5.9 DIFENOCONAZOLE (224)

RESIDUE AND ANALYTICAL ASPECTS

Difenoconazole is a systemic triazole fungicide and acts by inhibition of demethylation during ergosterol synthesis. It is applied by foliar spray or seed treatment and controls a broad spectrum of foliar, seed and soil-borne diseases caused by Ascomycetes, Basidiomycetes and Deuteromycetes, on a variety of crops. Difenoconazole was evaluated for the first time by JMPR 2007. The 2007 Meeting established an acceptable daily intake (ADI) of 0–0.01 mg/kg bw and an acute reference dose (ARfD) of 0.3 mg/kg bw. Maximum residue levels for a number of commodities were recommended by JMPR in 2007, 2010 and 2013.

Definition of residues for plant products (compliance with MRLs and dietary intake assessment): *difenoconazole.*

Definition of residues for animal products: sum of difenoconazole and CGA 205375 (1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1, 2, 4-triazol)-1-yl-ethanol), expressed as difenoconazole.

Difenoconazole was listed by the Forty-sixth Session of CCPR (2014) for the review of additional maximum residue levels. GAP information with supporting residue studies in strawberries, avocadoes, soya beans, cotton, peanuts, rice and oilseed rape (canola) was evaluated by the present Meeting.

Methods of analysis

The analytical method used for determination of difenoconazole residues in samples derived from supervised field trials and processing studies in strawberries, soya beans, rice and oilseed was evaluated by previous Meetings.

Two new pre-registration methods for plant matrices were presented to the 2015 Meeting. In these methods difenoconazole is extracted by high-speed homogenisation with an acetone/water mixture (2:1). After clean-up the residues were determined by (HPLC-MS/MS).The method has a validated LOQ of 0.01 mg/kg for difenoconazole in avocadoes, cotton, oilseed rape including processed commodities, peanuts, rice, soya beans and strawberries. The methods were used for determination of difenoconazole residues in samples from supervised field trials on cotton and peanuts presented to the current Meeting.

Stability of pesticide residues in stored analytical samples

The stability of residues from difenoconazole in stored samples was evaluated by the 2007 Meeting. The periods of demonstrated stability cover the frozen storage intervals used in the residue trials for which maximum residue levels were estimated.

Results of supervised residue trials on crops

The Meeting received new supervised trial data for foliar application of difenoconazole (EC or SC formulations) on strawberries, avocadoes, soya beans, rice, cotton, peanuts and oilseed rape, and noted that residue data from rice, soya beans and oilseed rape also were provided to the 2007 JMPR.

The results from new trials and those previously reported by the 2007 JMPR which either matched the critical GAP, or when results could be proportionally adjusted to reflect GAP application rates, were considered in estimating maximum residue levels, STMRs and HRs for the commodities for which GAP information was available. The proportionality approach was considered to scale the results from trials where the application rates range from 0.3× GAP to 4× GAP and where all other parameters matched the critical GAP.

Strawberry

Data from supervised trials on strawberries from USA conducted in 2008 and 2009 were presented to the Meeting. The critical GAP in USA is maximum foliar applications up to 0.129 kg/ha, an application interval of 7–14 days and a PHI of 0 days. The maximum application rate for difenoconazole is 0.515 kg ai/ha per crop and season.

Strawberries belong to the high acid category and storage data covering this category was not evaluated by 2007 JMPR and not included in the residue trials. As difenoconazole has a pKa of 1.1 an estimation of maximum residue levels was not made.

Avocado

Four independent supervised trials from Brazil conducted in 2007 and 2008 were presented to the Meeting. The critical GAP in Brazil is four foliar applications of 0.05 kg ai/ha at BBCH 62–79 (starting at flowering until fruit is around 5 cm) and with intervals of 14 days. The PHI is 14 days.

The trials from Brazil (4× 0.05 kg ai/ha at BBCH 71–79, interval 14 days, PHI 14 days) matched the critical GAP. Residues of difenoconazole in avocado fruits 14 days after the last application were (n=4) 0.02, 0.05 (2) and 0.26 mg/kg. The highest residue of 0.26 mg/kg was measured in an individual fruit sample.

The Meeting estimated a maximum residue level, an STMR value and an HR value for difenoconazole in avocado of 0.6 mg/kg, 0.05 mg/kg and 0.26 mg/kg, respectively.

Soya bean (dry)

Twenty one supervised trials from USA conducted in 2008 were presented to the Meeting. The critical GAP in USA is two foliar applications of 0.129 kg ai/ha, with an interval of seven days and a PHI of 14 days.

Six trials from Brazil (2× 0.075 kg ai/ha and a PHI of 30 days) presented to the 2007 JMPR did not match the critical GAP.

Eighteen independent trials from USA (2× 0.129 kg ai/ha, interval 7–10 days, PHI 14 days) matched the critical GAP. Residues of difenoconazole in soya beans were (n=18) < 0.01(12), 0.012, 0.013, 0.019, 0.021, 0.04 and 0.087 mg/kg. The highest residue of 0.15 mg/kg was measured in individual seed samples.

The Meeting estimated a maximum residue level and STMR value for difenoconazole in soya bean seeds of 0.1 mg/kg and 0.01 mg/kg, respectively. The Meeting withdraws its previous recommendation of 0.02* mg/kg for maximum residue level for soya beans (dry).

Rice

Eight supervised trials from Europe (Italy) conducted in 2009 and 2010 were presented to the current Meeting. A registered label was not available to the Meeting and an estimation of a maximum residue level was not made.

Cotton

Eight independent supervised trials from Brazil conducted in 2006–2008 were presented to the Meeting. The critical GAP in Brazil is three foliar applications of 0.075 kg ai/ha, an interval of 10–15 days and a PHI of 21 days.

Four trials (5× 0.075 kg ai/ha, BBCH 13–81, interval 21 days, PHI 30 days) were not according to GAP. Samples were only taken 30 days after last application, and the applications were two more than specified in the critical GAP.

Four trials were made with four applications of 0.075 kg ai/ha starting from BBCH 71 up to BBCH 83 and a PHI of 21 days. These trials matched the critical GAP from Brazil. Residues of difenoconazole in cotton were (n=4) < 0.01, 0.01 and 0.02 (2) mg/kg. An estimation of maximum residue levels was not made as four trials were considered insufficient.

Oilseeds

Peanut

Eight independent supervised trials from Brazil conducted in 2008–2010 were presented to the Meeting. The critical GAP in Brazil is three applications of 0.0875 kg ai/ha and a PHI of 22 day.

Four of the trials (3× 0.088 kg ai/ha, PHI 22 days) were according to the critical GAP and residues of parent difenoconazole were not detected. Another four trials (6× 0.125 kg ai/ha) were conducted as residue decline trials and residues of parent difenoconazole was not found.

As residues of difenoconazole not was detected at an exaggerated number of applications and application rates, the Meeting concluded a zero residue situation occurs after application of difenoconazole to peanuts in accordance with the Brazilian critical GAP.

Residues of difenoconazole in peanuts from eight independent trials matching GAP were (n=8) < 0.01 mg/kg.

The Meeting estimated a maximum residue level and STMR values for difenoconazole in peanut kernels of 0.01* mg/kg and 0 mg/kg, respectively.

Rape seed (canola)

Data from supervised trials on rape seed (canola) from Canada conducted in 2011 were presented to the Meeting. The critical GAP in Canada is one foliar application of 0.125 kg ai/ha and a PHI of 30 days.

Nine independent trials from Canada matching the critical GAP were available to the Meeting. Residues from difenoconazole in rape seed were (n=9) < 0.01, 0.011 (1), 0.015 (2), 0.033 (2), 0.038, 0.062 and 0.063 mg/kg.

The Meeting estimates a maximum residue level, and STMR value for difenoconazole in oilseed rape (rape seed) of 0.15 mg/kg and 0.03 mg/kg, respectively. The Meeting replaces its previous recommendation of 0.05 mg/kg for the maximum residue level for rape seed.

Animal feeds

Rape seed (canola), forage, fodder

Residue data for rape seed forage was not presented to the Meeting.

Soya bean

The Meeting noted that the GAP for difenoconazole in USA does not permit soya bean hay, forage or silage as animal feeds.

Rice whole crop (silage), and straw

Eight supervised trials from Europe (Italy) conducted in 2009 and 2010 were presented to the Meeting. Forage and straw samples were collected. A registered GAP was not available for rice. An estimation of maximum residues levels was not made.

Fate of residues during processing

The 2007 JMPR reported that difenoconazole was essentially stable during the hydrolysis conditions simulating food processing conditions and also estimated processing factors for a range of commodities. Relevant processing factors for difenoconazole and STMR-Ps for the commodities considered at this Meeting and used for dietary intake and risk assessment or for estimating livestock animal burden are summarised below.

Raw agricultural commodity	Processed commodity	Processing factors [a] (mean)	RAC (mg/kg)	STMR-P
			STMR	mg/kg
Soya bean	RAC		0.01	
	Meal	0.38		0.004
	Hulls	2		0.02
	Oil (refined)	0.8		0.08
	AGF [b]	622		6.22
Rape seed (canola)	RAC		0.03	
	Meal	0.55		0.016
	Refined oil	0.05		0.002

[a] The processing factor is the ratio of the total residue in the processed item divided by the total residue in the RAC

[b] Aspirated grain fraction

The Meeting noted that in the studies available difenoconazole residues did not concentrate in food commodities during processing. In feed commodities however residues increased in soya bean hulls and soya bean aspirated grain fractions (AGF).

Residues in animal commodities

Estimated dietary burdens of farm animals

The dietary burdens for beef cattle and dairy cattle were calculated using the OECD diets listed in Appendix IX of the 2009 edition of the FAO Manual. Potential feed items included: almond hulls, cabbage heads and leaves, bean vines, carrot hulls, canola meal, grape pomace, pea vines, potato culls, potato process waste, soya beans, soya bean aspirated grain fraction, sunflower meal, and wheat grain and hay.

The estimated the dietary burden for cattle and poultry and were not significantly different from the dietary burdens estimated by the 2013 JMPR. The only additional feed item included was soya bean.

The Meeting confirmed the 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 residue for plant products (compliance with MRLs and dietary intake assessment): *difenoconazole.*

Definition of residue for animal products (compliance with MRLs and dietary intake assessment): sum of difenoconazole and CGA 205375 (1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1, 2,4-triazol)-1-yl-ethanol), expressed as difenoconazole.

The residue is fat soluble (2007 JMPR Meeting).

DIETARY RISK ASSESSMENT

Long-term intake

The IEDI of difenoconazole based on the STMRs estimated by this and previous Meetings for the 17 GEMS/Food regional diets were 7–70% of the maximum ADI of 0.01 mg/kg bw (see Annex 3 of the Report). The Meeting concluded that the long-term dietary intake of residues of difenoconazole is unlikely to present a public health concern.

Short-term intake

The ARfD for difenoconazole is 0.3 mg/kg bw. The International Estimated Short-Term (IESTI) of difenoconazole for the commodities for which STMR, HR and maximum residue levels were estimated by the current Meeting are shown in Annex 4. The IESTI represented a maximum of 3% of the ARfD. The Meeting concluded that the short-term intake of difenoconazole residues from uses considered by the current Meeting was unlikely to present a public health concern.