PEER REVIEW REPORT ON **FLUOXASTROBIN** 15.08.2005

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

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	Section 1 Data requirements: 1 Open points: 9			Section 1 Data requirements: 0 Open points: 0
	Open point 1.1: The list of endpoints should be updated (minimum purity 940 g/kg instead of 910 g/kg). RMS to distribute (to EFSA and MSs) addendum 2 containing the new specification for discussion in the expert meeting. (B1 (Vol 1. Level 4.2.1) - see reporting table 1(4))		The list of end points has been amended. The minimum purity is now stated to be 940 g/kg. More member states have now acknowledge receiving Addendum 2 of the DAR for fluoxastrobin. A copy has been sent to EFSA by email.	EPCO 11 (07. – 09.09.2004): Open point fulfilled
	Open point 1.2: For transparency and better comprehensibility the representative uses evaluated which are not supported by available data should be highlighted as mentioned in the EPCO manual E4. (Vol 1. General. - see reporting table 1(6))		The list of representative uses presented in the list of end points and the list of uses appended to the Evaluation Table has been amended as required.	EPCO 11 (07. – 09.09.2004): Open point fulfilled

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1.1	Data concerning the effectivity of commercially available anti-foaming agent. (B2.2.17 (IIIA 2.8) (Vol 1. Level 4.2.2) - see reporting table 1(18))	Performed study attached HEC100_foaming_MO-04-007367	The evaluation of this study is presented in addendum 3 to the DAR A commercial antifoaming agent that contains dimethylpolysiloxane was demonstrated to reduce foam formation significantly. In addition, foam was reduced to zero ml within one minute. The RMS concludes that no further data are required.	EPCO 11 (07. – 09.09.2004): Data requirement fulfilled
	Open point 1.6: RMS to clarify whether a representative soil of crop growing was used for the validation or not. (Vol.3, B5.2/3/4, Table B.5.2 see reporting table 1(23))	The enforcement method was validated using the same soils as for the primary method. The soils originated from Höfchen (Burscheid, Germany) and , Elm Farm Development Station (EFDS, Great Britain; a control soil from the HEC5725 field dissipation study R812404). Two different soils were used in order to assess a possible influence of different soil types. The soil samples were classified according to DIN and USDA specifications. Soil textural classifications are summarized in Table 1. Complete classification data are reported in Schramel, 2001d (Appendix Table 11 and 12). Table 1: Soil Types Soil / type of soil / org. matter (%) Höfchen / heavy loamy silt (DIN) / silt loam (USDA) / 1.57 EFDS / sandy clay loam (DIN) / 2.30	RMS notes that the notifier has helpfully re-presented information that was contained in the original dossier but not presented in Table B.5.2 of the DAR. The notifier has confirmed that both soils used in method validation were obtained from typical crop growing areas and has provided adequate information to specify the soils. The RMS concludes that this point has been addressed.	EPCO 11 (07. – 09.09.2004): If an addendum is to be produced for another reason then this information should be included. Open point fulfilled

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	continued Open point 1.6: RMS to clarify whether a representative soil of crop growing was used for the validation or not. (Vol.3, B5.2/3/4, Table B.5.2 see reporting table 1(23))	(R812404) sandy clay loam (USDA) Both soil types are from typical crop growing areas.		
	Open point 1.7: The need of a confirmatory method to be discussed in an expert meeting. (Vol. 4, C1.4.3 impurities - see reporting table 1(27))		RMS notes that the identity of impurities was confirmed by comparison of retention times with those of certified standards. At the Evaluation Meeting on 25 May 2004, this generic point was considered to have been addressed for fluoxastrobin.	EPCO 11 (07. – 09.09.2004): Open point fulfilled.
	Open point 1.4: RMS to amend plant and animal residue definition in list of endpoints. (Updated list of endpoints, p. 9 - see reporting table 1(28))		In the list of end points: The definition of the residue in plants as been amended to “fluoxastrobin and z-fluoxastrobin”. The definition of the residue in animal tissue has been amended to “Sum of fluoxastrobin, z-fluoxastrobin and the phenoxy-pyrimidine metabolite (M55) expressed as fluoxastrobin”.	EPCO 11 (07. – 09.09.2004): Open point is fulfilled.

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	Open point 1.5: RMS to amend residue definition relevant to the environment in list of endpoints (Updated list of endpoints, p. 18 - see reporting table 1(29))		In the list of end points: The definition of the residue in soil, surface water, sediment and ground water has ben amended to "Fluoxastrobin (i.e E-isomer only)".	EPCO 11 (07. – 09.09.2004): Open point is fulfilled.
	New Open Point 1.8: The IUPAC name in the end points should be amended This open point was proposed at EPCO 11.		17.06.2005. The list of end points has been amended.	EPCO 11 (07. – 09.09.2004): Open point still open. Evaluation Meeting (19 – 20 07.2005): Open point fulfilled.

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	New Open Point 1.9: The end points for the methods of analysis must be amended so that the individual LOQs for each matrix are supplied. Additionally it must be made clear in the text that it is fluoxastrobin and its Z-isomer and not fluoxastrobin E and Z. This open point was proposed at EPCO 11.		17.06.2005. The list of end points has been amended.	EPCO 11 (07. – 09.09.2004): Open point still open. Evaluation Meeting (19 – 20 07.2005): Open point fulfilled.

2. Mammalian toxicology

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	Section 2 Data requirements: 1 Open points: 7			Section 2 Data requirements: 0 Open points: 2
	Open point 2.1: Toxicological effects of impurities to be discussed in expert meeting. (Volume 1, level 2, 2.3.1. page 18 - see reporting table 2(4))		The RMS view remains as follows. RMS considers that the applicant has provided data which adequately addresses the data requirements relating to the potential genotoxicity and skin sensitisation of impurities (see Fluoxastrobin DAR Addendum 1). The additional studies, together with other information, indicate that impurities (at the maximum levels proposed in the new technical specification) present no concerns for genotoxicity or skin sensitisation. The list of endpoints has been amended.	EPCO 14 (11.-14.10.2004): Open point fulfilled.
	Open point 2.2: RMS to comment on possible influences of fluoxastrobin on the female endocrine system (including mechanistic information) to be discussed in an expert meeting.	**Further comments from applicant in attached document:** **open point 2.2_endocrine expert meeting 2004_08.pdf**	The applicant has provided further information (particularly for controls in the concurrent study mentioned in the DAR) to support the view of the RMS that the increased incidence of uterine lesions at the top dose (adenocarcinoma and focal glandular	EPCO 14 (11.-14.10.2004): The meeting agreed that the historical control data and particularly data from a study run concurrently suggested the finding of uterine adenocarcinoma was incidental and that the concurrent control was low.

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	(Volume1, Appendix 1.2 Listing of end points, long term toxicity and carcinogenicity and Vol. 3, B.6.5.1 - see reporting table 2(12))		hyperplasia) are not substance related and hence are not of concern for hazard or risk assessment of fluoxastrobin. Notably: 1) Biological behaviour (eg time of detection, metastasis, etc) of these tumours was similar between high dose and study controls, and also compared with controls in a concurrent study. 2) The incidence of focal and diffuse glandular hyperplasia at the top dose was less than the incidence of glandular cystic hyperplasia in controls in a concurrent study (the applicant indicates that, although the terminology differs slightly, the lesions are comparable). 3) As reported in the DAR, incidences of adenocarcinoma at the top dose was less than in controls in the concurrent study 4) There were no significant effects on reproductive outcome in the multigeneration study with fluoxastrobin (this is consistent with fluoxastrobin not having endocrine effects). For completeness, the RMS notes that in addition to glandular hyperplasia,	Open point fulfilled. Evaluation Meeting (19 – 20 07.2005): The open point remains open. RMS to perform a combined consumer risk assessment wit the new ADI. This will be made available by the end of July 2005. Open point still open

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	Open point 2.2 (continued): RMS to comment on possible influences of fluoxastrobin on the female endocrine system (including mechanistic information) to be discussed in an expert meeting. (Volume1, Appendix 1.2 Listing of end points, long term toxicity and carcinogenicity and Vol. 3, B.6.5.1 - see reporting table 2(12))		other uterine hyperplastic lesions were seen at the following incidences with increasing dose in the main part of the study with fluoxastrobin: Endometrial hyperplasia 0,0,0,0,1* (*this was a severe lesion) Metaplasia/hyperplasia 1,0,2,5,1 The RMS considers that these other hyperplastic lesions do not provide good evidence for a substance related effect.	
2.1	Notifier to submit histopathologyical data of the thymus from multigeneration study. (Vol. 3, B.6.6.1 - see reporting table 2(14))	Study have been submitted via post to PSD (06/2004).	Amended study report was received by the RMS on 9 July 2004. (See Open Point 2.3) 17 June 2005. The evaluation of the hystopathological data was presented in addendum 4 to the DAR for fluoxastrobin. RMS considers this point to be addressed.	EPCO 14 (11.-14.10.2004): Meeting agreed reduced thymus weight in pups at 1000 ppm was non-adverse and that the developmental NOAEL should be 1000 ppm. Data requirement fulfilled. New open point 2.6: RMS to revise DAR / prepare addendum.

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	Open point 2.3: RMS to provide information on histopathologyical data of the thymus from multigeneration study in an addendum to the draft assessment report. (Vol. 3, B.6.6.1 - see reporting table 2(14))		The submitted histopathological data for the thymus of pups from the rat multigeneration study have now been evaluated by the RMS (see Fluoxastrobin DAR Addendum 4). The additional histological investigation has provided sufficient evidence to support raising the NOAEL for developmental effects in the rat multigeneration study to 1000 ppm, which is line with the applicant's proposal. Raising this NOAEL for developmental effects has no impact on the ADI, AOEL or ARfD which are all set based on adverse effects in dogs. 17 June 2005. The evaluation of the hystopathological data was presented in addendum 4 to the DAR for fluoxastrobin. RMS considers this point to be addressed.	EPCO 14 (11-14 October 2004): RMS to revise DAR / prepare addendum. See also data requirement 2.1. Open point still open. Evaluation Meeting (19 – 20 07.2005): Information has been presented in an addendum. The information will be presented in the EFSA conclusion. Open point fulfilled.
	Open point 2.4: The NOAEL (rats) to be discussed in an expert meeting. (Vol.3, B.6.6.2 – see reporting table 2(15))	Considering the comments of column C of the reporting table, no further comments from applicant.	The RMS view remains as follows.	EPCO 14 (11-14 October 2004): Meeting agreed that the NOAEL should be 1000 mg/kg bw/d for fetotoxicity. Open point fulfilled.

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	continued: Open point 2.4: The NOAEL (rats) to be discussed in an expert meeting. (Vol.3, B.6.6.2 – see reporting table 2(15))		300 and 1000 mg/kg bw/day. The RMS was especially concerned because the response appeared to be consistent with the known effect of fluoxastrobin/HEC 5725 on calcium and phosphorus homeostasis. However, as indicated in the DAR, further commentary from the applicant was considered to be sufficient for the RMS to conclude that there was **no substance-related adverse effect** on the fetal skeleton in this study.	

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	Open point 2.5: The AOEL to be discussed in an expert meeting. (Volume 1, point 2.3.4 AOEL - see reporting table 2(17)) Open point 2.5 (continued): The AOEL to be discussed in an expert meeting. (Volume 1, point 2.3.4 AOEL - see reporting table 2(17))	Considering the comments of column C of the reporting table, no further comments from applicant.	The RMS view remains as follows. The RMS agrees that NOAEL in the 1-year dog study (Jones and Hastings 2002) was 1.5 mg/kg bw/day. The RMS considers that this NOAEL is based on reduced body weight (bw) gain and increased serum alkaline phosphatase. **However for setting a short-term AOEL, the NOAEL after exposure for 90 days is the relevant value.** The RMS agrees that based on the proposed NOAELs for the two 90-day dog studies (Table B.6.21) the overall 90-day NOAEL appears to be 1.4-1.5 mg/kg bw/day (highest dose in second study) based on reduced bw gain of males at 3 mg/kg bw/day (lowest dose in first study). However bw gain data after exposure for 90 days in the 2 90-day dog studies **and** after 90 days in the 1-year dog study (see Table B.6.20) show **notable variation** at the lowest dose levels (0.7-8 mg/kg bw/day). Only at 24-25 mg/kg bw/day and above was there a clear and consistent reduction in bw gain. Hence, in the summary of short-term dog studies (page 129), **8 mg/kg bw/day is proposed as the overall NOAEL for effects on bw in dogs after 90 days.**	EPCO 14 (11-14 October 2004): The Meeting decided that the AOEL should be based on the 90 day time point NOAEL of 3 mg/kg bw/day from the 90 day and 1 year dog studies. An AOEL of 0.03 mg/kg bw/day was agreed. RMS to clarify in the addendum. Open point still open. Evaluation Meeting (19 – 20 07.2005): The addendum has been prepared. The information will be presented in the EFSA conclusion. Open point fulfilled.

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	Open point 2.5 (continued): The AOEL to be discussed in an expert meeting. (Volume 1, point 2.3.4 AOEL - see reporting table 2(17))		A lower 90-day NOAEL in dogs, is however indicated based on increased serum alkaline phosphatase in both sexes at 8 mg/kg bw/day after 87 days in the 1-year study and a NOAEL for this effect (3 mg/kg bw/day) in the first 90-day dog study. **Hence the 90-day NOAEL in dogs of 3 mg/kg bw/day should be used for setting a short-term systemic AOEL of 0.03 mg/kg bw/day** 17 June 2005. The proposal for the AOEL was based on the dog studies. The main effects in dog studies were decreased body weight gain and increased serum alkaline phosphatase, but the body weight response was not always consistent between studies. A table describing the body weight effects at different doses at 90 days in the 3 dog studies was in the DAR (Table B.6.20). Because of the variation in body weight gains in two 90 day studies and the 90 day time point in the 1 year dog study, overall the RMS considered the NOAEL to be 8 mg/kg bw/day for bw gain across these three studies at 90 days. However as there was an increase in alkaline phosphatase at 8 mg/kg	

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	continued Open point 2.5 (continued): The AOEL to be discussed in an expert meeting. (Volume 1, point 2.3.4 AOEL - see reporting table 2(17))		bw/day at 90 days in the one year study, the overall NOAEL at 90 days in these 3 studies was considered by the RMS to be 3 mg/kg bw/day. EPCO 14 discussed the range of findings in the dog studies before agreeing the RMS proposal. The above information has been reproduced in Addendum 5 to the DAR.	
	New open point 2.6: RMS to revise DAR / prepare addendum. (See data requirement 2.1) This open point was proposed at EPCO 14.		17 June 2005. The evaluation of the hystopathological data (Data requirement 2.1)was presented in addendum 4 to the DAR for fluoxastrobin. RMS considers this point to be addressed.	EPCO 14 (11-14 October 2004): Open point still open. Evaluation Meeting (19 – 20 07.2005): Open point fulfilled. (see above)
	New open point 2.7 RMS to prepare list of essential studies, NL to check. This open point was proposed at EPCO 14.		17 June 2005. RMS regrets that up until now, it has not had the opportunity to complete the list of essential studies. However, this should not delay the conclusion of the risk assessment for fluoxastrobin.	EPCO 14 (11-14 October 2004): Open point still open. Evaluation Meeting (19 – 20 07.2005): The list will be submitted as soon as possible. Open point still open

3. Residues

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Section 3 Data requirements: 0 Open points: 3			Section 3 Data requirements: 0 Open points: 0
	Open point 3.1: For transparency and better comprehensibility the representative uses evaluated which are not supported by available data should be highlighted as mentioned in the EPCO manual E4. (Vol 1, 1.5.3 and Vol 3, B.3.2.3 and B.3.2.4, intended uses - see reporting table 3(2))		The list of representative uses presented in the list of end points and the list of uses appended to the Evaluation Table has been amended as required. 17.06.2005 The foot note to the summary of representative uses has been amended as requested.	EPCO 15 (13.-14.10.2004): RMS is asked to amend the footnote of the summary of representative uses in the list of endpoints to make it clear that insufficient information was available for that particular formulation. Open point still open. Evaluation Meeting (19 – 20 07.2005): The amendment has been done. Open point fulfilled.
	Open point 3.2: RMS to provide MRL calculations according to guidance document 7039/VI/95, i.e. using EC Method I and II (Vol 3, B.7.13, Justification of MRL's - see reporting table 3(8))	Barley In deviation to the dossier, where the MRL proposal was based on the combined data set of northern and southern European residue studies, the rapporteur's proposal is derived from the southern European data set (endpoint list p.11). Only those studies are taken into consideration, where both products, HEC 5725 110 FS and HEC 5725 100 EC,	The comments of the notifier are noted. The justification for the MRL proposal for barley has been included in the list of end points. For wheat, rye and triticale, all residue values were less or at the LOQ.	EPCO 15 (13.-14.10.2004): The respective calculation was enclosed in the discussion table of the meeting. Open point fulfilled.

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	continued Open point 3.2: RMS to provide MRL calculations according to guidance document 7039/VI/95, i.e. using EC Method I and II (Vol 3, B.7.13, Justification of MRL's - see reporting table 3(8))	were applied. Comparing the different calculations, it becomes evident that both approaches lead to the same MRL proposal of 0.5 mg/kg. Calculation of MRL proposal according to guidance document 7039/VI/95: Method I (all values) 0.64 mg/kg Method II (75% quantile) 0.51 mg/kg (see separate document) Wheat, Rye, Triticale The MRL proposal is based on a total of 16 residue studies, which were performed in northern and southern Europe. All residue values of HEC 5725 were less or at the LOQ of 0.02 mg/kg 34 – 69 days after the last treatment, with one exception of 0.03 mg/kg, where the residues have increased again from day 35 to day 45. This result can certainly be contributed to analytical and/or biological variability of the population. As the equation of method I assumes normal distribution and the equation of method II results in the 2fold 75% quantile both equations were not applied for MRL calculation.		

section 3 – Residues

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	New open point 3.3: The rapporteur is asked to amend the list of end points in accordance with the agreements of the meeting. (plant and animal residues definition for risk assessment and monitoring; STMRs in summary of critical residues data; factor included in the NEDI in 'Consumer risk assessment'; Deletion of 'Justification for MRL proposal' section and % Transference column) New open point was proposed in the EPCO 15 meeting.		17.06.2005 The list of end points has been amended as requested	EPCO 15 (13.-14.10.2004): Need for further action on List of endpoints was identified. Open point still open. Evaluation Meeting (19 – 20 07.2005): The document has been amended. Open point fulfilled.

4. Environmental fate and behaviour

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Section 4 Data requirements: -0 Open points: 2			Section 4 Data requirements: 0 Open points: 0
	Open point 4.2: The inclusion of the Z isomer of fluoxastrobin in soil residue definition to be discussed in an expert meeting. (B.8.9. - see reporting table 4(11))	Considering the comments of column C of the reporting table, no further comments from applicant.	The RMS maintains the view that this is not necessary. Parent fluoxastrobin provides the best marker compound for soil residues (in bare soil field dissipation studies, Z isomer only represented up to 22% of the fluoxastrobin + Z isomer residue). With the presence of the crop canopy or drilled seed below the soil surface, in practice Z isomer levels will be lower than this due to reduced irradiation levels. Therefore for any soil monitoring, the rapporteur considers it is not necessary to include the Z isomer in the definition at least for the currently notified use patterns.	EPCO 12 (20.-23.09.2004): The Z isomer should be included in the residue definition for soil. RMS to amed list of end points accordingly Open point still open (for formal reasons) Ecotox meeting should be asked to consider whether this metabolite (the Z isomer) is ecotoxicologically significant. Evaluation Meeting (19 – 20 07.2005): The metabolite has been included into the definition of the residues. Open point fulfilled.
	Open point raised in a letter from NL (17th June) regarding open point 4.1			EPCO 12 (20.-23.09.2004): This has been addressed by discussion in the Evaluation meeting. Open point fulfilled.

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	Additional point raised at EPCO 12.			EPCO 12 (20.-23.09.2004): As a general point, the meeting noted that information on studies to indicate the non-relevance of metabolites are not included in the endpoints list. The ecotox meeting should consider updating the endpoints list to include information on non-relevant metabolites (M48).

5. Ecotoxicology

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Section 5 Data requirements: 0 Open points: 6			Section 5 Data requirements: 0 Open points: 1
	Open point 5.1: The revised risk assessment for aquatic organisms in the addendum to be discussed in an expert meeting. (Vol. 1, list of end points, toxicity data for aquatic species - see reporting table 5(5))	Taking into account all information presented in the addendum the results of the risk assessment based on the data of the chronic study on Mysid shrimps should not be transferred one-to-one to a freshwater organism risk assessment. Data deriving from saltwater species should only be used as indicator due to differences in physiology and taxonomy. In order to better understand the risk to freshwater organisms acute tests with additional 8 different species were conducted aiming at an identification of a very sensitive freshwater species. Based on these findings a higher tier chronic test was conducted with the most sensitive species, *Gammarus pulex*. The final risk assessment should be based on the results of this study with *Gammarus pulex* only leading to a safe use without any further mitigation measures.	In line with section 2.3.3 of the current SANCO 'Guidance document on aquatic ecotoxicology' (SANCO/3268/2001rev.4 (final) 17 October 2002) the available data on estuarine / marine invertebrates, which includes that for the mysid shrimp (*Americamysis bahia*) have been considered in the risk assessment as an indicator of the possible sensitivity of freshwater aquatic invertebrates. The submitted fluoxastrobin toxicity data, which includes acute tests on a total of eight freshwater aquatic invertebrates and chronic tests on two freshwater species (Daphnia and Gammarus), indicates Americamysis bahia to be of a similar sensitivity from acute exposure to that of the most sensitive tested freshwater species but to be significantly more sensitive than the two tested freshwater species from long-term exposure. Although these data indicate that *Americamysis bahia* is likely to be one of the most	EPCO 13 (21.-24.092004): Open point fulfilled. Generic question on lowering the uncertainty factor using additional chronic species sensitivity data to be sent to the PPR Panel. Evaluation Meeting (19 – 20 07.2005): This question was sent to the PPR Panel, the opinion is still awaited.

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	Open point 5.1 continued: The revised risk assessment for aquatic organisms in the addendum to be discussed in an expert meeting.		sensitive of aquatic organisms to fluoxastrobin (hence the proposed acceptability of the mysid shrimp long-term TER of 3.8 when using a 5 metre buffer zone), no evidence has been submitted to support the lack of representativeness of data for this salt water species data to freshwater species.	
	Open point 5.2: MS to discuss the risk assessment for non-target arthropods in an expert meeting. (Vol. 3, B.9.5.4, Risk assessment for non-target arthropods - see reporting table 5(23), see also 5(30))	PSD evaluated in the draft monograph the non-target arthropod risk assessment for fluoxastrobin EC 100 based on the EU directive and the recommendations of ESCORT (Barrett et al. 1994). Since ESCORT 2 has now been implemented by the newest Guidance Document on Terrestrial Ecotoxicology (October 2002) at the EU level, it should be considered for the risk assessment. If the risk assessment for fluoxastrobin EC 100 is performed according to ESCORT 2, no unacceptable effects on non-target arthropods will be expected and that on EU-level there is no need for a buffer zone at the field margin, see also M0-03-001230.pdf.	A risk assessment based on 'ESCORT 2' guidance is included in Vol. 3 at Section B.9.5.4.2. This indicates a potential in-crop risk to non-target arthropods. However given the limited persistence of fluoxastrobin, it is considered that adverse effects are likely to be short-term, with potential for population recovery within the cropping season. The need for consideration of risk mitigation measures at Member State level has been identified, however this does not require further consideration at this stage.	EPCO 13 (21.-24.092004): Open point fulfilled.

section 5 - Ecotoxicology

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Open point 5.3: The RMS is proposed to make a risk assessment for birds and mammals available according to SANCO/4145/2000 using the present data available. (Vol. 1, point 2.6.1Effects on terrestrial vertebrates - see reporting table 5(29))	BCS proposals are attached in documents MO-04-007354 EC 100.pdf MO-04-007353 FS 080.pdf	The dossier was submitted in March 2002, with detailed evaluation beginning in July 2002- i.e. several months before the current Guidance document on risk assessment for birds and mammals was finalised in September 2002. Therefore we do not consider it appropriate to update the risk assessment at this stage. Also, given the relatively low toxicity to birds and mammals and that the calculated acute and long-term TERs are well within Annex VI triggers, it is unlikely that using the new guidance would significantly change the risk assessment. Although the Notifier has submitted a revised risk assessment, it has not been checked in any detail by the Rapporteur. However, the RMS notes that according to the Notifier, even under the worst case assumptions of a tier 1 risk assessment, no unacceptable risks for birds or mammals can be expected from the proposed use of fluoxastrobin EC 100 under practical field conditions. 17 June 2005 Background information regarding the calculation of daily doses is presented in addendum 6 to the DAR	EPCO 13 (21.-24.092004): RMS to prepare an addendum with the recalculation to daily dose of the bird and mammal toxicity endpoints indicating the mean food consumption and body weight data on which these recalculations were based. Open point still open. Evaluation Meeting (19 – 20 07.2005): The addendum with the recalculations to daily dose has been submitted, but the risk assessment according to SANCO/4145/2000 is missing. Open point still open.

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	New Open point 5.4: In a written comment NL does not agree with RMS's reply to point 5(19) of the Reporting Table. NL states that ESCORT I trigger for effects on natural substrates is 25% (s-criterium).		17 June 2005 The list of end points has been amended in line with the comments made at the EPCO meeting. The trigger value (50%) is now used in accordance with ESCORT II Guidance.	EPCO 13 (21.-24.092004): RMS to amend the list of endpoints regarding the trigger value for NTA. Open point still open. Evaluation Meeting (19 – 20 07.2005): Open point fulfilled.
	New Open point 5.5 from EPCO 12, ecological relevance of z isomer			EPCO 13 (21.-24.092004): No further action required. Open point fulfilled.
	New open point 5.6. RMS to clarify status of anaerobic water/sediment study and essential status of data on anaerobic metabolite M40.			EPCO 13 (21.-24.092004): No further action required. Open point fulfilled.

List of representative uses evaluated

List of representative uses evaluated*

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	% product min max (n)	water L/ha min max	kg a.s./ha min max		
Wheat, rye, barley	EU North South	not defined	F	Rusts, Leave spot. Pyren. teres, Powd. mildew, Rhynchospor., Septoria	EC	100 g/L	overall spray	start 26 up to BBCH 69	1 – 2 #	14 days ref. to growth stage		200 - 400	0.1 - 0.2	35	# number application depends on disease incidence
Wheat, rye, triticale	EU North South	not defined	F	Fusarium nivale, Fusarium spp. Smut, Bunt	FS	37.5 HEC 37.5 JAU 5 Teb. g/L	seed treat-ment	pre sowing	1	n.a. (0)		up to 500 ml seed dressing solution*	7.5 HEC 7.5 JAU 1 Teb. g a.s./dt seed**	n.a.	* dilution with water 1:1 to 1:1.5, in small scale facilities up to 1:4 ** up to 230 kg seed/ha

Remarks:

* Uses for which risk assessment could not be concluded due to lack of essential data are marked grey

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)

(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds

(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989

(f) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench

(g) All abbreviations used must be explained

(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated

(i) g/kg or g/l

(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) The minimum and maximum number of application possible under practical conditions of use must be provided

(l) PHI - minimum pre-harvest interval

(m) Remarks may include: Extent of use/economic importance/restrictions