



**Food and Agriculture Organization
of the United Nations**



**World Health
Organization**

JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES

Rome, 11-20 September 2012

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 2012

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 31 pesticides, of which 7 were new compounds, and 7 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 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		
Acetamiprid (246) ADI: 0–0.07 mg/kg bw ARfD: 0.1 mg/kg bw	VL 0053	Leafy vegetables (except spinach)	3 ^a	3	0.64	1.9
<p>Definition of the residue (for compliance with the MRL for plant commodities and for estimation of dietary intake for plant and animal commodities): <i>acetamiprid</i>.</p> <p>Definition of the residue (for compliance with the MRL for animal commodities and for estimation of dietary intake for plant and animal commodities): <i>sum of acetamiprid and its desmethyl (IM-2-1) metabolite, expressed as acetamiprid</i>.</p> <p><i>The residue is not fat-soluble.</i></p> <p>^a 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 for children the consumption of lettuce, leaf; Chinese cabbage, type pak-choi; Chinese cabbage, type pe-tsai; spinach and endive was less than the ARfD.</p>						
Ametoctradin (253) ADI: Unnecessary ARfD: Unnecessary	FB 0269 DF 0269 VA 0381 VA 0385 VA 0388 VA 0389 VB 0040 VC 0045 VC 0424 VO 0050 DH 1100 HS 0444 VL 0053 VR 0589 VS 0624 PM 0110 PF 0111 PO 0111 PE 0112	Grapes Dried grapes (=currants, raisins and sultanas) Garlic Onion, Bulb Shallot Spring Onion Brassica (cole or cabbage) 9 vegetables, Head cabbages, Flowerhead brassicas Fruiting vegetables, Cucurbits, 3 except cucumber Cucumber Fruiting vegetables, other than cucurbits, except sweet corn and except mushroom Hops, dry Peppers Chili, dried Leafy vegetables Potato Celery Poultry meat Poultry fats Poultry, Edible offal of Eggs	6 20 1.5 1.5 1.5 20 9 3 0.4 1.5 30 15 50 0.05 20 0.03* 0.03* 0.03* 0.03*		0.605 (ldb) 4.1 nn nn nn nn nn nn nn 0.16 (ldb) nn nn nn nn nn nn nn nn nn nn nn nn	nn nn nn nn 7.5 (ldb) nn
<p>Definition of the residue for compliance with the MRL for plant commodities: <i>ametoctradin</i>.</p> <p>Definition of the residue for compliance with the MRL for animal commodities: <i>sum of ametoctradin, M650F01 and M650F06, expressed as Ametoctradin</i>.</p> <p><i>The residue is not fat-soluble</i></p> <p>nn: not needed</p> <p>ldb: STMR needed for livestock dietary burden calculation</p>						
Azoxystrobin (229) ADI: 0–0.2 mg/kg bw	FT 0289 DV 0604	Carambola Ginseng, dried including red ginseng	0.1 0.3		0.023 0.069	

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: Unnecessary	DM 0604	Ginseng, extracts Ginseng processed products(dried, red, ethanol and water extracts)	0.5 W	0.5	0.12	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: <i>azoxystrobin</i> . <i>The residue is fat soluble.</i>						
Bentazone (172) ADI: 0-0.09 mg/kg bw ARfD: Unnecessary Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant commodities: <i>Sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone.</i> Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for animal commodities: <i>Bentazone.</i>						
Buprofezin (173) ADI: 0-0.009 mg/kg bw ARfD: 0.5 mg/kg bw	FI 0327 DT	Banana Tea, Green	0.3 30		0.01 9.0	0.01 -
For compliance with the MRL and for estimation of dietary intake for plant and animal commodities: <i>buprofezin</i> .						
Carbofuran (096) ADI: 0-0.001 mg/kg bw ARfD: 0.001 mg/kg bw	FI 0327	Banana	0.01*	0.02*	0.01	0.01
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: <i>carbofuran and 3-hydroxy carbofuran expressed as carbofuran.</i> <i>The residue is not fat-soluble.</i>						
Chlorfenapyr (254) ADI: 0-0.03 mg/kg bw ARfD: 0.03 mg/kg bw Definition of the residue (for compliance with the MRL) for plant and animal commodities: <i>chlorfenapyr</i> Definition of the residue (for estimation of dietary intake) for plant and animal commodities: <i>a conclusion could not be reached.</i> <i>The residue is fat soluble.</i>						
Chlorothalonil (081) ADI: 0-0.02 mg/kg bw ARfD: 0.6 mg/kg bw	FI 0327 VL 0464	Bananas Chard	15 50	0.01* ^a	Chlorothalonil : 0.033 ^b Chlorothalonil : 16	Chlorothalonil: 0.71 ^b Chlorothalonil: 19
Definition of the residue for compliance with MRL for plant commodities: <i>chlorothalonil</i> . Definition of the residue for estimation of dietary intake for plant commodities: <i>chlorothalonil - SDS-3701 (2,5,6-trichloro-4-hydroxyisophthalonitrile) all considered separately.</i> Definition of the residue for compliance with MRL and for estimation of dietary intake for animal commodities: <i>SDS-3701</i>						

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
(2,5,6-trichloro-4-hydroxyisophthalonitrile).						
<i>The residue is not fat-soluble.</i>						
^a Based on bagged bananas						
^b For banana pulp						
<hr/>						
Chlorpyrifos-methyl (090)	GC 0645	Maize	W	3 Po		
ADI: 0-0.01 mg/kg bw						
ARfD: 0.1 mg/kg bw						
For compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: <i>chlorpyrifos-methyl</i> .						
<i>The residue is fat-soluble.</i>						
<hr/>						
Cyfluthrin (179)	VD 0071	Beans, dry	20	2	3	
ADI: 0-0.07 mg/kg bw	VP 0061	Beans except broad bean & soy: (green pods & immature seeds)	15		0.35	11
ARfD: 2 mg/kg bw for Women of childbearing Age. Not necessary for the general population.	VR 0574	Beetroot	0.2		0.09	0.10
	VB 0040	Brassica (Cole or Cabbage) Vegetables, Head Cabbage, Flowerhead Brassicas	7	2	1.5	6
	VR 0577	Carrot	5	0.5	0.44	3
	VR 0578	Celeriac	1		0.13	0.64
	MO 0105	Edible offal (Mammalian)	0.5		0.084	0.380
	PE 0112	Eggs	0.15		0.026	0.092
	FB 0269	Grapes	0.3	0.5	0.11	0.18
	VL 4355	Kale, curly	3		0.65	1.1
	VA 0384	Leek	4		0.36	2.3
	VL 0482	Lettuce, Head	1.5	0.2	0.335	1
	VL 0483	Lettuce, Leaf	1.5	0.2	0.335	1
	SO 0693	Linseed	7		1.9	
	MF 0100	Mammalian fats (except milk fats)	0.1		0.01	0.061
	GC 0645	Maize	0.2		0.09	
	AS 0645	Maize fodder (dry)	2		0.105	1.1
	MM 0095	Meat (from mammals other than marine mammals)	0.05		0.010	0.044
	ML 0106	Milks	0.02		0.004	
	VA 0385	Onion, Bulb	3		0.258	1.43
	VP 0063	Peas (pods and succulent=immature seeds)	W	1		
	VP 0072	Peas (dry)	20		3.2	
	VP 0064	Peas, Shelled (succulent seeds)	15	2	2.7	
	VO 0051	Peppers	9		1.55	5.3
	HS 0444	Peppers Chilli, dried	90		15.5	
	FP 0009	Pome fruits	0.09*		0.09	0.09
	VR 0589	Potato	3	2	0.735	1.6
	PM 0110	Poultry meat	0.03*		0	0.03
	PF 0111	Poultry fats	0.03*		0	0.03
	PO 0111	Poultry, Edible offal of	0.02		0.01	0.018
	SO 0495	Rape seed	7	2	1.9	
	GC 0649	Rice	0.09*		0.09	
	AS 0649	Rice straw or fodder Dry	0.09		0.09	0.09
	VD 4521	Soya bean (dry)	80	2	13	
	FS 0012	Stone fruits	0.09*		0.09	0.09
	FB 0275	Strawberry	3	0.5	0.53	1.4
	VR 0596	Sugar beet	0.2	0.2	0.09	0.10
	SO 0702	Sunflower seed	6		0.375	

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	VR 0497	Swede	0.2		0.09	0.10
	VO 0448	Tomato	1.5		0.445	0.89
<p><i>Definition of the residue for compliance with maximum residue levels and estimation of dietary intake in plant and animal commodities: Cycloxydim including degradation and reaction products which can be determined as 3-(3-thianyl) glutaric acid S-dioxide (cycloxydim-TGSO₂) and/or 3-hydroxy-3-(3-thianyl) glutaric acid S-dioxide (6cycloxydim-5-OH-TGSO₂) or methyl esters cycloxydim-TDME and/or cycloxydim-5-OH-TDME, calculated in total as cycloxydim.</i></p> <p><i>The residue is not fat soluble.</i></p>						
Cyfluthrin/beta-cyfluthrin (157)	VB 0041	Cabbages, Head	0.08	4	0.01	0.05
ADI: 0-0.04 mg/kg bw	MO 0105	Edible offal (mammalian)	0.02		0.005	0.01
ARfD: 0.04 mg/kg bw	MO 0098	Kidney of cattle, goats, pigs and sheep	W	0.05		
	MO 0099	Liver of cattle, goats, pigs and sheep	W	0.05		
	MM 0095	Meat (from mammals other than marine mammals)	0.2 fat	1.0	0.07 fat 0.01 muscle	0.16 fat 0.01 muscle
	ML 0106	Milks	0.01	0.04	0.004	
	VD 0541	Soya bean (dry)	0.03		0.01	
	AL 0541	Soya bean fodder	4		1.15 (fw)	2.2 (fw)
<p><i>Definition of the residue for compliance with the MRL and for estimation of dietary intake for plant and animal commodities: cyfluthrin (sum of isomers).</i></p> <p><i>The residue is fat-soluble.</i></p>						
Cyromazine (169)	VD 0524	Chick-pea (dry)	3	-	1.0	-
ADI: 0-0.06 mg/kg bw	VD 0533	Lentil (dry)	3	-	1.0	-
ARfD: 0.1 mg/kg bw	VD 0545	Lupin (dry)	3	-	1.0	-
<p><i>Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: cyromazine</i></p>						
Dichlorvos (025)	GC 0080	Cereal grains	W	5		
ADI: 0-0.004 mg/kg bw	MO 0105	Edible offal (mammalian)	0.01 *		0	
ARfD: 0.1 mg/kg bw	PE 0112	Eggs	0.01 *		0	
	MF 0100	Mammalian fats (except milk fats)	0.01 *		0	
	MM 0095	Meat (from mammals other than marine mammals)	0.01 *		0	
	ML 0106	Milks	0.01 *		0	
	PF 0111	Poultry fat	0.01 *		0	
	PM 0110	Poultry meat	0.01 *		0	
	PO 0111	Poultry, Edible offal of	0.01 *		0	
	GC 0649	Rice	7		2.8	5.2
	CM 1206	Rice bran, Unprocessed	15 PoP		2.94	5.46
	CM 0649	Rice, Husked	1.5 PoP		0.45	0.83
	CM 1205	Rice, Polished	0.15 PoP		0.014	0.03
	GC 0654	Wheat	7 Po		2.2	4.1
	CM 0654	Wheat bran, Unprocessed	15 PoP	10	4.33	
	CF 1211	Wheat flour	0.7PoP	1	0.22	
	CF 1210	Wheat germ	W	10		
	CF 1212	Wheat wholemeal	3 PoP	2	0.88	
<p><i>Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal</i></p>						

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
commodities: <i>dichlorvos</i>						
<i>The residue is not fat soluble.</i>						
Dicofol (026)	VD 0071	Beans (dry)	W	0.1		
ADI: 0–0.002 mg/kg bw	MM 0812	Cattle meat	W	3(fat)		
ARfD: 0. 2 mg/kg bw	MO 0812	Cattle, Edible offal of	W	1		
	FS 0013	Cherries	W	5		
	FC 0001	Citrus fruits	W	5		
	VP 0526	Common bean (pods and/or immature seeds)	W	2		
	SO 0691	Cotton seed	W	0.1		
	OC 0691	Cotton seed oil, Crude	W	0.5		
	OR 0691	Cotton seed oil, Edible	W	0.5		
	VC 0424	Cucumber	W	0.5		
	PE 0112	Eggs	W	0.05		
	FB 0269	Grapes	W	5		
	DH 1100	Hops, Dry	W	50		
	VC 0046	Melons, except watermelon	W	0.2		
	ML 0106	Milks	W	0.1		
	FS 0247	Peach	W	5		
	TN 0672	Pecan	W	0.01*		
	VO 0051	Peppers	W	1		
	HS 0444	Peppers Chili, dried	W	10		
	FS 0014	Plums (including prunes)	W	1		
	PM 0110	Poultry meat	W	0.1(fat)		
	PO 0111	Poultry, Edible offal of	W	0.05*		
	DF 0014	Prunes	W	3		
	VC 0431	Squash, summer	W	1		
	DT 1114	Tea, Green, Black (black, fermented and dried)	40 ^a	50	11.2	15.6
	TN 0678	Walnuts	W	0.01*		
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant commodities: <i>Dicofol</i> (sum of <i>o,p'</i> and <i>p,p'</i> isomers)						
<i>Residue is fat-soluble.</i>						
^a DDT may be present in tea as a result of its presence as a contaminant in the technical grade dicofol.						
Dinotefuran (255)	VB 0040	Brassica (Cole or Cabbage) Vegetables, Head Cabbage, Flowerhead Brassicas	2		0.40	1.1
ADI: 0-0.2 mg/kg bw	VS 0624	Celery	0.6		0.435	0.67
ARfD: 1 mg/kg bw	SO 0691	Cotton seed	0.2		0.15	
	FB 0265	Cranberry	0.15		0.06	0.1
	DF 0269	Dried grapes (= currants, Raisins and Sultanas)	3		0.81	2.47
	MO 0105	Edible offal (Mammalian),	0.1		0.03	0.076
	PE 0112	Eggs	0.02*		0	0
	VC 0045	Fruiting vegetables, Cucurbits	0.5		0.25	0.33
	VO 0050	Fruiting vegetables other than Cucurbits (except sweet corn and mushrooms)	0.5		0.15	0.55
	FB 0269	Grapes	0.9		0.22	0.67
	VL 0053	Leafy vegetables	6		1.2	4.4
	MM 0095	Meat (from mammals other than marine mammals)	0.1		0.03	0.062
	ML 0106	Milks	0.1		0.039	

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg																																																																																											
			New	Previous																																																																																													
	FS 0245	Nectarine	0.8		0.28	0.57																																																																																											
	VA 0385	Onion, Bulb	0.1		0.04	0.1																																																																																											
	FS 0247	Peach	0.8		0.28	0.57																																																																																											
	HS 0444	Peppers, Chili, dried	5		1.75	5.0																																																																																											
	PO 0111	Poultry, Edible offal of	0.02*		0	0																																																																																											
	PM 0110	Poultry meat	0.02*		0	0																																																																																											
	GC 0649	Rice	8		3.3																																																																																												
	GC 1205	Rice, Polished	0.3		0.132																																																																																												
	AS 0649	Rice straw and fodder, Dry	6		1.6	4.3																																																																																											
	VA 0389	Spring Onion	4		0.91	2.3																																																																																											
	VL 0473	Watercress	7		2.9	3.8																																																																																											
	OR 0691	Cotton seed oil			0.011																																																																																												
	JF 0269	Grape juice			0.264																																																																																												
	CM 1206	Rice bran, Unprocessed			0.264																																																																																												
	CM 1207	Rice hulls			2.112																																																																																												
	VW 0448	Tomato paste			0.46																																																																																												
		Tomato puree			0.16																																																																																												
<p>Definition of the residue (for compliance with the MRL) for plant commodities: dinotefuran</p> <p>Definition of the residue (for estimation of dietary intake) for plant commodities: <i>Sum of dinotefuran, 1-methyl-3-(tetrahydro-3-furylmethyl) urea (UF) and 1-methyl-3-(tetrahydro-3-furylmethyl)guanidium dihydrogen (DN) expressed as dinotefuran.</i></p> <p>Definition of the residue (for compliance with the MRL and estimation of dietary intake) for animal commodities: <i>Sum of dinotefuran, 1-methyl-3-(tetrahydro-3-furylmethyl) urea (UF) expressed as dinotefuran.</i></p> <p><i>The residue is not fat soluble.</i></p>																																																																																																	
<p>Fenbuconazole (197)</p> <p>ADI: 0-0.03 mg/kg bw</p> <p>ARfD: 0.2 mg/kg bw</p> <p>Definition of the residue for compliance with the MRL and for estimation of dietary intake for plant and animal commodities: <i>fenbuconazole.</i></p> <p><i>The residue is fat-soluble.</i></p>																																																																																																	
<p>Fenpropathrin (185)</p> <p>ADI: 0-0.03 mg/kg bw</p> <p>ARfD: 0.03 mg/kg bw</p> <p>For compliance with the MRLs and for estimation of the dietary intake: <i>fenpropathrin.</i></p> <p><i>The residue is fat-soluble.</i></p>																																																																																																	
<p>Fenvalerate (119)</p> <p>ADI: 0-0.02 mg/kg bw</p> <p>ARfD: 0.2 mg/kg bw</p> <table border="1"> <tbody> <tr> <td>AL 1020</td> <td>Alfalfa fodder</td> <td>W</td> <td>20</td> <td></td> <td></td> <td></td> </tr> <tr> <td>VP 0062</td> <td>Beans, Shelled</td> <td>W</td> <td>0.1</td> <td></td> <td></td> <td></td> </tr> <tr> <td>VP 0061</td> <td>Beans, except broad beans and soya beans</td> <td>W</td> <td>1</td> <td></td> <td></td> <td></td> </tr> <tr> <td>FB 0018</td> <td>Berries and other small fruits</td> <td>W</td> <td>1</td> <td></td> <td></td> <td></td> </tr> <tr> <td>VB 0400</td> <td>Broccoli</td> <td>W</td> <td>2</td> <td></td> <td></td> <td></td> </tr> <tr> <td>VB 0401</td> <td>Broccoli, Chinese</td> <td>3</td> <td></td> <td>0.81</td> <td>1.8</td> <td></td> </tr> <tr> <td>VB 0402</td> <td>Brussels sprouts</td> <td>W</td> <td>2</td> <td></td> <td></td> <td></td> </tr> <tr> <td>VB 0041</td> <td>Cabbages, Head</td> <td>W</td> <td>3</td> <td></td> <td></td> <td></td> </tr> <tr> <td>VB 0404</td> <td>Cauliflower</td> <td>W</td> <td>2</td> <td></td> <td></td> <td></td> </tr> <tr> <td>VX 0624</td> <td>Celery</td> <td>W</td> <td>2</td> <td></td> <td></td> <td></td> </tr> <tr> <td>GC 0080</td> <td>Cereal grains</td> <td>W</td> <td>2 (Po)</td> <td></td> <td></td> <td></td> </tr> <tr> <td>FS 0013</td> <td>Cherries</td> <td>W</td> <td>2</td> <td></td> <td></td> <td></td> </tr> <tr> <td>VL 0466</td> <td>Chinese cabbage (type pack-choi)</td> <td>W</td> <td>1</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>							AL 1020	Alfalfa fodder	W	20				VP 0062	Beans, Shelled	W	0.1				VP 0061	Beans, except broad beans and soya beans	W	1				FB 0018	Berries and other small fruits	W	1				VB 0400	Broccoli	W	2				VB 0401	Broccoli, Chinese	3		0.81	1.8		VB 0402	Brussels sprouts	W	2				VB 0041	Cabbages, Head	W	3				VB 0404	Cauliflower	W	2				VX 0624	Celery	W	2				GC 0080	Cereal grains	W	2 (Po)				FS 0013	Cherries	W	2				VL 0466	Chinese cabbage (type pack-choi)	W	1			
AL 1020	Alfalfa fodder	W	20																																																																																														
VP 0062	Beans, Shelled	W	0.1																																																																																														
VP 0061	Beans, except broad beans and soya beans	W	1																																																																																														
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VB 0041	Cabbages, Head	W	3																																																																																														
VB 0404	Cauliflower	W	2																																																																																														
VX 0624	Celery	W	2																																																																																														
GC 0080	Cereal grains	W	2 (Po)																																																																																														
FS 0013	Cherries	W	2																																																																																														
VL 0466	Chinese cabbage (type pack-choi)	W	1																																																																																														

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	FC 0001	Citrus fruits	W	2		
	SO 0691	Cotton seed	W	0.2		
	OC 0691	Cotton seed oil, Crude	W	0.1		
	OR 0691	Cotton seed oil, Edible	W	0.1		
	VC 0424	Cucumber	W	0.02		
	MO 0105	Edible offal (mammalian)	W	0.02		
	VL 0480	Kale (including among others: Collards, Curly kale, Scotch kale, thousand-headed kale; not including Marrow-stem kele)	W	10		
	FI 0341	Kiwifruit	W	5		
	VL 0482	Lettuce, Head	W	2		
	FI 0345	Mango	1.5	-	0.39	0.48
	MM 0095	Meat (from mammals other than marine mammals)	W	1 (fat)		
	VC 0046	Melons, except watermelons	W	0.2		
	ML 0106	Milks	W	0.1F		
	FS 0247	Peach	W	5		
	SO 0703	Peanut, whole	W	0.1		
	VP 0064	Peas, Shelled (succulent seeds)	W	0.1		
	VO 0445	Peppers, Sweet (including pimento or pimienta)	W	0.5		
	FP 0009	Pome fruits	W	2		
	VR 0075	Root and tuber vegetables	W	0.05		
	VD 0541	Soya bean (dry)	W	0.1		
	VC 0431	Squash, summer	W	0.5		
	SO 0702	Sunflower seed	W	0.1		
	VO 0447	Sweet corn (corn-on-the-cob)	W	0.1		
	VO 0448	Tomato	W	1		
	TN 0085	Tree nuts	W	0.2		
	VC 0432	Watermelon	W	0.5		
	CM 0654	Wheat bran, Unprocessed	W	5 (Po)		
	CF 1211	Wheat flour	W	0.2 (Po)		
	CF 1212	Wheat wholemeal	W	2 (Po)		
	VC 0433	Winter squash	W	2		
Definition of the residue (for compliance with MRL and for estimation of dietary intake) for plant and animal commodities: <i>sum of fenvalerate isomers</i> <i>The residue is fat-soluble.</i>						
Fludioxonil (211) ADI: 0-0.4 mg/kg bw ARfD: Unnecessary	FI 0345	Mango		2	0.02	
Definition of residue for compliance with the MRLs and estimation of dietary intake in plant commodities: <i>fludioxonil</i> Definition of residue for compliance with the MRLs and estimation of dietary intake: <i>sum of fludioxonil and its benzopyrrole metabolites, determined as 2,2-difluorobenzo[1,1]dioxole-4-carboxylic acid and expressed as fludioxonil</i> <i>The residue is fat-soluble</i>						
Fluopyram (243) ADI: 0-0.01 mg/kg bw ARfD: 0.5 mg/kg bw	FI 0327	Banana		0.8	0.175	0.51
	VD 0071	Beans (dry)		0.07	0.01	
	VR 0577	Carrot		0.4	0.09	0.19
	FS 0013	Cherries		0.7	0.205	0.47
	VD 0524	Chick-pea (dry)		0.07	0.01	
	MO 0105	Edible offal (mammalian)	W	0.7		

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or	HR or
			New	Previous	STMR-P mg/kg	HR-P mg/kg
	PE 0112	Eggs	0.3		0.008	
	MO 0098	Kidney of cattle, goats, pigs and sheep	0.5		0.06	0.32
	VD 0533	Lentil (dry)	0.07		0.01	
	MO 0099	Liver of cattle, goats, pigs and sheep	3		0.53	2.3
	VD 0545	Lupin (dry)	0.07		0.01	
	MM 0095	Meat (from mammals other than marine mammals)	0.5	0.1	0.05 (muscle) 0.06 (fat)	0.36 (muscle) 0.4 (fat)
	ML 0106	Milks	0.3	0.07	0.05	
	FS 0247	Peach	0.4		0.13	0.17
	SO 0697	Peanut	0.03		0.01	
	VO 0051	Peppers	0.5		0.085	0.24
	HS 0444	Peppers Chili, dried	5		0.85	2.4
	FP 0009	Pome fruits	0.5		0.135	0.28
	VR 0589	Potato	0.03		0.01	0.02
	PM 0110	Poultry meat	0.2		0.01 (muscle) 0.01 (fat)	0.13 (muscle) 0.2 (fat)
	PO 0105	Poultry, Edible offal of	0.7		0.02	0.58
	FB 0275	Strawberry	0.4		0.025	0.23
	VR 0596	Sugar beet	0.04		0.01	0.02
	VO 0448	Tomato	0.4		0.09	0.23
	TN 0085	Tree nuts	0.04		0.01	0.03
	DF 0226	Apples, dried			0.09	
	JF 0226	Apple juice			0.01	
		Apple sauce			0.05	
		Peanut butter			0.002	
	OR 0697	Peanut oil, Edible			0.0001	
		Potato (peeled)			0.006	0.013
		Potato chips (crisps)			0.006	
		Potato flakes			0.01	
		Strawberry jam			0.02	
		Strawberry preserve			0.008	
		Sugar beet (sugar)			0.01	
	JF 0448	Tomato juice			0.03	
	VW 0448	Tomato paste			0.04	
		Tomato preserve			0.02	
		Tomato puree			0.07	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant commodities: <i>fluopyram</i> .						
Definition of the residue (for compliance with the MRL) for animal commodities: <i>Sum of fluopyram and 2-(trifluoromethyl) benzamide, expressed as fluopyram</i> .						
Definition of the residue (for estimation of dietary intake) for animal commodities: <i>Sum of fluopyram, 2-(trifluoromethyl)benzamide and the combined residues N-((E)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethenyl)-2-trifluoromethyl benzamide and N-((Z)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethenyl)-2-trifluoromethyl benzamide, all expressed as Fluopyram</i> .						
<i>Although fluopyram (parent compound) is fat-soluble, the 2-(trifluoromethyl) benzamide metabolite (the major component of the residue) is not fat soluble.</i>						
Fluxapyroxad (256)						
ADI: 0-0.02 mg/kg bw	GC 0640	Barley	2		0.535	
ARfD: 0.3 mg/kg bw		Barley bran	4		1.0	
	AS 0640	Barley straw and fodder, Dry	30		4.1 dw	18
	VD 0071	Beans (dry)	0.3		0.04	

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	VP 0061	Beans, except broad bean and soya bean	2		0.65	0.74
	VP 0062	Beans, shelled	0.09		0.03	0.04
	VD 0524	Chick-pea (dry)	0.4		0.04	
	SO 0691	Cotton seed	0.01*		0	
	MO 0105	Edible offal (mammalian)	0.1		0.081	0.31
	PE 0112	Eggs	0.02		0.017	0.023
	VO 0050	Fruiting vegetables other than cucurbits (except sweet corn and mushrooms)	0.6		0.07	0.44
	VD 0533	Lentil (dry)	0.4		0.04	
	GC 0645	Maize	0.01*		0.01	
	AS 0645	Maize fodder (dry)	15		3.62 dw	6.57
	MM 0095	Meat (from mammals other than marine mammals) (fat)	0.2 (fat)		<0.02 (meat) 0.047 (fat)	0.033 (meat) 0.18 (fat)
	ML 0106	Milks	0.02		0.004	0.020
	FM 0183	Milk fats	0.5		0.09	0.45
	GC 0647	Oats	2		0.535	
	AS 0647	Oat straw and fodder, Dry	30		4.1dw	18.3
	SO 0088	Oilseed (except peanut and cotton)	1.5		0.09	
	AL 0072	Pea hay or Pea fodder (dry) (dry weight)	40		11	17
	VP 0063	Peas (pods and succulent = immature seeds)	2		0.65	0.74
	VP 0064	Peas, Shelled (succulent seeds)	0.09		0.03	0.04
	SO 0697	Peanut	0.01		0.01	
	VD 0072	Peas (dry)	0.4		0.04	
	HS 0444	Peppers Chili, dried	6		0.70	4.4
	FP 0009	Pome fruits	0.9		0.30	0.47
	VR 0589	Potato	0.03		0.01	0.02
	PM 0110	Poultry meat	0.02		0.02 (meat)	0.024 (meat)
	PM 0111	Poultry fats	0.05		0.021 (fat)	0.050 (fat)
	PO 0111	Poultry, Edible offal of	0.02		0.021	0.034
	DF 0014	Prunes	5		1.2	2.7
	GC 0650	Rye	0.3		0.085	
	AS 0650	Rye straw and fodder, Dry	30		4.1 dw	18
	VD 0541	Soya bean (dry)	0.15		0.01	
	AB 0541	Soya bean hulls	0.3		0.012	0.15
	VP 0541	Soya bean (immature seeds)	0.5		0.01	0.37
	AL 0541	Soya bean fodder (dry weight)	30		7.58	19.9
	VP 0546	Soya bean (young pod)	1.5		0.24	0.74
	FS 0012	Stone fruits	2		0.525	2.3
	VR 0596	Sugar beet	0.15		0.04	0.06
	VO 0447	Sweet corn (corn-on-the-cob)	0.15		0.01	0.08
	GC 0653	Triticale	0.3		0.085	
	AS 0653	Triticale straw and fodder, Dry	30		4.1dw	18
	GC 0654	Wheat	0.3		0.085	
	CM 0654	Wheat bran	1		0.25	0.61
	AS 0654	Wheat straw and fodder, Dry	30		4.1dw	18
	CF 1210	Wheat germ			0.10	0.26

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

Definition of the residue (for estimation of dietary intake for plant commodities): *Sum of fluxapyroxad and 3-(difluoromethyl)- N-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide (M700F008) and 3-(difluoromethyl)-*

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
<i>1-(β-D-glucopyranosyl)-N-(3',4',5'-trifluorobipheny-2-yl)-1H-pyrazole-4-carboxamide (M700F048) and expressed as parent equivalents</i>						
Definition of the residue (for estimation of dietary intake for animal commodities): <i>Sum of fluxapyroxad and 3-(difluoromethyl)-N-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide (M700F008) expressed as parent equivalents</i>						
<i>The residue is fat soluble</i>						
Glufosinate ammonium (175)	AM 0660	Almond hulls	W	0.5		
ADI: 0-0.01 mg/kg bw	VS 0621	Asparagus	0.4	0.05 (*)	0.05	0.27
ARfD: 0.01 mg/kg bw	FI 0030	Assorted tropical and sub-tropical fruits - inedible peel (except banana)	W	0.05 (*)		
	FI 0030	Assorted tropical and sub-tropical fruits - inedible peel (except banana and kiwifruit)	0.1		0.05	0.05
	FT0026	Assorted tropical and sub-tropical fruits - edible peel	0.1		0.05	0.05
	FI 0327	Banana	0.2	0.2	0.05	0.13
	AL 0061	Bean fodder	1		0.075 fw	0.63 fw
	FB 0018	Berries and other small fruits (except currants)	W	0.1	0.03	
	FB 0020	Blueberries	0.1		0.05	0.06
	VD 0523	Broad bean (dry)	W	2		
	VR 0577	Carrot	0.05	0.05 *	0.05	0.05
	FC 0001	Citrus fruits	0.05	0.1	0.05	0.05
	VD 0526	Common bean (dry)	0.05	2	0.04	
	SB 0716	Coffee beans	0.1		0.04	
	VP 0526	Common bean (pods and/or immature seeds)	0.05 *	0.05 *	0.05	0.05
	VL 0470	Corn salad	0.05	0.05 *	0.05	0.05
	SO 0691	Cotton seed	5		0.705	
	FB 0021	Currants, Black, Red, White	1	0.5	0.02	0.48
	MO 0105	Edible offal (mammalian)	3	0.1 *	0.21 K 0.65 L	0.57 K 1.89 L
	PE 0112	Eggs	0.05 *	0.05 *	0	0.02
	FB 0268	Gooseberry	0.1		0.02	0.02
	FB 0269	Grapes	0.15		0.02	0.12
	FI 0341	Kiwifruit	0.6		0.05	0.37
	VL 0482	Lettuce, Head	0.4		0.05	0.29
	VL 0483	Lettuce, Leaf	0.4		0.05	0.29
	GC 0645	Maize	0.1	0.1	0.05	
	AS 0645	Maize fodder (dry)	8	10	0.78 fw	5.3fw
	AF 0645	Maize forage	W	5	0.66 fw	1.6 fw
	MM 0095	Meat (from mammals other than marine mammals)	0.05	0.05 *	0.026 M 0.028 F	0.05 M 0.062 F
	ML 0106	Milks	0.02 *	0.02 *	0.01	0.02
	FT 0305	Olives	0.1		0.05	0.05
	VA 0385	Onion, Bulb	0.05	0.05	0.05	0.05
	VD 0072	Peas (dry)	W	3		
	FP 0009	Pome fruits	0.1	0.05 *	0.05	0.08
	VR 0589	Potato	0.1	0.5	0.05	0.05
	PM 0110	Poultry meat	0.05 *	0.05 *	0	0.02
	PO 0111	Poultry, Edible offal of	0.1 *	0.1 *	0	0.04
	DF 0014	Prunes	0.3		0.09	
	SO 0495	Rape seed	1.5	5	0.225	
	OC 0495	Rape seed oil, Crude	0.05 *	0.05 *		
	FB 0272	Raspberries, Red, Black	0.1		0.03	0.03
	GC 0349	Rice	0.9		0.09	

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or	HR or
			New	Previous	STMR-P mg/kg	HR-P mg/kg
	AS 0649	Rice straw and fodder, dry	2		0.26 fw	1.3 fw
	VD 0541	Soya bean (dry)	3	2	0.825	
	FS 0012	Stone fruits	0.15	0.05 *	0.05	0.08
	FB 0275	Strawberry	0.3		0.02	0.15
	VR 0596	Sugar beet	1.5	0.05 *	0.28	
	DM 0596	Sugar beet molasses	8		1.24	
	SO 0702	Sunflower seed	3	5	0.53	
	OC 0702	Sunflower seed oil, crude	0.05 *	0.05 *		
	TN 0085	Tree nuts	0.1	0.1	0.05	0.05
<p>Definition of the residue for compliance with MRL and estimation of dietary intake (for animal and plant commodities): <i>sum of glufosinate, 3-[hydroxy(methyl)phosphinoyl]propionic acid (MPP) and N-acetyl-glufosinate (NAG), calculated as glufosinate (free acid)</i></p> <p><i>The residue is not fat soluble</i></p> <p>fw = fresh weight basis</p>						
Imidacloprid (206)	VS 0624	Celery	6		0.365	
ADI: 0-0.06 mg/kg bw	VD 0072	Peas (dry)	W	2		
ARfD: 0.4 mg/kg bw	VD 0070	Pulses (except soya beans)	2		0.62	
<p>Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: <i>Sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid.</i></p>						
Indoxacarb (216)	VL 0483	Lettuce, Leaf	3	15	0.52	1.6
ADI: 0-0.01 mg/kg bw						
ARfD: 0.1 mg/kg bw						
<p>Definition of the residue for compliance with the MRL (for animal and plant commodities) and for estimation of dietary intake for plant commodities: <i>sum of indoxacarb and its R enantiomer.</i></p> <p>Definition of the residue for estimation of dietary intake for animal commodities: <i>sum of indoxacarb, its R enantiomer and methyl 7-chloro-2,5-dihydro-2-[[[4-(trifluoromethoxy)phenyl] amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate, expressed as indoxacarb.</i></p> <p><i>The residue is fat-soluble.</i></p>						
MCPA (257)	GC 0640	Barley	0.2		0.05	
ADI: 0-0.1 mg/kg bw	AS 0640	Barley straw and fodder, Dry	50		10.5	28.9
ARfD: 0.6 mg/kg bw	PE 0112	Eggs	0.05*		0.05	0.05
	SO 0693	Flax-seed	0.01*		0	
	AS 0162	Hay or fodder (dry) of grasses	500		74.35	217
	MO 0105	Edible offal (mammalian)	3		1.33	2.20
	GC 0645	Maize	0.01*		0	
	AS 0645	Maize straw and fodder, Dry	0.3		0.25	0.25
	MF 0100	Mammalian fats	0.2		0.13	0.16
	MM 0095	Meat from mammals other than marine mammals	0.1		0.08	0.08
	ML 0106	Milks	0.04		0.013	0.035
	GC 0647	Oat	0.2		0.05	
	AF 0647	Oat straw and fodder, Dry	50		10.5	28.9
	VD 0072	Peas, dry	0.01*		0	
	PF 0111	Poultry meat	0.05*		0.05	0.05

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	PF 0110	Poultry fats	0.05*		0.05	0.05
	PO 0111	Poultry, Edible offal of	0.05*		0.05	0.05
	GC 0650	Rye	0.2		0.05	
	AF 0650	Rye straw and fodder, Dry	50		10.5	28.9
	GC 0653	Triticale	0.2		0.05	
	AS 0653	Triticale straw and fodder, Dry	50		10.5	28.9
	GC 0654	Wheat	0.2		0.05	
	AF 0654	Wheat straw and fodder, Dry	50		10.5	28.9
	CM 0654	Wheat bran			0.024	
	CF 1211	Wheat flour			0.024	
	CF 1210	Wheat germ			0.024	
Definition of the residue for compliance with the MRL for plant and animal commodities: <i>MCPA</i>						
Definition of the residue for estimation of dietary intake for plant commodities: <i>Sum of MCPA, its conjugates, esters and salts, all expressed as MCPA.</i>						
Definition of the residue for the estimation of dietary intake for animal commodities: <i>Sum of MCPA and its conjugates, expressed as MCPA.</i>						
Methoxyfenozone (209)	FC 0001	Citrus fruits	2	0.7	0.28	1.7
ADI: 0-0.1 mg/kg bw	VC 0045	Fruiting vegetable, cucurbits, except watermelon	0.3		0.091	0.15
ARfD: 0.9 mg/kg bw	VA 0389	Spring Onion	6		0.48	2.8
	VP 0526	Common bean (pods and/or immature seeds)		2	0.065	0.99
	VP 0063	Peas (pods and succulent-immature seeds)	2		0.10	0.81
	VD 0072	Peas (dry)	5		0.17	
	MF 0100	Mammalian fats (except milk fats)	0.3	0.2	0.034	0.24
	MO 0105	Edible offal (mammalian)	0.2	0.1	0.025	0.096
	MM 0095	Meat (from mammals other than marine mammals)	0.3 (fat)	0.2 (fat)	0.036 (fat)	0.24 (fat)
					<0.003 (muscle)	0.0062 (muscle)
	AB 0001	Citrus pulp, Dry			0.31	
	JF 0001	Citrus juice			0.062	
	OR 0001	Citrus oil, Edible			12	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: <i>methoxyfenozone</i>						
<i>The residue is fat-soluble, but is not classified as fat-soluble with respect to its distribution in milk.</i>						
Penthiopyrad (253)	AL 1020	Alfalfa, fodder	20 (DM)	-	2.9 (fresh weight basis)	16 (fresh weight basis)
ADI: 0-0.1 mg/kg bw	AM 0660	Almond hulls	6 (DM)	-	2.4 (fresh weight basis)	
ARfD: 1 mg/kg bw	GC 0640	Barley	0.15	-	0.02	-

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	AS 0640	Barley, straw and fodder	80 (DM)	-	21 (fresh weight basis)	54 (fresh weight basis)
	VP 0061	Beans, except broad bean and soya bean (green pods and immature seeds)	3	-	0.9	1.6
	VP 0062	Beans, Shelled	0.3	-	0.0685	0.16
	VB 0041	Cabbages, Head	4	-	0.4	2.4
	VR 0577	Carrots	0.6	-	0.09	0.41
	VX 0624	Celery	15	-	3.1	8.8
		Cotton gin trash	20 (DM)	-	4.55	-
	SO 0691	Cotton seed	0.5	-	0.17	-
	HS 0444	Peppers Chili, dried	14	-	See fruiting vegetables, other cucurbits, except sweet corn and mushroom	See fruiting vegetables, other cucurbits, except sweet corn and mushroom
	PE 0112	Eggs	0.03	-	0.02	0.023
	VB 0042	Flowerhead brassicas (includes Broccoli: Broccoli, Chinese and Cauliflower)	5	-	1.4	2.4
	VC 0045	Fruiting vegetables, Cucurbits	0.5	-	Edible peel: 0.13 in-edible peel: 0.01	Edible peel: 0.3 in-edible peel: 0.01
	VO 0050	Fruiting vegetables, other than cucurbits, except sweet corn and mushroom	2	-	0.27	1.6
	VL 0053	Leafy vegetables, except brassica leafy vegetables	30	-	3.15	15
	GC 0645	Maize	0.01	-	0.01	-
	AS 0645	Maize fodder (dry)	10 (DM)	-	0.52 (fresh weight basis)	5.9 (fresh weight basis)
	CF 1255	Maize flour	0.05	-	0.014	-
	OC 0645	Maize oil, Crude	0.15	-	0.027	-
	GC 0646	Millet (Including Barnyard Millet, Bulrush Millet, Common Millet, Finger Millet, Foxtail Millet, Little Millet)	0.8	-	0.22	-
	AS 0646	Millet fodder, dry	10 (DM)	-	0.52 (fresh weight basis)	5.9 (fresh weight basis)
	VL 0485	Mustard greens	50 ^a	-	11	30
	GC 0647	Oats	0.15	-	0.02	-
	AS 0647	Oats, straw and fodder, Dry	80 (DM)	-	21 (fresh weight basis)	54 (fresh weight basis)
	VA 0385	Onion, Bulb	0.7	-	0.074	0.72
	VA 0387	Onion, Welsh	4	-	0.89	2.0
	AL 0072	Pea hay or pea fodder (dry)	60 (DM)	-	12 (fresh weight basis)	31 (fresh weight basis)
	SO 0697	Peanut	0.05	-	0.01	-
	OR 0697	Peanut oil, Edible	0.5	-	0.04	-
	AL 0697	Peanut fodder	30 (DM)	-	5.9 (fresh weight basis)	18 (fresh weight basis)
	VP 0063	Peas (pods and succulent=immature seeds)	3	-	0.9	1.6

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	VP 0064	Peas, Shelled (succulent seeds)	0.3	-	0.0685	0.16
	FP 0009	Pome fruits	0.4	-	0.15	0.27
	VR 0589	Potato	0.05	-	0.01	0.051
	PO 0111	Poultry, Edible offal of	0.03	-	0.02	0.023
	PF 0111	Poultry Fats	0.03	-	0.02	0.023
	PM 0110	Poultry meat	0.03	-	0.02	0.021
	VD 0070	Pulses, except soya beans	0.3	-	0.01	-
	VR 0494	Radish	3	-	0.305	1.2
	SO 0495	Rape seed	0.5	-	0.084	-
	OC 0495	Rape seed oil, Crude	1	-	-	-
	OR 0495	Rape seed oil, Edible	1	-	0.11	-
	GC 0650	Rye	0.04	-	0.01	-
	AS 0650	Rye, straw and fodder, Dry	80 (DM)	-	21 (fresh weight basis)	54 (fresh weight basis)
	GC 0651	Sorghum	0.8	-	0.22	-
	AS 0651	Sorghum, straw and fodder, Dry	10 (DM)	-	0.52 (fresh weight basis)	5.9 (fresh weight basis)
	VD 0054	Soya bean, dry	0.3	-	0.032	-
	AL 0541	Soya bean fodder	200 (DM)	-	52.5 (fresh weight basis)	125 (fresh weight basis)
	VA 0389	Spring Onion	4	-	0.89	2.0
	FS 0012	Stone fruits	4	-	1.3	1.9
	FB 0275	Strawberry	3	-	0.8	1.8
	VR 0596	Sugar beet	0.5	-	0.105	-
	SO 0702	Sunflower seed	1.5	-	0.12	-
	VO 0447	Sweet corn (on the cob)	0.02	-	0.01	0.01
	TN 0085	Tree nuts	0.05	-	0.01	0.047
	GC 0653	Triticale	0.04	-	0.01	-
	AS 0653	Triticale, straw and fodder, Dry	80 (DM)	-	21 (fresh weight basis)	54 (fresh weight basis)
	VL 0506	Turnip greens	50	-	9.4	23
	GC 0654	Wheat	0.04	-	0.01	-
	CF 0654	Wheat, bran	0.1	-	0.018	-
	CF 1210	Wheat, germ	0.1	-	0.019	-
	AS 0654	Wheat, straw and fodder, Dry	80 (DM)	-	21 (fresh weight basis)	54 (fresh weight basis)
	JF 0226	Apple juice	-	-	0.021	-
	-	Barley, beer	-	-	0.002	-
	-	Peeled potato	-	-	0.003	0.017
	DF 0014	Prunes	-	-	1.8	2.7
	OR 0541	Soya bean, refined oil	-	-	0.032	-
	-	Sugar beet, refined sugar	-	-	0.033	-
	JF 0048	Tomato, juice	-	-	0.092	-
	VW 0448	Tomato, paste	-	-	0.92	-
	-	Tomato, puree	-	-	0.54	-
	CF 1211	Wheat, flour	-	-	0.004	-

Definition of the residue for compliance with MRL for plant commodities: *penhiopyrad*

Definition of the residue for compliance with MRL for animal commodities and for the estimation of dietary intake for plant and animal commodities: *sum of penhiopyrad and 1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide (PAM), expressed as penhiopyrad*

The residue is not fat-soluble.

^a On the basis of information provided to the JMPR it was not possible to conclude from the estimate of short-term intake for

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
Penthiopyrad that the consumption of mustard greens was less than the ARfD.						
Phorate (112) ADI: 0-0.0007 mg/kg bw ARfD: 0.003 mg/kg bw	VR 0589	Potato	0.3	0.5	0.048	0.17
		Potato crisps			0.0034	
		Potato granules			0.12	
		Peeled potatoes			0.013	0.045
		Potatoes boiled with peel			0.006	0.022
		Potatoes boiled without peel			0.005	0.019
		Potatoes baked with peel			0.013	0.048
		Potatoes baked without peel			0.013	0.046
		French fries			0.018	
		Potatoes microwaved with peel			0.017	0.061
Definition of the residue for compliance with the MRL and for dietary risk assessment for plant and animal commodities: <i>sum of the parent, its oxygen analogue, and their sulfoxides and sulfones, expressed as phorate.</i> <i>The residue is not fat soluble.</i>						
Picoxystrobin (258) ADI: 0-0.09 mg/kg bw ARfD: 0.09 mg/kg bw						
Definition of the residue for compliance with the maximum residue levels for animal and plant commodities: <i>picoxystrobin.</i> Definition of the residue (for estimation of dietary intake) for plant and animal commodities: <i>a conclusion could not be reached</i> <i>The residue is fat soluble</i>						
Pyraclostrobin (210) ADI: 0-0.03 mg/kg bw ARfD: 0.05 mg/kg bw	OR 0001 OR 0004	Citrus oil, edible Orange oil, edible	10 W		3.03 10	8.17
Definition of the residue (for compliance with MRL and for estimation of dietary intake) for plant and animal commodities: <i>pyraclostrobin.</i> <i>The residue is fat-soluble.</i>						
Saflufenacil (251) ADI: 0-0.05 mg/kg bw ARfD: Unnecessary	VD 0071 VD 0072 VD 0070 VD 0541	Beans (dry) Peas (dry) Pulses Soya bean (dry)	W W 0.3 W	0.3 0.05 0.07	0.01	
Definition of the residue (for compliance with MRL and for estimation of dietary intake) for plant and animal commodities: <i>saflufenacil.</i> <i>The residue is not fat-soluble</i>						
Sedaxane (259) ADI: 0-0.1 mg/kg bw ARfD: 0.3 mg/kg bw	GC 0640 AS 0640 MO 0105 MF 0100 MM 0095 ML 0106 FM 0183	Barley Barley straw and fodder, Dry Edible offal (Mammalian) Mammalian fats (except milk fat) Meat (from mammals other than marine mammals) Milks Milk fats	0.01* 0.1 0.01* 0.01* 0.01* (fat) 0.01* 0.01*		0 0.01 0 0 0	0.075

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	GC 0647	Oat	0.01*		0	
	AS 0647	Oat straw and fodder, Dry	0.1		0.01	0.075
	PF 0111	Poultry fats	0.01*		0	
	PM 0110	Poultry meat	0.01*		0	
	PO 0111	Poultry, Edible offal of	0.01*		0	
	PE 0112	Eggs	0.01*		0	
	SO 0495	Rape seed	0.01*		0	
	GC 0650	Rye	0.01*		0	
	AS 0650	Rye straw and fodder, Dry	0.1		0.01	0.075
	GC 0653	Triticale	0.01*		0	
	AS 0653	Triticale straw and fodder, Dry	0.1		0.01	0.075
	GC 0654	Wheat	0.01*		0	
	AS 0654	Wheat straw and fodder, Dry	0.1		0.01	0.075
<i>Definition of the residue for compliance with the MRL for plants and animals: sedaxane.</i>						
<i>The residue is fat soluble.</i>						
Spinetoram (233)	VP 0061	Beans, except broad bean and soya bean (green pods and immature seeds)	0.05	-	0.024	
ADI: 0-0.05 mg/kg bw	FB 0020	Blueberries	0.2	-	0.12	
ARfD: Unnecessary	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	0.3	-	0.05	
	VS 0624	Celery	6		0.30	
	PE 0112	Eggs	0.01 *	-	0.01	
	FB 0269	Grapes	0.3	-	0.074	
	FS 0245	Nectarine	0.3	-	0.055	
	VA 00385	Onion, Bulb	0.01 *	-	0.01	
	VA 0387	Onion, Welsh	0.8	-	0.33	
	FS 0247	Peach	0.3	-	0.055	
	PF 0111	Poultry fats	0.01 *	-	0.01	
	PM 0110	Poultry meat	0.01 *	-	0.01 (fat) 0.01 (muscle)	
	PO 0111	Poultry, Edible offal of	0.01 *	-	0.01	
	FB 0272	Raspberries, Red, Black	0.8	-	0.42	
	VL 0502	Spinach	8	-	1.6	
	VA 0389	Spring onion	0.8	-	0.33	
<i>Definition of the residue for compliance with MRLs: Spinetoram.</i>						
<i>Definition of the residue for estimation of dietary intake: Spinetoram and N-demethyl and N-formyl metabolites of the major spinetoram component.</i>						
<i>The residue is fat soluble.</i>						
Spirotetramat (234)	ML 0106	Milks	0.005	0.01	0.005	0.005
ADI: 0-0.05 mg/kg bw						
ARfD: 1.0 mg/kg bw						
<i>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.</i>						
<i>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]decane-2-one, and enol glucoside metabolite glucoside of 3-(2,5-dimethylphenyl)-4-hydroxy-8-</i>						

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
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.						
Trifloxystrobin (213)	VS 0621	Asparagus	0.05*		0	
ADI: 0-0.04 mg/kg bw	VO 0440	Egg plant	0.7		0.08	
ARfD: Unnecessary	VL 0482	Lettuce, head	15		5.55	
	FT 0305	Olives	0.3		0.085	
	OC 0305	Olive oil, crude	0.9		0.255	
	OR 0305	Olive oil, refined	1.2		0.353	
	FI 0350	Papaya	0.6		0.2	
	VL 0494	Radish leaves	15		1.4	
	VR 0494	Radish	0.08		0.065	
	FB 0275	Strawberry	1	0.2	0.335	
		Strawberry, canned			0.097	
		Strawberry jam			0.194	
Definition of the residue for compliance with MRLs for plant commodities: <i>trifloxystrobin</i> ;						
Definition of the residue for estimation of dietary intake of plant commodities: <i>sum of trifloxystrobin and [(E,E)-methoxyimino-{2-[1-(3-trifluoromethylphenyl)ethylideneaminoxymethyl]phenyl}acetic acid] (CGA 321113), expressed as trifloxystrobin.</i>						
Definition of the residue for compliance with MRLs and estimation of dietary intake in animal commodities: <i>sum of trifloxystrobin and [(E,E)-methoxyimino-{2-[1-(3-trifluoromethylphenyl)ethylideneamino-oxymethyl]phenyl}acetic acid] (CGA 321113), expressed as trifloxystrobin.</i>						
<i>The residue is fat-soluble.</i>						

Edited versions of these general considerations will be published in the report of the 2012 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 ACETAMIPRID (246)

Background

The CCPR at its 44th Session (2012) noted the concerns expressed by the Delegation of the EU regarding the acetamiprid acute dietary risk assessment for scarole based on the ARfD established by JMPR and using the European diet.

The Committee advanced the draft MRL for leafy vegetables (except spinach) to Step 5, noting the reservation of the Delegation of the EU; returned the draft MRL for spinach to Step 4 awaiting clarification of the spinach consumption data.

Evaluation of acetamiprid by JMPR

Acetamiprid is a neo-nicotinoid insecticide considered for the first time by the 2010 JMPR, where an ADI of 0-0.07 mg/kg bw/day and an ARfD of 0.1 mg/kg bw/day were established and maximum residue levels were recommended for a range of commodities, including leafy vegetables.

Based on residue information on head lettuce, leaf lettuce, spinach and mustard greens, the 2010 JMPR recommended group maximum residue level of 3 mg/kg for leafy vegetables except spinach (HR of 1.9 mg/kg) and a separate maximum residue level of 5 mg/kg for spinach (HR of 2.5 mg/kg), noting however that for spinach, the IESTI that exceeded the ARfD by 180%.

For all other commodities considered by the JMPR for which consumption data were available, the IESTI represented 0-80 % of the ARfD and when used in ways that have been considered by the JMPR acetamiprid is unlikely to present a public health concern.

Evaluation of acetamiprid by the EC

The present meeting received a concern form relating to the proposed maximum residue level for leafy vegetables (except spinach), together with the results of their dietary intake calculation.

Based on their risk assessment using the 0.1 mg/kg ARfD established by JMPR and using the highest reported consumption and unit body-weight information reported by EU member states (EFSA PRIMo rev 2 risk assessment model), the EU concern is that the exposure related to the CXL proposal for scarole accounts for up to 166% of the ARfD.

Comments by JMPR

The 2010 JMPR acute dietary intake estimate for acetamiprid was conducted with the best available consumption data and unit body-weight information available to the Meeting at the time and did not include the information on scarole (as provided to EFSA by EU member states).

The Meeting noted the advice to CCPR that EU member states would be invited to submit their food consumption data to JMPR as soon as possible, and looks forward to receiving this new information.

With respect to the decision by CCPR to retain the proposed spinach maximum residue level at Step 4 awaiting clarification of the spinach consumption data, the most recent version of the data base of

consumption data and unit body-weight information used by the current Meeting includes revised information on a number of commodities, including spinach.

The Meeting therefore reassessed the acute intake estimate for acetamiprid on leafy vegetables (including spinach) using the new data, and concluded that for spinach and endive, the IESTI exceeded the ARfD by 110% (for children) and for lettuce, leaf and Chinese cabbages (raw pak-choi and pe-tsai) the IESTI for children exceeded the ARfD by 120%. For all other leafy vegetables for which information was available, the IESTI did not exceed the ARfD for any populations.

The Meeting agreed to revised the previous recommendation for acetamiprid for leafy vegetables (except spinach) by revising the existing footnote relating the ARfD exceedance for spinach to include pak-choi and pe-tsai cabbages and leaf lettuce, i.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 for children, the consumption of lettuce, leaf; Chinese cabbage, type pak-choi; Chinese cabbage, type pe-tsai; spinach and endive was less than the ARfD".

The Meeting noted the conclusions of the 2007 JMPR, that IESTI estimates above 100% of the ARfD should not necessarily be interpreted as giving rise to a health concern because of the conservatism in the derivation of the ARfD and in the estimation of intake. For example, a safety factor for inter-individual variation is included when the ARfD is established, and as such the ARfD is designed to protect those individuals at the upper-end of human susceptibility.

The Meeting confirmed the view that in cases where the ARfD is exceeded, additional considerations should be taken into account, e.g., the amount by which the ARfD is exceeded, the basis on which the ARfD has been established, likely conservatism and possible consequences, and the uncertainties in the estimate of intake.

1.2 CHLORPYRIFOS-METHYL (090)

Chlorpyrifos-methyl was last evaluated for residues by the 2009 JMPR under the periodic review program, when recommendations were made for various commodities, including wheat, barley and maize, post harvest. This recommendation was based on trials conducted on barley and wheat according to Spanish GAP for post-harvest use on wheat, barley and maize. Long-term dietary risk assessment for the compound indicated an exceedance of up to 140% of the ADI, with maize accounting for about 73 % of the IEDI.

At the 42nd session, the CCPR agreed to return the draft MRL for the cereal grains at Step 7 to Step 6 awaiting the review of alternative GAP by the 2012 JMPR. Additionally, CXLs for cattle fat; cattle meat; cattle, edible offal of; chicken fat; chicken meat and chicken, edible offal of were retained (ALINORM 10/33/24; par 36).

The current Meeting received a new Spanish label indicating that the post-harvest use of chlorpyrifos-methyl is no longer recommended on maize. The Meeting withdraw its previous recommendations of a maximum residue level of 3 mg/kg for chlorpyrifos-methyl on maize, post harvest. No trials were submitted to this or previous meetings that support an estimation of a maximum residue level for maize based on pre-harvest use.

Long-term dietary risk assessment

The ADI for chlorpyrifos-methyl is 0-0.01 mg/kg bw. The International Estimated Daily Intakes (IEDI) for chlorpyrifos-methyl was estimated for the 13 GEMS/Food cluster diets using the STMR or STMR-P values estimated by the previous JMPR, excluding maize (including flour, oil and beer). The results are shown in Annex 3. The IEDI ranged from 3-60 % of the maximum ADI. The Meeting concluded that the long-term intake of residues of chlorpyrifos-methyl from uses that have been considered by the JMPR is unlikely to present a public health concern.

1.3 DICAMBA (240)

Background

Dicamba was first evaluated by the 2010 JMPR and estimated maximum residue levels for 21 commodities which were adopted as Codex MRLs at the Codex Alimentarius Commission in 2011. The 2011 JMPR evaluated the results of supervised residue trials conducted on soya beans in the USA in 1994 and 1994. As the pre-harvest application rate in the trials was twice as much as the maximum GAP rate in the USA, the 2011 JMPR agreed to apply the proportionality approach to estimate a maximum residue level for soya bean (dry) at 5 mg/kg.

At the 44th Session, the CCPR advanced the proposed draft MRL for soya bean (dry) to Step 5 only due to concern of the EU on the use of proportionality concept. Subsequently, the Meeting received a concern form from the EU asking for clarification of scientific basis for estimating a maximum residue level by using the proportionality approach, in particular in relation to potential influence of pre-plant application to the final residues.

Comments by JMPR

The 2011 JMPR evaluated the results of 23 supervised residue trials with pre-plant application of 0.56 kg ai/ha 14 days before planting and pre-harvest foliar application of 2.24 kg ai/ha as harvest-aid 7 days before harvest. The pre-harvest application rate in the trials was twice as much as the maximum GAP rate on the new label in the USA (1.12 kg ai/ha applied 7 days prior to harvest).

In the same 23 trials mentioned above, forage and hay samples were taken before pre-harvest application in order to avoid abscission, i.e, after only pre-plant application at 0.56 kg ai/ha. Residues in those samples were mostly <0.01 mg/kg (in 21 trials including 4 trials using two pre-plant applications). In other two trials, quantifiable dicamba was found in forage taken 52 days after pre-plant application at 0.05 and 0.07 mg/kg. Residues of dicamba in hay 88 or 114 days after pre-plant application in these two trials as well as hay from other trials were all <0.01 mg/kg. Soya beans are not mature around 50-60 days after pre-plant application conducted 14 days before planting. And therefore, further decline may occur by the time of pre-harvest application and in general no or negligible residue of dicamba is expected to be found in leaves or seeds at the time of pre-harvest application.

The Meeting therefore confirmed that, since the contribution of pre-plant application is negligible in this case, it was appropriate to use the proportionality approach.

1.4 DIFLUBENZURON (130)

At the 44th Meeting of the CCPR, the EU raised concerns that the likely outcome of the on-going EU evaluation of diflubenzuron was “that certain metabolites will be classified as carcinogenic and/or genotoxic”. The EU requested that JMPR assess the potential formation of metabolites / degradation products during processing of commodities treated with diflubenzuron and consider consumer exposures to such substances.

JMPR noted that since its last toxicological evaluation in 2001 new data had become available on diflubenzuron and its metabolites; in particular genotoxicity data on the metabolite 4-chloroaniline (PCA) and in vitro metabolism data on diflubenzuron. Evaluation of these new data could be critical to the JMPR response to the EU concern form. The Meeting requested that the EU submit the new data and the final report of the EU evaluation, for consideration at a future Joint Meeting.

1.5 INDOXACARB (216)

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 bw and an ARfD of 0.1 mg/kg body weight were established by the 2005 JMPR.

The 2005 Meeting estimated maximum residue levels for a range of commodities, including one of 15 mg/kg for lettuce, leaf but was not able to calculate the IESTI 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 lettuce, leaf 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.

New consumption and unit weight data became available to the 2009 JMPR, including information on leaf lettuce. The 2009 Meeting calculated the IESTIs for leaf lettuce (60% of the ARfD for the general population and 150% of the ARfD for children); noted that there were limited opportunities to refine the consumption estimate or the dietary intake risk estimate and that there was no alternative GAP available.

In response to a request from the 40th CCPR, the 2011 JMPR conducted an alternative GAP evaluation for leaf lettuce, based on new GAP information and concluded that the existing supervised residue trials data evaluated by the 2005 JMPR were insufficient to recommend a maximum residue level to support an alternative GAP for indoxacarb on leafy lettuce.

The 44th CCPR requested JMPR to conduct a new alternative GAP evaluation based on information to be provided.

The Meeting received confirmation that the current GAP in Spain for indoxacarb on lettuce (both head and leaf lettuce) was consistent with that considered by the 2011 JMPR and that while there are no additional residue trials available, the existing data on leaf lettuce

and head lettuce, when combined, were considered sufficient for the EC to support an MRL for lettuce (i.e. head lettuce, lollo rosso (cutting lettuce), iceberg lettuce and romaine (cos) lettuce) with extrapolation to scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curled leaf endive, sugar loaf).

Lettuce – Alternative GAP Re-assessment

The Meeting re-evaluated the existing lettuce residue data reported by the 2005 JMPR. In trials from Southern Europe matching the GAP in Spain (0.038 kg ai/ha, 300-700 litres spray mix/ha, 1-day PHI), indoxacarb residues in 7 trials identified as 'head lettuce' were: 0.16, 0.19, 0.25, 0.39, 0.52, 0.55 and 0.88 mg/kg and residues in 3 trials identified as 'leaf lettuce' were: 0.52, 0.86 and 1.6 mg/kg.

Noting that these two data sets were similar (Mann-Whitney U test) and because of the wide range of different lettuce types (crisphead/iceberg, cos/romaine, butterhead, bunching, cutting, loose leaf) available in the market place, the Meeting agreed that the data sets should be combined to give a better representation of the distribution of residues expected in the range of lettuce types in the marketplace.

The combined data set for lettuce (including leaf lettuce) matching the GAP in Spain is: 0.16, 0.19, 0.25, 0.39, 0.52, 0.52, 0.55, 0.86, 0.88 and 1.6 mg/kg (n=10).

The Meeting estimated a maximum residue level of 3 mg/kg, an STMR of 0.52 mg/kg and an HR of 1.6 mg/kg for indoxacarb on lettuce, leaf and agreed to withdraw the previous recommended maximum residue level of 15 mg/kg for indoxacarb on lettuce, leaf.

The Meeting noted that based on the new food consumption and unit weight data used by 2012 JMPR, the leaf lettuce IESTI for the general population was up to 30% of the ARfD for the general population and up to 100% for children aged 1-6 years.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI assessment.

Definition of the residue (for compliance with the MRL for all commodities and for estimation of dietary intake for plant commodities): sum of indoxacarb and its R enantiomer. The residue is fat soluble.

Definition of the residue (for estimation of dietary intake for animal commodities): sum of indoxacarb, its R enantiomer and methyl 7-chloro-2,5-dihydro-2-[[[4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate, expressed as indoxacarb.

Summary of recommendations

CCN	Commodity	MRL (mg/kg)		STMR or	HR or
	Name	New	Prev	STMR-P	HR-P
FI 0327	Lettuce, leaf	3 ^(a)	15	0.52	1.6

(a) On the basis of the information provided to the JMPR it was not possible to conclude that for children, the estimate of short-term intake for indoxacarb from the consumption of lettuce, leaf was less than the ARfD.

1.6 ISOPYRAZAM (249)

At the 44th Meeting of the CCPR, the EU raised concerns that the ADI and ARfD established in their evaluation of isopyrazam differed from those established by the JMPR in 2011. The ARfD established by the EU of 0.2 mg/kg bw was based on a maternal NOAEL of 20 mg/kg bw per day for reduced maternal body weight observed during the first days of dosing in a developmental toxicity study in the rat with a safety factor of 100. The ADI established by the EU of 0.03 mg/kg bw was based on the same study as used by the JMPR, but on a different endpoint, for which effects were seen at the lowest dose tested. As a consequence, a higher safety factor (200) was used.

JMPR established an acute reference dose (ARfD) of 0.3 mg/kg bw on the basis of nonspecific clinical signs of toxicity (weak appearance and decreased activity), in an acute neurotoxicity study in the rat. A NOAEL of 30 mg/kg bw was identified for this effect. On this basis, and in view of the nature of the effects, a safety factor of 100 was used. In a rat developmental toxicity study, the NOAEL of 20 mg/kg bw per day for maternal toxicity was based on reduced body weight gain in dams from day 4 of treatment, accompanied by a reduction in food consumption. In view of the magnitude and nature of this effect, the Meeting did not consider that this was an appropriate basis on which to establish an ARfD. The ARfD established by JMPR would be protective of the decreased body weight gain observed in dams at day 4.

JMPR established an acceptable daily intake (ADI) for isopyrazam of 0-0.06 mg/kg bw on the basis of decreased body weight gain in females and increased incidences of foci of eosinophilic hepatocytes and clinical chemistry changes (triglycerides, bilirubin) of equivocal toxicological significance in both sexes, in a 104-week study in rats. A clear NOAEL of 5.5 mg/kg bw per day was identified for these effects. On this basis, and in view of the nature of the effects, a safety factor of 100 was used. Changes in liver (hepatocellular pigmentation in females, hepatocellular hypertrophy in both sexes) observed at 5.5 mg/kg bw per day were considered by the Meeting to be of minimal severity and/or adaptive and thus of no toxicological significance (JMPR, 2006).

1.7 OXAMYL (126)

Oxamyl was evaluated for residues and toxicology by the JMPR in 2002 under the periodic review programme, where a residue definition was established as the sum of oxamyl and oxamyl oxime, expressed as oxamyl (for both animal and plant commodities) for compliance and for dietary risk assessment. However the 2002 Meeting noted that for dietary

intake estimation, this definition could result in an overestimate of the dietary intake risk because the only residue of toxicological concern was the parent compound (oxamyl).

The 2002 JMPR established an ADI of 0-0.009 mg/kg bw/day and an ARfD of 0.009 mg/kg bw/day and concluded for apple, cucumber, grapefruit, lemon, mandarin, melons, oranges, peppers and tomato the estimated short-term intakes exceeded the ARfD.

At the request of the 39th Session of the CCPR in 2007, information on current and proposed GAPs, analytical methods and additional supervised trials data were submitted to the 2008 JMPR for an Alternative GAP evaluation for citrus fruits (orange and mandarin), cucurbits (cucumbers, courgettes, melons), peppers and tomatoes but the analytical method used in these trials reported residues of the parent compound only, and did not address the current residue definition (i.e. sum of oxamyl and oxamyl-oxime).

Although bridging studies were provided to support the extrapolation of the oxamyl results reported in the new supervised field trials to total oxamyl residues (this being the residue definition for MRL compliance), the 2008 JMPR concluded that there was insufficient data to support alternative GAP assessments for these commodities as the new data were residues of the parent compound only while the current residue definition included the oxime metabolite.

The CCPR at its 41st Session agreed to retain all CXLs and draft MRLs at step 7 awaiting a review of the residue definition and analytical methods by JMPR in 2012.

The current Meeting noted that the supervised field trials provided to the 2008 JMPR reported residues of oxamyl (i.e. parent only) following the use of oxamyl as a drip irrigation treatment on citrus (orange and mandarin) and on cucumbers, summer squash (courgettes), melons, peppers and tomatoes grown under cover and that these trials matched the 2008 GAPs in Spain and/or Greece. If the residue definition were to be changed to 'parent only', the existing data may be sufficient to support revised maximum residue levels for these commodities and the previous maximum residue levels recommended by the 2008 JMPR for these commodities (with acute intake concerns) could be replaced.

However the Meeting also noted that for CXLs for carrots, cotton seed, peanuts and potatoes, the supervised field trials conducted in USA and provided to the 2002 JMPR (to support the periodic review) only reported the combined residues of oxamyl plus oxamyl-oxime. If the residue definition were to be revised to 'parent only', the maximum residue levels recommended by the 2002 JMPR for these commodities would need to be withdrawn unless new residue data were available reporting 'parent only' residues.

The Meeting agreed that it was not appropriate to revise the existing residue definition until oxamyl is reconsidered under the periodic review programme or unless new GAP information and supporting data on carrots, cottonseed, peanuts and potatoes become available.

1.8 PYRACLOSTROBIN (210)

Background

Pyraclostrobin was first evaluated by JMPR in 2003 when an ADI of 0-0.03mg/kg bw and an ARfD of 0.05 mg/kg bw were established, and subsequently evaluated in 2004, 2006 and 2011 for the estimation of a number of maximum residue levels. At the Forty-fourth Session of the Codex Committee on Pesticide Residues (CCPR), concern was raised by CCPR requesting JMPR to re-evaluate the orange processing studies to see if the data support an MRL for citrus oil.

Comments by JMPR

The 2011 Meeting received trials conducted on grapefruits, lemon, mandarin and orange, and recommended an MRL 2012 of 2 mg/kg for pyraclostrobin in citrus group. Based on a processing study on orange, 2011 JMPR estimated a maximum residue level of 10 mg/kg for pyraclostrobin in orange oil. The 2012 JMPR agreed to extrapolate from orange oil to citrus oil, and estimated a maximum residue level of 10 mg/kg in citrus oil to replace the previous recommendation of 10 mg/kg in orange oil.

1.9 SAFLUFENACIL (251)

The 44th session of CCPR requested the JMPR to consider the possibility of estimating maximum residue level for saflufenacil residues in lentils.

The Meeting recalled the relevant GAP information and results of supervised trials evaluated by the 2011 JMPR, which reported that following the late season (desiccation) applications in USA according to GAP, the residues (mean of replicate samples) of parent saflufenacil were: *bean, dry* <0.01 (5), 0.01, 0.045, 0.096, 0.136, and 0.155 mg/kg. The maximum residue detected in an individual sample was 0.23 mg/kg; *pea, dry*: < 0.01 (3), 0.01, 0.02, and 0.03 mg/kg; soya bean, dry: <0.01 (14), 0.01 (2) 0.015 (2), 0.02, 0.05 mg/kg.

Conclusion:

The GAP in Canada and USA for desiccation of pulses permits the same maximum (0.05 kg ai/ha) dose with 3 and 2 days of PHI. The results of numerous trials conducted in USA indicated that the magnitude of residues of saflufenacil in pulses 2-3 days after treatment were similar. It was confirmed with Kruskal-Wallis test (P=0.277) indicating that the residue data sets in dry beans, peas and soya beans were not significantly different.

The Meeting decided to estimate a group maximum residue level for pulses.

Based on the combined residue data (<0.01 (22), 0.01 (4) 0.015 (2), 0.02 (2), 0.03, 0.045, 0.05, 0.096, 0.136, and 0.155 mg/kg) and taking into account the 0.23 mg/kg residue found in a bean sample, the Meeting estimated a maximum residue level of 0.3 mg/kg, and STMR of 0.01 mg/kg for pulses.

The Meeting withdrew its previous recommendations of 0.3 mg/kg for dried beans, 0.05 mg/kg for dried peas and 0.07 mg/kg for dried soybeans.

The change of recommendations does not affect the estimated long term intake of 0.1% of maximum ADI.

1.10 SPIROTETRAMAT (234)

The 44th CCPR noted the maximum residue level recommended by the 2011 JMPR for milk of 0.01 mg/kg was above the limit of analytical quantification (LOQ) of 0.005 mg/kg reported by the 2008 JMPR, even though the estimated residues were below 0.005 mg/kg, and questioned the proposal. The current Meeting re-considered the evaluation by the 2011 JMPR and acknowledged that residues in milk at the livestock dietary burden used to estimate the maximum residue level are expected to be below the LOQ. However, the Meeting also noted that finite residues occurred at the LOQ of 0.005 mg/kg in milk of cattle fed at a level slightly above the calculated maximum dietary burden for dairy cattle.

The current Meeting recommended a maximum residue level for milk of 0.005 mg/kg to replace its previous recommendation of 0.01 mg/kg.

2.1 Further considerations on “compounds no longer supported by the original sponsor”

The most usual reason for referring an item to the JMPR agenda is to obtain recommendations for MRLs for plant protection products, for consideration by CCPR. These would normally be products in commerce, with a commercial sponsor (i.e. an agrochemical company) that would be expected to generate and provide the appropriate data for consideration of the establishment of health-based guidance values and MRLs.

There may be a need for use of plant protection products no longer under patent and produced by generics companies or other manufacturers, with no support from the companies that generated the original data. Sometimes, older active ingredients have changed sponsor through merger or acquisition of companies on numerous occasions. As a consequence, the raw data generated many years ago for original registration, according to now-outdated protocols and standards, may not be available or may be only partially available and of limited utility for a modern evaluation. Nevertheless, JMPR may be asked, in the context of the periodic re-evaluations by CCPR, to consider such active ingredients for recommendations of MRLs. Recent examples include dicofol, dichlorvos, propylene oxide and fenvalerate.

In formulating the problem to be addressed by the risk assessment, it is of paramount importance that a dialogue be maintained between JMPR (WHO and FAO secretariats) and the risk managers requesting advice. Among issues that will need to be resolved are:

Is the compound supported by the data owner?

Is the compound or one of its isomers registered, reviewed or likely to be registered in a country or region?

Is there sufficient information available to enable a meaningful evaluation?

What is the specific concern (duration of exposure, population exposed, source of residue in food)?

What form of advice would be most helpful to the risk manager?

If such advice cannot be provided (e.g. because of data limitations), is there alternative advice that might be of value?

In situations where the active ingredient is supported by a data owner, JMPR would expect and require all relevant study reports as described in EHC 240¹ and the FAO JMPR Manual² to be submitted for consideration and that these would be of an adequate quality. For situations where a company no longer sponsors the product (typically older active ingredients), the information available may not comprise a full data package. In these cases, in order to maintain consistency in the quality of its assessments, JMPR would adhere to the following principles:

- The requesting country should be responsible for providing information on the intended uses, specification of the technical active substance used in the country and a justification for assessment by JMPR.
- The information required would be such that it would be possible to address the key questions for the human health assessment, including establishment of an ADI and/or ARfD, when required, and the definition of residues for enforcement of MRLs and dietary risk assessment. Furthermore, data on a sufficient number of supervised trials in or on food and feed crops reflecting the current use patterns specified on the relevant labels are required for estimation of maximum residue levels and STMR and HR values. Trial data may be complemented by relevant selective survey residue data. A complete list of information required is described in the FAO JMPR Manual.
- It is the responsibility of the requesting country to provide the available data and other relevant information, such as available assessments by supranational and national authorities and publications from a recently conducted literature search.
- If literature studies are to be relied upon, JMPR will weigh such studies for their quality and design. Because raw data will not be available, there needs to be sufficient information on methods and results to enable the study findings to be reconstructed.
- If critical data are missing, then JMPR may still determine whether an assessment is possible; in such cases, however, it is likely that conservative assumptions will be used to address the missing information. For example, in the evaluation of propylene oxide in 2011, JMPR used an additional safety factor of 10 in establishing the ADI and the ARfD, because of limitations in the database.
- If sufficient information is not available to enable the establishment of health-based guidance values, JMPR may provide alternative guidance, such

¹ FAO/WHO (2004) EHC 240

² FAO Manual (2009). Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed. FAO Plant Production and Protection Paper 197.

as characterization of the margin of exposure, or may conclude that it is not possible to provide any guidance in the absence of additional information.

- The suitability of the submitted information can be assessed only on a case-by-case basis. Three examples, taken from recent JMPR evaluations, illustrate some likely situations.

Fenvalerate

Fenvalerate was re-evaluated by JMPR for toxicity and residues in 2012. One country provided access to a comprehensive data package on the toxicology of fenvalerate. Overall, the information available, including the JMPR assessment of esfenvalerate from 2002, enabled the Meeting to establish an ADI and an ARfD for fenvalerate.

The 2002 JMPR evaluation of esfenvalerate for residues was comprehensive, was based mainly on studies for fenvalerate and included all critical information on metabolism in animals and plants, animal transfer studies, etc. The evaluation in 2002 reflects current scientific knowledge, and the conclusion could be used for the re-evaluation of fenvalerate. The conduct of supervised trials and their results enabled the estimation of residue levels and calculation of dietary intake for fenvalerate.

Dicofol

Prior to its re-evaluation in 2011, dicofol was last evaluated for toxicity by JMPR in 1992. One country provided a number of original studies to JMPR, on the basis of which, together with the previous evaluation, the Meeting was able to establish an ADI and an ARfD for the compound.

In the 1994 evaluation for residues, the data presented did not contain the necessary details on the nature of plant metabolites to enable the definition of residues for risk assessment purposes. The lack of critical plant metabolism data was identified by the Meeting, and after that the required information was provided by a country. On the basis of all data, residue levels for tea could be estimated.

Dichlorvos

In the 2011 JMPR re-evaluation of dichlorvos, the data package on residues contained only limited information on plant metabolism and animal metabolism following oral administration of the compound. Furthermore, only a few supervised trials reflected the current use pattern. One country submitted additional critical information on the behaviour of residues following use according to GAP, which made possible estimation of maximum residue levels and STMR and HR values. However, the Meeting could recommend limits for only two major crops; otherwise, the upper bound of the ADI would be exceeded.

2.2 Update of the GEMS/Food cluster diets

The GEMS/Food cluster diets are based on FAO food supply data and correspond to average per capita consumption. The clustering of countries with similar dietary patterns was performed in 1997 at the request of CCPR, and the resulting 13 cluster diets are used by the JMPR to estimate long-term intake of pesticide residues.

The WHO commissioned an update of the clustering based on a more accurate statistical technique as well as on the latest available FAO data (from 2002 to 2007). The new analysis has resulted in 17 cluster diets. A project will commence in 2013 to develop an automated spreadsheet to enable the new cluster diets to be used by the JMPR within the next two years.

2.3 Update of JMPR guidance document

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

Three main components were identified, relating to process and procedures, content and format of monographs and reports, and general criteria for interpretation of toxicological data. It is anticipated that the draft guidance will be discussed at the 2013 JMPR.

2.4 Hazard assessment in the 21st century: incorporating data from new mechanistic-based approaches in JMPR evaluations

The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) is not a regulatory body with specific data requirements. However, JMPR is a major user of data that are already available. The Meeting is committed to using the best information available, generated wherever by the most relevant scientific means, as long as the information is credible and addresses the needs of JMPR to evaluate the potential dietary risks of pesticides. JMPR encourages the development of more accurate, resource-effective guidance and assessment methods that are scientifically sound and, to the extent possible, internationally harmonized.

Since the publication of the United States National Research Council's report entitled *Toxicity testing in the 21st century: A vision and a strategy in 2007*, there has been great interest in the development of new molecular and computer-based approaches to increase the relevance, predictability and timeliness of safety evaluations, while reducing the need for animal studies to the extent possible. JMPR is committed to reducing unnecessary animal testing, but is of the view that, at present, it is not possible to avoid the use of *in vivo* studies if toxicity evaluations are to be as reliable as possible. Currently, mechanistically based approaches are of most value when integrated with traditional test methods to enable more hypothesis-based assessments and focused evaluations on the effects of concern.

A number of proposals to achieve more effective and efficient safety assessments have been put forward by governmental agencies/organizations and international organizations. In its 2006 report, JMPR welcomed initiatives to produce more accurate assessments, while utilizing fewer resources than with the current toxicity testing and assessment paradigm.

It should be noted that the use of hypothesis-driven approaches that permit the incorporation of existing knowledge and new scientific advancements in the evaluation of

toxicity have been in practice by JMPR for some time. Within the context of JMPR evaluations, assessment of data-poor compounds such as metabolites or degradates of pesticide active ingredients has included the use of structure–activity analysis and read-across methods. A number of JMPR evaluations have also included an assessment of the mode of action for a cancer or non-cancer end-point using the International Programme on Chemical Safety (IPCS) mode of action/human relevance framework. IPCS is currently updating this framework to incorporate current experience and in the context of new methodological developments.

A recent example of the use of data from mechanistically designed *in vitro* and *in vivo* models to evaluate the human relevance of rodent tumour and developmental toxicity responses is provided in the evaluation of sulfoxaflor (JMPR, 2011). The IPCS mode of action framework was employed to provide a structured, rigorous and transparent approach to support the integration of diverse types of data (i.e. *in vitro*, *in vivo*, traditional, mechanistic), including those from newer methods, through application of a weight of evidence approach using the Bradford Hill considerations to evaluate plausible causal linkages among key events at various levels of biological organization to the *in vivo* adverse outcomes of interest.

JMPR would rely on the demonstration that the methods used to produce toxicity data are fit for purpose and will consider such information in judgement of the suitability of data for use in its evaluations, since JMPR does not validate testing methods. It is the opinion of JMPR that scientific developments and understanding are not sufficient at this time to enable the replacement of *in vivo* testing with *in vitro* methods to predict hazards and potency for systemic toxicities. However, new approaches can be used to complement traditional testing.

The determination of when these approaches will be useful will depend not only on peer review, but on what the method predicts with respect to mode of action knowledge, including the understanding of causal linkages of key events with the adverse effects. Furthermore, to realize a paradigm shift to greater reliance on *in vitro* and *in silico* methods will require close collaboration within the scientific community, international organizations and government authorities. The transition of 21st century technologies will be a mutual learning experience.

In conclusion, it is important that methods are scientifically defensible and fit for purpose and that there is a transparent understanding of the uncertainties associated with any new method. JMPR is committed to fostering workable transitions from traditional methods to new methods within its practice. JMPR offers to evaluate data generated using new technologies as they become available, in parallel with the results of traditional toxicity testing, to determine their utility and role in pesticide evaluation.

2.5 Consideration of adaptive and minor responses to discriminate between adverse and non-adverse effects

In 2006, JMPR discussed and published a guidance on the interpretation of hepatocellular hypertrophy (JMPR 2006 report) to facilitate consistent and transparent decisions in pesticide evaluations. The purpose of that document was to provide general guidance for determining whether the observation of hepatocellular hypertrophy in different laboratory species is indicative of an adaptive or an adverse event, so that the most appropriate reference dose can be identified for the establishment of health-based guidance values. At the 2011 Meeting, JMPR agreed that guidance on additional minor and adaptive changes was necessary and formed a small working group to define the scope of such guidance, for discussion at the 2012 Meeting.

The working group prepared a discussion document, which was considered at the Meeting in 2012, at which time it was agreed to develop this guidance further. The structure of the document was agreed and tasks were allocated, with a view to preparing draft guidance for discussion at the 2013 Meeting of JMPR.

2.6 Changes in JMPR procedure

The issue of JMPR resourcing was discussed previously by both JMPR and CCPR. In parallel with the need for adequate resources for scientific advice, the need to increase JMPR capacity in coming years was recognized.

The WHO Core Assessment Group on Pesticide Residues implemented teleconferences in early July 2012 to resolve routine technical matters prior to the 2012 JMPR. These teleconferences helped to identify questions for industry that could be easily addressed by written communication before the meeting. That enabled the cancellation of the discussion with sponsors during the JMPR meeting, which consequently increased the meeting duration by more than half a day. The new procedure was considered to be efficient in terms of increasing JMPR capacity and will be implemented again for the 2013 JMPR.

The WHO Core Assessment Group also initiated the development of revised guidance for data submission and for monographers (see also section 2.1).

2.7 Assessment of compounds with very low toxicity

For some years, JMPR has not established an acute reference dose (ARfD) for a pesticide under consideration if the available data on acute effects indicate that the ARfD would be higher than 5 mg/kg body weight (bw). The grounds for this practice were discussed in the 2004 JMPR report (and in more detail in Solecki et al., 2005³) on guidance for setting acute reference doses. The maximum cut-off of 5 mg/kg bw for the ARfD was based on a consideration of maximum food consumption estimates and maximum residue levels in foods. This cut-off equates to a no-observed-adverse-effect level (NOAEL) of 500 mg/kg bw, with the application of the default uncertainty factor of 100. This upper limit for the ARfD has also been adopted in Organisation for Economic Co-operation and Development guidance on setting acute reference doses.⁴

With respect to toxicological effects after long-term dosing, JMPR notes that a number of pesticides developed in recent years cause no or minimal effects at limit doses in the extensive suite of repeated-dose mammalian toxicity tests required to support their regulatory approval.

One such chemical is the new fungicide ametoctradin, which was evaluated by JMPR for the first time in 2012. In the toxicology studies on this compound, no adverse effects were observed at or near the limit dose of approximately 1000 mg/kg bw per day (i.e. all individual

³ Solecki R et al. (2005). Guidance on setting of acute reference dose (ARfD) for pesticides. *Food and Chemical Toxicology*, 43:1569–1593.

⁴ OECD (2010). *Guidance for the derivation of an acute reference dose*. Organisation for Economic Co-operation and Development (ENV/JM/MONO(2010)15; Series on Testing and Assessment, No. 124).

NOAELs were well above the 500 mg/kg bw per day limit discussed above), there was no evidence of genotoxicity and there were no metabolites of any toxicological significance. Thus, the Meeting concluded that, in addition to it being unnecessary to establish an ARfD, there was also no need to establish an acceptable daily intake (ADI) for this compound. This decision, taken for the first time at the 2012 JMPR, was based on a reasonable estimate of a likely maximal daily intake of residues arising from the diet. By applying a similar principle to that considered for not establishing ARfDs, the 2012 Meeting considered that it would be possible to set an extreme upper-bound limit for the ADI, noting that the long-term 24-hour dietary intake of residues of a pesticide will be less than the international estimate of short-term intake (IESTI) of residues from that pesticide.

Thus, the ADI for ametoctradin was recorded as “ADI unnecessary”, and the margin of exposure between the intake resulting from the proposed maximum residue levels and the highest dose tested was reported.

The Meeting noted that adoption of this practice should also help to avoid the need to conduct repeated-dose toxicity testing of low-toxicity pesticides at doses above the limit dose in order to establish an ADI.

The proposal of JMPR not to establish ADIs for pesticides with very low or no apparent mammalian toxicity when tested at limit doses will be considered further by the FAO Panel of Experts on Pesticide Residues in Food and the Environment at the 2013 JMPR. A cut-off for the ADI may be refined by the FAO Panel, taking into account long-term, high-level consumption.

2.8 Update of the automated spreadsheet applications for the calculation of Short-Term 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 the Environment), of the Netherlands in cooperation with WHO/GEMS/Food incorporating available consumption data in Excel spreadsheets and, where possible, linking this consumption data to the Codex Commodities for which HR(-P)s and STMR(-P)s are estimated. The spreadsheets are used to calculate the IESTI using the formulas as described in Chapter 7 of the 2009 FAO manual. To use the spreadsheets, estimates made by JMPR (ARfD, STMR(-P), HR(-P)) 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). 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 for the JMPR 2011. As a result of the extension of the request the governments of Brazil, China, Finland, and Japan provided these data for the JMPR 2012. Denmark indicated that their large portion data were already covered by the JMPR 2011 data and refrained from sending further large portion data. The government of UK confirmed that the 2003 data were still valid. Large portion data already available to JMPR and provided by the governments of South Africa, and the USA were retained. Unit

weight data already available to the 2003 JMPR and provided by the governments of Belgium, Sweden, 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 ages), women of childbearing age (14-50 yrs), and children of 6 yrs and under. 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 used in the IESTI spreadsheet.

The JMPR 2011 accepted the large portion data without quality control. For the 2012 JMPR limited quality control of the data was conducted. Thus the individual countries that submitted large portion data were asked for confirmation as to what their large portion data represented. Based on this information, the data were allocated to total large portion (i.e. raw and processed commodities or unknown processed commodities converted to raw edible agricultural commodity) or to specific large portion fractions e.g. consumed as raw, consumed after household cooking/boiling, canned, dried, fruit juice). In order to compare large portions from one country to those of another country, processed commodities were expressed as processed product (i.e. commodity as such e.g. as juice, as dried). The total large portion and the large portions which represented consumption as raw were expressed as raw edible agricultural commodity (e.g. orange without peel). The countries involved confirmed that the final large portion consumption values were correct.

Every country, except USA and South Africa, reported the number of data points the large portion data was taken from. The minimum number of datapoints is 120 for a 97.5 percentile with a significance level of 5% based on non-parametric statistics. JMPR 2012 considers the large portion data robust, when the large portion is derived from at least 120 datapoints.

In case the large portion data were derived from less than 120 data points, the g/kg bw/d large portion values and/or the g/pers/d large portion values of the country in question were compared to data from other countries that had 120 datapoints. When the large portion in question was within 1.5x the large portion for a country with 120 datapoints, the large portion data were considered plausible. Large portion data derived from less than 120 data points, which were confirmed by the country in question to be plausible, were considered plausible as well. Data which were not considered plausible by the country in question, were replaced by the next highest large portion value in the JMPR 2012 database. The JMPR 2012 considers the 2012 large portion dataset robust.

Since 2011 the IESTI calculations can be done 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. Aggregate large portion data differ from the large portion data for the individual raw and processed commodities because they come from different countries and/or they are expressed as raw edible agricultural commodity.

The spreadsheet applications will be available on the WHO website .
http://www.who.int/foodsafety/chem/acute_data/en/index1.html.

2.9 Further consideration for using the proportionality approach

The 44th Session of the CCPR in 2012 requested JMPR to continue its explanation in using the proportionality approach in evaluation of residue data. In addition to specific considerations related to individual compounds the Meeting noted further aspects for applying the proportionality principle.

General aspects

The Meeting noted that in the considerations presented in the 2010 JMPR Report the conclusion on proportionality for spray concentrations was based on side-by-side trials conducted at comparable spray volumes. However, under practical conditions GAPs for foliar application are often expressed solely as spray concentrations without further specification of related spray volumes. The Meeting decided that proportionality based on spray concentrations can only be applied to residue data following careful consideration of spray concentrations and spray volumes on a case by case basis.

Since 2010 the Meeting regularly makes use of the OECD Calculator as a tool for the estimation of maximum residue levels. The Meeting points out that where application rates in supervised field trials were all within $\pm 25\%$ of the GAP, the normal practice is not to scale residue data. However, if the proportionality principle is applied to give recommendations, the Meeting decided to scale residue data from all trials to avoid bias in the outcome of the OECD Calculator.

Examples from 2012 JMPR

The 2012 JMPR decided to apply the principle of proportionality in several evaluations to make recommendations on commodities without sufficient supervised field trial data conducted according to the corresponding GAP: Ametoctradin (dried hops), Chlorfenapyr (tomato), Fluopyram (dry beans, cherries, dry chick peas, dry lentils, dry lupins, peaches, peppers, sugar beets, tomatoes), Imidacloprid (celery), Glyphosate-Ammonium (sunflowers), MCPA (barley, oats, rye, triticale and wheat forage, barley, oats, rye, triticale and wheat straw and fodder), Methoxyfenozide (fruiting vegetables, cucurbits) and Spinetoram (brassica vegetables).

As in most of the above cases the only dataset available was from supervised field trials involving application rates $>125\%$ or $<75\%$ of the GAP, without scaling according to the basic principles outlined by the 2010 JMPR no recommendations could be made.

In addition to this basic approach the following examples are presented including special considerations for glyphosate-ammonium, MCPA and spinetoram.

Glyphosate-Ammonium

The GAP from Germany for desiccation of sunflowers is 0.5 kg ai/ha with 14 day PHI. In 2012 the Meeting received two datasets, one including 4 trials at 0.6 kg ai/ha and a second with 5 trials conducted at 0.34 kg ai/ha. The Meeting concluded that the four trials approximating GAP are not sufficient for a major crop like sunflowers and applied proportionality on the whole dataset. Although glyphosate-ammonium is a non-selective herbicide, the use as a desiccant is conducted directly before harvest and does not affect

plant-growth. In the following table the scaling of residue data, including data within $\pm 25\%$ of the GAP, is summarised:

Target desiccation GAP (kg ai/ha)	Field trial application rate (kg ai/ha)	Scaling factor	Total residue (mg/kg)	
			Residue field trial	Scaled residue
0.5	0.6	0.83	0.79	0.66
	0.6	0.83	0.43	0.36
	0.6	0.83	1.21	1.0
	0.6	0.83	2.3	1.9
	0.35	1.43	0.25	0.36
	0.36	1.39	0.38	0.53
	0.34	1.47	0.27	0.36
	0.34	1.47	0.46	0.68
	0.36	1.39	0.05	0.07

MCPA – Barley, oats, rye, triticale and wheat forage

The Meeting noted that only residue data from Canada on wheat provided a sufficient basis for the estimation of STMR and highest residue values for cereal forage. However, supervised field trial data were conducted at approximately 2-times the application rate reported for the Canadian GAP, leading to residues of 3.1-21 mg/kg in forage. For the utilisation of cereal forage as a feed item the Meeting decided to apply proportionality to the data set, resulting in scaled residues of 1.6-9.5 mg/kg.

Generally the application of proportionality in case of compounds affecting plant growth needs to be considered carefully. For MCPA the Meeting concluded that the compound is a selective herbicide against broadleaf weeds without significant impact on the growth of monocotyleous plants like cereals and therefore decided that proportionality applies in this case.

Spinetoram

For spinetoram Australian GAP for brassica vegetables is 4 applications of up to 48 g ai/ha each and 3 day PHI. Supervised field trials conducted on broccoli involved treatment either first application at 35 g ai/ha, followed by three applications of 88-91 g ai/ha, or four applications at 18, 24 or 36 g ai/ha each. The Meeting decided that the field trials conducted according to GAP were insufficient for a recommendation and applied proportionality to the whole dataset.

In the following table the scaling of residue data, including data within $\pm 25\%$ of the GAP, is summarised:

Target GAP (g ai/ha)	Spinetoram				Spinetoram and two metabolites			
	Field rate (g ai/ha)	Scaling factor	Residue field trial (mg/kg)	Scaled residue (mg/kg)	Field rate (g ai/ha)	Scaling factor	Residue field trial (mg/kg)	Scaled residue (mg/kg)
48	24	2	0.08	0.16	24	2	0.08	0.16
	37	1.3	0.02	0.026	25	1.9	0.03	0.058
	26	1.8	0.09	0.17	26	1.8	0.10	0.18
	91	0.52	0.09	0.045	91	0.52	0.12	0.063
	89	0.54	0.04	0.022	89	0.54	0.06	0.033
	91	0.52	0.06	0.031	91	0.52	0.10	0.052
	90	0.52	0.10	0.052	90	0.52	0.14	0.073

