5.24 PROPICONAZOLE (160)

RESIDUE AND ANALYTICAL ASPECTS

The triazole fungicide propiconazole was evaluated in the periodic review program by th 2007 JMPR, when an ADI of 0–0.07 mg/kg bw and a ARfD of 0.3 mg/kg bw were stablished, and by the 2013 JMPR for residue aspects. Propiconazole was listed by the Forty-fifth Session of the CCPR (2013) for the review of additional uses. Residue trial data on bean (dry), bean (lima), and bean (snap), mint, pineapple following post-harvest application, barley, oat and wheat were submitted to current Meeting.

Residue definition for plant and animal commodities is *propiconazole* for compliance with the MRL and *propiconazole plus all metabolites convertible to 2,4-dichlorobenzoic acid, expressed as propiconazole* for the estimation of the dietary intakes.

Methods of analysis

Methods of analysis used in the trials submitted to this Meeting were evaluated by the 2007 JMPR and were considered fit for purpose for the estimations. Methods that used LC-MS/MS analyses propiconazole, and the results are used for the estimation of maximum residue level. The common moiety method measure all residues convertible to 2,4-dichlorobenzoic (2,4-DCBA), reported as total propiconazole, and the results were used for the estimation of STMR and HR. In the residue trials, samples were stored within the period that guarantee the integrity of the residues as shown in the storage stability studies.

Results of supervised residue trials in crops

No estimations were made for lima bean, snap bean, dry beans and mint, as only the total propiconazole residue was reported in pre-harvest treatment trials. Data for these crops will not be discussed further.

Pineapple

The GAP of the USA for propiconazole in pineapple is for one post-harvest dipping treatment in a 0.015 kg ai/hL solution. Three trials were conducted using this rate, giving total residue of 1.1, 1.8 and 3.6 mg/kg of total propiconazole (highest of 4.1 mg/kg in an individual sample). As it is unlikely that propiconazole metabolites are formed between treatment and sample preparation for analysis, the results comply with both the residue definition for MRL and dietary risk assessment.

The Meeting agreed that the number of trials was not sufficient to estimate a maximum residue level for propiconazole in pineapple followingf post-harvest treatment, and did not change its previous recommendation of 0.02* mg/kg.

Cereals

In the USA, GAP for propiconazole in barley, oats and wheat, is for up to 2 applications at 0.125 kg ai/ha, the second one being at least 14 days following an early season application and should not be performed after full head emergence, which corresponds to BBCH 59.

In one trial conducted in USA in barley, matching GAP, residues of propiconazole were < 0.01 mg/kg and of total propiconazole < 0.05 mg/kg. In eight other trials the second application was made after full head emergence (BBCH 71 to 85).

In one trial conducted in USA in oats according to GAP, residues of propiconazole were < 0.01 mg/kg and of total propiconazole were 0.26 mg/kg. In eleven other trials the second application was made after full head emergence (BBCH 69 to 71).

In one trial conducted in USA in wheat according to GAP residues of propiconazole were < 0.01 mg/kg and of total propiconazole 0.06 mg/kg. In fourteen other trials, the second application was made after full head emergence (BBCH 69 to 75).

The Meeting agreed that there were not enough trials matching US GAP to estimate a maximum residue level for propiconazole in barley, oats and wheat.

The Meeting did not change its previous recommendation of 0.02 mg/kg for propiconazole in wheat, rye and triticale and of 0.2 mg/kg for propiconazole in barley.

Animal feeds

Cereals

In the USA, the GAP for propiconazole in barley, oats and wheat, is for up to 2 applications at 0.125 kg ai/ha, the second at least 14 days following an early season application and should not be performed after full head emergence, corresponding to BBCH 59. No PHI is specified for straw, and the PHI is 7 days for forage and hay.

Forage

Eleven trials were conducted in oat forage in the USA matching US GAP, with total propiconazole residues of 0.50 (2), 0.78, 1.4, 1.5 (2), 1.7, 1.8, 1.9, 2.0 and 2.4 mg/kg (2.5 mg/kg highest of individual samples).

The Meeting estimated a medium and highest residue of 1.5 and 2.5 mg/kg, respectively, for propiconazole in oat forage.

Fifteen trials were conducted in wheat forage, gave total propiconazole residues of 1.2 (2), 1.3, 1.4, 1.6, 1.9, 2.1, 2.2, 2.8, 3.0, 3.4, 3.8, 3.9, 4.8 and 9 mg/kg.

The Meeting estimates a medium and highest residue of 2.2 and 9 mg/kg, respectively, for propiconazole in wheat forage.

Hay

Nine trials were conducted in barley hay with propiconazole residues of 0.19, 0.44, 0.73, 0.78, 0.81, 1.7, 2.2, 3.0 and 4.2 mg/kg. Total propiconazole residues were: 2.1, 2.6, 2.7, 4.0, 4.3, 6.2, 10, 11 and 12 mg/kg (highest 13 mg/kg).

The Meeting estimated a maximum residue level of 8 mg/kg for propiconazole in barley straw and fodder, dry. The Meeting also estimated medium and highest residue of 4.3 and 13 mg/kg, respectively, for propiconazole in barley hay.

In the 11 trials conducted with oat hay, according to US GAP, propiconazole residues were: 0.18, 0.24, 0.35, 1.1, 1.2, 1.4, 2.0, 2.4, 3.6, 4.2 and 4.5 mg/kg. Total propiconazole were: 0.80, 0.90, 1.1, 2.7, 3.2, 3.3, 4.8 (2), 6.2, 7.7 and 8.5 mg/kg.

The Meeting estimated a maximum residue level of 8 mg/kg for propiconazole in oat straw and fodder, dry. The Meeting also estimated a medium and highest residue of 3.3 and 8.5 mg/kg, respectively, for propiconazole in oat hay.

In 15 trials conducted in wheat hay, propiconazole residues were: 0.44, 0.75, 1.1, 1.3, 1.6, 1.9, 2.0 (2), 2.2, 2.8. 3.0, 3.3, 4.2, 5.4 and 9.6 mg/kg. Total propiconazole were: 2.0, 3.2, 3.4, 4.0, 4.1, 4.3, 4.4, 5.3, 6.7, 7.9, 9.3, 10 (2),12 and 21 mg/kg (highest of 22 mg/kg).

Taking into account the trials conditions, the Meeting concluded that the residues measured in hay are applicable for sraw and fodder, and recommended a maximum residue level of 15 mg/kg for propiconazole in wheat straw and fodder, dry, and extend this estimation for rye and straw and

fodder, dry. The Meeting also estimates a medium and highest residue of 5.3 and 2.2 mg/kg, respectively, for propiconazole in wheat hay.

The Meeting withdrew its previous maximum residue level recommendation for barley, rye, triticale and wheat straw of 2 mg/kg.

Residues in animal commodities

One cow and one poultry study were evaluated by the 2007 JMPR, and only the relevant information from these studies are summarized in this appraisal.

Lactating dairy cows

Dairy cows were dosed once daily either in the feed with propiconazole at 15 ppm, 75 ppm and 150 ppm for 14–28 consecutive days. No parent propiconazole was detected in any milk (< 0.01 mg/kg), muscle and kidney samples (< 0.05 mg/kg) at all feeding levels. The maximum level in liver was 0.14 mg/kg at the 15 ppm feeding level and 0.34 mg/kg in the 75 ppm feeding level; in fat it was < 0.05 mg/kg at the 15 ppm and 75 ppm feeding levels.

No total propiconazole (< 0.01 mg eq./kg) was found in milk at 15 ppm; at 75 ppm, the average was 0.044 mg eq./kg (maximum of 0.08 mg eq./kg). In muscle, no total propiconazole (< 0.05 mg/kg) was detected at 15 ppm and the maximum level was 0.11 mg/kg at the 75 ppm (average 0.08 mg/kg). In liver, residues were 0.81 mg/kg at the 15 ppm (average 0.63 mg/kg) and 4.3 mg/kg in the 75 ppm (average 3.7 mg/kg). In kidney, it was 0.63 mg/kg at the 15 ppm (average 0.60 mg/kg) and 4.7 mg/kg in the 75 ppm (average 3.8 mg/kg). In fat it was < 0.05 mg/kg at the 15 ppm and 0.23 mg/kg at the 75 ppm feeding level (average 0.15 mg/kg).

Laying hens

Hens were fed propiconazole at 7.5, 37.5 and 75 ppm in the feed. No propiconazole residues (< 0.05 mg/kg) were found in the eggs or the tissue sample analysed, regardless of feeding level.

At 7.5 ppm, no total propiconazole was detected in eggs, muscle, fat (< 0.05 mg/kg) and liver (< 0.1 mg/kg). At 37.5 ppm, residues reached 0.18 mg/kg in eggs, 0.16 mg/kg in liver and 0.07 mg/kg in fat, but no residues were detected in muscle.

Farm animal dietary burden

The Meeting estimated the dietary burden of propiconazole (as total propiconazole) in farm animals on the basis of the OECD Animal Feed data published in the 2009 FAO Manual, the STMR, STMR-Ps or highest residue levels estimated at the present and by the 2007 JMPR. Dietary burden calculations are provided in Annex 6 of the 2014 Report.

	US-Canada		**EU**		**Australia**		Japan	
Commodity	**Max**	Mean	**Max**	Mean	**Max**	Mean	**Max**	Mean
Beef cattle	3.9	2.1	15.9	4.3	36 [a]	12 [c]	10.1	1.62
Dairy cattle	15.8	7.2	13.5	4.0	29 [b]	12 [d]	10.5	5.56
Poultry – broiler	0.5	0.51	0.1	0.11	0.005	0.005		
Poultry – layer	0.51	0.51	5.1 [e]	1.88 [f]	0.005	0.005		

[a] Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues
[b] Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk
[c] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.
[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.
[e] Highest maximum poultry dietary burden suitable for maximum residue level estimated for poultry tissues and eggs.
[f] Highest mean poultry dietary burden suitable for STMR estimated for poultry tissues and eggs

Animal commodity estimations

Propiconazole residues, for the estimation of *maximum residue level*

	Feed level for milk or egg, ppm	Residues, mg/kg	Feed level for tissues, ppm	Residues, mg/kg			
				Muscle	Liver	Kidney	Fat
Maximum residue level for cattle							
Feeding study	15 75	< 0.01 < 0.01	15 75	< 0.01 < 0.01	0.14 0.34	< 0.01 < 0.01	< 0.05 < 0.05
Dietary burden and highest residue	29	< 0.01	36	< 0.01	0.25	< 0.01	< 0.05
Maximum residue level for poultry							
Feeding study	7.5	< 0.05	7.5	< 0.05	< 0.05		< 0.05
Dietary burden and highest residue	5.1	< 0.05	4.6	< 0.05	< 0.05		< 0.05

Total propiconazole residues, for the estimation of HR and STMR

	Feed level for milk or egg, ppm	Residues, mg/kg	Feed level for tissues, ppm	Residues, mg/kg			
				Muscle	Liver	Kidney	Fat
HR for cattle							
Feeding study			15 75	< 0.05 0.11	0.81 4.3	0.63 4.7	< 0.05 0.23
Dietary burden and highest residue			36	0.085	1.97	1.9	0.115
STMR for cattle							
Feeding study	15	0.044	15	0.08	0.63	0.60	< 0.05
Dietary burden	12	0.035	12	0.064	0.504	0.50	< 0.05
HR for poultry							
Feeding study	7.5	< 0.05	7.5	< 0.05	< 0.05		< 0.05
Dietary burden and highest residue	5.1	< 0.05	4.6	< 0.05	< 0.05		< 0.05
STMR for poultry							
Feeding study	7.5	< 0.05	7.5	< 0.05	< 0.05		< 0.05
Dietary burden	1.88	< 0.05	4.6	< 0.05	< 0.05		< 0.05

The maximum dietary burden for the estimation of maximum residue levels in cattle tissue and milk were 36 and 29 ppm, respectively. The Meeting confirmed its previous recommendation of 0.01* mg/kg for propiconazole in milks and meat (from mammals other than marine mammals) and estimated a maximum residue level of 0.5 mg/kg for edible offal (mammalian) and of 0.01* mg/kg in mammalian fat (except milk fats).

The Meeting withdrew the previous recommendation of 0.01* mg/kg for propiconazole in edible offal (mammalian).

The maximum dietary burden for the estimation of HR in cattle tissues was 36 ppm. Based on the feeding levels at 15 and 75 ppm, the Meeting estimated HRs of 0.085 mg/kg in meat (from mammals other than marine mammals), of 1.97 mg/kg in edible offal (mammalian) and of 0.115 mg/kg in mammalian fat (except milk fats).

The mean dietary burden for the estimation of STMR levels in cattle tissues and milk was 12 ppm. Based on the feeding study conducted at 15 ppm, the Meeging estimated a STMR of 0.035 mg/kg in milks, 0.064 mg/kg im meat (from mammals other than marine mammals), 0.504 mg/kg in edible offal and 0.05 mg/kg in mammalian fat.

The highest calculated dietary burden for poultry was 35.1 ppm. In eggs, muscle and fat no propiconazole or total propiconazole residues were detected at the 7.5 ppm feeding level. The Meeting confirms its previous recommendation of a maximum residue level of 0.01* mg/kg for

propiconazole in poultry meat and eggs, and a STMRs and HRs of 0.05 mg/kg in eggs, muscle and fat.

RECOMMENDATIONS

Residues: For plant and animal commodities is *propiconazole* for compliance with the MRL and *propiconazole plus all metabolites convertible to 2,4-dichlorobenzoic acid, expressed as propiconazole* for the estimation of the dietary intakes.

The residue is fat soluble

DIETARY RISK ASSESSMENT

Long-term intake

The IEDI of propiconazole based on the STMRs estimated by this and previous Meetings for the 17 GEMS/Food regional diets were 1–10% of the maximum ADI of 0.07 mg/kg bw (see Annex 3 of the 2014 Report). The Meeting concluded that the long-term dietary intake of residues of propiconazole is unlikely to present a public health concern.

Short-term intake

An ARfD for propiconazole is 0.3 mg/kg bw. The International Estimated Short-Term Intake (IESTI) of propiconazole for the commodities for which STMR, HR and maximum residue levels were estimated by the current Meeting. The results are shown in Annex 4 of the 2014 Report. The IESTI represented a maximum of 8% of the ARfD. The Meeting concluded that the short-term intake of propiconazole residues from uses considered by the current Meeting was unlikely to present a public health concern.