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0. General

General				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
0(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.	RMS: end points will be updated prior to any expert meeting/ teleconference. NOT: Agreed, the list of endpoints should be updated based on the conclusions of the Additional Report.	Open point: RMS to amend the end points using the current harmonised version (include UK as RMS, amend residue definitions)
0(2)	General	Applicant: The date of the Additional Report is incorrect and should be February **2009** and not February **2008.**	RMS: noted	Addressed.

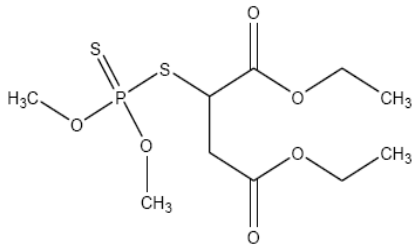
section 0 – General comments

General				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
0(3)	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.	RMS: Outdoor uses require further work to refine the risk to birds which MS should pay particular attention to. NOT: The Applicant understands that safe uses have been identified for both ornamentals (indoor use) and strawberries (field use) however, for strawberries and other outdoor uses MS should pay particular attention to items identified by the RMS.	Addressed.
0(4)	Additional report, LoEP RMS, p. 173	EFSA: probably UK should also be mentioned	RMS: end points will be updated in due course see comment at 0(1) NOT: Agreed	See open point in comment 0(1)
0(5)	Additional report, LoEP	EFSA: the new agreed template should be used	RMS: end points will be updated in due course see comment at 0(1) NOT: If required then agreed	See open point in comment 0(1)

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

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Physical and chemical properties of the active substance (B.2.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(1)	Additional report, LoEP	NL: The structural formula in the fys/chem. part of the LoEP does not match with the molecular formula.	RMS: end points to be amended NOT: Agreed. The structure is incorrect and should be as follows. 	Open point RMS to update the List of end points to be give with the correct structural formula for malathion.

Rapporteur: UK

Physical, chemical and technical properties of the formulation (B.2.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Further information (B.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Classification and labelling (B.4)

For comments on classification and labelling see the relevant sections.

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(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.	RMS: Agree the sentence must be removed. End points to be updated NOT: Agreed, a method for desmethyl malathion is not necessary.	Open point: RMS to delete the sentence "Method for desmethyl malathion could be necessary" from the LoEP See also comment 0(1)
1(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)	RMS: Agree with proposed amendment NOT: Agreed	Open point: RMS to amend end points to that methods are not required for the uses evaluated during the re-submission (strawberries and ornamentals)
1(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	RMS: Agree with proposed amendment NOT: Agreed	See open point in comment 0(1).

2. Mammalian toxicology

Toxicokinetics (B.6.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Acute toxicity (B.6.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Short-term toxicity (B.6.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Genotoxicity (B.6.4)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(1)	Additional report,	FI: Malathion technical containing 0.25 %	RMS: Agreed. There is a body of evidence that	Addressed.

Rapporteur: UK

Genotoxicity (B.6.4)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	B.6.4.1 Ames test (Bowles, 2005)	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 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.	malathion can be positive *in vitro* genotoxicity assays however *in vivo* it is negative. This is supported by the package of data submitted by the Applicant. There are a number of assay with a 0.2 % isomalathion content which are negative (see column 2) as well as assays with a 0.14 % isomalathion content which were both positive and negative *in vitro* and negative *in vivo*. The peer review considered that an Ames test was required using the Applicant's technical material with at least a 0.2 % isomalathion content to provided further reassurance. Please note the Additional Report refers to an earlier draft of the review report. The final version states that one area where the informtaion was insifficient to satisfy the requirements was 'the presence in the technical material of isomalathion, the genotoxicity of which cannot be excluded'. With the provision of the new Ames test this point is resolved see also commenst at 2(3) and 2(4). NOT: Agreed, this was discussed in the original expert peer review and a data requirement for a new Ames test was set which has now been addressed. Therefore the data requirement can be considered fulfilled and malathion containing 0.2% isomalathion is not genotoxic.	

Genotoxicity (B.6.4)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(2)	Vol 3., Appendix 1.3, List of Endpoints, Impact on Human and Animal Health, Toxicologically significant compounds (animals, plants and environment)	Applicant: It is proposed to reword this entry to read as follows: 'Malathion and malaoxon. Isomalathion which is an acetylcholinesterase inhibitor, which enhances the toxicity of malathion. Desmethyl malathion, Malathion mono- and dicarboxylic acids which are all cholinesterase inhibitors.	RMS: Agreed NOT: As an additional comment the new acute cholinesterase studies show no significant cholinesterase inhibition at dose levels up to 1500 mg/kg bw. The tested values far exceed any potential dietary exposure expected to occur to humans via dietary exposure to these compounds. Therefore, they are not considered to contribue to cholinesterase inhibition at dose levels at or below the acute reference dose established for malathion.	Open point: RMS to amend the list of end points.
2(3)	B.6.4.1 In vitro genotoxicity testing- Bowles 2005	EFSA: the outcome of the study presented is supported	RMS: Agreed NOT: Agreed	Addressed
2(4)	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.	RMS: Agreed NOT: Agreed	Addressed

Long-term toxicity and carcinogenicity (B.6.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Reproductive toxicity (B.6.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Neurotoxicity (B.6.7)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(5)	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.	RMS: The most import information provided by the new data is the cholinesterase inhibition potential. NOT: The effect of acetylcholinesterase in brain was studied in Barnett (2008) and Fulcher (2001). The relative potency of malathion and its metabolites to inhibit brain cholinesterase was also assessed in the benchmark dose modelling.	Open point: MSs to discuss the outcomes of the study by Pratt 2006, and the impact it might have on the relevant end points and on the risk assessment.
2(6)	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.	RMS: noted NOT: No comment required	Addressed
2(7)	Additional report, Comment on the need of toxicity studies on metabolites	FI: Considering the residue amounts of MMCA and the low amount of this metabolite in mammalian 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.	RMS: The data provided by the Applicant is adequate although we consider that they do not allow the metabolites to be excluded from the residues definition for risk assessment. In the rat metabolism study most of the radioactivity is excreted in the urine. The major metabolites in urine (consisting >80% of the recovered radiolabel) were monocarboxylic acids (MCA), and the dicarboxylic acid of malathion (DCA). The	Open point: Pending confirmation from the residue section group, MSs to discuss the relevance of metabolite MMCA

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			remaining radioactivity was distributed among seven other metabolites: desmethyl malathion; O,O-dimethyl phosphorothioc acid; fumaric acid; 2-mercapto-succinic acid; O,O-dimethyl phosphorodiothioic acid, monoethyl fumarate and malaoxon. NOT: The conclusion that there is a low amount of MMCA in the mammalian metabolism studies is incorrect. This is because MDCA can only be formed via metabolism from MMCA, the total amount of MMCA formed is conservatively estimated to be the sum of the measurements of MMCA and MDCA excreted in the urine and faeces. The low dose tested in the rat metabolism study recovered >80% of the malathion dose in urine and faeces as MMCA and MDCA. The low dose tested in the rat metabolism study is most relevant for risk assessment because it is nearest the dose level used to establish the ADI. If there is toxicity or no cholinesterase inhibition seen at the high doses tested in these acute cholinesterase studies, then it is entirely reasonable to conclude that these effects will not occur at lower doses.	
2(8)	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	RMS: The data provided by the Applicant indicates that MMCA is not as potent an inhibitor as the parent. We do not consider long term	Open point: MSs to discuss the need of further tox studies for MMCA

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		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.	testing is required given MMCA is a major rat metabolite. NOT: Available metabolism data demonstrate malathion is metabolised in rat and human mainly to malathion mono- and di-carboxylic acids (MMCA and MDCA). This is a common metabolic pathway catalysed by carboxylesterases, usually in the liver. The malathion carboxylic acids are rapidly excreted in the urine (60 - 80% of dose). Eight minor metabolites are formed (References 1 - 4). The ratio of mono- to di-carboxylic acid varies with individual study, species and dose level. At an oral dose of 40 mg/kg in rats, MDCA greatly exceeded MMCA but at 800 mg/kg yields were of a similar order. These two metabolites are in fact used as biomarkers for exposure monitoring (5). The metabolic route to MMCA (both the alpha and beta forms) is directly from malathion and is the first step in the metabolism of the insecticide. The metabolic route to MDCA is from MMCA. This is the only route available for the formation of MDCA. It is therefore valid to calculate the yield of	

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			MMCA *in vivo*, and thus exposure *in vivo*, by summation of the yields of MMCA and MDCA in urine. The low yield of MMCA under some conditions is due to its further metabolism to MDCA. However, MMCA may also be metabolised to its oxon form and then metabolised further by other routes (e.g. to dimethyl phosphate). So the summation of MMCA and MDCA *could* underestimate the *in vivo* yield of MMCA. However, as the de-esterification to form MMCA is **by far** the major route for biotransformation, such underestimation would be minimal. Doses of malathion used in chronic and oncogenicity studies were between 4 and 868 mg/day. A vast majority of these malathion doses would be expected to be metabolised to MMCA such that substantial 'auto-exposure' to MMCA is anticipated. Expected auto-exposure to MMCA via chronic exposure to malathion in the chronic toxicity/oncogenicity study can be calculated as follows: Total auto-exposure to MCA = A x B x C, where: A = the tested malathion dosage (mg/kg/day)) B = 0.8 (80% reflects the percentage of malathion dosage recovered in urine from the low dose used in the rat metabolism study) C = 0.8 (80% refects the percentage of	

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			radioactivity recovered in urine in the rat metabolism study that was represented by the sum of MDCA and MMCA) Using this equation, auto-exposure to MMCA is calculated to range from 2.6 to 479.9 mg/kg/day for males and from 3.2 to 555.5 mg/kg/day for females in the chronic toxicity/oncogenicity study. Using the NOAEL of 29 mg/kg/day established in this same study, a dose of 18.6 mg/kg/day is calculated to be the auto-exposure NOAEL to MMCA. Because the sum of MMCA and MDCA excreted in urine and faeces represents an overwhelming majority of the malathion dose, it is reasonable to conclude that the toxicity observed in the malathion chronic toxicity/oncogencity study already reflects the toxicity of malathion as well as auto-exposure to the significant amounts of MMCA and MDCA that are formed *in vivo* during the metabolism of malathion. We conclude that the chronic toxicity of MMCA and MDCA have been adequately characterized by the malathion chronic toxicity/oncogenicity study. 1. Pesticide Safety Directorate (1995) Evaluation No.135. 2. Reddy et al. (1989) FYF-031. Previously submitted 3. Bradway and Shafik (1977) J. Agric. Food	

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			Chem. 25, 1342-1344. 4. Roberts and Hutson (1999) Metabolic Pathways of Agrochemicals ", 360. 5. Bouchard et al. (2003) Tox. Sciences 73 183-194.	
2(9)	Additional report, Comment on the need of toxicity studies on metabolites	FI: Genotoxicity of MMCA has not been studied properly.	RMS: Given MMCA is a major rat metabolite it will have generated in many of the genotoxicity studies. NOT: It is concluded from the studies performed to date that malathion and its metabolites are not genotoxic.	Open point: MSs to agree on the need of further genotoxicity information on MMCA
2(10)	Vol. 3, B.6.8.1, Toxicity studies on metabolites	Applicant: 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.	RMS: Noted	Addressed

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(11)	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?	RMS: We consider that Benchmark dose modelling should be used with caution. The data are presented as they were provided by the Applicant. The approach was not used for the risk assessment presented in the Additional Report. NOT: No comment required, addressed to MS	Addressed
2(12)	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.	RMS: Agree NOT: No comment necessary	Addressed See open points in comments 2(8) and 2(9)

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(13)	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 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.	RMS: We consider that the additional safety factor mostly results from the potential increased toxicity resulting from the levels of isomalathion. We note that the concentration of isomalathion in the batches of technical malathion tested in the toxicological studies is lower than in the specification (between 0.018%-0.44%, if mentioned at all, of the current specification.). Therefore the additional safety factor still seems to be justified. NOT: Consideration of the requirement for an additional safety factor would be welcomed by the Applicant.	Open point: MSs to revise ADI and AOEL with regard to the SF applied

Toxicity of the product(s) (B.6.11)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Rapporteur: UK

Dermal absorption (B.6.12)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Toxicity of non-active substances (B.6.13)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(14)	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.	RMS : A safe use for protected ornamentals was identified in the original assessment presented in Volume 3 of the DAR (and also for strawberry). The issue for strawberries in the additional report is specific to this use. In addition, the applicant has drawn attention to the use of PPE in the assessment reported in Addendum 3 of the DAR. See Comment at 2(24). This refinement would give an acceptable outcome for all of the scenarios (e.g. half-life values) considered for the strawberry assessment. The use of PPE for workers can be addressed at MS level (as has been done for other active substances). The RMS does not therefore consider discussion of the assessment at the expert meeting is necessary. NOT: Using reasonable worst case assumptions, a safe worker exposure scenario has been demonstrated.	Open point: MSs to confirm worker exposure assessment after field application on strawberries See also 2(23), 2(24), 2(28) and 2(29)
2(15)	Additional report, Evaluation, summary and proposed decision. 1. Background	FI supports professional use only because the exposure during amateur use is above the AOEL.	RMS : The exposure assessment in the Additional report considers professional use on strawberry. Amateur use has not been considered. NOT: It is agreed that the representative uses supported at Annex I are based on professional use only and it is not relevant to consider amateur use at this time. Any other uses can be dealt with at MS level following Annex I listing	Open point: MSs to address the need of amateur exposure

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(16)	Additional report, Evaluation, summary and proposed decision . 1. Background	FI: On page 7, it is stated "The applicant 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.	RMS : The drafting is slightly unclear. The text is explaining that the applicant continues to support strawberry (field) and ornamentals (glasshouse) as indicated in the GAP table in Volume 3 B.7.4-1. The use pattern on strawberry has however been revised from that originally supported. NOT: This is a mis-interpretation of the document. The intended uses are clearly identified in the additional report on p15. The applicant continues to support strawberries in the field and ornamentals under glass	Addressed.
2(17)	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.	RMS : This conclusion is identified in the summary of operator exposure (given at B.6.14.1.3. MS will need to consider the PPE requirements of individual plant protection products at product authorisation. NOT: Any requirements for PPE can be adequately reflected in the labels for the product. This can be dealt with at MS level.	Addressed

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(18)	Additional report, B.6.14.1.3. Summary of Operator Exposure	FI: Higher tier data for evaluation of hand-held application should be requested.	RMS : Agree. The Tier 1 assessment indicates further information is needed to refine the assessment NOT: The use of the German model can be accepted recognising that it may overestimate exposure in low level crops such as strawberry. Therefore the NOT agrees with the RMS that hand-held use using the German model is acceptable.	Addressed.
2(19)	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.	RMS : The RMS does not understand this comment. The exposure assessment presented in the Additional report (B.6.14.3) considers re-entry for crop inspection and hand harvesting tasks in field strawberries. This assessment was presented as a new GAP for this use has been proposed. An assessment was not given for worker exposure for the ornamental ues as no changes to the GAP for ornamentals has been proposed. NOT: Refer to 2(16). Re-entry activities on strawberries in the field have been assessed on p70-76 of the additional report.	Addressed.

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(20)	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.	RMS : for the strawberry use the re-entry assessment concludes that from the available information it is uncertain whether levels of exposure for re-entry workers would be within or above the AOEL. Higher tier data are needed to address this uncertainty. However, as a safe use for re-entry workers has been previously identified for workers re-entering treated ornamental plants (roses), these data are not required to support the Annex I listing of malathion. NOT: Refer to 2(16). Using reasonable worst case assumptions, a safe worker exposure scenario can be demonstrated.	Addressed.
2(21)	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.	RMS : Agree this would have improved the transparency and continuity of the assessment. NOT: To simplify the accelerated review process the representative uses have been revised and the use rate on strawberry slightly modified. Therefore it would seem appropriate to focus on these uses at this time.	Addressed.
2(22)	Vol.3, B.6.14 Exposure Data, Dermal Absorption	Applicant: As highlighted on p65 of the Additional Report, the applicant 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.	RMS : The case presented for using these data was considered when the dermal absorption values were agreed for the 440 g/l emulsion oil in water formulation (see EFSA Scientific Report (2006) 63, 1-87, Conclusion on the peer review of malathion (p16)).	Addressed.

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(23)	Vol. 3, B.6.14.3, Worker exposure Also Section 2 p8	Applicant: 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 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	RMS : The assessment notes that for the correct residue definition the rate of decline is not as significant as shown in the trials to which the notifer refers at 2(23). This point is discussed further in the exposure assessment. It must be recognised that actual DFR data for the proposed use on strawberry are not available. There are uncertaines associated with using apple metabolism data to calculate the half-life value (differences between plant surfaces, small unreplicated dataset) and crucially there are no measurements for the first 24 hours after application to confirm a half-life of less than 1 day. The assessment recognises the uncertainties in the calculated half-life values of 1.86 days and 3.3 days and that these values are expected to be precautionary. However the RMS is of the view that a more robust calculation of the degradation (DT50) cannot be achieved from the available information.	See open point in comment 2(14)

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(24)	Vol. 3, B.6.14.3, Worker exposure Also Section 2 p8	Applicant: 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 Applicant therefore recommends that any concerns over worker exposure for strawberry could be dealt with at Member State level.	RMS : The RMS's view is that PPE for workers should only be considered where they are habitually worn as it cannot be assumed workers will be unaware of which products have been used on they crops they are to handle. There are no available usage data to support the conclusion that in the UK workers hand pickling strawberries would always wear protective gloves. It is recognised that some MS have a different view on this matter. On this basis the RMS accepts the use of PPE by workers could be considered at MS level.	See open point in comment 2(14)
2(25)	Vol. 3,, Appendix 1.3, List of Endpoints, Impact on Human and Animal Health, Acceptable exposure scenarios, Operator	Applicant: 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.	RMS : The German model values are 28% boom sprayer and 79% knapsack sprayer. The figure 163 is a typographical error	Addressed.

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(26)	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.	RMS : In the Summary of operator exposure (B.6.14.1.3) the conclusion states that for row crops such as strawberry, where forward speeds will be slower, a more realistic work rate would be 30 ha treated per day. Slower forward speeds are needed in row crops to avoid unnessary crop damage. A similar work rate could be justifed for other row crops such as sugar beet and potatoes. NOT: Treatment areas of 30ha in a single day is still considered to be a conservative estimate and is expected to be more related to professional sprayer operators working for cooperatives rather than individual farmers spraying their own fields. Based on field size and strawberries being planted in rows, it is expected that coverage per day would be less than 50 ha, typically used for large monocultures such as cereals.	Open point: MSs to agree on the number of hectares to be considered in the UK POEM for application in row crops.
2(27)	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?	RMS ; Bystander exposure to pesticides. Report of the bystander working group, Europoem II Project FAIR3 CT96-1406, December 2002 NOT: The Applicant understands the value of 0.03mL is reported in the EUROPOEM II Bystander Working Group Report FAIR3 CT96-1406, whilst the breathing rate and time for exposure are seen as reasonable worst case assumptions.	Addressed.

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(28)	B.6.14.3 Estimation of worker exposure	EFSA: the RMS presented a variety of assessment based on exposure for re-entry immediately after 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.	RMS : See comment at 2(14). NOT: Using reasonable worst case assumptions, a safe worker exposure scenario can be demonstrated. Therefore additional residue decline data are not considered necessary.	See open point in comment 2(14)
2(29)	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 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	RMS : Disagree. Inhalation exposure potentially may occur to residual vapour and airborne aerosols, which in turn are restricted to a relatively short period after application, e.g. in outdoor crops only during the time when the spray is drying For this substance, which has a low vapour pressure (4.5 x 10-4 Pa at 25 °C) levels of inhalation exposure to malation for workers re-entering crops of outdoor strawberry are expected to be negligible. This is the approach recommended by EUROPOEM. Reference Post-application exposure of workers to pesticides in agriculture. EUROPOEM II PROJECT FAIR3-CT96-1406 NOT: The formulae presented are related to specific indoor glasshouse re-entry exposure (p2 of Report of Europoem II Re-entry working group. FAIR3-CT96-1406). Since the use is on field strawberries a calculation	See open point in comment 2(14)

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			for inhalaton exposure is not required. The original assessment of indoor ornamentals did include inhalation exposure and was found to be acceptable.	

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(30)	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 %.	RMS: The specification is the same as that considered previously. The issue previously was whether this specification was acceptable. NOT: The specification has not changed	Addressed

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(31)	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 applicant does no longer support application on apple and alfalfa. Instead, the applicant 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.	RMS: Agree this is not fully clear. The supported uses are a subset of those supported previously. Strawberries in glasshouses is not supported – see 2(16). NOT: The representative uses supported in the re-submission are on outdoor strawberry and indoor ornamentals as indicated on p15 of the additional report.	Addressed
2(32)	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%?	RMS: The technical specification reported in the DAR has 0.2% isomalathion and this is the basis for the assessment. 0.4% has not been considered. NOT: The current 5 batch analysis supports a level of 0.2% isomalathion in the technical material. Toxicological endpoints have previously been considered assuming this level.	Addressed

3. Residues

Storage Stability (B.7.0)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(1)		A comment by FI referring to pages 97 and 98 of .pdf version. The presented reanalysis 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?	RMS: Agree the amount identified was low, however this in part maybe due to the length of time the samples were stored for (18-24 months) as stated in the DAR and the main aim was to investigate the range of potential metabolites present and set a revised residue definition which the study accomplishes. In addition, considering the residue definition set and the levels of metabolites seen in the residue trials, it is considered the risk is covered. NOT: Refer to 3(2)	See open point in comment 3(2)
3(2)	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	RMS: The applicant stated that the results were broadly similar, with differences in metabolites being due to new analytical techniques and the lower TTR due to the length of time the samples were stored for (18-24 months). The new results are not supported by storage data, the aim of the study was to look for potential metabolites,	Open point: Experts to discuss whether despite the shortcoming of the re-analysis metabolism data in apple with regard to storage stability (TRR has significantly decreased, degradation occurred) the study can still be

Rapporteur: UK

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		by storage stability data as required according to current guidance?	qualitative more than quantitative. NOT: As reported in the resubmission dossier, results of the further investigations can only be regarded as indicative because stability data to cover the storage period of the radio-labelled samples is not available. Whilst metabolic profiles were shown to be qualitatively similar to the original study, there were quantitative differences observed when samples were re-analysed. Therefore, no firm conclusions can be made concerning the quantitative levels of metabolites observed from this additional study. However, confirmation of the residue levels of the key metabolites identified in the study has been adequately demonstrated through the additional supervised crop residue trials on strawberry which confirms the low levels of malaoxon expected and observed in the other plant metabolism studies on lettuce, alfalfa, cotton and wheat. The differences in TRR identification are considered to be due to desmethyl malathion being incorrectly identified as a major metabolite. Additional work has shown desmethyl malathion to only be a minor metabolite (as confirmed by residue trials) and remaining radioactivity to be associated with polar radioactivity, heterogeneous	considered reliable to conclude on a residue definition and on comparability of metabolism in all crops See also comments in 3(1) and 3(5)

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			in nature. The currently submitted data are considered sufficient to confirm the residue definition as proposed.	
3(3)	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 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?	RMS: The new analytical techniques employed allowed better separation of peaks. Hydrolysis steps were employed. NOT: Summary details of the analytical methods used are provided in the resubmission dossier. Hydrolysis steps were included. Whilst results were qualitatively similar the levels of non polar metabolites were lower and higher levels of polar metabolites were found. Therefore it is possible that the non-polar compounds had partially degraded to polar compounds. Acid hydrolysis experiments showed non-polar degradation products are unstable and are converted to polar compounds/material. Glucose was detected which suggests malathion would have been completely degraded and incorporated into natural products.	Addressed: Details on the analytical method should be set out in a corrigendum/ addendum/ revised AR as appropriate

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(4)	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.	RMS: For risk assessment there would be no impact, as the residue definition for malathion is parent malathion plus its metabolite malaoxon, desmethyl-malathion, malathion monocarboxylic acid and malathion dicarboxcylic acid expressed as malathion. For MRLs there would be little impact as the samples were cryogenically milled, to minimise any egradation. NOT: Refer to 3(2) In terms of residue analysis it is common practise to store and ship samples whole prior to preparation in the analytical laboratory. In the case of strawberry, the samples were stored frozen and analysed within a short period after homogenising and therefore likely to reflect whole fruit residues. Stability of residues in homogenate under frozen conditions was confirmed.	Open point: Experts to consider the results generated in the strawberry residue trials in the light of the effect homogenisation of samples apparently has on the residue levels (upon comparative analysis of homogenised and intact samples in the fruit metabolism study a significant decrease of compounds in the residue definition was observed).

section 3 – Residues (B.7)

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(5)	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.	RMS: Agree period between re-analysis (18-24 months) is a long period of time, however the route of metabolism is the same in all the crops. In addition, the residues definition proposed (Malathion plus its metabolite malaoxon, desmethyl-malathion, malathion monocarboxylic acid and malathion dicarboxcylic acid expressed as malathion) it is likely the vast majority of the residue in the crop. NOT: Refer to 3(2)	See open point in comment 3(2)

Metabolism in livestock (B.7.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Rapporteur: UK

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(6)	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).	RMS: Conversion factors are very difficult to propose as depending on when malathion is applied (i.e. 3 or possibly 7 days before harvest depending when the grower chooses to apply the last treatment) will affect what the conversion factor is. A better approach would be were the MRL is exceeded the other components of the risk assessment are analysed for. NOT: In the 2008 trials the mean ratio of malathion + malaoxon (malaoxon assumed at 0.01 mg/kg) to total malathion (malathion + malaoxon + DMM + MMCA + MDCA) is 3.98. At the PHI of 3 days the ratio increases to between 4.4 to 5.9. However, this assumes and equivalent toxicity of metabolites. Taking account of relative potency factors of 0.41 for DMM, 0.43 for MMCA and 0.12 for MDCA (malaoxon not included refer to 3(10)), total malathion equivalent residues at PHI 3 days would range from 1.90 to 3.19 (n=4, mean 2.32, SD 0.59). Therefore a conversion factor of 3 could be proposed for short PHI crops such as strawberry.	Open point: Experts to discuss • whether the monitoring definition proposed for all crops can be confirmed as the most appropriate one considering that reliable conversion factors (monitoring to risk assessment) are difficult to establish • the approach suggested by the RMS not to establish conversion factors but to analyse for the full residue definition for risk assessment in case the MRL is exceeded See also comments in 3(7) to 3(9) and 3(13)

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(7)	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.	RMS: Conversion factors are very difficult to propose as depending on when malathion is applied (i.e. 3 or possibly 7 days before harvest depending when the grower chooses to apply the last treatment) will affect what the conversion factor is. A better approach would be were the MRL is exceeded the other components of the risk assessment are analysed for. NOT: Refer to 3(6)	See open point in comment 3(6)
3(8)	Vol. 1. LoEP	NL: Please propose a conversion factor (monitoring to risk assessment).	RMS: Conversion factors are very difficult to propose as depending on when malathion is applied (i.e. 3 or possibly 7 days before harvest depending when the grower chooses to apply the last treatment) will affect what the conversion factor is. A better approach would be were the MRL is exceeded the other components of the risk assessment are analysed for. NOT: Refer to 3(6)	See open point in comment 3(6)

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(9)	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.	RMS: The residues definition proposed is in-line with the previously set definitions in the EU and by JMPR, to include other metabolites may prevent the use of multi-residue methods and increase the cost of monitoring. NOT: Malathion and malaoxon are suitable marker compounds for monitoring. The PHI for strawberry is very short whereas other crops may have a longer PHI. Limited residue data on other crops have already shown DMM to be very low. MMCA and MDCA which are less toxic than the parent are likely to be transient in nature and in some cases may not be present. Also an additional method (negative ionisation by LC-MS-MS) is necessary to measure MMCA and MDCA which would increase monitoring costs. Therefore malathion and malaoxon are considered the most appropriate option.	See open point in comment 3(6)

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(10)	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?	RMS: The amount of malaoxon present in the sample in this case is insignificant, 0.01 mg/kg compared to the total residue of 0.74 mg/kg. NOT: This was addressed in Addendum 1 of the original DAR p51 where malaoxon was not considered to need a separate risk assessment due to being only slightly more toxic than malathion and residues being typically very low. New residue trials on strawberry confirm that malaoxon residues are low and typically do not exceed the LOQ (0.01 mg/kg) Therefore the impact of malaoxon within the risk assessment is likely to be negligible. In determining total residues of malathion and malaoxon, where residues of <0.01 mg/kg are measured for malaoxon a residue level of 0.01 mg/kg is assumed as a worst case. Therefore, to some extent, a factor has already been applied and so to apply another factor could be overly conservative.	See open point in comment 3(21)

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(11)	Vol. 3, B.7.5, Identification of critical GAPs	NL: Table B.7.5 Please include the interval between the applications (10 days).	RMS: 10-12 days NOT: This could be included as a footnote.	Addressed: To be amended and set out in a corrigendum/ addendum/ revised AR as appropriate
3(12)	Vol.3. B.7.6 Table B7.7	NL: Please include the interval between the applications.	RMS: 10-12 days NOT: This could be included as a footnote.	Addressed: To be amended and set out in a corrigendum/ addendum/ revised AR as appropriate
3(13)	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.	RMS: Conversion factors are very difficult to propose as depending on when malathion is applied (i.e. 3 or possibly 7 days before harvest depending when the grower chooses to apply the last treatment) will affect what the conversion factor is. A better approach would be were the MRL is exceeded the other components of the risk assessment are analysed for. NOT: Agreed	See open point in comment 3(6)

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(14)	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.	RMS: To include all the data would make the document over complicated. The data currently summarised allow a risk assessment to be carried out and supports the proposed residue definition. NOT: Whilst individual residue data for metabolites is not presented, data at different time points (0 - 3 days) is provided. Individual metabolite data are available in the re-submission dossier.	See open point in comment 3(21) To facilitate the discussion of open point in comment 3(21) the Individual residue data for malaoxon should be reported in an addendum/ revised AR as appropriate.
3(15)	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.	RMS: Agrees with comment that the acceptability of only 4 of the 8 trials being analysed for the correct residue definition can be discussed and for the other 4 trials whether an extrapolation of data can be made (residue levels corrected for MMCA and MDCA based on the levels in the trials were the correct residue definition was analysed for. A large margin has been established on the consumer risk assessment. With regards to the rainfall on the last day of treatment, residues at harvest were similar in all four trials 0.69 and 1 mg/kg no rainfall on last day of treatment and 0.69 and 0.74 mg/kg were rain had fallen. NOT: Based on the current residue definition proposal for monitoring MRLs, 8 new trials are available over 2 seasons. Field trial reports indicate on all occasions that the	Open point: It should be discussed by experts whether a sufficient number of appropriate and valid residues trials in strawberry are available that analyse for the full residue definition for risk assessment. See also comment in 3(17)

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			plants were dry at application and dry for 24 hr after sampling on Day 0. Results from 2008 trials are consistent across all trials and therefore there is no indication that rainfall could have affected the quality of the trials. It should also be noted that the weather station was 10-15km from the sites where rainfall was reported. The residue data generated in 2008 confirms the residue levels of MMCA and MDCA such that a risk assessment can be performed. Results show that the consumer risk is <3% ADI and <6% ARfD when all metabolites are taken into account indicating a very large margin of safety to the consumers. Further trials on strawberry can be performed to confirm this low risk if necessary.	

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(16)	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?	RMS: The MRL proposed in this document is 0.3 mg/kg based on a highest residue of malathion plus malaoxon of 0.17 mg/kg. NOT: We would be grateful if the comment could be clarified as we do not understand the relevance of MMCA and MDCA levels with respect to MRL values. For the purpose of providing a worst case risk assessment the higher value has been used to extrapolate likely total residues. Using this value still indicates a large margin of safety to the consumers. The highest residue of malathion and malaoxon from 2004/05 trials was 0.25 mg/kg at PHI 3 days which is still below the proposed MRL of 0.3 mg/kg.	Addressed: FR may specify their comment if not yet addressed in column 3
3(17)	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 trials on which no more than 0.01mg/kg of malaoxon	RMS: Agrees with comment that the acceptability of only 4 of the 8 trials being analysed for the full residue definition should be discussed and for the other 4 trials whether an extrapolation of data can be made (residue levels corrected for MMCA and MDCA based on the levels in the trials were the correct residue definition was analysed for. NOT: Refer to 3(15) and 3(10)	See open point in comment 3(15)

Processing (B.7.7)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(18)	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	RMS: the statement was based on the DAR, the EFSA comment based on addendum 1 is correct. NOT: It is reported on p47 of Addendum 1 that the recovery of radioactivity was 108.2% (pH4), 113.8% (pH 5) and 108.1% (pH 6) demonstrating that no significant losses of radioactivity occurred during the test period. Major degradation products accounting more than 10% of applied radioactivity were characterised by co-chromatography with authentic reference standards. Two major components were identified at low pH (considered representative of strawberry processing as strawberry products are adjusted to pH 3.5 prior to heating); one was confirmed as malathion and the other proposed as desmethyl malathion.	Open point: RMS to present information on the nature of the residue upon processing in the list of end points using the current harmonised version Information on processing should also be corrected in a corrigendum/ addendum/revised AR as appropriate
3(19)	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	RMS: The samples from the processing studies were analysed for a wide range of metabolites, which would have accounted for any degradation of malathion. With regards to the citric acid cycle, this was	Open point: Experts to discuss whether the available data on processing sufficiently address the fate of all compounds that are part of the residue definition for risk assessment.

Processing (B.7.7)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		they enter the citric aid cycle. This might be true for a living organism, but is this indeed applicable to processed products?	postulated by the applicant. NOT: Due to questions raised during the original review, the residues of concern (malathion, malaoxon, DMM, MMCA and MDCA) were measured following processing of strawberries with incurred residues. As there is a net dilution effect during jamming and canning through the addition of other ingredients such as sugar, total residues were not found to accumulate. Individual levels of parent and metabolites were shown to be reduced with the exception of jam where residues of DMM were higher than in the RAC which reflects the findings in the simulated study. In contrast, incurred residues of MDCA were significantly reduced during processing suggesting formation of other products. Aqueous hydrolysis has been investigated in two areas. Firstly, the results from the additional plant metabolism study (Lewis, 2006) provide an indication that non polar metabolites are unstable during acid hydrolysis and are degraded to minor components (see Figures 16 and 17 on p49-50 of the report) which, whilst recognising the harsher conditions (low pH at 60^{o}C for 2 hrs), could explain the absence and/or reduction of non-polar metabolites such as MDCA after processing. Secondly, the environmental aqueous hydrolysis study (Teeter, 1998) shows malathion is more stable at lower pH with only low levels of MMCA being formed at pH 5 along with low levels of	It should be noted that new information cannot be considered for 2nd stage resubmissions under the accelerated procedure (Commission Regulation (EC) No. 33/2008).

Processing (B.7.7)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			ethyl hydrogen fumarate. MDCA was not formed which could also explain the absence of MDCA following processing. Overall it is considered highly unlikely that degradation products other than those formed from the degradation of malathion itself would be seen. The most likely degradation pathways would be cleavage of the methyl ester bonds to form DMM, MMCA or MDCA (as already observed). Di and monoethyl fumarate are seen in aqueous hydrolysis studies so there is a likely entry to the citric acid cycle. It is therefore concluded that the metabolism of malathion under hydrolysis conditions will not be different to that observed in living organisms and that current residue definition for RA is complete.	
3(20)	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.	RMS: Agree if malaoxon residues were significant, however only in 1 of the trials was positive residues detected at 0.01 mg/kg compared to the total residue of 0.74 mg/kg. NOT Refer to 3(10).	See open point in comment 3(21)

Processing (B.7.7)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(21)	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?	RMS: In the case of strawberries yes, as only in 1 of the trials was positive residues detected at 0.01 mg/kg compared to the total residue of 0.74 mg/kg. NOT Refer to 3(10).	Open point: Experts to discuss how to deal with malaoxon in the consumer risk assessment, considering the residue data available, the higher chronic toxicity of malaoxon and the insufficient data on acute toxicity To facilitate the discussion RMS should report the individual residue data for malaoxon in an addendum/ revised AR as appropriate. See also comments in 3(10), 3(14) and 3(21)

Livestock feeding (B.7.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

section 3 – Residues (B.7)

No comments

Succeeding/Rotational crops (B.7.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(22)	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. 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.	RMS: In the vast majority of cases strawberries are not rotated. If this is a common practice then further evaluation can be considered at Member State level – it is noted that the notifers provided a case on this point. See also 3(24) DT50 of desmethyl-malathion in soil is not available as it is not considered to be a significant metabolite in soil, according to the fate evaluation NOT: A case has been provided see 3(23).	Open point: RMS to assess in an addendum the issue of potential residues in rotated crops as identified necessary (data gap) also for the strawberry use in the previous peer review on malathion. The assessment may consider the case made by the applicant. See also comments in 3(23), 3(24)
3(23)	Vol. 3, Annex B.7.10 Residues in succeeding or rotational crops	Applicant: 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.	RMS: Case not included as strawberries in the vast majority of cases are not rotated.	See open point in comment 3(22)

Rapporteur: UK

Succeeding/Rotational crops (B.7.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(24)	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 should be addressed for all the relevant compounds of the residue.	RMS: Still of the opinion that strawberries are not normally rotated, however fate colleagues have supplied DT 50's and DT90's for significant metabolites in soil, none of which exceeded 18 days. **Malathion** DT50 = 0.17 - 0.25 days DT90 = 0.55 - 0.84 days **MMCA** DT50 = 0.12 - 0.72 days DT90 = 0.38 - 2.4 days **MDCA** DT50 = 1.2 - 5.3 days DT90 = 4.1-17.8 days NOT: A case has been provided. Refer to 3(23)	See open point in comment 3(22)

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(25)	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	RMS: Apologies intakes rather than % in table, correct percentages are as follows; TMDI children = 2% TMDI children = 0.8% NOT: RMS to check input parameters.	Open point: RMS to present the corrected consumer risk assessment in the list of end points using the current harmonised version Risk assessment should be corrected in a corrigendum/ addendum/revised AR as appropriate See also comment in 3(26)
3(26)	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.	RMS: Apologies intakes rather than % in table, correct percentages are as follows; IESTI children = 5% IESTI children = 2% NOT: RMS to check input parameters.	See open point in comment 3(25)

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(28)	Vol. 3., pages 106 to 113	Applicant: The heading in these pages has changed, in error, from B.7: Residues to B.9 Ecotoxicology.	RMS: noted	Addressed: To be amended in a corrigendum/ addendum/revised AR as appropriate

4. Environmental fate and behaviour

4(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?	RMS: Samples were analysed by TLC and in the 'LUFA 2.1', 'Schwalbach' and 'Hofheim' test systems there was an unknown metabolite fraction with an Rf value of 0 (i.e unresolved from the origin) of >5% at 2 consecutive time points, as follows: LUFA 2.1 - 2 days and 4 days Schwalbach - 2 days and 4 days Hofheim - 4 days, 7 days, 14 days and 29 days. As no further solvent systems were examined to characterise that unknown fraction it is not clear whether that fraction was made up of a single metabolite or of several metabolites. On the basis of information available in the study report it is not possible to confirm definitively that there are no minor non-transient metabolites in all soils. NOT: Indications from the study are that these metabolites were minor and transient in nature. They are considered to be the next steps in the degradation of malathion, malathion monocarboxylic acid or malathion dicarboxylic acid.	Addressed EFSA note. In accordance with advice from COM, where there has been a peer review and a conclusion on the Draft Assessment Report, the Commission Regulation (EC) No. 33/2008 does not foresee that the original DAR is commented on or peer reviewed again. Comments were only requested on the additional report that addresses the outstanding issues identified in the Commission's non inclusion decision.

Adsorption,desroptionand mobility in soil (B.8.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(2)	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.	RMS: Noted – LoEP to be updated. NOT: RMS to respond	See open point at comment 0(1). The 1/n values range is already included in the LoEP of the first EFSA conclusion and the LoEP provided by the RMS in the additional report. If the RMS updates the LoEP as requested to the current template, then the individual 1/n and Kfoc values values will become available in the LoEP

PEC in soil (B.8.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(3)	Vol. 3, B.8.3, Predicted environmental concentrations in soil (PEC_s)	Applicant: 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 Applicant 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).	RMS: Noted. A comment was added to the final version of the additional report.	Addressed A statement as requested by the applicant is not contained in section B.8.3 of the additional report. RMS to consider in a corrigendum or amended additional report.

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(4)	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.	RMS: This comment will be addressed in an addendum prepared by the UK RMS. NOT: Submitted PEC_{sw} values at Step 4 were calculated following guidance in the final report of the FOCUS Landscape and Mitigation working group. This states that "Within the EU registration process, the actual measure to be applied to mitigate risk should not be specified. Rather, the listing on Annex I should state that the decision to authorise the active substance was made on the basis of a mitigated risk and state the level of mitigation that must be achieved for a particular input route in the different scenarios to assure safe use" [Recommendation 3]. The EFSA PPR opinion agreed with this recommendation. The FOCUS L&M report gives risk mitigation categories of 50, 75, 90 and 95% that can be used in the EU risk assessment at Annex I and notes that "At Annex III, it would then be the responsibility of the Member States to decide which mitigation measures were appropriate and practical to achieve the needed reduction in exposure for their particular circumstances." Therefore, the Applicant believes that the PEC_{sw} values for risk assessment at Annex I should be calculated based on 95% spray drift mitigation, without specifying how this must be achieved. The effect of different mitigation options such as	Open point. RMS to simulate and present FOCUS step 4 PECsw and sed for malathion which implements a 30m no spray buffer zone (equates to ca. 95% spray drift reduction) for simulations with 4 applications in an addendum to the additional report clearly reporting the model parameterisation used and also add this information to the LoEP. Step 4 values for a 40m no spray zone to be deleted from the LoEP. Consideration to be made of the comments of the applicant in column 3 of the reporting table when completing any new simulations. See reporting table comment 4(4).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			no-spray buffers zones and low drift nozzles were presented in the submission as examples how mitigation might be implemented at Member state level (where different mitigation options may be acceptable). In addition, the Applicant understands that the PEC_{sw} values at Step 4 for the 4 x 1.2 kg/ha application were calculated by the RMS using a minimum interval between applications of less that 10 d, which does not reflect the proposed GAP (e.g. for R2, appl. 2 = 20 May, appl. 3 = 27 May). The calculations were repeated by the Applicant with a min. interval of 10 d and with consideration of 95% spray drift mitigation. Malathion is applied to strawberries during fruit ripening, so the application window was set to 1 May to 31 July. This was considered to reflect the FOCUS SW guidance that "If multiple applications occur within the application window, it is important to make the window as large as possible (but still in agreement with the GAP) in order to prevent PAT from unnecessarily relaxing the precipitation rules." The resulting PEC_{sw} values for 4 x 1.2 kg/ha were as follows: • D6 = 0.256 µg/L • R2 = 0.226 µg/L • R3 = 0.238 µg/L • R4 = 0.169 µg/L These PEC_{sw} values are lower than the respective	

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			single application values submitted by the Applicant for 1 x 1.2 kg/ha application with 95% spray drift mitigation (application window 1 – 31 May), which were as follows: • D6 = 0.375 µg/L • R2 = 0.337 µg/L • R3 = 0.353 µg/L • R4 = 0.245 µg/L Thus, the Applicant believes that the above values should be used for the risk assessment purposes. Finally, the Malathion soil DT_{50} of 0.17 d used in PEC_{sw} calculations is the geometric mean of normalised values from the study of Knock, 2001 (detailed in the conclusion report), not the shortest value as stated by the RMS. The un-normalised DT_{50}s in this study ranged from 0.17 – 0.25 d. However, normalised DT_{50}s range from 0.11 – 0.21 d.	

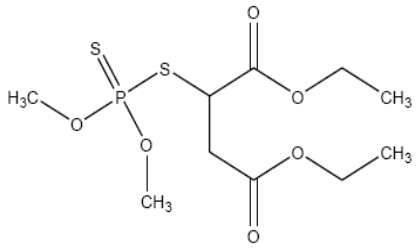
PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(5)	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 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.	RMS: Agreed. A maximum number of treatments will be specified. NOT: A maximum number could be stipulated however, based on the application rate, exposure to groundwater over the season would be negligible as already shown in the risk assessment submitted by the Applicant and in the RMS evaluation presented in the Additional Report.	Open point RMS to estimate and make a proposal for what the maximum number of treatments to ornamentals would be, that would ensure that the potential groundwater exposure would be within the available groundwater simulations in the original DAR and EFSA conclusion addenda in an addendum to the additional report.
4(6)	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.	RMS: The mass loadings per drift event are from SWASH. The drift value for a FOCUS Stream (4 applications of 1.2 kg a.s/ha) was incorrectly reported as 1.1519 mg/ m^2 (p 120). This was a typographical error and the correct values were used in the modelling. Revised STEP 4 calculations will be calculated in an addendum to the additional report and the correct drift value of 1.38 mg/m^2 will be reported there NOT: RMS to respond	See open point at comment 4(4). 40m buffer drift values are to be deleted.

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(7)	Additional report Vol.3, B.8.8.6 PECsw, step 4 p.121	FR: At the end of page 121, it is stated that "for the D6 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.	RMS: The RMS is preparing an addendum to the additional report which will contain STEP 4 calculations with spray drift mitigation of less than 95%, in accordance with the FOCUS Landscape and Mitigation report (see 4 (4)). NOT: No consideration of run-off mitigation has been made in any of the assessments. See previous applicant comment regarding spray drift mitigation.	See open point at comment 4(4). 40m buffer drift values are to be deleted.
4(8)	Additional report, LoEP, PECsw p. 193	FR: The time of application for Step 1-2 is missing.	RMS: Agree that the time of application should be added. LoEP to be updated. NOT: RMS to comment.	Open point RMS to add to the LoEP the time of application for Step 1-2 for PECsw and PECsed for malathion. The information was already included for the metabolites.
4(9)	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)".	RMS: Agree that the final column is unclear and heading will be changed to 'Site specific Kfoc (ml/g)'. NOT: Formatting comment.	Open point RMS to update the heading of the final column of the LoEP table for FOCUS modelling PECgw results to be headed 'Site specific Kfoc (ml/g)'

Fate and behaviour in air and PEC in air (B.8.7-8.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Definition of the residues (B.8.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(10)	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.	RMS: Agree. LoEP to be updated. The EFSA conclusion states that the potential for groundwater contamination of MMCA above 0.1 ug/l is low (all scenarios <0.001µg/l). NOT: MMCA is rapidly degraded in soil (DT_{50} <1 day) and is rapidly degraded in water (DT_{50} 3-4 days) and is therefore regarded as transient, forming MDCA. MDCA has already been included in the residue definition for ground water risk assessment as it is present at levels <0.05µg/l. MMCA has been assessed for risk and is shown not to be present to levels <0.001µg/l.	Open point RMS to update the list of end points to include MMCA in the residues definition for groundwater that requires exposure assessment.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(11)	Additional report, LoEP	NL: The structural formula in the fys/chem. part of the LoEP does not match with the molecular formula.	RMS: end points to be amended NOT: Agreed. The structure is incorrect and should be as follows. 	Addressed Point transferred to Phys chem section of the reporting table.
4(12)	Additional report General	NL: No further comments	RMS: No comment necessary NOT: No comment required	Addressed

5. Ecotoxicology

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(1)	B.9.1.2 Risk assessment birds	NL: The detailed evaluation of the residue study is very clear and much appreciated	RMS: Thank you! NOT: Agreed. However it should be noted that the evaluation was conducted as the EFSA assessment from 2006 had not been peer reviewed. The original EFSA assessment had not identified the risk assessment to birds as an area of concern and therefore the Applicant did not regard it as being necessary to further address in the re-submission	Open point MSs to discuss in an expert meeting the refined acute and long-term risk assessment to insectivorous birds based on measured residues on invertebrate from a field study of Knäbe 2004.
5(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).	RMS: The RMS agrees that it would be worth discussing the approach used in malathion at an expert meeting, although it will not change the outcome significantly in this case. NOT: The consistency between the Method 2 PPR Opinion (EFSA (2005), Bulletin 301, 1-45) derived value and the SSD derived value presented in Column 2, suggests that using the second most sensitive acute regulatory endpoint (from at least 6 fish studies conducted using the technical material) is scientifically valid. RMS to comment further.	Open point: MSs to discuss in an expert meeting the derivation of acute end point for fish (the acute endpoint was refined according to method 2 of the PPR Opinion (EFSA (2005), Bulletin 301, 1-45); however one MS suggests to use the SSD approach since it is scientifically more sound).

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(3)	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.	RMS: Agreed NOT: Refer to 5(1) and also details of refinement to risk assessment referenced in comments 5(4) and 5(5)	See open point on comment 5(1)
5(4)	Vol. 3, B.9.1.2 Effects on birds, risk assessment of use on strawberries	Applicant: 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.	RMS: See Response to Point 5(7).	See open point in comment 5(7)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(5)	Vol. 3, B.9.1.2 Effects on birds, risk assessment of use on strawberries Also Section 2 p 13	Applicant: 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 long-term risk. Further details are provided in Column 3.	RMS: The Applicant has submitted further information (see Column 3 of the evaluation table). The revised risk assessment considers refinements regards PD and RUD. Whilst the comments made by the Applicant are relevant it is not considered that these points adequately address the short-comings highlighted in the risk assessment. For example the Applicant has proposed that the skylark and the blackcap should be used as focal species and as these are not totally insectivorous then the risk is addressed. It is acknowledged that a range of birds will use strawberry fields, however it is felt that a small insectivorous bird is an appropriate indicator species. If the Applicant wishes to use other species, then these should be justified with appropriate data. The Applicant has also proposed using a DT50, the concerns behind the DT50 have been discussed in detail in the Additional Report and hence it is not considered to be totally appropriate.	Addressed It should be noted that new information cannot be considered for 2nd stage resubmissions under the accelerated procedure (Commission Regulation (EC) No. 33/2008).
5(6)	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	RMS The FIR is based on a 100 g bird consuming 100% fruit and has been calculated using the PSD spreadsheet – see www.pesticides.gov.uk/uploadedfiles/Web_Assets/PSD/Diet.xls. The information from the PPR opinion was not	Open point: MSs to agree the risk assessment to frugivorous birds provided in the colomn 3 of the evaluation table. RMS to consequently update the LoE and to provide the agreed risk assessment in an addendum or revised additional report.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		"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)	used in carrying out this assessment. It is appreciated that the range of generic focal species and corresponding diets (and RUD) quoted in this opinion are different from those used in this assessment, provided below is a risk assessment based on the data in EFSA (2008) . Using the information for EFSA (2008) the risk to a frugivorous bird (e.g. starling) is as follows: Acute exposure = 1.2 kg a.s./ha*27.0 (Shortcut value from Annex I of EFSA (2008)) * 1.5 (MAF factor from Table 11 of EFSA (2008) = 48.6 mg a.s./kg bw. The agreed acute LD50 is 214 mg a.s./kg, therefore the acute TER for a frugivorous bird is **4.4**. Long-term/reproductive exposure = 1.2 kg a.s./ha*13.4 (Shortcut value from Annex I of EFSA (2008)) * 1.9 (MAF factor from Table 14 of EFSA (2008) = 30.5 mg a.s./kg bw. The agreed reproductive NOEC is 13 mg a.s./kg, therefore the reproductive TER for a frugivorous bird is **0.4**. NOT: A 100 g passerine bird consuming 100% orchard topfruit. This results in a fresh food consumption of 201.78 g, which gives a FIR/bw of *2.02.	

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			*Based on the PSD diet calculator [www.pesticides.gov.uk/uploadedfiles/Web_Assets/PSD/Diet.xls] The RUD value used in the assessment is realistic, having been achieved in strawberry crop residue trials. RMS to comment further	
5(7)	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 (90^{th}) 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.	RMS: In the first tier risk assessment for frugivorous birds a 90^{th} percentile and mean RUD have been used and the resulting TERa, TERst and TERlt were determined to be 7.9, 99 and 2.4 respectively. The acute and long-term TER were refined using data from the original DAR and the refined risk assessment is presented in Table B.9.1.3 in the Additional Report. EFSA have correctly pointed out that additional data are available in Addendum 3. These data indicate that the 90^{th} and mean residues on strawberries following an application at the rate of 1.5 kg a.s./ha are 2.86 and 1.6 mg/kg respectively. These can be converted to 90^{th} and mean residue per unit doses of 1.9 and 1.1 mg/kg. If these are entered in to the assumptions presented in EFSA (2008) then the following exposure estimates are	Open point RMS to update the LoE with the refined risk assessment to frugivorous birds. This should be considered also in an addendum or revised additional report.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			generated: Acute exposure = Food intake rate/bw (see Appendix 3a) * mean RUD (see above) * MAF (see Table 11) * Application rate = 1.6*1.9*1.5*1.2 = **5.5** mg a.s./kg bw day Reproductive exposure = Food intake rate/bw * mean RUD * MAF * Application rate = 1.6*1.1*1.9*1.2 = **4.0** mg a.s./kg bw day The corresponding TERa and TERlt are 39 and 3.3 respectively. It should be noted that there has been not consideration of degradation in the TERlt. If the standard SANCO DT50 of 10 days is used, then the TERlt becomes 6.1. Using the Applicant's DT50 of 3.3 days would produce a reproductive TER of 15 (i.e. the DT50 of 3.3 days corresponds to a Ftwa of 0.22). NOT: RMS to comment however acute risk using 90th percentile data still shows an acceptable risk to frugivorous birds.	

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(8)	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 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.	RMS: It is accepted that the DT50 of 10 days is potentially worst case. The Applicant has highlighted DT50 of 0.5 to 3.3 days and the upper value has been used in 5(7) above. As regards adjusting the RUD figure to account for methods of application (i.e. orchard sprayer vs ground based sprayer), it is possible, however additional data would be required regarding difference in deposition rates to enable this to be done. NOT: Agreed. Also refer to 5(5)	See open point in comment 5(1)
5(9)	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.	RMS: The FIR of 1.92 was calculated assuming a 25 g mammal consumed 100% fruit and was calculated using the following www.pesticides.gov.uk/uploadedfiles/Web_Assets/PSD/Diet.xls. The reference to EPPO refers to the RUD presented in Table 6 of EPPO 2002. These values are for fruit-eating birds in orchards/vineyards and hop situations. The revised risk assessment presented above in 5(7) should be noted. NOT: In the PPR opinion on Science behind the Guidance document on Risk Assessment for Birds and Mammals (EFSA Journal 2008,	Open point MSs to agree the risk assessment to frugivorous mammals. RMS to consequently update the LoE and to provide the agreed risk assessment in an addendum or revised additional report.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			734: 1-181), the generic focal species of frugivorous mammal is the"Wood mouse " feeding on strawberries at this growth stage >40, representative body weight is 21.7g which compares favourably with a bodyweight of 25 g. Furthermore, the risk assessment considers an absolute worst exposure scenario, where wood mice are feeding solely on strawberries at the time of application. If the diet composition was to be further refined using PD and PT and associated residues, risk would be further reduced.	
5(10)	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.	RMS: Agreed. NOT: Typographical error in Additional report.	Addressed RMS to consider in a revised additional report that the reference to the table 7.4.1 is incorrect (it should be refer to B.7.6.1).

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(11)	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.	RMS: See Section 5(7) above for revised risk assessment for frugivorous birds. NOT: Refer to applicants comment 5(5)	See open point in comment 5(6)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(12)	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.	RMS: Agreed. NOT: 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 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.	See open point in comment 5(1)
5(13)	Vol. 3, Annex B-9, B-9.1.4, refinement of the risk assessment considered, use of a DT50 based on initial residue data from the Knäbe study to refine ETE.	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 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 applicant.	RMS: Agreed NOT: The DT50 value of 0.48 days used in the long-term assessment is considered appropriate and is similar to other environmental DT50 values already discussed in the additional report and list of endpoints.	See open point in comment 5(1)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(14)	Vol. 3, B.9.1.1 Risk to birds Vol 3, B.9.3.1 Risk to mammals	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. 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.	RMS: Noted It is accepted that according to SANCO 4145 the indicator species for strawberries is a herbivorous mammal, however strawberry foliage is unpalatable hence it was considered more appropriate to assess the risk to insectivorous mammals. NOT: comment provided late to RMS and not seen by applicant	See open point in comment 5(1) Addressed

Rapporteur: UK

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(15)	LoE, Aquatics	NL: Please include all endpoints for fish in the LoE and mention also the tested species for all tests.	RMS: LoE will be amended. NOT: Comment addressed to RMS	Open point: RMS to update the LoE including all endpoints for fish and mention also the tested species.
5(16)	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).	RMS: Point accepted. Additional Report will not be revised however. NOT: Suggest RMS to comment as this is a presentation issue. Suggest adding a footnote to clarify the endpoints presented are based on min. and max. trigger values.	Open point RMS to update the LoE with the actual endpoint from the mesocosm study (5 ug/L) and compare the resulting TER to the chosen trigger (in this case 3-5). This should be also considered in a revised additional report.
5(17)	Additional report, Vol. B.9.2, risk assessment for aquatics, pag 157 LoE: toxicity/exposure ratios for aquatics.	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 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.	RMS: The RMS is preparing an addendum to the additional report which contains STEP 4 calculations with spray drift mitigation of less than 95%, in accordance with the FOCUS Landscape and Mitigation report. NOT: See comment in fate section 4(4)	Open point: RMS to update the aquatic risk assessment in light of revised PECs that only mitigate spray drift by a mxiumum of 95% in addendum to the additional report and consequently update the list of endpoints ensuring that the TER for a buffer zone of 40 m are deleted.

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(18)	Vol. 3 B.9.2.2.4 FOCUS STEP 4	FI: The risk for the aquatic organisms has been 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).	RMS: The risk assessment presented in the Additional Report indicates those scenarios where a 'safe' use has been indicated. It is accepted that no all scenarios are 'safe', however it is proposed that MS should assess the relevance of these scenarios and hence the need for appropriate risk mitigation measures at product re-registration. Please also see response to 5(17). NOT: comment provided late to RMS and not seen by applicant	See open point in comment 5(17)

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(19)	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.	RMS: LoE will be amended. NOT: Comment addressed to RMS	Open point: RMS to amend the LoE including the study duration and the sampling dates of the aged-residue studies for non-target arthropods.

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(20)	Vol. 3, B.9.5.1, Effects on other arthropod species, risk assessment for use on strawberries Also Section 2 p12	Applicant: 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.	RMS: noted. The RMS does not consider this to be significant issue with respect to Annex I inclusion.	Addressed It should be noted that new information cannot be considered for 2nd stage resubmissions under the accelerated procedure (Commission Regulation (EC) No. 33/2008).
5(21)	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.	RMS: The risk mitigation has been left to MS to address, however it is assumed that it will be based on the agreed Annex V phrase. NOT: As identified in the Additional report, EPCO 17 concluded that risk mitigation measures should be set at a MS level. Expected mitigation measures, at member state level, could include application timing to avoid peak bee flight times and drift reducing nozzels thereby further reducing off-field risk.	Open point MSs to discuss in an expert meeting the risk to bees and the appropriate mitigation measures.

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(22)	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.	RMS: LoE will be amended. NOT: Comment addressed to RMS	Open point RMS to amend the LoE with a footnote indicating that the risk assessment for non-target arthropods was addressed only for formulation with a content of isomalathion <0.0017%.
5(23)	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.	RMS: Agreed. NOT: Please see Applicants coment 5(20)	See open point in comment 5(22).

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 DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Rapporteur: UK

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

No comments

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(24)	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.	RMS: Noted NOT: Comment addressed to RMS	Addressed
5(25)	Vol. 3, List of endpoints GAP table	Dk: In our view the GAP table should be gray for the strawberry use (risk to birds).	RMS: Outdoor uses require further work to refine the risk to birds which MS should pay particular attention to. NOT: Applicant believes that an acceptable risk to birds is achieved by use of refinement of the risk assessment through revision of default parameters (e.g. PD, RUD values) using published literature, available data on crop residues and data on environmental dissipation. See Applicants comments 5(4) and 5(5).	Addressed

Rapporteur: UK

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(26)	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).	RMS: List of endpoints will be amended. NOT: see Applicants comment 5 (16) Further comment addressed to RMS	See open point in comment 5(16)
5(27)	General – proposed decision, p13	Applicant: 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 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 Applicant contends no weight should be attached to this concern regarding the decision on Annex I inclusion.	RMS: noted	See open point in comment 5(1)

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(28)	General – proposed decision, p13	Applicant: 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.	RMS: Noted	Addressed RMS to consider in a revised additional report
5(29)	Vol 3.,, Appendix 1.6, List of Endpoints, Effects on non target species	Applicant: The invertebrate residue study is mentioned as not appropriate for refinement of risk to birds. Whilst the Applicant 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.	RMS: Agreed	See open point in comment 5(1).