IPRODIONE (111)

EXPLANATION

Iprodione was first evaluated for residues in 1977 and again in 1980, and in 1994 under the CCPR Periodic Review Programme, and for toxicology in 1992 and 1995. In the 1994 periodic review, the Meeting recommended withdrawal of the existing CXL of 5 mg/kg in tomato because an insufficient number of trials according to GAP had been carried out, but the 28th Session of the CCPR recommended maintaining the existing CXL, pending provision of new data. The 30th CCPR retained the CXL as the manufacturer confirmed the availability of new data from indoor trials. The 31st CCPR agreed to extend the 4-year period under the Periodic Review procedure and the evaluation was scheduled for 2001.

METHODS OF RESIDUE ANALYSIS

Analytical methods

In the 1977 evaluation of iprodione, limits of quantification ranging from 0.01 to 0.02 mg/kg were reported for most fruits and vegetables and 0.05 to 0.1 mg/kg for samples where interferences occurred. Quantification was by GLC with an ECD.

As part of a storage stability study, Plaisance (1994a) reported an analytical method for the determination of iprodione, its isomer *N*-(3,5-dichlorophenyl)-3-isopropyl-2,4-dioxoimidazolidine-1-carboxamide (RP 30228) and metabolite 3-(3,5-dichlorophenyl)-2,4-dioxoimidazolidine-1-carboxamide (RP 32490) in a number of whole commodities and processed fractions. The treated samples are blended with CH_3CN and filtered, before being partitioned with hexane. The lower CH_3CN/H_2O phase is collected and partitioned repeatedly with hexane. The hexane fractions are discarded and the aqueous CH_3CN is evaporated to a small volume. A 50:50 mixture of hexane and CH_2Cl_2 is added to the CH_3CN and the mixture is cleaned up on a Florisil column. The eluate is evaporated to 1-2 ml and filtered before analysis by HPLC with UV detection (λ = 200 or 210 nm). pH adjustment was required for grape samples. No modifications of the method were required for tomatoes. Iprodione, its isomer RP-30228 and its metabolite RP-32490 are observed on one chromatogram with retention times of 6.47, 8.91 and 3.84 min respectively. The limit of quantification is 2.5 mg/kg for each compound. Representative chromatograms of each of 43 commodities were provided. Validation recoveries were determined for all commodities, with fortifications at 2.5 and 5 mg/kg and the results for whole tomatoes are shown in Table 1.

Table 1. Recoveries of iprodione, its isomer and metabolite from whole tomatoes.

Compound	Fortification level (mg/kg)	Recovery (%)
Iprodione	2.5 5	90, 90, 91, 94 91, 93, 96, 96
RP-30228	2.5 5	86, 90, 91, 92 94, 96, 96, 96
RP-32490	2.5 5	84, 85, 89, 90 86, 86, 86, 91

Bourgade *et al.* (1997) reported a version of method CNG-An no. 20610E revised to meet contemporary registration requirements (AR 144-97) that involves extracting residues of iprodione from plant samples by homogenizing in acetone and clean-up by partitioning with CH_2Cl_2. For fruit, vegetable and cereal samples (citrus fruit, stone fruit, berries and other small fruit; root and tuber vegetables, fruiting vegetables, brassicas, leafy vegetables and fresh herbs, legume vegetables and pulses; cereals), the extracts are purified on a Florisil cartridge. For difficult samples (almonds, hazelnuts, grapes; carrots, stalk and stem vegetables; oilseeds) the extracts are purified on a diol cartridge. For oily products such as tree nuts and oilseeds, the extracts are washed with *n*-hexane before the diol cartridge. Quantification is by GLC on a semi-capillary column with an ECD and external standardization. The limit of quantification (LOQ) is 0.02 mg/kg. Specimen chromatograms of various samples were provided together with those of standard solutions. Recoveries from control samples taken from residue trials are shown in Table 2.

Table 2. Reported recoveries of iprodione from fruits and vegetables.

Sample	Fortification level (mg/kg)	Recovery (%)
Lemons	0.02 2 5	95, 96 80, 120 72
Oranges	0.02 0.1	106, 108 73
Cherries	0.02 0.1 1 2	74 76 91 94
Strawberries	0.02 5	121 96
Blackcurrants	8	80
Celeriac	0.02 10	112 106
Radish	0.02 0.5	83 115
Cucumbers	0.02 0.1 0.2 1	76, 102 98, 111 104 71
Melon	0.02 0.05 0.1 0.2 0.3	85 103 91, 92 81 94
Watermelon	0.05 0.1 0.2 0.4	109 118 128 71
Cauliflower	0.02 0.04 1	96, 133 87, 99 81
Broccoli	0.02 1	120 81
Brussels sprouts	0.02 0.1 0.2	100, 115 76 71
Chinese cabbage	0.02 0.1 2 5 15	81 119 85 100 119
Cabbage	0.02 0.05 0.1	93, 102 91 92, 108

Sample	Fortification level (mg/kg)	Recovery (%)
	0.25 0.5 1	80 92 107
Chicory	0.02	78, 88
Peas	0.02 0.1 1	81, 88 91, 93 90
Peas with pods	0.02 2	88 71
Lentils	0.02 0.1	99, 105 93, 109
Green beans	0.02 0.05 0.1 0.2 0.4 0.5 1 2	85, 95, 96, 106, 109 91 97, 113, 121 77, 83 73 87 87, 93, 99 78, 103
Wheat (grain)	0.02 0.05	86, 132 90, 91
Wheat straw	0.05 0.2 1	92, 99 80 91
Barley (grain)	0.02 0.05 0.1	86, 104 88, 111 101
Barley (straw)	0.05 0.2 1 2	79, 101 111 81 103
Sorghum	0.02	125

The modified method AR 144-97 was used to analyse tomatoes in many of the residue trials. Recoveries from some of the trials are shown below.

Table 3. Recoveries from tomatoes as determined in supervised residues trials.

Trial Ref.	Reported LOQ	Fortification level (mg/kg)	Recovery (%)
446165	0.02	0.02 0.4 0.8	80, 84, 95 94 90
444928	0.02	0.02 2	80, 84 96
427141	0.05	0.05	98
427214	0.05	0.05 0.09	95 100
412155	0.05	1 0.92 1.8	100 92 90
412161	0.05	0.5 0.95 2	100 95 98
405735	0.1	0.1	97

Stability of pesticide residues in stored analytical samples

The Meeting received several storage stability studies from the manufacturer. Maycey and Savage (1991) reported the stability of iprodione in strawberries, lettuce, blackcurrants, blackcurrant juice and prepared tomato extracts. Samples containing incurred residues obtained from residue trials were stored at -20°C for a maximum of 14 months after initial analysis. At varying intervals treated and control samples were re-analysed. Tomato extracts were prepared by homogenizing tomatoes with acetone, filtering, and evaporating the remaining filtrate to leave an aqueous sample. The samples were frozen until required, with further work-up before re-analysis. Concurrent recoveries were determined in the different samples at each interval. The results are shown in Table 4.

Table 4. Frozen storage stability of incurred iprodione residues in strawberries, lettuce, blackcurrants and blackcurrant juice and tomato extract.

Sample	Storage period (months)	Residue (mg/kg)		Concurrent recovery range (%)
		Initial analysis	Re-analysis	
Strawberries	8 14	2.4, 2.9 3.1, 3.1	2.5, 2.4 3.0, 3.1	93-95 (n = 3)
Lettuce	1 2.5 7 9 10	19.0, 20.3 19.0, 20.3 4.1, 4.2 5.0, 5.3 4.3, 4.7	20.4, 21.6 19.6, 21.0 3.4, 3.7 4.7, 4.4 5.4, 5.0	71-93 (n = 8)
Blackcurrants	12	1.4, 1.5 1.8, 2.2	1.2, 1.3 1.4, 1.6	82, 83
Juice	12	0.69, 0.78 0.60, 0.61	0.74, 0.75 0.58, 0.60	86, 90
Tomato extract	6 days 6.5 12.8	0.99, 1.0	0.93, 0.98 1.1, 1.1 0.84, 0.99	95-97 (n = 5)

The results show that iprodione residues in strawberries stored up to 14 months, lettuce for 10 months, blackcurrants and blackcurrant juice for 12 months and tomato extract for almost 13 months decrease negligibly.

Plaisance (1994b) investigated the stability of iprodione, its isomer RP 30228 and metabolite RP 32490 in 43 commodities and processed fractions during storage at -10°C but only the results for tomato are reported here. Samples of tomatoes were individually fortified with 5 mg/kg of iprodione, its isomer and its metabolite and stored up to 12 months. At 3-month intervals, the stored commodities were analysed and the results compared to those from freshly fortified samples; duplicate samples were analysed at each time. The method was validated by analysis of samples fortified with 2.5 and 5 mg/kg of iprodione, its isomer and its metabolite to demonstrate acceptable recoveries (Table 1).

In a continuation of the Plaisance study, Gillings (1995) investigated the storage stability of tomato samples over 24 months, and reported a modified analytical method. Data from both studies are shown in Table 5.

Table 5: Storage stability of iprodione, its isomer RP-30228 and metabolite RP-32490 in tomatoes fortified at 5 mg/kg (Plaisance, 1994; Gillings, 1995).

Analyte	Storage period (months)	Apparent % remaining in stored sample	Concurrent recovery (%)	Corrected %remaining
Iprodione	0	95, 98	106	90, 93
	3	82, 86	80	102, 107
	6	(88), (92)[1]	67	131, 137
	9	94, 88	97	97, 91
	12	90, 91	95	95, 95
	24	92, 91	84	103, 101
RP-30228	0	92, 89	101	91, 89
	3	74, 78	87	85, 90
	6	68, 82	83	83, 100
	9	89, 88	108	83, 81
	12	85, 88	94	91, 93
	24	87, 87	83	104, 104
RP-32490	0	92, 91	101	90, 90
	3	85, 80	86	99, 93
	6	115, 117	104	111, 112
	9	89, 87	96	92, 90
	12	97, 95	104	93, 91
	24	89, 87	88	100, 99

[1]Values in parentheses not taken into account because of poor procedural recoveries on that day.

The proportions of the original fortification remaining in tomatoes ranged from 81 to 137% for iprodione, its isomer and its metabolite:

Compound	Range, %	Mean, %
Iprodione	90-137	104
Isomer RP-30228	81-104	91
Metabolite RP-32490	90-112	97

The results show that residues of iprodione, its isomer and its metabolite in tomatoes are stable during frozen storage for at least 24 months.

USE PATTERN

Iprodione is registered as a contact fungicide on *solanaceae*, more specifically tomatoes, in Africa (Algeria, Ivory Coast, Cameroon, Kenya, Mauritius, Morocco, South Africa, Senegal, Togo, Tunisia, Zambia), North America (Canada), Latin America (Bolivia, Brazil, Chile, Costa Rica, Honduras, Nicaragua), EU (Belgium, France, Finland, Greece, Hungary, Italy, Portugal, Romania, Spain, Sweden, The Netherlands, the UK), Asia and Australasia (Australia, New Zealand, Japan, China, Thailand, Malaysia, Myanmar). Iprodione is used to control the fungal diseases *Alternaria spp.*, *Sclerotinia spp*. and *Botrytis spp.* in tomatoes. It is formulated as a wettable powder, suspension concentrate and water-dispersible granules for use in field and glasshouse. WP and WDG products are typically 500 g/kg, while SC products are 255 or 500 g/l.

The information reported to the Meeting on the registered uses on tomatoes is shown in Table 6.

Table 6: Registered uses of iprodione on tomatoes. All foliar applications.

Country	Form.	Field/ indoor	Application			PHI (days)
			Rate (kg ai/ha)	Spray conc. (kg ai/hl)	No.	
Belgium	WP 500 SC 500	[1]		0.05	6[2]	3
Brazil	WP 500 SC 500	Field	0.6-0.75	0.075[3]	1-3	1
Canada	WP 500 WG 500	Indoor		0.05	NS[4]	2
China	WP 500 SC 500	Field and indoor	0.375-0.75	0.056-0.17[5]	1-3	7
Denmark	SC 500 WP 750	Field and indoor		0.025-0.05 0.022-0.052	NS	3
France	SC 500	Field and indoor	0.75-1		NS[6]	3
Italy	WP 500 FL 250	Field		0.05-0.075[7]		21
Japan	WP 500 SC 40	Field and indoor	1	0.033-0.05 0.026-0.040	3[8]	1
Netherlands	SC 500	Field and indoor		0.025		3
UK	WP 500	Field and indoor		0.05	6[2]	1 (Indoor) 2 (Field)

[1] For use in market gardens.
[2] Re-treatment interval 14 days.
[3] Spray volumes 800-1000 l/ha; repeat at 7-day intervals.
[4] Application from 2nd flower stage; repeat at weekly intervals.
[5] Spray volumes 450-675 l/ha.
[6] Apply from 2nd flower stage; re-treatment interval 10-15 days indoors or 15-20 days in field.
[7] Similar rates for combination product with thiram.
[8] Application from flowering stage.

RESIDUES RESULTING FROM SUPERVISED TRIALS

The results from supervised residue trials are shown in Tables 7-15.

Tables 7-12 *Europe:* Belgium, Denmark, France, UK, Italy, The Netherlands
Table 13 Canada
Table 14 China
Table 15 Japan

Where residues were not detected the results are reported as below the limit of quantification (LOQ), e.g. <0.05 mg/kg. Residues, application rates and spray concentrations have generally been rounded to 2 significant figures. Although trials included results for untreated controls, these results are not reported in the Tables unless the residues in the control samples were above the LOQ. The prefix *"c"* in the Tables indicates samples from control plots. Where possible, residues are recorded uncorrected for analytical recoveries. It should be noted that unless stated otherwise concurrent recoveries were acceptable and any corrections small. NS indicates that a particular detail was not stated in the field report.

It is noted that a number of the trials described below were reviewed in the 1994 evaluation of iprodione. Unless otherwise stated, WP or WDG formulations were used in most trials.

Results from a single trial in Belgium were reported to the Meeting, but it was not stated whether the trial was in the field or under glass. Four foliar sprays were applied at intervals of 11, 21 and 14 days, and samples taken 3 hours after the last spray. The LOQ was reported as 0.01 mg/kg, although analytical details were not given.

Table 7. Residues in tomatoes from a trial in Belgium.

Location, year	Application				PHI	Residues (mg/kg)	Ref.
	kg ai/ha	kg ai/hl	No.	Interval			
Moerzeke, 1983	– –	0.025 0.05	4 4	11, 21, 14	3 h 3 h	0.28 1.60	Nangniot, 1983, Report 83/128 319549

Two glasshouse trials in Denmark were conducted in 1980 and 1981. In the 1980 trial, maturing fruit received a single foliar application by knapsack sprayer. Plots of 6 single plants were sprayed to run-off. Samples were analysed within 3-4 months of collection. In the 1981 trial, 7 sprays were applied to 15 plants at 14-day intervals, using a knapsack sprayer. The LOQ was reported as 0.1 mg/kg, the lowest fortification level for analytical recoveries.

Table 8: Residues in tomatoes from indoor trials in Denmark.

Location, year (variety)	Application				PHI (days)	Residues (mg/kg)	Ref.
	kg ai/ha	kg ai/hl	No.	Interval			
Koebenhavn, 1980 (Ida)	–	0.05	1	–	0 4 7	1.3 *c* 0.018 <u>0.74</u> 0.49	Brockelsby and Cooper, 1981 403185
Marslev, 1981 (Ida)	1.4		7	14 days	1 3 5 7 14	1.9 *c* 0.035 1.7 *c* 0.02 0.9 1.0 1.0	Maycey, 1982b 404347

Several field trials in Northern and Southern France, from 1978 to 1998, were reported. In the 1978 trials, either single or 4 foliar applications were made by pneumatic sprayer to tomatoes under cover. No detailed description of analysis was given.

In the first of the 1991 trials (at Coustellet) 2 foliar applications of an SC formulation were made by pneumatic sprayer, the first at flowering and the second 25 days later at orange fruit. The limit of quantification was 0.05 mg/kg; a full analytical report was provided. In the second trial, 3 sprays of an SC product were applied by pneumatic sprayer at intervals of 14 and 15 days. Rain fell 5 days after the last spraying and temperatures during the spraying were 26-29°C. Samples from both trials were analysed within 3 months but details of the field phase of the trials were in summary form only.

In 1998 in two glasshouse trials on tomatoes in Northern France an SC formulation was applied five times at 7-day intervals using a backpack sprayer, starting at BBCH 66 through to BBCH 81, to duplicate plots of 9 and 8 m^2 each consisting of 10 plants. Samples from the replicate plots were analysed individually within 3 months. A full description of the analytical method was provided with chromatograms, LOQ 0.02 mg/kg.

In another glasshouse trial in 1998 in Southern France 4 sprays of an SC formulation were applied by backpack sprayer at 7-day intervals to duplicate plots (8 m^2, 20 plants) at growth stages ranging from BBCH 64-71 to BBCH 65-74. Samples from each replicate plot were analysed within 5 months: a full method with chromatograms was provided.

Table 9. Residues in tomatoes from trials in France.

Location, year (variety)	Application				Field/ indoor	PHI (days)	Residues (mg/kg)	Ref.
	kg ai/ha	kg ai/hl	No.	Interval, days				
Avignon, France (Sth), 1978, (63-5)	0.83	0.15	1	–	indoor	9	0.19	Laurent and Chabassol, 1979 402126
Chavanne, France (Sth), 1978, (63-4)	0.75	0.15	4	17, 22, 33	indoor	7	0.85	
Coustellet. France (Sth), 1991, (Delta)	0.75		2	25	field	19	<0.05	Muller, 1991b 427141 (Study 91-261)
Robion, France (Sth), 1991, (Roma)	2.2		3	14, 15	field	0 4 7 14	0.1 <0.05 <0.05 <0.05	Muller, 1991a 427214 (Study 91-198)
Janze, France (Nth), 1998 (Felicia)		0.05	5	7	indoor	3	1.7, 1.6	Baudet, 1991b 444928 (Study 98-574)
St. Coulomb, France (Nth), 1998, (Felicia)		0.05	5	7	indoor	3	1.5, 1.7	
Vaucluse, France (Sth), 1998, (Felicia)		0.15	4	7	indoor	3	1.9, 1.3	Baudet, 1991c 446068 (Study 98-755

Several glasshouse trials were conducted in the UK during 1974, 1977 and 1981.

In 1974, trials were carried out at two sites in Essex, one in polythene greenhouses at Writtle and the other in a multispan glasshouse at Brentwood.

At Writtle 5 to 8 applications at 13- to 14-day intervals using a knapsack sprayer were made to plots of 12 plants, 30 cm apart (3 replicates of 4 plants). Crops were sprayed to run-off but spray volumes were not reported. Samples from each replicate (3 × 1 kg) were collected 14 days after the last spraying and analysed individually within 5 months. The reported LOQ was 0.05 mg/kg.

At Brentwood, in the first of two trials 5 applications were made at 14-day intervals to a plot of 36 plants, 45 cm apart (3 replicates of 12 plants), sprayed to run-off using a knapsack sprayer. Samples were collected 0-14 days after treatment and analysed within 4 months. In the other trial, 4 to 8 sprays were applied using a knapsack sprayer at 14-day intervals and samples collected 14 or 15 days after the last spraying (14 and 28 days later after 8 sprays) were analysed within 4 months. Treated plots consisted of 18 plants, 45 cm apart (3 replicates of 6 plants). The LOQ was 0.05 mg/kg.

An SC formulation was used in the 1981 UK trials. At Chichester, 6 sprays were applied by motorised knapsack sprayer at intervals of 10 to 17 days from early flowering to mature fruit stages. The plot consisted of 5 rows or 115 m^2; samples were analysed within 4 months. In the Ipswich trial 6 sprays were applied by hand-held lance sprayer at intervals of 5 to 48 days, from 2nd flowers to red fruit stages; plot size 3 double rows. Samples were analysed within 2 months of collection. In the Pershore trial, 11 sprays were applied by hand-held knapsack at 14- to 21-day intervals; no indication of growth stages or plot size was given. Samples were analysed one month after collection. Finite residues were found in all control samples. Replicate samples were analysed individually. The lowest fortification to test recovery was 0.2 mg/kg, although the limit of quantification was reported as 0.01 mg/kg.

In the 1977 glasshouse trials in England and Scotland a variety of formulations of iprodione were used. At Kirkham 2 applications were made at 14-day intervals by thermal fogging at a rate equivalent to 1.1 kg ai/ha, and at Milford 4 were made at 14-day intervals by fogging to a 0.4 ha plot and 2 replicate samples and a control were collected 2 days after treatment. In the first of two trials at Lea Valley 2 applications were made by spraying or fogging on the same day to 4 replicate plots, and in the second trial 4 or 5 applications by spraying or fogging but plot sizes were not reported. At Ayr in Scotland 4 applications were made by spraying using a hand-held lance or by a fogging machine to each replicate plot (size 9.7 × 35m). Samples from all the UK trials were analysed within 1 to 2 months of collection. The limit of quantification was reported as 0.02 mg/kg.

Table 10. Residues in tomatoes from indoor trials in the UK.

Location, year (variety)	Application				PHI (days)	Residues (mg/kg)	Ref.
	kg ai/ha	kg ai/hl	No.	Interval			
Writtle, Essex, 1974, (Eurocross B.B.)		0.05	5	16, 14, 14, 13	14	1.8, 2.6, 3.8	Laurent and Buys, 1975 445075 Spray to run-off
			6	16, 14, 14, 13, 14	14	2.9, 4.7, 3.7	
			7	16, 14, 14, 13, 14, 14	14	4.9, 5.0	
			8	16, 14, 14, 13, 14, 14, 14	14 27 41	2.9, 5.0, 4.6 1.8, 3.1, 1.9 3.2, 3.4	
Brentwood, Essex, 1974, (Sonato)		0.05	4 5 6 7 8	14 (3) 14 (3), 15 14 (3), 15, 14 14 (3), 15, 14 (2) 14 (3), 15, 14 (3)	15 14 14 14 14 28	1.4, 1.9, 2.0, 2.7 3.3, 2.4 4.9, 3.1, 3.1 4.1, 4.3 6.4, 5.3	445075
Brentwood, Essex, 1974, (Sonato)		0.05	5	14 (4)	0 2 5 7 9 14	2.2, 3.1, 3.9 4.2, 3.7, 2.4 3.5, 3.0, 2.5 1.2, 3.6, 2.7 1.4, 1.6, 3.4 3.6, 2.7, 1.7	445075
Chichester, 1981, (Sonatine)		0.05	6	14, 14, 14, 10, 17	1	2.6, 2.8 *c* 0.06	Maycey, 1982a 403960
Ipswich, 1981, (Shirley)		0.05	6	14, 20, 5, 44, 48	1	1.4, 2.1 *c* 0.40	
Pershore, 1981, (Sonatine)		0.05	11	14 (5), 21 (2), 14(2), 17	1	1.5, 1.4 *c* 0.47	
Kirkham, 1977, (Sonato)	1.1	0.08	2	14	2	0.85, 1.0, 0.24	Woods, 1978 445076
Milford, 1977 (Kirdford Cross)	1.1	0.06	4	14, 14, 14	2	1.4	
Lea Valley, 1977, (Sonato)	0.56	0.06	2	0 days	2	0.1	
Lea Valley, 1977, (Sonato)	0.56	0.06	4	14, 14, 7	3	0.23	
			5	14, 14, 7, 14	3	0.28	
Ayr, 1977 (Curabelle)	0.56	0.06	4	14, 15, 14	2	1.4	

In a single Italian field trial 3 sprays of a 250 SC formulation were applied by compressor. Plots were replicated with samples of 1.5 kg analysed individually within 2 months of collection. The limit of quantification was 0.03 mg/kg.

Table 11. Residues in tomatoes from a field trial in Italy.

Location, year (variety)	Application				PHI (days)	Residues (mg/kg)	Ref.
	kg ai/ha	kg ai/hl	No.	Interval			
Alfonsine, 1982 (UC 90)	0.75	0.075	3	15, 17	15 28	0.06 0.03	Chabassol and Aublet, 1983 405735

In three glasshouse trials in The Netherlands five foliar sprays were applied at intervals of 10 to 14 days (BBCH 60-89) using a motor sprayer with a spraystick at 1.1 kg ai/ha or 0.073 kg ai/hl to control and treated plots of 16 m^2 (1 double row 1.6 m wide by 10 m long). Samples were analysed within 4 months of collection. Replicate samples (12 fruits) were taken randomly from each plot. Quantification was by GLC with an ELCD (electroconductivity detector). The LOQ was 0.02 mg/kg.

Table 12. Residues in tomatoes from indoor trials in The Netherlands.

Year (variety)	Application			PHI (days)	Residues (mg/kg)	Ref.
	kg ai/hl	No.	Interval			
1998 (Elegance)	0.073	5	13, 10, 10, 11	3	0.58, 0.79	Baudet, 1999a 446165
	0.073	5	13, 10, 10, 11	3	0.50, 0.54	
	0.073	5	13, 10, 10, 11	3	0.86, 1.1	

In glasshouse trials in Canada in 1981/1982 two or three foliar sprays were applied at intervals of 37 or 14 and 35 days respectively by knapsack (1981 trial) or by electric greenhouse sprayer (1982). In the 1981 trial plots consisted of 10 plants by 4 replicates and spray volumes were 250 l/ha, and in the 1982 plots of 4 rows by 10m (row spacing 102 cm; plant spacing 31 cm) were sprayed to run-off. Composite samples were taken from 4 replicate plots. In the 1982 trials, residues in individual 1 kg samples were determined. All samples were analysed within 4 months of collection. The LOQ was 0.1 mg/kg; controls <0.03 mg/kg.

Table 13. Residues in tomatoes from indoor trials in Canada.

Location, year (variety)	Application			PHI (days)	Residue (mg/kg)	Ref.
	kg ai/hl	No.	Interval			
Ontario, 1981, (MR 13)	0.05	3	14, 35	2 7	0.2 0.4	Maycey, 1983 318322
	0.1	3	14, 35	2 7	0.5 0.5	
Ontario, 1982, (Vendor)	0.05	2	37	3	0.1, <0.1, 0.2, 0.2[1]	
(Jumbo)	0.05	2	37	3	0.2, 0.2, 0.3, 0.3	
(MR 13)	0.05	2	37	3	0.2, 0.3, 0.4, 0.2	

[1] 4 × 1 kg samples analysed individually instead of composite.

For trials in China only summary sheets were provided in English with field- and analytical-phase reports in Chinese. Recoveries were 85-87% with an LOQ of 0.01 mg/kg.

Table 14. Residues in tomatoes from field trials in China.

Location, year	Application			PHI (days)	Residue (mg/kg)	Ref.
	kg ai/ha	No.	Interval			
Hang Zhou, 1990	0.75	3	NS	3 7 10	1.7 1.6 1.9	Aventis 448474
		5	NS	3 7	0.71 1.1	

Location, year	Application			PHI	Residue	Ref.
	kg ai/ha	No.	Interval	(days)	(mg/kg)	
				10	0.60	
	1.5	3	NS	3	1.7	
				7	1.7	
				10	0.69	
		5	NS	3	1.1	
				7	2.0	
				10	2.0	
Shi Jia, 1990	0.75	3	NS	3	1.1	448474
				7	0.53	
				10	0.25	
		5	NS	3	1.1	
				7	0.99	
				10	0.23	
	1.5	3	NS	3	1.6	
				7	1.0	
				10	0.38	
		5	NS	3	2.1	
				7	1.3	
				10	0.26	
Hang Zhou, 1991	0.75	3	NS	3	0.24	448474
				7	0.15	
				10	0.04	
		5	NS	3	1.0	
				7	0.21	
				10	0.08	
	1.5	3	NS	3	1.7	
				7	0.15	
				10	0.12	
		5	NS	3	0.43	
				7	0.29	
				10	0.14	
Shi Jia, 1991	0.75	3	NS	3	0.26	
				7	0.09	
				10	0.05	
		5	NS	3	0.58	
				7	0.19	
				10	0.14	
	1.5	3	NS	3	0.51	
				7	0.40	
				10	0.16	
		5	NS	3	0.31	
				7	0.30	
				10	0.21	

A number of Japanese trials from 1975 to 1988 were reported to the Meeting. In the 1975 trials at Nagasaki, 3, 4 or 5 sprays were applied at 7-day intervals. Field details were brief, with no indication of plot sizes or samples sizes. Samples were analysed for iprodione and its isomer RP30228 within 7 months of collection. The limits of quantification were 0.05 mg/kg for iprodione and 0.1 mg/kg for RP-30228.

In the 1975 Ibaraki trial 1, 3 or 4 sprays of iprodione were applied at 7-day intervals. Field details were again brief with no indication of plot or sample sizes. Samples were analysed for iprodione and RP-30228 within 4 months of collection. The limits of quantification were 0.05 mg/kg for both compounds.

Table 15. Residues in tomatoes from indoor trials in Japan.

Location, year (variety)	Application				PHI (days)	Residue[1] (mg/kg)	Ref.
	kg ai/ha	kg ai/hl	No.	Interval			
Nagasaki, 1975	3	0.1	3	7, 7	1 3 7 14	2.1 3.4 1.8 3.0	Laurent and Buys, 1976a 412155
	3	0.1	4	7, 7, 7	1 3 7 14	4.6 3.6 4.1 2.8	
	3	0.1	5	7, 7, 7, 7	1 3 7 14	4.5 4.1 3.9 3.8	
Ibaraki, 1975	2.5	0.1	1		1 3 7 14	1.3 1.4 1.2 0.79	Laurent and Buys, 1976b 412161
	2.5	0.1	3	7, 7	1 3 7 14	5.3 3.5 3.0 2.4	
	2.5	0.1	4	7, 7, 7	1 3 7 14	5.6 5.4 4.3 3.5	
Gunma, 1978, (Ogata zuiko)	0.75-1	0.05	3	7, 7	3 7	1.1 0.90	IETJ 1978
	0.75 - 1.3		6	7, 7, 7, 7, 7	3 7	0.45 1.2	
Chiba, 1978, (Toko K)	1.5	0.05	3	7, 7	1 3 7	0.61 0.60 0.52	
			6	7, 7, 7, 7, 7	1 3 7	1.6 0.82 1.0	
Ibaraki, 1988, (TVR-2)	0.46	0.023	4	7, 7, 7	1 3 7	0.01 0.02 0.02	IETJ 1988a
Ishikawa, Japan 1998 (Kyoryoku reigyoku)	0.46	0.023	4	7, 7, 7	1 3 7	0.04 0.02 0.03	
Ibaraki, 1988, (TVR-2)	0.46	0.023	4	7, 7, 7	1 3 7	0.16 0.22 0.22	IETJ 1988b
Ishikawa, Japan 1998 (Kyoryoku reigyoku)	0.46	0.023	4	7, 7, 7	1 3 7	0.72 0.56 0.74	

IETJ: Institute of Environmental Toxicology, Japan
[1] Residues of RP30228 were determined in all samples, but were below the limits of quantification of 0.1 mg/kg in the Nagasaki trials and 0.05 mg/kg in the other trials.

FATE OF RESIDUES IN STORAGE AND PROCESSING

In processing

In trials in the USA tomatoes were sprayed five times with a wettable powder formulation at 7- or 14-day intervals at rates equivalent to 1.1 or 2.2 kg ai/ha. Samples of 0.9-2.2 kg of fruit were taken on the same day as the last application from each of 6 trial sites: Florida, California (2), New Jersey and Ohio (2) and analysed within 2 months of collection. Samples from one of the California trials were processed into wet and dry pomace, purée, juice and ketchup. Pilot plant scale equipment was used and the processing simulated commercial conditions. Iprodione, its isomer and metabolite were determined in all samples. The limit of quantification was 0.05 mg/kg for each compound. The results are shown in Tables 16 and 17.

Table 16. Residues of iprodione, RP-30228 and RP-32490 in whole treated tomatoes (Guyton, 1987).

Trial	Application (kg ai/ha)	PHI (days)	Residues (mg/kg)		
			Iprodione	RP-30228	RP-32490
Ohio site 1	1.1	0	0.22	<0.05	<0.05
	2.2	0	2.4	0.15	0.07
Ohio site 2	1.1	0	1.6	0.11	<0.05
	2.2	0	1.6	0.11	0.08
Florida	1.1	0	0.25	<0.05	<0.05
	2.2	0	1.9	0.07	0.08
California site 1	1.1	0	0.27	<0.05	<0.05
	2.2	0	0.46	<0.05	<0.05
California site 2	1.1	0	1.5	0.07	<0.05
	2.2	0	2.8	0.14	0.10
New Jersey	1.1	0	0.37	0.05	0.08
	2.2	0	0.76	0.06	0.06

Table 17. Residues of iprodione, RP-30228 and RP-32490 in processed tomato fractions from fruit treated in California at site 1 (Guyton 1987).

Sample	Application (kg ai/ha)	Residues (mg/kg)		
		Iprodione	RP-30228	RP-32490
Tomato	1.1 2.2	0.27 0.46	<0.05 <0.05	<0.05 <0.05
Wet pomace	1.1 2.2	1.4 1.4	0.16 0.06	<0.05 0.13
Dry pomace	1.1 2.2	5.7 9.8	0.44 0.35	0.24 0.41
Juice	1.1 2.2	0.15 0.21	0.14 0.12	<0.05 <0.05
Purée	1.1 2.2	0.09 0.33	<0.05 0.05	0.05 0.08
Ketchup	1.1 2.2	0.16 0.59	<0.05 0.10	<0.05 0.10

Mean processing factors for various fractions were calculated from residues in samples treated at 1.1 and 2.2 kg ai/ha.

Table 18. Calculated processing factors for residues of iprodione in processed tomato fractions.

Commodity	Processing factor		
	1.1 kg ai/ha	2.2 kg ai/ha	Mean
Tomato	-	-	-
Wet pomace	5.2	3.0	4.1
Dry pomace	21	21	21
Juice	0.6	0.5	0.5
Purée	0.3	0.7	0.5
Ketchup	0.6	1.3	0.9

Concentration of iprodione residues occurs in wet and dry pomace prepared from treated tomatoes.

Recoveries of iprodione, RP-30228 and RP-32490 from tomatoes and their processed fractions are shown in Table 19.

Table 19. Recoveries of iprodione, RP-30228 and RP-32490 from fortified tomatoes and their processed fractions.

Sample	Fortification (mg/kg)	Recoveries (%)		
		Iprodione	RP-30228	RP-32490
Tomato	5	99		
	4	93		
	2	102		
	1	130, 107	105	
	0.5	96	130	117
	0.2		86, 113	134, 104
Juice	0.05	127	99	92
Purée	0.2	116		
Wet pomace	5	105		
Dry pomace	10	113		

NATIONAL MAXIMUM RESIDUE LIMITS

The manufacturer reported the following national MRLs for iprodione in tomatoes.

Country	MRL (mg/kg)
Canada	0.5
Australia, Hungary, South Africa, Zambia	2
Bolivia, Brazil	4
China, Costa Rica, EU, Honduras, Israel, Japan, Kenya, New Zealand, Nicaragua, Switzerland, Tunisia	5
Peru	10

The current Codex CXL is 5 mg/kg.

APPRAISAL

Iprodione was first evaluated in 1977 and was subsequently reviewed for residues in 1980 and 1994. In the periodic review of iprodione in 1994, the Meeting recommended withdrawal of the CXL for tomato of 5 mg/kg, as there were insufficient supervised trials with corresponding GAP. The CCPR at its Twenty-eighth Session maintained the existing CXL, pending provision of new data. At its 30th Session, the CCPR retained the CXL, as the manufacturer confirmed the availability of new data from indoor trials. The evaluation was scheduled for 2001 by the CCPR at its Thirty-first Session.

The Meeting received information on analytical methods and GAP as well as supplementary data on residues, stability in storage and processing of tomatoes.

Methods of analysis

The Meeting received information on an HPLC and a GLC method for the determination of iprodione in crops and processed commodities. In the HPLC method, iprodione, its isomer N-(3,5-dichlorophenyl)-3-isopropyl-2,4-dioxoimidazolidine-1-carboxamide (RP-30228) and its metabolite 3-(3,5- dichlorophenyl_-2,4- dioxoimidazolidine-1-carboxamide (RP-34290) were measured, while the GC method can be used to determine residues of iprodione. The LOQs were 2.5 and 0.02 mg/kg for the HPLC and GC method, respectively. Both methods were validated for at least 25 crops, including tomatoes.

Stability of residues in stored analytical samples

Iprodione was stable in tomato extracts for at least 13 months when stored at –20°C. In another study, the stability of iprodione, its isomer RP-30228 and its metabolite RP-32490 in 43 commodities and processed fractions was investigated. Residues in tomatoes were stable for at least 24 months when stored at –10 °C.

Results of supervised trials

Labels from products registered in Belgium, Brazil, Canada, China, Denmark, France, Italy, Japan, The Netherlands and the UK were provided to the Meeting. Many of the labels indicated use indoors (glasshouse or under cover) and in the field. In the UK, two PHIs are indicated, one for indoor use and another for field use. The manufacturer indicated that re-registration of the compound in the European Union is pending; therefore, use in some of the more recent European trials did not correspond to existing labels.

Several of the trials provided to the Meeting had been reviewed by the 1994 JMPR. Data from field and indoor trials on <u>tomato</u> were provided.

Field trials

In China, iprodione is registered for use (in the field or under cover) at rates ranging 0.37 to 0.75 kg ai/ha, with a PHI of 7 days. One to three sprays are recommended. Concentrations of 1.6, 0.53, 0.15 and 0.09 mg/kg were found in trials corresponding to GAP, with samples taken 7 days after treatment at 0.75 kg ai/ha.

Iprodione is registered in Italy for field use only, with application at concentrations of 0.05-0.075 kg ai/hl and a PHI of 21 days. In one trial in Italy that did not correspond to GAP, iprodione was applied three times at 0.075 kg ai/hl, and samples were taken 15 and 28 days after treatment. A single value of 0.03 mg/kg was obtained 28 days after treatment.

Registered labels in France allow use of iprodione on tomatoes in the field at rates of 0.75–1 kg ai/ha and a re-treatment interval of 15–20 days; the PHI is 3 days. The field trials did not correspond to GAP, as the PHI was 19 days in one trial and the application rate was 2.2 kg ai/ha in the other.

The Meeting considered that there were inadequate data from field trials, which could not be pooled or directly compared with data from trials conducted under cover. Therefore, these data were not used in estimating a maximum residue level.

Indoor trials

Trials in glasshouses were conducted in Canada, Denmark, France, Japan, The Netherlands and the UK.

In four trials in Canada which approximated national GAP (0.05 kg ai/hl; PHI, 2 days), the concentrations of residues were 0.2, 0.3, 0.4 and 0.4 mg/kg 2–3 days after spraying at 0.05 kg ai/hl.

In one trial in Denmark, iprodione was applied once at 0.05 kg ai/hl, and samples were collected 0, 4 and 7 days after treatment. The trial approximated GAP in Denmark (0.022–0.052 kg ai/hl; PHI, 3 days). A concentration of 0.74 mg/kg was found on day 4. In a second trial, the spray volumes used were not reported, and low concentrations of iprodione were present in control samples taken on days 1 and 3. These data were not considered in estimating an MRL.

Registered labels in France allow use of iprodione on tomatoes under cover at rates of 0.75–1 kg ai/ha and a re-treatment interval of 10–15 days; the PHI is 3 days. Five trials conducted under cover in northern and southern France did not approximate national GAP. The data were evaluated by comparison with GAP in the UK (0.05 kg ai/hl; PHI, 1 day). A concentration of 1.7 mg/kg (2) was found in crops treated five times at 0.05 kg ai/hl and sampled 3 days after treatment.

The results of numerous trials conducted in Japan were provided to the Meeting. Iprodione is registered for use on tomatoes (in the field and under cover) at spray concentrations of 0.026–0.05 kg ai/hl and a PHI of 1 day; a maximum number of three sprays is recommended. Four trials which approximated national GAP showed concentrations of residues of 0.61, 1.1, 1.2 and 1.6 mg/kg 1–3 days after spraying at 0.05 kg ai/hl.

In three trials conducted in glasshouses in The Netherlands, a spray concentration of 0.075 kg ai/hl was applied five times to tomatoes. However, the trial did not correspond to registered uses in The Netherlands, which allow application at a spray concentration of 0.025 kg ai/hl and a PHI of 3 days.

In the UK, iprodione may be applied to tomatoes under cover at a spray concentration of 0.05 kg ai/hl. A maximum of six sprays may be applied, with a PHI of 1 day. In trials conducted in 1981, iprodione was present in untreated samples at concentrations 20–30% lower than in treated samples in two trials and 3% lower in a third trial. Only data from the trial with low contamination in the control sample were considered in estimating an MRL. Four trials conducted in 1977 approximated GAP in the UK, with application at 0.05 kg ai/hl and sampling 2 days after the last spray. The concentrations of residues in these trials were 0.23, 0.28, 1.4, 1.4, 2.8 and 4.2 mg/kg, in samples taken 1–2 days after treatment at 0.05 kg ai/hl.

The results of all indoor trials conducted at GAP showed concentrations, in ranked order (median underlined), of: 0.2, 0.23, 0.28, 0.3, 0.4 (2), 0.61, 0.74, <u>1.1</u>, 1.2, 1.4 (2), 1.6, 1.7 (2), 2.8 and 4.2 mg/kg. The Meeting estimated a maximum residue level of 5 mg/kg, an STMR value of 1.1 mg/kg and a highest residue value for iprodione in tomatoes of 4.2 mg/kg. The estimated maximum residue level confirms the current recommendation (5 mg/kg) for tomato.

Fate of residues during processing

A study of processing conducted in the USA which was reviewed by the 1994 JMPR was re-submitted by the manufacturer. Iprodione was applied five times at 7–14-day intervals, at a rate equivalent to 1.1 or 2.2 kg ai/ha. Samples of treated fruit were taken on the day of the final application. Residues of iprodione, its isomer and its metabolite were determined in all samples. The concentrations were 0.22–1.6 mg/kg after application at 1.1 kg ai/ha and 0.46–1.9 mg/kg after application at 2.2 kg ai/ha.

Tomatoes collected after both treatments were processed into wet and dry pomace, juice, purée and ketchup. The calculated processing factors for the concentration of iprodione were 4.2 in wet pomace and 21 in dry pomace. In the 1994 evaluation, factors of 5 and 21, respectively, were reported; however, the data had not been corrected for recovery. Processing factors of 0.5, 0.5 and 0.9 were calculated for juice, purée and ketchup, resulting in corresponding STMR-P values of 0.55, 0.55 and 0.99.

Recommendations

On the basis of the data from supervised trials, the Meeting concluded that the concentrations of residues listed below were suitable for establishing maximum residue limits and for assessing IEDI.

Definition of the residue (for compliance and for estimation of dietary intake): iprodione

Commodity		Recommended MRL (mg/kg)		STMR or STMR-P (mg/kg)	HR or HR-P (mg/kg)
CCN	Name	New	Previous		
VO 0448	Tomato	5	5	1.1	4.2
JF 0448	Tomato juice			0.55	
	Tomato purée			0.55	
	Tomato ketchup			0.99	

Dietary risk assessment

Long-term intake

The IEDIs for the five GEMS/Food regional diets, on the basis of the estimated STMR values, were 3–50% of the ADI. The Meeting concluded that long-term intake of residues of iprodione from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The present Meeting considered that the toxicological profile of iprodione includes effects of concern that might indicate a need for an acute RfD. The IESTI for iprodione was calculated as described in Section 3 for commodities for which maximum residue levels and STMR values were estimated and for which data on consumption were available. The results are shown in Annex 4 (Report 2001). The IESTI for tomatoes was 0.060 mg/kg bw for the general population and 0.244 mg/kg bw for children. As no acute RfD has been established, the risk assessment for iprodione was not finalized.

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