5. EVALUATION OF DATA FOR ACCEPTABLE DAILY INTAKE AND ACUTE DIETARY INTAKE FOR HUMANS, MAXIMUM RESIDUE LEVELS AND SUPERVISED TRIALS MEDIAN RESIDUE VALUES

5.1 ACEPHATE (095) AND METHAMIDIPHOS (100)

Acephate, a broad spectrum organophosphorus insecticide, has been evaluated many times by JMPR since 1976. It was reviewed for residues under the Periodic Re-evaluation Programme in 2003. The 2005 JMPR established an ADI of 0–0.03 mg/kg bw and an ARfD of 0.1 mg/kg bw to replace the previous recommendations.

The 2003 JMPR recommended the following residue definitions for acephate:

Definition of the residue for compliance with MRLs for plant and animal commodities: *acephate.*

Definition of residues for estimation of dietary intake for plant and animal commodities: *acephate and methamidophos.*

Acephate was included in the Priority List at the Forty-second Session of the CCPR in 2010 for the estimation of a maximum residue level for rice by the 2011 JMPR. Summary data were provided by the Government of People's Republic of China for estimation of an MRL for rice.

Plant metabolism

The 2003 JMPR reviewed plant metabolism studies on bean, cabbage and tomato seedlings, cotton and beans. No information was available on metabolism of acephate in rice. Taking into consideration information on metabolism of other plants and environmental fate in soil and water-sediment systems evaluated by the 2003 JMPR, the present Meeting considered that metabolism of acephate in rice would be similar to that in other plants.

Analytical methods

Analysis of acephate and methamidophos in rice involves extraction of ground husked rice with a mixture of acetonitrile and water (70:5), evaporation of the supernatant at 40 ˚C, dissolving the resulting dry matter in acetone, and quantitation of acephate and methamidophos using gas chromatography equipped with FPD. This method follows a similar approach to the methods reviewed by the 2003 JMPR.

The method was tested for recovery using husked rice, husk and straw as matrices resulting in acceptable recovery and RSD. The LOQ was 0.01–0.025 mg/kg for acephate and 0.01–0.05 mg/kg for methamidophos, depending on the participating laboratories.

Stability of pesticide residues in stored analytical samples

When spiked at 1 mg/kg, acephate and methamidophos in husked rice were stable for at least 360 days, the longest storage period tested, at -15 to -20 ˚C. About 85% of spiked acephate and 84% of spiked methamidophos remained after 360 days.

In the supervised residue trials, samples were analysed within one month of freezing.

Results of supervised trials on crops

The Meeting received information of supervised field trials of acephate on rice conducted in eight provinces in China in 2009.

The OECD MRL calculator was used as a tool to assist in the estimation of maximum residue levels from the selected residue data set obtained from the supervised residue trials. As a first step, the Meeting reviewed trial conditions and other relevant factors related to each data set to arrive at a best estimate of the maximum residue level using expert judgement. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value, a brief explanation of the derivation was supplied.

Rice

Residues of acephate and methamidophos arising from the use of acephate on rice were analysed in husked rice dried in two different ways from the applications of 2 similar formulations in the supervised trials.

The GAP in China allows the maximum of two applications at the maximum application rate of 1.01 kg ai/ha (30% EC) or 1.13 kg ai/ha (75% SP) with the PHI of 45 days.

Rice grains were harvested at their maturity and dried in two ways to reduce the moisture content to ≤ 13.5%. Immediately after the moisture content reached this level, rice grains were husked and the resulting husked rice was analysed. Husks from trials matching GAP were also analysed.

The residue concentrations in the trials conducted in Zhejiang Province were always significantly higher than those from trials conducted in other regions but this did not seem to be caused by analytical errors. The laboratory involved in the analysis of samples from the Zhejiang trials produced acceptable recoveries using the analytical method mentioned above. The Meeting agreed that there was no reason to disregard these values in the estimation of maximum residue levels.

As the Meeting considered trials in the same location with the same variety and timing, similar formulations and similar application rates not independent, the highest residue value of the four values in one location were selected and used for estimating a maximum residue level.

Residues of acephate selected as above were in rank order: < 0.025, 0.04, 0.04, 0.04, 0.07, 0.09, 0.10 and 0.69 mg/kg.

The Meeting estimated a maximum residue level at 1 mg/kg for acephate in husked rice.

The Meeting estimated a median residue at 0.055 mg/kg for acephate in husked rice for the purpose of calculating animal dietary burdens.

Residues of methamidophos selected as above were in rank order: 0.02, < 0.025, < 0.025, < 0.05, < 0.05, 0.05, 0.05 and 0.38 mg/kg.

The Meeting estimated a maximum residue level at 0.6 mg/kg for methamidophos in husked rice.

It also estimated a median residue at 0.025 mg/kg for methamidophos in husked rice for the purpose of calculating animal dietary burdens.

As the residue definition for estimation of dietary intake for plant and animal commodities was “acephate and methamidophos”, the combined adjusted residues of acephate and methamidophos were calculated after scaling the methamidophos residues to account for the difference in toxicity with the factors derived from the ratios of respective maximum ADI and ARfD values. These factors are 7.5 (maximum ADI of acephate and methamidophos, 0.03 and 0.004 mg/kg bw) and 10 (ARfD of acephate and methamidophos, 0.1 and 0.01 mg/kg bw) respectively for long-term and short-term intake estimates. The highest calculated value from each of eight locations was selected for estimating STMRs. For summing up, if acephate or methamidophos residues were below the LOQ, LOQ value of each was used.

For the estimation of long-term dietary intake, the calculated values of “acephate + 7.5 × methamidophos” were: 0.20, 0.21, 0.23, 0.40, 0.41, 0.45, 0.47 and 3.54 mg/kg. The Meeting estimated an STMR of 0.405 mg/kg for the estimation of long-term dietary intake.

For the estimation of short-term dietary intake, the calculated values of "acephate + 10 × methamidophos" were: 0.25, 0.28, 0.29, 0.53, 0.54, 0.56, 0.59 and 4.49 mg/kg. The Meeting estimated an STMR of 0.535 mg/kg for the estimation of short-term dietary intake.

Rice straw

Residues of acephate and methamidophos (arising from the use of acephate on rice) in straw from the application of 2 similar formulations in the supervised trials matching GAP were analysed.

Highest residues of acephate in each of the eight trial locations were in rank order: < 0.01, < 0.01, < 0.01, < 0.025, < 0.025, 0.08, 0.10 and 0.14 mg/kg.

The Meeting estimated a maximum residue level, highest residue and median residue at 0.3 mg/kg, 0.14 mg/kg and 0.025 mg/kg respectively for acephate in rice straw and fodder, dry.

Highest residues of methamidophos in each of the eight trial locations are in rank order: < 0.01, 0.01, < 0.025, < 0.025, 0.04, < 0.05, < 0.05 and 0.05 mg/kg.

The Meeting estimated a maximum residue level, highest residue and median residue at 0.1 mg/kg, 0.05 mg/kg, 0.0325 mg/kg respectively for methamidophos in rice straw and fodder, dry.

Fate of residues during processing

The Meeting received information on processing of husked rice to polished rice.

The mean processing factors were calculated for "acephate + (7.5 × methamidophos)" and "acephate + (10 × methamidophos)" to be 0.81 and 0.82 respectively.

STMR-Ps for polished rice were calculated using the STMRs of husked rice and these processing factors. An STMR for polished rice for long-term intake estimation was calculated to be 0.33 mg/kg. An STMR for polished rice for short-term intake estimation was calculated to be 0.44 mg/kg.

The mean processing factors were calculated for polished rice to be 0.63 and 0.85 respectively for acephate and methamidophos. An STMR of 0.021 mg/kg was calculated for methamidophos in polished rice.

No data were available to estimate processing factors or STMR-Ps for rice bran.

Residues in animal commodities

Farm animal dietary burden

Rice and/or its straw may be fed to dairy cattle, beef cattle, broilers and layers. The maximum and mean dietary burdens were calculated using the highest residue, STMR/STMR-P or median residue of acephate or methamidophos in commodities for which maximum residue levels were recommended and processed products thereof on a basis of the OECD Animal Feeding Table.

Resulting maximum and mean dietary burdens for beef and dairy cattle were smaller than those calculated for acephate in 2003 (2.2 and 1.1 ppm for maximum and mean dietary burden of beef cattle and dairy cattle respectively) because of the revision of the OECD Animal Feeding Table, or identical to those calculated for methamidophos.

Resulting maximum and mean dietary burdens for broilers and layers were larger than those calculated in 2003 (0.0067 ppm for the maximum and mean dietary burden of poultry for acephate and 0.0022 ppm for the maximum and mean dietary burden of poultry for methamidophos) but still much smaller than 3 ppm in diet dry matter, after feeding of which no residues above LOQ were found in any of edible tissues and eggs.

The Meeting concluded that there was no need to re-evaluate maximum residue levels, STMRs or HRs for commodities of animal origin.

Summary of livestock dietary burdens calculated (ppm of dry matter diet)

Acephate	US-Canada		EU		Australia		Japan	
	max	Mean	max	Mean	max	Mean	max	mean
Beef cattle	0.05	0.05	1.12	1.11	1.18[a]	1.11[b]	0.10	0.03
Dairy cattle	0.56	0.56	0.58	0.57	0.59[c]	0.57[d]	0.056	0.024
Broilers	0.02	0.02	0.04	0.04	0.05	0.05	0.01	0.01
Layers	0.02	0.02	0.02	0.02	0.05[e]	0.05[f]	0.01	0.01
Methamidophos	US-Canada		EU		Australia		Japan	
	max	Mean	max	Mean	Max	Mean	max	mean
Beef cattle	0.01	0.01	0.05	0.05	0.08[a]	0.07[b]	0.04	0.03
Dairy cattle	0.03	0.03	0.03	0.03	0.04[c]	0.04[d]	0.03	0.02
Broilers	0.01	0.01	0.01	0.01	0.02	0.02	0.01	0.01
Layers	0.01	0.01	0.01	0.01	0.02[e]	0.02[f]	0.01	0.01

[a] Suitable for estimating maximum residue levels for meat, fat and edible offal of cattle.

[b] Suitable for estimating STMRs for meat, fat and edible offal of cattle.

[c] Suitable for estimating maximum residue levels for milk of cattle.

[d] Suitable for estimating STMRs for milk of cattle.

[e] Suitable for estimating maximum residue levels for meat, fat and edible offal of poultry and eggs.

[f] Suitable for estimating STMRs for meat, fat and edible offal of poultry and eggs.

DIETARY RISK ASSESSMENT

Dietary intake estimates for the combined adjusted residues utilizing the scaling factors were compared with the maximum ADI and ARfD of acephate.

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of acephate were calculated for the 13 GEMS/Food cluster diets using STMRs and STMRPs estimated by the 2003, 2006 and current Meeting (Annex 3). The ADI is 0–0.03 mg/kg bw and the calculated IEDIs were 2–10% of the maximum ADI. The Meeting concluded that the long-term intake of residues of acephate (and methamidophos arising from use of acephate) resulting from the uses of acephate considered by the 2003, 2006 and current JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-Term Intakes (IESTI) of acephate (and methamidophos arising from use of acephate) were calculated for husked rice and polished rice using STMRs estimated by the current Meeting (Annex 4). The ARfD is 0.1 mg/kg bw and the calculated IESTIs were 3–4% of the ARfD. The Meeting concluded that the short-term intake of residues of acephate, when used in ways that have been considered by the current JMPR, is unlikely to present a public health concern.