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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.4, Section C.1.2.4., methods of analysis for impurities	UK: No details of the GC Headspace method of analysis for the impurity [redacted] appear to have been submitted.	(ii) We agree with this comment. Details of the GC headspace method of analysis for the impurity [redacted] have to be submitted.	Data requirement Notifier to submit details of the GC headspace method of analysis for the impurity [redacted] Evaluation Meeting (09.-10.02.2005): Data requirement confirmed but reworded to keep the confidentiality. Notifier to submit details of the GC headspace method of analysis for the impurity 5. Notifer stated that a new large scale batch analysis is now available that covers also the analytical methods and will be submitted to the RMS within the next 4 weeks. 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(2)	Vol. 1, 1.3.1, Name and address of applicant p. 4	Notifier: New address: Bayer CropScience AG Research and Development Global Regulatory Affairs Alfred-Nobel-Str. 50 D-40789 Monheim am Rhein	(ii) DAR will be amended.	Addressed. RMS to consider in a revised DAR or corrigendum.
1(3)	Vol. 1, 1.3.5, CAS, EEC and CIPAC numbers p. 5	Notifier: New **CIPAC** number: 737	(ii) DAR will be amended.	Addressed. RMS has amended the list of endpoints. RMS to consider in a revised DAR or corrigendum.
1(4)	Vol. 1, 1.3.7, Manufacturer of the active substance p. 5	Notifier: New address: [redacted]	(ii) DAR will be amended.	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)
1(5)	Vol. 1, 1.4.1, current, former and proposed trade names; p. 6	Notifier: Development code number: BAJ 2740 SC 240 proposed trade name: **Envidor** SC 240	(ii) DAR will be amended.	Open point RMS to amend the list of endpoints (list of representative uses) regarding the product name (code number). RMS to consider in a revised DAR or corrigendum. Evaluation Meeting (09.-10.02.2005): Open point confirmed. Open point still open.
1(6)	Vol. 1, 2.2.2, analytical method for the formulation analysis p. 14	Notifier: Interferences should be added, so that the last sentence reads: The method was validated with respect to the parameters: precision, linearity, accuracy, specificity and **interferences**.	(ii) We do not agree, interference is considered to be part of specificity	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)
1(7)	Vol 1, 2.2.3 p. 15	Notifier: Method 00568 is considered valid for determination of residues in **grapes**. To support the explanations in Column 3 the notifier will subject an extra sample from the grape metabolism study (stored frozen until today) to the Method 00568. Extraction efficiency will be compared with the result from the metabolism study. The extract will be subjected to chromatographic analysis to check whether the pattern of active substance and metabolites is the same as reported in the metabolism study. If so it confirms storage stability. If the extraction efficiency with both methods is the same and the storage stability is given then the question of the RMS is also answered experimentally. Results will be available by end of September 2004.	(ii) Notifier will supply extraction efficiency study. RMS is awaiting new results.	See data requirement in comment 3(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)
1(8)	Vol 1, 2.2.3 p. 15	Notifier: **No MRLs and no enforcement method for animal matrices** are necessary, because the cattle feeding study clearly shows that no residues are to be expected in milk, animal tissues and organs at the 1.7 and 5.1-fold overdose (1.38 and 4.14 mg/kg feed). In addition in the goat metabolism study no residues were found in goat tissues above 0.01 mg/kg considering the applied overdose.	(ii) RMS is of the opinion that the residue definition for monitoring for animal products is: sprirodiclofen + MO1.	Addressed.
1(9)	Vol. 1, Appendix 3, List of Endpoints; p. 86	Notifier: New CIPAC number: 737	(ii) LOEP will be amended	Addressed. RMS has amended the list of endpoints
1(10)	Vol. 1, Appendix 3, List of Endpoints; p. 87	Notifier: Henry's law constant: at 20°C <2 x 10^{-3} Pa m^3mole^{-1}	(ii) LOEP will be amended	Addressed. RMS has amended the list of endpoints
1(11) 1(11)'	Vol. 1, list of endpoints, Chapter 2.2. p. 91 *continued* Vol. 1, list of endpoints, Chapter 2.2.	Notifier: No enforcement method for animal matrices is considered necessary, because the cattle feeding study clearly shows that no residues are to be expected in milk, animal tissues and organs at the 1.7 and 5.1-fold overdose (1.38 and 4.14 mg/kg feed). In addition in the goat metabolism study no residues were found in goat tissues above 0.01 mg/kg considering the applied	(ii) See 1(8)	Addressed. See comment 1(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)
	p. 91	overdose.		
1(12)	Vol. 1, Level 4, demand for further information, 4.1 Identity of the active substance p. 126	Notifier: 1. A 5 batch analysis of the large scale production is under preparation 2. A confirmatory method is in preparation Both studies will be submitted as soon as possible.	(ii) Notifier will supply required data. DAR will be amended after receiving new studies.	Data requirement Notifier to submit: 1. A 5 batch analysis of the large scale production; 2. For the compound which is analysed with GC-FID, a confirmatory method using specific detectors with the same method (e.g. GC-MS) or 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). Evaluation Meeting (09.-10.02.2005): Data requirement confirmed Notifer stated that a new large scale batch analysis is now available which covers also the analytical methods and could be submitted to the RMS within the next 4 weeks.

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)
				Data requirement still open.
1(13)	Vol, 1, level 4, 4.5.1 p. 126	Notifier: No enforcement method for animal matrices is considered necessary, because the cattle feeding study clearly shows that no residues are to be expected in milk, animal tissues and organs at the 1.7 and 5.1-fold overdose (1.38 and 4.14 mg/kg feed). In addition in the goat metabolism study no residues were found in goat tissues above 0.01 mg/kg considering the applied overdose.	(ii) See 1(8)	Addressed See comment 1(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)
1(14)	Vol, 1, level 4, 4.5.2 p. 126	Notifier: Additional validations at levels up to 1 mg/kg spirodiclofen in dry apple pomace will be conducted.	(ii) Notifier will supply required data. RMS is awaiting new results.	Open point The need of further validation data from the point of view of enforcement purposes is arguable. In the DAR a method is presented that fulfils the requirement of Directive 94/46/EC. See also data requirement in comment 3(2). Evaluation Meeting (09.-10.02.2005): Due to the fact that this data gap relates rather to a data generation method [see data requirement in comment 3(2)] this open point is closed. Open point closed.

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(15)	Vol, 1, level 4, 4.5.3 and 4.5.5 p. 127	Notifier: Method 00568 is considered valid for determination of residues in grapes. To support the explanations in Column 3 the notifier will subject an extra sample form the grape metabolism study (stored frozen until today) to the Method 00568. Extraction efficiency will be compared with the result from the metabolism study. The extract will be subjected to chromatographic analysis to check whether the pattern of active substance and metabolites is the same as reported in the metabolism study. If so it confirms storage stability. If the extraction efficiency with both methods is the same and the storage stability is given then the question of the RMS is also answered experimentally. Results will be available by end of September 2004.	(ii) See 1(7)	See data requirement in comment 3(1) and comment 1(7)

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(16)	Vol 1, level 4, 4.5.4 p. 127	Notifier: Laboratory method MR-694/98 is identical with method 00568. The laboratory method MR-694/98 was validated as method 00568 in a separate document under report no. MR-351/99.	(ii) Comment is not understood. MR-694/98 is a report which has been requested to be submitted to be able to compare the 2 versions of method 00568. This information should be submitted. In the case the methods are the same no further information will be necessary.	Addressed.
1(17)	Vol 1, level 4, 4.5.6 p. 127	Notifier: Additional validations in animal matrices and milk for analytical method 109720 will be conducted.	(ii) Notifier will supply required data. RMS is awaiting new results.	Open point Due to the fact that an analytical method is not required, the need for further validation data is unclear. Evaluation Meeting (09.-10.02.2005): RMS clarified that this data gap relate to a data generation method and see therefore the need to require this data. However, due to this the open point is closed with respect to section 1, but a new data requirement should be set in the residue section. Data requirement Notifer to provide more validation data for the method 109 720 for the determination

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(17)	*continued* Vol 1, level 4, 4.5.6 p. 127			of residues in food of animal origin. Notifier stated that the data will be available within the next 8 weeks. However, depending on the outcome of the residue expert meeting [see open point in comment 3(5)], it could be necessary to require further data with respect to an enforcement method for food of animal origin.
1(18)	Vol. 1, level 4, 4.5.7 p. 127	Notifier: No MRLs and hence no enforcement method for animal matrices is considered necessary, because the cattle feeding study clearly shows that no residues are to be expected in milk, animal tissues and organs at the 1.7 and 5.1-fold overdose (1.38 and 4.14 mg/kg feed). In addition in the goat metabolism study no residues were found in goat tissues, milk and organs above 0.01 mg/kg considering the applied overdose.	(ii) See 1(8)	Addressed See comment 1(8)

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1(19)	Vol. 2, A.1, Identity p. 3	Notifier: Reference IIA, 4.1.1/01; Ruengeler, W.; 2000; **confidential information**; 1. please delete this reference from this list and add it to Vol.4 Annex C, Confidential information; 2. the reference to the annex points IIA, 1.10, IIA, 1.11, IIA, 4.1.2 and IIA, 4.1.3 should be added to reference Ruengeler, W., 2000; 3. the reference to the annex point, IIA, 4.1.1 should be removed from reference Ruengeler, W., 2000; 4.	(ii) DAR will be amended	Addressed. RMS to consider in a revised DAR or corrigendum.
1(20)	Vol. 2, A.2, Physical and chemical properties, references for the active substance p. 3	Notifier: The report Eberz, A., 1998 (reference IIA, 2.11.1/01) fulfils also requirements of the annex points IIA, 2.11.2 and 2.13; please add those in the reference list accordingly: Annex Point IIA, 2.11.2/01: ⇒ IIA, 2.11.1/01 Annex Point IIA, 2.13/01: ⇒ IIA, 2.11.1/01	(ii) DAR will be amended	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)
1(21)	Vol. 2, A.2, Physical and chemical properties, references for the active substance p. 3	Notifier: The reference Kaußmann, M., 2000 was amended. Therefore it should read: Spectral Data Set of BAJ 2740 Bayer AG, Report No.: 15-600-2116 Date: 2000-03-09, **amended 2000-09-01** GLP, unpublished	(ii) DAR will be amended	Addressed. RMS to consider in a revised DAR or corrigendum.
1(22)	Vol. 2, A.2, Physical and chemical properties, references for the active substance p. 3	Notifier: The report Krohn, J., 1997 (reference IIA, 2.1.1/01) is also the reference of the other annex points listed in column 3;	(ii) DAR will be amended	Addressed. RMS to consider in a revised DAR or corrigendum.
1(23)	Vol. 2, A.2, Physical and chemical properties, references for the plant protection product p. 4	Notifier: The report Eberz, A., 1998 (reference IIIA, 2.2.1/01) is also the reference of the annex point IIIA, 2.3/01; please add the list accordingly: Annex Point IIIA, 2.3/01: ⇒ IIIA, 2.2.1/01	(ii) DAR will be amended	Addressed. RMS to consider in a revised DAR or corrigendum.
1(24)	Vol. 2, A.2, Physical and chemical properties, references for the plant protection product p. 5	Notifier: The report Hess, T., 1998 (reference IIIA, 2.1/01) is also the reference to other annex points listed in column 3; please add the list accordingly.	(ii) DAR will be amended	Addressed. RMS to consider in a revised DAR or corrigendum.

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1(25)	Vol. 2, A.2, Physical and chemical properties, references for the plant protection product p. 5	Notifier: New reference: Gueldner, W. IIIA, 2.4.2/02 2002 Determination of pH value (1% and undiluted) of BAJ 2740 SC 240 (Article no.: 05304954) Bayer CropScience report no. 1410505220 Date: 2002-05-16 GLP, unpublished Data protection claimed: Y Owner: BCS	(ii) DAR will be amended	Addressed. RMS to consider in a revised DAR or corrigendum.
1(26)	Vol. 2, A.2, Physical and chemical properties, references for the plant protection product p. 5	Notifier: The report Zimmermann, M., 2000 (reference IIIA, 2.7.1/01) is also the reference of the annex point IIIA, 2.7.3/01; please add the list accordingly: Annex Point IIIA, 2.7.3/01: ⇒ IIIA, 2.7.1/01	(ii) DAR will be amended	Addressed. RMS to consider in a revised DAR or corrigendum.

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

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(27)	Vol. 2, A.5, Methods of analysis p. 7	Notifier: 1. Reference IIA, 4.1.1/01; Ruengeler, W.; 2000; **confidential information**; 2. please delete this reference from this list and add it to Vol.4 Annex C, Confidential information; 3. the reference to the annex points 4.1.2 and IIA, 4.1.3 should be added to reference Ruengeler, W., 2000; 4. the reference to the annex point, IIA, 4.1.1 should be removed from reference Ruengeler, W., 2000;	(ii) DAR will be amended	Addressed. RMS to consider in a revised DAR or corrigendum.
1(28)	Vol. 2, A.5, Methods of analysis p. 7	Notifier: New reference: Ruengeler, W. IIA, 4.1.1/01 2000 BAJ 2740; Assay of technical active ingredient; HPLC - Internal standard Bayer CropScience report no. 2005-0010101-99E Date: 2000-02-07 non GLP, unpublished Data protection claimed: Y Owner: BCS	(ii) DAR will be amended	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)
1(29)	Vol. 2, A.5, Methods of analysis p. 7	Notifier: New reference: zur Muehlen, U. IIA, 4.1.3/02 2000 Validation report VB1-2005-0010101-99E ; BAJ 2740 Technical, HPLC - internal standard; Bayer CropScience report no. VB12005-0010101-99 Date: 2000-02-07 non GLP, unpublished Data protection claimed: Y Owner: BCS	(ii) DAR will be amended	Addressed. RMS to consider in a revised DAR or corrigendum.
1(30)	Vol. 3, B.1.3, References relied on p.1	Notifier: Reference IIA, 4.1.1/01; Ruengeler, W.; 2000; **confidential information**; 1. please delete this reference from this list and add it to Vol.4 Annex C, Confidential information; 2. the reference to the annex points IIA, 1.10 and IIA, 1.11 should be added to reference Ruengeler, W., 2000; 3. the reference to the annex point, IIA, 4.1.1 should be removed from reference Ruengeler, W., 2000;	(ii) DAR will be amended	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)
1(31)	Vol. 3, B.2.1.4, relative density p. 3	Notifier: The correct reference is Krohn, J., 1997 ⇒ IIA, 2.1.1/01	(ii) DAR will be amended	Addressed. RMS to consider in a revised DAR or corrigendum.
1(32)	Vol. 3, B.2.1.6, volatility, Henry's law constant p. 3	Notifier: Henry's law constant: at 20°C <2 x 10^{-3} Pa m^3mole^{-1}	(ii) DAR will be amended	Addressed. RMS to consider in a revised DAR or corrigendum.
1(33)	Vol. 3, B.2.2.10, pH p. 10	Notifier: Additional data: pH 5.3 (1% dilution)	(ii) The pH of the undiluted formulation and the 1% solution is 5.3. DAR will be amended	Addressed. RMS to consider in a revised DAR or corrigendum.
1(34)	Vol. 3, B.2.3.1, Active substance p. 13	Notifier: The sentence "The log P_{OW} (5.83) is not pH dependable..." should be replaced by "The log P_{OW} (5.83) was measured at pH 4 only due to substance instability at higher pH values...."	(ii) DAR will be amended	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)
1(35)	Vol. 3, B.2.4, References for the active substance p. 14	Notifier: The reference Kaußmann, M., 2000 was amended. Therefore it should read: Spectral Data Set of BAJ 2740 Bayer AG, Report No.: 15-600-2116 Date: 2000-03-09, **amended 2000-09-01** GLP, unpublished	(ii) DAR will be amended	Addressed. RMS to consider in a revised DAR or corrigendum.
1(36)	Vol. 3, B.2.4, References for the plant protection product p. 16	Notifier: New reference: Gueldner, W. IIIA, 2.4.2/02 2002 Determination of pH value (1% and undiluted) of BAJ 2740 SC 240 (Article no.: 05304954) Bayer CropScience report no. 1410505220 Date: 2002-05-16 GLP, unpublished Data protection claimed: Y Owner: BCS	(ii) DAR will be amended	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)
1(37)	Vol 3, B.5.5.2.2 p. 61	Notifier: Method 00568 is considered valid for determination of residues in grapes. To support the explanations in Column 3 the notifier will subject an extra sample form the grape metabolism study (stored frozen until today) to the Method 00568. Extraction efficiency will be compared with the result from the metabolism study. The extract will be subjected to chromatographic analysis to check whether the pattern of active substance and metabolites is the same as reported in the metabolism study. If so it confirms storage stability. If the extraction efficiency with both methods is the same and the storage stability is given then the question of the RMS is also answered experimentally. Results will be available by end of September 2004.	(ii) Vol 3, B.5.5.2.2 p. 6**3** See 1(7)	See data requirement in comment 3(1).
1(38)	Vol 3, B.5.5.2.2 p. 63	Notifier: Method 00568: Additional recovery experiments in apple pomace up to 1.0 mg/kg spirodiclofen will be conducted. Results will be available end of 2004/beginning 2005.	(ii) See 1(14)	See open point in comment 1(14) See also data requirement in comment 3(2).

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

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(39)	Vol. 3, B.5.6, References relied on p. 65	Notifier: Reference IIA, 4.1.1/01; Ruengeler, W.; 2000; this reference should be replaced by the new reference Ruengeler, W. IIA, 4.1.1/01 2000 BAJ 2740; Assay of technical active ingredient; HPLC - Internal standard Bayer CropScience report no. 2005-0010101-99E Date: 2000-02-07 non GLP, unpublished Data protection claimed: Y Owner: BCS	(ii) DAR will be amended	Addressed. RMS to consider in a revised DAR or corrigendum.
1(40)	Vol. 3, B.5.6, References relied on p. 65	Notifier: Reference IIA, 4.1.2/01; Ruengeler, W.; 2000; **confidential information**; please delete this reference from this list and add it to Vol.4 Annex C, Confidential information;	(ii) DAR will be amended	Addressed. RMS to consider in a revised DAR or corrigendum..

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

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(41)	Vol. 3, B.5.6, References relied on p. 65	Notifier: Reference IIA, 4.1.3/01; Ruengeler, W.; 2000; **confidential information**; please delete this reference from this list and add it to Vol.4 Annex C, Confidential information;	(ii) DAR will be amended	Addressed. RMS to consider in a revised DAR or corrigendum..
1(42))	Vol. 3, B.5.6, References relied on p. 65	Notifier: New reference: zur Muehlen, U. IIA, 4.1.3/02, 2000 Validation report VB1-2005-0010101-99E ; BAJ 2740 Technical, HPLC - internal standard; Bayer CropScience report no. VB12005-0010101-99 Date: 2000-02-07 non GLP, unpublished Data protection claimed: Y Owner: BCS	(ii) DAR will be amended	Addressed. RMS to consider in a revised DAR or corrigendum..
1(43)	General	EFSA: It should be noted that references of studies which are unacceptable or not necessary in the light of Directives 94/37/EC and 96/46/EC (Annex IIA and IIIA of 91/414/EEC) should be removed from the chapter "References relied on", because it is not possible to rely on these references.	(ii) The chapter "References relied on" will be changed accordingly.	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)
1(44)	Vol. 1, p. 86, List of endpoints, Minimum purity	EFSA: For transparency, it should be indicated (e.g. with an asterisk) that the specification is based on the results of a pilot plant.	(ii) A 5 batch analysis of the large scale production is under preparation, see 1(12). LOEP will be amended if specification changes.	Open point Being aware that a data requirement is set for large scale batch analysis, this is not comprehensible from the list of endpoints. Therefore, it should be indicated that the minimum purity given in the list of endpoints in related to a pilot plant. See data requirement in comment 1(12) Evaluation Meeting (09.-10.02.2005): Open point confirmed. RMS will amend the list of end points taken the new five batch analysis into account. 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(45)	Vol. 1, p. 86, List of endpoints, Identity of relevant impurity	EFSA: Clarification is needed regarding the statement that the technical material does not contain any relevant impurity. Taken the given residue definition for monitoring purposes for soil and water into account, it seems to be that one of the mentioned compounds is also an impurity in the technical material. Therefore it is unclear, why on one hand this compound is regarded as toxicological and/or ecotoxicological relevant (only for such compounds an enforcement method is required) and on the other hand the same compound is regarded in the technical material as not relevant.	(ii) Clarification is requested from the fate section regarding the residue definition for monitoring. The given residue definitions for monitoring are including the metabolites which were formed at >10% AR. It is unclear if those metabolites are of toxicological and/or ecotoxicological relevance. The residue definitions for monitoring for soil and water should be confirmed. The compound which is also an impurity in the technical material should be listed in the LOEP as relevant impurity if it is (still) included in the residue definition.	Open point RMS to confirm the residue definitions for monitoring for soil and water. <u>Evaluation Meeting (09.-10.02.2005):</u> Open point confirmed. Depending on the outcome of the expert meetings (fate and behaviour, ecotoxicology and toxicology) further data could be required. Open point is still open.
1(46)	Vol. 1, p. 87, List of endpoints, temperature of decomposition	EFSA: A value or a range for the temperature of decomposition should be given (as mentioned in Vol. 3, table B.2.1). Also in the row "boiling point" it is stated that spirodiclofen decomposes. The statement that spirodiclofen is stable at the melting point is meaningless in this context.	(ii) Boiling point: Thermal decomposition Temperature of decomposition: Stable at the melting point LOEP will be amended: Boiling point: not determined due to thermal decomposition Temperature of decomposition: A weight loss was observed at 160°C	Addressed. RMS has amended the list of endpoints

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

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(47)	Vol. 1, p. 87, List of endpoints, relative density and Vol. 3, p. 3, B.2.1.4 Relative density	EFSA: For transparency, it should be mentioned that the density rather than the relative density was determined.	(ii) LOEP will be amended	Addressed. RMS has amended the list of endpoints
1(48)	Vol. 1, p. 87, List of endpoints, dissociation constant	EFSA: For clarification, it should be considered whether a statement such "*no dissociation is expected based on the chemical structure*" would be more helpful.	(ii) Due to instability at pH >4, dissociation could not be determined LOEP will be amended: Due to instability at pH >4, dissociation could not be determined, no dissociation is however expected based on the chemical structure.	Addressed. RMS has amended the list of endpoints
1(49)	Vol. 1, p. 89, Summary of intended uses	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.	(ii) Table is changed in list of endpoints	Addressed. RMS has amended the list of endpoints

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

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1(50)	Vol. 1, p. 126, 4.5 Methods of analysis 2.	EFSA Clarification is needed regarding the requirement for further validation data for dry apple pomace at levels up to 1.0 m/kg. It seems to be that no MRL is proposed, which support this requirement in respect to enforcement methods. It seems to be that this is rather an issue concerning data generation methods and should therefore be mentioned in chapter B.7. The same is also applicable to the requirements concerning the extraction efficiency.	(ii) See 1(14) See 1(7)	See open point in comment 1(50) See also data requirements in comment 3(1) and 3(2).

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

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(51)	Vol. 3, p. 4ff, Determination of pH depending properties (e.g. solubility in water and partition co-efficient)	EFSA: Clarification is needed regarding the non submission of data at higher pH values than pH 4. Taken the given DT_{50} values from the hydrolysis study into account, it seems to be that measurements at pH 7 are possible and reasonable.	(ii) We agree, it seems to be that measurements at pH 7 are possible and reasonable. Notifier will be requested to submit solubility in water and partition co-efficient data at pH 7.	Data requirement Notifier to submit solubility in water and partition co-efficient data at pH 7. Evaluation Meeting (09.-10.02.2005): Data requirement confirmed. Notifier stated that data or a justification for the argumentation that such data are not necessary will be provided within the next 4 months. Data requirement still open.
1(52)	Vol. 3, p. 7, B.2.1.21 Flash point	EFSA: Being aware that the determination of the flash point is not applicable for spirodiclofen, this should be indicated in the table B.2.1.	(ii) DAR will be amended	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)
1(53)	Vol. 3, p. 7 and 10, General point, oxidising properties	EFSA: It should be discussed in an expert meeting as a general point whether it is acceptable to address both annex points on oxidising properties (for the active substance and the formulation) only with justifications based on a theoretical assessment.		Open point MS to discuss in an expert meeting as a general point whether it is acceptable to address both annex points on oxidising properties (for the active substance and the formulation) only with justifications based on a theoretical assessment. Evaluation Meeting (09.-10.02.2005): This open point will be discussed at the expert meeting in March (EPCO 20) as a general point. Open point still open.
1(54)	Vol. 3, p. 10, B.2.2.10 pH value	EFSA: Clarification is needed regarding the comment that "*result for a 1% dispersion is required*". It seems to be that this requirement does not appear in Level 4 of Volume 1.	(ii) See 1(33)	See comment 1(33)

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

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(55)	Vol. 3, p. 31, B. 3.4.2.1 and p. 38, B.3.5.6.2 Controlled incineration	EFSA: Being aware that the annex point is addressed, it should be noted just for clarification purposes that in principle the content of halogens should be taken into account and not only the content of chlorine. Furthermore, the statement on page 38 that "*spirodiclofen contains no halogens at all*" is incorrect.	(ii) DAR will be amended	Addressed. RMS to consider in a revised DAR or corrigendum
1(56)	Vol. 3, p. 64, B.5.5.3 Analytical methods (residue) soil, water, air	EFSA: Clarification is needed regarding the assessment of the analytical method for soil. Taken the given residue definition for monitoring into account (Vol. 1, p. 31, 2.5.1) it seems to be that these metabolites are regarded as relevant. For clarification purposes, the residue definition and the relevance of the metabolites, respectively, should be confirmed.	(ii) Clarification is requested from the fate section regarding the residue definition for monitoring. The given residue definitions for monitoring are including the metabolites which were formed at >10% AR. It is unclear if those metabolites are of toxicological and/or ecotoxicological relevance and should indeed be monitored. The analytical method is not fully validated if the residue definition for monitoring for soil is indeed including the a.s. and 4 metabolites.	See open point in comment 1(45).

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. 3, B.6.1.6 Absorption, excretion and distribution studies	BE: From the toxicokinetic studies it appears that oral absorption of spirodiclofen reaches 60-76%. The use of a factor of 0.58 for oral absorption should be clarified	(ii): The use of 0.58 for oral absorption is considered worst-case for risk assessment purposes. The value of 0.58 was based on excretion of radiolabel in urine 24 hours after administration of 2 mg/kg bw. However, a longer collection period should have been considered. Within the available studies, data could have been derived after 48 hours, which would have resulted in oral absorption of 0.64 for males and 0.76. These latter data are now included in the endpoint list. For risk assessment purposes, the difference between 0.58 and 0.64 is considered negligible. A systemic AOEL of 0.009 mg/kg bw/day (0.63 mg/day) is calculated instead of an AOEL of 0.008 mg/kg bw/day (0.56 mg/day), and no new occupational risk assessment was performed. The AOEL however, is adapted in the critical endpoint list.	Open point The oral absorption value to be confirmed at an expert meeting. See also comments in 2(37), 2(44) as well as German comments provided in the meeting. Evaluation Meeting (09.-10.02.2005): 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.3, B.6.6.1 reproductive toxicity	BE: Agreement with NOAEL systemic toxicity<70 ppm (5.2 mg/kg bw/d) but we propose to take into account the decreased body weight observed in F2 pups at birth for fixing the NOAEL reprotoxicity. This gives a NOAEL repro= 70 ppm and not 350 ppm as proposed by the RMS.	(ii): Decreased body weights in pups are not considered reproductive effects. The NOAEL for reproductive effects was based on a decreased spermatogenesis and was set at 350 mg/kg food.	See open point in comment 2(12).
2(3)	Vol.3, B.6.8 Mechanistic studies	BE: BAJ 2510 concentration-dependently decreased the overall amount of reducing equivalents and of levels of NADH and NADPH in mitochondria. - We think that different aspects suggest that cholesterol synthesis is inhibited and this could reduce hormonal synthesis. - Is malate dehydrogenase the unique mitochondrial source of NADPH? What is the opinion of the RMS?	(ii): Spirodiclofen metabolite BAJ 2510 concentration-dependently decreased the overall amount of reducing equivalents and of levels of NADH and NADPH in mitochondria. These lower levels of reducing equivalents unspecifically lower the synthesis of cholesterol, triglycerides and steroid hormones. Besides the malic enzyme route of NADPH production in mitochondria, there are also other sources of mitochondrial NADPH as NADP linked isocitrate dehydrogenase and nicotinamide nucleotide transhydrogenase.	See open point in comment 2(4).

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(4)	Vol. 3, B.6.1.1, Toxicokinetic studies	UK: The lack of repeat dose data for females is of concern, particularly as there are marked sex differences in metabolism and there is evidence this compound might act as an endocrine disrupter. We also note the high log Kow	(ii): Indeed no data on repeated dose with females were available. Sex differences in metabolism after single dosing were indicated. The other aspects of toxicokinetic studies, absorption, excretion and distribution, were studied in females at relevant dose levels (2 and 125 mg/kg bw/day). As suitable repeated dose toxicity studies, including reproduction and teratogenicity studies were available, additional data on repeated dose toxicokinetic data for females were not considered necessary.	Open point The endocrine disrupting properties of the compound to be discussed at an expert meeting. See also comments in 2(3), 2(5) and 2(13). Evaluation Meeting (09.-10.02.2005): 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(5)	Vol. 3, B.6.1.1, Toxicokinetic studies	UK: Only limited data are presented for few tissues. In study 1, tabulation of the radioactivity levels in tissues would allow an independent assessment. It would also make it clear which tissues have been evaluated. As presented in the DAR, only the liver, kidney, plasma, gastro-intestinal tract and skin are mentioned (other tissues tells us nothing). Did it reach the bone marrow (mutagenicity) or sex organs (testes and uterine tumours)?	(ii): In the summary of study 1, in footnote 2 of table B.6.1.1, the tissues were given which were evaluated. The radioactivity levels for liver, kidneys, plasma, GI-tract and skin were given in the study summary. For all other tissues it was stated that tissue concentrations were below 0.01 µg eq/g.	Open point. RMS to present data (evaluated tissue of toxicokinetic studies) in an addendum. To be discussed together with open point in comment 2(4). Evaluation Meeting (09.-10.02.2005): Open point confirmed. This open point needs to be discussed in an expert meeting. Open point still open.
2(6)	Vol. 3, B.6.1.1, Toxicokinetic studies	UK: it would have been preferable to have labelled the molecule in two positions rather than one	(ii): One label is also considered acceptable. There is no reason to ask for an additional study with two labels.	Addressed.
2(7)	Vol.3, B.6.3, short term toxicity	UK: Tables for 28 day oral studies are not sufficiently transparent to enable an independent assessment	(ii): Studies were evaluated and all relevant effects were included in the table. For critical effects, percentages were given at the conclusion.	See open point in comment 2(9).

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2(8)	Vol 3, B.6.3.3 semichronic oral studies	UK: We would probably accept the LOEL for liver hypertrophy in rat and mouse as a NOAEL	(ii): In the study with mice, histological examination of the liver showed increased incidences of centrilobular hepatocellular hypertrophy in males in all dose groups. Based on this observation the NOAEL was set at < 15.3 mg/kg bw/d. In the study with rats, an increase in incidence and severity of adrenal cortical vacuolation was noted in males of all dose groups. Based on this observation the NOAEL was set at < 6.6 mg/kg bw/d. For both studies, a treatment-related adverse effect at the lowest dose level cannot be excluded.	See open point in comment 2(9).

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(9)	Vol 3, B.6.3.4 summary short term and semichronic oral studies	UK: We agree that the dog is the most sensitive species tested in this way, but note that a NOAEL has not been determined for short-term exposure in the dog.	(ii): a NOAEL for short-term toxicity has been derived in a 52-week study in dogs: 1.45 mg/kg bw/day (see B.6.5). Unfortunately, the 52-week study was included in B.6.5, however, a 52-week study in dogs is considered semichronic, and should have been included in B.6.3. As there seems to be no effect of exposure duration (based on studies in rat, mice and dogs), the NOAEL of 1.45 mg/kg bw/day is considered applicable for both short-term and chronic exposure.	Open point MS to confirm the relevant NOAEL for the short-term studies. See also open point 2(15) and comments in 2(7-8) and 2(28-30). Evaluation Meeting (09.-10.02.2005): Open point confirmed. This open point needs to be discussed in an expert meeting. Open point still open.

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2(10)	Vol 3, B.6.4.3 Genotoxicity summary	UK: Equivocal results in HPRT assay and significant increases in chromosome abberations in the cytogenetics assay in the absence of historical control data, lead us to conclude further clarification and possibly a second *in vivo* study should be required.	(ii): An increased mutation frequency with and without metabolic activation was only observed in one culture and was not confirmed in the parallel treated culture nor in the second trail. Therefore, the observed increase was not considered toxicologically relevant. The performance of a second *in vivo* genotoxicity study is not considered necessary.	Open point The genotoxicity to be discussed at an expert meeting. See also open point in comment 2(13) Evaluation Meeting (09.-10.02.2005): 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(11)	Vol 3, B.6.5.3, long term toxicity/carcinogenicity	UK: Increased organ weights and increased T3 (tri-iodothyroxine) levels in females suggest a treatment-relate effect at 20 ppm (the lowest dose used) but the lack of actual values in the table makes it difficult to interpret.	(ii): Observed changes in organ weights and T3 were not considered adverse effects, since the changes were slight, not dose-related and not accompanied by associated histopathological changes.	Open point MS to confirm the relevant NOAEL for the long-term studies. See also open point 2(14) and comments in 2(32-33). Evaluation Meeting (09.-10.02.2005): Open point confirmed. This open point needs 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)
2(12)	Vol 3, B.6.6.1, Reproductive toxicity	UK: RMS has determined a LOEL of 70 ppm (5.2 mg/kg bw/day), the lowest dose used. Again, there is insufficient information in the tables to make an independent assessment. The possible lack of evaluation of the spermatids/sperms at this dose is of particular concern.	(ii): For systemic effects a LOAEL of 5.2 mg/kg bw/day was derived. This LOAEL is based on a detailed evaluation by the RMS, and all relevant information is included in the study summary. If additional information is considered necessary, one can check the available electronical files of the K-documents. Although spermatids/sperms were not evaluated at 70 ppm, the study is considered suitable for evaluation and establishment of a NOAEL for reproductive effects, since no adverse effects on spermatid/sperm count was noted at the next higher dose level.	Open point MS to confirm the relevant NOAEL for the reproduction toxicity studies. . See also comments in 2(2) and 2(34). <u>Evaluation Meeting (09.-10.02.2005):</u> Open point confirmed. This open point needs 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)
2(13)	Vol 3, B6.8.1.2, mechanistic studies	UK: From a brief consideration of the DAR we could not find a proposal for clear mechanisms for the observed tumours, endocrine effects or immunotoxicity, however it does seem that spirodiclofen has more than one mechanism of toxicity	(ii): From the mechanistic studies it was concluded that the carcinogenic potential by BAJ 2510 should be regarded as a non-genotoxic carcinogenic mechanism, since based on the mechanistic studies, BAJ 2510 interferes with steroid hormone synthesis at the level of general biochemical pathways.	Open point The carcinogenic effects to be discussed at an expert meeting. See also open points in comments 2(4) and 2(10) and comment in 2(38). Evaluation Meeting (09.-10.02.2005): Open point confirmed. Open point still open.
2(14)	Vol 3, B.6.10.3, Proposed ADI	UK: The RMS proposed an ADI of 0015 mg/kg bw/day. We cannot accept this value at present without further clarification	(ii): it was concluded that spirodiclofen is non-genotoxic, and a non-genotoxic carcinogenic mechanism was proposed based on the mechanistic studies. Therefore, it is considered suitable to establish an ADI. The lowest overall NOAEL for non-neoplastic lesions of 1.45 mg/kg bw/day from a 52 week oral toxicity study in dogs, was supported by short-term toxicity studies with rat and dog, 18 months oral toxicity study with mice and a 2-generation rat toxicity study with LOAELs ranging from 2.9 to 8.0 mg/kg bw/day. Furthermore,	Open point MS to confirm the ADI at an expert meeting. See also open point in 2(11) Evaluation Meeting (09.-10.02.2005): 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(14)	*continued* Vol 3, B.6.10.3, Proposed ADI		these LOAELs were based on critical effects comparable to those observed in the 52 week oral toxicity study with dogs. Therefore, it was considered suitable to that the clear NOAEL of 1.45 mg/kg bw/day for the establishment of the ADI.	
2(15)	Vol 3, B.6.10.5, Proposed AOEL	UK: We suspect NOAELs could be set for at least 2 of the 3-month studies. (see comment at 2(8) above) If so this might affect the derivation of the AOEL.	(ii): Since treatment-related adverse effects could not be excluded at the lowest dose level, NOAELs could not be established (see evaluaton for comment 2(8)). Regardless the studies with rats and mice: as the dog is the most sensitive species, the NOAEL of 1.45 mg/kg bw/day should be considered for the establishment of the AOEL.	Open point MS to confirm the AOEL at an expert meeting. See also open points in 2(9) and 2(21) and comments in 2(7-8), 2(26) and 2(37). Evaluation Meeting (09.-10.02.2005): Open point confirmed. Open point still open.
2(16)	Vol 3, B.6.11, formulation toxicity	UK: we consider that two skin sensitisation studies supporting the same formulation is a misuse of animals. The active substance was positive for skin sensitisation and the formulation should be classified based on the GPMT test	(ii): the RMS agrees. Tests should not have been performed, based on the skin sensitizing properties of the active substance. Since the studies were available in the present dossier, they were summarized.	Addressed.

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2(17)	Vol 3, B.6.12, dermal penetration	UK: we consider the use of Rhesus monkeys for dermal penetration studies is an inappropriate use of primates.	(ii): the RMS agrees. *In vivo* studies with rats and *in vitro* studies with rat and human skin are the preferred studies. Since the study was available in the present dossier, it was summarized. However, a remark should have been made at „acceptability“.	Open point The dermal absorption value to be confirmed at the expert meeting as well as the scientific value of the rhesus monkey study. See also open point in 2(21) and comments in 2(18-20) as well as German comments provided in the meeting. Evaluation Meeting (09.-10.02.2005): 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(18)	Vol 3, B.6.12, dermal penetration	UK: It is not clear if the radio labelled active substance was applied in the formulation concentrate or a dilution. Values for the both concentrate and the dilution(s) are required.	(ii): ^{14}C-labelled BAJ 2740 was applied at a concentration of 6 µg/cm^2 in a BAJ 240 SC 240 formulation (undiluted). Normally, dermal absorption of the undiluted formulation will be lower than for the spray dilution. However, it can be assumed that dermal absorption through animal skin will be higher than through human skin. Therefore, it is considered acceptable to use the value of 2% for dermal absorption for both the undiluted formulation and spray dilution through human skin, as a reasonable worst-case value for dermal absorption.	See open point in 2(17)..
2(19)	Vol 3, B.6.12, dermal penetration	UK: The application site was not given in the text (some sites are more amenable to absorption than others), and only male monkeys were considered.	(ii): The test substance was applied on a shaved area of skin on the back of each animal. This part of the skin is considered suitable for evaluation of dermal absorption.	See open point in 2(17)..

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2(20)	Vol 3, B.6.12, dermal penetration	UK: Approximately 8% of the radioactivity was not recovered and there was no necropsy. Therefore, it must be assumed that this 8% remains in the body.	(ii): It is assumed that approximately 8% of radioactivity is located in the skin at the application site. Since 144 h after exposure, excretion of radiolabel was very low, it can be assumed that the 8% located in the skin will not become systemically available or very slowly. Therefore, the 8% of radioactivity, which was not recovered, was not considered as potentially absorbed.	See open point in 2(17)..

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2(21)	Vol 3, B.6.14.1, operator exposure	UK: For the UK POEM knapsack model the application parameters typically assumed are 1 ha or 400 litres of spray solution applied per day. A realistic worse case assessment for hand-held application would therefore be 0.4 ha (400 litres/1000 litres) rather than the 0.15 ha which has been modelled.	(ii): It is assumed that 6 tanks can be sprayed in one hour, manual spraying takes 5 hours. So 30 tanks can be sprayed. Assuming a tank volume of 15 L, and a spray volume of 1000-3000 L/ha, the treated area will be 0.15-0.45 ha. Within the UK POEM calculation, for mixing and loading 30 tank mixes were assumed and for application a duration of 5 hours was assumed. These assumptions are considered reasonable worst-case.	Open point The operator exposure to be discussed at an expert meeting. The RMS is asked to present the results of the estimations in relation to the systemic AOEL in the addendum. See also open points in comments 2(15) and 2(17) and comments in 2(26), 2(23) as well as German comments provided in the meeting Evaluation Meeting (09.-10.02.2005): Open point confirmed. Open point still open.
2(22)	Vol 3, B.6.14.1, operator exposure	UK: As there is currently no agreed model for the EUROPOEM database, details of which datasets have been used for the assessment should be given so that the assessment is transparent.	(ii): EUROPOEM guidance is available for the MS. 75th percentile values were taken and the used surrogate exposure values are given in the DAR. Its is not considered necessary to include additional information in the DAR.	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)
2(23)	Vol 3, B.6.14.4, risk assessment	UK: In Table 6.14.4 estimates of exposure for dermal exposure and inhalation exposure using the various predictive exposure models are compared individually to the proposed systemic AOEL of 0.008 mg/kg bw/day (0.56 mg/ 70 kg person/day). As route specific AOEL's have not been proposed for this substance, the assessment (operators and bystanders) should consider exposure on the basis of total systemic exposure, i.e. dermal and inhalation exposure should be combined. Recommendations should be based on these total systemic exposures.	(ii): Indeed total systemic exposure should be considered. However, both exposure data for both routes were given separately in Table 14.4.4, in order to give separate recommendations for the necessity of the use of PPE for each route. For risk assessments in the future, an additional row will be included giving the total systemic exposure for each scenario.	See open point in comment 2(21).
2(24)	Vol 3, B.6.14.3 Worker exposure	UK: This section concludes that worker exposure will probably be limited to a short period of re-entry tasks shortly after application. As it can be expected that pome fruit, stone fruit and grapes will be harvested by hand, this statement appears incorrect and the assessment for re-entry workers should consider hand-harvesting over a full working day.	(ii): The section concludes indeed that worker exposure will be limited to a short period. However, calculations were made based on a workday of 6 hours and with the assumption that no dissipation will occur. However, this is a worst-case scenario. The sentence „worker exposure will probably limited to a short period of re-entry tasks shortly after application" was based on the fact that the formulation will be applied only once during the growth season.	Addressed.

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2(25)	Vol 3, B.6.14.3 Worker exposure	UK: The use of protective clothing for re-entry workers to reduce levels of exposure to within acceptable levels may not be realistic, as these workers may not be aware of the compounds which have been used on the crops they are harvesting. Whilst it is expected that work clothing worn will offer some protection from dislodgeable foliar residues, the realistic worse case for these workers would be to consider exposure for an unprotected worker.	(ii): RMS agrees that use of PPE by workers may be a problem. In the NL workers have to be informed on the treatment of crops and the company should make PPE available by law. The risk without PPE is calculated for the dermal route. The use of gloves can be prescribed for working with crops treated with BAJ 2740 SC 240. However, the calculated risk index without PPE is in the range of 1.25 – 1.86. Considering the used safety margins in calculating the AOEL or exposure (no dissipation), the risk of the worker without PPE can be considered negligible.	Addressed.
2(26)	Vol 3, 6.14.4, risk assessment	UK: Clearly exposures would need to be compared against any revised AOEL (see comment 15 above)	(ii): preparation of an addendum is not considered necessary, since the AOEL is not changed and no new exposure calculations have been made.	See open points in comments 2(15) and 2(21).

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2(27)	Vol. 1; 2.3 p. 15 – 28 and list of endpoints	Notifier: For certain studies differences are evident between the assessments of the RMS and those of BCS as presented in the dossier: subacute feeding rat, subacute dermal rat, subchronic feeding mouse and rat, oncogenicity mouse, chronic combined rat, reproduction rat. Several of these discrepancies have relevance when setting the NOAEL for the studies concerned. A detailed justification supporting the BCS assessments has been provided specifically for each study in response to Volume 3 of B.6 "Toxicology and Metabolism". These justifications apply also for the study summaries of Volume 1 and should be implemented here and in the list of endpoints as well.	(ii): we have evaluated the justifications provided by BCS, but decided to maintain the conclusions drawn in the DAR. The notifier gave comments on the individual studies. NL responded on these comments for each individual study (see data points below). Since the RMS did not agree with the notifier, volume 1 and end-point list were not amended.	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)
2(28)	Vol. 3, B.6.3.1, NOAEL of the subacute feeding study in rats, p. 84 - 86	Notifier: BCS proposes a **NOAEL of 500 ppm** based on changes in clinical chemical parameters at 5000 ppm.	(ii): The notifier argued that observed haematological and ECOD changes should not be considered for the establishment of the NOAEL, since observed effects are not considered to be adverse effects. However, as a consequence of the small dose groups, observed effects may not be statistically significant at 500 mg/kg food, effects observed in the 500 ppm and 5000 ppm groups as indicated in the table are considered toxicologically relevant. Furthermore, effects on the immune system were noted at 500 and 5000 ppm. Therefore, the NOAEL is not adapted based on the comments made by the notifier.	See open point in comment 2(9).
2(29)	Vol. 3, B.6.3.2, NOAEL of the subacute dermal toxicity study in rats, p. 88-89	Notifier: BCS proposes a **NOAEL of 1000 mg/kg bw** based on the absence of adverse effects at this dose level.	(ii): Several effects were noted at 1000 mg/kg bw/day. Changes might be slight, however, they could not be clearly evaluated, since a limit test was performed and only a 5 animals per group were used. The NOAEL is not adapted.	See open point in comment 2(9).

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(30)	Vol. 3, B.6.3.3, NOAEL of the subchronic feeding study in mice, p. 90-92	Notifier: BCS has proposed a **NOAEL of 100 ppm** based on Leydig cell hypertrophy and cytoplasmic vacuolation of the adrenal cortex at 1000 ppm. We agree that with regard to effects on the liver, the no-observed effect level is < 100 ppm, but the centrilobular hepatocellular hypertrophy seen at this dose level is not considered to be an adverse effect.	(ii): The RMS proposed a NOAEL of < 100 ppm, based on centrilobular hepatocellular hypertrophy at doses of 100 ppm and above. Considering the observed effects in the liver after chronic exposure, the centrilobular hepatocellular hypertrophy is considered toxicologically significant.	See open point in comment 2(9).
2(31)	Vol. 3, B.6.3.3, NOAEL of the subchronic feeding study in rats, p. 92-94 *continued* Vol. 3, B.6.3.3, NOAEL of	Notifier: Based on an increased incidence of adrenal cortical vacuolation in males, the RMS considers the NOAEL to be < 100 ppm. BCS has proposed a **NOAEL of 500 ppm** for males and 100 ppm for females based on effects on lipid metabolism (cholesterol, triglycerides), liver (increased transaminase activities) and adrenals (cortical vacuolation).	(ii): The notifier should provide historical control data to make an additional evaluation of the renal cortical vacuolation in males possible. Historical control data should be made available for the same strain, performing laboratory, study duration and time period.	Data requirement Notifier to submit historical control data to make an additional evaluation of the renal cortical vacuolation in males possible. Evaluation Meeting (09.-10.02.2005): The notifier asked for clarification whether the data requirement refers to renal or adrenal cortical vacuolation. If it refers to adrenal cortical vacuolation the data can be submitted within 4 weeks. 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)
	the subchronic feeding study in rats, p. 92-94			
2(32)	Vol. 3, B.6.5.1, NOAEL of the oncogenic study in mice, p. 104 – 107	Notifier: Whereas the RMS concludes that the NOAEL in this study is < 25 ppm, BCS considers this dose level to be tolerated without **adverse** effects. Only at 3500 ppm treatment-related changes were seen.	(ii): The NOAEL of < 25 ppm was based on an increased incidence of adrenal pigmentation and vacuolation in females, an increased incidence of amyloid in several tissues of males and increased incidence of hepatocytomegaly in males. The notifier states that the observed increase in adrenal corticomedullary pigmentation was within the historical control range. However, since pigmentation increases with age, the provided historical control values of a 92 weeks exposure study are not comparable with the values in the present 78 weeks exposure study. The provided historical control values of a 81 weeks exposure study showed pigmentation in 12/50 females, which is comparable with the control values in females of the present study. The observed increase in the 25 ppm female group (20/49) is therefore considered a substance related effect. The difference in frequency between the lowest dose and the two higher doses is considered to be related to the great jump in doses (25 ppm vs 3500 and 7000 ppm).	See open point in comment 2(11).
2(32)	*continued* Vol. 3, B.6.5.1, NOAEL of the oncogenic study in mice, p. 104 – 107		Furthermore, the notifier states that 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)
2(32)	*continued* Vol. 3, B.6.5.1, NOAEL of the oncogenic study in mice, p. 104 - 107		observed incidence in adrenal cortical vacuolisation at 25 ppm in females was not increased over control levels and is a common finding. However, an increased vacuolation was noted in females of all dose groups. The difference in frequency between the lowest dose and the two higher doses is considered to be related to the great jump in doses (25 ppm vs 3500 and 7000 ppm). In addition, the notifier states that there was no increase in the number of animals with amyloidosis, and that the amyloidosis noted in the study was not compound related. However, increased incidence and/or increased average severity of amyloid in several tissues in the exposed animals. Increased incidence of amyloid was already observed in the lowest dose group in the heart, liver, thyroids and parathyroids of males. The historical control values of a 79-81 weeks exposure study are substantially lower than the observed increase in the 25 ppm group. The notifier additionally argued that the observed hepatocytomegaly at 25 ppm is a normal response and was not significantly increased over control. However, although not statistically significant,	

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			an increase in hepatocytomegaly at 25 ppm was noted in males. As no historical control data were available in the study report no additional evaluation of this finding could be made. Based on the above considerations, the RMS is of opinion that the NOAEL should be adapted based on the comments made by the notifier. The NOAEL is set at < 25 ppm.	
2(33) 2(33)	Vol. 3, B.6.5.1, NOAEL of the chronic combined feeding study in rats, p. 107 – 110 *continued* Vol. 3, B.6.5.1, NOAEL of the chronic combined feeding study in rats, p. 107 - 110	Notifier: On basis of alleged thymus and ovary weight changes at 350 ppm, the RMS considers 100 ppm to be the NOAEL for this study; BCS still proposes **350 ppm as a NOAEL**.	(ii): For both organs no statistically significant changes were noted. However, absolute and relative organ weights were increased more than 10% at final necropsy when compared to control values. Furthermore, the increases were dose-related. Therefore, the NOAEL was set at 100 ppm. Exact percentages are: Absolute thymus weight: 350 ppm: incr. of 19% compared to controls 2500 ppm: incr. of 25% compared to controls Relative thymus weight: 350 ppm: incr. of 11% compared to controls 2500 ppm: incr. of 20% compared to controls Absolute ovary weight: 350 ppm: incr. of 12% compared to controls 2500 ppm: incr. of 34% compared to controls Relative ovary weight:	Open point RMS to transfer information (effects chronic feeding study rats) in column 3 of the reporting table to an addendum. See also open point in comment 2(11). Evaluation Meeting (09.-10.02.2005): Open point confirmed. Addendum to be discussed in an expert meeting (see open point in comment 2(11)). 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)
			350 ppm: incr. of 12% compared to controls 2500 ppm: incr. of 31% compared to controls	
2(34)	Vol. 3, B.6.6.1, NOAEL of the 2-generation reproduction study in rats, p. 114 – 117	Notifier: The RMS considers 70 ppm to be an effect level (effects on body weights, brain and liver weights, triglycerides and cholesterol) whereas BCS still proposes a **NOAEL of 70 ppm.**	(ii): F1 animals showed decreased blood cholesterol (90% of control value) and triglyceride (70% of control value) concentration at 70 ppm. The decrease in blood cholesterol and triglyceride was noted in all dose groups and was dose-related. Absolute and relative liver weights were statistically significant decreased in males at 70 ppm (88 and 91% of control values, respectively). Considering the liver effects in other studies, observed changes in liver weight and cholesterol and triglyceride concentration, are considered toxicologically relevant. For the 70 ppm group, body weights were statistically significant decreased during weeks 1-6. Body weight gain was statistically significant decreased in first treatment week only. Relative brain weights were statistically significant increased (106% when compared to controls) at 70 ppm. Based on all effects observed at 70 ppm, mainly the effects indicative of liver toxicity, the NOAEL for systemic toxicity was set at < 70 ppm.	See open point in comment 2(12).
2(34)	*continued* Vol. 3, B.6.6.1, NOAEL of the 2-generation reproduction study in rats, p. 114 – 117			

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(35)	Vol. 3, B.6.8.1, Immunotoxicological and mechanistic studies, p. 137	Notifier: RMS: "Incubation of commercially available purified enzymes resulted in BAJ 2510-induced inhibition of mitochondrial malate dehydrogenase (MD), whereas malic enzyme was not affected." (also on further pages). Both mitochondrial and cytosolic malate dehydrogenase were inhibited by BAJ 2510. It is proposed to modify the sentence as follows: "Incubation of commercially available enzymes resulted in BAJ 2510-induced inhibition of mitochondrial **and cytosolic** malate dehydrogenase (MD), whereas malic enzyme was not affected.	(ii): The RMS agrees. BAJ 2510 both induced mitochondrial and cytosolic malate dehydrogenase.	Addressed. RMS to consider in a revised DAR.
2(35)	*continued* Vol. 3, B.6.8.1, Immunotoxicological and mechanistic studies, p. 137			
2(36)	Vol. 3, B.6.8.1, Immunotoxicological and mechanistic studies, p. 143	Notifier: RMS: " It cannot be excluded that this effect may contribute to reduction of testosterone synthesis in Spirodiclofen treated testicular tissue." Spirodiclofen was never detected in the plasma of laboratory animals. In order to stress this point, it should be indicated that this statement refers to the *in vitro*	(ii): The RMS agrees with the fact that spirodiclofen was never detected in plasma of laboratory animals. However, the DAR will not be adapted on this point, since it is clear from the study summary and overall summary that this sentence refers to an *in vitro* situation: "The observed inhibition by spirodiclofen of 3β-hydroxysteroid dehydrogenase-Δ4,5-isomerase in vitro may contribute to the	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)
		situation only.	observed reduction of testosterone synthesis in cultured, spirodiclofen-treated testicular tissue."	
2(37)	Vol. 3, B.6.10.5, AOEL, p. 152	Notifier: *Systemic AOEL / enteral absorption*: The RMS used a correction factor of 0.58 to reflect an allegedly incomplete absorption of spirodiclofen from the gastro-intestinal tract. This value obviously originates from a single dose study (3 mg/kg bw) where renal excretion was ca. 58 % in male rats and 75 % in females. A correction factor of 0.58 is regarded to be over-conservative as it does not include spirodiclofen excreted via bile. In a bile cannulation experiment ca. 12 % of the radioactivity was identified in the bile fluid. This finding and the fact that in a repeated dose study > 70 % of the radioactivity were excreted in the urine of males and females, support an overall correction factor of 0.7. Therefore, BCS proposes an **AOEL of 0.01 mg/kg bw/day.**	(ii): Indeed data on bile cannulation rats were available. Following administration of 1 mg ^{14}C-spirodiclofen/kg bw to bile duct cannulated male rats 62.8 % of recovered radioactivity was excreted within 24 h, i.e. 22.8% in urine, 28.7 % in faeces and 11.3 % in bile. For risk assessment purposes data after 48 hours from the studies with male and female rats given 2 mg ^{14}C-spirodiclofen/kg bw were taken. See also comment on 2(1).	See open points in comments 2(1) and 2(15).
2(38)	Vol. 3, B.6, p. 114&148	Notifier: R 40 labelling of the active ingredient: The actual wording for R 40 is **„Limited evidence of a carcinogenic effect"** and no longer "Possible risk of irreversible effects", please change everywhere in the DAR.	(ii): the DAR of April 2004, at pages 114 and 148 „possible risk of irreversible effects" is already included.	See open point in comment 2(13).

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(39)	Vol. 3, B.6, p. 89	Notifier: typing error: line 2: ..with the following deviat**i**on ...	(ii): Comment is correct.	Addressed. RMS to consider in a revised DAR.
2(40)	Vol. 3, B.6, p. 92	Notifier: typing errors: line 13: ...the NOAEL **is** 100 ppm; line 15: in accordance with the opinion of the study author, **is** set at 100 ppm	(ii): Comment is correct.	Addressed. RMS to consider in a revised DAR.
2(41)	Vol. 3, B.6, p. 101	Notifier: typing error: STUDY 2, table: Brendler-S**ch**waab	(ii): Comment is correct.	Addressed. RMS to consider in a revised DAR.
2(42)	Vol. 3, B.6, p. 123	Notifier: typing error: NOAEL: 70 mg/kg bw/da~~g~~**y**	(ii): Comment is correct.	Addressed. RMS to consider in a revised DAR.
2(43)	Vol. 3, B.6, several pages	Notifier: typing error: the term “jejenum” should be changed to “jejunum”	(ii): Comment is correct.	Addressed. RMS 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)
2(44)	Vol. 3, B 6.1.6, Toxicokinetics, absorption.	DK: In the summary and conclusions it is stated, that the absorption is at least 64% in males and 76% in females, but the absorption is stated as 58% in the list of End-Points.	(ii): see comment on 2(1).	See open point in comment 2(1).
2(45)	Vol. 3, B6.1.6. Toxicokinetics, Metabolism.	DK: There is a big difference in the metabolites of spirodiclofen found in urine of male and female rats. Is there any explanation for this?	(ii): An explanation for the difference in metabolites between males and females might be a higher capacity in the metabolisation of BAJ-enol (first metabolite) in male rats when compared to females rats.	Addressed.
2(46)	Late comments DE	DE supports comments from BE on oral absorption. DE also comments on the dermal absorption, the AOEL and the exposure data. In written comments of 21 Feb. DE commented on the unnecessary setting of an additional drinking water limit in the DAR, Vol. 3, B.6.10.6.		Evaluation Meeting (09.-10.02.2005): Comments of DE will be taken into account in the relevant discussion in the expert meeting. New open point: DE comments on the additional drinking water limit in the DAR, Vol. 3, B.6.10.6 to be taken into account in a revised DAR/corrigendum. New open point 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. 3, B.7.6.1, p. 206	Notifier: Method 00568 is considered valid for determination of residues in grapes. (see Vol. 3, B.5.5.2.2) To support the explanations in Column 3 the notifier will subject an extra sample form the grape metabolism study (stored frozen until today) to the Method 00568. Extraction efficiency will be compared with the result from the metabolism study. The extract will be subjected to chromatographic analysis to check whether the pattern of active substance and metabolites is the same as reported in the metabolism study. If so it confirms storage stability. If the extraction efficiency with both methods is the same and the storage stability is given then the question of the RMS is also answered experimentally. Results will be available by end of September 2004.	(ii) In the monograph a difference in residue height between metabolism study and rseidue trials was observed. Notifier was asked to provide information about the extraction efficiency, which might possibly be different, since different methods of analysis were used. Notifer explains the higher residue level found in the metabolism study by more intense spraying and smaller fruit size (having a higher surface/volume ratio). Notifier now performs an experiment to show extraction efficiency from method 00568 and storage stability in samples of the grape metabolism study. RMS is waiting new results.	Data requirement Notifier to submit a study to show extraction efficiency from method 00568 and storage stability in samples of the grape metabolism study. See also comment 1(2) Evaluation Meeting (09.-10.02.2005): The notifier will submit the requested data within 4 weeks. 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(2)	Vol. 3, B.7.6.1, p. 206	Notifier: Method 00568: Additional recovery experiments in apple pomace at 1.0 mg/kg spirodiclofen required (see Vol 3, B.5.5.2.2) Study will be conducted. Results will be available end of 2004/beginning 2005	(ii) RMS is awaiting new results.	Data requirement: Notifier to submit additional recovery experiments in apple pomace at 1.0 mg/kg spirodiclofen. See also comment 1(14) Evaluation Meeting (09.-10.02.2005): The notifier will submit the requested data within 4 weeks. Data requirement still open.

section 3 – Residues (B.7)

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)	Vol 3, B.7.16.3.2, p 250.	Residue definition animal products Notifier: No residue definition in animal tissues is needed, because the cattle feeding study clearly shows that no residues are to be expected in milk, animal tissues and organs at the 1.7 and 5.1-fold overdose (1.38 and 4.14 mg/kg feed). In addition in the goat metabolism study no residues were found in goat tissues above 0.01 mg/kg considering the applied overdose. Besides this, the notifier does not agree with the argumentation for the proposed residue definition in animal products. Spirodiclofen was not found in the goat. The results from the goat metabolism study do not support the inclusion of spirodiclofen into the residue definition.	(ii) Since the trigger value of 0.1 mg/kg dry feed is exceeded, a residue definition for animal products is needed for enforecement purposes (at possible misuse). M01 was found as a major metabolite, but not spirodiclofen, in the goat metabolism study. However, in feeding studies with lacting cows also spirodiclofen was found. Therefore RMS is of the opinion that the residue definition for animal products is: spirodiclofen + MO1.	Addressed. See also open point in comment 3(5) as the issue ‘residue definition/MRL for animal products’ will 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)
3(4)	Vol.3, B.7.12.2, Proposed MRLs	UK: An MRL has not been proposed for apples and pears in Southern Europe due to insufficient trials being performed to the proposed GAP. Comparing the data in Tables B.7.6.3.3a and B.7.6.3.3b, the data sets for both N and S Europe show very similar residue data. An extrapolation could therefore be valid from N to S Europe and therefore a full data set for S Europe may not be necessary.	(ii) It is stated in the monograph that not the number of trials but the *number of trial locations* is rather small for deriving a group MRL for pome fruit in S. However, since the result from S overlap (completely) with those from N as stated correctly by UK, it is proposed to derive a MRL for pome fruit for S at second view. Selected trials: <0.02, 0.024, 0.027, 0.035, 0.039, 0.043, 0.046, 0.055. STMR = 0.037, HR = 0.055, MRL I = 0.0742 and MRL II = 0.0905 (all mg/kg). Since the proposed MRL for both N and S are 0.1 mg/kg, a EU-(group) MRL of 0.1 mg/kg is proposed for pome fruit.	Open point RMS to present MRL calculation for pome fruit from southern uses in an addendum Evaluation Meeting (09.-10.02.2005): Open point confirmed. RMS to transfer information from column 3 of the reporting table into an addendum. 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)
3(5)	Vol 3, B.7.12.4, residue definition in animal products	UK: we agree with the RMS that the issues raised by a fat soluble parent and a metabolite which is not fat soluble should be discussed by appropriate experts to try and resolve this potential difficulty for monitoring.	(ii) To be discussed in a expert meeting.	Open point MS to discuss in an expert meeting the issues raised by a fat soluble parent and a metabolite which is not fat soluble to try and resolve this potential difficulty for monitoring. See also comments 3(3), 3(12), 3(13) and 3(15) Evaluation Meeting (09.-10.02.2005): Open point confirmed. Open point still open.
3(6)	B.7.1.2.	RMS:/DAR (Volume 1, level 4): The identity of metabolite M06 (2,4-dichloro-mandelic acid) in the orange and lemon metabolism study is not shown (Babczinski (1999a) and Babczinski and Bornatsch (1999b)). The notifier is requested to submit identification data on metabolite M06.	(ii) Question was answered by notifier and should have been removed before publishing the DAR See 3(17).	Addressed. See also comment 3(17)

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(7)	B.7.7.	RMS/DAR (Volume 1, Level 4) In the livestock feeding study on dairy cows the study authors referred to two processing studies which were not available to the Rapporteur Member State. The notifier should submit the following study reports for evaluation: - Krolski, M.E. 2000. BAJ 2740 240 SC. Magnitude of the residue in orange processed commodities. Bayer AG Div Report No. 109726. - De Haan, R.A. 2000. BAJ 2740 240 SC. Magnitude of the residue in apple processed commodities. Bayer AG Div Report No. 110025.	(ii) No information is provided until now.	Data requirement: Notifier to submit the following study reports for evaluation: - Krolski, M.E. 2000. BAJ 2740 240 SC. Magnitude of the residue in orange processed commodities. Bayer AG Div Report No. 109726. - De Haan, R.A. 2000. BAJ 2740 240 SC. Magnitude of the residue in apple processed commodities. Bayer AG Div Report No. 110025. See also comment 3(10) Evaluation Meeting (09.-10.02.2005): The notifier will submit the requested data within 4 weeks. 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.7.15.1, Table B.7.15.1a (Indicative calculation of TMDI …) and Table B.7.15.1b (Indicative calculation of NTMDI …), page 246	AT: Only a formal supplementation in the headline of the mentioned tables: There is written: "…. and an ADI of 0.015 mg/kg bw" There should be called: "…. and an ADI of 0.015 mg/kg bw**/d**"	(ii) RMS agrees: mg/kg bw/**d** is indeed the only possible time unit to express the Acceptable **Daily** Intake.	Addressed. RMS to consider in a revised DAR/corrigendum
3(9)	Vol. 1, Level 4	EFSA: ESFA confirms the following data requirements by the RMS: The identity of metabolite M06 (2,4-dichloro-mandelic acid) in the orange and lemon metabolism study is not shown. The notifier is requested to submit identification data on metabolite M06.	(ii) Question was answered by notifier and should have been removed before publishing the DAR See 3(17).	Addressed. See also comment 3(17)
3(10)	Vol. 1, Level 4	EFSA: ESFA confirms the following data requirements by the RMS: The notifier should submit the following study reports for evaluation: Krolski, M.E. 2000. BAJ 2740 240 SC. Magnitude of the residue in orange processed commodities. Bayer AG Div Report No. 109726.De Haan, R.A. 2000. BAJ 2740 240 SC. Magnitude of the residue in apple processed commodities. Bayer AG Div Report No. 110025.	(ii) No information is provided until now. See also 3(7).	See data requirement in comment 3 (7)

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(11)	Vol.3, B.7. General	EFSA: Acceptability of a study should be clearly stated. It becomes not always clear from the conclusion if a study is deemed to be acceptable, e.g. for processing studies reported under B.7.7.2 and B.7.7.4 (citrus and stone fruits). Studies deemed as not acceptable for evaluation have to be removed from the list of references relied on (B.7.17).	(ii) Agree. The references of unreliable studies should be removed from the reference list of Volume 3 (References relied on) but should be maintained in the complete reference list of Volume 2.	Addressed. RMS to consider in a revised DAR/corrigendum The acceptability of a study should preferably be stated under the conclusion of the individual studies.
3(12)	Vol.3, B.7.12.4 MRL and STMR proposals in animal products	EFSA: EFSA agrees that the proposal of the RMS to define the residue in animal products as partly fat soluble should be discussed in an expert meeting.	(ii) To be discussed in a expert meeting. See also 3(5)	See open point in comment 3(5)
3(13) 3(13)	Vol 1, 2.4.1 , p. 29 *continued* Vol 1, 2.4.1 , p. 29	Notifier: The notifier is convinced that no residue definition in animal tissues is needed (see argumentation above (7)). Besides this, the notifier does not agree with the argumentation for the proposed residue definition in animal products. Spirodiclofen was not found in the goat. The results from the goat metabolism study not support the inclusion of spirodiclofen into the residue definition.	(ii) Not agreed (2x) The trigger value of the 0.1 mg/kg dry feed was exceeded for beef and milk cattle (being up to 0.38 mg/kg). Therefore, RMS is of the opinion that a residue definition should be derived and a method of analysis should be provided. The residue definition proposed is: spirodiclofen parent + metabolite M01, since MO1 was the major metabolite found in the goat metabolism study and spirodiclofen parent was found in milk in the cow feeding study.	Addressed. See also open point in comment 3(5) as the issue ‘residue definition/MRL for animal products’ will 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)
3(14)	Vol 1, 2.4.4, p. 30	Notifier: For grapes a provisional MRL of 0.2 mg/kg is proposed by the rapporteur (0.1 in this chapter is probably a typing error)	(ii) Agree The MRL on wine gapes is 0.2 mg/kg instead of 0.1 mg/kg as typed om page 30 of Vol. 1.	Addressed. RMS to consider in a revised DAR/corrigendum
3(15)	Vol 1, 2.4.4, p. 30	Notifier: No MRLs for animal matrices are considered necessary, because the cattle feeding study clearly shows that no residues are to be expected in milk, animal tissues and organs at the 1.7 and 5.1-fold overdose (1.38 and 4.14 mg/kg feed). In addition in the goat metabolism study no residues were found in goat tissues above 0.01 mg/kg considering the applied overdose.	(ii) Not agree Since the trigger value of 0.1 mg/kg is exceeded, attention should be paid to residues in beef and milk cattle in general. Although no residues above the LOQ are expected in edible tissues (however, in kidney residues *might well* be expected) a residue definition should be derived and MRLs should be established at the LOQ, to ensure incorporation in enforcement and monitoring programs and to detect possible misuses of spirodiclofen.	See open point in comment 3(5)
3(16)	Vol 1, list of endpoints, Chapter 2.4. p. 97	Notifier: MRL in peach and whole peach group should be 0.2 mg/kg (0.1 in this chapter is probably a typing error)	(ii) Agree The MRL in peach is 0.2 mg/kg instead of 0.1 mg/kg as typed on page 97 of Vol. 1.	Addressed. RMS to consider in a revised DAR/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)
3(17)	Vol. 1,level 4, 4.7.1 p. 127	Notifier: Identification of metabolite M06 has been described previously in a position paper by BCS which has been accepted by the rapporteur (Memo of [redacted], CTB, to [redacted], Bayer CropScience 19-02-03 as answer on: commentaar van notifier op openstaande vragen monografie spirodiclofen onderdeel residuen (RIVM october 2002)	(ii) Agree Question was answered by the notifier and should have been removed before publishing the DAR: it was explained by the notifier that M06 was only present in citrus fruits and for less than 0.8%. Therefore its identity should not further be examined. Furthermore, in the DAR it was stated that the properties of M06 were used to explain the toxicity of M04, M07 and M08. This is true, but the identity of M06 in citrus has nothing to do with it. Since M06 occurred in rat metabolism this explantion was already valid(ated).	Addressed. RMS to consider in a revised DAR/corrigendum See also comment 3(6), 3(9)

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(18)	Vol. 1, p. 31, Proposed EU MRLs in relation to analytical methods	EFSA: Clarification is needed regarding the proposed MRL for food of animal origin. From the analytical point of view it is unclear why the MRL should be set at the limit of detection (LOD). However, it seems to be that this is a typing error, due to the fact that the given values are in line (except for milk) with the limit of quantification (LOQ), mentioned in Vol. 3 (p. 50, Table B.5.2.4). The proposed MRLs should be confirmed.	(ii) Agree Typing error in Vol 1, 2.4.4, p30: LOD should be LOQ	Addressed. RMS to consider in a revised DAR/corrigendum
3(19)	Data requirement trnasferred from section 1 (comment 1(17))			Evaluation Meeting (09.-10.02.2005): Data requirement: Notifer to provide more validation data for the method 109 720 for the determination of residues in food of animal origin. The notifier will submit the requested data within 8 weeks. Data requirement still open.

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)	PEC groundwater and PECsoil. Vol.1 2.5.2 list of end points Vol.3 B.8.2.4 & B.8.3	SLO: The assumed interception is not consistent. The predicted concentrations in ground water are based on interception values of 65, 70 and 40% for apple, citrus and grape, respectively. The predicted concentrations in soils are based on an interception value of 50% for all three crops.	ii) PECsoil was calculated using a method proposed by PSD with 50% crop cover for post emerge applications and 0% crop cover for pre-emerge applications. For the PECgroundwater the interception values are taken from the FOCUS table. MS to discuss which values should be used.	Open point MS to discuss in an expert meeting which interception values should be used for PEC soil calculation. Evaluation Meeting (09.-10.02.2005): Open point confirmed. This issue will be discussed as a general point in an expert meeting. Open point still open.
4(2)	Vol. 3 B 8.1.1.1 b (Oi, M. 1999a), Aerobic studies	PL: The RMS comment on the reliability of the results (i.e. „The lack of data points would result in values, which are considered less reliable than those from the previous study") is not very clear (it is somehow contradictory and thus confusing). Please explain its meaning.	ii) In the study soil samples were taken on few timepoints only. Furthermore, the first sample after zero timepoint is at 14 days when already more than 50% of the parent degraded and a timepoint which comes near a probable hinge point . From the other study it is clear that the DT_{50} is only a few days. Therefore fitting the data from this study will give less reliable results.	Addressed.

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 3. B.8 General.	EFSA: Acceptability and reliability of each of the studies should be clearly indicated in the DAR.	ii) We will look closely at the DAR and make this more clear thoughout the complete DAR.	Open point RMS to clearly indicate acceptability and reliability of the studies. Evaluation Meeting (09.-10.02.2005): Open point confirmed: RMS to provide an addendum or corrigendum. In particular, acceptability of studies mentioned in comments 4(4), 4(5) and 4(6) should be clarified. Open point still open.
4(4)	Vol.3. B.8.1.1.1. b) Oi, M. , 1999a	EFSA: Whereas, the study could not be used to derive reliable DT50, it should be considered reliable with respect to establishing the route of degradation since label position is placed in a different position to address formation of potential metabolites not identified in the Oi, M. and Bornatsch, W., 1999.	ii) Agreed, we will add some text to the study.	See open point in comment 4(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)
4(5)	Vol 3. B.8.2.3 Babczinsky, P., 2000a.	EFSA: It should be clarified if the study is acceptable and if it is used in the risk assessment.	ii) It will be made more clear that the study was acceptable and which values are used for risk assessment. The acceptability or reliability of studies will be clarified throughout the DAR.	See open point in comment 4(3).
4(6)	Vol 3. B.8.4.2. a) Hellpointer, E. 1998a.	EFSA: It should be clarified if the photolysis study Hellpointer, E. 1998a. is reliable.	ii) See point 4(3)	See open point in comment 4(3).
4(7)	Vol 3. B.8.4.2. c) Babczinski, P. 2000c	EFSA: Efforts to identify M4 and the other non identified photolysis compounds should be reported.	ii) No efforts to identify the photolysis product M4 were reported in the study. We think that no further information is required. Though M4 was formed >10% in this study with the metabolite BAJ 2740-enol, M4 is not a major metabolite in the photolysis of the parent.	Addressed.
4(8)	Vol 3. B.8.4.3. Ready biodegradability.	EFSA: Since the water sediment study indicates that spirodiclofen is not ready biodegradable, either the R53 should be proposed or a ready biodegradability test required.	ii) Ready biodegradability and biodegradation in water sediment system are 2 completely different tests that provide totally different endpoints. As there is no ready biodegradability test provided the substance is considered not readily biodegradable. However, RMS agrees that considering the data available R53 must be supposed.	Addressed. The substance is considered not ready biodegradable for labelling purposes.

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(9)	Vol 3. B.8.9. Definition of the residue.	EFSA: It should be clarified if metabolite BAJ 2740-enol is also proposed to form part of the residue definition in ground water.	ii) BAJ 2740-enol and none of the other metabolites show a potention for leaching. The metabolites need not to be included in the residue definition for groundwater.	Open point RMS to clarify in B.8.9 and in the list of end points (p 107) the residue definition in ground water (separated of surface water). Evaluation Meeting (09.-10.02.2005): Open point confirmed. Open point still open.

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 2.6.1.1 Birds List of end points	SLO: See comments 7-9 on volume 3.	(ii): See 5(7) – 5(9).	See open points in comments 5(7) and 5(9).
5(2)	Vol.1 2.6.1.2 Mammals	SLO: See comments 10-14 on volume 3.	(ii): See 5(10) – 5(14).	See open points in comments 5(7) and 5(12).
5(3)	Vol.1 2.6.2 Effects on aquatic species – chronic risk of spirodiclofen List of end points	SLO: There is no clear position in the DAR on the chronic risks of spirodiclofen for aquatic organisms. Volume 3 states that chronic exposure to spirodiclofen is unlikely as there was a fast dissipation from the water column in the water-sediment study (DT50 0.3-1.1 days). If this is supported no further assessment is needed in volume 1 and the list of end points.	(ii): It is right that chronic exposure to spirodiclofen is not likely to occur, so chronic tests with aqautic organisms should not be necessary. But in this case chronic studies were submitted and they have to be taken into account. There is a huge difference between the acute and the chronic values, so it seems that sublethal effects are much more critical than mortality. This indicates that the actual triggers for performing chronic studies may be not appropriate for all cases.	Open point: RMS to prepare an addendum to clarify if further data is needed to address the risk to aquatic organisms or not. See also comment 5(23) and data requirement and open point in comment 5(35). Evaluation Meeting (09.-10.02.2005): Open point confirmed. The notifier stated that no chronic risk could be identified. Open point still open.

section 5 – Ecotoxicology (B.9)

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(4)	Vol.1 2.6.3.2 Other arthropod species List of end points	SLO: See comments 16-17 on volume 3.	(ii): See 5(16) and 5(17).	See comments 5(16) and 5(17).
5(5)	Vol.1 2.6.4.2 Effects on other soil macro-organism	SLO: Reference should be made to 2.6.6 where the risks of metabolites for Collembola are assessed based on accepted studies.	(ii): The point is agreed. The DAR will be adjusted.	Addressed. RMS to consider in a revised DAR/corrigendum
5(6)	Vol.1 list of end points - Bioaccumulation	SLO: The BCF based on total radioactivity should also be reported.	(ii): OK. The endpoint-list will be adjusted.	Open point: RMS to amend the list of endpoints regarding the BCF (add or adjust based on total radio-activity). See also comment 5(9). Evaluation Meeting (09.-10.02.2005): 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(7)	Vol.3 B.9.1.4 Risk assessment for birds - acute risk assessment	SLO: In the acute risk assessment the RUD values used are not mentioned. Using the standard 90th percentile value of 52 for small insects according to SANCO/4145/2000 leads to a higher PECfeed (7.5 mg/kg wwt for orchard and 5.0 mg/kg wwt for vine).	(ii): The RUD values are based on an earlier version of the Guidance Document on birds and mammals (draft version of february 2001). An RUD value of 11 for small insects was mentioned in that document. In the final version of the Guidance Document (September 2002) the RUD-values have been changed. The risk assessment for birds and mammals will be adjusted according to the final version of the Guidance Document on birds and mammals.	Open point RMS to prepare an addendum with a revised risk assessment for birds and mammals according to the final version of the Guidance Document on Birds and Mammals. See also comments 5(8), 5(10), 5(13), 5(20), 5(31) and 5(32). Evaluation Meeting (09.-10.02.2005): Open point confirmed. Addendum to be discussed in an expert meeting. Open point still open.
5(8)	Vol.3 B.9.1.4 Risk assessment for birds - short-term risk assessment and long-term risk assessment	SLO: In the short-term risk assessment and the long-term risk assessment the RUD values used are not mentioned. Using the standard 50th percentile value of 29 for small insects according to SANCO/4145/2000 leads to a higher PECfeed (4.2 mg/kg wwt for orchard and 2.8 mg/kg wwt for vine).	(ii): See point 5(7).	See open point in comment 5(7).

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(9)	Vol.3 B.9.1.4 Risk assessment for birds - long-term risk assessment (bioaccumulation and food chain behaviour)	SLO: The BCF in fish of 491 L/kg based on total radioactivity should be used.	(ii): There is no guidance on this point; normally only the active substance is taken into account. However, the argument of SLO that the risks of metabolites formed in the bioaccumulation study should be covered by the assessment of the risk of bioaccumulation for fish eating birds for the active substance as most of these metabolites are not assessed separately, is valid. Therefore the risk assessment will be done using the BCF based on total radioactivity.	Open point: RMS to prepare an addendum with a revised risk assessment regarding bioaccumulation using the BCF-value based on total radioactivity (BCF of 491 L/kg). See also comments 5(6) and 5(14). Evaluation Meeting (09.-10.02.2005): 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)
5(10)	Vol.3 B.9.1.6 Risk assessment for mammals - acute risk assessment	SLO: In the acute risk assessment the RUD values used are not mentioned. Using the standard 90th percentile value of 85 for short grass according to SANCO/4145/2000 leads to a higher PECfeed. Several parameters are not in accordance with the final guidance of SANCO/4145/EC such as FIR/bw of 1.14 in stead of 1.39, interception of 0.5 in stead of 0.4.	(ii): See point 5(7).	See open point in comment 5(7).
5(11)	Vol.3 B.9.1.6 Risk assessment for mammals – long-term risk assessment	SLO: In the long-term risk assessment the RUD values used are not mentioned. Using the standard 90th percentile value of 46 for short grass according to SANCO/4145/2000 leads to a higher PECfeed. Several parameters are not in accordance with the final guidance of SANCO/4145/EC such as FIR/bw of 1.14 in stead of 1.39, interception of 0.5 in stead of 0.4. This proves to be crucial as also after the refinement the trigger of TERlt>5 is not met with the correct values.	(ii): See point 5(7).	See open point in comment 5(7).

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5(12)	Vol.3 B.9.1.6 Risk assessment for mammals – long-term risk assessment	SLO: Refinement of the NOEC based on the assumption that continuous exposure does not occur is not acceptable. The decline in residue is accounted for at the exposure side and should not be refined on the toxicity side.	(ii): The decline in residue is indeed accounted for at the exposure side, but only for a limited period (21 days). In the study there is a continuous exposure to constant levels of spirodiclofen for 16 weeks. Under a practical scenario involving a seasonal treatment only, continuous exposure for such a long time is very unlikely due to decline of residues.	Open point: MS to discuss the setting of the NOEC for mammals in an expert meeting. See also comment 5(22). Evaluation Meeting (09.-10.02.2005): Open point confirmed. Open point still open.
5(13)	Vol.3 B.9.1.6 Risk assessment for mammals - long-term risk assessment (bioaccumulation and food chain behaviour)	SLO: Several parameters are not in accordance with the final guidance of SANCO/4145/EC such as DFI for a earthworm-eating mammal of 1.1 in stead of 1.4 g fresh material/day and a DFI for a fish-eating mammal of 346 in stead of 390 g fresh material/day.	(ii): See point 5(7).	See open point in comment 5(7).
5(14)	Vol.3 B.9.1.4 Risk assessment for birds - long-term risk assessment (bioaccumulation and food chain behaviour)	SLO: The BCF in fish of 491 L/kg based on total radioactivity should be used.	(ii): See point 5(9).	See open point in comment 5(9).

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(15)	Vol.3 B.9.2.3.1.3 Bioaccumulation	SLO: See comment 9 and 13.	(ii): See point 5(7) and 5(9).	See open point in comments 5(7) and 5(9).
5(16)	Vol.3 B.9.5.3 Risk assessment – non-target arthropods	SLO: It is mentioned that the maximum recommended dose for foliage dwelling species is 40% of the field dose as recommended in SETAC guidance (1994), whereas in the actual risk assessment 50% of the field dose is used. This is not consistent.	(ii): Agreed. The 40% is mentioned in the SETAC Guidance (1994), whereas the figure of 50% is mentioned in the ESCORT 2 guidance document. These figures have been mixed up in the monograph and will be adjusted. The figure of 50% will be used because this is according to the latest guidance.	Addressed. RMS to consider in a revised DAR/corrigendum.
5(17)	Vol.3 B.9.5.3 Risk assessment – table B.9.40	SLO: Table B.9.40 reports the interception factor of 50% as in-crop vegetation distribution factor which is confusing.	(ii): It is in principle a vegetation distribution factor (in-crop). It is a factor which must be taken into account, because crops such as those in orchards and vineyards are not typically sprayed as a „two-dimensional structure“, as is the case for most arable crops.	Addressed.
5(18)	Vol.9.7 Effects on soil non-target macro-organisms	SLO: Reference should be made to B.9.3.3 where the risks of metabolites for Collembola are assessed based on accepted studies.	(ii): The point is agreed. Maybe it is even better to place the part about Collembola under B.9.7. The DAR will be adjusted on this point.	Addressed. RMS to consider in a revised DAR/corrigendum.
5(19)	Vol 3, B.9.1.4 Summary of avian toxicity data	UK: Given the concerns expressed in the mammalian toxicology section regarding the mechanisms of toxicity and possible endocrine effects of the a.s. and the -enol metabolite, we would liked to have seen	(ii): In the mammalian toxicology section it was concluded that spirodiclofen has been shown to disturb the endocrine balance by interfering with steroid hormone synthesis, not by a direct specific effect, but at the	Open point: RMS to transfer information (avian toxicity) from column 3 of the reporting table to an addendum to be discussed in

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5(19	*continued* Vol 3, B.9.1.4 Summary of avian toxicity data	some discussion here as to the suitability of the avian reproduction test and resulting end-point to address all the potential for reproductive effects in birds. It may well be a suitable test and end-point but some clarification would be welcome.	level of general biochemical pathways (Krebs cycle and pyruvate/citrate shuttle). Since the effect is non-specific, the nature of any effects caused is not well predictable.In teratogenicity studies in rabbit and rat, up to the highest tested dose of 1000 mg/kg bw/day no effects were observed which are specifically associated with disturbance of the endocrine balance. In the 2-generation reproduction study in rat, sperm count in F0 male rats was unaffected at all dosages, but spermatogenesis was reduced by 18-23% in F1 male rats at the highest test dose of 134.8 mg/kg bw/day (NOAEL for reproduction based on this effect 26.2 mg/kg bw/day). This reduced spermatogenesis however did not lead to any effects on litter size, survival index or sex ratio in the F2 pups. The NOAEL for systemic effects in this study was <5.2 mg/kg bw/day based, amongst other things, on decreased body weights of parental male F0 rats. The findings from the 2-generation reproduction study in rat suggest that endocrine effects (not leading to effects on reproductive success) occur at a much higher dose than systemic effects. The reproduction study in bobwhite quail showed an	an expert meeting. Evaluation Meeting (09.-10.02.2005): 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(19)	*continued* Vol 3, B.9.1.4 Summary of avian toxicity data		unequivocal lack of toxicity of spirodiclofen to male and female parental birds (mortality, behaviour, feed consumption, body weight, gross pathology), up to the highest tested dose of 51 mg a.s./kg bw/day. The one-generation reproductive study in birds is not specifically designed to identify endocrine disruptors. If however during the study there were any microscopic or biochemical effects on the sex organs of male and female bobwhites, this did not lead to any change in reproductive performance, as determined by the number of eggs laid, egg strength, egg fertility, embryo viability, hatching rate, and chick survival. Effects on reproduction in the second generation are considered unlikely, since the endocrine effect of spirodiclofen is non-specific and the compound is only applied once per season, giving disturbed processes time to redress. Considering finally, that the findings in the mammalian toxicological and mechanistic studies were no reason for the evaluating toxicologists to ask for further data to clarify endocrine effects (e.g. special studies on effects on reproduction), there appears to be no need to ask for further data on endocrine action in birds.	

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(20)	Vol 3, B.9.1.5 Risk assessment for birds	UK: This does not substantially affect the levels of risk determined - but for clarification could the RMS please explain how the ETE figures for small insects were arrived at?	(ii): See point 5(7).	See open point in comment 5(7).
5(21)	Vol 3, B.9.1.6 Risk assessment for mammals	UK: As above – we are not clear how the ETE for herbivorous mammals was calculated in accordance with SANCO/4145/2000.	(ii): See point 5(7).	See open point in comment 5(7).
5(22)	Vol 3, B.9.1.6 Risk assessment for mammals	UK: In the long term risk assessment for mammals, there is discussion of some of the effects seen in the rat multigeneration study but it is still not clear why a NOEC of 70 ppm has been chosen over the reproductive NOAEL stated in B.6.6.1 of 350 ppm. We note that concerns relating to the mechanisms of toxicity have been expressed regarding the mammalian toxicity package and these may further influence the choice of end-point.	(ii): Agreed. The risk assessment for mammals was done in a relatively early phase of the whole process of making the monograph. A that time the relevant endpoint was not fully clear and the lowest value of 70 ppm has been taken. Later it became clear that 350 ppm can be taken as the ecotoxicologically relevant endpoint. We will adjust the monograph on this point.	See open point in comment 5(12).

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5(23)	Vol 3, B.9.2.3.1.2 Long term risk to aquatic life	UK: Further clarification is required of the reason for concluding there is a chronic risk requiring large buffer zones for mitigation as the DAR states that chronic exposure to spirodiclofen is unlikely to occur	(ii): It is right that chronic exposure to spirodiclofen is not likely to occur, so chronic tests with aqautic organisms should not be necessary. But in this case chronic studies were submitted and they have to be taken into account. There is a huge difference between the acute and the chronic values, so it seems that sublethal effects are much more critical than mortality. The actual criteria for performing chronic studies seem to be questionable, because no studies were required, while there are critical sublethal effects.	See open point in comment 5(3).
5(24)	Vol 3, B.9.4.2 Risk to bees	UK: Will bees be exposed through the recommended use of spirodiclofen? Section B.3.2.3 would suggest that there is no use during the flowering periods of crops attractive to bees. However there may be residual activity which needs to be considered as well as the potential for flowering weeds to be sprayed. It may be possible to sufficiently minimise any exposure through appropriate labelling. If there is still considered to be potentially adverse levels of exposure through recommended use, then we would agree with the need for further data on bee brood development. Given the residual activity of the compound and the slow realisation of effects, the exposure and monitoring	(ii): It is agreed that it may be possible to sufficiently minimise any exposure through appropriate labelling. Therefore the applicant has been given the choice between submitting further data to address the effects on bee brood, or to include an appropriate warning phrase for bees on the label.	Data requirement: Notifier to address the effects on bee brood (e.g. a field study, labelling). Evaluation Meeting (09.-10.02.2005): The notifier will provide a position paper within 4 weeks. Data requirement still open.

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		periods studied should be of sufficient duration to pick up any longer term impacts.		
5(25)	Vol 3, B.9.5.3 Risk to other non-target arthropods	UK: Given the IGR mode of action of spirodiclofen and the remaining uncertainty about the precise mode of toxicity/action it would be helpful to have some further clarification about the specificity of activity. Is there for example any further information from screening studies that might be helpful in this respect?	(ii): The exact target molecule of spirodiclofen (acaricide, especially active against juvenile stages) has not yet been characterised (perhaps influence on molting). Screening data are presented in Vol. 3, point B.3.1.6.1. LC50 values obtained after exposure of all developmental stages on French bean leaves of the spider mite *T. urticae* ranged between 0.1 and 0.8 mg a.s./L (spray concentration). In other tests, the composite LC50 for 13 strains of *T. urticae* exposed on French bean plants was 0.33 mg a.s./L, and for 3 strains of the spider mite *P. ulmi* exposed on leaves of plum plants 0.36 mg a.s./L. For comparison, in extended laboratory tests with the predatory mite *T. pyri*, the LR50 was 2.4 g a.s./ha (exposure to treated isolated apple leaves), and >5.25 g a.s./ha (exposure of all stages to residues on apple trees). Based on the actual spray volume of 1000 and 200 L/ha, respectively, the spray concentration for the latter two LR50s corresponds to 12 and >5.25 mg a.s./L, which is a factor of at least 33 and >15 higher than the composite LC50s for spider mites. In a test with *C. carnea*, no	Open point: RMS to transfer information from column 3 of the reporting table to an addendum. <u>Evaluation Meeting (09.-10.02.2005):</u> Open point confirmed. Addendum to be discussed in an expert meeting. Open point still open.

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5(25)	*continued* Vol 3, B.9.5.3 Risk to other non-target arthropods		effects were noted at the highest test dose of 144 g a.s./ha, equivalent to 720 mg a.s./L, which is a factor of at least 2000 higher than the LC50s for the target organisms. The acute 48-hour EC50 for *Daphnia magna* is >100 mg a.s./L, indicating that adult stages of this cladoceran are not susceptible. The 21-day NOEC for *Daphnia magna* (flow-through regime) is 0.0248 mg a.s./L, but the EC50 was >0.07 mg a.s./L (highest tested concentration) for all parameters investigated. The 28-day EC50 for emergence of *C. riparius* was 0.094 mg a.s./L (static conditions). The chronic EC50 values for effects on juvenile stages of these two aquatic organisms are just below the LC50 values for the target spider mites, but it should be taken into consideration that the exposure regime for aquatic organisms (chronic exposure, fully immersed in test liquid) is worst case compared to that for target insects in screening tests (exposure to spray on plants). More data on screening than summarised above are not available. The available data however indicate that the predatory mite *T. pyri* is 1 to 2 orders of magnitude less sensitive than the target spider mites,	

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			the leaf dwelling *C. carnea* >3 orders of magnitude less sensitive, and that *Daphnia magna* and *C.riparius* are unlikely to be more sensitive. This suggests that the specificity for the target organisms is high.	
5(26)	Vol. 3, 2.6.3.2 Other arthropod species	SE: Could you please confirm that the most appropriate route of uptake has been used in the terrestrial arthropod studies? Testing with other IGRs has revealed that in some cases uptake through food is a more appropriate route of uptake. That does not necessarily need to be the case with spirodiclofen but could you please confirm this.	(ii): According to the Escort 2 guidance document testing of IGRs should be conducted with *T. pyri* and one other species (e.g. *Coccinella septempunctata, Orius laevigatus* or *Chrysoperla carnea*). For spirodiclofen testing was done with *T. pyri* and *Chrysoperla carnea*. In these tests not only mortality but also reproduction was evaluated. So, according to the available guidance the appropriate tests are available. Maybe other tests must be developed in which insects are tested by taking up food.	Open point: MS to discuss the risk to NTA in an expert meeting. See also comments 5(27) and 5(28). Evaluation Meeting (09.-10.02.2005): Open point confirmed. Open point still open.
5(27)	Vol. 3, 2.6.3.2 Other arthropod species	SE: The test conducted with ground dwelling arthropods (i.e. *Poexilus* and *Pardosa*) only investigated effects on mortality and food consumption. These are not typical endpoints for IGR, rather effects on fecundity may be much more sensitive and according to ESCORT 2 such endpoints should be studies for IGR. Can you please comment on that?	(ii): Indeed mortality and food consumption are not typical endpoints for IGRs, so the value of the tests with Poecilus and Pardosa can be questioned. But other tests with more sensitive species (*T. pyri* and *C. Carnea*) have been submitted and in these tests also reproduction effects were taken into account. See also point 5(26).	See open point in comment 5(26).

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5(28)	Vol. 3, 2.6.3.2 Other arthropod species	SE: We do not think that the risks for non target arthropods in off-field habitats have been fully evaluated. The TER values indicate that sensitive species may be affected in off field habitats at distances of < 20 m from treated fields. According to our interpretation of the data presented in the DAR only *Typhlodromus* and *Chrysoperla* (*Aphidius* is not a suitable species for IGRs according to ESCORT 2 p 15 and comment 2 above) have been tested using endpoints appropriate for IGRs. Hence very little information on the sensitivity of other NTA is available. Further, we do not agree with the conclusion that the field studies with Typhlodromus demonstrate that the off-crop risk is acceptable. We agree with that one year may be an acceptable time to recovery in-field, however regarding off-field effects a recovery period of one year cannot be considered acceptable. If an acceptable risk for NTA in off-crop areas cannot be demonstrated then a buffer zone should be considered.	(ii): We agree with the comments that one year is not an acceptable period for recovery off-field. The conclusion that the risk to non-target arthropods will be acceptable is based on the fact that the exposure will be lower than in-field (maximum 29.2% drift) and the fact that after treatment of grapevines in south west Germany at 96 g a.s./ha, no statistically significant differences in mite populations were found in treated and control plots up to 28 days after application.	See open point in comment 5(26).
5(29)	Vol. 1, 2.6.3.2. (p. 59)	Notifier: The rate tested in the laboratory glass plate test on *T. pyri* is **58** g a.s./ha, not 53.3. g a.s./ha	(ii): OK. Will be amended.	Addressed. RMS to provide a corrigendum/addendum or to consider in a revised DAR.

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5(30)	Vol. 3, B.9.1.3, Table B.9.4 (p. 328), line 22, and Table B.9.5, (p. 329)	Notifier: Number of 14-days chicks as percent of hatchlings as given in the dossier is 94.**8**%, not 94.6%	(ii): OK. Will be amended.	Addressed. RMS to provide a corrigendum/addendum or to consider in a revised DAR.
5(31)	Vol. 3, B.9.1.5.1 (p. 330)	Notifier: The DFI as given in the dossier is **10.05** g material/day, not 10.3 g material/day	(ii): What is meant is the DFI for an indicator insectivorous species as mentioned in the Guidance Document on Birds and Mammals. A DFI of 10.3 g material/day was mentioned in the draft version of the Guidance Document from february 2001. Acoording to the final version this figure must be 10.4. The monograph will be amended on this point.	See open point in comment 5(7).
5(32)	Vol. 3, Table B.9.12 (p. 336)	Notifier: ETE as given in the Dossier is **11.6**, not 11.7 mg/kg bw/d, resulting TER > **216**, not 214	(ii): The risk assessment on birds and mammals will be amended according to the final version of the Guidance Document on Birds and Mammals.	See open point in comment 5(7).
5(33)	Vol. 3, B.9.2.2.1.1 (p. 346)	Notifier: The citation has to be "DORGERLOH, M., **2001**", not "2000"	(ii): OK. Will be amended.	Addressed. RMS to consider in a revised DAR/corrigendum.
5(34)	Vol. 3, B.9.2.2.1.2 (p. 347)	Notifier: Concentrations in the 2nd paragraph have to be corrected from 49.3 and 70.7 **m**g a.s./L into 49.3 and 70.7 **µ**g a.s./L	(ii): OK. Will be amended.	Addressed. RMS to consider in a revised DAR/corrigendum

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5(35)	Vol. 3, B.9.2.3.1.2 Longterm Risk (Active substance) p. 357	Notifier: BCS proposes TERs for chronic risk assessment for fish which consider the TWA PEC for the same period of time (65 days) as the **sensitive** period of the ELS test (65 days of the 97 days). This means for example for Orchard use early and buffer zone of 20 m $TER = \frac{1.95\ \mu g/L\ NOEC}{0.032\ \mu g/L\ TWA(65d)\ PEC} = 60.9$ In case the above recommendation is followed, supported by the justification in Column 3, then all the TERs in Vol. 1 p. 109 ff. and the list of endpoints need to be recalculated. This would change all recommendations for buffer zones, which can be improved further with additional mitigation measures.	(ii): It is questionable if a TWA PEC over such a long period can be used for this compound. Effects determined at a later stage may have resulted from the exposure of the sensitive early stages during the initial study period. The notifier is performing another study which is not submitted yet. This study is determining chronic effects of BAJ 2740 on selected early life stages of rainbow trout (*Oncorhynchus mykiss*) under more realistic conditions of exposure. The notifier has already given some results of this study: " The chronic toxicity of BAJ 2740 to Rainbow Trout was determined for the most sensitive early life stage (between 60 and 70 days old fry, PHD 25-35) in a static indoor microcosm (water/artificial sediment-system) after a single application (pulse) of the test item on study day 0 into the water phase. 61 days old (PHD 27) fry were exposed over a total duration of 42 days. The overall chronic NOEC for BAJ 2740 on the most sensitive early life stage of rainbow trout under more realistic conditions of exposure is 20.0 µg a.s./L (based on growth effects) and the LOEC is 40.0 µg a.s./L. In this study relative to the submitted study 2 parameters were different: pulse versus	Data requirement: Notifier to submit the new chronic study with fish. Open point: MS to discuss the chronic risk to aquatic organisms in an expert meeting. See also comment 5(3). <u>Evaluation Meeting (09.-10.02.2005):</u> Data requirement: The notifier will submit the requested data within 4 weeks. Data requirement still open. Open point: Open point confirmed. Open point still open.

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5(35)	*continued* Vol. 3, B.9.2.3.1.2 Longterm Risk (Active substance) p. 357		constant exposure and sediment microcosm versus water flow-through only. This additional study clearly indicates that in reality with sediment and a pulse exposure with the high initial PEC not the same no effect level of 1.95 µg/L was observed but a 10-fold more favourable one 20 µg/L." It is clear that the exposure regime in the new study is more realistic than the exposure regime in the ELS test with fish. For that reason the results can be used for the risk assessment. But first the study has to be submitted. Then the study will be evaluated by the RMS.	

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5(35)	*continued* Vol. 3, B.9.2.3.1.2 Longterm Risk (Active substance) p. 357			
5(36)	Vol. 3, B.9.2.3.2.1, Table B.9.26 (p. 360)	Notifier: EC_{50} algae: For the risk assessment, the E**r**C50 should be used rather than the E**b**C50, as it will be done in the revised OECD 201 and ISO 8692 (See also: DORGERLOH, M. (2004): How to Express Growth Effects on Algae under 91/414/EEC? Poster presentation, SETAC 2004 (Prague). Therefore a value of **> 100 mg/L** should be used instead of 82.8 mg/L.	(ii): According to the Guidance Document on Aqautic Ecotoxicology the lowest of the ErC50 and EbC50 value must be used for risk assessment. Therefore the RMS does not agree with the notifier and will stick to the value of 82.8 mg/L.	Addressed.
5(37)	Vol. 3, B.9.4.1.3 Evaluation of the study of SCHUR (2002) (p. 368)	Notifier: RMS does not accept the Notifier's conclusion of the lack of effects at the drift rate of 45 g a.s./ha, since, according to the DAR, there was no significant effect of the toxic standard observed in this study. However, in the 2nd run of the study (2001), there was a clearly increased number of dead pupae observed in the toxic standard, which is a typical symptom	(ii): The notifier claims that in the second run of the 2001 study, there was a clearly increased number of dead pupae in the toxic standard. As this is a clear evidence of exposure, the 45 g a.s./ha treatment was claimed to be safe for bee brood. This claim is not acknowledged for two reasons. Firstly, in the second run of 2001, pre-treatment mortality of pupae (32 dead pupae) was higher in the toxic standard	See data requirement in comment 5(24).

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5(37)	*continued* Vol. 3, B.9.4.1.3 Evaluation of the study of SCHUR (2002) (p. 368)	of the effects of Insegar. Thus, it can be stated that at least in this run there was a clear evidence of exposure of the bee brood. Therefore, bee safety of the 45 g a.s./ha can be shown in this trial.	than in the BAJ 2740 240 SC treatment and in the control (no dead pupae). The increased post-treatment mortality in the toxic standard (97 dead pupae) may therefore not have resulted from effects of the toxic standard, but from other factors. Secondly, in the second experiment of 2001 a dose of 200 g a.s./ha of the toxic standard did not cause any effect on bee brood (as determined by the bee brood index), whilst in the first experiment of 2000 a lower dose of 150 g a.s./ha of the toxic standard caused a clear reduction of bee brood development on day 7 and 14. Hence in the second experiment of 2001 there is no evidence at all of an effect of the toxic standard on bee brood, and only an equivocal effect on pupae. Therefore, the result of this experiment is not accepted.	

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5(38)	Vol. 3, B.9.4.2.2 (p. 369)	Notifier: The risk mitigation measure of a **warning label** (no application into flowering, bee-attractive cultures) was already proposed by the Notifier.	(ii): A risk mitigation measure as proposed by the notifier: „no application into flowering, bee attractive cultures“ is not enough, because there can still be exposure of flowering weeds. RMS wants to propose the following sentences: „This product is dangerous to bees. To protect bees it is not allowed to use this product on flowering crops and on places where bees are actively foraging (e.g. on flowering weeds).“ An additional sentence could be: „Remove weeds before flowering“.	Addressed.
5(39)	Vol. 3, B.9.5.1, Table B.9.35 (p. 370)	Notifier: The rate tested in the laboratory glass plate test on *T. pyri* is **58** g a.s./ha, not 53.3. g a.s./ha	(ii): OK. Will be amended.	Addressed. RMS to consider in a revised DAR/corrigendum
5(40)	Vol. 3, B.9.6.1.4.1 (p. 383)	Notifier: The LC_{50} for earthworms of the SC 240 formulation is not 226 mg a.s./kg, but **245** mg a.s./kg	(ii): Not agreed. The figures in the monograph are including a correction for the density of 1.085 g/mL formulation.	Addressed.

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5(41)	Comments DE			Evaluation Meeting (09.-10.02.2005): DE proposed that aquatic risk assessment (endocrine potential for fish) should be discussed in an expert meeting. EFSA stated that the aquatic risk assessment will be discussed in an expert meeting anyway. But, DE should sent a written comment, so that the RMS can prepare for discussion. DE stated that further data is available which is not included in the DAR. A new data requirement was set: Notifier to submit summary on endocrine effect on fish to the RMS. New data requirement still open.

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5(42)	Comments DE on list of end points.			Evaluation Meeting (09.-10.02.2005): List of end points should be revised regarding chronic risk for fish pending on the outcome of the discussion in the expert meeting.