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0. General

General				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
0(1)	Vol. 1, General	EFSA: RMS should consider to use the current harmonised version of the list of end points.	The endpoints have been updated. These will be revised to use the most recent harmonised version of the endpoints prior to expert meeting discussion.	Open point: RMS should consider to use the current harmonised version of the list of end points. See also 0(2).
0(2)	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.	RMS: see 0(1) above.	See open point in comment 0(1)
0(3)	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.	RMS: The notifier has presented further studies to support commercial production. This includes a revised technical specification. The evaluation is presented in an Addendum to Annex C (Volume 4) of the DAR. The Addendum considers the toxicological significance of the impurities listed in the new proposed technical specification at C.1.2.d. A comparison table of the batches used for toxicological testing compared with the original and new proposed technical specifications is given at Table C.1.8 of the Addendum. All impurities in the proposed technical	**Addressed:** **Tox to consider the new information in the addendum.**

General				
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			specification are present at <1% [redacted] The toxicological commentary at C.1.2.d of the Addendum takes into account the view that at concentrations of <1% the main concern from impurities comes from potential genotoxicity (see guidance document on the assessment of the equivalence of technical materials SANCO/10597/2003 –rev7 final 2, 14 December 2005). It is notable that none of these impurities contain obvious structural alerts for potential DNA reactivity according to the model of Tennant and Ashby (1991). Other information, including the magnitude of the difference in impurity levels, has also been considered. The conclusions are: a) None of the listed impurities, at the levels in the proposed technical specification are considered to be of clear toxicological concern.	

General				
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			b) The proposed technical specification is adequately supported by the submitted toxicology studies with proquinazid synthesised by the original and current production process. RMS considers that the point raised by EFSA is addressed.	
0(4)	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.	RMS Two samples were used for studies involving the testing of the technical material. Batch DPX-KQ926-45 was used in all non-radiolabelled studies involving the technical material apart from the study by Hertl (2002). For the Hertl study (*DPX-KQ926 technical: Activated sludge, respiration inhibition test*) the batch DPX-KQ926-85 was used. Both these batches were also used in the toxicological testing. Information on the composition of both the above batches is given at Table c.1.8 of the Addendum.	Addressed: Ecotox to consider the new information in the addendum.

section 0 – General comments

General				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
0(5)	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.	RMS: noted.	Addressed.

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

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(1)	Vol. 1, LOE minimum purity	AT: It should be added that the value refers to a pilot plant.	RMS: Noted. The notifier has now presented further studies to support commercial production. This includes a revised technical specification. The evaluation is presented in an Addendum to Annex C (Volume 4) of the DAR. The LOEP therefore now reflects the proposed technical specification for commercial production.	Open point: The new specification and supporting data in the addendum to Vol 4 should be considered by a meeting of experts. See also 1(2), 1(3), 1(6), 1(7), 1(8), 1(9). 1(11), 1(12), 1(13)
1(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.	RMS: Please refer to point 1 (1) above.	See open point in comment 1(1).
1(3)	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.	RMS: Noted: the RMS has received the reports. The evaluation is presented in Addendum 1 to Annex C of the DAR (confidential volume) dated December 2007.	See open point in comment 1(1).
1(4)	Vol. 4, C.1.1 manufacturing process	AT: The suppliers and purity of all starting materials are missing.	RMS: Agree. This information is presented in Addendum 1 to Annex C of the DAR (confidential volume) dated December 2007. The information presented relates to the pilot plant production. It is proposed the notifier be asked for this information in relation to commercial production.	Open point: The suppliers and purity of all starting materials are missing. The rapporteur stated that the information was included in the addendum but this was not the case. See also 1(5)
1(5)	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.	Please refer to point 1 (5) above.	See open point in comment 1(4)

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(6)	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.	RMS: Agree: the information in this table is not as clear as it should be. However this table relates to pilot scale batches and data relating to full scale production are now available (see point 1(3) above). An evaluation of the submitted information on commercial production is presented in Addendum 1 to Annex C of the DAR (confidential volume) dated December 2007.	See open point in comment 1(1)
1(7)	Vol 4, annex C, table C.1.2	NL: Please include standard deviation of the mean results.	RMS: Please refer to point 1 (6) above.	See open point in comment 1(1)
1(8)	Vol. 4, Table C.1.2 Summary of 6-batch analysis, p. 7	EFSA: The given maximum values for [redacted] 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?	RMS: Please refer to point 1 (6) for the first part of this comment and to point 1 (9) for the second part.	See open point in comment 1(1)

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(9)	Vol. 4, AIIA 1.10, identity of impurities	DE: For the impurities [redacted] no specification was clearly stated.	RMS: In relation to Annex C of the DAR, impurity [redacted]5 is not included in the specification as the batch data indicate that levels are [redacted] The Notifier proposed that the other [redacted] were included in the specification although full information on these impurities and their proposed specification levels are missing from the DAR. This was an oversight. Data in Annex C currently relate to pilot scale production and data relating to full scale production are now available (see point 1(3) above). An evaluation of the submitted information on commercial production is presented in Addendum 1 to Annex C of the DAR (confidential volume) dated December 2007. The RMS the specification for full scale production is clearly stated in this addendum.	See open point in comment 1(1)
1(10)	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).	The RMS agrees. The majority of standards used in the methods were prepared "in house" by the Notifier and no information regarding their structural identify was provided. The Notifier will be asked to address this issue.	Data requirement: How was the identity of the impurities confirmed. See also 1(14)

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(11)	Vol. 4, AIIA 1.10, identity of impurities	DE: The specification of the impurity [redacted] s not reproducible from the batch analyses.	RMS: The batch analysis is for pilot scale production and data relating to full scale production are now available (see point 1(3) above). An evaluation of the submitted information on commercial production is presented in Addendum 1 to Annex C of the DAR (confidential volume) dated December 2007. The RMS the specification for full scale production is clearly stated in this addendum.	See open point in comment 1(1)
1(12)	Vol. 4, AIIA 4.1.3, precision of analytical method	DE: The precision for the analytical method of the impurity [redacted] is not stated.	RMS: [redacted] was not detected in the batch analysed for precision validation data, which meant that no precision data were available. Data for full scale production are now available. An evaluation of the submitted information on commercial production is presented in Addendum 1 to Annex C of the DAR (confidential volume) dated December 2007. The RMS the specification for full scale production is clearly stated in this addendum. The impurity is not present at significant levels in full scale batches (a comparison table of the batches comparing the original and new proposed technical specifications is given at Table C.1.8 of the Addendum) and therefore the Notifier will not be required to address the precision.	See open point in comment 1(1)

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(13)	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?	RMS: It is not clear why the Notifier chose to present the information to the RMS as reproduced in the DAR. It should be noted that data for full scale production are now available. An evaluation of the submitted information on commercial production is presented in Addendum 1 to Annex C of the DAR (confidential volume) dated December 2007.	See open point in comment 1(1)
1(14)	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.	RMS agrees. Please refer to point 1 (10) above.	See comment in open point 1(10)
1(15)	Vol 1, LOEP, analytical methods for impurities	NL: NL regards [redacted] as confidential information. Please consider rephrasing to residual solvent.	RMS agrees. The LOEP have been updated.	Addressed: See also 1(16)
1(16)	Vol. 1, LOE analytical methods, impurities	AT: Impurities ([redacted] should not named explicitly.	RMS: Please refer to point 1 (15) above.	See open point 1(15)

Physical and chemical properties of the active substance (B.2.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(17)	Vol. 3, B.2.1 in general	AT: The concentrations of the pure and technical substances should be added to the table.	RMS: The purity of "pure" and "technical" in terms of % purity are defined at the top to table B.2.1 (pure = 99.2%m, technical = 97%). As stated in the DAR this applies to all properties unless specifically stated in the table.	Addressed.
1(18)	Vol. 3, B.2.1.1 melting point	AT: The test used (e.g. Kofler..) should be included.	RMS: The melting point was determined using the capillary method. The RMS considers that this point is addressed.	Addressed.
1(19)	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.	RMS: Please refer to point 1 (21).	See data requirement in comment 1(21)
1(20)	Vol 1, LOEP, boiling point & Vol 3, B.2.1.2	NL: NL regards the statement given here as not relevant. Measurements should be continued up to 360 °C, unless both melting and boiling point are determined or decomposition takes place.	RMS: Please refer to point 1 (21).	See data requirement in comment 1(21)
1(21)	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.	RMS: The RMS agrees. The comment presented in the DAR was the opinion of the Notifier however no further justification was provided for not conducting the test to the required temperature. The RMS considers that a data requirement be set for the Notifier to address these points.	Data requirement: The boiling point and temperature of decomposition needs to be addressed. See also 1(19), 1(20), 1(22)
1(22)	Vol 3, B.2.1.3, temperature of decomposition	NL: Measurements should be continued up to 360 °C. This endpoint is required, unless melting and boiling points are determined.	RMS: Please refer to point 1 (21).	See data requirement in comment 1(21)

Rapporteur: UK

Physical and chemical properties of the active substance (B.2.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(23)	Vol 1, LOEP	NL: Please state the purity of the active substance under appearance, relative density	RMS: The LOEP have been updated.	Addressed.
1(24)	Vol 1, LOEP, UV/VIS	NL: Please state ε for the absorption maximum at 325nm.	RMS: Noted. The LOEP have been updated.	Addressed.
1(25)	Vol. 1, LOE UV spectrum	AT: The values for **ε** should be inserted.	RMS: Please refer to point 1(24)	Addressed.
1(26)	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).	RMS: Noted. The LOEP have been updated.	Addressed.
1(27)	Vol. 3, B.2.1.10 UV spectrum	AT: The unit for **ε** should be **L**.mol^{-1}.cm^{-1}.	RMS: Noted.	Addressed.
1(28)	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.	RMS: Noted. The LOEP have been updated.	Addressed.
1(29)	Vol. 3, AIIA 2.11.2, auto-flammability	DE: In the used study from (Gravell 1997) no temperature/time curve is included.	RMS: Agree. Requirement for the Notifier to address the absence of a temperature/time curve in the Gravell 1997 study.	Data requirement: Applicant to address the absence of a temperature/time curve in the Gravell 1997 study auto-flammability.
1(30)	Vol 1, LOEP, flammability	NL: NL considers it to be better to state „not highly flammable' instead of „non-flammable'.	RMS: Agree. The LOEP have been updated.	Addressed.

Physical and chemical properties of the active substance (B.2.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(31)	Vol 1, LOEP, surface tension	NL : Please state the concentration at which the surface tension was determined.	RMS: Noted. The LOEP have been updated.	Open point: Please state the concentration at which the surface tension was determined. It has been stated that this has been done in the end points however, this is not the case.
1(32)	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 °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.	RMS: (i) The test was conducted on a 9:1 dilution of a saturated solution of the a.s. (ii) The RMS understands that this comment is perhaps more relevant to Vol 3, B.2.2.11 (surface tension of the preparation), however given that NL agrees with the RMS that the study is acceptable this point is addressed.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.

Physical, chemical and technical properties of the formulation (B.2.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(33)	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?	RMS: EC method A21 (oxidising properties for liquids) is based on UN test O.2 therefore the RMS considers that further justification is not required.	Addressed.

Rapporteur: UK

Physical, chemical and technical properties of the formulation (B.2.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(34)	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.	RMS has no comments to add as the study is considered acceptable.	Addressed.
1(35)	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?	RMS: (i) The material was stored in sealed glass containers for the accelerated storage test. This is considered acceptable. (ii) This comment refers to the low temperature stability tests. RMS agrees that the statement in the DAR is ambiguous. The study report states that the samples remained homogenous throughout the storage period and that no phase separation occurred. A very small amount of brown residue was visible at the bottom of the tubes. The RMS considers that these points are addressed.	Addressed: The packaging is not of concern in the accelerated study
1(36)	Vol 3, B.2.2.17, persistence of foam	NL: At what concentration was the determination performed?	RMS: The test was conducted at a concentration of 0.16%v/v. This is equivalent to the maximum use rate proposed. The RMS considers that this point is addressed.	Addressed. See also 1(40)

Physical, chemical and technical properties of the formulation (B.2.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(37)	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.	RMS: CIPAC MT 36.3 was used and the test was conducted at a concentration of 0.16%v/v. This is equivalent to the maximum use rate proposed. The RMS considers that this point is addressed.	Addressed.
1(38)	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	RMS: This information is noted.	Data requirement: Two year shelf-life study. See also 1(39)
1(39)	Vol. 3, B.2.2.15 shelf life	AT: Is the study which was announced for Q1/2006 completed?	RMS: Please refer to point 1 (38) above.	See data requirement in comment 1(38)
1(40)	Vol. 3, B.2.2.17 persistent foaming	AT: The concentration of the substance used is requested.	RMS: Please refer to point 1 (36) above.	See comment 1(36)
1(41)	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.	RMS: Noted. This information was provided for the UK provisional approval and should have been removed from the DAR.	Addressed.

Physical, chemical and technical properties of the formulation (B.2.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(42)	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.	RMS: All studies were conducted to GLP except the following: 2.1.17 – quantum yield calculation. 2.1.19 - stability in air. 2.1.23 – oxidising properties 2.2.14 – low temp stability. In all cases except for the stability in air tests it was not necessary for these studies to be to GLP as they were either justifications/ calculations provided by the Notifier or are not required to be conducted to GLP (Storage stability tests). The Notifier will be asked to address the GLP requirements for the stability in air test. The title of the tables already indicates that the studies were conducted to an acceptable standard unless stated otherwise, however RMS appreciates this may not be clear and so in future will state the GLP status of each study. Requirement for the Notifier to address the GLP requirements for the stability in air test.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.

Further information (B.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(43)	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.	RMS: Noted.	Open point: The GAP should be clarified. Given the comment from the applicant.

Classification and labelling (B.4)

For comments on classification and labelling see the relevant sections.

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(44)	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.	RMS: The RMS agrees that this statement in could be misinterpreted as a general statement rather than referring specifically to the method under discussion. However in this particular instance (monitoring method for residues in food) the GC-MS method uses 1 ion for quantification with a further 2 ions (out of a choice of 4) for confirmation. As all ions proposed have an m/z ratio > 100 - this is sufficient for the method to be considered highly specific according to current guidance (SANCO/825/00 rev 7.).	Addressed.
1(45)	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.	RMS: The residue method also utilised GC-ECD as an alternative detection system and validation data for the crops/fortification levels mentioned were generated using GC-ECD. This was not made clear in the evaluation; This information is presented in Addendum 1 to Annex B of the DAR dated December 2007.	Open point: The method for plants should be considered by a meeting of experts. The full validation data is on the GC-ECD, ILV with a reduced data set is with GC-MS and the ILV is also the confirmatory method. See also 1(46)
1(46)	Vol 3, B.5, table B.5.4	NL: For oil seed rape no recovery experiments or repeatability study were carried out?	RMS: Please see point 1 (45) above.	See open point in comment 1(45)

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(47)	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?	RMS: (i) The LOQ for the ILV in Table B.5.5 should have read 0.02 mg/kg. Thank – you for pointing out this error. (ii) Agree that the recoveries for this fortification level are not within the acceptable limits; however the weight of evidence indicates that overall the method is suitable. (iii) An explanation was provided in the text for section B.5.5 (p58). Please note that a method for the determination of residues in animal products is not required as no residue definition has been proposed [see comments under points 1 (48) & 1 (49)]	Open point: The analytical method for milk should be considered by a meeting of experts given the poor recoveries. The egg method should also be considered given the high RSD.
1(48)	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).	RMS: Noted: these will be removed from the final version of the list of tests and studies relied on.	Addressed.
1(49)	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.	RMS: Noted. The LOEP have been updated.	Addressed.

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(50)	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.	RMS: Noted. The LOEP have been updated.	Addressed.
1(51)	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.	RMS: Please refer to point 1(50)	Addressed.
1(52)	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.	RMS: Please refer to point 1(50). The LOEP have also been updated to include the matrices.	Addressed.
1(53)	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%.	RMS: The study report states that “ambient air” is defined as 25°C and 31% relative humidity and that “warm/humid air” is defined as 38°C and 84% relative humidity. The RMS considers that this point is addressed.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.

2. Mammalian toxicology

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

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

Short-term toxicity (B.6.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(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 morphological 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.	RMS: in the absence of any EU agreed approach to the interpretation of the toxicological significance of increased liver weight, the RMS has followed the guidance (dated 2005) agreed by the UK's Advisory Committee on Pesticides (ACP). The ACP guidance addresses increased liver weight in regulatory toxicity studies in rodents. Interpretation of increased liver weight in the 90-day rat study with proquinazid manufactured by the previous production process (pp 109 -110): attention is not only drawn to absence of information on the specific P-450 enzymes induced but also to the	Addressed.

Short-term toxicity (B.6.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			evidence for progression of liver effects at 300 ppm to substance-related lesions at this dose in the 2-year rat study. However**, importantly**, assessment of whether increased liver weight in rodents is adverse or not is not critical for the overall risk assessment of proquinazid, (it is not the critical effect for setting the ADI, ARfD or short term systemic AOEL) and does not affect the list of endpoints. On this basis the RMS considers that the point raised by Du Pont is addressed in the context of proquinazid and does not merit further discussion at an expert meeting. However, as a separate exercise the RMS would welcome the development of EU-agreed guidance for interpretation of the toxicological significance of increased liver weight. Recent guidance developed by JMPR (2006) is noted. [On considering this comment the RMS noted an error in the text - the LOAEL of 300 ppm in the mechanistic study for thyroid effects (B.6.8.1) equals 19 mg/kg bw/day and not 919 mg/kg bw/day. The same correction also applies to Table B.6.93.]	
2(2)	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	1) Cause of ocular discharge RMS agrees that the cause of the ocular	Open point: MSs to agree on the relevant NOAEL of the 1-year dog study, taking into account

Short-term toxicity (B.6.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		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.	discharge in dogs is <u>not clear</u>. Ocular discharge was seen in the one-year dog study (capsule dosing) and the 90-day dog study (dietary administration). A commentary on the likely cause is presented in the DAR Volume 3 on pp 125-6 (taking into account comments from the UK ACP and the applicant). The RMS concludes that: "as ocular discharge in dogs was most frequent at the time of test substance administration (dietary or capsule) it suggests that ocular discharge was principally due to direct (non systemic) ocular contact with the test substance at the time of dosing. However systemic exposure of the eye to the test substance/metabolites may have contributed to the ocular irritation seen at other times." <u>2) NOAEL in 1-year dog study</u> RMS agrees that the setting of a NOAEL for females of < 15 mg/kg bw/d is very conservative. Indeed PSD initially proposed a NOAEL of 15	the occurrence of ocular discharge and its toxicological relevance. See also 2(3)

Short-term toxicity (B.6.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			mg/kg bw/d because at this dose there was only a slight increase in the incidence of ocular discharge compared with the highest control incidence at the time of dosing and with no evidence for the effect lasting through to the next day. However a NOAEL of <15 mg/kg bw/d was finally proposed because of concern expressed by the UK ACP. As the conservative NOAEL of <15 mg/kg bw/d has no impact on the ADI (see pp 248) because there is an adequate margin of safety for this minor effect the RMS considers this point is addressed and does not merit discussion at an expert meeting.	
2(3)	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	RMS: see response at 2 (2).	See open point in comment 2(2)

Genotoxicity (B.6.4)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(4)	Vol. 3, Annex B.6. page	DuPont: We agree with the conclusion in the	RMS agrees that proquinazid is not a genotoxic	Addressed.

Genotoxicity (B.6.4)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	132 – 158, B.6.4; Genotoxicity Studies	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.	concern, but considers it necessary to report limitations in certain studies. *In vitro* chromosome aberration test and the CHO/HGPRT test with proquinazid: the limitations reported in the DAR agree with the views of the UK's Committee on Mutagenicity who also evaluated the genotoxicity data for proquinazid (see Appendix 6 to the DAR). In response to the advice of the Committee on Mutagenicity, the applicant was asked to conduct a mouse lymphoma assay because of the limitations in the submitted CHO/HPRT assay. The Committee on Mutagenicity assessed the report of the mouse lymphoma assay with proquinazid and concluded that the study was acceptable and gave negative results. Further investigation of the potential to cause chromosome damage *in vitro* was not considered necessary for the reasons stated at B.6.4.4. As a general point, the RMS considers it important to draw attention to the limitations in the conduct and/or reporting of critical studies. This is particularly important for genotoxicity studies when a substance presents a carcinogenic concern.	

Genotoxicity (B.6.4)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			RMS considers that the point raised by Du Pont is addressed.	

Long-term toxicity and carcinogenicity (B.6.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(5)	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.	RMS agrees The statement "more data have been requested" can be deleted because this information on historical control tumour incidence has been provided and is included in the DAR (see footnote to Table B.6.6.7). RMS considers that this point is addressed.	Addressed. RMS to consider in a revised DAR or corrigendum.

Reproductive toxicity (B.6.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(6)	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"	RMS agrees the statement needs to be re-written because the very few deaths in P1 and F1 rats (including one high dose F1 female) are considered to be not substance related. The statement should be rewritten as follows: "There were no substance-related deaths and no test substance-related clinical signs were observed" RMS considers that this point is addressed.	Addressed. RMS to consider in a revised DAR or corrigendum.

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

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(7)	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	RMS: In the DAR at First Aid Measures (B.6.9.5), before the applicant's advice, the RMS always inserts the following clarifying statement: " The medical basis of the following proposals	Addressed.

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		are not readily available. We do not agree with the language which discounts these first-response recommendations.	by the applicant has not been assessed in this evaluation. It is recommended that the information should not be used as a basis for treatment advice in the event of a poisoning incident. Specialist advice should be sought from an appropriate source such as a National or Regional Poisons Unit or similar organisation. " The RMS considers it necessary to provide this clarifying statement in the DAR because the toxicology assessors of the RMS are NOT medically qualified. The qualifying statement is intended to alert only readers of the DAR. It is not proposed that this clarifying statement is included in the label or safety data sheet for proquinazid.	

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(8)	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	RMS is acknowledges the concerns expressed by DE. PSD initially proposed an ARfD of 0.3 mg/kg bw derived in the same way as proposed by DE in a UK draft of the DAR. However the UK ACP was concerned about the evidence for ocular discharge at the time of feeding on the first day in one out of 4 female dogs at 500 ppm (=19 mg/kg bw/day at this time) in the 90-day study, see Table B.6.33a on	Open point: MSs to discuss the ARfD value.

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		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.	p 115 and text on p 116. The UK ACP considered there was a need to have a safety margin of 100 between this dose of 19 mg/kg bw and the ArfD; the ACP therefore asked PSD to lower the proposed ARfD to 0.2 mg/kg bw. The document was therefore amended to reflect this more conservative position.	

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

Dermal absorption (B.6.12)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(9)	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	RMS disagrees with the DE proposal (even though it is only very slightly higher than the RMS proposal). There are some uncertainties in the dermal absorption data provided (e.g. the dilution tested was not as dilute as the intended in-use dilutions). However, the approach followed by the RMS is considered to be sufficiently	Open point: MSs to discuss dermal absorption of proquinazid representative formulation.

Dermal absorption (B.6.12)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		15% (dilution) are suggested instead of 2 and 12%.	precautionary and in line with EU guidance (SANCO/222/2000 rev 7). RMS does not support the DE proposal because the data clearly show that for rat skin the absorbable dose of proquinazid was much greater when determined *in vitro* than when determined *in vivo*. Hence it would seem likely that the absorbable dose of proquinazid through human skin *in vitro* would over estimate absorption through human skin *in vivo*. Addressed.	

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

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(10)	Vol. 3, B.6.14, Exposure data	DE: Proposal: On the basis of the proposed dermal absorption rates [3% concentrate and 15% dilution; [see (2 (3) above)] a new risk assessment should be carried out by the RMS.	RMS: if it is decided that the dermal absorption values should be revised (from 2% for the concentrate and 12% for the dilution) to 3% and 15% for the concentrate and dilution respectively, then a new risk assessment would need to be carried out to reflect these changes. The small change in values would not result in a change to the conclusion reached in the risk assessment that potential exposure for the supported uses is below the AOEL in all scenarios using the German model.	Addressed.
2(11)	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.	RMS: Data from the EUROPOEM database was used to estimate/refine the exposure estimates for application of proquinazid to grapevines only for the UK POEM estimates. Justification for this approach is given in the DAR, Vol 3, Section B. 6. 14. 1. 2, Estimation of Operator Exposure – UK POEM. It should be note that potential exposure for the supported uses is below the AOEL in all scenarios using the German model. On this basis, for the assessment of proquinazid, the RMS does not consider that specific discussion of the EUROPOEM refinement used is required to reach a conclusion on the acceptability of exposure to proquinazid.	Open point: MSs to agree on the input parameters and models to calculate operator, worker and bystander exposure.

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

3. Residues

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

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(1)	Vol. 1, level 2, 2.4 (metabolism data)	NL: In the first paragraph „non-fruit' should be replaced by „cereal'	RMS: Agreed that the wording of the group as „cereals' is much better, however wheat is clearly stated along-side so there is no doubt as to the cereal group being covered, cereals is also expressed appropriately as the crop group in the end-points. Addressed.	Addressed.
3(2)	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.	RMS: Agree. This table is incorrect and refers purely to the unextractable residues. Table 7.7 provides full details of the distribution of ^{14}C residues in grape fruit at the various intervals and this table includes the correct values for the TRR results for the grape (fruit) which are 0.25 mg/kg, 0.24 mg/kg and 0.23 mg/kg after 0, 14 and 29 days after the last application respectively. Addressed.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(3)	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.	RMS: Agree. Please refer to explanation under No. 3 (2). Addressed.	See comment 3(2)
3(4)	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?	RMS: Agree. It appears that the unextractable residues associated with lignin was only postulated and not proven. The DAR explains (page 319) under „*Release of the lignin fraction*' the alkaline and acid methods that were used and indicates that the applicant proposed that the released material was lignin incorporated. Addressed.	Open point: In the grape metabolism study the lignin fraction was only postulated and this should be considered by a meeting of experts.

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(5)	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?	RMS: There was no explanation by the applicant on why fast-growing leafy crops were not tested in the rotational crop study. The rotational crop study was conducted at 3N rate (cereal) and1N rate (grape)and the application of phenyl-^{14}C(U)proquinazid was made to the bare soil. Samples of oil seed rape forage, soybean forage, sugar beet forage and wheat forage were analysed 30 days after planting indicating residue levels ranging from 0.019 mg/kg in oil seed rape forage to 0.056 mg/kg in wheat forage. Therefore, it is unlikely that residues of proquinazid in the soil would contribute significantly to the residue potential following crops. Addressed.	Addressed: At least oilseed rape crops would be a fast growing leafy crop in the early stages of development.
3(6)	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 …."	RMS: Agree.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.

Metabolism in livestock (B.7.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(7)	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.	RMS: In the goat metabolism study, the actual administered dose was 91.5 mg/kg (via oral capsule rather than in the diet itself) and the food consumption of the goats was 2.4 kg/day. The applicant did not report whether this amount of food consumed was on a dry matter or as received basis. Addressed.	Data requirement: In the goat metabolism study it should be clarified what the intake was on a feed dry matter basis. Once this is clarified the study should be reconsidered.
3(8)	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.	RMS: In the poultry metabolism study, the actual administered dose was 15.6 mg/kg (via oral capsule rather than in the diet itself) and the food consumption of the hens was 0.1297 kg/day. The applicant did not report whether this amount of food consumed was on a dry matter or as received basis. Addressed.	Data requirement: In the hen metabolism study it should be clarified what the intake was on a feed dry matter basis. Once this is clarified the study should be reconsidered.

Metabolism in livestock (B.7.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(9)	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?	RMS: Agree; in the metabolism study residues increased in eggs over the five days of the study (a plateau was not reached at this stage). No further consideration or investigation to support the bio-accumulation of proquinazid in fatty matrices in poultry. However, due to the highly exaggerated rate of the study (400N rate) it is considered unlikely that accumulation would lead to detectable residues in products of animal origin. In addition estimated poultry intakes (0.05 mg/kg diet (dry matter basis) and 0.04 mg/kg diet (as received basis) Table B.7.39 section B.7.16.1 are below the Directive 96/68/EC trigger for needing an animal metabolism study (>0.1 mg/kg diet as received) for poultry, so the poultry metabolism study is not strictly necessary.	Open point: It should be considered by a meeting of experts if there is a need for any further data on residues in poultry given that the compound is fat soluble and may accumulate.

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(10)	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.	RMS: the way the end-points has been drafted is in accordance with usual convention/guidance. Therefore the expression of this end-point does not need changing Addressed.	Addressed.
3(11)	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.	RMS: When residues are not expected to be found in animal products based on an animal metabolism study, we do not consider it is necessary to set a residue definition for animal products (even if the mg/kg diet intake trigger is exceeded). The metabolism study gives an indication of potential for residues based on experimental observation whereas the intake value highlights a theoretical estimate of exposure. However if a residue definition is to be proposed, please refer to the discussion in the response No. 3 (12) below. Addressed	Open point: It should be considered by a meeting of experts if it is necessary to set a residue definition for ruminants. If it is necessary then it should be considered if the available data are sufficient for risk assessment purposes. See also 3(12)
3(12)	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	RMS: No residue definition was applied in this assessment; it is regarded that no individual component residues (parent or metabolites) would be above 0.01 mg/kg following the expected use rate.	See open point in comment 3(11)

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		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.	We agree with the need to be cautious in extrapolating to much lower dose rates and linearity in response should not be assumed. Despite this, the results of exaggerated studies can still be used to help decide when feeding studies are not needed. In the goat metabolism study, the main component identified in all matrices was the metabolite IN-MU210 (also identified as a metabolite in the rat). This metabolite was not specifically considered in the toxicology section of the DAR but it was noted that like a number of other metabolites it lacked obvious structures of particular toxicological concern (Section B.6.10). Further commentary by RMS toxicologist: IN-MU210 was a minor metabolite in rat excreta (urine +faeces) being found at 4.5-5.1% of an oral dose of 1 mg proquinazid/kg bw/day. The presence of this metabolite in rat tissues was not investigated but would be expected based on the goat data. IN-MU210 is of similar structure to parent, with a methyl group on a side chain being replaced by COOH. The COOH group should make the molecule more polar than parent, favouring more ready excretion which under certain circumstances can reduce systemic toxicity. Overall it is concluded that IN-MU210 is likely to be of broadly similar toxicity to parent.	

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			IN-MU210 was found up to a maximum level of 0.84 mg/kg in kidney in the goat metabolism study. Parent proquinazid was found at a maximum level of 0.02 mg/kg in fat and milk (even in view of the high log Pow for proquinazid). It was not possible to deduce when a plateau was reached in this study, however, in view of the exaggerated rate that the goat metabolism study was conducted at (200N rate) it was considered not appropriate to set a data requirement for feeding studies or to propose a residue definition. If a residue definition were to be proposed, parent does not seem an appropriate candidate as it is extremely unlikely to be determinable in animal products even if proquinazid as a potentially fat-soluble residue were to be found at a higher level than seen in this study. Therefore a residue definition (for ruminants) of IN-MU210 would be preferable however for the reasons given above the RMS has not considered it necessary to propose a definition. Intakes are very low (below the 0.1 mg/kg diet trigger) for poultry and a residue definition is not considered relevant for poultry products. Addressed.	

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(13)	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.	RMS: Noted.	Open point: The GAP should be clarified. Given the comment from the applicant.
3(14)	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?	RMS: Agree. Validation data was available for grapes and was found to be acceptable. Grapes were extracted using accelerated solvent extraction using ethyl acetate. Interferences were removed using solid phase extraction. Samples were analysed using GC-MSD for the determination of proquinazid and the metabolite IN-MM671. The validation data can be summarised as follows: Linearity - 5 concentrations with correlation coefficients all acceptable. Precision - 3 concentrations with acceptable relative standard deviations. Accuracy – recoveries all within acceptable limits. Specificity – chromatograms submitted and acceptable.	Addressed.

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(15)	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.	RMS: Agree that the reasons for not selecting some of the trials is not apparent in the table. These additional residue trials for cereals were conducted using another EC formulation which contained 25 g/L of proquinazid. As the trials were conducted on the same day, on the same trial site as the proposed formulation it was concluded that these trials were almost identical to the trial conducted using the EC formulation containing 200 g/L proquinazid. Therefore, the residue trial which provided the highest residue results was underlined for inclusion in the calculation STMR and HR; the different trial results underlined are therefore independent from one another.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.

Processing (B.7.7)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(16)	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).	RMS: The approach of including grape pomace as a feeding stuff for animals is not normally taken due to grapes not being considered under fruit pomace (Lundehn guidance Appendix G states apples and citrus). For the past evaluation of metrafenone grapes was not included in the animal intake assessment also in accordance with the Lundehn guideline and we consider that the actual amount of grape consumed by animals would be low and on an infrequent basis. Addressed.	Addressed: Currently grape pomace is not considered an animal feed item.
3(17)	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.	RMS: Under section B.7.8.2, Tables 7.36 and 7.37 support the view that proquinazid is hydrolytically stable and although proquinazid is partitioned into the wet pomace (and then residues concentrate further upon drying into dry pomace), it is essentially not seemingly converting to other components during the production of juice and wine. In table B.7.36, the corresponding average processing factor (taking account of tests 3 and 4 as for the other fractions) for wet pomace would be x 3.5. Table B 7.37 presents a mass balance shows that accounting for proquinazid residues only, 91% and 117% overall balances were achieved in test 3 and 4 respectively, with wet pomace containing virtually all of the residue accounted for. Although the above was not emphasised in the summary of data on processing, the data in this section B.7.8.2 provides full details on the levels of residues in	Addressed: The residue is left in the pomace.

Processing (B.7.7)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			different fractions and provides a consistent profile with the data in section B.7.8.1 reporting that proquinazid is hydrolytically stable.	

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

Succeeding/Rotational crops (B.7.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(18)	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.	Yes the mg/kg residues reported in the rotational crop metabolism are mg/kg parent equivalent of TRR. Addressed.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(19)	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 toxicology] a new short intake calculation for the consumer risk assessment should be carried out by the RMS.	RMS: Noted. The short term intake calculation has been conducted on the proposed ARfD of 0.2 mg/kg bw/day and is acceptable. The basis for establishing the ARfD is given at 2(8).	Open point: If the tox reference values are changed a revised risk assessment will be required.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(28)	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.'	RMS: Agree.	Addressed. Rapporteur to consider in a revised DAR or corrigendum

4. Environmental fate and behaviour

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(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.	RMS: we agree this would be useful information in the LOEP and will be added.	Addressed.
4(2)	Vol 1. LoEP. Rate of degradation in soil. Laboratory studies. Vol 3B.8.5 Predicted environmental concentrations in GW, SW and sediment. Table B.8.85 p 485.	EFSA: to normalize 10 °C to 20 °C in order to have an additional degradation data is not acceptable. Moreover, when a degradation rate in the same soil measured at 20 °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	RMS: we are not necessarily convinced by this argument. Previously it has been considered acceptable for there to be an absence of data at 10˚C and RMS have been asked to enter a 10˚C DT50 in the LOEP on the basis of calculation from 20˚C data using a Q10 value. In the case of proquinazid, the two Nambsheim soils are distinctly different in their properties (please compare soil properties in Tables B.8.4 and B.8.15) and may be treated as two distinct soils. Therefore we consider it reasonable to normalise the 10˚C value to 20˚C. For the metabolites, we agree with hindsight that the procedure is not appropriate as the same soil was used in the same study. However, we would point out that the difference in the DT50 used in the modelling for IN-MM671 and that calculated by EFSA is relatively small in comparison with the magnitude of the DT50 used (58 days vs. 54 days). In addition, the 80th percentile concentrations calculated by the groundwater modelling are all<0.001 µg/l indicating that changing the DT50 values is unlikely to alter the regulatory decision. The	Open point: MS to discuss in a meeting of experts the selection of laboratory soil DT50 values of proquinazid and its metabolites to be considered in the risk assessment. See also open point in comment 4(26).

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			RMS proposes that it is unnecessary to recalculate PEC values.	
4(3)	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: At the time of evaluation, the FOCUS Degradation Kinetic guidance document was still in a draft form. During the evaluation, there was concern over the validity of combining non-first order and first order kinetics when calculating degradation parameters for parent and metabolites. This concern was particularly in relation to selection of input parameters for PEC calculation, which would need to be derived by first order kinetics for parent and metabolites.	Addressed.
4(4)	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: see comment for 4(3).	Addressed.

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(5)	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: No additional comment.	Addressed.
4(6)	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: Noted.	Addressed.

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(7)	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: see comment for 4(3).	Addressed.
4(8)	Vol 3. B.8.1.3 Soil rate of degradation. a) Spare 1999a. p 420 - 421	EFSA: it is not clear from the text whether the rate of degradation recalculated by the RMS made use of the FMOC model to fit the data of the parent and the metabolite.	RMS: to clarify, the calculations described here are those conducted by the Applicant. Calculations first used SFO-SFO for parent - metabolite, and then FOMC-SFO for parent – metabolite.	Addressed.

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(9)	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: see comment for 4(3).	Addressed.
4(10)	Vol 3. B.8.1.3 Soil rate of degradation. Table B.8.15	EFSA: foot note b should read 10 °C instead of 20°C.	RMS: EFSA comment is correct. There is a mistake in the original study report with respect to the foot note.	Addressed. RMS to consider in a revised DAR or corrigendum.
4(11)	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	RMS: footnote 1 should state, „Sequential 1st order used to calculate DT50'. Footnote 2 should state, „Not used in calculation of DT50'.	Addressed. RMS to consider in a revised DAR or corrigendum.

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(12)	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. (e.g. 0 DAT, 0.125 + 0.01 + 0.01 + 0.02 = 0.129 << 0.220.	RMS: we consider this can be explained by the fact that the results for metabolites are expressed as mg *equivalents* of proquinazid /kg rather than actual concentrations. As EFSA points out, there is a mismatch between results in Tables B.8.24 and 8.25. Taking mean day 0 results as an example, 14.5% AR was unextracted, 62.45% AR was a.s., 5.05% AR was IN-MM671, 10.1% AR was IN-MM986, <5.05% AR was IN-MM991, <5.05% AR was an unidentified substance M1 and 5.05% AR as „others' (radioactivity not represented as discrete peaks). Treating „<' values as 5.05% AR gives a total of 107.25% AR; note that day 0 radioactivity was taken to be 100%. It is likely that treating the „<' values as actual values accounts for the additional 7.25% AR.	Open point: RMS to provide in an addendum clarifications on the results on material balance and concentration of proquinazid and degradates (Tables B.824 and B.8.25) obtained in the field dissipation study by Dean and Fisher (1999).
4(13)	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 co-formulated with proquinazid in these studies.	RMS: we have no information on the identity of DPX-KZ165 other than it is another fungicide. The notifier will be asked to provide this information. Requirement notifier to provide information on the identity of DPX-KZ165.	Data requirement: Applicant to provide information on the identity of DPX-KZ165 co-formulated with proquinazid in the field dissipation studies (Zietz et al., 2003a; Zietz et al., 2003b) and soil residue studies.

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(14)	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: No additional comment.	Addressed.
4(15)	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: No additional comment.	Addressed.
4(16)	Vol 3. B.8.1.4.2 Soil residue studies a) Table B.8.46	EFSA: Table B.8.46 g / ha per season should read 450 instead of 45.	RMS: we agree with the comment.	Addressed. RMS to consider in a revised DAR or corrigendum.
4(17)	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.	RMS: we agree with the comment. Please note that the summary and assessment section (B.8.1.5) does not consider the soil residues studies any further.	Addressed.

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(18)	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: No additional comment.	Addressed.

Adsorption, desorption and mobility in soil (B.8.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(19)	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.	RMS: please refer to Tables B.8.51 and B.8 52. In aerobic lab soil, range of DT50 for IN-MM671 was 35 - 305 days. In the field, the range is 29 – 394. Methods of calculation were similar.	Addressed.

Adsorption, desorption and mobility in soil (B.8.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(20)	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.	RMS: comment relates to IN-MM991. This must be taken in the context of the overall low observed formation for this metabolite in the field. The maximum level reached in field studies was 7.4% (based on peak concentrations of parent and metabolite)and thus we conclude that under field conditions that there will be a relatively low occurrence.	Open point: MS to discuss in a meeting of experts the suitability of the use of soil DT50field of 54 days in PECsoil calculations for metabolite IN-MM991.

PEC in soil (B.8.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(21)	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 of % AR in radiolabel led studies). Maximum for IN-MM986 would be 32.8 %). These percentages should be used for PEC soil calculation.	RMS: The value of 7.4% for IN-MM991 is based on the peak concentration (mass) compared to that of the parent. For PECsoil calculation of a metabolite, if a % AR or molar % is used, a correction for molecular weight must be built into the calculation. Therefore there is no need to revise the PEC values.	Addressed.

PEC in soil (B.8.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(22)	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: No additional comment.	Addressed.

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(23)	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: No additional comment.	Addressed.

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(24)	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.	RMS: Noted. The LOEP has been revised to include IN-MM986.	Addressed. RMS to consider in a revised DAR or corrigendum for Vol. 3 B.8.5.(Table B.8.83. Metabolism).
4(25)	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: No additional comment.	Addressed.

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(26)	Vol 3. B.8.5 Predicted environmental 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.	RMS: an explanation for use of laboratory derived degradation DT50 values rather than use of field derived dissipation rates is made in section B.8.5.1.1 of Volume 3 of the DAR. Slow dissipation of metabolite IN-MM671 is probably linked to slow formation in the field. It was also considered that using metabolite degradation data from studies where the metabolites had been used as the starting material was a reasonable approach. This is because this approach removes some uncertainty generated due to the correlation which occurs between metabolite formation and degradation parameters calculated from studies on active substances.	Open point: MS to discuss in a meeting of experts the appropriate DT50 values of soil metabolites of proquinazid for FOCUS GW and SW modelling. See also comment 4(28).
4(27)	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.	RMS: this is a typographical error, the units should read mg/l.	Addressed. RMS to consider in a revised DAR or corrigendum.

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(28)	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.	RMS: selection of input parameters for modelling generally involves the use of a mean or median value from the database. There was no obvious dependence on any particular soil property for formation or degradation for any metabolites. Our *overall* view from the field studies was that formation and decline of metabolites tended to be extended and often variable, although there were some exceptions to this. As indicated previously in our response to comment 4(26), selection of DT50 calculated from these field studies would have involved more uncertainty due to the fact that formation and degradation parameters derived from kinetic modelling of parent together with metabolites are often strongly correlated. Therefore we considered it reasonable to use data from the laboratory degradation studies for the metabolites which used as starting materials.	See open point in comment 4(26).
4(29)	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.	RMS: this part of the evaluation did not intend to imply that IN-MT884 was formed in soil. Apologies if this was not clear.	Addressed. RMS to consider in a revised DAR or corrigendum.

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(30)	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.	RMS: we had a concern over use of the 497 day value due to the decline phase being unclear. Hence the use of a 300 day default. We have checked the impact of using DT50s of both 497 d and 1000 d on the Steps 1 and 2 PEC values. There is no change to the initial PEC values, but a change to PEC values over time (actuals and TWAs). Therefore, in the context of the risk assessment, there is no actual impact of using a longer whole system DT50.	Open point: RMS to provide in an addendum the explanation on the selection of the DT50whole system for metabolite IN-MM671 used in FOCUS SW calculation. See also comment 4(32).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(31)	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.	RMS: we have checked as suggested and the correct value of 0.93 mg a.s./L was used in the modelling. There is a typographical error in the DAR in respect to the units used for this value.	Addressed. RMS to consider in a revised DAR or corrigendum.

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(32)	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.	RMS: please see response to comment 4(30). Please also note that this evaluation was conducted at a time when, to the best of our knowledge, the sections on water/sediment studies and parameter selection were either not written or at a very early draft stage.	See open point in comment 4(30).

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

Definition of the residues (B.8.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(33)	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.	RMS: at the time of writing the DAR, the current approach of listing the residue definition for risk assessment had not been adopted. However, in this section we tried to reflect that, according to the risk assessments conducted in the DAR, the metabolites did not need to be included in the residue definition for monitoring, but they had been included in risk assessment. WE have updated the LOEP in line with the current approach for residue definition for risk assessment.	Addressed. EFSA note: the finalisation of the definition of the residue for monitoring is pending on the final assessment on the ecotox/tox relevance of the compounds.
4(34)	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.	RMS: agree that the units are incorrect and should be µg/l.	Addressed. RMS to consider in a revised DAR or corrigendum.
4(35)	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 field studies.	RMS: we agree that terrestrial and groundwater assessments were made for these three metabolites. We have amended the LOEP with the format of residue definition for risk assessment now being used.	Addressed.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(36)	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.	RMS: we will check and amend the references as necessary.	Open point: RMS to amend the list or references of studies including the studies Huber, A. 2003.

5. Ecotoxicology

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(1)	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.	RMS: Agree. The text should state „The data provided indicates proquinazid is of low to moderate toxicity to birds'. However, based on the reasoned case included in the metabolite risk assessment (Volume 3, Section B.9.1.4.3), the risk posed from metabolite exposure is covered by that considered for proquinazid.	Addressed.
5(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.	RMS: There is insufficient evidence to determine the reasons for the higher intake levels at the highest or two highest test doses in the mallard duck and bobwhite quail reproductive toxicity studies. However, the calculation of the daily dose takes into account actual intake levels and the concluded NOELs are not affected.	Addressed.
5(3)	Vol. 3, B.9.1.4, Avian risk assessment	EFSA: There is an inconsistency between the NOEL given for mallards in Table b.9.10 (and in the list of endpoints) and the study summary on page558. Please clarify although this	RMS: Agree. In line with the study summary, the NOEL for the mallard duck reproductive toxicity study should be reported as 29.6 mg/kg bw/day (females) and 31.5 mg /kg bw /day (males). The mallard duck reproductive toxicity NOEC quoted in the Endpoint table	Addressed.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		value was not used for the RA.	has been amended to „NOEC 255 ppm a.s. in diet (equivalent to 29.6 mg/kg bw/day for females and 31.5 mg /kg bw /day for males)'.	
5(4)	Vol. 3, B.9.1.4, Avian risk assessment Vol. 3 B.9.3.2.3 Risk assessment to mammals.	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.	RMS: We agree that given the 14 day application interval it would be logical to use a 14 day twa when estimating foliar residues. However, the current SANCO guidance (Section 3.5 of SANCO/4145/2000) states that, although residues may be under-estimated when the interval is shorter than the time window, „with a time window of 3 weeks and a DT50 of 10 days [as assumed in the first tier risk assessment] the inaccuracy is small and the [twa] factor of 0.53 can be used uncorrected'.	Open Point The use of a time window of 14 days instead 21 days in the estimation of the factor time weighted average (f_{twa}) used to estimated the TERlt for birds and mammals should be discussed in a PRAPeR experts meeting.
5(5)	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?	RMS: In Sections B.9.1.4.1-2 & B.9.3.2.3, the cereal use MAFs of 1.25 (acute) and 1.38 (short/long term) and the vineyard use MAFs of 1.36 (acute) and 1.58 (long-term) have been calculated based on the formula given in SANCO/4145/2000 guidance. These values have been calculated to two decimal points - whereas MAF values included in tables in the SANCO guidance are to one decimal point – this accounting for the slight difference in values. In Section B.9.3.2.3 (Mammals), the acute MAF of 1.38 used in the vine metabolite (IN-MM671) and formulation acute risk assessment is in error and should read (as above) „1.36', with corrected ETEs 12.05 mg metabolite or product /litre and corrected mammalian acute TERs of 170 (IN-MM671) and 16.6 („Proquinazid 200g /l EC'). The	Addressed.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			endpoints table has been amended to reflect this.	
5(6)	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?	RMS: We do not have any readily available information on the stonechat diet. If the indicator species used in the risk assessment are not considered to be representative for certain Member States, then this issue should be considered at product re-registration as a Member State issue.	Open point MS to discuss in a PRAPeR expert meeting the relevant species proposed by the applicant to refined the long-term risk identified for the insectivorous birds in vines.
5(7)	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	RMS: To clarify: No avian toxicity data are available for IN-MM671. However, mammalian acute toxicity data indicate this metabolite to be of similar toxicity to proquinazid and data on the acute toxicity of proquinazid to birds and mammals indicates a similar level of toxicity to each group. On this basis, it is considered likely that IN-MM671 will be of no greater toxicity to birds than the parent proquinazid. Residues in vegetation of IN-MM671 will be significantly lower than proquinazid and fish bioconcentration data indicate a lower potential for bioconcentration. Therefore the risk to birds from exposure to this metabolite will be covered by that for the active substance.	Addressed.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		the assessment for the metabolite is similar reproductive toxicity is assumed.		
5(8)	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.	RMS: We agree that additional refinements could have been made but are not needed for the specified application scenario, given the acceptable refined TERs calculated in Table B.9.15 of Vol. 3, B.9.1.4.4. The inclusion of further refinements could be made at Member State level when considering product re-registration.	Addressed.
5(9)	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.	RMS: Agree. The list of endpoints has been amended to include TERs in relation to the risk to vertebrates (birds and mammals) from secondary poisoning.	Addressed.
5(10)	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	RMS: Agree that a more detailed justification would have been useful. The reproductive and development toxicity studies are summarised in Section B.6.6.4 of Volume 3. Studies were submitted for two batches: DPX-KQ926-85 produced by the more recent manufacturing process and DPX-KQ926-45 produced by the old manufacturing process. Section B.6.6.4	Addressed.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		for the selected endpoint should be provided.	states that DPX-KQ926-85 is less toxic than DPX-KQ926-45 and concludes that, although adverse effects were reported in rat and rabbit developmental effects studies with DPX-KQ926-45, the „weight of evidence indicates that it [i.e. proquinazid from the more recent production process] would not have specific effects on development'. The appropriate endpoint is therefore the NOAEL of 35 mg a.s./kg b.w./d from the rat multigeneration study conducted with DPX-KQ926-85 (Mylchreest, 2003).	
5(11)	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.	RMS: We agree that the RUDs in Table B.9.56 are incorrect and should be as stated by EFSA. However, we believe that the MAF of 1.36 used in relation to foliar residues from multiple applications of proquinazid on vines is correct. A foliar residue MAF was not included in the vine avian risk assessment since this relates only to insectivorous species. Corrected mammalian acute TER values are: SHM in cereals 392.8, IM in cereals 8791, SHM in vine 402. Also as mentioned under point 5.5, in Section B.9.3.2.3 (Mammals), the acute MAF of 1.38 used in the vine metabolite (IN-MM671) and formulation acute risk assessments is in error and should read (as above) „1.36'. The list of endpoints has been amended to include the corrected TERs.	See open point 5(4) Open point RMS to correct the acute TERs in the list of endpoints and include the following TER values: SHM in cereals 391.8, IM in cereals 10989, SHM in vine 396 values in to include in an Addendum.
5(12)	Vol. 3, B.9.3.2.3, Risk	EFSA: There seem to be some typing	RMS: Agree RUDs in Table B.9.57 are	Open point

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	to mammals	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.	incorrect and need to be amended. As stated by EFSA, the RUD should be 76 for SHM in cereals and 5.1 for IM in cereals. The specified long-term RUD for SHM in vines is also in error and should be amended to 46. We believe that the long-term 21 day Ftwa used in the 1st tier risk assessment is inline with SANCO guidance (see point 5(4) above) and is therefore appropriate. Corrected mammalian long-term TER values are: SHM in cereals 9.06, IM in cereals 218, SHM in vine 8.72. The list of endpoints has been amended to include the corrected TERs.	The TERlt for small herbivorous mammals should be update, pending of the outcome of the discussion in the open point 5(4). EFSA noted that if f_{twa} = 0.64 will be used, then long-term TERs values were 10.35 for small herbivorous mammals (SHM) 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. The TERlt for insectivorous birds should be 217.8 in cereals. RMS to include the agreed long-term TERs values in an Addendum and to amend the LoEP.
5(13)	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	RMS: Agree. See also points 5 (11) and 5 (12) above.	See open points 5 (11) and 5 (12) above.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		values.		
5(14)	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.	RMS: We agree that the rat acute oral LD50 should read > 2000 mg product /kg bw and not > 2000 mg a.s. /kg bw. „Proquinazid 200g/l EC' contains 10% w/v a.s. and therefore in terms of a.s., the LD50 is >200 mg a.s. /l. Corrected formulation acute TERs for small herbivorous mammals are 16.2 in cereals and 16.6 in vines (the latter including use of a corrected MAF of 1.36). For insectivorous mammals in cereals, the acute TER is 454. The list of endpoints has been corrected.	Addressed.
5(15)	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.	RMS Significant accumulation of contaminated water in leaf axils is not considered likely in treated cereals or vines and therefore the main source of proquinazid uptake via drinking water will be from contaminated surface waters. Maximum FOCUS Step 3 surface water PECs are reported as 0.316 µg a.s./l (cereal use) and 1.311 µg a.s./l (vine use). These a.s. contamination levels in drinking water are much lower than that likely in foliage and insects from cereal use - estimated for acute exposure (individual dose x RUD x [for foliage only] MAF) to be 8.9 mg a.s./kg (foliage) and 2.6 mg a.s./kg (insects), - with higher residues likely from the higher applied dose in vines. Given the much higher residues in foliage and insects than in surface water, the dietary route of exposure is considered to be the main source of exposure. The assessment	Addressed.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			of the risk from the dietary route of exposure will therefore cover that from intake of contaminated drinking water.	

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(16)	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).	RMS: Given that proquinazid's metabolites are of lower toxicity to aquatic life than proquinazid and will be present at lower maximum concentrations, the statement is appropriate in this case. No changes to the risk assessment are required.	Addressed.
5(17)	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.	RMS: The algal studies / endpoints used in the risk assessment appear valid and appropriate.	Open point RMS to include the summaries of the alga studies with the proquinazid in an Addendum.

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(18)	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).	RMS: We agree that the text is incorrect in relation to the most sensitive test species – this being the green algae *Pseudokirchneriella subcapitata* with a formulation acute toxicity 72h EbC50 of 1.3 mg product /l. However, the formulation acute aquatic toxicity classification of „R51' (Very toxic) and the risk assessment is not affected by this.	Open point Even taking into account that the classification should not change of R51, RMS should correct the text to clarify that most sensitive specie was being the green algae *Pseudokirchneriella subcapitata* with a formulation acute toxicity 72h EbC50 of 1.3 mg product /l instead the *Daphnia magna*.
5(19)	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.	RMS: Agree; we apologise for these cross referencing errors.	Open point RMS should correct the wrong references in an Addendum/Corrigendum.
5(20)	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?	RMS: The field studies referred to relate to field soil dissipation and residue studies reported in Section B.8.1.4.	Open point RMS should include the reference in an Addendum/Corrigendum.
5(21)	Vol.1, List of endpoints, TERs for aquatic organisms	EFSA: For FOCUS Step 4 (proquinazid) the distance for cereals should be 3 m.	RMS: Agree – the Step 4 cereal buffer zone distance should be stated as 3 metres. For Steps 1-3 there are no buffer zones included and therefore the buffer zone column should either be absent or state „Not applicable' (N/A). The list of endpoints has been corrected.	Addressed.

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(22)	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.	RMS: Agree; see point 5(21) above.	Addressed.
5(23)	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.	RMS: Proposal appears useful for the most sensitive aquatic organism, with use of maximum Step 3 and 4 PECs values also included for test organisms failing at lower Steps (as at present). The endpoints list has been amended to clarify the current use of maximum Step 3 and 4 values.	Open Point MS to discuss the proposal from the EFSA 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.

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(24)	Vol. 3, Annex B.9, Page B.9.4.1.1, Table B.9.62 Effects on bees	DuPont: The authors name is miss-spelt. It should be Engelhard not Englehard	RMS: Noted, with apologies for the typographical error.	Open point RMS should correct the wrong authors name f th e reference included in Table B.9.62 in an Addendum/Corrigendum.

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(25)	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.	RMS: We agree that ideally control corrected mortality levels should have been calculated and presented. However, given the low levels of mortality reported, these are not essential for the risk assessment. To provide a comparison with the control, control mortality levels have now been included (in brackets) under „% Effect' in the list of endpoints. Reproductive effects are presented in terms of the % of control levels, so the % reduction can be readily deduced. The column headed „Annex VI trigger' should read „ESCORT 2 trigger' (or similar) - the table has therefore also been amended to include this.	Addressed.
5(26)	Vol. 3, B.9.5.1.2, table B9.67	NL: Please add corrected mortality and decrease in reproduction	RMS: It is not usually possible to make changes to Volume 3 at this stage. The list of endpoints has however been amended to provide a comparison between treated and untreated results – see 5(25) above.	Addressed.
5(27)	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.	RMS: Please see response to points 5(25) and 5(26) above.	Addressed.

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(28)	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).	RMS: Agree – corrected in list of endpoints. Thank you.	Addressed.
5(29)	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?	RMS No significant effects from proquinazid treatment occurred in the German field study on predatory spider mite numbers (mites or eggs) and there were no statistically significant effects from proquinazid on either predatory mite or pest mite numbers in the other two similar field studies. Much higher and significant increases in pest mite populations occurred following use of the toxic reference. The overall field evidence therefore indicates that proquinazid treatment is not likely to result in significant adverse effects on predatory mites.	Open point The relevance of the significant increase in pest mites in the formulated in the German field study should be discussed by the MS.
5(30)	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…'	RMS. Point noted.	Addressed.

Earthworms and other soil non-target organisms (macro and micro) (B. 9.6, B.9.7 and B.9.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(31)	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.	RMS: The standard deviation range for body weight increases in the control and highest test concentration group overlap, therefore the numerical differences may not be significant. Also, numerically differences are small – body weight increases in adults on day 28 being 22.9% in the control and 15.7% in the highest treatment group (100 mg IN-MM671 /kg soil).	Open point The chronic endpoint for earthworms exposed to the metabolite IN-MM671 should be discussed in a PRAPeR meeting.
5(32)	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.	RMS: The Annex VI requirement is for nitrogen mineralization processes in laboratory studies not to be adversely affected by greater than 25% after 100 days. The study results indicate that after 28 days the maximum reduction in ammonium and nitrate formation was 4.3% and 11% respectively. Therefore with respect to the risk assessment this is acceptable.	Addressed.
5(33)	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 ?	RMS: The Annex VI requirement in relation to effects on soil micro-organism is that nitrogen and carbon mineralization processes in laboratory studies should not be adversely affected by greater than 25% after 100 days. The submitted studies indicated that after 28 days there were only small numerical differences between treated and control groups, with all differences being less than 25%.	Addressed.

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(34)	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).	RMS: We agree that the lack of GLP compliance is not ideal. However, this glasshouse study is considered scientifically valid and included treatment of six test species at the highest application rate of 75g a.s./ha – the results for which are presented in Table B.9.97 of Volume 3. The common cowpea was not tested in this study but in a separate field test – along with several other crop species – details for which are included in Table B.9.98.	Open point MS to discuss in a PRAPeR expert meeting the validity and representativness of the post-emergence tier 1 test for non-target plants.
5(35)	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).	RMS: We consider that this is a valid point and suggest further consideration is given in the written process to the need for further evidence to support the lack of pre-emergence effects (soon after application).	Open point MS to discuss in an expert meeting the need of further information (studies) to assess the effects of proquinazid to non-target plants.
5(36)	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.	RMS: We agree that data is required to support the lack of adverse effects to non-target plants. However adequate „tier 2' studies can replace the need for „tier 1' screening data.	See open point 5(35).

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(37)	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.	RMS: The list of endpoints has been amended to include TER values for earthworm- and fish-eating birds and mammals (as per point 5(9) above).	Addressed.
5(38)	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.	RMS: The presently used template has been used, with amendments to it where necessary.	Addressed.