5.15 HEXYTHIAZOX (176)

RESIDUE AND ANALYTICAL ASPECTS

Hexythiazox is a non-systemic insecticide and miticide first evaluated by the JMPR in 1991 and a number of times subsequently. It was recently reviewed for toxicology by the 2008 JMPR within the periodic review program of the CCPR. An ADI of 0–0.03 mg/kg bw was established. An ARfD was not considered necessary by the Meeting. It was then reviewed for residues by the 2009 JMPR as part of the periodic review program. Additional GAP information, analytical method (hops only), residue data and processing information for strawberries, hops and tea were submitted for evaluation by the present Meeting.

Analytical methods

The 2011 Meeting received additional information on the analysis of hexythiazox in hops.

The method submitted involves analysis of hexythiazox in combination with the metabolite trans-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine (PT-1-3) using gas chromatography and either ECD or MSD detection. The data indicated a very high recovery (> 150%), when external standard in solvent is used. Matrix based external standard gave acceptable recoveries of 110% up to 115%. The LOQ for this method was validated at 0.5 mg/kg.

Stability of pesticide residues in stored analytical samples

The 2011 Meeting received additional information on the storage stability in hops and beer.

Although the procedural recoveries gave some variation during the whole storage period, the Meeting concluded that hexythiazox residues in hops (fresh and dry) and spent hops are stable for at least 24 months.

In beer a significant degradation was observed after 12 months or more. The Meeting concluded that hexythiazox in beer is stable for a period of up to 6 months only, still providing more than 70% of the initial residue remaining.

Results of supervised trials on crops

New data were submitted for strawberries, hops and tea.

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided.

Strawberries

In the USA hexythiazox is approved for use on strawberries with one spray application at 0.21 kg ai/ha and a PHI of 3 days. Various supervised field trials were submitted involving treatment of strawberries at lower and higher application rates. At a PHI of 3 days, hexythiazox residues in fruit were:

- for 0.07 kg ai/ha: 0.18 mg/kg
- for 0.14 kg ai/ha: 0.19 mg/kg
- for 0.17 kg ai/ha: 0.50 mg/kg

- for 0.21 kg ai/ha: 0.13, 0.17, 0.3, 1.8 mg/kg
- for 0.28 kg ai/ha: 0.87, 5.5 mg/kg.

However, the five data points matching the US GAP (± 25%: application rates 0.17–0.21 kg ai/ha) are not sufficient to estimate a maximum residue level. Applying the principle of proportionality to the US data set, the residues in strawberries following scaling were:

- for 0.07 kg ai/ha (scaling factor 3) 0.07➔0.21 kg ai/ha: 0.54 mg/kg
- for 0.14 kg ai/ha (scaling factor 1.5) 0.14➔0.21 kg ai/ha: 0.29 mg/kg
- for 0.17 kg ai/ha (scaling factor 1.23) 0.17➔0.21 kg ai/ha: 0.62 mg/kg
- for 0.21 kg ai/ha (no scaling): 0.13, 0.17, 0.3, 1.8 mg/kg
- for 0.28 kg ai/ha (scaling factor 0.75) 0.28➔0.21 kg ai/ha: 0.65, 4.1 mg/kg.

The total range of residues in strawberry fruits (n = 9) was: 0.13, 0.17, 0.29, 0.30, 0.54, 0.62, 0.65, 1.8 and 4.1 mg/kg.

The application of proportionality resulted in nine data points being available to estimate a maximum residue level. Based on the total dataset, according to the US GAP, the Meeting estimated a maximum residue level of 6 mg/kg for hexythiazox in strawberries and an STMR of 0.54 mg/kg.

Hops, dry

In Germany hexythiazox is approved for use on hops as a single application at 0.0045 kg ai/hL with a PHI of 28 days. In corresponding supervised field trials conducted in Germany residues in dried hops were (n = 9): 0.61, 0.64, 0.71, 0.79, 0.79, 0.88, 0.93, 1.3 and 1.5 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg for hexythiazox in hops (dried cones) and an STMR of 0.79 mg/kg.

Tea

For tea a GAP from India was reported involving two treatments at 0.025 kg ai/ha each with no specified PHI. Eight Indian supervised field trials carried out in 2008 and 2009 corresponding to this GAP were submitted.

The residue in dry tea green or black, fermented) after 0 days were (n = 8): 3.2, 3.7, 4.1, 4.5, 4.6, 4.8, 4.9 and 5.2 mg/kg.

The Meeting estimated a maximum residue level of 15 mg/kg for hexythiazox in tea (green or black, fermented) and an STMR of 4.55 mg/kg.

Fate of residues during processing

The Meeting received information on the fate of hexythiazox residues during the processing of strawberries to canned fruits and jam, of hops to beer and of tea to tea infusions. The processing factors and the derived STMR-P values are summarized as follows:

RAC	Processed commodity	Calculated processing factors	PF (median or best estimate)	RAC STMR, mg/kg	STMR-P mg/kg
Strawberry	Canned fruit	0.36, 0.4, 0.52, 0.99	0.46	0.54	0.248
	Jam	0.5, 0.54, 0.79, 1.1	0.665	0.54	0.359
Hops	Beer	< 0.03, < 0.04, < 0.05, < 0.06	<0.045	0.79	0.036
Tea	Infusion, green tea	0.02(3), < 0.03, 0.03(5), < 0.04, 0.04(4), 0.05, 0.05, 0.06, 0.06, < 0.07, < 0.08, < 0.09, < 0.1, < 0.1, < 0.25	0.04	4.55	0.182

RAC	Processed commodity	Calculated processing factors	PF (median or best estimate)	RAC STMR, mg/kg	STMR-P mg/kg
	Infusion, fermented tea	0.01, 0.02(6), 0.03(6), <0.04, 0.05, 0.05, < 0.07, 0.07, < 0.08, < 0.09, < 0.1, < 0.1, < 0.25, 0.34	0.03	4.55	0.137

Residues in animal commodities

Since strawberries, hops or tea are not potential animal feed items, the recommendations for animal commodities as made by the 2009 Meeting are still valid.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of hexythiazox were calculated for the 13 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the JMPR in 2009 and the current Meeting. The ADI is 0–0.03 mg/kg bw and the calculated IEDIs were 0–3 % of the maximum ADI. The results are shown in Annex 3. The Meeting concluded that the long-term intakes of residues of hexythiazox, resulting from the uses considered by the JMPR, are unlikely to present a public health concern.

Short-term intake

The 2008 Meeting decided that an ARfD for hexythiazox is unnecessary and concluded that the short-term intake of residues resulting from the use of hexythiazox is unlikely to present a public health concern.