ANNEX I

ACCEPTABLE DAILY INTAKES, RESIDUE LIMITS AND SUPERVISED TRIALS MEDIAN RESIDUES PROPOSED AT THE 1996 MEETING

The Table of recommendations includes maximum Acceptable Daily Intakes (ADIs) and Maximum Residue Limits (MRLs). It should be noted that MRLs include draft MRLs and Codex MRLs (CXLs). The MRLs recommended by the JMPR on the basis of its estimates of maximum residue levels enter the Codex procedure as draft MRLs. They become Codex MRLs when they have passed through the procedure and have been adopted by the Codex Alimentarius Commission.

In general, the recommended MRLs listed for compounds which have been reviewed previously are additional to, or amend, those recorded in the reports of earlier Meetings. For compounds re-evaluated in the CCPR periodic review programme however, both new and previous recommendations are listed because such re-evaluations are regarded as replacing the original evaluation rather than supplementing it.

Some ADIs may be temporary: this is indicated by the letter T and the year in which re-evaluation is scheduled in parenthesis below the ADI. All recommended MRLs for compounds with temporary ADIs are necessarily temporary, but some recommendations are designated as temporary (TMRLs) until required information has been provided and evaluated, irrespective of the status of the ADI. Such recommendations are followed by the letter T in the table. (See also the list of qualifications and abbreviations below.)

In response to recommendations of a Joint FAO/WHO Consultation on Guidelines for predicting the Dietary Intake of Pesticide Residues held in York, the UK, in 1995, the 1996 Meeting has extended its estimations of residues to include calculations of the median residues found in supervised trials (STMRs) in order to provide a basis for the estimation of the dietary intake of the pesticides reviewed. The estimated STMRs are included in the Table of ADIs and MRLs. Further details of the response of the Meeting to the York Consultation are given in Section 2.2.1 of this report, and information about an informal workshop held in The Hague, The Netherlands, in April 1996 to consider the implementation of its recommendations by the JMPR in Section 2.2.3. The report of this Workshop is reproduced as Annex III.

Attention is drawn to Section 3.1 of the report of the present Meeting: 'Definition of the residues of fat-soluble compounds'. Residues of such compounds are distinguished in the Table of Recommendations by the parenthetic note '(fat-soluble residue)' on a line below the residue definition.

The following qualifications and abbreviations are used.

* following recommended MRL	At or about the limit of determination
* following name of pesticide	New compound

** following name of pesticide	Compound reviewed in CCPR periodic review programme
E	Extraneous Residue Limit (ERL).
F following recommendations for milk	The residue is fat-soluble and MRLs for milk and milk products are derived as explained in the introduction to Part 2 of the Guide to Codex Maximum Limits for Pesticide Residues and to Volume II of the Codex Alimentarius.
(fat) following recommendations for meat	The recommendation applies to the fat of the meat.
Po	The recommendation accommodates post-harvest treatment of the commodity.
PoP following recommendations for processed foods (classes D and E in the Codex Classification)	The recommendation accommodates post-harvest treatment of the primary food commodity.
STMR	Supervised Trial Median Residue (see explanation on previous page).
STMR-P	An STMR for a processed commodity calculated by applying the mean concentration or reduction factor for the process to the STMR calculated for the raw agricultural commodity.
T following ADIs	The ADI is temporary, and due for re-evaluation in the year indicated.
T following MRLs	The MRL is temporary, irrespective of the status of the ADI, until required information has been provided and evaluated.
V following recommendations for commodities of animal origin	The recommendation accommodates veterinary uses.
W in place of an MRL	The previous recommendation is withdrawn.

If a recommended MRL is an amendment, the previous value is also recorded. The absence of a figure in the "Previous" column indicates that the recommendation is the first for the commodity or group concerned.

The Table includes the Codex Classification Numbers (CCNs) of both the compounds and the commodities listed, to facilitate reference to the Guide to Codex Maximum Limits for Pesticide Residues and other Codex documents.

Commodities are listed in alphabetical order. This is a change from earlier practice where commodities were listed in the order of the "Types" in the Codex Classification of Foods and Animal Feeds, and in alphabetical order within each Type. The change was made to facilitate checking and comparison with the CCPR Tables of MRLs, which are in alphabetical order.

ACCEPTABLE DAILY INTAKES (ADIs), MAXIMUM RESIDUE LIMITS (MRLs) AND SUPERVISED TRIALS MEDIAN RESIDUES (STMRs) [1]

Pesticide (Codex ref. No.)	ADI (mg/kg bw)	Commodity		Recommended MRL or ERL (mg/kg)		STMR (mg/kg)
		CCN	Name	New	Previous	
Acephate	0.03	VB 0400	Broccoli	2	-[1]	0.11
(095)		VB 0041	Cabbages, Head	2	-[1]	0.33
		VB 0404	Cauliflower	2	-[1]	0.11
		VO 0448	Tomato	1	-[1]	0.38
			Tomato, canned			0.19 P[2]
			Tomato, canned juice			0.35 P
			Tomato, bulk paste			1.52 P
			Tomato, canned puree			0.68 P
			Tomato, wet pomace			0.23 P
			Tomato, dry pomace			0.38 P
		Residue	(for MRLs & STMRs): acephate			
		Notes:	[1]Previous recommendation withdrawn by 1994 JMPR [2]STMR-P			
Aldicarb	0.003	VR 0589	Potato	0.5	0.5 T	0.077
(117)			Potato chips			0.056 P[1]
			Potato fries			0.045 P
			Potato, microwaved			0.065 P
			Potato, baked			0.050 P
		Residue	(for MRLs & STMRs): Sum of aldicarb, its sulfoxide and its sulfone, expressed as aldicarb.			
		Notes:	[1]STMR-P			
Bifenthrin	0.02	GC 0654	Wheat	0.5 Po	0.05*	0.255
(178)		CM 0654	Wheat bran, unprocessed	2 PoP	-	0.89 P[1]
		CF 1211	Wheat flour	0.2 PoP	-	0.076 P
		CF 1212	Wheat wholemeal	0.5 PoP	-	0.21 P
		Residue	(for MRLs & STMRs): bifenthrin (fat-soluble residue)			
		Notes:	[1]STMR-P			
Carbaryl** (008)	0.003	Notes:	Previous ADI was 0.01 mg/kg bw. Periodic review was only for toxicology			
Carbofuran** (096)	0.002	Notes:	Previous ADI was 0.01 mg/kg bw. Periodic review was only for toxicology			
Chlorfenvinphos**	0.0005	VB 0400	Broccoli	W	0.05	

[1]See explanation on pp. xv and 617

Pesticide (Codex ref. No.)	ADI (mg/kg bw)	Commodity		Recommended MRL or ERL (mg/kg)		STMR (mg/kg)
		CCN	Name	New	Previous	
(014)		VB 0402	Brussels sprouts	W	0.05	
		VB 0041	Cabbages, head	W	0.05	
		VR 0577	Carrot	W	0.4	
		VB 0404	Cauliflower	W	0.1	
		VS 0624	Celery	W	0.4	
		FC 0001	Citrus fruits	W	1	
		SO 0691	Cotton seed	W	0.05	
		VO 0440	Egg plant	W	0.05	
		VR 0583	Horseradish	W	0.1	
		VA 0384	Leek	W	0.05	
		GC 0645	Maize	W	0.05	
		MM 0095	Meat (from mammals, other than marine mammals)	W	0.2 (fat) V	
		ML 0107	Milk of cattle, goats and sheep	W	0.008 F V	
		VO 0450	Mushrooms	W	0.05	
		VA 0385	Onion, bulb	W	0.05	
		SO 0697	Peanut	W	0.05	
		VR 0589	Potato	W	0.05	
		VR 0494	Radish	W	0.1	
		GC 0649	Rice	W	0.05	
		CM 1205	Rice, polished	W	0.05	
		VR 0497	Swede	W	0.05	
		VR 0508	Sweet potato	W	0.05	
		VO 0448	Tomato	W	0.1	
		VR 0506	Turnip, Garden	W	0.05	
		GC 0654	Wheat	W	0.05	
		Residue (for MRLs & STMRs): chlorfenvinphos, sum of *E*- and *Z*- isomers (fat-soluble residue) Notes: Periodic review was only for residues.				
2,4-D** (020)	0.01	Notes: ADI refers to acid equivalent. Previous ADI was 0.3 mg/kg bw. Periodic review was only for toxicology				
DDT (021)	0.02 (PTDI[1]	MM 0095	Meat (from mammals other than marine mammals)	5 (fat) E	1 (fat) E	
		Residue (for MRLs & STMRs): sum of *p,p*¢DDT, *o,p*¢DDT, *p,p*¢DDE, and *p,p*¢TDE (*p,p*¢ DDD) (fat-soluble residue) Notes: [1]provisional tolerable daily intake. See 1994 report, Section 2.3				
Diazinon[1]	0.002	PO 0840	Chicken, Edible offal of	0.02*	-	0
(022)		PE 0840	Chicken eggs	0.02*	-	0
		PM 0840	Chicken meat	0.02*	-	0
		MM 0814	Goat meat	2 (fat) V	-	0.3 (fat) 0.02 (whole muscle)
		MO 0098	Kidney of cattle, goats, pigs and sheep	0.03 V	-	0.01
		MO 0099	Liver of cattle, goats, pigs and sheep	0.03 V	-	0.01

Pesticide (Codex ref. No.)	ADI (mg/kg bw)	Commodity		Recommended MRL or ERL (mg/kg)		STMR (mg/kg)
		CCN	Name	New	Previous	
		MM 0097	Meat of cattle, pigs and sheep	2 (fat) V	W[1]	0.3 (fat) 0.02 (whole muscle)
		ML 0106	Milks	0.02 F V	W[1]	0.02
	Residue (for MRLs & STMRs): diazinon (fat-soluble residue) Notes: [1]Withdrawal of existing CXL proposed by 1993 JMPR.					
Dimethoate** (027)	0.002	Notes: ADI is for the sum of dimethoate and omethoate expressed as dimethoate. Previous ADI was 0.01 mg/kg bw. Periodic review was only for toxicology				
Disulfoton (074)	0.0003	Acute RfD 0.003 mg/kg bw.				
Dithiocarbamates		AM 0660	Almond hulls	20[1] mb[2], zm	20	
(105)		TN 0660	Almonds	0.1* mb, zm	0.1*	
		TN 0672	Pecan	0.1* T zm	-	
		FP 0009	Pome fruits	5 mz, mt, pb, th, zm	5	
		FS 0012	Stone fruits	7[3] T th, zm	-	
		FB 0275	Strawberry	5 th	-	
		Residue: total dithiocarbamates, determined as CS_2 evolved during acid digestion and expressed as mg CS_2/kg. Notes: MRLs refer to total residues from the use of any or each of the groups of dithiocarbamates. [1] The estimated temporary maximum residue level for dithiocarbamates arising from the use of ziram is 10 mg/kg, but the current draft MRL of 20 mg/kg recommended by the 1993 JMPR should be maintained to accommodate uses of maneb. [2] Based on trials with mb maneb, mz mancozeb, mt metiram, pb propineb, th thiram, zm ziram. Underlined compounds are those on which estimates of maximum residue levels are mainly based. [3] The estimated maximum residue level for dithiocarbamates arising from the use of thiram on plums and cherries is 1 mg/kg, but a TMRL of 7 mg/kg is recommended to accommodate uses of ziram on stone fruits.				
Fenarimol	0.01	AB 0226	Apple pomace,dry	5	5 T	
(192)		VS 0620	Artichoke, Globe	0.1	0.1 T	
		FI 0327	Banana	0.2	0.2 T	
		MO 1280	Cattle, kidney	0.02*	0.02* T	
		MO 1281	Cattle, liver	0.05	0.05 T	
		MM 0812	Cattle meat	0.02*	0.02* T	
		FS 0013	Cherries	1	1 T	
		DF 0269	Dried grapes (= Currants, Raisins and Sultanas)	0.2	0.2 T	
		FB 0269	Grapes	0.3	0.3 T	
		DH 1100	Hops, dry	5	-	
		VC 0046	Melons, except Watermelon	0.05	0.05 T	
		FS 0247	Peach	0.5	0.5 T	
		TN 0672	Pecan	0.02*	0.02* T	
		VO 0445	Peppers, Sweet	0.5	0.5 T	
		FP 0009	Pome fruits	0.3	0.3 T	
		FB 0275	Strawberry	1	1 T	

Pesticide (Codex ref. No.)	ADI (mg/kg bw)	Commodity		Recommended MRL or ERL (mg/kg)		STMR (mg/kg)
		CCN	Name	New	Previous	
	Residue (for MRLs & STMRs): fenarimol					
Ferbam** (Dithiocarbamates, 105)	0.003	Notes: group ADI for ferbam and ziram. Previous ADI was 0.02 mg/kg bw, also for ferbam and ziram.				
Flumethrin* (195)	0.004	MM 0812	Cattle meat	0.2 (fat)[1] V	-	0.01 (fat) 0.005 (whole muscle)
		ML 0812	Cattle milk	0.05 F V	-	0.01
			Honey	0.005*	-	0.005
	Residue (for MRLs & STMRs): flumethrin (fat-soluble residue) Notes: [1]maximum residue in whole meat (muscle) reflecting approved uses was 0.01 mg/kg. Recommended MRL is on carcase fat basis.					
Haloxyfop	0.0003	AL 1021	Alfalfa forage (green)	W	Prov.[1]	
(194)		FI 0327	Banana	0.05*	Prov.[1]	0
		MO 0812	Cattle, Edible offal of	W	Prov.[1]	
		MF 0812	Cattle fat	W	Prov.[1]	
		MM 0812	Cattle meat	W	Prov.[1]	
		ML 0812	Cattle milk	W	Prov.[1]	
		FM 0812	Cattle milk fat	W	Prov.[1]	
		PO 0840	Chicken, Edible offal of	0.1	Prov.[1]	0.01
		PE 0840	Chicken eggs	0.01*	Prov.[1]	0.01
		PM 0840	Chicken meat	0.01*	Prov.[1]	0.01
		FC 0001	Citrus fruits	0.05*	Prov.[1]	0
		SO 0691	Cotton seed	0.2	Prov.[1]	0.09
		OC 0691	Cotton seed oil, crude	0.5	Prov.[1]	0.1 P[2]
		AM 1051	Fodder beet	0.3	Prov.[1]	0.02
		AV 1051	Fodder beet leaves or tops	W	Prov.[1]	
		FB 0269	Grapes	0.05*	Prov.[1]	0
		SO 0697	Peanut	0.05	Prov.[1]	0.03
		VP 0063	Peas (pods and succulent = immature seeds)	0.2	-	0.02
		FP 0009	Pome fruits	0.05*	Prov.[1]	0
		VD 0070	Pulses (dry)	0.2	Prov.[1]	0.03
		VR 0589	Potato	0.1	Prov.[1]	0.04
		SO 0495	Rape seed	2	Prov.[1]	0.17
			Rape seed meal			0.15 P
		OC 0495	Rape seed oil, crude	5	Prov.[1]	0.36 P
		OR 0495	Rape seed oil, edible	5	Prov.[1]	0.28 P
		CM 1206	Rice bran, unprocessed	0.02*	Prov.[1]	0.02 P
		CM 0649	Rice, husked	0.02*	Prov.[1]	0
		CM 1205	Rice, polished	0.02*	Prov.[1]	0
			Soya bean			0.03 (Pulses (dry))
			Soya bean meal			0.03 P
		OC 0541	Soya bean oil, crude	0.2	Prov.[1]	0.02 P
		OR 0541	Soya bean oil, refined	0.2	Prov.[1]	0.02 P
		VR 0596	Sugar beet	0.3	Prov.[1]	0.02

Pesticide (Codex ref. No.)	ADI (mg/kg bw)	Commodity		Recommended MRL or ERL (mg/kg)		STMR (mg/kg)
		CCN	Name	New	Previous	
		AV 0596	Sugar beet leaves or tops	W	Prov.[1]	
			Sugar beet pressed pulp			0.008 P
			Sugar, refined			0.002 P
		SO 0702	Sunflower seed	0.2	Prov.[1]	0.05
	Residue (for MRLs & STMRs): haloxyfop esters, haloxyfop and its conjugates expressed as haloxyfop Notes: [1]Provisional estimates of maximum residue levels were made by the 1995 JMPR, but were not recommended for use as MRLs. [2]STMR-P					
Maleic hydrazide** (102)	0.3	Notes: Previous ADI was 5 mg/kg bw. Periodic review was only for toxicology				
Methamidophos	0.004	VB 0041	Cabbage, Head	0.5	-[1]	0.01
(100)		VB 0404	Cauliflower	0.5	-[1]	0.01
		FS 0247	Peach	1	-[1]	0.16
			Peach, washed fruit			0.10
			Peach, juice (100% basis)			0.11 P[2]
			Peach, jam			0.10 P
			Peach, canned fruit			0.08 P
		VO 0448	Tomato	1	-[1]	0.12
	Residue (for MRLs & STMRs): methamidophos Notes: [1]Withdrawn by 1994 JMPR [2]STMR-P Recommended MRLs are based on residues from the use of methamidophos or acephate					
Mevinphos** (053)	0.0008	Notes: Acute RfD 0.003 mg/kg bw. Previous ADI was 0.0015 mg/kg bw. Periodic review was only for toxicology				
Phorate (112)	0.0005	Notes: Previous ADI confirmed				
Propoxur	0.02	VL 0482	Lettuce, Head	0.5	3	
(075)		VR 0589	Potato	0.02*	0.1*	
	Residue (for MRLs): propoxur					
Tebufenozide*	0.02	FB 0269	Grapes	0.5	-	0.12
(196)		FP 0009	Pome fruits	1	-	0.16
		CM 0649	Rice, husked	0.1	-	0.03
		TN 0678	Walnut	0.05	-	0.003
			Apple pomace, wet			0.4 P[1]
			Apple juice			0.02 P
			Apple puree			0.04 P
			Grape pomace, wet			0.36 P
			Wine			0.03 P
	Residue (for MRLs & STMRs): tebufenozide (fat-soluble residue) Notes: [1]STMR-P					
Teflubenzuron*	0.01	VB 0402	Brussels sprouts	0.5	-	0.21
(190)		VB 0041	Cabbages, Head	0.2	-	0.05
		FS 0014	Plums (including Prunes)	0.1	-	0.04
		FP 0009	Pome fruits	1	-	0.48

Pesticide (Codex ref. No.)	ADI (mg/kg bw)	Commodity		Recommended MRL or ERL (mg/kg)		STMR (mg/kg)
		CCN	Name	New	Previous	
		VR 0589	Potato	0.05*	-	0
	Residue (for MRLs & STMRs): teflubenzuron (fat-soluble residue) Notes: First evaluation of residue and analytical aspects. Toxicology was evaluated in 1994.					
Thiram**	0.01		Apple juice			0.55 P[1]
(Dithiocarbamates, 105)			Apple pomace, wet			1.9 P
			Apple pomace, dry			6.93 P
		FS 0013	Cherries	1	-	0.72
		FS 0014	Plums (including Prunes)	1	-	0.72
		FP 0009	Pome fruits	5	5	1.9
		FB 0275	Strawberry	5	-	2.1
	Residue for MRLs: see dithiocarbamates for STMRs: thiram Notes: [1]STMR-P Periodic review was only for residues.					
Ziram**	0.003	AM 0660	Almond hulls	10 T	20	10.6
(Dithiocarbamates,		TN 0660	Almonds	0.1* T	0.1*	0.04
105)			Apple juice			0.204 P
			Apple pomace, wet			2.81 P
			Apple pomace, dry			3.82 P
		TN 0672	Pecan	0.1* T	-	0.04
		FP 0009	Pome fruits	5 T	5	2.1
		FS 0012	Stone fruits	7 T	-	2.2
		Residue for MRLs: see dithiocarbamates for STMRs: ziram Notes: group ADI for ferbam and ziram. Previous ADI was 0.02 mg/kg bw, also for ferbam and ziram.				

ANNEX II

PREVIOUS FAO AND WHO DOCUMENTS

1. FAO/WHO. 1962 — Principles governing consumer safety in relation to pesticide residues. Report of a meeting of a WHO Expert Committee on Pesticide Residues held jointly with the FAO Panel of Experts on the Use of Pesticides in Agriculture. FAO Plant Production and Protection Division Report, No. PL/1961/11; WHO Technical Report Series, No. 240.

2. FAO/WHO. 1964 — Evaluations of the toxicity of pesticide residues in food. Report of a Joint Meeting of the FAO Committee on Pesticides in Agriculture and the WHO Expert Committee on Pesticide Residues. FAO Meeting Report, No. PL/1963/13; WHO/Food Add./23.

3. FAO/WHO. 1965a — Evaluations of the toxicity of pesticide residues in food. Report of the Second Joint Meeting of the FAO Committee on Pesticides in Agriculture and the WHO Expert Committee on Pesticide Residues. FAO Meeting Report, No. PL/1965/10; WHO/Food Add./26.65.

4. FAO/WHO. 1965b — Evaluations of the toxicity of pesticide residues in food. FAO Meeting Report, No. PL/1965/10/1; WHO/Food Add./27.65.

5. FAO/WHO. 1965c — Evaluation of the hazards to consumers resulting from the use of fumigants in the protection of food. FAO Meeting Report, No. PL/1965/10/2; WHO/Food Add./28.65.

6. FAO/WHO. 1967a — Pesticide residues in food. Joint report of the FAO Working Party on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 73; WHO Technical Report Series, No. 370.

7. FAO/WHO. 1967b — Evaluation of some pesticide residues in food. FAO/PL:CP/15; WHO/Food Add./67.32.

8. FAO/WHO. 1968a — Pesticide residues. Report of the 1967 Joint Meeting of the FAO Working Party and the WHO Expert Committee. FAO Meeting Report, No. PL:1967/M/11; WHO Technical Report Series, No. 391.

9. FAO/WHO. 1968b — 1967 Evaluations of some pesticide residues in food. FAO/PL:1967/M/11/1; WHO/Food Add./68.30.

10. FAO/WHO. 1969a — Pesticide residues in food. Report of the 1968 Joint Meeting of the FAO Working Party of experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 78; WHO Technical Report Series, No. 417.

11. FAO/WHO. 1969b — 1968 Evaluation of some pesticide residues in food. FAO/PL:1968/M/9/1; WHO/Food Add./69.35.

12. FAO/WHO. 1970a Pesticide residues in food. Report of the 1969 Joint Meeting of the FAO Working Party of experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 84; WHO Technical Report Series, No. 458.

13. FAO/WHO. 1970b 1969 Evaluation of some pesticide residues in food. FAO/PL:1969/M/17/1; WHO/Food Add./70.38

14. FAO/WHO. 1971a Pesticide residues in food. Report of the 1970 Joint Meeting of the FAO Working Party of experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 87; WHO Technical Report Series, No. 474.

15. FAO/WHO. 1971b 1970 Evaluation of some pesticide residues in food. AGP:1970/M/12/1; WHO/Food Add./71.42.

16. FAO/WHO. 1972a Pesticide residues in food. Report of the 1971 Joint Meeting of the FAO Working Party of experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 88; WHO Technical Report Series, No. 502.

17. FAO/WHO. 1972b 1971 Evaluation of some pesticide residues in food. AGP:1971/M/9/1; WHO Pesticide Residues Series, No. 1.

18. FAO/WHO. 1973a Pesticide residues in food. Report of the 1972 Joint Meeting of the FAO Working Party of experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 90; WHO Technical Report Series, No. 525.

19. FAO/WHO. 1973b 1972 Evaluation of some pesticide residues in food. AGP:1972/M/9/1; WHO Pesticide Residues Series, No. 2.

20. FAO/WHO. 1974a Pesticide residues in food. Report of the 1973 Joint Meeting of the FAO Working Party of experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 92; WHO Technical Report Series, No. 545.

21. FAO/WHO. 1974b 1973 Evaluation of some pesticide residues in food. FAO/AGP/1973/M/9/1; WHO Pesticide Residues Series, No.3.

22. FAO/WHO. 1975a Pesticide residues in food. Report of the 1974 Joint Meeting of the FAO Working Party of experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 97; WHO Technical Report Series, No. 574.

23. FAO/WHO. 1975b 1974 Evaluation of some pesticide residues in food. FAO/AGP/1974/M/9/11; WHO Pesticide Residues Series, No.4.

24. FAO/WHO. 1976a Pesticide residues in food. Report of the 1975 Joint Meeting of the FAO Working Party of experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Plant Production and Protection Series, No.1; WHO Technical Report Series, No. 592.

25. FAO/WHO. 1976b 1975 Evaluation of some pesticide residues in food. AGP:1975/M/13; WHO Pesticide Residues Series, No. 5.

26. FAO/WHO. 1977a Pesticide residues in food. Report of the 1976 Joint Meeting of the FAO Panel of Experts on Pesticide Residues and the Environment and the WHO Expert Group on Pesticide Residues. FAO Food and Nutrition Series, No. 9; FAO Plant Production and Protection Series, No. 8; WHO Technical Report Series, No. 612.

27. FAO/WHO. 1977b 1976 Evaluation of some pesticide residues in food. AGP:1976/M/14.

28. FAO/WHO. 1978a Pesticide residues in food - 1977. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 10 Rev.

29. FAO/WHO. 1978b Pesticide residues in food: 1977 evaluations. FAO Plant Production and Protection Paper 10 Sup.

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ANNEX III

Report of an informal workshop on data evaluation in the estimation of dietary intake of pesticide residues for the JMPR

INTRODUCTION

A Joint FAO/WHO Consultation on Guidelines for predicting the Dietary Intake of Pesticide Residues was held in York, United Kingdom from 2-6 May 1995. The main objectives of the Consultation were to review the existing guidelines and to recommend feasible approaches for improving the reliability and accuracy of methods for predicting dietary intake of pesticide residues. The final published report of this Consultation[2] became available in February 1996.

An informal Workshop was convened in the Hague, Netherlands from 11th-12th April 1996. Dr W. H. van Eck, of the Netherlands Ministry of Health, Welfare and Sport served as chairman. The Workshop had been arranged at the request of the FAO Panel members in order to consider the consequences of the recommendations of the York Consultation for individual reviewers as well as for the JMPR.

The focus of the Workshop was on the issues relating to the reviews of residue data undertaken by the FAO Panel members.

A list of participants is given. The participants considered a number of working examples on quintozene, dithiocarbamates, parathion-methyl and fenpropimorph, which illustrated issues of interest to the FAO Panel.

OBJECTIVES

The chairman explained that the implementation of the York consultation recommendations would have practical consequences for the way the FAO Panel members carried out their evaluations, how those data would be presented and how consumer risk assessments would be carried out by the JMPR. Guidance was needed for the FAO Panel members as to how recommendations are to be implemented. In addition, criteria need to be established in order to ensure consistency and transparency in the work of the FAO Panel.

The Workshop focused mainly on practical considerations of the application of the York consultation recommendations to the work of the FAO Panel. Discussion centred on the following issues:

- the criteria for the selection of residues trials data used to calculate the Supervised Trials Median Residue (STMR) level.
- the presentation in the JMPR monographs of intake related information (eg. median residue levels).
- the approach for dealing with residues at the limit of determination (LOD), also referred to as the limit of quantitation (LOQ).
- practical considerations of the cases where the residue definition for consumer risk assessment is different from that recommended for enforcement
- evaluation of data on edible portion and processing (combined supervised trials data with

[2] 'Recommendations for the revision of the guidelines for predicting dietary intake of pesticide residues', Report of a FAO/WHO Consultation; World Health Organisation 1995.

processing information)

- .identification of appropriate residue values for acute intake assessments

Guidelines were developed in order to give guidance to the FAO Panel reviewers. In addition, a few general recommendations were made. The Workshop recognised that additional guidelines will need to be developed by the JMPR in the future, as experience is gained by the reviewers.

GUIDANCE TO THE FAO PANEL REVIEWERS ON THE IMPLEMENTATION OF THE YORK CONSULTATION RECOMMENDATIONS

The Workshop recommended that:

Comparability

Residues data from countries are evaluated against the GAP in the country of the trials or a neighbouring country with similar climate and cultural practices.

In identifying the STMR, the trials values selected should be comparable with the maximum registered use (ie. maximum application rate, maximum number of treatments, minimum PHI) on which the MRL is based.

In establishing comparability of uses in the residue trials to the maximum registered use, the application rates in the trials should generally be no more than ± 25 to 30% of the maximum application rate. Deviations from this should be explained in the appraisal. Similarly, ± 25 to 30% should also be used as a guide for establishing comparability of PHI; however, in this case the latitude of acceptable PHIs will also depend on the rate of decline of residues of the compound under evaluation. Consideration as to whether the number of treatments reported in trials are comparable to the registered maximum number of treatments will depend on the persistence of the compound and the interval between applications. Nevertheless, when a large number of treatments are made in the trials (more than 5 or 6) the residue level should be considered very little influenced by further treatments unless the compound is persistent or the treatments are made with unusually short intervals.

In establishing comparability of residue trials data in which more than one parameter (i.e application rate, number of treatments or PHI) deviate from the maximum registered use, consideration should be given to the combination effect on the residue value which may lead to an underestimation or overestimation of the STMR. For example, a trial result should not normally be selected for the estimation of the STMR if both the application rate is lower (perhaps 0.75 kg/ha in the trial; 1kg ai/ha GAP) than the maximum rate registered and the PHI is longer (perhaps 18 days in the trial, 14 days GAP) than the minimum registered PHI, since these parameters would combine to underestimate the residue. When results are selected for the estimation of STMRs, despite combination effects, the reasons should be explained in the appraisal.

If the residue value arising from a use considered comparable with the maximum registered use is lower than another residue value from the same trial which is within GAP, then the higher residue value should be selected in identifying the STMR. For example, if the GAP specified a minimum PHI of 21 days and the residue levels in a trial reflecting GAP were 0.7, 0.6 and 0.9 mg/kg at 21, 28 and 35 days respectively, then the residue value of 0.9 mg/kg would be selected.

Trials with more than one residue value

In identifying the STMR only one data point should be take from each trial (ie. site location)

Where several residue values have been reported from replicate plots from a single trial (ie. site location) the highest residue should be selected for the purpose of identifying the STMR.

Where several residue values have been reported from replicate analyses of the same field sample taken from a single trial (ie. site location) the mean residue should be selected for the purpose of identifying

the STMR.

Rounding of results

In identifying the STMR from a residue trial the actual residue value should be used in the estimation of dietary intake without rounding up or down. This would even be the case where the actual results were below the practical limit of determination considered appropriate for enforcement purposes. Rounding of residue values is inappropriate since the STMRs are used at an intermediate stage in the dietary intake calculation.

Residue definition

The WHO Panel consider routinely indicating in their evaluations which metabolites should be included in the dietary risk assessment.

If it is recommended that the residue definition for the risk assessment is different from that for enforcement, then this is clearly stated in the appraisal.

Close communication should be established between the FAO Panel reviewers and the respective reviewers on the Toxicological and Environmental Groups, on questions such as which metabolites are of toxicological significance, prior to the JMPR meeting.

In tabulating the residue trials data the FAO Panel reviewer should indicate the levels of relevant metabolites separately from those of the parent compound, but in a way which would allow subsequent combination, in order to ensure that changes in the residue definition can be accommodated at the JMPR meeting.

In those cases where it is not possible to finalise the risk assessment at the JMPR (September, year 1) usually because of a change in residue definition, then the MRLs would still be recommended to the CCPR (by way of Codex circular letter for comment at step 3) and the compound would be rediscussed at the following years JMPR meeting (September, year 2). The recommended MRLs together with the conclusion of the risk assessment would be available for the next CCPR (April, year 3).

If two compounds, for which STMRs can be calculated, produce the same analyte in compliance monitoring (eg. CS_2 for dithiocarbamates) it is possible to separate the intake assessments, if required, because the intake assessment is no longer based on the MRL but is based on residue data specific to the individual compounds.

Combining of populations of data for the calculation of STMRs

In identifying the STMR, residue data reflecting different countries GAPs would normally be combined. However, if the trials data reflecting different countries GAPs appear to give rise to different populations of data then these data sets should not be combined. In these cases the STMR should be calculated from the population(s) of data which is (are) driving the MRL. In deciding whether the results of trials reflecting different countries GAPs give rise to different populations of residues data, the size of the database reflecting the different countries GAPs should be taken into account.

Residues below the limit of determination

That as a general rule, where all residue trials data are <LOD, the STMR would be assumed to be at the LOD, unless there is scientific evidence that residues are "essentially zero". Such supporting evidence would include residues from related trials at shorter PHIs, exaggerated, but related, application rates or a greater number of applications, expectations from metabolism studies or data from related commodities.

Where there are two or more sets of trials with different LODs, and no determinable residues have been reported in the trials, then the lowest LOD should normally be used for the purpose of STMR selection (unless the residues can be assumed to be essentially zero as given above). The size of the trials database supporting the lowest LOD value should be taken into account in the decision.

Processing, cooking factors and edible portion residue data

In using data on the effects on residue levels of processing or cooking practices, the mean reduction or concentration factor should be applied to the STMR estimated for the raw agricultural commodity as already described. The STMR value estimated in this way for the processed commodity should be referred to as the STMR-P.

If data are available for the residues in the edible portion of the commodity (eg. banana pulp) then a STMR should be estimated directly using the edible portion residue values from maximum registered use trials (as opposed to using pesticide values for the whole commodity).

Acute dietary intake

The attention of the FAO Panel members is drawn to the recommendation that for the purpose of acute risk assessment the MRL, or the highest residue in the edible portion, should be used in estimating dietary intake.

Estimation of MRLs for products of animal origin

In estimating MRLs for products of animal origin, theoretical feed intakes for domestic animals should be calculated using the STMR for each feed item (derived from supervised trials comparable with the maximum registered use), rather than the MRL, together with the maximum feed incorporation rates. This is in conformity with past JMPR decisions.

Estimation of STMRs for commodity groups

Where there are adequate trials data the STMRs should, in principle, be identified for the individual commodities and these values used for the intake assessment. However, where the MRL has been established for a group of commodities (eg. pome fruit) a single STMR should be calculated for the group of commodities.

Presentation of STMRs in the JMPR monographs and report

The GAP(s) on which trials data have been selected for the purpose of identifying the STMR should be clearly identified in the monographs.

In tabulating trials data in the monographs the reviewer should ensure that in addition to the normal underlining of trials data that are within GAP (and therefore have been used for the MRL evaluation), the single residue values selected for the estimation of the STMR should be double underlined.

Information on the residue values on which the STMR is based should not only be identified in the tabulated trials data (see above) but a list of the residue values selected should be included in the appraisal, in numerical order, with the median residue underlined. Where the residue situation is complex (eg. a number of metabolites to be considered) these data may best be tabulated in the appraisal. In addition, the STMR values should be included in the recommendation table in the appraisal and in Annex 1 of the report.

The range for the rates and PHIs used in the selection of residue values for STMR should be clearly identified in the appraisal (eg. trials data with application rates from 1.8 - 3.0 kg ai/ha have been selected).

RECOMMENDATIONS

The Workshop recommended that:

a) The recommendations of the York Joint FAO/WHO Consultation are implemented in full into the work of the JMPR.

b) The acronym "STMR" be used in the JMPR monographs and report for the Supervised Trials Median Residue level.

c) The FAO Panel identify STMRs routinely for each commodity as part of all future evaluation of compounds in order to facilitate more realistic estimates of long-term dietary intake.

d) The guidance given in section 3 above is used by the FAO Panel reviewers in their evaluations for the 1996 JMPR.

e) The report of the York Consultation be considered by 1996 JMPR together with worked examples that demonstrate the FAO Panel guidance given in section 3.

f) GAP information when submitted by either the manufacturer or member governments, clearly identify which of the rates and PHIs are statutory conditions of use or taken directly from the product label and which are estimates made by the manufacturer or member governments (eg. whether the application rates in kg ai/ha have been calculated from the kg ai/hl application concentrations).

g) The concepts contained in the FAO Panel guidance, as given in section 3, be incorporated into the draft document currently entitled "FAO Guidelines in the evaluation of pesticide residues data and the estimation of the Maximum Residue Limits in Food and Feed".

OTHER CONSIDERATIONS

As a result of the examination of a worked example for STMR estimation, the Workshop noted that significant residues of HCB may result in commodities following applications of quintozene. When quintozene is re-evaluated by the JMPR, consideration should be given to the risk associated with the residues of the impurity HCB.

The WHO informed the Workshop that in revising the Guidelines for the prediction of dietary intake of pesticide residues, they would include hypothetical worked examples of intake calculations in order to give further guidance to member governments.

LIST OF PARTICIPANTS *(in alphabetical order)*

Dr U. Banasiak, Chemistry Division, Federal Biological Research Centre for Agriculture and Forestry,Braunschweig, Germany.

Mr S. J. Crossley, Pesticides Safety Directorate, Ministry of Agriculture, Fisheries and Food, York, United Kingdom *(Report writer)*

Mr D. J. Hamilton, Resource Management Institute, Brisbane, Australia.

Dr J. Herrman, International Programme for Chemical Safety, World Health Organisation, Geneva, Switzerland (*WHO Joint Secretary to the JMPR*)

Mr F. Ives, Health Effects Division, Office of Pesticides Programmes, Environmental Protection Agency, Washington, D.C., United States of America

Dr F. Kopisch-Obuch, Pesticide Group, Plant Protection Service, Plant Production and Protection Division, FAO, Rome, Italy (*FAO Joint Secretary to the JMPR)*

Mr G. Moy, GEMS/Food Co-ordinator, Food Safety Unit, Division of Food and Nutrition, WHO, Geneva, Switzerland

Dr W. H. van Eck, Head of Food and Veterinary Policy, Directorate for Public Health, Ministry of Health, Welfare and Sport, Rijswijk, The Netherlands *(Chairman)*

Dr Y. Yamada, Joint FAO/WHO Food Standards Programme, Food Quality and Standards Service, Food Quality and Standards Service, Food Policy and Nutrition Division, FAO, Rome, Italy