

IMAZAPYR (267)

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EXPLANATION

Imazapyr is a broad-spectrum herbicide in the imidazolinone family. It was evaluated at the 2013 JMPR for the first time for toxicology and residues. The 2013 JMPR allocated an ADI of 0-3 mg/kg bw, and ARfD was considered unnecessary. It also determined that the definition of 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; and 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, regardless of transgenic or not. Due to the lack of approved GAP, the Meeting did not estimate a maximum residue level for soya beans.

Imazapyr was included on the priority list by the CCPR at the 46th Session in 2014 for evaluation for additional MRLs by this Meeting. The current Meeting received information on analytical methods, use patterns and supervised residue trials to support estimation of maximum residue levels for soya bean and grasses.

RESIDUE ANALYSIS

Analytical methods

The Meeting received information on the analytical method (Method M3023) for the determination of imazapyr in grass, forage and hay (Fletcher, 1999: IZ-244-011).

Residues of imazapyr were extracted from forage and hay of grass with acidic acetone-water (50:148:2 acetone/water/conc. hydrochloric acid). After centrifugation, a 20 mL aliquot was partitioned with dichloromethane. The dichloromethane layer was subsequently cleaned up on a SCX cartridge followed by a RP102 cartridge. The eluted sample was evaporated to dryness and re-dissolved in water for capillary electrophoresis analysis or LC-MS confirmatory analysis.

The M3023 method was validated for the determination of residues of imazapyr in grass, forage and hay. The results were summarized in Table 1. The LOQ for imazapyr was 0.5 mg/kg.

Table 1 Recovery results obtained for the determination of imazapyr by the method M3023

Commodity	Fortification level (mg/kg)	N	Recovery (%)	Mean recovery (%)	Reference Method
Grass, forage	0.5	2	81, 85	83	IZ-244-011 M 3023
	1.0	2	82, 82	82	
	5.0	2	85, 86	86	
	50	2	86, 88	87	
Grass, hay	0.5	2	81, 85	83	
	1.0	2	82, 85	84	
	5.0	2	81, 87	84	
	50	2	86, 86	86	

USE PATTERN

The Meeting received labels from Brazil and the USA. The authorized uses relevant to the supervised residue trials data submitted to the current Meeting are summarized in Table 2.

Table 2 Registered uses of imazapyr relevant to the residue evaluation by the current Meeting

Crop	Country	Formulation		Application				PHI, days
		Type	Conc. of imazapyr	Method	Rate kg ai/ha	Volume L/ha	No. max	
Pulses								
Soya bean (imidazolinone-tolerant)	Brazil	WG	525 g/kg	Ground application	0.042-0.053	100-200	1	60
				Aerial application	0.042-0.053	40-50	1	
Straw, fodder and forage of cereal grains and grasses (including buckwheat fodder)								
Bermudagrass and Bahiagrass	USA	SL	278 g/L	Ground application ^a	0.035-0.84 ^b	47-935	1	7 ^c
				Aerial application ^a	0.035-0.84 ^b	19-281	1	7 ^c

^a Spot applications: may not exceed more than 1/10 of the area to be grazed or cut for hay.

^b Rate per treated hectare

^c Do not cut forage grass for hay for 7 days after application. There are no grazing restrictions.

RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

The Meeting received information on imazapyr supervised field trials for the following crops.

Group	Commodity	Table
Pulses	Soya bean (dry)	Table 3
Straw, fodder and forage of grasses	Grasses	Table 4

Imazapyr formulation was applied by foliar treatment. Each of the field trial sites generally consisted of an untreated control plot and a treated plot. Residues, application rates and spray concentrations have generally been rounded to two significant figures.

Residue values from the trials, which have been used for the estimation of maximum residue levels, STMRs and HRs, are underlined.

Laboratory reports included method validation with procedural recoveries from spiking at residue levels similar to those occurring in samples from the supervised trials. Date of analyses and duration of residue sample storage were also provided. Although trials included control plots, no control data are recorded in the tables except when residues were found in samples from control plots. Residue data are not corrected for percent recovery.

Conditions of the supervised residue trials were generally well reported in detailed field reports. Most field reports provided data on the sprayers used, plot size, field sample size and sampling date.

Pulses

Soya bean (dry)

The 2013 Meeting received supervised residue trials on imidazolinone-tolerant soya bean conducted in Brazil, which were summarized in the Evaluation of the 2013 JMPR. Table 3 was reproduced to add information related to the application of imazapyr.

Table 3 Imazapyr residues on imidazolinone-tolerant soya bean seeds from supervised trials in Brazil

Soya bean, seed country, year (variety)	Application							DALA Days	Residues, mg/kg	Ref
	Form	kg ai/ha	kg ai/hL	water, L/ha	Growth Stage ^a		no.			
					ap- plica- -tion	harvest				
GAP, Brazil	WG	0.042-0.053		100-200 (ground) 40-50 (aerial)			1	60		
Brazil, 2007 Santo Antônio de Goiás/GO ^b (CV 603)	SL	0.072		200	77 71 66 59 39	97 97 97 97 97	1	40 60 80 100 120	1.8 1.7 2.0 < 0.05 < 0.05	2008/1097472 Resende, 2008 Sampling to analysis: 46-87 days
Brazil, 2007 Santo Antônio de Goiás/GO ^c (CV 603)	SL	0.072		200	67	97	1	60	1.4	
Brazil, 2007 Uberaba/MG ^d (CV 603)	SL	0.072		200	78 73 51 29 19	97 97 97 97 97	1	40 60 80 100 120	1.7 1.3 1.5 0.05 < 0.05	
Brazil, 2007 Uberaba/MG ^e (CV 603)	SL	0.072		200	73	97	1	60	2.0	
Brazil, 2007 Brasília/DF (CV 603)	SL	0.072		200	75	97	1	60	1.9	
Brazil, 2007 Santo Antônio de Posse/SP ^f (CV 603)	SL	0.072		200	72	89	1	60	0.92	
Brazil, 2007 Santo Antônio de Posse/SP ^g (CV 603)	SL	0.072		200	29 24 18 15 12	89 89 89 89 89	1	40 60 80 100 120	0.06 0.41 0.08 < 0.05 < 0.05	
Brazil, 2007 Londrina/PR (CV 603)	SL	0.072		200	71	86	1	60	< 0.05	
Brazil, 2007 Santo Antônio de Goiás/GO ^h (CV 603)	WG	0.053		200	77 71 66 59 39	97 97 97 97 97	1	40 60 80 100 120	1.4 0.45 0.30 0.07 < 0.05	2008/1097470 Resende, 2008 Sampling to analysis: 49-65 days
Brazil, 2007 Santo Antônio de Goiás/GO ⁱ (CV 603)	WG	0.053		200	71	97	1	60	1.3	
Brazil, 2007 Uberaba/MG ^j (CV 603)	WG	0.053		200	77 73 51 29 19	97 97 97 97 97	1	40 60 80 100 120	2.3 2.5 0.09 < 0.05 < 0.05	
Brazil, 2007 Uberaba/MG ^k (CV 603)	WG	0.053		200	73	97	1	60	3.0	
Brazil, 2007 Brasília/DF	WG	0.053		200	75	97	1	60	1.3	

Soya bean, seed country, year (variety)	Application							DALA Days	Residues, mg/kg	Ref
	Form	kg ai/ha	kg ai/hL	water, L/ha	Growth Stage ^a		no.			
					applica- -tion	harvest				
(CV 603)										
Brazil, 2007 Santo Antônio de Posse/SP ^l (CV 603)	WG	0.053		200	78 72 65 53 38	89 89 89 89 89	1	40 60 80 100 120	0.85 0.48 0.08 < 0.05 < 0.05	
Brazil, 2007 Santo Antônio de Posse/SP ^m (CV 603)	WG	0.053		200	24	89	1	60	0.27	
Brazil, 2007 Londrina/PR (CV 603)	WG	0.053		200	67	86	1	60	< 0.05	
Brazil, 2008 Santo Antônio de Posse/SP (CV 127)	WG	0.053	0.026	200	79-83 75 66 51 13	86 86 86 86 86	1	40 60 80 100 120	0.10 0.07 0.01 < 0.01 < 0.01	2010/1010261 2010/1079212 Sampling to analysis: 613 days
Brazil, 2010 Ponta Grossa /PR (L 08)	WG	0.053	0.026	200	83 75 68 66	91 91 91 91	1	20 40 60 80	< 0.01 0.07 0.90 1.0	2010/1127505 Jones, 2011
Brazil, 2010 Santo Antônio de Posse/SP (CV 127)	WG	0.053	0.026	200	89 87 77 73	89 89 89 89	1	20 40 60 80	< 0.01 < 0.01 0.35 0.20	Sampling to analysis: 27-78 days
Brazil, 2011 Ponta Grossa /PR (BRZ 08-200151)	WG	0.053	0.026	200	79 75 73 64 62	83 83 83 83 83	1	20 40 60 80 100	< 0.01 < 0.01 0.26 0.83 0.25	2012/3000423 Jones, 2012
Brazil, 2011 Senador Canedo/PR (BRZ 5384)	WG	0.053	0.026	200	66	87	1	60	0.11	Sampling to analysis: 162-273 days
Brazil, 2011 Anápolis/GO (BRZ 5384)	WG	0.053	0.026	200	69	85	1	60	0.07	
Brazil, 2011 Santo Antônio de Posse/SP (BRZ 5384))	WG	0.053	0.026	200	73	89	1	60	1.3	
Brazil, 2011 Castro/PR (BRZ 08-200151	WG	0.053	0.026	200	71	83	1	60	0.55	

^a Code of BBCH Scale^b Test site: Rodovia Goiânia, km 12 - Nova Veneza. Planting: 7/11/2006 – Harvest 6/4/2007^c Test site: Rodovia Goiânia, km 12 - Nova Veneza. Planting: 7/11/2006 – Harvest 6/4/2007^d Test site: Rua Afonso Rato, 301. Planting 21/11/2006 – Harvest 13/4/2007^e Test site: Rua Afonso Rato, 301. Planting 21/11/2006 – Harvest 14/4/2007^f Test site: Rodovia SP 340, km 144. Planting 11/11/2006 – Harvest 31/3/2007^g Test site: Rodovia SP 340, km 144. Planting 11/11/2006 – Harvest 31/3/2007^h Test site: Rodovia Goiânia, km 12 - Nova Veneza. Planting: 7/11/2006 – Harvest 6/4/2007ⁱ Test site: Rodovia Goiânia, km 12 - Nova Veneza. Planting: 7/11/2006 – Harvest 6/4/2007

^j Test site: Rua Afonso Rato, 301. Planting 21/11/2006 – Harvest 13/4/2007

^k Test site: Rua Afonso Rato, 301. Planting 21/11/2006 – Harvest 14/4/2007

^l Test site: Rodovia SP 340, km 144. Planting 11/11/2006 – Harvest 31/3/2007

^m Test site: Rodovia SP 340, km 144. Planting 11/11/2006 – Harvest 31/3/2007

Straw, fodder and forage of grasses

Fourteen field trials were conducted in the USA to determine the residue level of imazapyr on grasses. The SL formulation was applied once as broadcast foliar application. Samples of forage were collected at 0 (pre-treatment), 0.1, 7, 14, 28 and 56 days after application. Hay samples were collected on the same day as forage and left to dry before being sampled. Residue concentrations were not adjusted for moisture content and expressed on as received basis.

The Method M 3023 was used for analysis of imazapyr residues in grass forage and hay samples quantifying the analyte by capillary electrophoresis with an LOQ of 0.50 mg/kg.

Table 4 Imazapyr residues on grass from supervised trials

Grass country, year (variety)	Application					DALA Days	Residues ^a , mg/kg	Ref
	Form	kg ai/ha	water, L/ha	Analytical portion	no.			
GAP, USA		0.035-0.84			1	7 (hay) no restriction (forage)		
USA, 1996 York/NE (bluegrass)	SL	0.83	185	Forage	1	0.1 7 14 28	65, 66 (66) 6.0, 6.6 (6.3) 4.3, 4.5 (4.4) 2.3, 2.6 (2.5)	IZ-731-029 Khunachak, 1999 Sampling to analysis: 378-409 days
				Hay	1	0.1 7 14 28	75, 88 (82) 17, 20 (19) 9.8, 10 (9.9) 4.4, 4.6 (4.5)	
USA, 1996 Newport/AR (common bermudagrass)	SL	0.83	186	Forage	1	0.1 7 14 28	32, 42 (37) 7.4, 7.9 (7.6) 3.9, 4.3 (4.1) 1.5, 1.5 (1.5)	IZ-731-019 Khunachak, 1998 Sampling to analysis: 301-323 days
				Hay	1	0.1 7 14 28	112, 115 (113) 18, 18 (18) 8.2, 8.3 (8.3) 2.0, 2.1 (2.1)	
USA, 1996 Hawkinsville/GA (common bermudagrass)	SL	0.84	243	Forage	1	0.1 7 14 28	50, 57 (54) 6.8, 9.9 (8.3) 4.3, 5.4 (4.8) 0.72, 0.95 (0.84)	IZ-731-022 Khunachak, 1998 Sampling to analysis: 310-339 days
				Hay	1	0.1 7 14 28	111, 151 (131) 13, 13 (13) 9.1, 11 (9.9) 2.2, 2.3 (2.2)	
USA, 1996 Payette/ID (tall fescue grass)	SL	0.85	264	Forage	1	0.1 7 14 28 58	38, 38 (38) 3.6, 3.9 (3.7) 1.6, 1.6 (1.6) 1.0, 1.1 (1.1) < 0.50	IZ-731-023 Khunachak, 1998 Sampling to analysis: 298-350 days
				Hay	1	0.1 7 14 28 58	132, 168 (150) 9.5, 15 (12) 4.5, 4.9 (4.7) 2.5, 2.6 (2.5) 0.66	
USA, 1996 Sears/MI (bromegrass)	SL	0.83	208	Forage	1	0.1 7 14 28	33, 34 (33) 0.59, 0.81 (0.70) < 0.50, < 0.50 < 0.50, < 0.50	IZ-731-024 Khunachak, 1998

Grass country, year (variety)	Application					DALA Days	Residues ^a , mg/kg	Ref
	Form	kg ai/ha	water, L/ha	Analytical portion	no.			
				Hay	1	0.1 7 14 28	65, 65 (65) 0.88, 2.1 (1.5) 0.51, 0.84 (0.67) < 0.50, 0.56	Sampling to analysis: 481-505 days
USA, 1996 Halsey/OR (bluegrass)	SL	0.84	373	Forage	1	0.1 7 14	69, 81 (75) 4.7, 5.6 (5.2) 3.1, 3.5 (3.3)	IZ-731-025 Khunachak, 1999
				Hay	1	0.1 7 14	139, 139 (139) 10, 11 (11) 5.2, 5.3 (5.3)	Sampling to analysis: 319-333 days
USA, 1996 Germansville/PA (tall fescue grass)	SL	0.87	231	Forage	1	0.1 7 14 28	38, 62 (50) 6.8, 6.9 (6.9) 2.2, 3.4 (2.8) 1.8, 1.9 (1.8)	IZ-731-026 Khunachak, 1999
				Hay	1	0.1 7 14 28	153, 186 (169) 18, 22 (20) 10, 11 (11) 4.1, 4.3 (4.2)	Sampling to analysis: 391-414 days
USA, 1996 Verona/WI (bromegrass)	SL	0.84	198	Forage	1	0.1 7 14 28	64, 71 (68) 3.9, 4.5 (4.2) 1.9, 2.1 (2.0) 0.70, 0.80 (0.75)	IZ-731-027 Khunachak, 1999
				Hay	1	0.1 7 14 28	164, 197 (181) 12, 13 (12) 3.7, 3.9 (3.8) 1.7, 1.9 (1.8)	Sampling to analysis: 315-343 days
USA, 1996 Spearman/TX (tall fescue grass)	SL	0.83	276	Forage	1	0.1 7 14 28	39, 50 (44) 4.1, 4.7 (4.4) 3.0, 4.3 (3.6) 2.0, 2.7 (2.3)	IZ-731-028 Khunachak, 1999
				Hay	1	0.1 7 14 28	189, 196 (193) 11, 14 (13) 9.8, 11 (10) 3.7, 4.1 (3.9)	Sampling to analysis: 286-313 days
USA, 1997 Grand Island/NE (bluegrass)	SL	0.85	187	Forage	1	0.1 7 14 28	63, 66 (65) 4.4, 4.6 (4.5) 2.6, 2.6 (2.6) 0.81, 0.92 (0.87)	IZ-731-030 Garrett, 1999
				Hay	1	0.1 7 14 28	140, 159 (150) 10, 10 (10) 5.0, 5.1 (5.1) 1.9, 1.9 (1.9)	Sampling to analysis: 192-231 days
USA, 1997 Hillsboro/OR (tall fescue grass)	SL	0.82	205	Forage	1	0.1 7 14 28	34, 39 (36) 4.8, 5.1 (5.0) 1.9, 2.6 (2.2) 1.5, 1.9 (1.7)	IZ-731-031 Garrett, 1999
				Hay	1	0.1 7 14 28	121, 164 (143) 24, 27 (25) 5.8, 6.6 (6.2) 3.6, 3.6 (3.6)	Sampling to analysis: 204-258 days
USA, 1997 Brookshire/TX (common Bermuda grass)	SL	0.86	231	Forage	1	0.1 7 14 28	60, 63 (61) 10, 12 (11) 10, 11 (11) 6.1, 6.4 (6.2)	IZ-731-032 Garrett, 1999
				Hay	0 1	0 0.1 7 14 28	< 0.50, 1.3 129, 149 (139) 23, 24 (24) 16, 20 (18) 7.9, 8.6 (8.2)	Sampling to analysis: 184-224 days

Grass country, year (variety)	Application					DALA Days	Residues ^a , mg/kg	Ref
	Form	kg ai/ha	water, L/ha	Analytical portion	no.			
USA, 1997 Noblesville/IN (Bluegrass)	SL	0.85	213	Forage	1	0.1 7 14 28 56	97, 98 (<u>97</u>) 6.0, 6.8 (6.4) 3.1, 3.5 (3.3) 1.5, 1.7 (1.6) < 0.50, < 0.50	IZ-731-033 Garrett, 1999 Sampling to analysis: 85-174 days
				Hay	1	0.1 7 14 28 56	261, 277 (269) 11, 12 (<u>12</u>) 5.6, 6.5 (6.0) 2.3, 2.4 (2.4) < 0.50, < 0.50	
				Forage	1	0.1 7 14 28	27, 28 (<u>28</u>) 6.5, 7.9 (7.2) 4.9, 5.3 (5.1) 1.8, 1.8 (1.8)	
				Hay	0 1	0 0.1 7 14 28	< 0.50, 0.55 65, 78 (71) 22, 22 (<u>22</u>) 12, 12 (12) 3.4, 4.0 (3.7)	
USA, 1997 Read/CO (bromegrass)	SL	0.84	213	Forage	1	0.1 7 14 28	27, 28 (<u>28</u>) 6.5, 7.9 (7.2) 4.9, 5.3 (5.1) 1.8, 1.8 (1.8)	IZ-731-034 Garrett, 1999
				Hay	0 1	0 0.1 7 14 28	< 0.50, 0.55 65, 78 (71) 22, 22 (<u>22</u>) 12, 12 (12) 3.4, 4.0 (3.7)	Sampling to analysis: 119-163 days

^a Average in parenthesis

FATE OF RESIDUES IN STORAGE AND PROCESSING

In Processing

The Meeting had received information on the fate of imazapyr residues during the processing of soya bean seeds in 2013. Processing factors were calculated for imazapyr residues in soya bean seeds.

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

APPRAISAL

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.

CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
		New	Previous		
MO 0105	Edible offal (mammalian)	0.2	0.05*	0.041	
AS 0162	Hay or fodder (dry) of grasses	6		1.3	2.5
VD 0541	Soya bean (dry)	5		0.69	
OC 0541	Soya bean oil, crude		0		
	Forage of grasses			5.2	9.7
	Soya bean asp gr fn ^a			0.028	
AB 0541	Soya bean hulls			0.46	
AB 1265	Soya bean meal			0.9	

^a aspirated grain fractions

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.

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