

Food and Agriculture Organization of the United Nations



World Health Organization

JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES

Rome, 21-30 September 2010

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 2010 MEETING

Issued October 2010

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 23 pesticides, of which 8 were new compounds, and 5 were reevaluated 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. Application of HR levels is explained in Chapter 7 (7.3.) of the FAO Manual on the submission and evaluation of pesticide residue data for the estimation of MRLs in food and feed (2009). 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, as explained in detail in the report of the 1999 Meeting (section 2.2). Footnotes 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 reevaluated 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.

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/corethemes/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	HR or HR-P
			New	Previous	mg/kg	mg/kg
	.,				_	
Bifenazate (219)	VD 0071	Beans (dry)	0.3		0.01	
ADI: 0-0.01 mg/kg bw	FB 0264	Blackberries	7		2.25	
	FB 0266	Dewberries (including	7		2.25	
		Boysenberry and Loganberry)				
	FB 0272	Raspberries	7		2.25	
ARfD: Unnecessary	VP 0060	Legume vegetables	7		1.5	

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): Sum of bifenazate and bifenazatediazene (diazenecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl-3-yl] 1-methylethyl ester), expressed as bifenazate.

The residue is fat-soluble.

Bifenthrin (178)**	FI 0327	Banana	0.1		0.01	0.01
ADI: 0-0.01 mg/kg bw	GC 0640	Barley	W	0.05 *		
ARfD: 0.01 mg/kg bw	AS 0640	Barley straw and fodder, dry	W	0.5		
	FB 0264	Blackberries	1		0.29	0.51
	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	0.3		0.115	0.19
	MF 0812	Cattle fat	W	0.5		
	MO 1280	Cattle kidney	\mathbf{W}^{a}	0.05*		
	MO 1281	Cattle liver	\mathbf{W}^{a}	0.05*		
	MM 0812	Cattle meat	\mathbf{W}^{a}	0.5 (fat)		
	ML 0812	Cattle milk	\mathbf{W}^{a}	0.05*		
	PE 0840	Chicken eggs	W	0.01*		
	PF 0840	Chicken fat	W	0.05*		
	PM 0840	Chicken meat	W	0.05* (fat)		
	PO 0840	Chicken, Edible offal of	W	0.05*		
	FC 0001	Citrus fruits	0.05		0.05	0.05
	SO 0691	Cotton seed	0.5		0.05	
	AB 1203	Cotton seed meal			0.003	
	OR 0691	Cotton seed oil, edible			0.005	
	FB 0266	Dewberries (including Boysenberry and Loganberry)	1		0.29	0.51
	MO 0105	Edible offal (Mammalian)	0.2		0.07	0.165
	VO 0440	Egg plant	0.3		0.05	0.1
	FC 0203	Grapefruit	\mathbf{W}^{b}	0.05*		
	DH 1100	Hops, dry	20	10	1.9	
		Beer			0.011	
	FC 0204	Lemon	W b	0.05*		
	GC 0645	Maize	0.05*	0.05*	0	
	AS 0645	Maize fodder	15	0.2	2.2 dw	5.5 dw
	OC 0645	Maize oil, crude			0	
	OR 0645	Maize oil, edible			0	
	CF 1255	Maize flour			0	
		Maize grits			0	
		Maize starch			0	
	FI 0345	Mango	0.5 ^c		0.01	0.01
	MM 0095	Meat (from mammals other than marine mammals)	3 (fat)		0.59 fat 0.07 muscle	1.9 fat 0.104

Pesticide (Codex reference number)	CCN	Commodity		ended MRL g/kg	STMR or STMR-P	HR or HR-P
			New	Previous	mg/kg	mg/kg
						muscle
	FM 0183	Milk fats	3		0.49	
	ML 0106	Milks	0.2		0.053	
	VL 0485	Mustard greens	4		1.16	2.1
	VO 0442	Okra	0.2		0.07	0.11
	FC 0208	Orange, sweet	\mathbf{W}^{b}	0.05*		
	FI 0350	Papaya	0.4 ^c		0.01	0.01
	AL 0072	Pea hay or Pea fodder (dry)	0.7		0.093 dw	0.39 dw
	FP 0230	Pear	W	0.5		
	VO 0051	Peppers	0.5		0.14	0.31
	HS 0444	Peppers, chili (dried)	5		1.4	
	VR 0589	Potato	$\mathbf{W}^{ ext{ d}}$	0.05*		
	VD 0070	Pulses	0.3		0.05	
	VL 0494	Radish leaves (including Radish tops)	4		1.75	2.3
	SO 0495	Rape seed	0.05		0.05	
	OR 0495	Rape seed oil, edible	0.1		0.08	
		Rape seed meal			0.027	
	FB 0272	Raspberries, Red, Black	1		0.29	0.51
	VR 0075	Root and tuber vegetables	0.05		0.05	0.05
	AB 1265	Soya bean meal			0.01	
	OR 0541	Soya bean oil, refined			0.05	
	FB 0275	Strawberry e	3	1	0.46	2.3
	DT 1114	Tea, Green, Black (black, fermented and dried)	30		5.2	
	VO 0448	Tomato	0.3		0.06	0.15
	VW 0448	Tomato paste			0.04	
		Tomato puree			0.04	
	TN 0085	Tree nuts	0.05		0.05	0.05
	GC 0654	Wheat	0.5 Po	0.5 Po	0.25	0.4
	CM 0654	Wheat bran, unprocessed	2 PoP	2 PoP	0.79 PoP	1.26 PoP
	CF 1211	Wheat flour	\mathbf{W}^{f}	0.2 PoP		
	CF 1210	Wheat germ	1 Po		0.45 PoP	0.72 PoP
	AS 0654	Wheat straw and fodder, dry	W	0.5		
	CF 1212	Wheat wholemeal	W^{f}	0.5 PoP		

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): bifenthrin (sum of isomers).

The residue is fat soluble.

The recommendations for cattle kidney and cattle liver are withdrawn, to be replaced by a recommendation for mammalian edible offal. Recommendations for cattle fat, meat and cattle milk are withdrawn and replaced by recommendations for mammalian meat and milks.

b The recommendations for grapefruit, lemon and orange, sweet are withdrawn to be replaced by recommendation for citrus fruits.

^c The recommendations for mango, okra and papaya are based on reported use conditions provided appropriate protection of the crop, but were not supported by official information on uses.

 $[\]frac{d}{d}$ The recommendation for potato is withdrawn to be replaced by recommendation for root and tuber vegetables.

 $[\]frac{e}{}$ For strawberry, the ARfD is exceeded. No alternative GAP is available.

^f The recommendations for maximum residue levels for wheat flour and whole meal are withdrawn, because they are covered by the recommendation for wheat.

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P	HR or HR-P
			New	Previous	mg/kg	mg/kg
Boscalid (221)	FC 0001	Citrus fruits	2		0.05	
ADI: 0-0.04 mg/kg bw	AB 0001	Citrus pulp, dry	6		1.5	
ARfD: Unnecessary	DH 1100	Hops, dry	60		21.5	
	VL 0053	Leafy vegetables	40	30	3.65	
		Orange juice			0.0108	
	VS 0078	Stalk and stem vegetables	30		8.55	
		Citrus oil	50		27.7	

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

Definition of the residue (for estimation of dietary intake for animal commodities): sum of boscalid, 2-chloro-N-(4'-chloro-5-hydroxybiphenyl-2-yl)nicotinamide including its conjugate, expressed as boscalid.

The residue is fat soluble.

Cadusafos (174) **	FI 0327	Banana	0.01	0.01	0.005	0.005
ADI: 0-0.0005 mg/kg bw	VR 0589	Potato	W	0.02		
ADED: 0.001/I I						

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): Cadusafos

The residue is not fat-soluble.

Chlamantum ilimusla (220)	AL 1020	Alfalfa fodder	50		17.2
Chlorantraniliprole (230)					17.3
ADI: 0–2 mg/kg bw	FB 0018	Berries and other small fruits	1		0.119
ARfD: Unnecessary	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	2		0.385
	FC 0001	Citrus fruits	0.5		0.07
	MO 0105	Edible offal (Mammalian)	0.2	0.01*	0.03 kidney
					0.047 liver
	PE 0112	Eggs	0.1	0.01*	0.052
	FB 0269	Grapes	W	1	
	AS 0645	Maize fodder	25		3.1
	MM 0095	Meat (from mammals other	0.2 (fat)	0.01 * fat	0.05 fat
		than marine mammals)			0.009 muscle
	FM 0183	Milk fats	0.2	0.1	0.048
	ML 0106	Milks	0.05	0.01*	0.006
	HH 0738	Mints	15		4.6
	PO 0111	Poultry, Edible offal of	0.01*		0.0016
	PM 0110	Poultry meat	0.01 * (fat)		0.0008 fat
					0.00007
					muscle
	GS 0659	Sugar cane	0.5		0.145
	VO 0447	Sweet corn (corn-on-the- cob)	0.01*		0.01

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

The residue is fat-soluble

Pesticide (Codex reference number)	CCN	Commodity		nded MRL g/kg	STMR or STMR-P	HR or HR-P mg/kg
			New	Previous	mg/kg	mg/kg
Chlorothalonil (081)**	FI 0327	Bananas	W	0.01* ^c		
ADI: 0-0.02 mg/kg bw	GC 0640	Barley	W	0.1		
ARfD: 0.6 mg/kg bw	AS 0640	Barley straw and fodder, dry	W	20		
	VD 0071	Beans (dry)	W	0.2		
Chlorothalonil metabolite R611965 (3-carbamyl-2,4,5-trichlorobenzoic acid) ADI: Covered by the parent compound.						
ARfD: Covered by the parent compound.						
	ED 0010	D : 1 d 116 :			CDC 2701 0.01	CDC 2701
4-Hydroxy-2,5,6- trichloroisophthalonitrile ^a	FB 0018	Berries and other small fruit (except grapes)			SDS-3701: 0.01	0.06
ADI: 0-0.008 mg/kg bw	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas			SDS-3701: 0.01	SDS-3701: 0.02
ARfD: 0.03 mg/kg bw	VB 0400	Broccoli	W	5		
Thus, olde mging on	VB 0402	Brussels sprouts	6	5	Chlorothalonil:	Chlorothalo
		-			1.5	nil: 2.8
3-amido-2,4,5- trichlorobenzoic acid b	VA 0035	Bulb vegetables			SDS-3701: 0.01	SDS-3701: 0.04
	VB 0041	Cabbages, Head	W	1		
	VR 0577	Carrots	W	1		
	VB 0404	Cauliflower	W	1		
	VX 0624	Celery	20	10	Chlorothalonil: 2.65	Chlorothalo nil: 7.5
	HH 0624	Celery leaves	W	3	2.00	
	GC 0080	Cereal grains			SDS-3701: 0.02	
	FS 0013	Cherries	W	0.5		
	VP 0526	Common beans (pods an/or immature seeds)	W	5		
	FB 0265	Cranberry	W	5		
	VC 0424	Cucumber	3	5	Chlorothalonil:	Chlorothalo
	FB 0021	Currants, Black, Red, White	20	5	0.41 Chlorothalonil:	nil: 1.3 Chlorothalo
	DF 0269	Dried grapes (= currants, Raisins and Sultanas)			20 ^d Chlorothalonil: 0.248	nil: 20 ^d Chlorothalo nil: 0.416
		,			SDS-3701:	SDS-3701:
	MO 0105	Edible offal (Mammalian)		0.2	0.0079 SDS-3701:0.16	0.19 SDS-3701: 0.18
	PE 0112	Eggs		0.05	SDS-3701: 0.031	SDS-3701: 0.04
	VB 0042	Flowerhead brassicas (includes Broccoli, Broccoli, Chinese and Cauliflower)	5		Chlorothalonil: 5 °	Chlorothalo nil: 5 °
	VC 0045	Fruiting vegetables, Cucurbits			SDS-3701: 0.015	SDS-3701: 0.06
	VO 0050	Fruiting vegetables, other than Cucurbits			SDS-3701: 0.015	SDS-3701: 0.06
	VC 0425	Gherkin	3		Chlorothalonil: 0.41	Chlorothalo nil: 1.3
	FB 0268	Gooseberry	20		Chlorothalonil:	Chlorothalo

Pesticide (Codex reference number)	CCN	Commodity		ended MRL g/kg	STMR-P	HR or HR-P
			New	Previous		mg/kg
	FB 0269	Grapes	3	0.5	20 d Chlorothalonil: 0.955 SDS-3701: 0.01	nil: 20 ^d Chlorothalo nil: 1.6 SDS-3701: 0.15
	JF 0269	Grape juice			Chlorothalonil: 0.134 SDS-3701: 0.0027	0.13
	AB 0269	Grape, pomace dry			Chlorothalonil: 0.745 SDS-3701: 0.031	
		Grape, pomace wet			Chlorothalonil: 1.24 SDS-3701: 0.012	
	HH 0092	Herbs			SDS-3701: 0.02	SDS-3701: 0.19
	VL 0053	Leafy vegetables			SDS-3701: 0.02	
	VA 0384	Leek	40		Chlorothalonil: 17.5	Chlorothalo nil: 22
	AL 0157	Legume animal feeds			SDS-3701: 0.03	
	VP 0060	Legume vegetables			SDS-3701: 0.01	SDS-3701: 0.02
	MF 0100	Mammalian fats (except milk fat)		0.07	SDS-3701: 0.025	SDS-3701: 0.05
	MM 0095	Meat (from mammals other than marine mammals)		0.02	SDS-3701:	SDS-3701: 0.012
	VC 0046	Melons, except Watermelon	2	2	Chlorothalonil: 0.04	Chlorothalo nil: 0.21
	ML 0106	Milks		0.07	SDS-3701: 0.05	
	SO 0088	Oilseed			SDS-3701: 0.02	
	VA 0385 VA 0386	Onion, Bulb Onion, Chinese	W 15	0.5	Chlorothalonil:	Chlorothalo
	VA 0387	Onion, Welsh	13		0.835	nil: 7.5
	FI 0350	Papaya	20		Chlorothalonil:	Chlorothalo
	FS 0247	Peach	W	0.2	2.3	nil: 6.4
	SO 0697	Peanut	0.1	0.05	Chlorothalonil:	
	VO 0440	Pepper, Chili (dry)	W	70	0.01	
	VO 0445	Pepper, sweet (including Pimento or pimiento)	W	7		
	VR 0589	Potato	W	0.2		
	PF 0111	Poultry fats		0.01	SDS-3701:	SDS-3701: 0.01
	PM 0110	Poultry meat		0.01	SDS-3701: 0.01	SDS-3701: 0.01
	PO 0113	Poultry skin		0.01	SDS-3701: 0.01	SDS-3701: 0.01
	PO 0111	Poultry, edible offal of		0.07	SDS-3701: 0.039	SDS-3701: 0.05
	VD 0070	Pulses	1		Chlorothalonil: 0.19 SDS-3701: 0.02	
	VR 0075	Root and tuber vegetables	0.3		Chlorothalonil: 0.3 d SDS-3701: 0.02	Chlorothalo nil: 0.3 ^d SDS-3701:

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR-P	HR or HR-P
			New	Previous	mg/kg	mg/kg
						0.03
		Root and tuber vegetables, tops and leaves			SDS-3701: 0.02	SDS-3701: 0.04
	VA 0389	Spring onion	15		Chlorothalonil: 0.835	Chlorothalo nil: 7.5
	VC 0431	Squash, Summer	3	5	Chlorothalonil: 0.41	Chlorothalo nil: 1.3
	VS 0078	Stalk and stem vegetables			SDS-3701: 0.01	SDS-3701: 0.02
	AS 0081	Straw and fodder (dry) of cereal grains			SDS-3701: 0.03	SDS-3701: 0.08
	FB 0275	Strawberry	5		Chlorothalonil: 2.05	Chlorothalo nil: 3
	VO 0447	Sweet Corn (corn-on-the-cob)	W	0.01*		
	VO 0448	Tomato	W	10		
	GC 0654	Wheat	W	0.1		
	AS 0654	Wheat, straw and fodder, dry	W	20		
		Wine			Chlorothalonil: 0.0096 SDS-3701: 0.019	
	VC 0433	Winter squash	W	5		

Definition of the residue (for compliance with MRL) for plant commodities: chlorothalonil

Definitions of the residue (for estimation of dietary intake) for plant commodities:

- chlorothalonil
- SDS-3701 (2,5,6-trichloro-4-hydroxyisophthalonitrile)

Definition of the residue (for compliance with MRL and for estimation of dietary intake) for animal commodities: SDS-3701 (2,5,6-trichloro-4-hydroxyisophthalonitrile)

 $The\ residue\ is\ not\ fat\text{-}soluble.$

^d Based on the maximum residue level

		·			
Clothianidin (238)*	FC 0001	Citrus fruits	0.07 (T)	0.02	0.02
ADI: 0–0.1 mg/kg bw	FP 0009	Pome fruits	0.4 (C,t)	0.10	0.20
ARfD: 0.6 mg/kg bw	FS 0012	Stone fruits	0.2 (cT)	0.04	0.12
	DF 0014	Prunes	0.2 (cT)	0.07	-
	FB 0018	Berries and other small fruits	0.07 (c,T)	0.01	0.05
		(except grapes)			
	FB 0269	Grapes	0.7 (C,t)	0.12	0.41
	DF 0269	Dried grapes (= currants,	1 (C,t)	0.31	1.066
		Raisins and Sultanas)			1.000
	JF 0269	Grape juice	0.2 (C,t)	0.18	-
	FI 0327	Banana	0.02 (C,t)	0.02	0.02
	FI 0350	Papaya	0.01* (T)	0	0
	FI 0353	Pineapple	0.01* (T)	0	0
	VB 0040	Brassica (cole or cabbage)	0.2 (T)	0.015	0.04
		vegetables, Head cabbages,			
		Flowerhead brassicas			
	VC 0045	Fruiting vegetables, Cucurbits	0.02* (T)	0.02	0.02
	VO 0050	Fruiting vegetables, other	0.05 (T)	0.02	0.03
		than cucurbits (except sweet			

^a Company Code SDS-3701

b 3-carbamyl-2,4,5-trichlorobenzoic acid (R611965) - ADI and ARfD considered unnecessary as covered by the parent compound

^c Based on bagged bananas

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg	STMR or STMR-P	HR or HR-P
			New Previous	mg/kg	mg/kg
		corn)			
	VO 0447	Sweet corn (corn-on-the-cob)	0.01*(C,T)	0.01	0.01
	HS 0444	Pepper Chilli, dried	0.5 (T)	0.2	0.3
	VL 0053	Leafy vegetables	2 (T)	0.52	0.80
	VP 0060	Legume vegetables	0.01*(T)	0.01	0.01
	VD 0070	Pulses	0.02 (T)	0.02	-
	VR 0075	Root and tuber vegetables	0.2 (C,T)	0.02	0.15
	VS 0078	Stalk and stem vegetables (except artichoke and celery)	0.04 (C)	0.01	0.025
	VS 0620	Artichoke, Globe	0.05 (T)	0.024	0.029
	VS 0624	Celery	0.04 (T)	0.01	0.02
	GC 0640	Barley	0.04 (cT)	0.01	-
	GC 0645	Maize	0.02 (cT)	0.02	_
	GC 0656	Popcorn	0.01 (c,T)	0.01	-
	GC 0649	Rice	0.5 (C)	0.145	
	GC 0651	Sorghum	0.01* (C)	0.01	_
	GC 0654	Wheat	0.02*(c,T)	0.02	_
	GS 0659	Sugar cane	0.4 (C)	0.03	0.14
	TN 0672	Pecan	0.01*(T)	0.01	0.01
	SO 0088	Oilseed	0.02*(c,T)	0.02	-
	SB 0715	Cacao beans	0.02*(T)	0.02	
	SB 0716	Coffee beans	0.05 (T)	0.02	_
	AL 0072	Pea hay or Pea fodder (dry)	0.2, dw (T)	0.013 0.05 dw	0.10 dw
	AS 0640	Barley straw and fodder, dry	0.2, dw	0.05 dw	0.10 dw 0.14 dw
	AS 0645	Maize fodder	(T,c) 0.01 * dw (T)	0.01 dw	0.01 dw
	AS 0651	Sorghum straw and fodder, dry	0.01* dw (C)	0.01 dw	0.01 dw
	AS 0654	Wheat straw and fodder, dry	0.2 dw	0.05 dw	0.14 dw
	115 000 .	who is a war and is a delight of y	(T,c)	0.00 4	011 . 4
	DT 1114	Tea, Green, Black (black, fermented and dried)	0.7 (T)	0.12	-
	MM 0095	Meat (from mammals other than marine mammals)	0.02* (C, t)	0.02	0.02
	MF 0100	Mammalian fats (except milk fats)	0.02* (C, t)	0.02	0.02
	MO 0105	Edible offal (Mammalian)(except liver)	0.02* (C, t)	0.02	0.02
	MO 0099	Liver of cattle, goats, pigs and sheep			
	ML 0106	Milks	0.02	0.002	-
	PM 0110	Poultry meat	0.01*	0.01	0.01
	PF 0111	Poultry fats	(C, t) 0.01* (C, t)	0.01	0.01
	PO 0111	Poultry, edible offal of	0.1 (T, c)	0.018	0.05
	PE 0112	Eggs	0.01* (C, t)	0.01	0.01

Definition of the residue for compliance with the MRL and for estimation of dietary intake for plant commodities: sum of clothianidin and its Z-isomers.

Definition of the residue for compliance with the MRL and for estimation of dietary intake for animal commodities: sum of clothianidin and its Z-isomers.

The residue is not fat-soluble.

Pesticide (Codex reference number)	CCN	Commodity		nded MRL g/kg	STMR or STMR-P	HR or HR-P
			New	Previous	mg/kg	mg/kg
Cyproconazole (239)*	VD 0071	Beans (dry)	0.02*	,	0.02	0.02
ADI: 0–0.02 mg/kg bw	GC 0080	Cereal grains (except maize, rice and sorghum)	0.08		0.02	0.07
ARfD: 0.06 mg/kg bw	MO 0105	Edible offal (Mammalian)	0.5		0.14	0.46
	PE 0112	Eggs	0.01*		0.01	0.01
	GC 0645	Maize	0.01*		0.01	0.01
	AS 0645	Maize fodder	2		0.28	1.5
	MM 0095	Meat (from mammals other than marine mammals)	0.02 (fat)		0.003 muscle 0.003 fat	0.003 muscle
						0.02 fat
	ML 0106	Milks	0.01		0.009	
	VD 0072	Peas (dry)	0.02*		0.02	0.02
	VP 0064	Peas, shelled (succulent seed)	0.01		0.01	0.01
	PO 0111	Poultry, edible offal of	0.01*		0	0.01
	PM 0110	Poultry meat	0.01*		0.01 muscle 0.01 fat	0.01 muscle 0.01 fat
	SO 0495	Rape seed	0.4		0.065	0.23
	OR 0495	Rape seed oil, edible			0.0052	
	VD 0541	Soya bean (dry)	0.07		0.02	0.05
	AL 0541	Soya bean fodder	3		0.66	1.9
	OR 0541	Soya bean oil, refined	0.1		0.036	
	AB 1265	Soya bean meal			0.013	
	AS 0081	Straw and fodder (dry) of cereal grains (except maize, rice and sorghum)	5		0.785	3.6
	VR 0596	Sugar beet	0.05		0.02	0.04

Definition of the residue for compliance with the MRL and for estimation of dietary intake for plant commodities: Cyproconazole.

Definition of the residue for compliance with the MRL for animal commodities: Cyproconazole

Definition of the residue for estimation of dietary intake for animal commodities except milk: Cyproconazole.

Definition of the residue for estimation of dietary intake of milk: sum of cyproconazole and metabolites M21 ((5-(4-chlorophenyl)-5-hydroxy-4-methyl-6-[1,2,4]triazol-1-yl-hex-2-enoic acid) and M36 (δ-(4-chlorophenyl)- β ,δ-dihydroxy- γ -methyl-1H-1,2,4-triazole-1-hexenoic acid) expressed as cyproconazole..

The residue is fat-soluble.

Dicamba (240)*	VS 0621	Asparagus	5	0.87	3.3
ADI: 0-0.3 mg/kg bw	GC 0640	Barley	7	1.7	
				1.6 ^a	
ARfD: 0.5 mg/kg bw	AS 0640	Barley straw and fodder, dry	50	3.65 ^a	30 a
	SO 0691	Cotton seed	0.04 *	0.04	
	OR 0691	Cottonseed oil, edible		0.008	
	AS 0162	Hay or fodder (dry) of grasses	30	6.3 ^a	19 ^a
	MO 0105	Edible offal (Mammalian)	0.7	0.160	0.331
				kidney	kidney
				0.028	0.082
				Liver	Liver
	GC 0645	Maize	0.01 *	0.02	
				0.01 ^a	
	AS 0645	Maize fodder	0.6	0.06 a	0.33 a
	OC 0645	Maize oil, crude		0.00058	
	MF 0100	Mammalian fats (except milk fats)	0.07	0.023	0.036

Pesticide (Codex reference number)	CCN	Commodity		nded MRL g/kg	STMR or STMR-P	HR or HR-P
			New	Previous	mg/kg	mg/kg
	MM0095	Meat (from mammals other than marine mammals)	0.03		0.01	0.02
	ML 0106	Milks	0.2		0.021	
	PF 0111	Poultry fats	0.04		0.01	0.01
	PM 0110	Poultry meat	0.02		0.01	0.012
	PO 0111	Poultry, edible offal of	0.07		0.01 Liver	0.044 Liver
	PE 0112	Eggs	0.01 *		0.01	0.01
	GC 0651	Sorghum	4		2.0	
					1.0 a	
	AS 0651	Sorghum straw and fodder, dry	8		1.3 ^a	5.4 ^a
	GS 0659	Sugar cane	1		0.095	1.1
	DM 0659	Sugar cane molasses			3.4	
					4.0 a	
		White sugar			0.05	
	VO 1275	Sweet corn (kernels)	0.02		0.04	0.04
	GC 0654	Wheat	2		0.26	
					0.22 a	
	CF 0654	Wheat bran, processed			0.26	
	CF 1211	Wheat flour			0.02	
	AS 0654	Wheat straw and fodder, dry	50		3.8 ^a	30 ^a

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

highest residue and median residue for the estimation of animal dietary burden expressed on a dry weight basis (residues of dicamba only)

Difenoconazole (224)	AB 0660	Almond hulls		1.24	3.22
ADI: 0-0.01 mg/kg bw	VP 0060	Legume vegetables	0.7	0.07	0.5
ARfD: 0.3 mg/kg bw	MO 0105	Edible offal (Mammalian)	0.2	0.041	0.12
	VR 0604	Ginseng	0.5	0.02	0.36
	MM 0095	Meat (from mammals other than marine mammals)	0.05 (fat) ^a	0.01 muscle 0.012 fat	0.021 muscle 0.031 fat
	ML 0106	Milks	0.005* a	0.001	
	FI 0350	Papaya	0.3^{b}	0.065	0.13
	FI 0351	Passion fruit	0.05	0.01	0.04
	TN 0085	Tree nuts	0.03	0.01	0.02

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 diffenoconazole and 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethano), expressed as diffenoconazole.

The residue is fat-soluble

^a The maximum residue limit recommended by the 2007 JMPR remained the same.

^b The recommendation is based on reported use conditions provided appropriate protection of the crop, but it is not supported by official information on use

Pesticide (Codex reference number)	CCN	Commodity		nded MRL /kg	STMR or STMR-P	HR or HR-P
			New	Previous	mg/kg	mg/kg
Dithianon (180) ** ADI: 0–0.01 mg/kg bw ARfD: 0.1 mg/kg bw						
Endosulfan (032)	DT 1114	Tea, Green, Black (black, fermented and dried)	10	W	4.1	
ADI: 0–0.006 mg/kg bw ARfD: 0.08 mg/kg bw		,				
Definition of the residue (for sum of alpha endosulfan, beta The residue is fat soluble.	-	ith the MRL and for estimation of and endosulfan sulfate.	the dietary in	take) for plo	ant commo	dities:
Etoxazole (241)*	AM 0660	Almond hulls	3		0.23	
ADI: 0–0.05 mg/kg bw	FC 0001	Citrus fruits	0.1		0.23	
	JF 0001	Citrus juice	0.1		0.005	
ARfD: Unnecessary	VC 0424	Cucumber	0.02			
					0.01	
	FB 0269	Grapes	0.5		0.04	
	DF 0269 JF 0269	Dried grapes (= currants, Raisins and Sultanas)			0.044	
		Grape juice	0.01*			
	MO 0105	Edible offal (mammalian)	0.01*		0	
	DH 1100	Hops, dry	15		4.2	
	MM 0095	Meat (from mammals other than marine mammals)	0.01* (fat) 0.01*		0	
	ML 0106	Milks			0	
	HH 0738	Mints	15		4.9	
	DT 1114	Mint oil Tea, Green, Black (black,	15		7.8 4.75	
	TN 0085	fermented and dried) Tree nuts	0.01*		0	
Definition of the residue (for commodities: etoxazole The residue is fat soluble	compliance wi	th the MRL and for estimation of	the dietary in	take) for plan	et and animal	
Fenpyroximate (193)	FP 0226	Apple	W a	0.3		
ADI: 0–0.01 mg/kg bw	FC 0001	Citrus fruits	0.5		0.034	0.067
ARfD: 0.02 mg/kg bw	VC 0424	Cucumber	0.03		0.01	0.02
	DF 0269	Dried grapes	0.3		0.06	0.14
	FB 0269	Grapes	0.1	1	0.02	0.05
	VO 0050	Fruiting vegetables, other than Cucurbits (except sweet corn and mushrooms)	0.1	1	0.02	0.14
	VC 0046	Melons, except Watermelon	0.05		0.05	0.05
	EC 0004		\mathbf{W}^{a}	0.2		
	FC 0004	Oranges, Sweet, Sour (including Orange-	VV	0.2		

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P	HR or HR-P
			New	Previous	mg/kg	mg/kg
		like hybrids): several cultivars				
	HS 0444	Peppers, chili (dried)	1		0.37	0.9
	FP 0009	Pome fruits	0.3		0.09	0.16
	TN 0085	Tree nuts	0.05 *		0.05 *	0.05 *

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

^a Replaced by commodity group maximum residue level recommendation

				.	
Flubendiamide (242)*	AB 0660	Almond hulls	10	2.45	
ADI: 0-0.02 mg/kg bw	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	4	0.365	2.7
ARfD: 0.2 mg/kg bw	VS 0624	Celery	5	1.7	2.6
	SO 0691	Cotton seed	1.5	0.15	
	VC 0045	Fruiting vegetables, Cucurbits	0.2	0.045	0.09
	MO 0105	Edible offal (Mammalian)	1	0.32	0.57
	FB 0269	Grapes	2	0.42	0.81
	GC 0645	Maize	0.02	0.01	
	CF 1255	Maize flour		0.021	
	VP 0060	Legume vegetables	2	0.43	0.90
	VL 0482	Lettuce, Head	5	0.875	2.2
	VL 0483	Lettuce, leaf	7	1.7	4.0
	MM 0095	Meat (from mammals other than marine mammals) (fat)	2 (fat)	0.06 muscle 0.62 fat	0.13 muscl 1.2 fat
	ML 0106	Milks	0.1	0.066	
	FM 0183	Milk fats	5	1.6	4.0
	AL 0072	Pea hay	40	13.5	26
	VO 0051	Peppers	0.7	0.09	0.37
	HS 0444	Peppers, Chili (dried)	7	0.9	
	FP 0009	Pome fruits	0.8	0.25	0.59
	VD 0070	Pulses	1	0.18	
	AL 0541	Soya bean fodder	60	27.5	41
	FS 0012	Stone fruits	2	0.585	1.0
	VO 0447	Sweet corn (corn-on-the-cob	0.02	0.01	0.01
	DT 1114	Tea, Green, Black (black, fermented and dried)	50	23	29
	VO 0448	Tomato	2	0.35	0.63
	TN 0085	Tree Nuts	0.1	0.015	0.05

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

The residue is fat soluble

Fludioxonil (211)	FC 0001	Citrus fruits	10 Po	7 Po	0.41
ADI: 0-0.4 mg/kg bw	FI 0355	Pomegranate	2 Po		1.0
ARfD: Unnecessary	VR 0508	Sweet potato	10 Po		3.5
	VR 0600	Yams	10 Po		3.5

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

Pesticide (Codex reference	CCN	Commodity	Recommended MRL		STMR or	HR or
number)			mg/kg		STMR-P	HR-P
			New	Previous	mg/kg	mg/kg

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for animal commodities: fludioxonil and metabolites determined as 2,2-difluoro-1,3-benzodioxole-4-carboxylic acid and calculated as fludioxonil.

The residue is fat-soluble.

					
Fluopyram (243)*	VC 0424	Cucumber	0.5	0.19	0.11
ADI: 0-0.01 mg/kg bw	FB 0269	Grapes	2	1	0.58
ARfD: 0.5 mg/kg bw	DF 0269	Dried grapes (=	5		
		currants, Raisins and		2.9	1.68
		Sultanas)			
	MO 0105	Edible offal (mammalian)	0.7	0.574 (liver)	0.472
				0.059 (kidney)	(liver) 0.051
				(Kidney)	(kidney)
	MM 0095	Meat (from mammals other	0.1	0.054 muscle	0.043
		than marine mammals)		0.076 fat	(muscle)
					0.061 (fat)
	ML 0106	Milks	0.07		0.039
	AB 0269	Grape pomace, dry			12.4
		Wine			0.1
	JF 0269	Grape juice			0.012

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

Definition of the residue (for compliance with the MRL) for animal commodities: Sum of fluopyram and 2-(trifluoromethyl)benzamide, expressed as fluopyram.

Definition of the residue (for estimation of dietary intake) for animal commodities: Sum of fluopyram, 2-(trifluoromethyl)benzamide and the combined residues of the E-olefine and Z-olefine isomers of fluopyram, all expressed as fluopyram.

Although fluopyram (parent compound) is fat soluble, the 2-(trifluoromethyl)benzamide metabolite (the major component of the residue) is not fat soluble.

Meptyldinocap (244)*	VC 0431	Squash, Summer	0.07^{a}	0.02
ADI: 0-0. 0.02mg/kg bw	VC 0424	Cucumbers	0.07 ^a	0.02
ARfD: Unnecessary	VC 0046	Melons, except Watermelon	0.5 ^a	0.005
	FB 0269	Grapes	0.2 ^a	0.025
	JF 0269	Grape juice		0.002
		Wine		0.00072
	FB 0275	Strawberry	0.3 ^b	0.085
		Strawberry jam		0.024
		Strawberry preserve		0.024

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant commodities: the sum of meptyldinocap, and the corresponding phenol 2, 4-DNOP, expressed as parent meptyldinocap.

^a The maximum residue level accommodates the residues derived from the use of dinocap on fruiting vegetables, cucumbers. The Meeting recommended to reevaluate the current CXL of 0.05*.

^b The current dinocap Codex MRL of 0.5 mg/kg covers the use of meptyldinocap.

Pesticide (Codex reference number)	CCN	Commodity		nded MRL g/kg	STMR or STMR-P	HR or HR-P
			New	Previous	mg/kg	mg/kg
Novaluron (217)	VD 0071	Beans (dry)	0.1		0.05	
ADI: 0-0.01 mg/kg bw	FB 0020	Blueberries	7		2.1	
ARfD: Unnecessary	VB 0400	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassica	0.7		0.105	
	VP 0526	Common bean (pods and/or immature seeds)	0.7		0.165	
	MO 0105	Edible offal (Mammalian)	0.7	0.7	0.13	
	PE 0112	Eggs	0.1	0.01*	0.029	
	VC 0045	Fruiting vegetables, Cucurbits	0.2		0.05	
	VO 0050	Fruiting vegetables, other than Cucurbits (except sweet corn)	0.7		0.1	
	MM 0095	Meat (from mammals other than marine mammals)	10 (fat)	10 (fat)	0.08 muscle 1.7 fat	
	ML 0106	Milks	0.4	0.4	0.13	
	FM 0183	Milk fats	7	7	2.6 cream	
	VL 0485	Mustard greens	25		3.6	
	PM 0110	Poultry meat	0.5 (fat)	0.01* (fat)	$\begin{array}{c} 0.005 \text{ muscle} \\ 0.13 \text{ fat} \end{array}$	
	PO 0111	Poultry, edible offal of	0.1	, ,	0.015	
	DF 0014	Prunes	3		1.27	
	FS 0012	Stone fruits	7		2.2	
	FB 0275	Strawberry	0.5		0.15	
	GS 0659	Sugar cane	0.5		0.08	
	VL 0464	Chard	15		4.0	
	VO 0448	Tomato	\mathbf{W}^{a}	0.02 *		
		Tomato puree			0.073	
	VW 0448	Tomato paste			0.11	

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

The residue is fat-soluble.

Tebuconazole (189)**

ADI: 0-0.03 mg/kg bw 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: tebuconazole

Thiamethoxam (245)*	VS 0620	Artichoke, Globe	0.5	0.23	0.24
ADI: 0-0.08 mg/kg bw	FI 0327	Banana	0.02*	0.02	0.02
ARfD: 1 mg/kg bw	GC 0640	Barley	0.4	0.12	
	AS 0640	Barley straw and fodder, dry	2	0.39	1.7
	FB 0018	Berries and other small fruits	0.5	0.055	0.26
	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	5	0.53	1.1
	SB 0715	Cacao beans	0.02	0.02	
	VS 0624	Celery	1	0.21	0.43
	FC 0001	Citrus fruits	0.5	0.028	0.104

^a Replaced by commodity group MRL.

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg	STMR or STMR-P	HR or HR-P
			New Previous	mg/kg	mg/kg
	SB 0716	Coffee beans	0.2	0.035	
	MO 0105	Edible offal (Mammalian)	0.01*	0.01	0.01
	PE 0112	Eggs	0.01*	0.01	0.01
	VC 0045	Fruiting vegetables, Cucurbits	0.5	0.105	0.29
	VO 0050	Fruiting vegetables, other than Cucurbits (except sweet corn)	0.7	0.08	0.47
	VL 0053	Leafy vegetables	3	0.54	1.9
	VP 0060	Legume vegetables	0.01*	0.01	0.01
	GC 0645	Maize	0.05	0.02	
	AS 0645	Maize fodder	0.05	0.01	0.04
	MM 0095	Meat (from mammals other than marine mammals)	0.02	0.01 muscle 0.01 fat	0.01 muscle 0.01 fat
	ML 0106	Milks	0.05	0.006	
	SO 0088	Oilseed	0.02	0.02	
	FI 0350	Papaya	0.01*	0	0
	AL 0072	Pea hay or Pea fodder (dry)	0.3	0.05	0.24
	TN 0672	Pecan	0.01	0.01	0.01
	HS 0444	Peppers Chili, dried	7	0.8	4.7
	FI 0353	Pineapple	0.01*	0	0
	FP 0009	Pome fruits	0.3	0.07	0.15
	GC 0656	Popcorn	0.01	0.01	
	PM 0110	Poultry meat	0.01*	0.01	0.01
	PO 0111	Poultry, Edible offal of	0.01*	0.016	0.042
	VD 0070	Pulses	0.04	0.02	
	VR 0075	Root and tuber vegetables	0.3	0.01	0.20
	FS 0012	Stone fruits	1	0.195	0.60
	VO 0447	Sweet corn (corn-on-the-cob)	0.01	0.01	0.01
	DT 1114	Tea, Green, Black (black, fermented and dried)	20	4.1	
	GC 0654	Wheat	0.05	0.02	
	AS 0654	Wheat straw and fodder, dry	2	0.39	1.7
		Apple juice		0.065	
		Barley flour		0.010	
		Barley, pearled		0.030	
		Coffee, roasted		0.0049	
		Cotton seed oil, Refined		0.0004	
		Orange juice		0.031	
		Prunes, dried		0.16	0.50
	TT 66.45	Semolina		0.014	
	JF 0048	Tomato juice		0.054	
	VW 0448	Tomato paste		0.24	
		Tomato pulp		0.08	
		Wheat bran		0.020	
		Wheat bread		0.014	
		Wheat flour		0.014	
		Wine		0.055	

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

Definition of the residue (for the estimation of dietary intake) for plant and animal commodities (except poultry): thiamethoxam and CGA 322704 (CGA 322704 to be included with clothianidin and considered separately from thiamethoxam

Definition of the residue (for the estimation of dietary intake) for poultry: sum of thiamethoxam, CGA 322704 and MU3 and

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P	HR or HR-P
			New	Previous	mg/kg	mg/kg
See also clothianidin The residue is not fat-soluble	e.					
Triazophos (143)	CM 0649	Rice, husked	2		0.421	1.19
ADI: 0–0.001 mg/kg bw ARfD: 0.001 mg/kg bw	VP 0541	Soya beans, immature seed	0.5		0.07	0.15

Definition of the residue for compliance with the MRL for all commodities and for estimation of dietary intake for plant and animal commodities: triazaphos

The residue is not fat-soluble.

Recommended MRLs, STMRs and HR values for Spices

				ended MRL g/kg	Median residue	HR mg/kg
Codex Number	Commodity	Pesticide	New	Previous	mg/kg	
028B	Fruit or berry	•	0.8		0.1	0.78
		Carbendazim	0.1		0.1	0.1
		Cypermethrin	0.5	0.2	0.05	0.43
		Aldicarb	0.07		0.07	0.07
		Bifenthrin	0.03		0.03	0.03
		Carbosulfan	0.07		0.07	0.07
		Cyfluthrin	0.03		0.03	0.03
		Cyhalothrin	0.03		0.03	0.03
		Deltamethrin	0.03		0.03	0.03
		Fenvalerate	0.03		0.03	0.03
		Methidathion	0.02		0.02	0.02
		Methiocarb	0.07		0.07	0.07
		Methomyl	0.07		0.07	0.07
		Omethoate	0.02		0.02	0.02
		Oxamyl	0.07		0.07	0.07
		Profenofos	0.07		0.07	0.07
		Triazophos	0.07		0.07	0.07
0.28D	Root and	Deltamethrin	0.5		0.05	0.33
	rhizome					
		Aldicarb	0.02		0.02	0.02
		Bifenthrin	0.05		0.05	0.05
		Captan	0.05		0.05	0.05
		Carbaryl	0.1		0.1	0.1
		Carbendazim	0.1		0.1	0.1
		Carbosulfan	0.1		0.1	0.1
		Cyfluthrin	0.05		0.05	0.05
		Cyhalothrin	0.05		0.05	0.05
		Fenvalerate	0.05		0.05	0.05
		Methidathion	0.05		0.05	0.05
		Methiocarb	0.1		0.1	0.1
		Omethoate	0.05		0.05	0.05
		Oxamyl	0.05		0.05	0.05
		Profenofos	0.05		0.05	0.05
		Triazophos	0.1		0.1	0.1
		*				

Edited versions of these general considerations will be published in the report of the 2010 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)

Background

At the fourty-second session of CCPR, concern was raised by the EU, France and Croplife international regarding the ARfD for bifenthrin established by the JMPR in 2009. A concern form was submitted to the JMPR Secretariat by Kenya on 15th September 2010.

Comments by JMPR:

The concern form was submitted long after the deadline established by CCPR, and only a few days before the start of the JMPR meeting. Nevertheless, JMPR considered the concern and the points raised. However, the information provided in the concern form was very limited and the short time available did not allow a thorough consideration of the concerns raised. The Meeting therefore decided to defer this item to the next meeting.

1.2 cypermethrin(s) (118)

Background

On the request of CCPR 42 (ALINORM 10/33/24, para 43-44), the EU submitted a concern form to the present Meeting. The concern form stated that using the CXL MRLs on plant and animal commodities as inputs in the EFSA PRIMo rev. 2A, a chronic dietary intake concern was identified with up to 176 % of the ADI (NL child) as well as acute intake concerns with regards to the following crops: citrus (Oranges: 479% ARfD-VF=5; Grapefruit: 446% ARfD-VF=5; Mandarins: 209% ARfD-VF=5; Lemons: 127% ARfD-VF=5), scarole (broad-leaf endive) (153% ARfD-VF=5)-covered by leafy vegetables, apples (126% ARfD-VF=5), pears (114% ARfD-VF=5)-covered by pome fruits, apricots (123% ARfD-VF=5), plums (133% ARfD-VF=5), peaches (217% ARfD-VF=5)-covered by stone fruits, cauliflower (165% ARfD-VF=5) and broccoli (104% ARfD-VF=5)-covered by brassica vegetables.

The EU requested revocation of these CXL MRLs.

Evaluation of cypermethrin(s) by the JMPR and CCPR

Cypermethrin, alpha-cypermethrin and zeta-cypermethrin (pyrethroid compounds), are nonsystemic broad spectrum insecticides acting by ingestion and contact. Cypermethrin was first evaluated by the 1979 JMPR and a number of times subsequently. It was reviewed for toxicology by the 2006 JMPR within the periodic review programme of the CCPR; the review included alphacypermethrin and zeta-cypermethrin, which had not previously been considered by the JMPR. A group ADI of 0-0.02 mg/kg bw and a group ARfD of 0.04 mg/kg bw was established for cypermethrins (including alpha- and zeta-cypermethrin). The periodic review for residues was scheduled for 2008. Three manufacturers submitted residue data to JMPR on cypermethrins (including alpha and zeta cypermethrin) for consideration by the 2008 JMPR. The 2008 Meeting agreed that metabolism studies, environmental fate studies, methods of analysis and freezer storage stability studies of the cypermethrins were mutually supportive and should be considered together. Separate monographs were prepared for each of the three compounds, but they were considered together in a single appraisal. Definition of the residue (for plants and animals; for compliance with the MRL and for estimation of dietary intake): cypermethrin (sum of isomers). The residue is fat soluble. The 2008 Meeting estimated a large number of maximum residue levels. In 2009, an additional evaluation was performed on the use of cypermethrin as grain protectant.

The 41th session of CCPR in 2009 decided to advance the draft MRLs for all commodities (as proposed by 2009 JMPR) except asparagus for adoption at Step 5/8, noting the EU and Norway reservations on the MRLs for cauliflower; scarole (broad-leaf); apple (covered by pome fruits) and peach (covered by stone fruits) because of their acute intake concerns (ALINORM 09/32/24, para 90-94). Later in 2009, the CAC adopted all draft MRLs at step 5/8 as CXLs.

The 42th session of CCPR invited the EU to submit a concern form clearly outlining their acute intake concerns. (ALINORM 10/33/24, para 43-44).

Comments by JMPR

The Meeting noted that for the long-term intake, it is unrealistic to assume that person will for his whole lifetime consume commodities with on all of them the pesticide present at the level of the CXL. Using the STMRs in the IEDI calculation revealed no exceedance of the ADI.

In addition the Meeting noted that also for the short-term dietary intake calculations the CXL values were used, not the HR values for the edible portion. For example, the intake of the residue from citrus fruits is largely overestimated when the calculation is based on the residue in whole fruit. In addition, a variability factor of 5 was used where JMPR employs a variability factor of 3.

Based on the above, the present Meeting confirmed that the short-term dietary intake of cypermethrin(s) from its use on citrus, scarole, apples, pears, apricots, plums, peaches, cauliflower and broccoli, as based on the results presented by the 2009 Meeting, is unlikely to present a public health concern.

1.3 Fluopicolide

Background

At the Forty-second Session of the CCPR, the Delegation of Switzerland raised concerns regarding the ARfD for fluopicolide that had been established by the JMPR in 2009. The JMPR is requested to reconsider the derivation of the ARfD for fluopicolide.

Evaluation of fluopicolide by the JMPR

Fluopicolide was reviewed for the first time by the JMPR in 2009 at the request of the CCPR. The JMPR established an ARfD for fluopicolide of 0.6 mg/kg bw for women of child-bearing age on the basis of a NOAEL of 60 mg/kg bw per day to which a safety factor of 100 was applied. This NOAEL was identified based on a marginally increased incidence of skeletal defects of the vertebrae and sternebrae, which might be attributable to a single exposure to fluopicolide at 700 mg/kg bw per day in a study of developmental toxicity in rats.

The Meeting concluded that the establishment of an ARfD for the general population was not necessary for fluopicolide on the basis of its low acute toxicity, the lack of evidence for any acute neurotoxicity and the absence of any other toxicologically relevant effect that might be attributable to a single dose.

Concern submitted by Switzerland

The JMPR was requested to reconsider the rabbit developmental studies as an alternative basis for the derivation of the ARfD for fluopicolide:

In the rabbit range-finding (4 animals per group) and the definitive developmental toxicity study (23 animals per group), 60 mg/kg bw per day, the level of the rat maternal and fetal NOAEL, proved to be lethal for 3/23 dams within three weeks of treatment and for 3/4 dams at 100 mg/kg bw per day (and 4/4 dams at higher doses). Additionally, 15/23 dams aborted at 60 mg/kg bw per day, one dam at the next lower dose level of 20 mg/kg bw per day, and none at 5 mg/kg bw per day and in the control group, respectively. The high incidence of abortions at 60 mg/kg bw per day are treatment-related and the abortion seen in one dam at a dose level only three fold lower should not be ignored as this might also be treatment related. Mortality

and abortions could be seen as either an acute effect or as the final severe manifestation of not yet evident effects accumulating in the study period before.

In view of the severe effects at 60 mg/kg bw per day, possibly being an acute effect or a final manifestation of sub-clinical effects accumulating in the study period before, the identification of the relevant NOAEL as the basis for an ARfD should be reconsidered as well as the relevance of these effects for the general population.

It is proposed by Switzerland to use 20 mg/kg bw per day as the basis for an ARfD and to apply a safety factor of 200.

Comments by the JMPR

After consideration of the concerns from Switzerland and after reviewing the conclusions of the 2009 JMPR, which included a reassessment of the original report from the rabbit range-finding study and the main developmental study in rabbits, the present Meeting highlighted the following points:

- In the rabbit range-finding study (four animals per group), dosing was on days 6–28 of gestation. All rabbits from the 100, 250, 500 and 1000 mg/kg bw per day dose groups were found dead, killed while in a moribund condition or killed after abortion from day 13 to day 23 of the study. The dose of 100 mg/kg bw per day was lethal after at least 10 days of dosing for four of four dams (days 16, 20, 22, 22). Nonspecific symptoms, including impaired motility and consciousness, respiratory sounds, decreased defecation and hay consumption, hyperactivity, hypoactivity and discoloured urine, were observed from day 13 to day 23 of the study. At 50 mg/kg bw per day, one of four dams showed decreased defecation and discoloured tray and aborted on day 29. Therefore, it was killed on day 29. The other animals at this dose did not show any clinical signs. The dose of 50 mg/kg bw per day was considered to be a suitable high dose for the main study.
- In the main study, dosing was on days 6–28 of gestation (0, 5, 20 and 60 mg/kg bw per day). At 60 mg/kg bw per day, 15 of 23 dams aborted from days 22 to 29; 1 dam at the next lower dose level of 20 mg/kg bw per day was killed after premature delivery on day 28.
- The high incidence of abortions at 60 mg/kg bw per day was treatment related, and the abortion seen in one dam at a dose level only 3-fold lower might also be treatment related. However, mortality and abortions cannot be seen as an acute effect. The affected animals showed decreased defecation, reduced hay consumption, hypoactivity, bristling coat, pultaceous faeces and discoloured urine between days 22 and 29. This is considered as a manifestation of subchronic effects. The mean food consumption in the 60 mg/kg bw per day

group, expressed as a percentage of food consumption per unit body weight before treatment, was statistically significantly decreased between days 23–26 and days 26–29 and not immediately after treatment began on day 6 of gestation. This decrease was only slight in the first week but prominent thereafter. With an obvious delay, the body weights in the 60 mg/kg bw per day group were also lower between days 26 and 29. No teratogenic effects were observed in the fetuses.

 Because the severe effects at 60 mg/kg bw per day occurred in the latter part of the treatment period, they are considered a manifestation of the subchronic effects of the prior dosing period. The NOAEL for these findings is not a relevant basis for an ARfD.

In conclusion, the JMPR does not agree with the proposal to use the effects observed in the developmental study in the rabbit at 20 mg/kg bw per day as the basis for an ARfD. The Meeting reaffirmed the ARfD for fluopicolide of 0.6 mg/kg bw for women of child-bearing age based on a NOAEL of 60 mg/kg bw per day.

1.4 Paraquat

Background

On the request of CCPR 42 (ALINORM 10/33/24, para 33-34), the EU submitted a concern form to the present Meeting. The concern form stated that using EU endpoints (ARfD 0.005 mg/kg bw/day) and risk assessment methodologies (PRIMo rev2), for children dried beans are 150% and potatoes are 154% of the ARfD, using HR values of 0.41mg/kg (39 trials) and 0.05mg/kg (25 trials) for pulses and root and tuber vegetables respectively. It was acknowledged that a higher ARfD of 0.006 mg/kg bw/day is accepted by JMPR, but indicated that EU risk assessment methodologies using these endpoints still indicate 125% and 128% of the ARfD using the JMPR HRs.

Evaluation of paraquat by the JMPR and CCPR

Paraquat, a non-selective contact herbicide, is usually available as the dichloride salt or the bis(methylsulfate) salt but is determined as paraquat ion in analysis. It can be used for pre-plant and pre-emergence weed control, resulting in little or no residues in the harvested crop, but also for post-emergence weed control and as a harvest aid desiccant. When used for pre-plant and pre-emergence weed control, paraquat is not sprayed directly onto crops and is strongly adsorbed to soil.

Paraquat was first evaluated by the JMPR for toxicology and residues in 1970. The Meeting reviewed paraquat toxicologically within the Periodic Review Programme in 2003 and established an ADI of 0–0.005 mg/kg bw and an ARfD of 0.006 mg/kg bw as paraquat cation. The 2004 JMPR evaluated paraquat for residues under the Periodic Review Programme and concluded that the definition of residue for compliance with MRLs and for estimation of dietary intake was paraquat cation. Maximum residue levels were recommended for several fruits, several vegetables, maize,

sorghum, cotton-seed, sunflower, hops, tea and animal commodities. In addition, the 2009 JMPR estimated a maximum residue level for rice.

The 37th session of CCPR in 2005 decided to advance all MRLs as proposed by JMPR 2004 to Step 5. The Committee decided to consider for withdrawal at its next Session all existing CXLs (ALINORM 05/28/24, para 99-100).

The 38th session of CCPR in 2006 decided to revoke most existing CXLs as recommended by the 2004 JMPR (except the CXL for rice, because new data would become available). The Committee decided to advance all draft MRLs except those for animal forage to Step 8 (ALINORM 06/29/24, para 67-68). Later in 2006, the CAC adopted all draft MRLs at step 8 as CXLs.

The 42d session of CCPR in 2010, when considering a new draft MRL on rice as proposed by the 2009 JMPR noted the acute dietary intake concern of the EU for pulses and potatoes, and invited the EU to submit a concern form clearly outlining their concern (ALINORM 10/33/24, para 33-34).

Comments by JMPR

The Meeting noted that the current CXLs are generally in the range of 0.01* - 0.05 mg/kg, except for animal feed commodities and oil seeds. However, a CXL for pulses (VD 0070) of 0.5 mg/kg is in place. For Root and tuber vegetables (VR 0075; includes potatoes) the CXL is 0.05 mg/kg. Currently, all EU MRLs are set at the LOQ (either 0.02 mg/kg or 0.05 mg/kg).

JMPR 2004 reported that the levels of residues arising from harvest desiccant uses of paraquat on legume vegetables and pulses were higher than those from pre-emergence or post-emergence application. The 2004 Meeting combined the results of trials on field peas and chick peas in Australia and on soya beans in Brazil and the USA in which paraquat was used as a harvest aid desiccant to estimate a group maximum residue level for pulses. The combined residue levels in seeds were, in ranked order: < 0.01 (two), < 0.02, 0.02 (four), 0.03 (four), 0.04 (two), < 0.05 (two), 0.05 (two), 0.06, 0.07 (two), 0.08 (three), 0.09 (two), 0.10, 0.11 (two), 0.12, 0.13 (two), 0.15, 0.16 (two), 0.23, 0.25, 0.28 (three), 0.31 and 0.41 mg/kg.

The present Meeting noted, that the EU dietary intake calculations for beans employed the IESTI equation case 1 (based on HR, no variability factor). JMPR 2004 employed case 3, which is based on the STMR value (also no variability factor). Case 3 is for those processed commodities where bulking or blending means that the STMR-P represents the likely highest residue level. The case 1 equation only applies to pulse commodities when the estimates are based on post-harvest use of the pesticide. The Meeting noted, that harvest desiccant use can not be considered as a post-harvest use. A post-harvest use is defined as a use where crops from different farms are put together and treated at the same time, resulting in a lot containing the same residue and marketed to the same location. In a pre-harvest use crops from different farms are put together, thereby averaging out a possible high residue on the lot coming from one of the farms.

The use patterns of paraquat on root and tuber vegetables as considered by the 2004 JMPR concerned pre-plant, pre-emergence treatments in Japan and the USA. Since paraquat binds strongly to soil, limited uptake by the roots and tubers is expected. This is in line with the residue levels in potato trials of pre- and post-emergence application: < 0.01 (eight) and 0.02 mg/kg. The Meeting noted that the combined results from trials on beetroot, sugar-beet, carrot, turnip and potato on which the 2004 JMPR recommendations were based were, in ranked order: < 0.01 (12), 0.02, < 0.03 (four), 0.03 (two) and < 0.05 (six) mg/kg. The HR for the group of Root and tuber vegetables (including potatoes) is therefore based on the highest LOQ of 0.05 mg/kg as reported for 6 trials on sugar-beet root. The actual HR for potatoes is probably lower, as the highest residue found in potato trials was 0.02 mg/kg. Furthermore, the dietary risk assessments performed so far are based on consumption of raw potatoes. Processing information for potato as reported by the 2004 JMPR shows that most of the residue is in/on the peel (PF for peeled potato is 0.27). Furthermore, the EU dietary intake model employed a variability factor of 7 in the IESTI calculation, whereas the JMPR dietary intake model employs a variability factor of 3.

Based on the above, the present Meeting confirmed that the short-term dietary intake of paraquat from its use on pulses and potato, based on the results presented by the 2004 Meeting, is unlikely to present a public health concern.

2. Considerations regarding JMPR capacity and resources

The 42nd session of CCPR held a discussion about the limited resources of JMPR, and CCPR agreed that the USA with assistance from Cameroon and Croplife will prepare a discussion paper on how to address JMPR resource issues for consideration by the next Session of CCPR in 2011. Since this is an important subject for JMPR this topic was discussed at the current meeting to give a view from its perspective

Requests to JMPR for pesticide assessments for new compounds, for compounds within the periodic review program of CCPR, as well as requests for assessments for additional MRLs have increased in recent years.

Also, the complexity of questions, the amount of data provided per compound and the cost for meetings and publications have increased. In contrast financial and staff resources for the work of JMPR and for the JMPR Secretariat at FAO and WHO, have not increased but rather decreased. This has led to some backlog in the requested evaluations.

The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) is an independent international scientific expert group. JMPR serves as a scientific advisory body to FAO, WHO, to FAO and WHO member governments, and to the Codex Alimentarius Commission. Advice to the Codex Alimentarius

Commission on pesticides is provided via the Codex Committee on Pesticide Residues (CCPR). The outcome of the JMPR meetings feed directly into national and international food standard setting, as well as into the development of WHO recommendations and guidelines. The Meeting also plays an important role in the continued improvement of risk assessment principles and methods, taking new scientific developments into account.

Procedures and responsibilities for JMPR (as risk assessors) and CCPR (as risk managers) are laid down in the Risk Analysis Principles applied by the CCPR, CAC Procedural Manual, 19th Edition, Section IV.

Current JMPR working procedures:

Procedural guidelines for JMPR have been published by WHO and FAO.

(WHO http://www.who.int/ipcs/food/jmpr/guidelines/en/index.html;

FAO http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-docs/en/).

Key procedural aspects are:

- preparation of meetings starts approximately 1 year before meeting date with public call for data,
- experts are selected according to FAO and WHO rules for expert meetings (from a standing roster of experts) and are invited as independent experts and do not represent their country or organization
- tasks are assigned to experts who prepare in advance of the meeting draft evaluation monographs, which undergo also an initial review
- final conclusions are reached at the meeting and the final report adopted before close of the meeting.
- conclusions and recommendations are by consensus

Operational aspects:

- in advance of the meeting experts prepare and review working papers on a *pro bono* basis, no consultancy fees or honoraria are provided
- during the preparation period extensive interactions via electronic means occur between experts
- estimated average time investment for preparation of working papers is 2-3 person-months for each expert doing the preparatory work.
- experts often work on their own time, i.e. perform this work to a large degree in addition to their normal work load.
- only cost of participation at meetings (travel and per diem) is covered by FAO and WHO
- original study reports (electronic format) are at hand and are consulted during the meeting as needed

- frequent interactions and intense discussions within and between the groups (FAO and WHO expert groups) is critical and impossible to be replaced by telephone- or video-conferencing, in particular to resolve critical issues
- reports and evaluations (residue and toxicology) undergo technical editing to enhance consistency and clarity
- over the course of 10 days (Joint Meeting, plus 5 days pre-meeting for FAO panel) final conclusions on safe intake levels, ADI and ARfD, (compared to chronic and acute exposure) and recommendation on acceptable Maximum Residue Levels of pesticides in agricultural commodities are reached.
- for example, at the 2009 meeting 31 experts evaluated a total of 24 pesticides for use in many different crops, and several hundreds of MRLs, HRs and STMRs recommended (2008: 28 pesticides; 2007: 31 pesticides; 2006: 30 pesticides; 2005: 21 pesticides; 2004: 31 pesticides). The vast majority of these MRL proposals have been adopted as Codex MRLs.
- currently JMPR on average evaluates within a one-year time-frame (from call for data until final conclusion) between 25-30 pesticides and recommends several hundreds of MRLs (and HRs and STMRs) for many pesticide/crop combination.
- overall direct cost to FAO and WHO per meeting is estimated at 370'000 US\$, excluding staff cost.
- with currently available resources, JMPR secretariat and available experts, the meeting has reached maximum capacity. E.g for the WHO group a maximum of 10 full evaluations per meeting are possible, considering one full evaluation per expert for preparing the working paper.

Recent improvements of JMPR working procedures include:

- transparency of the decisions taken has been increased
- Work-sharing process to build on existing national/regional evaluations to the extent possible
- Preparatory work via electronic means has increased
- FAO pre-meeting is working in 2 separate working groups to increase efficiency and to be able to accommodate evaluation of more compounds
- consolidation and update of the principles and methods for the risk assessment of chemicals in food, including pesticide residues, recently published as Environmental Health Criteria 240 (ref)
- FAO Manual on the submission and evaluation of pesticide residue data was updated in 2009 (ref)

Factors affecting efficiency of the current JMPR work:

- largely based on the goodwill of experts who work on a voluntary basis
- workload of experts in their regular jobs has increased and less time can be allocated to JMPR work
- based to a large degree on employer's willingness to let experts participate in JMPR meetings
- extension of current meeting (more experts, more compounds, longer time) not feasible
- in the end overall conclusions have to be agreed upon on all aspects by all experts, longer meetings would require even longer absence of experts from their offices.

- the effort to increase transparency of the decision-making process has led to very detailed and lengthy reports and evaluations. This could be reviewed to update guidance for preparatory work and reporting
- there is sometimes a lack of understanding of sponsors of the importance to submit complete data packages for JMPR evaluations in a timely manner

Advantages of JMPR work and format:

- effective mechanism for problem solving and scientific consensus building
- recommendations are agreed upon and finalized within a specific time-frame by an independent international expert panel
- dissemination of best practices through involvement of participants from regulatory authorities and academia from many different countries
- serves as capacity building and training for national evaluators
- decisions are based on scientific considerations only, using latest scientific knowledge in risk assessment
- MRL recommendations as basis for international safety standards, Codex MRLs, which are in practice also applied to facilitate international trade

CONCLUSIONS:

- JMPR is the independent scientific advisory body for CCPR, providing the basis for recommendation of international standards for pesticide residues in food and feed
- Therefore the independence of this international expert meeting is crucial and should be maintained
- JMPR/CCPR have improved and stream-lined working procedures and this is now a very
 efficient system within Codex, with a large number of standards recommended each year and a
 short time frame between requests for scientific advice and establishment of global standards.
- Globally harmonized international standards for pesticide residues are of increasing importance, and experience from work-sharing exercises from previous JMPR meetings as well as from registration authorities need to be followed up and recommendations implemented to improve efficiency
- Any changes to the current system, including increasing the frequency of JMPR meetings, would have profound impact, including financial ones, and would need to be carefully considered
- in particular implication for CCPR work also needs to be considered, with respect to timing of meetings but also regarding the amount of recommendations coming from JMPR for consideration by CCPR

- The priority setting process at CCPR needs to be strengthened and existing criteria possibly reviewed and then enforced
- It needs to be clarified if the current increasing number of requests for evaluation is only a temporary situation or expected to be long-term

3. Dietary risk assessments conducted by the JMPR: need for appropriate consumption data and for further method development.

In the Codex Procedural Manual (19 ed, section IV, Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, para 23), the following is stated: 'Constraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.'

The Meeting recognizes that evaluation of the uncertainties in a risk assessment increases transparency and, therefore, the credibility of the process. Consequently, reliance on worst-case assumptions can be reduced and decision support improved. Uncertainty analysis also identifies important data gaps, which can be filled to improve the accuracy of estimation1.

JMPR performs both long-term (chronic) and short-term (acute) dietary risk assessments. In the majority of cases where there is an exceedance of a toxicological reference value, it is the ARfD that is exceeded, by the short-term exposure assessment. In 2006 and 2007 (Report 2006, general consideration 2.4, and Report 2007, general consideration 2.1), the Meeting discussed in detail the uncertainties in the calculation of the international estimated short-term intake (IESTI), as well as the interpretation of the outcome. Ways in which the dietary risk assessments could be refined, both for hazard and for exposure assessment, are provided in the JMPR Report at the end of each compound's evaluation, in the section named 'Dietary risk assessment'. From 2009 onwards, to improve dissemination, this information has also been listed at the end of Chapter 4, in which all of the dietary risk assessment results are summarized.

However, it should be noted that the uncertainties addressed in these evaluations are compound specific, relating e.g. to the derivation of ADI, ARfD, MRL, HR, STMR, processing factors. Generic uncertainties arising from the default parameters used in the IESTI model, such as consumption values, are not addressed. Nor is the conservativeness of the model as used.

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¹ IPCS 'Guidance Document on Characterizing and Communicating Uncertainty in Exposure Assessment' (WHO 2008)

IESTI calculations are performed per pesticide/commodity combination and the outcomes are compared to the ARfD. It is a routine screening assessment that does not require an analysis of uncertainty on every occasion, provided that appropriately conservative assumptions or safety factors are included to take account of uncertainty. The EFSA PPR panel in its Opinion on acute dietary intake assessment has shown that the IESTI methodology is, in general, is sufficiently conservative when applied in the MRL setting process 2. However in several fora (among others, JMPR) changes to the IESTI methodology are under discussion, e.g. the possible replacement of HR by MRL in the IESTI equations. To ensure international hamonization of the methodology, changes cannot be implemented by JMPR alone and a FAO/WHO consultation is recommended to address this, as the Meeting noted in 2006 and 2007.

In addition, whilst risk assessments by JMPR are aimed at the global population, the Meeting uses Large Portion data collected by WHO/GEMS/Food from only a limited number of countries. Moreover the GEMS/Food data are sometimes older than those used for the same country in regional assessments e.g. Europe. The Meeting concluded that the IESTI calculations should be based on the best available data and therefore, in view of these potential limitations, the WHO/GEMS/Food Large Portion database and its related unit weight database should be updated (see also general consideration 2.2).

In conclusion, that in order to strengthen its dietary risk assessments, the Meeting strongly recommends that:

FAO and WHO to host a consultation, the main objectives of which would be the continued refinement of the estimation of the short-term dietary intake of pesticides and the interpretation of the outcomes of short-term dietary risk assessment conducted by JMPR, including characterization of uncertainties.

Codex Member States prioritize the submission of their most recent data on Large Portions and unit weights to WHO/GEMS/Food, to ensure that JMPR uses the best available information in its dietary exposure assessments.

² Opinion of the Scientific Panel on Plant protection products and their Residues on a request from the Commission on acute dietary intake assessment of pesticide residues in fruit and vegetables (Question N° EFSA-Q-2006-114) adopted on 19 April 2007. *The EFSA Journal* (2007) **538**, **1-88** http://www.efsa.europa.eu/en/scdocs/scdoc/538.htm

4. Use of proportionality in evaluation of residue data

At the 2010 CCPR delegations suggested that 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 in situations where there were no dietary intake risks (CCPR, Report of the 42nd Session, April 2010, ALINORM 10/33/24, paragraph 72).

In the estimation of maximum residue levels, JMPR accepts that the nominal rate of application in a trial would normally be considered consistent with GAP when it is within approximately ±25 % of the GAP rate, which includes the probable variation in commercial practice (2009 FAO Manual, Second Edition, available on the web:

http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/FAO_manual2nded_Oct07.pdf)..

The policy is similar to that adopted by regulators, for instance the OECD crop field trial guideline states "to date there are no definitive analyses that would allow trials with widely varying application rates or PHIs to be combined. However, variation of $\pm 25\%$ of application rate is currently deemed acceptable (i.e., 25% rule)".

A proportional relationship between pesticide application rate and residues on the harvested commodity would imply that residues from field trials with higher or lower application rates could be proportionately adjusted (or "scaled") allowing estimates to be made of residues that would have been present if the application rate matched the maximum on the product label. Use of such a procedure would often increase the size of the residue database supporting an MRL and potentially allow better results from statistical methods for MRL estimation.

In the current Meeting residue trial evaluation reports of the JMPR for the period 2000 through 2009 were used to investigate the effect of application rates on residues, where side-by-side sets of field trials were available. A total of 1146 sets of trials were located where crops were treated in side-by-side trials with application rate or spray concentration being the only parameter varied. Data were located for 52 different active ingredients encompassing herbicides, insecticides and fungicides. Preharvest intervals (PHIs) ranged from 0 to 294 days.

The analysis of residue trial data confirms the assumption that residues of insecticides and fungicides in plant commodities do indeed scale with application rate, allowing prognosis on residue levels resulting from field trials conducted using deviating application rates. Proportionality was found to be independent of the ratio of application rates, at least for the range 1.3× to 10× or their

reciprocal, formulation type, application type (foliar spray, soil spray and seed treatment), PHI, residue concentration, crop or pesticide (except herbicides or growth regulators).

The Meeting decided it would only consider the method of proportionality in cases, where residue data according to GAP are not sufficient for a recommendation or where additional information on residues in treated commodities useful for the evaluation may be achieved. When considering proportionality, the following aspects need to be taken into account:

General aspects

Active substances: Proportionality of application rates to the residue concentration was investigated mainly for insecticides and fungicides. For herbicides and growth regulators proportionality of residues is not probable, since changes in application rates may strongly interfere the plant development itself and thus with the resulting residue concentration remaining. The Meeting decided that the principle of proportionality may not be used in cases, where application of a pesticide may affect crop growth.

Commodity type: Proportionality may not apply to residues in commodities intended for trade, human consumption or animal feed purposes resulting from unpredictable residue transfer (e.g., as a side effect following mechanical harvesting or shuck-splitting).

Special consideration is required for scaling of residues in protected edible parts of the commodities for dietary intake purposes. While residues are generally proportional in the whole commodity (e.g. citrus fruit), careful application of scaling factors is required for the corresponding protected parts.

Type of application: Proportionality of residues was investigated for spray (foliar and soil) and seed treatments only. Based on the characteristics of the use as soil spray treatment, proportionality may also be assumed for related modes of application like drenching, drip irrigation or hydroponic application. For other forms of treatment (e.g., granular application) the effect on the proportionality has, as yet not been investigated.

Scaling of residue data

Guidance is required for the use of scaling in residue evaluation and for the selection of residue values from trials, where data for a range of application rates are available. As a general approach the scaling of individual trial results should be calculated according to the following equation:

Scaled Residue= Measured residue
$$\times$$
 $\frac{\text{GAP rate}}{\text{Trial application rate}}$

In the data investigated the differences in the ratios of application rates ranged up to a factor of x10 for the field trials analysed. Due to the structure of the data a satisfying number of individual results were reported for a ratio of application rates of 1.15 to 4.4 only.

Under consideration of the likely larger relative uncertainty of low residues the Meeting decided to limit the up-scaling of residues to a factor of 3. On the other hand more reliable results obtained from overdosed field trials might be down-scaled by a factor of up to 5 (multiplication by a factor of 0.2), normally providing a more reliable data basis in comparison to measured low residues. This approach results in an acceptable range of scaling factors of 0.2 to 3. A general example for the scaling of residues is presented below:

Example 1: Application rate < GAP rate

	kg ai/ha	Commodities	Scaling factor	PesticideA residue (mg/kg)
Trial	0.045	Gin trash		0.32

Example 2: Application rate > GAP rate

	kg ai/ha	Commodities	Scaling factor	PesticideA residue (mg/kg)
Trial	0.225	Gin trash		1.9

Special consideration is required for field trial results below the LOQ of the analytical method. In general the LOQ represents the minimum amount of residue still being quantifiable with an acceptable certainty of measurement and identification. Normally this situation requires an appropriate substitution method for these results followed by sensitivity analysis to describe the impact of the respective trial on the overall assessment. It is proposed to not apply the method of scaling to residue data below the LOQ.

In cases of up-scaling the elevated uncertainty within multiplying non-detects to levels, where finite results may be possible, was considered no appropriate. Therefore data below the LOQ should be taken into account for up-scaling.

On the other hand down-scaling of residue data below the LOQ would result in even lower residues. For these cases the Meeting agreed that, as a conservative approach, the LOQ may also be used in the scaled dataset for an assessment.

Example 3: Application rate < GAP rate, residue below the LOQ

	kg ai/ha	Commodities	Scaling factor	PesticideA residue (mg/kg)
Trial	0.045	Gin trash		<0.01
Scaled residue according to GAP	0.07		No scaling possible	Do not use value

Example 4: Application rate > GAP rate, residue below the LOQ

	kg ai/ha	Commodities	Scaling factor	PesticideA residue (mg/kg)
Trial	0.225	Gin trash		<0.01

Scaled residue	0.07	No scaling factor used	< 0.01
according to GAP			

Reporting of scaled residues within the JMPR evaluation

The application of scaling is part of a part of the assessment process and should be reported in the appraisal. It is therefore proposed to separate the scaling into up to three steps, which include the reporting of the unadjusted data, the application of scaling factors and finally the combination of data generated with different application rates. For a better understanding one simple example (requiring only 2 steps) from the 2010 JMPR Report for chlorantraniliprole and an artificial consideration are presented below:

Example 1

Chlorantraniliprole field trials on alfalfa were made available to the Meeting from the USA (GAP: 73 g ai/ha, 1 application/cutting, PHI of 0 days and a maximum application per season of 224 g ai/ha).

Chlorantraniliprole residues on alfalfa forage treated at 1.5× the maximum rate were 2.0, 2.1, 3.0, 3.0, 3.2, 3.7, 4.1, 4.6, 4.8, 5.2, 5.3, 5.4, 5.7, 5.7, 5.7, 5.9, 5.9, 6.2, 6.2, 6.3, 6.7, 6.8, 6.9, 6.9, 7.5, 7.6, 7.6, 7.8, 8.3, 11 mg/kg (fresh weight basis). When corrected for reported moisture contents the residues were 9.5, 9.7, 11, 13, 14, 16, 19, 19, 20, 23, 23, 23, 24, 24, 25, 26, 26, 27, 29, 29, 30, 30, 31, 32, 33, 34, 34, 36, 42, 43 mg/kg (dry weight basis).

The residues scaled to the same application rate as GAP were calculated by dividing by 1.5 and are (n=30): 6.3, 6.5, 7.3, 8.7, 9.3, 10.7, 12.7, 12.7, 13.3, 15.3, 15.3, 15.3, 16, 16, 16.7, 17.3, 17.3, 18, 19.3, 20, 20, 20.7, 21.3, 22, 22.7, 22.7, 24, 28, 28.7 mg/kg. Using the data scaled for application rate, the Meeting estimated an STMR value for chlorantraniliprole in alfalfa forage of 17 mg/kg (dry weight basis).

Example 2

PesticideA is registered on green beans with one spray application of 0.073 kg ai/ha with a PHI of 0 days.

Supervised field trials conducted at different application rates are available resulting in the following residues in green beans after a PHI of 0 days:

Application rate 0.03 kg ai/ha: <0.01, <0.01, 0.05, 0.07, 0.08 mg/kg

Application rate 0.06 kg ai/ha: 0.02, 0.03, 0.09, 0.15 mg/kg

Application rate 0.12 kg ai/ha: <0.01, 0.11, 0.19, 0.19 and 0.2 mg/kg

Additional supervised trial data were available on green beans treated at rates of 0.02 kg ai/ha, which would require scaling higher than the maximum factor of 3 for up-scaling to comply with GAP.

Scaled residues of PesticideA in green beans after a PHI of 0 days were:

Application rate 0.03 kg ai/ha scaled to GAP (scaling factor: 0.073 kg ai/ha / 0.03 kag ai/ha = 2.4): 0.12, 0.17, 0.19 mg/kg

Application rate 0.06 kg ai/ha (±25% GAP, no scaling required): 0.02, 0.03, 0.09, 0.15 mg/kg Application rate 0.12 kg ai/ha scaled to GAP (scaling factor: 0.073 kg ai/ha / 0.12 kg ai/ha = 0.61): <0.01, 0.067, 0.12, 0.12, 0.12 mg/kg

The Meeting concluded that scaled residues residues in green beans treated at different application rates are not significantly different and may be combined for a recommendation. The combined scaled residues of PesticideA in green beans were: <0.01, 0.02, 0.03, 0.067, 0.09, 0.12(4), 0.15, 0.17 and 0.19 mg/kg.

The Meeting estimated a maximum residue level, and STMR and an HR for PesticideA based on scaled residue data on green beans of 0.3, 0.12 and 0.19 mg/kg, respectively.

5. Further consideration of expert judgement in evaluating residue trials

The Meeting considered the use of expert judgment in evaluating supervised residue trials at the 2009 Meeting and provided an item describing in general terms how this occurs. A paper has recently been published that contains information that may be of use in informing expert judgment (MacLachlan and Hamilton 2010). The authors have assembled a database of residues on crops receiving a single foliar spray application normalized to an application rate of one kg ai/ha (or one kg ai/hL for spray concentrations). The approach is similar to that used for many years in the estimation of residues on vegetation used in initial tiers of environmental risk assessment (Hoerger and Kenaga 1972; Fletcher et al. 1994; Pfleeger et al. 1996). It is assumed that provided the interval between application and measurement is short, the measured residues provide a good measure of the volume of spray intercepted by the part of the plant that is of interest when normalized for application rate. It is anticipated that the crop specific information on residues at day of application can be used in two ways to assist the work of the JMPR:

to derive expected median and highest residues on the day of a spray application; and to predict likely median and high residues following multiple applications at various intervals after the last spray. The latter is only possible for those pesticides for which the decline of residues in supervised trials follow simple first order kinetics and for which information is available on DT50 values.

The likely median and high residues can be compared with results from actual supervised residue trials and estimates provided by statistical calculators to support recommendations for maximum residue levels.

It was generally felt the tool might be suitable for use in 20% of cases. The day 0 residue database only applies to foliar application of pesticides.

The paper provides details of how the information may be used.

At the present Meeting the approach was as an adjunct to other considerations and statistical calculations in estimating maximum residue levels used in the evaluation of chlorantraniliprole residues in oranges and cabbages.

Fletcher JS, Nellessen JE, Pfleeger TG. 1994. Literature review and evaluation of the EPA food-chain (Kenaga) nomogram, an instrument for estimating pesticide residues on plants. Environ Toxicol Chem. 13:1383–1391.

Hoerger FD, Kenaga EE. 1972. Pesticide residues on plants, correlation of representative data as a basis for estimation of their magnitude in the environment. Environ Qual. 1:9–28.

Maclachlan DJ and Hamilton D. 2010. A new tool for the evaluation of crop residue trial data (dayzero-plus decline), Food Additives & Contaminants: Part A, 27:347 — 364.

Pfleeger TG, Fong A, Hayes R, Ratsch H, Wickliff C. 1996. Field evaluation of the EPA (Kenaga) nomogram, a method for estimating wildlife exposure to pesticide residues on plants. Environ Toxicol Chem. 15:535–543.

6. Information on the use of pesticide required for estimation of residue levels in minor crops

The 42nd Session of CCPR recommended that when residue data on minor crops are submitted by developing countries, the application of pesticides should match the critical GAP and that an official letter would be acceptable if labels were not available.

As a follow up of the discussions at the CCPR, reports of field trials on mango, okra and papaya were provided by the Pesticides Initiative Programme for evaluation by the current Meeting. But, no approved label or an official letter from the responsible government department was provided. The general rules specified in the FAO Manual do not allow evaluation of the residue data for estimation of maximum residue levels, STMR and HR values when critical information is missing.

However, the Meeting recognised the need to develop Codex MRLs for minor crops, and the diverging practices in developing countries evaluated the residue data submitted, and conditionally made recommendations for maximum residue levels, STMR and HR for bifenthrin (mango, papaya, okra) and difenoconazole (papaya) in , as appropriate. The acceptability of the recommendations should be decided by CCPR, noting the lack of information on official use patterns.

The Meeting emphasised that this exception should not be a general practice and that data submitters should comply with the requirements specified in the FAO Manual.

The Chapter 3 of the 'FAO Manual on the submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed' provides detailed information on the data requirements for estimation of maximum residue levels.

http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/FAO_manual2n ded_Oct07.pdf

GAP summaries are intended as an aid to the evaluation of submitted data and are to be provided in addition to certified labels. It is emphasised that copies of original labels have to be provided by the manufacturer(s) (or other data submitters), in addition to the summary information.

The most essential information, which should be provided for the registered/authorised use of a pesticide includes:

- -- Exact description of crops and use situations with English name and the commodity descriptions given in the Codex Classification of Foods and Animal Feeds;
- -- The formulation of the pesticide product using the two-letter coding system used in FAO pesticide specifications and given in Appendix III of FAO Manual;
- -- The concentration of active ingredient in the formulated product expressed in g/l for liquid and w/w basis as g/kg or % of active ingredient in the solid product;
- -- The type of treatment such as ULV, high volume sprayer, etc., growing stage at the last application;
- -- Maximum application rate expressed as kg a.i./ha or kg a.i./hl, number of applications, interval between applications and pre-harvest interval corresponding to specified application rate, if relevant, and maximum total application rate per season where specified;

In cases in which the indications on the label are given in g/hl or kg/hl (spray concentration), state this spray concentration but do not calculate the kg ai/ha equivalent with the average amount of spray liquid used per hectare.