

5.18 IMAZAPIC (266)

RESIDUE AND ANALYTICAL ASPECTS

Imazapic is an imidazolinone herbicide for the control of grasses and broadleaf weeds. It was reviewed for the first time by JMPR in 2013 when the residue definition was established for plant and animal commodities to be imazapic for compliance with the MRL and for estimation of dietary intake (The residue is not fat soluble). The Meeting established an ADI of 0–0.7 mg/kg bw and that no ARfD was necessary.

The 2013 JMPR received and considered the plant metabolism study and supervised residue trials on transgenic soya beans; analytical methods, storage stability studies and processing studies on soya beans.

Imazapic was included in the priority list by the CCPR at its Forty-sixth Session in 2014 for evaluation for additional MRLs by this Meeting. The current Meeting received information on the registration of imazapic for application on soya bean cultivars tolerant to imidazolinone herbicides in Brazil. The information on supervised residue trials on imidazolinone-tolerant soya beans provided to the 2013 JMPR is reviewed by the current Meeting against the new GAP in Brazil.

Results of supervised residue trials on crops

The 2013 Meeting received supervised trial data for imazapic on transgenic soya beans. The current Meeting evaluated the data against the new GAP for soya bean cultivars tolerant to imidazolinone herbicides.

Soya bean (dry)

A total of 16 supervised trials were conducted on imidazolinone-tolerant soya beans (transgenic) in different years in Brazil.

The new GAP in Brazil allows a single application of a WG formulation of imazapic (also containing imazapyr) to imidazolinone-tolerant cultivars at the rate of 0.014–0.0175 kg ai/ha (in acid equivalents; for both ground and aerial application) with a PHI of 60 days. For ground applications, the water volume should be 100–200 L/ha and for the aerial application, 40–50 L/ha. The trials employed an application rate of 0.0175 kg ai/ha and the application volume of 200 L/ha.

In one trial in the 2007/2008 growing season, the samples were stored for about 600 days; imazapic was demonstrated to be stable for up to 10 months, the longest storage period tested for imazapic in soya bean. The result of this trial was < 0.01 mg/kg.

Residues arising from the independent supervised residue trials following the critical GAP in Brazil were, in rank order (n=12): < 0.01, < 0.01, < 0.05, < 0.05, 0.05, 0.07, 0.07, 0.10, 0.12, 0.15, 0.23 and 0.25 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR of 0.07 mg/kg.

Fate of residues during processing

Processing

The 2013 Meeting received information on processing of soya beans. The processing factor for imazapic in soya bean processed products is described below.

Processed commodity	N	Processing factor	Best estimate	STMR-P mg/kg
Soya bean				0.07 (STMR)
Oil	2	0.13, 0.14	0.14	0.01

The residues of imazapic concentrate marginally in defatted meal (processing factor of 1.29), and toasted defatted meal (1.14).

For the purpose of calculating the animal dietary burden, the Meeting calculated median residues for soya bean meal and hulls to be 0.09 mg/kg and 0.07 mg/kg, respectively, using the STMR of soya bean and the processing factors of 1.29 (highest of similar processed commodities) and 1.00, respectively.

Residues in animal products

Estimation of dietary burdens

The maximum and mean dietary burdens were calculated by the 2013 JMPR using the highest residues or median residues of imazapic estimated at that Meeting on a basis of the OECD Animal Feeding Table. As the highest maximum and mean dietary burden for estimating maximum residue levels and STMRs for foods of bovine origin were calculated on the basis of a ration of 100% grass forage, the inclusion of soya bean feed items, with significantly lower residue levels, would not have any measurable impact on the highest maximum and mean dietary burden.

The addition of soya bean feed items in the calculation of dietary burdens increases by approximately 0.2% the highest maximum and mean dietary burden for poultry. The highest maximum dietary burden calculated at this Meeting (9.65 ppm in feed as compared to 9.63 ppm calculated in 2013) was still lower than the dose of 10.9 ppm in the diet used in the metabolism study in which the TRR in all edible tissues were below the LOQ of 0.01 mg/kg

RECOMMENDATIONS

On the basis of the data from supervised 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.

Definition of the residue for plant and animal commodities (for compliance with the MRL and for estimation of dietary intake): *Imazapic*.

Residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of imazapic were calculated for the 17 GEMS/Food cluster diets using STMRs estimated by the 2013 JMPR and STMR/STMR-P for soya bean and soya bean oil estimated by the current Meeting (see Annex 3 to the 2015 Report). The ADI is 0–0.7 mg/kg bw and the calculated IEDIs were in the same range as those calculated by the 2013 JMPR using the 13 GEMS/Food Cluster Diet (0% of the maximum ADI). The Meeting confirmed its conclusion in 2013 that the long-term intake of residues of imazapic resulting from the uses considered by the current JMPR is unlikely to present a public health concern.

Short-term intake

The 2013 JMPR decided that an ARfD is unnecessary. The current Meeting therefore concluded that the short-term intake of residues of imazapic is unlikely to present a public health concern.