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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Section 1 Data requirements: ***3*** Open points: ***4***			Section 1 Data requirements: - Open points: - Data gaps: ***3***
1.1	Notifier to submit details of the GC headspace method of analysis for the impurity 5. (see reporting table 1(1))	Impurity 5 is analysed by Method 2005-0013102-02; Kraemer, F.; Date 2002-10-18; BCS Report No, Mo-02-016109. The validation report is "Validation Report for Method 2005-0013102-02 VB1.4-[redacted]", Kraemer, F.; date 2002-11-05; BCS Report no. MO-02-017600. Both studies were submitted on March 9, 2005.	June 2005: Details of the GC headspace method of the analysis for the impurity 5 ([redacted]) are given. Method: see Kraemer, F.; MO-02-016109 Validation: see Kraemer F.; MO-02-017600	EPCO 30 (05. – 07.07.2005): Data requirement fulfilled
	Open point 1.1: RMS to amend the list of endpoints (list of representative uses) regarding the product name (code number). (see reporting table 1(5))		June 2005: List of endpoints has been amended. September 2006: List of endpoints has been amended. Open point considered closed.	EPCO 30 (05. – 07.07.2005): Open point still open Evaluation meeting (4-6.12.2006) The endpoints have been amended and the open point is closed.

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

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1.2	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). (see reporting table 1(12))	The new 5 batch analysis of the large scale production is described in Rüngeler, W., 2004-09-15; BCS Report No. MO-04-009359 in connection with the corresponding analytical methods and validation reports. The 5 batch analysis also contains the confirmatory methods mentioned in the data requirement. A bridging statement explaining and justifying the new specification (P. Linke-Ritzer, L. Diesing, C. Maus, 2005-02-01, BCS Report No. MO-05-004882; including references) was also submitted. The MA study, the bridging statement, and all references were submitted on March 9, 2005.	June 2005: A 5-batch analysis of the large scale production has been submitted. Including the analytical methods and validation data of all (specified) impurities. The compound which is analysed with GC-FID in the 5-batch analysis of the pilot plant batches, is in the new 5-batch analysis analysed with HPLC, identity is confirmed by UV-spectrum comparison. The large scale production pathway is shortened as two intermediates are commercially available. Purity of the commercially available intermediates [redacted] and [redacted] are not submitted. A bridging statement explaining and justifying the new specification was also submitted. This should be evaluated by (eco)tox.	EPCO 30 (05. – 07.07.2005): Data requirement fulfilled. Data gap 1.4 identified.

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1.4	Notifier to provide purity of two new starting materials. This data gap was indentified at the EPCO 30 meeting		September 2006: [redacted] ≥ [redacted]% [redacted] ≥ [redacted]% See revised addendum to volume 4 (September 2006). Data gap considered fulfilled.	EPCO 30 (05. – 07.07.2005): Data gap identified. Evaluation meeting (4-6.12.2006) The data gap is addressed the data is summarised in addendum to volume 4 dated September 2006.
	Message from EPCO 30 to experts of the sections ecotoxicology and mammalian toxicology: To confirm that new specification from full-scale production is acceptable.		September 2006: See sections mammalian toxicology and ecotoxicology. Point considered closed for FCE	Evaluation meeting (4-6.12.2006) This message has been conveyed to tox and ecotox and is closed for physchem.
	Note: Depending on the outcome of the residue expert meeting [see open point 3.3], it could be necessary to require further data with respect to an enforcement method for food of animal origin. (see reporting table 1(17))	A new method for enforcement of animal matrices (muscle, milk, liver, fat) for parent and BAJ 2740-enol was developed and is submitted together with the evaluation tables: Zimmer (2005), MO-05-005229 (ILV: Bacher (2005), MO-05-005724)	June 2005: For animal products spirodiclofen-enol is the residue of concern. An enforcement method to determine spirodiclofen-enol (M01) in cattle products (meat, milk, kidney, liver, fat) should be provided, since deuterated internal standards are not commonly available (Method 109720, see B.5.2.4 in the monograph) and implementation in an multiresidue method was not tested (Enforcement method 00086/M030 [extended revision of DFG Method S19], see B.5.2.1 in the	EPCO 30 (05. – 07.07.2005): Fulfilled

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			A new method (Zimmer (2005) MO-05-005229) for enforcement of animal matrices (muscle, milk, liver, fat) for parent and BAJ 2740-enol and an ILV (Bacher (2005), MO-05-005724) are submitted. List of endpoints has been amended.	
	Open point 1.2: 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 is related to a pilot plant. (see reporting table 1(44))	The minimum purity of 95.5% which is currently given in the list of endpoints refers to a pilot plant production scale. According to the new MA-study (large scale production) the minimum purity is increased to 96.5%.	June 2005: The large-scale production leads to a technical product of higher purity than the pilot plant material. Therefore the certified limit of the active substance was increased from 955 g/kg to 965 g/kg. This has also been amended in the list of endpoints.	EPCO 30 (05. – 07.07.2005): Open point fulfilled

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	Open point 1.3: RMS to confirm the residue definitions for monitoring for soil and water. Depending on the outcome of the expert meetings (fate and behaviour, ecotoxicology and toxicology) further data could be required. (see reporting table 1(45)) *continued* Open point 1.3: RMS to confirm the residue definitions for monitoring for soil and water. Depending on the outcome of the expert meetings (fate and behaviour, ecotoxicology and toxicology) further data could be required. (see reporting table 1(45))	The open point under 1(45) in the reporting table covers two different aspects: a) the question about the residue definition in soil and water and b) the question about the relevance of an impurity. a) residue definition in soil and water: The residue definition for <u>water</u> includes the parent compound and BAJ 2740-enol, which is a major hydrolysis product. Concerning a separate residue definition for ground water, see Open point 4(3). The residue definition for <u>soil</u> as given in the DAR should only include the parent compound and BAJ 2740-enol. All other metabolites are ecotoxicologically not relevant – See also BCS **position paper 1_3a** (Kaune, A., Maus, C., 2005; BCS Document no MO-05-006082). b) relevant impurities: In reporting table 1(45) EFSA additionally raises the question about the relevance of an impurity in the technical material. Please see Bayer CropScience **position paper 1_3b** (Linke-Ritzer, P., Nicolaus, B., 2005; BCS Document no MO-05-006689).	June 2005: The residue definition for <u>water</u> and <u>soil</u> includes the parent compound and BAJ 2740-enol. BAJ 2740-Enol is an impurity in technical spirodiclofen, which has to be categorised as significant because of its concentration in the technical active substance. However, due to its toxicological and ecotoxicological properties it is not a relevant impurity. <u>September 2006:</u> Outcome EPCO-26: groundwater res.def = parent surface water res.def = parent + enol Outcome EPCO 27: soil res.def = parent For water acceptable analytical methods for monitoring are available. For soil acceptable methods for monitoring the parent and for the -enol methods are available. No data requirements. Open point considered closed.	<u>EPCO 30 (05. – 07.07.2005):</u> Open point still open. <u>Evaluation meeting (4-6.12.2006)</u> The first point to be addressed was the residue definition for water and soil and this has been clarified. The second point was related to the impurity BAJ 2740-Enol and its relevance and this has been transferred to Tox and Ecotox and it is closed for physchem.

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1.3	Notifier to submit solubility in water and partition co-efficient data at pH 7. (see reporting table 1(51))	The studies have been started; the reports are not finalised yet and will be submitted as soon as possible. The report numbers, the titles and the preliminary results are: Report No.: PA05/027 Title: Spirodiclofen, BAJ 2740 (AE 1344097) Water Solubility at pH 7 Result: Solubility in water at 20°C: cs = 0.19 mg / L = 190 µg / L Report No.: PA05/028 Title: Spirodiclofen, BAJ 2740 (AE 1344097) Partition Coefficient 1-Octanol / Water at pH 7 Result: log Pow = 5.1	June 2005: The notifier submitted studies of the water solubility and partition co-efficient of spirodiclofen at pH 7, which full-fill data requirement 1.3. List of endpoints has been amended.	EPCO 30 (05. – 07.07.2005): Data requirement fulfilled
	Open point 1.4: 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. (see reporting table 1(53))		June 2005: According to expert meeting (EPCO 25), 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.	EPCO 30 (05. – 07.07.2005): Open point fulfilled

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1.5	Data dap proposed at the evaluation meeting:		April 2009: a report with a storage stability study of Spirodiclofen 240 SC in HDPE (2 weeks, 54°C) was submitted and evaluated. The a.s. content and the content of the impurities N,N-dimethylacetamide (<[redacted]% before and after storage) and BAJ 2740-enol (<[redacted]% before and after storage) were unchanged. The package was found to be stable. Point considered addressed.	Evaluation Meeting (04.-06-12.2006): As the impurities 3-(2,4-dichlorophenyl)-4-hydroxy-1-oxaspiro[4.5]dec-3-en-2-one (BAJ-2740 enol) and N,N-dimethylacetamide are consider relevant storage stability data where the impurities are analysed forin the PPP before and after storage is missing. Data requirement open. PRAPeR 66 (21 – 24 April 2009): Data requirement closed

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1.6	Data requirement proposed at the evaluation meeting:		April 2009: a report with a description of HPLC/UV method AM011108MF1 to determine spirodiclofen and the impurities BAJ-2740 enol and N,N-dimethylacetamide in the plant protection product and another one with validation for this method were submitted and evaluated. The submitted validation was acceptable for spirodiclofen and supported LOQs of 0.05% w/w for N,N-dimethylacetamide and 0.08% for BAJ-2740 enol. Whether the method of analysis for the byproducts is capable to determine each byproduct at the maximum level, cannot be established at present, since no maximum levels for both byproducts have been agreed yet (List of Endpoints of EFSA Scientific Report (2007) 104). List of Endpoints amended.	Evaluation Meeting (04.-06-12.2006): As the impurities 3-(2,4-dichlorophenyl)-4-hydroxy-1-oxaspiro[4.5]dec-3-en-2-one (BAJ-2740 enol) and N,N-dimethylacetamide are consider relevant validated methods of analysis for these compounds in the PPP are missing. Data requirement open. PRAPeR 66 (21 – 24 April 2009): Data requirement closed New open point: Method for relevant impurities to be transferred to Vol 3 New open Point EFSA: Check whether the methods are appropriate for the maximum levels of the impurities set following the Tox meeting.
	New open point 1.5 Method for relevant impurities to be transferred to Vol 3		June 2009: Method for relevant impurities is transferrd from Vol 4 to Vol 3.	PRAPeR 66 (21 – 24 April 2009): Open point open Written procedure Open point fulfilled The data has been transferred to an addendum to Vol 3

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	New open Point 1.6: EFSA:to check whether the methods are appropriate for the maximum levels of the impurities set following the Tox meeting.		June 2009: Open point for EFSA	PRAPeR 66 (21 – 24 April 2009): Open point open Written procedure This is addressed in the conclusion
1.7	Data requirement proposed at the evaluation meeting:		April 2009: reports with spectra (IR-,1H-NMR, 13C-NMR, MS- and UV–spectra of the impurities N,N-dimethylamine and BAJ 2740-enol were submitted, evaluated and found to be acceptable. Point considered addressed.	Evaluation Meeting (04.-06-12.2006): As the impurities 3-(2,4-dichlorophenyl)-4-hydroxy-1-oxaspiro[4.5]dec-3-en-2-one (BAJ-2740 enol) and N,N-dimethylacetamide are consider relevant spectra are missing. Data requirement open. PRAPeR 66 (21 – 24 April 2009): Data requirement closed
	New open point 1.7: RMS to amend the list of end points according to the discussions during thef PRAPeR 66 meeting.		June 2009: List of endpoints amended	PRAPeR 66 (21 – 24 April 2009): Open point open Written procedure Open point fulfilled The end points have been amended

2. Mammalian toxicology

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	Section 2 Data requirements: ***1*** Open points: ***14***			Section 2 Data requirements: 0**-** Open points: 0**-**
	Open point 2.1: The oral absorption value to be confirmed at an expert meeting. (see reporting table 2(1)) *continued*	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.	June 2005: 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 for females. 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 and addendum Furthermore, indeed data on bile cannulation rats were available.	EPCO 28 (27.06. – 01.07.2005): A value of 65% was considered appropriate on the basis of radioactivity in urine and tissues in males. Open point closed.

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	Open point 2.1: The oral absorption value to be confirmed at an expert meeting. (see reporting table 2(1))		However, in this study the urinary excretion was quite low: following administration of 1 mg 14C-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.	
	Open point 2.2: The endocrine disrupting properties of the compound to be discussed at an expert meeting. (see reporting table 2(4))	An independent scientific evaluation by OpdenKamp, title “The possible endocrine effects of BAJ 2740. A critical evaluation” is available as BCS **position paper 2_2** (van Sittert, N. J., Krüse, J., Groeneveld, C. N., 2002; BCS Document no MO-02-011326).	June 2005: See addendum.	EPCO 28 (27.06. – 01.07.2005): Spirodiclofen is considered an endocrine disruptor in that it interferes with steroid hormone synthesis. NOAELs were determined in reproduction and chronic studies, together with the mechanistic investigations indicated no additional safety factors were appropriate. Open point closed.
	Open point 2.3: RMS to present data (evaluated tissue of toxicokinetic studies) in an addendum. To be discussed together with open point 2.1 at an expert meeting. (see reporting table 2(5)) *continued*	Apart from liver, kidney, plasma, gastro-intestinal tract and skin, the following tissues were analysed: erythrocytes, spleen, renal fat, adrenal gland, testes, muscle, bone femur, hear, lung, brain, thyroid gland and carcass (Appendices 18-20, including the footnotes, p. 182-188 of Andersch, I. and Koester, J. (2000a), BCS Report no. MO-00-015111). In total bone femur (including the bone marrow) of male and female rats (single and repeated oral	June 2005: See addendum. Data on all studied tissues is now explicitly mentioned in the text.	EPCO 28 (27.06. – 01.07.2005): Data presented in Addendum Open point closed (see open point 2.1).

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	Open point 2.3: RMS to present data (evaluated tissue of toxicokinetic studies) in an addendum. To be discussed together with open point 2.1 at an expert meeting. (see reporting table 2(5))	administration), no radioactivity was detected (p. 183, 185 and 187 of Andersch, I. and Koester, J. (2000a), BCS Report no. MO-00-015111). Radioactivity in testes was 0.003 and 0.0008 µg/g and thus below the limit of quantification (p. 34 of Andersch, I. and Koester, J. (2000a), BCS Report no. MO-00-015111)). Also, no radioactivity was detected in uterus and ovary of female rats and in the adrenal gland and thyroid gland of both male and female rats (p. 182-188 of Andersch, I. and Koester, J. (2000a), BCS Report no. MO-00-015111)).		
	Open point 2.4: MS to confirm the relevant NOAEL for the short-term studies at an expert meeting. (see reporting table 2(9))	See separate BCS **position paper 2_4** (Diesing, L., 2005)	June 2005: See addendum. Several details were included in the study summaries, and the NOAEL in the 14-w oral study in rats is increased to 8.1 mg/kg bw/d, after evaluation of newly submitted historical data on adrenal vacuolation in males. The lowest NOAEL (1.45 mg/kg bw/d) is found in the 1-year oral toxicity study in dogs.	EPCO 28 (27.06. – 01.07.2005): The RMS increased the NOAEL for the 14 week rat study to 100 ppm (8.1 mg/kg bw) based on adrenal cortical vacuolisation in females. The NOAEL was increased as a result of the historical control data provided by the notifier, which demonstrated that the vacuolisation observed in males at the next highest dose level was within the historical control range. The lowest overall short term NOAEL was considered to be that of 1.45 mg/kg bw (50 ppm) from the 1 year dog study and appropriate for the derivation of the AOEL.

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				Open point closed.
	Open point 2.5: The genotoxicity to be discussed at an expert meeting. (see reporting table 2(10))	BCS fully supports the RMS response and argumentation in reporting table 2(10). All available studies demonstrate that spirodiclofen has no genotoxic potential.	June 2005: No comments, besides our comments in the reporting table 2 (10): 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 trial. Therefore, the observed increase was not considered toxicologically relevant. The performance of a second in vivo genotoxicity study is not considered necessary.	EPCO 28 (27.06. – 01.07.2005): The meeting agreed with the opinion of the RMS that spirodiclofen had no genotoxic potential and that a further in vivo study was not necessary. Open point closed.
	Open point 2.6: MS to confirm the relevant NOAEL for the long-term studies at an expert meeting. (see reporting table 2(11))	See separate BCS **position paper 2_6** (Diesing, L., 2005a)	June 2005: See addendum. Several details were included in the study summaries, and the position paper was evaluated. However, the RMS is of the opinion that the NOAELs do not have to be adapted.	EPCO 28 (27.06. – 01.07.2005): The experts concluded that the relevant NOAEL for the long-term exposures (ADI) was confirmed as 1.45 mg/kg bw derived from the 1 year dog study. It was noted that a similar value for reference doses would be derived using the LOAEL of 4.1 mg/kg bw/day from the mouse study, which would require the use of an additional safety factor for extrapolation from a LOAEL to a NOAEL. The NOAEL in the 2 year rat is 6 mg/kg bw/day. Open point closed.

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	Open point 2.7: MS to confirm the relevant NOAEL for the reproduction toxicity studies at an expert meeting. (see reporting table 2(12))	See separate BCS **position paper 2_7** (Diesing, L., 2005b)	June 2005: See addendum. Several details were included in the study summaries, and the position paper was evaluated. However, the RMS is of the opinion that the NOAELs do not have to be adapted.	EPCO 28 (27.06. – 01.07.2005): The experts concluded that the proposed NOAEL for the reproduction toxicity studies was appropriate. It was noted that no NOAEL for parental effects was derived. However, effects noted were consistent with those seen in general toxicity studies. Open point closed.
	Open point 2.8: The carcinogenic effects to be discussed at an expert meeting. (see reporting table 2(13))	BCS fully supports the RMS response and argumentation in reporting table 2(13). See also separate BCS **position paper 2_2** (van Sittert, N. J., Krüse, J., Groeneveld, C. N., 2002; BCS Document no MO-02-011326).	June 2005: No comments in addition to reporting table (2(12)): 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. See also addendum.	EPCO 28 (27.06. – 01.07.2005): Carcinogenic effects were confirmed at high dose levels, but clear NOAELs were demonstrated. Classification with R40 was supported. Open point closed.
	Open point 2.9: MS to confirm the ADI at an expert meeting. (see reporting table 2(14))	Based on the argumentation provided for open points 2(6) and 2(7), BCS supports an ADI value of 0.015 mg/kg bw/day.	June 2005: No comments in addition to in reporting table (2(14)). It was concluded that spirodiclofen is non-genotoxic, and a non-genotoxic carcinogenic mechanism was proposed based on	EPCO 28 (27.06. – 01.07.2005): The ADI of 0.015 mg/kg bw confirmed by experts based on the 1 year dog study with a 100 fold factor.

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	continued Open point 2.9: MS to confirm the ADI at an expert meeting. (see reporting table 2(14))		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, these LOAELs were based on critical effects comparable to those observed in the 52 week oral toxicity study with dogs. As there seems to be no effect of exposure duration, it was considered suitable to use the clear NOAEL of 1.45 mg/kg bw/day for the establishment of the ADI. See also addendum. ADI is set at 0.015 mg/kg bw/d	Open point closed.

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	Open point 2.10: MS to confirm the AOEL at an expert meeting. (see reporting table 2(15))	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.	June 2005: See comments on open points 2.1 and 2.4. The lowest NOAEL (1.45 mg/kg bw/d) is found in the 1-year oral toxicity study in dogs. Since this is considered a short-term study, this NOAEL is suitable as a starting point for derivation of the AOEL. See also addendum. AOEL is set at 0.009 mg/kg bw/d.	EPCO 28 (27.06. – 01.07.2005): AOEL of 0.009 mg/kg bw/day confirmed by expects including an of oral absorption correction factor of 0.65 giving an overall factor of 154). Open point closed.

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	Open point 2.11: The dermal absorption value to be confirmed at the expert meeting as well as the scientific value of the rhesus monkey study. (see reporting table 2(17))	BCS supports the dermal absorption value of approx. 2% as derived from the monkey study. We consider the monkey dermal penetration study as appropriate; it was performed as an EPA requirement for the spirodiclofen registration in USA and was subsequently submitted in EU as well. Monkey studies are explicitly mentioned in the EU Guidance Document on Dermal Absorption (Sanco/222/2000 rev. 6 (2002)), where they are described as giving the closest values to human data. Our data were used without further correction by *in vitro* data. - We cannot follow the UK comment that the use of the monkeys is inappropriate since the monkeys (in contrast to rats) are not sacrificed after the study.	June 2005: See comments in reporting table on 2(17), 2(18), 2(19) and 2(20). September 2006: The RMS reassessed the study and concluded that the assumption of the experts in the meeting (namely that the study was performed with the concentrate, not with the spray), is not valid. The applied concentration and area dose is representative for the spray dilution, hence the RMS proposes a dermal absorption of 10% for both the concentrate and the spray dilution (see addendum).	EPCO 28 (27.06. – 01.07.2005): 1. The experts discussed the validity of the monkey study and determined a value of 10% for the concentrate based on the physical chemistry properties (kow >5), supported by the monkey. 2. A value of 65% was proposed for the dilution based on f the oral absorption value. Open point closed.
	Open point 2.12: 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 reporting table 2(21))	See separate BCS **position paper 2_12** (Wicke, H., 2004; BCS Document no MO-05-006760) which is based on BCS´s proposed AOEL of 0.01 mg/kg bw/d, a correction factor of 70% bioavailability and a dermal absorption of 2%.	June 2005: Regarding the comments on the sprayed area (knapsack, UK POEM): the note in the DAR is not correct and should read: 'Assuming a tank volume of 15 L, the treated area will be 0.15-0.45 ha (15 L x 30 operations /1000 or 3000 L/ha)'. This shall be taken into account in a revised DAR.	EPCO 28 (27.06. – 01.07.2005): Operator exposure to be recalculated. See 2.1. Open point still open. Evaluation meeting (4-6.12.2006) Operator, worker and bystander exposure was recalculated, showing exposure levels below the AOEL for mechanical and

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	continued Open point 2.12: 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 reporting table 2(21))		The RMS is of the opinion that the AOEL, dermal absorption, and exposure values have not changed considerably; therefore no recalculation of the risk assessment was considered necessary at this point. September 2006: Recalculations of the operator, worker and bystander exposures and the risk assessments were provided in the revised addendum. Open point considered closed.	manual upward spraying in pome fruits, stone fruits, citrus and grapes using the German model (operator, with the use of PPE) and EUROPOEM 2002 data (worker and bystander) Open point closed
2.1	Notifier to submit historical control data to make an additional evaluation of the renal cortical vacuolation in males possible. (see reporting table 2(31))	The historical control data were submitted on March 9, 2005. They show that the incidences of adrenal cortical vacuolation seen at 100 and 500 ppm in male rats are covered by the historical control data.	June 2005: See addendum. The submitted data indicated that the observed adrenal vacuolation in males at the lowest two dose levels (100 and 500 ppm) was within the historical data. Since no historical data for females was presented, the NOAEL was changed to 8.1 mg/kg bw/d, based on adrenal vacuolation in females at 500 ppm and above.	EPCO 28 (27.06. – 01.07.2005): Data requirement closed.

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	Open point 2.13: RMS to transfer the information (effects chronic feeding study rats) in column 3 of the reporting table to an addendum to be discussed at an expert meeting. (see reporting table 2(33) and 2(11))	See comments under Open Point 2.6.	June 2005: See addendum. More detailed information on weights of several organs were included, However, the NOAEL of the study was not changed.	EPCO 28 (27.06. – 01.07.2005): Open point closed.
	Open point 2.14: RMS to consider in a revised DAR/corrigendum DE comments on the additional drinking water limit in the DAR, Vol. 3, B.6.10.6. (see reporting table 2(46))		June 2005: The drinking water limit should not exceed the EU drinking water limit for pesticides of 0.1 µg/L and should not be more than 10% of the ADI. Since the EU limit is the lowest of these two, the EU drinking water limit for pesticides of 0.1 µg/L is applicable for spirodiclofen, as indicated in the DAR. We admit that the wording could have been clearer.	EPCO 28 (27.06. – 01.07.2005): Open point closed.
	New open point 2.15: RMS to revise the list of end points according the amendments proposed by EPCO 28.		September 2006: List of endpoints is revised. Open point considered closed.	EPCO 28 (27.06. – 01.07.2005): Open point still open. Evaluation meeting (4-6.12.2006) The list of end points was revised. Open point closed

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	Message from EPCO 30 to experts of the sections ecotoxicology and mammalian toxicology: To confirm that new specification from full-scale production is acceptable.		September 2006: It was concluded that the toxicological profile of spirodiclofen did not change with the new production process; see for the evaluation the revised addendum (B.6.8.1.3). Open point considered closed.	
	Added by RMS, as it was only mentioned in the discussion table, and not copied to evaluation table: Metabolites M01-M16 are toxicologically relevant. The RMS is to clarify whether BAJ 2740- dihydroxy and BAJ 2740-ketohydroxy are rat metabolites.		September 2006: BAJ2740-ketohydroxy and BAJ2740-dihydroxy do not appear in the rat. Predicted environmental concentrations in groundwater (PECgw) are equal to or less than 0.001 ug/L, hence these metabolites are not considered toxicologically significant. Open point considered closed.	Evaluation meeting (4-6.12.2006) BAJ2740-ketohydroxy and BAJ2740-dihydroxy are not rat metabolites.
	Transferred from section 1, open point 1.3: To address the toxicological relevance of the impurity BAJ 2740-Enol.			Evaluation meeting (4-6.12.2006) As spirodiclofen is proposed for classification as R40, all rat metabolites of spirodiclofen (e.g. BAJ 2740-enol) are considered toxicologically relevant.

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	New open point 2.16 (added by RMS): Evaluation of the full scale specification.		April 2009: In the DAR the production process of pilot batches and the pilot plant specification have been evaluated. At the end of the peer review process, information became available on the full scale production batches. The full scale production resulted in three new impurities. For mammalian toxicology, an evaluation of the full scale specification has already been performed, but this has not yet been peer reviewed. See the final addendum from November 2006, and specifically the Chapter with the revised addendum B6 B7 from September 2006, B.6.8.1.3 (Toxicological assessment of the new proposed specification), page 56-58. The argumentation provided by the notifier on the toxicological equivalence of the new production process is considered acceptable.	PRAPeR 69 (4 – 9 May 2009): Open point fulfilled Experts considered that the new specification form full scale production is acceptable

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	New open point 2.17 (added by RMS): Evaluation of the developmental neurotoxicity (DNT) study and the supplementary DNT study.		April 2009: In the final addendum from November 2006, in the Chapter with the revised addendum B6 B7 from September 2006, a DNT study has been evaluated, but this has not yet been peer reviewed. See B.6.7 (neurotoxicity), page 49-53. Subsequently, in order to address specific questions by EPA and PMRA, the notifier repeated parts of the DNT study. The RMS recently received the new study (d.d. 01-08-2008) which is evaluated in the addendum from April 2009. No neurodevelopmental effects were observed in these studies.	PRAPeR 69 (4 – 9 May 2009): Open point fulfilled. The experts concluded that there were no developmental nerotoxicology effects and the NOAEL can be set as 1500 ppm (119 mg/kg bw/d).

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	New open point 2.18 (added by RMS): The dermal absorption values and the revised risk assessment to be confirmed at the expert meeting.		April 2009: The RMS recently received new dermal absorption data (d.d. 26.11.2008) which is evaluated in the addendum from April 2009. Taking all dermal absorption data into account, the RMS proposes a dermal absorption value of 0.4% for the concentrate and 3% for the spray dilution. Because new dermal absorption values are proposed based on the new dermal absorption data, a revised risk assessment is performed in the addendum from April 2009, resulting in safe uses for the operator, bystander and worker.	PRAPeR 69 (4 – 9 May 2009): Open point fulfilled. Experts agreed to the proposal of the RMS.

3. Residues

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Section 3 Data requirements: ***4*** Open points: ***3***			Section 3 Data requirements: **-** Open points: **-** Data gaps: **-**
3.1	Notifier to submit a study to show extraction efficiency from method 00568 and storage stability in samples of the grape metabolism study. (see reporting table 3(1))	A study to address this point (Report No. MEF-04/453 (MO-04-013634)) was submitted on March 9, 2005. The extraction efficiency of residue method 00568 was 93 %. Re-analysis of a grape sample that had been stored for 7 years at -20 °C yielded a BAJ 2740 residue of 1.70 mg/kg, compared to 1.80 mg/kg for the original analysis. Thus, the recovery is 93 %, demonstrating that residues of BAJ 2740 are stable for at least 7 years at -20 °C.	June 2005: Report: Extraction efficiency testing of the residue method for the determination of BAJ2740 in grapes using aged radioactive residue - which is summarised in the addendum - shows that extractability of aged radioactive residue is 93%. Data requirement considered fulfilled.	EPCO 29 (29.06.-01.07.2005): Data requirement is met. The additional data were acceptable and there are no outstanding concerns
3.2	Notifier to submit additional recovery experiments in apple pomace at 1.0 mg/kg spirodiclofen. (see reporting table 3(2))	The study (Zimmer and Gnielka, 2005, MO-04-013344) was submitted on March 9, 2005. The report describes the successful validation of the method at 1 mg/kg in apple pomace.	June 2005: Report: Addendum 01 to report no. MR-351/99: Validation of the residue analytical method 00568 for the determination of BAJ 2740 in plant materials by LC-MS/MS - which is summarised in the addendum - shows that recoveries of spirodiclofen in apple pomace at 1.0 mg/kg is 94 ± 3.1%	EPCO 29 (29.06.-01.07.2005): Data requirement is met. The additional data were acceptable and there are no outstanding concerns

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			Data requirement considered fulfilled.	
	Open point 3.2: RMS to present MRL calculation for pome fruit from southern uses in an addendu taken into account the information given in column 3 of the reporting table. (see reporting table 3(4))	Notifier agrees with the proposal of the rapporteur (see reporting tables 3(4))	June 2005: Addressed in addendum. Open point considered closed.	EPCO 29 (29.06.-01.07.2005): Open point fulfilled. New presentation supports the same MRL proposal.
	Open point 3.3: 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. Depending on the outcome of the residue expert meeting, it could be necessary for the phys-chem experts to require further data with respect to an enforcement method for food of animal origin. (see reporting table 3(5))	See open point 1.2: A new method for enforcement of animal matrices (muscle, milk, liver, fat) for parent and BAJ 2740-enol was developed and is submitted together with the evaluation tables: Zimmer (2005), MO-05-005229 (ILV: Bacher (2005), MO-05-005724)	June 2005: No comment.	EPCO 29 (29.06.-01.07.2005): Open point fulfilled. The meeting agreed the RMS proposal for the residue definition for risk assessment and monitoring purposes to include metabolite M01 only. If the use is extended to other crops fed to animals, if animal intakes are significantly increased then the residue definition would need to be re-considered. EPCO 30 were informed of the monitoring residue definition.

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3.3	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 reporting table 3(7))	Both reports were submitted on March 9, 2005; the corresponding analytical method (Moore et al. (2002), MO-02-005920) is submitted together with these comments (see attachments).	June 2005: Studies reports provide and evaluated in the addendum. Report No. 110025 is not of author De Haan but Harbin, AM. As only parent spirodiclofen was measured, and degradation into M01 takes place (toxicological relevant) during heating at a large extend, and due to inconsistencies in results of apple processing studies, it is concluded that no processing factors should be proposed. Data requirement considered fulfilled.	EPCO 29 (29.06.-01.07.2005): Data requirement has been met. The studies have been submitted and evaluated. As parent only was analysed rather than also including the relevant metabolite M01 these studies have not been used to propose processing factors (studies not relied upon).
3.4	Notifer to provide more validation data for the method 109 720 for the determination of residues in food of animal origin. (see reporting table 1(17))	A statement was submitted on March 9, 2005, to show that the animal method 109720 used in the feeding study is sufficiently validated. Additional validations are available from the ILV (Nelson, S; Hoshowski, J. (2001), MO-02-017505, see attachments) and as concurrent recoveries from the feeding study.	June 2005 Notifier provided a statement, consisting of recovery data from the original report describing the analysis method, the ILV-report and the livestock feeding study. Although the number of recoveries is variable for the different matrices and metabolites (i.e parent or M01), al least 3 recoveries are assayed per level (LOQ and 10*LOQ) and at least 8 samples per matrix are tested. Except from M01 in milk at the lowest level	EPCO 29 (29.06.-01.07.2005): Data requirement met. All the available validation data combined support the view that the method of analysis used in the feeding study has been sufficiently validated.

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	continued Notifer to provide more validation data for the method 109 720 for the determination of residues in food of animal origin. (see reporting table 1(17))		(0.002 mg/kg: 143 ± 28%, n=3, however overall recovery for M01 in milk = 111 ± 18.4%) all calculations show recoveries between 82-112% with relative standard deviations < 19.3% RMS is of the opinion that the method is validated well for the underlying goal (i.e. evaluation of the feeding study in cow) Data requirement considered fulfilled.	
	New open point 3.4: RMS to check the residue levels at 1x dose rate in the lactating cow feeding study and to up date the end points to reflect the metabolite M01. Further consideration will need to be given as to whether there will be a need to set MRLs for animal products. This open point was proposed at the EPCO29 meeting.		*September 2006* Next to residue levels at 34x dose rate residue levels at 10x and 3.4x dose rate are included in the addendum No residues expected at 3.4N, however close to 0.05* mg/kg in liver at 3.4N. MRLs are proposed at the LOQ for each matrix Open point considered closed.	EPCO 29 (29.06.-01.07.2005): Point still open Evaluation meeting (4-6.12.2006) Open point fulfilled
	New open point 3.5: RMS to update endpoints		September 2006: List of end points and list of essential	EPCO 29 (29.06.-01.07.2005): Point still open

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	and list of essential studies to reflect the discussion of the EPCO 29 meeting.		studies is updated and checked, respectively Open point considered closed.	Evaluation meeting (4-6.12.2006) Open point fulfilled

4. Environmental fate and behaviour

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	Section 4 Data requirements: **-** Open points: ***3***			Section 4 Data requirements: **-** Open points: **-** Data gaps: **-**
	Open point 4.1: MS to discuss in an expert meeting which interception values should be used for PEC soil calculation. (see reporting table 4(1))	The RMS re-calculated PEC soil with an interception rate of 50 %. According to the EU guidance document 95/36/EC, this default worst case value should be used "unless actual experimental data give more specific information". The FOCUS working group provides such specific information, i.e. interception rates of 65 % for apple, 70 % for citrus and 40 % for grape. These crop-specific interception values should be used to calculate PEC soil values. In the PECsoil calculations, a DT50 of 29.5 d (rather than 49 d) should be used for BAJ 2740-dihydroxy, and a DT50 of 10 d (rather than 21 d) should be used for BAJ 2740-ketohydroxy in Fresno soil; please see BCS **position paper 4_1** (Kaune, A., 2005a; BCS Document no MO-05-006081).	May 2005: We don't consider the interception values from the FOCUS groundwater group to be 'specific information on actual experimental data'. Therefore we think the PECs values calculated according to the EU guidance document 95/36/EC using the default value for the fraction reaching the soil correct. September 2006: Calculations performed with 50% interception were considered acceptable. Calculation were checked once again and some minor changes deemed necessary. May 2005: Further inspection of the study and the raw data shows that a DT_{50} of 49d. is indeed too worst case. It can be agreed to use the value of 29.5 d. In a position paper BCS questions the use of the upper limit of c.i. as DT_{50}	EPCO 26 (06.– 09.06.2005): Open point fulfilled.

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	continued Open point 4.1: MS to discuss in an expert meeting which interception values should be used for PEC soil calculation. (see reporting table 4(1))		value after recalculation by RMS using Modelmaker instead of ACSL. This can be agreed upon. Considering the recommendations by FOCUS kinetics (which of course has not been accepted) the mean value of the modelmaker calculations should be used, DT_{50}=14d. September 2006: Calculation with corrected values included.	
	Open point 4.2: RMS to clearly indicate acceptability and reliability of the studies in an addendum or corrigendum. (see reporting table 4(3), 4(4), 4(5) and 4(6)) *continued*	In the notifier's opinion, the studies mentioned in 4(4), 4(5) and 4(6) of the reporting tables are reliable and acceptable. Concerning reporting table 4(4), the study is reliable and acceptable with respect to establishing the route of degradation. The same metabolites as with the dihydrofuranon label (investigated by Oi and Bornatsch, 1999) were found. No additional metabolites exceeded 10 % AR. The pathway established with the dihydrofuranon label was confirmed in this study, using a different label position. Concerning reporting table 4(5), the Notifier agrees with the RMS that the study is acceptable.	May 2005: 4(4) The report by Oi (1999a) provides acceptable information on the route of degradation with another label position. In the study no DT_{50} values were provided and these were not recalculated by RMS. The values from the study by Oi and Bornatsch (1999) were considered more reliable. 4(5)The aged leaching column study is a reliable study and provides useful information on metabolites in the column leachate. However, if the data are used to derive Koc values there are some shortcomings that make the Koc values less reliable for further use in a risk assessment.	EPCO 26 (06.– 09.06.2005): Open point remains open: RMS to transfer the conclusions on the acceptability of the studies in column C of the evaluation table to the addendum. Evaluation meeting (4-6.12.2006) Information on acceptability of studies included in revised DAR. Open point closed

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	Open point 4.2: RMS to clearly indicate acceptability and reliability of the studies in an addendum or corrigendum. (see reporting table 4(3), 4(4), 4(5) and 4(6))	Concerning reporting table 4(6), the comments from the RMS in the DAR clearly show that the experimental conditions of the photolysis study (Hellpointer, E. 1998a) do not have a negative impact on the results. Hence, the study is reliable and acceptable.	4(6) The study by Hellpointer (1998a) was designed to determine the quantum yield of photolysis in water and should be considered acceptable for that. The DT_{50} that is derived from this study should be considered less reliable and as better data are available these data should not be used for risk assessment. This will be made clear in a corrigendum. September 2006: Information on acceptability of studies included in revised DAR. Open point considered closed.	
	Open point 4.3: 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). (see reporting table 4(9))	The residue definition for water is spirodiclofen (BAJ 2740) and BAJ 2740-enol. A separate residue definition for ground water should include only the parent compound because the 80th percentile concentration in groundwater according to FOCUS-PEARL is ≤ 0.001 µg/L for BAJ 2740-enol for all scenarios.	May 2005: The residue definition for surface water is the parent and BAJ 2740-enol. For groundwater it is only the parent. The endpointslist has been amended as such. In B8.9 this should be clarified in a corrigendum.	EPCO 26 (06.– 09.06.2005): Open point fulfilled.

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	New open point 4.4 RMS to update endpoints and addendum tables of soil DT50 values to include the correct values for metabolite BAJ 2740-dihydroxy (29.5 days) and BAJ2740-ketohydroxy (27 days). RMS to verify that the PECs were calculated using the appropriate values. This open point was identified at the EPCO 26 meeting.		September 2006: Endpoints and addendum updated accordingly. Open point considered closed.	EPCO 26 (06.– 09.06.2005): Open point still open. Evaluation meeting (4-6.12.2006) Endpoints and addendum have been amended Open point closed.

5. Ecotoxicology

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	Section 5 Data requirements: ***3*** Open points: ***9***			Section 5 Data requirements:0**-** Open points: ***0***
	Open point 5.1: RMS to prepare an addendum to clarify if further data is needed to address the risk to aquatic organisms or not. (see reporting table 5(3))	The use pattern of spirodiclofen with a single seasonal application as well as the very fast dissipation from surface water (<2 d) indicates that chronic exposure of aquatic organisms is unlikely. However, the toxicity observed under chronic exposure conditions has been taken into consideration and a full risk assessment has been provided by the notifier, including risk mitigation options.	May 2005: The toxicity observed under chronic exposure conditions has been taken into consideration and a full risk assessment has been provided in the addendum of May 2005. Open point fulfilled.	EPCO 27 (06.– 10.06.2005): Open point 5.1 fulfilled. New open points 5.10 and 5.11 proposed.
	New open point 5.10. RMS to establish how the sensitive life stage of fish was determined for the ELS test. This open point was proposed at the EPCO 27 meeting.		September 2006: At first a range-finder ELS-pulse-experiment was conducted as limit-test at the concentration of 40 ug a.s./L (practical limit of water solubility of BAJ 2740) to determine the most sensitive early life stage of rainbow trout with regard to growth effects after a limited duration (10 days) of exposure. Eight groups (A-H; 2 replicates per group, each with 35 eggs/15 alevins) at different early life stages (from freshly fertilized eggs up to the juvenile fry after swim-up) between	EPCO 27 (06.– 10.06.2005): Open point still open. Evaluation meeting (4-6.12.2006) Open point fulfilled

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			study day 0 and study day 80 were consecutively exposed to a 10-day-pulse of BAJ 2740 under flow-through conditions. The range-finder was terminated after a total duration of 97 days. The early life stage which was pulsed between study day 60-70 (PHD 25-35) was indicated to be the most sensitive early life stage based on growth effects, expressed as dry weight and standard length. In a second range-finder test a dose-response pulse-experiment with the most sensitive early life stage of rainbow trout (juvenile fry/PHD 25-35) was conducted to show whether the initial sensitivity to BAJ 2740 (NOEC = 1.95 ug a.s./L) is still given with a limited exposure time of only 10 days. Five test levels each with 30 fish (PHD 26 at test beginning) were continuously exposed for 10 days of the 36 day test at 2.50, 5.00, 10.0, 20.0 and 40.0 ug a.s./L under flow-through conditions. After 10 days the entire test system was converted to clean water. The test was terminated after a total duration of 36 days (fish were in total 96 days old) and the overall NOEC (based on standard length) was < 2.50 ug a.s./L. Thus the results of the regular ELS-	

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			study were confirmed even though fish were shorter exposed. Open point considered closed.	
	New open point 5.11: RMS to amend list of endpoints (TERs to be recalculated comparing NOECs for fish and *Daphnia* with initial PECs) This open point was proposed at the EPCO 27 meeting.		September 2006: The list of endpoints has been amended by comparing the NOEC-values for fish and *Daphnia* with initial PEC-values. Open point considered closed.	EPCO 27 (06.– 10.06.2005): Open point still open. Evaluation meeting (4-6.12.2006) Open point fulfilled
	Open point 5.2: RMS to amend the list of endpoints regarding the BCF (add or adjust based on total radio-activity). (see reporting table 5(6))		May 2005: The list of endpoints has been amended regarding the BCF. Open point fulfilled.	EPCO 27 (06.– 10.06.2005): Open point 5.2 fulfilled.

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	Open point 5.3: 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 to be discussed in an expert meeting. (see reporting table 5(7))	A risk assessment to birds and mammals according to the final version of the Guidance Document on Birds and Mammals for review by the RMS has been provided by the notifier. See BCS **position paper 5_3** (Nicolaus, B., 2005; BCS Document no MO-05-006379) and Bowers (2001), MO-03-005295.	May 2005: Revised risk assessment for birds and mammals according to the final version of the Guidance Document on Birds and Mammals has been made. See addendum of May 2005. Open point fulfilled.	EPCO 27 (06.– 10.06.2005): Open point 5.3 fulfilled. New open point 5.12 proposed.
	New open point 5.12: RMS to amend list of endpoint with respect to the Mammalian repro LOEC of 350 mg a.s./kg diet (26.2 mg a.s./kg bw). This open point was proposed at the EPCO 27 meeting.		September 2006: The list of endpoints has been amended on this point. Open point considered closed.	EPCO 27 (06.– 10.06.2005): Open point still open. Evaluation meeting (4-6.12.2006) Open point fulfilled
	Open point 5.4: 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).	For the risk assessment on birds and mammals with respect to secondary poisoning and food chain accumulation the notifier considers the BCF for spirodiclofen itself as the most appropriate value to assess the risk posed by the parent compound. Following the OECD testing guideline	May 2005: Revised risk assessment regarding bioaccumulation using the BCF-value on total radioactivity (BCF of 491 L/kg) has been made. See addendum of May 2005.	EPCO 27 (06.– 10.06.2005): Open point 5.4 fulfilled.

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	(see reporting table 5(9))	305 the BCF_{fish} should be based upon the parent compound in fish despite total radioactive residues are additionally determined. To address the risk of secondary poisoning caused by **metabolites** of spirodiclofen, a BCF of 491 may be taken into account.	Open point fulfilled.	
	Open point 5.5: MS to discuss the setting of the NOEC for mammals in an expert meeting. (see reporting table 5(12)) *continued* Open point 5.5: MS to discuss the setting of the NOEC for mammals in an expert meeting. (see reporting table 5(12))	BCS supports the argumentation by the RMS (reporting tables 5(22)) that the ecotoxicologically relevant endpoint is 350 ppm.	May 2005: The comment of SLO was: *"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."* 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.	EPCO 27 (06.– 10.06.2005): Open point 5.5 fulfilled.
	Open point 5.6: RMS to transfer information (avian toxicity) from column 3 of the reporting table to an addendum to be discussed in	An avian reproduction study conducted with Mallard Duck is available, confirming the results on the first species (Bobwhite quail). No effects on reproduction up to the highest tested	May 2005: The information from column 3 of the reporting table has been transferred to an addendum. See addendum of May 2005.	EPCO 27 (06.– 10.06.2005): Open point 5.6 fulfilled.

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	an expert meeting. (see reporting table 5(19))	dose were observed, the no effect level was calculated to be 111 mg/kg b.w./day. (Bowers (2001), MO-03-005295; see attachment).	Open point fulfilled.	
5.1	Notifier to address the effects on bee brood (e.g. a field study, labelling). (see reporting table 5(24))	The notifier has proposed an appropriate labelling in order to minimize the risk to bee brood. The comment of the Rapporteur to address, in addition to the restriction on application during flowering crops, also flowering weeds, is accepted by the notifier.	May 2005: To address the risk to bee brood the notifier has proposed an appropriate labelling in order to minimize the risk to bee brood, e.g. no use of the product during flowering of the crop and avoiding that there are flowering weeds present (e.g. by mowing the weeds). See also addendum of May 2005. Data requirement fulfilled.	EPCO 27 (06.– 10.06.2005): Data requirement fulfilled (provided labelling is practical)
	Open point 5.7: RMS to transfer information regarding risk to other non-target arthropods from column 3 of the reporting table to an addendum to be discussed in an expert meeting. (see reporting table 5(25))		May 2005: The information from column 3 of the reporting table has been transferred to an addendum. See addendum of May 2005. Open point fulfilled.	EPCO 27 (06.– 10.06.2005): Open point fulfilled.
	Open point 5.8: MS to discuss the risk to NTA in an expert meeting. (see reporting table 5(26))	Spirodiclofen has a unique, novel Mode of Action which is clearly different to that of IGRs (spirodiclofen inhibits lipid biosynthesis but has no effects on chitin biosynthesis). Furthermore the symptoms of	May 2005: RMS can agree with the statement provided by the notifier. But even when the compound is considered as an IGR the data	EPCO 27 (06.– 10.06.2005): Open point fulfilled.

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		poisoning as well as the biological spectrum for spirodiclofen are different to IGRs. Consequently it is also classified differently to IGRs (MoA group 23 vs 15 for IGRs) by IRAC. Therefore the comparison with IGRs is not justified.	requirements have been fulfilled. 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. See also addendum of May 2005.	
5.2	Notifier to submit the new chronic study with fish. (see reporting table 5(35))	A higher tier study on the chronic toxicity of spirodiclofen to fish was conducted simulating exposure conditions that are more realistic to potential entrance into surface water and its behaviour therein (BCS Document No: MO-02-014087, Dorgerloh, M, & Sommer, H., Chronic effects of BAJ 2740 on selected early life stages of rainbow trout (Oncorhynchus mykiss) under more realistic conditions of exposure) The study has been submitted by BCS on March 9, 2005. A revised assessment of the chronic	May 2005: Notifier has submitted the new chronic study with fish. This study has been evaluated by the RMS. The NOEC is 0.020 mg/L. The results of the study are used for risk assessment. The revised risk assessment is presented in the addendum of May 2005. Data requirement fulfilled.	EPCO 27 (06.– 10.06.2005): Data requirement fulfilled.

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		risk to aquatic organisms is presented in BCS **position paper 5_9** (Nicolaus, B., 2005a; BCS Document no MO-05-006867).		
	Open point 5.9: MS to discuss the chronic risk to aquatic organisms in an expert meeting. (see reporting table 5(35))	A revised assessment of the chronic risk to aquatic organisms is presented in BCS **position paper 5_9** (Nicolaus, B., 2005a; BCS Document no MO-05-006867).	May 2005: A revised chronic risk assessment for aquatic organisms is presented in the addendum of May 2005. Open point fulfilled.	EPCO 27 (06.– 10.06.2005): Open point fulfilled.
5.3	Notifier to submit summary on endocrine effect on fish to the RMS. (see reporting table 5(41))	Statement has been submitted by BCS on March 9, 2005.	May 2005: The notifier has submitted a statement regarding the endocrine effect on fish. This is presented in the addendum of May 2005. Data requirement fulfilled.	EPCO 27 (06.– 10.06.2005): Data requirement fulfilled. New open point 5.13 proposed.
	New open point 5.13: RMS to consider German national assessment of the ELS study using the enol metabolite. This open point was proposed at the EPCO 27 meeting.		September 2006: The German national assessment of the ELS study using the enol metabolite has been considered. The conclusion of the German assessment is that the study can be accepted. In place of a NOEC-value of 190 µg/L, Germany has the opinion that an EC10-value of 21.3 µg/L for effects on the sex ratio of the enol-metabolite must be taken for assessment. NL agree with this endpoint. The EC10-value of 21.3 µg/L is higher than the long-term endpoint for the	EPCO 27 (06.– 10.06.2005): Open point still open. Evaluation meeting (4-6.12.2006) Open point fulfilled.

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			parent (20 µg/L) and the exposure of the metabolite will be lower than the exposure value of the parent. Therefore, the risk of the enol-metabolite is sufficiently covered by the parent. The endpoint list is amended on this point. Open point considered closed.	
	Message from EPCO 30 to experts of the sections ecotoxicology and mammalian toxicology: To confirm that new specification from full-scale production is acceptable		<u>September 2006:</u> The large-scale production leads to a technical product of higher purity than the pilot plant material. As a consequence the limits of some impurities could be considerably decreased ([redacted] from [redacted] g/kg to [redacted] g/kg and [redacted] from [redacted] g/kg to [redacted] g/kg). All other impurities identified in the material from the pilot plant production process occur in about the same amount in the samples from the large-scale production. Therefore their certified limits remain unchanged. Three additional impurities were identified in the new batches which were not detected in the pilot plant batches: [redacted], N,N-dimethylacetamide and [redacted]. Their limits were	<u>Evaluation meeting (4-6.12.2006)</u> The new specification is considered as acceptable with regard to mammals and aquatic organisms. The information is insufficient to conclude on soil dwelling organisms. Data requirement Applicant to submit the studies on the aquatic organisms and soil organisms confirming the equivalence of technical material and the ecotoxicological non-relevance of the 3 new impurities. This data requirement is regarded as a technical data requirement since the RMS already received the studies with aquatic organisms and the studies with soil organisms are expected to be submitted in March 2007.

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			set between ma. [redacted] g/kg and [redacted] g/kg. The notifier has sent the following ecotoxicological assessment with regard to the new impurities: *The impurity and byproduct profile of the current composition statement of the technical material differs from the profile of the former composition statement. Three new impurities or byproducts are specified:* [redacted] *(impurity # 05),* ***N,N-Dimethylacetamide*** *(impurity # 06), and* [redacted] *(impurity # 07). For two of them basic ecotoxicological data are available, for the third one, they can be extrapolated from a structurally related substance. On* [redacted] *(impurity # 05), no ecotoxicological data are available. However, this impurity is structurally very similar to* [redacted]*, which is an* [redacted] *in the* [redacted] *(for chemical structure see page 5 above). The* [redacted] *was examined for its effects to fish and Daphnia. The* LC_{50}/EC_{50} *figures found were ≥ 0.4 mg/L (fish), and ≥ 0.77 mg/L (Daphnia), respectively. Due to the structural similarity of both substances, it can be assumed that the intrinsic*	PRAPeR 68 (4 – 8 May 2009): Data requirement closed.

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			toxicity is comparable. Therefore the values of [redacted] were taken for the risk assessment of [redacted]. When the maximum concentration of the impurity in the technical material ([redacted]g/kg = [redacted]kg/kg) is compared to the toxicity values for [redacted] to fish and Daphnias, the resulting toxicity figures are equal to or even in excess of the EU trigger value of 100 mg/L ([redacted] mg/L : [redacted] = 100 mg/L; [redacted] mg : [redacted] = 192.5 mg/L). *Furthermore [redacted] is less soluble in water and more lipophilic than [redacted] Therefore, uptake in animal and plant tissues and thereby also toxicity to aquatic organisms is expected to be greater in [redacted]. With respect to bioavailability the impurity [redacted] has a decreased ecotoxicity potential. Therefore the new certified limit of [redacted] in technical spirodiclofen is of no ecotoxicological significance.* ***N,N - Dimethylacetamide** (impurity # 06) is of low toxicity to fish, Daphnia and algae, with LC_{50} values above 500 mg/l (data from the material safety data sheet). This compound is therefore not classified (LC_{50} > 100 mg/L) for*	

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			ecotoxicological properties under EU classification criteria. The new certified limit of N,N - Dimethylacetamide in technical spirodiclofen is of no ecotoxicological significance. [redacted] *(impurity # 07) is not toxic neither to fish nor to Daphnia following data from the material safety data sheet (Daphnia: LC_{50} (estimated) > 100 mg/L; for algae (estimated) EC_{50} between 10 and 100 mg/L).* *The new technical Spirodiclofen has a specified limit of max. [redacted] g/kg [redacted]. When the toxicity value for [redacted] to algae is compared to the new certified limit, the resulting toxicity figure is in excess of the EU trigger value of 100 mg/L ([redacted] mg/L : [redacted] = 2000 mg/L). The level of [redacted] in technical Spirodiclofen is therefore not of ecotoxicological significance.* **Reaction RMS:** The conclusion of the notifier is that all three new impurities are not of ecotoxicological significance. But this conclusion is only based on data for aquatic organisms. To the opinion of the RMS more ecotoxicological data	

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			should be available to prove the ecotoxicological insignificance of the impurities. At least data on several soil organisms, e.g. earthworms and soil micro-organisms, are necessary. Further the underlying studies of the aquatic toxicity results, presented above, are not available. These studies should be submitted by the notifier. Hence, at this moment no conclusion regarding the ecotoxicological significance of the three new impurities can be drawn. April 2009 The notifier has submitted the underlying studies of the aquatic toxicity results and the toxicity studies on earthworms and soil micro-organisms. These studies are summarised and evaluated in the addendum of April 2009. The overall conclusion is that based on the submitted studies on the toxicity of the active substance (together with the new impurities) and the new impurities itself for aquatic organisms and soil organisms it can be concluded that the new impurities are not of ecotoxicological significance.	

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	Transferred from section 1, open point 1.3: To address the ecotoxicological relevance of the impurity BAJ 2740-Enol.			Evaluation meeting (4-6.12.2006) BAJ 2740-enol is also a metabolite in the environment. The risk to the environment was assessed as low. Therefore BAJ 2740-enol is not considered to be an ecotoxicologically relevant impurity. Open point closed