5.8 CYPRODINIL (207)

RESIDUE AND ANALYTICAL ASPECTS

Cyprodinil was firstly evaluated by JMPR in 2003, when an ADI of 0–0.03 mg/kg bw/day was established. The meeting decided that an ARfD was unnecessary. The residue definition for both plants and animal commodities, for both compliance with MRLs and estimation of dietary intakes, is defined as cyprodinil. The residue is fat soluble.

In 2013 and 2015 the JMPR evaluated additional uses for cyprodinil on multiple crops.

At the forty-seventh session of the CCPR (2015), cyprodinil was scheduled for evaluation of additional use patterns by the 2017 JMPR. The current meeting received residue data for artichoke (globe), carrots, celery, fresh beans with pods, guava, pomegranate, potato, almonds, pecan and pistachio.

Methods of analysis

Residues were determined in the crops using several different analytical methods, some of which have been considered previously by the JMPR. In general the data generation methods involved the extraction with methanol/water or acetonitrile/water with a final determination using LC-MS/MS. An LOQ of 0.01 mg/kg was supported for cyprodinil. The meeting concluded that suitable methods are available for the determination of cyprodinil in the crops under consideration.

Stability of residues in stored analytical samples

Data have previously been evaluated by the JMPR for crops of a high water content, high starch content and high oil content. The meeting concluded that these data supported the length of storage in the residue trials.

In this meeting stability data were provided for guava (which showed stability for at least 657 days), pomegranate (which showed stability for at least 302 days) and artichoke (which showed stability for at least 247 days). These data are consistent with the stability data assessed previously by the JMPR and the meeting concluded the data support the length of storage in the trials.

Results of supervised trials on crops

The meeting received residue trials data for cyprodinil on artichoke, carrots, celery, fresh beans with pods, guava, pomegranate, potato, almond, pecan and pistachio.

Guava

The critical GAP is for the USA which is four applications at 368 g ai/ha with a PHI of 0 days. Four residue trials support the GAP for guava in the USA. The meeting concluded that the data were sufficient to establish a maximum residue level and an STMR.

Residues in guava in rank order (n=4) were: 0.37, 0.48, 0.49, and 0.52 mg/kg.

The meeting estimated a maximum residue level of 1.5 mg/kg and an STMR of 0.485 mg/kg for guava.

Pomegranate

The critical GAP is for the USA which is a post-harvest dip/drench treatment at 54 g ai/hl. One application is made before storage and one application is made before trading. The PHI is 0 days. Crop samples were collected prior to treatment from known trial sites. The post-harvest treatments were conducted at the same test facility on different dates using different dip/drench solutions. Four residue trials support the GAP for pomegranate in the USA. The meeting concluded that the data were sufficient to establish a maximum residue level and an STMR.

Residues in pomegranate in rank order (n=4) were: 2.6, 3.3, 3.3, and 3.4 mg/kg

The meeting estimated a maximum residue level of 10 (Po) mg/kg and an STMR of 3.30 mg/kg for pomegranate.

Beans with pods

The critical GAP is for Spain which is a protected use of two applications at 375 g ai/ha with a PHI of 3 days. Nine residue trials conducted at a rate of 375 g ai/ha with three applications were provided.

The trials do not reflect the GAP. However, the meeting concluded that the decline observed on consideration of all the trials demonstrated that the first application had a minimal impact on the final residue and the data were sufficient to establish a maximum residue level and STMR.

Residues in beans with pods in rank order (n = 9) were: 0.34, 0.47, 0.54, 0.58, <u>0.60</u>, 0.61, 0.75, 0.83, and 1.2 mg/kg.

The meeting estimated a maximum residue level of 2 mg/kg and an STMR of 0.60 mg/kg for the subgroup beans with pods

These recommendations replace the previous recommendations of a maximum residue level of 0.7 mg/kg and an STMR of 0.165 mg/kg for beans with pods (*Phaseolus* spp.).

Artichoke, Globe

The critical GAP is for the USA which is four applications at 366 g ai/ha with a PHI of 3 days. Four residue trials were provided. Three of the trials reflect the GAP in the USA. In a fourth trial, five applications were made. The total application rate in the trial with five applications supports the GAP and the residue obtained is comparable to the residue levels obtained with four applications. Therefore the meeting agreed that the first application had a minimal impact on the final residue and the trial with five applications can be regarded as supporting the GAP. The meeting concluded that the data were sufficient to establish a maximum residue level and an STMR.

Residues in globe artichoke in rank order (n=4) were: 0.93, 1.1, 1.3, and 1.3 mg/kg

The meeting estimated a maximum residue level of 4 mg/kg and an STMR of 1.20 mg/kg for globe artichoke.

Celery

The critical GAP is for the USA which is four applications at 368 g ai/ha with a PHI of 0 days. Eight residue trials support the GAP for celery in the USA. The meeting concluded that the data were sufficient to establish a maximum residue level and an STMR.

Residues in celery in rank order (n=8) were: 3.5, 3.6, 5.9, 7.2, 9.7, 11, 12, and 16 mg/kg.

The meeting estimated a maximum residue level of 30 mg/kg and an STMR of 8.45 mg/kg for celery.

Carrot

The critical GAP is for Germany which is three applications at 375 g ai/ha with a PHI of 7 days. Twenty residue trials support the GAP for carrot in Germany. The meeting concluded that the data were sufficient to establish a maximum residue level and an STMR.

Residue in carrot in rank order (n=20) were: 0.04, 0.06, 0.08 (3), 0.09, 0.11, 0.12, 0.14, <u>0.18,</u> 0.21, 0.27, 0.33, 0.41, 0.48, 0.50, 0.51, 0.53, 0.68, and 1.0 mg/kg.

The meeting estimated a maximum residue level of 1.5 mg/kg and an STMR of 0.195 mg/kg for carrot.

These recommendations replace the previous recommendations of a maximum residue level of 0.7~mg/kg and an STMR of 0.09~mg/kg for carrot.

Potato

The critical GAP is for the USA which is four applications at 366 g ai/ha with a PHI of 14 days. Fifteen residue trials support the GAP for potato in the USA. The meeting concluded that the data were sufficient to establish a maximum residue level and an STMR.

Residues in potato (n=15) were < 0.01 mg/kg

The meeting estimated a maximum residue level of $0.01*\ mg/kg$ and an STMR of $0.01\ mg/kg$ for potato.

Tree nuts (except almond and pistachio)

The critical GAP for tree nuts (except almond and pistachio) is for the USA which is four applications at 366 g ai/ha with a PHI of 14 days.

Ten residue trials were provided (five trials on almond and five trials on pecan).

The five trials for pecan support the GAP in the USA.

Residues in pecan in rank order (n=5) were: < 0.01 (2), < 0.0.010, 0.011, and 0.026 mg/kg

For almond four of the five trials support the GAP in the USA. In a fifth trial six applications were made.

Residues in almond in rank order (n=4) were: < 0.01 (2), < 0.0.012, 0.014 mg/kg

Almond is regarded as a representative crop for tree nuts and the trials conducted on almonds and pecan both reflect the critical GAP in the USA for tree nuts (except almond and pistachio). The two data sets are similar. The meeting concluded that the combined data were sufficient to extrapolate to tree nuts (except almond and pistachio) and to establish a maximum residue level and an STMR.

Residues in tree nuts, for the combined data set, in rank order (n=9) were < 0.01 (4), $\underline{0.01}$, 0.011, 0.012, 0.014, and 0.026 mg/kg

The meeting estimated a maximum residue level of 0.04 mg/kg and an STMR of 0.01 mg/kg for tree nuts (except almond and pistachio).

Pistachio

The critical GAP for pistachio is for the USA which is four applications at 368 g ai/ha with a PHI of 7 days. Three residue trials support the GAP for pistachio in the USA.

Residues in pistachio in rank order (n= 3) were < 0.02, 0.026, and 0.035 mg/kg

The meeting concluded that the data were insufficient to establish a maximum residue level and STMR.

Animal feedstuffs

The meeting received data for almond hulls. These data did not comply with the GAP and were not considered for maximum residue level or animal dietary burden estimation.

Fate of residues during processing

The fate of cyprodinil residues on processing was evaluated by the JMPR in 2003, 2013 and 2015 where the processing of residues in various crops was evaluated and where applicable processing factors were established.

For the current meeting information was received on the fate of cyprodinil residues on the processing of carrots and potatoes. A summary of the relevant cyprodinil processing factors are provided below.

Raw commodity	Processed fraction	Individual processing factors (PF)	Mean or best estimate processing factor (PF)	STMR-P = STMR × PF
				(mg/kg)
Carrot	Canned	0.16, 0.16, 0.21, 0.26	0.20	0.039
	Juice (pasteurised)	0.17, 0.17, 0.22, 0.33	0.22	0.043
	Carrot Peel	1.2, 1.4. 2.2, 2.9	1.9	-
	Cooked/boiled (without	0.07, 0.07, 0.07, 0.13	0.085	-
	peel)			
	Cooked/boiled (with	0.26	0.26	0.051
	peel)			
Potato	Dried (granules/flakes)	< 0.29, < 0.95	0.62	< 0.01
	Crisps	< 0.29, < 0.95	0.62	< 0.01
	Deep-fried (chips/French	< 0.29, < 0.95	0.62	< 0.01
	fries without peel)			

Residues in animal commodities

Carrots and potatoes can be fed to livestock.

Dietary burden calculations incorporating these commodities and those considered by the JMPR in 2003, 2013 and 2015 have been undertaken for beef cattle, dairy cattle poultry (broiler) and poultry (layer). The calculations were made for the dietary burdens for each geographic region (USA/Canada, Europe, Australia and Japan) using the OECD diets listed in Appendix IX of the 2016 edition of the FAO Manual.

The additional contribution to the dietary burden using the estimated median and highest residue levels is less than 10% of the total and the meeting confirmed the previous recommendations of maximum residue levels in animal products.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the values listed in Annex 1 are appropriate for establishing maximum residue levels and for an IEDI assessment.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The International Estimated Dietary Intakes (IEDIs) of cyprodinil were calculated for the 17 GEMS/food cluster diets using STMRs/STMR-Ps estimated by the current Meeting and by the JMPR in 2003, 2013 and 2015. The ADI is 0–0.03 mg/kg bw and the calculated IEDIs were 8–70% of the maximum ADI (0.03 mg/kg bw). The Meeting concluded that the long-term dietary exposure to residues of cyprodinil resulting from the uses considered by the current Meeting and by the JMPR in 2003, 2013 and 2015, is unlikely to present a public health concern.

Short-term dietary exposure

The 2003 JMPR decided that an ARfD was unnecessary and concluded that the short-term dietary exposure to residues of cyprodinil is unlikely to present a public health concern.