5.11 DICAMBA (240)

RESIDUE AND ANALYTICAL ASPECTS

Dicamba, a systemic broad-spectrum herbicide, was first evaluated by the 2010 JMPR which estimated an ADI of 0-0.3 mg/kg bw and ARfD of 0.5 mg/kg bw, and recommended the following residue definitions for plant commodities:

Definition of the residue for plant commodities (for compliance with the MRL): Dicamba

Definition of the residue for plant commodities (for estimation of dietary intake): Sum of dicamba and 5-OH dicamba expressed as dicamba

Definition of the residue for animal commodities (for compliance with the MRL and for estimation of dietary intake): *Sum of dicamba and DCSA expressed as dicamba*

The 2010 Meeting reviewed metabolism, method of analysis, storage stability, supervised residue trials and processing studies of dicamba in soya beans. However, as no supervised trials matched US GAP, the Meeting could not estimate a maximum residue level for soya bean (dry). The 2011 Meeting decided to apply the concept of proportionality to the residues from these trials to recommend a maximum residue level.

The Forty-fith Session of the Codex Committee on Pesticide Residues in 2013 agreed to the Principles and Guidance for Application of the Proportionality Concept to Estimation of Maximum Residue Limits for Pesticides and further agreed that desiccants should be excluded from the application of the proportionality concept.

The current Meeting received information on new supervised trials on soya beans following the US GAP and analytical methods used for the determination of dicamba and related compounds in the new supervised trials on soya beans.

Method of analysis

The current Meeting received information on the analytical method used for the determination of dicamba, 5-OH dicamba and 3,6-dichloro-2-hydroxybenzoic acid (DCSA) arising in soya bean seeds, forage and hay in newly conducted supervised residue trials. The method analysed these compounds using LC-MS/MS, monitoring ion transitions from m/z 219 \rightarrow 175 for dicamba; m/z 235 \rightarrow 155 for 5-OH-dicamba; and m/z 205 \rightarrow 161 for DCSA.

The method was found suitable for the determination of the three analytes in soya bean seeds, forage and hay with mean recoveries in the acceptable range of 70-110% at the fortification levels between 0.01 and 10 mg/kg.

The limit of quantitation (LOQ) is 0.01 mg/kg for the determination of dicamba, 5-OH dicamba and DCSA in soya bean seeds, forage and hay, except that this LOQ was not achievable in forage or hay for the 2010 season analysis.

Results of supervised residue trials on crops

Soya bean (dry)

A total of twelve supervised residue trials were conducted in the USA in 2010 and 2012.

The approved use of dicamba in soya bean in the USA consists of two different applications: application of up to 0.56 kg ai/ha as a broadcast application made approximately 14 days prior to planting, and/or up to 1.12 kg ai/ha applied to soya bean plants after soya bean pods have reached mature brown color and at least 75% leaf drop has occurred with a PHI of 7 days. If both pre-plant

and pre-harvest applications are used in one season, the maximum seasonal use rate must not exceed 2.24 kg ai/ha. After a pre-harvest application soya bean fodder and hay must not be fed to animals.

After one pre-plant and one pre-harvest applications using the three different salt types, residues in the seed (dry) samples were primarily the parent compound and mostly relatively low (< 0.1 mg/kg). However, residue concentrations vary hugely, due possibly to the split of pods causing seeds to come into contact with dicamba itself or dicamba residue on the outer surface of pods. Since all the trials approximated normal agricultural practices, the Meeting decided to use these trial results in estimating a maximum residue level. No significant difference or pattern was observed among the trials using these different formulations.

Residues of dicamba in soya bean (dry) from those trials matching the GAP of the USA were, in rank order (n=12): < 0.01 (2), 0.01, 0.02, 0.025 (2), 0.035, 0.06, 0.12, 0.545, 5.4 and 5.6 mg/kg.

The Meeting estimated a maximum residue level of 10 mg/kg to replace the previous recommendation of 5 mg/kg. For the purpose of calculating animal dietary burden, the Meeting estimated a median residue of 0.03 mg/kg.

Corresponding total residues (dicamba and 5-OH dicamba) of dicamba were (n=12): < 0.01, < 0.02, 0.02 (2), 0.025, 0.03, 0.035, 0.06, 0.13, 0.555, 5.635 and 6.06 mg/kg.

The Meeting estimated an STMR of 0.033 mg/kg.

Soya bean forage and hay

Soya bean forage and hay samples were collected before the second application was made to avoid abscission. Therefore, residues in these commodities came from a pre-plant application only. The US label prohibits the use of fodder or hay after a pre-harvest application.

The residues from the pre-plant application were expected to be very low as shown in the trials (mostly < 0.05 mg/kg and in one trial 0.06 mg/kg for dicamba) and, as such, residues in soya bean forage and hay from only pre-plant application would not have impacted on the livestock dietary burden. Therefore, the Meeting confirmed the decision of the 2010 and 2011 JMPR that there was no need for estimating a maximum residue level, median residue or highest residue for soya bean fodder and hay.

Fate of residues during processing

The 2010 JMPR received and reviewed information on processing of soya bean seed to oil and meal.

| Processed | Processing factor | | STMR/STMR-P |
|-------------|-------------------|----------------|-------------|
| Product | Dicamba | Total residues | |
| Soya bean | | | 0.033 |
| Refined oil | < 0.019 | < 0.036 | 0.001 |

As there is no concentration of dicamba and 5-OH dicamba observed in refined oil, the estimation of a maximum residue level is not necessary for this commodity.

On the basis of the processing factor of 0.35 for dicamba only, a median residue of 0.0105 mg/kg was calculated for soya bean meal, which may be used as a livestock feed item.

Residue concentration was observed in soya bean hulls and grain dust which may also be used as animal feeds. The processing factors of dicamba only, calculated for these commodities, were 3.9 and 676, respectively. From these factors, median residues in soya bean hulls and grain dust for the estimation of animal burden were calculated to be 0.117 and 20.3 mg/kg, respectively.

Dicamba

Residues in animal commodities

Soya beans and processed soya bean products may be fed to dairy cattle, beef cattle, broilers and layers. The maximum and mean dietary burdens were calculated using the highest residues and median residues of dicamba in commodities for which maximum residue levels were recommended by the 2010 JMPR and current JMPR and their processed products on a basis of the OECD Animal Feeding Table.

Residues of 5-OH dicamba was not included in the calculation of animal dietary burden as its concentrations in animal feeding items were very low and the feeding study with 5-OH dicamba resulted in very low uptake (< 0.01 mg/kg) of 5-OH dicamba into tissues, milk or blood of cattle at a dose equivalent to 59 ppm in the diet.

The resulting maximum and mean dietary burdens to be used for estimating maximum residue levels for commodities of animal origin (both mammals and poultry) were identical to those of the 2010 and 2011 JMPR.

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

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 and IESTI assessment.

Definition of the residue for plant commodities (for compliance with the MRL): Dicamba.

Definition of the residue for plant commodities (for estimation of dietary intake): Sum of dicamba and 5-OH dicamba expressed as dicamba.

Definition of the residue for animal commodities (for compliance with MRLs and for estimation of dietary intake): *Dicamba and 3,6-dichlorosalicylic acid (DCSA) expressed as dicamba*.

Residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of dicamba were calculated for the 13 GEMS/Food cluster diets using STMRs and STMRPs estimated by the 2010 and current Meeting (Annex 3). The ADI is 0–0.3 mg/kg bw and the calculated IEDIs were 0–1% of the maximum ADI. The Meeting concluded that the long-term intake of residues of dicamba resulting from the uses considered by the current JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-Term Intakes (IESTI) of dicamba were calculated for soya bean and its processed commodity using STMRs/STMR-Ps estimated by the current Meeting (Annex 4). The ARfD is 0.5 mg/kg and the calculated IESTIs were 0% of the ARfD. The Meeting concluded that the short-term intake of residues of dicamba, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.