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RESIDUE AND ANALYTICAL ASPECTS

Dicamba, a systemic broad-spectrum herbicide used in a variety of crops, it was first evaluated by the JMPR in 2010. The 2010 Meeting estimated an ADI of 0–0.3 mg/kg bw/day and an ARfD of 0.5 mg/kg bw. It recommended the following residue definition for plant and animal 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.

The 2010 Meeting estimated maximum residue levels for 21 commodities, which were adopted as Codex MRLs by the Codex Alimentarius Commission in 2011 (REP 11/CAC, Appendix III, Part 2).

The 2010 JMPR received information on metabolism, method of analysis, storage stability, supervised residue trials and processing studies on soya beans. However, supervised trials were conducted in the USA with PHI of 7 days while the approved US label at that time indicated a PHI of 14 days. As no trials matched this GAP, the Meeting could not estimate a maximum residue level for soya bean (dry).

The label of one formulation, relevant to the trials, has since been revised and approved with a PHI of 7 days, matching that of the supervised trials. The current Meeting was therefore able to evaluate the trial data on soya beans provided to the 2010 Meeting against the newly approved use on soya beans in the USA.

Results of supervised trials on crops

The information on supervised field trials of dicamba on soya beans conducted in the USA were received and summarized by the 2010 JMPR. All trials were conducted in the USA.

For all analytes and matrices, generally the LOQ was 0.01 mg/kg unless as otherwise stated. In summing for total residues, if dicamba and/or 5-OH dicamba were below the LOQ, the LOQ value of each was used for calculation.

Soya bean

A total of 23 trials were conducted. The new US GAP allows two different applications: an application of 0.56 kg ai/ha as a broadcast spray made approximately 14 days prior to planting and an application of 1.12 kg ai/ha applied 7 days prior to harvest. The maximum total application rate per season is 2.24 kg ai/ha.

In the supervised trials, pre-plant application of 0.56 kg ai/ha 14 days before planting and preharvest application of 2.24 kg ai/ha 7 days before harvest were made. The pre-harvest application rate was two times the GAP rate.

As foliar pre-harvest application was used throughout the supervised trials, the Meeting agreed to apply the proportionality approach to estimate a maximum residue level for soya bean (dry).

Residues of dicamba from trials with a pre-harvest application rate of 2.24 kg ai/ha and a PHI of 7 days, in ranked order were: 0.07, 0.07, 0.08, 0.10, 0.14, 0.17, 0.27, 0.28, 0.46, 0.48, 0.55, 0.65, 0.68, 0.70, 0.81, 1.00, 1.30, 1.40, 1.43, 1.90, 2.10, 3.30 and 8.1 mg/kg.

Applying a factor of 0.5 to estimate residues of dicamba 7 days after a pre-harvest application at the GAP rate of 1.12 kg ai/ha, residues of dicamba were estimated to be: 0.035, 0.035, 0.04, 0.05,

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0.07, 0.085, 0.135, 0.14, 0.23, 0.24, 0.275, <u>0.325</u>, 0.34, 0.35, 0.405, 0.50, 0.65, 0.70, 0.715, 0.95, 1.05, 1.65 and 4.05 mg/kg.

Based on these residue concentrations, the Meeting estimated a maximum residue level of 5 mg/kg for soya bean (dry). The Meeting also estimated a median residue for the purpose of calculating animal dietary burdens at 0.325 mg/kg.

The OECD Calculator indicated a maximum residue level of 4 mg/kg. However, the highest residue concentration calculated from all the supervised trials was 4.05 mg/kg. Normally the JMPR would not set a maximum residue level lower than the highest actual residue concentration, and therefore it recommended a maximum residue level of 5 mg/kg.

Corresponding total residues of dicamba and 5-OH dicamba in ranked order were: 0.04, 0.04, 0.045, 0.055, 0.075, 0.09, 0.14, 0.145, 0.245, 0.255, 0.28, <u>0.335</u>, 0.345, 0.355, 0.41, 0.505, 0.655, 0.72, 0.835, 0.975, 1.055, 1.81 and 4.055 mg/kg.

The Meeting estimated an STMR of 0.335 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 pre-plant application only.

The label prohibits the use of fodder or hay after a pre-harvest application.

Since the residues from the pre-plant application were expected to be very low and harvesting soya bean plants before harvesting soya bean seeds does not seem to be a common practice, the Meeting confirmed the decision of the 2010 JMPR that there was no need for estimating a maximum residue level for soya bean forage and hay.

Fate of residues during processing

The 2010 Meeting received information on processing of soya beans to meal and oil.

Processing factor calculated for refined oil and its STMR-Ps are shown below:

| Product | Processing factor | Processing factor | | |
|-------------|-------------------|-------------------|---------|--|
| | Dicamba | Total residues | (mg/kg) | |
| | | | | |
| Soya bean | | | 0.335 | |
| Refined oil | < 0.019 | < 0.036 | 0.012 | |

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, a median residue of 0.117 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 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 1.3 and 226 mg/kg respectively.

Residues in animal commodities

Estimation of dietary burdens

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 residue,

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STMR/STMR-Ps or median residue of dicamba in commodities for which maximum residue levels were recommended by the 2010 and current JMPR and their processed products on a basis of the OECD Animal Feeding Table.

5-OH Dicamba was not included in the calculation of animal burden as its concentrations in animal feeding items were very low and the feeding study with 5-OH dicamba resulted in very low uptake of 5-OH (< 0.01 mg/kg) 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 JMPR.

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

The HR for poultry fat estimated by the 2010 JMPR was corrected to be 0.020 mg/kg.

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 food commodity and its processed commodity using STMRs/STMR-Ps or HRs/HR-Ps estimated by the current Meeting (Annex 4). The ARfD is 0.5 mg/kg bw 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.