5.25 TOLFENPYRAD (269)

RESIDUE AND ANALYTICAL ASPECTS

Tolfenpyrad is a broad spectrum insecticide and a miticide, with contact activity against target pests on eggs, larvae, nymphs, and adults. It also has anti-feeding activity on lepidopteran insects. It belongs to the pyrazole class of insecticides. It has activity against several economically important insect pests of vegetables, fruits, nuts, vines and row crops. It was first evaluated by JMPR in 2013 for toxicology and residues. The 2013 Meeting established an ADI of 0–0.006 mg/kg bw and an ARfD of 0.01 mg/kg bw, and an MRL for green tea was recommended.

Tolfenpyrad was listed by the 47th Session of the CCPR for the evaluation of additional uses. The current Meeting received information on the latest use patterns and supervised residue trials on potato and tree nuts conducted in the USA.

The 2013 JMPR recommended the following definition for tolfenpyrad:

Definition of the residue for compliance with the MRL and estimation of dietary intake for plant commodities: *Tolfenpyrad*.

Definition of the residue for compliance with the MRL and estimation of dietary intake for animal commodities: *sum of tolfenpyrad and free and conjugated PT-CA* (4-[4-[(4-chloro-3-ethyl-1-methylpyrazol-5-yl)carbonylaminomethyl] phenoxy]benzoic acid and OH-PT-CA (4-[4-[[4-chloro-3-(1-hydroxyethyl)-1-methylpyrazol-5-yl]carbonylaminomethyl]phenoxy] benzoic acid) (released with alkaline hydrolysis) expressed as tolfenpyrad.

The residue is not fat soluble.

Results of supervised residue trials on crops

The current Meeting received information on the latest use patterns and supervised residue trials for foliar application of tolfenpyrad on potato and tree nuts conducted in the USA. For estimating HR or highest residue, the highest individual residue value from the trials conducted in accordance with GAP was used.

Potatoes

The GAP for tolfenpyrad on <u>potato</u> in the USA is two foliar spray applications at 230 g ai/ha with a re-treatment interval of 14 days and a 14-day PHI. A total of sixteen supervised trials on potato were conducted in the USA. The residues of tolfenpyrad in potato from fifteen independent trials in accordance with US GAP were: < 0.01(15) mg/kg. The total residues of tolfenpyrad from one trial in which the application rate was 5 times the GAP rate were also < 0.01 mg/kg.

The Meeting estimated a maximum residue level, an STMR and a HR at 0.01^* , 0 and 0 mg/kg for tolfenpyrad in potato, respectively.

Tree nuts

The GAP for tolfenpyrad on <u>tree nuts</u> in the USA consists of a single foliar spray application at 310 g ai/ha and a PHI of 14 days.

Residue trials conducted in the USA in almonds and pecans were made available to the Meeting.

Tolfenpyrad

Almonds

Four independent trials were conducted on <u>almonds</u> in the USA, 2×310 g ai/ha applications. Tolfenpyrad residues in nutmeat at a 14-day PHI were < 0.01 (3) and 0.027 mg/kg (n = 4). All trials were overdosed with two applications instead of one. The Meeting noted that the trials did not match GAP and concluded that a maximum residue level could not be estimated for almonds.

Pecan

Five independent trials were conducted on <u>pecans</u> in the USA, 2×310 g ai/ha applications. Tolfenpyrad residues in nutmeat at a 14-day PHI were all < 0.01 mg/kg (n = 5). All trials were overdosed with two applications instead of one.

The Meeting noted that the additional application above GAP did not result in finite residues in pecans and considered that the data could be used for estimation of a maximum residue level. The Meeting estimated a maximum residue level, an STMR and an HR at 0.01*, 0.01 and 0.01 mg/kg respectively for tolfenpyrad_in pecan.

Animal feed

Almond hulls

The US GAP in almonds is 1×310 g ai/ha application with a 14-day PHI. Results from supervised trials on <u>almond hulls</u> conducted in the USA were provided to the Meeting. Four independent trials were conducted on almond, involving two applications at 310 g ai/ha.

The Meeting noted that the trials did not match GAP, with two applications rather than one being made. The Meeting did not estimate a maximum residue level or median residue for tolfenpyrad in almond hulls.

Fate of residues during processing

A processing study on potato was reviewed by the 2013 JMPR. One trial had an additional plot treated at an exaggerated rate $(5\times)$ with the EC formulation to provide samples for processing. Neither the RAC nor the processed fractions contained residues of tolfenpyrad and OH-PT above the LOQ of 0.01 mg/kg. Therefore, no processing factors could be calculated for potato.

Residues in animal commodities

Estimation of dietary burdens

The only commodity used as a livestock feed and for which the JMPR has estimated a maximum residue level is for potatoes; the estimated STMR and HR values are 0. Therefore the additional livestock dietary burden for tolfenpyrad is nil.

Farm animal feeding studies

As the livestock dietary burden is zero, no maximum residue levels are estimated for animal commodities.

RECOMMENDATION

On the basis of the data obtained from supervised residue trials the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and IESTI assessment

Tolfenpyrad

Definition of the residue_for compliance with the MRL and estimation of dietary intake for plant commodities: *Tolfenpyrad*.

(1-hydroxyethyl)-1-methylpyrazol-5-yl]carbonylaminomethyl]phenoxy] benzoic acid) (released with alkaline hydrolysis) expressed as tolfenpyrad.

The residue is not fat soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The evaluation of tolfenpyrad resulted in recommendations for MRLs and STMR values for potato and tree nut. Where data on consumption were available for the listed food commodities, dietary intakes were calculated from the seventeen GEMS/Food Cluster Diets. The results are shown in Annex 3 of the 2016 JMPR Report. The IEDIs in the seventeen Cluster Diets, based on the estimated STMRs were 0–8% of the maximum ADI (0.006 mg/kg bw). The Meeting concluded that the long-term exposure to residues of tolfenpyrad from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term dietary exposure

The IESTI for tolfenpyrad calculated on the basis of the recommendations made by the Meeting represented 0% of the ARfD (0.01 mg/kg bw) for children and 0% for the general population. The results are shown in Annex 4 of the 2016 JMPR Report.

The Meeting concluded that the short-term dietary exposure to residues of tolfenpyrad resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.