5.10 CYPERMETHRIN (118)

RESIDUE AND ANALYTICAL ASPECTS

Cypermethrin was subject to a periodic review for residues in 2008. Further information has now been provided on the registration of cypermethrin as a grain protectant.

Cereal grains

A cypermethrin UL formulation containing 20 g/L cypermethrin and 57 g/L piperonyl butoxide is registered in France for post-harvest use on cereal grains as a grain protectant with an application rate equivalent to 1.7 g cypermethrin per tonne of grain. The authorisation is for 'céréales à paille'. In France, this is understood as barley, oats, rye and wheat.

In four supervised post-harvest trials on wheat in Belgium, the grain (12–20 kg) was treated with a UL cypermethrin formulation at a rate equivalent to 1.7 g ai/tonne and stored for 7 days (two trials) and 270 days (two trials).

Cypermethrin residues one day after treatment were 1.11, 1.17, 1.2 and 1.35 mg/kg and at day 7 were: 1.07, 1.3, 1.4 and 1.5 mg/kg. As can often occur with the application of grain protectants, the concentration on the grain was less than the intended application rate. Residues on samples taken at days 180 (1.3 and 0.96 mg/kg) and 270 (1.3 and 0.99 mg/kg) after treatment suggest that the residues are quite stable during grain storage at the conditions of the trials (10 °C and 13.6–13.8% moisture).

The highest residue measured in each of the four trials (median underlined) was: 1.11, <u>1.35</u>, <u>1.40</u> and 1.5 mg/kg.

In estimating the maximum residue level, the Meeting also took account of the application rate (1.7 g ai/tonne) which would theoretically produce a residue of 1.7 mg/kg.

The Meeting estimated an STMR value of 1.38 mg/kg and a maximum residue level of 2 mg/kg for wheat. The HR was 1.5 mg/kg.

The same values are recommended for barley, oats and rye.

The previous recommendation of 0.3 mg/kg for cereal grains except rice is changed to 0.3 mg/kg for cereal grains except rice, barley, oats, rye and wheat.

The group MRL for 'cereals, except …..' should be maintained even though major cereals (rice, wheat and barley) are exceptions. Three compounds are involved – cypermethrin, alpha-cypermethrin and zeta-cypermethrin – and pre-harvest and post-harvest uses, which produce quite different residue levels. Also, alpha-cypermethrin has registered pre-harvest uses for the crop group 'cereals', so residues could legitimately occur on the non-major cereals.

The 2008 JMPR summarised studies on wheat (post-harvest treatment with cypermethrin, pre-harvest treatment with zeta-cypermethrin) and barley (pre-harvest treatment with alpha-cypermethrin) that investigated the fate of residues during food processing.

The processing factors (post-harvest treatment with cypermethrin) for cypermethrin residues for wheat grain → bran were: 2.4 and 2.6 – median 2.5. <u>*Note*</u>: bran produced by the milling of wheat is described as the Codex commodity 'Wheat bran, unprocessed'.

The processing factors (post-harvest treatment with cypermethrin) for cypermethrin residues for wheat grain → flour were: 0.27 and 0.43 – median 0.35.

A small-scale processing study for wheat following pre-harvest treatment with zeta-cypermethrin was reported by the 2008 JMPR. Information was also available in the open literature (1985) on the fate of cypermethrin during commercial scale milling of post-harvest treated wheat. The results of the zeta-cypermethrin study and the commercial scale milling trial with cypermethrin

both supported the current processing study in the sense that residue levels in flour were less than in the grain and residue levels in the bran exceeded the levels in the grain.

The Meeting agreed to use the processing factors from the recent post-harvest wheat study. The processing factors for bran (2.5) and flour (0.35) were applied to the estimated STMR and HR for wheat (1.38 and 1.5 mg/kg) to produce STMR-P and HR-P values for bran (3.45 and 3.75 mg/kg) and flour (0.48 and 0.53 mg/kg).

The estimate for flour falls below the maximum residue level for wheat (2 mg/kg), so a maximum residue level for flour is not needed.

The Meeting estimated an STMR-P value of 3.45 mg/kg and a maximum residue level of 5 mg/kg for wheat bran, unprocessed.

The 2008 JMPR reported on the fate of alpha-cypermethrin residues in barley (from pre-harvest uses) during processing. The processing factors for alpha-cypermethrin residues for barley → beer were: < 0.03, < 0.04, < 0.04, < 0.09, < 0.17, and < 0.5 – best estimate < 0.03.

The processing factor for beer (< 0.03) was applied to the estimated STMR for barley (1.38 mg/kg) to produce an STMR-P value for beer (0.04 mg/kg).

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are provided in Annex 6. The calculations were made according to the livestock diets from US-Canada, EU and Australia in the OECD Table (Annex 6 of the 2006 JMPR Report).

	Livestock dietary burden, cypermethrin, ppm of dry matter diet					
	US-Canada		EU		Australia	
	max	mean	max	mean	max	mean
Beef cattle	21.2	8.47	24.4	8.48	31.4 [a]	11.3 [b]
Dairy cattle	15.9	6.79	17.1	7.73	21.6 [c]	8.47 [d]
Poultry - broiler	2.98	2.74	2.05	1.89	2.05	1.88
Poultry - layer	2.98	2.74 [f]	3.89 [e]	2.27 [f]	1.80	1.36

[a] Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian meat.

[b] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat.

[c] Highest maximum dairy cattle dietary burden suitable for MRL estimates for milk.

[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

[e] Highest maximum poultry dietary burden suitable for MRL estimates for poultry meat and eggs.

[f] Highest mean poultry dietary burden suitable for STMR estimates for poultry meat and eggs.

Animal commodities, MRL estimation

Cattle

The estimated maximum dietary burden (31.4 ppm) for beef cattle and dairy cattle (21.6 ppm) have not changed from the estimates by the 2008 JMPR, so there is no change in estimated maximum residue levels for meat, offal and milk.

The STMR dietary burdens for beef cattle (11.3 ppm) and dairy cattle (8.5 ppm) are very little changed from previous values (11.3 and 8.3 ppm) and the changes do not influence the calculated residues in tissues and milk.

Poultry

In the table, dietary burdens are shown in round brackets (), feeding levels and residue concentrations from the feeding study are shown in square brackets [] and estimated concentrations related to the dietary burdens are shown without brackets.

Dietary burden (ppm) Feeding level [ppm]	Eggs	Muscle	Liver	Fat
MRL				
	highest	highest	highest	highest
MRL laying hens (3.9) [0, 1.6, 7.2]	0.0060 [0, < 0.01, 0.011]	0.007 [0, < 0.05, < 0.05]	0.007 [0, < 0.05, < 0.05]	0.048 [0, < 0.05, 0.088]
STMR				
	mean	mean	mean	mean
STMR laying hens (2.74) [0, 1.6, 7.2]	0.0042 [0, < 0.01, 0.011]	0.002 [0, < 0.05, < 0.05]	0.002 [0, < 0.05, < 0.05]	0.0.034 [0, < 0.05, 0.088]

The data from the laying hen feeding studies were used to support poultry meat and egg MRLs.

For poultry liver and muscle, residues were below LOQ (0.05 mg/kg) even at the 15 ppm feeding level, so changes to dietary burden made no difference.

The Meeting estimated an STMR value of 0.034 mg/kg for poultry fat to replace the previous value (0.008 mg/kg). The HR was 0.048 mg/kg, replacing 0.027 mg/kg. Cypermethrin is fat-soluble, so allowance should be made for the fact that the feeding study was on laying hens where some residue is eliminated from the hen via the eggs, a process that would not occur for broilers. Higher residues could therefore, be expected in the fat of broilers.

The Meeting estimated a maximum residue level of 0.1 mg/kg for poultry meat (fat). The previous recommendation of 0.05(*) mg/kg for poultry meat (fat) was withdrawn.

For eggs, residues were below LOQ (0.01 mg/kg) at the 1.6 ppm feeding level, so an estimate of the STMR was made by dividing the dietary burden (2.74 ppm) by 7.2 ppm and multiplying by the residue at that dosing level (0.011 mg/kg) to produce a value of 0.0042 mg/kg. Similarly, a calculation for the HR for eggs produced a value of 0.0060 g/kg.

There is no change to the recommended maximum residue level of 0.01(*) mg/kg for eggs from 2008. The Meeting estimated an STMR value and an HR value of 0.0042 and 0.0060 mg/kg respectively for eggs to replace recommendations from 2008 of 0.001 and 0.0033 mg/kg, respectively.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of cypermethrin, alpha-cypermethrin and zeta-cypermethrin resulted in recommendations for MRLs and STMR values for raw and processed commodities. Where data on consumption were available for the listed food commodities, dietary intakes were calculated for the thirteen GEMS/Food Consumption Cluster Diets. The calculated intakes were essentially unchanged from the values calculated in 2008.

The IEDIs in the thirteen GEMS/Food Consumption Cluster Diets, based on estimated STMRs were 7−30% of the maximum ADI (0.02 mg/kg bw). The Meeting concluded that the long-term intake of residues of the cypermethrins from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-Term Intake (IESTI) for cypermethrin, alpha-cypermethrin and zeta-cypermethrin was calculated for the food commodities (and their processing fractions) for which maximum residue levels and HRs and STMRs were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4.

The IESTI varied from 0–20% of the ARfD (0.04 mg/kg bw) for the general population and from 0–40% of the ARfD for children 6 years and below. The Meeting concluded that the short-term intake of residues of the cypermethrins from used considered by the Meeting was unlikely to present a public health concern.