5.2 AZOXYSTROBIN (229)

RESIDUE AND ANALYTICAL ASPECTS

Azoxystrobin was first evaluated for toxicology and residues by the JMPR in 2008. The Meeting derived an ADI of 0–0.2 mg/kg bw per day, decided that an ARfD was unnecessary and concluded that the residue definition for plant and animal commodities for compliance with MRL values and for consumer risk assessment was parent azoxystrobin. The compound was re-evaluated for residues by the JMPR in 2011, 2012 and 2013.

Azoxystrobin was listed for the review of additional MRLs by the JMPR in 2017. The Meeting received information on GAP and supervised residue trials on guava, pitaya (dragon fruit), sugar cane and rape seed.

Methods of analysis

The meeting received recovery data on analytical methods for guava and dragon fruit. After extraction with acetonitrile, the residues were determined by LC-MS/MS with an LOQ of 0.01 mg/kg. Analytical methods for sugarcane and rape seed utilised extraction with acetonitrile: water (9:1) (v/v) and quantification by LC-MS/MS and LC-MS, respectively. The LOQs of the two methods were both 0.01 mg/kg.

Stability of residues in stored analytical samples

The 2008 JMPR indicated that azoxystrobin residues were stable at freezer conditions in the following crop commodities for the intervals tested, most for 24 months: apples, orange oil, orange juice, orange pulp, peaches, grapes, wine, bananas, tomatoes, tomato juice, tomato paste, cucumbers, carrots, lettuce, oilseed rape, soya bean meal, corn grits, wheat straw, wheat grain, wheat forage, peanuts, peanut oil, peanut meal and pecans.

The Meeting received storage stability data on guava, dragon fruit, and rapeseed. Residues of azoxystrobin in these commodities stored frozen are stable for at least 403, 203, 146 days, respectively.

The Meeting agreed that the demonstrated storage stability on various representative crop commodities covered the residue sample storage intervals used in the field trials considered by the current Meeting.

Results of supervised residue trials on crops

The Meeting received new supervised trial data for foliar applications of azoxystrobin on guava, dragon fruit, sugarcane and rape. If two field samples were taken or results of two replicate plots were submitted, the mean value was calculated. From two trials carried out side-by-side the higher residue was chosen. Residues from trials which were not matching the cGAP were scaled if they were in an acceptable range for scaling data.

Assorted tropical and sub-tropical fruits - edible peel

Results from supervised trials on guavas conducted in Egypt were provided to the Meeting.

Guava

The critical GAP for azoxystrobin on guava from Egypt is for up to 3 foliar applications of 0.1 kg ai/ha applied at least 7–14 days RTI with a PHI of 10 days.

Six trials on guavas in Egypt were considered not to match GAP.

The Meeting noted that as the trials did not match GAP no maximum residue level or STMR values could be estimated.

Assorted tropical and sub-tropical fruits - inedible peel

Results from supervised trials on dragon fruits (pitaya) in Indonesia and Vietnam were provided to the Meeting.

Pitaya

The critical GAP for azoxystrobin on dragon fruit (Pitaya) in Indonesia and Vietnam is for up to 3 foliar applications of 0.08 kg ai/ha applied at 10 days RTI, with a PHI of 7 days.

The applications of azoxystrobin were 3 foliar of 0.15 kg ai/ha in the 7 independent trials on dragon fruit in Indonesia and Vietnam. The residues were (n=7): 0.034, 0.037, 0.069, 0.077, 0.11, 0.14 and 0.35 mg/kg. The Meeting decided that the proportionality principle could be applied in this case. Therefore, residues were divided by scale factor of 1.875 and the scaled data set was (n=7): 0.018, 0.020, 0.037, 0.041, 0.059, 0.075 and 0.19 mg/kg.

The Meeting estimated an STMR of 0.041 mg/kg, and a maximum residue level of 0.3 mg/kg for azoxystrobin on pitaya.

Grasses for sugar or syrup production

Results from supervised trials on sugarcane conducted in Brazil were provided to the Meeting.

Sugar cane

The critical GAP for azoxystrobin on sugar cane in Brazil is for up to 5 foliar applications of 0.06 kg ai/ha applied at 30 days RTI and with a PHI of 30 days.

Four trials with an exaggerated rate of 0.18 kg ai/ha, which were for processing studies, were not considered in the data set for estimation of a maximum residue level or an STMR. In six trials from Brazil matching Brazilian GAP residues in sugar cane stalks were (n=6): < 0.01, 0.01, 0.02 (3) and 0.03 mg/kg.

The Meeting estimated an STMR of 0.02 mg/kg, and a maximum residue level of 0.05 mg/kg for azoxystrobin on sugar cane.

Oilseeds

Oilseed rape

The Meeting received GAP information for canola use in USA and Canada. The GAP allows max. 3 applications: 0.125 kg ai/ha at BBCH 12–16, 0.250 kg ai/ha at BBCH 60–63 and 0.125 kg ai/ha at BBCH 67–79 with a PHI of 30 days.

Nine trials in USA and Canada matched this cGAP. Residues in rape seeds were (n=9): < 0.01 (2), 0.01, 0.02 (2), 0.06, 0.13, 0.17 and 0.23 mg/kg.

The Meeting estimated an STMR of 0.02 mg/kg and a maximum residue level of 0.5 mg/kg for azoxystrobin on rape seed.

Fate of residues during processing

Four processing studies on sugarcane were conducted in Brazil during 2011. Azoxystrobin was applied at 3-5 times exaggerated rates in five foliar applications, with RTIs and PHIs consistent with GAP. Sugarcane stalks were pressed, separated into juice and bagasse. Fractions of juice were further processed to sugar and molasses. The effects of processing on residues of azoxystrobin in sugarcane processed fractions are summarized below.

Summary of selected processing factors and STMR-P values for azoxystrobin

RAC	Matrix	Processing factor	Best Estimate Processing Factors [a]	STMR (mg/kg)	STMR-P (mg/kg)
Sugarcane				0.02 mg/kg	
	Bagasse	3.6, 5.8, 7.3, 7.5,8.5,9, 9.5	7.5		0.15
	Refined sugar	< 0.13,< 0.25, < 0.25,< 0.33,< 0.5,< 0.5, < 0.5,	0.33		0.0066
	Molasses	< 0.33,< 0.5, < 0.5, < 0.5, 0.25,0.25,0.5	0.25		0.005

[a] Each PF value is the median of 2–4 separate studies where residues were above the LOQ in the RAC. The PF in each study was the ratio of the azoxystrobin residues in the processed item divided by the residues in the RAC.

The Meeting noted that in the above studies, azoxystrobin residues did not concentrate in processed commodities except for Bagasse.

Residues in animal commodities

Estimation of livestock dietary burdens

The only commodities used as a livestock feed and for which the JMPR has made recommendations are rape seed and molasses. The additional contribution to the dietary burden using the estimated median and highest residue levels is less than 10% of the total. Based on the minor change in livestock dietary burden, the Meeting did not recalculate residues in animal commodities or revise its recommendations for maximum residue levels.

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 assessments.

Definition of the residue (for MRL-compliance and estimation of dietary intake) for plant commodities: *azoxystrobin.*

Definition of the residue (for MRL-compliance and estimation of dietary intake) for animal commodities: *azoxystrobin.*

The residue is fat soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The International Estimated Daily Intake (IEDI) for azoxystrobin was calculated for the food commodities for which STMRs or HRs were estimated and for which consumption data were available. The results are shown in Annex 3.

The International Estimated Daily Intakes of azoxystrobin for the 17 GEMS/Food Cluster diets, based on estimated STMRs were 2–20% of the maximum ADI of 0.2 mg/kg bw (Annex 3). The Meeting concluded that the long-term dietary exposure to residues of azoxystrobin from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term dietary exposure

The 2008 JMPR decided that an ARfD for azoxystrobin was unnecessary. The Meeting therefore concluded that the short-term dietary exposure to azoxystrobin residues is unlikely to present a public health concern.