TEBUFENOZIDE (196)

APPRAISAL

At the 35th Session of the CCPR, the Delegation of Australia requested the JMPR to consider the extrapolation of recommendations for MRLs for tebufenozide in cattle commodities to all mammalian species.

The Meeting recalled that tebufenozide was evaluated by the JMPR in 2001, while in 2002 the Meeting decided that it would generally use cattle feeding studies to estimate maximum residue levels for mammalian commodities to cover the potential exposure of an animal to a pesticide in the diet (JMPR, 2002). With hindsight, the treatment of tebufenozide was not consistent with this approach.

The Meeting recommended the withdrawal of the draft MRLs for cattle kidney (0.02* mg/kg), cattle liver (0.02* mg/kg), cattle meat (fat) (0.05 mg/kg) and cattle milk (0.01* mg/kg), to be replaced by recommendations of 0.02* mg/kg for edible offal (mammalian), 0.05 mg/kg (fat) for meat (from mammals other than marine mammals) and 0.01* mg/kg for milks.

RECOMMENDATIONS

The Meeting concluded that the residue levels listed in Table 1 are suitable for establishing MRLs and for dietary risk assessment.

Definition of the residue for compliance with MRLs and for estimation of dietary intake for plant and animal commodities: *tebufenozide*.

The residue is fat-soluble.

Table 1. Summary of recommendations.

CCN	Commodity	7, 0 0		STMR, STMR-P,	HR, HR-P,
		New	Previous	mg/kg	mg/kg
MO 1280	Cattle, kidney	W	0.02*	0.006	0.006
MO 1281	Cattle, liver	W	0.02*	0.02	0.02
MM 0812	Cattle meat	W	0.05 (fat)	0.006	0.006
ML 0812	Cattle milk	W	0.01*	0.003	
MO 0105	Edible offal (mammalian)	0.02*	-	0.02	0.02
MM 0095	Meat (from mammals other than marine mammals)	0.05 (fat)	-		muscle 0.006 fat 0.029
ML 0106	Milks	0.01*	-	0.003	

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes of tebufenozide for the five GEMS/Food regional diets, based on the STMRs estimated for 35 commodities by the 1996, 1997, 1999, 2001 and present Meetings, were in the range of 1 to 20% of the ADI (Table 2). The Meeting concluded that the long-term intake of residues of tebufenozide, resulting from its uses that have been considered by JMPR, is unlikely to present a public health concern.

Table 2. International Estimated Dietary Intakes (IEDIs) for the five GEMS/Food regional diets (ADI = 0-0.02 mg/kg bw/day).

Code	Commodity	STMR or	Diets: g/person/day. Intake = daily intake: μg/person									
		STMR-P	Mid-East		Far-East		African		Latin		Eur	opean
		mg/kg							American			
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
TN 0660	Almonds	0.0205	0.5	0.0	0.0	0.0	0.0	0.0	0.1	0.0	1.8	0.0
FI 0326	Avocados	0.21	0.0	0.0	0.0	0.0	0.2	0.0	3.3	0.7	1.0	0.2
FB 0020	Blueberries	0.685	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.5	0.3

Code	Commodity	STMR or		Diets:	g/per	son/day	. Intak	e = dail	ly intal	ke: µg/r	person	
	,	STMR-P	Mid	l-East		-East		rican		atin		opean
		mg/kg							Ame	erican		•
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VB 0400	Broccoli	0.11	0.5	0.1	1.0	0.1	0.0	0.0	1.1	0.1	2.7	0.3
	Cabbages (head & leafy brassicas,	0.34	5.0	1.7	9.7	3.3	0.0	0.0	10.5	3.6	26.8	9.1
	kohlrabi) ^{1/}											
FC 0001	Citrus fruits	0.079	47.1	3.7	6.3	0.5	5.1	0.4	54.6	4.3	44.6	3.5
FB 0265	Cranberry	0.042	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.0
	Edible offal (mammalian)	0.02	4.2	0.1	1.4	0.0	2.8	0.1	6.1	0.1	12.4	0.2
PE 0112	Eggs	0	14.6	0.0	13.1	0.0	3.7	0.0	11.9	0.0	37.6	0.0
	Grapes (fresh, wine, dried)	0.745	16.1	12.0	1.0	0.7	0.0	0.0	1.6	1.2		12.0
	Grapes, dried (= currants, raisins and	0.551	0.3	0.2	0.0	0.0	0.0	0.0	0.3	0.2	2.3	1.3
	sultanas)											
FI 0341	Kiwi fruit	0.14	0.0	0.0	0.0	0.0	1.9	0.3	0.1	0.0	1.5	0.2
	Leafy vegetables	2.45	7.8	19.1	9.7	23.8	0.7	1.7		40.4	51.7	126.7
MM 0095	Meat from mammals other than	0.015	7.4	0.1	6.6	0.1	4.8	0.1	9.4	0.1	31.1	0.5
	marine mammals: 20% as fat											
MM 0095	Meat from mammals other than	0.006	29.6	0.2	26.2	0.2	19.0	0.1	37.6	0.2	124.4	0.7
	marine mammals: 80% as muscle					0.4		0.4		0 -		
	Milks	0.003	116.9	0.4	32.1	0.1	41.8	0.1	160.1	0.5	289.3	0.9
	Mints	8.35	-	-	-	-	-	-	-	-	-	-
	Nectarines	0.11	1.3	0.1	0.3	0.0	0.0	0.0	0.4	0.0	6.3	0.7
	Orange juice	0.0077	7.3	0.1	0.0	0.0	0.0	0.0	0.3	0.0	4.5	0.0
FS 0247	Peaches	0.11	1.3	0.1	0.3	0.0	0.0	0.0	0.4	0.0	6.3	0.7
	Pecans	0.01	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.0
	Peppers	0.064	3.4	0.2	2.1	0.1	5.4	0.3	2.4	0.2	10.4	0.7
	Pome fruits	0.17	10.8	1.8	7.5	1.3	0.3	0.1	6.5	1.1	51.3	8.7
	Poultry meat: 10% as fat	0.02	3.1	0.1	1.3	0.0	0.6	0.0	2.5	0.1	5.3	0.1
	Poultry meat: 90% as muscle	0	27.9	0.0	11.9	0.0	5.0	0.0	22.8	0.0	47.7	0.0
	Rape seed Rape seed oil, crude	0.95	0.0	0.0 9.9	2.7	0.0 5.9	0.0	0.0	0.0	0.0	7.3	0.0 16.1
	Raspberries, red, black	0.56	4.5 0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.7	0.5	0.3
	Rice, husked	0.03	0.0	0.0	1.8	0.0	34.7	1.0	21.0	0.6	2.5	0.3
	Sugar cane	0.03	18.5	2.2	7.3	0.1	15.9	1.9	3.5	0.6	0.0	0.0
	Sugar, refined	0.12	73.0	0.2	43.0	0.9	25.5		97.3	0.4	96.8	0.0
	Tomatoes (fresh)	0.003	44.1	5.7	5.7	0.1	14.6	1.9	25.5	3.3	34.9	4.5
	Tomato juice	0.13	0.3	0.0	0.0	0.7	0.0	0.0	0.0	0.0	2.0	0.0
91. 0 44 0	Tomato juice Tomato paste	0.023	5.8	0.6	0.0	0.0	0.0	0.0	0.0	0.0	4.0	0.0
TN 0678	Walnuts	0.093	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.5	0.4
	Wine only	0.003	0.0	0.0	0.0	0.0	0.8	0.0	19.8	4.3		21.1
		ake (µg/per			0.0	38.0	0.0	8.3	12.0	62.5		209.7
	Bodyweight per				55		60		60		60	
		ADI (µg/per				1100		1200		1200		1200
	F	, U I	ADI =	4.9		3.5		0.7		5.2		17.5
	Rounded % ADI					3.3		1		5.2		20
		5		5		1		J		20		

This is a worst-case calculation. The recommendation is for VB 0041, Cabbage head, only.

Short-term intake

At the 2001 Meeting, International Estimated Short Term Intake (IESTI) calculations exceeded the acute RfD for leafy vegetables, cabbage, pome fruits and grapes. At the present Meeting, on the basis of a study better suited to assess acute toxic effects, the acute RfD of 0.05 mg/kg bw was revised to 0.9 mg/kg bw (JMPR, 2003). The IESTIs for tebufenozide were therefore recalculated for the food commodities for which maximum residue levels were estimated and for which consumption data were available. The results are shown in Tables 3 and 4.

The IESTI represented 0-10% of the acute RfD for the general population and 0-40% of the acute RfD for children. The Meeting concluded that the short-term intake of residues of tebufenozide resulting from its uses that have been considered by the JMPR is unlikely to present a public health concern.

Table 3. International Estimated Short-term Intakes (IESTIs) of tebufenozide by the general population (acute RfD = 0.900 mg/kg bw/day or 900 μ g/kg bw).

Codex	Commodity	STMR or	HR or	Large portion diet Unit weight							Case	IESTI	% acute
Code		STMR-P	HR-P,	Coun-	Body	Large	Unit	Coun-	Unit	-bility		μg/kg	RfD
		mg/kg	mg/kg	try	wt	portion,	wt	try	wt,	factor		bw/day	rounded
		0 0			(kg)	g/person	(g)	12.5	edible				
					(118)	8 Person	(8)		portion				
									(g)				
TN 0660	Almonds	_	0.045	JPN	52.6	74	_	_	- 187	_	1	0.06	0
FP 0226	Apples	_	1.1	USA	65.0	1348	138	USA	127	3	2a	27.11	3
JF 0226	Apple juice	0.02	-	-	-	-	-	-	-	-	3	-	-
FI 0326	Avocados	-	0.5	FRA	62.3	260	300	FRA	180	3	2a	4.97	1
FB 0020	Blueberries	-	1.7	AUS	67.0	158	300	TKA	100	3	1	4.01	0
	Broccoli	-	0.34	USA	65.0	376	150	JPN	150	3	2a	3.54	0
	Cabbages, head		4.6	SAF	55.7	362	908	USA	717	3	2b	89.70	10
PE 0840	Chicken eggs	-	0.02	FRA	62.3	219	908	USA -	-	-	1	0.07	0
1/ 1/	Chicken eggs	-	0.02	FKA	02.3	219	-	_	_	_	1	0.07	U
FB 0265	Cranberries	_	0.28	USA	65.0	229	_	_	_	_	1	0.99	0
MO	Edible offal	-	0.28	FRA	62.3	277		_			1	0.09	0
0105	(mammalian)	_	0.02	TKA	02.3	211	_	_	_	_	1	0.09	U
FC 0203	Grapefruit	_	0.18	JPN	52.6	947	340	UNK	160	3	2a	4.33	0
FB 0269	Grapes (fresh,	-	1.5	AUS	67.0	513	125	FRA	118	3	2a	16.75	2
FB 0209	dried, excluding	-	1.5	AUS	67.0	313	123	FKA	110	3	Za	10.73	2
	wine)												
DF 0269	Grapes, dried (=	-	1.1	FRA	62.3	135		_	_	_	1	2.39	0
DI 0209	currants, raisins	-	1.1	TKA	02.3	133	-	_	-	_	1	2.39	U
	and sultanas)												
VL 0480	Kale	_	8.1	NLD	63.0	337					1	43.34	5
FI 0341	Kiwi fruit	-	0.22	NLD	63.0	355	75	FRA	65	3	2a	1.69	0
										3			0
FC 0204	Lemons	-	0.18	FRA	62.3	115	100	FRA	64		2a	0.70	
VL 0482	Lettuce, head	-	8.1	USA	65.0	213	539	USA	512	3	2b	79.46	9
VL 0483	Lettuce, leaf	-	8.1	NLD	63.0	152	10	USA	10	1	1	19.52	2
FC 0206	Mandarins	-	0.18	JPN	52.6	409	100	FRA	72	3	2a	1.89	0
MM	Meat from	-	0.029	AUS	67.0	104	-	-	-	-	1	0.05	0
0095	mammals other												
	than marine												
	mammals: 20%												
101	as fat Meat from		0.006	ATIC	(7.0	417					1	0.04	0
MM 0095		-	0.006	AUS	67.0	417	-	-	-	-	1	0.04	0
0093	mammals other than marine												
	mammals: 80% as												
	muscle												
ML 0106		0.003		USA	65.0	2466	_	_	_	_	3	0.11	0
HH 0738		-	8.6	AUS	67.0	8	-	_	_	-	1	1.00	0
	Nectarines	-	0.23	USA	65.0	590	110	FRA	99	3	2a	2.79	0
FC 0004	Oranges, sweet,	_	0.23	USA	65.0	564	190	FRA	137	3	2a 2a	2.79	0
rC 0004	oranges, sweet, sour (incl. orange-	-	0.10	USA	05.0	304	190	FKA	13/	3	∠a	2.32	U
	like hybrids)												
FS 0247	Peaches	_	0.23	SAF	55.7	685	110	FRA	99	3	2a	3.65	0
	Pears		1.1	USA	65.0	693	166	USA	151	3	2a 2a	16.84	2
		-			67.0						2a 1		0
	Pecans Pannara abili	-	0.01	AUS		23	- 15	TIC A	- 12	- 2		0.00	
	Peppers, chili	-	0.64	USA	65.0	90	45	USA	43	3	2a	1.74	0
VO 0445	Peppers, sweet	-	0.64	FRA	62.3	207	172	UNK	160	3	2a	5.42	1
DM 0110	(incl. pim(i)ento)		0.0006	ATIC	67.0	42					1	0.00	0
PM 0110	Poultry meat: 10%	-	0.0006	AUS	67.0	43	-	-	-	-	1	0.00	U
DM 0110	as fat		1E 00	ATIC	67.0	200					1	0.00	0
rw 0110	Poultry meat: 90%	-	1E-09	AUS	67.0	388	-	-	-	-	1	0.00	0
	as muscle											1	

Codex	Commodity	STMR or	HR or	Larg	ge porti	on diet	J	Jnit we	ight	Varia	Case	IESTI	% acute
Code		l I	HR-P, mg/kg	Country	Body wt (kg)	Large portion, g/person	Unit wt (g)	Coun- try	Unit wt, edible portion (g)	-bility factor		μg/kg bw/day	RfD rounded
PO 0111	Poultry, edible offal of	-	0.02	USA	65.0	248		-	-	-	1	0.08	0
OR 0495	Rape seed oil, edible	2.2	-	AUS	67.0	65		-	-	-	3	2.13	0
FB 0272	Raspberries, red, black	-	0.86	FRA	62.3	324	-	-	ı	1	1	4.47	0
CM 0649	Rice, husked	-	0.07	JPN	52.6	319	-	-	-	-	1	0.42	0
VL 0502	Spinach (bunch)	-	8.1	NLD	63.0	820	111	UNK	90	3	2a	128.50	10
GS 0659	Sugar cane	-	0.62	SAF	55.7	89	-	-	-	-	1	0.99	0
	Sugar, refined	0.003	-	-	1	-	-	-	-	-	3	-	-
VO 0448	Tomatoes (fresh, juice, paste, peeled)	-	0.53	USA	65.0	391	123	USA	123	3	2a	5.19	1
JF 0448	Tomato juice	0.023	-	-	-	-	-	-	-	-	3	-	-
	Tomato paste	0.007	-	-	-	-	-	-	-	-	3	-	-
TN 0678	Walnuts	-	0.02	FRA	62.3	136	-	-	-	-	1	0.04	0
	Wine only	0.081	-	AUS	67.0	1131	-	-	-	-	3	1.37	0

¹ Through lack of information on large portion size of PE 0112 Eggs, the calculation was made for PE 0840 Chicken eggs.

Table 4. International Estimated Short-term Intakes (IESTIs) of tebufenozide by children up to 6 years (acute RfD = 0.900 mg/kg bw/day or 900 μ g/kg bw).

Codex	Commodity	STMR or	HR or	Larg	ge porti	on diet	J	Jnit we	ight	Variab	Case	IESTI	% acute
Code		STMR-P	HR-P	Coun-	Body	Large	Unit	Coun-	Unit wt,	-ility		μg/kg	RfD
		mg/kg	mg/kg	try	wt	portion,	wt, g	try	edible	factor		bw/day	rounded
					(kg)	corrected			portion,				
						g/person			g				
TN 0660	Almonds	-	0.045	FRA	17.8	31	-	-	-	-	1	0.08	0%
FP 0226	Apples	-	1.1	USA	15.0	679	138	USA	127	3	2a	68.40	8%
JF 0226	Apple juice	0.02	-	-	-	-	-	-	-	-	3	-	-
FI 0326	Avocados	-	0.5	USA	15.0	131	300	FRA	180	3	2b	13.05	1%
FB 0020	Blueberries	-	1.7	FRA	17.8	138	-	-	-	-	1	13.21	1%
VB 0400	Broccoli	-	0.34	USA	15.0	164	150	JPN	150	3	2a	10.52	1%
VB 0041	Cabbages, head	-	4.6	SAF	14.2	220	908	USA	717	3	2b	213.90	20%
PE 0840	Chicken eggs	-	0.02	FRA	17.8	134	-	-	-	-	1	0.15	0%
FB 0265	Cranberry	-	0.28	USA	15.0	102	-	-	-	-	1	1.90	0%
II	Edible offal (mammalian)	-	0.02	FRA	17.8	203	-	-	-	-	1	0.23	0%
FC 0203	Grapefruit	-	0.18	FRA	17.8	381	340	UNK	160	3	2a	7.09	1%
FB 0269	Grapes (fresh, dried, excluding wine)	-	1.5	AUS	19.0	342	125	FRA	118	3	2a	45.55	5%
	Grapes, dried (= currants, raisins and sultanas)	-	1.1	USA	15.0	59	-	-	-	-	1	4.35	0%
VL 0480	Kale	-	8.1	NLD	17.0	149	-	-	-	-	1	70.79	8%
FI 0341	Kiwi fruit	-	0.22	JPN	15.9	162	75	FRA	65	3	2a	4.03	0%
FC 0204	Lemons	-	0.18	JPN	15.9	88	100	FRA	64	3	2a	2.45	0%
VL 0482	Lettuce, head	-	8.1	NLD	17.0	84	539	USA	512	3	2b	119.56	10%
VL 0483	Lettuce, leaf	-	8.1	NLD	17.0	102	10	USA	10	1	1	48.60	5%
FC 0206	Mandarins	-	0.18	JPN	15.9	353	100	FRA	72	3	2a	5.63	1%

Codex	Commodity	STMR or	HR or	Larg	ge porti	on diet	J	Jnit we	ight	Variab	Case	IESTI	% acute
Code		STMR-P	HR-P	Coun-	Body	Large	Unit	Coun-	Unit wt,	-ility		μg/kg	RfD
		mg/kg	mg/kg	try	wt	portion,	wt, g	try	edible	factor		bw/day	rounded
					(kg)	corrected			portion,				
						g/person			g				
	Meat from mammals	-	0.029	AUS	19.0	52	-	-	-	-	1	0.08	0%
0095	other than marine												
	mammals: 20% as												
	fat		0.005	1 7 7 0	10.0	200						0.05	00/
MM 0095	Meat from mammals other than marine	-	0.006	AUS	19.0	208	-	-	-	-	1	0.07	0%
0093	mammals: 80% as												
	muscle												
ML 0106		0.003	-	USA	15.0	1286	-	-	-	-	3	0.26	0%
HH 0738	Mint	-	8.6	AUS	19.0	34	-	-	-	-	1	15.28	2%
FS 0245	Nectarines	-	0.23	AUS	19.0	302	110	FRA	99	3	2a	6.05	1%
FC 0004	Oranges, sweet, sour	-	0.18	UNK	14.5	495	190	FRA	137	3	2a	9.54	1%
	(incl. orange-like												
	hybrids)												
	Peaches	-	0.23	AUS	19.0	315	110	FRA	99	3	2a	6.22	1%
	Pears	-	1.1	UNK	14.5	279	166	USA	151	3	2a	44.08	5%
	Pecans	-	0.01	AUS	19.0	22	-	-	-	-	1	0.01	0%
	Peppers, chili	-	0.64	AUS	19.0	31	45	USA	43	3	2b	3.08	0%
	Peppers, sweet (incl. pim(i)ento)	-	0.64	AUS	19.0	60	172	UNK	160	3	2b	6.07	1%
	Poultry meat: 10% as fat	-	0.0006		19.0	22	-	-	-	-	1	0.00	0%
PM 0110	Poultry meat: 90% as muscle	-	1E-09	AUS	19.0	201	-	-	-	-	1	0.00	0%
PO 0111	Poultry, edible offal	-	0.02	USA	15.0	37	-	-	-	-	1	0.05	0%
OR 0495	Rape seed oil, edible	2.2	_	AUS	19.0	18	-	-	-	-	3	2.13	0%
	Raspberries, red,	-	0.86	FRA	17.8	76	-	-	-	-	1	3.68	0%
	black												
CM 0649	Rice, husked	-	0.07	FRA	17.8	223	-	-	-	-	1	0.88	0%
	Spinach (bunch)	-	8.1	SAF	14.2	420	111	UNK	90	3	2a	342.33	40%
GS 0659	Sugar cane	-	0.62	SAF	14.2	60	-	-	-	-	1	2.60	0%
	Sugar, refined	0.003	-	-	-	-	-	-	-	-	3	-	-
VO 0448	Tomatoes (fresh,	-	0.53	USA	15.0	159	123	USA	123	3	2a	14.31	2%
	juice, paste, peeled)	0.5.7.7	 										
FJ 0448	Tomato juice	0.023	-	-	-	-	-	-	-	-	3	-	-
T 10.550	Tomato paste	0.007	-	-	-	-	-	-	-	-	3	-	-
TN 0678	Walnuts	-	0.02	USA	15.0	6	-	-	-	-	1	0.01	0%
	Wine only	0.081	-	AUS	19.0	4	-	-	-	-	3	0.02	0%

¹ Through lack of information on large portion size of PE 0112 Eggs, the calculation was made for PE 0840 Chicken eggs.

REFERENCES

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