4. DIETARY RISK ASSESSMENT

Assessment of risk from long-term dietary intake

At the present Meeting risks associated with long-term dietary intake were assessed for compounds for which MRLs were recommended and STMRs estimated. International estimated daily intakes (IEDIs) were calculated by multiplying the concentrations of residues (STMRs and STMR-Ps) by the average daily per capita consumption estimated for each commodity on the basis of the 13 GEMS/Food Consumption cluster diets.[22] IEDIs are expressed as a percentage of the maximum ADI for a 55 kg or 60 kg person, depending on the cluster diet.

New Evaluations

Clothianidin, cyproconazole, dicamba, etoxazole, flubendiamide, fluopyram, meptyldinocap and thiamethoxam were evaluated for toxicology and/or residues for the first time and the Meeting established ADIs and conducted long-term dietary risk assessments for these compounds.

Periodic Evaluations

Bifenthrin, cadusafos and chlorothalonil were evaluated for toxicology and/or residues under the Periodic Re-evaluation Programme and previous Meetings have established ADIs for these compounds. Long-term dietary risk assessments were conducted for these compounds.

Dithianon and tebuconazole were evaluated for toxicology under the Periodic Re-evaluation Programme and the Meeting established ADIs for these compounds. Long-term dietary risk assessments will be considered during the periodic review for residues at subsequent Meetings.

Evaluations

Bifenazate, boscalid, chlorantraniliprole, difenoconazole, endosulfan, fenpyroximate, fludioxonil, novaluron and triazophos were considered for residues and the Meeting conducted long-term dietary risk assessments for these compounds.

The outcome of the evaluation of a range of compounds on spices, performed at this Meeting, was such that the long-term dietary intake assessment was not necessary.

A summary of the long-term dietary risk assessments conducted by the present meeting is shown on Table 1. The detailed calculations of long-term dietary intakes are given in Annex 3. The upper bound percentages are rounded to one significant decimal up to 0.4, to the whole number up to 9 and nearest 10 above that. Percentages above 100 should not necessarily be interpreted as giving rise to a health concern because of the conservative assumptions used in the assessments. Calculations of dietary intake can be further refined at the national level by taking into account more detailed information, as described in the Guidelines for predicting intake of pesticide residues.[23]

Table 1 Summary of long-term dietary of risk assessments conducted by the 2010 JMPR

CCPR code	Compound Name	ADI (mg/kg bw)	Range of IEDI, as % of maximum ADI
219	Bifenazate	0–0.01	3–20
178	Bifenthrin	0–0.01	8–20
221	Boscalid	0–0.04	10–40

[22] http://www.who.int/foodsafety/chem/gems/en/index1.html

[23] WHO (1997) Guidelines for predicting dietary intake of pesticide residues. 2nd Revised Edition, GEMS/Food Document WHO/FSF/FOS/97.7, Geneva

CCPR code	Compound Name	ADI (mg/kg bw)	Range of IEDI, as % of maximum ADI
174	Cadusafos	0–0.0005	0–1
230	Chlorantraniliprole	0–2	0–0 [0.1–0.4]
081	Chlorothalonil SDS-3701	0–0.02 0–0.008	9–40 5–10
238	Clothianidin	0–0.1	1–2
239	Cyproconazole	0–0.02	1–2
142	Dicamba	0–0.3	0–1
224	Difenoconazole	0–0.01	0–10
180	Dithianon	0–0.01	
032	Endosulfan	0–0.006	2–20
241	Etoxazole	0–0.05	0–1
193	Fenpyroximate	0–0.01	0–6
242	Flubendiamide	0–0.02	3–20
211	Fludioxonil	0–0.4	1–2
243	Fluopyram	0–0.01	0–6
224	Meptyldinocap	0–0.02	
217	Novaluron	0–0.01	7–50
189	Tebuconazole	0–0.03	
245	Thiamethoxam	0–0.08	1–4
143	Triazophos	0–0.001	0–50

Assessment of risk from short-term dietary intake

Consumption data of large portions from the GEMS/Food database were used at the present Meeting to assess the risks associated with short term dietary intake for compounds with STMR and HR estimated values and established acute reference doses (ARfDs). The procedures for calculating the short-term intake were defined primarily in 1997 at an FAO/WHO Geneva Consultation[24] refined at the International Conference on Pesticide Residues Variability and Acute Dietary Risk Assessment sponsored by the Pesticide Safety Directorate and at subsequent JMPR Meetings.

Data on the consumption of large portions were provided to GEMS/Food by the governments of Australia, France, The Netherlands, Japan, South Africa, Thailand, the UK and the USA. Data on unit weights and per cent edible portions were provided to GEMS/Food by the governments of Belgium, France, Japan, Sweden, the UK and the USA. The body weights of adults and children aged ≤ 6 years were provided to GEMS/Food by the governments of Australia, France, the Netherlands, South Africa, Thailand, the UK and the USA. The consumption, unit weight and body weight data used for the short-term intake calculation were compiled by GEMS/Food[25]. The documents are dated April, 2008 (large portions and body weights) and May, 2003 (unit weights). The procedures used for calculating the International estimated short-term intake (IESTI) are described in detail in Chapter 3 of the 2003 JMPR report. Detailed guidance on setting ARfD is described in Section 2.1 of the 2004 JMPR report[26].

On the basis of data received by the present or previous Meetings, the establishment of an ARfD was considered to be unnecessary for bifenazate boscalid, chlorantraniliprole, etoxazole, fludioxonil, meptyldinocap and novaluron. Therefore, it was not necessary to estimate the short-term intakes for these compounds.

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[24] WHO (1997) Food consumption and exposure assessment of chemicals. Report of a FAO/WHO Consultation. Geneva, Switzerland, 10–14 February 1997, Geneva

[25] http://www.who.int/foodsafety/chem/acute_data/en/

[26] Pesticide Residues in Food–2004. Report of the JMPR 2004, FAO Plant Production and Protection Paper 178. Rome, Italy, 20–29 September 2004

Clothianidin, cyproconazole, dicamba, flubendiamide, fluopyram and thiamethoxam were evaluated for toxicology at this Meeting for the first time and ARfDs were allocated. Short-term dietary risk assessments for these compounds were also conducted for these compounds.

Bifenthrin, cadusafos, chlorothalonil were evaluated for toxicology at previous Meetings under the Periodic Re-evaluation Programme and ARfDs were allocated. The current Meeting conducted short-term dietary risk assessments for these compounds.

Dithianon and tebuconazole were evaluated for toxicology at this Meeting under the Periodic Re-evaluation Programme and ARfDs were allocated. The short-term dietary risk assessment for these compounds will be considered during the periodic review for residues at subsequent Meetings.

The short-term intakes as percentages of the ARfDs for the general population and for children are summarized in Table 2. The upper bound percentages are rounded to one significant decimal up to 0.4, to the whole number up to 9 and nearest 10 above that. Percentages above 100 should not necessarily be interpreted as giving rise to a health concern because of the conservative assumptions used in the assessments. The detailed calculations of short-term dietary intakes are given in Annex 4.

Table 2 Summary of short-term dietary risk assessments conducted by the 2010 JMPR

CCPR code	Compound Name	ARfD (mg/kg bw)	Commodity	Percentage of ARfD	
				General population	Children aged ≤ 6 years
219	Bifenazate	Unnecessary			
178	Bifenthrin	0.01	strawberries other commodities	230 0–50	430 0–90
221	Boscalid	Unnecessary			
174	Cadusafos	0.001	all	0–20	0–40
230	Chlorantraniliprole	Unnecessary			
081	Chlorothalonil SDS-3701	0.6 0.03	all	0–20 0–20	0–100 0–50
238	Clothianidin	0.6	all	0–3	0–10
239	Cyproconazole	0.06	all	0–5	0–4
142	Dicamba	0.5	all	0–4	0–9
224	Difenoconazole	0.3			
180	Dithianon	0.1			
032	Endosulfan	0.02	tea infusion	1	1
241	Etoxazole	Unnecessary			
193	Fenpyroximate	0.02	all	0–20	0–60
242	Flubendiamide	0.2	all	0–40	0–60
211	Fludioxonil	Unnecessary			
243	Fluopyram	0.5	all	0–4	0.10
224	Meptyldinocap	Unnecessary			
217	Novaluron	Unnecessary			
189	Tebuconazole	0.3			
245	Thiamethoxam	1	all	0–4	0–10
143	Triazophos	0.001	rice other commodities	0–260 0–40	0–270 0–60

Possible risk assessment refinement when IESTI exceeds the ARfD

Bifenthrin on strawberries

The Meeting noted that the short-term dietary risk assessment of strawberries could be refined if alternative GAP was available.

A concern form regarding the ARfD was received late and with limited information and will be considered at the next meeting.

Triazophos in rice

The Meeting noted that the short-term dietary risk assessment of rice was based on residue data for brown rice and could be refined if additional processing information were available on rice as consumed.

In the current evaluation short-term intakes were estimated for 4 commodities (cotton seed, edible cottonseed oil, immature soya been seed and rice) for which STMR values have been recommended by the 2007 and present JMPR Meetings. The estimated short-term intake derived from residues in soya bean (immature), cotton seed and cotton seed oil for general population and children ranged from 0–40% and 0–60% of the acute reference dose, respectively. However, the short-term intake from residues in rice was 270% and 260% of the ARfD for children and general population, respectively. The results are shown in Annex 4.

The meeting noted that the ARfD of 0.001 mg/kg of body weight is based on a 3 week study in human volunteers with a NOAEL of 0.0125 mg/kg bw, supported by a 52 week study on dogs. The meeting also noted that the NOAEL in the human volunteer study was the highest dose tested and that the LOAEL in the dog study was 30-fold the NOAEL. In addition, limited data from preliminary studies in human volunteers suggest that the NOAEL might indeed be higher than 0.125 mg/kg bw. Consequently, the ARfD is likely to be conservative and it might be refined (e.g., by conducting an acute oral toxicity study in rats)[27].

There was no alternative GAP to be considered.

Studies on the effect of processing (polishing, cooking, frying) are desirable to obtain more realistic information on residue levels in food actually consumed.

[27] Acute Oral Toxicity (OECD Test Guideline 420)