5.12 DIFENOCONAZOLE (224)

RESIDUE AND ANALYTICAL ASPECTS

Difenoconazole was first evaluated by the JMPR in 2007 for toxicology when an ADI of 0–0.01 mg/kg bw and an ARfD of 0.3 mg/kg bw were established. In 2007 and 2010, the JMPR evaluated for residues and recommended numerous maximum residue levels. The compound was listed by the Forty-fourth Session of the CCPR for residue evaluation for additional MRLs by the JMPR in 2013.

The residue is defined, for plant commodities, as parent difenoconazole for compliance with the MRL and for estimation of dietary intake. For animal commodities, it is defined as sum of difenoconazole and 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethanol (CGA 205375), expressed as difenoconazole, for compliance with the MRL and for estimation of dietary intake. The residue is fat soluble.

The present Meeting received residue trial information on citrus fruits, pome fruits, grapes, Japanese persimmon, bulb vegetables, brassica vegetables, fruiting vegetables, ginseng and post-harvest treated potato. Further, processing studies on oranges, apples, grapes, tomatoes, potatoes and ginseng were provided. According to a request from the Forty-fourth Session of the CCPR, the Meeting re-evaluated the ginseng processing studies evaluated in 2010 to estimate MRLs complying with the new classification for processed products.

Methods of analysis

The analytical methods used for the determination of difenoconazole in samples from supervised trials, had already considered by the JMPR in 2007 and 2010. The methods are based on LC-MS/MS and GC-NPD determination and the limits of quantitation were 0.01 mg/kg. The validity of the analytical results was supported by validation data on representative crops and results of concurrent recovery studies.

The methods used for ginseng and the processed products were also considered by the 2010 J MPR. The limits of quantitation for difenoconazole based on GC-ECD were between 0.003 and 0.007 mg/kg and concurrent recoveries ranged between 86% and 113% .

Difenoconazole in Japanese persimmon were extracted with acetone and partitioned with dic hloromethane. The LOQ by GC-ECD determination was 0.02 mg/kg and concurrent recoveries ranged from between 88% and 107%.

The Meeting additionally received information on analytical methods used for the determinat ion of triazole metabolites 1, 2, 4-triazole, triazole alanine and triazole acetic acid residues in the same plant commodity samples from t he supervised trials. The methods involved extraction with organic solvents, SPE clean-up and/or derivatization steps, partition with ethyl acetate and determination by LC-MS/MS. The limits of quantitation for all metabolites were 0.01 mg/kg and procedural recoveries ran ged from 70% to 115%.

Stability of residues in stored analytical samples

The 2007 JMPR concluded that difenoconazole was stable for 2 years in most plant commodities when deep frozen. This covered the stability of difenoconazole in samples from the supervised trials. New data on ginseng and Japanese persimmon were provided. The storage stability tests were conducted simultaneously with storage of field trial sample for 4–31 days in ginseng and the products and for 51 days in Japanese persimmon. The results indicated that residues in the samples were stable during the storage period.

Results of supervised residue trials on crops

Citrus fruits

Difenoconazole is registered in the USA for use on citrus fruits at a GAP of 4 × 0.14 kg ai/ha (total seasonal rate of 0.56 kg ai/ha), 7 day interval and a PHI of 0 days. Residue trials on citrus fruits were conducted in the USA, matching the critical GAP. Residue concentrations of difenoconazole in citrus fruit, determined on a whole fruit basis, were: 0.11, 0.13, 0.13, 0.14, 0.15, 0.15, 0.23, 0.26 and 0.37 mg/kg in oranges (n=9); 0.17, 0.38 mg/kg in mandarin (n=2); 0.49 mg/kg in tangerine (n=1); 0.075, 0.09, 0.11, 0.13, 0.18 and 0.18 mg/kg in grapefruit (n=6); 0.09, 0.16, 0.17, 0.19 and 0.24 mg/kg in lemons (n=5).

The Meeting noted that as the GAP in USA was for citrus fruits and that the medians of data sets for oranges, mandarins, grapefruits and lemons differed by less than 5-fold, agreed to consider a group maximum residue level. In deciding on the data set to use for estimating a group maximum residue level, given a Kruskal-Wallis H-test indicated that the residue populations were not different, it was agreed to combine the results to give a data set of: 0.075, 0.09, 0.09, 0.11, 0.11, 0.13, 0.13, 0.13, 0.14, 0.15, 0.15, 0.16, 0.17, 0.17, 0.18, 0.18, 0.19, 0.23, 0.24, 0.26, 0.37, 0.38 and 0.49 mg/kg (n=23) for citrus.

The Meeting agreed to estimate a maximum residue level of 0.6 mg/kg, an STMR of 0.16 mg/kg and an HR of 0.49 mg/kg for whole citrus fruits.

Pome fruits

Difenoconazole is registered in the USA for use on pome fruits at a GAP of 5 × 0.078 kg ai/ha (total seasonal rate of 0.37 kg ai/ha), 7 day intervals and a PHI of 14 days. Residue trials on apple and pear were conducted in the USA and complied with the US GAP.

Residues in apples were (n=13): 0.02, 0.07, 0.07, 0.08, 0.13, 0.16, 0.21, 0.25, 0.28, 0.37, 0.38, 0.39 and 0.47 mg/kg.

Residues in pears were (n=6): 0.07, 0.12, 0.12, 0.14, 0.19 and 0.27 mg/kg.

A national use pattern in the Republic of Korea permits up to five foliar applications of difenoconazole WP 10 (%, w/w) on Japanese persimmon at a rate of 0.0054 kg ai/L with 10 day intervals and a PHI of 7 days. Six trials were conducted in the Republic of Korea in 2011 (3) and 2012 (3) matching the critical GAP.

However, all trials were conducted with the same variety. In each year, three trials were performed at the same dates of application and under the same weather conditions, thus the trials were not considered as independent. As a result the Meeting considered that for this evaluation, only two residue values (0.37, 0.43 mg/kg) were available. In addition, the GAP differed from that of the US GAP for pome fruits. Consequently, the persimmon residue values could not be combined with residues from apple and pear.

The Meeting noted that the GAP in USA was for pome fruits and that the medians of the apple and pear data sets differed by less than 5-fold and agreed to consider a group maximum residue level. In deciding on the data set to use for estimating a group maximum residue level, since a Mann-Whitney U-test indicated that the residue populations for apple and pear were not different it was agreed to combine the results to give a data set of: 0.02, 0.07 (3), 0.08, 0.12 (2), 0.13, 0.14, 0.16, 0.19, 0.21, 0.25, 0.27, 0.28, 0.37, 0.38, 0.39 and 0.47 mg/kg (n=19) for pome fruits group.

The Meeting estimated a maximum residue level of 0.8 mg/kg, an STMR of 0.16 mg/kg and an HR of 0.47 mg/kg for pome fruits. The Meeting withdrew its previous recommendation of 0.5 mg/kg for pome fruits.

Grapes

A national use pattern in the USA permits up to four foliar applications of difenoconazole EC 250 (250 g/L) on grapes at a rate of 0.13 kg ai/ha (total seasonal rate of 0.52 kg ai/ha) with 10 days interval and a PHI of 7 days. Twelve trials conducted in the USA matched the critical GAP, of which two trials were not considered independent as they were carried out on the same variety at a nearby location (experiencing the same weather conditions) and shared the same dates of application. In addition, one trial was excluded as it was carried out with a grape variety for which use was not allowed.

Residues in grapes were (n=10): 0.11, 0.17, 0.19, 0.23, 0.40, 0.64, 0.65, 0.67, 1.3 and 1.5 mg/kg.

The 2007 JMPR estimated a maximum residue level of 0.1 mg/kg for grapes, based on residu e trials conducted in southern Europe matching Italian GAP (four applications to grape vines with a s pray concentration of 0.005 kg ai/hL with a PHI of 21 days).

As the US use pattern is considered the more critical GAP than the Italian GAP, the Meeting recommended a maximum residue level of 3 mg/kg, an STMR of 0.52 mg/kg and an HR of 1.5 mg/kg for grapes, using residue data from the USA. The Meeting withdrew its previous recommendation of 0.1 mg/kg for grapes.

Bulb vegetables

Onion, bulb

A national use pattern in the USA permits up to four foliar applications of difenoconazole EC 250 (250 g/L) on bulb onions at a rate of 0.13 kg ai/ha (total seasonal rate of 0.52 kg ai/ha), with a 7 day interval and a PHI of 7 days.

Residues in onion, bulb were (n=8): < 0.01 (3), 0.01, 0.02, 0.02, 0.03 and 0.07 mg/kg.

Based on the residue values, the Meeting estimated a maximum residue level of 0.1 mg/kg, an STMR of 0.015 mg/kg and an HR of 0.07 mg/kg for onion, bulb.

Spring onion

A national use pattern in the USA permits up to three foliar applications of difenoconazole EC 250 (250 g/L) on green onions including spring onions at a rate of 0.13 kg ai/ha (total seasonal rate of 0.38 kg ai/ha), with 7 days interval and a PHI of 7 days. Three trials conducted in the USA matched the critical GAP.

Residues in whole spring onion were (n=3): 2.3, 2.8 and 3.8 mg/kg.

The Meeting estimated a maximum residue level of 9 mg/kg, an STMR of 2.8 mg/kg and an HR of 3.8 mg/kg for spring onions.

Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead cabbages

A national use pattern in the USA permits up to four foliar applications of difenoconazole EC 250 (250 g/L) on Brassica (cole) leafy vegetables at a rate of 0.13 kg ai/ha (total seasonal rate of 0.52 kg ai/ha) with 7 days interval and a PHI of 1 day. Six trials on head cabbage and broccoli each were conducted in the USA according to the critical US GAP.

Residues in head cabbage with wrapper leaves were (n=6): 0.09, 0.30, 0.34, 0.46, 0.94 and 1.3 mg/kg.

Residues in broccoli (head and stem) were (n=6): 0.15, 0.32, 0.32, 0.35, 0.37 and 0.53 mg/kg.

Based on GAPs of various European countries, the 2007 JMPR recommended a maximum residue level of 0.2 mg/kg for Brussels sprouts, head cabbage and cauliflowers, respectively, and 0.5 mg/kg for broccoli. As the USA GAP allows a shorter PHI (1 day) than the European GAP, the Meeting decided to use the US trials for maximum residue level estimation.

The Meeting noted that the GAP in USA was for Brassica vegetables and that the medians of the two data sets differed by less than 5-fold and agreed to consider a group maximum residue level. In deciding on the data set to use for estimating a group maximum residue level, since a Mann-Whitney U-test indicated that the residue populations for head cabbage and broccoli were not different, it was agreed to combine the results to give a data set of: 0.09, 0.15, 0.3, 0.32, 0.32, 0.34, 0.35, 0.37, 0.46, 0.53, 0.94 and 1.3 mg/kg (n=12) for Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead cabbages.

The Meeting estimated a maximum residue level of 2 mg/kg, an STMR of 0.35 mg/kg and an HR of 1.3 mg/kg for the crop group, Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead cabbages. The meeting withdrew its previous recommendations for Brussels sprouts, Head cabbage and Cauliflowers of 0.2 mg/kg and for Broccoli of 0.5 mg/kg.

Fruiting vegetables, Cucurbits

Melons

A national use pattern in the USA permits up to four foliar applications of difenoconazole EC 250 (250 g/L) on cucurbit vegetables at a rate of 0.13 kg ai/ha (total seasonal rate of 0.52 kg ai/ha), 7 day interval and a PHI of 0 days. Six trials on cantaloupe conducted in the USA were provided for this Meeting. Five trials were performed according to the US critical GAP, however in one trial the harvest was made 4 days after the last application.

Residues in whole melon were (n=5): 0.06, 0.08, 0.14, 0.19 and 0.35 mg/kg.

The Meeting estimated a maximum residue level 0.7 mg/kg, an STMR of 0.14 mg/kg and an HR of 0.35 mg/kg for melons, except watermelon.

Cucumber, summer squash

A national use pattern in the USA permits up to four foliar applications of difenoconazole EC 250 (250 g/L) on cucurbit vegetables at a rate of 0.13 kg ai/ha (total seasonal rate of 0.52 kg ai/ha), 7 day interval and a PHI of 0 days. Six trials on gherkins and five trials on summer squash were provided to the Meeting. The trials were conducted in the USA complied with the critical US GAP.

Residues in gherkin were (n=6): < 0.01, 0.01, 0.03, 0.04, 0.04 and 0.15 mg/kg.

Residues in summer squash were (n=5): < 0.01, 0.02, 0.05, 0.06 and 0.06 mg/kg.

The Meeting noted that the GAP in USA is for fruiting vegetables, cucurbits with edible peel and that the medians of the two data sets differed by less than 5-fold and agreed to consider a group maximum residue level. In deciding on the data set to use for estimating a group maximum residue level, since a Mann-Whitney U-test indicated that the residue populations for gherkin and summer squash were not different it was agreed to combine the results to give a data set of < 0.01, < 0.01, 0.01, 0.02, 0.03, 0.04, 0.04, 0.05, 0.06, 0.06 and 0.15 mg/kg (n=11) for fruiting vegetable, cucurbits with edible peel.

The Meeting estimated a maximum residue level of 0.2 mg/kg, an STMR of 0.04 mg/kg and an HR of 0.15 mg/kg for fruiting vegetables, cucurbits with edible peel (cucumber, gherkin and summer squash).

Fruiting vegetables, other than Cucurbits

A national use pattern in the USA permits up to four foliar applications of difenoconazole EC 250 (250 g/L) on fruiting vegetables (tomatoes and peppers) at a rate of 0.13 kg ai/ha (total seasonal rate of 0.52 kg ai/ha), 7 day interval and a PHI of 0 days. Trials conducted in the USA (11 trials for tomatoes, six trials for sweet peppers, three trials for chili pepper) were provided to the current Meeting. The trials were performed according to the critical US GAP.

Residues in tomato were (n=11): 0.01, 0.10, 0.11, 0.11, 0.14, 0.15, 0.16, 0.26, 0.27, 0.39 and 0.39 mg/kg.

Residues in sweet pepper were (n=6): 0.06, 0.10, 0.11, 0.14, 0.14 and 0.18 mg/kg.

Residues in chili pepper were (n=3): 0.10, 0.16 and 0.26 mg/kg.

Residue data for sweet pepper and chili pepper was combined for mutual support. Further, the Meeting noted that the GAP in USA was for fruiting vegetable other than cucurbits and that the medians of the two data sets differed by less than 5-fold and agreed to consider a group maximum residue level. In deciding on the data set to use for estimating a group maximum residue level, as a Mann-Whitney U-test indicated that the residue populations for tomatoes and peppers were similar, it was agreed to combine the results to give a data set of 0.01, 0.06, 0.10(3), 0.11 (3), 0.14 (3), 0.15, 0.16, 0.16, 0.18, 0.26, 0.26, 0.27, 0.39 and 0.39 mg/kg (n=20) for fruiting vegetables other than cucurbits.

The 2007 JMPR recommended a maximum residue level of 0.5 mg/kg for tomato from eleven trials conducted on tomatoes in Europe (France, Greece, the UK, Spain) matching the Italian GAP (2 applications at 0.13 kg ai/ha with a PHI of 7 days). However, the GAP of the USA was considered to be the critical GAP.

Therefore, based on the combined dataset on tomato and peppers from the US trials the Meeting estimated a maximum residue level of 0.6 mg/kg, an STMR of 0.14 mg/kg and an HR of 0.39 mg/kg for fruiting vegetables other than cucurbits except sweet corn and mushrooms. The Meeting withdrew its previous recommendation for tomatoes of 0.5 mg/kg.

Furthermore, the Meeting estimated a maximum residue level of 5 mg/kg, an STMR of 1.1 mg/kg and an HR of 1.8 mg/kg for chili peppers dried.

Potato (post-harvest treatment)

A national use pattern in the USA permits a single post-harvest application of difenoconazole to potatoes at a rate of 3.19 g ai/t tubers with in an line aqueous spray application using T-jet controlled droplet applicator (CDA) or similar application system. The US GAP does not specify a withholding period.

Residue trials on potatoes involving post-harvest application were conducted at five sites in different regions of the USA. In the trials, difenoconazole FS 360 (360 g/L) was applied once to potatoes as a post-harvest treatment at a rate of 3.5–3.8 g ai/t tubers, spraying directly to tubers falling from a conveyor belt or moving along a roller table. Post-harvest treated tubers were then collected on the day of treatment (0 day) once the test substance had dried. In decline studies, tubers were stored for up to 231 days in typical storage conditions of 5–10 °C.

At one site, potato tubers were cut at the field site. At another one site, in addition to a conveyor belt treatment, three additional application methods (surface, spray chamber and brush table) were utilized. The two methods using surface spraying and spray chamber did not comply with US GAP.

Therefore, in total five trials matching US GAP were available for use in estimating a maximum residue level.

In the USA, a pre-harvest application using difenoconazole formulation is also authorized on potatoes. No residue was detected in pre-treatment samples.

Residues in potatoes from post-harvest treatment (n=5): 0.61, 0.87, 1.2, 1.3 and 1.9 mg/kg.

The Meeting estimated a maximum residue level of 4 mg/kg, an STMR of 1.2 mg/kg and an HR of 1.9 mg/kg for post-harvest treated potato. The Meeting withdrew its previous recommendation of 0.02 mg/kg for potato that had been based on the residues resulting from pre-harvest treatment.

Ginseng

The maximum GAP in the Republic of Korea allows five applications of difenoconazole SC 10 (%, w/w) on ginseng at a rate of 0.0054 kg ai/hL, with a 10 day interval and a PHI of 14 days.

Two trials, using ready to harvest ginseng plantations (5 years old), were conducted in the Republic of Korea, complying with the maximum GAP. The resulting residues were: 0.030 and 0.044 mg/kg.

Of five trials evaluated by the 2010 JMPR, four trials matched the maximum GAP of the Republic of Korea. Thus the residues were (n=6): 0.006, 0.017, < 0.02, < 0.02, 0.030 and 0.044 mg/kg.

The Meeting estimated a maximum residue level 0.08 mg/kg, an STMR of 0.02 mg/kg and an HR of 0.044 mg/kg for ginseng. The Meeting withdrew its previous recommendation of 0.5 mg/kg for ginseng.

Animal feed

Residue information on animal feeds was not provided to the current Meeting.

Fate of residues during processing

The Meeting received information on the fate of difenoconazole residues during the processing of oranges, apples, grapes, tomatoes, potatoes and ginseng. The following table summarizes processing factors, STMR-Ps and HR-Ps estimated by the Meeting.

Raw agricultural commodity	Processed commodity	Pf (best estimate)	RAC STMR/HR	STMR-P/HR-P
Citrus	Citrus juice	< 0.01	0.16	0.002
	Citrus oil	47		7.5
	Citrus dry pulp	4.0		0.64
Pome fruit	Apple juice	0.03	0.16	0.005
	Apple pomace, wet	9.5		1.5
Grape	Raisin	2.1	0.52/1.5	1.1/3.2
	Juice	0.46		0.24
Tomatoes	Paste	1.6	0.14	0.22
	Puree	0.57		0.08
Potato	Flakes	< 0.024	1.2	0.029
	Chips	0.073		0.088
	Peel, wet	3.2		3.8
Ginseng	Dried including red ginseng	2.6	0.02/0.044	0.052/0.11
	Extracts	7.0	-	0.14

For dried grapes (raisin), the Meeting estimated a maximum residue level of 6 mg/kg, based on the processing factor of 2.1 for raisins and the maximum residue level of 3 mg/kg for grapes.

The Meeting re-calculated a processing factor for dried ginseng including processing study results for red ginseng, for a processing factor of 2.6. Based on the processing factor of 2.6 and a maximum residue level of 0.08 mg/kg for the ginseng raw commodity, the Meeting recommended a maximum residue level of 0.2 mg/kg for ginseng, dried including red ginseng. For ginseng extracts, applying the calculated processing factor of 7.0, a maximum residue level of 0.6 mg/kg was estimated.

Residues in animal commodities

Estimated dietary burdens of farm animals

Dietary burden calculations for beef cattle and dairy cattle and poultry are provided below. The dietary burdens were estimated using the OECD diets listed in Appendix IX of the 2009 edition of the FAO Manual.

Potential feed items include: almond hulls, apple pomace, bean forage, cabbages, head, carrot culls, citrus dried pulp, grape pomace, dry, pea vines, potato culls, potato process waste (wet peel), rape seed fodder, rape seed meal, soya bean seed, sugar beet leaves or tops, sunflower seed meal, wheat straw and fodder.

The Japanese animal diet contained only soya bean seed and rape seed meal of those commodities for which the JMPR estimated highest and median residues. The residues in the two commodities resulted in an animal dietary burden of less than 0.01 ppm on dry matter basis, therefore those values are not included in the summary table.

	Livestock dietary burden, difenoconazole, ppm of dry matter diet					
	US-Canada		EU		Australia	
	max	mean	max	mean	max	mean
Beef cattle	12.56	11.42	17.88[a]	15.30[b]	11.39	10.80
Dairy cattle	4.87	4.36	14.91[c]	12.37[d]	11.31	10.71
Poultry, broilers	0.01	0.01	0.96	0.61	0.01	0.01
Poultry, layers	0.01	0.01	1.89[e]	1.11[f]	0.01	0.01

[a] Highest maximum beef or dairy cattle dietary burden suitable for maximum residue level estimates for mammalian meat and edible offal

[b] Highest mean beef of dairy cattle dietary burden suitable for STMR estimates for mammalian meat and edible offal

[c] Highest maximum dairy cattle dietary burden suitable for maximum residue level estimates for milk

[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk

[e] Highest maximum broiler or layer poultry dietary burden suitable for maximum residue level estimates for poultry meat, edible offal and eggs

[f] Highest mean broiler or layer poultry dietary burden suitable for STMR estimates for poultry meat, edible offal and eggs

Estimated residues in animal commodities

For MRL estimation, the residues in the animal commodities are the 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.

Cattle

The 2007 JMPR evaluated two animal transfer studies carried out with Holstein dairy cows administering difenoconazole at 1, 3, 10 ppm (study 1) or 1, 5, 15 ppm (study 2) in the dry-weight diet for 29–30 consecutive days. The Meeting concluded that the two feeding studies were generally in good agreement of transfer factors. Thus, the present Meeting used the study with the 5 and 15 ppm feeding levels as most closely bracketing the dietary burdens.

For maximum residue level estimation, the high residues in the tissues were calculated by interpolating the maximum dietary burden of 17.88 ppm (in 2010 it was 2.42 ppm) between the relevant feeding levels (5 and 15 ppm) from the dairy cow feeding study and using the highest tissue concentrations from individual animals within those feeding groups.

The STMR values for the tissues were calculated by taking the STMR dietary burden of 15.30 ppm between the relevant feeding levels (5 and 15 ppm) from the dairy cow feeding study and using mean residue of the three animals.

The following table shows the expected residues in animal commodities.

	Feed level (ppm) for milk residues	Residues (mg/kg) in milk	Feed level (ppm) for tissue residues	Residues (mg/kg) in			
				Muscle	Liver	Kidney	Fat
Maximum residue level beef or dairy cattle							
Feeding study [a]	5	< 0.005	5	0.012	0.29	0.046	0.058
	15	0.013	15	0.058	0.80	0.14	0.16
Dietary burden and residue estimate	14.91	0.013	17.88	0.071	0.95	0.17	0.19
STMR beef or dairy cattle							
Feeding study [b]	5	< 0.005	5	0.012	0.25	0.043	0.046
	15	0.013	15	0.046	0.70	0.13	0.14
Dietary burden and residue estimate	12.37	0.011	15.30	0.047	0.71	0.13	0.14

[a] Highest residues for tissues and mean residue for milk

[b] Mean residues for tissues and milk

For muscle, the residues arising from dietary burdens of 17.88 ppm and 15.30 ppm were 0.071 mg/kg and 0.047 mg/kg, respectively. In fat, the residues arising from dietary burdens of 17.88 ppm and 15.30 ppm were 0.19 mg/kg and 0.14 mg/kg, respectively.

The residues in milk were 0.013 mg/kg and 0.011 mg/kg from dietary burdens of 14.91 ppm and 12.37 ppm, respectively.

For liver, the residues arising from dietary burdens of 17.38 ppm and 15.30 ppm were 0.95 mg/kg and 0.71 mg/kg, respectively. In kidney, the residues arising from dietary burdens of 17.88 ppm and 15.30 ppm were 0.17 mg/kg and 0.13 mg/kg.

The Meeting estimated a maximum residue level for difenoconazole in mammalian fat of 0.2 mg/kg. STMR and HR values for mammalian muscle and fat were estimated as 0.047 and 0.071 mg/kg in muscle, 0.14 and 0.19 mg/kg in fat, respectively.

For milk, the Meeting estimated a maximum residue level of 0.02 mg/kg and an STMR value of 0.011 mg/kg. Information on fat distribution in milk was not available.

The Meeting estimated a maximum residue level, an STMR value and an HR value for difenoconazole in mammalian edible offal of 1.5, 0.71 and 0.95 mg/kg, respectively, reflecting residues in liver of higher residue level.

The Meeting withdrew its previous recommendations on commodities of mammalian origin and milks.

Poultry

The 2007 JMPR evaluated a transfer study carried out with laying white leghorn hens. Four groups of 15 laying hens were fed rations treated with difenoconazole at 0.3, 1, 3 and 10 ppm for 28 consecutive days. Eggs were collected on 10 occasions for analysis (days 0 before treatment, 1, 3, 6, 9, 13, 16, 20, and 23). Poultry tissue and egg samples from the 0.3 ppm feeding group were not analysed because residues were at or below LOQ (< 0.01 mg/kg) in the 1 ppm feeding group. For poultry tissue, residues in 1 ppm feeding level were also not analysed as the residues in 3 and 10 ppm feeding levels were at or below LOQ (< 0.01 mg/kg).

	Feed level (ppm) for egg residues	Residues (mg/kg) in egg	Feed level (ppm) for tissue residues	Residues (mg/kg) in			
				Muscle	Liver	Skin	Fat
Maximum residue level broiler or laying hen							
Feeding study [a]	1	< 0.01	3	< 0.01	< 0.01	< 0.01	< 0.01
	3	0.046	10	< 0.01	< 0.01	< 0.01	< 0.01
Dietary burden and residue estimate	1.89	0.026	1.89	< 0.01	< 0.01	< 0.01	< 0.01
STMR broiler or laying hen							
Feeding study [b]	1	< 0.01	3	< 0.01	< 0.01	< 0.01	< 0.01
	3	0.032	10	< 0.01	< 0.01	< 0.01	< 0.01
Dietary burden and residue estimate	1.11	0.011	1.11	< 0.01	< 0.01	< 0.01	< 0.01

[a] Highest residues for tissues and mean residues for egg

[b] Mean residues for tissues and mean residues for egg

For poultry tissues, residues arising from the maximum dietary burden of 1.89 ppm were below LOQ (0.01 mg/kg). The Meeting confirmed the maximum residue level recommendation of < 0.01 mg/kg for poultry tissues (fat, edible offal). Further, the Meeting estimated an STMR value and an HR value, 0.001 mg/kg and 0.002 mg/kg, respectively, for the tissues (muscle, fat and edible offal).

For eggs, residues arising from dietary burdens of 1.89 ppm and 1.11 ppm were 0.026 mg/kg and 0.011 mg/kg. The Meeting estimated a maximum residue level of 0.03 mg/kg and an STMR value 0.011 mg/kg and an HR value of 0.026 mg/kg for eggs. The Meeting withdrew its previous recommendation for eggs of 0.01* mg/kg.

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue concentrations listed below are suitable for establishing MRLs and for assessing IEDIs and IESTIs.

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

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for animal commodities: *sum of difenoconazole and 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethanol), expressed as difenoconazole*.

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The ADI for difenoconazole is 0-0.01 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for difenoconazole were estimated for the 13 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the previous and present JMPR. The results are shown in Annex 3. The IEDIs ranged 4-60% of the maximum ADI. The Meeting concluded that the long-term intake of residues of difenoconazole from uses considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The ARfD for difenoconazole is 0.3 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for difenoconazole were calculated for the food commodities for which STMRs or HRs were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4. The IESTIs varied from 0–30% of the ARfD for children and 0–20% for the general population.

The Meeting concluded that the short-term intake of residues of difenoconazole from other uses that have been considered by the present Meeting is unlikely to present a public health concern.