceptable. This brings the long term TERs to acceptable levels.	EPCO 22 (11.04.-15.04.2005): Argumentation of the Notifier on open point 5.17 is forwarded to EPCO 21. Open point still open. Waiting for the answer from EPCO 21. Answer from EPCO 21: EPCO 21 is happy with the PEC soil values provided in the new list of end points.
5.2	Notifier to address the risk to other non-target fauna and flora. (see reporting table 5(54))	No data are available. Captan is not a herbicide, and there are no indications of phytotoxicity from its actual use. Hence, additional data are not needed.		EPCO 22 (11.04.-15.04.2005): Data requirement still open.

section 5 – Ecotoxicology (B9)

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Open point 5.18: Pending on the discussion of the PECgw values in the section on Fate and behaviour, data on pesticidal activity of the major ground water metabolites may be necessary (see reporting table 5(54))	A new groundwater modelling report has been provided (*Terry, A. and Price, O. (2005). Predicted Environmental Concentrations of captan and its major degradation products in groundwater in the European Union using the FOCUS groundwater scenarios*). Some scenarios give PECgw values >0.1 µg/l for THPI and THPAM. However, clear 'safe use' scenarios with PECgw <0.1 µg/l have been demonstrated. Therefore, Annex 1 listing can be recommended. In addition, a study on the pesticidal (fungicidal) activity of THPI and THPAM has now been submitted. This study shows the metabolites to be non-relevant in this context.	Two studies have been submitted on the fungicidal activity of THPI and THPAM . THPAM showed no effect on Botrytis cinerea (grey mold) or Venturia inaequalis (apple scab) for conidial germination or mycelial growth. THPI showed no effect on Venturia for either endpoints. THPI at 100 mg/l decreased by 35% the mycelial growth of Botrytis cinerea inomparison with a 100% reduction for captan at 25 mg/l. I t can be concluded that the activity of the metabolites is less than 50% of the parent molecule and therefore not relevant.	EPCO 22 (11.04.-15.04.2005): Open point fulfilled.
	Open point 5.19: MS to discuss the need for further data to address the risk to sewage treatment in an expert meeting. (see reporting table 5(56))	Captan is rapidly hydrolysed. In addition, its use as an agricultural fungicide would not lead to contamination of the domestic drainage system. Hence, it is very unlikely to reach sewage treatment plants. Therefore, data are not needed.		EPCO 22 (11.04.-15.04.2005): Open point fulfilled.

REPORT OF EPCO EXPERT MEETING 23

CAPTAN

Rapporteur Member State: Italy

Specific comments on the active substance in the section

2. Mammalian Toxicology

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
03 November 2004	Greece	Captan comments GR (03-11-2004)

2. Documents submitted for meeting:

Date	Supplier	File Name
15 October 2004	RMS/ Italy	Captan consultation report (15-10-2004)
27 April 2005	RMS/ Italy	Captan Addendum Vol3 B6 2005-04-27
17 January 2005	RMS/ Italy	Captan reporting table rev1-3 (17-01-2005)
27 April 2004	RMS/ Italy	Captan list of endoints tox 2005-04-27
06 April 2005	RMS/ Italy	Captan summary of representative uses
27 April 2005	RMS/ Italy	Captan evaluation table rev 0-1 tox 2005-04-27

3. Documents tabled at the meeting:

Date	Supplier	File Name
12.05.2005	Chairman	Captan US EPA Cancer reclassification

The conclusions of the meeting were as follows:

4. **Data on preparations:** Data for two formulations (Merpan 80 WDG, Malvin WG) have been submitted by two different notifiers, which have been regarded to cover the requirements.

5. **Classification and labelling:** T, R 23, R 40, R 41, R 43 has been proposed.

6. **Recommended restrictions/conditions for use:** only applied wearing appropriate PPE (at least gloves), which is pending on the new estimation of operator and worker exposure.

7. **Reference List: ---**

Areas of concern: genotoxicity at cytotoxic dose levels

Appendix 1: EPCO discussion table: CAPTAN

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Captan (Fu)

2. Mammalian Toxicology

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Section 2 Data requirements: 4 Open points: 18		Section 2 Data requirements: 0 Open points: 5
	Open point 2.1: MS to discuss the canceriogenic properties in an expert meeting. (see reporting table 2(1))	No carcinogenicity has been observed in rats. In the mouse trials tumours in the duodenum have been observed at a dose level of ≥ 800 mg/kg bw/day. The classification has been proposed to be category 3, R 40 U.S. EPA judged that tumours of the islet cells were not treatment related. The substance has been concluded unlikely to be a human carcinogen at dose levels that do not cause cytotoxicity and regenerative cell hyperplasia. Long term rat studies: If the incidences of adenoma and sarcoma are combined that values are within the historical control data The values for pancreas tumours are within the historical control, data (14%), as well as values for uterine tumours (32%). The proposed entry in the list of end points has been agreed by the experts, which reads: "Not carcinogenic in rat. Carcinogenic (duodenal tumours) in mice, non-genotoxic mechanism, clear NOEL established. The classification category 3, R 40 was proposed and agreed by the majority of the experts. The list of end points should be amended accordingly.	<u>EPCO 23 (10 – 13.5.2005):</u> Open point fulfilled. Not carcinogenic in rat. Carcinogenic (duodenal tumours) in mice, non-genotoxic mechanism, clear NOAEL established. Proposal for classification of Category 3, R 40

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 2.2: The setting of ARfD to be discussed at an expert meeting. (see reporting table 2(3))	The ARfD has been proposed to be based on the NOAEL from the rabbit developmental study. It was agreed to base the ARfD on the overall NOAEL value of 10 mg/kg bw/day for both developmental and parental toxicity, with a safety factor of 100which will resulted in a value of 0.1 mg/kg.	<u>EPCO 23 (10 – 13.5.2005):</u> Open point fulfilled. ARfD: 0.1 mg/kg bw with a safety factor of 100.
2.1	Notifier to submit the position paper Gordon and Kinzell (2004) and the study Moore and Creasey (2004). (see reporting table 2(3))	The information has been submitted and the evaluation has been presented in the addendum (p 18 ff)	<u>EPCO 23 (10 – 13.5.2005):</u> Data requirement fulfilled.
	Open point 2.3: MS to agree on the ADI value at an expert meeting. (see reporting table 2(4))	The ADI has been proposed to be 0.1 mg/kg with a SF of 100, based on the NOAEL of 10 mg/kg bw/dayfrom the rabbit developmental toxicity study, supported by the multi-generation study in the rat. The same will apply for the AOEL, resulting in 0,1 mg/kg (see open point 2.10)	<u>EPCO 23 (10 – 13.5.2005):</u> Open point fulfilled. ADI and AOEL: 0.1 mg/kg, safety factor 100.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 2.4: The dermal absorption value should be discussed at an expert meeting. (see reporting table 2(6))	Initial proposal from the RMS was 3%. Information on dermal absorption has been presented in the addendum (p. 23 ff) and the DAR (p. 148 ff) From the in vivo rat study a value of 10% (skin not included) can be derived. The dermal absorption in human skin will be less than in rat skin. Based on the limited information and poor quality of the in vitro studies a reduction can not be verified. Therefore the 10% value was supported by the experts.	<u>EPCO 23 (10 – 13.5.2005):</u> Open point fulfilled. Dermal absorption: 10% based on in vivo data. RMS to amend the list of endpoints.
	Open point 2.5: The setting of the highest relevant NOAEL for the long-term studies should be discussed at an expert meeting. (see reporting table 2(9))	NOAEL: 25 mg/kg bw/day, based on the 3 generation rat study NOAEL: 25 mg/kg bw/day, based on the 2 year rat study, based on reduction of body weight gain and increased liver weight. The list of end points should be amended. The 2 year rat study should be mentioned instead of the 3 generation study. With regard to the target/critical effect the species (rat) should be specified. The mouse study is a carcinogenicity study, which will be mentioned in that part of the list of end points.	<u>EPCO 23 (10 – 13.5.2005):</u> Open point fulfilled. NOAEL: 25 mg/kg bw/day, 2 year rat study RMS to amend the list of end points.
2.2	Notifier to submit new toxicokinetic study. (see reporting table 2(10))	The information has been submitted and the evaluation has been presented in the addendum. Thiophosgene disappears rapidly when added in excess (100 µg/mL) to human whole blood *in vitro.* The half-life was calculated to be 0.6 seconds. This study demonstrates why neither captan (with the DT_{50} of 0.97 sec. in human blood) nor thiophosgene are likely to reach sensitive target distant to the mucosal surface of the gastrointestinal tract and as part of the mechanism data it further supports the captan mode of action.	<u>EPCO 23 (10 – 13.5.2005):</u> Data requirement fulfilled. The half-life of thiophosgene is 0.6 sec.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 2.6: The RMS to provide a summary of the new toxicokinetic study in the addendum to be discussed in an expert meeting. (see reporting table 2(11))	See data requirement 2.1	<u>EPCO 23 (10 – 13.5.2005):</u> Open point fulfilled.
	Open point 2.7: The need of performing a 90-day oral study in rat should be discussed at an expert meeting. (see reporting table 2(13))	A 90-day oral rat is not likely to affect the endpoints or NOELs used for risk assessments. The mode of action for captan is constant over time and does not change with enzyme induction or other changes as test animals age. It has been discussed whether the study should be required on the basis of the requirements laid down in the Commission Directive 91/414/EEC. In general the 90 day oral rat and dog study has to be reported unless it is not scientifically necessary. A statement from the notifier has been presented by the RMS in the addendum (5.3.2, p 27). This has been agreed on by the majority of the experts.	<u>EPCO 23 (10 – 13.5.2005):</u> Open point fulfilled. A 90 day oral rat study is not required.
	Open point 2.8: The setting of the NOAEL(C) in the 90-day inhalatory study should be discussed at an expert meeting. (see reporting table 2(14))	The notifier contends that the NOEL in the 90-day inhalation study in rat is 0.6 µg/L. RMS tends to agree that the rat larynx is particular sensitive to irritants but the NOAEC 0.6 µg/l is sustainable since the only effect was the reduction of body weight (-8%) registered during the treatment that returned to control levels after the end of the exposure. The NOAEC (systemic) proposed in the DAR is 0,6 µg/l has been agreed on by the experts.	<u>EPCO 23 (10 – 13.5.2005):</u> Open point fulfilled. NOAEC (systemic): 0.6 µg/L

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 2.9: MS to discuss the highest relevant NOAEL in the reproductive toxicity studies at an expert meeting. (see reporting table 2(17))	The experts confirmed the RMS's approach, presented in the list of end points: Reproductive toxicity: NOAEL (fertility reproductive effects) 500 mg/kg bw/day NOAEL (parental toxicity) 25 mg/kg bw/day (parental toxicity) NOAEL (pup offspring toxicity) 12.5 mg/kg bw/day Developmental toxicity: NOAEL 10 mg/kg bw/day (rabbit) NOAEL 90 mg/kg bw/day (rat)	EPCO 23 (10 – 13.5.2005): Open point fulfilled. Developmental toxicity: NOAEL 10 mg/kg bw/day (rabbit) NOAEL 90 mg/kg bw/day (rat)
2.3	Notifier to submit the position paper "Comments on captan Monograph Volume III" for RMS to provide a summary in an addendum. (see reporting table 2(17))	The information has been submitted and the evaluation has been presented in the addendum (p. 28 ff) This has already been discussed.	EPCO 23 (10 – 13.5.2005): Data requirement fulfilled.
	Open point 2.10: MS to agree on the AOEL value at an expert meeting. (see reporting table 2(18))	See open point 2.3. AOEL: 0,1 mg/kg, based on the rabbit developmental toxicity study.	EPCO 23 (10 – 13.5.2005): Open point fulfilled. AOEL: 0.1 mg/kg bw/day
	Open point 2.11: The RMS to present new exposure	New calculations have been submitted with a 3% value for the dermal absorption. A rough estimation has been done during the meeting. On this basis the operator exposure below the AOEL is expected for the use in peaches	EPCO 23 (10 – 13.5.2005):

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	calculations in an addendum, to be discussed at an expert meeting. (see reporting table 2(18))	wearing PPE. Nevertheless new calculations have to be submitted with an appropriate body weight for the operator and the dermal absorption default value of 10 %.	Open point still open A new calculation on operator exposure has to be submitted.
	Open point 2.12: The risk for bystanders should be discussed in an expert meeting. (see reporting table 2(26))	According to the addendum the bystander exposure is 36% after 14 days, based on the AOEL on 0.1 mg/kg. Even taking into account all changed values of the AOEL, the bystander exposure is below the AOEL. This point is therefore addressed.	<u>EPCO 23 (10 – 13.5.2005):</u> Open point fulfilled. A new calculation on bystander exposure has to be submitted.
	Open point 2.13: The RMS to clarify which PPE that was included in the operator exposure calculations, together with open point 2.11 (in comment 2(18) in the reporting table). (see reporting table 2(27))	See open point 2.11	<u>EPCO 23 (10 – 13.5.2005):</u> Open point still open A new calculation on operator exposure has to be submitted.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 2.14: The RMS to provide clarifications of the measurements of worker exposure in an addendum. The worker exposure should be discussed at an expert meeting. (see reporting table 2(30))	The worker exposure needs to be re-calculated with regard to the new value for dermal absorption and to the foliar residues.	EPCO 23 (10 – 13.5.2005): Open point still open A new calculation on worker exposure has to be submitted taking into account the new value for dermal absorption and foliar residues.
	Open point 2.15: Acceptability of the genotoxicity studies to be clarified by the RMS. If they are not acceptable they should be deleted from the reference list. (see reporting table 2(33))	The acceptability of the studies were discussed since many of them are of of old date (around 1970). Many studies are performed with a source with a higher purity than the specification technical material. A dominant-lethal mutation test in rats reported in the DAR (p 77 ff) gives the indication of low mutagenicity. The *in vivo* studies show positive results in one case, negative effects in four cases. The study (Feng, Lin 1987, published) showing positive results was discussed intensively. The notifier has concluded this study not to be reliable because of the protocol, the source and the purity of the test material. Only with the material from the Chinese source positive effects have been observed. The Chinese material seems to be totally different. All other studies are publications where the detailed information is not available. The studies have been performed within the a different impurity content. Two of the submitted *in vivo* studies have been performed with the technical material, according to GLP and the guideline. These studies have been concluded to be acceptable. Jacoby, 1985; micronucleus test (bone marrow in mouse) 94% purity, negative results. Kenelly, 1990, UDS test, 91% purity, negative results There is no evidence only for the technical material, supplied by the notifier, based on two studies (Jacoby 1985, and Kenelly, 1990). The conclusion is not valid for other sources.	EPCO 23 (10 – 13.5.2005): Open point fulfilled. Based on two recent studies (Jacoby 1985, and Kenelly, 1990), there is no evidence of genotoxicity for the technical material.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 2.16: The genotoxic effect of Captan to be clarified by the RMS and to be discussed at an expert meeting. (see reporting table 2(34))	See open point 2.15	EPCO 23 (10 – 13.5.2005): Open point fulfilled.
	Open point 2.17: RMS to check the publications mentioned in the comment from GR (e.g.: Reuber MD, 1989; Cabral R et al., 1991; Hasegawa R et al., 1993; Perocco P et al, 1995) regarding the carcenogicity of Captan and to summarize in an addendum. (see reporting table 2(35))	This has been done by the RMS and has been discussed together with data requirement 2.4 and open point 2.1. The mechanistic studies have been evaluated in the submitted addendum (p. 12 ff). Identification of neoplastic and non neoplastic lesions in short term assays have been reported. Classification has been proposed to be category 3, R 40	EPCO 23 (10 – 13.5.2005): Open point fulfilled. Classification has been proposed to be category 3, R 40

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 2.18: RMS to review the study mentioned in the comment from GR (Mills PK, 1998 and MCDuffie HH et al, 2001) regarding medical data. (see reporting table 2(36))	This has been discussed together with data requirement 2.4 and open point 2.1.	EPCO 23 (10 – 13.5.2005): Open point fulfilled.
2.4	Notifier to submit the two rat carcinogenicity studies by Goldenthal et al., 1982 and Bruyntjes, 1984. (see reporting table 2(37))	See open point 2.1	EPCO 23 (10 – 13.5.2005): See open point 2.1

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Message from EPCO 24 to EPCO 23: Please clarify the toxicological relevance of the metabolites THPI, THPI epoxide, 3 OH-THPI and 5 OH-THPI .	THPI is the first product of metabolism: LD_{50} > 2000mg/kg THPAM is the second metabolite. It is an animal metabolite which will be covered by the ADI. Therefore no additional information is required. It shows negative genotoxicity. 3 OH-THPI and 5 OH-THPI (animal metabolites) show up in low amounts. They are hydrophilic. Nevertheless they are covered by the ADI as well. Information on THPI epoxide is not available.	Message from EPCO 24 to THPI is the first product of metabolism: LD_{50} > 2000 mg/kg bw/day THPAM is the second metabolite. It is an animal metabolite which would be covered by the ADI for captan.. It shows negative genotoxicity. 3 OH-THPI and 5 OH-THPI (animal metabolites) show up in low amounts. They are hydrophilic. Nevertheless they are said to be covered by the ADI as well. Information on THPI epoxide is not available.
	New open point. 2.19 Since ~~folpet~~ captan is to be classified as Toxic an analytical method for determining folpet or folpet residue(s) in body fluids or tissues (blood) must be available.	~~Folpet~~ Captan is rapidly degraded and would is not present in blood. Another marker should be identified by the RMS.	<u>EPCO 23 (10 – 13.5.2005):</u> Open point still open. RMS to identify a marker for ~~folpet~~ captan in blood as well as an analytical method for the determination..
	New open point 2.20: RMS to amend the list of end points		<u>EPCO 23 (10 – 13.5.2005):</u> Open point still open.

Appendix 2: Evaluation table

2. Mammalian Toxicology

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Section 2 Data requirements: 4 Open points: 18			Section 2 Data requirements: 0 Open points: 5
	Open point 2.1: MS to discuss the canceriogenic properties in an expert meeting. (see reporting table 2(1))	The notifier response by Makhteshim and Calliope (2005) to comments made by Greece on the toxicology section of the DAR is summarised in the new addendum under Annex Point IIA 5.10/02. This paper summaries and refers to various other new studies which are submitted and summarised in the new addendum, under Points IIA, 5.5.3/01, 5.5.3/02, 5.5.3/03, 5.9.3/02, 5.9.3/03.	April 2005 The RMS deems acceptable the responses stated in the addendum made to the comments made by Greece. Neither the experimental data nor the epidemiological observations are sufficient to change the overall conclusions regarding the judgement of no cancer risk to man.	EPCO 23 (10 – 13.5.2005): Open point fulfilled. Not carcinogenic in rat. Carcinogenic (duodenal tumours) in mice, non-genotoxic mechanism, clear NOAEL established. Proposal for classification of Category 3, R 40
	Open point 2.2: The setting of ARfD to be discussed at an expert meeting. (see reporting table 2(3))	The notifier contends that an ARfD is not applicable for captan. The arguments supporting this contention are presented in the paper by Gordon and Kinzell (2004) summarised in the new addendum under Point IIA, 5.10/01, supported by Moore and Creasey (2004) summarised in the new addendum under Point IIA,	April 2005 The RMS deems that the data summarised in the new addendum under Point IIA, 5.8.2/06 are applicable to Captan and support that the short term toxicity (irritancy) can result in a maternotoxic effect that in turn leads to developmental toxicity. The need of a ArfD will be discussed at an EPCO	EPCO 23 (10 – 13.5.2005): Open point fulfilled. ARfD: 0.1 mg/kg bw with a safety factor of 100.

2. mammalian toxicology

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
		5.8.2/06. Note: Moore and Creasey (2004) is a study on folpet but is directly applicable to captan.	meeting.	
2.1	Notifier to submit the position paper Gordon and Kinzell (2004) and the study Moore and Creasey (2004). (see reporting table 2(3))	The paper by Gordon and Kinzell (2004) is summarised in the new addendum under Point IIA, 5.10/01. The study by Moore and Creasey (2004) is summarised in the new addendum under Point IIA, 5.8.2/06. Note: Moore and Creasey (2004) is a study on folpet but is applicable to captan.	April 2005 Paper available and summarized in the addendum. See above	EPCO 23 (10 – 13.5.2005): Data requirement fulfilled
	Open point 2.3: MS to agree on the ADI value at an expert meeting. (see reporting table 2(4))	Awaiting expert meeting comments.	April 2005 The RMS already agreed to lower to 0.1 mg/kg b.w. the ADI based on the NOAEL for maternal and developmental toxicity of 10 mg/kg b.w. in rabbit.	EPCO 23 (10 – 13.5.2005): Open point fulfilled. ADI and AOEL: 0.1 mg/kg, safety factor 100.
	Open point 2.4: The dermal absorption value should be discussed at an expert meeting. (see reporting table 2(6))	The notifier contends that a dermal absorption value of 3% is appropriate for captan for use in risk assessment. The notifier's arguments supporting this contention and the notifier's response to comments received from Member States on the dermal	April 2005 RMS confirms the acceptability of the Notifier's comments based, in accordance with some shortcomings of the in vivo studies, on the worst case data. RMS does not consider the shortcomings so critical to repeat the	EPCO 23 (10 – 13.5.2005): Open point fulfilled. Dermal absorption: 10% based on in vivo data.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
		absorption studies with captan is presented the new addendum under Point IIIA 7.3. This conclusion is also supported by the RMS.	study.	RMS to amend the list of endpoints.
	Open point 2.5: The setting of the highest relevant NOAEL for the long-term studies should be discussed at an expert meeting. (see reporting table 2(9))	Awaiting expert meeting comments.	April 2005 The NOAEL of the three generation study (25 mg/kg b.w) is acceptable since the treatment can be assimilate to a chronic treatment, i.e. rat chronic 2-years exposure, that shows a NOAEL of 24 and 25 mg/kg b.w.	EPCO 23 (10 – 13.5.2005): Open point fulfilled. NOAEL: 25 mg/kg bw/day, 2 year rat study RMS to amend the list of end points.
2.2	Notifier to submit new toxicokinetic study. (see reporting table 2(10))	[Should read reporting table 2(11)]. The study by Arndt, T. and Dohn, D. (2004) is summarised in new addendum under Point IIA 5.1/08. Thiophosgene (a captan reactive metabolite intermediate) disappears rapidly when added in excess (100 µg/mL) to human whole blood *in vitro.* The half-life was calculated to be 0.6 seconds. **Conclusion:** This study demonstrates why neither captan (with the DT_{50} of 0.97 sec. in human blood) nor thiophosgene are likely to reach sensitive target distant to the mucosal	April 2005 The study is acceptable but RMS still needs some clarifications on the metabolism of Captan before the fungicide enters into the blood (i.e. in the skin, in the gut etc.). Would Captan per se in tissues different from blood react with the thiols within seconds as thiophosgene does when the parent compound is degraded?	EPCO 23 (10 – 13.5.2005): Data requirement fulfilled. The half-life of thiophosgene is 0.6 sec.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
		surface of the gastrointestinal tract and as part of the mechanism data it further supports the captan mode of action.		
	Open point 2.6: The RMS to provide a summary of the new toxicokinetic study in the addendum to be discussed in an expert meeting. (see reporting table 2(11))	The study by Arndt, T. and Dohn, D. (2004) is summarised in new addendum under Point IIA 5.1/08. Thiophosgene (a captan reactive metabolite intermediate) disappears rapidly when added in excess (100 µg/mL) to human whole blood *in vitro.* The half-life was calculated to be 0.6 seconds. **Conclusion:** This study demonstrates why neither captan (with the DT_{50} of 0.97 sec. in human blood) nor thiophosgene are likely to reach sensitive target distant to the mucosal surface of the gastrointestinal tract and as part of the mechanism data it further supports the captan mode of action.	April 2005 See above	PCO 23 (10 – 13.5.2005): Open point fulfilled.
	Open point 2.7: The need of performing a 90-day oral study in rat should be discussed at an expert meeting. (see reporting table 2(13))	The notifier contends that a 90-day rat study is not required. The reasons supporting this contention are summarised in the new addendum under Point IIA 5.3.2. The reasons are as follows: 1. The mode of action (MOA) for captan for toxicity is well established. This MOA is based on the rapid chemical reaction of captan and	April 2005 RMS fully support the Notifier's comments. It is unlikely that a 90-day study in rats will identify a new target or adverse effect that has not been already observed.	EPCO 23 (10 – 13.5.2005): Open point fulfilled. A 90 day oral rat study is not required.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	continued: Open point 2.7: The need of performing a 90-day oral study in rat should be discussed at an expert meeting. (see reporting table 2(13))	thiophosgene with thiol (-SH) groups. 2. The basis for the waiver as set forth in the DAR is believed adequate: a. Given the well established captan MOA, it is unlikely that transitory changes in clinical chemistry or hematology, seen at 90 days in the two year study would lower the NOEL already established by the rat two year study, should a new 90-day study be initiated. b. The collective data in mice, rats and dogs have not identified an organ, other than the gastrointestinal tract, that captan targets. It is unlikely that a 90-day study in rats will identify a new target or adverse effect that has not already been evaluated. 3. A 90-day oral rat is not likely to affect the endpoints or NOELs used for risk assessments. The mode of action for captan is constant over time and does not change with enzyme induction or other changes as test animals age. This conclusion is also supported by the RMS.		

2. mammalian toxicology

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

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 2.12: The risk for bystanders should be discussed in an expert meeting. (see reporting table 2(26))	An estimate of dermal exposure of bystanders is presented in the DAR. This shows a wide margin of safety. Furthermore, the vapour pressure of captan is low 4.2 x 10^{-6} Pa at 20^{o}C and so the inhalation risk to bystanders is considered to be negligible. Therefore, the overall risk to bystanders is considered to be negligible. This conclusion is consistent with the conclusion of the RMS.	April 2005 RMS agrees	EPCO 23 (10 – 13.5.2005): Open point fulfilled. A new calculation on bystander exposure has to be submitted.
	Open point 2.13: The RMS to clarify which PPE that was included in the operator exposure calculations, together with open point 2.11 (in comment 2(18) in the reporting table). (see reporting table 2(27))	The operator exposure study represents a worst-case as the mixing/loading was done with a WP formulation which would lead to higher exposure than with the WG formulations supported in the dossier. Also, the applications were made by tractors without cabs. The operators wore what are described in the report as 'overalls'; these are not described in the report as chemical proof coveralls. A full description of the overalls is not given. The photographs indicate that the workers were not wearing heavy chemical proof garments.	April 2005 More information are needed from the Notifier.	EPCO 23 (10 – 13.5.2005): Open point still open A new calculation on operator exposure has to be submitted.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
		The notifier contends that the use of PPE in the form of protective gloves will provide sufficient protection for operators.		
	Open point 2.14: The RMS to provide clarifications of the measurements of worker exposure in an addendum.The worker exposure should be discussed at an expert meeting. (see reporting table 2(30))	New calculations of worker exposure for workers with uncovered arms and legs are summarised in new addendum under Point IIIA, 7.2.3.3. **Conclusion**: The risk to all workers involved with the handling of crops treated with 'Merpan' 80 WDG/'Malvin' WDG in the absence of protective clothing is considered to be low. It is not necessary to set additional re-entry periods longer than the PHI for workers after the spray has dried or for workers to wear gloves when handling treated crops. This conclusion is consistent with the conclusion of the RMS.	April 2005 RMS agrees	EPCO 23 (10 – 13.5.2005): Open point still open A new calculation on worker exposure has to be submitted taking into account the new value for dermal absorption and foliar residues.
	Open point 2.15: Acceptability of the genotoxicity studies to be clarified by the RMS.If they are not acceptable they should be deleted fom the reference list. (see reporting table 2(33))	See notifier response to comments made by Greece on the toxicology section of the DAR summarised in the new addendum under Annex Point IIA 5.10/02. The notifier concludes that there remain no data gaps in the genotoxicity database for captan.	April 2005 The overall weight of evidence indicates that Captan is unlikely to be an in vivo mutagen. In in vitro test systems captan and/or its metabolites, particularly thiophosgene, have the ability to induce mutagenic effects. The mutagenic potency is markedly reduced in the presence of material presenting thiol groups. Neither captan	EPCO 23 (10 – 13.5.2005): Open point fulfilled. Based on two recent studies (Jacoby 1985, and Kenelly, 1990), there is no evidence of genotoxicity for the technical material.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
			nor its breakdown products are likely to reach the stem cells within the duodenal crypts due their short half-life. There is no evidence of any chromosomal aberrations in the duodenal cells following oral administration.	
	Open point 2.16: The genotoxic effect of Captan to be clarified by the RMS and to be discussed at an expert meeting. (see reporting table 2(34))	See notifier response to comments made by Greece on the toxicology section of the DAR summarised in the new addendum under Annex Point IIA 5.10/02. The notifier concludes that captan does not pose a risk of mutagenicity *in vivo*	April 2005 See above	EPCO 23 (10 – 13.5.2005): Open point fulfilled.
	Open point 2.17: RMS to check the publications mentioned in the comment from GR (e.g.: Reuber MD, 1989; Cabral R et al., 1991; Hasegawa R et al., 1993; Perocco P et al, 1995) regarding the carcenogicity of Captan and to summarize in an addendum. (see reporting table 2(35))	See notifier response to comments made by Greece on the toxicology section of the DAR summarised in the new addendum under Annex Point IIA 5.10/02. In addition, the notifier's summary and interpretation of the Reuber, Cabral Hasegawa studies are presented in the new addendum under Points IIA 5.5.3/01, 5.5.3/02 and 5.5.3/03. Based on the new Guidelines for Carcinogen Risk Assessment, EPA's current B2 (probably human) carcinogen classification for captan is inappropriate.	April 2005 RMS agrees with the Notifier's comments. Reuber's conclusions are based just on his personal judgement and are not shared by other scientific and/or regulatory bodies. The data published by Cabral, Hasegawa and Perocco, although scientifically valid, do not add value to the overall toxicological data on which RMS has drawn his assessment.	EPCO 23 (10 – 13.5.2005): Open point fulfilled. Classification has been proposed to be category 3, R 40

2. mammalian toxicology

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 2.18: RMS to review the study mentioned in the comment from GR (Mills PK, 1998 and MCDuffie HH et al, 2001) regarding medical data. (see reporting table 2(36))	The notifier's summary and interpretation of the epidemiology studies is presented in the new addendum under Annex Point IIA 5.9.3 (5.9.3/02, 5.9.3/03). **Conclusion**: These epidemiology studies have suggested captan is associated with human cancer. The study conclusions are judged suspect in light of the well-established mode of action of captan, its rapid degradation in vivo, and the absence of collaborating cancers in populations of workers manufacturing captan (Palshaw, 1980, Palshaw, 1987). It should be concluded that there is insufficient epidemiologic evidence to link captan to human cancer.	April 2005 RMS agrees with the Notifier's comments suggesting more rigorous study designs to further determine any possible correlation between Captan exposure and human cancer.	EPCO 23 (10 – 13.5.2005): Open point fulfilled.
2.4	Notifier to submit the two rat carcinogenicity studies by Goldenthal et al., 1982 and Bruyntjes, 1984. (see reporting table 2(37))	See notifier response to comments made by Greece on the toxicology section of the DAR summarised in the new addendum under Annex Point IIA 5.10/02. This document includes background data by Bruyntjes, 1984. Note that the Goldenthal et al., 1982 report is included in the DAR referenced under original author Rajesekaran (Report R-9282/TMN-0768).	Goldenthal et al., 1982 is already summarized in the DAR referenced under the original Author Rajesekaran (report R-9282/TMN 0768 IIA 5.5.1/01). Bruyntjes 1984 is available to the RMS.	EPCO 23 (10 – 13.5.2005): See open point 2.1

2. mammalian toxicology

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Message from EPCO 24 to EPCO 23: Please clarify the toxicological relevance of the metabolites THPI, THPI epoxide, 3 OH-THPI and 5 OH-THPI .			EPCO 23 (10 – 13.5.2005): Message from EPCO 24 to THPI is the first product of metabolism: LD_{50} > 2000 mg/kg bw/day THPAM is the second metabolite. It is an animal metabolite which would be covered by the ADI for captan.. It shows negative genotoxicity. 3 OH-THPI and 5 OH-THPI (animal metabolites) show up in low amounts. They are hydrophilic. Nevertheless they are said to be covered by the ADI as well. Information on THPI epoxide is not available.
	New open point. 2.19 Since folpet is to be classified as Toxic an analytical method for determining folpet or folpet residue(s) in body fluids or tissues (blood) must be available.			EPCO 23 (10 – 13.5.2005): Open point still open. RMS to identify a marker for folpet in blood as well as an analytical method for the determination..
	New open point 2.20: RMS to amend the list of end points. (See above)			EPCO 23 (10 – 13.5.2005): Open point still open.

REPORT OF EPCO EXPERT MEETING 24

CAPTAN

Rapporteur Member State: Italy

Specific comments on the active substance in the section

3. Residues

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

None.

2. Documents submitted for meeting:

Date	Supplier	File Name
March 2005	RMS/Italy	Captan Addendum vol3 B7 (March 2005)
22 April 2005	RMS/Italy	Captan evaluation table rev0-1 residues 2005-04-22
22 April 2005	RMS/Italy	Captan list of endpoint residues 2005-04-22
15 October 2004	RMS/Italy	Captan_consultation_report_(15-10-2004)
17 January 2005	RMS/Italy	Captan_reporting_table_rev1-3_(17-01-2005)
April 2005	RMS/Italy	Captan summary of representative uses

3. Documents tabled at the meeting:

Date	Supplier	File Name
11 May 2005	RMS/Italy	Captan + THPI residues in processed crops

The conclusions of the meeting were as follows:

4. **Data on preparations:** According to the new residue definition it is obvious that there are still outstanding data.

5. **Classification and labelling:** None.

6. **Recommended restrictions/conditions for use:** None.

7. **Reference List** None.

Areas of concern: acute intake

Appendix 1: EPCO discussion table: CAPTAN

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Captan (Fu)

3. Residues

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 3.1: RMS to provide an addendum to be considered in expert meeting with the new MRL proposal for peaches and nectarines, new TMDI and I(N)EDI calculations, as well as new STMR calculations. (see reporting table 3(1))	RMS provided the addendum. The notifier required a change in the GAP for peaches/nectarines – the PHI should be changed from 7 days to 21 days. Therefore, the MRL = 3 mg/kg and STMR = 0.78 mg/kg were changed by the RMS. RMS stated that for the acute dietary risk assessment the changed GAP does not cause any problems. EFSA pointed out that it was not agreed on that the GAP can be changed concerning the PHI. A change in the GAP during the evaluation process is not acceptable. In fact, the question behind the open point was whether the MRL proposal of 5 mg/kg or 10 mg/kg covers the unchanged GAP for peaches and nectarines with a PHI of 7 days. Therefore, the meeting agreed that this open point can not be regarded as fulfilled.	Information in the addendum do not address the issue. Open point still open.
	Open point 3.2: RMS to amend the list of end points on the following points: - summary of residue data: GAPs in N and S for pome fruits should be addressed separately (in accordance with the EPCO manual) - TMDI and I(N)EDI calculations	RMS amended the list of end points accordingly. UK asked why the crops should stated separately and divided into North and South. Chair stated that for a MRL proposal this procedure is helpful because e.g. the intake for apples and pears are different. So the risk assessment can be done for single crops and special regions.	List of end points has been amended. Open point fulfilled.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	- Proposed MRLs (see reporting table 3(1))		
	Open point 3.3: RMS to prepare an addendum to be discussed in expert meeting addressing uncharacterized material in fruit wash, foliage, peel and pulp extracts of the metabolism study on apples (level and number of individual fractions…). (see reporting table 3(2))	RMS submitted the requested addendum. The RMS stated that the occurrence of uncharacterised material can be accepted in fruit wash, foliage, peel and pulp extracts. UK agreed that this point can be regarded as addressed since UK made the initial comment in the reporting table. The meeting agreed on this proposal.	RMS provided the addendum. Open point fulfilled.
3.1	A hydrolysis study in representative hydrolytic conditions. (see reporting table 3(4))	RMS proposed that this data requirement should be regarded as still open since the position paper of the notifier does not address this issue. By taking into account that hydrolysis studies are ongoing the meeting agreed that this data requirement is still open.	Results of ongoing hydrolysis studies still have to be awaited. Data requirement still open.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 3.4: RMS to address in an addendum to be discussed in expert meeting the position paper of the notifier "Captan. Position Paper on Effects on the Nature of the Residue (2004)". Open point relates to data requirement 3.1. (see reporting table 3(4) and 3(22))	RMS provided the requested information in an addendum. RMS proposed that this open point should be regarded as still open since the position paper of the notifier do not sufficiently address this point. Chair suggested that this open point can be closed because the data requirement 3.1 is still open. The meeting agreed on this proposal.	Open point closed. See data requirement 3.1.
3.2	A whole balance study for tomato washed, peeled and canned or used for juice, plus a follow-up study in canned tomato and tomato juice. (see reporting table 3(4))	RMS received the requested study from the notifier. The residues were below the LOQ in the balance study on tomatoes. Therefore, the transference can not be calculated. THPI seems not to have been analyzed in these studies. Nevertheless, the Chair stated that sufficient information according to the processing (e.g. apples) are available. The meeting agreed that this data requirement can be regarded as fulfilled.	Data requirement fulfilled. According to the new residue definition the study needs to be revisited by the RMS. (See new open point 3.15)

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 3.5: RMS to evaluate in an addendum to be considered in expert meeting the studies provided by the notifier: "Faessel, V. (2004). Residue study in and on tomatoes following 4 applications of the test item Malvin WG. Anadiag report R A3154.", "Faessel, V. (2004). Residue study in and on tomatoes following 4 applications of the test item Malvin WG. Anadiag report R A3156." and "Faessel, V.(2004). Validation study of the analytical method for the determination of captan and tetrahydrophthalimide (THPI) in tomato processed fractions. Anadiag report R A3153." Open point relates to data requirement 3.2. (see reporting table 3(4) and 3(28))	RMS evaluated the studies in an addendum (see data requirement 3.2). The studies were regarded as acceptable by the meeting, but not relevant if the residue definition in products of plant origin is extended to other compounds than captan.	RMS presented an addendum. Open point fulfilled. If THPI is included in the residue definition for plant products, the submitted studies have to be considered as not relevant. (See new open point 3.15)

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
3.3	A balance study and 3 follow-up studies for canned peaches/nectarines. (see reporting table 3(4))	Two studies are already included in the DAR, but concerning canned apples. THPI was not taken into account in the investigations. Further studies will be conducted by the notifier during the 2005 season. Therefore, the meeting agreed that this data requirement remains open.	Data requirement still open.
	Open point 3.6: MSs to discuss residue definition for processed commodities and processing yields in an expert meeting. Open point relates to open point 1.16. (see reporting table 3(7))	This open point was discussed together with open point 3.7. The discussion on yield factors was postponed to a later stage due to the lack of time.	Open point fulfilled.
	Open point 3.7: MSs to discuss in an expert meeting the residue definition for animal products. Open point relates to open point 1.16. (see reporting table 3(9))	Message was sent to EPCO 23 to clarify the toxicological relevance of the metabolites THPI, THPI epoxide, 3 OH-THPI and 5 OH-THPI. After receiving the answer from the EPCO 23 meeting: The meeting discussed whether the metabolite THPI can be regarded to be as toxic as the parent compound. Chair stated that according to the DAR THPI is negative in the AMES test, not embryo-toxic nor teratogenic or carcinogenic. NL stated that therefore THPI seems not to be a relevant metabolite. Chair stated that captan as well as THPI can occur in the plant material. Intake calculation which considers only captan is not sufficient since there will be also an intake of THPI for the animals. For correct dietary animal burdens and for correct residues in products of animal origin determination of THPI in the plant is needed. Therefore, THPI (and as the case may be 3 OH-THPI and 5 OH-THPI) should be added to the residue definition. Even	Open point fulfilled. RMS to amend the list of end points. See new open point 3.16. New open point 3.15: RMS to go back to the available data set and make new evaluation of the available data so that the MRL proposals and the risk assessment can be done on the basis of the new residue

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	continued Open point 3.7: MSs to discuss in an expert meeting the residue definition for animal products. Open point relates to open point 1.16. (see reporting table 3(9))	though it can not clearly be stated that THPI is as toxic as captan. Therefore the meeting agreed to change the residue definition as follows: - plant residue definition for monitoring: Sum of captan and THPI expressed as captan - plant residue definition for risk assessment: Sum of captan and THPI expressed as captan According to the metabolism study captan seems not to be the correct residue definition for animals. Therefore the residue definitions for animals were also changed as follows: - the animal residue definition for risk assessment: Sum of THPI, 3 OH-THPI and 5 OH-THPI expressed as captan - the animal residue definition for monitoring: Sum of THPI, 3 OH-THPI and 5 OH-THPI expressed as captan According to the THPI epoxide the meeting is of the opinion that this metabolite is not stable and the amount found is low. Therefore, this metabolite is not taken into account. The list of end points needs to be revised accordingly. See new open point 3.16.	definitions. The new calculations should be summarised in an addendum. Open point still open. Message from EPCO 24 to EPCO 23: Please clarify the toxicological relevance of the metabolites THPI, THPI epoxide, 3 OH-THPI and 5 OH-THPI.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Message from EPCO 24 to EPCO 23: Please clarify the toxicological relevance of the metabolites THPI, THPI epoxide, 3 OH-THPI and 5 OH-THPI .	At this stage it was considered that the toxicological end point of captan should also apply to THPI and its hydroxylated forms.	Answer from EPCO 23 to EPCO 24: THPI is the first product of metabolism: LD50 > 2000mg/L THPAM is the second metabolite. It is an animal metabolite which will be covered by the ADI. Therefore no additional information is required. It shows negative genotoxicity. 3 OH-THPI and 5 OH-THPI (animal metabolites) show up in low amounts. They are hydrophilic. Nevertheless they are covered by the ADI as well. Information on THPI epoxide is not available.
	Open point 3.8: RMS to provide in an addendum information in column 3 of comments 3(8) and 3(9) of the reporting table. (see reporting table 3(9))	RMS presented the information in an addendum. For raw crops the residues should be expressed as captan alone,. Chair proposed to classify this point as fulfilled. The meeting agreed on this proposal.	RMS provided the information in an addendum. Open point fulfilled.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 3.9: MSs to discuss the reliability of the residue of 8.0 mg/kg in pome fruits in an expert meeting. (see reporting table 3(11))	RMS stated that the residue of 8.0 mg/kg in pome fruits can be considered as an outlier. UK disagreed because the residue should only be excluded if a valid reason or problem has been identified in the trial. Chair stated that the identification of an outlier is complicated, if there is no clear reason in the trial. Furthermore, the chair is not of the opinion that the value is an outlier although the notifier stated that monitoring show 99.97% of the total number of samples containing residues at or below the proposed MRL of 5 mg/kg. GR confirmed that according to the data set the value can not be easily considered an outlier, but the MRL of 10 mg/kg nevertheless is too high and should be reduced. Chair stated that the MRL proposal of 10 mg/kg is justified since 8.0 mg/kg can not be considered as an outlier. AT argued that even without the outlier the MRL of proposal should be 10 mg/kg. EFSA stated that there is enough evidence that 8.0 mg/kg is not an outlier (e.g. the high variation in the data set, similar initial deposit in other trials). RMS disagreed and stated that according to the EU rules (EC document 7039/VI/95 EN, Appendix I, 4.1 Elimination of outlier) the value was identified as an outlier. Chair stated that the statistical calculations in all cases indicate that the MRL 5 mg/kg is too low even if 8 mg/kg is considered an outlier. Therefore, the MRL of 10 mg/kg should apply. The meeting agreed on this proposal.	The experts are of the opinion the value 8 mg/kg can not be considered an outlier. This leads to the MRL proposal of 10 mg/kg in pome fruits. Open point fulfilled.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
3.4	Clarification of the results of the McKay study on storage stability, providing stability data for captan and THPI separately. If not available new experimental data are required. (see reporting table 3(16))	RMS provided an addendum on this issue. No significant degradation of captan were detected. UK stated that the results in the addendum indicate degradation in tomatoes. Therefore, the list of end points should be amended regarding the stability of the residues. On whole tomatoes they can be regarded as stable in macerated tomatoes they are regarded as unstable. As tomatoes were stored as whole fruits in residue trials, it can be considered that these trials are reliable	Data requirement fulfilled. RMS to amend the list of end points. See new open point 3.16.
	Open point 3.10: RMS to provide an addendum with summary table of the processing studies where THPI data are included to be discussed in an expert meeting. (see reporting table 3(20))	Residue data for processed and unprocessed products were tabled at the meeting. Therefore, the meeting agreed that this open point can be regarded as fulfilled.	Relevant information was tabled at the meeting. Open point fulfilled.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 3.11: RMS to discuss on how the risk assessment specifically for processed commodities is to be carried out in an expert meeting. (see reporting table 3(20a)	The risk assessment has to be done with the new residue definition (new open point 3.15). Due to the revision of the residue definition it is not longer necessary to discuss how the risk assessment has to be carried out because we are in a rather common situation with the new residue definition.	Discussion not needed due to the new residue definition. Open point fulfilled.
	Open point 3.12: RMS to amend the list of end points for apple pasteurized juice and apple puree by mentioning TF < 0.05 rather than as an accurate figure. (see reporting table 3(21))	List of end points has been amended accordingly.	RMS amended the list of end points. Open point fulfilled.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 3.13: RMS to include calculations of the potential exposure of animals by consumption of apple pomace in an addendum to be considered in expert meeting. (see reporting table 3(30))	RMS provided information in an addendum. This open point is still open due to the decision of an apple MRL of 10 mg/kg. But, the current calculations base on a MRL of 5 mg/kg. In addition as it is a blended commodity, STMR should be used. The presence of THPI in pomace should also be addressed.	Due to the new MRL of 10 mg/kg for apple this point remains open since the current calculations base on a MRL of 5 mg/kg for apple. Open point still open.
	Open point 3.14: RMS to include acute intake calculation in an addendum to be considered in an expert meeting. (see reporting table 3(38))	RMS stated that using the UK model for toddlers the ARfD is exceeded by 237 % for apples, 319% for pears, 118% for peaches and 158% for nectarines. But, the meeting agreed that the formula used for the calculation was not the latest revision. Therefore, the calculation has to be redone.	Recalculations according to the latest formula is necessary. Open point still open.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	New open point 3.16: RMS to revise the list of end points according the amendments proposed by EPCO 24.	- Stability of the residues (stable on whole tomatoes, unstable in macerated tomatoes) to be revised - Plant residue definition for risk assessment: Sum of captan and THPI expressed as captan - Plant residue definition for monitoring: Sum of captan and THPI expressed as captan - Animal residue definition for monitoring: Sum of THPI, 3-OH-THPI and 5-OH-THPI expressed as captan - Animal residue definition for risk assessment: Sum of THPI, 3-OH-THPI and 5-OH-THPI expressed as captan - Modify entries where relevant as a result of the new evaluation of data based on the new residue definitions.	Open point still open.

Appendix 2: Evaluation table

3. Residues

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Section 3 Data requirements: ***4*** Open points: ***14***			Section 3 Data requirements: ***2*** Open points: ***5*** Data gaps: **-**
	Open point 3.1: RMS to provide an addendum to be considered in expert meeting with the new MRL proposal for peaches and nectarines, new TMDI and I(N)EDI calculations, as well as new STMR calculations. (see reporting table 3(1))	The GAP for peaches/nectarines is amended – the PHI is changed from 7 days to 21 days. No other changes to the GAP have been made. The change in PHI for peaches/nectarines has no affect on the existing assessments of risk of captan to operators or the environment. No new data are submitted to support this change. The same residue trials as those summarised in Table B.7.6.3.1 of the DAR are relevant to the amended GAP as all trials included a measurement of residue levels at 20-22 days. Calculations of the MRL for a PHI of 21 days are included in new addendum under Point IIA, 6.7 Proposed maximum residue Levels (MRLs) and residue definition. Amended consumer calculations are included in Point IIA, 6.9 Estimation of the potential and actual exposure	Addendum provided. After change of the GAPs (PHI 21 days) for peaches and nectarines we agree with new proposals of MRL = 3 mg/kg and STMR = 0.78 mg/kg. New TMDI and IEDI have been calculated and included into the addendum. TMDI is less than the ADI for captan in adults (WHO and UK diets), children (UK and German diets) and infants (UK diet) and exceed ADI in toddler (UK diet). However in these subjects (toddlers), NEDI is less than the ADI (UK model).	EPCO 24 (11.05. – 13.05.2005): Information in the addendum do not address the issue. Open point still open.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 3.3: RMS to prepare an addendum to be discussed in expert meeting addressing uncharacterized material in fruit wash, foliage, peel and pulp extracts of the metabolism study on apples (level and number of individual fractions…). (see reporting table 3(2))	A new table of results for the apple study together with discussion of the results is presented in the new addendum, under Annex Point IIA, 6.1. **Conclusion:** Based on the information for apple, tomato and lettuce crops, it is concluded that captan is metabolised via a common route in plants. It is therefore also concluded that unidentified residues observed in apples will be of a similar nature to those observed in tomato and lettuce and as such will be present as a multi-component residue composed of polar products most likely containing conjugates of captan metabolites. This conclusion is consistent with the conclusion of the RMS in the reporting table.	Addendum prepared (a new table of results for the apple study has been included, See point IIA 6.1 of the addendum) and open to discussion., Our opinion is that uncharacterised material (UM) represents polar products that are formed following the slow adsorption of captan into the peel and pulp. Based on the metabolism observed in tomato and lettuce these polar products are considered likely to be conjugates of captan metabolites. This is consistent with the observation that UM is low in fruit wash and foliage, increase in peel and is maximum in pulp.	EPCO 24 (11.05. – 13.05.2005): RMS provided the addendum. Open point fulfilled.
3.1	A hydrolysis study in representative hydrolytic conditions. (see reporting table 3(4))	A position paper is summarised in new addendum under Annex Point IIA, 6.5.1/01. **Conclusion:** Sufficient data already exist to predict the effect of processing hydrolysis on the nature of the residue and therefore new studies are not required.	Data discussed in the position paper do not fulfil the point. Specific studies are still required. Moreover we have been informed from the applicant that hydrolysis studies are on going and results will be available soon. Data requirement still open.	EPCO 24 (11.05. – 13.05.2005): Results of ongoing hydrolysis studies still have to be awaited. Data requirement still open.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 3.4: RMS to address in an addendum to be discussed in expert meeting the position paper of the notifier **"Captan. Position Paper on Effects on the Nature of the Residue (2004)"**. Open point relates to data requirement 3.1. (see reporting table 3(4) and 3(22))	Summarised in new addendum under Annex Point IIA, 6.5.1/01. **Conclusion:** Sufficient data already exist to predict the effect of processing hydrolysis on the nature of the residue and therefore new studies are not required.	Addendum prepared and open to discussion (see RMS comments, under the point IIA 6.5). Our opinion is that data discussed in the position paper do not fulfil the point. Specific studies are still required.	EPCO 24 (11.05. – 13.05.2005): Open point closed. See data requirement 3.1.
3.2	A whole balance study for tomato washed, peeled and canned or used for juice, plus a follow-up study in canned tomato and tomato juice. (see reporting table 3(4))	Results of one balance study and one follow-up study are summarised in new addendum under Annex Point IIA, 6.5.2/07 and 6.5.2/08. **Conclusion:** There was no concentration of captan residues in any processed tomato commodity.	Study accepted and included into the addendum (point IIA 6.5.2/07 and /08).	EPCO 24 (11.05. – 13.05.2005): Data requirement fulfilled. According to the new residue definition the study needs to be revisited by the RMS. (See new open point 3.15)

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 3.5: RMS to evaluate in an addendum to be considered in expert meeting the studies provided by the notifier: **"Faessel, V. (2004). Residue study in and on tomatoes following 4 applications of the test item Malvin WG. Anadiag report R A3154.", "Faessel, V. (2004). Residue study in and on tomatoes following 4 applications of the test item Malvin WG. Anadiag report R A3156." and "Faessel, V.(2004). Validation study of the analytical method for the determination of captan and tetrahydrophthalimide (THPI) in tomato processed fractions. Anadiag report R A3153."** Open point relates to data requirement 3.2. (see reporting table 3(4) and 3(28))	Results of one balance study and one follow-up study are summarised in new addendum under Annex Point IIA, 6.5.2/07 and 6.5.2/08. **Conclusion:** There was no concentration of captan residues in any processed tomato commodity.	Study evaluated, accepted and included into the addendum (point IIA 6.5.2/07 and /08). New TFs values included in the addendum and list of end points.	EPCO 24 (11.05. – 13.05.2005): RMS presented an addendum. Open point fulfilled. If THPI is included in the residue definition for plant products, the submitted studies have to be considered as not relevant. (See new open point 3.15)

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	continued Open point 3.6: MSs to discuss residue definition for processed commodities and processing yields in an expert meeting. Open point relates to open point 1.16. (see reporting table 3(7))	**Conclusion**: The discussion paper expands on the discussion of the toxicological significance of the degradates of captan and concludes in conformity with the JMPR (FAO/WHO 2000) and US-EPA, based on the DG SANCO Guideline for Metabolism and Distribution in Plants (European Commission 1997) that the metabolites present a significantly lower hazard to man than captan, evidenced by the complete lack of systemic toxicity observed in the captan long term and subchronic toxicity studies. In addition, direct comparisons of captan and THPI aquatic toxicity further reinforces the differences due primarily to its mode of action as a primary irritant. Key to resolving the differences in toxicity between captan, THPI and other systemically circulating THPI-metabolites is the exceptionally rapid degradation of captan in the presence of blood. As such, all systemic toxicity observed in captan studies is attributed to the metabolites along with secondary effects of captan's irritation of the GI tract. The definition of the residue in plants including processed commodities is therefore captan alone.	However, heating convert captan into THPI . Therefore in processed commodities monitoring should include captan plus THPI, expressed as captan equivalents (converting factor for THPI to captan =). Accepting this view, residue definition in processed commodities should be captan for Risk Assessment and captan plus THPI, expressed as captan equivalents for monitoring. This position is open to discussion.	

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	continued Open point 3.7: MSs to discuss in an expert meeting the residue definition for animal products. Open point relates to open point 1.16. (see reporting table 3(9))	of blood. As such, all systemic toxicity observed in captan studies is attributed to the metabolites along with secondary effects of captan's irritation of the GI tract. The main animal residue is a collective of THPI-based molecules and do not confer toxicity that is considered toxicologically significant. None of these degradates or metabolites are judged candidates for inclusion in the residue expression. The definition of the residue in animal products is therefore captan alone. This conclusion is consistent with the conclusion of the RMS.	This position is open to discussion.	
	New open point 3.15: RMS to go back to the available data set and make new evaluation of the available data so that the MRL proposals and the risk assessment can be done on the basis of the new residue definitions. The new calculations should be summarised in an addendum. This open point was proposed at EPCO 24.			EPCO 24 (11.05. – 13.05.2005): Open point still open.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	continued Open point 3.8: RMS to provide in an addendum informations in column 3 of comments 3(8) and 3(9) of the reporting table. (see reporting table 3(9))	Distribution in Plants (European Commission 1997) that the metabolites present a significantly lower hazard to man than captan, evidenced by the complete lack of systemic toxicity observed in the captan long term and subchronic toxicity studies. In addition, direct comparisons of captan and THPI aquatic toxicity further reinforces the differences due primarily to its mode of action as a primary irritant. Key to resolving the differences in toxicity between captan, THPI and other systemically circulating THPI-metabolites is the exceptionally rapid degradation of captan in the presence of blood. As such, all systemic toxicity observed in captan studies is attributed to the metabolites along with secondary effects of captan's irritation of the GI tract. The main animal residue is a collective of THPI-based molecules and do not confer toxicity that is considered toxicologically significant. None of these degradates or metabolites are judged candidates for inclusion in the residue expression. The definition of the residue in animal products is therefore captan alone. This conclusion is consistent with the conclusion of the RMS.	point IIA 6.7 (proposed residue definition) of the addendum.	

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
3.4	*continued* Clarification of the results of the McKay study on storage stability, providing stability data for captan and THPI separately . If not available new experimental data are required. (see reporting table 3(16))	months and tomatoes were stored for up to 5 months. Freezer storage stability data have demonstrated that residues of captan are stable when stored for at least 14 months in apple fruit and for at least 9.5 months in tomato fruit. Therefore, all the trials in apple and tomato are validated by the freezer storage data. Freezer storage stability data have demonstrated that residues of captan are stable when stored for 15 months in apple juice, 9.5 months in apple sauce (puree), 9.5 months in apple pomace (based on extrapolation from data on grape and tomato pomace), for 9/9.5 months in tomato pomace and tomato sauce (ketchup) and for 15 months in tomato juice (based on extrapolation from data on apple juice). All commodities were stored for less than the maximum period tested in all the available storage studies except for apple sauce in study 6.5.2/04 and 6.5.2/05 and apple pomace in study 6.5.2/05. No degradation is expected to have occurred during storage and the processing studies in apple and tomato are validated by the freezer storage data. The residue data for peaches/ nectarines are validated by storage data already summarised in the DAR.		

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 3.10: RMS to provide an addendum with summary table of the processing studies where THPI data are included to be discussed in an expert meeting. (see reporting table 3(20))	The definition of the residue in plants including processed commodities is captan alone. See response to open point 3.6, 3.7 and 3.8. Studies on the toxicity and biological activity of potential captan metabolites are summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/01, 02, 03. In addition a discussion paper by Gordon (2005) is summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/04. Therefore, THPI data from processing studies are not relevant.	Data are presently not available. They have been requested to the MDS and, if provided, will be presented and discussed during the next expert meeting.	EPCO 24 (11.05. – 13.05.2005): Relevant information was tabled at the meeting. Open point fulfilled.
	Open point 3.11: RMS to discuss on how the risk assessment specifically for processed commodities is to be carried out in an expert meeting. (see reporting table 3(20a))	The definition of the residue in plants including processed commodities is captan alone. See response to open point 3.6, 3.7 and 3.8. Studies on the toxicity and biological activity of potential captan metabolites are summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/01, 02, 03. In addition a discussion paper by Gordon (2005) is summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/04.	See replay to open point 3.6	EPCO 24 (11.05. – 13.05.2005): Discussion not needed due to the new residue definition. Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	continued Open point 3.11: RMS to discuss on how the risk assessment specifically for processed commodities is to be carried out in an expert meeting. (see reporting table 3(20a))	Therefore, THPI data from processing studies are not relevant.		
	Open point 3.12: RMS to amend the list of end points for apple pasteurized juice and apple puree by mentioning TF < 0.05 rather than as an accurate figure. (see reporting table 3(21))		List of end points amended.	EPCO 24 (11.05. – 13.05.2005): RMS amended the list of end points. Open point fulfilled.
	Open point 3.13: RMS to include calculations of the potential exposure of animals by consumption of apple pomace in an addendum to be considered in expert meeting. (see reporting table 3(30))	Calculations of the potential exposure of animals by consumption of apple pomace are presented in new addendum under Annex Point IIA, 6.4 **Conclusion:** In metabolism studies in goats, captan was administered at a dietary concentration of 50 mg/kg for seven days and only 1-2% of the administered radioactivity was detected in animal tissues and milk; no parent captan was found in milk and tissues. The dietary concentration in the study	Calculation of the potential exposure of animals by consumption of apple pomace has been included in the addendum (point IIA 6.4).	EPCO 24 (11.05. – 13.05.2005): Due to the new MRL of 10 mg/kg for apple this point remains open since the current calculations base on a MRL of 5 mg/kg for apple. Open point still open.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	continued Open point 3.13: RMS to include calculations of the potential exposure of animals by consumption of apple pomace in an addendum to be considered in expert meeting. (see reporting table 3(30))	was approximately 7 times the worst-case dietary burden (based on the MRL) and 26 times the realistic dietary burden (based on the STMR) for beef cattle, and approximately 21 times the worst-case dietary burden (based on the MRL) and 81 times the realistic dietary burden (based on the STMR) for dairy cattle. Therefore, no residues in excess of the LOQ for captan in milk and bovine tissues are expected and a feeding study in ruminants is not required.		
	Open point 3.14: RMS to include acute intake calculation in an addendum to be considered in an expert meeting. (see reporting table 3(38))	The notifier contends that an ARfD is not applicable for captan. The arguments supporting this contention are presented in the paper by Gordon and Kinzell (2004) summarised in the new addendum under Point IIA, 5.10/01, supported by Moore and Creasey (2004) summarised in the new addendum under Point IIA, 5.8.2/06. Note: Moore and Creasey (2004) is a study on folpet but is directly applicable to captan.	Acute intake calculation has been included in the addendum (Point IIA, 6.9). Using the UK model for the determination of the acute intake, the ARfD is exceeded in toddler by the 237 % for apples, 319% for pears, 118% for peaches and 158% for nectarines. Conclusions are open to discussion.	EPCO 24 (11.05. – 13.05.2005): Recalculations according to the latest formula is necessary. Open point still open.

section 3 – Residues

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	New open point 3.16: RMS to revise the list of end points according the amendments proposed by EPCO 24.			EPCO 24 (11.05. – 13.05.2005): Open point still open.

List of representative uses evaluated*

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

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

REPORT OF EPCO EXPERT MEETING 25

CAPTAN

Rapporteur Member State: Italy

Specific comments on the active substance in the section

1. Physical and Chemical Properties

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
29 October 2004	Germany	Captan com01 DE

2. Documents submitted for meeting:

Date	Supplier	File Name
15 October 2004	RMS/Italy	Captan consultation report
17 January 2005	RMS/Italy	Captan reporting table rev1-3
April 2005	RMS/Italy	Captan summary of representative uses
May 2005	RMS/Italy	Captan addendum vol3 phys-chem
May 2005	RMS/Italy	Captan list of end points
09 May 2005	RMS/Italy	Captan evaluation table rev0-1

3. Documents tabled at the meeting:

Date	Supplier	File Name
24 May 2005	RMS/Italy	Doc J_mak_captan May 2005-Final.doc

The conclusions of the meeting were as follows:

4. **Data on preparations:** Merpan 80 WDG, Malvin WG

5. **Classification and labelling:** not discussed.

6. **Recommended restrictions/conditions for use:** none.

7. Reference List

Areas of concern: from the analytical point of view the technical materials cannot be regarded as equivalent; data gap for the determination of relevant impurities and a data gap for enforcement methods.

Appendix 1: EPCO discussion table: CAPTAN

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Captan (Fu)

1. Physical and Chemical Properties

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 1.1: RMS to clarify the discrimination between captan and the [redacted] (R290236). (see reporting table 1(2))	RMS informed that clarification is given in the new report (Grabarnik, 2005) submitted by the notifier and that the list of end points has been amended. It was questioned whether an analytical method is available. RMS answered that there has been a new five batch analysis submitted. It was questioned if the original method used for the quantification is still adequate. Document tabled at the meeting was examined. There is no method stated for the determination of the impurity. It is unclear who prepared the document tabled at the meeting. Thus for Makteshim there is no analytical method stated the impurities have been identified. Calliope has provided analytical methods but Makteshim did not.	<u>EPCO 25(24.-26.05.2005):</u> Open point closed, but refer to the two general open points. General new open point: RMS to present the evaluation of the new submitted information presented in the addendum to the dossier and all information in an addendum to the DAR. Second general point: RMS to clarify whether the document or addendum to the dossier (tabled at the meeting) was written by the RMS or the notifier. Furthermore, it should be distinguished between confidential and non confidential information. Data gap identified: Notifier (Makteshim) to submit validated analytical method for the impurity R290236.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
			New open point: Depending on the assessment of the recently submitted data further data could be required.
	Open point 1.2: RMS to clarify the biological activity of the [redacted] (see reporting table 1(4))	See open point 1.1. The information is given in the new document. Is there a need for an analytical method confirming that the technical material contains only the *cis*-isomer. Meeting agreed not to ask for further study.	<u>EPCO 25(24.-26.05.2005):</u> Open point closed. New open point: RMS to indicate clearly in the list of end points that only the [redacted] is present.
	Open point 1.3: RMS to clarify for transparency and better comprehensibility the reason/background for the given minimum purities, which are higher than the FAO value (e.g. based on actual batch analysis or due to "tox/ecotox" effects). (see reporting table 1(10))	The results are presented in Doc J. Concerns to use 930 g/Kg, if the materials are not equivalent. The technical material should be used as pure as possible. Meeting cannot agree because there are now new quantifications available. In Doc J only the old batch analysis is mentioned. The minimum purity after the FAO specification is 890 g/Kg. Thus there is a harmonised minimum purity for captan available. But for the EU a higher purity should be used. In case materials are regarded as equivalent 910 g/Kg should be used but if not it has to be divided in 910 g/Kg for Calliope and Makteshim should be asked to accept 930 g/Kg. MSs prefer to use better one lowest minimum purities for both materials. Meeting agreed: If technical materials are equivalent: one specification for the minimum purity. If technical materials are not equivalent: inclusion of minimum purity of makteshim and	<u>EPCO 25(24.-26.05.2005):</u> Open point closed New open point: RMS to indicate the new minimum impurity in the list of end points. Note to toxicology and ecotoxicology: From the analytical point of view

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
		Ar /sta In Doc J from the notifier Makteshim it is stated that the minimum purity is 930 g/Kg. At the moment it is not clear whether the technical materials can be regarded as equivalent. For clarification a statement of experts from toxicology and ecotoxicology is needed. It was agreed that from the analytical point of view the technical materials cannot be regarded as equivalent.	the technical materials cannot be regarded as equivalent.
	Open point 1.4: RMS to clarify the relevance of the given impurities. The acceptable maximum values for relevant impurities must be set and the maximum values given in the FAO specification should be mentioned in the row "FAO specification". (see reporting table 1(11))	Folpet is a relevant impurity of toxicological significance; PMM (trichloromethane sulphenyl chloride or perchloromethylmercaptan) is the only relevant impurity mentioned in the FAO specification; RMS disagrees with the comments from notifier regarding the FAO limits for impurities, that are clearly not confidential. Box of identity of relevant impurities the first sentence has to be changed and for the PMM the value has to be given and the maximum value from Folpet has to be given too Note to toxicology and ecotoxicology section to confirm the proposed max value for Folpet of [redacted] as a relevant impurity.	EPCO 25(24.-26.05.2005): Open point still open. RMS to amend the list of end points: Box of identity of relevant impurities: The first sentence has to be changed and for the PMM (perchloromethylmercaptan) the value has to be given and the maximum value from Folpet has to be given too. New open point: Note to toxicology and ecotoxicology section to confirm the proposed max value for Folpet of [redacted] as a relevant impurity.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
1.1	Data regarding the boiling point or temperature of decomposition must be provided according to Directive 94/37/EC. (see reporting table 1(13))	RMS informed that the list of endpoints has been amended The meeting agreed on this.	EPCO 25(24.-26.05.2005): Data requirement fulfilled, but refer to the two general open points.
	Open point 1.5: RMS should indicate in the list of endpoints that data are required (e.g. as open point). (see reporting table 1(13))	See data requirement 1.1	EPCO 25(24.-26.05.2005): Open point fulfilled.
	Open point 1.6: RMS to amend the list of endpoints regarding the hazard classification and labelling symbol "T". (see reporting table 1(18))	The list of endpoints has been amended. This belongs to the toxicology section. There it is mentioned.	EPCO 25(24.-26.05.2005): Open point fulfilled.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
1.2	A new batch analysis must be provided (Tomen source). (see reporting table 1(23))	RMS regarded this as addressed. This was submitted but not evaluated.	EPCO 25(24.-26.05.2005): Data requirement is still open Because this information hasn't been presented in a confidential addendum. Open for technical reasons.
1.3	A new specification or a justification for the set limit must be provided (Makhteshim source). (see reporting table 1(23))	RMS informed that Makhteshims justification was provided and regarded the data requirement as addressed. For Folpet it is fulfilled. R016907 specification level is not acceptable. The five batch analysis the declared concentration is ten times higher than in the provided batches.	EPCO 25(24.-26.05.2005): Data requirement fulfilled, but refer to the two general open points. New data gap: A justification or a new maximum value of the impurity R016907 must be given because the proposed value is not reliable from the presented batches.
	Open point 1.7: RMS to clarify the identity of the used pure material [redacted] (see reporting table 1(24))	See New open point: in open point 1.2	EPCO 25(24.-26.05.2005): Open point closed.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
1.4	Spectra of relevant impurities have to be provided according to Directive 94/37/EC. (see reporting table 1(28))	It was provided by Makteshim but only for one relevant impurity. There are two relevant impurities and two notifiers. General point: It was discussed whether dossiers (discriminate by notifiers) or the "whole" package for the active substance should be discussed. the meeting agreed on the following: The experts of EPCO 25 clarified that active substances rather than dossiers will be discussed. Consequently, a differentiation between the data packages of different notifiers will be done, if necessary, only with respect to data of the technical materials (i.e. Volume 4 and some physical and chemical properties).	<u>EPCO 25(24.-26.05.2005):</u> Data requirement is still open All the relevant impurities have to be addressed.. Thus spectra for PMM (perchloromethylmercaptan) are missing.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 1.8: a) RMS to clarify for transparency and better comprehensibility the given justification in respect to the given minimum purities of 920 g/kg and 910 g/kg, respectively. b) RMS to clarify whether the justification that the two technical materials will not reveal significantly differences in the physical and chemical properties is based on practical experiences or on a theoretical assessment. The acceptability on the argumention will be discussed in an expert meeting. (see reporting table 1(30))	a) is covered by the open point 1.3 b) Makteshim presented new data. Thus this is closed.	<u>EPCO 25(24.-26.05.2005):</u> a) Open point closed. b) Open point open for technical reasons see general open point in open point 1.1.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 1.9: The need to conduct the studies regarding the flammability and auto-flammability with both technical materials should be discussed in an expert meeting. (see reporting table 1(32))	The new report by Turner (2005b) has been evaluated, accepted and included into the addendum. The meeting agreed on this.	EPCO 25(24.-26.05.2005): Open point fulfilled, but refer to the two general open points..
1.5	Notifier to clarify whether the formulations "Captan 80 WDG" and "Merpan 80WDG" are identical or not. (see reporting table 1(33))	RMS regarded the data requirement as addressed. Both formulations are regarded as identical. The content given in the updated Doc J (May 2005, Makhteshim) is still unclear. Further clarification is needed concerning the content of captan pure and captan technical material. EFSA stated that the two formulations cannot be regarded easily identical, because the risk from a granule or a powder could different, e.g. regarding exposure or efficacy. MS agreed with this opinion.	EPCO 25(24.-26.05.2005): Data requirement is still open. Notifier to provide the composition of the captan 80 WDG formulation. To be able to confirm that these formulations can be regarded as identical. Notifier Makteshim to clarify the content of captan technical and pure in the two formulations. “Merpan 80 WDG” and “Merpan 83 WP” (refer to tables 1.4.1-1 and -2 in Doc J, updated May 2005).

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
1.6	Notifier to clarify whether the formulations "Captan 80 WDG" and "Malvin 83" are identical or not (see reporting table 1(34))	See discussion above (data requirement 1.5). Notifier Calliope is asked to present the information too. No new Doc J or an addendum to volume 4 was available at the meeting.	<u>EPCO 25(24.-26.05.2005):</u> Data requirement is still open Notifier to provide the composition of the “captan 80 WDG” formulation. To be able to confirm that these formulations can be regarded as identical Notifier Calliope to clarify the content of captan technical and pure in the two formulations. "Captan 80 WDG"and "Malvin 83".

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 1.10: The need for a measurement of the pH value of the in use concentration should be discussed in an expert meeting. (see reporting table 1(37))	Notifier concluded that the need for a measurement of the pH at in-use concentrations is not necessary. RMS agreed on this. Original comment mentioned that there are two measurements mentioned in the DAR and the pH values are differing. The spray ability does not address the problem. The meeting agreed on this. Is the pH value of the 1% dilution necessary? The degradation is very quick. This is not a critical issue. Is a pH of 9.73 is problem for the operator exposure? One expert explained that these differences doesn't cause a problem. Sufficient information to address the concerns is available. The meeting agreed on this.	EPCO 25(24.-26.05.2005): Open point closed, but refer to the two general open points.
	Open point 1.11: RMS to clarify whether the physical stability (in terms of physical/technical properties) was examined **after** the accelerated storage. (see reporting table 1(39))	RMS stated that justification for non sub-submission of technical properties is based on the fact that two-years ambient shelf life data are available (see addendum). The meeting agreed on this.	EPCO 25(24.-26.05.2005): Open point closed, but refer to the two general open points.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
1.7	Notifer to clarify the test conditions to determine the wettability for "Captan 80 WDG". (see reporting table 1(41))	Wettability was acceptable after storage for 24 months and so the 'before storage' result is considered to be anomalous. The RMS accepted this explanation. New open point: EFSA to indicate in the conclusion that it should be labelled that agitation must be used during mixing and loading and until spraying complete'	EPCO 25(24.-26.05.2005): Open point closed New open point: EFSA to indicate in its conclusion that a label like "Agitation must be used during mixing and loading and until spraying complete" should be considered.
	Open point 1.12: The need for a sprayability study should be discussed in an expert meeting. (see reporting table 1(42))	The meeting accepted the explanation given in the evaluation table.	EPCO 25(24.-26.05.2005): Open point closed, but refer to the two general open points.
	Open point 1.13: The need for further investigation regarding the friability and attrition for "Captan 80 WDG" should be discussed in an expert meeting. (see reporting table 1(47))	RMS stated that the study is acceptable and it has been included into the addendum. The meeting accepted the approach from the RMS.	EPCO 25(24.-26.05.2005): Open point closed, but refer to the two general open points.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
1.8	Notifier to clarify the stability of the active substance in the spray tank until application. (see reporting table 1(48))	A new report (Pollman, 2004) has been provided. The study is acceptable and it has been included into the addendum. Data requirement addressed.	EPCO 25(24.-26.05.2005): Data requirement fulfilled, but refer to the two general open points.
	Open point 1.14: EFSA to highlight the concern of wettability of the formulation in its conclusion. (see reporting table 1(49))	See data requirement 1.7	EPCO 25(24.-26.05.2005): See data requirement 1.7
1.9	Data to confirm the identity of the impurities revealed by chemical analysis must be provided for folpet, perchloromethylmercaptan [redacted] to address the requirement of the Directive on the specificity of the method(s). (see reporting table 1(52))	The meeting agreed that in the updated Doc J (May 2005, Makhteshim) this point is not addressed. However, information given by the MRS in Column C of the evaluation table indicates that data to address this point is available. However, the meeting has not received this information, neither in an addendum to the DAR nor in an addendum to the dossier. .	EPCO 25(24.-26.05.2005): Data requirement is still open.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 1.15: RMS to clarify the origin of folpet in the technical material, if it is not formed in the manufacturing process or during storage. Depending on this information, the need for an analytical method for the determination of folpet in the formulation should be discussed in an expert meeting. (see reporting table 1(54))	RMS stated that the origin of folpet has been explained in the Makhteshim Document J (updated May 2005). A general discussion took place. The experts discussed whether the requirement 5.1.2 in Directive 94/37/EC is applicable for relevant impurities in general or only for those which are formed during the manufacturing process of the preparation or by degradation during storage of the preparation. It was not possible to finalise this discussion. EFSA offered to present all the previous data in terms of "was a method required" or "included in the dossier" for the substances EFSA has the responsibility for the peer review. This was welcome by the experts. The discussion will be continued as soon as this overview is available. The meeting agreed on to close this open point in this certain case. See also note to toxicology and ecotoxicology section to confirm the maximum content.	EPCO 25(24.-26.05.2005): Open point closed, but refer to the two general open points.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 1.16: Analytical methods for the determination of residues in food could be required depending on the outcome of the discussion concerning the residue definition [see also 3(7), 3(8) and 3(9) in the reporting table] and the evaluation of the recently submitted methods. Open point relates to open points 3.6 and 3.7. (see reporting table 1(55))	A validation study of the analytical method for the determination of captan and tetrahydrophthalimide (THPI) in tomato processed fractions has been submitted (Faessel, 2004). The new report has been evaluated, accepted and included into the addendum. The residue definition changed. For food of plant origin it is Captan and THPI. Methods were checked. There is nothing mentioned in the DAR with respect to the determination of THPI. But for the use of tomatoes a new study has been submitted (see addendum to the dossier), but this is not acceptable at the moment because only validation data for captan are mentioned. Data gap: Analytical methods for the validation of THPI are missing. This is open only for technical reasons, because the data have been submitted. In the intended uses in VOL 1 just potato is given and not tomato. Tomatoes and potatoes are in the same group of uses containing high amount of water. But ketchup (mentioned in the study) is a manufactured product, thus this is no representative use in the original meaning.	EPCO 25(24.-26.05.2005): Open point closed, but refer to the two general open points. Data gap identified: A validated analytical method for the determination of THPI in food of plant origin (matrices with high water content) according to Directive 96/46/EC incl. an ILV. It seems that this data are already submitted, but the data gap is set for technical reasons due to the fact that no validation data for THPI are given. Notifier has to present an ILV according to Directive 96/46/EC
1.10	Notifier to provide a validated analytical method for the determination of residues in air. (see reporting table 1(57))	RMS stated that data discussed in the position paper do not fulfil the point, because the previously submitted method (Jones and Freeman, 1994) has not been sufficiently validated. A validated method is still required (the validation of the method is regarded as not sufficient). Data requirement not addressed. The meeting agreed with this.	EPCO 25(24.-26.05.2005): Data requirement is still open.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 1.17: DT_{90} values must be confirmed by the fate and behaviour section. Provided that the values will be confirmed, an analytical method is not required. => Discussion in expert meeting (fate and behaviour) Open point relates to open point 4.17. (see reporting table 1(65))	The EPCO 21 meeting confirmed: *DT_{90} in water is below three days.* According to SANCO/825/00 an analytical method is therefore not necessary required. But if the other sections indicate that the a.s. has effects, an analytical method is not available. Is in this case than a need to require a method? The meeting agreed that at the moment there is no need for any new requirements.	<u>EPCO 25(24.-26.05.2005):</u> Open point closed.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
1.11	A validated analytical method for the determination of residue in blood. (see reporting table 1(68))	The meeting has not received any new information. Therefore the data requirement is still open. In addition the meeting took note of the fact that the residue definition for food of animal origin has been changed to sum of THPI, 3-OH-THPI and 5-OH-THPI expressed as captan. Provided that MRLs will be proposed a new analytical method must be required. Therefore a new data requirement was set. At the moment it looks like that it is likely that MRLs will be proposed. However, the experts had some doubts whether it is feasible to required an analytical method for the determination of captan in blood. This should be confirmed by tox experts.	<u>EPCO 25(24.-26.05.2005):</u> Date requirement still open. New data gap identified: Notifier to present an analytical method (including ILV) for the determination of residue in food of animal origin according to the residue definition provided than an MRL will be proposed. At the moment it looks like that it is likely that MRLs will be proposed. Message to the toxicology experts: The respective residue in blood should be confirmed. Is it feasible to require an analytical method for the determination of captan in blood?

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 1.18: RMS to evaluate the comparability of the two technical materials. (see reporting table 1(73))	RMS stated that the technical materials cannot be regarded as equivalent from an analytical point of view. The meeting agreed on this. Note to tox and ecotox: The technical materials cannot be regarded as equivalent from an analytical point of view.	<u>EPCO 25(24.-26.05.2005):</u> Open point closed, but refer to the two general open points Message to toxicology and ecotoxicology section: The technical materials cannot be regarded as equivalent from an analytical point of view. .
1.12	Data regarding the purity and source (commercially available or not) of the starting material must be provided according to Directive 94/37/EC. (see reporting table 1(74))	RMS regarded the data requirement addressed. The meeting agreed on this.	<u>EPCO 25(24.-26.05.2005):</u> Data requirement open for technical reasons. See general open point in open point 1.1.
1.13	New batch analysis must be provided. (see reporting table))	RMS regarded the data requirement addressed. The meeting agreed on this.	<u>EPCO 25(24.-26.05.2005):</u> Data requirement open for technical reasons. See general open point in open point 1.1.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 1.19: RMS to reflect on the different impurity pattern in the evaluation of the comparability of the two technical materials. (see reporting table 1(76))	See open point 1.18	EPCO 25(24.-26.05.2005): see open point 1.18 .
	Open point 1.20: RMS to indicate in the list of endpoints that a CIPAC method is available for the determination of captan in the technical material. (see reporting table 1(77))	Done. Meeting accepted this.	EPCO 25(24.-26.05.2005): Open point fulfilled.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 1.21: RMS to clarify the basis of the assumption that the CIPAC method for WP and DP formulations is also applicable for WG formulations. (see reporting table 1(77))	EFSA stated that it is not possible at the moment that the CIPAC method can be extended to other formulations, due to the fact that CIPAC has clear rule on the process of method extension.	<u>EPCO 25(24.-26.05.2005):</u> Open point closed. At the moment, the CIPAC method for WP and DP formulations cannot be regarded as applicable for WG formulations
1.14	Data to confirm the identity of the impurities revealed by chemical analysis must be provided to address the requirement of the Directive on the specificity of the method(s). (see reporting table 1(80))	RMS informs that this is covered with data requirement: 1.9 The meeting agreed on this.	<u>EPCO 25(24.-26.05.2005):</u> Data requirement closed. See data requirement: 1.9

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
1.15	Notifier to clarify the investigated fortification levels in the method for the determination of folpet and the impurities. (see reporting table 1(82))	Clarification is given by Makhteshim (in the updated DOC J, May 2005) The meeting accepted this.	<u>EPCO 25(24.-26.05.2005):</u> Data requirement open for technical reasons. See general open point in open point 1.1.
	Open point 1.22: For transparency and better comprehensibility, RMS to confirm that the notifier has changed from Tomen to Calliope and in this context to confirm which formulations belongs to which notifier. (see reporting table 1(98))	Clarification is given in the addendum to the dossier (May 2005)	<u>EPCO 25(24.-26.05.2005):</u> Open point still open for technical reasons. See general open point in open point 1.1.
		The technical material contains carbon tetrachloride. Therefore, the meeting wonder whether or not carbon tetrachloride has to be regarded as a relevant impurity, because it is classified as toxic (T) and Carc. Cat. 3. Note to tox experts: To confirm that the carbon tetrachloride has not be regarded as a relevant impurity in the technical material of captan.	Message to toxicology experts: To confirm that carbon tetrachloride has not to be regarded as a relevant impurity in the technical material of captan.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	List of end points	- RMS to use the template given in EPCO manual E4 - p. 3 ff the confidential information has to be deleted. - Open point 1.3 - UV/VIS absorption box. The molar extinction coefficient is not correct.	<u>EPCO 25(24.-26.05.2005):</u> New open point: RMS to amend the list of end point.

Appendix 2: Evaluation table

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Section 1 Data requirements: ***15*** Open points: ***22***			Section 1 Data requirements: ***10*** Open points: ***10*** Data gaps: ***4***
	Open point 1.1: RMS to clarify the discrimination between captan and the [redacted] (R290236). (see reporting table 1(2))	In the original dossier, one of the impurities found in Captan technical was incorrectly identified. The impurity labelled as R290236 was incorrectly assigned the structure of the [redacted] A report is now provided which re-assigns R290236 as [redacted] **Conclusion:** Based on the available data, it is most likely that the [redacted] R290236 is [redacted]	Apr. 05 Clarification is given in the new report (Grabarnik, 2005) submitted by the notifier. EP list amended.	EPCO 25(24.-26.05.2005): Open point closed, but refer to the two general open points. General new open point (1.23) Second general point (1.24) Data gap identified (1.16) New open point (1.25)

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	General new open point 1.23: RMS to present the evaluation of the new submitted information presented in the addendum to the dossier and all information in an addendum to the DAR. See open point 1.1. This open point was proposed at EPCO 25.			EPCO 25(24.-26.05.2005): Open point still open.
	General new open point 1.24: RMS to clarify whether the document or addendum to the dossier (tabled at the meeting) was written by the RMS or the notifier. Furthermore, it should be distinguished between confidential and non confidential information. See open point 1.1. This open point was proposed at EPCO 25.			EPCO 25(24.-26.05.2005): Open point still open.
1.16	Data gap: Notifier (Makteshim) to submit validated analytical method for the impurity R290236. See open point 1.1. This data gap was identified at EPCO 25.			EPCO 25(24.-26.05.2005): Data gap identified.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	New open point 1.25: Depending on the assessment of the recently submitted data further data could be required. See oper point 1.1. This open point was proposed at EPCO 25.			EPCO 25(24.-26.05.2005): Open point still open.
	Open point 1.2: RMS to clarify the biological activity of the [redacted] (see reporting table 1(4))	See the comment above (Open Point 1.1, Reporting Table 1(2)). The [redacted] is not present as an impurity in Captan technical. There is therefore no need to evaluate the relative biological activity of the [redacted] It should also be noted that the [redacted] is a sterically hindered and stressed structure which is likely to be unstable and unlikely to be formed during synthesis.	Apr. 05 See point 1.1	EPCO 25(24.-26.05.2005): Open point closed. New open point (1.26)
	New open point 1.26: RMS to indicate clearly in the list of end points that only the *cis*-isomer is present. See open point 1.2. This open point was proposed at EPCO 25.			EPCO 25(24.-26.05.2005): Open point still open.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 1.3: RMS to clarify for transparency and better comprehensibility the reason/background for the given minimum purities, which are higher than the FAO value (e.g. based on actual batch analysis or due to "tox/ecotox" effects). (see reporting table 1(10))	Specification for purity: Makhteshim: 92.0% w/w Arysta Paris: 91.0% w/w	Apr. 05 The given minimum purity provided by Arysta (91,0%) is in accord with the actual batch analysis (new Doc J) and with FAO specification (910 g/Kg ± 30 g/Kg). The given minimum purity provided by Makhteshim is 92,0%, while on the basis of actual batch analysis this value is higher (95%). Further explanations will be provided by the notifier: in fact, based to statistical quality control tests from the recent years, Makhteshim can raise the stated minimum purity of the Captan Tech. to 93%. This is a result of significant improvement of the manufacturing process over the years which consequently cause the increase of the active ingredient purity. Makhteshim will amend the composition statement in a new DOC. J that will be provided.	EPCO 25(24.-26.05.2005): Open point closed. New open point (1.27): Message to toxicology and ecotoxicology section: From the analytical point of view the technical materials cannot be regarded as equivalent.
	New open point 1.27: RMS to indicate the new minimum impurity in the list of end points. See open point 1.3. This open point was proposed at EPCO 25.			EPCO 25(24.-26.05.2005): Open point still open.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 1.4: RMS to clarify the relevance of the given impurities. The acceptable maximum values for relevant impurities must be set and the maximum values given in the FAO specification should be mentioned in the row "FAO specification". (see reporting table 1(11))	The FAO limits for impurities are stated in both Arysta and Makhteshim Document J under annex Point IIA 1.10. This information is confidential and not for disclosure. This is consistent with the conclusions of the RMS that the data should not be included in the endpoint list.	Apr. 05 Folpet is the only relevant impurity of toxicological significance, whose maximum value has been set to be [redacted] PMM is the only impurity which has FAO specifications (Maximum of 10 g/kg). We disagree with the notifier comments regarding the FAO limits for impurities, that are clearly not confidential. EP list amended.	EPCO 25(24.-26.05.2005): Open point still open. RMS to amend the list of end points: Box of identity of relevant impurities: The first sentence has to be changed and for the PMM (perchloromethylmercaptan) the value has to be given and the maximum value from Folpet has to be given too. Message to toxicology and ecotoxicology section to confirm the proposed max value for Folpet of [redacted] as a relevant impurity.
1.1	Data regarding the boiling point or temperature of decomposition must be provided according to Directive 94/37/EC. (see reporting table 1(13))	Data are presented in the new Addendum under Point IIA 2.1.3. **Conclusion:** Captan decomposes on melting starting at 173°C.	Apr. 05 Data requirement addressed EP list amended	EPCO 25(24.-26.05.2005): Data requirement fulfilled, but refer to the two general open points.
	Open point 1.5: RMS should indicate in the list of endpoints that data are required (e.g. as open point). (see reporting table 1(13))		Apr. 05 Noted – EP list amended	EPCO 25(24.-26.05.2005): Open point fulfilled.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 1.6: RMS to amend the list of endpoints regarding the hazard classification and labelling symbol "T". (see reporting table 1(18))		Apr. 05 Noted – EP list amended	EPCO 25(24.-26.05.2005): Open point fulfilled.
1.2	A new batch analysis must be provided (Tomen source). (see reporting table 1(23))	Arysta have provided a new 5 batch report. This is summarised in the Arysta Document J under Point IIA 1.11.	Apr. 05 Data requirement addressed	EPCO 25(24.-26.05.2005): Data requirement is still open Because this information hasn't been presented in a confidential addendum. Open for technical reasons.
1.3	A new specification or a justification for the set limit must be provided (Makhteshim source). (see reporting table 1(23))	A new specification and justification for the set limit is provided in Makhteshim Document J (Annex Point IIA 1.11).	Apr. 05 Makhteshim justification provided Data requirement addressed	EPCO 25(24.-26.05.2005): Data requirement fulfilled, but refer to the two general open points. New data gap (1.17)
1.17	Data gap: A justification or a new maximum value of the impurity R016907 must be given because the proposed value is not reliable from the presented batches. See data gap 1.3. This data gap was identified at EPCO 25.			EPCO 25(24.-26.05.2005): Data gap identified.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 1.7: RMS to clarify the identity of the used pure material (incl. [redacted] (see reporting table 1(24))	EFSA noted that clarification is needed, regarding the identity of the used pure material. This issue has arisen because the impurity identified as R290236 was incorrectly assigned the structure of the [redacted] A report is provided which re-assigns R290236 as [redacted]	Apr. 05 On the basis of the new data, the pure material used is very likely the [redacted] – See open point 1.1	EPCO 25(24.-26.05.2005): Open point closed.
1.4	Spectra of relevant impurities have to be provided according to Directive 94/37/EC. (see reporting table 1(28))	Folpet spectra summary has been added to the amended Makhteshim Doc J; re-dated Mar 05. Referenced under Annex Point IIA 2.5.2.	Apr. 05 Data requirement addressed	EPCO 25(24.-26.05.2005): Data requirement is still open All the relevant impurities have to be addressed. Thus spectra for PMM (perchloromethylmercaptan) are missing.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 1.8: a) RMS to clarify for transparency and better comprehensibility the given justification in respect to the given minimum purities of 920 g/kg and 910 g/kg, respectively. b) RMS to clarify whether the justification that the two technical materials will not reveal significantly differences in the physical and chemical properties is based on practical experiences or on a theoretical assessment. The acceptability on the argumention will be discussed in an expert meeting. (see reporting table 1(30))	(a) Specification for purity: Makhteshim: 92.0% w/w Arysta Paris: 91.0% w/w (b) Makhteshim have provided data to show that flammability and auto-flammability do not differ between sources of technical material.	Apr. 05 a) Probably the comment to point 30 in reporting table was badly interpreted, because the given justification was in relation to the melting point test (vol.3, B.2.2.1): the test was considered acceptable taking account that the content of captan in technical material, once declared and determined, shall not differ from the declared by more than ± 30 g. b) Justification was initially based on a theoretical assessment, by comparing the results obtained for some physical and chemical properties (melting point, relative density) using technical or pure active substance, and further supported by the data provided by Makhteshim in the Addendum to dossier. This opinion is open to discussion	EPCO 25(24.-26.05.2005): c) Open point closed. d) Open point open for technical reasons see general open point in open point 1.1.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 1.9: The need to conduct the studies regarding the flammability and auto-flammability with both technical materials should be discussed in an expert meeting. (see reporting table 1(32))	Makhteshim have provided data to show that flammability and auto-flammability do not differ between sources of technical material. **Conclusion:** Neither technical material is 'Highly Flammable' and neither self ignites.	Apr. 05 The new report by Turner (2005b) has been evaluated, accepted and included into the addendum. Open point fulfilled	EPCO 25(24.-26.05.2005): Open point fulfilled, but refer to the two general open points.
1.5	Notifier to clarify whether the formulations "Captan 80 WDG" and "Merpan 80WDG" are identical or not. (see reporting table 1(33))	"Captan 80 WDG" and "Merpan 80WDG" are the same material; this is stated in the Makhteshim 'Merpan 80 WDG', Annex III, Tier II, Section 1, Point 2 summary. (Merpan being the generic name used for the studies). Text to confirm similarity of Merpan 80WDG' and 'Merpan 83 WP has been added to new Makhteshim Doc J under Point IIIA 1.4.1.	Apr. 05 Data requirement addressed	EPCO 25(24.-26.05.2005): Data requirement is still open. Notifier to provide the composition of the captan 80 WDG formulation. To be able to confirm that these formulations can be regarded as identical. Notifier Makteshim to clarify the content of captan technical and pure in the two formulations. "Merpan 80 WDG" and "Merpan 83 WP" (refer to tables 1.4.1-1 and -2 in Doc J, updated May 2005).

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
1.6	Notifier to clarify whether the formulations "Captan 80 WDG" and "Malvin 83" are identical or not (see reporting table 1(34))	"Captan 80 WDG" and "Malvin WG" are the same material; this is stated in the Tomen 'Malvin WG, Annex III, Tier II, Section 1, Point 2 summary. (Captan 80 WDG is a generic name used for the studies). In addition Captan 80WG (YF7851) was used for several tests but only used exclusively for the Friability test. Text to confirm similarity of 'Malvin WG' and 'Malvin 83 (WP)' has been added to new Arysta Paris Doc J under Point IIIA 1.4.1.	Apr. 05 Data requirement addressed	EPCO 25(24.-26.05.2005): Data requirement is still open. Notifier to provide the composition of the "captan 80 WDG" formulation. To be able to confirm that these formulations can be regarded as identical Notifier Calliope to clarify the content of captan technical and pure in the two formulations. "Captan 80 WDG"and "Malvin 83".
	Open point 1.10: The need for a measurement of the pH value of the in use concentration should be discussed in an expert meeting. (see reporting table 1(37))	A discussion of this issue is presented in the new Addendum under this Open Point reference. **Conclusion:** The need for a measurement of the pH at in-use concentrations is not necessary.	Apr. 05 Conclusions can be considered acceptable, also taking into account the new submitted study (Pollman, 2004) that demonstrates the reproducibility of the sprayer performance using Merpan 80WDG (evaluation of captan content in the spray tank). See also open point 1.12.	EPCO 25(24.-26.05.2005): Open point closed, but refer to the two general open points.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 1.11: RMS to clarify whether the physical stability (in terms of physical/technical properties) was examined **after** the accelerated storage. (see reporting table 1(39))	A justification for non-submission of technical properties data from accelerated storage stability trial has been included in Point IIIA 2.7.1 in the Addendum.	Apr. 05 In the original study (Wells, 1996) the test substance was visually inspected after the accelerated storage for changes in physical characteristics (color, phase separation, crystallization and clumping) and no changes were observed. Justification for non sub-submission of technical properties is based on the fact that two-years ambient shelf life data are available (see addendum).	EPCO 25(24.-26.05.2005): Open point closed, but refer to the two general open points.
1.7	Notifer to clarify the test conditions to determine the wettability for "Captan 80 WDG". (see reporting table 1(41))	For Merpan 80 WDG the conditions of the test (swirling and without swirling) are clearly and correctly stated in the summary. All results are within the 1 minute acceptance limit and so no further comment is required. It is believed that the comment actually refers to Malvin WG where there is one undesirable result at the beginning of the storage stability study. This issue is discussed in the Addendum under Point IIIA 2.8.1. Wettability was acceptable after storage for 24 months and so the 'before storage' result is considered to be anomalous.	Apr. 05 Clarification acceptable	EPCO 25(24.-26.05.2005): Data requirement fulfilled. New open point (1.28):

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	New open point 1.28: EFSA to indicate in its conclusion that a label like "Agitation must be used during mixing and loading and until spraying complete" should be considered. See data requirement 1.7. This open point was proposed at EPCO 25.			EPCO 25(24.-26.05.2005): Open point still open.
	Open point 1.12: The need for a sprayability study should be discussed in an expert meeting. (see reporting table 1(42))	Sprayability report is provided and summarised in the new addendum under Point IIIA 2.8.3/01. **Conclusion:** The spraying solution of Merpan 80 WDG was homogenous throughout the spraying operation the content of captan in the spray tank did not change during spraying.	Apr. 05 A new report (Pollmann, 2004) has been provided. The study is acceptable and it has been included into the addendum. .	EPCO 25(24.-26.05.2005): Open point closed, but refer to the two general open points.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 1.13: The need for further investigation regarding the friability and attrition for "Captan 80 WDG" should be discussed in an expert meeting. (see reporting table 1(47))	This Annex point is intended to show the increase in dust content caused by attrition during transport and handling. In this case the data supplied (MT171, the measure of dust content) was conducted on the granules following attrition caused by routine transport and handling. This process is believed to meet the requirements of the Annex point before the CIPAC attrition resistance test was widely available. Makhteshim have now submitted a study, conducted to MT178, which confirms the earlier results that showed Captan 80 WDG is resistant to attrition. The Notifiers's conclusion is consistent with the conclusion of the RMS.	Apr. 05 A new report (Comb, 2001) has been provided. The study is acceptable and it has been included into the addendum. .	EPCO 25(24.-26.05.2005): Open point closed, but refer to the two general open points.
1.8	Notifier to clarify the stability of the active substance in the spray tank until application. (see reporting table 1(48))	See Open Point 1.10, reporting table 1(37) and Open Point 1.12, reporting table 1(42) above. A Sprayability report is provided conducted with 'Merpan 80 WDG' and summarised under Point IIIA 2.8.3 of the new addendum which confirmed that the content of captan in the spray tank did not reduce during spraying. **Conclusion:** The spraying solution of Merpan 80 WDG was homogenous throughout the spraying operation. The content of captan in the spray tank did not change during spraying.	Apr. 05 A new report (Pollman, 2004) has been provided. The study is acceptable and it has been included into the addendum. Data requirement addressed.	EPCO 25(24.-26.05.2005): Data requirement fulfilled, but refer to the two general open points.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 1.14: EFSA to highlight the concern of wettability of the formulation in its conclusion. (see reporting table 1(49))	This issue is addressed in the new Addendum under Point IIIA 2.8.1 It is believed that the comment actually refers to Malvin WG where there is one anomalous result. Wettability was acceptable after storage for 24 months and so the 'before storage' result is considered to be anomalous.	Apr. 05 Clarification of the existing data has been provided: acceptable.	EPCO 25(24.-26.05.2005): open point closed. See data requirement 1.7 and new open point 1.28.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
1.9	Data to confirm the identity of the impurities revealed by chemical analysis must be provided for folpet, perchloromethylmercaptan [redacted] to address the requirement of the Directive on the specificity of the method(s). (see reporting table 1(52))	Specificity of the impurity methods has been adequately addressed in the dossier. Specificity was confirmed by comparison of chromatograms of certified analytical standards and blank solvent. Absence of interfering peaks is taken as confirmation of specificity. Regarding identity of the impurities, this has been confirmed by the use of certified reference standards in the validation procedures. There is no sound scientific basis on which to reject this argument. Confirmation of the identity of the impurities is inherent in the proven specificity of the method. The Directive does not directly require any further confirmation of the identity of the impurities. It should be noted that both applicants have supplied batch analysis reports which include mass spectrometric data on impurities.	Apr. 05 If the requirement of the Directive for confirmation of analyte identification relates to the initial confirmation of compound identity, this has been done for folpet (NMR and MS data have been included in the new Doc J from Makhteshim). In addition Arysta provided a batch analysis report (Rose 2005 in the new Doc J) which includes structure confirmation o[redacted] by LC-MS analysis. The same LC-MS approach was employed to identify all the other minor impurities in captan technical. Data for PMM should be provided.	EPCO 25(24.-26.05.2005): Data requirement is still open.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 1.15: RMS to clarify the origin of folpet in the technical material, if it is not formed in the manufacturing process or during storage. Depending on this information, the need for an analytical method for the determination of folpet in the formulation should be discussed in an expert meeting. (see reporting table 1(54))	The occurrence of folpet in the Makhteshim technical material is discussed in the Makhteshim Document J (Annex Point IIA 1.10).	Apr. 05 The origin of folpet has been explained in the Makhteshim Document J. We agree with EFSA conclusion that the need for an analytical method for folpet determination in the formulation should be discussed in an expert meeting.	EPCO 25(24.-26.05.2005): Open point closed, but refer to the two general open points.
	Open point 1.16: Analytical methods for the determination of residues in food could be required depending on the outcome of the discussion concerning the residue definition [see also 3(7), 3(8) and 3(9) in the reporting table] and the evaluation of the recently submitted methods. Open point relates to open points 3.6 and 3.7. (see reporting table 1(55))	Position paper summarised in new Addendum under Annex Point IIA, 4.2.1/07. The new report by Faessel (2004) is summarised in the new addendum under Point IIA 4.2.1/08. **Conclusion:** No additional data are necessary to fulfil the Annex point requirement. For animal tissues, it is considered unnecessary to conduct further work or confirmation when there are numerous existing chromatographic conditions available and an analytical method for monitoring purposes is not required due to the lack of residues of captan in edible animal tissues.	Apr. 05 A validation study of the analytical method for the determination of captan and tetrahydrophthalimide (THPI) in tomato processed fractions has been submitted (Faessel, 2004). The new report has been evaluated, accepted and included into the addendum. We agree with EFSA conclusions.	EPCO 25(24.-26.05.2005): Open point closed, but refer to the two general open points. Data gap identified (1.18):

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
1.18	Data gap: A validated analytical method for the determination of THPI in food of plant origin (matrices with high water content) according to Directive 96/46/EC incl. an ILV. It seems that this data are already submitted, but the data gap is set for technical reasons due to the fact that no validation data for THPI are given. Notifier has to present an ILV according to Directive 96/46/EC. See open point 1.16. This data gap was identified at EPCO 25.			EPCO 25(24.-26.05.2005): Data gap identified.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
1.10	Notifier to provide a validated analytical method for the determination of residues in air. (see reporting table 1(57))	Position paper included in Addendum. Referenced under Annex Point IIA, 4.2.4. **Conclusion:** It is concluded that the requirements of the Commission Directive 96/48/EC, in terms of method validity, have been adequately met and the method presented is suitable for monitoring. It is considered unnecessary to conduct further work on confirmation when there are numerous existing chromatographic conditions available.	Apr. 05 Data discussed in the position paper do not fulfil the point, because the previously submitted method (Jones and Freeman, 1994) has not been sufficiently validated. Specific studies are still required. Data requirement not addressed.	EPCO 25(24.-26.05.2005): Data requirement is still open.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 1.17: DT_{90} values must be confirmed by the fate and behaviour section. Provided that the values will be confirmed, an analytical method is not required. => Discussion in expert meeting (fate and behaviour) Open point relates to open point 4.17. (see reporting table 1(65))	An analytical method for the determination of captan in water in not required due to the extremely rapid hydrolysis. It has been calculated from hydrolysis data that the DT_{90} for captan is in the range 8 minutes to 1.3 days depending on pH. The details of the DT_{90} calculations are presented in "**Captan. Position Paper on Residue Analytical Methods** (April 2004)". The analytical methods guidance document SANCO/825/00 states that a monitoring method for water is not required for an active substance with a DT_{90} in water of less than three days. In addition, the results of the water/sediment study described under IIA, 7.2.1.3.2/01, demonstrated that captan was not detectable in the surface water 24 hours after application. Therefore, it is concluded that, as degradation of captan in water is extremely rapid, it would be practically impossible to monitor the active substance in the aquatic environment. Consequently, a monitoring method is not appropriate for captan.	Apr. 05 New evidences provided by the MDS seem to confirm that an analytical method is not required. This position is open to discussion.	EPCO 25(24.-26.05.2005): Open point closed.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
1.11	A validated analytical method for the determination of residue in blood. (see reporting table 1(68))	Arysta Paris has commissioned a study. The report will be supplied in April or May 2005.	Apr. 05 New data will be evaluated. Data requirement not addressed.	EPCO 25(24.-26.05.2005): Date requirement still open. New data gap identified (1.19) Message to toxicology expert: The respective residue in blood should be confirmed. Is it feasible to require an analytical method for the determination of captan in blood?
1.19	Data gap: Notifier to present an analytical method (including ILV) for the determination of residue in food of animal origin according to the residue definition provided than an MRL will be proposed. At the moment it looks like that it is likely that MRLs will be proposed. See data requirement 1.11. This data gap was identified at EPCO 25.			EPCO 25(24.-26.05.2005): Data gap identified.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 1.18: RMS to evaluate the comparability of the two technical materials. (see reporting table 1(73))	A comparison of the technical captan from both notifiers is presented in the Confidential Document J (Contains industrial and commercial secrets which are to be kept confidential from both applicants). **Conclusion:** Captan technical, produced by both applicants can be considered to be comparable for the purposes of safety evaluation.	Apr. 05 The pattern of impurities in the two technical materials is slightly different, both from a qualitative and quantitative point of view. Anyway, this difference is minimized in the plant protection products and I think that the two products can be considered comparable for the purposes of performance and safety evaluation. This position is open to discussion.	EPCO 25(24.-26.05.2005): Open point closed, but refer to the two general open points. Message to toxicology and ecotoxicology section: The technical materials cannot be regarded as equivalent from an analytical point of view.
1.12	Data regarding the purity and source (commercially available or not) of the starting material must be provided according to Directive 94/37/EC. (see reporting table 1(74))	Data regarding the purity and source (commercially available or not) of the starting materials are provided in the Makhteshim Document J and the Arysta Document J under Point IIA 1.8.	Apr. 05 Data requirement addressed	EPCO 25(24.-26.05.2005): Data requirement open for technical reasons. See general open point in open point 1.1.
1.13	New batch analysis must be provided. (see reporting table))	A new 5 batch analysis has been conducted by Arysta Paris and the report is presented in Arysta Document J under Point IIA 1.9.	Apr. 05 Data requirement addressed	EPCO 25(24.-26.05.2005): Data requirement open for technical reasons. See general open point in open point 1.1.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 1.19: RMS to reflect on the different impurity pattern in the evaluation of the comparability of the two technical materials. (see reporting table 1(76))	A comparison of the technical captan from both notifiers is presented in the Confidential Document J (Contains industrial and commercial secrets which are to be kept confidential from both applicants). **Conclusion:** Captan technical, produced by both applicants can be considered to be comparable for the purposes of safety evaluation.	Apr. 05 See open point 1.18	EPCO 25(24.-26.05.2005): see open point 1.18
	Open point 1.20: RMS to indicate in the list of endpoints that a CIPAC method is available for the determination of captan in the technical material. (see reporting table 1(77))		Apr. 05 Noted – EP list amended	EPCO 25(24.-26.05.2005): Open point fulfilled.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 1.21: RMS to clarify the basis of the assumption that the CIPAC method for WP and DP formulations is also applicable for WG formulations. (see reporting table 1(77))	A comparison of the composition of captan WP and WG products is presented in the Confidential Document J (Contains industrial and commercial secrets which are to be kept confidential from both applicants). This concludes that WG formulations containing captan have very similar compositions to WP formulations containing captan. Both have closely similar active substance content, the same wetting/dispersing agents at the same or similar concentrations, and the remaining ingredients are inorganic minerals. The CIPAC technical and WP analytical methods (40/TC/M 3/-, 40/TC/M 4/-, 40/WP/M 3/- or 40/WP/M 4/-) consists of a simple non-aqueous extraction which would be unaffected by the minor differences in composition. It can therefore be assumed that the CIPAC method for WP and DP formulations is also applicable to WG formulations.	Apr. 05 Conclusions acceptable.	EPCO 25(24.-26.05.2005): Open point closed. At the moment, the CIPAC method for WP and DP formulations cannot be regarded as applicable for WG formulations

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
1.14	Data to confirm the identity of the impurities revealed by chemical analysis must be provided to address the requirement of the Directive on the specificity of the method(s). (see reporting table 1(80))	Specificity of the impurity methods has been adequately addressed in the dossier. Specificity was confirmed by comparison of chromatograms of certified analytical standards and blank solvent. Absence of interfering peaks is taken as confirmation of specificity. Regarding identity of the impurities, this has been confirmed by the use of certified reference standards in the validation procedures. There is no sound scientific basis on which to reject this argument. Confirmation of the identity of the impurities is inherent in the proven specificity of the method. The Directive does not directly require any further confirmation of the identity of the impurities.	Apr. 05 See data requirement 1.9	EPCO 25(24.-26.05.2005): Data requirement closed. See data requirement: 1.9
1.15	Notifier to clarify the investigated fortification levels in the method for the determination of folpet and the impurities. (see reporting table 1(82))	Makhteshim Document J and Arysta Document J have been amended accordingly.	Apr. 05 Data requirement addressed.	EPCO 25(24.-26.05.2005): Data requirement open for technical reasons. See general open point in open point 1.1.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 1.22: For transparency and better comprehensibility, RMS to confirm that the notifier has changed from Tomen to Calliope and in this context to confirm which formulations belongs to which notifier. (see reporting table 1(98))	Details of the amended names, organisations and contacts details are included in the new Addendum under Point IIA 1.1, IIA 1.2, IIIA 1.1 and IIIA 1.2. The formulation Merpan 80 WDG belongs to Makhteshim. The formulation Malvin WG belongs to Arysta Paris.	Apr. 05 The notifier has changed from Tomen to Calliope. The formulation Merpan 80 WDG belongs to Makhteshim. The formulation Malvin WG belongs to Arysta Paris.	EPCO 25(24.-26.05.2005): Open point still open for technical reasons. See general open point in open point 1.1.
	Message to the toxicology experts: To confirm that carbon tetrachloride has not to be regarded as a relevant impurity in the technical material of captan.			

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	New open point 1.29: RMS to amend the list of end point. - RMS to use the template given in EPCO manual E4 - p. 3 ff the confidential information has to be deleted. - Open point 1.3 - UV/VIS absorption box. The molar extinction coefficient is not correct. This open point was proposed at EPCO 25.			EPCO 25(24.-26.05.2005): Open point still open.

Report of PRAPeR Expert MEETING 39

CAPTAN

Rapporteur Member State: IT

Specific comments on the active substance in the section

2. Mammalian Toxicology

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
Nov 2007	IT	Captan addendum Vol3 B6 ARfD (Nov 2007).doc
Nov 2007	IT	Captan addendum Vol3 B6 ARfD (Nov 2007).pdf
Nov 2007	IT	Captan JMPR eval DRAFT final_ed_2007.pdf
6.07.2006	EFSA	Captan_EFSA_conclusion_rev4_final_MS.pdf

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** xxx

5. **Classification and labelling:** xxx

6. **Recommended restrictions/conditions for use:** xxx

7. **Reference List:** xxx

Areas of concern: xxx

Appendix 1: Discussion table: CAPTAN

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Captan

2. Mammalian toxicology

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		Italy, as Rapporteur Member State, requested a revision of the Acute Reference Dose of the active substances captan and folpet. Both substances were included in Annex I. **Captan** During the experts' meeting (May 2005) the experts proposed an ARfD of 0.1 mg/kg bw based on a NOAEL 10 mg/kg bw/day (developmental study in rabbit, maternal and embryofoetal toxicity at 30 mg/kg bw/day), SF 100. It was noted that JMPR (2004) set a value of 0.3 mg/kg bw (SF 100) from the same developmental study in rabbit, but based on a different endpoint. Apparently JMPR dismissed skeletal variations at 30 mg, and considered as relevant the NOAEL of 30 mg/kg bw/day based on the increased incidences of early and late intra-uterine deaths together with malformations. JMPR concluded that due to developmental effects of concern, an ARfD should be set only for women of child bearing age, with no need of an acute reference value for the general population. However the db was considered insufficient, in particular with regard to the possible developmental effects of THPI metabolite. Recently the applicant submitted three new studies: a developmental study with THPI and two new studies to investigate the effects of	

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		captan and THPI on microrganisms representative of the rabbit gut. <u>Discussion on the toxicological relevance of metabolites of captan THPI, 3OH -THPI and 5 OH -THPI</u> The Chairman reported that there were three crop metabolites under discussion, THPI, 3OH -THPI and 5 OH -THPI. For the first one there was an acute oral study, two in vitro bacterial genotoxicity tests and a developmental study available while for the latter two no studies were existing. EFSA reported that in groundwater THPI and THPAM (another captan metabolite) were found and consequently according to SANCO/221/2000 – rev10. further information on would be required on those two metabolites (see EFSA conclusion, March 2006). **It was agreed that the RMS provides further information on the following endpoints on the metabolites THPI, 3OH -THPI and 5 OH -THPI: Acute toxicity, genotoxicity, carcinogenicity, relevance of dog study and developmental effects in comparison to the parent compound.** <u>Discussion on the setting of the ARfD of Captan</u> The RMS (IT) introduced the addendum “Captan - Position paper relating to non-setting and ARfD”. The experts considered that the developmental effects might be	

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		considered to be a consequence of acute exposure. The early and late intra-uterine deaths and fetal malformations were considered of relevance for deriving an ARfD. Therefore the meeting established an ARfD of 0.3 mg/kg bw, based on a NOAEL of 30 mg/kg bw per day for increased incidences of intra-uterine deaths and malformations at 100 mg/kg bw per day in the study in rabbits and a safety factor of 100. The experts agreed to revise the ARfD from currently 0.1 mg/kg bw to 0.3 mg/kg bw.	

REPORT OF PRAPeR EXPERT MEETING 40

CAPTAN

Rapporteur Member State: IT

Specific comments on the active substance in the section

3. Residues

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
Nov 2007	IT	Captan addendum Vol3 B6 ARfD (Nov 2007).doc
Nov 2007	IT	Captan addendum Vol3 B6 ARfD (Nov 2007).pdf
Nov 2007	IT	Captan addendum Vol3 B7 (Nov 2007).doc
Nov 2007	IT	Captan addendum Vol3 B7 (Nov 2007).pdf
06.07.2006	EFSA	Captan_EFSA_conclusion_rev4_final_MS.pdf

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** Not relevant

5. **Classification and labelling:** Not relevant

6. **Recommended restrictions/conditions for use:** Not relevant

7. **Reference List:** Not relevant

Areas of concern: Not relevant

Appendix 1: Discussion table: CAPTAN

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Captan ()

3. Residues

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Review of the EFSA conclusions published in July 2006 with regard to the proposed ArfD value and the proposed residue definitions.	The EFSA conclusions on captan and folpet were published in July 2006. The applicant contested however the EFSA conclusion, in particular the toxicological end points and the residue definitions set for these substances. New data have been provided by the applicant and post-inclusion addenda were provided by the RMS. In order to address the issues raised by the applicant, the following four questions concerning captan and folpet were submitted by the residue section to the mammalian toxicology section: - Does the mammalian toxicology meeting confirm the ARfD adopted in the EFSA conclusion on 24th April 2006 or adopt another value? - Does the mammalian toxicology meeting still confirm that the ARfD applies to the general population? - In case the mammalian toxicology meeting considers that the ARfD applies to women of child-bearing age only, does the active substance exhibit at higher dose another acute toxicological effect which would be relevant for the general population, including infants and toddlers, and what would be the ARfD related to this effect ? - Does the mammalian toxicology meeting consider that captan metabolites (THPI, 3-OH THPI and 5-OH THPI) and folpet metabolite (phthalimide) participate to the effects selected for setting reference values (ADI and ARfD) of the respective parent compounds? Following these questions, the mamalian toxicology meeting decided to revise the ARfD values and the ARfD values of the JMPR have been adopted by the meeting (0.2 mg/kg bw/d for folpet and 0.3 mg/kg bw/d for captan). These end points are considered to be applicable to the total population. Concerning the metabolites the mamalian toxicology meeting didn't reach a conclusion yet because some data were not fully reported in the addenda. The discussion in the tox section concerning these metabolites has been	The new ARfD values proposed by the mammalian toxicology section will not affect the overall outcome of the residue risk assessment. Concerning the residue definitions the residue section awaits the outcome of the mammalian toxicology section on the relevance of the metabolites.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		postponed to a next meeting (probably in April 2008). When using the new ARfD values in the risk assessment, the uses supported in the the framework of the peer review still lead to an exceedances of the ARfD for toddlers. Therefore the new ARfD values don't influence the outcome of the previous assessment. In addition the meeting disagrees with the fact that the mamalian toxicology section didn't restrict the proposed ARfD values to the appropriate subpopulation and that it didn't consider the need for an alternative reference dose for the rest of the population. The approach followed by the mamalian toxicology meeting results in a risk assessment comparing an ARfD to the exposure of the wrong subpopulation.	

Report of PRAPeR Expert MEETING 44

CAPTAN

Rapporteur Member State: IT

Specific comments on the active substance in the section

2. Mammalian Toxicology

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
Nov 2007	IT	Captan addendum Vol3 B6 ARFD (Nov 2007).doc
Mar 2008	IT	Captan addendum Vol3 B6 B7 (Mar 2008).doc
Nov 2007	IT	Captan addendum Vol3 B7 (Nov 2007).doc
07.03.2006	IT	Captan evaluation table rev2-1 (07-03-2006).doc
2007	IT	Captan JMPR evaluation DRAFT (2007).pdf
April 2006	EFSA	praper_concl_sr71_captan_rev4_public_en.pdf
10.05.2005	EFSA	Report EPCO 23 – 02 Captan.doc
13.12.2007	EFSA	Report_PRAPeR_39_03_Captan.doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** no need to discuss

5. **Classification and labelling:** no need to discuss

6. **Recommended restrictions/conditions for use:** no need to discuss

7. **Reference List:** no need to discuss

Areas of concern: no need to discuss

Appendix 1: Discussion table: CAPTAN

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Captan (Fu)

2. Mammalian toxicology

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		Captan is included in Annex I to the Directive 91/414. After the inclusion, the RMS Italy asked for a revision of the toxicological profile of metabolites THPI, 3OH-THPI and 5OH-THPI, based on the availability of new toxicological studies. <u>Discussion on the toxicological relevance of metabolites of captan THPI, 3OH -THPI and 5 OH -THPI</u> The Chairman reported that there were three crop metabolites under discussion, THPI, 3OH -THPI and 5 OH -THPI. For the first one there was an acute oral study, two in vitro bacterial genotoxicity tests and a developmental study available while for the latter two no studies were existing. The RMS presented extensively the information on the toxicological properties of captan and its metabolites which had been laid down in detail in the addendum to Volume 3, Annex B, submitted in March 2008. THPI is a main metabolite of captan. The parent compound has been proposed for classification as a carcinogen and a reprotoxic agent and the metabolite should be considered to have the same toxicity profile unless the contrary is proven. Captan and the metabolites THPI, 3OH-THPI and 5 OH-THPI are currently in the residue definition. The proposal of the RMS is to remove the metabolites from the residue definition since the data indicated that THPI and its hydroxylated metabolites have a lower toxicity profile. The toxicological information on captan and THPI were compared:	

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		• Acute oral toxicity: Captan LD50>5 g/kg THPI LD50>5 g/kg • Genotoxicity Captan is mutagenic *in vitro* THPI is not mutagenic *in vitro* • Carcinogenicity Captan induces gastrointestinal tumours in mice, primarily in the duodenum (due to local chronic irritation) THPI was not tested for carcinogenicity; however the absence of treatment-related systemic tumours would indicate that captan products of degradation are not carcinogenic. • Developmental toxicity Captan induces secondary developmental delays in rabbit foetuses in presence of maternal toxicity. Relevant NOAEL 10 mg/kg bw/day. THPI is not teratogenic in rabbit, nor does induce maternal toxicity at equivalent captan doses (based on a ratio of about 2:1 captan:THPI). Relevant NOAEL 22.5 mg/kg bw/day (equivalent to 45 mg/kg bw/day captan) As for the hydroxy metabolites of THPI it is assumed that have also lower toxicity than captan since they represent detoxification products of THPI. There is also mechanistic information available that the part of the molecule responsible for the toxic effects of concern is thiophosgene that is formed immediately after administration of captan. The THPI and its hydroxy metabolites do no not contain the moiety trichloromethyltio (TCMT) that is responsible for both pesticidal activity and mammalian toxicity of captan. The TCMT moiety reacts with thiol groups resulting in protein denaturation and captan degradation, whose product is thiophosgene, responsible for degradation of thiols and other functional groups. The weight of evidence indicates that captan induces gastrointestinal tumours in mice by a non genotoxic mechanism involving citotoxicity and consequent cell hyperplasia, responsible of the cascade of events leading to cancer, but for which a threshold is recognized.	

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		The experts agreed that the results of the existing studies demonstrate less toxicity of the metabolites compared with the parent. Also mechanistic data indicate that THPI and 3- and 5-OH THPI do not have the potential to induce critical effects (carcinogenic, reprotoxic effects).	

Appendix 2: Evaluation table

No amendment of the evaluation table necessary or foreseen at this stage.

REPORT OF PRAPeR EXPERT MEETING 45

CAPTAN

Rapporteur Member State: IT

Specific comments on the active substance in the section

3. Residues

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
Dec 2007	EFSA	Captan – information.doc
March 2008	IT	Captan addendum Vol3 B6 B7 (Mar 2008).doc
Nov 2007	IT	Captan addendum Vol3 B7 (Nov 2007).doc
07.03.2006	IT	Captan evaluation table rev2-1 (07-03-2006).doc
April 2006	EFSA	praper_concl_sr71_captan_rev4_public_en.pdf

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** none

5. **Classification and labelling:** not discussed

6. **Recommended restrictions/conditions for use:** none

7. **Reference List:** not discussed

Areas of concern: none

Appendix 1: Discussion table: CAPTAN

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Captan (Fu)

3. Residues

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
3.1	EPCO 24 (11.05. – 13.05.2005): Results of ongoing hydrolysis studies still have to be awaited. Data requirement still open. Evaluation Meeting (06.-09.02.2006): Data requirement still open.	According to the RMS these studies were reported in an addendum to the dossier of February 2006. This addendum indicates that in processed commodities captan is completely transformed to THPI. However, the document was not available to all experts in advance to the meeting and the data requirement therefore remains open.	Data requirement still open
3.3	EPCO 24 (11.05. – 13.05.2005): Data requirement still open. Evaluation Meeting (06.-09.02.2006): Data requirement still open.	The data requirement was set for processing studies in canned fruits. No data have been submitted and the data requirement remains open. PRAPeR 45 (10 – 11 April 2008):	Data requirement still open

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	New open point Residue definition to be rediscussed.	The applicant asks for THPI and the hydroxylated THPI compounds to be excluded from the residue definitions. Toxicological data have been provided to the toxicological section in order to demonstrate that the metabolites are not of toxicological significance. The toxicological section clearly concluded that the metabolites do not show the same toxicity profile as the parent compound and that no signs of toxicity have been identified for it. However, a complete toxicological data set for these metabolites was not available and the toxicological section was not able to derive toxicological end points. The toxicological meeting therefore decided that for the time being that the toxicological end points of the parent compound should be used also for the metabolites. Due to the extensive formation of THPI in processed commodities produced with a heating step and the dominance of THPI, 3-OH THPI, 5-OH THPI residues in food of animal origin (no captan is virtually present in processed products and edible animal matrices), and considering the opinion of the toxicological section, the residues meeting concludes that metabolites need to be retained in the residue definitions. The residue definitions are not modified. The meeting notes that the ARfD for captan has been raised from 0.1 to 0.3 mg/kg bw/d.	Open point fulfilled.

Appendix 2: Evaluation table

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

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	(see reporting table 3(1))			
	Open point 3.3: RMS to prepare an addendum to be discussed in expert meeting addressing uncharacterized material in fruit wash, foliage, peel and pulp extracts of the metabolism study on apples (level and number of individual fractions…). (see reporting table 3(2))	A new table of results for the apple study together with discussion of the results is presented in the new addendum, under Annex Point IIA, 6.1. **Conclusion:** Based on the information for apple, tomato and lettuce crops, it is concluded that captan is metabolised via a common route in plants. It is therefore also concluded that unidentified residues observed in apples will be of a similar nature to those observed in tomato and lettuce and as such will be present as a multi-component residue composed of polar products most likely containing conjugates of captan metabolites. This conclusion is consistent with the conclusion of the RMS in the reporting table.	Addendum prepared (a new table of results for the apple study has been included, See point IIA 6.1 of the addendum) and open to discussion., Our opinion is that uncharacterised material (UM) represents polar products that are formed following the slow adsorption of captan into the peel and pulp. Based on the metabolism observed in tomato and lettuce these polar products are considered likely to be conjugates of captan metabolites. This is consistent with the observation that UM is low in fruit wash and foliage, increase in peel and is maximum in pulp.	EPCO 24 (11.05. – 13.05.2005): RMS provided the addendum. Open point fulfilled.
3.1	A hydrolysis study in representative hydrolytic conditions. (see reporting table 3(4))	A position paper is summarised in new addendum under Annex Point IIA, 6.5.1/01. **Conclusion:** Sufficient data already exist to predict the effect of processing hydrolysis on the nature of the residue and therefore new studies are not	Data discussed in the position paper do not fulfil the point. Specific studies are still required. Moreover we have been informed from the applicant that hydrolysis studies are on going and results will be available soon.	EPCO 24 (11.05. – 13.05.2005): Results of ongoing hydrolysis studies still have to be awaited. Data requirement still open.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
		required.	Data requirement still open. Oct. 05 Data requirement still open.	Evaluation Meeting (06.-09.02.2006): Data requirement still open. PRAPeR 45 (10 – 11 April 2008): Data requirement still open.
	Open point 3.4: RMS to address in an addendum to be discussed in expert meeting the position paper of the notifier **"Captan. Position Paper on Effects on the Nature of the Residue (2004)"**. Open point relates to data requirement 3.1. (see reporting table 3(4) and 3(22))	Summarised in new addendum under Annex Point IIA, 6.5.1/01. **Conclusion:** Sufficient data already exist to predict the effect of processing hydrolysis on the nature of the residue and therefore new studies are not required.	Addendum prepared and open to discussion (see RMS comments, under the point IIA 6.5). Our opinion is that data discussed in the position paper do not fulfil the point. Specific studies are still required.	EPCO 24 (11.05. – 13.05.2005): Open point closed. See data requirement 3.1.
3.2	A whole balance study for tomato washed, peeled and canned or used for juice, plus	Results of one balance study and one follow-up study are summarised in new addendum under Annex Point IIA,	Study accepted and included into the addendum (point IIA 6.5.2/07 and /08).	EPCO 24 (11.05. – 13.05.2005): Data requirement fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	a follow-up study in canned tomato and tomato juice. (see reporting table 3(4))	6.5.2/07 and 6.5.2/08. **Conclusion:** There was no concentration of captan residues in any processed tomato commodity.	Oct. 05 Following results of the last toxicological evaluations (see the Addendum "definition of the residue" of July 2005) the residue definition for captan was changed going back to the parent compound alone, (residue definition for captan=captan). Data requirement is therefore fulfilled	According to the new residue definition the study needs to be revisited by the RMS. (See new open point 3.15)
	Open point 3.5: RMS to evaluate in an addendum to be considered in expert meeting the studies provided by the notifier: "Faessel, V. (2004). Residue study in and on tomatoes following 4 applications of the test item Malvin WG. Anadiag report R A3154.", "Faessel, V. (2004). Residue study in and on tomatoes following 4 applications of the test item Malvin WG. Anadiag report R A3156." and "Faessel, V.(2004). Validation study of the analytical method for the determination of captan and tetrahydrophthalimide (THPI) in tomato processed fractions. Anadiag report R A3153."	Results of one balance study and one follow-up study are summarised in new addendum under Annex Point IIA, 6.5.2/07 and 6.5.2/08. **Conclusion:** There was no concentration of captan residues in any processed tomato commodity.	Study evaluated, accepted and included into the addendum (point IIA 6.5.2/07 and /08). New TFs values included in the addendum and list of end points. Oct. 05 Following results of the last toxicological evaluations (see the Addendum "definition of the residue" of July 2005) the residue definition for captan was changed going back to the parent compound alone, (residue definition for captan=captan). Data requirement is therefore fulfilled	EPCO 24 (11.05. – 13.05.2005): RMS presented an addendum. In addition a room document was tabled including results of these processing studies for THPI metabolite Open point fulfilled. (See new open point 3.15)

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point relates to data requirement 3.2. (see reporting table 3(4) and 3(28))			
3.3	A balance study and 3 follow-up studies for canned peaches/nectarines. (see reporting table 3(4))	Studies to investigate the effects on residue levels of captan in peaches and nectarines after processing have not been carried out. Effects of canning are not normally required for apple but two studies have been done and are included in the DAR (see Table B.7.7.2.5 on page 47). These show that no residues above the LOQ were found in canned fruit. Based on the studies in canned apple, no residues of captan are expected to be found above the LOQ in canned peaches and nectarines or canned juice. The notifier contends that the existing studies in apple should be sufficient to reduce the requirements for peaches/ nectarines from 1 balance plus 3 follow-up studies to 1 balance plus 1 follow-up study. These studies will be conducted during the 2005 season.	Our opinion is that 1 balance plus 1 follow-up study are enough if it is confirmed that the levels of the residues in processed commodities are below the LOD. According to the MDS studies will be conducted during the 2005 season. Data requirement still open. Oct. 05 Data requirement still open	EPCO 24 (11.05. – 13.05.2005): Data requirement still open. Evaluation Meeting (06.-09.02.2006): Data requirement still open. PRAPeR 45 (10 – 11 April 2008): Data requirement still open.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 3.6: MSs to discuss residue definition for processed commodities and processing yields in an expert meeting. Open point relates to open point 1.16. (see reporting table 3(7)) *continued* Open point 3.6: MSs to discuss residue definition for processed commodities and processing yields in an expert meeting. Open point relates to open point 1.16. (see reporting table 3(7))	Studies on the toxicity and biological activity of potential captan metabolites are summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/01, 02, 03. In addition a discussion paper by Gordon (2005) is summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/04. **Conclusion**: The discussion paper expands on the discussion of the toxicological significance of the degradates of captan and concludes in conformity with the JMPR (FAO/WHO 2000) and US-EPA, based on the DG SANCO Guideline for Metabolism and Distribution in Plants (European Commission 1997) that the metabolites present a significantly lower hazard to man than captan, evidenced by the complete lack of systemic toxicity observed in the captan long term and subchronic toxicity studies. In addition, direct comparisons of captan and THPI aquatic toxicity further reinforces the differences due primarily to its mode of action as a primary irritant. Key to resolving the differences in toxicity between captan, THPI and other systemically circulating THPI-metabolites is the exceptionally rapid	New information provided by the MDS seems to confirm that the captan metabolite THPI is of low toxicological concern, compared to the parent compound captan (see addendum). The residue definition, for Risk Assessment, should be therefore captan alone. However, heating convert captan into THPI . Therefore in processed commodities monitoring should include captan plus THPI, expressed as captan equivalents (converting factor for THPI to captan =). Accepting this view, residue definition in processed commodities should be captan for Risk Assessment and captan plus THPI, expressed as captan equivalents for monitoring. This position is open to discussion.	EPCO 24 (11.05. – 13.05.2005): Residue definition : refer to open point 3.7 Processing yields : general discussion postponed due to the lack of time. Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
		degradation of captan in the presence of blood. As such, all systemic toxicity observed in captan studies is attributed to the metabolites along with secondary effects of captan's irritation of the GI tract. The definition of the residue in plants including processed commodities is therefore captan alone.		

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 3.7: MSs to discuss in an expert meeting the residue definition for animal products. Open point relates to open point 1.16. (see reporting table 3(9))	Studies on the toxicity and biological activity of potential captan metabolites are summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/01, 02, 03. In addition a discussion paper by Gordon (2005) is summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/04. **Conclusion**: The discussion paper expands on the discussion of the toxicological significance of the degradates of captan and concludes in conformity with the JMPR (FAO/WHO 2000) and US-EPA, based on the DG SANCO Guideline for Metabolism and Distribution in Plants (European Commission 1997) that the metabolites present a significantly lower hazard to man than captan, evidenced by the complete lack of systemic toxicity observed in the captan long term and subchronic toxicity studies. In addition, direct comparisons of captan and THPI aquatic toxicity further reinforces the differences due primarily to its mode of action as a primary irritant. Key to resolving the differences in toxicity between captan, THPI and other systemically circulating THPI-metabolites is the exceptionally rapid	After captan administration to lactating goats, about 1-1.5% of the dose is retained in tissues and 2% in milk. Levels of parent captan are below the LOD since captan is rapidly converted to intermediate like THPI, THPI epoxide, 3-OH THPI and 5-OH THPI, that are subsequently incorporated into natural products . There is no evidence that they could be of toxicological concern and new information provided by the MDS seems to confirm that captan metabolites are of low toxicological concern, compared to the parent compound (see addendum). For residue definition we see three possibilities: 4) no needs for residue definition 5) sum of THPI, THPI epoxide, 3-OH THPI and 5-OH THPI (expressed as captan equivalents? And only for monitoring?) 6) the most abundant metabolite, 3-OH THPI (expressed as captan equivalents? And only for monitoring?)	EPCO 24 (11.05. – 13.05.2005): The meeting agreed on the following residue definitions: Plant products (for monitoring and risk assessment: sum of captane and THPI expressed as captane Animal products (for monitoring and risk assessment: sum of THPI, 3-OH THPI and 5-OH THPI expressed as captane Open point fulfilled. RMS to amend the list of end points accordingly. See new open point 3.16. New open point 3.15: RMS to go back to the available data set and make new evaluation of the available data so that the MRL proposals and the risk assessment can be done on the basis of the new residue definitions. The new calculations should be summarised in an addendum. Message from EPCO 24 to EPCO 23:

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	continued Open point 3.7: MSs to discuss in an expert meeting the residue definition for animal products. Open point relates to open point 1.16. (see reporting table 3(9))	degradation of captan in the presence of blood. As such, all systemic toxicity observed in captan studies is attributed to the metabolites along with secondary effects of captan's irritation of the GI tract. The main animal residue is a collective of THPI-based molecules and do not confer toxicity that is considered toxicologically significant. None of these degradates or metabolites are judged candidates for inclusion in the residue expression. The definition of the residue in animal products is therefore captan alone. This conclusion is consistent with the conclusion of the RMS.	This position is open to discussion. Oct. 05 Following results of the last toxicological evaluations (see the Addendum "definition of the residue" of July 2005) the residue definition for captan was changed going back to the parent compound alone, (residue definition for captan=captan). The new open point is therefore invalid.	Please clarify the toxicological relevance of the metabolites THPI, THPI epoxide, 3 OH-THPI and 5 OH-THPI.
	New open point 3.15: RMS to go back to the available data set and make new evaluation of the available data so that the MRL proposals and the risk assessment can be done on the basis of the new residue definitions. The new calculations should be summarised in an addendum.		Oct. 05 Following results of the last toxicological evaluations (see the Addendum "definition of the residue" of July 2005) the residue definition for captan was changed going back to the parent compound alone, (residue definition for captan=captan). The new open point is therefore invalid.	EPCO 24 (11.05. – 13.05.2005): Open point still open. Evaluation Meeting (06.-09.02.2006): The required re-evaluation has been made in the addendum prepared by the EFSA Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	This open point was proposed at EPCO 24.			
	Message from EPCO 24 to EPCO 23: Please clarify the toxicological relevance of the metabolites THPI, THPI epoxide, 3 OH-THPI and 5 OH-THPI.			Answer from EPCO 23: THPI is the first product of metabolism: LD50 > 2000mg/L THPAM is the second metabolite. It is an animal metabolite which will be covered by the ADI. Therefore no additional information is required. It shows negative genotoxicity. 3 OH-THPI and 5 OH-THPI (animal metabolites) show up in low amounts. They are hydrophilic. Nevertheless they are covered by the ADI as well. Information on THPI epoxide is not available.
	Open point 3.8: RMS to provide in an addendum informations in column 3 of comments 3(8) and 3(9) of the reporting table. (see reporting table 3(9))	Studies on the toxicity and biological activity of potential captan metabolites are summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/01, 02, 03. In addition a discussion paper by Gordon (2005) is summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/04. **Conclusion**: The discussion paper expands on the discussion of the	For row crops THPI and THPAM represent only a minor part of the residue. Residues should be therefore expressed as captan alone. For processed commodities see point 3.6 For commodities of animal origin see	EPCO 24 (11.05. – 13.05.2005): RMS provided the information in an addendum. Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	continued Open point 3.8: RMS to provide in an addendum informations in column 3 of comments 3(8) and 3(9) of the reporting table. (see reporting table 3(9))	toxicological significance of the degradates of captan and concludes in conformity with the JMPR (FAO/WHO 2000) and US-EPA, based on the DG SANCO Guideline for Metabolism and Distribution in Plants (European Commission 1997) that the metabolites present a significantly lower hazard to man than captan, evidenced by the complete lack of systemic toxicity observed in the captan long term and subchronic toxicity studies. In addition, direct comparisons of captan and THPI aquatic toxicity further reinforces the differences due primarily to its mode of action as a primary irritant. Key to resolving the differences in toxicity between captan, THPI and other systemically circulating THPI-metabolites is the exceptionally rapid degradation of captan in the presence of blood. As such, all systemic toxicity observed in captan studies is attributed to the metabolites along with secondary effects of captan's irritation of the GI tract. The main animal residue is a collective of THPI-based molecules and do not confer toxicity that is considered toxicologically significant. None of these degradates or metabolites are judged	point 3.7 New information provided by the MDS have been included into the addendum. RMS comments are reported under point IIA 6.7 (proposed residue definition) of the addendum.	

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
		candidates for inclusion in the residue expression. The definition of the residue in animal products is therefore captan alone. This conclusion is consistent with the conclusion of the RMS.		

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
3.4	required. (see reporting table 3(16)) *continued* Clarification of the results of the McKay study on storage stability, providing stability data for captan and THPI separately . If not available new experimental data are required. (see reporting table 3(16))	the freezer prior to analysis. Apple samples were stored for up to 11 months and tomatoes were stored for up to 5 months. Freezer storage stability data have demonstrated that residues of captan are stable when stored for at least 14 months in apple fruit and for at least 9.5 months in tomato fruit. Therefore, all the trials in apple and tomato are validated by the freezer storage data. Freezer storage stability data have demonstrated that residues of captan are stable when stored for 15 months in apple juice, 9.5 months in apple sauce (puree), 9.5 months in apple pomace (based on extrapolation from data on grape and tomato pomace), for 9/9.5 months in tomato pomace and tomato sauce (ketchup) and for 15 months in tomato juice (based on extrapolation from data on apple juice). All commodities were stored for less than the maximum period tested in all the available storage studies except for apple sauce in study 6.5.2/04 and 6.5.2/05 and apple pomace in study 6.5.2/05. No degradation is expected to have occurred during storage and the processing studies in apple and tomato are validated by the freezer	 Oct. 05 New open point 3.16 invalid. List of end point amended. Data requirement fulfilled	See new open point 3.16.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
		storage data. The residue data for peaches/ nectarines are validated by storage data already summarised in the DAR.		
	Open point 3.10: RMS to provide an addendum with summary table of the processing studies where THPI data are included to be discussed in an expert meeting. (see reporting table 3(20))	The definition of the residue in plants including processed commodities is captan alone. See response to open point 3.6, 3.7 and 3.8. Studies on the toxicity and biological activity of potential captan metabolites are summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/01, 02, 03. In addition a discussion paper by Gordon (2005) is summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/04. Therefore, THPI data from processing studies are not relevant.	Data are presently not available. They have been requested to the MDS and, if provided, will be presented and discussed during the next expert meeting.	EPCO 24 (11.05. – 13.05.2005): Relevant information was tabled at the meeting. Open point fulfilled.
	Open point 3.11: RMS to discuss on how the risk assessment specifically for processed commodities is to be carried out in an expert meeting. (see reporting table 3(20a))	The definition of the residue in plants including processed commodities is captan alone. See response to open point 3.6, 3.7 and 3.8. Studies on the toxicity and biological activity of potential captan metabolites are summarised in new addendum	See replay to open point 3.6	EPCO 24 (11.05. – 13.05.2005): Discussion not needed due to the new residue definition. Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	continued Open point 3.11: RMS to discuss on how the risk assessment specifically for processed commodities is to be carried out in an expert meeting. (see reporting table 3(20a))	under Point IIA 6.7 and Point II 5.8.1/01, 02, 03. In addition a discussion paper by Gordon (2005) is summarised in new addendum under Point IIA 6.7 and Point II 5.8.1/04. Therefore, THPI data from processing studies are not relevant.		
	Open point 3.12: RMS to amend the list of end points for apple pasteurized juice and apple puree by mentioning TF < 0.05 rather than as an accurate figure. (see reporting table 3(21))		List of end points amended.	EPCO 24 (11.05. – 13.05.2005): RMS amended the list of end points. Open point fulfilled.
	Open point 3.13: RMS to include calculations of the potential exposure of	Calculations of the potential exposure of animals by consumption of apple pomace are presented in new	Calculation of the potential exposure of animals by consumption of apple pomace has been included in the	EPCO 24 (11.05. – 13.05.2005): Due to the new MRL of 10 mg/kg for apple this point remains open since the current

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	animals by consumption of apple pomace in an addendum to be considered in expert meeting. (see reporting table 3(30)) *continued* Open point 3.13: RMS to include calculations of the potential exposure of animals by consumption of apple pomace in an addendum to be considered in expert meeting. (see reporting table 3(30))	addendum under Annex Point IIA, 6.4 **Conclusion:** In metabolism studies in goats, captan was administered at a dietary concentration of 50 mg/kg for seven days and only 1-2% of the administered radioactivity was detected in animal tissues and milk; no parent captan was found in milk and tissues. The dietary concentration in the study was approximately 7 times the worst-case dietary burden (based on the MRL) and 26 times the realistic dietary burden (based on the STMR) for beef cattle, and approximately 21 times the worst-case dietary burden (based on the MRL) and 81 times the realistic dietary burden (based on the STMR) for dairy cattle. Therefore, no residues in excess of the LOQ for captan in milk and bovine tissues are expected and a feeding study in ruminants is not required.	addendum (point IIA 6.4). Oct. 05 Calculations considering an MRL of 10 mg/kg for apple are provided in the addendum. Open point fulfilled	calculations base on a MRL of 5 mg/kg for apple. Open point still open. Evaluation Meeting (06.-09.02.2006): This topic is covered by the addendum prepared by EFSA Open point fulfilled.

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
			These results are not acceptable for the current EFSA rules	
	New open point 3.16: RMS to revise the list of end points according the amendments proposed by EPCO 24.		Oct. 05 Following results of the last toxicological evaluations (see the Addendum “definition of the residue” of July 2005) the residue definition for captan was changed going back to the parent compound alone, (residue definition for captan=captan). The new open point is therefore invalid.	EPCO 24 (11.05. – 13.05.2005): Open point still open. Evaluation Meeting (06.-09.02.2006): Open point fulfilled.