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

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(1)	Vol. 1, Listing of End Points, Identity	Oct 04 UK: The end points should list only 'relevant' impurities in the technical material, i.e. **impurities of toxicological, environmental and/or other significance**.	Nov 04 RMS: Noted –	Partly addressed Open point RMS to clarify whether [redacted] has to be regarded as a relevant impurity or not. Evaluation Meeting (14.-15.12.2004): Open point confirmed. The notifier stated that an argumentation will be submitted to the RMS. Open point still open.
1(2)	Vol 1, Listing of End Points, Identity of relevant impurities	Oct 04 UK: Should this information be moved to the confidential information in Vol 4?	Nov 04 RMS: Noted	Addressed RMS has amended the list of endpoints See also comment 1(1)

Rapporteur: IT

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1(3)	Vol. 1, Listing of End Points, Methods of Analysis	Oct 04 UK: MoAs for impurities in the technical material should detail principle of methods only and not disclose details of identities of impurities.	Nov 04 RMS: EP list amended	Addressed RMS has amended the list of endpoints to keep the confidentiality.
1(4)	Vol. 1, p. 6, 1.3.9 Specification of purity of the active substance	Oct 04 EFSA: It should be noted that the minimum purity of the active substances can not be regarded as confidential.	Nov 04 RMS: Noted –	Addressed RMS to consider in a revised DAR or corrigendum
1(5)	Vol. 1, p. 52, List of endpoints, FAO specification	Oct 04 EFSA: For clarification, the acceptable deviation of ± 20 g/kg from the declared content should be mentioned.	Nov 04 RMS: Noted – See new list of endpoints	Open point RMS to amended the list of endpoints regarding the declared content of the folpet in the FAO specification and to clarify the amended value for the minimum purity. Evaluation Meeting (14.-15.12.2004): Open point confirmed. According to the FAO

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1(5)	*continued* Vol. 1, p. 52, List of endpoints, FAO specification			specification the given value should be read as 880 g/kg ± 20 g/kg. The minimum purity should be given without a range. Open point still open.
1(6)	Vol. 1, p. 53, List of endpoints, Boiling point/temperature of decomposition in relation to Volume 3, B.2	Oct 04 EFSA: The given argumentation is not applicable. According to Directive 94/37/EC the measurements has to be carried out up to 360 °C. Therefore, it should be indicated in the list of endpoints, that data are required (e.g. as open point).	Nov 04 RMS: Noted - See new list of endpoints	Data requirement Notifier to provide data concerning the boiling point and temperature of decomposition, respectively. Evaluation Meeting (14.-15.12.2004): The notifier will submit the requested data in beginning of April 2005. Data requirement still open.

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1(7)	Vol. 1, p. 53, List of endpoints, relative density in relation to Vol. 3, B.2.1.4	Oct 04 EFSA: It should be clarified whether the relative density or the density was determined.	Nov 04 RMS: Since density and relative density, D^{20}_4, are numerically identical, this comment is irrelevant	Open point RMS to indicate in the list of endpoints that the density was determined. For clarification, according to Volume 3, B.2 it seems that only the density was determined (1.72 kg/m³). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
1(8)	Vol. 1, p. 56, List of endpoints, Summary of intended uses	Oct 04 EFSA: For transparency and better comprehensibility, instead of the "summary of intended uses", the list of representative uses evaluated, as mentioned in EPCO Manual E4, should be used.	Nov 04 RMS: Noted	Open point RMS to include the list of "representative uses evaluated" in the list of endpoints. Evaluation Meeting (14.-15.12.2004):

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1(8)	*continued* Vol. 1, p. 56, List of endpoints, Summary of intended uses			Open point confirmed. Open point still open.
1(9)	Vol. 1, 4.5, and Vol 3, B.5.2.1, methods of analysis in plants, plant products	Oct 04 NOT: The DAR volume 1 concludes the following: Analytical methods are available for all of these crop groups, but confirmatory assays have been provided only for wheat. Confirmatory assays for all crops other than wheat are required. This deficiency identified by the RMS has been addressed (see Column 3) and in conclusion, no additional data are considered necessary. Confirmatory procedures It is considered that residues may be confirmed using the many other chromatographic conditions presented for folpet residue determination (crops, soil, water, air). These methods are based on capillary GC with electron capture detection using a range of stationary phases of varying polarity and reverse-phase HPLC with either ultraviolet or diode array detection. The various conditions	Nov 04 RMS: When available, data will be evaluated	Data requirement Notifier to submit the position paper: **"**Folpet. Position Paper on Residue Analytical Methods (May 2004)". Open point The need for a confirmatory method for food of plant origin should be discussed in an expert meeting See also comment 1(14) Evaluation Meeting (14.-15.12.2004): Data requirement: The notifier will submit the requested data by April 2005.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(9)	*continued* Vol. 1, 4.5, and Vol 3, B.5.2.1, methods of analysis in plants, plant products	will be sufficient for use in confirmation of folpet residues. The guidance document SANCO/825/00 states that acceptable confirmatory techniques may be based on differences in the chromatographic principle (HPLC, GC), alternative detection, and different stationary and/or mobile phases. Therefore, it is considered unnecessary to conduct further work on confirmation when there are numerous existing chromatographic conditions available. Summaries of all the analytical methods, the validation data, a summary of the various chromatographic methods available for determination of folpet and the response to the data requirements/deficiencies are presented in the following position paper: **"Folpet. Position Paper on Residue Analytical Methods (May 2004)".** Will be included in the addendum to be submitted to the RMS.		Data requirement still open. Open point: Open point confirmed. Open point still open.

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1(10)	Vol. 3, p. 15ff, Table B.2.2.1 Summary of the physical and chemical properties of the plant protection product	Oct 04 EFSA: Clarification is needed regarding the properties where more than one batch is mentioned. Does this mean that the tests were performed for all the mentioned batches?	Nov 04 RMS: Yes - The tests relative to B.2.2.15, B.2.2.16, B.2.2.17, B.2.2.18, B.2.2.19, B.2.2.22 and B.2.2.24 were performed for all the mentioned batches.	Addressed RMS to consider in a revised DAR or corrigendum
1(11)	Vol. 3, p. 19, B.2.2.8 Flowability	Oct 04 EFSA: More information is needed to assess whether the remained residues after 20 liftings are acceptable or not.	Nov 04 RMS: Flowability is point B.2.2.28 Since water dispersible granules are mixed with and dispersed in water, this parameter has no commercial significance. The dispersability of the product was shown to be acceptable.	Open point The need for further information regarding the flowability should be discussed in an expert meeting. For clarification, it seems that different approaches exist in different MS. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

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1(12)	Vol. 3, p. 34, B.4 Proposals for classification and labelling	Oct 04 EFSA: For transparency and better comprehensibility, a justification for the proposed classification and labelling should be given.	Nov 04 RMS: The justification is given in the Summary dossier.	Addressed (RMS refers to Volume 1, 2.1.4) RMS to consider in a revised DAR or corrigendum.
1(13)	Vol. 3, p. 35, B.5.1 Analytical methods for formulation analysis	Oct 04 EFSA: A statement concerning the applicability of CIPAC method(s) is missing.	Nov 04 RMS: Agree. Noted - A statement concerning the applicability of CIPAC methods was included in the Document MIII.	Open point RMS to amend the list of endpoints regarding the applicability of CIPAC method(s), if appropriate. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(14)	Vol. 3, p. 35ff, B.5.2.1 Plants, plants products and B.5.2.2 Animal tissues and milk in relation to Volume 1, Level 4	Oct 04 EFSA: The assessment of the analytical methods for the determination of residues in food should be discussed in an expert meeting. According to the mentioned methods and issue-related information, it seems to be that sufficient data/methods are available or not necessary.	Nov 04 RMS: Noted – See also point 1(9)	See open point and data requirement in comment 1(9)
1(15)	Vol. 3, B.5.2.1 Analytical methods (residue) for plant material	Oct 04 DE/Statement: . The standard multi-residue method DFG S-19 has been adequately validated for applications to plant products. It is tested in interlaboratory tests for dry and water content samples. Results are published in the Collection of Official Methods under Article 35 of the German Federal Food Act (method L 00.00-34)	Nov 04 RMS: Noted – See point 1(9)	See open point and data requirement in comment 1(9).
1(15)	*continued* Vol. 3, B.5.2.1 Analytical methods (residue) for plant material			

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1(16)	Vol. 3, B.5.2.2, MoA for animal tissues.	Oct 04 UK: A validated MoA was presented for these samples, but do we need to insist on an ILV given that intakes for animals are very low; is there likely to be a need for monitoring of animal products?	Nov 04 RMS: Noted – See also point 1(17) Refer to **"Folpet. Position Paper on Residue Analytical Methods (May 2004)"**. A monitoring method is not required. Therefore, ILV is not necessary	Open point RMS to amend the list of endpoints regarding the analytical method for food of animal origin with a phrase that an analytical method is not required since no MRLs are proposed. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
1(17)	Vol. 1, 4.5, and Vol 3, B.5.2.2, methods of analysis in animal tissues and milk	Oct 04 NOT: The DAR volume 1 concludes that the method can be acceptable in principle, but requires independent laboratory validation and a confirmatory assay. It is considered unnecessary to conduct further work or confirmation when there are numerous existing chromatographic conditions available and an analytical method for monitoring	Nov 04 RMS: When available, data will be evaluated	See open point in comment 1(16) and data requirement in comment 1(9)

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1(17)	*continued* Vol. 1, 4.5, and Vol 3, B.5.2.2, methods of analysis in animal tissues and milk	purposes is not required due to the lack of residues of folpet in edible animal tissues. The metabolism studies in goat demonstrated that residues of folpet in edible animal tissues following administration of a worst-case dietary concentration were below the limit of quantification. Therefore, feeding studies in ruminants are not required. Metabolism and feeding studies in poultry are not required as the dietary concentration of folpet is less than 0.1 mg/kg total diet as received. Consequently, MRLs for animal tissues, milk and eggs are not applicable. Therefore, an analytical method for monitoring purposes is not required under these circumstances (as defined by Commission Directive 96/46/EC) and the validity of the methods presented need not be evaluated. The method presented for determination of folpet in animal tissues, eggs and milk should be considered as supporting information for the methods dossier and any deficiencies in their validation are irrelevant. Summaries of all the analytical methods, the validation data, a summary of the various chromatographic methods available for determination of folpet and the response to the data requirements/deficiencies are presented in		

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1(17)	*continued* Vol. 1, 4.5, and Vol 3, B.5.2.2, methods of analysis in animal tissues and milk	the following position paper: **"Folpet. Position Paper on Residue Analytical Methods (May 2004)".** Will be included in the addendum to be submitted to the RMS.		
1(18)	Vol. 3, p. 45, B.5.3.2 Analytical method in water	Oct 04 EFSA: The argumentation for the non submission of an analytical method for the determination of residues in surface water is not acceptable. A validated analytical method must be submitted also for surface water, due to the fact that in general the matrix surface water is less clean than drinking water. However, taken issue related information into account, the need for an analytical method is maybe questionable. This should be discussed in an expert meeting.	Nov 04 RMS: We agree for a discussion in an expert meeting also at the light that for DE (Point 19) method for surface water is not required.	Open point The need for an analytical method for the determination of residues in surface water should be discussed in an expert meeting. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Depending on the outcome of the fate and behaviour meeting, it could be that no analytical method for the determination of residues of folpet in surface water is required. Open point still open.

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1(19)	Vol. 3, B.5.3.2 Analytical methods in water	Oct 04 DE/Statement: A method for residues in surface water is not required because of the low stability of Folpet (DT90 < 1 day)	Nov 04 RMS: Noted. See point 1(18)	See open point in comment 1(18)
1(20)	Vol. 3, B.5.3.3 Analytical methods in air	Oct 04 DE/Data Requirement: For determination of Folpet in air a confirmatory method is missing and should be provided.	Nov 04 RMS: We agree	Open point The need for a confirmatory method for air should be discussed at the **evaluation meeting**. For clarification, it was agreed at expert level that a confirmatory method for air is not required, provided that sufficient confirmatory methods are available for soil and water. It seems that this applies in the case under consideration. Evaluation Meeting (14.-15.12.2004): DE agreed at the meeting with the approach given in column 4

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1(20)	*continued* Vol. 3, B.5.3.3 Analytical methods in air			and rejects the proposed requirement. The meeting agreed on this proposal. Therefore this point can be regarded as closed. Point closed.
1(21)	Vol. 3, B.5.4, MoA for human fluids and tissues.	Oct 04 UK: The toxicological assessment does not seem to warrant a requirement for human fluids and tissues.	Nov 04 RMS: Noted – Agreed. Folpet is not classified as toxic or highly toxic and, therefore, analytical methods for body fluids and tissues are not required. we agree (see also point 16)	Open point RMS to amend the list of endpoints to clarify that an analytical method for body fluids (blood) is not required since folpet is not classified as toxic or highly toxic Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(22)	Vol. 1, 4.5, and Vol 3, B.5.4, methods of analysis in body fluids and tissues	Oct 04 NOT: The DAR volume 1 concludes that a validated method is required. This data requirement is not applicable to folpet. Commission Directive 96/46/EC and the EU guidance document SANCO/825/00 both state that methods for the determination of residues in body fluids and tissues are only required for those active substances that are classified as toxic or highly toxic. Folpet is not classified as toxic or highly toxic and, therefore, analytical methods for body fluids and tissues are not required.	Nov 04 RMS: See point 1(21)	See open point in comment 1(21)
1(23)	Vol. 4, p. 4, 1.8 Method of manufacture	Oct 04 EFSA: It seems to be that information regarding the purity and source (commercially available or not) of the starting material are missing.	Nov 04 RMS: Noted	Data requirement Notifier to submit data regarding the the purity and source (commercially available or not) of the starting material. Depending on the outcome of the check by the RMS "vedere se MOR ha mandato" this data requirement can be convert into an open point for the RMS

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1(23)	*continued* Vol. 4, p. 4, 1.8 Method of manufacture			Evaluation Meeting (14.-15.12.2004): The notifier will submit the requested data by April 2005. Data requirement still open.
1(24)	Vol. 4, p. 11, Table 1.11-2 Folpet technical composition statement	Oct 04 EFSA: Clarification it needed concerning the given maximum levels for the impurities. Some of the specified limits are not reliable according to the submitted batch analyses. A new specification or a justification for the mentioned values should be required. According to the presented data, it seems to be that no different batches were used for the toxicological and the ecotoxicological studies. Therefore it must be confirmed that a specified limit above the maximum value found in the batch analyses is acceptable.	Nov 04 RMS: Noted - An expert meeting is requested to refer to the "**Folpet. Position Paper on Residue Analytical Methods (May 2004)**".	Open point RMS to clarify the need to discuss the position paper on residue analytical methods under this topic. Data requirement Notifier to justify the given specification for the impurities or submit a new one. Evaluation Meeting (14.-15.12.2004): Open point: Open point confirmed.

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1(24)	*continued* Vol. 4, p. 11, Table 1.11-2 Folpet technical composition statement			Open point still open. Data requirement: The notifier will submit the requested data by April 2005. Data requirement still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(25)	Vol. 4, p. 12ff, 4.1.2 Methods for the determination of significant and/or relevant impurities	Oct 04 EFSA: Data to confirm the identity of the impurities revealed by chemical analysis must be provided to address the requirement of the Directive on the specificity of the method(s).	Nov 04 RMS: Specificity of the impurity methods has been adequately addressed in the dossier. Regarding identity of the impurities, this has been confirmed by the use of certified reference standards in the validation procedures.	Data requirement Data to confirm the identity of the impurities revealed by chemical analysis must be provided to address the requirement of the Directive on the specificity of the method(s). For clarification, it was agreed at expert level that retention time match with reference standard is only acceptable as confirmatory methodology, if the identity of the impurities is confirmed appropriately. Evaluation Meeting (14.-15.12.2004): The notifier will submit the requested data by April 2005. Data requirement still open.

2. Mammalian toxicology

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2 (1)	Vol.1, List of endpoints, Short-term toxicity, oral.	Oct 04 NL: RMS gives a lowest relevant oral NOAEL of 44.5 mg/kg bw/d from a 90d feeding study with rats. Based on the 4 studies with dogs (4 wk, 13 wk and 2x 1y) it is clear that the dog is more sensitive to adverse effects of folpet. Since the NOAEL in the 4 wk study was < 20 mg/kg bw/d and the NOAEL for 1 y studies in dogs is 10 mg/kg bw/d, the most relevant short term NOAEL is 10 mg/kg bw/d. NL: NOAEL's short term rat and dog 90d rat 44,5 mg/kg bw/d (m), 58,5 mg/kg bw/d (f) (N.B.: in the text in Vol 1. p.20, Vol.3, B.6.53.5 other values are given for the NOAEL, i.e. 67 mg/kg bw/d (m) and 56 mg/kg bw/d (f) 4 wk dog <20 mg/kg bw/d 13 wk dog <790 mg/kg bw/d 1 y dog <325 mg/kg bw/d 1 y dog 10 mg/kg bw/d	Nov 04 RMS: List of end points amended with the new most relevant short term NOAEL of 10 mg/kg bw/d. for 1 y study in dogs	Open point RMS to provide more detailed summary of short term oral toxicity for discussion of short term NOAEL at an expert meeting. See also comment in 2(13). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2 (2)	Vol. 1, Level 2, 2.1.4, Classification and labelling	Oct 04 SE: Cancer category 3 would be added, according to the List of classification and labelling (ref: Annex I of Directive 67/548/EEC)	Nov 04 RMS see point 3	Open point MS to discuss the carcinogenic properties at an expert meeting See also open point in comment 2(22) and comments 2(3), 2(23), 2(24) and 2(25). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
2 (3)	Vol. 1, 2.1.4, Classification and labelling	Oct 04 DE: In accordance to the 28th Time Council Directive 67/548/EC, folpet has to be classified and labelled for toxicological properties as follows: Xn; R20-36-40-43. The risk phrase R40 is necessary because of the clear neoplastic effect in mice and must be amended, therefore. Note: For the classification and labelling of the preparation the risk phrase R 40 should also be considered into account.	Nov 04 RMS on a basis of a pure hazard characterization we can agree with R 40 labelling of folpet. However, at the light of risk assessment for man the toxicology expert of RMS still believes that folpet does not require R40 in view of the fact that: i) folpet is not considered genotoxic and ii) mice tumours are species specific and appear only above a dose that causes chronic toxicity.	See open point in comment 2(2). See also comments 2(22), 2(22), and 2(25).

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2 (4)	Vol. 1, 2.3.3	Oct 04 NOT: An ARfD of 0.1 mg/kg bw is proposed. We propose that, based on an evaluation of the toxicology database for folpet, an ARfD for folpet is not needed. NOT: An ARfD is not required for folpet for the following reasons: 1) There is minimal irritation seen in the gastrointestinal tract after one day exposures to folpet at doses above 500 mg/kg. 2) There are minimal effects at doses above 500 mg/kg in a development study. 3) Gastrointestinal irritation following repeated folpet oral exposure is rapidly reversed upon cessation of treatment. 4) Folpet is not present in the systemic circulation and is not a systemic toxin. 5) Folpet will not induce adverse effects when residues are ingested continuously, even at the theoretical maximum residue values. 6) Folpet's oral toxicity is greater than 5 g/kg. Full and detailed comments on all aspects of the ARfD for folpet are presented in a position paper: **"Gordon, E (2004). Folpet. A summary basis for why an acute reference**	Nov 04 RMS agrees that ArfD is required since Folpet produces teratogenic effects at doses not maternal toxic, at which no g-i. irritation was observed	Data requirement Notifier to submit the position paper by Gordon E., 2004 and the study Moore and Creasey (2004). Open point RMS to provide more detailed summary of the studies which lead to the derivation of the ARfD for discussion at an expert meeting. See also comment 2(13). Evaluation Meeting (14.-15.12.2004): Data requirement: The notifier has already submitted a position paper. Data requirement still open. Open point: Open point confirmed. Open point still open.

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2(4)	*continued* Vol. 1, 2.3.3	**dose (aRfD) is not needed. Submitted to the JMPR for the 2004 toxicological evaluation of folpet".** This position paper is supported by a new previously unsubmitted acute intestinal irritation study, namely **"Moore, G.E. and Creasey, D. (2004). Intestinal irritation in CD-1 mice after a 24-hour exposure to folpet. [redacted] unpublished report number 13763 (Company file: R-16283)"** This study concludes that folpet administered by oral gavage at 900 mg/kg/bw or in the diet for 24 hours at 5000 ppm (as well as 500 ppm, 200 ppm, and 50 ppm) caused only minimal ("borderline") irritation of the proximal duodenum. The initial finding of apparent irritation in the first study was shown to be due to artefacts upon thorough (eight step serial section) examination of the expanded second study. It was concluded that folpet was borderline for producing irritancy at 5000 ppm. The position paper and the new study will be included in the addendum to be submitted to the RMS.		

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2 (5)	Vol. 1, 2.3.3	Oct 04 NOT: An AOEL of 0.125 mg/kg bw is proposed in the DAR based on a NOEL of 12.5 mg/kg bw/day from the 2-generation study. However, taking the two reproductive toxicity studies together, the NOEL for the critical developmental effect is 800 ppm, equivalent to approximately 40 mg/kg bw/day. The AOEL should be based on the NOEL of 40 mg/kg bw/day, which with a safety factor of 100, gives an AOEL of 0.4 mg/kg bw/day. NOT: Dietary administration of folpet at a concentration of 5,000 ppm for two generations (Rubin 1986) resulted in reduced body weight and food consumption of the parental animals and reduced body weights of the offspring from Day 7 *post-partum* of the F_0 generation and on Day 21 of the F_1 generation. At 1,500 ppm, slight but statistically significant reductions in body weight were seen in the parental animals and also in the offspring from Day 21 of the F_0 generation. There were no effects on the pregnancy rates, fertility indices, gestation periods and litter sizes at any of the dose levels. Findings at histopathological examination showed effects on the target organs at 5,000 and 1,500 ppm, including hyperkeratosis of the	Nov 04 RMS agrees to increase the NOAEL of the two generation studies from 12.5 mg/kg to 40 mg/kg b.w. On the basis of the 4 studies in dog, the dog is the most sensitive species (see point 1). The new AOEL of 0.1 mg/kg bw., based on the 1-yr dog study (NOAEL=10 mg), is also supported by the results of developmental studies in rabbit.	Data requirement The notifier to send position paper regarding reproductive toxicity and teratogenicity of folpet to the RMS. Open point RMS to provide more detailed summary of the 2-generation reproduction toxicity study for derivation of NOAEL and discussion in an expert meeting. See also open point in comment 2(26). Regarding AOEL, see open point in comment 2(6) and comments 2(9), 2(10), 2(11), 2(13) and 2(32). Evaluation Meeting (14.-15.12.2004): Data requirement: The notifier has already submitted

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2(5)	*continued* Vol. 1, 2.3.3	non-glandular stomach in both generations with occasional incidences of squamous epithelial hyperplasia in high dose F_0 males and one incidence of focal inflammatory ulceration in the high dose F_1 males, increased incidences of the foci of renal basophilic tubules in high dose males of both generations, and hyperkeratosis of the oesophagus in intermediate and high dose F_1 females. This increased incidence of hyperkeratosis of the oesophagus in the F_1 females, when there was no occurrence in the F_0 generation, may be explained either by the younger age of these animals at the start of treatment possibly increasing susceptibility to this lesion at this site, or by the longer duration of exposure to folpet in the F1 generation increasing the opportunity for the lesion to develop. (The lesion was seen only on examination of adult animals, and not on examination of pups.) The hyperkeratosis reflects the direct irritant agent of the compound, and whether oesophageal or in the non-glandular stomach has origin in a similar tissue type by the same mechanism. It shpuld be noted that direct exposure to the F1 animals starts prior to weaning, and by the time of weaning the amount of test material consumed is, on a bodyweight basis, 2-3x the amount consumed by		the data. Data requirement still open. Open point: Open point confirmed. Open point still open.

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2(5)	*continued* Vol. 1, 2.3.3	an adult rat. Thus no quantitative difference in susceptibility is demonstrated by this F1 finding, but rather the effects of the increased feed consumption and lower body weights during the rapid peri-weaning growth period. In a second two generation study (Richter 1985), with each generation producing two litters, administration of 3,600 ppm in the diet resulted in lower body weights and food consumption in the F_0 males and in the F_1 males and females, although the F_1 female body weight change was comparable to the controls. Mean pup weights in all litters were reduced by Day 21 in the F_0 generation and on Days 14 and 21 in the F_1 generation. There were no effects at 800 or 200 ppm administration. There were no effects on the mating performance, pregnancy rates, fertility indices, gestation periods and litter sizes at any of the dose levels in the F_0 generation. There was a slight decrease in the pregnancy rate and fertility index for both matings with the F_1 animals in the intermediate and/or high dose groups but was not significant; other indices and litter sizes for the F_1 generation were without effect. There were no treatment–related findings at the macroscopic and microscopic examinations (it should be noted that stomach tissues were not examined microscopically in		

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2(5)	*continued* Vol. 1, 2.3.3	this study). The multigeneration studies performed with folpet do not include assessment of all of the latest guideline reproductive parameters (vaginal smears were taken, but spermiology and hormonal assessments were not performed). There is no need to perform further investigations, as the present studies showed a definite adult maximum tolerated dose (MTD), with no adverse effects on reproduction. There were no adverse histopathological findings in testes of rodents or dogs in longer-term studies, and no indication of a dominant-lethal effect. There is no need to investigate specific possible effects of folpet on hormonal systems, because the half-life of Folpet in blood is so short (4.9 seconds, see Point IIA 5.1/05), any active substance that may be systemically available would degrade rapidly. The multi-generation studies of folpet were conducted using the same rat strain and similar conditions of exposure. Thus the data may be combined in a weight-of-the-evidence assessment to derive the NOEL for the critical reproductive or developmental effect. Neither study demonstrated significant reproductive toxicity potential for folpet, up to the highest dose tested (5,000 ppm in the Rubin		

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2(5)	*continued* Vol. 1, 2.3.3	study). Adult toxicity included decreased weight gain and hyperkeratosis of the oesophagus and non-glandular stomach at 1,500 ppm and higher in the Rubin study, and decreased weight gain in the Richter study at 3,600 ppm. (Stomachs were not evaluated microscpically in the Richter study.) The NOEL for the body weight effect in the Richter study was 800 ppm. This was also the NOEL for hyperkeratosis of the stomach at one year in the Cox 1985 chronic toxicity oncogenicity study which was conducted with SD rats. Thus an adult NOEL can with confidence be set at 800 ppm, using the data from both reproductive toxicity studies, supplemented by the one-year data form the chronic toxicity study using the same rat strain. Toxicity to the pups was limited to decreased body weight gain in both studies. This was evident in the Rubin study at dose of 1,500 ppm ; the weight gain decreases were slight but statistically significant at PND 21 of the F0 generation. In the Richter study, this finding was made at 3,600 ppm, but not at 800 ppm. Taking the two reproductive toxicity studies together, the NOEL for this critical developmental effect is 800 ppm, which is equivalent to approximately 40 mg/kg bw/day.		

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2(5)	*continued* Vol. 1, 2.3.3	[Note this effect was used as the driving effect/study for the AOEL; however, in drafting the original monograph, the two reproductive studies were not analyzed together, leading to the erroneous conclusion that the NOEL was 12.5 mg/kg bw/day.] Full and detailed comments on all aspects on the reproductive toxicity and teratogenicity of folpet will be presented in a position paper to be included in the addendum to be submitted to the RMS.		
2 (6)	Vol. 1, 2.3.6, Impact on human and animal health	Oct 04 DE: The numeric value of the suggested systemic AOEL [0.1 mg/kg bw/d (4)], is slightly lower than proposed by the RMS [0.125 mg/kg bw/d]. A new risk assessment would not be needed. Also with a systemic AOEL of 0.1 mg/kg bw/d, no risk would be anticipated under the proposed conditions of use, even without PPE (German model)	Nov 04 RMS: A new risk assessment should be performed in the addendum, taking into account the new AOEL.	Open point MS to agree on the AOEL at an expert meeting. See also comments 2(5), 2(9), 2(10), 2(11), 2(13) and 2(32), Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

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2 (7)	Vol. 1, 3.1, Background to the proposed decision, paragraph on classification and labelling	Oct 04 DE: Indeed, folpet is classified as "Harmful by inhalation". However, the appropriate risk phrase is not R22 but R20.	Nov 04 RMS: We agree	Addressed List of endpoint has been amended
2 (8)	Vol. 1, 2.3.2 and Vol.3, B.6.10.1, ADI	Oct 04 DE: Proposal: An ADI of 0.1 mg/kg bw is suggested, based on the NOAEL of 10 mg/kg bw/d in the 12-month dog study and supported by the NOAELs obtained in the long-term and multigeneration rat studies and the developmental toxicity study in rabbits. In principle, the proposed ADI of ~~1.25~~ **0.125** mg/kg bw that was established on the basis of the NOAEL (ca 12.5 mg/kg bw/d) in the long-term study in rats could be agreed with, too. However, this numeric value would be (1) higher than the proposed ARfD of 0.1 mg/kg bw, and (2) higher than the ADI suggested for the closely related compound captan although the definition of residues comprises both active ingredients ("sum of captan and folpet"). A slightly lower ADI of 0.1 mg/kg bw would be also in compliance with the conclusions of the 1995 JMPR.	Nov 04 RMS accepts the suggestion of establishing an ADI of 0.1 mg/kg b.w. based on the NOAEL of 10 mg/kg b.w. derived from one year dog study (safety factor 100)	Open point RMS to provide more detailed summary of studies leading to the derivation of the ADI value to be discussed at an expert meeting See also comments 2(13) and 2(31). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

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2 (9)	Vol. 1, 2.3.4 and Vol. 3, B.6.10.3, AOEL	Oct 04 DE: Proposal: An AOEL of 0.1 mg/kg bw is suggested, based on the NOAEL of 10 mg/kg bw/d in the 12-month dog study and supported by the NOAELs obtained in the developmental toxicity study in rabbits. The numeric value is slightly lower than proposed by the RMS. However, the AOEL should be derived from so-called mid-term studies. Taking this approach, the subchronic dog study and the rabbit teratogenicity study appear to be best-suited.	Nov 04 RMS: (see comment 5)	See open point in comment 2(6). See also comments 2(5), 2(10), 2(11), 2(13) and 2(32).
2 (10)	Vol. 1, 2.3.4, Vol. 3, BB.6.10.3, list of end points, Derivation of AOEL	Oct 04 NL: Since the dog is clearly more sensitive in short term studies, the AOEL should be based on the NOAEL of 10 mg/kg bw/d in the 1 y dog studies.	Nov 04 RMS: (see comment 5) .	See open point in comment 2(6). See also comments 2(5), 2(9), 2(11), 2(13) and 2(32).
2 (11)	Vol. 1, 2.3.6, Impact on human and animal health	Oct 04 DE: The numeric value of the suggested systemic AOEL [0.1 mg/kg bw/d (4)], is slightly lower than proposed by the RMS [0.125 mg/kg bw/d]. A new risk assessment would not be needed. Also with a systemic AOEL of 0.1 mg/kg bw/d, no risk would be anticipated under the proposed conditions of use, even without PPE (German model)	Nov 04 RMS: (see comment 5)	See open point in comment 2(6). See also comments 2(5), 2(9) and 2(10).

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2 (12)	Vol. 1, 4.6, and Vol 3, B.6.6 reproductive toxicity	Oct 04 NOT: The DAR volume 1 concludes that new teratogenic studies in rat and rabbit are required with histopathological examination of the gastro-intestinal tract of the mothers. Based on several factors (see below), we believe no useful information would be gained from further reproductive or developmental toxicity studies conducted with folpet. NOT: Reproductive toxicity studies The NOEL for effects on pup body weight for folpet in reproductive toxicity studies is revised from 12.5 mg/kg bw/day to 40 mg/kg bw/day, based on a weight-of-the-evidence evaluation of the two studies. This dose level is equivalent to the parental NOEL, demonstrating a lack of unique susceptibility of the young to folpet toxicity. Using 12.5 mg/kg bw/day as the basis for the folpet AOEL as currently recommended provides a very conservative additional margin of safety for risk extrapolation. Developmental toxicity studies We concur with the RMS reviewer that the axial abnormalities observed at maternally toxic dose levels in several folpet developmental toxicity studies may be related to the maternotoxic effect	Nov 04 RMS: Noted	See open points in comments 2(5) and 2(26) See also comments 2(9) 2(10) and 2(11) and data requirement in comment 2(5).

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2(12)	*continued* Vol. 1, 4.6, and Vol 3, B.6.6 reproductive toxicity	elicited by folpet on the gastrointestinal tract. In addition to the noted irritant action of folpet on the gastrointestinal mucosae, high bolus gavage doses of folpet are likely to adversely affect the intestinal flora, leading to nutrient malabsorption or deficiencies. The developmental NOAELs for folpet are 150 mg/kg bw/day and 40 mg/kg bw/day, for the rat and rabbit, respectively. There is no evidence of unique susceptibility of the foetus to folpet, and a weight-of-the- evidence evaluation does not support a conclusion that folpet is teratogenic. Further, distribution of folpet to the foetus is considered unlikely because of the very short half-life of folpet in aqueous media, and the primary metabolite phthalimide produced no malformations in a supplementary teratogenicity evaluation in rabbits. Conclusion The existing database provides adequate information regarding the reproductive and developmental toxicity of folpet to permit informed and conservative risk assessment. There is no evidence that there is any unique developmental susceptibility of the developing young to folpet. Further reproductive or		

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2(12)	*continued* Vol. 1, 4.6, and Vol 3, B.6.6 reproductive toxicity	developmental toxicity testing of folpet should not be required Response to the Requirement for Further Reproductive or Developmental Toxicity Studies of Folpet The existing database provides adequate information regarding the reproductive and developmental toxicity of folpet to permit informed and conservative risk assessment. For reproductive toxicity evaluation, we concur with the RMS reviewer that in cases where the studies are not congruent with existing guidelines, the absence of any evidence of reproductive toxicity in a study producing overt toxicity to the parental animals suggests no additional useful information would be obtained from further studies. For developmental toxicity evaluation, we respectfully disagree with the reviewer that additional useful information would be obtained through replication of the rat and rabbit developmental toxicity studies, and that animals and resource expenditure in such an effort is therefore not justifiable. The basis for our conclusion is that: • Existing studies comply with Guidelines in		

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2(12)	*continued* Vol. 1, 4.6, and Vol 3, B.6.6 reproductive toxicity	effect at the time the studies were performed, and provide information on the most critical elements in current Testing Guidelines. • NOELs are available for all endpoints of concern, • Folpet does not show unique evidence of developmental susceptibility, and a weight-of-the evidence evaluation does not support a concern for teratogenicity. The one remaining question is that the postulated mechanism for maternotoxicity resulting in the axial respecifications observed in several developmental studies of folpet at maternally toxic dose levels has not been clearly demonstrated in the existing data. If this mechanism were confined to nutritional deficiencies resulting from gastrointestinal irritation, it could possibly be demonstrated through histopathological evaluation of the maternal gastrointestinal tract. However, it seems likely that the bacteriostatic action of folpet when administered in high gavage doses also plays a significant role in subsequent maternal nutrient deficiencies, contributing to the axial respecifications observed in some studies of captan. Such a mechanism would not		

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2(12)	*continued* Vol. 1, 4.6, and Vol 3, B.6.6 reproductive toxicity	be possible to demonstrate in a conventional developmental toxicity study, and it is difficult to conceive of a study design to adequately test this mechanism. Folpet is used commercially as a bacteriostat in cosmetic formulations, and evidence of bacteriostatic action of captan (which is a closely structurally related chemical) is available in the published literature. Based on these factors, we believe no useful information would be gained from further developmental toxicity studies of folpet. Full and detailed comments on all aspects on the reproductive toxicity and teratogenicity of folpet will be presented in a position paper to be included in the addendum to be submitted to the RMS		
2 (13)	Vol.3. B.6 General comment	Oct 04 EFSA: The results in the studies are sometimes poorly described. There is a lack of informative tables and/or the effect as % of control and if it as NOEL or a NOAEL value. The concentration of the compound is often presented in ppm without demonstrating the corresponding value in mg/kg bw/day. Furthermore, the conclusions are very brief and in some cases even lacking.	Nov 04 RMS: noted. More details will be reported in the addendum	See open points in comments 2(1), 2(4), 2(5), 2(6) and 2(8), and comments 2(9), 2(10), 2(11), 2(31) and 2(32).

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2(13)	*continued* Vol.3. B.6 General comment	The provision of an addendum where more information is provided, for instance for the studies being considered as crucial for setting of ADI, AOEL and ARfD, would be appreciated in order to increase understanding and transparency. Proposed studies are: B.6.3. one year dog study (Daly 1986) B.6.5. 2-year rat study (Crown, 1989) B.6.6. 2-generation reproduction, rat (Rubin, 1986) B.6.6. teratogenicity study, rabbit, (Rubin 1985c)		
2 (14)	Vol. 3, B.6.1.1	Oct 04 A study to measure the half-life of folpet in whole blood is included in the DAR (see page 13 of Volume 3). A new study is available which reports the half-life of thiophosgene (a folpet degradate) in human blood. A method to measure the presence of thiophosgene in human blood was developed. Blood was fortified with thiophosgene, quenched with an acidic acetone solution and the remaining thiophosgene was derivatized to the	Nov 04 RMS: The new study and the evaluation will be included in the addendum	Data requirement Notifier to submit the new toxicokinetic study Arndt and Dohn (2004). Evaluation Meeting (14.-15.12.2004): The notifier has already submitted the requested study. Data requirement still open.

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2(14)	*continued* Vol. 3, B.6.1.1	cyclic compound (R)-2-thioxo-4-thiazolidinecarboxylic acid using L-cysteine and analyzed by HPLC-UV. Pre-quenched blood fortified with 10, 30 and 100 µg/mL thiophosgene resulted in an average recovery of 42% ± 8.6%. The method was employed to measure the half-life of an exaggerated concentration of thiophosgene (100 µg/mL) in human blood. Thiophosgene was added to 10 human blood samples (at 37˚C) and allowed to react for times ranging from 1.9 seconds to 31.1 seconds. The reactions were then arrested and the remaining thiophosgene was determined. The thiophosgene % recovered data was normalized to account for a threshold level of about 1% found in samples reacted for at least 7 seconds believed to be attributed to saturation of the relevant blood nucleophiles by the exaggerated rate of thiophosgene employed. An exponential equation (of the form $y = a + b*\exp^{(-k*x)}$) was used to fit the normalized % thiophosgene recovered vs. reaction time data with a correlation coefficient of > 0.99 when the data point of 100% recovery at time zero is assumed. The half-life of thiophosgene in human blood was found to be 0.6 seconds. This study		

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2(14)	*continued* Vol. 3, B.6.1.1	demonstrates why neither folpet (with the DT_{50} of 4.9 sec. in human blood) nor thiophosgene are likely to reach sensitive target distant to the mucosal surface of the gastrointestinal tract and as part of the mechanism data it further supports the folpet mode of action. The new study is listed below: **"Arndt, T and Dohn, D. (2004). Measurement of the Half-Life of Thiophosgene in Human Blood. PTRL West unpublished report number 1146W-1"** This new study and our evaluation of this study (in Tier 2 format) will be included in the addendum to be submitted to the RMS		
2 (15)	Vol. 3, B.6.2.3, Acute inhalation toxicity	Oct 04 UK: Evidence of respiratory irritation was seen in this study (Cracknell, 1983); this finding is also consistent with the known mechanism of action of the breakdown product thiophosgene. Consideration should therefore be given to classification of folpet as 'Irritating to respiratory system' (R37).	Nov 04 RMS: On the basis of the data we support the classification R 20= harmful by inhalation The active substance will be classified as Xn R20 Harmful by inhalation, based on deaths in an acute (4-hour) inhalation toxicity study. The Directive (67/548, as amended by 2001/59) is quite clear in defining the criteria for R37: there should be evidence that the substance or preparation can cause serious irritation to the respiratory system based on practical observations in humans, or positive	Open point MS to discuss the irritating properties, also in relation to classification, at an expert meeting. See also comments 2(16) and 2(33). Evaluation Meeting (14.-15.12.2004):

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2(15)	*continued* Vol. 3, B.6.2.3, Acute inhalation toxicity		results from appropriate animal tests.	Open point confirmed. Open point still open.
2 (16)	Vol. 3, B.6.2.5, Eye irritation	Oct 04 UK: We consider that the severity and irreversibility of the findings in the eye irritation study (Dreher, 1992c) warrant R41 classification.	Nov 04 RMS: On the basis of the data we think that the classification R 36 = Irritating to eyes is sufficient. The weight of evidence shows that eye damage is restricted to surface areas (including the cornea) but that these insults do recover.The collective eye irritation study data, however, do not support the "irreversible" nature of the adverse effects.	See open point in comment 2(15). See also comment 2(33).
2 (17)	Vol.3, B.6.3.2, Short-term toxicity studies in the rat	Oct 04 UK: It is not considered possible to determine a NOAEL for the 90-day rat study (Reno, 1981), as histopathology was not performed on the stomachs of rats from the lower dose groups.	Nov 04 RMS agrees	Open point MS to agree on NOAEL in rat 90-day study at an expert meeting. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

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2 (18)	Vol.3, B.6.4.2.2, *In vivo* genotoxicity studies in germ cells	Oct 04 UK: An additional published study (Collins, 1972a) reporting a positive result in a rat dominant lethal assay with folpet following oral and intraperitoneal dosing must be taken into consideration.	Nov 04 RMS: The study by Collins cited will be described under the item B.6.4.2.2. However, despite the statistical significance, the relevance of the experimental findings of the study in relation to the assessment of genotoxicity of folpet in germ cells is doubtful: genetic damage mainly results in pre-implantation losses, with the reduction of the number of implants per pregnancy. In this study, an increased incidence of early death is reported, with no concurrent reduction in the mean number of implants.	Open point The RMS to summarize the the study (Collins, 1972a) in an addendum. See also open point in comment 2(19) and comments 2(20), 2(21).and 2(29). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
2 (19)	B.6.4.3.1 Genotoxicity	Oct 04 DK consider classification for genotoxicity. Folpet induces a wide range of genotoxic events in vitro including gene mutations/DNA damage in bacteria and mammalian cells, chormosomal aberrations in mammalian cells and mitotic recombination in yeast (not present in DAR). Although folpet was active in both the +/- S9 activation, the response was generally more pronounced without S9 activation.	Nov 04 RMS: Folpet does not meet the EC classification criteria for mutagenicity (as laid down in Commission Directive 2001/59/EC). Classification on the basis of in vitro test results is only exceptionally considered, i.e. for substances with no in vivo data and structural resemblance with known mutagens/carcinogens.	Open point MS to discuss the genotoxicity, also in relation to classification, and the need of additional studies to be performed at an expert meeting See also open point in comment 2(18) and comments 2(20),

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2(19)	*continued* B.6.4.3.1 Genotoxicity			2(21).and 2(29). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
2 (20)	Vol.3, B.6.4.3, Summary of genotoxicity studies	Oct 04 UK: A number of additional studies of the genotoxicity of folpet *in vivo* are available. These include a mouse spot test (negative), a mouse dominant lethal assay (negative, but concerns about the study quality) and the rat dominant lethal assay discussed above. All studies should be considered. The relevance of the tissues investigated in each study should also be considered, given the known rapid degradation of the folpet molecule and the likely reactive species.	Nov 04 RMS: Apart from the study by Collins (1972), the other in vivo studies mentioned are already duly described under B6.4.2.1. and B.6.4.2.2 and considered in the Summary of genotoxicity studies (B.6.4.3), where the plausibility of internal exposure in relation to the short half-life of folpet is discussed.	See open points in comments 2(18) and 2(19) and comments 2(21) and 2(29).

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2 (21)	Vol.3, B.6.4.3, Summary of genotoxicity studies	Oct 04 UK: Given the positive studies *in vitro* and conflicting *in vivo* data, we consider that further reassurance must be provided as to the genotoxicity of folpet in the mouse. An *in vivo* assay in the mouse gastro-intestinal tract, e.g. a comet assay, is considered to be preferable.	Nov 04 RMS: In vivo studies on folpet are not contradictory but almost uniformly negative (apart from the questionable study by Collins, 1972). The possibility of genotoxic effects at the site of contact is covered by the investigations carried out with captan, which can be considered a worst case compared to folpet because ot its longer half-life in body fluids. Indeed a comet assay in the g.i. tract can be considered to get further reassurance on the lack of genotoxicity in vivo, even though the interpretation of the experimental findings is likely to be complicated by the toxic effect exerted by folpet in the tissues analysed	See open points in comments 2(18) and 2(19) and comments 2(20) and 2(29).
2 (22)	Vol. 3, B.6.5.1, Long-term toxicity and carcinogenicity in the rat	Oct 04 UK: The endpoint used to determine the NOAEL in the study of Crown (1989) is considered to be appropriate; however the demonstrated decomposition of folpet in the diet should be taken into consideration. The NOAEL for this study is therefore calculated to be 190 ppm (equivalent to 12 and 16 mg/kg bw/d in males and females respectively).	Nov 04 RMS: Noted	Open point MS to confirm the NOAELs in the long term studies at an expert meeting. See also comments in 2(23), 2(24) and 2(25). Evaluation Meeting (14.-

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2(22)	*continued* Vol. 3, B.6.5.1, Long-term toxicity and carcinogenicity in the rat			15.12.2004): Open point confirmed. Open point still open.
2 (23)	Vol. 3, B.6.5.1, Long-term toxicity and carcinogenicity in the rat	Oct 04 UK: The NOAEL in the rat carcinogenicity study of Crown (1985) is considered to be 500 ppm, based on hyperkeratosis of the forestomach epithelium at 1000 ppm.	Nov 04 RMS agrees	See open point in comment 2(22). See also comments 2(24) and 2(25).
2 (24)	Vol. 3, B.6.5.2, Long-term toxicity and carcinogenicity in the mouse	Oct 04 UK: The NOAEL in the chronic mouse study of East (1994) is considered to be 150 ppm; the histopathological findings in the gastro-intestinal tract at 450 ppm are considered to be treatment-related.	Nov 04 The RMS agrees. EP amended	See open point in comment 2(22). See also comments 2(23) and 2(25).
2 (25)	B.6.5.3 (Long time toxicitity)	Oct 04 DK suggest classification for carcinogenicity. Based on the increased incidences of adenomas and carcinomas in the duodenum of male and female mice in two strains (CD-1 and B6C3F1). The highly reactive thiophosgene is most likely the metabolite responsible for duodenal tumor	Nov 04 RMS: see comment 2 (3)	See open points in comments 2(2) and 2(22). See also comments 2(3), 2(23) and 2(24).

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2(25)	*continued* B.6.5.3 (Long time toxicitity)	formation in mice. In rats, folpet was classified as a carcinogen in males based on an increase in the incidences of C-cell adenomas and carcinomas of the thyroid as well as interstitial cell tumors of the testes. There was no evidence of duodenal tumors in the rat; however, there was a dose related increase in incidence and severity of hyperkeratosis of the esophagus and stomac which may be due to thiophosgene. DK: The increase in the incidence of duodenal adenocarcinomas in the CD-1 mouse study occurred at relatively high doses. A similar response was observed in a 2-year feeding study with B6C3F1 mice.		
2 (26)	Vol.3. B.6.6. Developmental toxicity	Oct 04 EFSA: There seems to be evidence of teratogenic potential of folpet at maternal non-toxic doses both in rat and rabbit. Thus, classification of R63 is proposed.	Nov 04 RMS: after considering that folpet might exert its developmental toxicity through its primary effect on the g.i.-tract of the dams and could disrupt the normal g.i. flora, causing nutritional deficiencies, RMS is not convinved to classify Folpet as R 63 and proposes to discuss this subject in an expert meeting.	Open point Teratogenic properties, also in respect of classification and labelling, to be discussed at an expert meeting See also open point in comment 2(5) and comments 2(12), 2(27) and 2(28). Evaluation Meeting (14.-15.12.2004):

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2(26)	*continued* Vol.3. B.6.6. Developmental toxicity			Open point confirmed. Open point still open.
2 (27)	Vol. 3, B.6.6.2, Developmental toxicity in the rabbit	Oct 04 UK: The maternal NOAEL in the rabbit developmental study (Rubin, 1995) is considered to be 10 mg/kg bw, based on the slight initial reduced body weight gain at 40 mg/kg bw. Developmental effects however are not serious enough to warrant further investigation in either rat or rabbit, and might be expected given the level of maternal toxicity seen.	Nov 04 RMS agrees	See open point in comment 2(26). See also comments 2(5), 2 (12) and 2(28).
2 (28)	B.6.6.4 Reproducitive toxicity	Oct 04 DK suggests classification for developmental toxicity. Folpet caused an increase in the incidence of hydrocephaly in fetuses with associated domed skull and irregularly-shaped fontanelles in NZW rabbits in the presence of maternal toxicity. Both fetal and litter incidences of this malformation were increased. There was also evidence of fetal effects (delayed ossification of the sternebrae) in rabbits at a lover dose than that causing maternal toxicity.	Nov 04 RMS: See point 2 (26)	See open point in comment 2(26). See also comments 2(5), 2 (12) and 2(27).

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2 (29)	Vol.3 B.6.10, Summary of mammalian toxicity	Oct 04 UK: Further reassurance as to the *in vivo* genotoxicity of folpet is required, as detailed above. Until additional data are provided, no safe level of exposure can be assumed.	Nov 04 RMS does not agree that additional data would add more useful information	See open points in comments 2(18) and 2(19). See also comments 2(20) and 2(21).
2 (30)	Vol.3 B.6.10, Summary of mammalian toxicity	Oct 04 UK: Further consideration of the toxicological significance of the metabolites phthalimide and phthalic acid and their potential inclusion in the residue definition is required.	Nov 04 RMS: phthalimide, phthalamic acid and phthalic acid do not pose significant risk since they are excreted mostly within 24 hours after administration and show no potential of accumulation.	Open point MS to discuss the toxicity of the metabolites phthalimide and phthalic acid and their possible inclusion in the residue definition at an expert meeting. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open. See also comment 3(12).

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2 (31)	Vol.3 B.6.10.1, Acceptable Daily Intake	Oct 04 UK: The ADI should be derived from the lowest relevant NOAEL rather than just considering the NOAELs from the chronic toxicity studies. An ADI of 0.1 mg/kg bw/d can therefore be derived from the NOAELs of 10 mg/kg bw/d in the rat (Hobermann, 1983) and rabbit (Rubin, 1985) developmental studies and the 1-year dog study (Daly, 1986). A safety factor of 100 is appropriate.	Nov 04 The RMS agrees (see point 2 (8))	See open point in comment 2(8). See also comment 2(13).
2 (32)	Vol.3 B.6.10.3, Acceptable Operator Exposure Level	Oct 04 UK: The AOEL can be derived from the NOAELs of 10 mg/kg bw/d in the rat and rabbit developmental toxicity studies. An AOEL of 0.1 mg/kg bw/d is therefore appropriate. Correction for oral absorption is not required, as folpet was found to be well absorbed (>75%) in the rat following oral dosing.	Nov 04 RMS: see comment 2 (5)	See open point in comment 2(6) See also comments 2(5), 2(9), 2(10), 2(11) and 2(13).
2 (33)	Vol.3 B.6.11.3, Acute inhalation toxicity	Oct 04 UK: Based on the inhalation LC50 for folpet of 1.89 mg/l (Cracknell, 1993), the product should also be classified as 'Harmful by inhalation' (R20). Evidence of an irritant response was also seen in this study, therefore consideration should also be given to classification of the product as 'Irritating to respiratory system' (R37).	Nov 04 RMS: see comment 2 (15)	See open point in comment 2(15) See also comment 2(16).

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2 (34)	Vol.3 B.6.12, Dermal penetration	Oct 04 UK: The design of this study is sub-optimal as full-thickness skin was used. Additionally, 24-hour absorption following an 8-hour skin wash was not measured; figures for residual skin radioactivity and total recovery are not reported. It is therefore not possible to propose dermal absorption values of 1% from this study.	Nov 04 RMS: Folpet has a molecular weight of about 300, with log Pow of 3.017. A possible disadvantage of full-thickness skin is that lipophilic compounds may be retained in the dermis instead of entering into the receptor fluid. However, the overall evaluation of *in vivo* and *in vitro* studies indicates that Folpet is poorly absorbed through human skin, and that a figure of 1% is reliable.	Open point MS to discuss the dermal absorption value at an expert meeting. See also comment 2(36). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
2 (35)	Vol. 3, B.6.12, Dermal absorption	Oct 04 A: With respect to dermal absorption, there is an *in vivo* study* available (submitted for national registration in Austria) that is not evaluated in the DAR. As a result of this study (^{14}C-labelled Folpet has been applied), about 90 % of the applied dose were considered “absorbed” (based on amounts detected in excreta, carcass and in the skin). In the light of the results of this study, the proposed dermal absorption rate of 1 % (DAR) cannot be agreed upon.	Nov 04 RMS: This study was not submitted for EU registration and should be made availbale by the Notifier (to the RMS and to the MSs) and discussed in the addendum. Dermal penetration will be re-evaluated.	Data requirement The notifier to submit the study Wilson, 1990 (dermal absorption). Evaluation Meeting (14.-15.12.2004): AT stated that there is a dermal absorption study available which has not been evaluated so far. The notifier will submit the study

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2(35)	*continued* Vol. 3, B.6.12, Dermal absorption	*Wilson, A.S.: A Study of Dermal Penetration of ^{14}C-Folpet in the Rat, [redacted] Toxicol Study No. MAG/1/PH; 17.10.1990		as well as a clarification to the RMS in April 2005. Data requirement still open.
2 (36)	Vol. 3, B.6.12, Dermal absorption List of endpoints	Oct 04 NL: Disagree with the value of 1% for dermal absorption based on the information in the DAR. RMS concludes to a dermal absorption of 1%, based on an vitro study with rat and human skin and a publication of in vivo data in rats. The data are entirely based on the amount absorbed through the skin. No data are given for the amount of folpet in the treated skin (dermal depot) and its possible systemic availability. In the in vitro study the amount absorbed through the skin is much higher after 24 h than after 8 h exposure. This could (at least partly) be the result of dermal depot becoming systemically available. Without data on the dermal depot a higher value for dermal absorption should be considered. Since the study was done in a laboratory which always gives data on the dermal depot in its report, a better estimation of dermal absorption should be possible.	Nov 04 RMS: see comments 34	See open point in comment 2(34).

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2 (37)	Vol. 3, B.6.14.1, text below Table B.6.2.1.1.1: use of the UK predictive operator exposure model (POEM)	Oct 04 UK: The statement that 'the German model based on geometric mean values is considered appropriate for EC regulatory use' appears in PSD's guidance document for the German Model not the guidance document for the UK POEM as stated here. This guidance states that the accepted version of the German model (based on geometric mean values) should be used rather than the alternative version of the German model based on 75th percentile exposure values for EC evaluations. PSD has not suggested that the German model should be used in preference to the UK POEM. Therefore, the current version of the UK POEM (with exposure data for mixing and loading solid formulations) is an appropriate model to use (in addition to the German model) in this DAR.	Nov 04 RMS: The use of two models for operator risk assessment is not a requirement. The German model is appropriate and suitable to estimate exposure with Folpan 80WDG	Addressed
2 (38)	Vol. 3, B.6.14.1, Table B.6.2.1.1.1	Oct 04 UK: It is possible that grapevines may also be treated using hand-held sprayers.	Nov 04 RMS: The DAR contains an estimate of exposure for hand-held knapsack (for application to tomatoes). The recommended rate for tomatoes (1.6 kg a.s./ha) is higher than the recommended rate for grapes (1.5 kg a.s./ha). The worst case for operators using hand-held equipment is already addressed.	Addressed

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2 (39)	Vol. 3, B.6.14.1, exposure estimates for the use on grapevines.	Oct 04 UK: The EUROPOEM database has exposure values relating specifically to the use of tractor-mounted/trailed sprayers to treat grapevines. These data are more appropriate than those in the UK POEM or German models when considering this use.	Nov 04 RMS: The use of two models for operator risk assessment is not a requirement. The German model is appropriate and suitable to estimate exposure with Folpan 80WDG	Addressed
2 (40)	Vol. 3, B.6.14.1, exposure estimates for glasshouse uses	Oct 04 UK: Although neither the UK POEM nor the German model have data relating to indoor uses, the EUROPOEM database contains studies on the use of hand-held equipment in glasshouses. Exposure estimates based on these data are likely to be more appropriate than those presented.	Nov 04 RMS: Exposure in glass-houses should be estimated and reported in the Addendum.	Open point RMS to present an estimation of exposure in glass-houses in an addendum. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
2 (41)	Vol. 3, B.6.14.2, bystander exposure	Oct 04 UK: The bystander exposure estimate, based on published drift data, does not take into account inhalation exposure. It may be more appropriate to base this risk assessment on simulated bystander exposure studies which are available	Nov 04 RMS: Vapour pressure of folpet is low 2.1 x 10-5 Pa at 25oC. Inhalation risk is negligible.	Open point The bystander exposure needs to be discussed at an expert meeting. Evaluation Meeting (14.-

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2(41)	*continued* Vol. 3, B.6.14.2, bystander exposure	for orchard and field crops.		15.12.2004): Open point confirmed. Open point still open.
2 (42)	Vol. 3, B.6.14.3.1, worker exposure	Oct 04 UK: Although it is stated that workers are not expected to enter treated cereal crops, this may occur (for example, for crop inspection or roguing activities). An estimate for this situation can be calculated using the German worker re-entry exposure model in conjunction with appropriate published transfer coefficients.	Nov 04 RMS: Inspection of cereal crops is not likely to involve significant handling of treated cereals. Furthermore, worker exposure assessments have been provided for tomatoes which are treated at 1.6 kg a.s/ha, more than twice the recommended rate for cereals (0.75 kg a.s./ha). Therefore, the worst-case for workers has been addressed.	Addressed
2 (43)	Vol. 3, B.6.14.3, worker exposure	Oct 04 UK: As repeat applications can be made on all crops (with a maximum of 10 applications being supported on grapevines), an assessment of the risks to workers resulting from the build up of foliar residues would be useful, possibly based on the residue decline data mentioned briefly in this section.	Nov 04 RMS: The notifier states that up to 10 applications are recommended on grapes over a period of approximately 6 months (from shoot emergence up to ripening). According to the exposure estimate in the DAR, no risk would be anticipated, even in the case of 10 applications over a shorter period of time, because of the large margin of safety. The available residue decline data should still be	Open point MS to discuss available residue decline data with respect to worker exposure at an expert meeting. Evaluation Meeting (14.-15.12.2004):

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2(43)	*continued* Vol. 3, B.6.14.3, worker exposure		considered and discussed with regard to worker exposure estimate.	Open point confirmed. Open point still open.

3. Residues

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3 (1)	Vol. 1, 2.4.4, Proposed EU MRLs and compliance with existing MRLs	Oct 04 AT: There are no currently EU-MRLs for cereals; 0.1 mg/kg for other products according to Directive 1976/895/EEC does not include cereals	Nov 04 RMS: Correct.	Addressed RMS to provide an addendum/corrigendum or to consider a revised DAR.
3 (2)	Vol. 1, list of endpoints, summery of critical residues data, page 64	Oct 04 AT: editorial advice: due to the formatting of page 64, the last two columns of the table "Summery of critical residues data (Annex IIA, Point 6.3) are missing in the hardcopy	Nov 04 RMS: OK	Addressed RMS to provide an addendum/corrigendum or to consider a revised DAR.
3 (3)	Vol. 1, level 3, 3.2 Proposed decision concerning annex I inclusion	Oct 04 EFSA: We note that an annex I inclusion is proposed although a complete risk assessment for the safety of the consumer is not yet achieved. Acute risk assessment is still to be done and no data are at this stage available concerning the effect of processing on the nature of residues.	Nov 04 RMS: Correct. Inclusion is at the moment pending. A complete risk assessment is needed before inclusion.	Open point RMS to prepare an acute risk assessment in an addendum to be discussed in expert meeting. See also comments 3(5), 3(18), 3(19), 3(20), 3(21) and 3(22). Evaluation Meeting (14.-15.12.2004):

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3 (3)	*continued* Vol. 1, level 3, 3.2 Proposed decision concerning annex I inclusion			Open point confirmed. Open point still open.
3 (4)	Vol. 1, level 4, 4.7, Further residue data needed	Oct 04 EFSA: We agree with the data requirements proposed by RMS, namely Two greenhouse trials for tomato A hydrolysis study, in representative hydrolytic conditions A whole balance study for tomato washed, peeled and canned or used for juice, 3 follow-up studies in juice and canned tomato.	Nov 04 RMS: no comments	See data requirements in comments 3(5), 3(6) and 3(7).
3 (5)	Vol. 1, 4.7, and Vol 3, B.7.7.1 effects of processing on the nature of the residue	Oct 04 NOT: The DAR Volume 1 concludes that a hydrolysis study in representative hydrolytic conditions is required. It is concluded that sufficient data already exist to predict the effect of processing hydrolysis on the nature of the residue and therefore new studies are not required.	Nov 04 RMS: Specific hydrolisis studies are required in specific pH and temperature conditions. Such studies, in such conditions, are not available and therefore are still required. See also comment from EFSA, point 4. We will examine the mentioned position paper when available.	Data requirement Notifier to provide hydrolysis studies in representative hydrolytic conditions. Evaluation Meeting (14.-15.12.2004): The notifer has already submitted

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3(5)	*continued* Vol. 1, 4.7, and Vol 3, B.7.7.1 effects of processing on the nature of the residue	NOT. Hydrolysis studies with folpet have already been conducted and are considered to be adequate to evaluate the effects of processing. Under acid conditions (pH5) [carbonyl-^{14}C] folpet degraded rapidly to phthalimide with phthalamic acid and phthalic acid also observed at lower levels. Under neutral conditions (pH7) the same metabolites were observed, but with the amounts formed shifted in favour of phthalic acid. Phthalimide is hydrolysed, via phthalamic acid, to phthalic acid. Phthalic acid is the stable end point of [carbonyl-^{14}C] folpet hydrolysis under acid and neutral conditions. In the study with [trichloromethyl-^{14}C] folpet, the primary metabolite formed under acid and neutral conditions (pH5 and pH7) was carbon dioxide. The pH conditions of the proposed simulated processing study (pH, 4, 5 and 6) would expose folpet residues to the same conditions as those described in the above tests. Therefore the stable hydrolytic end points (phthalic acid and carbon dioxide) are expected to be the same. The only effect of increased temperature in a simulated processing study will be to drive the hydrolytic reaction to its conclusion at a faster rate. At pH4 and 100°C phthalimide degrades with a half-life of 5.5 hours, considerably longer than the incubation time required in the proposed		the requested data in a position paper. Data requirement still open.

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3(5)	*continued* Vol. 1, 4.7, and Vol 3, B.7.7.1 effects of processing on the nature of the residue	tests. Therefore, studies under simulated processing conditions would only provide additional data on the rate of formation of the known degradation products and would not alter the route of degradation already established. The metabolites phthalimide and phthalic acid are not considered to be of toxicological concern because they were found in both plants and animals and do not form part of the definition of the residue in crops. Potentially toxic metabolites would not be formed during a simulated processing study and so a new study is not considered necessary. The requirement for a new study and the response to the data requirement is fully addressed in the following position paper: **"Folpet. Position Paper on Effects on the Nature of the Residue (2004)".** Will be included in the addendum to be submitted to the RMS		
3 (6)	Vol. 1, 4.7, and Vol 3, B.7.7.2 effects of processing on residue levels	Oct 04 NOT: The DAR Volume 1 concludes that new processing studies (1 balance plus 3 follow up studies) in tomato are required. Studies are ongoing.	Nov 04 RMS: no comments	Data requirement. Notifier to provide a whole balance study for tomato washed, peeled and canned or used for juice, 3 follow-up studies in juice

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3 (6)	*continued* Vol. 1, 4.7, and Vol 3, B.7.7.2 effects of processing on residue levels			and canned tomato. Evaluation Meeting (14.-15.12.2004): The notifier will submit the requested data in February 2005. Data requirement still open.
3 (7)	Vol. 1, 4.7, and Vol 3, B.7.6.1 residue trials in tomato	Oct 04 NOT: The DAR Volume 1 concludes that two new residue studies in greenhouse tomato are required. A new freezer stability study to validate additional crop residue studies in greenhouse tomato is ongoing. NOT: Some residue trials in greenhouse grown tomatoes submitted in the dossier were rejected by the RMS due to an excessive storage period between sampling and analysis (see page 188 of Volume 3 of the DAR). A new freezer storage stability study is ongoing and will be submitted to validate the rejected trials instead of conducting new trials in greenhouse tomatoes.	Nov 04 RMS: no comments	Data requirement. Notifier to provide 2 greenhouse residue trials for tomatoes. Evaluation Meeting (14.-15.12.2004): The notifier will submit the requested data in April 2005. Data requirement still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3 (8)	Vol. 3, B.7.1.a) Metabolism study in winter wheat	Oct 04 EFSA: There is a discrepancy between the results of the metabolism study and residue trials as far as the a.s. is concerned. In the metabolism study folpet was identified at a level of 8.56 mg/kg while its highest amount in residue trials was 0.13 mg/kg, with very similar rates of application. Can an explanation be given?	Nov 04 RMS: Treatment conditions in metabolism studies cannot be considered representative of field studies. Application of folpet to wheat in metabolism studies was carried out in a closed spray chamber. The use of this chamber is supposed to concentrated the treatment solution on the plants, therefore causing higher residues in the harvested crop.	Addressed
3 (9)	Vol. 3, B.7.1.b) Metabolism study in grapes	Oct 04 EFSA: In fruits, identified compounds and unknown 1 accounted for 85.88% of the TRR, while the rinsate and plant extracts represented in total 98.51% of the radioactivity. Is there an explanation for this apparent loss of radioactivity?	Nov 04 RMS: In the fruit, 54.03% of the TRR was present as water soluble radioactivity. This radioactivity was concentrated by solid phase extraction (SPE), resulting in a 77% recovery into methanol. The loss of radioactivity (23%) is therefore equivalent to 12.43% of the TRR and accounts for the difference between the two values.	Addressed

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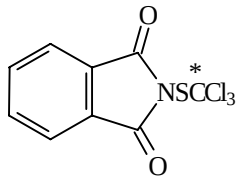
3 (10)	Vol. 3, B.7.2 Metabolism in livestock	Oct 04 EFSA Indication of the label position in the case [trichloromethyl-^{14}C] folpet seems not correct.	Nov 04 RMS: Correct. The correct label position for [trichloromethyl-^{14}C] is in Point IIA 6.2 of the dossier and is shown below: 	Addressed RMS to provide an addendum/corrigendum or to consider a revised DAR.
3 (11)	Vol. 3, B.7.2 Metabolism in livestock	Oct 04 EFSA: The exposure rate of the animals in both goat studies should be expressed in mg/kg bw as well to allow easier comparison with the expected exposure level calculated from the amount of residues in feedingstuffs.	Nov 04 RMS: Exposure rates expressed in mg/kg bw and a comparison with the doses used in metabolism studies will be included in Addendum.	Addressed RMS to provide an addendum/corrigendum or to consider a revised DAR.
3 (12)	Vol. 3, B.7.3 Residue definition	Oct 04 EFSA: Proposed residue definitions are understood as relevant for monitoring. With regard to the amount of metabolites present in the metabolism studies, the residue definition for risk assessment and the need for conversion factor(s) should be addressed.	Nov 04 RMS: The definition of the residue in plants for risk assessment is folpet only. The metabolites phthalimide and phthalic acid are not considered of toxicological concern. Moreover in wheat and grapes folpet represent the majority of the TRR.	Open point. MS to discuss the residue definition for risk assessment in an expert meeting. RMS to prepare an assessment of the toxicological relevance of metabolites (including their contribution to the toxicological

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3 (12)	*continued* Vol. 3, B.7.3 Residue definition			burden). See also comment 3(14). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
3 (13)	Vol. 3, B.7.3 Residue definition	Oct 04 EFSA: In products of animal origin, folpet cannot be considered as a valid indicator of the residue situation.	Nov 04 RMS: We consider folpet as the only possible indicator. Table B.7.2.4 shows that folpet administered to goats is rapidly transformed in muscle and milk in natural compounds.	Open point. MS to discuss the residue definition for animal commodities, including the need for it, in an expert meeting. See also comment 3(15). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

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3 (14)	Vol. 3, B.7.3, Residue definition in plants	Oct 04 UK: Residue definition does not address the relevance of the metabolites: phthalimide and phthalic acid. UK:These are major metabolites in plants and their toxicological relevance and therefore relevance to the residue definition in plants does not appear to have been addressed.	Nov 04 RMS: See point 3 (12.)	See open point in comment 3(12).
3 (15)	Vol. 3, B.7.3, Residue definition in animals	Oct 04 UK: Is it necessary to set a residue definition in animals as data indicate it is unlikely any residue will be present?	Nov 04 RMS: Residues might be present in animal commodities for greater levels of residues in feedstuffs and in case of extension to other supported uses might be necessary to fix MRL values for animal commodities. A residue definition might be therefore necessary.	See open point in comment 3(13).
3 (16)	Vol. 3, B.7.6.1 Residue trials in tomatoes	Oct 04 EFSA: Considering the fact that the storage stability of residues on tomatoes is weak, the freezer storage duration should be explicitly mentioned for tomatoes as key point of the acceptability of the trials.	Nov 04 RMS: OK. However, according to the Notifier A new freezer storage stability study in tomato is ongoing and will be submitted soon.	Addressed

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3 (17)	Vol. 3, B.7.12 Proposed MRLs	Oct 04 EFSA: the reason why the result at 0.13 mg/kg in wheat was disregarded for MRL proposal is not mentioned in the DAR.	Nov 04 RMS: In 7 trials residues of folpet in grain were 0.01 – 0.02 mg/kg. The value 0.13 mg/kg was considered an outlier.	Addressed
3 (18)	Vol. 3, B.7.12, Proposed Eu MRLs	Oct 04 DE: Based on UK consumption data and an ARfD of 0.1 mg/kg bw the proposed MRLs for tomato and grapes exceed the ARfD for toddlers. Tomato (var.factor 7): 125 %; Grapes (var.factor 5): 272 %. An acute dietary risk assessment must be made before an inclusion into Annex 1 can be proposed.	Nov 04 RMS: Correct for grapes. Our calculation for tomato gives different results. Using HR values of 2 mg/kg for tomato and 4.7 mg/kg for grape and the UK consumption data for toddler, the acute dietary intake is 256% of the ARfD for Grape and 82% for tomato. Considering the subsequently proposed ARfD of 0.1 mg/kg bw, the use of folpet in table grapes should be probably reconsidered. The ARfD is exceeded by more than 200% Using the UK consumption data for toddlers. According to Dutch comments the same is for adults and children using Dutch consumption data (see point 21).	See open point in comment 3(3).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3 (19)	Vol. 3, B.7.15 Estimates of dietary exposure	Oct 04 EFSA: Acute intake calculations have not been carried out.	Nov 04 RMS: The ARfD of 0.1 mg/kg bw was subsequently proposed. Acute intake calculations will be included in the addendum to the dossier	See open point in comment 3(3).
3 (20)	Vol. 3, B.7.15, Acute exposure assessment	Oct 04 UK: Acute risk assessment not complete. This is needed before the recommendation for Annex I listing can be assessed.	Nov 04 RMS: Correct. See point 3 (3)	See open point in comment 3(3).
3 (21)	Vol. 3, B.7.15, Acute exposure	Oct 04 NL : Although an ArfD has been proposed, no acute dietary intake calculations are presented in the monograph. On the basis of the Dutch food consumption survey (1997, 97.5% for large portions), we anticipate that the ArfD will be exceeded by the intake through table grapes (149% and 277%, for the general population and children from 1-6 years old respectively).	Nov 04 RMS: Correct. See point 3 (18)	See open point in comment 3(3).
3 (22)	Vol. 3, B.7.15, acute exposure	Oct 04 AT: considering the subsequently proposed ARfD of 0,1 mg/kg bw, the use of folpet in table grapes should be reconsidered. AT: Using the UK model for the determination	Nov 04 RMS: Correct. See also point 18	See open point in comment 3(3).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3 (22)	*continued* Vol. 3, B.7.15, acute exposure	of the acute intake, for toddlers the ARfD will be exceeded by 212% (using the HR of SEU 3.9 mg/kg).		

4. Environmental fate and behaviour

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4 (1)	Vol 1. List of end points. Mineralisation after 100d. p. 65.	Oct 04 EFSA: Preferably only mineralization form phenyl labelled folpet should be given of label position ot be indicated.	Nov 04 RMS: We consider that should be better to indicate the value for each label position. We will better specify in List end points	Addressed RMS has amended list of endpoints
4 (2)	Vol 1. List of end points. Rate of degradation in soil.	Oct 04 EFSA: Please include number of studies and range of r^2. Specify kinetic model. Specify parameters used for FOCUS modelling (mean or median DT_{50} normalised to 1okPa of pF2, 20oC with Q10 of 2.2).	Nov 04 RMS: We agree. EP amended	Open point RMS to amend the list of end points to give number of studies and range of r^2 and specify parameters used for FOCUS modelling (mean or median DT_{50} normalised to 1okPa of pF2, 20oC with Q10 of 2.2). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

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

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4 (3)	Vol 1. List of end points. PEC soil. Method of calculation.p. 67	Oct 04 EFSA: Please, indicate here kinetic used, soil depth, soil density and DT_{50}. Detailed formulas should preferably be removed from the list of end points.	Nov 04 RMS: . EP amended	Addressed RMS has amended the list of endpoints
4 (4)	Vol 1. List of end points. Distribution in w/s system.p.69 (active substance).	Oct 04 EFSA: It should be stated clearly if folpet is found in the sediment compartment.	Nov 04 RMS: We agree. We will amend when data will be available	Open point RMS to clarify if folpet or metabolites are found in the sediment. Evaluation Meeting (14.-15.12.2004): Open point confirmedn and reworded as: RMS to clarify if folpet or metabolites are found in the sediment in an addendum. Open point still open.

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

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4 (5)	Vol 1. List of end points. Distribution in w/s system.p.69.	Oct 04 EFSA: Preferably, indicate maximum amount of each metabolite in water and sediment phases.	Nov 04 RMS: We agree. EP amended	Addressed RMS has amended the list of endpoints
4 (6)	Vol 1. List of end points. PEC ground water. p. 70.	Oct 04 EFSA: Please indicate the model used for FOCUS modelling, the crops and if the nine scenarios have been considered.	Nov 04 RMS: . EP amended	Addressed RMS has amended the list of endpoints
4 (7)	Vol. 1, appendix 3, list of end points	Oct 04 FR: because 2 label positions were used, mineralization and non-extractable residues should be reported for each moiety.	Nov 04 RMS: See comment 4 (1)	Addressed
4 (8)	Vol. 1, appendix 3, list of end points	Oct 04 FR: from table B.8.1.1.6, the metabolites phthalamic acid and phthalic acid can exceed 10 % in aerobic soils. This should be reported in the end points.	Nov 04 RMS: We agree. EP amended	Addressed RMS has amended the list of endpoints
4 (9)	Vol. 1, appendix 3, list of end points	Oct 04 FR: the rate of degradation of the metabolites phthalamic acid and phthalic acid should be reported in the end points.	Nov 04 RMS: We agree it should be added. . EP amended	Open point RMS to report in the list of end points the rate of degradation of the metabolites phthalamic acid and phthalic acid.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(9)	*continued* Vol. 1, appendix 3, list of end points			Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
4 (10)	Vol. 1, appendix 3, list of end points	Oct 04 FR: it is not clear why the Freundlich adsorption parameters for phthalimide have not been reported in the end points.	Nov 04 RMS: Koc and Kd values are reported. Kf values should be added	Addressed RMS has amended the list of endpoints
4 (11)	Vol. 1, appendix 3, list of end points	Oct 04 FR: results from the aged residues leaching (Heintz, 2001) should be summarized in the end points.	Nov 04 RMS: We agree . EP amended	Addressed RMS has amended the list of endpoints
4 (12)	Vol. 1, appendix 3, list of end points	Oct 04 FR: the DT50 value used for PEC soil calculation should be specified in the end points.	Nov 04 RMS: We agree the value should be reported (4.3 days)	Addressed RMS has amended the list of endpoints
4 (13)	Vol. 1, appendix 3, list of end points	Oct 04 FR: the hydrolysis products should be reported in the end points.	Nov 04 RMS: We agree. EP amended	Addressed RMS has amended the list of endpoints

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4 (14)	Vol. 1, appendix 3, list of end points	Oct 04 FR distribution/amounts of folpet and its metabolites in water and sediment should be reported in the end points as well as DT50 values.	Nov 04 RMS: . EP amended	Addressed RMS has amended the list of endpoints
4 (15)	Vol. 1, appendix 3, list of end points	Oct 04 FR: values of the input parameters (DT50 and Koc) used for PECgw calculation should be reported in the end points.	Nov 04 RMS: . EP amended	See open point in comment 4(37).
4 (16)	Vol. 1, Appendix 3, Listing of endpoints	Oct 04 DE: In the table on PEC surface water (p. 70) no units are given. In the table on PEC sediment (p. 70) no values are reported (see comment No. 1 and No.4). In the table on toxicity data for aquatic species (p. 72) effect concentrations are given in mg/L, but the EAC appears in µg/L. Consistent reporting of units would be preferable.	Nov 04 RMS: Unit for PECsw, µg/L Values to be changed, to be consistent with units.	Open point RMS to indicate units of PEC sw in the list of end points. See also comment 4(17). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4 (17)	Vol. 1, List of endpoints, PEC surface water	Oct 04 AT: Concentration unit for PEC_{sw} is missing. Information about concentration of major metabolites is missing.	Nov 04 RMS: Unit for PECsw, µg/L.	See open point in comment 4(16).
4 (18) 4(18)	Vol. 1, Point 2.5.3, Fate and behaviour in water and Vol. 3, Point B.8.4.4, Water sediment studies *continued* Vol. 1, Point 2.5.3, Fate and behaviour in water and Vol. 3, Point B.8.4.4, Water sediment studies	Oct 04 DE: Considerable amounts of bound sediment residues of approx. 25% AR were detected 7 and 14 days after application of folpet. After 100 days, the residues decreased to approx. 10 %. Since folpet (1.5 kg a.s./ha) might be applied up to 10 times with weekly intervals, it is assumed that the bound residues will accumulate due to multiple application. This issue should be addressed in the discussion to this chapter and might also be of relevance in the risk assessment for aquatic compartment including the sediment dwelling organisms. The importance of this comment might increase, if it would be demonstrated that a large portion of the bound residues is still related to the parent compound that can be mobilised and/or taken up by sediment dwelling organisms	Nov 04 RMS: We agree It should be better to have more details on the bound residues and to identify the nature of the adsorbed residues to better understand if they may have an unacceptable impact on the environment (for bioavailability – biodegradradation and for the effect on sediment dwelling organism)	Data requirement Notifier to give more details on bound residues and on identity of the absorbed residue Evaluation Meeting (14.-15.12.2004): Data requirement confirmed and reworded as: Notifier to give more details on bound residues and on identity of the absorbed residue in the sediment. The notifier will provide a clarification in April 2005. Data requirement still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4 (19)	Vol. 1, Point 2.5.3, Fate and behaviour in water and Vol. 3, Point B.8.6, PEC in surface water and in ground water	Oct 04 DE: PEC calculations for surface water and sediment according to the Guidance Document on Aquatic Ecotoxicology (Sanco/3268/2001 rev.4 (final)) from October 17th, 2002, i.e. using the current FOCUS surface water modelling tools might yield more reliable data on the concentrations in sediment. Loading to surface water via spray drift was calculated using the spray drift tables of Ganzelmeier et al. (1995). PEC sediment values were not reported due to the rapid degradation of folpet in surface water. For the same reason, runoff and drainage were not considered for the parent compound. PEC surface water values for metabolites were calculated assuming a runoff event of 0.5 % of the applied product entering a standard water body 3 days after application. Since some essential input parameters and assumptions are different in the FOCUS models, the use of the current FOCUS software (FOCUS Steps 1-2 and FOCUS SWASH) would lead to different PEC values. At least at FOCUS-Step1/2 level, the PEC values are expected to be higher than those presented in the DAR. MS should discuss, whether the available information on the fate of the compound in	Nov 04 RMS: Should be better to conduct calculations of surface water PEC's according to FOCUS guidelines.	Open point MS should discuss in the evaluation meeting, whether the available information on the fate of the compound in water/sediment might justify the additional use of FOCUSsw steps 1-2 for PEC calculation. See also data requirement in comment 4(39). Evaluation Meeting (14.-15.12.2004): The meeting agreed that this open point needs to be reworded: The need for PEC sw and PEC sediment taking into account run-off and drainage to be discussed in an expert meeting. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(19)	*continued* Vol. 1, Point 2.5.3, Fate and behaviour in water and Vol. 3, Point B.8.6, PEC in surface water and in ground water	water/sediment might justify the additional use of FOCUSsw steps 1-2 for PEC calculation, even though they are usually not applied to second list compounds.		
4 (20)	Vol.1, list of end points, soil adsorption studies	Oct 04 SI: Please give the average/median value for the Koc as requested according to the guidance for the end point list.	Nov 04 RMS: We agree. . EP amended	Open point RMS to amend the list of end points to give the average/median value for the Koc as requested according to the guidance on the list of end points. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
4 (21)	Vol.1, list of end points, distribution in water-sediment systems (metabolites)	Oct 04 SI: Please mention maximum % in which individual metabolites were found in water phase and sediment phase.	Nov 04 RMS: See comment 4 (5)	Addressed RMS has amended the list of end points

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No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4 (22)	Vol. 1, List of endpoints, Classification and proposed labelling	Oct 04 AT: Classification and labelling with regard to fate and behaviour data are missing.	Nov 04 RMS: Agreed. . EP amended	Addressed RMS has amended the list of end points
4 (23)	Vol 3. B8. General.	Oct 04 EFSA: Acceptability and relevance of each study should be given.	Nov 04 RMS: Already included in the text of the study summary.	Addressed RMS to consider in the revised DAR and the list of essential studies. See also comments 4(24), 4(28), 4(29) and 4(45). Evaluation Meeting (14.-15.12.2004): See open point in 4(28) Open point confirmed. Open point still open.
4 (24)	Vol 3. B8. General.	Oct 04 EFSA: Reports are generally poorly quoted in the main text. In some sections, reports are not quoted at all. Please, amend.	Nov 04 RMS: Some minor modification to be made to DAR.	See comment 4(23).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4 (25)	Vol. 3, B.8.1.1, Aerobic and anaerobic studies	Oct 04 FR: in Table B.8.1.1.2, bound residues seem to have been underestimated (for example on day 14 fulvic acid fraction =14.6 % in text and bound residues = 9.2 % in table). Could this point be clarified.	Nov 04 RMS: Agree Data provided in the study report should be used to correct the values in the table.	Addressed RMS to consider in a revised DAR or corrigendum.
4 (26)	Vol. 3, B.8.1.1, Aerobic and anaerobic studies	Oct 04 FR: from Table B.8.1.1.2, the apparent DT50 for phthalimide is 7.3 d using linear 1st order for the 5-30 d period (R^2 0.81) at 25° C or 10.6 d at 20° C (1st order should be preferred instead of square root 1st order).	Nov 04 RMS agrees to revise to 1st order DT_{50} values	Open point RMS to revise to 1st order DT_{50} values for phthalimide in an addendum. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open. Addendum to be discussed in an expert meeting.
4 (27)	Vol. 3, B.8.1.1, Aerobic and anaerobic studies	Oct 04 FR: in table B.8.1.1.9 it is not clear why fulvic acid and humic acid fractions were excluded from bound residues. Could this point be	Nov 04 RMS agrees	Open point RMS to clarify amount of bound residues taking into account fulvic and humic acid in an addendum.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(27)	*continued* Vol. 3, B.8.1.1, Aerobic and anaerobic studies	clarified.		Evaluation Meeting (14.-15.12.2004): Open point confirmed. Addendum to be discussed in an expert meeting. Open point still open.
4 (28)	Vol. 3, B.8.1.1, Aerobic and anaerobic studies	Oct 04 FR: the second aerobic/anaerobic study should not be used (significant deviation from guideline). The first study suggests that anaerobic degradation could be similar to aerobic degradation but would occur at slower rate.	Nov 04 RMS agrees. The second study is a guideline study. The first study contains useful supporting information.	Open point RMS to clarify wich aerobic/anaerobic studies are essential for the assessment. See also comment 4(23). Evaluation Meeting (14.-15.12.2004): Open point reworded at the meeting as: RMS to clarify wich aerobic/anaerobic studies are acceptable and essential for the assessment.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4 (28)	*continued* Vol. 3, B.8.1.1, Aerobic and anaerobic studies			Open point confirmed. Open point still open. Addendum to be discussed in an expert meeting.
4 (29)	Vol 3. B.8.1.3 Field studies.	Oct 04 EFSA: Field soil degradation studies should not be considered essential since: 1) there are not required by the directive in this case, 2) are not necessary to refine risk assessment and 3) do not reflect the fate of folpet under European field conditions. (Note for the list of essential studies).	Nov 04 RMS: We agree: field studies are not essential, but could be useful as supporting data	Addressed. See also comment 4(23).
4 (30)	Vol 3. B.8.1.4. Summary and assessment. Table B.8.1.4.1.	Oct 04 EFSA: R^2 should be indicated for each determination. Normalised DT_{50} to 1okPa of pF2, 20oC with Q10 of 2.2 should be calculated for FOCUS ground water modelling.	Nov 04 RMS agrees. This would need to be calculated, where not provided	Open point RMS to provide r^2 for each determination and normalised DT_{50} in an addendum. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Addendum to be discussed in an

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4 (30)	*continued* Vol 3. B.8.1.4. Summary and assessment. Table B.8.1.4.1.			expert meeting. Open point still open. Addendum to be discussed in an expert meeting.
4 (31)	Vol 3. B.8.1.4. Summary and assessment.	Oct 04 EFSA: Degradation of the thio(trichloromethyl) side chain is addressed with some studies of the active substance captan. These studies should be properly summarised and included in the list of references relied on. Formation of thiophosgene should be assessed.	Nov 04 RMS: Relevant Captan studies to be included.	Open point RMS to provide an addendum with a summary of studies that address the fate of side chain of folpet. Formation of thiophosgen should be addressed. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Addendum to be discussed in an expert meeting. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4 (32)	Vol. 3, B.8.2.1, Adsorption and desorption	Oct 04 FR: Koc for phthalamic acid and phthalic acid has been estimated by means of the EWIWIN program but this is not described in the monograph. This point should be completed.	Nov 04 RMS: Agree. Further details to be added to DAR from study report	Open point RMS to provide an addendum with Koc estimation of phthalamic acid and an assessment of its reliability. See also comment 4(33). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Addendum to be discussed in an expert meeting. Open point still open.
4 (33)	Vol 3. B.8.2.1. Adsorption / desorption.	Oct 04 EFSA: Acceptability of EWIWIN program to determine Koc of folpet metabolites should be discussed and justified.	Nov 04 RMS: Text from study report to be transferred to DAR.	See open point in comment 4(32)

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4 (34)	Vol.3, B.8.2.1 Adsorption and desorption	Oct 04 SI: The value of 1/n is too low for the loam soil (EUROSOIL 3) and sand soil (LUFA 2.1) in the study of Geffke, 2000. This means that adsorption/desorption behaviour is not adequately described by the Freundlich theory. Corresponding Koc values should not be further considered in the risk assessment.	Nov 04 RMS: The comment refers to the 1/n value for the desorption step. The values for the adsorption step are higher and these are the values that should be used.	Open point Acceptability of Koc for soils loam EUROSOIL 3 and sand soil LUFA2.1 to be discussed in an expert meeting. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
4 (35)	Vol 3. B.8.4.4. Water sediment studies.	Oct 04 EFSA: The underlaying kinetics under the ”computerized statistical model” used to calculate the degradation parameters should be given.	Nov 04 RMS: Agree. This can be added where available in the study report. Where not available, re-calculation can be carried out.	Open point RMS to provide an addendum to clarify and assess kinetic models employed to evaluate water sediment studies. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Addendum to be discussed in an expert meeting.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4 (35)	*continued* Vol 3. B.8.4.4. Water sediment studies.			Open point still open.
4 (36)	Vol. 3, Point B.8.4.4, Water sediment studies	Oct 04 DE: The first sentence is not complete ("The degradation… was investigated… in accordance…" with?).	Nov 04 RMS: Insert missing wording " in accordance with SETAC/BBA guidelines in a 1999 study."	Addressed RMS to consider in a revised DAR or corrigendum.
4 (37)	Vol 3. B.8.6. PEC ground water.	Oct 04 EFSA: The input parameters used for FOCUS ground water simulations and the rationale for their selection should be given in the DAR.	Nov 04 RMS: Agree. Study summary in DAR to be expanded.	Open point RMS to provide an addendum with an expanded summary of FOCUS gw modelling and recalculations if necessary. See also comments 4(38) and 4(42). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Addendum to be discussed in an expert meeting. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4 (38)	Vol. 3, B.8.6, Groundwater	Oct 04 FR: for phthalimide, the lower Kdoc (56) was used for PECgw calculation. However Kfoc was available and was < Kdoc. Could this choice be explained. For phthalamic acid and phthalic acid it is stated that PECgw are not expected to exceed 0.001 µg/L but the input parameters have not been specified so it is not possible to conclude (even if low risk is expected with regard to fast degradation). This point should be completed.	Nov 04 RMS: Agree, Kfoc should have been used.	See open point in comment 4(37).
4 (39)	Vol 3. B.8.6 PEC surface water.	Oct 04 EFSA: PEC surface water for the metabolites should be provided.	Nov 04 RMS: Agree. Calculation should be performed	Data requirement Notifier to submit PEC surface water for the metabolites See also comment 4(40). Evaluation Meeting (14.-15.12.2004): The notifier will submit the requested data in April 2005. Data requirement still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4 (40)	Vol. 3, B.8.6, Surface water	Oct 04 FR: PECsw should be calculated for the metabolites.	Nov 04 RMS: See comment 4 (39)	See data requirement in comment 4 (39)
4 (41)	Vol 3. P.8.6. PEC sediment.	Oct 04 EFSA: PEC sed should be provided for the metabolites.	Nov 04 RMS: Agree. Calculation should be performed	Data requirement Notifier to submit PEC sediment calculations. Evaluation Meeting (14.-15.12.2004): The notifier will submit the requested data in April 2005. Data requirement still open.
4 (42)	Vol. 3, B.8.6 and Vol 1, list of endpoints, PEC in groundwater	Oct 04 SE: Please clarify what input values - DT50 and Koc - in the final PECgw simulation for FOCUS EU scenarios, for folpet and all metabolites. For Phthalic acid och Phthalamic acid, it is stated (in B.8.2.1) that the Koc were estimated by EWIWIN program but the results are not presented.	Nov 04 RMS: We agree. Input parameters to be added to endpoints listing from study summary. The estimated values to be added, 10 and 73.05 mL/g for Phthalamic acid and Phthalic acid, respectively.	See open point in comment 4(37)

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4 (43)	Vol 3. B.8.7.	Oct 04 EFSA: Thiophosgene should be considered for the residue definition in air.	Nov 04 RMS: It should be useful to calculate PEC air	Data requirement Notifier to assess potential relevance of thiophosgene in the air compartment. Evaluation Meeting (14.-15.12.2004): The notifier will submit the requested data in April 2005. Data requirement still open.
4 (44)	Vol. 3, B.8.9 Definition of the residue	Oct 04 SE: We agree to include only folpet in the definition of residues in soil and in aquatic systems. However, as justification for excluding the metabolites, please also refer to the ecotoxicological studies available. Before concluding on the definition of the residues in groundwater, the input values used for metabolites needs to be clarified.	Nov 04 RMS: Ecotoxicological endpoints to be added to justification in B.8.9.	Addressed RMS to consider in a revised DAR or corrigendum.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4 (45)	Vol 3. B.8.10. References relied on.	Oct 04 EFSA: Please revise the list. Some studies are missing, e.g. Annex III studies.	Nov 04 RMS: Study reference list of Annex III studies needs to be included	See comment 4(23).
4 (46)	New open point			Evaluation Meeting (14.-15.12.2004): MS to discuss the DT90 in surface water is < 3d in an expert meeting. See comment 1(18). New open point set.
4 (47)	New open point			Evaluation Meeting (14.-15.12.2004): Followin the proposal of DK the meeting agreed to discuss the residues definition in an expert meeting. New open point set.

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

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4 (48)	New open point			Evaluation Meeting (14.-15.12.2004): Proposed by EFSA in relation with comment 4(31). RMS to clarify wich studies of captan are used in the assessement of folpet and if these studies have actually been submitted in the folpet dossier.

5. Ecotoxicology

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5 (1)	Vol.1, List of Endpoints, Birds and mammals	Oct 04 NL: Please report all endpoints for birds and mammals in mg/kg bw/d. NL:Future risks assessments should be based on daily dose according to the guidance in SANCO/4145/EC.	Nov 04 RMS: The risk to birds has been fully addressed by the Notifier in a new risk assessment according to the EU guidance document on risk assessment for birds and mammals (SANCO/4145/2000). This assessment will be summarised in an addendum to the DAR. This includes conversion of endpoints from dietary studies into daily dose (mg/kg bw/day).	Open point RMS to prepare an addendum with an evaluation of the revised risk assessment for birds and mammals presented by the notifier. Open point: RMS to amend the list of endpoints for birds and mammals (values in daily dose, long term endpoint mammals). See also comments 5(10), 5(15), 5(19), 5(21)-5(29), 5(37) and 5(39)-5(42). Evaluation Meeting (14.-15.12.2004): Open points confirmed. Open points still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5 (2)	Vol.1, List of Endpoints, Aquatic organisms	Oct 04 NL thinks it would be useful to include the 28-d semi-static fish study (Jenkins, 1999) in the List of Endpoints, to show that the risk from repeated acute exposure has been adressed.	Nov 04 RMS: The LC50 values for 2, 4 and 28 days will be quoted in the endpoint list to show that multiple applications will no lead to a build-up of acute effects.	Addressed.
5 (3)	Vol.1, List of Endpoints, Aquatic organisms	Oct 04 NL thinks it would be useful to include the toxicity data on the metabolites in the LoE.	Nov 04 RMS: Endpoints from studies on aquatic organisms for metabolites will be included in the list of endpoints.	Addressed.
5 (4)	Vol. 1, List of Endpoints, Effects on non-target arthropods	Oct 04 NL thinks a column with effect percentages should be added to the table 'Effects on non-target arthropods' in the List of Endpoints.	Nov 04 RMS: A column of effect percentages will be added as requested	Open point: RMS to amend the list of endpoints regarding the endpoints for NTA (control mortality *C. septempunctata*). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5 (5)	Vol. 1, List of Endpoints, Earthworms	Oct 04 NL thinks the reproductive NOEC for earthworms should be included in the LoE.	Nov 04 RMS: The NOEC from the earthworm reproduction study will be added to the list of endpoints.	Addressed.
5 (6)	Vol. 1, List of Endpoints, micro-organisms	Oct 04 NL thinks it would be useful to report the tested concentrations in the LoE.	Nov 04 RMS: The test concentrations will be added to the list of endpoints.	Addressed.
5 (7)	Vol. 1, List of Endpoints	Oct 04 NL thinks endpoints for terrestrial plants should be included in the LoE.	Nov 04 RMS: Endpoints for terrestrial plants will be added to the list of endpoints.	Open point: EFSA proposes the RMS to amend the list of endpoints for terrestrial plants. See also comment 5(18). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5 (8)	Vol. 1, List of endpoints, Toxicity data for aquatic species	Oct 04 AT: Volume 1, page 36 is stated ”The major metabolites of folpet were much less toxic to aquatic organisms…”, however no toxicity data for major metabolites and related TER values are mentioned in list of endpoints.	Nov 04 RMS: The endpoints from toxicity studies on aquatic organisms for the metabolites need to be added to the list of endpoints.	Addressed.
5 (9)	Vol. 1, List of endpoints, Classification and proposed labelling	Oct 04 AT: Classification and labelling with regard to ecotoxicological data are missing.	Nov 04 RMS: Noted. Classification added in the new EP	Addressed.
5 (10)	Vol. 1, 2.6.1, and Vol 3, B.9.1 and B.9.3	Oct 04 NOT: In response to a request from the RMS, a revised risk assessment for birds and wild mammals has been conducted, in accordance with the ‘Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC’ (SANCO/4145/2000); 25 September 2002. This concludes that overall, there is a low risk to birds and mammals. NOT: The revised risk assessment in accordance with the ‘Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC’ (SANCO/4145/2000); 25 September 2002,	Nov 04 RMS: Noted	See open point in comment 5(1).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(11)	*continued* Vol. 1, 2.6.1, and Vol 3, B.9.1 and B.9.3	concludes that overall, there is a low risk of folpet to birds and mammals. The risk assessment is presented in the paper below: **"Norman, S. and Wyness, L. (2003). Folpet: Response to Rapporteur Member State request for a revised avian and mammalian risk assessment in accordance with EU Guidance Document on Risk Assessment for Birds and Mammals (SANCO/4145/2000."** Will be included in the addendum to be submitted to the RMS.		
5 (11)	Vol. 1, 2.6.3, and Vol 3, B.9.5	Oct 04 NOT: The DAR Volume 1 concludes that new laboratory studies on arthropods with GAP application rates are required. Additional studies have been undertaken on four species which cover the proposed rates and the ESCORT 2 multiple application factor. Based on the new studies, it is concluded that there is a low risk to non-target arthropods in-field and off-field. Data have been reviewed by the RMS on	Nov 04 RMS: when available new data will be evalauated	Data requirement: Notifier to submit the study by Moll, M., Bützler, R (2004). Effects of Folpan 80 WDG on the parasitoid *Aphidius rhopalosiphi*, extended laboratory study, aged residue test. Unpublished report. IBACON project number 18201003. Date: 13 January 2004. (Company file R-16400).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(11)	*continued* Vol. 1, 2.6.3, and Vol 3, B.9.5	toxicity to non-target arthropods. These studies indicated a general low toxicity. The application rates tested in the laboratory and extended laboratory studies do not cover the highest rates notified in the EU review. Hence, additional extended laboratory studies have been undertaken on *Aphidius rhopalosiphi*, *Typhlodromus pyri*, *Coccinella septempunctata* and *Chrysoperla carnea* which cover the proposed rates, and also the ESCORT 2 multiple application factor (MAF). Testing on these four species represents a complete dataset under ESCORT 2. From the proposed uses, the worst case is use on grapevines with a maximum of 10 applications at 1.5 kg a.s./ha. The highest rate in the new studies (5.25 kg a.s/ha, including MAF) was selected to cover the grapevine use. At this rate, there were no significant effects on *T. pyri*, *C. septempunctata* or *C. carnea*. *A. rhopalosiphi* gave 76% mortality at 5.25 kg/ha for fresh residues (i.e. greater than ESCORT 2 trigger of 50%). Effects for fresh residues were less than 50% for 3.38 kg a.s./ha (to cover proposed use on tomato). For 14 day aged residues at 5.25 kg/ha, there were no effects on *A. rhopalosiphi*. Hence, the ESCORT 2 criterion for potential for		Data requirement: Notifier to submit the study by Moll, M (2004). Effects of Folpan 80 WDG on the ladybird beetle *Coccinella septempunctata*, extended laboratory study, aged residues test. Unpublished report. IBACON project number 18203013. Date: 13 January 2004. (Company file R-16402). Data requirement: Notifier to submit the study by Rosenkranz, B. (2004a). Effects of Folpan 80 WDG on the predatory mite *Typhlodromus pyri*, extended laboratory study, aged residues test. Unpublished report. IBACON project number 18202060. Date: 27 January 2004. (Company file R-16401). Data requirement: Notifier to submit the study by Rosenkranz, B. (2004b). Effects of Folpan 80 WDG on the

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(11)	*continued* Vol. 1, 2.6.3, and Vol 3, B.9.5	recovery/recolonisation within 1 year is satisfied. Overall, it can be concluded that there is a low risk to non-target arthropods in-field and off-field. The new studies and the updated risk assessment are listed below: Moll, M., Bützler, R (2004). Effects of Folpan 80 WDG on the parasitoid *Aphidius rhopalosiphi*, extended laboratory study, aged residue test. Unpublished report. IBACON project number 18201003. Date: 13 January 2004. (Company file R-16400). Moll, M (2004). Effects of Folpan 80 WDG on the ladybird beetle *Coccinella septempunctata*, extended laboratory study, aged residues test. Unpublished report. IBACON project number 18203013. Date: 13 January 2004. (Company file R-16402). Rosenkranz, B. (2004a). Effects of Folpan 80 WDG on the predatory mite *Typhlodromus pyri*, extended laboratory study, aged residues test. Unpublished report. IBACON project number 18202060. Date: 27 January 2004. (Company file R-16401).		lacewing *Chrysoperla carnea*, extended laboratory study, aged residues test. Unpublished report. IBACON project number 18204048. Date: 27 January 2004. (Company file R-16398). Data requirement: Notifier to submit revised risk assessment by Norman, S. (2004). EU Review of folpet: Non-target arthropods: Updated risk assessment incorporating new extended laboratory studies at higher application rates than previously tested." Open point: RMS to revise the risk assessment for NTA in an addendum to be discussed in an expert meeting. See also comments 5(45), 5(47), 5(48), 5(49), 5(50), 5(51) and 5(52).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(11)	*continued* Vol. 1, 2.6.3, and Vol 3, B.9.5	Rosenkranz, B. (2004b). Effects of Folpan 80 WDG on the lacewing *Chrysoperla carnea*, extended laboratory study, aged residues test. Unpublished report. IBACON project number 18204048. Date: 27 January 2004. (Company file R-16398). "Norman, S. (2004). EU Review of folpet: Non-target arthropods: Updated risk assessment incorporating new extended laboratory studies at higher application rates than previously tested." The new studies (and Tier 2 summaries of the new studies) and the new risk assessment paper will be included in the addendum to be submitted to the RMS.		Evaluation Meeting (14.-15.12.2004): All data requirements: The notifier stated that the data already has been submitted. Data requirements still open. Open point: Open point confirmed. Open point still open.
5 (12)	Vol. 1, Point 2.6.4, Effects on earthworms and other soil macro-organisms	Oct 04 DE: According to Vol. 1, Point 2.6.4 as well as to the Listing of Endpoints (Appendix 3), only earthworm acute tests were performed. This is not sufficient, since an earthworm reproduction test must be performed if the number of applications is higher than 6	Nov 04 RMS: The comment is noted. Different crop interception rates in Volume 8 are included to illustrate the default (50%) then a modified (70%) value to explain in a stepwise manner the use of the more realistic interception rate in accordance	Open point MS to discuss the risk to earthworms in an expert meeting. See also comments 5(53), 5(54), 5(55) and 5(56).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(12)	*continued* Vol. 1, Point 2.6.4, Effects on earthworms and other soil macro-organisms	(irrespective of persistence). In Vol. 3, the results of a reproduction study with a formulation are given. (According to this study, the TER_{lt} is clearly below 5 (3.5; assuming 50% crop interception) or just above 5 (5.8; assuming 70% crop interception). It is not acceptable to use different ground cover values in different parts of the DAR.)	with the use of the product.. This issue could be discussed at an EPCO Expert Working group meeting	Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
5 (13)	Vol. 1, Point 2.6.5, Effects on soil micro-organisms	Oct 04 DE: The RMS states that the highest rate tested is 65 times higher than the PECsoil. In fact this ratio is only 14 times higher (21.24 mg a.s./kg / 1.48 mg a.s./kg = 14.4). However, this mistake does not have an impact on the outcome of the ERA.	Nov 04 RMS: The comment is noted.	Addressed. RMS to provide a corrigendum/addendum or to consider in a revised DAR.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5 (14)	Vol. 1, Point 2.6.6, Effects on other non-target organisms (flora and fauna) and Vol. 3, Point B.9.9, Effects on other non-target organisms believed to be at risk	Oct 04 DE: The risk of folpet to plants was assessed using field screening tests. These studies are not well documented (e.g. the test species are not given in all cases). In addition, it is stated by the RMS that the basic requirements of OECD Guideline 208 are fulfilled which is not the case (this guideline covers only laboratory or glasshouse tests). In addition, only single applications were used.	Nov 04 RMS: The comment is noted. The statement on the fulfilment of the criteria in OECD 208 should be removed. The studies presented are considered to be sufficient for an assessment of hazard to non-target higher plants.	Open point: MS to discuss the risk to non target plants in an expert meeting. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
5 (15)	Vol. 1, list of end points, effects on terrestrial vertebrates	Oct 04 SI: Please report LC50 and NOEC for birds and NOEC for mammals also as daily as these are the end points to be used according to the final guidance.	Nov 04 RMS: These endpoints should be quoted as daily doses, in the list of endpoints.	See open points in comment 5(1).
5 (16)	Vol. 1 List of end points, effects on other terrestrial arthropods	Oct 04 SI: Please mention the effect percentages in the table.	Nov 04 RMS: the list of endpoints amended	Addressed.
5 (17)	Vol. 1 List of end points, effects on earth worms	Oct 04 SI: The reproductive end point and the long term risk assessment for grapes should be included.	Nov 04 RMS: included in the endpoint list.	Addressed.

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5 (18)	Vol. 1 List of end points, effects on other non-target organisms	Oct 04 SI: The test results with non-target plants should be included.	Nov 04 RMS: This information should be included in the endpoint list	See open point in comment 5(7).
5 (19)	Vol. 3, B.9.1.3, Avian risk assessment	Oct 04 NL would like to know where the assumption comes from that earthworms will contain 30% of PECsoil. Based on the logPow of 3.017 and the worst case Koc of 304, a BCFworm of 1.8 can be calculated, which is a factor 6 higher than the assumed 0.30.	Nov 04 RMS: Based on the formula in the EU guidance document on risk assessment for birds and mammals (SANCO/4145/2000), using a log Pow of 3.017 and a Koc of 304, the BCFworm is 1.8 (as concluded by NL). For the use in grapevines (10 applications), assuming 70% foliar interception, and 14 day time-weighted average PECsoil after the final application (0.35 mg/kg soil), the TERlt for earthworm-eating birds is 130. This is greater than the trigger of 5, indicating low risk. (this calculation is also included in the addendum to the DAR).	See open point in comment 5(1).
5 (20)	Vol. 3 Section B.9.1.1.3 b) Bobwhite quail reproductive toxicity study - determination of NOEC	Oct 04 UK: We would consider the small, but statistically significant, effects on mean body weight of hatchlings in all folpet treatments (at dietary concentrations of 100, 300 and 1000 ppm) of possible importance to survival in the wild, with the reproductive NOEC being < 100 ppm.	Nov 04 RMS: The comment from UK is noted. However, the difference in mean hatchling bodyweight between the 100 ppm treatment group and the control was only 3%. There were no statistically significant differences from the control for reproductive parameters and 14 day chick weight at the	Open point: MS to discuss the risk to birds in an expert meeting. Evaluation Meeting (14.-15.12.2004):

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5 (20)	*continued* Vol. 3 Section B.9.1.1.3 b) Bobwhite quail reproductive toxicity study - determination of NOEC	. UK:This differs from that concluded in the DAR, where effects on body weight of hatchlings were not considered significant, with a concluded NOEC of 1000 ppm. Given this difference in interpretation, it is recommended that the matter is considered further at an EPCO Expert Working Group meeting.	three treatment levels in the study (100, 300, 1000 ppm). There was also no dose response relationship for the small differences in hatchling weight (the difference from the control was also 3% for the 1000 ppm treatment level). It is proposed by the RMS (in agreement with study author) that the 3% difference from the control in mean hatchling weight is not biologically significant.	Open point confirmed. Open point still open.
5 (21)	Vol.3 B.9.1.3. Risk to birds	Oct 04 SI: The risk assessment is not in line with the final guidance document. Please make clear which version of SANCO/4145 was used.	Nov 04 RMS:The risk to birds has been fully addressed by the Notifier in a new risk assessment according to the EU guidance document on risk assessment for birds and mammals (SANCO/4145/2000). This assessment is summarised and evaluated in an addendum to the DAR.	See open point in comment 5(1).
5 (22)	Vol 3 Section B.9.1.3 Risk to birds:	Oct 04 UK: The calculated predicted residues of folpet in avian food items (Table B.9.1.3.2) assumes only one application at 1.5 kg a.s./ha, whereas the proposed GAP in vines relates to ten such applications at 7 day intervals. The estimation of residue levels in vegetation needs to take account of the effect of multiple	Nov 04 RMS: The risk to birds has been fully addressed by the Notifier in a new risk assessment according to the EU guidance document on risk assessment for birds and mammals (SANCO/4145/2000). This assessment includes appropriate multiple application factors (MAF) for residues on	See open point in comment 5(1).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5 (22)	*continued* Vol 3 Section B.9.1.3 Risk to birds:	applications. (e.g. by the use of a Multiple Application Factor, as in the non-target arthropod risk assessment, Vol 3, B 9.5.2), although it is accepted (as per current SANCO 2002 guidance) that insects will be exposed to one application	vegetation. This assessment is summarised in an addendum to the DAR.	
5 (23)	Vol 3 Section B.9.1.3 Risk to birds:	Oct 04 UK: The daily food intake values used in the risk assessment (Table B.9.1.33) for small, medium and large herbivorous birds and for small, medium, and insectivorous birds are much lower than that agreed in the SANCO (2002) risk assessment . Therefore the calculated TERs (Tables B.9.1.3.6-8) for birds under- estimate the risk and require re-calculating based on revised consumption levels and on food residue levels that take account of the use of multiple applications. Further consideration of the appropriate avian reproductive NOEC for use in the long-term risk assessment is also required. (as comment 1). UK:The daily food intake values used in the risk assessment (Table B.9.1.33) for small, medium and large herbivorous birds (equivalent to respectively 7.4%, 1.2% and	Nov 04 RMS: The risk to birds has been fully addressed by the Notifier in a new risk assessment according to the EU guidance document on risk assessment for birds and mammals (SANCO/4145/2000). This assessment includes appropriate values for daily food intake rate (FIR). This assessment is summarised and evaluated in an addendum to the DAR.	See open point in comment 5(1).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(23)	*continued* Vol 3 Section B.9.1.3 Risk to birds:	4.2 % of body weight) and for small, medium, and insectivorous birds (equivalent to respectively 29%, 13% and 7.4% of body weight) are much lower than that agreed in the SANCO (2002) risk assessment guidance (i.e. 76% and 44% of body weight for medium and large herbivorous birds respectively, and 104% of body weight for insectivorous birds). Also, the current guidance assumes medium sized (100g) birds consume 113g earthworms /day whereas the DAR assumes much lower levels of consumption. These large differences in intake estimates may partly be due to the use of dry weight consumption data, which should be corrected to wet weight before assessing maximum daily active substance intake values based on fresh weight residue estimates (the UK has previously used a conversion factor of x 2.4 for this).		
5 (24)	Vol. 3, Annex B, point B.9.1.3. risk to birds.	Oct 04 FR: folpet is intended to be used for a period ranging from 2 weeks to up to 10 weeks in some crops (e.g. vineyards). It is not sure that the risk arising from repeated exposure over a 2-month and a half period is addressed by the proposed calculations.	Nov 04 RMS: The risk to birds has been fully addressed by the Notifier in a new risk assessment according to the EU guidance document on risk assessment for birds and mammals (SANCO/4145/2000). This assessment will be summarised in an addendum to the DAR.	See open point in comment 5(1).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(24)	*continued* Vol. 3, Annex B, point B.9.1.3. risk to birds.		cording to SANCO/4145/2000, for birds in vineyards, only exposure via insects is relevant, and there will be no build-up of residues on insects from multiple applications. The potential for exposure over an extended period due to the multiple applications is addressed by the avian reproduction studies on folpet in which exposure was continuous for around 18 weeks (NOEC 1000 ppm in mallard and bobwhite, the highest concentrations tested and no effects at 4640 ppm in an eight week exposure study with bobwhite quail. Folpet is rapidly absorbed and excreted in birds and so latent effects from multiple acute exposures are highly unlikely.	
5 (25)	Vol. 3, B.9.1.3, Avian risk assessment	Oct 04 NL: For the estimation of residues on food items (Table B.9.1.3.2), the multiple applications should be taken into account (see SANCO/4145/2000 for MAF factors; these are based on a DT50 of 10 days, so they are applicable for folpet).	Nov 04 RMS: The risk to birds has been fully addressed by the Notifier in a new risk assessment according to the EU guidance document on risk assessment for birds and mammals (SANCO/4145/2000). This assessment will be summarised in an addendum to the DAR. Appropriate multiple application factors (MAF) have been used in the assessment.	See open point in comment 5(1).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5 (26)	Vol. 3, B.9.1.3, Avian risk assessment	Oct 04 NL: Values for daily food intake (Table B.9.1.3.3) are (much) lower than values in SANCO/4145/2000. It is not clear whether the values in Table B.9.1.3.3 are based on fresh or dry material; if based on dry, this should be corrected to fresh weight (generally a factor 30% is applied) and even then, values for herbivorous birds will be considerably lower than in SANCO/4145.	Nov 04 RMS: The risk to birds has been fully addressed by the Notifier in a new risk assessment according to the EU guidance document on risk assessment for birds and mammals (SANCO/4145/2000). This assessment will be summarised in an addendum to the DAR. This assessment included appropriate daily Food Intake Rates (FIR) as specified in the EU guidance document.	See open point in comment 5(1).
5 (27)	Vol. 3, B.9.1.3 Risk assessment for birds	Oct 04 SE: The short term and the long term risk assessments for birds are based on the dietary concentrations. According to the guidance document the toxicity endpoint should be expressed as daily dose (mg as/kg bw per day), in order to take into account the different feed intake between laboratory and wild animals. We suggest this minor change should be adopted also for substances at the 2nd stage of the review programme. The difference in feed intake depends mainly on different energy expenditure of the animals, and on different energy and moisture content of the food in the laboratory compared to that in the field.	Nov 04 RMS: The risk to birds has been fully addressed by the Notifier in a new risk assessment according to the EU guidance document on risk assessment for birds and mammals (SANCO/4145/2000). This assessment includes conversion of dietary endpoints to daily doses, and appropriate values for daily food intake rate (FIR). This assessment is summarised in an addendum to the DAR.	See open point in comment 5(1).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5 (28)	Vol.3 Section B.9.1.3.Risk to birds.	Oct 04 DK: The daily food intake in Table B.9.1.33 (stated to be according to the SANCO 2002 risk assessment) for small, medium and large herbivorous birds and for small, medium insectivorous birds is very low. This does not seem to be correct.	Nov 04 RMS: The risk to birds has been fully addressed by the Notifier in a new risk assessment according to the EU guidance document on risk assessment for birds and mammals (SANCO/4145/2000). This assessment included appropriate values for daily food intake rate (FIR). This assessment is summarised in an addendum to the DAR.	See open point in comment 5(1).
5 (29)	Vol.3, Point B. 9.1.3, Risk to birds	Oct 04 DE: It might helpful, if the ERA for birds would be presented according to the Working Document SANCO/4145/2000. The use of the interception factor should be justified. This is of particular importance since the interception factor for fungicides is 0.4 according to SANCO/4145/2000. Furthermore, not only secondary poisoning from fish to fish eating birds but also from earthworm to earthworm eating birds should be presented.	Nov 04 RMS: A new risk assessment for birds according to the EU guidance document on birds and mammals (SANCO/4145/2000) has been submitted by the Notifier. This assessment is summarised and evaluated in the addendum to the DAR. This includes the default assumption from foliar interception in vineyards of 0.4 (i.e. deposition factor 0.6). The assessment also includes risk to earthworm-eating birds (also please see below). Based on the formula in the EU guidance document on risk assessment for birds and mammals (SANCO/4145/2000), using a log Pow of 3.017 and a Koc of 304, the	See open point in comment 5(1).

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5(29)	*continued* Vol.3, Point B. 9.1.3, Risk to birds		BCFworm is 1.8. For the use in grapevines (10 applications), assuming 70% foliar interception, and 14 day time-weighted average PECsoil after the final application (0.35 mg/kg soil), the TERlt for earthworm-eating birds is 130. This is greater than the trigger of 5, indicating low risk. (this calculation is also included in the addendum to the DAR).	
5 (30)	Vol. 3 B.9.2.1.1 Fish	Oct 04 SI: According to the summaries the lower test concentrations were below the limit of quantification (102 µg/L). This has to be clarified. It is impossible to conclude on an end point if test concentrations cannot be adequately measured. It is not clear if initial concentrations in these media were >80% of nominal.	Nov 04 RMS:The series of acute static toxicity tests with fish are those of greatest significance in the risk assessment. The limitations of the analytical method and the very rapid dissipation of folpet in water precluded the determination of recovery of folpet in water in some cases. To take account of this, stock solutions were analysed. Where possible initial concentrations in the test media were analysed. Based on all of the suite of static studies (all conducted at the same time in the same laboratory), the measured concentrations of folpet in the stock solutions were 78 to 121% of nominal with an average of 90 to 105% of nominal. This provides confidence that the initial test media were prepared according to the	Open point: MS to discuss the risk to aquatic organisms in an expert meeting. See also comments 5(31)-5(33), 5(35) and 5(36). Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(30)	*continued* Vol. 3 B.9.2.1.1 Fish		expected nominal concentration. In addition, where it was possible to measure initial concentrations in the test media the recoveries were 67 to 103% (139% for carp but this species was particularly insensitive relative to the other species) of nominal. Therefore, based on the rapid dissipation and analytical method limitations the reported endpoints, based on nominal concentrations, are considered to be a reasonable approach given that stock solutions were within acceptable limits and that where possible measured initial concentrations were reasonably consistent with nominal concentrations.	
5 (31)	Vol.1, Point 2.6.2, Effects on aquatic species and Vol. 3, Point B.9.2.5, Risk to aquatic organisms	Oct 04 DE: A higher-tier risk assessment based on an EAC is presented. A Tier-1 risk assessment including the calculation of TERa and TERlt values as required by the Guidance Document on Aquatic Ecotoxicology (Sanco/3268/2001 rev.4 (final), 17 October 2002) should be conducted and reported prior to a higher-tier risk assessment. According to the Guidance Document on Aquatic Ecotoxicology (Sanco/3268/2001 rev.4(final), 17 October 2002) an EAC is	Nov 04 RMS: The tier 1 acute TER values for fish, *Daphnia*, and algae are already included in volume 3 section B.9.2.5 (Tables B.9.2.5.6 to B.9.2.5.6.10). TERlt values have been omitted due to short DT50 of 24 minutes in the water phase. It is proposed that this omission does not affect the outcome of the risk assessment, which should be focused on acute effects.	See open point in comment 5(30).

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5(31)	*continued* Vol.1, Point 2.6.2, Effects on aquatic species and Vol. 3, Point B.9.2.5, Risk to aquatic organisms	estimated for the refined risk assessment, taking into account the overall evaluation of the compound in the aquatic compartment.		
5 (32)	Vol.1, Point 2.6.2, Effects on aquatic species and Vol. 3, Point B.9.2.5, Risk to aquatic organism	Oct 04 DE: a) The higher-tier risk assessment is based on an EAC of 9.8 µg/L which is derived from the most sensitive fish species (LC50 of 98 µg/L for brown trout). b) Since chronic effects on fish are not covered by this approach, it is recommended to base the risk assessment on the NOEC value from the 28-day chronic toxicity test with rainbow trout. c) A safety factor of 5 should be applied to the NOEC (resulting in approx. 4 µg a.s./L) with respect to the uncertainty due to inter-species sensitivity distribution and possible effects in fish life cycle which are not covered by the ELS test. d) PECmax surface water values derived by current FOCUS modelling tools might be used for the risk assessment.	Nov 04 RMS: Regarding the 28 day semi-static test in rainbow trout (Jenkins, 1999) the effects in this study were acute rather than chronic, as the study was effectively on repeated acute exposure. Only at the highest treatment level (156 µg a.s./l) was there an effect on growth, but this was for the one fish (10%) that survived at this treatment level. Sublethal symptoms (principally hyperventilation) which were observed at 39 µg a.s./l and higher were the result of acute exposure, and were reversible. At 39 µg a.s./l a maximum of 5 fish out of 10 was observed hyperventilating, and all fish recovered (no mortality). At the next treatment level (78 µg a.s./l), one fish died, but the sublethal symptoms for	See open point in comment 5(30).

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5 (32)	*continued* Vol.1, Point 2.6.2, Effects on aquatic species and Vol. 3, Point B.9.2.5, Risk to aquatic organism	a) The use of an EAC in the risk assessment based on a LC_{50} instead of a NOEC from chronic toxicity testing is reasoned by the RMS with a static test approach to be more realistic than a flow-through system due to the rapid hydrolysis of folpet in the water phase. b) Since folpet might be applied several times (up to 10 x 1.5 kg a.s.s/ha) in weekly intervals, the semi-static approach from the prolonged toxicity study with rainbow trout (12 applications in total with 2-3 days intervals) is believed to be more realistic and to cover the chronic risks for fish. c) Inter-species sensitivity distribution investigated in acute tests with several fish species showed a factor of about 2.5. Additionally, as described in the literature, a factor of approx. 2 can be assumed from comparison of the endpoint sensitivity of fish life-cycle (FLC) and early life-stage (ELS) tests. d) Since the NOEC values from the cited fish study are based on nominal concentrations, TER calculations should be performed with PECmax values.	the surviving fish were reversible. The study showed that acute effects did not build up after successive application (1, 4, and 28 day LC50 values were similar and so latency was not observed). It is proposed to regard the 28 day study simply as evidence that multiple applications do not increased the acute risk to fish. It is still preferred to base the risk assessment on the LC50 for brown trout, with a TER trigger of 10 given that the acute risk assessment should focus on acute endpoints. It would be useful for the risk assessment to be discussed at an EPCO Expert Working Group meeting.	

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5 (33)	Vol.1, Point 2.6.2, Effects on aquatic species and Vol. 3, Point B.9.2.5, Risk to aquatic organism	Oct 04 DE: It should be reconsidered if it is reasonable to estimate an ecologically acceptable concentration EAC which is based on acute effects on one group of organisms (fish) only. Since the toxicity of folpet to daphnids is not much different compared to the toxicity against fish, it is doubted that this EAC covers possible risks to the whole aquatic community. See comment No. 2 In order to reduce the uncertainty of potential effects on the aquatic community and to derive a reliable EAC, the performance of a semi-realistic multi-species effect study would be helpful.	Nov 04 RMS: The TERa values for aquatic invertebrates, represented by *D. magna*, are greater than 100 at 5 and 10 m for the various crops presented in the DAR and the acute risks may be considered acceptable. The acute toxicity to invertebrates was shown to be slightly less compared to fish, but the risks to invertebrates were shown to be low (exceeding TER triggers of concern). This illustrates clearly that the risks to fish were also low (not very different to invertebrates), taking into account the very conservative assumptions in the first tier of the risk assessment, but did not exceed the acceptable TER. It is not generally advisable to run a multi-species (microcosm) experiment studying both fish and invertebrates, because the fish exert a heavy feeding pressure on the invertebrates in these small systems (report of CLASSIC workshop; Giddings *et al*, 2002). For practical reasons, the issues of invertebrates and fish have to be handled separately. This is the usual approach in regulatory risk assessments	See open point in comment 5(30).

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5(33)	*continued* Vol.1, Point 2.6.2, Effects on aquatic species and Vol. 3, Point B.9.2.5, Risk to aquatic organism		which are based on single species laboratory studies.	
5 (34)	Vol. 3 B.9.2.5 Risk to aquatic organisms:	Oct 04 UK: Given folpet's very rapid breakdown both in water and sediment (whole system DT50 of 0.018 days) we agree the use of the results from static (as opposed to flow through) studies is appropriate in the risk assessment.	Nov 04 RMS: No action required.	Addressed.
5 (35)	Vol. 3, Annex B, point B. 9.2.5., risk to aquatic organisms	Oct 04 FR: it is proposed in the DAR to re-assess risks based on a probabilistic approach. We are not convinced that a safety factor of 10 is sufficient as the assessment remains based on acute effects. Moreover it is not clear how this safety factor was introduced into calculations. In addition, it is not so sure that under field conditions a chronic exposure would not occur because application occur each week during up to 2 months and a half.	Nov 04 RMS:For clarification, it is not proposed to re-assess risk based on a probabilistic approach. Results of species sensitivity distribution (SSD) for acute toxicity to fish have been presented. The SSD is a probabilistic method of presenting toxicity data, but it is used in the context of a *deterministic* risk assessment. The SSD is only included to support the TER-based approach.	See open point in comment 5(30).

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5(35)	*continued* Vol. 3, Annex B, point B. 9.2.5., risk to aquatic organisms	Finally, DT50 of metabolites should be reminded to support the hypothesis of a lower PEC than the PEC for the parent. It should be demonstrated that their DT50 is so low that multi-application is not relevant to calculate PECsw for metabolites.	Six species of fish were tested in acute studies. This is greater than the minimum of 5 recommended by HARAP (Campbell et al, 1999), which are required to reduce a trigger by an order of magnitude (100 to 10 in this case). The range of sensitivity is narrow, with only a factor of 2.4 covering the LC50 values for the five most sensitive species (the sixth species, carp, was not sensitive). Hence, uncertainty due to interspecies variation in sensitivity has been minimised. Only acute effects are relevant due to the mode of toxicity (irritant to gill membranes) and short DT50 in water (24 minutes). A 28 day semi-static study on rainbow trout (Jenkins, 1999), has been submitted. This assessed acute effects and also influence on growth. Growth over 28 days was only affected at the highest treatment level of 150 µg a.s./l, where there was also substantial mortality (90%). It is acute effects that should determine the outcome of the assessment. Overall, using the lowest acute LC50 (for brown trout) of 98 µg/l, the trigger of 10 is considered to be sufficient. This gives an Ecologically Acceptable Concentration (EAC) of 9.8 µg a.s./l.	

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5(35)	*continued* Vol. 3, Annex B, point B. 9.2.5., risk to aquatic organisms		With multiple applications there will be no chronic exposure due to a short DT50 in water (24 minutes) resulting from rapid hydrolysis. Multiple applications may lead to repeated acute exposure. This issue is addressed by a 28 day semi-static study on rainbow trout (Jenkins, 1999) which effectively included 12 acute exposures (12 media replacements) at 48 h or 72 hour intervals. There was minimal difference between the 48 hour LC50 (156 µg a.s./l) and the 28 day LC50 (133 µg a.s./l), indicating no accumulation of acute effects. This indicates that an assessment based on acute studies with a single exposure, is protective. In a sediment water study (including two different sediment water systems) the maximum percentage formation (applied radioactivity) of metabolites and DT50 values in the water phase of the two systems are as follows: phthalimide: max % formation = 31.8%, DT50= 0.5 – 0.6 days phthalic acid: max % formation = 41.3%, DT50= 1.4 – 6.5 days phthalamic acid: max % formation =	

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5(35)	*continued* Vol. 3, Annex B, point B. 9.2.5., risk to aquatic organisms		13.4%, DT50 = 3.5 - 6.1 days benzamide: max % formation = 10.2%, DT50 1.6 days 2-cyanobenzoic acid: max % formation = 40.3%, DT50 0.3 - 0.7 days (ref: Crowe, 1999) The metabolites are the products of hydrolysis. Their short DT50s in the water phase do not warrant the calculation of a PEC for multiple applications. In any case, they are of low acute toxicity to fish in laboratory studies, and they would have been present in static and semi-static studies on the active substance (so they are already taken into account in the risk assessment). In any case, the risk assessment should be based on the active substance, which is clearly more toxic than the metabolites	
5 (36)	Vol. 3, B.9.2.5, Risk assessment for aquatic organisms	Oct 04 SE: We do not agree to the suggested use of probabilistic risk assessment approach and the suggestion to disregard any potential interspecies difference in sensitivity. These approaches should be discussed and agreed upon before they are used as a basis for conclusion, thus we should await the outcome	Nov 04 RMS: It was not the intention to propose the use of a probabilistic approach. The EU guidance document on aquatic ecotoxicology (SANCO/3268/2001, section 5.3), advises that uncertainty factors may be reduced in the deterministic risk assessment through the submission of data on	See open point in comment 5(30).

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5 (36)	*continued* Vol. 3, B.9.2.5, Risk assessment for aquatic organisms	of the EUFRAM project. We suggest that conclusions should be drawn only from the first part of the risk assessment presented, indicating that risk mitigation (e.g., spray free zone of 20 m) is warranted.	additional species. The EU guidance document does not specify the number of species which need to be tested. However, some advice is provided in the HARAP guidance, an internationally accepted guidance document (Campbell *et al*, 1999), that a minimum number or 5 fish species need to be tested. Six fish species have been tested, and the range in sensitivity is narrow (which can be explained by the toxic mode of action: irritation of gill membranes). Hence, it may be considered that inter-species variation in sensitivity has been sufficiently addressed, and that a TER trigger of 10 can be used together with the LC50 for the most sensitive species tested (brown trout).	
5 (37)	Vol. 3 Section B.9.3.1 Effects on other terrestrial vertebrates.	Oct 04 UK: We would consider the appropriate long-term NOAEL for use in the risk assessment was 250ppm (13.7-18.3 mg/kg bw/day) based on results of a two generation study in rats (Rubin Y 1986) where use at the next higher dose of 1500ppm (83.1-109.6 mg/kg bw/day) resulted in reduced pup weight during lactation and non-reproductive effects in the parents (hyperkeratosis of the oesophagus and	Nov 04 RMS: A new risk assessment for mammals according to the EU guidance document on birds and mammals (SANCO/4145/2000) has been submitted by the Notifier. This assessment is summarised and evaluated in the addendum to the DAR. A discussion on the appropriate endpoint for the long term risk assessment for mammals is included in the addendum (and is stated below):	See open point in comment 5(1). Open point: MS to discuss the risk to mammals in an expert meeting. See also comment 5(38). Evaluation Meeting (14.-

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5(37)	*continued* Vol. 3 Section B.9.3.1 Effects on other terrestrial vertebrates	forestomach). UK:We consider that a more detailed justification of the selection of the long-term toxicity endpoint for use in the environmental risk assessment is required, with the selection of the appropriate endpoint being confirmed at an EPCO Expert Working Group meeting.	The EU guidance document states that 'an endpoint relating to overall reproductive success should be selected to define the long term NOEC for birds and mammals'. An endpoint of 1500 ppm was previously used in the risk assessment in the DAR. However, this has been revised based on the EU guidance. The two generation study in the rat (Rubin, 1986) has been used to derive the endpoint. At the three treatment levels (250, 1500 and 5000 ppm) in this study there were no effects on any reproductive parameters. Reduced food consumption was observed in the parents at 5000 ppm throughout the study. This was probably related to reduced palatability of the test diet due to the high concentration of folpet. In the F0 generation, before the first pairing, the reduction in feeding was 8 to 9% compared with the control. This was accompanied by 7 to 10% lower body weights than in the control in males and females, respectively. Thus the effect on food consumption and bodyweight were of a similar magnitude, suggesting they are linked.	15.12.2004): Open point confirmed. Open point still open.

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5(37)	*continued* Vol. 3 Section B.9.3.1 Effects on other terrestrial vertebrates		The initial mean body weights of the F1 animals as weanlings at 5000 ppm were approximately 3% lower than in the control. By the end of lactation, the mean F1 weanling body weight at 5000 ppm was significantly less than the controls (by around 10%)(effect noted in comment from UK). This was related to reduced food intake of the F0 parents. At 5000 ppm, in the F1 generation food consumption and body weight were lower than the controls, to the same degree as observed in the F0 generation. There were a few occasions at 1500 ppm, generally in the pre-pairing periods, when food consumption was slightly reduced but was not statistically significant (no greater than a 4% reduction from the control treatment). There was no effect at 250 ppm. In terms of histopathological findings, hyperkeratosis (thickening of skin) of the non-glandular gastric mucosa and oesophagus was observed at 1500 ppm and to a greater degree at 5000 ppm. These findings are noted in the comment from UK. This was related to these high	

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5(37)	*continued* Vol. 3 Section B.9.3.1 Effects on other terrestrial vertebrates		concentrations of folpet irritating the mucal membranes, which may have been the explanation for the reduced palatability of the feed. Such an effect on mucal membranes is symptomatic of the high concentrations in the test diet. In the field, potential dietary exposure concentrations (for example on grass between rows in vineyards) would be very much lower than 1500 ppm. Hence, the observation of hyperkeratosis is not relevant to the risk assessment. In any case, it is not linked to reproductive performance, so should not be used to determine the ecological NOAEC. Overall, an ecological NOAEC of 5000 ppm (mean daily dose: 548.6 mg a.s./kg bw day) can be used, as there were no effects on reproductive performance at this treatment level. Moderate effects on food consumption, and hence, bodyweight at this test level are probably related to the palatability of the test diet. It is agreed with UK that this issue should be discussed at an ECPO Expert Working Group meeting.	

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5 (38)	Vol. 3.Section B.9.3.1. Effects on other terrestrial vertebrates (mammals)	Oct 04 DK: Concerning the risk assessment for mammals based on the results from the two generation study in rats (Y. Rubin 1986) we suggest to use 250 ppm in stead of 1500 ppm for the long-term risk assessment. A food content of 1500 ppm reduced the pup weight and caused hyperkeratosis (a thickening of the epidermis cells) in the stomach of the parents.	Nov 04 RMS: A new risk assessment for mammals according to the EU guidance document on birds and mammals (SANCO/4145/2000) has been submitted by the Notifier. This assessment is summarised and evaluated in the addendum to the DAR. A discussion on the appropriate endpoint for the long term risk assessment for mammals is included in the addendum (and is stated below): The EU guidance document states that 'an endpoint relating to overall reproductive success should be selected to define the long term NOEC for birds and mammals'. An endpoint of 1500 ppm was previously used in the risk assessment in the DAR. However, this has been revised based on the EU guidance. The two generation study in the rat (Rubin, 1986) has been used to derive the endpoint. At the three treatment levels (250, 1500 and 5000 ppm) in this study there were no effects on any reproductive parameters. Reduced food consumption was observed in the parents at 5000 ppm throughout the study. This was probably related to reduced palatability of the test diet due to the high concentration of	See open point in comment 5(37).

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5(38)	*continued* Vol. 3.Section B.9.3.1. Effects on other terrestrial vertebrates (mammals)		folpet. In the F0 generation, before the first pairing, the reduction in feeding was 8 to 9% compared with the control. This was accompanied by 7 to 10% lower body weights than in the control in males and females, respectively. Thus the effect on food consumption and bodyweight were of a similar magnitude, suggesting they are linked. The initial mean body weights of the F1 animals as weanlings at 5000 ppm were approximately 3% lower than in the control. By the end of lactation, the mean F1 weanling body weight at 5000 ppm was significantly less than the controls (by around 10%). This was related to reduced food intake of the F0 parents. At 5000 ppm, in the F1 generation food consumption and body weight were lower than the controls, to the same degree as observed in the F0 generation. There were a few occasions at 1500 ppm, generally in the pre-pairing periods, when food consumption was slightly reduced but was not statistically significant (no greater than a 4% reduction from the control treatment). There was no effect at 250 ppm.	

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5(38)	*continued* Vol. 3.Section B.9.3.1. Effects on other terrestrial vertebrates (mammals)		In terms of histopathological findings, hyperkeratosis (thickening of skin) of the non-glandular gastric mucosa and oesophagus was observed at 1500 ppm and to a greater degree at 5000 ppm. This was related to these high concentrations of folpet irritating the mucal membranes, which may have been the explanation for the reduced palatability of the feed. Such an effect on mucal membranes is symptomatic of the high concentrations in the test diet. In the field, potential dietary exposure concentrations (for example on grass between rows in vineyards) would be very much lower than 1500 ppm. Hence, the observation of hyperkeratosis is not relevant to the risk assessment. In any case, it is not linked to reproductive performance, so should not be used to determine the ecological NOAEC. Overall, an ecological NOAEC of 5000 ppm (mean daily dose: 548.6 mg a.s./kg bw day) can be used, as there were no effects on reproductive performance at this treatment level. Moderate effects on food consumption, and hence, bodyweight at this test level are probably related to the palatability of the test diet.	

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5(38)	*continued* Vol. 3.Section B.9.3.1. Effects on other terrestrial vertebrates (mammals)		This issue should be discussed at an ECPO Expert Working Group meeting (as was also proposed by UK).	
5 (39)	Vol. 3 Section B.9.3.2 Risk to terrestrial vertebrates other than birds	Oct 04 UK: Maximum daily intakes for terrestrial vertebrates given in Table B.9.9.3.2.1 are under-estimates due to a lack of consideration of the effects of multiple applications on residue levels and use of inappropriate food intake values. The risk to terrestrial vertebrates therefore needs to be re-assessed, based on a comparison of corrected intake levels with the appropriate toxicity endpoint. UK: It is stated that exposure estimates for multiple applications 'are not considered to differ significantly from those based on a single application due to rapid dissipation of folpet in vegetation'. However, a foliar DT50 of 9.3 days has been estimated in Table B.9.1.3.4 (from 4 wheat residue trials) and multiple applications with a short application interval are proposed (e.g. use in vines of up to 10 applications with a 7 day minimum spray interval). Given the predicted foliar residue decline rate and short application interval,	Nov 04 RMS: The risk to mammals has been fully addressed by the Notifier in a new risk assessment according to the EU guidance document on risk assessment for birds and mammals (SANCO/4145/2000). This assessment includes appropriate multiple application factors (MAF) for residues on vegetation, and agreed values for daily food intake rate (FIR). This assessment is summarised in an addendum to the DAR.	See open point in comment 5(1).

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5(39)	*continued* Vol. 3 Section B.9.3.2 Risk to terrestrial vertebrates other than birds	multiple applications are likely to significantly increase residue levels and this should be taken into account when estimating these levels (e.g. by use of an appropriate Multiple Application Factor as in the non-target arthropod risk assessment Vol 3. B.9.5.2). Intake values of 10% and 30% of body weight for large and small mammals have been assumed. However these intake values are based on dry weight consumption levels and must be converted to wet weight values before assessing maximum daily active substance intake values based on fresh weight residue estimates (the UK has previously used a conversion factor of x 2.4 for this).		
5 (40)	Vol.3, B.9.3.2, Risk assessment for mammals	Oct 04 NL does not agree with the assumption that multiple applications of folpet are not expected to increase the risk because of the rapid dissipation. The estimated DT50 in/on plants was 9.3 days, which does not exclude risk from multiple applications with an interval of 7 days. See also previous comment on avian risk assesment.	Nov 04 RMS: The risk to mammals has been fully addressed by the Notifier in a new risk assessment according to the EU guidance document on risk assessment for birds and mammals (SANCO/4145/2000). This assessment will be summarised in an addendum to the DAR. This assessment included appropriate daily Food Intake Rates (FIR) as specified in the EU guidance document.	See open point in comment 5(1).

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5 (41)	Vol. 3, Annex B, point B.9.3.2, risk assessment to mammals.	Oct 04 FR: folpet is intended to be used for a period ranging from 2 weeks to up to 10 weeks in some crops (e.g. vineyards). It is not sure that the risk arising from repeated exposure over a 2-month and a half period is addressed by the proposed calculations.	Nov 04 RMS: The report by Nengel 1996a (Report 95195/01-BLCe; R-8869) was copied to report Nengel 1996c (Report 95195/01-BLEU; R-8867) in error. The report of Nengel 1996c should therefore be included in the DAR. The outcome of this latter report (acute oral LD50 > 223.87µg/bee and acute contact LD50 > 200 µg/bee) do not alter the outcome of the bee risk assessment but the final endpoint selection and calculation should be revised accordingly. A new summary in the DAR can be prepared accordingly.	See open point in comment 5(1).
5 (42)	Vol 3, B.9.3.2. Risk assessment for wild mammals	Oct 04 SE: The short term and the long term risk assessments for mammals are based on the dietary concentrations. According to the guidance document the toxicity endpoint should be expressed as daily dose (mg as/kg bw per day), in order to take into account the different feed intake between laboratory and wild animals. We suggest this minor change should be adopted also for substances at the 2nd stage of the review programme. The difference in feed intake depends mainly on different energy expenditure of the animals,	Nov 04 RMS: The risk to mammals has been fully addressed by the Notifier in a new risk assessment according to the EU guidance document on risk assessment for birds and mammals (SANCO/4145/2000). This assessment includes conversion of dietary endpoints to daily doses, and appropriate values for daily food intake rate (FIR). This assessment is summarised in an addendum to the DAR.	See open point in comment 5(1).

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5(42)	*continued* Vol 3, B.9.3.2. Risk assessment for wild mammals	and on different energy and moisture content of the food in the laboratory compared to that in the field. In addition, we suggest it be considered to use the NOEL of 10 mg/kg bw/d from teratology study in rabbit as a basis for the short-term risk assessment since the effects described in B.6.6.3 appear to be relevant.	Regarding the possible use of the rabbit teratology study in the risk assessment. The dosing method, endpoints, and observations and in this study are considered to be of low ecological relevance. The dosing method (oral gavage) is of low relevance to a risk assessment where exposure is via the diet. The rat multigeneration study (a dietary study) is more useful in this respect. The endpoints in the teratology study are to support judgements on potential hazard to foetal development at the individual level to support the risk assessment for human health. The study provides little or no information about endpoints that are relevant at the *population* level, which should be the focus of the vertebrate risk assessment (as stated in the EU birds and mammals guidance document, SANCO 4145/2000). Specifically, the study provides no information on litter size or pup survival. The observation of a difference in minor skeletal variations at 40 mg/kg bw/day compared with the control is not relevant to the ecological risk assessment as the study does not provide information on influence on pup survival or fitness. In any case, the total number of	

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5(42)	*continued* Vol 3, B.9.3.2. Risk assessment for wild mammals		foetuses showing skeletal variations was actually the same for control and the treated group. :reased post implantation loss at the highest treatment level (160 mg/kg bw) and increased number of small foetuses were a result of direct maternal toxicity (clinical signs and reduced food consumption were observed at this treatment level). Overall, the risk assessment should be based on the rat multigeneration study. As a note, there is no short-term assessment of risk for wild mammals, in accordance with SANCO 4145/2000 only an acute and long-term risk to wild mammals is required.	
5 (43)	Vol. 3, Point B.9.4, Effects on bees	Oct 04 DE: In order to avoid confusion the correct abbreviation “HQ” (Not QHC) should be used throughout the text.	Nov 04 RMS: The comment is noted. However, the abbreviations QHC and QHO are those used in Directive 91/414/EEC and are, therefore, used in the DAR.	Addressed. RMS to provide a corrigendum/addendum or to consider in a revised DAR.
5 (44)	Vol 3, Annex B, point B.9.4.2.1.2.toxicity of formulated products to bees	Oct 04 FR: the summary of the study references Nengel, 1996c is exactly similar to the summary of the study referenced Nengel, 1996a. is this the same study?	Nov 04 RMS: The report by Nengel 1996a (Report 95195/01-BLCe; R-8869) was copied to report Nengel 1996c (Report 95195/01-BLEU; R-8867) in error. The report of	Open point: RMS to summarise and evaluate the study by Nengel 1996c on bees in an addendum and revise the risk assessment for bees

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5(44)	*continued* Vol 3, Annex B, point B.9.4.2.1.2.toxicity of formulated products to bees		Nengel 1996c should therefore be included in the DAR. The outcome of this latter report (acute oral LD50 > 223.87µg/bee and acute contact LD50 > 200 µg/bee) do not alter the outcome of the bee risk assessment but the final endpoint selection and calculation should be revised accordingly. A new summary in the DAR can be prepared accordingly.	accordingly. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.
5 (45)	Vol. 1, Point 2.6.3, Effects on bees and other arthropod species and Vol. 3, Point B.9.5, Effects on other arthropod species	Oct 04 DE: The RMS states that "there are serious doubts that the available studies could be used for risk assessment". This statement is strongly supported since all presented studies (laboratory as well as field) did not use the highest application rate or the highest number of applications. Despite the clear statement cited from Vol. 1 in Column 2, the RMS states in Vol. 3, Point B.9.5 that the formulation Folpan 80 WDG fulfils the criterion for the authorisation. This seems to be a contradiction. For an ERA according to ESCORT II, new data are necessary as recommended by the RMS in Vol. 1.	Nov 04 RMS: New extended laboratory studies on *Typhlodromus pyri*, *Aphidius rhopalosiphi*, *Coccinella septempunctata*, and *Chrysoperla carnea* have been submitted by the Notifier, together with a new risk assessment. The new studies cover the proposed application rates including the use of appropriate MAF values (3.8 for grapevine use; 2.7 for tomato use). Summaries of the studies and a revised risk assessment are presented in the addendum to the DAR. A low risk to non-target arthropods can be concluded.	See data requirements in comment 5(11).

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5 (46)	Vol. 3, Point B.9.5, Effects on other arthropod species	Oct 04 DE: In Table B.9.5.1.9, in the control column at day 8, a CR is given of 42%. However, it is impossible by definition to give a CR here.	Nov 04 RMS: This value is a typographical error, and should be deleted.	Addressed. RMS to provide a corrigendum/addendum or to consider in a revised DAR.
5 (47)	Vol 3, B.9.5.2, risk to other arthropods	Oct 04 UK: Given the in-field risk to non-target arthropods identified in the tier 1 risk assessment for the proposed use in tomatoes and grapevines together with the significant reductions in *T pyri* reported in the grapevine field trials, Member States should consider the need for risk mitigation measures to protect non-target arthropod populations from the high dose uses. UK: We accept that there is potential for populations to recover following use of folpet and the lack of adverse effects reported in the lower application rate field trials indicates there is no need for mitigation measures for these uses. (eg wheat).	Nov 04 RMS: Four field studies on *T. pyri* were submitted. In all studies there were 8 applications of folpet. In two of the studies there were no significant differences from the control. In the other two studies, after 5 applications, when mite numbers were high in both control and treatments, there was a maximum difference from the control of 19% (Ipach, 199b) and 27% (Ipach, 1999a). Only late in these studies (after 8 applications) when mite numbers were declining in both the control and folpet treated plots, were larger differences between the treatment and controls observed, with maximum differences from the control of 49% (Ipach, 1999a) and 67% (Ipach, 1999b). It is considered that the late season differences in counted numbers are not significant for the risk assessment, given that all populations in control and	See data requirements in comment 5(11).

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5(47)	*continued* Vol 3, B.9.5.2, risk to other arthropods		treatments were already in decline. New extended laboratory studies on *Typhlodromus pyri*, *Aphidius rhopalosiphi*, *Coccinella septempunctata*, and *Chrysoperla carnea* have been submitted by the Notifier, together with a new risk assessment. The new studies cover the proposed application rates including the use of appropriate MAF values (3.8 for grapevine use; 2.7 for tomato use). Summaries of the studies and a revised risk assessment are presented in the addendum to the DAR. A low risk to non-target arthropods can be concluded, without the need for risk mitigation	
5 (48)	Vol. 3, B 9.5.2, Risk to other arthropods	Oct 04 NL doesn't agree with the MAF factor of 1.5 which is used in the risk assessment. Looking at the MAF factors in Appendix III from ESCORT 2, it is clear that the MAF factor should be at least 2.0. Conform the formula in Gonzalez-Valero (1999), based on DT50 9.3 d and interval 7 d, a MAF factor of 2.4 can be calculated. NL: Formula for calculating the MAF factor: $MAF = (1-e^{-kni})/(1-e^{-ki})$	Nov 04 RMS: New extended laboratory studies on *Typhlodromus pyri*, *Aphidius rhopalosiphi*, *Coccinella septempunctata*, and *Chrysoperla carnea* have been submitted by the Notifier, together with a new risk assessment. The new studies cover the proposed application rates including the use of appropriate MAF values (3.8 for grapevine use; 2.7 for tomato use). Summaries of the studies and a revised risk assessment are presented in the addendum	See open point in comment 5(11).

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5(48)	*continued* Vol. 3, B 9.5.2, Risk to other arthropods	in which: k = ln2/DT50 i= interval (d) n = number of applications.	to the DAR. A low risk to non-target arthropods can be concluded.	
5 (49)	Vol. 3, B 9.5.2, Risk to other arthropods	Oct 04 NL: Could RMS please give a more elaborate argumentation on why adverse effects up to 69% after the last application on numbers of *T.pyri* in field studies are considered to show no unacceptable risk? From the summaries, NL cannot make up whether recovery takes place.	Nov 04 RMS: In this study, there were 8 applications of folpet. After 5 applications, when mite numbers were high in both control and treatments, there was a maximum difference from the control of only 19%. Only late in the study (after 8 applications) when mite numbers were declining in both the control and folpet treated plots, were larger differences between the treatment and controls observed (maximum difference 69%, 4 weeks after 8th application). It is considered that the late season differences in counted numbers are not significant for the risk assessment, given that all populations in control and treatments were already in decline. A new extended laboratory study on *T. pyri* has been submitted, with a highest application rate of 5.25 kg a.s./ha (representing the multiple applications to grapevines at 1.5 kg a.s./ha, using a MAF of 3.8). At 5.25 kg/ha, there	See open point in comment 5(11).

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5(49)	*continued* Vol. 3, B 9.5.2, Risk to other arthropods		were no effects on survival or reproduction of *T. pyri*. Hence, there is a low risk to *T. pyri* (and other taxa represented by the sensitivity of *T.pyri*).	
5 (50)	Vol. 3, B 9.5.2, and Vol. 1, Level 2, 3 and 4, Risk to other non-target arthropods	Oct 04 NL: Since there is a risk for *T.pyri* in the first Tier, testing on more species is required. These tests are available, but with dosages much lower than the proposed application rates. NL agrees with the conlusion in Vol.1 that new studies are required, and wonders why this conlusion in Vol. 3 is not the same.	Nov 04 RMS: New extended laboratory studies on *Typhlodromus pyri*, *Aphidius rhopalosiphi*, *Coccinella septempunctata*, and *Chrysoperla carnea* have been submitted by the Notifier, together with a new risk assessment. The new studies cover the proposed application rates including the use of appropriate MAF values (3.8 for grapevine use; 2.7 for tomato use). Summaries of the studies and a revised risk assessment are presented in the addendum to the DAR. A low risk to non-target arthropods can be concluded.	See data requirements in comment 5(11).
5 (51)	Vol. 3, B.9.5.2, Risk assessment to non-target arthropods	Oct 04 AT: The field studies on *T. pyri* do not sufficiently address the maximum intended use of 10 appl.s of 1.5 kg ai/ha. Only 8 appl.s have been investigated and the potential effects of 2 further appl.s can not be predicted. Furthermore the first appl.s in all trials were performed with rates significantly lower than	Nov 04 RMS: It is recognised that in the field trials on *T. pyri*, not all of the 8 applications were at the maximum notified rate of 1.5 kg a.s./ha. However, it is considered that the studies still provide useful supporting information on the responses of predatory mite populations following a typical spray	See data requirements in comment 5(11).

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5(51)	*continued* Vol. 3, B.9.5.2, Risk assessment to non-target arthropods	1.5 kg ai/ha and therefore a more pronounced initial damage to the population can be expected. According to Escort 2, where the in-field HQ > 2 one additional species has to be tested. For folpet, additional species have been tested with only one third of the intended single rate. In our opinion the multiple appl. scenario should also be addressed for one additional species. The HQs for *A. rhopalosiphi* have been calculated based on a LD50 figure which is derived from an extended lab study. As the HQ trigger has been validated for artificial substrate, it should at least be indicated that the HQs for *Ar* should be regarded as "tier 2" figures. The data provided are not sufficient to support acceptability of effects on nta`s.	program. It is also noted that the studies did not cover the maximum proposed number of applications. However, it is suggested that an additional two applications in the studies are unlikely to have made a large difference to the results. New extended laboratory studies on *Typhlodromus pyri*, *Aphidius rhopalosiphi*, *Coccinella septempunctata*, and *Chrysoperla carnea* have been submitted by the Notifier, together with a new risk assessment. The new studies cover the proposed application rates including the use of appropriate MAF values (3.8 for grapevine use; 2.7 for tomato use). Summaries of the studies and a revised risk assessment are presented in the addendum to the DAR. A low risk to non-target arthropods can be concluded. As commented by AT, tier 1 HQ values should be based on glass plate studies. For the higher tier risk assessment for non-target arthropods emphasis is now placed on the new extended laboratory studies (as listed above), which meet the requirements of ESCORT 2.	

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5 (52)	Vol.3 B. 9.5.2. Risk to other arthropods	Oct 04 SI It is not appropriate to use the trigger of 2 in combination with an extended laboratory study on *Aphidius*. The trigger of 2 for the Hazard Quotient is validated for worst-case tests with exposure on glass plates and not for extended laboratory tests.	Nov 04 RMS:The comment is correct. In any case, risk assessment should be based on the new extended laboratory studies submitted by the notifier.	See open point in comment 5(11).
5 (53)	Vol 3, Annex B, point B.9.6.3., risk to earthworms	Oct 04 FR: the use of twaPEC for long term risk assessment is not justified since dissipation of the a.s. within time was already considered in the reproduction test. Moreover, this is not conservative when considering repeated uses of folpet. If PEC had to be time-weighted, it should rather be done over a 7 days interval (interval between applications) which would be more representative of the expected exposure of soil organisms. Moreover, it is proposed that metabolites are covered by the risk assessment with the parent, but this is not true anymore if PEC are time-weighted.	Nov 04 RMS: In fact a time-weighted average was not used in the risk assessment. This was a typographical error in the text preceding Table B.9.6.3 in the DAR. The maximum PECsoil following 10 applications in vineyards was stated in the DAR to be 1.478 mg/kg soil, based on 50% foliar interception. However, a value of 70% interception is more relevant to the use, which gives maximum PEC of 0.887 mg/kg soil. The NOEC from the earthworm reproduction study is 5.17 mg/kg, which gives a TER of 5.8. This TER is greater than the trigger of 5, indicating a low risk.	See open point in comment 5(12).

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5 (54)	Vol.3, B.9.6.3, Risk to earthworms	Oct 04 NL: Occurrence of the metabolite phtalamide in the earthworm test should be supported by measurements, but considering the low toxicity to aquatic organisms NL can agree with not asking for studies with the metabolite.	Nov 04 RMS: No action required.	See open point in comment 5(12).
5 (55)	Vol. 3, B.9.6.3 and Vol. 1, List of endpoints, Effects on earthworms	Oct 04 AT: According to the GAP Folpet is applied up to 10 times per season in grapes. Sublethal effects on earthworms have to be tested if the number of applications is >6, regardless of persistence (GD Terrestrial Ecotoxicology). Although otherwise stated in Volume 1 of the DAR, an earthworm reproduction study was conducted (see Vol. 3 of DAR). In this study a NOEC of 5.2 mg ai/kg soil was determined. To account for potential toxicity in soils with lower amounts of organic matter than the artificial substrate used in toxicity studies, this number is divided by a factor 2 (EPPO). The PECmax was determined to be 1.478 mg ai/kg soil (50% interception) or 0.887 mg/kg (70% interception). NOECcorr. = 2.6. Thus TERlt is either 1.76 (assuming 50% interception) or 2.9 (assuming 70% interception). In both cases the Annex VI trigger of 5 is not met and save use for the application in vine not proven.	Nov 04 RMS: The logPow for folpet is >2, which means (according to EPPO, 2002, and EU terrestrial guidance document) that the earthworm endpoint should be divided by 2. The adjustment of an earthworm NOEC to account for the organic matter content of different substrates or soils is only valid if there is a relationship between the organic matter content of soil and toxicity. Toxicity will be determined by the adsorption properties of the substance (pore water concentration being a manifestation of adsorption). Regarding long-term exposure for earthworms, folpet rapidly degrades in soil to such an extent that the adsorption/desorption coefficients cannot be calculated. Therefore, a relationship between soil organic matter and possible hazard cannot be established. However, the soil adsorption/desorption of one of the significant soil metabolites of folpet,	See open point in comment 5(12). Open point: RMS to transfer the information on earthworms from column 3 of the reporting table to an addendum. Evaluation Meeting (14.-15.12.2004): Open point confirmed. Open point still open.

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5(55)	*continued* Vol. 3, B.9.6.3 and Vol. 1, List of endpoints, Effects on earthworms		phthalimide, was measured. Phthalimide is structurally very similar to folpet. There was no relationship between soil organic matter and soil adsorption of phthalimide. Therefore, the NOEC does not need to be adjusted in this particular case. To support this argument the the estimated Koc for folpet is relatively low 304 – 1167. Currently, without the use of the factor, the TER for use in vineyards is 5.8 (assuming 70% foliar interception). For use in wheat at 0.75 kg a.s./ha (2 applications) assuming 70% crop interception (PECsoil after 2 applications = 0.379 mg a.s./kg), the TER is 13 (without the factor of 2). For use in tomatoes at 1.25 kg a.s./ha (4 applications) assuming 80% crop interception (PEC soil after 4 applications: 0.487 mg a.s./kg), the TER is 10.6 (without the factor of 2). Hence, the use of the factor of 2 would not affect the conclusion of low risk (TER trigger = 5) (interception values from FOCUSgw guidance). In any case, the number of applications is less than 5, so the requirement for a earthworm reproduction test would not be triggered	

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5 (56)	Vol.3 B.9.6.3 Risk to earthworms	Oct 04 SI We consider it more appropriate to use 50% interception as realistic worst case in grapes for the long-term risk assessment.	Nov 04 RMS: As mentioned in a previous comment, this issue could be discussed at an EPCO Expert Working Group meeting	See open point in comment 5(12).