MYCLOBUTANIL (181)

EXPLANATION

Myclobutanil was evaluated in 1992 and 1997. In 1997 the JMPR evaluated six field trials on hops conducted in the UK but the four trials which complied with GAP were considered insufficient to estimate a maximum residue level. Several post-harvest trials on bananas were according to proposed GAP, but since only proposed GAP was reported the 1997 Meeting could not estimate a maximum residue level. The present Meeting was informed that further trials in Germany were in progress which included processing studies, and that there was now registered GAP for bananas which would allow the recommendation of an MRL

The manufacturer requested the present Meeting to evaluate additional data on hops and re-evaluate the data on bananas in the light of the recently established GAP.

METHODS OF RESIDUE ANALYSIS

Analytical methods

The analytical method used to determine myclobutanil and its hydroxy metabolite RH-9090 in hops in the trials reported to the present Meeting was described in the 1992 evaluation.

The method involves maceration with methanol or alkaline methanol followed by liquid-liquid partition with petroleum ether and hexane, then transfer into dichloromethane. The extracts are purified by silica gel, Florisil and/or C18 column chromatography, and the residues are determined by GLC with an ECD or NPD (Brackett, 1984). The method was validated for many plant commodities (Gilbert, 1998a)

The LOD was 0.02 mg/kg for green hops, spent hops, trubs and yeast, 0.5 mg/kg for dried hops and 0.01 mg/kg for beer. Mean recoveries for dried hops fortified with 0.5 to 5.0 mg/kg were 79% for myclobutanil and 88% for RH-9090, for spent hops at 0.02 to 2.0 mg/kg 76% and 84%, for green hops at 0.02 to 2.0 mg/kg 76% and 86%, and for beer at 0.02 to 2.0 mg/kg 83-101% and 76-92%.

USE PATTERN

The UK GAP for hops was recorded in the 1997 evaluation. The new GAP for bananas in Costa Rica was reported to the present Meeting and is shown in Table 1.

Table 1. Registered uses of myclobutanil on hops and bananas.

Crop	Country	Form.	Application				PHI, days
			Method	kg ai/ha	kg ai/hl	No.	
Banana	Costa Rica	WP	Spray/dip or cascade		0.02-0.04 (200-400 mg/l)		
Hops	UK	SC	F	0.045-0.135	0.0045	6	10

RESIDUES RESULTING FROM SUPERVISED TRIALS

Hops. Six trials in England were evaluated in 1997. The residues in the dried cones ranged from 0.3 to 1.2 mg/kg.

Eight supervised field trials were carried out in Germany in 1996 and 1997, in which myclobutanil 20 EW was applied four times at 10-14-day intervals with a total application of 1.02 to 1.15 kg ai/ha. In four trials 0.006 kg ai/hl was sprayed at high volume almost to run-off, and in the other four 0.009 kg ai/hl was sprayed at medium volume. The plots were 4 rows of 30 or 15 m. Sampling-to-analysis intervals ranged from 12 to 519 days.

The residues of myclobutanil in dried hops ranged from 0.3 to 1.54 mg/kg. The results of the UK and German trials are shown in Table 2.

Table 2. Myclobutanil residues in hops from supervised trials. The underlined residues are from treatments according to GAP and were used to estimate maximum residue levels.

Country Year	Application				Sample	PHI, days	Residues, mg/kg		Ref.
	Form.	No.	kg ai/ha	kg ai/hl			Myclob.	RH-9090	
UK 1991	EW	6	0.101	0.0045	dried cones	7	0.5	<0.2	Nat. Hop 1995
UK 1991	EW	6	0.101	0.0045	dried cones	13	0.3	<0.2	
UK 1992	EW	6	0.103	0.0045	dried cones	8	1.2	<0.2	
UK 1992	EW	6	0.103	0.0045	dried cones	9	0.27	<0.2	
UK 1991	EW	6	0.103	0.0045	dried cones	3	1.8	<0.2	
UK 1991	EW	6	0.103	0.0045	dried cones	4	1.6	<0.2	
Germany 1996	EW	4	0.18-0.30	0.006	green hops	0	0.27	0.07	Gilbert 1998b
			1.02[1]			7	0.15	0.04	
						14	0.28	0.09	
					dried hops	14	1.02	<0.5	
Germany 1996	EW	4	0.18-0.3	0.006	green hops	0	0.22	0.02	Gilbert 1998b
			1.03[1]			7	0.46	0.1	
						14	0.22	0.03	
					dried hops	14	0.53	nd	
Germany 1996	EW	4	0.2-0.31	0.009	green hops	0	0.63	0.14	Gilbert 1998b
			1.15[1]			7	0.49	0.04	
						14	0.41	0.07	
					dried hops	14	1.54	<0.5	
Germany 1996	EW	4	0.19-0.31	0.009	green hops	0	0.97	0.13	Gilbert 1998b
			1.06[1]			7	0.17	<0.02	
						14	0.35	0.04	
					dried hops	14	1.06	<0.5	
Germany 1997	EW	4	0.18-0.3	0.006	green hops	0	2.42	0.23	Gilbert 1998c
			1.05[1]			7	0.25	0.07	
						14	0.35	0.16	
					dried hops	14	1.08	<0.5	
Germany 1997	EW	4	0.18-0.3	0.006	green hops	0	2.63	0.13	Gilbert 1998c
			1.02[1]			7	0.89	0.11	
						14	0.49	0.05	
					dried hops	14	<0.5	<0.5	
Germany 1997	EW	4	0.18-0.3	0.009	green hops	0	2.41	0.1	Gilbert 1998c
			1.02[1]			7	1	0.16	
						14	0.16	0.03	
					dried hops	14	0.63	<0.5	
Germany 1997	EW	4	0.18-0.3	0.009	green hops	0	0.82	0.05	
			1.03[1]			7	0.21	0.06	

Country Year	Application				Sample	PHI, days	Residues, mg/kg		Ref.
	Form.	No.	kg ai/ha	kg ai/hl			Myclob.	RH-9090	
						14	0.33	0.09	
					dried hops	14	0.73	<0.5	

[1] Total application

Bananas. Residue trials in which myclobutanil was used post-harvest at 200 and 400 mg/l in the USA (California and Hawaii) and Costa Rica were reviewed by the 1997 JMPR. The present Meeting re-evaluated the data in the light of the recently established GAP in Costa Rica.

Myclobutanil residues in whole bananas from trials which complied with the new GAP ranged from 0.64 to 1.7 mg/kg. The residues in the edible pulp were 0.1, 0.17, 0.19, 0.2, 0.21, 0.22, 0.27, 0.35, 0.39 and 0.41 mg/kg.

FATE OF RESIDUES IN STORAGE AND PROCESSING

In processing

Hops. In processing studies in Germany green hops (5 kg) from supervised trials were dried just after harvest and processed in a pilot plant by simulated commercial procedures. The steps in the process were as follows.

1. Boiling the wort from malted barley with hops.
2. Separation of trubs (flocs).
3. Fermentation.
4. Cool storage and maturing.
5. Filtration and bottling.

Each processing step was planned to simulate "worst case" conditions to keep possible residues of the test substance as high as possible, reducing the processing steps to a minimum. The hops were added to the boiling wort as dry hops instead of as hop extracts, the proportion of dry hops (450 g/100 l) was relatively high, the period of boiling the wort (75 minutes) was as short as possible, and fermentation was carried out under pressure to shorten the following cool storage. The residues of myclobutanil and its metabolite in beer were below the LOD (0.01 mg/kg). The results of these studies are shown in Table 3.

Table 3. Residues of myclobutanil in hops and brewing fractions in Germany, 1996 and 1997 (Gilbert, 1998b,c).

Application				PHI, days	Sample	Residues, mg/kg	
Form.	kg ai/ha	kg ai/hl	No.			Myclobut.	RH-9090
EW	0.18-0.3	0.006	4	14	dried hops	1.02	<0.5
	1.02 (total)				spent hops	0.09	<0.02
					trub	<0.02	<0.02
					yeast	<0.02	<0.02
					beer	<0.01	<0.01
EW	0.18-0.30	0.006	4	14	dried hops	1.08	<0.5
	1.05 (total)				spent hops	0.04	n.d.
					trub	<0.02	<0.02
					yeast	n.d.	<0.02
					beer	<0.01	<0.01

APPRAISAL

Myclobutanil was evaluated in 1992 and 1997. In 1997 the JMPR evaluated six field trials on hops conducted in the UK but the four trials which complied with GAP were considered insufficient to estimate a maximum residue level. Several post-harvest trials on bananas were according to proposed GAP, but since only proposed GAP was reported the 1997 Meeting could not estimate a maximum residue level. The present Meeting was informed that further trials in Germany were in progress which included processing studies, and that there was now registered GAP for bananas which would allow the recommendation of an MRL.

The manufacturer requested the present Meeting to evaluate additional data on hops and re-evaluate the data on bananas in the light of the recently established GAP.

The analytical methods for myclobutanil and its hydroxy metabolite RH-9090 used in the trials on hops and bananas reported in 1997 were described in the 1992 and 1997 monographs. The method used in the hop trials in Germany was described in the 1992 evaluation. The LODs for dried hops and beer were 0.5 and 0.01 mg/kg respectively. This method was validated for many plant commodities.

Four of the six UK trials reported in 1997 complied with GAP (6 applications, 0.0045 kg ai/hl, 10 days PHI). The residues of myclobutanil on hops (dried cones) ranged from 0.27 to 1.2 mg/kg. Eight supervised trials on hops were conducted in Germany in 1996 and 1997, four of which can be considered to comply with UK GAP. The residues of myclobutanil in dried hops in these trials ranged from <0.5 to 1.08 mg/kg.

The residues of myclobutanil in dried hops in the eight trials according to GAP in rank order (median underlined) were 0.27, 0.3, <0.5, 0.5, 0.53, 1.02, 1.08 and 1.2 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg and an STMR of 0.515 mg/kg for dried hops.

Bananas. The trials evaluated by the 1997 JMPR showed myclobutanil residues in whole bananas treated according to Costa Rica GAP from 0.64 to 1.7 mg/kg. The residues in the edible pulp in rank order (median underlined) were 0.1, 0.17, 0.19, 0.2, 0.21, 0.22, 0.27, 0.35, 0.39 and 0.41 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg (whole fruit) and an STMR of 0.215 mg/kg for banana.

Processing studies. Dried hops from two supervised trials containing residues of 1.02 and 1.06 mg/kg were brewed into beer. The residues in the beer in both studies were below the LOD. The calculated processing factor for hops to beer is 0 (<0.009), and the estimated STMR for beer is 0 mg/kg.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue level listed below is suitable for establishing maximum residue limit.

Definition of residue for compliance with MRL and for estimation of dietary intake: myclobutanil

Commodity		MRL, mg/kg		STMR, mg/kg
CCN	Name	new	previous	
FI 0327	Banana	2	-	0.215
	Beer			0
DH 1100	Hops (dry)	2	-	0.515

DIETARY RISK ASSESSMENT

Recommendations for myclobutanil MRLs on bananas and hops have been added to the previous recommendations and STMRs have been estimated for these commodities. The other values used for the intake estimation were previously estimated STMRs for six commodities and CXLs established for ten commodities. The International Estimated Daily Intakes of myclobutanil for the five GEMS/Food regional diets were 0 to 4% of the ADI. The Meeting concluded that the intake of residues of myclobutanil resulting from its uses that have been considered by the JMPR is unlikely to present a public health concern.

REFERENCES

Gilbert, J. 1998a. Myclobutanil and its Metabolites RH-9090. Validation of the Method of Analysis for the Determination of Residues in Green Hops, Beer, Dry and Spent Hops, Trub and Yeast, Cherries, Cherries, Grapes, GRAPE Juice and wine, Apples, Artichokes, Strawberry Preserves and Jam, Tomatoes, Tomato Puree, Juice and Preserves, Peppers and Cucumbers. Rohm & Haas Report No. 49.5/TR34-98-16.

Gilbert, J. 1998b. To Determine the Magnitude of Residues of Myclobutanil and the Metabolite RH-9090 During the Fourteen Days Following the Final Application in the Raw and Processed Agricultural Commodity of Hops Resulting from Sequential Directed Application of Systhane 20EW in Germany. Rohm & Haas Report No. 99.3/TR-34-98-22.

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