

## 5.11 Fluazifop-P-butyl (283)

### RESIDUE AND ANALYTICAL ASPECTS

Fluazifop-P-butyl is a herbicide used for the post-emergence control of grasses in a wide range of broad-leaved crops. Fluazifop-P-butyl was first evaluated for toxicology and residues by the 2016 JMPR. An ADI of 0–0.004 mg/kg bw and an ARfD of 0.4 mg/kg bw were established. The residue definitions were established as follows:

Residue definition for compliance with the MRL in plant commodities: total fluazifop, defined as the sum of fluazifop-P-butyl, fluazifop-P-acid (II) and their conjugates, expressed as fluazifop-P-acid.

Residue definition for dietary risk assessment in plant commodities: the sum of fluazifop-P-butyl, fluazifop-P-acid (II), 2-[4-(3-hydroxy-5-trifluoromethyl-2-phenoxy)pyridyloxy] propionic acid (XL), 5-trifluoromethyl-2-pyridone (X) and their conjugates, expressed as fluazifop-P-acid.

Residue definition for compliance with the MRL and for dietary risk assessment in animal commodities: total fluazifop, defined as the sum of fluazifop-P-butyl, fluazifop-P-acid (II) and their conjugates, expressed as fluazifop-P-acid. The residue is fat-soluble.

Fluazifop-P-butyl was scheduled at the Fiftieth Session of the CCPR for the evaluation of additional uses by the 2019 JMPR. The current Meeting received new information on the validation of analytical methods and storage stability for green onion, a label and supervised residue trials on strawberry. Since new GAP information had become available for cane berries, blueberries, strawberries and green onion, the Meeting evaluated previously submitted supervised residue trial data on these commodities against the new GAP.

#### **Analytical methods**

Method GRM044.01A (modification B) for the determination of total fluazifop (fluazifop-butyl, fluazifop acid (II) and its conjugates) in plant commodities as fluazifop acid was reviewed by the 2016 JMPR. Based on the validation data of method GRM044.01A for cane berries, blueberries and strawberries, and radiovalidation data, the 2019 JMPR considered that method GRM044.01A was suitable for determination of fluazifop-P-butyl residues in the supervised field trials on cane berries, blueberries and strawberries. The LOQs are 0.02 mg/kg for blueberries and cane berries, and 0.01 mg/kg for strawberries.

The current Meeting received validation data for green onion (GRM044.01A modification B). The Meeting considered that method GRM044.01A (modification B) was suitable for determination of fluazifop-P-butyl residues in the supervised field trials on green onion as fluazifop acid with an LOQ of 0.01 mg/kg.

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

The storage stability of fluazifop acid was evaluated by the 2016 Meeting in cane berries, blueberries and strawberries. The 2016 Meeting concluded that fluazifop acid is stable when stored frozen for at least 27 months at -1 °C, 8 months at -15 °C and for 31 months at -20 °C in raspberries, blueberries and strawberries.

The current Meeting received new data on storage stability of fluazifop in green onion (spiked with fluazifop and determined by GRM044.01A modification B) at -18 °C, and concluded that fluazifop was stable for at least 20 months.

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

The Meeting received supervised residue trial data for directed ground spray applications of fluazifop-P-butyl on cane berries and blue berries, and foliar applications on strawberries and green onion.

### *Cane berries*

The current Meeting evaluated the USA trials provided to the 2016 Meeting against the GAP from the USA. Critical GAP for cane berries in the USA allows two ground banded spray applications at a rate of 0.42 kg ai/ha with an interval of 14 days and a PHI of 1 day.

Five independent supervised field trials were conducted on cane berries in the USA approximating the critical GAP.

The total fluazifop residues in blackberry were (n = 3): < 0.020 (3) mg/kg. The total fluazifop residues in raspberry were (n = 2): < 0.020, 0.05 mg/kg.

The combined total fluazifop residues in cane berries were (n = 5): < 0.020 (4), 0.05 mg/kg.

The Meeting noted that the GAP of the USA is for the cane berries subgroup, and that blackberry and raspberry are representative commodities for the subgroup of cane berries. The Meeting decided to estimate a maximum residue level of 0.08 mg/kg for the subgroup of cane berries to replace the previous recommendation. The Meeting estimated a median of 0.02 mg/kg and highest residue of 0.07 mg/kg (highest individual).

Using the multiplication factor of 1.05 to the median and highest residues, the Meeting estimated an STMR of 0.021 mg/kg and an HR of 0.074 mg/kg (highest individual  $0.07 \times 1.05$ ).

### *Bush berry*

#### *Blueberry*

The current Meeting evaluated the data from the USA provided to the 2016 Meeting against the new GAP from the USA. Critical GAP in the USA for bush berries (high bush) allows two ground banded spray applications at a rate of 0.42 kg ai/ha with an interval of 14 days and a PHI of 1 day.

Seven independent trials on blueberries were conducted in the USA approximating the cGAP. The total fluazifop residues in blueberries were (n = 7): < 0.020 (5), 0.05, 0.19 mg/kg.

The Meeting noted that the USA GAP is for the bush berries subgroup, and that blueberry is the representative commodity for the subgroup. The Meeting decided to estimate a maximum residue level of 0.3 mg/kg for the subgroup of bush berries. The Meeting estimated a median of 0.02 mg/kg and highest residue of 0.25 mg/kg (highest individual).

Using the multiplication factor of 1.05 to the median and highest residues, the Meeting estimated an STMR of 0.021 mg/kg and an HR of 0.26 mg/kg (highest individual  $0.25 \times 1.05$ ).

The Meeting noted that the USA GAP for bush berries (high bush) also covers high bush cranberries and elderberry, listed in the Codex Classification as Guelder rose (*Viburnum opulus* L) and elderberries (*Sambucus spp.*) in the subgroup of large shrub/tree berries, and agreed to extrapolate the maximum residue level of 0.3 mg/kg, STMR of 0.021 mg/kg and HR of 0.26 mg/kg for fluazifop to Guelder rose and elderberries.

The Meeting decided to withdraw the previous recommendations of 0.01(\*) mg/kg for currants, black, red, white, and for gooseberries.

#### *Strawberry*

The critical GAP in the USA for strawberry allows one foliar spray application at a rate of 0.28 kg ai/ha with a PHI of 14 days.

The Meeting received six supervised field trials conducted on strawberry in the USA approximating the critical GAP.

The total fluazifop residues in strawberry were (n = 6): 0.27, 0.37, 0.60, 0.70, 1.1 and 1.4 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg for strawberry to replace the previous recommendation. The Meeting estimated a median of 0.65 mg/kg and highest residue of 1.43 mg/kg (highest individual).

Using the multiplication factor of 1.05 to the median and highest residues, the Meeting estimated an STMR of 0.685 mg/kg and an HR of 1.5 mg/kg (highest individual 1.43 x1.05) for strawberry.

### *Green onion*

The critical GAP in the USA for green onion allows two foliar applications of 0.42 kg ai/ha with an interval of 14 days and a PHI of 14 days.

Four independent trials were conducted in the USA on green onion approximating the US GAP, total fluazifop residues were (n = 4): 0.13, 0.36, 0.48 and 0.59 mg/kg.

The Meeting concluded that the data were insufficient for estimating a maximum residue level for green onion.

### **Residues in animal commodities**

None of the commodities for which supervised trial data were submitted to the current Meeting or their by-products are fed to animals. 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 in Annex 1 are suitable for establishing maximum residue limits and for IEDI and IESTI assessment.

Definition of the residue for compliance with the MRL in plant commodities: total fluazifop, defined as the sum of fluazifop-P-butyl, fluazifop-P-acid (II) and their conjugates, expressed as fluazifop-P-acid.

Definition of the residue for dietary risk assessment in plant commodities: the sum of fluazifop-P-butyl, fluazifop-P-acid (II), 2-[4-(3-hydroxy-5-trifluoromethyl-2-phenoxy)pyridyloxy] propionic acid (XL), 5-trifluoromethyl-2-pyridone (X) and their conjugates, expressed as fluazifop-P-acid.

Definition of the residue for compliance with the MRL and for dietary risk assessment in animal commodities: total fluazifop, defined as the sum of fluazifop-P-butyl, fluazifop-P-acid (II) and their conjugates, expressed as fluazifop-P-acid.

The residue is fat-soluble.

## **DIETARY RISK ASSESSMENT**

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

The ADI for fluazifop-P-butyl is 0–0.004 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for fluazifop-P-butyl 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 JMPR Report. The IEDIs ranged from 30–160% of the maximum ADI of 0.004 mg/kg bw. An exceedance was found for GEMS/Food cluster diet G16 (160%).

Based on the decision of CCPR 2017 (REP17/PR) to withdraw the draft MRLs for sweet potato and yam the IEDIs ranged from 20–90% of the maximum ADI of 0.004 mg/kg bw. On this basis, the Meeting concluded that the long-term dietary exposure to residues of fluazifop-P-butyl from uses considered by the JMPR (excluding sweet potato and yam) is unlikely to present a public health concern.

***Acute dietary exposure***

The ARfD for fluazifop-P-butyl is 0.4 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for fluazifop-P-butyl were calculated for food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMP-Ps were estimated by the current Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2019 JMPR Report.

The IESTIs varied from 0–6% of the ARfD for children and 0–3% for the general population. The Meeting concluded that acute dietary exposure to residues of fluazifop-P-butyl from uses considered by the current Meeting is unlikely to present a public health concern.