Food and Agriculture Organization of the United Nations

JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES

Geneva, 17-26 September 2013

SUMMARY REPORT

ACCEPTABLE DAILY INTAKES, ACUTE REFERENCE DOSES, SHORT-TERM AND LONG-TERM DIETARY INTAKES, RECOMMENDED MAXIMUM RESIDUE LIMITS AND SUPERVISED TRIALS MEDIAN RESIDUE VALUES RECORDED BY THE 2013 MEETING

Issued October 2013

The following extracts of the results of the annual Joint FAO/WHO Meeting on Pesticide Residues (JMPR) are provided to make them accessible to interested parties at an early date.

The Meeting evaluated 37 pesticides, of which 11 were new compounds, and 3 were re-evaluated within the periodic review programme of the Codex Committee on Pesticide Residues (CCPR). The Meeting established acceptable daily intakes (ADIs) and acute reference doses (ARfDs).

The Meeting estimated maximum residue levels, which it recommended for use as maximum residue limits (MRLs) by the CCPR. It also estimated supervised trials median residue (STMR) and highest residue (HR) levels as a basis for estimation of the dietary intake of residues of the pesticides reviewed. The allocations and estimates are shown in the table.

Pesticides for which the estimated dietary intakes might, on the basis of the available information, exceed their ADIs are marked with footnotes, which are also applied to specific commodities when the available information indicated that the ARfD of a pesticide might be exceeded when the commodity was consumed. It should be noted that these distinctions apply only to new compounds and those re-evaluated within the CCPR periodic review programme.

The table includes the Codex reference numbers of the compounds and the Codex classification numbers (CCNs) of the commodities, to facilitate reference to the Codex maximum limits for pesticide residues (*Codex Alimentarius*, Vol. 2B) and other documents and working documents of the Codex Alimentarius Commission. Both compounds and commodities are listed in alphabetical order.

Apart from the abbreviations indicated above, the following qualifications are used in the Table.

* (following name of pesticide)	New compound
** (following name of pesticide)	Compound reviewed within CCPR periodic review programme
* (following recommended MRL)	At or about the limit of quantification
HR-P	Highest residue in a processed commodity, in mg/kg, calculated by multiplying the HR in the raw commodity by the processing factor
Po	The recommendation accommodates post-harvest treatment of the commodity.
PoP (following recommendation for processed foods (classes D and E in the Codex classification)	The recommendation accommodates post-harvest treatment of the primary food commodity.
STMR-P	An STMR for a processed commodity calculated by applying the concentration or reduction factor for the process to the STMR calculated for the raw agricultural commodity.
W (in place of a recommended MRL)	The previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.

More information on the work of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) is available at:

http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-rep/en/

http://www.who.int/foodsafety/chem/jmpr/en/index.html

Established ADI and ARfD values and recommended maximum residue level, STMR and HR values

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
Azoxystrobin (229)	GC 0640	Barley	1.5	0.5	0.05	
ADI: 0–0.2 mg/kg bw	SB 0716	Coffee beans	0.03	0.02	0.01	
ARfD: Unnecessary	GC 0647	Oats	1.5	0.5	0.05	
	AL 0072	Pea hay or fodder (dry) [a]	20 [a]		1.9 [b]	
	VR 0589	Potato	7 Po		2.3 Po	
	VD 0070	Pulses, dry, except soya beans	0.07		0.01	
	VR 0075	Root and tuber vegetables	W	1		
	VR 0075	Root and tuber vegetables, except potato	1		0.23	
	GC 0651	Sorghum	10		1.85	
	AS 0651	Sorghum straw and fodder, dry	30 [a]		3.85 [b]	
	AS 0081	Straw and fodder of cereal grains, except maize and sorghum	15 [a]		1.5 [b]	
	AS 0081	Straw and fodder of cereal grains, except maize	W	15		
		Beer			0.0015	
	SM 0716	Coffee beans, roasted			0.006	
		Instant coffee			0.0106	
	MO 0105	Edible offal (Mammalian)			0.02	
	MF 0100	Mammalian fats (except milk fats)			0.015	
	MM 0095	Meat (from mammals other than marine mammals)			0.01 (muscle) 0.015 (fat)	
		Potato flakes			0.0253	
		Potato chips			0.0276	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: *azoxystrobin.*						
The residue is fat-soluble.						
[a] Dry weight basis [b] Fresh weight basis						
Bentazone (172)**	AL 1020	Alfalfa fodder	0.5		0.09	
ADI: 0–0.09 mg/kg bw	GC 0640	Barley	W	0.1		
ARfD: Unnecessary	AS 0640	Barley straw and fodder, dry	0.3		0.04	
	VD 0071	Beans (dry)	0.04	0.05*	0.02	
	VP 0061	Beans, except broad bean and soybeans (green pods and immature seeds)	0.01*		0.01	
	VP 0062	Beans, shelled (succulent=immature seeds)	0.01*		0.01	
	GC 0080	Cereal grains	0.01*		0.01	
	VP 0526	Common bean (pods and/or immature seeds)	W	0.2		
	PE 0112	Eggs	0.01*	0.05*	0	

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	VD 0561	Field pea (dry)	W	1		
	VP 0528	Garden pea (young pods)(=succulent, immature seeds)	W	0.2		
	AS 0162	Hay of fodder (dry) of grass	2		0.215	1.16 [a]
	HH 0092	Herbs	0.1		0.05	
	VP 0534	Lima bean (young pods and /or immature beans)	W	0.05		
	SO 0693	Linseed	0.02*	0.1	0.02	
	GC 0645	Maize	W	0.2		
	AS 0645	Maize fodder	0.4	0.2	0.02	
	MM 0095	Meat (from mammals other than marine mammals)	W	0.05*	0	
	ML 0106	Milks	0.01*	0.05*	0	
	AS 0646	Millet fodder, dry	0.3		0.04	0.14 [a]
	GC 0647	Oats	W	0.1		
	AF 0647	Oat straw and fodder, dry	0.3	0.1	0.04	0.14 [a]
	VA 0385	Onion, Bulb	0.04	0.1	0.01	
	SO 0697	Peanut	0.05*	0.05	0	
	VP 0063	Peas (pods and succulent = immature seeds)	1.5		0.05	
	VR 0589	Potato	0.1	0.1	0.01	
	PM 0110	Poultry meat (fat)	0.03		0	
	PO 0111	Poultry, Edible offal of	0.07		0	
	GC 0649	Rice	W	0.1		
	GC 0650	Rye	W	0.1		
	AF 0650	Rye straw and fodder, dry	0.3		0.04	0.14 [a]
	GC 0651	Sorghum	W	0.1	0.01	
	VD 0541	Soya bean (dry)	0.01*	0.1	0.01	
	VA 0389	Spring onion	0.08		0.01	
	VO 0447	Sweet corn (corn-on-the-cob)	0.01*		0.01	
	AS 0653	Triticale straw and fodder, dry	0.3		0.04	0.14 [a]
	GC 0654	Wheat	W	0.1	0.01	
	AF 0654	Wheat straw and fodder, dry	0.3		0.04	0.14 [a]
	CM 1207	Rice hulls			0.089	
	CF 0649	Rice bran, processed			0.0037	

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

Definition of the residue (for compliance with the MRL and estimation of dietary intake for plant commodities): *Sum of bentazone, 6-OH-bentazone and 8-OH-bentazones, expressed as Bentazone.*

The residue is not fat-soluble.

[a] for the purpose of estimating animal dietary burdens.

Benzovindiflupyr (261)*

ADI: 0–0.05 mg/kg bw

ARfD: 0.1 mg/kg bw

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
Bixafen (262)*						
ADI: 0–0.02 mg/kg bw						
ARfD: 0.2 mg/kg bw						
Definition of the residue for compliance with MRL for plant commodities: *bixafen*						
Definition of the residue for compliance with MRL for animal commodities and (for the estimation of dietary intake) for plant and animal commodities: *sum of bixafen and N-(3',4'-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1H-pyrazole-4-carboxamide (bixafen-desmethyl), expressed as bixafen*						
The residue is fat-soluble.						
Chlorantraniliprole (230)	VS 0620	Artichoke, Globe	2		0.56	
ADI: 0–2 mg/kg bw	VP 0061	Beans, except broad bean and soya bean (green pods and immature seeds)	0.8		0.16	
ARfD: Unnecessary	VR 0577	Carrot	0.08		0.02	
	GC 0080	Cereal grains	W	0.02		
	GC 0080	Cereal grains, except rice	0.02		0.01	
	SB 0716	Coffee beans	0.05		0.015	
	PE 0112	Eggs	0.2	0.1	0.07	
	DH 1100	Hops, dry	40		10.9	
	VL 0053	Leafy vegetables	W	20		
	VL 0053	Leafy vegetables, except radish leaves	20			
	VP 0063	Peas (pods and succulent = immature seeds)	2		0.545	
	VP 0064	Peas, shelled (succulent seeds)	0.05		0.025	
	FI 0355	Pomegranate	0.4		0.11	
	PM 0110	Poultry meat	0.01 *	0.01*	0	
	PO 0111	Poultry, Edible offal of	0.01 *	0.01*	0.995	
	VR 0494	Radish	0.5		0.055	
	VL 0494	Radish leaves, including radish tops	40		10.5	
	SO 0495	Rape seed	2		0.295	
	GC 0649	Rice	0.4		0.115	
		Rice, polished	0.04		0.013	
	VR 0075	Root and tuber vegetables	W	0.02		
	VR 0075	Root and tuber vegetables, except carrot and radish	0.02		0.01	
	SO 0702	Sunflower seed	2		0.185	
	CF 0649	Rice bran, processed			0.196	
Definition of the residue (for compliance with MRL and for estimation of dietary intake) for plant and animal commodities: *chlorantraniliprole*						
The residue is fat-soluble						
Chlorfenapyr (254)						

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
ADI: 0–0.03 mg/kg bw ARfD: 0.03 mg/kg bw						
Chlorpyrifos-methyl (090)	GC 0640	Barley	W	3		
ADI: 0–0.01 mg/kg bw	GC 0080	Cereals, except maize and rice	5 Po		3	4.7
ARfD: 0.1 mg/kg bw	CM 0649	Rice, husked	1.5 Po		0.66	1.04
	CM 1205	Rice, polished	0.2 Po		0.101	0.15
	GC 0654	Wheat	W	3		
		Barley beer			0.03	
		Rice, polished, cooked			0.036	0.056
	CF 1211	Wheat flour			0.5	
	CF 1210	Wheat germ			5.7	10.8
	CF 1212	Wheat wholemeal			3	4.7
	CM 0654	Wheat bran, unprocessed			7.35	11.5
For compliance with MRLs and estimation of dietary intake in plant and animal commodities: *Chlorpyrifos-methyl.* The residue is fat soluble						
Cyantraniliprole (263)*	FP 0009	Pome fruits	0.8		0.16	
ADI: 0–0.03 mg/kg bw	FS 0013	Cherries	6.0		0.93	
ARfD: Unnecessary	FS 0014	Plums (including prunes)	0.5		0.07	
	FS 0247	Peach	1.5		0.34	
	FB 2006	Bush berries	4.0		0.68	
	VA 0385	Onion, Bulb	0.05		0.02	
	VA 0381	Garlic	0.05		0.02	
	VA 0388	Shallot	0.05		0.02	
	VA 0389	Spring onion	8		1.3	
	VA 0387	Onion, Welsh	8		1.3	
	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	2		0.56	
	VC 0045	Fruiting vegetables, Cucurbits	0.3		0.065 [a] 0.01 [b]	
	VO 0050	Fruiting vegetables, other than Cucurbits (except mushrooms & sweet corn)	0.5		0.08	
	VL 0053	Leafy vegetables (except Lettuce, Head)	20		4.7	
	VL 0482	Lettuce, Head	5		0.79	
	VR 0075	Root and tuber vegetables except potato	0.05		0.01	
	VR 0589	Potato	0.05		0.02	
	VX 0624	Celery	15		2.0	
	SB 0716	Coffee beans	0.03		0.01	

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	AL 0157	Legume animal feeds	0.8 [c]		0.17	
	AS 0161	Straw, fodder (dry) & hay of cereal grains and other grass like plants	0.2 [c]		0.05	
	AM 1051	Fodder beet	0.02		0.01	
	AM 0506	Turnip fodder	0.02		0.01	
	MM 0095	Meat from mammals (other than marine)	0.01		0.002 (muscle) 0.006 (fat)	
	MO 0105	Edible offal (Mammalian)	0.05		0.025	
	ML 0106	Milks	0.02		0.015	
	PM 0110	Poultry meat	0.01		0	
	PF 0111	Poultry fat	0.01		0	
	PO 0111	Poultry, Edible offal of	0.01		0.072	
	PE 0112	Eggs	0.015		0.01	
	DF 0014	Prunes	0.8		0.54	
	HS 0444	Peppers Chili, dried	5		0.7	
	JF 0226	Apple juice			0.05	
	JF 0048	Tomato juice			0.014	
	VW 0448	Tomato paste			0.07	
		Tomato (canned)			0.004	
		Spinach (cooked)			5.3	

Definition of the residue (for compliance with the MRL, animal and plant commodities)*: cyantraniliprole.*

Definition of the residue (for estimation of dietary intake for unprocessed plant commodities): *cyantraniliprole.*

Definition of the residue (for estimation of dietary intake for processed plant commodities): *sum of cyantraniliprole and 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazolinecarbonitrile.*

Proposed definition of the residue (for estimation of dietary intake for animal commodities*: sum of:-*
cyantraniliprole
2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazolinecarbonitrile
2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-1,4-dihydro-8-methyl-4-oxo-6-quinazolinecarbonitrile
3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1H-pyrazole-5-carboxamide
3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2[[(hydroxymethyl)amino]carbonyl]-6-methylphenyl]-1H-pyrazole-5-carboxamide expressed as cyantraniliprole

The residue is not fat soluble

[a] edible peel

[b] inedible peel

[c] Dry weight basis

Cyproconazole (239)	SB 0761	Coffee beans	0.07		0.03	
ADI: 0–0.02 mg/kg bw	SM 0716	Coffee beans roasted	0.1		0.039	
ARfD: 0.06 mg/kg bw		Instant coffee			0.048	

Definition of the residue (for compliance with the MRL, animal and plant commodities)*:cyproconazole.*

Definition of the residue (for estimation of dietary intake for plant commodities): *cyproconazole.*

Definition of the residue (for estimation of dietary intake for animal commodities): *cyproconazole, free and conjugated.*

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
The residue is fat-soluble.						
Cyprodinil (207)	FP 0226	Apple	W	0.05		
ADI:0–0.03 mg/kg bw	FI 0326	Avocado	1		0.265	
ARfD: Unnecessary	VD 0071	Beans (dry)	0.2		0.03	
	VP 0061	Beans, except broad bean and soya bean (green pods and immature seeds)	0.7	0.5	0.165	
	VP 0062	Beans, shelled	0.06		0.02	
	FB 0018	Berries and other small fruits, except grapes	10		2.2	
	VL 0054	Brassica leafy vegetables	15		0.37	
	VB 0041	Cabbages, Head	0.7		0.03	
	VR 0577	Carrot	0.7		0.09	
	VC 0424	Cucumber	W	0.2		
	DH 0170	Dried herbs, except hops, dry	300		25	
	MO 0105	Edible offal (Mammalian)	0.01	0.01*	0	
	VO 0440	Egg plant	W	0.2		
	VB 0042	Flowerhead Brassicas (includes Broccoli: Broccoli , Chinese and Cauliflower)	2		0.27	
	VC 0045	Fruiting vegetables, Cucurbits	0.5		0.09	
	VO 0050	Fruiting vegetables, other than Cucurbits, except sweet corn and mushroom	2		0.24	
	HH 0092	Herbs	40		5.05	
	VL 0053	Leafy vegetables, except brassica leafy vegetables	50		11	
	VL 0482	Lettuce, Head	W	10		
	VL 0483	Lettuce, Leaf	W	10		
	VR 0588	Parsnip	0.7		0.09	
	FP 0230	Pear	W	1		
	HS 0444	Peppers Chili, dried	9		2.0	
	VO 0445	Peppers, Sweet (including Pimento or pimiento)	W	0.5		
	FP 0009	Pome fruits	2		0.48	
	VR 0494	Radish	0.3		0.01	
	FB 0272	Raspberries, Red, Black	W	0.5		
	VC 0431	Squash, Summer	W	0.2		
	FB 0275	Strawberry	W	2		
	VO 0448	Tomato	W	0.5		
	JF 0226	Apple juice			0.015	
	JF 0448	Tomato juice			0.036	
		Tomato purée			0.11	
	VW 0448	Tomato paste			0.48	
Definition of the residue for plant and animal commodities (for compliance with MRLs and for estimation of dietary intake): *cyprodinil.*						

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
The residue is fat soluble.						
Dicamba (240)	VD 0541	Soya bean (dry)	10	5	0.033	
ADI: 0–0.3 mg/kg bw	OR 0541	Soya bean oil, refined	-		0.001	
ARfD: 0.5 mg/kg bw						
Definition of the residue for plant commodities (for compliance with the MRL): *Dicamba*						
Definition of the residue for plant commodities (for estimation of dietary intake): *Sum of dicamba and 5-OH dicamba expressed as dicamba*						
Definition of the residue for animal commodities (for compliance with the MRL and for estimation of dietary intake): *Sum of dicamba and DCSA expressed as dicamba*						
Residue is not fat-soluble.						
Difenoconazole (224)	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	2		0.35	1.3
ADI: 0–0.01 mg/kg bw	VB 0400	Broccoli	W	0.5		
ARfD: 0.3 mg/kg bw	VB 0402	Brussels sprouts	W	0.2		
	VB 0041	Cabbages, Head	W	0.2		
	VB 0404	Cauliflowers	W	0.2		
	FC 0001	Citrus fruits	0.6		0.16	0.49
	VC 0424	Cucumber	0.2		0.04	0.15
	DF 0269	Dried grapes (=currants, Raisins and Sultanas)	6		1.1	3.2
	MO 0105	Edible offal (Mammalian)	1.5	0.2	0.71	0.95
	PE 0112	Eggs	0.03	0.01*	0.011	0.026
	VO 0050	Fruiting vegetables , other than Cucurbits, except sweet corn and mushroom	0.6		0.14	0.39
	VO 0448	Tomato	W	0.5		
	VC 0425	Gherkin	0.2		0.04	0.15
	VR 0604	Ginseng	0.08	0.5	0.02	0.044
	DV 0604	Ginseng, dried including red ginseng	0.2		0.052	0.11
	DM 0604	Ginseng, extracts	0.6		0.14	
	FB 0269	Grapes	3	0.1	0.52	1.5
	MM 0095	Meat (from mammals other than marine mammals)	0.2 (fat)	0.05 (fat)	0.047 (muscle) 014 (fat)	0.071 (muscle) 0.19 (fat)
	VC 0046	Melons, except Watermelon	0.7		0.14	0.35
	ML 0106	Milks	0.02	0.005*	0.011	
	VA 0385	Onion, Bulb	0.1		0.015	0.07
	HS 0444	Peppers, Chili, dried	5		1.1	1.8
	FP 0009	Pome fruits	0.8	0.5	0.16	0.47

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	VR 0589	Potato	4 Po	0.02	1.2	1.9
	VA 0389	Spring Onion	9		2.8	3.8
	VC 0431	Squash, Summer	0.2		0.04	0.15
	JF 0226	Apple juice			0.005	
	JF 0001	Citrus juice			0.002	
	OR 0001	Citrus oil, Edible			7.5	
	JF 0269	Grape juice			0.24	
		Potato chips			0.088	
		Potato flakes			0.029	
	VW 0448	Tomato paste			0.22	
		Tomato purée			0.08	
	JF 0048	Tomato juice			0.031	
		Tomato canned			0.01	
		Wine			0.094	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant commodities: *difenoconazole*						
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for animal commodities: *sum of difenoconazole and 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethanol), expressed as difenoconazole*.						
The residue is fat-soluble.						
Diquat (031)**	AL 1020	Alfalfa fodder	W	100		
ADI: 0–0.006 mg/kg bw	FI 0327	Banana	0.02*		0	0
ARfD: 0.8 mg/kg bw	GC 0640	Barley	W	5		
	VD 0071	Beans (dry)	0.05	0.2	0.05	
	FT 2352	Cajou (pseudofruit)	0.02 *		0	0
	FT 0292	Cashew apple	0.02 *		0	0
	TN 0292	Cashew nut	0.02 *		0	0
	FC 0001	Citrus fruits	0.02 *		0	0
	SB 0716	Coffee beans	0.02 *		0	
	MO 0105	Edible offal (Mammalian)	0.01 *	0.05	0	0
	PE 0112	Eggs	0.01 *	0.05	0	0
	VO 0050	Fruiting vegetables, other than cucurbits (except sweetcorn, fungi and mushrooms)	0.01*		0	0
	VD 0533	Lentil (dry)	W	0.2		
	GC 0645	Maize	W	0.05		
	MM 0095	Meat (from mammals other than marine mammals)	0.01 *	0.05	0	0
	ML 0106	Milks	0.001 *	0.01	0	0
	GC 0647	Oats	W	2		
	VD 0072	Peas (dry)	0.3	0.2	0.05	
	AL 0072	Pea fodder	50		16	25
	FP 0009	Pome fruits	0.02 *		0	0
	VR 0589	Potato	0.1	0.05	0.05	0.06
	PM 0110	Poultry meat	0.01 *	0.05	0	0
	PO 0111	Poultry, Edible offal of	0.01 *	0.05	0	0

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	SO 0495	Rape seed	1.5	2	0.49	
	GC 0649	Rice	W	10		
	CM 0649	Rice, husked	W	1		
	CM 1205	Rice, polished	W	0.2		
	GC 0651	Sorghum	W	2		
	VD 0541	Soya bean (dry)	0.3	0.2	0.03	
	FS 0012	Stone fruits	0.02 *		0	
	FB 0275	Strawberry	0.05 *		0	
	SO 0702	Sunflower seed	0.9	1	0.11	
	OC 0172	Vegetable oils, Crude	W	0.05		
		Vegetables (except as otherwise listed)	W	0.05		
	GC 0654	Wheat	W	2		
	CM 0654	Wheat bran, unprocessed	W	2		
	CF 1211	Wheat flour	W	0.5		
	CF 1212	Wheat wholemeal	W	2		
	OR 0495	Rape seed oil, edible	0.0098			
	OR 0702	Sunflower seed oil, edible	0.066			
	OR 0541	Soya bean oil, refined	0.00165			
Definition of the residue for compliance with MRL and for estimation of dietary intake (for animal and plant commodities): *Diquat* The residue is not fat soluble.						
Dithianon (180)**	TN 0660	Almonds	0.05*		0	0
ADI: 0–0.01 mg/kg bw	FS 0013	Cherries	W	5[a]		
ARfD: 0.1 mg/kg bw	FB 0021	Currants, Black, Red, White	2		0.105	0.89
	DF 0269	Dried grapes (= currants, Raisins and Sultanas)	3.5		1.03	2.13
	MO 0105	Edible offal (Mammalian)	0.01*		0	0
	PE 0112	Eggs	0.01*		0	0
	FB 0269	Grapes	W	3[b]		
	DH 1100	Hops, dry	300	100	64	
	FC 0206	Mandarin	W	3		
	MM 0095	Meat (from mammals other than marine mammals)	0.01*		0	0
	ML 0106	Milks	0.01*		0	0
	FP 0009	Pome fruits	1	5	0.15	0.65
	PM 0110	Poultry meat	0.01*		0	0
	PO 0110	Poultry, Edible offal of	0.01*		0	0
	FC 0005	Shaddocks or pomelos (including Shaddock-like hybrids, among others than grapefruit)	W	3		
	FS 0012	Stone fruits	2		0.43	1.6
	FB 1235	Table-grapes	2		0.63	1.3
	FB 1236	Wine-grapes	5		0.69[c]	
		Apples, canned			0.009	

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	DF 0226	Apples, dried			0.015	
	JF 0226	Apple juice			0.0045	
		Apple sauce			0.0045	
		Apple syrup			0.006	
		Beer			0.019	
		Cherries, canned			0.024	
		Cherry jam			0.024	
		Cherry juice			0.024	
	JF 0269	Grape juice			0.002 [b]	
		Grape wine			0.002 [b]	
		Plum puree			0.015	
	DF 0014	Prunes			0.22	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: *Dithianon.* The residue is not fat-soluble. [a] STMR-P based on median residue of the whole fruit [b] STMR-P based on median residue of wine grapes						
Fenamidone (264)* ADI: 0–0.03 mg/kg bw ARfD: 1 mg/kg bw						
Fenbuconazole (197) ADI: 0–0.03 mg/kg bw ARfD: 0.2 mg/kg bw	FC 0001	Citrus fruit (except Lemons and Limes)	0.5	-	0.01	0.01
	OR 0001	Citrus oil, edible (except Lemons and Limes)	30	-	5.2	-
	AB 0001	Citrus pulp, dry	4	-	0.63	-
	FC 0002	Lemons and Limes (including Citron)	1	-	0.018	0.085
	JF 0001	Citrus juice (except lemons and limes)			0.021	
		Juice of lemons and limes			0.067	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake, for plant and animal commodities): *fenbuconazole* The residue is not fat soluble						
Fenpyroximate (193) ADI: 0–0.01 mg/kg bw ARfD: 0.02 mg/kg bw	FI 0326	Avocado	0.2	-	0.055	0.10
	MO 1280	Cattle kidney	W	0.01*		
	MO 1281	Cattle liver	W	0.01*		

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	MM 0812	Cattle meat	W	0.02 (fat)		
	ML 0812	Cattle milk	W	0.005* F		
	FS 0013	Cherries	2	-	0.57	0.90
	VP 0526	Common bean (pods and/or immature seeds)	0.4	-	0.09	0.19
	VC 0424	Cucumber	0.3	0.03	0.07	0.19
	MO 0105	Edible offal (Mammalian)	0.02		0.003 Liver 0.003 Kidney	0.004 Liver 0.011 Kidney
	MM 0095	Meat (from mammals other than marine mammals)	0.2 (fat)		0.011 (muscle) 0.021(fat)	0.021 (muscle) 0.084 (fat)
	ML 0106	Milks	0.01*		0.005	
	VR 0589	Potato	0.05	-	0	0
	DF 0014	Prunes	0.7	-	0.18	0.50
	FS 0012	Stone fruits (except cherries)	0.4	-	0.13	0.29
	FB 0275	Strawberry	0.8	-	0.215	0.59
Definition of the residue for both plant and animal commodities (for compliance with the MRL and for estimation of dietary intake): *fenpyroximate.* The residue is fat soluble						
Fludioxonil (211)	FI 0326	Avocado	0.4		0.05	
ADI: 0–0.4 mg/kg bw	HH 0772	Basil, sweet	W	10		
ARfD: Unnecessary	DH 0772	Basil, dry	W	50		
	VP 0061	Beans, except broad bean and soya bean (green pods and immature seeds)	0.6	0.3	0.04	
	VP 0062	Beans (shelled)	0.4		0.02	
	VD 0071	Beans (dry)	0.5	0.07	0.04	
	VC 4199	Melons	W	0.03		
	HH 0727	Chives	W	10		
	DH 0727	Chives, dry	W	50		
	HS 0444	Peppers Chili, dried	2		1.2	
	DH 0092	Dried herbs	60		16.5	
	PE 0112	Eggs	0.01*	0.05*	0	
	VC 0045	Fruiting vegetables, Cucurbits	0.5		0.065	
	VR 0604	Ginseng	4		0.29	
	HH 0092	Herbs	9		2.65	
	VL 0483	Lettuce, leaf	40		8.3	
	VP 0063	Peas (pods and succulent=immature seeds)	0.6	0.3	0.04	
	VO 0051	Peppers	1		0.18	
	VO 0445	Peppers, sweet (including pimento or pimiento)	W	1		
	VR 0589	Potato	5 Po	0.02	1.4	
	PM 0110	Poultry meat	0.01*	0.01*	0	
	PO 0111	Poultry, Edible offal of	0.05*	0.05*	0	
	VR 0494	Radish	20		3.8	

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	VP 4453	Snap beans (young pods)	0.6		0.04	
	VL 0502	Spinach	30		5.8	
	VO 0448	Tomato	2	0.5	0.605	
		Potato chips			0.056	
		Tomato purée			0.028	
	JF 0048	Tomato juice			0.026	
For compliance with the MRL and for estimation of dietary intake for plant commodities: *fludioxonil*.						
For compliance with the MRL and for estimation of dietary intake for animal commodities: *fludioxonil and its benzopyrrole metabolite,s determined as 2,2-difluoro-1,3-benzodioxole-4-carboxylic acid and expressed as fludioxonil.*						
The residue is fat-soluble.						
Fluensulfone (265)* ADI: 0–0.01 mg/kg bw ARfD: 0.3 mg/kg bw						
Flutolanil (205) ADI: 0–0.09 mg/kg bw ARfD: Unnecessary	VL 0054	Brassica leafy vegetables	0.07	-	0.05	
	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	0.05*	-	0	
	MO 0105	Edible offal	0.5	-	0.147 Liver 0.036 Kidney	
	MO 0098	Kidney of cattle, goats, pigs and sheep	W	0.1		
	MO 0099	Liver of cattle, goats, pigs and sheep	W	0.2		
Definition of the residue for plant commodities (for compliance with MRLs and for estimation of dietary intake): *flutolanil.*						
Definition of the residue for animal commodities (for compliance with MRLs and for estimation of dietary intake): *flutolanil and transformation products containing the 2-trifluoromethylbenzoic acid moiety, expressed as flutolanil.*						
The residue is not fat-soluble						
Glyphosate (158) ADI: 0–1 mg/kg bw ARfD: Unnecessary	SO 0495	Rape seed	30	20	3.0	
	OR 0495	Rape seed oil, edible			0.009	
Definition of the residue for compliance with MRL (for plant commodities): *for soya bean, maize and rape: sum of glyphosate and N-acetylglyphosate, expressed as glyphosatefor other crops: glyphosate.*						
Definition of the residue for compliance with MRL (for animal commodities): *sum of glyphosate and N-acetylglyphosate, expressed as glyphosate*						

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
Definition of the residue for estimation of dietary intake (for plant and animal commodities): *glyphosate, N-acetylglyphosate, AMPA and N-acetyl AMPA, expressed as glyphosate.* The residue is not fat soluble.						
Imazapic (266)*	GC 0645	Maize	0.01*		0.01	
ADI: 0–0.7 mg/kg bw	GC 0649	Rice	0.05*		0	
ARfD: Unnecessary	GC 0654	Wheat	0.05*		0	
	GS 0659	Sugar cane	0.01*		0	
	SO 0697	Peanut	0.05*		0	
	SO 0495	Rape seed	0.05*		0	
	PF 0111	Poultry fats	0.01*		0	
	PM 0110	Poultry meat	0.01*		0	
	PO 0111	Poultry, edible offal of	0.01*		0	
	PE 0112	Eggs	0.01*		0	
	MO 0105	Edible offal (Mammalian)	1		0.05 Liver 0.287 Kidney	
	MF 0100	Mammalian fats (except milk fats)	0.1		0.05	
	MM 0095	Meat (from mammals other than marine mammals)	0.1		0.05	
	ML 0106	Milks	0.1		0.019	
	AS 0654	Wheat straw and fodder, dry	0.05*		0 [a]	0 [a]
	AS 0162	Hay or fodder (dry) of grasses	3		0.5 [a]	2.3 [a]
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. [a] for the purpose of estimating animal dietary burdens.						
Imazapyr (267)*	MO 0105	Edible offal (Mammalian)	0.05*		0.0008	
ADI: 0–3 mg/kg bw	PE 0112	Eggs	0.01*		0	
ARfD: Unnecessary	VD 0533	Lentil (dry)	0.3		0.07	
	GC 0645	Maize	0.05*		0.05	
	MF 0100	Mammalian fats (except milk fats)	0.05*		0	
	MM 0095	Meat (from mammals other than marine mammals)	0.05*		0	
	ML 0106	Milks	0.01*		0	
	PO 0111	Poultry, Edible offal of	0.01*		0	
	PF 0111	Poultry fats	0.01*		0	
	PM 0110	Poultry meat	0.01*		0	
	SO 0495	Rape seed	0.05*		0	
	SO 0702	Sunflower seed	0.08		0.01	
	GC 0654	Wheat	0.05*		0	
	AS 0654	Wheat straw and fodder, dry	0.05*		0	

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	OR 0645	Maize oil, edible			0.025	
Definition of the residue for plant commodities (for compliance with the MRL and for estimation of dietary intake): *Imazapyr* The residue is not fat soluble.						
Indoxacarb (216) ADI: 0–0.01 mg/kg bw ARfD: 0.1 mg/kg bw	DT1114	Tea, green, black (black, fermented and dried)	5		0.41	
		Tea infusion			0.025	
Definition of the residue for compliance with the MRL for all commodities and for estimation of dietary intake for plant commodities: *sum of indoxacarb and its R enantiomer.* Definition of the residue for estimation of dietary intake for animal commodities: sum of indoxacarb, its R enantiomer and methyl 7-chloro-2,5-dihydro-2-[[[4-(trifluoromethoxy)phenyl] amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate, expressed as indoxacarb. The residue is fat soluble.						
Isoxaflutole (268)*	VO 0447	Sweet corn (corn-on-the-cob)	0.02*		0	
ADI: 0–0.02 mg/kg bw	VD 0524	Chick-pea (dry)	0.01*		0	
ARfD: Unnecessary	GC 0645	Maize	0.02*		0.02	
	GS 0659	Sugar cane	0.01*		0	
	SO 0698	Poppy seed	0.02*		0	
	AL 0524	Chick-pea fodder	0.01*		0.01	0.01 [a]
	AS 0645	Maize fodder	0.02*		0.02	0.02 [a]
	MM 0095	Meat (from mammals other than marine mammals)	0.01*		0	
	MO 0105	Edible offal (Mammalian)	0.1*		0.2	
	MF 0100	Mammalian fats (except milk fats)	0.01*		0	
	ML 0106	Milks	0.01*		0	
	PM 0110	Poultry meat	0.01*		0	
	PF 0111	Poultry fats	0.01*		0	
	PO 0111	Poultry, Edible offal of	0.2		0.1	
	PE 0112	Eggs	0.01*		0	
Definition of the residue for compliance with the MRL and for dietary risk assessment for plant commodities: *sum of isoxaflutole and isoxaflutole diketonitrile, expressed as isoxaflutole.* Definition of the residue for compliance with the MRL for animal commodities: *sum of isoxaflutole and isoxaflutole diketonitrile, expressed as isoxaflutole.* Definition of the residue for dietary risk assessment for animal commodities: *sum of isoxaflutole, isoxaflutole diketonitrile, RPA 205834 (2-aminomethylene-l-cyclopropyl-3-(2-mesyl-4-trifluoromethylphenyl)-propane-1,3-dione) and RPA 207048 (1-cyclopropyl-2-hydroxymethylene-3-(2-mesyl-4-trifluoromethylphenyl)-propane-1,3-dione), including their conjugates, expressed as isoxaflutole.* The residue not fat soluble. [a] for the purpose of estimating animal dietary burdens.						
Malathion (049) ADI: 0–0.3 mg/kg bw ARfD: 2 mg/kg bw	FS0013	Cherries	3		0.535	1.21

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
Definition of the residue (for compliance with the MRL and for estimation of dietary intake for plant and animal commodities): *malathion* The residue is fat soluble						
Mandipropamid (231) ADI: 0–0.2 mg/kg bw ARfD: Unnecessary	DH 1100	Hops, dry	90		28.5	
	-	Beer	-		0.057	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake for plant and animal commodities)*: mandipropamid.* The residue not fat soluble.						
Penthiopyrad (253) ADI: 0–0.1 mg/kg bw ARfD: 1 mg/kg bw	GC 0640	Barley	0.2	0.15	0.086	-
	MO 0105	Edible offal (Mammalian)	0.08	-	0.043	0.065
	MF 0100	Mammalian fats (except milk fats)	0.05	-	0.031	0.036
	MM 0095	Meat (from mammals other than marine mammals)	0.04	-	0.012	0.026
	ML 0106	Milks	0.04	-	0.013	-
	GC 0647	Oats	0.2	0.15	0.086	-
	GC 0650	Rye	0.1	0.04	0.01	-
	GC 0653	Triticale	0.1	0.04	0.01	-
	GC 0654	Wheat	0.1	0.04	0.01	-
	CM 0654	Wheat, bran	0.2	0.1	0.018	-
	CF 1210	Wheat, germ	0.2	0.1	0.019	-
		Barley, beer			0.021	
		Barley, pearl			0.058	
Definition of the residue for compliance with MRL for plant commodities: *penthiopyrad* Definition of the residue for compliance with MRL for animal commodities and for the estimation of dietary intake for plant and animal commodities: *sum of penthiopyrad and 1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide (PAM), expressed as penthiopyrad* The residue is not fat-soluble						
Propiconazole (160) ADI: 0–0.07 mg/kg bw ARfD: 0.3 mg/kg bw	FS 0247	Peach	5 Po		1.55	2.2
	FS 0014	Plums (including prunes)	0.6 Po		0.185	0.22
	FC 0004	Oranges, Sweet, Sour (including Orange-like hybrids): several cultivars	9 Po		2.95	4.9
	VO 0448	Tomato	3		0.72	1.76

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	JF 0001	Citrus juice			0.07	
Definition of the residue for compliance with MRL (for plant and animal commodities): *propiconazole* Definition of the residue for estimation of dietary intake (for plant and animal commodities): *propiconazole plus all metabolites convertible to 2.4-dichlorobenzoic acid, expressed as Propiconazole* The residue is fat soluble						
Pyrimethanil (226)	FP 0009	Pome Fruits	15 Po	7	1.6	
ADI: 0–0.2 mg/kg bw	DV 0604	Ginseng, dried including red ginseng	1.5		0.41	
ARfD: Unnecessary	FB 2009	Low growing berries	3		1.2	
	FB 0275	Strawberry	W	3		
	JF 0226	Apple, Juice			0.72	
Definition of the residue (for compliance with MRL and dietary intake) for plant commodities: *pyrimethanil* The residue is not fat-soluble						
Spirotetramat (234)	VS 0620	Artichoke, Globe	1		0.41	0.70
ADI: 0–0.05 mg/kg bw	FB 2006	Bush berries	1.5		0.63	1.6
ARfD: 1.0 mg/kg bw	FB 0265	Cranberry	0.2		0.066	0.15
Definition of the residue (for compliance with MRL for plant commodities: *Spirotetramat and its enol metabolite, 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat.* Definition of the residue (for estimation of dietary intake)for plant commodities: *Spirotetramat, enol metabolite 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, ketohydroxy metabolite 3-(2,5-dimethylphenyl)-3-hydroxy-8-methyoxy-1-azaspiro[4.5]decane-2,4-dione, monohydroxy metabolite cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one, and enol glucoside metabolite glucoside of 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat.* Definition of the residue (for compliance with MRL and estimation of dietary intake) for animal commodities: *Spirotetramat enol metabolite, 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat*. The residue is not fat-soluble.						
Sulfoxaflor (252)	VD 0071	Beans (dry)	0.3		0.075	
ADI: 0–0.05 mg/kg bw	VR 0577	Carrots	0.05		0.01	0.03
ARfD: 0.3 mg/kg bw Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: *sulfoxaflor*. The residue is not fat soluble.						

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
Tolfenpyrad (269)*		Tea, green	30		5.65	
ADI: 0–0.006 mg/kg bw						
ARfD: 0.01 mg/kg bw		Green tea infusion			0.24	
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 for animal commodities tolfenpyrad and free PT-CA (and conjugated *PT-CA and OH-PT-CA) expressed as tolfenpyrad*.						
Definition of the residue for estimation of dietary intake for animal commodities: *sum of tolfenpyrad, and free and conjugated PT-CA (and OH-PT-CA) expressed as tolfenpyrad.*						
The residue is not fat soluble.						
Triazophos (143)	CM 0649	Rice, husked	2		0.12	
ADI: 0–0.001 mg/kg bw	CM 1205	Rice, polished	0.6		0.041	
ARfD: 0.001 mg/kg bw						
Definition of residue (for compliance with the MRL and for estimation of dietary intake): *triazophos*.						
Triflumizole (270)*	FS 0013	Cherries	4		1.17	1.5
ADI: 0–0.04 mg/kg bw	FB 0269	Grapes	4		0.41	2.0
ARfD: 0.3 mg/kg bw	FI 0350	Papaya	2		0.71	0.89
	DH 1100	Hops, dry	30		8.9	11
	MF 0100	Mammalian fats (except milk fat)	0.02		0.01	0.02
	ML 0106	Milks	0.02 *		0.02	0.02
	MM 0095	Meat (from mammals other than marine mammals)	0.05 (fat)		0 (Muscle) 0.01 (Fat)	0 (Muscle) 0.03 (Fat)
	MO 0105	Edible Offal (Mammalian)	0.2		0.11	0.12
	JF 0269	Grape juice			0.17	
	DF 0269	Dried grapes (=currants, Raisins and Sultanas)			0.06	
Definition of the residue for plant and animal commodities (for compliance with the MRL and for estimation of dietary intake): *Residues analysed as 4-chloro-2-(trifluoromethyl)aniline and expressed as parent triflumizole.*						
The residue is fat soluble						
Trinexapac-ethyl (271)*	GC 0640	Barley	3		0.57	
ADI: 0–0.3 mg/kg bw		Barley bran	6		1.08	
ARfD: Unnecessary	AS 0640	Barley straw and fodder, dry	0.9 [a]		0.19	1.34 [b]
	MO 0105	Edible offal (Mammalian)	0.1		0.015	
	PE 0112	Eggs	0.01*		0	
	MF 0100	Mammalian fats (except milk fats)	0.01 *		0	
	MM 0095	Meat (from mammals other than marine mammals)	0.01 *		0	
	ML 0106	Milks	0.005 *		0	
	GC 0647	Oats	3		0.57	

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	AS 0647	Oat straw and fodder, dry	0.9 [a]		0.19	1.34 [b]
	PF 0111	Poultry fats	0.01 *		0	
	PM 0110	Poultry meat	0.01 *		0	
	PO 0111	Poultry, Edible offal of	0.05		0.015	
	SO 0495	Rape seed	1.5		0.24	
	GS 0659	Sugar cane	0.5		0.07	
	GC 0653	Triticale	3		0.57	
	AS 0653	Triticale straw and fodder, dry	0.9 [a]		0.19	1.34 [b]
	GC 0654	Wheat	3		0.57	
	CM 0654	Wheat bran	8		1.08	
	AS 0654	Wheat straw and fodder, dry	0.9 [a]		0.19	1.34 [b]
		Barley flour			0.25	
		Pearled barley			0.68	
	OR 0495	Rape seed oil, edible			0.01	
	CF 1211	Wheat flour			0.25	
	CF 1210	Wheat germ			0.63	

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

Definition of the residue (for estimation of dietary intake for plant commodities): *Trinexapac and its conjugates, expressed as trinexapac acid*

The residue is not fat soluble

[a] Dry weight basis

[b] for the purpose of estimating animal dietary burdens.

Edited versions of these general considerations will be published in the report of the 2013 JMPR. They are reproduced here so that the information is disseminated quickly. These drafts are subject to technical editing.

1. Response to specific concerns raised by CCPR

1.1 Buprofezin (173)

Buprofezin was evaluated by JMPR in 1991 for the first time and then in 1995 and 1999. It was also reviewed under the Periodic Re-evaluation Programme in 2008 for toxicity and residues followed by residue evaluations in 2009 and 2012.

The 2012 Meeting received information on supervised trials on coffee conducted in Brazil and the USA and relevant information on analytical method and storage stability. The Meeting concluded that it was not possible to estimate a maximum residue level for coffee beans as the Meeting did not have sufficient information on normal agricultural practices in coffee in Brazil or the USA to determine their similarity.

The current Meeting received a concern form from the USA along with information on the cultivation practices and field trial conditions of the trial sites in Brazil and the USA.

The Meeting considered from the information provided that their cultivation practices are sufficiently similar.

However, according to the study reports, there was a significant difference in the processing of coffee berries (cherries) to green coffee which is the raw agricultural commodity.

In the trials in Hawaii, the ripe coffee berries harvested were placed in hand-cranked pulper to separate the green beans from the berries. Beans were put in buckets with water to cover and left to ferment overnight. Pulp was then removed and the beans were dried in an oven for approximately 14–16 hours at 50 °C.

In the trials in Brazil, the collected fresh coffee berries were processed according to standard local practices to produce green coffee. The coffee berries were sun-dried during the day and moved inside each night. Once the desired moisture level was obtained, the outer part of the coffee beans was removed with a hand-held shelling device and samples were cleaned manually using sieves. The time from harvesting fresh berries in the field and obtaining the green bean sample was 17 days.

The Meeting recognized that while the cultivation practices in the trials conducted in Hawaii and those in Brazil were similar, the processing methods of harvested coffee berries to produce green coffee were significantly different. This difference may have impact on residue concentrations in green coffee. The Meeting therefore concluded that, as it is not appropriate to combine the residue populations from trials in Hawaii and those in Brazil for the reason above to estimate a maximum residue level, it was not possible to estimate a maximum residue level for coffee.

1.2 Clothianidin (238)

Background

During the Forty-third Session of the CCPR meeting in 2011, the EU expressed a reservation regarding the advancement of the clothianidin MRL proposal for root and tuber vegetables. The concern regarding the procedure used by JMPR to propose this group MRL was expressed again by the EU delegation during the Forty-forth Session of the CCPR in 2012 (cf. REP12/PR §65). The Committee retained the proposed draft MRL for root and tuber vegetables at Step 7, noting the reservation of the Delegation of the EU; and awaiting further clarification from JMPR.

Evaluation of clothianidin and thiamethoxam by JMPR

Clothianidin is a neonictinoid insecticide and is related to the neonictinoid insecticide thiamethoxam in that clothianidin is a metabolite of thiamethoxam and thiamethoxam use may lead to clothianidin residues. Clothianidin and thiamethoxam were evaluated for toxicology and residues as a new compound in 2010, resulting in a number of MRL recommendations. Additional residue data were evaluated in 2011 and 2012.

The 2010 Meeting established an acceptable daily intake (ADI) of 0–0.1 mg/kg bw per day and estimated the acute reference dose (ARfD) as 0.6 mg/kg bw for clothianidin. The residue definition for clothianidin in plant commodities for enforcement and dietary risk assessment is clothianidin.

The 2010 Meeting established an acceptable daily intake (ADI) of 0–0.08 mg/kg bw per day and estimated the acute reference dose (ARfD as 1 mg/kg bw for thiamethoxam. The residue definition for thiamethoxam in plant commodities for enforcement is thiamethoxam, while the residue definition for dietary risk assessment is thiamethoxam and the metabolite CGA 322704 (i.e. clothianidin), considered separately.

Clothianidin residues may arise from use of clothianidin as well as from use of thiamethoxam (through metabolite CGA 322704, i.e., clothianidin). The 2010 Meeting considered it unlikely that both pesticides were used on the same crop and therefore the maximum estimated levels, the maximum STMR, and the maximum HR of each use was taken as recommendation. This is summarized in the table below.

CCN	Commodity name	Origin	Recommendation mg/kg	STMR mg/kg	HR mg/kg
VR 0075	Root and tuber vegetables	CGA 322704	0.2	0.01	0.15
VR 0577	Carrot	clothianidin	insufficient data		
VR 0469	Chicory, roots	clothianidin	insufficient data		
VR 0589	Potato	clothianidin	0.05	0.02	0.033
VR 0596	Sugar beet roots	clothianidin	0.03	0.01	0.019
VR 0075	Root and tuber vegetables	both uses	0.2 [a, b]	0.02	0.15

[a] based on clothianidin use as derived from 2010 clothianidin evaluation

[b] based on thiamethoxam use as derived from 2010 thiamethoxam evaluation (metabolite CGA 322704).

Evaluation of clothianidin by EU

The present meeting received a concern form from the EU relating to the proposed maximum residue level of clothianidin for root and tuber vegetables.

A MRL recommendation of 0.2 mg/kg on clothianidin (CGA 322704) arising from thiamethoxam use was derived from a complete residue database on potato seed pieces (seed treatment) and was extrapolated to the root and vegetables group including sugar beet root. The EU noted that all the trials were performed at a dose rate 30% higher than the critical one.

The EU noted that the performed extrapolations were on crops with widely differing GAPs and application methods. GAPs for thiamethoxam were reported for carrots, potatoes, radishes and sugar beet. In addition, GAPs for clothianidin were reported for chicory roots, tuberous and corm vegetable and sugar beet, but they were less critical than the use of thiamethoxam. The EU noted that the GAPs were not comparable: seed treatment for potatoes and for sugar beets, foliar application and/or soil treatment for the other crops,

different application rate for carrots and radishes compared with potatoes and only GAP for clothianidin on chicory roots (not supported by sufficient trial data). An overview as made by EU is given in the table below.

Therefore the EU concluded that extrapolation of residues, found on potatoes (following treatment with thiamethoxam), to the whole group of root and tuber vegetables is not acceptable. The EU indicated that there are sufficient data to set individual MRLs for carrots, potatoes, radishes, and sugar beet root.

	origin	**recommendation (mg/kg)**	**STMR (mg/kg)**	**HR (mg/kg)**
Carrots Clothianidin:	clothianidin	insufficient data (trials involving seed treatments available, but no GAP)		
no GAP Thiamethoxam Foliar treatment at 0.070 kg ai/ha Soil treatment at sowing at 0.21 kg ai/ha	CGA 322704		[≤ LOQ 0.01 mg/kg (n=8)] [≤ LOQ 0.01 mg/kg (n=6)]	
Radish roots Thiamethoxam Foliar treatment at 0.070 kg ai/ha Soil treatment at sowing at 0.21 kg ai/ha	CGA 322704		[≤ LOQ 0.01 mg/kg (n=6)] [≤ LOQ 0.01 mg/kg (n=4)]	
Chicory roots Clothianidin Seed treatment at 0.3 mg ai/seed	clothianidin	insufficient data (only 1 trial matching GAP (<0.01 mg/kg))		
Potato Clothianidin Soil treatment (at planting) at 224 g ai/ha *Less critical:* Foliar treatment at 224 g ai/ha per season Thiamethoxam Seed treatment at 6.2 g thiamethoxam/100 kg seed) *Less critical:* Foliar treatment at 0.025 kg ai/ha (EU) or 0.053 kg ai/ha (USA)	clothianidin	0.05	0.02	0.033
			[<0.02 mg/kg at exaggerated dose]	
	CGA 322704	**0.2**	0.01 [30% overdosed trials]	0.15 [30% overdosed trials]
			[<LOQ 0.02 mg/kg (n=13)] [<LOQ 0.01 mg/kg (n=14); 100% overdosed trials]	
Sugar beet roots Clothianidin Seed treatment at 0.6 mg ai/seed Thiamethoxam Seed treatment at 60 g ai/100,000 seeds	clothianidin	0.03	0.01	0.019
	CGA 322704		[≤ LOQ 0.02 mg/kg (n=9)]	

Comments by JMPR

The current recommendation for clothianidin for the root and tuber vegetables group is based on thiamethoxam treatment of potato seed pieces. Since clothianidin residues result from clothianidin use and thiamethoxam use, clothianidin residues cannot be judged on their own. In this case thiamethoxam (parent) residues determined whether a group MRL was appropriate. Once a group MRL for thiamethoxam (parent) is set, also a group MRL for clothianidin needs to be set. Therefore, thiamethoxam data for thiamethoxam parent need to be evaluated first.

Response to specific concerns raised by CCPR

For thiamethoxam use, the 2010 Meeting received several supervised field trials on root and tuber vegetables. In trials on carrots, thiamethoxam levels were < 0.01 mg/kg (n=8) after foliar spray (0.070 kg ai/ha, PHI 7 days) and < 0.01 (2), 0.01, 0.02 (2), 0.04 mg/kg (n=6) after soil treatment (0.21 kg ai/ha, at planting). In trials on potatoes, thiamethoxam levels were < 0.02 mg/kg (n=7) or < 0.01 mg/kg (n=15, at 2× label rate) after foliar treatment. In trials on potatoes after seed treatment, thiamethoxam levels were < 0.01 (11), 0.02, 0.05, 0.14, 0.18, 0.20 mg/kg (n=16). The GAP for treatment of potato seed pieces (4.3-6.2 g ai per 100 kg pieces) resulted in higher thiamethoxam residues than the GAP for foliar treatment of potatoes (0.025 kg ai/ha with PHI 7 days or 0.053 kg ai/ha with PHI 14 days). It was noted that all the trials with seed treatments were performed at a dose rate 30% higher than the critical one. In trials on radish roots, thiamethoxam residues were < 0.01 (4), 0.01 (2) mg/kg mg/kg (n=6) after foliar spray (0.070 kg ai/ha, PHI 7 days) or < 0.01 (3), 0.02 mg/kg (n=4) after soil treatment (0.11 kg ai/ha, at planting). In trials on sugar beets, thiamethoxam did not exceed the LOQ: < 0.02 mg/kg (n=9) after seed treatment (60 g ai/100000 seeds).

The 2013 Meeting agreed that a group maximum residue level for thiamethoxam (parent) in root and tubers would normally not be considered, since the thiamethoxam GAPs for potatoes, carrots, radishes and sugar beets are different. But although the GAPs are different (soil and foliar treatments on carrots and radishes and seed treatments on potatoes and sugarbeet), the dataset for potatoes is not significantly different from those for carrots, radishes and sugarbeets (Kruskall-Wallis test). To make the best use of the available data in a complex situation with a range of crops and a range of applications, the 2013 Meeting considered it appropriate to propose a group MRL for root and tuber vegetables for thiamethoxam residues and thereby confirmed its previous recommendation 0.3 mg/kg for thiamethoxam for root and tubers. Also the EU did not have a concern regarding thiamethoxam residues for the whole group of root and tubers. When a group maximum residue level is proposed for thiamethoxam residues, also a group maximum residue level needs to be proposed for clothianidin. The Meeting therefore confirmed its previous recommendation of 0.2 mg/kg for clothianidin for roots and tubers.

1.3 Glufosinate-ammonium (175)

Background

Glufosinate-ammonium was last evaluated by JMPR in 2012, when an ADI of 0–0.01 mg/kg bw was established, on the basis of an overall NOAEL of 1 mg/kg bw per day for reductions in glutamine synthetase activity in the brain of dogs. A safety factor of 100 was applied. The 2012 Meeting concluded that this ADI should also apply to its metabolites *N*-acetyl-glufosinate (NAG), 3-methylphosphinico-propionic acid (MPP) and 2-methylphosphinico-acetic acid (MPA). However, the 2012 Meeting noted that in view of the lower toxicity of NAG, MPP and MPA compared with glufosinate-ammonium, the application of the ADI to these metabolites is likely to be conservative.

In 2012, the Meeting also established an ARfD for glufosinate-ammonium of 0.01 mg/kg bw. This was based on the NOAEL of 1 mg/kg bw per day in a 28-day capsule study in dogs for an increase in spontaneous motor activity that occurred within a few days after the start of treatment and reductions in body weight gain and feed consumption observed during the 1st week of treatment with 8 mg/kg bw per day. A safety factor of 100 was applied. The 2012 Meeting concluded that this ARfD should also apply to its metabolites NAG, MPP and MPA and noted that in view of the lower acute toxicity of NAG, MPP and MPA compared with glufosinate-ammonium, the application of the ARfD to these metabolites is likely to be conservative.

At the request of CCPR, the present Meeting considered the possible use of relative toxic potencies of glufosinate-ammonium and its metabolites NAG, MPP and MPA to enable refinement of the dietary risk assessment. The Meeting reviewed the previously evaluated data from the 2012 JMPR as well as newly submitted data from a one-generation study of reproductive toxicity with MPP.

Evaluation of the new reproductive toxicity study with MPP

In a one-generation dietary reproductive toxicity study not previously evaluated by JMPR[1], Wistar Crl:WI(Han) rats (25 of each sex per group) were fed MPP (purity 99.6%) at a concentration of 0, 1000, 3200 or 10 000 ppm. The corresponding MPP intakes during the different phases of the study are presented in Table 1.

Table 1 MPP intake in parental rats and their offspring during different phases of a one-generation reproductive toxicity study

Generation	Duration of treatment (days)	Sex	Intake (mg/kg bw per day)		
			1000 ppm	3200 ppm	10 000 ppm
F_0 premating	21	Male	86	276	896
F_0 premating	21	Female	88	266	844
F_0 gestation	22	Female	87	260	844
F_0 lactation	21	Female	177	564	1678
F_1 PND 21–28	7	Male	174	600	2017
F_1 PND 21–28	7	Female	186	665	1989

From Milius (2011)

PND, postnatal day

Clinical examination of parental rats was performed daily. Parental body weight and feed consumption were recorded weekly during the premating and mating phases in both sexes, during the gestation period in females and on postnatal days (PNDs) 1, 4, 7, 14 and 21 in females. The rats were mated after 3 weeks of treatment. After birth, all litters were examined for number of pups, sex of pups, number of

[1] Milius AD (2011). Technical grade: AE F061517: A one-generation reproductive toxicity study in the Wistar rat. Unpublished report no. 11-P72-UI from Xenometrics, LLC, Stilwell, Kansas, USA. Submitted to WHO by Bayer CropScience, Monheim, Germany.

stillbirths, number of live births and pup viability. Litters were culled to eight pups per litter on PND 4. Pups were examined daily for clinical signs and weighed on PNDs 1, 4, 7, 14 and 21. In a selection of pups, body weight and feed consumption were measured on PND 28. Macroscopic examination was performed on all parental males after mating, on all parental females and about half the pups after weaning on PND 21 and on all pups kept until PND 28. Statements of adherence to quality assurance and GLP were included.

No effect of treatment was observed on any of the parameters examined in parental rats. In male and female pups at 10 000 ppm, lower body weights compared with control pups were observed at PND 4 (4–5%), PND 7 (5–6%), PND 14 (7%), PND 21 (12–13%) and PND 28 (12%), reaching statistical significance from PND 14 onwards. Feed consumption from PND 21 to PND 28 was not affected by treatment of the pups.

The NOAEL for parental toxicity was 10 000 ppm (equal to 844 mg/kg bw per day), the highest dose tested.

The NOAEL for offspring toxicity was 3200 ppm (equal to 564 mg/kg bw per day, based on maternal test substance intake during lactation), on the basis of a reduced body weight gain during and after lactation at 10 000 ppm (equal to 1678 mg/kg bw per day, based on maternal test substance intake during lactation).

The NOAEL for reproductive toxicity was 10 000 ppm (equal to 844 mg/kg bw per day), the highest dose tested.

Overview of toxicity data on glufosinate ammonium, NAG and MPP

Glufosinate-ammonium and its metabolites NAG and MPP have been tested in a number of toxicity studies of similar duration and design in mice, rats, rabbits and dogs (Table 2). It should be noted, however, that the parameters examined in the studies of similar duration are not always the same. Where the NOAEL for a certain compound is based solely on a parameter that was not investigated for the other compounds, this is indicated in the notes below the table. Short-term studies in mice were not included, as the only toxicologically relevant effect in the studies with NAG (i.e. inhibition of glutamine synthetase) was not investigated in the short-term studies with glufosinate-ammonium. Data from studies in which for all compounds the NOAEL was the highest dose tested (e.g. parental toxicity in reproductive toxicity studies) are not presented. On the basis of the comparison of NOAELs and LOAELs in the relevant studies of these three compounds, an indication of their relative toxic potency can be obtained.

Table 2 NOAELs and LOAELs in studies of glufosinate-ammonium (GA), NAG and MPP, and relative potency based on comparison of NOAELs

Species	Study type	GA		NAG		MPP		NOAEL NAG/ NOAEL GA	NOAEL MPP/ NOAEL GA
		NOAEL (mg/kg bw per day)	LOAEL (mg/kg bw per day)	NOAEL (mg/kg bw per day)	LOAEL (mg/kg bw per day)	NOAEL (mg/kg bw per day)	LOAEL (mg/kg bw per day)		
Rat	Thirty-eight-day neurotoxicity	1.5[a]	15	159[a]	—	—	—	106	—
Rat	Thirteen-week (neuro)toxicity	6.2[b]	63.6	63.2[b]	658	546[c]	—	10	—
Dog	Four-week toxicity	1[d]	8	—	—	—	—	—	—
Dog	Thirteen-week toxicity	2.0	7.8	20[e]	76	103	—	10	52
Dog	Fifty-two-week toxicity	4.5	10.6–13.6[h]	325	—	—	—	72	—
Mouse	Two-year toxicity	10.8	23	1188	—	—	—	110	—
Rat	Two-year toxicity	7.6	26.7	91[f]	998	—	—	12	—
Rat	One- and two-generation reproductive toxicity[g]								
	Offspring toxicity	44	—	—	—	564	1678	—	13
	Reproductive toxicity	8.7	18	622		844	—	74	97
Rat	Developmental toxicity								
	Maternal toxicity	10	50	1000	—	300	900	100	30
	Embryo and fetal toxicity	10	50	1000	—	300	900	100	30
Rabbit	Developmental toxicity								
	Maternal toxicity	6.3	20	64	160	50	100	10	8
	Embryo and fetal toxicity	6.3	20	64	160	50	100	10	8

[a] GA and NAG were tested in the same 38-day neurotoxicity study. The study included measurements of glutamine synthetase activity in brain, liver and kidney.

[b] GA and NAG were tested in the same 13-week neurotoxicity study. The study included measurements of glutamine synthetase activity in brain, liver and kidney.

[c] In the 13-week neurotoxicity study with MPP, measurements of glutamine synthetase activity were not included.

[d] The 28-day study in the dog was the basis for the ADI and ARfD.

[e] In the 13-week study with NAG in the dog, the NOAEL was 500 ppm (equal to 20 mg/kg bw per day), based on reduction in brain glutamine synthetase activity (≥ 16%) at 2000 ppm (equal to 76 mg/kg bw per day). No other effects were observed at doses up to 8000 ppm (equal to 294 mg/kg bw per day). Glutamine synthetase activity was not measured in the 13-week study with glufosinate-ammonium in the dog.

[f] The NOAEL in the 2-year study with glufosinate-ammonium was, among others, based on effects on GSH and GSSG levels and reduction of brain glutamine synthetase. These parameters were not assessed in the study with NAG.

[g] In the one- and two-generation reproductive toxicity studies with glufosinate-ammonium, NAG and MPP, the NOAELs for parental toxicity were the highest doses tested. Therefore, only data on the NOAELs and LOAELs for offspring and reproductive toxicity are presented. For glufosinate-ammonium, the overall NOAEL and LOAEL from a one- and a two-generation reproductive toxicity study are presented.

[h] Doses are based on exposure to 375 ppm (equal to 10.6–13.6 mg/kg bw per day) for the first 10–17 days, after which the dose was reduced to 250 ppm (equal to 8.4 mg/kg bw per day).

Assessment of relative toxic potencies of NAG, MPP and MPA compared with glufosinate-ammonium

Glufosinate-ammonium, NAG and MPP have been tested in a number of toxicity studies with similar designs and durations in mice, rats, rabbits and dogs. Based on these studies, an indication of the relative toxic potencies of NAG and MPP compared with the parent compound can be obtained. Table 2 shows that the NOAELs for NAG are at least 10 times higher than those of glufosinate-ammonium, and generally the NOAELs for NAG are higher than the LOAELs for glufosinate-ammonium. The critical effect for glufosinate-ammonium, which formed the basis for its ADI and ARfD, is the inhibition of glutamine synthetase in the brain and (possibly acute) clinical signs of neurotoxicity observed in a 28-day study in dogs. NAG also caused inhibition of glutamine synthetase activity in in vivo studies and an in vitro study, at dose levels that were considerably higher than those of glufosinate-ammonium causing comparable inhibition. The inhibition of glutamine synthetase by NAG was attributed to the presence of glufosinate-ammonium as an impurity in the test substance and to the metabolic deacetylation of NAG to form free glufosinate. Biotransformation studies in rats indicate that after administration of a low dose (2.1–3.4 mg/kg bw) of NAG, up to 10% of the administered NAG may be deacetylated to glufosinate by the intestinal microflora. At higher doses, a lower percentage of NAG is converted to free glufosinate in the gut.

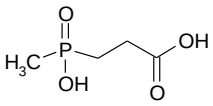
For NAG, the lowest NOAEL of 20 mg/kg bw per day, based on reduction in brain glutamine synthetase activity, was observed in a 13-week study in the dog. This NOAEL is 20 times higher than the NOAEL of 1 mg/kg bw per day for effects of glufosinate-ammonium in the 28-day toxicity study in dogs, which formed the basis for the ADI and ARfD.

In view of the above data, it seems reasonable to assume that after oral administration, NAG is at least 10 times less toxic than glufosinate-ammonium. Therefore, a factor of 0.1 can be applied to the dietary exposure estimate of NAG for acute and chronic dietary risk assessment of glufosinate-ammonium and its metabolites in food.

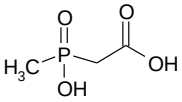
Table 2 shows that the NOAELs for MPP are at least 8 times higher than those of glufosinate-ammonium in similar studies. The lowest NOAEL for MPP was observed in a developmental toxicity study in the rabbit. This NOAEL of 50 mg/kg bw per day, for maternal and developmental toxicity, is 50 times higher than the NOAEL of 1 mg/kg bw per day for effects of glufosinate-ammonium in the 28-day toxicity study in dogs, which formed the basis for the ADI and ARfD. It is noted that the critical effect in the 28-day dog study is inhibition of glutamine synthetase activity and that MPP has no effect on this enzyme.

In view of the above data, it seems reasonable to assume that after oral administration, MPP is at least 10 times less toxic than glufosinate-ammonium. Therefore, a factor of 0.1 can be applied to the dietary exposure estimate of MPP for acute and chronic dietary risk assessment of glufosinate-ammonium and its metabolites in food.

For the metabolite MPA, only a limited toxicological database (i.e. an acute oral toxicity study, a 2-week dietary range-finding study and a 90-day dietary study in rats) is available, which in itself was considered insufficient by the Meeting to establish the toxic potency relative to that of glufosinate ammonium. However, the Meeting noted that MPA is structurally closely related to MPP, of which it is a metabolite (see Figure 1). The Meeting considered therefore that read-across from MPP to MPA was justified and concluded that the toxicity of MPA was likely to be similar to that of MPP. This is supported by the low toxicity observed in the available studies with MPA: in the acute toxicity study, the LD_{50} was greater than 2000 mg/kg bw, with diarrhoea as the only observed adverse effect. In the repeated-dose studies, no adverse effects were observed at the highest dose tested (1128 mg/kg bw per day in the 2-week range-finding study, 684 mg/kg bw per day in the 90-day study). Therefore, the Meeting concluded that the factor of 0.1 for MPP can also be applied to the dietary exposure estimate of MPA for acute and chronic dietary risk assessment of glufosinate-ammonium and its metabolites in food.



MPP



MPA

Figure 1 Chemical structures of MPP and MPA

Conclusion

The present Meeting established the relative toxic potencies of glufosinate-ammonium and the metabolites NAG, MPP and MPA on the basis of all available data.

In view of the identified differences in toxic potency of glufosinate-ammonium and its metabolites NAG, MPP and MPA, the Meeting concluded that the previously established ADI of 0–0.01 mg/kg bw, derived on the basis of an overall NOAEL of 1 mg/kg bw per day for glufosinate-ammonium for reductions in glutamine synthetase activity in the brain of dogs and application of a safety factor of 100, should be compared with the sum of the dietary exposure to glufosinate-ammonium + 0.1 × (the dietary exposure to NAG + MPP + MPA).

The Meeting concluded that the ARfD of 0.01 mg/kg bw, previously established on the basis of a NOAEL of 1 mg/kg bw per day in a 28-day capsule study of glufosinate-ammonium in dogs for an increase in spontaneous motor activity that occurred within a few days after the start of treatment and reductions in body weight gain and feed consumption observed during the 1st week of treatment with 8 mg/kg bw per day, and application of a safety factor of 100, should be compared with the sum of the dietary exposure to glufosinate-ammonium + 0.1 × (the dietary exposure to NAG + MPP + MPA).

Should new toxicological data on glufosinate-ammonium and/or its metabolites become available, the definitions of the ADI and ARfD may have to be reconsidered by a future Meeting.

Recalculation of STMR, HR, PF, STMR-P and HR-P values

The STMR and HR values as well as PFs, STMR-P and HR-P values estimated by the 2012 JMPR for foods have been recalculated using the above approach and are tabulated below.

For estimation of maximum residue levels the residues are calculated as the sum of glufosinate-ammonium, NAG, MPP and MPA without the need for adjustment for relative toxicity and as such the values used in estimating MRLs and also median and highest residues for use in livestock dietary burden do not need to be recalculated.

Table 3 Revised processing factors for glufosinate-derived residues for use in dietary intake estimation and calculated STMR-P and HR-P values

Raw commodity	Processed commodity	Individual PFs	Best estimate PF	$STMR_{RAC}$	STMP-P	HR_{RAC}	HR-P
Orange	Juice	0.96	0.96	0.05	0.048	0.05	0.048
	Dried peel / pulp	2.1	2.1		1.05		1.05
	Oil	<0.53	<0.53		<0.265		<0.265
Plum	Dried fruit	1.13	1.1	0.05	0.055	0.05	0.055
Grape	Wine	ND ND ND ND					
Olive	Oil	< 0.38	<0.38	0.05	<0.019	0.05	<0.019
Potato	Chips	2.3	2.3	0.05	0.106	0.05	0.106
	Flakes	2.0 3.0 3.0 3.8 4.0	3.0		0.15		0.15
	Crisps	1.7 1.8 1.9 2.5	1.85		0.0925		0.0925
	French fries	0.85 1.2 1.3 1.6	1.25		0.0575		0.0575
	Boiled potatoes	0.7 0.8 1.4 1.7	1.1		0.055		0.055

Raw commodity	Processed commodity	Individual PFs	Best estimate PF	$STMR_{RAC}$	STMP-P	HR_{RAC}	HR-P
	Fried potatoes	1.2 2.3 4.2 5.3	3.25		0.1625		0.1625
	Baked potatoes	1.4 1.5 1.7 1.9	1.6		0.08		0.08
Sugar beet	Molasses	3.8 5.0 6.3 11	5.65	0.225	1.27		
	Raw or refined sugar	<0.055<0.16 <0.18 <0.84	<0.17		<0.03825		
Soya bean	Oil	<0.11 <0.12 <0.22 <0.9	<0.17	0.714	<0.121		
Rapeseed	Oil	<0.04 <0.79 <0.98 <0.98	<0.04	0.225	<0.009		
Cottonseed	Oil	<0.013	<0.013	0.677	<0.0088		
Sunflower seed	Oil	0.023 <0.071 <0.074	0.023	0.47	0.0108		
Maize	Starch (wet milling)	ND ND					
	Oil (wet milling)	ND ND					
	Flour (dry milling)	ND ND					
	Oil (dry milling)	ND ND					
Rice	Bran	0.76 0.95	0.855	0.08	0.0684		
	Polished grain	<0.86 1.15	1.15		0.092		

ND: not determined. Denotes processing trials in which no processing factor could be derived because the residues were found to be < LOQ in both the raw agricultural commodity and the processed fractions.

The revised calculation for mammalian commodities is shown below:

Table 4 Revised calculation of STMR and HR values for mammalian commodities.

Glufosinate + MPP feeding study	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
HR beef or dairy cattle							
Feeding study [a]	4.0 12	< 0.02 0.02	4.0 12	< 0.05 < 0.05	0.28 0.42	0.041 0.20	0.06 0.08
Dietary burden and high residue	4.4	< 0.02	4.7	< 0.05	0.292	0.055	0.062
STMR beef or dairy cattle							
Feeding study [b]	4.0	< 0.02	4.0	< 0.05	0.157	0.038	0.05
Dietary burden and residue estimate	2.3	< 0.012	2.4	< 0.03	0.094	0.023	0.03

[a] highest residues for tissues and mean residues for milk

[b] mean residues for tissues and mean residues for milk

Table 5 Revised STMR and HR values for use in dietary intake calculations and for calculation of STMR-P and HR-P values.

Commodity CCN	Name	STMR (mg/kg)	HR (mg/kg)
VS 0621	Asparagus	0.05	0.27
FI 0030	Assorted tropical and sub- tropical fruits - inedible peel (except banana and kiwifruit)	0.05	0.05
FT0026	Assorted tropical and sub- tropical fruits - edible peel	0.05	0.05
FI 0327	Banana	0.05	0.054
FB 0018	Berries and other small fruits (except currants)	0.03	
FB 0020	Blueberries	0.05	0.06
VR 0577	Carrot	0.05	0.05
FC 0001	Citrus fruits	0.05	0.05
VD 0526	Common bean (dry)	0.04	
SB 0716	Coffee beans	0.04	
VP 0526	Common bean (pods and/or immature seeds)	0.05	0.05
VL 0470	Corn salad	0.05	0.05
SO 0691	Cotton seed	0.677	
FB 0021	Currants, Black, Red, White	0.02	0.403
MO 0105	Edible offal (mammalian)	0.023 Kidney 0.094 Liver	0.055 Kidney 0.292 Liver
PE 0112	Eggs	0	0.02
FB 0268	Gooseberry	0.02	0.02

Commodity CCN	Name	STMR (mg/kg)	HR (mg/kg)
FB 0269	Grapes	0.02	0.12
FI 0341	Kiwifruit	0.05	0.05
VL 0482	Lettuce, Head	0.05	0.05
VL 0483	Lettuce, Leaf	0.05	0.05
GC 0645	Maize	0.05	
MM 0095	Meat (from mammals other than marine mammals)	0.03 Muscle 0.03 Fat	0.05 Muscle 0.062 Fat
ML 0106	Milks	0.01	0.02
VA 0385	Onion, Bulb	0.05	0.05
FP 0009	Pome fruits	0.05	0.05
VR 0589	Potato	0.05	0.05
PM 0110	Poultry meat	0	0.02
PO 0111	Poultry, Edible offal of	0	0.04
SO 0495	Rape seed	0.225	
FB 0272	Raspberries, Red, Black	0.03	0.03
GC 0349	Rice	0.08	
VD 0541	Soya bean (dry)	0.714	
FS 0012	Stone fruits	0.05	0.05
FB 0275	Strawberry	0.02	0.15
VR 0596	Sugar beet	0.225	
SO 0702	Sunflower seed	0.47	
TN 0085	Tree nuts	0.05	0.05

Dietary risk assessment

Long-term intake

The WHO Panel of the 2012 JMPR established an Acceptable Daily Intake (ADI) of 0–0.01 mg/kg bw for glufosinate-ammonium.

The current Meeting re-evaluated the STMR values for glufosinate-ammonium. Where data on consumption were available for the listed food commodities, dietary intakes were calculated for the 13 GEMS/Food Consumption Cluster Diets. The results are shown in Annex 3 of the 2013 JMPR Report.

The IEDIs in the thirteen Cluster Diets, based on the estimated STMRs were 3–9% of the maximum ADI (0.01 mg/kg bw). The Meeting concluded that the long-term intake of residues of glufosinate-ammonium from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The WHO Panel of the 2012 JMPR established an Acute Reference Dose (ARfD) of 0.01 mg/kg bw for glufosinate-ammonium.

For soya bean (dry) the IESTI represented 110% of the ARfD of 0.01 mg/kg bw. For all other commodities the revised IESTI represented 0–100% of the ARfD. The Meeting concluded that, other than for soya beans, the short-term intake of residues of glufosinate-ammonium resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.

No alternative GAP was identified for soya beans (dry). Processing studies from soya bean for cooked soya bean products, including tofu, are desirable for further refinement of the exposure.

In 2012, the Meeting established an acute reference dose (ARfD) for glufosinate-ammonium of 0.01 mg/kg bw. This was based on the NOAEL of 1 mg/kg bw per day in a 28-day capsule study in dogs for an increase in spontaneous motor activity that occurred within a few days after the start of treatment and reductions in body weight gain and feed consumption observed during the 1st week of treatment with 8 mg/kg bw per day, and application of a safety factor of 100. The present Meeting concluded that it might be possible to refine the ARfD if new data became available.

1.4 Propylene oxide (250)

Background

JMPR reviewed the toxicology data on propylene oxide (PPO) and its metabolites propylene chlorohydrin (PCH) and propylene bromohydrin (PBH) in 2011. The Meeting established an ADI of 0–0.04 mg/kg bw and an ARfD of 0.04 mg/kg bw for PPO, both based on a NOAEC of 100 ppm (equivalent to approximately 40 mg/kg bw per day orally) for systemic effects from a chronic inhalation study in rats, with the application of a 1000-fold safety factor. The additional factor of 10 was applied due to limitations in the database. The 2011 Meeting was unable to establish any reference doses for PCH or PBH due to deficiencies in the databases.

At the 44th Session of CCPR, the delegation of the United States of America informed the Committee that it would submit residue data for tree nuts for JMPR evaluation in 2014. After the 44th Session of CCPR, the delegation of the USA submitted a concern form in May 2013 requesting clarification on a number of aspects of the JMPR consideration of PPO and its metabolites. The present Meeting has considered the issues raised in the concern form and the review of PPO by the United States Environmental Protection Agency (USEPA)[2] and reviewed the decisions of the 2011 Meeting. The conclusions of the present Meeting are set out below, against the concerns identified by the USA in the concern form.

Propylene oxide

Concern

"Regarding PPO, the U.S. respectfully requests that additional explanation be provided for the additional 10-fold uncertainty factor. Specifically, identification of the missing information from the relevant study(ies) is requested. As the ARfD was based on a chronic inhalation study in the rat, application of a total uncertainty factor of 1,000 to this endpoint seems excessively conservative without further explanation. Recommend consideration of a study demonstrating a single dose effect, such as the developmental study in the rat, be considered for establishment of the ARfD."

Response

The present Meeting noted that the USEPA and the 2011 JMPR agreed that there were deficiencies in the database for the toxicity of PPO and that both had used 1000-fold safety factors in establishing ADIs and ARfDs; the difference in the derived values was in the points of departure chosen. The Meeting noted that the USEPA had established an ARfD of 0.21 mg/kg bw based on a NOAEC of 300 ppm (equivalent to 209 mg/kg bw per day) from a rat developmental study, applying a 1000-fold safety factor. A poor quality developmental toxicity study in rabbits indicated that the NOAEC from such a study, which might be relevant to establishing an ARfD, could be below 75 mg/kg bw per day (oral dose equivalent). The absence of non-rodent studies and an adequate developmental toxicity study in rabbits from the database on PPO is considered important, as both these study types are used routinely in establishing ARfDs; without these studies, it was not possible to reliably assess the acute toxicity of PPO. Therefore, the present Meeting confirmed the conclusion of the 2011 JMPR that the ARfD for PPO should remain at the value of 0.04 mg/kg bw (i.e. the upper bound of the ADI).

The sponsor has the opportunity to submit additional cases or data[3] that would enable JMPR to consider if an ARfD was necessary or if the current value could be refined. However, the present Meeting believes that this might not be necessary, as it is possible that acute exposures from PPO treatment of tree nuts will be below the current JMPR ARfD. Any consideration of generating

[2] http://www.epa.gov/oppsrrd1/REDs/propylene_oxide_red.pdf

[3] See Solecki R *et al*. (2005). Guidance on setting of acute reference dose (ARfD) for pesticides. *Food and Chemical Toxicology*, 43:1569–1593 (http://www.who.int/foodsafety/chem/jmpr/arfd/en/).

additional data relevant to refining the ARfD for PPO should therefore be delayed until the JMPR exposure assessment has been performed.

Propylene chlorohydrin

Concern

"The JMPR could not establish an ADI or ARfD for PCH due to the absence of data to characterize the hazard to fetuses. However, oral exposure is the relevant route for this metabolite, and the 1998 NTP [United States National Toxicology Program] studies identify both NOAELs and LOAELs following short-term and chronic exposure to PCH via the oral route (rats and mice) and there is a rat reproduction study. Recommend consideration of the two-generation reproduction study in the rat, along with an additional uncertainty factor of 10, for establishment of an ADI for PCH."

Response

The 2011 JMPR could not establish an ADI or ARfD for PCH in the absence of any reliable data to characterize the hazard to fetuses. The USEPA evaluation agrees that the database for PCH is incomplete in respect of developmental studies and non-rodent studies and that the chronic carcinogenicity studies in rats and mice used inadequate doses. The 2011 JMPR considered that in the absence of key study types of adequate quality, it was not possible to reliably assess the toxicity of PCH. The present Meeting stressed that a two-generation reproduction study was not adequate for establishing the hazard to fetuses. The Meeting confirmed the conclusion of the 2011 JMPR that no ADI or ARfD could be established for PCH and that it was not possible to read across from PPO.

Propylene bromohydrin

Concern

"PCH is genotoxic in vitro. The Meeting could not establish an ADI or ARfD for PBH due to the absence of any *in vivo* data. Genotoxicity data show that PBH is genotoxic in vitro. Request citation of the study where the genotoxicity of PBH was observed."

Response

The genotoxicity data on PBH are in Leifer, Hyman & Rosenkranz (1981)[4]. Related data on the relative potency of chloro- versus bromo- short-chain hydrocarbons and alcohols are in Pfeiffer & Dunkelberg (1980)[5], Stolzenberg & Hine (1979, 1980)[6], Hooberman et al. (1993)[7] and Rosenkranz (1977)[8].

Concern

"Regulation of PPO should be protective of any toxicity from PBH based on structure activity relationship considerations. Moreover, given the trace levels of PBH in crops, reconsideration of the need to include PBH as a residue of concern for dietary risk assessment is requested."

[4] Leifer Z, Hyman J, Rosenkranz HS (1981). Determination of genotoxic activity using DNA polymerase-deficient and -proficient *E. coli*. In: Stich HF, San RHC, eds. Short-term tests for chemical carcinogens. New York, Springer-Verlag, pp. 127–139.

[5] Pfeiffer EH, Dunkelberg H (1980). Mutagenicity of ethylene oxide and propylene oxide and of the glycols and halohydrins formed from them during the fumigation of foodstuffs. *Food and Cosmetics Toxicology*, 18:115–118.

[6] Stolzenberg SJ, Hine CH (1979). Mutagenicity of halogenated and oxygenated three-carbon compounds. Journal of Toxicology and Environmental Health, 5(6):1149–1158; Stolzenberg SJ, Hine CH (1980). Mutagenicity of 2- and 3-carbon halogenated compounds in the *Salmonella*/mammalian-microsome test. Environmental Mutagenesis, 2(1):59–66.

[7] Hooberman BH, Chakraborty PK, Sinsheimer JE (1993). Quantitative structure–activity relationships for the mutagenicity of of propylene oxides with *Salmonella*. *Mutation Research*, 299:85–93.

[8] Rosenkranz HS (1977). Mutagenicity of halogenated alkanes and their derivatives. Environmental Health Perspectives, 21:79–84.

Response

The 2011 JMPR could not establish an ADI or ARfD for PBH, as there were no in vivo data available. Submitted as part of the concern form were comparative acute oral toxicity data on PCH and PBH. These showed that PBH was approximately 3 times as potent for acute lethality as PCH (acute oral LD_{50}s in rats of 175 mg/kg bw for PBH versus 532 mg/kg bw for PCH). The present Meeting noted that acute lethality studies have no direct relationship to the critical values used to establish ADIs or ARfDs and are normally not used for this purpose. These new data do not address the potential in vivo genotoxicity of PBH. The present Meeting confirmed the conclusion of the 2011 JMPR that no ADI or ARfD could be established for PBH and that as the chemical properties of PBH are different from those of PPO, it was not possible to read across from PPO.

Limited residue data for PBH were included as part of the concern form submission. These data showed that levels of PBH in almonds and walnuts were lower than the LOQ. Previously evaluated data showed levels of PBH of approximately 3 ppm in nuts, cocoa powder and herbs and spices. The upper range of estimated chronic intakes of PBH, based on the previously evaluated data, are estimated to be in the range of 13.5–94.3 µg/person per day. As PBH has been shown to be genotoxic in vitro and has not been tested in vivo for genotoxic potential, a threshold for toxicological concern (TTC) of 0.15 µg/person per day would apply. Estimated exposures are significantly above this; therefore, on the basis of the available data, human exposures to PBH cannot be discounted as irrelevant.

Additional, good quality residue data on PBH levels in a range of crops treated with PPO would help refine the intake estimates.

2.1 Guidance document for WHO monographers

At the 2012 JMPR, the WHO Core Assessment Group on Pesticide Residues agreed to update its guidance document to incorporate the experience gained over the years and advances in scientific knowledge and to improve the transparency and efficiency of JMPR decisions. The new guidance should be of use for industry and for Codex member states submitting dossiers, as well as for experts writing or peer reviewing the JMPR reports and monographs.

The guidance document was discussed during a 1-day workshop of the WHO Core Assessment Group held on 26–27 September. The document describes the JMPR procedures for toxicological assessment, the content of the toxicological monographs and the interpretation of toxicological studies, with a particular focus on minor and adaptive effects.

A final version is expected by March 2014.

2.2 Hazard assessment in the 21st Century: Incorporating data from new mechanistic-based approaches in JMPR evaluations

At the 2012 Meeting, JMPR discussed the incorporation of data from new mechanistic-based approaches ("Tox 21") in the risk assessment of dietary exposure to pesticide residues. JMPR offered to evaluate data generated using new technologies as they become available, in parallel with the results of traditional toxicity testing, to determine their utility and role in pesticide evaluation. Little such information was submitted for consideration by the 2013 Meeting. JMPR repeats this offer and notes that information obtained using new technologies could be of particular value in the assessment of metabolites and degradates of pesticides and in evaluation of postulated modes of action.

The Meeting agreed that this offer should be included in the call for data, starting with the 2014 Meeting.

2.3 Risk assessment of metabolites and degradates of pesticides

Residues of the pesticides to which consumers are exposed often comprise not just (or even) the parent compound, but also metabolites produced in treated plants, environmental degradation products and possibly other pesticide-derived compounds (e.g. during food processing). Where such a compound is also produced at significant levels in test species, it is assumed that its hazard will have been addressed in assessment of the parent compound. When this is not the case, or where levels produced in test species are low, additional assessment of the compound is necessary. With improvements in analytical sensitivity and greater awareness of the potential for exposure to metabolites and degradates, the number of compounds identified of potential concern is increasingly appreciably. It is not feasible or appropriate to insist on comprehensive toxicity testing of all such compounds, a fact recognized in a recent opinion of the European Food Safety Authority (EFSA) (EFSA Journal 2012;10(07): 2799. [187pp.] doi:10.2903/j.efsa.2012.2799).

JMPR agrees with many of the principles outlined in the EFSA opinion in determining the toxicological relevance of pesticide metabolites and degradates for the purposes of dietary risk assessment. The present Meeting agreed to produce guidance on this issue in time for it to be taken into account at the 2014 Meeting. Key elements will likely include the following:

- Where there is adequate exposure of test species to the compound of concern, hazard characterization will have been addressed by evaluation of the parent compound.
- Otherwise, a preliminary assessment of dietary exposure to the compound of concern should be undertaken.
- The tiered threshold of toxicological concern approach, as recommended by EFSA (2012), should be adopted.

- Where appropriate, read-across from the parent or other metabolites/degradates with relevant toxicological information should be undertaken.
- Where adequate data are available, and when necessary, relative toxic potencies will be determined, for use in calculating an appropriate exposure estimate for comparison with the respective reference value.
- The JMPR report will clearly indicate whether it was possible to assess significant metabolites or degradates for toxicological concern.
- Three possible outcomes will be identified:
  - Evaluation was possible, and there is no concern.
  - Evaluation was possible, and there is concern.
  - No evaluation is possible. This does not necessarily mean that there is a concern, rather that it is not possible reach such a conclusion on the basis of available data.

2.4 Review of the need to update the *Principles and Methods for the Risk Assessment of Chemicals in Food* (EHC 240)

JMPR, like other expert groups advising WHO and FAO, has codified the general principles by which it evaluates pesticides for their possible risk from dietary exposure to residues. These were published in of the Environmental Health Criteria series. Since initial publication (in EHC 104, for pesticides), a number of additional principles were agreed by JMPR, which were published as general considerations in the respective meeting report. WHO sought to consolidate these evolving principles and to harmonize, to the extent possible, the approaches used by the various expert groups (JECFA, JMPR, etc.). This culminated in the publication of EHC 240: *Principles and Methods for the Risk Assessment of Chemicals in Food* in 2009. Even at the time of publication, it was recognized that regular updating would be necessary, and it was envisaged that this could be done by providing updates online.

The present Meeting agreed that a review of EHC 240 should be a standing item on its agenda from 2014, and that any sections of chapters requiring updating would be identified. In such cases, the Meeting would make specific recommendations on how this might be achieved.

2.5 Identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile

The Meeting noted the request for comment on a recent opinion from EFSA defining criteria and a methodology for grouping pesticides, based on their toxicological characteristics, for the purpose of taking account of cumulative effects during the setting of MRLs (EFSA Journal 2013;11(7):3293. [131 pp.]. doi:10.2903/j.efsa.2013.3293). JMPR noted that the EFSA opinion included useful collation of information on the common effects of pesticides acting on the thyroid and nervous system. However, the Meeting was of the view that in creating cumulative assessment groups (CAGs), exposure characteristics as well as hazard and potency considerations should be used early in the process as criteria for inclusion in CAGs. Indeed, this was noted in the EFSA opinion. JMPR looks forward to the opportunity to comment on the methodology developed by EFSA for the refinement of CAGs based on such further considerations.

The Meeting noted that the issue of cumulative risk assessment of pesticides would benefit from the engagement of interested parties, perhaps through the recently launched WHO Chemical Risk Assessment Network. JMPR agreed to explore the possible application of cumulative risk assessment to its evaluation of pesticides, for example, through conducting a case-study for the purpose, for consideration at a future meeting.

2.6 Guidance for the preparation and processing of large commodities for analysis of pesticide residues

The MRLs apply to the average residue in the laboratory sample complying with the minimum requirements of the number of primary samples and the mass of the laboratory samples[9], prepared according to the corresponding Codex Guidelines[10].

Prior experience indicated that the interaction of surface residues with the internal part of plant materials may cause very rapid degradation of the residues. Classical examples are, for instance, benomyl, captan, chlorothalonil, dithiocarbamates, etoxazole and folpet. Fifty to 90% of the parent compounds may decompose within minutes during the chopping of various plant materials at room temperature. There are many other pesticides which may decompose at various extents when the residues come into contact with plant enzymes and other liquids released from the plant cells during processing.

Since the rate of such decomposition is a function of several factors including but not limited to: chemical properties of the residues, plant matrix, temperature, and duration of the contact; without specific information on the stability of the residue the only option provided in the guidelines is to not to permit the cutting individual commodity units prior to analysis.

In order to avoid or minimize the degradation of residues as much as possible, the Codex Sampling Guidelines[9] states: "Where the bulk sample is larger than is required for a laboratory sample, it should be divided to provide a representative portion. A sampling device, quartering, or other appropriate size reduction process may be used *but units of fresh plant products or whole eggs should not be cut or broken."*

The Codex Guidelines on Good Laboratory Practice in Residue Analysis, CAC/GL 40-1993, Rev.1-2003 reiterates the same principle, stating that: "Sample processing and sub-sampling should be carried out using procedures that have been demonstrated to provide a representative analytical portion and to have no effect on the concentration of residues present."

The OECD Guideline for the Testing of Chemicals[11] states: "It is acceptable to subsample large commodities (e.g., head cabbage, melons, etc.) with procedures in the field such as quartering and collecting opposing quarters. However, if analyses are planned on matrices such as pulp and peel (e.g., for dietary risk assessment refinement), the whole commodity should be shipped to the analysis lab to avoid cross contamination of peel and pulp."

Neither the Codex Guidelines nor the OECD Guidelines provide guidance on what should be done to prove that the cutting, peeling or shelling of sampled commodities would not affect the initial residue concentration.

The Meeting recognised that cutting large bulky commodities or fruits with hard peel such as, for instance, jackfruit, watermelon, cabbage, pineapple and avocado in deep-frozen condition is very difficult. Furthermore, storing several samples of such fruits would require very large freezing capacity which is not available to many laboratories in developing countries, and consequently would limit their capacity to generate residue data to support the establishment of Codex MRLs for specific commodities of national importance.

Keeping in mind the importance of assuring that the residue levels in the laboratory samples are the same or very similar to that at the time of sampling, the Meeting recommends:

- locating trial sites at distances from which samples can be transported to the testing laboratory within 24 hours. Allowing the large commodities to be immediately sub-sampled, appropriate representative sub-sample portions further homogenised and the test portions withdrawn and stored deep-frozen prior to extraction and analysis. This

[9] Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLs , *CAC/GL 33-1999.*
[10] Portion of Commodities to which Codex Maximum Residue Limits Apply and which Is Analysed, CAC/GL 41-1993
[11] OECD Guideline for the Testing of Chemicals 507 (adapted September 2009)

procedure concurs with the allowance given by both the Codex and OECD Guidelines on transporting fresh plant materials without the need for deep-freezing; or

- Carry out a pre-test before conducting the supervised trials to verify the stability of residues in cut commodity. The test involves:
  - surface treatment of the crops with a mixture of pesticides including two of known stability and those compounds which are the intended subject of the trials,
  - performing the sub-sampling and homogenisation of the representative portions of sub-samples according to normal laboratory practice at room temperature, and analysing the residues remaining in the test portions.

If the ratio of the stable reference compounds and unknown stability residues remain the same (statistically not significantly different) taking into account the average procedural recoveries, the tested pesticides can be considered stable in the halved or quartered portions. In such cases cutting large crops is acceptable at the field site, provided that it can be done to avoid cross contamination. The applicability of the method has been extensively tested and described[12,13,14,15].

The selected sub-portions should be packed separately in suitable labelled bags for transportation to the analytical laboratory.

2.7 Principles for assessing the performance of analytical methods based on few recovery tests

The JMPR considers the suitability of analytical methods used in supervised trials based on the results of method validation studies performed in the laboratory that developed the method and verified in an independent laboratory. Further, the concurrent recovery data obtained at the time of the analysis of the samples are also considered. If the method performance raises doubt about the reliability of the reported residue concentrations, the corresponding trials are not considered in estimation of residue levels.

The number of recovery tests performed at various spike concentrations typically range from 3–7, occasionally higher numbers of replicates are available. The results of these studies are compared with the reference values given in the Codex Guidelines on Good Laboratory Practice in Residue Analysis[16], which agree with the general performance criteria adopted by Codex Alimentarius[17].

The Codex Guidelines specify the acceptable recovery ranges and the relative standard deviation for the within laboratory repeatability of replicate analyses. These reference values are based on large numbers of collaborative studies, as a result the range for the repeatability relative standard deviation derived from few recovery tests is not directly comparable.

[12] Ambrus Á, Solymosné M.E., Korsós I., and. Estimation of Unecertainty of Sample Preparation for the Analysis of Pesticide Residues**,** J. Environ. Sci. Health. B31. No. 3 443-450, 1996.
[13] Maestroni, B., Ghods, A., El-Bidaoui M., Rathor, N., Jarju O.P., Ton, T., and Ambrus A., Testing the efficiency and uncertainty of sample processing using ^{14}C labelled Chlorpyrifos Part I in Fajgelj A., Ambrus A., eds. Principles of Method Validation pp. 49-58, Royal Society of Chemistry Cambridge UK 2000
[14] Fussell, R.J. Hetmanski, M.T. Macarthur, R. Findlay, D., Smith, F., Ambrus, Á. and Brodesser, J. P. Measurement Uncertainty Associated with Sample Processing of Oranges and Tomatoes for Pesticide Residue Analysis. J. Agric. Food Chem., 55, 1062-1070, 2007
[15] Yolci Omeroglua*, A´. Ambrusb, D. Boyaciogluc and E. Solymosne Majzikd Uncertainty of the sample size reduction step in pesticide residue analysis of large-sized crops, Food Additives & Contaminants: Part *Part A* (30 (1): 116-126 (DOI:10.1080/19440049.2012.728720Ö
[16] CAC/Gl 40-1993, Rev.1-2003.
[17] Codex Alimentarius Commission, Procedural Manual 21st ed. Joint FAO/WHO Food Standards Programme, FAO, Rome, 2013, p.66.

Studies with n≥15 replicates, the within laboratory repeatability of analytical step (CV_A) is expected to be in the range of 0.5–0.7 of repeatability of the analysis predicted from the "Horwitz equation". However values between 0.5 and 2 may be acceptable[18].

The estimation of standard deviation based on few data points is very imprecise. The significance of differences between the experimentally obtained standard deviation or relative standard deviation (CV_{exp}) and the reference value should be verified by applying the F-test.

$$F_{calc} = \frac{CV_{exp}^2}{CV_{Ref}^2}$$

If the calculated F value is larger than the critical one, the difference is considered significant. The F_{crit} depends on the selected probability and number of replicate tests.

The reference values taken from the Codex Guidelines and the minimum experimental CV values, rounded to a whole number, which can be considered significantly different from the reference CV values at 95% confidence level depending on the number of replicate tests performed in the laboratory are summarised hereunder.

Concentration	CV_{ref} %	Significantly different CV_{exp} values from the CV_{Ref} based on replicate recovery tests (n)		
		n=3	n=5	n=7
<1 µg/kg	35	61	54	51
> 1 µg/kg ≤0.01 mg/kg	30	52	47	44
> 0.01 mg/kg ≤ 0.1 mg/kg	20	35	31	29
> 0.1 mg/kg ≤ 1 mg/kg	15	26	24	22
> 1 mg/kg	10	18	16	15

Consequently, where the reported laboratory CV_A value is smaller than those given in the above table the repeatability of the laboratory/method is considered to be within acceptable limits.

2.8 Guidance for use of residue trial data from different geographical locations for estimation of pesticide residue levels

The best use of available residue data is always the primary objective of the JMPR when estimating maximum residue levels, therefore the Meeting regularly re-evaluates and revises its procedures. The FAO Manual notes that under practical conditions the number of trials which can be performed for a given commodity is limited. Nevertheless, a larger data set provides a more accurate estimation of the selected percentile than a small data set derived from trials representing only one critical use condition (cGAP).

As a result of evolving working principles, the proportionality approach has been elaborated to adjust residues deriving from trials conducted with different application rates to a common one. The recommended method was adopted by the Codex Alimentarius Commission[19] in 2013 for inclusion in the Procedural Manual as an Annex to the Risk Analysis Principles applied by the CCPR.

In addition, the JMPR agreed that from 2012, geographical location should not be a barrier in selecting trials for estimation of maximum residue levels[20].

[18] Horwitz W, The potential use of quality control data to validate pesticide residue method performance, in Fajgelj A and Ambrus Á eds. Principles and practices of Method Validation, Royal Society of Chemistry pp.1-8, 2000.
[19] Thirty-sixth Session of the Codex Alimentarius Commission, Rome, Italy 1-5 July 2013, http://www.codexalimentarius.org/meetings-reports/en/?sortingDate=012013.
[20] Food and Agriculture Organisation, Pesticide residues in food 2012 Report http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Report11/JMPR_2011_Report.pdf

The present Meeting took into account the experience gained during previous years, and decided to build on the current practice and elaborated the following principles for utilising the globally available supervised trial residue data for estimation of residue levels, provided that the growing and processing practices to produce RAC are comparable.

Step1. Residues deriving from supervised trials reflecting the national or regional cGAP will be considered and the relevant residues selected.

- If sufficient numbers of residue data are available from the country or region representing the cGAP, that dataset is used for estimating residue levels according to the current practice of the JMPR.
- Where residue data from trials conducted in the country or region are not sufficient, then trials conducted with different application rates will be considered, and the residue values adjusted, based on the proportionality approach to obtain the largest possible residue dataset.

Step 2. Where sufficient residue data are not available from Step 1, then suitable residue data from the trials performed in other countries that meet cGAP, or can be adjusted using proportionality to the cGAP, the data can be considered with those from step 1.

The datasets obtained in Steps 1 and 2 can be combined if the residue values are within 7 times the median of the newly combined data set. As detailed analysis of the residue data sets selected by the JMPR between 1997 and 2011, for estimation of maximum residue levels, revealed that about 90% of the residues were within the seven times median range, regardless whether the residue data was derived from a single country or countries in different regions21.

Where the spread of residues exceeds the 7 times median range, the suitability of the dataset for estimation of residue levels would then need further careful examination, taking into account all relevant information.

The JMPR will apply the above principles in further evaluations of the residue data and evaluate their applicability on a case by case basis. If the principles are considered not applicable the reason will be explained in the report. Upon gaining sufficient experience the JMPR would reconsider and further elaborate the principles if needed.

2.9 Guidance for estimating pesticide residue levels for commodity groups

Aiming to cover the residues in minor commodities without separate supervised trials, the JMPR has recommended maximum residue levels, HR and STMR values for commodity groups whenever the available dataset was considered appropriate.

In order to make the data assessment process transparent and facilitate its consistent application in various situations, the JMPR considered and evaluated past experience and decided on the following basic principles in estimation of residue levels for commodity groups.

- Group maximum residue levels are only estimated if the pesticide is registered for a group or sub-group of commodities, also allowing for the differences in Codex and national commodity group classifications.
- Residue datasets reflecting cGAP will be compiled. Once the data sets have been established for individual commodities, the recommendations for residue levels for commodity groups would be considered according to the following principles.
    - The establishment of a commodity group residue level will generally be considered if the median residues of the commodities are within the 5 times range;

[21] Árpád Ambrus, Zsuzsanna Horváth, Zsuzsa Farkas, István J. Szabó, Enikő Dorogházi, Mária Szeitzné-Szabó, Nature of the field-to-field distribution of pesticide residues. Submitted for publication to J. Environ Sci and Health

i. Where the residues in individual commodities in the commodity group are statistically not different (Mann-Whitney or Kruskal-Wallis tests) the residue data can be combined for the estimation of group residue levels;
ii. Where the residue datasets in individual commodities are statistically different then the dataset leading to the highest maximum residue level would be used for the group, provided that sufficient residue data points are available ;
iii. If the dataset identified under (ii) does not contain sufficient data points (preferably ≥ 8) required to estimate a group maximum residue level, the commodity should be considered as an exception.

- If the median of residues in an individual commodity dataset differs more than 5 times than those of other commodities, that commodity would not be included in the group and indicated as an exception.
- If the medians of residues in more than one commodity of the group differ larger than five times, then recommending group residue levels may not be appropriate and would require decision based on all information available

In view of the large diversity of residue data dependant on the pesticide and other factors, the case-by-case evaluation of the available residue data is considered necessary. Where the Meeting deviates from the above principles, the rational for the divergence will be provided in the report.

Upon gaining sufficient experience the JMPR would reconsider and further elaborate the principles if needed.

2.10 Update of GEMS/Food diets for the estimation of the IEDI

The WHO GEMS/Food diets were originally collected in 1989 to predict dietary exposure to radionuclides in food following the Chernobyl accident. They were derived from FAO food Supply Utilisation Account (SUA) data to represent five regional dietary patterns, namely Middle Eastern, Far Eastern, African, Latin American and European. These five Regional Diets were used in the period 1989-2005 to predict the potential exposure to various chemicals occurring in food (e.g. pesticide residue exposure estimates by the JMPR). For this purpose, the need for regional grouping became less important than that of groupings based on similarities between the diets.

In 1997, the WHO introduced the GEMS/Food cluster diets. The first cluster diets were based on the 1990-1994 FAO food SUA data. The method used cluster analysis and an iterative approach based on the use of 19 marker foods to define 13 diets representing 183 countries. The 13 cluster diets were later updated using food SUA data from 1997 to 2001. The updated 13 cluster diets were used by JMPR to predict pesticide residue exposures in the period 2006 to now.

In 2012, WHO introduced a new methodology to cluster the FAO food SUA data into 17 diets based on statistical similarities between dietary patterns in 179 countries. The new cluster diets were based on the more recent average 5-year FAO food supply utilisation account data from 2002–2007. These average data were weighted by the population size to get average kg/person/cluster over a 5 year period.

These 17 Cluster Diets have now been incorporated in the JMPR IEDI model by RIVM[22] in cooperation with the WHO. The JMPR IEDI model is an automated Excel spreadsheet for the calculation of chronic dietary intake of pesticide residues. To use the IEDI model, estimates made by JMPR (ADI, STMR (-P), and when necessary MRL values) are entered according to the manual attached to the model. Then calculations and generation of an overview table are performed automatically. The Meeting noted that the mean body weights used in the IEDI model are still 55 kg for cluster G09 and 60 kg for all others.

[22] Rijksinstituut voor Volksgezondheid en Milieu (Dutch National Institute for Public Health and the Environment)

The main difficulty in building the IEDI model is that the FAO food SUA data does not match, one-to-one, with the Codex Classification of Foods and Animal Feeds, as used in the dietary exposure assessment for pesticide residues. These two classification systems have several incompatibilities in the definition of the commodity and in the commodity codes. The 17 cluster diets contain several food items, which need to be linked to multiple Codex commodities. In addition, the FAO food SUA data are sometimes given separately for fresh and processed commodities. In such cases, the FAO SUA data were recalculated in such a way that the IEDI model contains three types of consumption values: fresh including processed, fresh only and processed only. In this way, JMPR is able to refine the dietary intake by using processing factors.

In the 17 clusters the consumption of a food important to a certain country is now distributed together with countries where the same food is important. The main impact of the 17 cluster diet will be that for that specific country there will be an increased intake of such a food when compared with the 13 cluster diets. Furthermore, because the 17 cluster diet data are based on more aggregated food commodities as collected in the FAO database, higher exposure levels may be estimated for certain commodities. For example, FAOSTAT item code 358 (cabbages) was linked to Codex brassica leafy vegetables, head cabbages, Brussels sprouts and kohlrabi. Individual data for head cabbages, broccoli, cauliflower, Brussels sprouts, kohlrabi and leafy brassicas are not available in the FAO food SUA database. In such cases the 17 cluster diet IEDI model may overestimate the chronic dietary exposure. In the previous 13 cluster diet IEDI model consumption data for individual brassica commodities were estimated based on national consumption data.

The JMPR used the draft 17 cluster diet IEDI model on the compounds evaluated in the 2013 Meeting to gain experience in the differences in exposure that can be expected and to identify food commodities where more detailed consumption data or additional recalculations are necessary. Results are listed in the table below. For several compounds the 17 cluster diets resulted in higher exposure estimates, which are attributed to the use of aggregate consumption data.

For the commodities identified in the table below JMPR recommends that a questionnaire be sent to relevant countries seeking the submmission of more detailed consumption data in order to have the 17 cluster diet IEDI model ready for use at the 2014 Meeting.

Information on the FAO food SUA data is available at (http://faostat3.fao.org). The 17 Cluster diets are available at (http://www.who.int/foodsafety/chem/acute_data/en/index1.html). The 17 cluster diet IEDI model will be available on the same web address and will be updated when necessary.

Compound	No of entries in spreadsheets	Min-max %ADI (13 clusters)	Min-Max %ADI (17 clusters)	Additional consumption data (C) or recalculation (R) needed for:
azoxystrobin	88	2-10%	2-20%	C: celery, witloof R: citrus fruits (G12 high)
bentazone	17	0%	0%	C: peas with pods, peas without pods
chlorantraniliprole	65/52	4-30%	4-40%	C: peas with pods, peas without pods
cyantraniliprole	39	1-10%	4-20%	C: celery, head lettuce, summer squash, pumpkins, brassicas, brassica leafy vegs, R: root and tubers, except potato; cucurbits inedible peel; cucurbits edible peel; fruiting vegs other than cucurbits excl specified processed tomato commodities; leafy vegs except head lettuce
dicamba	21	0-1%	0-1%	C: wheat bran
difenoconazole	59	4-60%	4-80%	C: passion fruit, celeriac, summer squash, head lettuce, leaf lettuce, witloof chicory, celery, peas with pods R: potato (G02 high)
Diquat	24	0-4%	0-5%	-
dithianon	13	0-7%	0-7%	-
fenbuconazole	39	0-2%	0-3%	C: wheat bran
fenpyroximate	26	1-7%	3-5%	-
flutolanil	11	0-1%	0-1%	C: Brassica leafy vegs, rice bran

Compound	No of entries in spreadsheets	Min-max %ADI (13 clusters)	Min-Max %ADI (17 clusters)	Additional consumption data (C) or recalculation (R) needed for:
glyphosate	36	0-1%	0-1%	-
Glufosinate-ammonium	38	3-9%	3-10%	-
imazapic	14	0%	0-0.2%	-
imazapyr	14	0%	0%	-
indoxacarb	46	1-30%	1-50%	C: pumpkins, summer squash, cauliflower, head cabbage, leaf lettuce
isoxaflutole	13	0-1%	0-1%	R: Sugarcane incl sugar
malathion	none	-	-	-
mandipropamid	25	0-2%	0-3%	C: summer squash, cauliflower, head cabbage, sweet peppers, chilli peppers, celery
penthiopyrad	66	0-6%	1-10%	C: mustard greens, turnip greens, celery, summer squash, pumpkins, peas without pods, radish roots, cereal brans, tomato puree
propiconazole	23/22	0-6%	0-6%	-
pyrimethanil	34	0-5%	0-10%	-
Sulfoxaflor	40	1-7%	1-6%	-
triazophos	3	1-40%	2-30%	C: Green soya beans with pods, green soya beans without pods R: Cotton seed raw excl oil, rice excl husked & excl polished.
trinexapac-ethyl	21	1-9%	0-7%	C: wheat bran
triflumizole	9/8	0-2%	0-1%	R: grapes for wine only, grapes for fresh consumption only

2.11 Revision of the Codex Classification of Foods and Animal Feeds

The Meeting was aware of the progress being made by the CCPR on the revision of the Codex Classification of Foods and Animal Feeds and recognized that the revised classification of fruit commodities was adopted by the Codex Alimentarius Commission in 2012. The current Meeting started using the revised classification on fruit commodities in its work. As the Codex Classification has significant impacts on the estimation of maximum residue levels by the JMPR, the Meeting continues to watch the development of the revision of classification for other commodities with strong interests and looks forward to the completion of revision by the CCPR.