Food and Agriculture Organization of the United Nations

World Health Organization

JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES

Geneva, 20-29 September 2011

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 2011 MEETING

Issued October 2011

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 27 pesticides, of which 8 were new compounds, and 4 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/core-themes/theme/pests/pm/jmpr/en/

http://www.who.int/ipcs/food/jmpr/en/index.html

Established ADI and ARfD values and recommended MRL, STMR and HR values

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
Acephate (095)	CM 0649	Rice, husked	1		0.405 [a] 0.535 [b] 0.055 [c]	
ADI: 0–0.03 mg/kg bw	CM 1205	Rice, polished			0.33 [a] 0.44 [b]	
ARfD: 0.1 mg/kg bw	AS 0649	Rice straw and fodder, dry	0.3		0.025 [c]	0.14 [c]
Definition of the residue for compliance with MRLS for plant and animal commodities: acephate *Definition of the residue for estimation of dietary intake for plant and animal commodities:* acephate and methamidophos [a] *for long term intake estimate* [b] *for short-term intake estimate* [c] *for calculation of animal dietary burden.*						
Acetamiprid (246)*	VP 0061	Beans, except broad bean and soya bean	0.4		0.01	0.18
ADI: 0–0.07 mg/kg bw	VP 0062	Beans, shelled	0.3		0.03	0.18
ARfD: 0.1 mg/kg bw	FB 0018	Berries and other small fruit (except grapes and strawberries)	2		0.64	1
	VB 0041	Cabbages, Head	0.7		0.02 0.09 [d]	0.05 0.5 [d]
	VX 0624	Celery	1.5		0.3	0.78
	FS 0013	Cherries	1.5		0.45	0.88
	FC 0001	Citrus fruits	0.8		0.25	0.45
	SO 0691	Cotton seed	0.7		0.09 [c]	
	HS 0444	Peppers Chili, dried	2		0.4	1.4
	DF 0014	Prunes	0.6		0.12	0.32
	MO 0105	Edible offal (Mammalian)	0.05		0.011 liver 0.018 kidney	0.03 liver 0.05 kidney
	PE 0112	Eggs	0.01 *		0.0	0.0
	VB 0042	Flowerhead brassicas (includes Broccoli: Broccoli, Chinese and Cauliflower)	0.4		0.02	0.22
	VC 0045	Fruiting vegetables, Cucurbits	0.2		0.05	0.11
	VO 0050	Fruiting vegetables, other than Cucurbits (except sweet corn & mushrooms)	0.2		0.04	0.14
	VA 0381	Garlic	0.02		0.01	0.01
	FB 0269	Grapes	0.5		0.085	0.25
	VL 0053	Leafy vegetables (except spinach)	3		0.64	1.9
	MF 0100	Mammalian fats (except milk fats)	0.02		0.003	0.01
	MM 0095	Meat (from mammals other than marine mammals)	0.02		0.003 fat 0.004 muscle	0.01 fat 0.01 muscle
	ML 0106	Milks	0.02		0.004	0.009
	FS 0245	Nectarine	0.7		0.2	0.44
	VA 0385	Onion, Bulb	0.02		0.01	0.01
	FS 0247	Peach	0.7		0.2	0.44
	VP 0064	Peas, shelled (succulent seeds)	0.3		0.03	0.18
	FS 0014	Plums (including Prunes)	0.2		0.04	0.11
	FP 0009	Pome fruits	0.8		0.225	0.59

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
	PM 0110	Poultry meat	0.01 *		0.0	0.0
	PO 0111	Poultry, Edible offal of	0.05 *		0.01	0.0
	VL 0502	Spinach	5 [e]		0.51	2.5
	VA 0389	Spring onions	5		0.38	2
	FB 0275	Strawberry	0.5		0.1	0.24
	TN 0085	Tree nuts	0.06		0.01	0.05
	JF 0226	Apple juice				0.2
	JF 0001	Citrus juice				0.03
	OR 0001	Citrus oil				0.04
		Citrus peel				0.71
	OR 0691	Cotton seed oil, edible				0.004
	DF 0269	Dried grapes (= currants, Raisins and Sultanas)			0.23	0.08
	JF 0269	Grape juice				0.13
	VW 0448	Tomato paste				0.09
		Tomato purée				0.04

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

Definition of the residue (for compliance with the MRL for animal commodities and for estimation of dietary intake for plant and animal commodities): sum of acetamiprid and its desmethyl (IM-2-1) metabolite, expressed as acetamiprid

The residue is not fat-soluble.

[d] With wrapper leaves
[e] On the basis of information provided to the JMPR it was not possible to conclude from the estimate of short-term intake for Acetamiprid that the consumption of spinach was less than the ARfD

Azoxystrobin (229)	SB 0716	Coffee beans	0.02		0.01
ADI: 0–0.2 mg/kg bw	VR 0604	Ginseng	0.1		0.025
ARfD: Unnecessary		Ginseng processed products	0.5		
		Ginseng, dried			0.075
		Ginseng, red			0.05
		Ethanol extract of dried ginseng			0.13
		Water extract of dried ginseng			0.12
		Ethanol extract of red ginseng			0.12
		Water extract of red ginseng			0.05

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

The residue is fat-soluble.

Clothianidin (238)
ADI: 0–0.1 mg/kg bw
ARfD: 0.6 mg/kg bw

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

The residue is not fat-soluble.

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
Cypermethrins (including alpha- and zeta-cypermethrin) (118) [f]	VS 0621	Asparagus	0.4 *a,C*	0.01*	0.09	0.2
ADI: 0–0.02 mg/kg bw	FC 0001	Citrus fruits (except shaddocks or pomelos)	0.3 *a,Z*	2 [g]	0.05	0.05
ARfD: 0.04 mg/kg bw	PE 0112	Eggs	0.01*	0.01*	0.0042	0.0047
	PO 0111	Poultry, Edible offal of	0.05*	0.05*	0.002	0.022
	PM 0110	Poultry meat	0.1 (fat)	0.1 (fat)	0.002 muscle 0.034 fat	0.022 muscle 0.048 fat
	PF 0111	Poultry fats	0.1		0.038	0.048
	FC 0005	Shaddocks or pomelos	0.5 *a, C, z*		0.05	0.05
	DT 1114	Tea, Green, Black (black, fermented and dried)	15 *C*	20 [g]	3.75	
	TN 0085	Tree nuts	0.05* *a,Z*		0.05	0.05

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: cypermethrin (sum of isomers).

The residue is fat soluble.

[f] Source of data supporting the proposed MRLs: *a: alpha-cypermethrin. c: cypermethrin. z: zeta-cypermethrin*. Capital letters show the source of data responsible for the MRL estimate. Small letters show the sources of other data for that commodity.

[g] The Codex MRL was retained under the four year rule awaiting the evaluation of data by the 2011 Meeting of JMPR.

Dicamba (240)	VD 0541	Soya bean (dry)	5		0.335	
ADI: 0–0.3 mg/kg bw	OR 0541	Soya bean oil, refined			0.012	
ARfD: 0.5 mg/kg bw						

Definition of the residue for compliance with the MRL for plant commodities: dicamba

Definition of the residue for estimation of dietary intake for plant commodities: sum of dicamba and 5-OH dicamba expressed as dicamba

Definition of the residue for compliance with the MRL and for estimation of dietary intake for animal commodities: sum of dicamba and 3,6-dichlorosalicylic acid (DCSA) expressed as dicamba

The residue is not fat-soluble

Dichlorvos (025) **

ADI: 0–0.004 mg/kg bw

ARfD: 0.1 mg/kg bw

Dicofol (026) **

ADI: 0–0.002 mg/kg bw

ARfD: 0. 2 mg/kg bw

Diflubenzuron (130)	FS 0247	Peach	0.5		0.17	
ADI: 0–0.02 mg/kg bw	FS 0014	Plum (including Prunes)	0.5		0.17	
ARfD: Unnecessary	FS 0245	Nectarine	0.5		0.17	
	VL 0485	Mustard greens	10		1.4	
	VO 0445	Peppers, Sweet (including pimento or pimiento)	0.7		0.16	

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
	VO 0444	Peppers, Chili	3		0.92	
	HS 0444	Peppers Chili, dried	20		6.44	
	GC 0640	Barley	0.05*		0.05	
	GC 0654	Wheat	0.05*		0.05	
	GC 0647	Oats	0.05*		0.05	
	GC 0653	Triticale	0.05*		0.05	
	AS 0162	Hay or fodder (dry) of grasses	3		0.625	1.4
	AS 0081	Straw and fodder (dry) of cereal grain	1.5		0.29	0.90
	TN 0085	Tree nuts	0.2		0.05	
	SO 0697	Peanut	0.15		0.05	
	AL 0697	Peanut fodder	40		7.5	18.4
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: diflubenzuron. *The residue is fat soluble.*						
Emamectin benzoate (247)*						
ADI: 0–0.0005 mg/kg bw	VP 0061	Beans, except broad bean and soya bean	0.015		0.001	0.009
ARfD: 0.03 mg/kg bw	VL 0510	Cos lettuce	1		0.20	0.62
	SO 0691	Cotton seed	0.002*		0.002	0.002
	MO 0105	Edible offal (Mammalian)	0.08		0.006	0.072
	FB 0269	Grapes	0.03		0.0025	0.022
	VC 0045	Fruiting vegetables, Cucurbits	0.007		0.001	0.002
	VO 0050	Fruiting vegetables, other than Cucurbits (except sweet corn and mushrooms)	0.02		0.003	0.013
	VL 0482	Lettuce, Head	1		0.20	0.62
	VL 0483	Lettuce, Leaf	1		0.20	0.62
	MF 0100	Mammalian fats (except milk fats)	0.02		0.002	0.011
	MM 0095	Meat (from mammals other than marine mammals)	0.004		0.002	0.004
	ML 0106	Milks	0.002		0.0005	
	VL 0485	Mustard greens	0.2		0.010	0.11
	FS 0245	Nectarine	0.03		0.0095	0.015
	FS 0247	Peach	0.03		0.0095	0.015
	HS 0444	Peppers, Chili (dried)	0.2		0.03	0.13
	FP 0009	Pome fruits	0.02		0.004	0.011
	JF 0226	Apple juice			0.0028	
	OR 0691	Cotton seed oil, edible			0.00078	
Definition of the residue for compliance with the MRL and for estimation of dietary intake for plant commodities: emamectin B1a benzoate, expressed as emamectin (free base). *Definition of the residue for compliance with the MRL and for estimation of dietary intake for animal commodities*: emamectin B1a benzoate, expressed as emamectin (free base). *The residue is not fat-soluble.*						

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
Etofenprox (184)**	FP 0226	Apple	0.6		0.2	0.34
ADI: 0–0.03 mg/kg bw	VD 0071	Beans (dry)	0.05		0.05	
ARfD: 1 mg/kg bw	DF 0269	Dried grapes (= currants, Raisins and Sultanas)	8		1.5	5.5
	MO 0105	Edible offal (Mammalian)	0.05		0.03 liver 0.03 kidney	0.03 liver 0.03 kidney
	PE 0112	Eggs	0.01 *		0	0
	FB 0269	Grapes	4		0.73	2.6
	GC 0645	Maize	0.05 *		0.05	0.05
	MM 0095	Meat (from mammals other than marine mammals)	0.5 (fat)		0.03 muscle 0.21 fat	0.03 muscle 0.3 fat
	ML 0106	Milks	0.02		0.013	
	FS 0245	Nectarine	0.6		0.16	0.37
	FP 0230	Pear	0.6		0.2	0.34
	FS 0247	Peach	0.6		0.16	0.37
	FP 0009	Pome fruits	W	1		
	VR 0589	Potato	W	0.01 *		
	PM 0110	Poultry meat	0.01 *		0.0	0.0
	PO 0111	Poultry, Edible offal of	0.01 *		0.0	0.0
	SO 0495	Rape seed	0.01 *		0.01	0.01
	GC 0649	Rice	0.01 *		0.0	0.0
	AS 0649	Rice straw and fodder, dry	0.05		0.01	0.025
		Apple purée			0.05	
	JF 0226	Apple juice			0.012	
	JF 0269	Grape juice			0.029	
		Peach juice			0.008	
		Canned apples			0.018	
		Canned peaches			0.018	
		Wine			0.029	
Definition of the residue (for compliance with the MRL for plant and animal commodities and for estimation of dietary intake for plant and animal commodities): etofenprox *The residue is fat soluble.*						
Etoxazole (241) ADI: 0–0.05 mg/kg bw ARfD: Unnecessary	FP 0009	Pome fruits	0.07		0.01	
Definition of the residue (for compliance with the MRL for plant and animal commodities and for estimation of dietary intake for plant commodities): etoxazole. *The residue is fat soluble.*						
Flutriafol (248) *						
ADI: 0–0.01 mg/kg bw	FI 0327	Banana	0.3		0.05	0.09
ARfD: 0.05 mg/kg bw	SB 0716	Coffee beans	0.15		0.05	
	DF 0269	Dried grapes (= currants, Raisins and Sultanas)	2		0.59	1.7

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
	FB 0269	Grapes	0.8		0.21	0.61
	SO 0697	Peanut	0.15		0.02	
	AL 0697	Peanut fodder	20		2.6	8.9
	VO 0445	Peppers, Sweet (including pimento or pimiento)	1		0.28	0.41
	HS 0444	Peppers Chili, dried	10		2.7	4.1
	FP 0009	Pome fruits	0.3		0.07	0.16
	VD 0541	Soya bean (dry)	0.4		0.055	
	GC 0654	Wheat	0.15		0.015	
	CM 0654	Wheat bran, unprocessed	0.3		0.032	
	AS 0654	Wheat straw and fodder, dry	8		1.45	4.1
	JF 0226	Apple juice			0.034	
	SM 0716	Coffee beans, roasted			0.048	
	JF 0269	Grape juice			0.13	
	OR 0697	Peanut oil, edible			0.028	
		Peppers, Sweet, preserved			0.22	0.32
	OR 0541	Soya bean oil, refined			0.072	
	CF 1211	Wheat flour			0.005	
	CF 1210	Wheat germ			0.042	
Definition of the residue (for compliance with the MRL for plant and animal commodities and for estimation of dietary intake for plant and animal commodities): Flutriafol *The residue is fat-soluble.*						
Glyphosate (158) ADI: 0–1mg/kg bw ARfD: Unnecessary	VD 0533	Lentils (dry)	5		0.5	2.1
	VR 0596	Sugar beet	15		3.4	7.3
	VO 0447	Sweet corn (corn-on-the-cob)	3		0.325	2.8
	CF 1255	Maize flour			0.12	3.0
	CF 0645	Maize meal			0.12	3.0
Definition of the residue for compliance with MRL for soya bean and maize: sum of glyphosate and N-acetylglyphosate, expressed as glyphosate *Definition of the residue for compliance with MRL (for other plant commodities):* glyphosate. *Definition of the residue for compliance with MRL (for animal commodities):* sum of glyphosate and N-acetylglyphosate, expressed as glyphosate *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*						
Hexythiazox (176) ADI: 0–0.03 mg/kg bw ARfD: Unnecessary	DH 1100	Hops, dry	3	2 [h]	0.79	
	FB 0275	Strawberry	6	0.5 [h]	0.54	
	DT 1114	Tea, Green, Black (black, fermented and dried)	15		4.55	
		Beer			0.036	
		Green tea infusion			0.182	
		Fermented tea infusion			0.137	
		Strawberry, canned			0.248	
		Strawberry jam			0.359	

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL 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 for plant commodities: hexythiazox. *Definition of the residue (for estimation of dietary intake) for plant commodities:* sum of hexythiazox and all metabolites containing the trans-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine-moiety (PT-1-3), expressed as hexythiazox *Definition of the residue (for compliance with MRL and for estimation of dietary intake) for animal commodities:* sum of hexythiazox and all metabolites containing the trans-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine-moiety (PT-1-3), expressed as hexythiazox *The residue is fat-soluble* [h] The Codex MRL was retained under the four year rule awaiting the evaluation of data by the 2011 Meeting of JMPR						
Isopyrazam (249)*	FI 0327	Banana	0.06		0.015	
ADI: 0–0.06 mg/kg bw	GC 0640	Barley	0.07		0.0375 0.022 [g]	
ARfD: 0.3 mg/kg bw	AS 0640	Barley straw and fodder, dry	2		0.356 [g]	1.06 [g]
		Malt			0.022	
		Beer			0.0045	
		Pot barley			0.012	
	MO 0105	Edible offal (Mammalian)	0.02		0.0056	0.008
	MF 0100	Mammalian fats (except milk fats)	0.01*		0.0056	0.008
	MM 0095	Meat (from mammals other than marine mammals)	0.01*		0.0056 fat 0.0056 muscle	0.008
	ML 0106	Milks	0.01*		0.0042	-
	FM 0183	Milk fats	0.02		0.0042	-
	PF 0111	Poultry fats	0.01*		0.01	0.01
	PM 0110	Poultry meat	0.01*		0.01 fat 0.01 muscle	0.01
	PO 0111	Poultry, Edible offal of	0.01*		0.01	0.01
	PE 0112	Eggs	0.01*		0.01	0.01
	GC 0650	Rye	0.03		0.015 0.01 [g]	
	AS 0650	Rye straw and fodder, dry	3		0.952 [g]	1.51 [g]
	GC 0653	Triticale	0.03		0.015 0.01 [g]	
	AS 0653	Triticale straw and fodder, dry	3		0.952 [g]	1.51 [g]
	GC 0654	Wheat	0.03		0.015 0.01 [g]	-
	AS 0654	Wheat straw and fodder, dry	3		0.952 [g]	1.5 [g]
	CM 0654	Wheat bran, unprocessed	0.15		0.066 0.041 [g]	
		White flour			0.0035	
		Wholemeal flour			0.012	
	CP 1212	Wholemeal bread			0.0083	
	CF 1210	Wheat germ			0.0038	
Definition of the residue (for compliance with MRL) for plant commodities: isopyrazam (sum of syn-isomer and anti-isomer) *Definition of the residue for estimation of dietary intake for plant commodities:* sum of isopyrazam and 3-difluoromethyl-1-methyl-1H-pyrazole-4-carboxylic acid [9-(1-hydroxyl-1-methylethyl)-(1RS, 4RS, 9RS)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]amide expressed as isopyrazam. *Definition of the residue (for compliance with the MRL the estimation of dietary intake) for animal commodities*: isopyrazam (sum of syn-isomer and anti-isomer)						

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
The residue is fat-soluble. [g] for the purpose of calculating animal dietary burdens. Expressed on an "as received" basis.						
Methamidophos (100)	CM 0649	Rice, husked	0.6 [h]	-	0.025	-
ADI:0-0.004 mg/kg bw	CM 1205	Rice, polished			0.021	-
ARfD: 0.1 mg/kg bw	AS 0649	Rice straw and fodder, dry	0.1 [h]	-	0.0325 [i]	0.05 [i]
Definition of the residue for compliance with MRLs and for estimation of dietary intake for plant and animal commodities: methamidophos. *Residue is not fat-soluble.* [h] Arising from the use of acephate on rice. [i] for the calculation of animal dietary burden						
Penthiopyrad (253)*						
ADI: 0–0.1 mg/kg bw						
ARfD: 1 mg/kg bw						
Profenofos (171)						
ADI: 0–0.03 mg/kg bw	VO 0444	Peppers, Chili	3	5 [l]	0.78	1.42
ARfD: 1.0 mg/kg bw	HS 0444	Peppers Chili, dried	20	50 [l]	5.46	9.94
Definition of the residue (for compliance with MRL and for estimation of dietary intake) for plant and animal commodities: profenofos *The residue is not fat-soluble.* [l] The Codex MRL was retained under the four year rule awaiting evaluation of data by the 2011 Meeting of JMPR						
Propylene oxide (250)*						
ADI: 0–0.04 mg/kg bw						
ARfD: 0.04 mg/kg bw						
propylene chlorohydrin						
ADI: None established [m]						
ARfD:None established						
propylene bromohydrin						
ADI: None established						
ARfD: None established						
Definition of the residue(for compliance with MRL) for plant commodities: propylene oxide *Definition of the residue (for estimation of dietary intake) for plant commodities*: propylene oxide, propylene chlorohydrin and propylene bromohydrin. Propylene chlorohydrin and propylene bromohydrin to be considered separately from propylene oxide *The residue is not fat-soluble.* [m] The Meeting could not establish an ADI or ARfD for propylene chlorohydrin and propylene bromohydrin due to insufficient data						

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
Pyraclostrobin (210)	AL 1020	Alfalfa fodder	30		8.38	22.28
ADI: 0–0.03 mg/kg bw	TN 0660	Almond	W [n]	0.02*		
ARfD: 0.05 mg/kg bw	AM 0660	Almond hulls	W [o]	2		
	VS 0620	Artichoke, globe	2		0.25	1.44
	GC 0640	Barley	1	0.5	0.345	
	FB 0264	Blackberries	3		0.87	1.32
	FB 0020	Blueberries	4	1	0.78	2.08
	FS 0013	Cherries	3		0.51	1.57
	FC 0001	Citrus fruits	2	1	0.035 (pulp)	0.1 (pulp)
	VC 0424	Cucumber	W [p]	0.5		
	VC 0045	Fruiting vegetables, Cucurbits	0.5		0.06(edible peel) 0.0525 (inedible peel)	0.41(edible peel) 0.14 (inedible peel)
	VA 0381	Garlic	0.15	0.05*	0.02	0.09
	VC 0046	Melons, except Watermelon	W [p]			
	FS 0245	Nectarine	0.3		0.065	0.13
	GC 0647	Oats	1	0.5	0.345	
	SO 0089	Oil seed except peanut	0.4		0.055	
	VA 0385	Onion, bulb	1.5	0.2	0.06	0.62
	VA 0389	Spring onion	1.5		0.42	0.60
	FI 0350	Papaya	0.15	0.05*	0.05	0.06
	FS 0247	Peach	0.3		0.065	0.13
	TM 0672	Pecan	W [n]	0.02*		
	FS 0014	Plums (including Prunes)	0.8		0.09	0.40
	FB 0272	Raspberries, Red, Black	3	2	0.87	1.32
	OR 0495	Rape seed oil, edible			0.053	
	GC 0650	Rye	0.2		0.02	
	GC 0651	Sorghum	0.5		0.025	
	VC 0431	Squash, Summer	W [p]	0.3		
	FS 0012	Stone fruits	W	1		
	FB 0275	Strawberry	1.5	0.5	0.20	0.75
	SO 0702	Sunflower seed	W [q]	0.3		
	TN 0085	Tree nuts	0.02*		0	0.02
	GC 0653	Triticale	0.2		0.02	
		Beer			0.23	
		Brewing malt			0.40	
		Cherry juice			0.08	
		Cotton gin by-products			1.575	16.73
		Malt germ			0.80	
		Orange oil	10		3.03	8.17
		Pearl barley			0.23	
		Plum puree			0.17	
	DF 0014	Prunes			0.41	1.84
		Strawberry jam			0.04	

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

The residue is not fat-soluble.

[n] The recommendations for almonds and pecan are withdrawn to be replaced by a recommendation for Tree nuts.
[o] The recommendation for almond hulls is withdrawn as the commodity is not traded.
[p] The recommendations for cucumber, melons and squash are withdrawn to be replaced by a recommendation for Fruiting

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
vegetables, Cucurbits [q] The recommendation for sunflower seed is withdrawn to be replaced by a recommendation for Oilseed except peanut.						
Saflufenacil (2251)*	FI 0327	Banana	0.01		0	0
ADI: 0–0.05 mg/kg bw	AS 0640	Barley straw and fodder, dry	0.025		0.025	0.025
ARfD: Unnecessary	VD 0071	Beans (dry)	0.3		0.01	
	GC 0080	Cereal grains	0.01		0	
	FC 0001	Citrus fruits	0.01		0	0
	SB 0716	Coffee beans	0.01		0	
	SO 0691	Cotton seed	0.2		0.025	
	FB 0269	Grapes	0.01		0	0
	MO 0105	Edible offal (Mammalian)	0.3		0.14	0.26
	AS 0645	Maize fodder	0.05		0.025	0.025
	MF 0100	Mammalian fats (except milk fats)	0.01		0.01	0.01
	MM 0095	Meat (from mammals other than marine mammals)	0.01		0.01	0.01
	ML 0106	Milks	0.01		0.01	0.01
	VP 0063	Peas (pods and succulent = immature seeds)	0.01		0.01	
	VP 0064	Peas, shelled (succulent seeds)	0.01		0.01	
	VD 0072	Peas, dry	0.05		0.01	
	FP 0009	Pome fruits	0.01		0	
	SO 0495	Rape seed	0.6		0.054	
	AS 0651	Sorghum straw and fodder dry	0.025		0.025	0.025
	VP 0541	Soya bean (immature seeds)	0.01		0.01	
	VD 0541	Soya bean (dry)	0.07		0.01	0
	FS 0012	Stone fruits	0.01		0	
	SO 0702	Sunflower seed	0.7		0.12	
	GC 0447	Sweet corn	0.01		0	0
	TN 0085	Tree nuts	0.01		0	
	AS 0654	Wheat straw and fodder, dry	0.025		0.025	0.025
	OR 0702	Sunflower seed oil edible			0.0036	
	OR 0541	Soya bean oil, refined			0.0025	
Definition of the residue (for compliance with MRL and for estimation of dietary intake) for plant and animal commodities: saflufenacil *The residue is not fat-soluble.*						
Spinosad (203)	TN 0660	Almonds	W [r]	0.01*		
	AM 0660	Almond hulls	W [s]	2	2.2	
ADI: 0–0.02 mg/kg bw	FB 0264	Blackberries	1		0.14	
ARfD: Unnecessary	FB 0020	Blueberries	0.4		0.11	
	FB 0265	Cranberry	0.02		0.01	
	FB 0266	Dewberries (including Boysenberry and Loganberry)	1		0.14	
	VA 0385	Onion, Bulb	0.1		0.01	
	FI 0351	Passion fruit	0.7		0.23	
	FB 0272	Raspberries, Red, Black	1		0.14	

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
	VA 0389	Spring onion	4		0.2	
	TN 0085	Tree nuts	0.07		0.026	
Definition of the residue (for compliance with MRL and for estimation of dietary intake) for plant and animal commodities: sum of spinosyn A and spinosyn D. *The residue is fat-soluble.* *(Residues in milk should be determined in the whole milk.)* [r] The recommendation for almonds is withdrawn to be replaced by a recommendation for Tree nuts [s] The recommendation for almond hulls is withdrawn as the commodity is not traded.						
Spirotetramat (234)	SO 0691	Cotton seed	0.4		0.095	
ADI: 0–0.5 mg/kg bw	AB 1203	Cotton seed meal	1		0.12	0.36
ARfD: 1.0 mg/kg bw	MO 0105	Edible offal (Mammalian)	1	0.03	0.16	0.55
	PE 0112	Eggs	0.01		0.0023	0.0048
	AL 0157	Legume animal feeds	30		12	17
	VP 0060	Legume vegetables	1.5		0.505	0.84
	FI 0343	Litchi	15		1.6	6
	FI 0341	Kiwifruit	0.02 *		0.055	0.066
	FI 0345	Mango	0.3		0.16	0.25
	MM 0095	Meat (from mammals other than marine mammals)	0.05	0.01*	0.006 muscle 0.012 fat	0.019 muscle 0.043 fat
	ML 0106	Milks	0.01	0.005*	0.005	0.005
	VA 0385	Onion, Bulb	0.4		0.11	0.27
	FI 0350	Papaya	0.4		0.17	0.22
	PM 0110	Poultry meat	0.01*		0 muscle 0 fat	0.00037 muscle 0.00037 fat
	PO 0111	Poultry, Edible offal of	0.01		0.0016	0.0033
	VD 0070	Pulses [except soya bean (dry)]	2		0.21	
	VD 0541	Soya bean (dry)	4		0.45	
	OR 0691	Cotton seed oil, edible			0	0
	OR 0541	Soya bean oil, refined			0	0
		Soya bean flour (defatted)			0.46	2.7
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-methoxy-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)* [t]	*GC 0640*	*Barley*	*0.6*		*0.063*	
ADI: 0–0.05 mg/kg bw	*AS 0640*	*Barley straw and fodder, dry*	*3*		*0.14*	*1.8*
ARfD: 0.3 mg/kg bw	*VB 0400*	*Broccoli*	*3*		*0.074*	*1.6*
	VB 0041	*Cabbages, Head*	*0.4*		*0.099*	*0.19*
	VB 0404	*Cauliflower*	*0.04*		*0.012*	*0.021*
	VS 0624	*Celery*	*1.5*		*0.19*	*0.77*
	FC 0001	*Citrus fruits*	*0.9*		*0.31*	*0.44*

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
	SO 0691	*Cotton seed*	*0.4*		*0.02*	
	DF 0269	*Dried grapes (= Currants, Raisins, and Sultanas)*	*6*		*0.49*	*5.6*
	MO 0105	*Edible offal (Mammalian)*	*0.6*		*0.13*	*0.47*
	PE 0112	*Eggs*	*0.1*		*0.013*	*0.071*
	VC 0045	*Fruiting vegetables, Cucurbits*	*0.5*		*0.029*	*0.27*
	VO 0050	*Fruiting vegetables, other than Cucurbits (except sweet corn and mushrooms)*	*1.5*		*0.11*	*0.60*
	VA 0381	*Garlic*	*0.01 **		*0.01*	*0.01*
	FB 0269	*Grapes*	*2*		*0.14*	*1.6*
	VL 0053	*Leafy vegetables*	*6*		*1.2*	*2.9*
	MM 0095	*Meat (from mammals other than marine mammals)*	*0.3*		*0.045 muscle 0.03 fat*	*0.2 muscle 0.073 fat*
	ML 0106	*Milks*	*0.2*		*0.05*	
	VA 0385	*Onion, bulb*	*0.01**		*0*	*0*
	VA 0389	*Spring onion*	*0.7*		*0.11*	*0.39*
	HS 0444	*Peppers, Chili (dried)*	*15*		*1.1*	*6.0*
	FP 0009	*Pome fruits*	*0.4*		*0.07*	*0.26*
	PM 0110	*Poultry meat*	*0.1*		*0.015 muscle 0.005 fat*	*0.05 muscle 0.021 fat*
	PO 0111	*Poultry, Edible offal of*	*0.3*		*0.046*	*0.18*
	SO 0495	*Rape seed*	*0.15*		*0.045*	
	VR 0075	*Root and tuber vegetables*	*0.03*		*0.01*	*0.023*
	AL 0541	*Soya bean fodder*	*3*		*0.79*	*1.5*
	VP 0541	*Soya bean (immature seeds)*	*0.3*		*0.011*	
	FS 0012	*Stone fruits (except cherry)*	*2*		*0.13*	*0.9*
	FB 0275	*Strawberry*	*0.5*		*0.19*	*0.21*
	TN 0085	*Tree nuts*	*0.015*		*0.01*	*0.012*
	GC 0653	*Triticale*	*0.2*		*0.025*	
	VL 0473	*Watercress*	*6*		*1.0*	*2.9*
	GC 0654	*Wheat*	*0.2*		*0.025*	
	AS 0654	*Wheat straw and fodder, dry*	*3*		*0.14*	*1.8*
	JF 0226	*Apple juice*			*0.060*	
		Barley flour			*0.036*	
		Barley, pearled			*0.032*	
		Cherry, dried			*4.0*	*7.7*
	JF 0004	*Orange juice*			*0.022*	
	JF 0048	*Tomato juice*			*0.052*	
	VW 0448	*Tomato paste*			*0.23*	
		Tomato puree			*0.10*	
		Wine			*0.098*	
Definition of the residue (for compliance with MRL and for estimation of dietary intake) for plant and animal commodities: sulfoxaflor *The residue is not fat-soluble.* [t] Recommendations made as part of the CCPR Pilot project and are not based on official GAP.						
Tebuconazole (189)**	FP 0226	Apple	1		0.275	0.5
ADI: 0–0.03 mg/kg bw	FS 0240	Apricot	2		0.46	
	VS 0620	Artichoke, globe	0.6	0.5	0.145	0.32

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
ARfD: 0.3 mg/kg bw	FI 0327	Banana	0.05	0.05	0.01	
	GC 0640	Barley	2	0.2 [u]	0.85	
	AS 0640	Barley straw and fodder, dry	40	10 (30 [u])		
	VD 0071	Beans (dry)	0.3		0.05	
	VB 0400	Broccoli	0.2		0.015	0.11
	VB 0402	Brussels sprout	0.3		0.095	0.19
	VB 0041	Cabbages, Head	1		0.05	0.56
	VB 0404	Cauliflower	0.05*		0.05	0.05
	VR 0577	Carrot	0.4	0.5 [u]	0.11	0.22
	MO 0812	Cattle, edible offal of	W	0.05*		
	FS 0013	Cherries	4	5	0.86	3.1
	SO 0691	Cotton seed	2		0.05	
	SB 0716	Coffee beans	0.1	0.1	0.04	
	SM 0716	Coffee beans, roasted	W	0.5	0.08	
	VC 0424	Cucumber	0.15	0.2	0.05	0.09
	DF 0269	Dried grapes (=currants, Raisins and Sultanas)	7	3	0.86	5.5
	MO 0105	Edible offal (Mammalian)	0.2	0.5	0.06	0.15
	VO 0440	Egg plant	0.1		0.04	0.10
	PE 0112	Eggs	0.05*	0.05*	0	0
	FB 0267	Elderberries	1.5	2	0.345	0.70
	VA 0381	Garlic	0.1	0.1 [u]	0.02	0.06
	FB 0269	Grapes	6	2	0.72	4.6
	DH 1100	Hops, dry	40	30	9.65	
	VA 0384	Leek	0.7	1 [u]	0.195	0.44
	GC 0645	Maize	W	0.1 [u]		
	AS 0645	Maize fodder	6			
	FI 0345	Mango	0.05	0.1 [u]	0.05	0.05
	MM 0095	Meat (from mammals other than marine mammals)	0.05*	0.05*	0	0
	VC 0046	Melons, except Watermelon	0.15	0.2	0.02	0.02
	ML 0106	Milks	0.01*	0.01*	0	
	FS 0245	Nectarine	2		0.46	1
	GC 0647	Oats	2	0.05*	0.085	
	FT 0305	Olives	0.05*		0	
	VA 0385	Onion, bulb	0.1	0.1	0.02	0.06
	FI 0350	Papaya	2	2 [u]	0.18	1.2
	FI 0351	Passion fruit	0.1		0.1	0.1
	FS 0247	Peach	2	1	0.46	1
	SO 0697	Peanut	0.15	0.1 [u]	0.035	
	AL 0697	Peanut fodder	40	30		
	FP 0230	Pear	1		0.275	0.50
	HS 0444	Peppers Chili, dried	10	5	1.85	6.2
	VO 0445	Peppers, Sweet (including pimento or pimiento)	1	0.5	0.185	0.62
	FS 0014	Plums (including Prunes [except prunes]	1	0.2 [u]	0.08	0.47
		Plum preserve			0.054	
	DF 0014	Prunes	3	0.5 [u]	0.232	1.36
	PM 0110	Poultry meat	0.05*	0.05*	0	0
	PO 0111	Poultry, Edible offal of	0.05*	0.05*	0.05	0.05
	SO 0495	Rape seed	0.3	0.5	0.10	
	GC 0649	Rice	1.5	2	0.275	
	GC 0650	Rye	0.15	0.05*	0.05	
	AS 0650	Rye straw and fodder, Dry	40	5		

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
	VD 0541	Soya bean (dry)	0.15	0.1	0.02	
	OR 0541	Soya bean oil, refined			0.001	
	VC 0431	Squash, Summer	0.2	0.02	0.05	0.10
	VO 0447	Sweet corn (corn-on-the-cob)	0.6	0.1 [u]	0.06	0.36
	VO 0448	Tomato	0.7	0.2 (0.5 [u])	0.15	0.46
	GC 0653	Triticale	0.15		0.05	
	TN 0085	Tree nuts	0.05*		0	0
	VC 0432	Watermelon	W	0.1 [u]		
	GC 0654	Wheat	0.15	0.05	0.05	
	AS 0654	Wheat straw and fodder, dry	40	10		
	JF 0226	Apple juice			0.063	
		Apple sauce			0.094	
		Beer			0.002	
		Beans, cooked			0.01	
		Cabbage, cooked			0.019	0.23
	OR 0691	Cotton oil, edible			0	
		Peach juice			0.092	
		Peach jam			0.006	
		Peach preserve			0.006	
	JF 0048	Tomato juice			0.033	
	VW 0448	Tomato paste			0.19	
		Tomato preserve			0.018	
		Tomato puree			0.02	
		Wine			0.20	

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: tebuconazole
The residue is fat-soluble.

[q] Recommendation of the 2008 JMPR

Thiamethoxam (245)
ADI: 0–0.08 mg/kg bw
ARfD: 1 mg/kg bw

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

Definition of the residue (for estimation of the dietary intake) for plant and animal commodities (except poultry): thiamethoxam and clothianidin (considered separately)

Definition of the residue for estimation of the dietary intake for poultry: sum of thiamethoxam, CGA 265307 and MU3, expressed as thiamethoxam; and clothianidin (clothianidin to be considered separately from thiamethoxam).

See also clothianidin

The residue is not fat-soluble.

Edited versions of these general considerations will be published in the report of the 2011 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 Bifenthrin (178)

Issue on Toxicology

Background

At the Forty-second Session of the Codex Committee on Pesticide Residues (CCPR), concern was raised by the Kenya Plant Health Inspectorate Service regarding the acute reference dose (ARfD) for bifenthrin established by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in 2009. Information was also provided by the sponsor regarding this concern in 2011.

The toxicity of bifenthrin was first evaluated by the 1992 JMPR. The 2009 JMPR reviewed bifenthrin within the periodic review programme of CCPR and established an ARfD of 0.01 mg/kg body weight (bw) based on a threshold dose (an estimate of the highest no-effect level at which treated rats would not display any decrease in motor activity) of 1.3 mg/kg bw in an acute rat gavage study for a decrease in motor activity from the published study by Wolansky et al. (2006)[1] and using a safety factor of 100. Although this study was conducted with male rats only, it was considered appropriate, as there was no evidence of sex differences in the bifenthrin database. This ARfD was supported by the gavage study of developmental toxicity in rats[2] in which the no-observed-adverse-effect level (NOAEL) of 1.0 mg/kg bw per day was based on the increased fetal and litter incidences of hydroureter without hydronephrosis seen at the highest dose of 2.0 mg/kg bw per day and was thereby also protective of developmental effects.

The 2011 JMPR agreed to reconsider the ARfD for bifenthrin based upon the concern form submitted by Member State Kenya (Annex 5, reference *119*). The Meeting also considered the "Comprehensive Rationale for Establishing an ARfD for Bifenthrin" submitted by the sponsor in support of the concern raised.

Concern from Kenya

"The studies used for the derivation of the ARfD may not be most appropriate and therefore resulting in an overly conservative ARfD. In particular, we would like to highlight a number of areas which would require a scientific re-evaluation:

- Effect of dosing in corn oil and the influence of corn oil volume on toxicity
- The lack of consideration of using a benchmark dose approach
- Use of a lower safety factor (50) is justified due to toxicokinetic factor
- Lack of statistics used in the Wolansky (2006) study

[1] Wolansky MJ, Gennings C & Crofton KM (2006). Relative potencies for acute effects of pyrethroids on motor function in rats. *Toxicological Sciences*, 89(1):271–277.

[2] DeProspo JR (1984a). *Teratology study in rats with FMC 54800 technical*. FMC A83-1091.

- The use of NOEL from the DeProspero (1984) study which is not appropriate for an ARfD
- The use of non statistically significant teratogenic endpoints"

Comments by JMPR

- Effect of dosing in corn oil and the influence of corn oil volume on toxicity

The JMPR agrees that use of corn oil as a vehicle and the dosing volume of corn oil can influence the toxic potency of pyrethroids. It is not unusual for some standard test guideline studies to be conducted using gavage dosing and corn oil as vehicle. The data from such studies have been used for the derivation of ARfDs previously, including for several pyrethroids, by the JMPR. Further, several types of vehicles are used in pyrethroid gavage studies, and corn oil is used most often. The rationale of vehicle/dose volume in the Wolansky et al. (2006) study is consistent with the routine dosing volume used in many laboratories.

In fact, the study proposed by the sponsor for establishing the ARfD was conducted using corn oil as the vehicle.

- The lack of consideration of using a benchmark dose approach

The Meeting acknowledges that benchmark dose (BMD) modelling provides a more quantitative analysis of uncertainty in the dose–response relationship than the NOAEL/lowest-observed-adverse-effect level (LOAEL) process. However, in the case of the motor activity data in Wolansky et al. (2006), the BMD can only be modelled down to a 30% response due to variability in the measurements. The lower limit on the benchmark dose (BMDL) of 4 mg/kg bw per day proposed by the sponsor for bifenthrin would need to be adjusted to allow for the fact that the BMD is based on a 30% response. Further, the BMDL of 4 mg/kg bw per day would not be sufficiently protective of developmental effects at 2.0 mg/kg bw per day in a developmental toxicity study in rats (gavage). Suitable adjustment of the BMDL for a 30% response rather than the conventional 5% response will result in a reference value similar to the "threshold dose" of 1.3 mg/kg bw given in Wolansky et al. (2006).

- Use of a lower safety factor (50) is justified due to toxicokinetic factor

When considering the safety factors for acute toxicological effects dependent on the peak concentration in plasma (C_{max}), the compound needs to have toxicokinetic properties that result in rapid absorption and elimination and toxicodynamic properties such that there is no opportunity for cumulative effects to result from one exposure to another. These properties are not supported by the data provided by the sponsor in the case of bifenthrin. The Meeting in 2009 did consider the Selim (1986)[3] study. In this study, radioactivity peaked 4 and 6 hours after the administration of doses of 5.4 and 35 mg/kg bw, respectively. Ten hours after dosing, the chemical concentration in blood declined to less than 50% of the concentration at peak in both doses. The data from Selim (1986) showed a slow decline of radioactivity. The 2009 JMPR did not apply a compound-specific C_{max} adjustment factor. The current Meeting confirmed this view and concluded that there are inadequate pharmacokinetic data to support such a factor. Additionally, the relationship between C_{max} and the developmental toxicity of bifenthrin is unknown.

[3] Selim S (1986). *The kinetics of FMC 54800 in the blood of rats following a single oral dose.* FMC PC-0048. February 1986.

- Lack of statistics used in the Wolansky (2006) study

The non-linear exponential threshold additivity model was used in Wolansky et al. (2006) to obtain the threshold dose and its 95% confidence intervals for each individual chemical. This threshold dose represents an estimate of the highest no-effect level at which treated rats would not display any decrease in motor activity. As stated in Wolansky et al. (2006), the adequacy of the fit of the additivity model to the data on single chemicals was assessed graphically and through goodness-of-fit statistics. As stated previously, a $BMDL_{30}$ would have to be adjusted, which would result in a value similar to the threshold dose value reported in Wolansky et al. (2006) (see comment on BMD above).

- The use of NOEL from the DeProspero (1984) study which is not appropriate for an ARfD

The Meeting assumes that "NOEL" (no-observed-effect level) in the statement of concern meant NOAEL. In the developmental toxicity study in rats via gavage (DeProspo, 1984a), the NOAEL was 1.0 mg/kg bw per day, based on the 3-fold increased incidence of hydroureter at 2.0 mg/kg bw per day. Furthermore, the litter incidences for hydroureter without hydronephrosis were 0/23, 0/24, 0/25 and 5/23 at 0, 0.5, 1.0 and 2.0 mg/kg bw per day, respectively. As this effect was not observed in the concurrent control and positive control study and increased in incidence in both fetuses and litters, and because of the lack of historical control data and lack of detailed description of the effects, including photographs, in the study report, the Meeting concluded that the effect of treatment with bifenthrin cannot be dismissed. The JMPR has no evidence to conclude that these effects could not occur following a single-dose exposure during the critical window of fetal development.

The sponsor points out that the developmental effects of bifenthrin were not observed in the dietary developmental toxicity study in rats.[4] The JMPR notes, however, that differences in response due to route of administration are not unusual. Unless there is information to the contrary, an effect is not disregarded based on route of administration. The sponsor also notes that these effects were not seen in the developmental toxicity study in rabbits.[5] Species differences in response are also not unusual, and, unless there is information to the contrary, the most sensitive species is used to establish health-based guidance values. The sponsor further points out that these developmental effects were not found in the reproductive toxicity study[6] and the developmental neurotoxicity toxicity study in rats.[7] However, these effects were not looked for in these studies.

- The use of non statistically significant teratogenic endpoint

Although statistical significance was not achieved for increases in the incidence of hydroureter without hydronephrosis, the fetal and litter incidences were increased at the highest dose level of 2.0 mg/kg bw per day and therefore cannot be ignored, especially because the effect was very rare and not seen in the concurrent controls. No historical control data were provided to the Meeting. In addition, higher doses were not tested in the developmental toxicity study in rats; therefore, the dose–response relationship cannot be

[4] Watt B & Freeman C (2001). *Bifenthrin technical: prenatal developmental toxicity study in rats*. FMC A2000-5263.
[5] DeProspo JR (1984b). *Teratology study in rabbits with FMC 54800 technical.* FMC A83-1092.
[6] DeProspo JR (1986). *Multi-generation reproduction study with FMC 54800 technical in rats.* FMC A83-977.
[7] Nemec MD (2006). *A dietary developmental neurotoxicity study of bifenthrin technical in rats.* FMC A2004-5860.

assessed. The JMPR has no evidence to conclude that these effects could not occur following a single-dose exposure during the critical window of fetal development.

Conclusion
Based on the data available during the 2009 JMPR and having considered the rationale provided by the sponsor on behalf of Kenya, the 2011 Meeting confirmed the AfRD of 0.01 mg/kg bw established by the 2009 JMPR.

Issue on residues

Background

At the 43rd Session of the CCPR, the Delegation of the European Community (EC) raised concerns regarding the MRL proposal for bifenthrin in strawberry. A concern form was submitted.

Evaluation by the 2010 JMPR

The 2010 JMPR estimated a maximum residue level for bifenthrin in strawberries of 3 mg/kg to replace the previous recommendation of 1 mg/kg. The Meeting estimated an STMR of 0.46 mg/kg and an HR of 2.3 mg/kg.

The 2010 JMPR noted that the ARfD is exceeded for children (430%) and the general population (230%) by the dietary intake calculation. No alternative GAP is available.

Comment by the 2011 JMPR

In case of the evaluation of bifenthrin residues in strawberry, the JMPR followed the procedure as usual:

(1) estimation of a maximum residue level which is proposed as MRL (3 mg/kg)
(2) calculation of the dietary intake on the basis of the STMR (0.46 mg/kg) for long-term and the HR (2.3 mg/kg) for the short-term intake with the result that the ARfD was exceeded
(3) looking for an alternative GAP with the result that no alternative GAP was available.

In the Report of the 2010 JMPR it is clear indicated that the ARfD is exceeded and that no alternative GAP for bifenthrin use in strawberry is currently available.

Based on the evaluation of the JMPR, the Report of the 43rd Session of the CCPR is noted: "*Due to short term intake concern identified by JMPR, the Committee decided to retain the proposed draft MRL for strawberry at Step 4, awaiting data from the manufacturer to support a review of alternative GAP by JMPR in 2014.*[8]"

The JMPR as risk assessors have prepared the relevant information for CCPR as risk managers to make a decision.

1.2 Indoxacarb (216)

Background

[8] Report of the 43rd Session of the CCPR, paragraph 53, Beijing, 4-9 April 2011, REP11-PR-Rev

Indoxacarb, an indeno-oxadiazine insecticide used for control of Lepidoptera and other pests, was first evaluated by the 2005 JMPR, with additional commodities and commodity groups being considered at the 2007 and 2009 JMPR Meetings. An ADI of 0-0.01 mg/kg body weight and an ARfD of 0.1 mg/kg body weight were established by the 2005 JMPR.

The 2005 Meeting recommended maximum residue levels for a range of commodities, including levels of 7 mg/kg for head lettuce and 15 mg/kg for leaf lettuce but was not able to calculate the IESTI for leaf lettuce because leaf lettuce unit weight data were not available at that time.
The 38th CCPR in 2006 advanced the proposed draft MRL of 15 mg/kg for leafy lettuce to Step 5, noting the acute dietary intake concerns for children expressed by the EC [Alinorm 06/29/24 - para 135]. This draft MRL was subsequently advanced to Step 8 by the 39th CCPR in 2007.
In 2009, new consumption data were available to JMPR, including information on leaf lettuce consumption, and the 2009 Meeting calculated the IESTIs for leaf lettuce (60% of the ARfD for the general population and 150% of the ARfD for children) and noted that there were limited opportunities to refine the consumption estimate or the intake risk estimate and that there was no alternative GAP available.

The 40th CCPR, in 2010, in addition to advancing a number of new and revised MRLs, requested JMPR to conduct an alternative GAP evaluation for leafy lettuce and the 41st CCPR scheduled this evaluation for this JMPR Meeting. New GAP information was provided by the manufacturer and the Meeting reviewed the data submitted to the 2005 JMPR on leafy lettuce in light of this new GAP.

Comments by JMPR:

The GAP in Italy is for up to 3 applications of 0.038 kg ai/ha with a PHI of 1 day.
In three trials conducted in France and Greece, involving 6 applications of 0.038 kg ai/ha, PHI 1 day, residues were: 0.36, 0.75 and 1.25 mg/kg.

The Meeting agreed that the data were not sufficient to recommend a maximum residue level to support an alternative GAP for indoxacarb on leaf lettuce.

2. Update of the automated spreadsheet applications for the calculation of dietary intake: New Large Portion data

The 2003 Meeting agreed to adopt automated spreadsheet applications for the calculation of dietary intake in order to harmonize and facilitate the process. The spreadsheet applications were constructed by RIVM (National Institute for Public Health and theEnvironment), of the Netherlands in

cooperation with WHO/GEMS/Food incorporating all available consumption data in Excel spreadsheets and, where possible, linking this consumption data to the Codex Commodities for which MRLs, HR(-P)s and STMR(-P)s are estimated. The spreadsheets are used to calculate the IEDI and IESTI using the formulas as described in Chapter 7 of the 2009 FAO manual. To use the spreadsheets, estimates made by JMPR (ADI, acute RfD, STMR(-P), HR(-P), and when necessary MRL values) are entered according to the manual attached to the spreadsheets. Then calculations and generation of a final table are performed automatically.

In its 2010 Report, JMPR highlighted the importance of current consumption data for a reliable risk assessment (General Considerations 2.2 and 2.3). Some issues were identified with respect to the Large Portion database:

1. In the current GEMS/Food LP database, several regions of the world are not, or not very well, represented in the LP database.
2. The GEMS/Food LP data are sometimes older than those used by the same country in national or regional assessments (e.g. Europe).

As a result of a WHO/GEMS/Food request to provide or update national large portion data for acute dietary risk assessment (March 2011), the governments of Australia, France, Germany, Netherlands and Thailand provided new or updated information on large portion data and/or commodity unit weights and percent edible portions. Large portion data already available to JMPR and provided by the governments of Japan, South Africa, the UK and the USA were retained. Unit weight and edible portion data already available to the JMPR and provided by the governments of Belgium, Japan, Sweden, the UK and the USA were retained.

The population age groups for which large portion data have been provided differed between countries. Large portion data are now available for general population (all, 1 years and above, 2 years and above, 3 years and above, 10 years and above, 16-64 yrs, 14-80 yrs), women of childbearing age (14-50 yrs), and children of various ages ranging from babies to teenagers (6 yrs and under, 8-20 months, 1-5 yrs, 1-6 yrs, 1.5-4.5 yrs, 2-4 yrs, 2-6 yrs, 3-6 yrs, 2-16 yrs). Since data were available on so many different population groups, the highest large portion (based on g/kg bw/d) for each commodity from all population groups has been chosen to do the IESTI spreadsheet calculations with. The data were accepted as such, no quality check was done. The responsibility for the data lies with the respective governments.

Large portion data provided were either expressed as raw agricultural commodity (e.g. orange with peel), as raw edible portion (e.g. peeled orange) or as processed product (e.g. orange juice). To be able to select the highest large portion for a certain commodity from different countries, all large portion

data need to be expressed in the same way. For this reason the submitted large portion data have been modified in such a way that the large portion data for raw consumed commodities and aggregated commodities are expressed as raw edible portion, while the large portion data for individual processed commodities are expressed as processed product.

Until recently the IESTI calculations were only done for aggregated large portion data (i.e. raw plus unspecified processed commodies). With the new data it is now possible to do IESTI calculations for individual raw and processed commodities (e.g. raw apples, apple juice, apple sauce, dried apples) as well as for aggregated large portion data (e.g. sum of raw apples, apple juice and dried apples). Large portion data for individual raw and individual processed commodities are listed separate from aggregate large portion data in the spreadsheet.

Generally the large portion data for the aggregated commodities will result in the highest IESTI for a certain commodity. When the ARfD is exceeded for the aggregated commodities, it may be possible to refine the IESTI calculation by calculating the IESTI for all individual raw and processed commodities by making use of the processing factors derived from processing studies.
The spreadsheet applications will be available on the WHO website .
http://www.who.int/foodsafety/chem/acute_data/en/index1.html . The call for data is still open and the spreadsheet will be updated when new data become available. .

3. MRL estimation using the proportionality approach

The 2010 JMPR provided an approach to use the concept of proportionality in MRL estimation (General Consideration 2.8 of the 2010 JMPR Report). This approach was based on suggestions of some delegations of the 2010 CCPR: JMPR could have recommended MRLs for a number of commodities when the supporting residue data were from trials involving treatments more than 25% higher than the authorized GAP maximum application rates (CCPR, Report of the 42nd Session, April 2010, ALINORM 10/33/24, paragraph 72).
At its 43rd Session, the CCPR agreed that it would be useful if the JMPR could elaborate MRL proposals with and without making use of the concept of proportionality so that the results could be compared. (CCPR, Report of the 43rd Session, April 2011, paragraph 86).

The 2011 JMPR made use of the proportionality approach to estimate maximum residue levels for dicamba in soya beans, etofenprox in grapes, flutriafol in grapes and hexythiazox in strawberries as well as of a median residue for diflubenzuron in almond hulls to estimate the animal dietary burden. Recommendations for these commodities could not have been made without using the proportionality approach.

The table below shows the results with and without scaling of residue data for comparing and decision by CCPR. The table columns are described as follows: (1) the critical GAP on which the evaluation based on; (2) the application rate used in the corresponding supervised residue trials; (3) scaling factor, GAP application rate ÷ actual application rate (4) the residue data points selected from the supervised trials without scaling, residues according to the GAP are underlined; (5) the residue data points selected from the supervised trials scaled if necessary; (6) the estimated MRL without making use of the concept of proportionality; (7) the estimated MRL with use of the concept of proportionality.

Treatment		Scaling	Residue data (mg/kg)		MRL proposal (mg/kg)	
GAP, country (1)	Rate, kg ai/ha (2)	factor (3)	not scaled (4)	scaled (5)	Without scaling (6)	With scaling (7)
Dicamba in soya bean (dry)						
1.12 kg ai/ha USA	2.24	0.5	0.07	0.035	**No MRL**	**5**
	2.24	0.5	0.07	0.035		
	2.24	0.5	0.08	0.04		
	2.24	0.5	0.10	0.05		
	2.24	0.5	0.14	0.07		
	2.24	0.5	0.17	0.085		
	2.24	0.5	0.27	0.135		
	2.24	0.5	0.28	0.14		
	2.24	0.5	0.46	0.23		
	2.24	0.5	0.48	0.24		
	2.24	0.5	0.55	0.275		
	2.24	0.5	0.65	0.325		
	2.24	0.5	0.68	0.34		
	2.24	0.5	0.70	0.35		
	2.24	0.5	0.81	0.405		
	2.24	0.5	1.0	0.50		
	2.24	0.5	1.3	0.65		
	2.24	0.5	1.4	0.70		
	2.24	0.5	1.43	0.715		
	2.24	0.5	1.9	0.95		
	2.24	0.5	2.1	1.05		
	2.24	0.5	3.3	1.65		
	2.24	0.5	8.1	4.05		
Etofenprox in grapes						
0.028 kg ai/hL Italy	0.015	1.87	0.25	0.47	**No MRL**	**4**
	0.015	1.87	0.29	0.54		
	0.015	1.87	0.35	0.65		
	0.015	1.87	0.38	0.71		
	0.015	1.87	0.39	0.73		
	0.015	1.87	0.39	0.73		
	0.015	1.87	0.53	0.99		
	0.015	1.87	0.63	1.2		
	0.015	1.87	0.96	1.8		
	0.015	1.87	1.37	2.6		
	in kg ai/hL					
Diflubenzuron in almond hulls						
4×0.28 kg	4×0.28	1	<u>2.1</u>	2.1		**1.15**

Treatment		Scaling	Residue data (mg/kg)		MRL proposal (mg/kg)	
GAP, country (1)	Rate, kg ai/ha (2)	factor (3)	not scaled (4)	scaled (5)	Without scaling (6)	With scaling (7)
USA	4×0.28	1	4.0	4.0		Median residue for animal dietary burden
	4×0.56	0.5	1.0	0.5		
	4×0.56	0.5	1.6	0.8		
	4×0.56	0.5	2.1	1.05		
	4×0.56	0.5	2.3	1.15		
	4×0.56	0.5	4.4	2.2		
Flutriafol in grapes						
6×0.073-0.091 kg ai/ha USA	7×0.128	0.71	0.12	0.09	**No MRL**	**0.8**
	7×0.128	0.71	0.21	0.15		
	7×0.128	0.71	0.21	0.15		
	7×0.128	0.71	0.25	0.18		
	7×0.128	0.71	0.28	0.20		
	7×0.128	0.71	0.30	0.21		
	7×0.128	0.71	0.30	0.21		
	7×0.128	0.71	0.31	0.22		
	7×0.128	0.71	0.35	0.25		
	7×0.128	0.71	0.37	0.26		
	7×0.128	0.71	0.43	0.31		
	7×0.128	0.71	0.61	0.43		
	7×0.128	0.71	0.86	0.61		
Hexythiazox in strawberry						
1×0.21 kg ai/ha USA	0.07	3	0.18	0.54	**No MRL**	**6**
	0.14	1.5	0.19	0.29		
	0.17	1.23	0.50	0.62		
	0.21	1	0.13	0.13		
	0.21	1	0.17	0.17		
	0.21	1	0.30	0.30		
	0.21	1	1.8	1.80		
	0.28	0.75	0.87	0.65		
	0.28	0.75	5.5	4.1		

4. Geographical Zones and Estimation of Maximum Residue Levels

At the 2003 JMPR, the Meeting considered the Zoning Report (Report of the OECD/FAO Zoning Project Series on Pesticides, Number 19, ENV/JM/MONO(2003)4 16 May 2003) [www.oecd/dataoecd/27/0/2955870.pdf] and agreed with the conclusion that the impact of climatic zones on pesticide residues is small, and residue data derived from similar use patterns and growing conditions may be compared regardless of the geographical location of the trials.

The JMPR has used trials complying with GAP irrespective of geographical location, but on a case-by-case basis. Recognizing the experience gained since 2003, the Meeting agreed that from 2012, geographical location should not be a barrier in selecting trials for estimation of maximum residue levels. However, the Meeting noted that there will be cases where regional differences in cultural practices will need to be considered.

Sulfoxaflor data were used to illustrate MRL estimates obtained using geographical zones (Current Practice) and assuming residues do not primarily depend on zones (Global Dataset Method). This comparison is provided in the attached "MRL Estimates for Sulfoxaflor" table. Combining data from different geographical zones results in MRL estimates based on larger data sets that more accurately reflect data variability and are more appropriate for use with statistical-based MRL calculations.

MRL Estimates for Sulfoxaflor

Crop/Crop Group	Current Practice		Global Dataset Method	
	# Trials	MRL (mg/kg)	# Trials	MRL (mg/kg)
Carrot	4	No MRL[a]	11	0.05
Dry Bean	4	No MRL[a]	6	0.2
Common Bean	3	No MRL[a]	6	4
Citrus Fruit	10	0.9	26	0.7
Pome Fruit	18	0.4	36	0.5
Stone Fruit	6	3	14	3
Tree Nuts	6	0.015	6	0.015
Fruiting Vegetables, Cucurbit	6	0.5	16	0.4
Fruiting Vegetables, other than cucurbits (except sweet corn and mushroom)	11	1.5	20	0.7
Leafy Vegetables	6	6	7	6
Root and Tuber Vegetables[b]	8	0.03	11	0.05
Barley	6	0.6	25	0.4
Barley straw and fodder,dry	11	3	36	2
Broccoli	5	3	15	2
Cabbages, Head	6	0.4	14	0.5
Cauliflower	6	0.04	10	0.07
Celery	6	1.5	6	1.5
Cotton seed	6	0.4	22	0.2
Garlic	Extrapolated[c]	0.01*	Extrapolated[c]	0.01*
Grapes	12	2	33	2
Dried Grape	Processing[d]	6	Processing	6
Okra	Extrapolated[c]	1.5	Extrapolated[c]	0.7
Onion, bulb	6	0.01*	6	0.01*
Spring onion	6	0.7	6	0.7
Dried chili pepper	Extrapolated[c]	15	Extrapolated[c]	7
Pistachio nut	Extrapolated[c]	0.015	Extrapolated[c]	0.015
Rape seed	8	0.15	14	0.4
Soya bean fodder	15	3	19	2
Soya bean (immature seed)	14	0.3	18	0.2
Strawberry	9	0.5	13	0.7
Triticale	Extrapolated[c]	0.2	Extrapolated[c]	0.15
Watercress	6	6	7	6
Wheat	6	0.2	33	0.15
Wheat straw and fodder, dry	11	3	36	2

MRL Estimates for Sulfoxaflor

[a] No recommendation due to insufficient number of trials.

[b] Except carrot for regional; with carrot for global.

c Extrapolated from another crop.

d From processing study.

Note: Identical MRL recommendations for mammals (0.3 meat; 0.6 offal), milk (0.2), poultry (0.1 meat; 0.3 offal), and eggs (0.1).

5. General discussions related to the toxicological evaluation of compounds

The World Health Organization (WHO) Core Assessment Group on Pesticide Residues discussed several items relevant to the toxicological evaluation of agricultural pesticides.

The group agreed on the need to update the guidance for monographers, to take account of changes in process since it was last published and to use the opportunity to improve and harmonize the monograph format to facilitate data submission and exchange of evaluations.

Current practices in rounding when expressing health-based guidance values (acceptable daily intake [ADI], acute reference dose [ARfD]) were also discussed, and the current Joint FAO/WHO Meeting on Pesticide Residues (JMPR) practice was confirmed.

After a brief presentation by Dr Andy Hart on ongoing activities on how to more systematically express the uncertainty underlying hazard assessments, the group decided that it would be beneficial to explore ways to more systematically express underlying uncertainties. For this, it was recommended that one or two JMPR experts should participate in the ongoing activity within WHO/International Programme on Chemical Safety (IPCS). The group also recommended that the Joint FAO/WHO Expert Committee on Food Additives (JECFA) should consider this approach.

Following a brief presentation regarding ongoing activities in the United States of America on high-throughput screening assays (Tox21), the group decided to form a small working group to develop a draft position for JMPR on the use of such data in risk assessment, for discussion at the next meeting.

The group further agreed to form another small working group to define the scope of the need to develop further guidance on minor and adaptive effects, as a follow-up to previous discussions held at the 2006 meeting, for further discussion at the next meeting. Practical experience from the work of JMPR will serve as guidance when developing this scope.