ANNEX B

Metconazole

B.7 Residue data
(Addendum August 2004)

B.7.6 Residues resulting from supervised trials (Annex IIA 6.3; Annex IIIA 8.1)

B.7.6.1 Residues resulting from supervised trials – Cereals

Introduction :
During the 2003 growing season, four field trials were conducted on spring barley growing areas in Southern France to determine the residue levels of BAS 555 00 F. The fungicidal test substance BAS 555 00 F (60 g active substance / L), a SL formulation of metconazole was applied twice at a rate of 90 g a.s./ha, 49 (± 1) and 35 (± 1) days before harvest.

Spring barley whole plant samples were collected at BBCH stage 77-83 just after the last application. Ears and remainder of the plant samples were collected at BBCH stage 85-89, 21 and 28 days after the last application. Grain and straw samples were collected at BBCH stage 89, 35 and 41-42 days after the last application.

The samples were analyzed for BAS 555 00 F with BASF method No. FAMS 050-01 which quantifies BAS 555 00 F at a limit of quantitation of 0.01 mg/kg. The total amount of metconazole residues was calculated as the sum of the amounts of the *cis*- and *trans*-isomers.

LC/MS/MS was used to quantify metconazole in barley matrices and the method was successfully validated resulting in average recoveries of 77-96% with a relative standard deviation of ≤ 14.

-*Winter/spring barley*
In 2003, BASF had performed 4 additional supervised residue trials in barley which were conducted in the Southern part of France.
Findings :
*North, barley, 89-96 g a.s./ha, 2 applications BBCH 33; 71-75, PHI : 35-37 days :
-grain : <0.01, 0.09, 0.03, 0.02, 0.01, 0.03, 0.01, <0.01, 0.05, 0.05, 0.03, 0.03, 0.01, 0.03, <0.01, <0.01 mg/kg
-straw : 0.13, 1.06, 1.61, 0.23, 0.82, 0.99, 0.37, 0.15, 0.18, 0.73, 0.22, 1.33, 0.74, 1.37, 0.32, 0.03 mg/kg
*South : The 4 trials submitted were carried out under GLP conditions with the representative formulation metconazole 60 g/L SL applied 2 times (BBCH 51-83) at a target dose rate of 90 g a.s./ha with a PHI of 35 days
-grain : 0.03, 0.03, 0.05, 0.04 mg/kg
-straw : 1.5, 1.3, 2.6, 1.4 mg/kg
The residue data from these additionally 4 barley trials run in Southern Europe showed a residue profile for grain and straw which is comparable to those obtained by the results from the trials run in the Northern part of the EU.
Conclusion :
In the North : 16 trials – 3 x mean: 0.08 – STMR: 0.025 – Rmax: 0.081 – Rber: 0.06 mg/kg;
In the South : 4 trials.

MRL proposal for barley grain : 0.1 mg/kg with possible extrapolation to oat (for Northern Europe only) according to EU Doc. 7525/VI/95-rev.7 (Table 3).

RESIDUE DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name) : metconazole
Crop/crop group : Spring Barley / cereals
Responsible body for reporting (name, address) : BASF AG, 67117 Limburgerhof
Country : France
Content of active substance (g/kg or g/L) : 60 g/l
Formulation (e.g. WP) : SL (formulation code BAS 555 00 F)

Commercial Product (name) : -
Producer of commercial pro : BASF AG
Indoor/Glasshouse/Outdoor : outdoor
Other active substance in the formulation (common name and content : none
Residues calculated as: : metconazole (BAS 555 F)

1	2	3	4	5			6	7	8	9	10	11
Report-No. Location (trial no.)	Commodity/ Variety	Date of 1 Sowing or planting 2 Flowering 3. Harvest	Method of treatment	Application rate per treatment			Dates of treatment(s) or no of treatment(s) and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
				kg as/hL	Water L/ha	kg as/ha						
BASF Doc ID 2004/1000755 26750 Génissieux France (FBD/10/03)	Spring Barley / Nevada	1 22/02/03 2 n/a 3. 28.06-29.06.03	medium volume soil application using boom sprayer	0.06 0.06	147 158	0.088 0.095	22.05.03 04.06.03	57 77	Whole plant Ears Rest of plant Ears Rest of plant Grain Straw Grain Straw	2.8 0.34 2.6 0.02 1.9 0.03 1.5 0.03 1.2	0 21 21 28 28 35 35 42 42	Analytical method used for all analyses: FAMS 050-01
BASF Doc ID 2004/1000755 26750 St Paul les Romans (FBD/11/03)	Spring Barley / Nevada	1 22/02/03 2 n/a 3. 28.06-29.06.03	medium volume soil application using boom sprayer	0.06 0.06	155 163	0.093 0.098	22.05.03 04.06.03	57 77	Whole plant Ears Rest of plant Ears Rest of plant Grain Straw Grain Straw	2.4 0.33 1.7 0.03 1.5 0.03 1.3 0.03 1.2	0 21 21 28 28 35 35 41 41	Analytical method used for all analyses: FAMS 050-01

RESIDUE DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name) : metconazole
Crop/crop group: : Spring Barley / cereals
Responsible body for reporting (name, address) : BASF AG, 67117 Limburgerhof
Country : France
Content of active substance (g/kg or g/L) : 60 g/l
Formulation (e.g. WP) : SL (formulation code BAS 555 00 F)

Commercial Product (name) : -
Producer of commercial pro : BASF AG
Indoor/Glasshouse/Outdoor : outdoor
Other active substance in the formulation (common name and content) : none
Residues calculated as: : metconazole (BAS 555 F)

1	2	3	4	5			6	7	8	9	10	11
Report-No. Location (trial no.)	Commodity/ Variety	Date of 1 Sowing or planting 2. Flowering 3. Harvest	Method of treatment	Application rate per treatment			Dates of treatment(s) or no of treatment(s) and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
				kg as/hL	Water L/ha	kg as/ha						
BASF Doc ID 2004/1000755 82200 Pompignan France (FTL/13/03)	Spring Barley / Nevada	1 24/02/03 2 n/a 3. 05.07-14.07.03	medium volume soil application using boom sprayer	0.06 0.06	153 158	0.092 0.095	23.05.03 06.06.03	51 83	Whole plant Ears Rest of plant Ears Rest of plant Grain Straw Grain Straw	4.8 0.56 1.6 0.37 1.3 0.05 2.6 0.02 1.1	0 21 21 28 28 35 35 42 42	Analytical method used for all analyses. FAMS 050-01
BASF Doc ID 2004/1000755 82200 Pompignan France (FTL/14/03)	Spring Barley / Nevada	1 24/02/03 2 n/a 3. 05.07-14.07.03	medium volume soil application using boom sprayer	0.06 0.06	163 180	0.098 0.108	23.05.03 06.06.03	51 83	Whole plant Ears Rest of plant Ears Rest of plant Grain Straw Grain Straw	2.8 0.43 2.0 0.33 2.6 0.04 1.4 0.02 1.3	0 21 21 28 28 35 35 42 42	Analytical method used for all analyses. FAMS 050-01

B.7.11 Estimates of the potential and actual exposure through diet and other means (Annex IIA 7.9; Annex IIIA 8.8)

Adults, children and infants from United Kingdom

	Adults 70.1 kg b.w.		**Child 43.3 kg b.w.**		**Infant 8.7 kg b.w.**	
	«High level » intakes from single commodities					
	97.5th percentile consumption (kg/day)	**TMDI for single commodity (mg/kg b.w./day)**	**97.5th percentile consumption (kg/day)**	**TMDI for single commodity (mg/kg b.w./day)**	**97.5th percentile consumption (kg/day)**	**TMDI for single commodity (mg/kg b.w./day)**
Wheat	0.25	0.000208	0.2199	0.000366	0.0614	0.000409
Barley (assuming 1% beer consumption)	0.0236	0.000039	0.0036	0.000012	L/C	L/C
Oat	0.0409	0.000068	0.0305	0.000102	0.0182	0.000243
Bran	0.0156	0.000026	0.0216	0.000072	L/C	L/C
Oilseeds total	0.0745	0.000124	0.0608	0.000203	0.0172	0.000229
	Total dietary intakes from combinations of commodities (total TMDI) (mg/kg b.w./day)					
Total	0.000341		0.000576		0.000721	

The TMDIs of UK adults, children and infants are respectively **3.41 %**, **5.76 %** and **7.21 %** of the ADI (0.01 mg/kg b.w./day).

Conclusion :
There is no chronic concern for the adults and the extreme consumers when applying metconazole.

B.7.16 References relied on

Annex point(s) 91/414/EEC	**Author(s)**	**Title** **Generated by (company or organisation)** **Submitted by (company(ies) or organisation)** **Report/file No. of submitting company** **Date of report** **for publication : reference**	**Data protection claimed**	**GLP GEP**	**Published or not**
II A 6.3.1/30	Perny A.	Study on the residue behaviour of metconazole in spring barley after application of BAS 555 00 F under field conditions in France, in 2003 – BASF Doc ID 2004/1000755.	No	Yes	No
II A 6.3.1/31	Perny A.	Study on the residue behaviour of metconazole in spring barley after application of BAS 555 00 F under field conditions in France, in 2003 – Report Amendment N° 1 to Final Report – Study code 159427 - BASF Doc ID 2004/1006466.	No	Yes	No