PEER REVIEW REPORT ON **MALATHION** 26 06 2009

TABLE OF CONTENTS

	Document	**File Name**
00	Cover page	00 malathion cover
01	**All comments received on the DAR**	**01 malathion all comments**
02	Reporting table all sections	02 malathionrep table rev 1-1
03	All reports from PRAPeR Expert Meetings	03 malathionall reports.
04	Evaluation table	04 malathioneval table rev 2-1

Comments on the Draft Assessment Report on malathion (EAS)

RMS UK

End of commenting period: 15 March (MS, NOT)

Date	Supplier	File
12.03.2009	AT	01 malathion comments AT 2009-03-12.doc
13.03.2009	NL	02 malathion comments NL 2009-03-13
13.03.2009	FI	03 malathion comments FI 2009-03-13
13.03.2009	DE	04 malathion comments DE 2009-03-13
15.03.2009	DK	05 malathion comments DK 2009-03-15
13.03.2009	NOT	06 malathion comments NOT 2009-03-15
16.03.2009	EFSA	07 malathion comments EFSA 2009-03-16
17.03.2009	FR	08 malathion comments FR 2009-03-17

Section 1 – Physical/Chemical Properties; Details of Uses and Further Information; Methods of analysis (B.1 – B.5)

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

No comments

2. Mammalian toxicology (B.6)

No comments

3. Residues (B.7)

Residue definition (B.7.3)			
No.	Column 1 Reference to additional report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.7.3, definition of residue	AT: It was stated by the RMS that different residue definitions for risk assessment and monitoring have to be applied: Crops (MRL and monitoring): Malathion plus its metabolite malaoxon expressed as malathion (inline with provisional EU residues definition and CODEX definition) Crops (Risk Assessment): Malathion plus its metabolite malaoxon, desmethyl-malathion, malathion monocarboxylic acid and malathion dicarboxcylic acid expressed as malathion Since different residue definitions are proposed, a conversion factor has to be applied (converting the residue definition for monitoring to the residue definition for risk assessment).	

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

4. Environmental fate and behaviour (B.8)

No comments

5. Ecotoxicology (B.9)

No comments

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

7. Mammalian toxicology (B.6)

Exposure data (B.6.14)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Additional report, B.6.14.3, worker exposure	NL: The calculations of the worker exposure after field application on strawberries and whether or not field application on strawberries is a safe use for the worker should be discussed in an expert meeting.	

Section 3 - Residues (B.7)

8. Residues (B.7)

Residue definition (B.7.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3. B.7.3 Definition of the residue	NL: Please propose a conversion factor (monitoring to risk assessment), this is useful for monitoring authorities.	
(2)	Vol. 1. LoEP	NL: Please propose a conversion factor (monitoring to risk assessment).	

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.7.5, Identification of critical GAPs	NL: Table B.7.5 Please include the interval between the applications (10 days).	
(2)	Vol.3. B.7.6 Table B7.7	NL: Please include the interval between the applications.	

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

9. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
1	Additional report, LoEP	NL: The structural formula in the fys/chem. part of the LoEP does not match with the molecular formula.	The molecular formula is correct.
2	Additional report General	NL: No further comments	

10. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
1	B.9.1.2 Risk assessment birds	NL: The detailed evaluation of the residue study is very clear and much appreciated.	
2	B.9.2 Acute endpoint fish	NL: We prefer the SSD method to Method 2 of the PPR Opinion, since it is scientifically more sound. In the current situation, we would calculate the relevant acute regulatory endpoint for fish as explained in Column 3, leading to an endpoint of 0.36 ug as/L. This is close to the endpoint used by the RMS (0.4 ug as/L), so the outcome of the risk assessment will probably not change much. However, we would like to discuss this issue in an expert meeting (also for consistency reasons, since the SSD-method has been used for abamectin).	The HC5 is calculated with the ETX-programme. For fish, at least six real values are needed. Only four real LC50-values are available (there seems to be an error in Table B.9.2.1: according to the original DAR, the LC50 for common carp is >10 mg as/L instead of 10 mg as/L. This leaves only four real values). Furthermore, for fish, the HC5 must always be based on LC10/NOEC values, because they are vertebrates and they have a relatively long life cycle. The six acute NOECs amount: 0.00501, 0.018, 0.032, 0.091, 0.946 and 1.0 mg as/L. The mean HC5 based on these six NOECs is 1.821 ug as/L. Based on the acute and chronic studies with rainbow trout, the ratio between the acute and the chronic NOEC is 0.091/0.021 ≈ 5. This factor can be used to correct for multiple application. Using this factor of five, the regulatory endpoint is 1.821/5=0.36 ug as/L. See for more information the revised addendum of abamectin of March 2008.
3	LoE, Aquatics	NL: Please include all endpoints for fish in the LoE and mention also the tested species for all tests.	
4	LoE, Non-target arthropods	NL: It would be good to include the study duration and the sampling dates of the aged-residue studies, as now it cannot be read from the LoE whether the adverse effects on A.rhopalosiphi, C.carnea and O.laevigatus were lower than 50% after the mentioned DATs or whether this was not measured.	

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

No comments

12. Mammalian toxicology (B.6)

(1)	Additional report, Evaluation, summary and proposed decision. 1. Background, page 7; General comment	FI: It is stated that the specification of the active substance in the re-submission application is the same as was the subject of the non-inclusion decision. This is a bit confusing and can be even misleading. The specification for the re-submission application should have been expressed clearly and in a transparent way. Based on the data presented from the EFSA Scientific Report (2006) 63, it can be concluded that the isomalathion content in the re-submission application has to be 0.2 %.	
(2)	Additional report, Evaluation, summary and proposed decision. 1. Background, page 7; General comment	FI: It is stated, that the supported uses are the same as those that were the subjects of the non-inclusion decision. This is an indistinct way to express the supported uses. The notifier does no longer support application on apple and alfalfa. Instead, the notifier continues to support the use of malathion on strawberries and ornamentals under glass. However, strawberries in greenhouses were not intended uses in the original application.	The intended uses in the original application were apple, alfalfa and strawberries outdoors and ornamentals indoor. Hence, strawberries under glass was not included in the intended uses and was not assessed in the DAR. Strawberries under glass was neither assessed in this Additional report which should be the case with the applied uses.

Genotoxicity (B.6.4)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Additional report, B.6.4.1 Ames test (Bowles, 2005)	FI: Malathion technical containing 0.25 % isomalathion was negative in an Ames test.	Some positive results in the genotoxicity studies of the original malathion dossier and the knowledge from the literature strongly support the hypothesis that isomalathion and possibly other impurities, as well, affect the genotoxicity of malathion. As the 0.2 % isomalathion content was concluded to be relevant in the malathion specification, a new Ames test

Genotoxicity (B.6.4)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
			was required. Based on the negative results in the new Ames test (Bowles, 2005) and in the original dossier submitted *in vitro* mammalian UDS test (Pant, 1989) and *in vivo* chromosome aberration test (Gudi, 1990) which were performed with malathion containing 0.2 % isomalathion, it can be concluded that malathion containing 0.2 % isomalathion is not genotoxic.

Long-term toxicity and carcinogenicity (B.6.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Reproductive toxicity (B.6.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Neurotoxicity (B.6.7)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>,	<<MS/notifier>>: <<comment>>	

Neurotoxicity (B.6.7)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	<<description>>		

Other toxicological studies & Medical data (B.6.8-B.6.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Additional report, B.6.8.1, Toxicity studies on metabolites, Comparison of toxicity and cholinesterase inhibition potential, (Pratt, 2006)	FI: EPCO (18) decided that the critical effect of malathion is acetylcholinesterase inhibition in brain. In this study (Pratt, 2006), only effect on erythrocyte AChE is determined. Repeated measurements for a longer period than 24 hours would have given valuable information on the AChE inhibition and recovery after a single large dose of malathion or desmethyl-malathion.	Desmethyl-malathion and malathion were compared in their toxicity and cholinesterase inhibition potential following a single oral administration of 1500 mg/kg bw of these substances. In general, malathion causes greater inhibition on erythrocytes than in brain. It is not known, whether this is true also on desmethyl-malathion. Hence, brain AChE inhibition should have been measured. The notifier criticised that the RMS had chosen AChE inhibition in erythrocytes as the critical effect in the malathion DAR. In the case of desmethyl-malathion they have chosen exactly the same end point. Blood samples for erythrocyte AChE inhibition were taken only at 2 hours and 24 hours after dosing although the clinical signs of the animals were observed for 14 days.
(2)	Additional report, B.6.8.1, Toxicity studies on metabolites, Comparison of toxicity and cholinesterase inhibition potential, (Barnett, 2008)	FI: In this acute dose range-finding study, desmethyl-malathion, malathion monocarboxylic acid and malathion dicarboxylic acid generally showed lower severity of toxicity and AChE inhibition in erythrocytes and brain than malathion after two or eight hours after dosage.	
(3)	Additional report, Comment on the need of	FI: Considering the residue amounts of MMCA and the low amount of this metabolite in mammalian	The notifier has submitted acute toxicity studies and Ames tests on the metabolites desmethyl-malathion, malathion monocarboxylic acid and

Other toxicological studies & Medical data (B.6.8-B.6.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	toxicity studies on metabolites	metabolism, acute toxicity studies and a comparative cholinesterase study can not guarantee the safety. Those studies have been performed with high dosages and the extrapolation from a high dose to low doses is difficult.	malathion dicarboxylic acid. In addition, they have studied cholinesterase inhibition potential of these metabolites compared to malathion after a single large dosage.
(4)	Additional report, Comment on the need of toxicity studies on metabolites	FI: Chronic exposure to MMCA has not been studied. Based on the results of the residue trials on strawberries in Italy (Additional report B.7.8.2) and the toxicokinetic studies on malathion (DAR), it can be concluded that the toxicity of malathion monocarboxylic acid (MMCA) and the health risks caused by this metabolite have not been properly clarified.	In the residue trials on strawberries in Italy (Additional report B.7.8.2), the amounts of malathion monocarboxylic acid (MMCA) in the fruit were consistently high and often twice as high as the amount of malathion. The amounts of malathion dicarboxylic acid (MDCA) were more variable but the highest amounts were three to even four times higher than the amounts of malathion. The amounts of these metabolites decreased in the processed products. MDCA is present in high amount in rat metabolism and can be considered of equivalent toxicity to malathion. It is possible that the metabolite MMCA possesses risk for AChE inhibition. The problem in chronic AChE inhibition is that the longer the exposure period is the smaller amount of AChE inhibitor is needed for getting an effect. In order to get an assumption of the magnitude of chronic AChE inhibition, the study should be conducted for a longer period with daily dosing at different dose levels.
(5)	Additional report, Comment on the need of toxicity studies on metabolites	FI: Genotoxicity of MMCA has not been studied properly.	The minimum data package for genotoxicity of MMCA requires an Ames test, an *in vitro* mammalian cell gene mutation test and an *in vitro* chromosome aberration test.

Summary of mammalian toxicology and setting ADI, AOEL, ARfD (B.6.10)

Section 2 - Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Toxicity of the product(s) (B.6.11)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Dermal absorption (B.6.12)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Toxicity of non-active substances (B.6.13)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Exposure data (B.6.14)

Section 2 - Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Additional report, Evaluation, summary and proposed decision. 1. Background	FI supports professional use only because the exposure during amateur use is above the AOEL.	
(2)	Additional report, Evaluation, summary and proposed decision . 1. Background	FI: On page 7, it is stated "The notifier continues to support strawberries and ornamentals under glass". However, in the original DAR made by FI strawberry under glass was not assessed and this assessment is neither done in the Additional report.	On page 64, it is stated that risk assessment is presented for use on outdoor strawberries.
(3)	Additional report, B.6.14.1.3. Summary of Operator Exposure	FI: Operator exposure is acceptable only with PPE. Therefore the use of PPE (gloves during mixing and loading and spraying, coverall and sturdy footwear during spraying) should be emphasised.	
(4)	Additional report, B.6.14.1.3. Summary of Operator Exposure	FI: Higher tier data for evaluation of hand-held application should be requested.	According to the Additional report, hand-held application is acceptable only when evaluated with the German model using PPE. Assessment performed with UK POEM using PPE shows unacceptable exposure. UK POEM contains a more representative dataset than the German model. UK POEM is based on applications for low level targets. German model data are gathered from high target applications.
(5)	Additional report, B.6.14.3 Worker exposure	FI: Re-entry activities on strawberries were not assessed in the additional report as a safe use for re-entry workers re-entering treated ornamental plants (roses) was previously identified. However, application rates on ornamentals in greenhouses are much smaller (0.114 kg as/ha) than on strawberries (1.2 kg as/ha). Hence, the assessment of worker exposure on ornamentals does not cover the worker exposure on strawberries.	

Section 2 - Mammalian toxicology (B.6)

Exposure data (B.6.14)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(6)	Additional report, B.6.14.3 Worker exposure	FI: FI supports the requirement of higher tier data (such as dislodgeable foliar residue) for worker exposure assessment.	
(7)	Additional report (general comment on the operator exposure assessment)	FI: A summary table about all evaluated operator exposures (data from the original evaluation presented in the Addendum 3, 9 September 2005 and Additional report) would be beneficial.	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

13. Residues (B.7)

Storage Stability (B.7.0)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Metabolism in plants (B.7.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		<<MS/notifier>>: <<comment>>	
(1)	Vol. #, <<data point>>, <<description>>	A comment by FI referring to pages 97 and 98 of .pdf version. The presented renalysis data gives identification covering only a few percent of TRR as presented in Table B.7.4. If new data are relied upon, it follows that there were identification issues in the original data. The question is, were the rest of the metabolites in the new data, approx. 95%TRR, left unidentified and should the study still be considered as acceptable?	

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

14. Environmental fate and behaviour (B.8)

No comments

15. Ecotoxicology (B.9)

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.9.1.1 Risk to birds	FI: We agree that the 90th percentile value for arthropods are missing due to bulking of the arthropods and therefore the acute risk assessment for insectivorous birds cannot be performed. We also agree with the conclusions that the use of the residue decline data in the long-term risk assessment is uncertain and therefore further risk refinement for the birds should be performed.	
	Vol 3, B.9.3.1 Risk to mammals	FI: In the risk assessment of mammals the insectivorous mammal has been selected as an indicator species for strawberry. However, according to the SANCO 4145 insectivorous mammal is not presented as an indicator species in leafy crop. However, we think that the risk for insectivorous mammal can be calculated and is useful for the risk assessment.	

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3 B.9.2.2.4	FI: The risk for the aquatic organisms has been	

Section 5 - Ecotoxicology (B.9)

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	FOCUS STEP 4	refined by FOCUS STEP 4 modelling. Most of the scenarios show acceptable risk with the buffer zone of 40 meters. However, the risk should be refined so that all the scenarios show acceptable risk or an explanation should be given if the risk cannot be refined for the few scenarios where risk still occurs (R2 stream fish, R4 stream fish, R4 stream aquatic invertebrates, R4 stream aquatic invertebrates).	

Bees and non-target arthropods (B.9.4 and B.9.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Earthworms and other soil non-target organisms (macro and micro) (B.9.6, B.9.7 and B.9.8)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)

Section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

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

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Additional report, appendix I , list of end points, p. 173 to 177	DE: The current harmonised version (Sept. 2005) of the end points should be used. The list of end points should be amended consequently and not only partially: • Either the entry "RMS" or "co-RMS" needs to be updated as UK has written the additional report. • Taken the clarifications given on page 10 into account it seems that the entries in the boxes for food of plant and animal origins are not up-to-date. • Taken the clarifications given on page 10 and the assessment on pages 16 and 17 into account it seems that the entry in the box for soil is not up-to-date.	

17. Residues (B.7)

Residue definition (B.7.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol.3, B.7.3 Residue definition	DE: We agree with the proposed new residue definition for risk assessment, which includes malathion, malaoxon, desmethyl-malathion, monocarboxcylic acid-malathion and dicarboxylic acid-malathion expressed as malathion. A conversion factor (monitoring to risk assessment) should be derived accordingly and be included in the list of endpoints.	

Succeeding/Rotational crops (B.7.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol 1. 2. Overall conclusions	DE: The assumption that strawberries are not relevant for crop rotation is incorrect. It is common practice to use fast-growing strawberry ”frigo” plants from May to September and e.g. winter rye or mustard seed as following crop (either for a short period as green manure or during the full ripening period until common harvest). New strawberry ”frigo” plants may be planted again after that.	

Section 3 - Residues (B.7)

Succeeding/Rotational crops (B.7.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		At least further information on the DT50 value for desmethyl-malathion in soil is needed to cover the still open point concerning rotational crops. Further information on the behaviour in succeeding crops might then be needed.	

Section 5 - Ecotoxicology (B.9)

18. Ecotoxicology (B.9)

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B 9.1.2.1. Refined risk assessment for birds. Filed study on residue decline; Overall assessment p. 148	Dk: We generally agree with the RMS assessment of the field study – it can not be used for the acute assessment and its use for long-term assessment is limited/uncertain. In addition to the listed concerns it should be mentioned that all samples were pooled – and therefore no distinction between small and large insects/relevance of food items has been undertaken.	

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, Aquatic risk assessment B.9.2.2.4 FOCUS Step 4 Table B.9.2.5 TERs… p. 157	Dk: For transparency reasons we would recommend to use the actual endpoint from the mesocosm study (5 ug/L) in the risk assessment and compare the resulting TER to the chosen trigger (in this case 3-5). As the table stands one needs to go back to a previous section to understand why two different values are given under endpoint (1 and 1.67 and which trigger these values are based on).	

Other comments

Section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol 3, B.9 11 General conclusion	Dk: It should be mentioned that these conclusion concern the uses in ornamentals under cover and strawberry only. Furthermore the risk to birds, which has not been demonstrated to be acceptable should be mentioned.	
(2)	Vol. 3, List of endpoints GAP table	Dk: In our view the GAP table should be gray for the strawberry use (risk to birds).	
(3)	Vol. 3, List of endpoints Aquatic risk assessment	Dk: For transparency reasons we would recommend to use the actual endpoint from the mesocosm study (5 ug/L) in the risk assessment and compare the resulting TER to the chosen trigger (in this case 3-5). As the table stands one needs to go back to a previous section to understand why two different values are given under endpoint (1 and 1.67 and which trigger these values are based on).	

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

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

Physical and chemical properties of the active substance (B.2.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Physical, chemical and technical properties of the formulation (B.2.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

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

Methods of analysis (B.5)

Section 1 – Physical/Chemical Properties; Details of Uses and Further Information; Methods of analysis (B.1 – B.5)

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

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	General	Notifier: The date of the Additional Report is incorrect and should be February **2009** and not February **2008.**	

20. Mammalian toxicology (B.6)

Toxicokinetics (B.6.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Acute toxicity (B.6.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Short-term toxicity (B.6.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Genotoxicity (B.6.4)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol 3., Appendix 1.3, List of Endpoints, Impact on Human and Animal Health, Toxicologically significant compounds	Notifier: It is proposed to reword this entry to read as follows: 'Malathion and malaoxon. Isomalathion which is an acetylcholinesterase	It is proposed to delete the sentence 'Impurities (especially isomalathion) may increase the genotoxicity of malathion'. The wording is inconclusive;"..*may* increase the genotoxicity.." (italics added by Notifer) and it has been shown that isomalathion did not increase the genotoxicity of malathion at the levels of the specification.

Genotoxicity (B.6.4)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	(animals, plants and environment)	inhibitor, which enhances the toxicity of malathion. Desmethyl malathion, Malathion mono- and dicarboxylic acids which are all cholinesterase inhibitors.'	

Long-term toxicity and carcinogenicity (B.6.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Reproductive toxicity (B.6.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Neurotoxicity (B.6.7)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Section 2 - Mammalian toxicology (B.6)

Other toxicological studies & Medical data (B.6.8-B.6.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.6.8.1, Toxicity studies on metabolites	Notifier: On p51, within the summary of the report Reiss R., Edwards M. (2008), there is a reference to a previously submitted study by Fulcher (2001). However, no details of this study are given to allow the reader to know that the study was submitted previously and to provide a detailed reference. The Fulcher (2001) study is fully referenced in the subsequent section (d) on p52 of the Additional Report.	

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

Toxicity of the product(s) (B.6.11)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Section 2 - Mammalian toxicology (B.6)

Dermal absorption (B.6.12)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: See Exposure data B.6.14	

Toxicity of non-active substances (B.6.13)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Exposure data (B.6.14)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol.3, B.6.14 Exposure Data, Dermal Absorption	Notifier: As highlighted on p65 of the Additional Report, the notifier considers dermal absorption values generated using the actual EW formulation to be more appropriate for risk assessment and could be used for refinement of the risk.	
(2)	Vol. 3, B.6.14.3, Worker exposure Also Section 2 p8	Notifier: The RMS comments on the uncertainties of using surface residues from apple to extrapolate to strawberry fruit and leaves. Supervised crop residue data on strawberry fruit presented on p71 of the Additional Report can be used to support the apple data as it shows residues to be significantly lower after 1 day indicating that the DT_{50} of malathion on strawberry fruit would be less than 1 day. In addition, the data presented by	

Exposure data (B.6.14)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		Yanghong Li *et al* also shows a biphasic decline of malathion on strawberry leaves supporting the use of this type of decline. Overall, it is considered that using a DT_{50} greater than 1 day would over estimate potential worker exposure.	
(3)	Vol. 3, B.6.14.3, Worker exposure Also Section 2 p8	Notifier: No consideration of PPE (gloves) has been used in this recent assessment. The previous assessment undertaken in Addendum 3 of the DAR considered a Transfer Coefficient value of 750 cm^2/h when gloves are worn. Using this value it can be shown worker exposure is 32% AOEL for crop inspection and 60%AOEL for harvesting assuming a DT_{50} of 1.86 days and 45% AOEL for crop inspection and only 109% AOEL for harvesting assuming a DT_{50} of 3.3 days. The Notifier therefore recommends that any concerns over worker exposure for strawberry could be dealt with at Member State level.	
(4)	Vol. 3,, Appendix 1.3, List of Endpoints, Impact on Human and Animal Health, Acceptable exposure scenarios, Operator	Notifier: The estimated exposure values are not completely in agreement with the values on page 66. The figures for the German model should be 28% and 79%. The figure 163 appears to be a typing error.	

Section 2 - Mammalian toxicology (B.6)

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

21. Residues (B.7)

Storage Stability (B.7.0)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Metabolism in plants (B.7.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Metabolism in livestock (B.7.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Residue definition (B.7.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Section 3 - Residues (B.7)

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Processing (B.7.7)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Livestock feeding (B.7.8)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Succeeding/Rotational crops (B.7.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, Annex B.7.10 Residues in succeeding or rotational crops	Notifier: The case for no further data being necessary for rotational crops is presented in Column 3. This case is also available in the re-submission dossier. Based on aerobic soil metabolism and confined crop rotation data, desmethyl malathion, MMCA and MDCA are shown not to persist in soil.	The aerobic metabolism study conducted on malathion (Knoch, 2001) showed that malathion rapidly degraded in soil (DT50 = 0.17 – 0.25 days at 20°C, 45% MWHC). Extensive data were generated to demonstrate the rate and route of degradation. Where significant metabolites were formed, these were successfully identified and their formation and decline measured. MMCA and MDCA were formed in soil at >10% AR. Both degradates were of transient character and reached maximum values equal

Succeeding/Rotational crops (B.7.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
			or less than 3.2% AR by Day 29 (MMCA max. 25%, DT_{50} = 0.12 – 0.72 days at 20°C, 45% MWHC, MDCA max. 65%, DT_{50} = 1.2 – 5.3 days at 20°C, 45% MWHC). Total recoveries of radioactivity ranged from 94.4 to 105.3%. Other than MMCA and MDCA there were no other metabolites detected at >10% AR (equivalent to ≥0.2ppm). Desmethyl malathion was not identified as a significant metabolite in soil. According to the EU Guidance document 7524/VI/95 rev.2, 1997 relating to potential residues in rotational crops, studies are not required if, 30 days after application, less than 10% of the of the originally applied active substance remains in the soil, including any bio-available metabolites. Based on these data it is concluded that desmethyl malathion, MMCA and MDCA would not be present in soil nor at persistent levels that would warrant consideration of possible plant uptake into rotational crops. Furthermore the confined crop rotation study conducted by Wootton, M., Johnson, T. (1993) did not identify desmethyl malathion as a metabolite in soil or crops even though it was used as one of the reference standards for metabolite identification. The results therefore provide further evidence that desmethyl malathion would not be present as a significant metabolite in rotational crops. This conclusion is in line with comments presented by the RMS in the evaluation table who concluded that desmethyl malathion should not trigger further requirements for studies in rotational crops.

Section 3 - Residues (B.7)

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3., pages 106 to 113	Notifier: The heading in these pages has changed, in error, from B.7: Residues to B.9 Ecotoxicology.	

22. Environmental fate and behaviour (B.8)

Route and rate of degradation in soil (B.8.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Adsorption, desorption and mobility in soil (B.8.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

PEC in soil (B.8.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.8.3, Predicted environmental concentrations in soil (PEC_s)	Notifier: Under PEC_{sw} and PEC_{gw} (Section B.8.6), it is noted that the risk assessment for ornamentals is covered by the risk assessment for strawberries because less malathion is applied and ornamentals will be grown under protection, thus, spray drift and runoff will be largely prevented. For soil, no PEC_{soil} has been calculated for ornamentals as the proposed rate of application falls within the use rate for strawberries. The Notifier requests that it should also be stated that the soil risk assessment for ornamentals is covered by the risk assessment for strawberries (for avoidance of future doubt).	

Fate and behaviour in water and impact on water treatment procedures (B.8.4 – B.8.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

PEC in surface water and ground water (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Fate and behaviour in air and PEC in air (B.8.7 – B.8.8)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Definition of the residues (B.8.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

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

23. Ecotoxicology (B.9)

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.9.1.2 Effects on birds, risk assessment of use on strawberries	Notifier: Page 130 – In the refinement of the risk assessment for frugivorous birds, it is noted that there is no standard value available for residue decline on fruit. However residue data were provided in the submission and discussed in Section B.6.14.3, Worker Exposure. DT50 values for malathion in fruit were estimated as 0.5 days to 3.3 days. These values can be considered relevant to the refinement of risk for frugivorous birds.	
(2)	Vol. 3, B.9.1.2 Effects on birds, risk assessment of use on strawberries Also Section 2 p 13	Notifier: Page 149 - According to the assessment presented in the additional report, the acute TER for insectivorous birds is less than 10 and it is not considered appropriate, due to the lack of a 90th percentile figure, to refine the risk assessment on the basis of residue data in insects, therefore further work is still required to identify an 'acceptable' acute risk. Pragmatic but still moderate refinement of the acute risk assessment through revision of currently default parameters (e.g. PD, RUD values) using published literature and the higher tier residues data shows an acceptable acute risk assessment can be achieved. This in combination with accepted environmental dissipation can also be used to show an acceptable	For insectivorous birds, Table B.9.1.7 in the Additional Report, 2009, presents a refinement to the bird acute and long-term risk assessment for insectivorous birds, with an acute default RUD value of 52. A default RUD was used as a 90th percentile value insect residues value for crop dwelling insects was not available. The AV, PD and PT factors are not refined (all are set to the default of 1). Thus refinement of the RUD and/or the AV, PD or PT values could provide an acceptable risk assessment. Proposal for PD refinement: Under field conditions, it is unrealistic to assume that a bird would obtain all of its feed within the treated area. Consideration of the feeding ecology of a relevant bird species indicates that such a reduction in exposure, leading to an acceptable risk, is likely to be the case. The refinement presented in the Additional Report, is therefore considered to be an overly conservative assessment of exposure risk to insectivorous birds.

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		long-term risk. Further details are provided in Column 3.	Strawberries are considered to be a leafy crop at the proposed time of application, therefore, indicated bird species in a crop of this type are frugivorous (eg. Black-cap) and insectivorous bird (eg. Skylark) species. For frugivorous birds, a safe use has already been illustrated in the Tier 1 assessment. For insectivorous birds, Skylarks are representative bird species in strawberry crops at the proposed application times; KEMI (2006), Buxton et al (1998). Consideration of the insect component of a Skylark's diet and its feeding habits are appropriate to this risk assessment. For example, in Buxton et al (1998), the proportion of arthropods in the Sklylarks' diet is 42%. Therefore, risk from exposure to malathion from contaminated arthropods would be reduced. Although the Skylark is considered to be an insectivorous bird, the diet (in common with other insectitivorous bird species), comprises other non-arthropod items such as weeds seeds and earthworms, typically obtained from off-field areas, reducing the potential risk from residues even further. Proposal for RUD refinement: The highest initial measured malathion residue on crop dwelling insects is 9.4 mg/kg (Knabe, 2004), based on an application rate of 1.8 kg as./ha on apples. Cheminova considers that, taking account of rate reduction, and given a similar level of crop interception, between 0.6 and 0.7 (FOCUS 2001), the residues on insects may be expected to be similar over the two crops. This argument is supported by residue data on crops. The mean initial residue of malathion on strawberries determined in eight residue trials conducted in 2007- 2008 (Brice 2008) at an application rate of 1.5 kg as./ha was 0.78 mg/kg with a 90th percentile value of 1.25 mg/kg. Thus, for strawberries the RUD value is 0.83 (1.25 mg/kg normalised for 1.0 kg as./ha). Given the 90th percentile measured

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
			concentration in strawberries is 1.25 mg/kg, the use of 9.4 mg/kg for risk assessment in insectivorous birds is considered conservative as it is extremely unlikely that residues in insects would be more than 8 times greater than those in strawberries. Based on the above, refinement of the risk assessment for acute risk to birds results in a TER value well in excess of the Annex VI trigger. With regard to the longer-term risk assessment for insectivorous insects, the DT50 value of 0.48 days used in the long-term assessment is considered appropriate and is broadly similar to other environmental DT50 values already observed. On p 138 of the Additional Report, the DT50 value of 11.69 hours (0.48 days) is considered acceptable for malathion. Thus, the refinement of the RUD, together with the accepted DT50, provide a TER value well in excess of the Annex VI trigger.

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Bees and non-target arthropods (B.9.4 and B.9.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.9.5.1, Effects on other arthropod species, risk assessment for use on strawberries Also Section 2 p12	Notifier: The significance of the isomalathion content of the formulation used in non-target arthropod testing has been investigated to provide further information to the open point raised. New information, discussed in Column 3, indicates that isomalathion present at specification limits, will not significantly affect the toxicity of the product to non-target arthropods. Cheminova recognise that new data cannot be submitted under the accelerated procedure (Article 17(3) of Regulation 33/2008), and further details on the testing will be available for review at Member State level.	A literature review has revealed that the effect of malathion with variable isomalathion content, on non-target arthropods, has not been widely investigated. Nevertheless there were no indications of concern found in the review. In the previously submitted studies, the risk of malathion exposure to non-target arthropods was investigated using a malathion formulation that had an isomalathion content of between 0.014 - 0.017%. The most sensitive of the tier I species was *Aphidius rhopalosiphi*, with a 48 hour LR50 value of 0.06215 g as./ha. There was no mortality at concentrations up to 0.01096 g as./ha. In the fecundity assessment, fecundity was reduced by 50% at 0.01096 g as./ha. Cheminova have since investigated the impact of a malathion formulation (440 g/L EW) on *Aphidius rhopalosiphi,* with an isomalathion content of 0.089%, which is in agreement with the specification limit (0.088%). In an equivalent GLP study performed at nominal a.s. concentrations of 0.00548, 0.01096, 0.02192, 0.04384, 0.08768 and 0.13152 g as./ha, the results were very similar to those achieved in the previous study for a sample containing lower isomalathion levels, with a 48 hr LR50 value of 0.05018 g as./ha (CI = 0.04324 to 0.05777 g as./ha) and a similar reduction in fecundity at 0.01096 g as./ha. It can therefore be concluded that a malathion 440 g/L EW formulation containing isomalathion at 0.088% is unlikely to show increased non-target arthropod sensitivity, based on the response of the most sensitive species tested (*Aphidius rhopalosiph).* In the same test, an increase in isomalathion content by at least 80% resulted in only approximately 19% difference in the toxic response, which for same species testing, is within a considered expected range of variability (approximately 25%) for equivalent tests

Bees and non-target arthropods (B.9.4 and B.9.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
			conducted with different populations of test organisms.

Earthworms and other soil non-target organisms (macro and micro) (B.9.6, B.9.7 and B.9.8)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		Notifier: No comments	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	General – proposed decision, p13	Notifier: In the proposed decision, it is indicated that an additional issue has been identified regarding the risk to birds from outdoor uses which was not stated in the non-inclusion decision as a particular issue. This additional issue is not due to any changes in scientific and technical knowledge since the submission of the data which led to the	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		non-inclusion decision. According to Commission regulation (EC) No. 33/2008, on making a re-submission application the applicant shall be required to submit "any additional data necessary to address the specific issues that led to the adoption of the non-inclusion Decision concerned" As this issue had not been previously identified the Notifier contends no weight should be attached to this concern regarding the decision on Annex I inclusion.	
(2)	General – proposed decision, p13	Notifier: There is a grammatical error in the first line of the proposed decision – "the risk to birds (because *the risk* the acute and long-term risk…)". The italicised letters should be removed.	
(3)	Vol 3.,, Appendix 1.6, List of Endpoints, Effects on non target species	Notifier: The invertebrate residue study is mentioned as not appropriate for refinement of risk to birds. Whilst the Notifier can agree that the study design is not ideal to support the strawberry use, some aspects of the study have been used to support the risk assessment.	

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

Identity (B.1, Annex C)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Additional report, Proposed decision, p.13, B.1.3 GAP table, p. 15	EFSA: the statement of the RMS that indoor uses are acceptable, have a presentiment that field uses are not. If this would be the case, the use on strawberries would have had been grayed out.	

Physical and chemical properties of the active substance (B.2.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations

Physical, chemical and technical properties of the formulation (B.2.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations

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

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

Section 1 – Physical/Chemical Properties; Details of Uses and Further Information; Methods of analysis (B.1 – B.5)

Methods of analysis (B.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Additional report, Vol. 3, B.5.2 Residue methods for plants p. 16, LoEP Residue methods for plants, p. 177	EFSA: according to the representative uses of the re-submission and the residue definition for plants, the sentence "Method for desmethyl malathion could be necessary" might be misleading. The previous peer review concluded that desmethyl-malathion should be included in the residue definition for monitoring only in case is more toxic than malathion. If this peer review confirms the conclusions of the tox studies, probably the sentence should be deleted from the LoEP.	
(2)	Additional report, Vol. 3, B.5.2 Residue methods for animal products, p. 16, LoEP Residue methods for food of animal origin, p. 177	EFSA: the two affirmations are contradictory, probably it would be better to state in the LoEP that methods are not required for the uses evaluated during the re-submission (strawberries and ornamentals)	
(3)	Additional report, Vol. 3, B.5.3.1 Residue methods for soil, p. 16, LoEP Residue methods for soil, p. 177	EFSA: the entry in the LoEP should be updated to MDCA	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Additional report, LoEP RMS, p. 173	EFSA: probably UK should also be mentioned	

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

Section 1 – Physical/Chemical Properties; Details of Uses and Further Information; Methods of analysis (B.1 – B.5)

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(2)	Additional report, LoEP	EFSA: the new agreed template should be used	

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

25. Mammalian toxicology (B.6)

Genotoxicity (B.6.4)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	B.6.4.1 In vitro genotoxicity testing- Bowles 2005	EFSA: the outcome of the study presented is supported	

Other toxicological studies & Medical data (B.6.8-B.6.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	B.6.8.1 Toxicity studies on metabolites	EFSA: the Benchmark dose modelling approach and the relative potency factors calculated for metabolites are proposed to assess the relevance of the main metabolites of malathion. As it is quite new approach in the current process and some possible drawbacks are highlighted, could MSs please comment and give their views?	

Summary of mammalian toxicology and setting ADI, AOEL, ARfD (B.6.10)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Setting of ADI and AOEL	EFSA: in the assessment concluded with the EFSA conclusion in 2006, an additional safety factor of 10 was added at the 100 default depending on the technically estimated amount of isomalathion up	

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

Summary of mammalian toxicology and setting ADI, AOEL, ARfD (B.6.10)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		to 0.2%, taking into account its unknown genotoxic potential (now an Ames test is under assessment) and also the effects of isomalathion on the ChE inhibition (isomalathion estimated more acutely toxic than malathion by a factor 2-10). The additional factor could be reconsidered in the light of the new information provided.	

Exposure data (B.6.14)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	B.6.14.1.2 Estimation of operator exposure – UK POEM	EFSA: the operator exposure assessment for application in strawberries outdoor calculated with the UK POEM is presented. Correctly, the RMS presented the calculations according to the currently used default of 50 ha area treated; a refinement was then presented considering a lower area of 30 ha, considered as more realistic. Further details might be helpful to decide on the acceptance of the assessment.	
	B.6.14.2 Estimation of bystander exposure	EFSA: Could the RMS please give the references for the use of an inhalation rate of 0.03 ml spray liquid/m3 and a respiratory rate of 1.2 m3/h for 1 hour?	
	B.6.14.3 Estimation of worker exposure	EFSA: the RMS presented a variety of assessment based on exposure for re-entry immediately after	

Exposure data (B.6.14)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		treatment, and with refinements based on decline data of residues. The conclusion based on malathion DFR after 4 treatments and a PHI of 3 could be further discussed whether sufficient to request additional residue decline data to conclude on the estimated exposure.	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Technical specification	EFSA: the assumptions made in the previous and in the current assessments are based on a hypothetical level of isomalathion of 0.2%, as well as the reference values were modified upon this. Is this assumption still in place, also considering the FAO specification accounting for a level of isomalathion of 0.4%?	

Section 3 - Residues (B.7)

26. Residues (B.7)

Storage Stability (B.7.0)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Metabolism in plants (B.7.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol.3, B.7.1.1 Plant metabolism	EFSA: A significant difference in the rate of identification of total radioactivity is noted between the original data (ca 60%TRR identified) and the reanalysed apple data (2-13% TRR identified). Has the applicant given any interpretation/ explanation on these results? Are the new results supported by storage stability data as required according to current guidance?	
	Vol.3, B.7.1.1 Plant metabolism	EFSA: It was reported that apple samples were reanalysed with more robust/complex analytical methods and that on characterisation of residues significant differences were seen when compared to the results in the original apple study. In this context it would have been useful to report the used analytical methods in more detail to better understand why these significant differences were	

Metabolism in plants (B.7.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		found. It was also mentioned that residues might have become conjugated. Where there any hydrolysis steps used in the methods that may confirm this statement on conjugates?	
	Vol.3, B.7.1.1 Plant metabolism (Tab. B.7.4)	EFSA: There was a clear difference in terms of the metabolites quantity in homogenised vs. intact samples, however any discussion of these observed differences is missing. Apparently homogenisation has effects on the quantity of some of the compounds present on fruits (e.g. malathion, DCAM). How does this observation impact results generated with homogenised fruits and used in the risk assessment (e.g. residue trials data). It is noted that strawberries may be eaten as intact fresh fruits by the consumer.	

Metabolism in livestock (B.7.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Section 3 - Residues (B.7)

Residue definition (B.7.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol.3, B.7.3. Residue definition monitoring	EFSA: Considering the marker concept for monitoring it could be discussed whether the chosen compounds for the monitoring residue definition are indeed the most appropriate ones.	
	Vol.3, B.7.3. Residue definition risk assessment	EFSA: Given the higher toxicity of malaoxon and (determinable) residues of malaoxon found in 1 trial, shouldn't a factor be used in the risk assessment to take into account for the different toxicity?	

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol.3, B.7.6 Residue trials	EFSA: To understand how individual components of the residue definition degrade and may change ratio, it would have been appropriate to report all available results (according to agreed format when more than compound is included in the residue definition), and not only the results on the defined PHI. It is noted that data requirements comprise also decline studies, and they should be evaluated in the assessment report.	

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

Section 3 - Residues (B.7)

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	Vol.3, B.7.6 Residue trials	EFSA: It may be discussed whether the 4 available trials on strawberries that analyse for the full residue definition are indeed sufficient for a major crop. It is noted that in 2 out of the 4 trials used to interpolate to the whole data set rainfall occurred on the last day of application.	

Processing (B.7.7)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.7.8.1. Processing - Nature of the residue	EFSA: The RMS reports that malathion is not degraded under processing conditions. However, there is clear evidence from a hydrolysis study simulating processing conditions (addendum 1 to DAR), that significant degradation of malathion to desmethyl-malathion occurred. The recovery of radioactivity in the study was less than 100%, and thus other components might have been built, too.	
	Vol. 3, B.7.8.3. Processing - Summary	EFSA: The fate of all parts of the residue definition for RA under processing conditions is still unclear, as not addressed by data. For MMCA and MDCA it is presumed based on plant metabolism data they enter the citric aid cycle. This might be true for a	

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

Section 3 - Residues (B.7)

Processing (B.7.7)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		living organism, but is this indeed applicable to processed products?	

Livestock feeding (B.7.8)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Succeeding/Rotational crops (B.7.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol.3, B.7.1.2 and B.7.10, Rotational crops	EFSA: In the previous review of malathion a data gap on rotational crop residue data was identified (including the use on strawberries; see EFSA conclusion; List of studies to be generated …). RMS' view that rotational crop data are not required for the use on strawberries as they are not rotated is not agreed. The bulk of modern commercial production uses annual cultivation (replacing the plants each year) to improved yields. Even in perennial cultivation, the plantation should be renewed every second or third year. Therefore, the issue of rotational crop residues	

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

Section 3 - Residues (B.7)

Succeeding/Rotational crops (B.7.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		should be addressed for all the relevant compounds of the residue.	

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.7.16.2.1 Chronic intake	EFSA: It is not clear why in the EFSA model the HR was used in the chronic intake assessment. Moreover, the results presented for FR and IR consumer as %ADI seem to be incorrect. The calculation should be checked and corrected.	
	Vol.3, B.7.16.2.2 Acute intake	EFSA: It is noted that the results presented for DE and NL consumer as %ARfD seem to be incorrect. The calculation should be checked and corrected.	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

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

27. Environmental fate and behaviour (B.8)

PEC in surface water and ground water (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	B.8.6, Predicted environmental concentrations in surface water pages 120-121 LoEP Predicted environmental concentrations in surface water for malathion step 4 page 196	EFSA: At step 4 PECsw including mitigation measures have been implemented for malathion. FOCUS landscape and mitigation indicated that spray drift inputs should not be mitigated by more than 95%. For the uses assessed in the additional report this equates to a no spray buffer zone somewhere between 30 and 35m for calculations with 1 application and ca. 30m for calculations with 4 applications. So the buffer zone of 40m provides too much spray drift mitigation. Simulations implementing a 30m no spray buffer zone and 4 applications would therefore appear to be needed still, for the EU level assessment that EFSA has to present in the conclusion to be in line with the noted guidance. The Step 4 PECsw and sed for malathion for a 40m no spray zone need to be deleted and appropriate values for a 30m no spray zone calculated and presented.	
(1)	B.8.6, Predicted environmental concentrations in groundwater pages 125	EFSA: A case is made that groundwater exposure from the protected ornamental use will be covered by the simulations that were in the original DAR and the EFSA conclusion addendum for the originally requested (no longer maintained) uses on apples and strawberries. In principle this	

PEC in surface water and ground water (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		seems reasonable. However as no maximum number of treatments per year is stipulated in the GAP table for the use in protected ornamentals, the case cannot be accepted without an upper limit being stipulated for the number of applications allowed.	

Section 5 - Ecotoxicology (B.9)

28. Ecotoxicology (B.9)

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Additional report, Vol. B.9.1.2, risk assessment for birds (frugivorous), table B.9.1.2	EFSA: for transparency causes more details would be necessary to explain the FIR of 2.02. As for RUD different values are available in the appendix 3a of the PPR opinion on Science behind the Guidance document on Risk Assessment for Birds and Mammals (EFSA Journal 2008, 734: 1-181). In particular for the generical focal species frugivorous bird "Starling" on strawberries the 90th RUD value is 16.7 (*vs* 11 from EPPO2003) and the mean is 8.3 (*vs* 2.3 from EPPO 2003).	
(2)	Additional report, Vol.B.9.1.2, refined risk assessment for birds (frugivorous), pag 130 LoE: toxicity/exposure ratios for terrestrial vertebrates.	EFSA: In the addendum 3 the RUD values of 2.86 (90th) and 1.6 (mean) to refine the acute and long-term risk assessment for frugivorous birds were reported. It is unclear why only the mean value was used in the additional report.	
(3)	Additional report, B Vol..9.1.2, refined risk assessment for birds (insectivorous), pag 130	EFSA: agrees with the most issues underlined by RMS in the evaluation of the residue study from Knäbe S. 2004. However, considering in general the residue decline of malathion both in insects and in strawberries (less than 1 day) the use of the default DT50 of 10 days might be too	

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

Section 5 - Ecotoxicology (B.9)

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		conservative. Furthermore, In the table B.9.1.6 the RMS mentioned that adjustment can be made to take account the difference between orchards and strawberries in the application method and rate; it would be interesting to have more details on which kind of adjustment can be made.	
(4)	Additional report, Vol. B.9.3, risk assessment for mammals (frugivorous), pag 160 LoE: toxicity/exposure ratios for terrestrial vertebrates.	EFSA: It is unclear how the FIR of 1.92 was derived. RMS stated that it is based on 25 g mammal. This might be unrealistic for frugivorous mammals. No RUD values for fruit-eating mammal were reported in EPPO 2003. For the tier I risk assessment it would be better to assume the same figures reported in the SANCO4145 for medium herbivorous mammals (i.e. FIR 0.28, 90th RUD 87 and mean RUD 40). The 90th and the mean measured residues in strawberries should be use to refine the risk.	

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(5)	Additional report, Vol. B.9.2, risk assessment for aquatics, pag 157 LoE: toxicity/exposure	EFSA: the higher tier risk assessment for aquatics was based on FOCUS step 4 PECsw calculated with a no-spay buffer zone of 40 m. According to the FOCUS Landscape and Mitigation the drift can be mitigate not more than 95% (i.e. no-spray buffer	

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

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	ratios for aquatics.	zone of c.30 m). (See EFSA related comment on fate section, for more details). The present aquatic risk assessment needs updating in line with higher PEC with less spray drift mitigation.	

Bees and non-target arthropods (B.9.4 and B.9.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(6)	Additional report, Vol. B.9.4, risk assessment for bees, pag 161	EFSA: the risk to bees was considered low in strawberries and according to the supported use (applications at ripening fruit) the exposure is not expected. However, the potential off-field exposure was not considered. The mitigation measures proposed to manage the risk should be better defined.	
(7)	Additional report, LoE, risk assessment for non-target arthropods	EFSA: since the risk assessment for non-target arthropods was addressed only for formulation with a content of isomalathion <0.0017%, it would be better to indicate this in the LoE by adding a footnote.	

Earthworms and other soil non-target organisms (macro and micro) (B.9.6, B.9.7 and B.9.8)

Section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	Additional report, Vol. B.9.6 – 9.8, earthworms, and other soil non-target organisms (macro and micro)	EFSA: no comments	

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	Additional report, Vol. B.9.9, non-target fauna	EFSA: no comments	

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

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

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

No comments on this section.

30. Mammalian toxicology (B.6)

Genotoxicity (B.6.4)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol.3.B.6.4.1 In vitro genotoxicity testing- Bacterial assay for gene mutation	FR : We can consider that the potential for genotoxicity of malathion (0.25% isomalathion) has been sufficiently investigated and we agree with the overall conclusion of the RMS that malathion is unlikely to be genotoxic..	

Other toxicological studies & Medical data (B.6.8-B.6.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol.3.B.6.8.1 Toxicity studies on metabolites	FR : We agree with the RMS' conclusion : malathion monocarboxylic acid, malathion dicarboxylic acid and desmethyl malathion should be considered toxicologically relevant based on acute oral toxicity, genotoxicity and cholinesterase inhibition activity testing.	

Exposure data (B.6.14)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	B.6.14.3 Worker exposure	FR : The inhalation, as well as dermal, re-entry exposure estimations must be calculated using updated recommendations of the EUROPOEM II final, December 2002. The worker inhalation exposure should be considered, even if it is negligible, using the following formula: I=inhalation exposure	

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

Exposure data (B.6.14)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		I=AR Application rate x TSF Transfert specific factor x WR Work rate The Systemic exposure has to be estimated using the following formula : SE=(D x DA dermal absorption +I x AI absorption by inhalation)/bw	

31. Residue

No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Additional report, B.7.1 Metabolism, distribution and expression of residue in plants (IIA 6.1) Metabolism on apple p.97-99	FR: Storage stability studies were validated on high water content matrix, cereals and high lipid content matrix for 12 months on malathion and malaoxon. Others metabolites (MMCA, MDCA, Desmethyl-malathion) proposed into residue definition were not covered by this period (or with only 3 or 2 months in term of new trials provided on strawberries). In addition, since re-analysis were realized after a 18-24 month period, results comparison should be considered very carefully before conclusions on the real comparability with others metabolisms results on wheat, cotton, lettuce and alfafa.. This point should be strongly validated to consider the only metabolism on fruit as similar with others to maintain the use on strawberries.	
(2)	Additional report, B.7.6.3.1 Summary of residues resulting from supervised trials – strawberries p.106	FR: The sum of MMCA plus MDCA in trials conducted on new trials on strawberries are said very close : 0.49 to 0.87mg/kg. Can we really say that since the initial MRL based only on malathion plus malaoxon in strawberries was proposed at 0.5mg/kg in monograph?	
(3)	Additional report, B.7.6.3.1 Summary of residues resulting from supervised trials – strawberries p.106	FR : Since the residue definition for risk assessment is proposed as the sum of malathion + malaoxon + MMCA + MDCA + Desmethyl-malathion, only four trials on strawberries comply with this definition. Hence can we judge sufficient the representativeness of these results since normally 8 trials are necessary? In addition, in monograph 2 trials with similar GAP were conducted and showed a HR of 0.03mg/kg of malaoxon. This scheme was not observed with new	

No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		trials on which no more than 0.01mg/kg of malaoxon was observed.	
(4)	Additional report, B.7.16.2 Intakes by humans – chronic exposure p.110-111	FR : For risk assessment, chronic exposure take into account the sum of malathion + malaoxon + MMCA + MDCA + Desmethyl-malathion expressed as malathion. Nevertheless since malaoxon was known 3 times more toxic (ADI of 0.01mg/kg bw/d) than malathion (ADI of 0.01mg/kg bw/d), the malaoxon's ADI should be taken as the reference for chronic exposure or factor of 3 should be applied for malaoxon's levels.	
(5)	Additional report, B.7.16.2 Intakes by humans – acute exposure p.110-111	FR : For risk assessment, acute exposure take into account the sum of malathion + malaoxon + MMCA + MDCA + Desmethyl-malathion expressed as malathion and with the malathion's ArfD of 0.3mg/kg. As referred in addendum 1(B7.15 p51) :"no ArfD value has been proposed for malaoxon as no adequate study has been submitted". Hence no ArfD was defined for malaoxon through lack of adequate studies and not in relation with non- relevant toxicity. In consequence, can we judge sufficient the estimation only based on the malathion's ArfD since acute toxicity of malaoxon is under suspicions?	

32. Environmental fate and behaviour (B.8)

Route and rate of degradation in soil (B.8.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	DAR Vol.3 B.8.1.1 Aerobic degradation p.288-289	FR: In the original DAR, in the study of Knoch 2001, table 8.1.1-4, there is a column for "Sum of others". It is reported that the summed value contains multiple minor peaks, each <10%. Could you also confirm that there is no minor non-transient metabolite please?	

Adsorption, desorption and mobility in soil (B.8.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Additional report, LoEP, p. 190	FR: It seems the values of 1/n associated to the Kfoc of malathion are not reported in the original DAR. Could it be possible to add these values at least in the LoEP for each soil, as in the new template of the LoEP please? This would make the assessment at national level easier.	

PEC in surface water and ground water (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Additional report Vol.3, B.8.8.6 PECsw, step 4 p.120-121	FR: Please, could you specify if the FOCUS drift values and the 40m buffer drift values reported in table p.120 and 121 come from the drift calculator available in SWASH? Using the drift calculator values, we have higher drift values than the ones reported in the table.	
(2)	Additional report Vol.3,	FR: At the end of page 121, it is stated that "for the D6	

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

PEC in surface water and ground water (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	B.8.8.6 PECsw, step 4 p.121	and R4 scenarios the 40m buffer zone mitigation results in a greater than 95% reduction in PECsw". It seems it is not in accordance with the FOCUS Landscape and Mitigation which recommends a maximum mitigation of 90% for run-off.	
(3)	Additional report, LoEP, PECsw p. 193	FR: The time of application for Step 1-2 is missing.	
(4)	Additional report, LoEP, PECgw p. 201	FR: The table FOCUS modelling results for PECgw would be clearer if the head of the last column was "Kfoc (mL/g)".	

Definition of the residues (B.8.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Additional report, LoEP, Residue definition p. 201	FR: We think metabolite MMCA should be included in the residue definition for the groundwater compartment: it is a major metabolite in soil, and then its risk to groundwater has to be assessed.	

33. Ecotoxicology (B.9)

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, Annex B-9, B-9.1.2.1, refined risk assessment for frugivorous birds	FR: The reference to the table B.7.4.1 is incorrect. It should be referred to table B.7.6.1, which contains the initial mean residues data from field trials.	
(2)	Vol. 3, Annex B-9, B-9.1.2.1, refined risk assessment for frugivorous birds	FR: As it was done in the DAR, the RMS has used the same RUD value for both acute and long-term refined risk assessment. This RUD value of 1.2 mg a.s./kg is the mean of the data available from field trials in strawberries, which are the initial mean day 0 RUD. However, in the final addendum, the 90th percentile RUD value of 1.91 mg/kg was used. Please justify the use of the mean RUD value instead of 90th percentile for calculation of acute ETE and justify that this figure reflects the real acute exposure pattern for birds (no underestimation). We agree with the TER calculation and the conclusions of the RMS. The acute risk for frugivorous birds is acceptable, whereas the long-term risk needs to be further refined.	
(3)	Vol. 3, Annex B-9, B-9.1.2.1, refined risk assessment for insectivorous birds	FR: We agree with the RMS that the use of the residues data from the trail conducted in orchards for refinement of acute exposure in strawberries is not appropriate.	The study from Knäbe (2004) has been evaluated and is considered well conducted. The residue data measured in this trial would be of key interest for refinement of exposure for the apple scenario but this use is no more supported by the notifier. There are too many divergences in the way insects can be exposed to malathion in treated apple trees and strawberries field (as listed by RMS); moreover no peak residues are available, only the mean values from pooled data have been given, which is not appropriate for use in acute risk refinement.
(4)	Vol. 3, Annex B-9, B-9.1.4, refinement of the risk assessment	FR: We agree with the RMS that the DT50 of 0.48 days for residues of malathion in crop-dwelling arthropods must be used with	There is evidence from the overall information on malathion residues infield trials that the use of the generic value of 10 days

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	considered, use of a DT50 based on initial residue data from the Knäbe study to refine ETE.	caution for risk assessment for insectivorous birds in strawberries. The long-term risk is considered not acceptable for insectivorous birds and further refinement should be required from the notifier.	overestimates the risk for insectivorous birds. The real DT50 for crop-dwelling arthropods is probably 5-10 fold lower, which would result in TER_{LT} value > 5. However, data obtained in one site are considered not representative of the diversity of conditions in Europe. Further information on the dissipation of malathion residues in arthropods in different sites and conditions would be necessary for determining a relevant DT50 to be used for risk assessment.

Bees and non-target arthropods (B.9.4 and B.9.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, Annex B-9, B-9.5.3, Conclusions of the risk assessment for other arthropods.	Fr: We agree with the RMS that the expected amount of impurity (isomalathion) in the product is not covered by the current tests on non-target arthropods, which could have conducted to underestimate the risk. Further information on the toxicity of this impurity and / or the formulation (with a content of 0.027 % isomalathion) to *Typhlodromus pyri* and *Aphidius rhopalosiphi* are required. Otherwise, a statement or justification for not submitting these new tests is required.	