5.33 SULFOXAFLOR (252)

RESIDUE AND ANALYTICAL ASPECTS

At the Forty-fifth Session of the Codex Committee on Pesticide Residues (2013) concern was raised by the USA regarding MRL recommendations by the 2011 JMPR for sulfoxaflor in/on bean (dry), common bean and carrots which were based on a regional approach to the selection of residue trial data for use in MRL estimation, as opposed to a global approach.

The 2011 JMPR evaluated sulfoxaflor as part of the CCPR pilot project in which JMPR would conduct an evaluation and recommend maximum residue levels prior to registration by national governments. At the same Meeting, the JMPR considered a change in its practices for selection of residue trials for estimating maximum residue levels and agreed to consider residue data from all geographic regions in selecting residue trials matching a particular GAP (global approach). The 2011 meeting prepared a general consideration item to communicate the planned change to CCPR and provided notification that the change would be introduced at its 2012 meeting. The aim was to allow the CCPR time to consider the change prior to its implementation. The general consideration item also listed MRL recommendations that would have been made if a global approach had been taken allowing CCPR as the risk managers the option of utilising these recommendations.

The Forty-fourth Session of CCPR (2012) indicated their support for the change and suggested JMPR develop clear guidance and criteria on identifying and combining comparable data sets from different geographical regions.

The current Meeting prepared a general consideration item providing guidance on the use of the global approach (General considerations item 2.8) and agreed to the request to re-evaluate the residue data for bean (dry), Common bean and carrots using the global approach to data selection.

Beans (dry)

Sulfoxaflur is registered in the USA for use on beans (GAP: 4 × 0.08 kg ai/ha, a 14 day RTI, and a 7 day PHI).

In 2011 the JMPR reported that six trials on dry beans were available from Brazil (4) and Northern Europe (1), and Southern Europe (1).

Residues of sulfoxaflor, in ranked order, found in dry beans from:

Brazil: 0.05, 0.07, 0.08, and 0.10 mg/kg.

Germany: 0.10 mg/kg.

Spain: 0.022 mg/kg.

Using the global dataset the Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.075 mg/kg.

Common bean (pods and/or immature seeds)

The registered use pattern in the USA for sulfoxaflor on common beans is 4 × 0.1 kg ai/ha, a 7 day RTI, and a 7 day PHI.

The 2011 JMPR reported six trials on common bean that matched the GAP of the USA, one each from Germany, Greece, Hungary, Italy, Poland and Spain. Residues were: 0.03, 0.07, 0.08, 0.12, 0.31, 1.9 mg/kg. No reason was found for the large difference between the highest and other residue values. The Meeting suggested additional residue trial data are required to estimate an appropriate maximum residue level.

Carrots

In the USA sulfoxaflor is registered for use on carrots at 4 × 0.1 kg ai/ha with a 7 day RTI and a 7 day PHI. Seven trials from Europe and four from the USA matched the GAP of the USA with residues of: < 0.01, < 0.01, 0.01, 0.01, 0.02, 0.03, 0.03 mg/kg from Europe and < 0.01, < 0.01, 0.01, 0.01 mg/kg from the USA.

The Meeting estimated a maximum residue level of 0.05 mg/kg for carrots, an STMR of 0.01 mg/kg and an HR of 0.03 mg/kg.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) for sulfoxaflor was estimated for the 13 GEMS/Food cluster diets using the STMR or STMR-P values estimated by the current Meeting. The results are shown in Annex 3 of the 2013 JMPR Report. The IEDI ranged from 1 to 7% of the ADI (0–0.05 mg/kg bw). The Meeting concluded that the long-term intake of residues of sulfoxaflor, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

Short-term intake

The International Estimated Short Term Intake (IESTI) for sulfoxaflor was calculated for the plant and livestock commodities (and their processing factions) for which STMRs and HRs were estimated and for which consumption data were available. The results are shown in Annex 4 of the 2013 JMPR Report.

The IESTI varied from 0 to 60% of the ARfD (0.3 mg/kg bw). The Meeting concluded that the short-term intake of residues of sulfoxaflor, from uses that have been considered by the JMPR, is unlikely to present a public health concern.