ZOXAMIDE (227)

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EXPLANATION

Zoxamide, benzamide fungicide, was first evaluated by the 2007 JMPR which allocated ADI of 0–0.5 mg/kg bw and agreed that an ARfD was unnecessary and the definition of residues for plant commodities for compliance with the MRL and for estimation of dietary intake was zoxamide.

The 2007 JMPR estimated a maximum residue level of 1 mg/kg on a basis of supervised trials conducted in Europe and Polish GAP. The current Meeting received information on new use pattern on cucurbits in the USA.

USE PATTERNS

The Meeting received information about a new use pattern on cucurbits in the USA with shorter PHI as summarized in Table 1.

Table 1Registered uses of zoxamide on cucurbits

Crop	Country	Formulation	Application		PHI days	Note
			Rate kg ai/ha	Number max		
Cucurbit [a]	USA	80W	0.14-0.22	8	0	Application up to day of harvest

[a] Including cucumber, melons (cantaloupe, casaba, Crenshaw, honeydew, muskmelon), summer squash (including crookneck squash, scallop squash, straightneck squash, vegetable marrow and zucchini), and watermelon.

RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

Fruiting Vegetables, Cucurbits

A total of 17 supervised field trials on cucurbits (six cantaloupe, five zucchini, and six cucumber trials) were conducted in major melon, squash, and cucumber production areas of the USA in 1999 (Graves, 1999; DERBI 92644). Each treated plot received 8 foliar-directed applications of a wettable powder formulation containing 800 g/kg zoxamide at the rate of approximately 0.22 kg ai/ha (0.2 lbs/acre) per application. The three bridging trials included an additional plot treated with 8 applications of a soluble concentrate formulation containing 240 g/L zoxamide at the rate of approximately 0.22 kg ai/ha (0.2 lbs/acre) per application. The treatment interval was 5–10 days. The period of time from harvest to analysis ranged from 67 to 463 days. Analyses were performed using method TR 34-99-43 (Guo, 1999; DERBI 92230). The LOQ of the method was 0.01 mg/kg; the LOD was 0.003 mg/kg. The average percent recovery was 89% with a standard deviation of 14.6%.

These trials had been submitted to the 2007 JMPR and the current Meeting evaluated the results of these trials against the new US GAP.

Residue data are recorded as mg zoxamid/kg and not corrected for recovery. Residue values from the trials conducted according to maximum GAP were used for the estimation of maximum residue levels. Where duplicate plots were used or duplicate samples were taken, the higher analytical result was used as previously agreed by the Meeting. These results are underlined.

Table 2 Zoxamide residues in cucurbits from supervised trials in the USA

Cucurbits country, year (variety)	Application Form	kg ai/ha	kg ai/hL	water, L/ha	no.	PHI days	Residues[a], mg/kg	Reference Trial number
US GAP (max)	*WP*	*0.22*			*8*	*0*		
Cucumber								
Georgia, USA, 1999 (Poinsett-76)	WP	0.22	0.18	192	8	0 3 5 7	0.13, 0.12 0.06, 0.06 0.04, 0.04 0.04, 0.03	Graves, 1999, DERBI 92644 60998012
New Jersey, USA, 1999 (Cyclone)	WP	0.22	0.079	284	8	0	0.12, 0.11	Graves, 1999, DERBI 92644 60998013
Florida, USA, 1999 (Meteor)	WP	0.22	0.081	277	8	0	0.02, 0.03	Graves, 1999, DERBI 92644 60998014
Michigan, USA, 1999 (Marketmore)	SC	0.22	0.10	215	8	0	0.05, 0.03	Graves, 1999, DERBI 92644 60998015
	WP	0.22	0.10	217	8	0	0.03, 0.05	
Michigan, USA, 1999 (Marketmore)	WP	0.22	0.10	216	8	0	0.02, 0.02	Graves, 1999, DERBI 92644 60998016
Texas, USA, 1999 (Straight 8)	WP	0.22	0.17	134	8	0	0.01, 0.01	Graves, 1999, DERBI 92644 60998017
Cantaloupe								
Georgia, USA, 1999 (Planter's Jumbo)	WP	0.22	0.11	196	8	0	0.48, 0.73	Graves, 1999, DERBI 92644 60998001
Wisconsin, USA, 1999 (Saticoy)	WP	0.22	0.12	188	8	0	0.03, 0.06	Graves, 1999, DERBI 92644 60998002
Texas, USA, 1999 (Hales Best)	WP	0.22	0.12	135	8	0	0.05, 0.08	Graves, 1999, DERBI 92644 60998003
California, USA, 1999 (PMR 45)	WP	0.22	0.10	220	8	0	0.19, 0.37	Graves, 1999, DERBI 92644 60998004
California, USA, 1999 (Summit)	WP	0.22	0.094	238	8	0	0.44, 0.43	Graves, 1999, DERBI 92644 60998005
	SC	0.22	0.094	238	8	0	0.08, 0.40	
Arizona, USA, 1999 (Mission)	WP	0.22	0.062	362	8	0 2 4 6	0.04, 0.04 0.04, 0.04 0.04, 0.04 0.04, -	Graves, 1999, DERBI 92644 34P-98-43SA-1
Summer squash								
New York, USA, 1999 (Zucchini Select)	WP	0.22	0.097	232	8	0	0.19, 0.15	Graves, 1999, DERBI 92644 60998007
Florida, USA, 1999 (Zucchini)	SC	0.22	0.080	280	8	0	0.02, 0.08	Graves, 1999, DERBI 92644 60998009
	WP	0.22	0.091	245	8	0	0.06, 0.04	

Cucurbits country, year (variety)	Application					PHI days	Residues[a], mg/kg	Reference Trial number
	Form	kg ai/ha	kg ai/hL	water, L/ha	no.			
Wisconsin, USA, 1999 (Dividend)	WP	0.22	0.12	188	8	0	0.39, 0.10	Graves, 1999, DERBI 92644 60998010
California, USA, 1999 (Zucchini)	WP	0.22	0.079	284	8	0	0.15, 0.13	Graves, 1999, DERBI 92644 60998011
Georgia, USA, 1999 (Black Beauty)	WP	0.22	0.077	293	8	0 0.375 3 5 7	0.04, 0.04 0.08, 0.04 0.04, 0.05 0.03, 0.04 0.10, 0.08	Graves, 1999, DERBI 92644 34P-98-43SA-2

[a] Analytical results of replicate samples from the same plot.

APPRAISAL

Zoxamide, a benzamide fungicide, was first evaluated by the 2007 JMPR which allocated ADI of 0-0.5 mg/kg bw and agreed that an ARfD was unnecessary. The definition of residues for plant commodities for compliance with the MRL and for estimation of dietary intake was zoxamide.

The 2007 JMPR estimated a maximum residue level for cucumber of 1 mg/kg on the basis of supervised trials conducted in Europe and the Polish GAP. The current Meeting received information on a new use pattern for cucurbits in the USA, with a shorter PHI, which was used for the estimation of a maximum residue level for cucurbits.

Results of supervised trials on crops

The NAFTA calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the NAFTA calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was supplied. Some common factors that may lead to rejection of the statistical estimate include when the number of data points in a data set is less than 15 or when there are a large number of values < LOQ.

Fruiting vegetables, Cucurbits

The Meeting evaluated the results of supervised outdoor trials conducted on cucurbits in the USA submitted to the 2007 JMPR against the new US GAP.

Six trials were conducted on cucumber in the USA in compliance with the GAP of the USA for cucurbits (maximum rate of 0.22 kg ai/ha, 8 applications, PHI 0 days). The residues in rank order were: 0.01, 0.02, 0.03, 0.05, 0.12, 0.13 mg/kg.

Six trials on cantaloupe were conducted in the USA in compliance with US GAP for cucurbits. The residues in rank order were: 0.04, 0.06, 0.08, 0.37, 0.44, 0.73 mg/kg.

Five trials on summer squash were conducted in the USA in compliance with US GAP for cucurbits. The residues in rank order were: 0.08, 0.10, 0.15, 0.19, 0.39 mg/kg.

On the basis the trial results on cantaloupe which gave the highest residues in the group, the Meeting estimated a maximum residue level of 2 mg/kg for fruiting vegetables, cucurbits. The

Meeting estimated an STMR of 0.225 mg/kg. The previously recommended maximum residue level of 1 mg/kg for cucumber should be withdrawn.

The maximum residue level estimate derived from use of the NAFTA calculator was 1.8 mg/kg (UCLMedian 95th). The normal JMPR procedure is to use one significant figure for maximum residue levels below 10 mg/kg. Rounding up the value obtained from the calculator results in an estimate of 2 mg/kg, which coincides with the recommendation of the present Meeting.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI assessment.

Plant commodities:

Definition of the residue (for compliance with the MRL and for estimation of dietary intake): zoxamide

Commodity		Recommended MRL mg/kg		STMR/ STMR-P mg/kg	HR/HR-P mg/kg
CCN	Name	New	Previous		
VC 0424	Cucumber	W	1		
VC 0045	Fruiting vegetables, cucurbits	2	-	0.225	-

DIETARY RISK ASSESSMENT

Long-term intake

The IEDIs of zoxamide were calculated for the 13 GEMS/Food Consumption Cluster Diets using STMRs/STMR-Ps estimated by the current and 2007 JMPR (see Annex 3 of the 2009 JMPR Report). The ADI is 0–0.5 mg/kg bw and the calculated IEDIs were 0–0.3% of the maximum ADI. The Meeting concluded that the long-term intakes of residues of zoxamide, resulting from the uses considered by the current and 2007 JMPR, are unlikely to present a public health concern.

Short-term intake

The 2007 JMPR decided that an ARfD is unnecessary. The Meeting therefore concluded that the short-term intake of residues of zoxamide is unlikely to present a public concern.

REFERENCES

Code	Author(s)	Year	Title
92230	Guo, I.	1999	Preliminary Residue Analytical Method For Parent RH-7281 in Cucurbits
224320	Perny, A.	2001	Determination Of Mancozeb (As CS2) and RH-7281 Residues in Cucumber Following Treatments With The Preparations RH-7281 2F and RH-7281/Mancozeb 75WG Under Greenhouse Conditions in France in 1999 / RH-7281 2F, Northern Europe (France)
224321	Perny, A.	2001	Determination Of Mancozeb (As CS2) and RH-7281 Residues in Cucumber Following Treatments With The Preparations RH-7281 2F and RH-7281/Mancozeb 75 WG Under Greenhouse Conditons in France in 1999 / RH-7281/Mancozeb 75 WG, Northern Europe (France)
224329	Wais, A.	2000	Determination Of Residues Of RH-117,281 in/on Cucumber (RAC Fruits) Following Treatment With RH-7281 2F From One Field Trial (Residue Decline

Code	Author(s)	Year	Title
			Study) Under Protection in Spain; 1999
224789	Perny, A.	2001	Determination Of Mancozeb (As CS2) and RH-7281 Residues in Cucumber Following Treatments With The Preparations RH-7281 2F and RH-7281/Mancozeb 75WG Under Greenhouse Conditions in France in 1999 / RH-7281 2F, Southern Europe (France)
224790	Perny, A.	2001	Determination Of Mancozeb (As CS2) and RH-7281 Residues in Cucumber Following Treatments With The Preparations RH-7281 2F and RH-7281/Mancozeb 75WG Under Greenhouse Conditions in France in 1999 / RH-7281/Mancozeb 75 WG, Southern Europe (France)
238367	Wais, A.	2001	Determination Of Residues Of RH-117,281 in/on Cucumber (RAC Fruits) Following Treatment With RH-7281/Mancozeb 75 WG From Two Field Trials (Residue Decline Studies) Under Protection in Spain, 1999
92644	Graves, D. D.	1999	RH-117281 Fungicide Field Residue Trials in The Cucurbit Vegetable Group
238418		1998	Zoxamide Crop Residue Study On Cucumber