PEER REVIEW REPORT ON **PROQUINAZID** 29 09 2009

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00	Cover page	00 proquinazid cover
01	**All comments received on the DAR**	**01 proquinazid all comments**
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03	All reports from PRAPeR Expert Meetings	03 proquinazid all reports.
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Comments on the Draft Assessment Report on proquinazid (EAS)

RMS UK

End of commenting period: 11 September 2009 (MS, NOT)

Date	Supplier	File
06.09.2006	Germany	01 proquinazid comment DE 2006-09-06.doc
07.09.2006	The Netherlands	02 proquinazid comments NL 2006-09-07.doc
08.09.2006	Notifier	03 proquinazid comments NOT 2006-09-08.doc
14.09.2006	Austria	04 proquinazid comments AT 2006-09-14.doc
20.10.2006	France	05 proquinazid comments FR 2006-10-20.doc
16.02.2007	EFSA	06 proquinazid comments EFSA 2007-02-16.doc

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, AIIA 2.1.1 and 2.1.3, melting point and temperature of decomposition	DE: A study for the melting point and the temperature of decomposition up to 360 °C must be submitted.	
(2)	Vol. 3, AIIA 2.11.2, auto-flammability	DE: In the used study from (Gravell 1997) no temperature/time curve is included.	This temperature/time curve should be included in the study report according to EEC method A16. Clarification is needed.
(3)	Vol. 4, AIIA 1.10, identity of impurities	DE: For the impurities [redacted] no specification was clearly stated.	It should be clarified why the specifications are missing.
(4)	Vol. 4, AIIA 1.10, identity of impurities	DE: The specification of the impurity [redacted] is not reproducible from the batch analyses.	The specification [redacted] of the impurity [redacted] must be clarified. The highest measured value was just [redacted] in one batch. All other concentrations were below [redacted]
(5)	Vol. 4, AIIA 4.1.3, precision of analytical method	DE: The precision for the analytical method of the impurity [redacted] not stated.	It should be clarified why this was no additional claim.

2. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.6.12, Dermal absorption	DE: Proposal: For an estimate of dermal absorption rate, worst-case assumptions based on the outcome of in vivo and in vitro studies should be used. At least, these assumptions should cover the absorbable dose as obtained in the in vitro study using human skin. Therefore, 3% (concentrate) and 15% (dilution) are suggested instead of 2 and 12%.	
(2)	Vol. 3, B.6.14, Exposure data	DE: Proposal: On the basis of the proposed dermal absorption rates [3% concentrate and 15% dilution; see (1)] a new risk assessment should be carried out by the RMS.	
(3)	Vol. 3, B.6.10.2, ARfD	DE: Proposal: An ARfD of 0.3 mg/kg bw is proposed instead of 0.2 mg/kg bw. The developmental toxicity study in rats should be used to derive the ARfD. In the rat study, loss of bodyweight and reduced feed consumption in dams were seen over the first 2 days of dosing at 60 mg/kg bw/d (NOAEL: 30 mg/kg bw/d). The proposal by the RMS is not supported because there was only one low dose female dog affected (ocular discharge). Safety factor of 100 should be applied deriving the ARfD of 0.3 mg/kg bw.	

3. Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.7.8.2, Effects on residue levels & Vol.3, B.7.16.1, Intakes by domestic animals	DE: Proposal: We suggest to calculate a processing factor for grape pomace and to include grape pomace as feeding stuff in the calculation of the maximum intake by domestic animals, since grape pomace is part of the livestock diet (cattle).	
(2)	Vol. 3, B.7.16.2.2	DE: Proposal: On the basis of the ARfD [0.3 mg/kg bw – see comment (3) to mammalian toxycology] a new short intake calculation for the consumer risk assessment should be carried out by the RMS.	

4. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, List of endpoints; Vol. 3, B.8.5.2, (PECs in) Surface waters and sediment	DE: A maximum water solubility of 0.93 µg a.s./L is given for proquinazid in the tables listing the input parameters for FOCUS surface water modelling. The value should read, however, 0.93 mg a.s./L. The RMS is asked to check whether the correct value has been chosen as input value for the FOCUS model.	

5. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.9.1.4.4, Bioaccumulation (Risk to birds from secondary poisoning)	DE: The refinement steps for the 75 g a.s./ha dose scenario in vines are considered to be acceptable. However, additional refinements steps with respect to feeding indicator species and feeding behaviour would be still possible. Therefore an acceptable risk in the vine application scenarios can be assumed even without using specific assumptions concerning BBCH stages and related interceptions.	Assumptions on type of diet (e.g. PD=1 for earthworm in feed) and fraction of contaminated diet (PT=1) are still conservative. Despite of the fact that calculated TER of 4.51 falls slightly below the trigger of 5 the risk is considered to be low considering underlying assumptions on feeding behaviour.
(2)	Vol. 3, B.9.2, Effects on aquatic organisms	DE: The RMS is asked to check whether the submitted algae studies are valid, especially the ones used in the risk assessment.	Several algae studies with technical and formulated products of proquinazid were ranked invalid by the German UBA due to insufficient exponential growth (24-h lag phase) and high variation coefficients (> 35 %). The invalid studies include the algae test of Sloman (1993), which endpoint (72-h EbC50 = 0. 259 mg a.s./L) was used in the aquatic risk assessment by the RMS.

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol 1, level 2, 2.2.3, analytical methods for residue analysis	NL: NL disagrees with the general statement that GC-MS in itself is highly specific, making a confirmatory method unnecessary. This is only the case for GC-MS methods using at least three mass fragments. Two or less mass fragments will still require further confirmation.	
(2)	Vol 1, LOEP	NL: Please state the purity of the active substance under appearance, relative density	
(3)	Vol 1, LOEP, flammability	NL: NL considers it to be better to state „not highly flammable' instead of „non-flammable'.	
(4)	Vol 1, LOEP, surface tension	NL : Please state the concentration at which the surface tension was determined.	
(5)	Vol 1, LOEP, UV/VIS	NL: Please state ε for the absorption maximum at 325nm.	
(6)	Vol 1, LOEP, log Pow	NL: Please state the pH at which the log Pow was determined. In case pH is not relevant, please include a brief statement like under water solubility (no effect of pH).	
(7)	Vol 1, LOEP, boiling point	NL: NL regards the statement given here as not relevant. Measurements should be continued up to 360 ^{o}C, unless both melting and boiling point are determined or decomposition takes place.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(8)	Vol 1, LOEP, analytical methods for impurities	NL: NL regards [redacted] as confidential information. Please consider rephrasing to residual solvent.	
(9)	Vol 1, LOEP, residue definition for monitoring (environment)	NL: The definition of the residue for monitoring of residues in the environment was found in the LOEP. Furthermore, although not impossible, it is highly unlikely a total of four different metabolites can be monitored.	
(10)	Vol 3, B.2.1.2, boiling point	NL: (see comment (7))	
(11)	Vol 3, B.2.1.3, temperature of decomposition	NL: Measurements should be continued up to 360 ^{o}C. This endpoint is required, unless melting and boiling points are determined.	
(12)	Vol 3, B.2	NL: Please state for every study whether GLP compliant. Maybe including this in the table's title would be a suitable solution.	
(13)	Vol 3, B.2.1.24, surface tension	NL: (i) Please state the concentration at which the surface tension was determined. (ii) Surface tension should be determined at 40 ^{o}C for labelling purposes (Xn/R65). However the limit of 10% hydrocarbons in the preparation is not exceeded. NL therefore agrees with acceptability of this study.	
(14)	Vol 3, B.2.2.5, oxidising properties	NL: Why was UN test O2 accepted and how does it compare to EC test A21 for liquids?	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(15)	Vol 3, B.2.2.12, viscosity	NL: Viscosity should be determined at 40 °C for labelling purposes (Xn/R65). However the limit of 10% hydrocarbons in the preparation is not exceeded. NL therefore agrees with acceptability of this study.	
(16)	Vol 3, B.2.2.14, storage stability	NL: (i) What packaging was used for storage? (ii) Stating „no crystal growth' raises questions. How about phase separation and precipitation?	
(17)	Vol 3, B.2.2.17, persistence of foam	NL: At what concentration was the determination performed?	
(18)	Vol 3, B.2.2.26, emulsion characteristics	NL: At what concentration were determinations performed? There are various types of CIPAC MT36 (.1, .2 and .3), which differ in concentration of the product in water.	
(19)	Vol 3, B.5, table B.5.4	NL: For oil seed rape no recovery experiments or repeatability study were carried out?	

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(20)	Vol 3, B.5, table B.5.5	NL: (i) How were LOQ's derived for the ILV in milk, meat and egg? An LOQ of 0.01 does not seem possible here. Is this a typo? (ii) For the ILV in milk, recoveries at 0.20 mg/kg are not within acceptable limits. Why is this considered acceptable? (iii) For the first validation of egg, the RSD at LOQ is 22%. This is above acceptable limits. Why is this considered acceptable?	
(21)	Vol 4, annex C, table C.1.2	NL: Please include standard deviation of the mean results.	
(22)	Vol 4, annex C, C.1.3 detailed specification of the preparation	NL: (i) A quite minor issue: in tables C.1.4 and C.1.5 it is very obvious 95% of 210.53 g/l TGAI is higher than 200 g/L, implying the TGAI has a specification limit of (although only very slightly) below 95%. Why is the specification not given using nominal purities, instead of minimum purity? (ii) In table C.1.6 proquinazid technical has a minimum purity of 98%. Where does this material come from?	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(23)	Vol 4, annex C, C.1.4.1, methods of analysis for impurities	NL: How was the identity of the impurities during analysis confirmed? It seems for both the HPLC-UV and GC-FID method, confirmation of identities of the impurities should be provided.	

section 2 - Mammalian toxicology (B.6)

7. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.6.3.3.b), 1-year dog study (capsule)	NL: The cause of the ocular discharge is not known. However, the suggestion of a local effect when the substance is administered by capsules seems almost impossible (assuming good quality capsules). Furthermore, the NOAEL of <15 mg/kg bw/d for the females is very conservative and a NOAEL of 15 mg/kg bw/day is proposed. However, this has no consequences for the overall risk assessment.	

section 3 - Residues (B.7)

8. Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(0)	Vol. 1, LOEP	NL: Plant residue definition for monitoring: proquinazid (cereals and grape only)) Next to residue definition for risk assessment for cereals and grape, a category „others : not derived' should be given. Next to a conversion factor for cereals and grapes, a factor for others: not derived' should be given.	
(1)	Vol. 1, level 2, 2.4 (metabolism data)	NL: In the first paragraph „non-fruit' should be replaced by „cereal'	
(2)	Vol. 1, level 2, 2.4 (rotational crops)	NL: Residue levels are expressed in mg/kg. It should be stated whether it is mg/kg parent equivalent of TRR.	
(3)	Vol. 3, B.7.1.2 (metabolism in grapes)	NL: In Table B.7.6 (TRR) the same data are depicted as in Table B.7.7, however, in Table 7.7. they account for the fraction „unextractable' as % TRR. This I not clear.	

section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(4)	B.7.8.2 (effect on residue levels)	NL: A processing factor of 0.2 was derived for the preparation of juice and wine from grape. However, it is not clear what happened during processing. Since proquinazid is hydrolytically stable, an explanation is required of the fate of the proquinazid residue is juice and wine (is it bound to peels/pomace of is it destructed during fermentation. Might the fermentation product possibly be toxicologically relevant?? A remark explaining this issue should be provided to the assessment, to understand the value of the processing factors derived.	

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

9. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment NL	Column 3 Further explanations
(1)	Vol.1, 2.5.1; Vol. 3 B.8.9	NL: Point b) Please change the units µg / ml into µg / l . Please delete and thus these metabolites are considered non relevant.	
(2)	Vol.1, 2.5.2.3; Vol. 3 B.1.5	NL: The statement that the dissipation of IN-MM671 was observed to be within a similar range in both field and laboratory studies is not agreed. Under field conditions not only the average was longer, also the maximum value is almost 6 times higher. Range under laboratory studies 47-67 days and under field conditions 29-394 days.	
(3)	Vol.1, 2.5.2.3; Vol. 3 B.1.5	NL: Under field conditions only 1 DT50 value is available. This is a DT50 of 54 d in the S France location. Looking at the results on the parent and IN-MM671 this is the best case location resulting in the lowest DT50. No general conclusion can be drawn from this value. Neither a reliable PECs can be calculated.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment NL	Column 3 Further explanations
(4)	Vol.1, 2.5.3; Vol. 3 B.8.5.2 PEC sw and sed	NL: In the PEC sw and sed calculation a default of 300 days has been used for DT50 water and/or sediment in the absence of a calculated degradation time. According to FOCUS degradation kinetics this should be 1000 days.	

section 5 - Ecotoxicology (B.9)

10. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, LOEP, other arthropods	NL: Please add values of the control (mortality), corrected mortality and % reduction (% adverse effect) in reproduction in order to compare with the Annex IV trigger.	
(21)	Vol. 3, B.9.2.3.2	NL: The most sensitive test species was the green algae with an EbC50 of 1.3 mg product/L. This is lower than for Daphnia (1.8 mg product/L).	
(3)	Vol. 3, B.9.5.1.2, table B9.67	NL: Please add corrected mortality and decrease in reproduction	
(4)	Vol 3, B.9.5.2	NL: What about the significant increase in pest mites in the toxic reference and formulation treatment in the German field study?	
(5)	Vol 3, B.9.6.2.2	NL: A treatment related effect can be seen at the highest concentrations. Considering the SD, the % body weighty increase should be significantly different between the control and highest treatment.	
(6)	Vol 3, B.9.8.1.3	NL: According to the OECD guideline, results should concern nitrogen formation rates, not levels. Differences in formation rates are not visible in the text and tables.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, Level 1, page 9	**DuPont:** Since submission of the dossier applying for inclusion of proquinazid in Annex I of Directive 91/414/EEC Proquinazid 200 g/L EC has been authorised in a total of 8 EU Member States.	Proquinazid 200 g/L EC is has been authorised as follows: Poland (March 2005, cereals), Slovakia (March 2005, cereals), Hungary (May 2005, cereals and grapes), Austria (October 2005, cereals and grapes), Ireland (November 2005, cereals), Germany (February 2006, cereals), UK (February 2006, cereals) and Czech Republic (February 2006, cereals).
(2)	Vol. 1, Level 1, page 10-13, Table 1.1, Appendix 3, page 60 - 63, Vol. 3, Annex B.3, page 28 - 31, Table 3.1 ; Summary of GAP	**DuPont:** The minimum application rate for Italy and Germany is cited as 40 g a.s./ha. The minimum application rate for Greece is cited as 25 g a.s./ha. However on the basis of the proposed use rate of a 5 g/hL dilution applied at a volume of 300 – 1500 L/ha for Greece and Italy and at 400 – 1500 L/ha for Germany the minimum rate that could be applied is 15 g a.s./ha in Greece and Italy and 20 g a.s./ha in Germany.	The revised risk assessment for earthworm eating birds and mammals after application of proquinazid to vines (DuPont-15688) was carried out on the basis of assumed typical worst case exposures based on the likely highest application volumes used at each growth stage when proquinazid may be applied. These maximum rates at each growth stage window are reflected in the remarks column of the GAP table. However at the early growth stages a lower application volume, and thus rate of active substance, than the worst case assumed for the risk assessment could be used. Based on current application practices in Greece and Italy the lowest expected water volume for early application in grapes would be 300 L/ha which would result in a minimum application rate of 15 g proquinazid /ha. Based on current application practices in Germany the lowest expected water volume would be 400 L/ha which would result in a minimum application rate of 20 g a.s./ha. As these potential application rates are lower than those assumed for the earthworm eating bird and mammal risk assessment there will be no negative impact on the final conclusion of the risk assessment that proquinazid presents a low risk to earthworm eating birds and mammals in treated vineyards.

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

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(3)	Vol. 1, Level 2, page 15, 2.1.2, Level 4, page 125, 4.2.2, Vol. 3, Annex B.2, page 15 & 18, B.2.2.15, B.2.3.2 Physical and chemical properties – storage stability	**DuPont :** The 2 year storage stability study is complete and will be submitted to the RMS	
(4)	Vol. 1, Level 4, page 125, 4.2.1, Identity	**DuPont:** Analysis of commercially produced technical proquinazid is currently underway. A report will be available by December 2006.	
(5)	Vol. 3, Annex B.2, page 18, B.2.2.32. Physical and chemical compatibility with other products	**DuPont:** The data summarised here was not submitted as part of the EU data package, rather it formed part of the application for approval in the UK. Phys/chem. compatibility data will be provided at the Member State level in support of locally required tank mixes.	Physical and chemical compatibility testing is most appropriately performed at the National level as tank-mix partners will vary between countries.

section 2 - Mammalian toxicology (B.6)

12. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, Annex B.6, page 109 (and elsewhere), point B.6.3.1 b, 90 day feeding study in rat	**DuPont:** As previously noted, DuPont believes that liver weight increases occurring without morpholoigcial or clinical chemical evidence of liver toxicity should not be considered adverse. Proquinazid was shown in some studies to induce P450 enzymes. Irrespective of the specific enzymes induced, liver weight increases which produce no alterations in traditional endpoints of target organ toxicity, even after subchronic dosing, are generally not considered adverse.	
(2)	Vol. 3, Annex B.6, page 124, point B.6.3.3; Oral One-year study in dogs.	**DuPont:** We consider the NOAEL of 60 mg/kg bw/day for female dogs, as proposed by the study author, to be the most appropriate NOAEL rather than the RMS proposal of < 15 mg/kg bw/day	As noted in the review, ocular discharge in 15 mg/kg bw/day females was observed in association with the dosing procedure and apparently did not persist to the following day. In addition, discharge was mostly clear rather than purulent or mucopurulent. These observations are consistent with the RMS conclusion that this effect was minor. Therefore, DuPont does not believe this finding should be used to set the NOAEL in female dogs, especially since the objective of this study is a chronic NOAEL while the ocular effects appear to be acute and related to the dose administration procedure and to be non-persistent. Rather, DuPont proposes a NOAEL of 60 mg/kg bw/day as recommended by the study author based on decrements in body weight parameters.

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(3)	Vol. 3, Annex B.6. page 132 – 158, B.6.4; Genotoxicity Studies	**DuPont**: We agree with the conclusion in the DAR that proquinazid does not pose a genotoxic concern. However we are concerned about several statements in the DAR regarding two of the genotoxicity studies conducted with proquinazid - the *in vitro* chromosome aberration test and the CHO/HGPRT test where we do not agree with the limitations noted by the rapporteur.	In some cases the deficiency noted is due to a comparison of the study protocol with a revised test guideline rather than the test guideline prevailing at the time the study was conducted (i.e., lack of continuous treatment in the *in vitro* chromosome aberration assay) or is due to the preference for one test method which is one of several acceptable methods recommended by the test guideline (i.e., mouse lymphoma assay). Also, we disagree with the suggestion that a study may be potentially insensitive because the response of the positive controls in some treatments is at the lower end of the historical range (i.e. *in vitro* chromosome aberration assay). In fact the sensitivity of genotoxicity assays is often judged by the ability to detect borderline positive responses. Given the consistently negative results in the broad array of *in vitro* and *in vivo* genotoxicity studies conducted with proquinazid, it is DuPont's opinion that the review of these two studies was unnecessarily critical. We would encourage a "weight of the evidence approach" to be used in the assessment of the genotoxic potential of future substances, particularly in cases where additional testing may be considered.
(4)	Vol. 3, Annex B.6. page 177, B.6.5.2 , Carcinogenicity study in mice	**DuPont:** In the study details summary table under the heading "Study Acceptable", the parenthetical statement that "more data have been requested" can be deleted.	Additional historical control data were supplied in response to questions from PSD during the preparation of the DAR, Brown, J. (2004) DuPont response to questions from PSD dated 17 September 2004 regarding proquinazid mammalian toxicology. (email of 6/10/04)

section 2 - Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(5)	Vol. 3, Annex B.6, page 190, point B.6.6.1, General observations	**DuPont:** The statement under General observations: "There were deaths and no test substance-related clinical signs were observed" Should read "There were no deaths and no test substance-related clinical signs were observed"	The first „no' has been omitted from the sentence.
(6)	Vol. 3, Annex B.6, page 236, B6.9.5., First Aid measures,	**DuPont:** The general first aid measures presented are appropriate for their respective routes of potential exposure and always include recommendations to call a physician. The measures given are of great value in an emergency situation where physician or a poisoning centre are not readily available. We do not agree with the language which discounts these first-response recommendations.	According to the data requirements: "The first aid measures to be used in the event of poisoning (actual and suspected) and in the event of contamination of eyes must be provided.

section 3 - Residues (B.7)

13. Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, Annex B.7, page 323, B.7.1.6, Summary Assessment,	**DuPont**: DAR reads: "Primary crop studies investigating the metabolism of phenyl-^{14}C(U)proquinazid are available in oilseed rape, soybean, sugar beets and wheat." This should be corrected to read: "Confined rotational crop studies investigating the uptake and metabolism of …."	

section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(2)	Vol. 3, Annex B.7, Pages 346 – 348, B.7.4, Table 7.25, Summary of GAP	**DuPont:** The minimum application rate for Italy and Germany is cited as 40 g a.s./ha. The minimum application rate for Greece is cited as 25 g a.s./ha. However on the basis of the proposed use rate of a 5 g/hL dilution applied at a volume of 300 – 1500 L/ha for Greece and Italy and at 400 – 1500 L/ha for Germany the minimum rate that could be applied is 15 g a.s./ha in Greece and Italy and 20 g a.s./ha in Germany.	The revised risk assessment for earthworm eating birds and mammals after application of proquinazid to vines (DuPont-15688) was carried out on the basis of assumed typical worst case exposures based on the likely highest application volumes used at each growth stage when proquinazid may be applied. These maximum rates at each growth stage window are reflected in the remarks column of the GAP table. However at the early growth stages a lower application volume, and thus rate of active substance, than the worst case assumed for the risk assessment could be used. Based on current application practices in Greece and Italy the lowest expected water volume for early application in grapes would be 300 L/ha which would result in a minimum application rate of 15 g proquinazid /ha. Based on current application practices in Germany the lowest expected water volume would be 400 L/ha which would result in a minimum application rate of 20 g a.s./ha. As these potential application rates are lower than those assumed for the earthworm eating bird and mammal risk assessment there will be no negative impact on the final conclusion of the risk assessment that proquinazid presents a low risk to earthworm eating birds and mammals in treated vineyards.
(3)	Vol. 3, Annex B.7, page 396, B.7.17 Summary and evaluation	**DuPont:** The statement in the 1st sentence of the 4th paragraph should read „….is different for wheat and grapes'. Rather than …'wheat and straw.'	

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

14. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, Annex B.8, page 412, point B.8.1.1.1, Route and rate of degradation in soil – aerobic studies – Soil microbial studies (no first order kinetics in Arrow soil, Spare, 1999a)	**DuPont:** The revised $DT_{50/90}$values of 449/492515 days and 225/754 days for parent and IN-MM671 (conversion factor of 0.91) for the Arrow soil (Spare, 1999a) as presented in the DuPont response to e-fate questions in July 2004 (FOMC-SFO model) are reliable estimates of the rate of degradation. However, the RMS preferred to use field data for the PECsoil calculation and the laboratory data are therefore not relevant in this respect.	RMS comment: The degradation rate for proquinazid and IN-MM671 was also calculated using a non-linear first-order multicompartment regression technique for parent and one metabolite in series. This returns DT_{50} and DT_{90} values of 449 and 492515 days respectively for proquinazid, and 225 and 754 days respectively for IN-MM671, with an r^2 value of 0.987. Clearly the degradation rate for proquinazid calculated using this model does not obey first order kinetics, and a reasonable estimate must be made for an input value for PEC calculations. DuPont Response – further explanations: DuPont agrees that the degradation rate in the Arrow soil (Spare, 1999a) is not simple first order kinetics. Therefore, revised $DT_{50/90}$values for the Arrow soil (Spare, 1999a) as presented in the DuPont response to e-fate questions in July 2004 using a FOMC-SFO model. The calculation considered the actual sampling times from the study report and returned DT_{50} values of 449 days and 225 days for parent and IN-MM671 with a conversion factor of 0.91. The χ^2 error for the fit of proquinazid degradation was 4 (re-calculated with ModelMaker using the same data set and kinetic model) and the χ^2 error for the fit of IN-MM671 degradation was 8 (rate constant significantly different from zero at p=0.05) indicating that the FOMC-SFO model provides reliable estimates for the both modelling and persistence endpoint.

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(2)	Vol. 3, Annex B.8, point B.8.1.1.1, page 415 Route and rate of degradation in soil – aerobic studies – Soil microbial studies (fractionation rate of 200% in Speyer soil, Spare, 1999b)	**DuPont:** For the Speyer soil (Spare 1999b), FOMC-SFO calculations by Smyser (2003, report no. DuPont-13715) were included in the DAR with a DT_{50} (DT_{90}) of 149 days (14841 days) for proquinazid and a DT_{50} (DT_{90}) of 305 days (1010 days) for IN-MM671. The respective conversion factor obtained from this kinetic model was 0.945 (parent to IN-MM671) and the degradation rate is considered reliable. However, the RMS preferred to use field data for the PECsoil calculation and the lab data are therefore not relevant in this respect.	RMS comment: It should be noted that the degradation rates for proquinazid and IN-MM671 in the Speyer soil were calculated using a regression model with the fractionation rate set to 200 %. In practice this is impossible, and although it establishes a better curve fit, it has the effect of significantly shortening the degradation times, and the times given below are therefore considered by the rapporteur to be unreliable. For further calculations, see section B.8.1.3 b. DuPont Response – further explanations: Please note that the conversion factor is a fitted parameter which is not set to a specific value. In the DuPont response to e-fate questions (July 2004, points 1, 10 and 11), DuPont commented on the acceptability of conversion factors if their confidence intervals include 1. DuPont re-calculated the endpoints for the Speyer soil (Spare 1999b) using the same data set and model (FOMC-SFO) as in Smyser (2003, report no. DuPont-13715) and the obtained a DT_{50} (DT_{90}) of 153 days (11891 days) for proquinazid and a DT_{50} (DT_{90}) of 278 days (924 days) for IN-MM671. The χ^2 error of 18 for the fit of proquinazid degradation was 5, for the fit of IN-MM671 it was 11 (rate constant significantly different from zero at p=0.05) and the respective conversion factor was 0.99 (parent to IN-MM671). The parameter estimate is therefore considered reliable.

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(3)	Vol. 3, Annex B.8, point B.8.1.2.1, page 418 Route and rate of degradation – anaerobic degradation (reliability of DT_{90} for IN-MM671 which was increasing throughout the study of Zhang and Glunt, 1999)	**DuPont:** The sequential model (SFO-SFO) used by Smyser (2003) is the best technical approach to derive IN-MM671 endpoints from the available data. DuPont accepts the general point that there is uncertainty about the further formation/degradation of IN-MM671, if no clear degradation of a metabolite is observed during the experiment. However, IN-MM671 is a metabolite observed in soil under aerobic conditions and was addressed in the risk assessment.	RMS comment: The DT_{50} for the degradation product IN-MM671 in the total system was estimated from the study with the parent molecule, using a simple non-linear first order equation. The DT_{50} was 584 days. The % AR of IN-MM671 increased throughout the experiment, thus the DT_{90} could not be estimated with confidence. DuPont Response – further explanations: The sequential model (SFO-SFO) used by Smyser (2003) allows the simulation of metabolites formation and degradation simultaneously and can provide the most reliable kinetic results based on the available data. A sequential model (SFO-SFO) for proquinazid and IN-MM671 was employed by Smyser (2003) using ModelManager. Recent re-calculations with ModelMaker confirmed the degradation rates and the conversion factor of IN-MM671 (DT_{50}/DT_{90} of 561/1864 days, conversion factor 0.74, χ^2 error of 18 – fit visually acceptable, rate constant significantly different from zero). As in Smyser (2003), the DT_{50} was extrapolated beyond study period and clearly the DT_{90} estimate of almost 5 times the study period must be treated with caution.
(4)	Vol. 3, Annex B.8, point B.8.1.2.2 page 420, Route and rate of degradation – photolytic degradation in soil (formation factor of IN-MM6781 > 100%; Misra, 1997)	**DuPont:** DuPont submitted a re-calculation of the endpoints using a FOMC-SFO Model for the soil photolysis study in the DuPont response to e-fate questions (July 2004, point 11). The conversion factor was 0.55 and the DT_{50} was 186 hours (7.8 days) for IN-MM671. However, IN-MM671 is a metabolite observed in soil under aerobic conditions and was addressed in the risk assessment.	RMS comment: It should be noted that the formation factor of IN-MM671 in these calculations was > 100 %. In practice this is unrealistic, and therefore the degradation rates for IN-MM671 may be inaccurate. DuPont Response – further explanations: Confirmatory ModelMaker calculations were conducted using a SFO-SFO model and a conversion factor of 1 for the formation of IN-MM671. The calculation gives a DT_{50} (DT_{90}) for IN-MM671 of 3.2 (10.6) days (χ^2 of 13, rate constant significantly different from zero) confirming that the results from Smyser (2003) are rather conservative.

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(5)	Vol. 3, Annex B.8, point B.8.1.3 a), page 421, Soil rate of degradation studies – laboratory (no first order kinetics in Arrow soil, Spare, 1999a)	**DuPont:** DuPont agrees that the degradation rate is not simple first order kinetics. We believe that the revised $DT_{50/90}$values presented in the DuPont response to e-fate questions in July 2004 (FOMC-SFO model, considering the actual sampling times from the study report, 449 days and 225 days for parent and IN-MM671 with a conversion factor of 0.91) are reliable estimates for the Arrow soil (Spare, 1999a). However, the RMS preferred to use field data for the PECsoil calculation and the laboratory data are therefore not relevant in this respect (compare point 1 above).	RMS comment: It should be noted that these degradation rates for proquinazid and IN-MM671 were calculated using a regression model with the fractionation rate estimated as 358 %. In practice this is not realistic, and although it establishes a better curve fit, it has the effect of significantly shortening the degradation times, and the times given above are therefore considered by the rapporteur to be unreliable. … Clearly the degradation rate for proquinazid calculated using this model does not obey first order kinetics, and a reasonable estimate must be made for an input value for PEC calculations.
(6)	Vol. 3, Annex B.8, point B.8.1.3 b), page 421, Soil rate of degradation studies – laboratory (fractionation rate of 200% in Speyer soil, Spare, 1999b)	**DuPont:** For the Speyer soil (Spare 1999b), FOMC-SFO calculations by Smyser (2003, report no. DuPont-13715) were included in the DAR with a DT_{50} (DT_{90}) of 149 days (14841 days) for proquinazid and a DT_{50} (DT_{90}) of 305 days(1010 days) for IN-MM671. The respective conversion factor obtained from this kinetic model was 0.945 (parent to IN-MM671) and the degradation rate is considered reliable. However, the RMS preferred to use field data for the PECsoil calculation and the lab data are therefore not relevant in this respect (compare point 2 above).	RMS comment: As with the Arrow soil above, the fractionation rate was set to an unrealistic value (200 %), and although it establishes a better curve fit, it has the effect of significantly shortening the degradation times, and the times given above are therefore considered by the rapporteur to be unreliable. … Again, the degradation rate for proquinazid calculated using this model does not obey first order kinetics, and a reasonable estimate must be made for an input value for PEC calculations. DuPont Response – further explanations: Please note that the conversion factor is a fitted parameter which is not set to a specific value. In the DuPont response to e-fate questions (July 2004, points 1, 10 and 11), DuPont commented on the acceptability of conversion factors if their confidence intervals include 1.

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(7)	Vol. 3, Annex B.8, point B.8.1.4.1 c), page 439, Field dissipation IN-MM671 half-life in Gebstedt soil, Zietz *et al.*, 2003b)	**DuPont:** DuPont does not believe that a DT_{50} of 256 days appropriately represents the behaviour of IN-MM671 in field soils for the reasons outlined in the DuPont Response to e-fate questions (submitted July 2004, point 6). However, DuPont accepts that there is no effect on the PECs where the longest field half-life was used.	RMS comment: It should be noted that the applicant has excluded the day 352 sample data from the Gebstedt trial from their DT_{50} calculations. At this point proquinazid had entirely dissipated, but there remained a detectable concentration of IN-MM671. The applicant has explained that this data point was excluded because if it were included it would assume that all possible data points between 184 and 352 days can be represented by the single data point at 352 days, and this ignores normal variability that can occur in field studies. Whilst the rapporteur understands that forcing the degradation curve to fit the 352 day data point for IN-MM671 would increase the confidence limit, it is nevertheless pertinent to calculate a DT_{50} which includes these data. For IN-MM671 this had the effect of increasing the DT_{50} from 78 to 256 days. However, as this is a shorter DT_{50} than that in the Alconbury and Le Thor studies, it will not affect the PECsoil calculations, in which the longest field DT_{50} is used.
(8)	Vol. 3, Annex B.8, point B.8.1.4.1 d), page 442, Field dissipation (recoveries and endpoints for metabolite in Brentwood soil, Old 2003)	**DuPont:** DuPont agrees that proquinazid dissipated very rapidly in this study and slight deviations of the recovery from the acceptance range will not affect the calculation of the DT_{50} (compare DAR page 442 and 443).	RMS comment: It should be noted that on several occasions the procedural recovery for the metabolites, at the LOQ, fell outside acceptable limits: for IN-MM671, three samples had recoveries of 179 %, 35.5 % and 12.9 %. For IN-MM986, a recovery of 126 % was recorded, and for IN-MM991, recoveries of 138 % and 166 % were recorded. All of these data points were excluded from the calculation of the mean procedural recovery for each metabolite. The applicant has suggested that these anomalous data points were each from samples with no significant residues present. It is not clear from the study report which sample used for procedural recovery experiments relates to sample points in the field. Thus, there is some uncertainty regarding the recovery in this field study, and the calculated DT_{50} and DT_{90}, particularly of IN-MM671, should be treated with caution.

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(9)	Vol. 3, Annex B.8, point B.8.1.5), page 454, Summary and assessment – soil deg studies (formation fractions for IN-MM671 in Arrow and Speyer soil studies)	**DuPont:** Re-calculated endpoints from FOMC-SFO models were provided with realistic conversion factors (compare points 1 and 2 above). Furthermore, it is not of regulatory relevance, because field data were used for PEC calculations by the RMS.	RMS comment: The degradation rates for the metabolite IN-MM671 in the Arrow sandy loam (Spare, 1999a) and the Speyer loamy sand (Spare, 1999b) should be treated with caution. Those values calculated using the preferred SFO/SFO sequential model have been calculated with an unrealistic formation fraction (358 % for Arrow, and 200 % for Speyer) in order to force a better fit in the regression curve. This has the effect of artificially shortening degradation rates. The same data has been analysed using an FOMC/SFO model, but the calculated DT_{50} and DT_{90} values for the active substance do not obey first order kinetics. DuPont Response – further explanations: Please note that the conversion factor is a fitted parameter which is not set to a specific value. In the DuPont response to e-fate questions (July 2004, points 1, 10 and 11), DuPont commented on the acceptability of conversion factors if their confidence intervals include 1. The FOMC-SFO model provides a reliable fit for the active substance (χ^2 error of 2 from re-calculation with ModelMaker) and IN-MM671 (χ^2 error of 8 and rate constant significantly different from zero at p=0.05).

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(10)	Vol. 3, Annex B.8, point B.8.3), page 462, Summary and assessment – soil deg studies (recalculation of PECs values using field data)	**DuPont:** DuPont used the respective worst-case values from laboratory studies to provide a worst-case assessment for the parent compound which is the only residue of concern in environmental compartments. The rapporteur used worst-case formation fractions and half-lives from field dissipation studies which resulted in higher PECsoil values for some metabolites. The use of degradation parameters from field studies does not change the risk assessment for the soil compartment.	RMS comment: All PEC_S values have been recalculated from the original study data by the rapporteur. The rapporteur disagrees with the PEC_S values provided by the applicant in their dossier, since only laboratory degradation rates and formation rates of metabolites were used. Eight field studies were provided by the applicant, and these are considered to reflect degradation properties more realistically. Proquinazid degraded more quickly in field studies, whereas the metabolites IN-MM671 and IN-MM986 degraded more slowly in comparison to laboratory studies. In addition, maximum observed formation rates of two metabolites, IN-MM986 and IN-MM991 were significantly higher in the field. The recalculated PEC_S values for metabolites are therefore larger than those submitted by the applicant.

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(11)	Vol. 3, Annex B.8, point B.8.4.2 a, page 473, Aqueous photolysis (kinetic evaluation of IN-MM991 and IN-MT884 - Table B.8.76)	**DuPont:** A sequential SFO-SFO-SFO fit for proquinazid and the two metabolites IN-MM671 and IN-MM991 was recalculated using ModelMaker setting the conversion factor for IN-MM991 to 1. The χ^2 error for the fit of IN-MM991 was 84 (particularly because the model cannot pick up the very rapid initial formation), but the k-rate passes the t-test at p=0.05. The resulting DT_{50} value for IN-MM991 is 4.6 days and confirms the value from Smyser (2003). The fit from the maximum observed formation of IN-MT884 represents four time points with 2 replicates each. The fit was also repeated with ModelMaker and the parameters submitted to statistical evaluation according to FOCUS (2006). The DT_{50} of IN-MT884 was confirmed to be 39 days with a χ^2 error of 2 and the k-rate significantly different from zero (p=0.05). Furthermore, IN-MT884 was not considered a metabolite to be addressed in the risk assessment by the RMS.	RMS comments (referring to Table B.8.76): Values recalculated from original study by Smyser (2003). It should be noted that the DT_{50} of IN-MM991 was calculated using a simple first order model with the parent and two metabolites (IN-MM671 and IN-MM991) in sequence, with a formation fraction > 100 %. Therefore this value cannot be considered reliable. The DT_{50} value in the original study, calculated using a simple first order model with the parent and one metabolite in sequence, was 1.39×10^7 days. ** The DT_{50} of IN-MT884 was calculated using a simple first order model of the metabolite only, from the point of maximum formation. Only four data points were plotted, thus whilst providing an indication of the likely degradation rate, this value cannot be considered entirely reliable. DuPont Response – further explanations: The pathway for the aqueous photolysis study is difficult to fit. In the original study, the fit leading to a very long half-life of IN-MM991 only included proquinazid and IN-MM991 which is not an appropriate approach for this data set (compare r^2 of 0.58 and large confidence intervals including zero for the conversion factor and the metabolite rate constant). Regarding the formation fraction of >100% in Smyser (2003, DuPont-13715), please note that the conversion factor is a fitted parameter which is not set to a specific value. In the DuPont response to e-fate questions (July 2004, points 1, 10 and 11), DuPont commented on the acceptability of conversion factors if their confidence intervals include 1. In the recalculation, the DT_{50} of the precursor, IN-MM671, is also confirmed with 4.7 days (χ^2 error of 10 and k-rate significantly different from zero at p=0.05). Although these fits are not in all cases meeting the statistical criteria recommended by the FOCUS kinetics guidance document (FOCUS, 2006), the fit is much more reliable than the one from the original study ($r^2 < 0.6$).

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(12)	Vol. 3, Annex B.8, point B.8.4.4, page 478 Water/sediment studies. (total system half-life of IN-MM671 in Town Park system)	**DuPont:** DuPont agrees that it is difficult to calculate an accurate total system DT_{50} for metabolites which do not show decline during the study period. However, DuPont took a sequential approach for proquinazid and IN-MM671 in the total system which takes into account the simultaneous formation and degradation of IN-MM671. Setting the conversion factor to 1, the resulting $DegT_{50}$ for IN-MM671 was 289 days in the total system (χ^2 error of 7, rate constant significantly different from zero) which confirms that the worst case default of 300 days used by Huber (2003; DuPont-13553) in the risk assessment which can therefore be considered as sufficiently conservative.	RMS comment: The rapporteur has recalculated these values using a simple first order model, which returns DT_{50} values of 0.82 (Red Oak) and 0.75 (Town Park). It should be noted that the degradation rates for IN-MM671 in the total system at Town Park were calculated using a regression model with a formation fraction (parent to metabolite) > 100 %. In practice this is unrealistic, and has the effect of significantly shortening the degradation rates, and the rates given above are therefore considered unreliable. In addition, IN-MM671 was still forming at the conclusion of the study, thus it is difficult to establish an accurate DT_{50} using the available models. The rapporteur has recalculated the DT_{50} of IN-MM671 in the total system at Town Park using a non-linear first order regression model, with the maximum formation factor set to 100 %. This technique calculated a minimum DT_{50} of IN-MM671 of 497 days (r^2 = 0.987). However, given that no decline phase occurs within the study period, an accurate degradation rate is difficult to calculate for this metabolite. DuPont Response – further explanations: A position paper by Huber (2004, DuPont-14198) with revised kinetic calculations using ModelMaker 4.0 was submitted in July 2004 but not referred to in the reference list of the DAR. Proquinazid DT_{50} in water was 0.76 days in both water/sediment systems and the DT_{50} in sediment was 148 days and 46 days in the Red Oak Stream and Town Park Pont, respectively. IN-MM671 DT_{50} was 34 days in water and >1000 days in sediment of both water/sediment systems. Additional detailed comments on the formation and decline of the metabolite IN-MM671 were submitted in the DuPont response to e-fate questions (July 2004, point 10).

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section 5 - Ecotoxicology (B.9)

15. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, Annex B.9, Page B.9.4.1.1, Table B.9.62 Effects on bees	DuPont: The authors name is mis-spelt. It should be Engelhard not Englehard	
(2)	Vol. 3, Annex B.9, Page 623 B.9.5.2, Field tests with plant protection products	DuPont: In the second paragraph it should read „All three studies were GLP compliant ….' Rather than „...GLP complaint…'	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, LOE minimum purity	AT: It should be added that the value refers to a pilot plant.	
(2)	Vol. 1, LOE UV spectrum	AT: The values for **ε** should be inserted.	
(3)	Vol. 1, LOE analytical methods, impurities	AT: Impurities [redacted] should not named explicitly.	
(4)	Vol. 1, LOE analytical methods, residues in soil and water	AT: It should be indicated whether the LOQ refers to the active substance and metabolites as sum or to each substance.	
(5)	Vol. 3, B.2.1 in general	AT: The concentrations of the pure and technical substances should be added to the table.	
(6)	Vol. 3, B.2.1.1 melting point	AT: The test used (e.g. Kofler..) should be included.	
(7)	Vol. 3, B.2.1.10 UV spectrum	AT: The unit for **ε** should be **L**.mol^{-1}.cm^{-1}.	
(8)	Vol. 3, B.2.2.15 shelf life	AT: Is the study which was announced for Q1/2006 completed?	
(9)	Vol. 3, B.2.2.17 persistent foaming	AT: The concentration of the substance used is requested.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(10)	Vol. 3, B.5.2.1 residue method, plant (primary method)	AT: The second fortification at 10 times LOQ is missing for apple, grape and wheat grain. For oilseed rape no validation data are included in the table.	
(11)	Vol. 4, C.1.1 manufacturing process	AT: The suppliers and purity of all starting materials are missing.	
(12)	Vol. 4, C.1.2 c) profile of 6 batches	AT: The min./max. values given in the table should refer to the values reported.	

section 2 - Mammalian toxicology (B.6)

17. Mammalian toxicology (B.6)

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

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section 3 - Residues (B.7)

18. Residues (B.7)

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

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

19. Environmental fate and behaviour (B.8)

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

section 5 - Ecotoxicology (B.9)

20. Ecotoxicology (B.9)

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

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section 5 - Ecotoxicology (B.9)

21. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, Level 2, Appendix 3, Listing of endpoints	FR: The endpoints are filled in the old version. The new version dated September 2005 seems more appropriate to the current data and requirements.	
	Birds and mammals		
(2)	Vol. 3, B 9.1.4.1, Background (for birds), p.561 Vol. 3, B.9.3.2.3 Tier 1 risk assessment (for mammals) p.608-609	FR: The MAF values for acute exposure was 1.25 in cereals and 1.36 or 1.38 in vines. The MAF values recommended in the SANCO 4145 guidance are slightly different. What is the justification behind the new values used in this risk assessment ?	
(3)	Vol. 3, B 9.1.4.4, Bioaccumulation (Risk to birds from secondary poisoning), p.568-575 Vol. 1 appendix 3 p. 99-100	FR: The risk to birds from secondary poisoning was not reported in the list of endpoints.	
(4)	Vol. 1, 2.6.1 Effect on terrestrial vertebrate, p. 41	FR: It is said that “The data provided indicates that proquinazid and its metabolites are of low to moderate toxicity to birds.” but no data were provided for the metabolites.	

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(5)	Vol. 3, B.9.3.1 Toxicity (to other terrestrial vertebrates), p. 606	FR: The selected NOAEL is 35 mg a.s./kg b.w./d from the rat multigeneration study of Mylchreest, 2003. Several developmental endpoints in rat and rabbit were lower (11, 30 and 2.5 mg a.s./kg b.w./d). Therefore, a more detailed justification for the selected endpoint should be provided.	
(6)	Vol. 3, B.9.3.2.3 Tier 1 risk assessment, p. 608	FR: In Table B.9.56 for acute TER, the RUD values are those used for the long-term assessment of exposure. In Table B.9.57 for long-term TER, the RUD values are those used for the acute assessment of exposure. However, exposures and TER values are calculated with the right RUD values.	
(7)	Vol. 3, B.9.3.2.5 Risk to mammals (from the preparation), p. 610	FR: The LD50 for the preparation is considered to relate to the a.s. content (i.e. > 2000 mg a.s./ kg bw p.610). However the same endpoint is reported as being related to the product in B.6 section and in the listing of endpoints. The TER values should probably be corrected accordingly.	

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	Aquatic organisms		
(8)	Vol. 1, Level 2, Appendix 3, Listing of endpoints, p.103	FR: As a minor comment, the distance reported in the step 4 assessment for the use in cereals should be 3 m instead of 1 m.	
(9)	Vol.1, Level 2, 2.6.2 Effects on aquatic species, p.42	FR: It is said that the "Data supplied for metabolites of proquinazid … indicate these to be of lower toxicity to aquatic life than the structurally similar parent, so the risk assessment for the metabolites is covered by the risk assessment for the active substance. ». This assessment could be agreed in the case of proquinazid, however it could not be generalised (i.e., a lower toxicity combined to a higher exposure could lead to a higher risk than the parent).	
	Other non-target arthropods		
(10)	Vol.3 Table B.9.67 Effect on non-target arthropods, p.619-622	FR: The mortality figures were not corrected for the control mortalities.	

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(11)	Vol.3 Table B.9.67 Effect on non-target arthropods, *Orius laevigatus*, p.621 Vol.1, Level 2, 2.6.2 Appendix 3, Listing of endpoints, p.106	FR: The endpoints obtained on fresh residues after 3 and 4 applications appears to be switched (i.e., 3.75% mortality after 3 application in Table B.9.67 and after 4 applications in the list of endpoints for instance).	
	Soil organisms		
(12)	Vol.1, Level 2, 2.6.5 Effects on soil micro-organisms, p.43	FR: No TERlt were calculated and the trigger for effects should not apply to TERlt. Is it possible to clarify this point ?	
	Terrestrial plants		
(13)	Vol.3, B.9.9 Effects on other non-target flora, p.651-654	FR: It is noticed that the post-emergence tier 1 test is not GLP. The highest application rate 75 g a.s./ha is covered by only one test (common cowpea, 200 g/ha).	
(14)	Vol.3, B.9.9 Effects on other non-target flora, p.651-654	FR: No tier 1 pre-emergence test was provided. It is questionable whether the results of the succeeding crop trials are appropriate to address this point even at a higher level (i.e., a 7 to 15 months ageing period of the residues in soil is not similar to an exposure to fresh residues).	

section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(16)	Vol.3, B.9.9 Effects on other non-target flora, p.651-654	FR: This *a priori* assessment "As a fungicide, proquinazid and its metabolites … would not be expected to pose a risk to non-crop plants." Should not be sufficient to avoid the submission of conventional first tier risk assessment for non-target terrestrial plants adjacent to the treated crops.	

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

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, General	EFSA: RMS should consider to use the current harmonised version of the list of end points.	
(2)	Vol. 1, list of end points, minimum purity, p. 58	EFSA: For transparency, it should be mentioned that the proposed minimum purity is based on a pilot plant.	
(3)	Vol. 1, list of end points, solubility in organic solvents, p. 59	EFSA: For transparency, the purity of the test material should be mentioned taken into account that the measurement was carried put with pure instead of technical material.	
(4)	Vol. 1, list of end points, analytical methods for residues, p. 64	EFSA: It should be clarified in the box of "Food/feed of animal origin" that a method is not required since no residue definition is proposed.	
(5)	Vol. 1, list of end point, analytical methods for residues, soil, p. 64	EFSA: For transparency, it should be mentioned that the LOQ refers to each analyte and that it is not a sum parameter.	
(6)	Vol. 1, list of end point, analytical methods for residues, water, p. 64	EFSA: For transparency, it should be mentioned that the LOQ refers to each analyte and that it is not a sum parameter. In addition, the matrices such as surface water and drinking water should be mentioned.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(7)	Vol. 3, B.2.1 physical and chemical properties…, p. 7	EFSA: The given argument for not submitting either a "boiling point"- or a "temperature of decomposition"- study is incorrect. According to Directive 94/37/EC, the boiling point has to be determined up to 360 °C unless the substance decomposes beforehand.	
(8)	Vol. 3, B.5.2.2 Animal matrices, p. 44	EFSA: The RMS should delete the studies of Mörtl and Class (1998) and Reichert (2003b) from the references relied on, since these methods are not required (no residue definition is set).	
(9)	Vol. 3, B. 5.3.3 residues in air, method for air in relation to table 5.6 on page 57.	EFSA: For transparency, could the RMS confirm that "warm/humid" means 35 °C and at least a relative humidity of 80%.	
(10)	Vol. 4, C.1.1 b) method of manufacture…, p. 3	EFSA: Information on the identity of the starting material (in terms of purity and commercial availability) should be given.	
(11)	Vol. 4, Table C.1.2 Summary of 6-batch analysis, p. 7	EFSA: The given maximum values for IN-MU563 and IN-MZ772 need to clarify. Taken the individual values into account these max values are not reliable. In addition, if the values are above 1 g/kg, why are there no specified limits?	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(12)	Vol. 4, C. 1.4.1 Methods of analysis for impurities, p. 13	EFSA: Data to confirm the identity of the impurities revealed by chemical analysis must be provided to address the requirement of the Directive on the specificity of the method(s).	

section 2 - Mammalian toxicology (B.6)

23. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	General comment	EFSA: Considering the proposed technical specification, it seems that the level of many impurities will be increased compared to the batches tested in tox.	
(2)	Vol 3, B. 6.14 Operator and worker exposure	EFSA: the application of the EUROPOEM database to estimate/refine exposure to be discussed in a meeting of experts.	

section 3 - Residues (B.7)

24. Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol.3, B.7.1.2 Metabolism in grapes	ESFA: There seems to be a discrepancy between the TRR values in grapes reported in the tables B.7.6 and B.7.7. The TRR values differ by a factor of approx. 3. In comparison with the residue trials results the values in table B.7.7. appear to be more plausible. Clarification should be given.	
(2)	Vol.3, B.7.1.2 Metabolism in grapes	EFSA: Was it only postulated or could it finally be proven that the unextractable residues were associated with lignin?	
(3)	Vol.3, B.7.1.5 Metabolism in succeeding crops	EFSA: Did the applicant give any reason why fast-growing leafy crops were not tested in the rotational crop study?	
(4)	Vol.3, B.7.2.2 Goat metabolism	ESFA: It should be clarified whether the applied dose of 91.5 mg/kg diet refers to the dry matter content or to the feed as received. In the latter case the composition of the diet in the goat study should be reported.	
(5)	Vol.3, B.7.2.3 Poultry metabolism	ESFA: It should be clarified whether the applied dose of 15.6 mg/kg diet refers to the dry matter content or to the feed as received. In the latter case the composition of the diet in the hen study should be reported.	

section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(6)	Vol.3, B.7.2.3 Poultry metabolism	EFSA: Residue level were highest in poultry fat after 5 days of dosing. Given the log pow of 5.5 it might be expected that parent could accumulate in fatty tissues of poultry. Was there any consideration or even investigation of such a possible accumulation and/or how was this issue addressed?	
(7)	Vol.3, B.7.3 Definition of the residue	EFSA: Since the estimated dietary intake by livestock (ruminants) exceeds the trigger of 0.1 mg/kg diet and metabolism studies in livestock have been a requirement, a risk assessment residue definition for animal products should be proposed.	
(8)	Vol.3, B.7.6 Supervised trials	EFSA: Only validation data on the method used to analyse cereals samples are reported. Is there any method validation data on the data generation method used in the grape residue trials available?	
(9)	Vol.3, B.7.6 Supervised trials - cereals	EFSA: The selection of the cereal residue trial results for the assessment is not very comprehensible. Some trials seem to be excluded (at least results were not underlined) without any apparent reason, e.g. trials in winter wheat Belgium 1997, Germany 1997 (no replicates) and others. For the sake of transparency it should be commented in the table why the respective trials were not considered any further in the assessment.	

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section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(10)	Vol.3, B.7.16.1 Intake by domestic animals	ESFA: RMS concluded that “residues of proquinazid in products of animal origin are not expected to be above 0.01 mg/kg” Does this mean that the residue definition applied in this assessment was parent compound? Can it be confidently concluded that there should be no residues above 0.01 mg/kg given the exaggerated dose rate in the metabolism study? The uncertainty by assuming linearity and extrapolating to much lower dose rates is noted.	

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

25. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol 1. LoEP. Relevant metabolites.	EFSA: The percentage of these metabolites found in the field studies should be given to understand the reason why they are considered major metabolites in soil.	
(2)	Vol 1. LoEP. Rate of degradation in soil. Laboratory studies. Vol 3B.8.5 Predicted environemtal concentrations in GW, SW and sediment. Table B.8.85 p 485.	EFSA: to normalize 10 ^{o}C to 20 ^{o}C in order to have an additional degradation data is not acceptable. Moreover, when a degradation rate in the same soil measured at 20 ^{o}C is already available. In this case this has the effect of reducing the geometric mean of half lives calculated for parent and metabolite IN-MM671. The values should be: DT50 (proquinazid) = 76 d DT50 (IN-MM671) = 58 d DT50 (IN-MM986) = 16 d DT50 (IN-MM991) = 25 d	
(3)	Vol 1. LoEP. Metabolism scheme. P 94. Vol 3. B.8.5.Table B.8.83. Metabolism.	EFSA: Metabolite IN-MM986 is missing in these schemes.	
(4)	Vol 3. B.8.1.3 Soil rate of degradation. a) Spare 1999a. p 420 - 421	EFSA: it is not clear from the text weather the rate of degradation recalculated by the RMS made use of the FMOC model to fit the data of the parent and the metabolite.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(5)	Vol 3. B.8.1.3 Soil rate of degradation. Table B.8.15	EFSA: foot note b should read 10 ^{o}C instead of 20^{o}C.	
(6)	Vol 3. B.8.1.3 Soil rate of degradation. Table B.8.19	EFSA: foot notes 1 and 2 are missing in table B.8.19	
(7)	Vol 3. B.8.1.4.1 Field dissipation. a) Tables B.8.24, B.825, B.8.26	EFSA: Comparing the results of table B.8.24 and B.8.25 either there is a significant procedural loss during the identification of the residues components, significant unextracted radioactivity and / or unidentified components. (eg. 0 DAT, 0.125 + 0.01 + 0.01 + 0.02 = 0.129 << 0.220.	
(8)	Vol 3. B.8.1.4.1 Field dissipation .b) c). B.8.1.4.2 Soil residue studies a), b), c)	EFSA: Please, indicate to which substance corresponds the code DPX-KZ165 coformulated with proquinazid in these studies.	
(9)	Vol 3. B.8.1.4.2 Soil residue studies a) Tab;le B.8.46	EFSA: Table B.8.46 g / ha per season should read 450 instead of 45.	
(10)	Vol 3. B.8.1.4.2 Soil residue studies	EFSA: Soil residue studies are not useful to evaluate the persistence of proquinazid in soil since actual levels just after the last application are not available. Only 0-10 cm or 0-15 cm soil horizons are analyzed in these studies.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(11)	Vol 3. B.8.3 PEC soil (IIIA 9.1). p 462. Table B.8.61	EFSA: Maximum IN-MM991 was 13.4 % AR after 120 d in Alconbury and not 7.4 % as stated in p. 462. Maximum for IN-MM671 is 40.5 % in Asti (mol basis, equivalent ot % AR in radilabelled studies). Maximum for IN-MM986 would be 32.8 %). These percentages should be used for PEC soil calculation.	
(12)	Vol 3. B.8.5 Predicted environemtal concentrations in GW, SW and sediment. Table B.8.85 p 485..	EFSA: It is not clear why dissipation rates for metabolites derived from field studies are not used in the PEC calculations. At least for metabolite IN-MM671 were field studies consistently show much longer half lives than in the laboratory studies. Also data half lives calculated from the laboratory studies performed with the parent compound seem to have been disregarded for the risk assessment.	
(13)	Vol 3. B.8.5.1.1 Groundwater. FOCUS PELMO modelling. Table. B.8.83	EFSA: In the table of input parameters for FOCUS calculation it is stated that solubility in water is 0.93 μg / L, however in the LoEP (PhysChem section) solubility ranged from 0.73 – 0.97 mg / L (three orders of magnitude higher). Please clarify.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(14)	Vol 3. B.8.5.1.1 Groundwater. FOCUS PELMO modelling. DT50 pg 484 -485	EFSA: The use of the laboratory degradation rates for the metabolites is not well justified. In fact the formation of metabolites was faster in field studies than in the laboratory ones. However the degradation of metabolites IN-MM671 and IN-MM986 in the field studies available seem to be slower than in laboratory.	
(15)	Vol 3. B.8.5.2.1 FOCUS SW Step 1 and Step 2. pg 489 and Table B.8.89.	EFSA: From the text and the table it seems that it has been assumed that photolysis metabolite IN-MT884 may also be formed in soil. However, it was only identified in the aqueous photolysis study, please clarify.	
(16)	Vol 3. B.8.5.2.1 FOCUS Step 1 and Step 2. pg 489 and Table B.8.89.	EFSA: For metabolite IN-MM671 a default whole system DT50 of 300 d is assumed in the FOCUS SW calculations. However, the RMS already calculated a minimum half life of 497 d from the water sediment study. A worst case assumption of 1000 d seems more appropriate for this metabolite.	
(17)	Vol 3. B.8.8 Definition of the residue	EFSA: the three soil metabolites IN-MM671, IN-MM991 and IN-MM986 should be considered major soil metabolites since appear at levels > 10 % AR or 10 % of applied amount on molar basis in the filed studies.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(18)	B.8.10 References relied on. Plant protection product.	EFSA: The references of studies Huber, A. 2003, are not quoted in the test of the corresponding sections. In fact all the calculations were repeated by the RMS and RMS results were used for the risk assessment. At any case one of the reports should be labelled as 2003 a.	

section 5 - Ecotoxicology (B.9)

26. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol.3, B.9 , General	EFSA: Information on composition of the technical material used in the ecotoxicological studies is lacking. I was noted that such information is given for batches used for toxicological testing in Annex C but not for ecotox.	
(2)	Vol. 3, B.9.1.3, Reproductive toxicity to birds	EFSA: A significant increase in food consumption was observed in both species at the highest dose and in quails at the two highest doses. No increase in bw was observed and a waste of food was given as a possible explanation. However, in the dietary studies a distinct trend towards decreased bw was observed with increasing concentrations of proquinazid in the food. Thus, a possible explanation could also be an effect on the metabolism. Taking this into account would however lead to the same NOEL.	
(3)	Vol. 3, B.9.1.4, Avian risk assessment	EFSA: There is an inconsistency between the NOEL given for mallards in Tableb.9.10 (and in the list of endpoints) and the study summary on page558. Please clarify although this value was not used for the RA.	

section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(4)	Vol. 3, B.9.1.4, Avian risk assessment	EFSA: A time window of 21 days (averaging time) was used in the calculation of long-term TER. Since the interval between applications is 14 days this time period should be used. The resulting TER would be 5.27 and hence still above the trigger of 5.	
(5)	Vol. 3, B.9.1.4, Refined avian risk assessment	EFSA: We have information that stonechat has been proposed to be a relevant species in Italian orchards and vineyards. Would the diet of this species be considered to be similar to that of yellowhammer and Cirl bunting?	

section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(6)	Vol. 3, B.9.1.4.3, Risk to birds from exposure to metabolites	EFSA: For the assessment of risk to earthworm-eating birds from the metabolite IN-MM671 a comparison of acute oral toxicity in rats between parent and the metabolite is used. However, in the assessment of secondary poisoning the NOEL from reproduction studies is used. There is no information available on the comparative reproductive toxicity for the metabolite in birds. We noted that the TER values for earthworm-eating birds for the parent are not far above the trigger, especially in vine, even with some refinements of the exposure. Nevertheless, since the bioaccumulation potential for the metabolite is lower and the plateau PEC_{soil} is lower than the PEC for the parent, the risk would be covered by the assessment for the metabolite is similar reproductive toxicity is assumed.	
(7)	Vol. 3, B.9.3.2..3, Risk to mammals	EFSA: There seem to be some typing mistakes in Table B.9.56 but we also obtained some different TER values. RUD for SHM in cereals should be 142, for IM in cereals 14 and for SHM in vive 85. A MAF of 1.38 was used for birds in vine and for consistency this value should be used also for mammals. We obtained the following TER values: SHM in cereals 391.8, IM in cereals 10989, SHM in vine 396.	

section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(8)	Vol. 3, B.9.3.2..3, Risk to mammals	EFSA: There seem to be some typing mistakes in Table B.9.57 but we also obtained some different TER values. RUD values should be 76 for SHM in cereals and 5.1 for IM. Ftwa should be 0.64 using a 14 day averaging period. We obtained TER values as 10.35 for SHM in cereals, 217.8 for IM in cereals and **3.9** for SHM in vine following 4 x 75 g a.s./ha. This means that the trigger of 5 is not met in vine with the higher application rate and a refined assessment is needed. If 4x50 g a.s./ha is applied a TER of 5.86 will be the result.	
(9)	Vol.3 B.9.1.4 and B.9.3.2, Risk to birds and mammals	EFSA: It was noted that no assessment of risk from intake of contaminated drinking water was presented in the DAR. A justification for why this is not considered necessary should be provided.	
(10)	Vol. 3, B.9.2.5.5, Risk to sediment dwelling invertebrates	EFSA: The references to tables in the fate section seem to be wrong. On page 603, last sentence, the references should presumably be Tables B.8.91 and B.8.92 and on page 604 in the paragraph before Table B.9.55 the reference should be to Table B.8.107.	
(11)	Vol.3, B.9.2.5.3, Risk to aquatic life from metabolites	EFSA: In the first paragraph of this section it is mentioned that IN-MT884 was not detected in field studies. What field studies are you referring to?	

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(12)	Vol.1, List of endpoints, TERs for aquatic organisms	EFSA: For FOCUS Step 4 (proquinazid) the distance for cereals should be 3 m.	
(13)	Vol.1, List of endpoints, TERs for aquatic organisms	EFSA: Our proposal is to include all relevant FOCUS Step 3 and Step 4 scenarios but only for the most sensitive organism, which drives the RA, in the list of endpoints. It may be useful to see how many and which scenarios meet the trigger. However, we would like to discuss this in an expert meeting in order to get the views of MS.	
(14)	Vol. 1, list of endpoints	EFSA: Please add TER values for earthworm- and fish-eating birds and mammals to the list of endpoints and indicate the assumptions made for the refinement steps.	
(15)	Vol.1, list of endpoints	EFSA: Please consider to use the EPCO No E 4, revision 4 (September 2005) template for the list of endpoints and fill in results for all groups of organisms where relevant.	