

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.

5.19 IMAZAPYR (267)

RESIDUE AND ANALYTICAL ASPECTS

Imazapyr is a broad-spectrum herbicide in the imidazolinone family. It was evaluated in the 2013 JMPR for the first time for toxicology and for residues. The 2013 JMPR allocated an ADI of 0–3 mg/kg bw; an ARfD was unnecessary. It also determined that the definition of the residue was imazapyr for plant and animal commodities (for compliance with MRLs and for estimation of dietary intake). It recommended maximum residue levels for various commodities.

The 2013 JMPR received and considered the plant metabolism study and supervised residue trials on imidazolinone-tolerant soya beans; analytical methods, storage stability studies and processing studies on soya beans. However, at the time of the 2013 JMPR, no GAP had been approved for soya beans, transgenic or not. Due to the lack of an approved GAP, it was not possible for the Meeting to estimate maximum residue level for soya beans.

Imazapyr was included on 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 analytical methods, use pattern and supervised residue trials to support estimation of maximum residue levels for soya beans and grasses.

Methods of analysis

The Meeting received information on the analytical method used for the determination of imazapyr residues in grass forage and hay. Samples were fortified with imazapyr at 0.5–50 mg/kg and analysed by capillary electrophoresis or LC-MS. The analytical method was validated; the LOQ was 0.5 mg/kg.

The freezer storage stability studies were reported on maize (grain, forage and fodder) and soya bean (seeds and processed fractions) samples in 2013. Storage stability results indicated that imazapyr residues were stable for at least 10 months in soya bean seed, at least 3 months in soya bean processed fractions (laminated soya bean, meal and oil) and at least 27 months in maize (grain, forage and fodder).

Residues resulting from supervised residue trials on crops

The 2013 Meeting received supervised trial data for the foliar application of imazapyr on soya bean (imidazolinone-tolerant) from Brazil and the current Meeting received supervised trial data on grasses from the USA.

Labels were available from Brazil and the USA describing the registered uses of imazapyr.

Soya bean (dry)

Supervised trials were conducted on imidazolinone-tolerant soya bean in Brazil.

The GAP on imidazolinone-tolerant soya bean of Brazil is a foliar application at a maximum rate of 0.053 kg ai/ha with a PHI of 60 days.

Imazapyr residues in soya bean seeds from independent trials in Brazil matching GAP were (n=12): < 0.05, 0.07, 0.11, 0.35, 0.48, 0.55, 0.83, 1.0, 1.3 (3) and 3.0 mg/kg.

Based on the residues for soya bean from trials in Brazil, the Meeting estimated a maximum residue level and an STMR value for imazapyr in soya bean seeds of 5 and 0.69 mg/kg respectively.

Animal feedstuffs

Straw, fodder and forage of grasses

Data were available from supervised trials on grasses in the USA.

The GAP on grasses in the USA is a spot application at a maximum rate of 0.84 kg ai per treated hectare with a PHI of 7 days for hay and no PHI for forage. The spot applications must not exceed more than 1/10 of the area to be grazed or cut for hay.

The trials were conducted with the broadcast foliar application to the whole trial area but the application does not correspond to the GAP. Therefore, the Meeting decided to use a factor of 0.1 to account for the difference between the application in the trials and that in the GAP for the estimation of a maximum residue level.

Calculated residues of imazapyr in forage of grasses were: 2.8, 3.3, 3.6, 3.7, 3.8, 4.4, 5.0, 5.4, 6.1, 6.5, 6.6, 6.8, 7.5 and 9.7 mg/kg.

Based on the calculated residues for forage grasses, the Meeting estimated a median residue value and a highest residue value for imazapyr in forage of grasses of 5.2 and 9.7 mg/kg, respectively on an “as received” basis.

Calculated residues of imazapyr in hay of grasses were: 0.15, 1.0, 1.1, 1.2 (3), 1.3 (2), 1.8, 1.9, 2.0, 2.2, 2.4 and 2.5 mg/kg.

Based on the calculated residues in hay grasses, the Meeting estimated a median residue value of 1.3 mg/kg, a highest residue value of 2.5 mg/kg on an as received basis and after correction for an average 88% dry matter content, estimated a maximum residue level of 6 mg/kg for imazapyr in hay of grasses.

Fate of residues during processing

Residues in processed commodities

The fate of imazapyr residues has been examined in soya bean seeds in processing studies. Estimated processing factors and the derived STMR-Ps are summarized in the Table below.

Processing factors, STMR-P for food and feed

Raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors*	PF (Mean or best estimate)	RAC STMR (mg/kg)	STMR-P (mg/kg)
Soya bean seeds	Crude oil	<0.005, <0.006, <0.008, <0.01, <0.06, <0.07	<0.009	0.69	0
	Meal	0.91, 1.0, 1.2, 1.2, 1.3, 1.3, 1.5, 1.8	1.3		0.897
	Aspirated grain fractions	0.04	0.04		0.0276
	Hulls	0.54, 0.79	0.67		0.462

* Each value represents a separate study. The factor is the ratio of the residue in processed commodity divided by the residue in the RAC.

Residue in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of imazapyr in farm animals on the basis of the diets listed in Appendix IX of the FAO Manual 2009. Calculations derived from highest residue, STMR (some bulk commodities) and STMR-P values provide estimations of levels in feed suitable for estimating MRLs, while calculations from STMR and STMR-P values for feed is suitable for estimating STMR values for animal commodities. The percentage dry matter is taken as 100% when the highest residue levels and STMRs are already expressed on a dry weight basis.

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are provided in Appendix IX of the FAO manual. The calculations were made according to the animal diets from US-Canada, EU, Australia and Japan in the Table (Appendix IX of the FAO manual).

Since the GAP for grasses is only registered in the USA, median residue value and highest residue value in forage of grasses are used only for the calculation of dietary burden in US-Canada.

Livestock dietary burden, imazapyr, ppm of dry matter diet								
	US-Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0.61	0.40	1.7	1.0	2.8	1.5	1.7	1.2
Dairy cattle	18a	9.6bc	2.0	1.2	2.0	1.2	2.3	1.3
Poultry – broiler	0.43	0.43	0.57	0.57e	0.37	0.37	0.38	0.38
Poultry – layer	0.43	0.43	0.68d	0.54	0.37	0.37	0.33	0.33

^a Highest maximum cattle dietary burden suitable for MRL estimates for mammalian meat, fat, edible offal and milk

^b Highest mean cattle dietary burden suitable for STMR estimates for mammalian meat, fat and edible offal

^c Highest mean dairy cattle dietary burden suitable for STMR estimates for milk

^d Highest maximum poultry dietary burden suitable for MRL estimates for poultry meat, fat, edible offal and eggs

^e Highest mean poultry dietary burden suitable for STMR estimates for poultry meat, fat, edible offal and eggs

Farm animal feeding studies

The 2013 JMPR received a lactating dairy cow feeding studies using imazapyr, which provided information on likely residues resulting in animal commodities and milk from imazapyr residues in the animal diet.

A poultry feeding study was not submitted as the expected residues of imazapyr in poultry feed were low. A poultry metabolism study at a dose rate of 9.7 ppm imazapyr in feed demonstrated that there was very low transfer to eggs and tissues with all residues of imazapyr less than 0.01 mg/kg.

Animal commodities maximum residue levels

For MRL estimations, the residue in the animal commodities is imazapyr.

Residues in tissues and milk at the expected dietary burden for dairy cattle are shown in the Table below. The mean estimated residue in milk was calculated using the residue values of day 3 to the final day.

	Feed level (ppm) for milk residues	Residues (mg/kg) in milk	Feed level (ppm) for tissue residues	Residues (mg/kg) in			
				Muscle	Liver	Kidney	Fat
MRL beef or dairy cattle							
Feeding study	58	0.013	58	< 0.05	< 0.05	0.36	< 0.05
Dietary burden and residue estimate	18	0.004	18	< 0.05	< 0.05	0.11	< 0.05
STMR beef or dairy cattle							
Feeding study	58	0.010	58	< 0.05	< 0.05	0.25	< 0.05
Dietary burden and residue estimate	9.6	0.001	9.6	< 0.05	< 0.05	0.041	< 0.05

For beef and dairy cattle, the calculated maximum dietary burden is 18 ppm dry weight of feed.

Based on the highest estimated residue in milk (0.004 mg/kg), the Meeting estimated a maximum residue level of 0.01 (*) mg/kg in milk. The Meeting confirmed the previous recommendation for milks.

Based on the highest estimated residue in kidney (0.11 mg/kg), the Meeting estimated a maximum residue level of 0.2 mg/kg in mammalian edible offal to replace the previous recommendation for mammalian edible offal of 0.05 (*) mg/kg.

Based on the mean estimated residues in kidney, the Meeting estimated an STMR value of 0.041 mg/kg in edible offal.

In the lactating dairy cow feeding study, imazapyr residues in meat and fat were less than the LOQ (0.05 mg/kg) at the dose level of 58 and 157 ppm. The mean cattle dietary burden of 9.6 ppm is still lower than the both dose level.

The Meeting confirmed the previous recommendations for mammalian meat and fat.

The maximum dietary burden for broiler and layer poultry is 0.68 ppm and is lower than the dose level in the laying hen metabolism study of 9.7 ppm. In the metabolism study, in which imazapyr equivalent to 9.7 ppm in the diet was dosed to laying hens for 7 consecutive days, no residues of imazapyr exceed 0.01 mg/kg were detected in tissues and eggs.

The Meeting confirmed the previous recommendations for poultry meat, fat, edible offal and eggs.

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for estimating 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): *Imazapyr*

The residue is not fat soluble

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of imazapyr were calculated for the 17 GEMS/Food cluster diets using STMRs/STMR-Ps estimated by the 2013 JMPR and the current Meeting (Annex 3 to the 2015 Report). The ADI is 0-3 mg/kg bw and the calculated IEDIs were 0% of the maximum ADI (3 mg/kg bw). The Meeting concluded that the long-term intakes of residues of imazapyr, resulting from the uses considered by current JMPR, are unlikely to present a public health concern.

Short-term intake

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