PEER REVIEW REPORT ON **FLUOXASTROBIN** 15.08.2005

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REPORT OF EPCO EXPERT MEETING 11

FLUOXASTROBIN

Rapporteur Member State: United Kingdom

Specific comments on the active substance in the section

1. Physical and Chemical Properties

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
17 June 2004	The Netherlands	Fluoxastrobin com01 NL

2. Documents submitted for meeting:

Date	Supplier	File Name
07 April 2004	RMS/United Kingdom	Fluoxastrobin consultation report
07 April 2004	RMS/United Kingdom	Fluoxastrobin addendum 1
07 April 2004	RMS/United Kingdom	Fluoxastrobin addendum 2 vol4
02 July 2004	RMS/United Kingdom	Fluoxastrobin reporting table rev1-2
12 August 2004	RMS/United Kingdom	Fluoxastrobin addendum 3
13 August 2004	RMS/United Kingdom	Fluoxastrobin end points rev2
13 August 2004	RMS/United Kingdom	Fluoxastrobin evaluation table rev0-1
13 August 2004	RMS/United Kingdom	Fluoxastrobin list of studies phys-chem
28 July 2004	RMS/United Kingdom	Fluoxastrobin com01 NL

3. Documents tabled at the meeting:

None.

The conclusions of the meeting were as follows:

4. **Data on preparations:** The formulation assessed was Bayer UK831 (HEC 5725 EC 100) .

5. **Classification and labelling:** Not discussed.

6. **Recommended restrictions/conditions for use:** Not discussed.

7. **Reference List**

Areas of concern: None

Appendix 1: EPCO discussion table: FLUOXASTROBIN

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Fluoxastrobin (Fu)

1. Physical and Chemical Properties

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	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 end point table has been amended	Open point is 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 end point table has been amended	Open point is fulfilled

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
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))	The data has been provided and included in an addendum.	Data requirement has been 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 data are acceptable. If an addendum is to be produced for another reason then this information should be included.	Open point fulfilled
	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))	The information provided in the evaluation table was accepted by the meeting.	Open point fulfilled

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	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))	The end points table has been amended.	Open point is fulfilled
	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))	The end points table has been amended.	Open point is fulfilled
	New Open Point 1.6: The IUPAC name in the end points should be corrected		New open point 1.6

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	New Open Point 1.7: 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.		New open point

Appendix 2: Evaluation table

1. Physical and Chemical Properties

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
				Section 1 Data requirements: - Open points: 2
	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 is 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 is fulfilled

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
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 has been 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) 1.57 silt loam (USDA) 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

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
	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

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
	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 1.6: The IUPAC name in the end points should be amended			EPCO 11 (07. – 09.09.2004): New open point 1.6
	New Open Point 1.7: 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.			EPCO 11 (07. – 09.09.2004): New open point 1.7

*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 been 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

REPORT OF EPCO EXPERT MEETING 12

FLUOXASTROBIN

Rapporteur Member State: UNITED KINGDOM

Specific comments on the active substance in the section

4. Environmental Fate and Behaviour

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
17 June 2004	The Netherlands	Fluoxastrobin com01 NL

2. Documents submitted for meeting:

Date	Supplier	File Name
07 April 2004	RMS/United Kingdom	Fluoxastrobin consultation report
07 April 2004	RMS/United Kingdom	Fluoxastrobin addendum 1
02 July 2004	RMS/United Kingdom	Fluoxastrobin reporting table rev1-2 (02-07-2004)
24 August 2004	RMS/United Kingdom	Fluoxastrobin endpoints rev2-1 2004-08-24
01 September 2004	RMS/United Kingdom	Fluoxastrobin evaluation table rev0-2 fate (2004-09-01)
01 September 2004	RMS/United Kingdom	Fluoxastrobin open point 5.3 MO-04-007354 EC 100
10 September 2004	RMS/United Kingdom	Fluoxastrobin list of studies

3. Documents tabled at the meeting:

None.

The conclusions of the meeting were as follows:

4. **Data on preparations:** Complete

5. **Classification and labelling:** Candidate for R53

6. **Recommended restrictions/conditions for use:**
Spray and seed treatment uses on cereals were considered for this new substance.

7. **Reference List**
The meeting did not assess this issue as fluoxastrobin is a new substance.

Areas of concern: No new areas of concern were identified during this meeting.

Appendix 1: EPCO discussion table: FLUOXASTROBIN

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Fluoxastrobin (Fu)

4. Environmental Fate and Behaviour

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	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))	The RMS did not consider this appropriate – the best marker in soil residue studies was considered to be fluoxastrobin (Z isomer only represented up to 22% of the total fluoxastrobin and Z isomer residue in bare soil field studies). In practice, the reduced contribution of photolysis at the times of application under the proposed GAP is likely to reduce the levels of the Z isomer. The level of Z isomer was not considered to affect the biological activity of the substance. The RMS considered that including the Z isomer in the residue definition may significantly increase the complexity of the methods of analysis required to separate each moiety. The meeting concluded that the Z isomer be considered as a photolysis metabolite that may form at up to 22% in the field. The Z isomer should be included in the fate residue definition for soil. Ecotox meeting should be asked to consider whether this metabolite (the Z isomer) is ecotoxicologically significant. The point raised in a letter from NL (17th June) has been satisfactorily addressed by these discussions.	Point fulfilled **EPCO 12 (20-23 Sep 04)** The Z isomer should be included in the residue definition for soil. Ecotox meeting should be asked to consider whether this metabolite (the Z isomer) is ecotoxicologically significant.
	Open point raised in a letter from NL (17th June) regarding open point 4.1	This has been addressed by discussion in the Evaluation meeting.	Point fulfilled.
	Additional point raised at EPCO 12.	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.	**EPCO 12 (20-23 Sep 04)** The ecotox meeting should consider updating the endpoints list to include information on non-relevant metabolites (M48).

Appendix 2: Evaluation Table

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: - Open points: 1
	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 Sep 04)** 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.
	Open point raised in a letter from NL (17th June) regarding open point 4.1	This has been addressed by discussion in the Evaluation meeting.		**EPCO 12 (20-23 Sep 04)** Open point fulfilled
	Additional point raised at EPCO 12.	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.		**EPCO 12 (20-23 Sep 04)** The ecotox meeting should consider updating the endpoints list to include information on non-relevant metabolites (M48).

*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*	7.6 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 been 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

REPORT OF EPCO EXPERT MEETING 13

FLUOXASTROBIN

Rapporteur Member State: UNITED KINGDOM

Specific comments on the active substance in the section

5. Ecotoxicology

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
17 June 2004	The Netherlands	Fluoxastrobin com01 NL

2. Documents submitted for meeting:

Date	Supplier	File Name
07 April 2004	RMS/United Kingdom	Fluoxastrobin consultation report
07 April 2004	RMS/United Kingdom	Fluoxastrobin addendum 1
02 July 2004	RMS/United Kingdom	Fluoxastrobin reporting table rev1-2
03 August 2004	Bayer CropScience	Fluoxastrobin risk assessment notifier (MO-04-007354 EC 100) to open point 5.3
24 August 2004	RMS/United Kingdom	Fluoxastrobin end points rev2-1
24 August 2004	RMS/United Kingdom	Fluoxastrobin evaluation table rev0-2
10 September	RMS/United Kingdom	Fluoxastrobin list of studies

3. Documents tabled at the meeting: None

None.

The conclusions of the meeting were as follows:

4. **Data on preparations:** Complete.

5. **Classification and labelling:** active substance R50/R53, N, Formulation R51/R53, N.

6. **Recommended restrictions/conditions for use:** Risk mitigation measures required to protect aquatic life.

7. **Reference List**

Areas of concern: none

Appendix 1: EPCO discussion table: FLUOXASTROBIN

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Fluoxastrobin (Fu)

5. Ecotoxicology

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	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))	Endpoints have been updated to include new GLP studies. Addendum 1 provides a higher tier assessment of the risk to aquatic life, mainly to refine risk management measures. DAR was used for both UK and EU registration. Additional species data indicate that *Daphnia* is not the most sensitive species. Copepod and *Gammarus pulex* more sensitive (along with mysid shrimp). Meeting agreed with RMS proposal that new additional species data indicate that acute risk is acceptable, assuming a reduction of TER from 100 to 28 (based on Mysid shrimp endpoint) due to the range of species tested. Therefore no buffer zone is required based on acute risk from spray drift at 1 m. Long term risk assessment (Section 6.3 of Addendum 1). Mysid long term end-point (NOEC 0.6 µg a.s./L based on mortality) results in TER of 0.29 at 1 m and would therefore require MS risk management measures. New long term study has been submitted with *Gammarus* including sediment, where NOEC is 31.6 µg a.s./L. *Gammarus* NOEC compared to initial PEC at 1 m gives TER of 14.9. Meeting considered that data for the Mysid shrimp (salt water species) should still be used for both the acute and chronic risk assessments. The chronic risk assessment based on the Mysid shrimp NOEC gives a TERlt of 10.2 at 15 m and it was agreed that this formed the basis of a 'safe use' for Annex 1 listing. However, it was noted that additional chronic invertebrate data are available. Meeting agreed that some lowering of the chronic uncertainty would be acceptable in this case. These additional data may be used to refine the risk assessment at MS level. A general question on lowering the uncertainty factor using additional chronic species sensitivity data is to be sent to the PPR. Endpoints have been amended.	Open point fulfilled. EPCO 13 (21-24 Sept 04) Generic question on lowering the uncertainty factor using additional chronic species sensitivity data to be sent to the PPR Panel.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	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))	In the DAR, RMS proposed advisory (ie. not legally binding) labelling at National level to mitigate short-term in-field effects. This is a UK concern and was only mentioned because of dual function of DAR. This was not intended to be an Annex 1 issue and the need for risk management measures at MS level need not be specifically highlighted in Review Report. Potential for population recovery in-field within timescales currently defined as 'acceptable' at EU level was seen in extended lab. study.	Open point fulfilled.
	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))	NOT has provided revised risk assessment, RMS does not intend to evaluate this assessment as it is not a critical issue in this case. RMS to supply background information regarding the calculation of daily doses.	EPCO 13 (21-24 Sept 04) 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.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	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).	Source of 25% trigger thought to be from earlier version of EPPO scheme, it is not regulatory trigger. RMS to amend trigger in endpoints table to be in line with latest ESCORT 2 criteria, ie. 50% trigger.	<u>EPCO 13 (21-24 Sept 04)</u> RMS to amend the list of endpoints regarding the trigger value for NTA. Open point still open.
	New Open point 5.5 from EPCO 12, ecological relevance of z isomer	EPCO 12 indicated that the Z-isomer can be present at up to 20% in soil. This is an increase over the technical material ratio of E-isomer 98%: Z-isomer 2%. DAR (Background B.9) contains section on biological screening data (fungicidal/herbicidal and insecticidal activity), also data on *Daphnia* and some mammalian data. Overall conclusion is that z-isomer is unlikely to be of greater toxicity than the E-isomer, or the racemic mixture. Meeting confirmed that this was not an issue.	No 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	RMS confirmed that the anaerobic study evaluated at B.1.1.1(c) in DAR is not a core fate data requirement and was discounted as being relevant in DAR and EPCO 12. Therefore the Ecotox data on metabolite M40 (which was only 'major' in this study) were not essential.	No further action required. Open point fulfilled.
		The meeting had no further comments on the list of endpoints.	

Appendix 2: Evaluation table

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: 0Open points: 3
	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*	EPCO 13 (21-24 Sept 04) Generic question on lowering the uncertainty factor using additional chronic species sensitivity data to be sent to the PPR Panel.

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
	continued Open point 5.1: The revised risk assessment for aquatic organisms in the addendum to be discussed in an expert meeting.		*bahia* is likely to be one of the most 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 Sept 04) Open point fulfilled.

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.	EPCO 13 (21-24 Sept 04) 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.

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
	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).			EPCO 13 (21-24 Sept 04) RMS to amend the list of endpoints regarding the trigger value for NTA. Open point still open.
	New Open point 5.5 from EPCO 12, ecological relevance of z isomer			EPCO 13 (21-24 Sept 04) No 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 Sept 04) No further action required. Open point fulfilled.

*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*	7.7 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 been 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

REPORT OF EPCO EXPERT MEETING 14

FLUOXASTROBIN

Rapporteur Member State: UNITED KINGDOM

Specific comments on the active substance in the section **Mammalian Toxicology** are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	**Supplier**	**File Name**
01 July 2004	France	Fluoxastrobin com01 FR
August 2004	Bayer CropScience	Fluoxastrobin com02 notifier

2. Documents submitted for meeting:

Date	**Supplier**	**File Name**
07 April 2004	RMS/United Kingdom	Fluoxastrobin consultation report
07 April 2004	RMS/United Kingdom	Fluoxastrobin addendum 1
02 July 2004	RMS/United Kingdom	Fluoxastrobin reporting table rev1-2
August 2004	RMS/United Kingdom	Fluoxastrobin addendum 4
24 August 2004	RMS/United Kingdom	Fluoxastrobin end points rev2-1
24 August 2004	RMS/United Kingdom	Fluoxastrobin evaluation table rev0-2
10 September 2004	RMS/United Kingdom	Fluoxastrobin list of studies rev2

3. Documents tabled at the meeting:

   None.

The conclusions of the meeting were as follows:

4. **Data on preparations**: HEC 5725 100 EC (= ‘Bayer UK 831’)

5. **Classification and labelling:** None.

6. **Recommended restrictions/conditions for use:** None.

7. **Reference List:** N/A

Areas of concern: No areas of concern outstanding.

Appendix 1: EPCO discussion table: FLUOXASTROBIN

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Fluoxastrobin (Fu)

2. Mammalian Toxicology

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	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))	Comments from one member state were that the new studies (Ames tests and a skin sensitisation study) are not satisfactory to allay toxicological concern and additional data would also be required. The RMS explained that a detailed review of the toxicity data on different batches and impurities was in the addendum 1 (pages 6-22). 2% of the active substance is the Z isomer. The contents of other impurities vary between 0.4-0.8%. . A number of the impurities were present in the batches used for the main toxicity studies. Meeting agreed that a satisfactory investigation of the impurities had been performed and no further genotoxicity data were required. The meeting was also satisfied with the approach taken to address skin sensitisation potential of fluoxastrobin impurities.	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. (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))	One member state queried whether uterine effects (hyperplasia, tumours) occurred by chance or were substance related. It was agreed these were primarily high dose effects and of no relevance for the risk assessment, but general conclusions may be affected. 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 incidence was low.	Open point fulfilled.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
2.1	Notifier to submit histopathologyical data of the thymus from multigeneration study. (Vol. 3, B.6.6.1 - see reporting table 2(14))	See Addendum 4 A precautionary approach had been adopted originally by the RMS with respect to a dose-related thymus weight reduction in F2 pups (driven mainly by females at 1000ppm, 16% reduction relative, 15% reduction absolute, NOAEL at 100ppm). No histopathology was provided initially. New histopathology results were in the addendum and no adverse effects were seen on thymus of F2 pups at 1000 ppm. Hence the RMS concluded that there is no specific concern and reduced thymus weight at 1000 ppm is not assessed as an adverse effect. This had no impact on the reference doses. Meeting agreed that 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.
	Open point 2.3: RMS to provide information on histopathological 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))	See data requirement 2.1.	Open point still open. RMS to revise DAR / prepare addendum
	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))	One member state noted that in the rat developmental study there was an increase in the litter incidence of incomplete ossification of distal phalanx of digit 2 in each forelimb. Commentary from the applicant was provided. Ultimately it was not thought to be a treatment related effect (very slight effect, fetal and litter incidence were not both statistically significant, probably incidental, even though above the historical control range). Meeting agreed that the NOAEL should be 1000 mg/kg bw/d for fetotoxicity.	Open point fulfilled.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	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))	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 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. The meeting discussed the range of findings in the dog studies before agreeing the RMS proposal. Some clarification would be added to an addendum. Also, based on Survey of UK seed treatment plants (which looked at duration of plant operation over a year: winter and Spring cereals :95% of plants upto 15 weeks total per year. 3-4% of plants - period upto 26 weeks[1]) the UK considered that an additional longer-term AOEL should not be set. The meeting noted the small proportion of plants working in excess of 15 weeks and that exposure was unlikely to be continuous over this period. The meeting considered that a second AOEL might confuse member states over which AOEL to apply for particular uses. EFSA agreed and added whether this would lead to proliferation of reference values. In this case the Meeting decided that just one AOEL would be preferable and it 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. [1]survey of UK seed treatment practice carried out the by SeedTROPEX industry task force in 2001	Open point still open. RMS to revise DAR / addendum
	New open point 2.7 Essential studies list This open point was proposed at EPCO 14.	To be agreed post meeting	Open point still open. RMS to prepare list of essential studies, NL to check.

Appendix 2: Evaluation table

2. Mammalian Toxicology

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 2 Data requirements: 0 Open points: 4
	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 October 2004): Open point fulfilled.

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
	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. (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))	**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 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	EPCO 14 (11-14 October 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. Open point fulfilled.

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
	continued: 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. (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))		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, 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)	EPCO 14 (11-14 October 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.

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
	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.	EPCO 14 (11-14 October 2004): Open point still open. RMS to revise DAR / prepare addendum. See also data requirement 2.1.
	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. On first evaluating this study the RMS, like SE, was concerned about the increases in litter incidence of incomplete ossification of the distal phalanx of digit 2 from each forelimb at 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.	EPCO 14 (11-14 October 2004): Meeting agreed that the NOAEL should be 1000 mg/kg bw/d for fetotoxicity. Open point fulfilled.

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
	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))		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. Notably, it is unlikely that retarded ossification would only occur at these single locations beginning at 300 mg/kg bw/day while the remaining skeleton does not reveal any convincing evidence* of substance-related retarded ossification (even at 1000 mg/kg bw/day). Indeed more progressed ossification with statistical significance on a fetal basis was evident for some digital bones at 300 and/or 1000 mg/kg bw/day. • (slight, non statistically significant increases in the litter incidence of incomplete ossification in a few other digital bones at 1000 mg/kg bw/day is NOT convincing evidence of a substance-related effect.)	

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
	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))	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. Open point still open. RMS to clarify in the addendum

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
	continued: 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))		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.	
	New open point 2.6: RMS to revise DAR / prepare addendum. (See data requirement 2.1) This open point was proposed at EPCO 14.			EPCO 14 (11-14 October 2004): Open point still open.
	New open point 2.7 Essential studies list This open point was proposed at EPCO 14.			EPCO 14 (11-14 October 2004): Open point still open. RMS to prepare list of essential studies, NL to check.

*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*	7.8 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 been concluded due to lack of essential data are marked grey	(h)	Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(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)	(i)	g/kg or g/l
(b)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(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
(c)	*e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds		
(d)	*e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989		
(f)	Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench	(l)	PHI - minimum pre-harvest interval
(g)	All abbreviations used must be explained	(m)	Remarks may include: Extent of use/economic importance/restrictions

REPORT OF EPCO EXPERT MEETING 15

FLUOXASTROBIN

Rapporteur Member State: UNITED KINGDOM

Specific comments on the active substance in the section

3. Residues

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

None

2. Documents submitted for meeting:

Date	Supplier	File Name
02 July 2004	RMS/United Kingdom	Fluoxastrobin reporting table rev1-2
24 August 2004	RMS/United Kingdom	Fluoxastrobin end points rev2-1
01 September 2004	RMS/United Kingdom	Fluoxastrobin evaluation table rev0-2
10 September 2004	RMS/United Kingdom	Fluoxastrobin list of studies rev2

3. Documents tabled at the meeting:

None

The conclusions of the meeting were as follows:

4. **Data on preparations:** Not considered at EPCO 15.

5. **Classification and labelling:** Not considered at EPCO 15.

6. **Recommended restrictions/conditions for use:** None.

7. **Reference list:** The meeting concluded that all studies were relied on.

Areas of concern: None

Appendix 1: EPCO discussion table: FLUOXASTROBIN

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Fluoxastrobin (Fu)

3. Residues

<table>
<tr><th>No.</th><th>Subject</th><th>Discussion EPCO Expert Meeting</th><th>Conclusions EPCO Expert Meeting</th></tr>
<tr><td></td><td>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))</td><td>The summary of representative uses in the list of end point has been amended. RMS is asked to amend the footnote to make it clear that insufficient information was available for that particular formulation.</td><td>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.</td></tr>
<tr><td></td><td>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 - <u>see reporting table 3(8))</u></td><td>The list of end points has been updated. However, the calculations may be confusing whilst situated in the end points list. Therefore these will be deleted from list of end points. For completeness the calculations are shown here:

Justification for MRL proposal - Barley
<table><tr><td>Method I (Weinmann/Nolting)</td><td>R</td><td>0.120</td></tr><tr><td>(all values)</td><td>s</td><td>0.124</td></tr><tr><td></td><td>k</td><td>4.190</td></tr><tr><td></td><td>Rmax=R+k*s</td><td>0.641</td></tr></table></td><td>Open point fulfilled.</td></tr>
</table>

<table>
<tr><th>No.</th><th>Subject</th><th>Discussion EPCO Expert Meeting</th><th>Conclusions EPCO Expert Meeting</th></tr>
<tr><td></td><td>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 - <u>see reporting table 3(8))</u></td><td>
<table>
<tr><td>Method II (Wilkening)</td><td>R (0.75)</td><td>0.255</td></tr>
<tr><td>(75 % quantile)</td><td>Rber=2*R(0.75)</td><td>0.510</td></tr>
</table>
Maximum residue values for a pre-harvest interval of: 35 days
<table>
<tr><td>Method I (all values)</td><td>0.64 mg/kg</td></tr>
<tr><td>Method II (75% quantile)</td><td>0.51 mg/kg</td></tr>
</table>
However for the sake of comprehensibility the RMS is still asked to present the calculation in an addendum/corrigendum to the DAR.
</td><td></td></tr>
<tr><td></td><td>New open point 3.3:
The rapporteur is asked to amend the list of end points.</td><td>For 'Metabolism in plants' the RMS is asked to amend the plant residues definition for risk assessment and monitoring to 'fluoxastrobin + Z isomer (cereals only)'.
For 'Metabolism in livestock' the RMS is asked to amend the animal residues definition for risk assessment and monitoring to 'fluoxastrobin, Z isomer and the phenoxy-hydroxy-pyrimidine metabolite (M55) expressed as fluoxastrobin'.
In the 'The summary of critical residues data' table the RMS is asked to amend the STMRs to less than 0.02.
RMS to delete the 'Justification for MRL proposal' section.
In the 'Consumer risk assessment' table the STMR should be stated as a factor included in the NEDI.
In 'Processing factors' table the % Transference column should be deleted.
RMS is asked to amend the footnote of the summary of representative uses evaluated for fluoxastrobin table to make it clear that insufficient information was available for that particular formulation.</td><td><u>EPCO 15 (13-14 October 2004)</u>
New open point.
The rapporteur is asked to amend the list of end points in accordance with the agreements of the meeting.</td></tr>
</table>

Appendix 2: Evaluation table

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: **-** Open points:2
	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.	EPCO 15 (13-14 October 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.
	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, were applied	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.

section 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
	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

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
	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.			EPCO 15 (13.-14.10.2004): Need for further action on List of endpoints was identified. Open point still open.