

## 5.12 GLYPHOSATE (158)

### RESIDUE AND ANALYTICAL ASPECTS

Glyphosate is a widely used non-selective herbicide. Glyphosate was first evaluated for toxicology and residues by the JMPR in 1986. It was further evaluated for residues on multiple occasions by the JMPR including a periodic review of residues in 2005.

The 2011 JMPR established a group ADI of 0–1 mg/kg bw for the sum of glyphosate, N-acetyl glyphosate, AMPA and N-acetyl-AMPA. The same Meeting confirmed that an ARfD was unnecessary.

Definition of the residue for compliance with the MRL (for plant commodities): *for soya bean, maize and rape - sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate; and for other crops - glyphosate.*

Definition of the residue for compliance with the MRL (for animal commodities): *sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate.*

The residue definition for dietary risk assessment (for plant and animal commodities): *glyphosate, N-acetyl-glyphosate, AMPA and N-acetyl AMPA, expressed as glyphosate.*

The residue is not fat soluble.

Glyphosate was scheduled at the Fiftieth Session of the CCPR for the evaluation of additional uses at the Extra 2019 JMPR. The current Meeting received information on analytical method for lentil, storage stability, use pattern and supervised residue trials on conventional varieties of lentil, bean dry and tree nuts.

#### **Methods of analysis**

An HPLC-FLD analytical method used for determining residues of glyphosate and AMPA in pea dry, bean dry, and tree nuts was previously evaluated by the 2005 JMPR. A new analytical method for lentils along with validation data was received by the Meeting. The residues in lentil were extracted with a 0.1% formic acid solution, centrifuged and analysed by LC-MS/MS. The method was validated with LOQs of 0.05 mg/kg for both glyphosate and AMPA in lentils.

#### **Storage stability of residues**

In 2005, JMPR confirmed that glyphosate residues were stable under frozen storage conditions (-20 °C) in/on the following commodities (storage interval in parentheses): beans, rape and linseed (at least 18 months), and soya bean seed (at least 6 months).

All samples in new residue trials were stored frozen for less than 5 months before extraction and analysis.

#### **Results of supervised residue trials on crops**

The Meeting received supervised trial data for foliar applications of glyphosate on lentils, bean dry, almond, pecan and walnut.

To calculate the sum of glyphosate and AMPA, expressed as parent equivalents (total residues), the Meeting used the approach agreed at the 2005 JMPR.

“When glyphosate and AMPA were summed, AMPA was converted to glyphosate equivalents (AMPA mg/kg × 1.523). All numerical figures for glyphosate application rates (kg ae/ha) or residue levels (mg/kg) are expressed as glyphosate acid equivalents (molecular weight 169 atomic mass units (amu)), and do not include any mass amounts for the salt cation (e.g., isopropylamine).”

“If AMPA residues are < 0.05 mg/kg, they are not summed with glyphosate, because they are typically much less than glyphosate residues. If both glyphosate and AMPA are < LOQ, then sum is < LOQ of glyphosate. The exception is where there is evidence that AMPA residues are comparable to

glyphosate residues such as for soya beans in which case the residues are summed and if both glyphosate and AMPA residues are < LOQ, the sum is less than the combined LOQs for glyphosate and AMPA. “

The Meeting noted that soya bean is a representative crop for metabolism of pulses and decided to extend the above approach to pulses.

The table below describes how total residues were calculated for each trial.

Glyphosate (mg/kg)	AMPA (mg/kg)	Total (mg/kg)
<0.05	<0.05	<0.05
<0.05	<0.05	<0.1 (Pulses)
0.05	<0.05	0.05
0.05	0.05	0.13 (0.05+(0.05×1.523))

### *Dry peas, subgroup of*

The critical GAP for dry peas, lentils and chickpeas in the USA is 2 applications of 4.2 kg ai/ha pre-emergence and 2.5 kg ai/ha pre-harvest with a PHI of 7 days.

Trials received by the current Meeting were conducted on lentils (four from the USA and seven from Canada) approximating GAP in the USA.

Glyphosate residues were (n=11) 0.37, 0.41, 0.90, 1.3, 1.6, 1.8, 1.9, 2.0, 2.9, 5.3, and 6.3 mg/kg. Total residues from these 11 trials in ranked order were (n=11) 0.37, 0.41, 0.90, 1.3, 1.6, 1.8, 1.9, 2.0, 2.9, 5.3, and 6.4 mg/kg (express as glyphosate).

In 2011, JMPR received five additional field trials on conventional peas (dry) performed in the USA in 1998, matching the US GAP. Glyphosate residues (glyphosate only) in seeds in rank of order were (n=5): 0.70, 0.77, 1.1, 3.4, and 4.2 mg/kg at DALA 7 days. As the residue of AMPA was below 0.05 mg/kg even when glyphosate residue was 5.3 mg/kg, the Meeting concluded that the residue of AMPA in peas, dry were below 0.05 mg/kg.

As the US GAP covers the subgroup of dry peas, the Meeting decided to recommend a maximum residue level for the subgroup of dry peas. The data on lentils and peas, dry, were not significantly different according to the Mann-Whitney U test. The Meeting decided to combine the datasets.

Combined residues of glyphosate were: (n=16) 0.37, 0.41, 0.70, 0.77, 0.90, 1.1, 1.3, 1.6, 1.8, 1.9, 2.0, 2.9, 3.4, 4.2, 5.3 and 6.3 mg/kg. The total residues were: (n=16) 0.37, 0.41, 0.70, 0.77, 0.90, 1.1, 1.3, 1.6, 1.8, 1.9, 2.0, 2.9, 3.4, 4.2, 5.3 and 6.4 mg/kg.

The Meeting estimated a maximum residue level for the subgroup of dry peas at 10 mg/kg, and an STMR at 1.7 mg/kg, and withdrew the previous maximum residue level recommendations for pea dry and lentil of 5 mg/kg.

### *Dry beans, except soya bean*

The critical GAP for dry beans in the UK is one application at 1.44 kg ai/ha pre-harvest with a PHI of 7 days.

Thirteen trials in beans, dry were conducted in the USA at an application rate of 4.20 kg ai/ha pre-emergence and an application rate of 1.71 kg ai/ha pre-harvest with harvest 7 DALA. The Meeting considered that the pre-emergence applications would not contribute significantly to residue levels at harvest.

The glyphosate residues found in these trials were (n=13): < 0.05, 0.06, 0.19 (2), 0.20, 0.21, 0.32, 0.53, 0.63, 0.80, 1.8, 2.6 and 10 mg/kg. The total residues of glyphosate residues were (n=13): < 0.1, 0.06, 0.19(2), 0.20, 0.21, 0.32, 0.53, 0.63, 0.80, 1.8, 2.6 and 11 mg/kg.

The Meeting noted that dry bean is the representative commodity for the dry beans subgroup, and estimated a maximum residue level of 15 mg/kg and a STMR of 0.32 mg/kg for glyphosate for the

dry beans subgroup (except soya bean). The Meeting withdrew its previous recommendation of 2 mg/kg for beans, dry.

### ***Tree nuts***

The critical GAP for tree nuts in the USA is for one or more ground directed applications of 4.2 kg ai/ha up to a maximum seasonal rate of 8.8 kg ai/ha and a PHI of 3 days.

The 2005 JMPR received trial data for glyphosate on almond, pecan, and walnut from the USA, which included one directed application of 8.9 kg ai/ha with harvest 3 DALA. The residue trials submitted did not match the GAP.

The current Meeting did not receive new residue data. The Meeting concluded that the proportionality approach could not be applied to the available data, thus an estimate of a maximum residue level could not be performed.

### ***Animal feed commodities***

The maximum dietary burdens calculated by the 2005 JMPR for cattle and poultry were 381 ppm for cattle and 22.7 ppm for poultry. The current Meeting calculated the additional contribution to the dietary burdens for cattle and poultry from the residues in pea dry and bean dry represented a minor portion (up to 0.79 ppm) of the dietary burdens calculated by the 2005 JMPR. The Meeting confirmed its previous recommendations for animal commodities.

## **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 plant commodities): for soya bean, maize and rape - sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate, and for other crops - glyphosate.

Definition of the residue for compliance with the MRL (for animal commodities): sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate.

Definition of the residue for dietary risk assessment (for plant and animal commodities): glyphosate, N-acetyl-glyphosate, AMPA and N-acetyl AMPA, expressed as glyphosate.

The residue is not fat soluble.

## **DIETARY RISK ASSESSMENT**

### ***Long-term dietary exposure***

The ADI for glyphosate is 0–1 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for glyphosate were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2019 Extra JMPR Report.

The IEDIs ranged from 1–4% of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of glyphosate from uses considered by the JMPR is unlikely to present a public health concern.

### ***Acute dietary exposure***

The 2011 JMPR decided that an ARfD for glyphosate was unnecessary. The Meeting therefore concluded that the acute dietary exposure to residues of glyphosate from the uses considered is unlikely to present a public health concern.

