

CARBOSULFAN (145)

EXPLANATION

Carbosulfan was first reviewed for residues by the 1984 JMPR. Although substantial data were reviewed for a number of commodities, the Meeting recommended only a temporary limit for citrus fruits (as the sum of carbosulfan, carbofuran, 3-hydroxy-carbofuran and 3-keto-carbofuran) pending the submission of required information. Critical supporting studies and GAP information relevant to citrus were especially needed.

At the request of the CCPR the 1991 Meeting reconsidered the definition of the residue with a view to making it compatible with that of its major metabolite carbofuran (also a pesticide). It recommended that limits for carbosulfan should be for carbosulfan *per se* and that separate limits should be set for the sum of carbofuran and 3-hydroxy-carbofuran to accommodate residues resulting from the use of carbosulfan or carbofuran. Keto-carbofuran was deleted from the definition.

The 1991 JMPR reviewed additional GAP and residue data for citrus, but other data on citrus and other crops were received too late for consideration. The Meeting decided not to propose a new limit for citrus, pending review of the additional data and of additional required information. Information required for the 1993 JMPR included:

1984 JMPR

1. GAP information relevant to data from supervised trials.
2. Root crop metabolism studies.
3. Identification of residues found in ruminant tissues and milk.
4. A conventional ruminant feeding study.
5. Identification of residues in eggs from metabolism studies with ring-labelled carbosulfan.
6. Further information on the times and conditions of storage of Brassica samples.

1991 JMPR

7. Clarification of conflicting information on Spanish citrus GAP.
8. Information on sampling-to-analysis intervals in Israeli trials on oranges (FMC, 1991b).

The present Meeting reviewed data on a number of crops submitted too late for the 1991 JMPR, a manufacturer's response to requirements 2, 3, 4, 5, 7 and 8 above (an index of relevant reports with a summary/overview and/or selected pages of each), and comments from the German government explaining its view that the current 2 mg/kg TMRLs for carbosulfan and carbofuran in citrus fruits were not justified.

USE PATTERN

The information provided is summarized in Table 1. Because the use patterns available to the 1984 JMPR are out of date and because they were in any case incomplete, Table 1 includes only the new information provided to the present Meeting and that submitted too late for review in 1991. If conflicting GAP information has been supplied, it has been assumed that the most recently submitted is current and only that is listed.

Table 1. Summary of registered or authorized uses of carbosulfan on selected commodities

Crop/ Country	Formu- lation	Application		PHI (Days)	Comments
		kg ai/ha (g ai/hl)	No. ¹		
Citrus Brazil	250EC	(10-12.5)		7	foliar, 8l/tree
Cyprus	250EC	(12.5-50)	>1	14	
Israel	250EC	(12.5-25) 1.25		60	high volume low volume
Spain	250EC ² 25%LE ²	(25-37.5) (50-75)	repeat	28	
Tunisia	250EC	(50)		20	
Greece	250EC	(25-50)		60	
Thailand	250EC	(37.5-62.5)		15	
Cotton seed Spain	250EC 25%LE	(37.5-50) (50-75)	-	28	
Hops Spain	25%LE	(50-75)	-	28	
Maize Spain	GR	0.6 ³	-	60	application to soil
Melons Spain	25%LE	(50-75)	-	21	
Pome fruit Spain	250EC 25%LE	(37.5-50) (50-75)	-	28	
Potatoes Spain	250EC 25%LE	0.38-0.5 ³ (50-75)	- -	28	
Sorghum Spain	GR	0.6 ³	-	60	application to soil
Stone fruit Spain	250EC 25%LE	(50)* (50-75)	-	28	* peaches
Sugar beet Spain	GR	0.6 ³	-	60	
Watermelon Spain	25%LE	(50-75)	-	21	

¹ In most cases the number of applications was not given.

² For Spanish GAP, LE refers to uses of an EC formulation reported by the Spanish government and usually confirmed by one of two labels. EC refers to uses reported by the manufacturer and confirmed by the other label. All

Spanish information refers to registered uses to be considered by the EU. There is at least the appearance of a conflict where both LE and EC are recorded, as noted by the 1991 JMPR. No explanation was provided to the present Meeting.

³ Corrects an obvious error in the 1991 JMPR evaluation (Table 1, p.215).

RESIDUES RESULTING FROM SUPERVISED TRIALS

In plants

The 1984 JMPR required further information on storage conditions and times for Brassica samples. Additional field trials with shorter PHIs might be needed, depending on the answer. No further information was provided.

Extensive data on a variety of crops were examined by the Meeting. Unfortunately, most of it was merely summary information, much of it had been previously reviewed and some submitted several times. Summaries without accompanying detailed reports were not useful to the Meeting, and generally were not evaluated. Those data which included full field reports or were otherwise sufficiently detailed were considered.

Citrus. A 2 mg/kg temporary MRL the sum of carbosulfan, carbofuran, 3-hydroxy-carbofuran and 3-keto-carbofuran in citrus was recommended by the 1984 JMPR pending the submission of required information. The 1991 JMPR reviewed additional data and replaced the recommendation by separate limits for carbosulfan alone and for the sum of carbofuran and 3-hydroxycarbofuran, both at the previous 2 mg/kg level, pending the evaluation of required information and of data submitted too late for review by the 1991 JMPR. Clarification of apparently conflicting Spanish GAP was requested (see Table 1 notes above). The German government provided comments to the Meeting on its view that a 2 mg/kg limit is not justified for carbosulfan or carbofuran.

As noted in Table 1 GAP information is available for Brazil, Cyprus, Israel, Spain, Tunisia, Greece and Thailand. The Meeting considered data reviewed in 1984 (from the USA and Italy) and in 1991 (from Brazil and Israel), together with data submitted too late for review in 1991 (a Spanish submission of Italian data (Report FFC40A/82583) reviewed by the 1984 JMPR) and Spanish data on peel and pulp residues (Report FCC 408/82584), apparently not previously reviewed. Brazilian and Israeli data reviewed by the 1991 JMPR were re-submitted, but the re-submitted Israeli results included residue levels in the whole fruit which were not in the 1991 submission. The 1991 JMPR assumed the peel to pulp ratio in the Israeli results in order to estimate whole fruit residue levels, but could not do so for the Brazilian data since only pulp residues were provided. A brief summary of the available data with comments is provided below.

1984 JMPR (see 1984 Monograph, Table 3c). Most data were from US trials, although the use is not GAP in the United States. The results could not be linked to application rates reported for other countries, since the rates in the trials were 0.94 to 4.6 kg ai/ha whereas the reported GAP was in terms of g ai/hl. The Israeli GAP was in terms of kg ai/ha (1.25), but the Israeli PHI is 60 days compared to the maximum of 28 days in the US trials. The GAP PHI is 7 days for Brazil and 28 days for Spain. Maximum residues in the US trials at 7 and 28 days were as shown below.

	Residues, mg/kg			
	Carbosulfan	Carbofuran (A)	3-OH Carbofuran (B)	$\bar{A}+B$
Oranges:				
<u>7 days</u>	0.01	0.05	0.03	
0.08	0.03	0.3	0.4	0.7
	0.02	0.2	0.4	0.6
	0.06	0.6	0.6	1.2
	0.05	0.2	0.7	0.9
	0.01	0.05	0.02	
0.07	0.9	0.9	0.4	1.3
	0.4	0.9	0.2	1.1
<u>28 days</u>	ND	0.03	0.01	
0.04	ND	0.28	0.41	
0.69	0.01	0.17	0.34	
0.51	0.02	0.26	0.34	0.6
	<0.01	0.01	0.02	
0.03	0.11	0.31	0.22	
0.53	0.1	0.51	0.09	0.6
Grapefruit:				
<u>7 days</u>	0.01	0.2	0.2	0.4
	0.09	0.7	0.5	1.3
<u>28 days</u>	ND	0.17	0.23	0.4
	0.02	0.62	0.46	1.1
	ND	0.19	0.42	0.6

Residues in oranges in Italian trials which conformed to reported Spanish GAP of 75 g ai/ha and a 28-day PHI were as shown below.

Day	mg/kg			
28	0.5	1.5	0.2	1.7
	0.3	0.8	0.08	0.9
42	0.3	1.1	0.06	1.2
	0.3	1	0.05	1.1
56	0.7	0.08	--	
0.08	0.3	0.7	0.05	0.8

Spanish peel and pulp residues (FMC 1983). Field reports were not available to determine the formulation used, the PHIs or other important information. Application rates were referred to as 0.15 or 0.2%, but the meaning of this could not be determined nor related to Spanish GAP. Residues of carbosulfan, carbofuran and 3-hydroxy-carbofuran were reported as <0.05 mg/kg in pulp, although one sample gave an unquantifiable positive response for the hydroxy metabolite. Peel residues were reported as <0.05 mg/kg carbosulfan and 0.6/0.2, 0.6/0.2, and 0.8/0.3 mg/kg carbofuran/3-hydroxy-carbofuran. If it could be assumed that the trials represented GAP and that the peel to pulp ratio was 30:70, a residue in the whole fruit of approximately 0.3 mg/kg could be estimated for the sum of carbofuran and 3-hydroxy-carbofuran. This estimate is not in good agreement with estimates based on the Italian results under the conditions of Spanish GAP shown above.

Israeli data. Although the Israeli data were summarized by the 1991 JMPR, the levels in the whole fruit were only estimates based on an assumed peel

to pulp ratio. The new whole fruit data (FMC, 1984) for single applications are summarized below to show the sum of carbofuran and 3-OH carbofuran.

Rate	PHI, days	mg/kg			
		carbosulfan	carbofuran (A)	3-OH-carbofuran (B)	A+B
12.5 g ai/hl	90	<0.05	<0.05	<0.05	0.1
		<0.05	<0.05	0.07	0.12
		<0.05	0.06	0.08	0.14
		<0.05	0.21	0.18	0.39
		<0.05	0.07	0.13	0.2
		<0.05	0.12	0.08	0.2
1.25 k gai/ha	60	<0.05	0.11	0.08	0.19
		<0.05	0.06	<0.05	0.11
		<0.05	0.05	0.13	0.18
	120	<0.05	0.05	0.13	0.18
		<0.05	<0.05	0.08	0.13
		<0.05	0.07	0.12	0.19
Controls		<0.05	<0.05	<0.05	

All of these results are from treatments within Israeli GAP, although only from a single application, and 12.5 g ai/hl is only half the maximum concentration permitted Israel. The difference between a 60-day and a 120-day PHI appears to have little effect on the levels. The maximum residues within Israeli GAP (half the maximum GAP concentration) were therefore <0.05 mg/kg carbosulfan and 0.4 mg/kg carbofuran + 3-OH carbofuran.

Brazilian data. As noted above the 1984 submission was re-submitted to the Meeting, but with more detail including the whole fruit values. No residues (<0.05 mg/kg) were reported for carbosulfan, carbofuran or 3-hydroxy-carbofuran 7 to 14 days after single applications of a 250 EC formulation at 150, 200 or 400 g ai/ha. However, these application rates could not be compared to the g ai/hl concentrations reported as Brazilian GAP.

Hops. Extensive data from Germany were available to the 1984 JMPR on green, dry and spent hops and beer, based on supervised trials in Germany with 6 applications of an EC formulation at 9.75 kg ai/ha and sampling at 0, 7, 14, 21 and 28 days after the last application. No MRL was recommended because no GAP information was provided. Information on Spanish GAP (50-75 g ai/hl, 28-day PHI) and what appear to be the data reviewed by the 1984 JMPR were provided to the Meeting (Spain, 1993). The 14-, 21- and 28-day results are shown in more detail below in Table 2, which also gives the g ai/hl concentrations which can be compared to Spanish GAP. All 28-day residues reflect Spanish GAP, although 37.5 g ai/hl is only half the reported maximum allowable concentration. Maximum residues in any hops after 28 days were 2 mg/kg carbosulfan, 0.2 mg/kg carbofuran and 7.8 mg/kg 3-hydroxy-carbofuran, and in dry hops 2.1 mg/kg carbosulfan, 0.2 mg/kg carbofuran and 6.5 mg/kg 3-hydroxy-carbofuran. The highest combined residues of carbofuran and 3-hydroxy-carbofuran were 8 mg/kg in green hops and 6.7 mg/kg in dry hops. Considerable variation was observed in the results. As also indicated in the 1984 monograph, the maximum residues in beer and spent hops 21 days after the same treatments to hops were <0.05 mg/kg.

Table 2. Residues of carbosulfan and metabolites in hops from supervised trials in Germany, all with 6 applications at 9.75 kg ai/ha and 37.5 kg ai/hl. Spanish GAP is 50-75 g ai/hl with a 28-day PHI.

Year	Green or Dry	PHI, Days	Residues (mg/kg)	Ref.
Location /Variety				

carbosulfan

		carbosulfan	carbofuran	3-OH-carbofuran		
1981						
Pischlsdorf /Hersbrucker	green	14	1.4	0.3	22	73/21
		21	0.6	0.2	8	
		28	0.4	0.1	6	
	dry	14	2	0.8	17	
		21	1.1	0.3	7.4	
		28	0.6	0.2	5.3	
Pischlsdorf /Hallertauer	green	14	1.1	0.3	9.8	73/21
		21	2.2	0.4	9.5	
		28	0.3	0.07	4.8	
	dry	14	0.9	0.3	12	
		21	3.4	0.9	7	
		28	0.4	0.09	5.1	
Pischlsdorf /N. Brewer	green	14	1.4	0.9	18	73/21
		21	1.9	0.2	7.6	
		28	2	0.2	7.8	
	dry	14	1.7	1.6	19	
		21	1.4	0.3	11	
		28	2.1	0.2	6.5	
1982						
Durren Mungenau /Spalter	green	14	0	0	0.08	73/32
		21	0	0	0.2	
		28	0	0	0.2	
	dry	14	0.09	0	0.4	
		21	0.4	0.1	1.5	
		28	0.07	0	0.3	
Pischlsdorf /N. Brewer	green	14	0.2	0.3	0.8	73/32
		21	0.08	0	0.6	
		28	0	0	0.7	
	dry	14	0.3	0.09	0.8	
		21	0.2	0.09	0.7	
		28	0.1	0.06	1.4	
Pischlsdorf /Hallertauer	green	14	0.3	0.07	1.9	73/32
		21	0	0.1	1	
		28	0.6	0.06	0.8	
	dry	14	0.4	0.1	8.1	
		21	0.7	0.5	2.8	
		28	0.2	0.06	1.2	
Obermecken-Beuren /Tettmanger	green	14	0.1	0	1.2	73/32
		21	0	0	1.5	
		28	0	0	1.1	
	dry	14	0.3	0.07	2.5	
		21	0.2	0.2	1.2	
		28	0.08	0	0.3	
Pilschsdorf /Hersbrucker Spät	green	14	0.2	0.06	2.1	73/32
		21	0.1	0	2.8	
		28	0.2	0.06	2.5	
	dry	14	0.6	0.1	33	
		21	0.04	0.3	3	
		28	0.2	0	0.06	
Controls	green	21	<0.05-0.04	<0.05	<0.05	
	dry	21	<0.05	<0.05-0.1	<0.05-0.08	

Melons. Residue trials with carbosulfan on melons have not previously been reviewed. The Spanish government provided Spanish GAP (50-75 g ai/hl, 21-day PHI) and data from 1989 indoor supervised trials in Spain (Spain, 1993, Table 3). Maximum residues of carbosulfan in whole fruit under Spanish GAP conditions were 0.01 mg/kg and no residues (<0.001 mg/kg) of carbofuran were detected. Samples were not analyzed for 3-hydroxy-carbofuran.

Table 3. Residues of carbosulfan and carbofuran in melons resulting from 1989 supervised trials in Spain (Spain, 1991). All single applications of EC.

Spray concn. (g ai/hl)	Portion of crop	Interval, days	Residue, mg/kg
---------------------------	--------------------	-------------------	----------------

			Carbosulfan	Carbofuran
(38)	whole fruit	0	0.2, 0.2	-
	peel	0	0.3, 0.4	-
	pulp	0	-	-
	whole fruit	2	0.1, 0.2	-
	peel	2	0.2, 0.4	NQ, NQ
	pulp	2	-	-
	whole fruit	14	NQ ¹	-
	peel	14	NQ, 0.002	-
	pulp	14	-	-
(74)	whole fruit	21	-	-
	peel	21	-	-
	pulp	21	-	-
	whole fruit	0	0.3, 0.2	-
	peel	0	-	NQ, NQ
	pulp	0	-	-
	whole fruit	2	0.2, 0.3	-, 0.083
	peel	2	0.4, 0.7	-, 0.2
	pulp	2	-	-
	whole fruit	14	0.03, 0.04	-
	peel	14	0.05, 0.09	-
	pulp	14	-	-
	whole fruit	21	0.01, 0.01	-
	peel	21	0.03, 0.02	-
	pulp	21	NQ, NQ	-

¹ Not quantifiable. A dash is presumed to mean that no residue was detected at the reported 0.001 mg/kg limit of detection for carbosulfan or carbofuran.

Pome fruit. The 1984 JMPR reviewed apple studies from the United States, the United Kingdom and Italy. No limits were recommended because (1) the use is not authorized in the USA, (2) critical supporting information was not provided for many of the studies and (3) the information on GAP was not relevant to the trials. Desirable information on storage conditions and intervals for pome fruit was not provided.

The Meeting received information on Spanish GAP, and summarized reports of supervised trials on apples in Italy, the UK and the USA (Spain, 1993). Most of the trials reports had been reviewed by the 1984 Meeting, as had a summary report of US pear trials which was also supplied.

Of the Italian data only the trials reviewed in 1984, for which there was no critical supporting information, include the Spanish application rates and 28-day PHI (maximum residues reflecting GAP of 1.2 mg/kg carbosulfan, 0.9 mg/kg carbofuran, 0.4 mg/kg 3-hydroxy-carbofuran). Additional summarized results from 1983 Italian trials provided to the present Meeting were from applications at Spanish GAP rates, but the PHI was 100 days. After 28 days in the UK trials reviewed in 1984 maximum residues were 1.1 mg/kg carbosulfan, 1.1 mg/kg carbofuran and 0.8 mg/kg 3-hydroxy-carbofuran, but the kg ai/ha application rates could not be compared with the g ai/hl concentrations specified in the Spanish GAP. In the additional UK trials reported to the Meeting maximum residues after 28 days were 0.6 mg/kg carbosulfan, 0.25 mg/kg carbofuran and 0.17 mg/kg 3-hydroxy-carbofuran, but again only summaries were provided and the application rates could not be compared with Spanish GAP.

Potatoes. Data from French, Italian and United Kingdom trials were reviewed by the 1984 JMPR. Critical supporting information was sketchy and metabolism studies on a root crop after both foliar and soil applications were required. The Meeting received summary information on metabolism (see "Fate of residues") and a summary of the French and United Kingdom supervised trials data which were reviewed in 1984 (Spain, 1993). Of 13 trials, the PHIs in two were shorter than the Spanish 28-day PHI, two were close to it and the rest were 66 to 207 days.

Stone fruit. Carbosulfan trials on stone fruit have not previously been reviewed by the JMPR. The Meeting was provided with Italian data on nectarines, French data on peaches and summary Spanish data on peaches (Spain, 1993, Reports E88-312 and E88-314). Only the Italian and French data included adequate field reports giving critical information such as storage interval and conditions. However, it could not be determined from

the French data whether the residues (maximum 0.2 mg/kg after 37 days) were of carbosulfan alone or carbosulfan and metabolites (probably the latter). The Spanish Report E88-312 showed maximum total residues of carbosulfan and (unidentified) metabolites of 0.44 mg/kg from Spanish GAP rates and at the 28-day Spanish PHI. Maximum residues of 1 mg/kg after 28 days were reported in E88-314, but whether these were total residues or only carbosulfan was not indicated. Only the Italian results were marginally adequately reported, and these are summarized in Table 4.

Table 4. Residues of carbosulfan, carbofuran and 3-hydroxycarbofuran in nectarines resulting from supervised trials in Italy (1983) with an EC formulation (Spain, 1991).

Application		Interval (days)	Carbosulfan	Carbofuran (A)	3-OH Carbofuran (B)	A+B	Report
Rate kg ai/ha (g ai/hl)	No.						
0.7 (50)	1	83	<0.05	<0.05	0.05	<0.1	73/39
	1	83	<0.05	<0.05	0.07	<0.12	
0.53 (30)							
	1	83	<0.05	<0.05	<0.05	<0.1	
Controls			<0.05	<0.05	<0.05	<0.1	
			<0.05	<0.05	<0.05	<0.1	

Sugar beet. Extensive data from supervised trials in France and the United Kingdom were reviewed by the 1984 JMPR, but MRLs were not recommended because information on relevant GAP and critical supporting studies were lacking and a root crop metabolism study was required. The Meeting received summary Italian data indicating residues (whether of carbosulfan or carbosulfan plus metabolites was not indicated) of <0.05 mg/kg 79 to 120 days after treatments at 0.6 to 1 kg ai/ha (Spain, 1993). Spanish GAP requires 0.6 kg ai/ha soil applications and a PHI of 60 days. Most results from in-furrow treatments reviewed by the 1984 JMPR were after 104 days or longer. Maximum residues were 0.3 mg/kg (most were <0.06 mg/kg at these extended PHIs) from Spanish GAP rates and 0.4 mg/kg from double rates. In the trials reviewed in 1984 residues of both carbofuran and 3-hydroxycarbofuran in the roots were <0.05 mg/kg.

In animals

The 1984 JMPR required, or listed as desirable, information on residue levels in various animal tissues and milk. The Meeting received an index of relevant reports not previously provided, together with a manufacturer's summary or overview and selected pages or tables from them.

A conventional ruminant feeding study was specifically required. Summaries and selected tables were provided on carbosulfan and cholinesterase-inhibiting metabolites in cow tissues (Tilka, 1982) and milk (Leppert, 1982); carbosulfan phenolic residues in cow milk and tissues (Witkonton, 1982a); residues of dibutylamine in cow milk and tissues (Witkonton, 1982b) and methods of analysis for dibutylamine in milk and tissues (Witkonton, 1982c). These are all referenced under FMC, 1993, Volume 2.

Desirable information on residues of 3-hydroxy-N-hydroxy-carbofuran and dibutylamine in poultry tissues and eggs was not provided.

FATE OF RESIDUES

The 1984 Meeting required or desired information on the fate of residues in specific plants and animals. The requests were reiterated in 1991. The index of reports with the summary and selected pages or tables mentioned above included references to the fate in plants and animals.

In animals

The 1984 JMPR required the identification of residues found in ruminant tissues and milk and in eggs resulting from feeding ring-labelled carbosulfan. Summaries and selected extracts of relevant reports were provided but were not reviewed in the absence of the complete reports.

In plants

The 1984 JMPR required a metabolism study on a root crop, after uptake from both foliar and soil treatments. A summary and selected information from a carbosulfan metabolism study on sugar beet (Robinson, 1982) were provided but were not reviewed in the absence of the complete reports.

A citrus metabolism study, recorded as desirable in 1984, was not provided.

In storage and processing

Desirable studies were not provided.

Stability of pesticide residues in stored analytical samples

The additional storage stability data listed as desirable were not provided.

NATIONAL MAXIMUM RESIDUE LIMITS

The Spanish MRLs listed below were reported to the Meeting.

<u>Crop</u>	<u>MRL (mg/kg)</u>
Citrus	2
Cotton seed	0.1
Hops	2
Maize	0.1
Maize fodder	2
Melons	0.1
Pome fruit	1
Potatoes	0.2
Sorghum	0.1
Sorghum fodder	2
Sugar beet	0.1
Water melon	0.1

APPRAISAL

Carbosulfan was first reviewed for residues by the 1984 JMPR. Although extensive data were reviewed for a number of commodities, the Meeting recommended only a temporary limit for citrus fruits pending the submission of required and desirable information, in particular critical supporting studies and GAP information.

The 1991 Meeting recommended that limits for carbosulfan should be for carbosulfan *per se* and that separate limits should be set for the sum of carbofuran and 3-hydroxy-carbofuran to accommodate residues resulting from the use of carbosulfan or carbofuran. Keto-carbofuran was deleted from the definition. The 1991 JMPR decided not to propose a new limit for citrus fruits, pending the review of additional data received too late for consideration. Additional requirements were added to those listed by the 1984 Meeting.

The Meeting received a discussion paper, summary comments and selected pages and summary tables from a number of reports on the identification and fate of residues in animal products in response to the 1984 JMPR requirements. The Meeting did not review these documents in the absence of the complete reports from which the summaries came. The required information on brassica vegetables was not provided. GAP information and

trials data on a number of commodities were also provided, much but not all of which had been reviewed by the 1984 JMPR.

Citrus. The 1984 JMPR recommended a 2 mg/kg temporary limit for citrus fruits, pending the submission of required information. The definition of the residue was revised to separate the limits for carbosulfan from those of its metabolites by the 1991 JMPR, resulting in separate limits at 2 mg/kg for carbosulfan *per se* and 2 mg/kg for the sum of carbofuran and 3-hydroxy-carbofuran. No change in the carbosulfan numerical level was proposed, pending the review of additional information. Clarification of apparent discrepancies in Spanish GAP was also requested but the GAP has not been fully clarified. One Codex delegation provided written comments explaining its view that a 2 mg/kg limit was not justified for carbosulfan or carbofuran, citing the general lack of data reflecting GAP and the low residues of carbosulfan in particular. In order to address the issues the Meeting considered newly submitted information on GAP and new and re-submitted residue trials data, and took into account data reviewed by the 1984 JMPR as well as the Codex comments.

The most extensive data (1984 JMPR) are those from trials in the USA. However, the use is not yet GAP in the United States and the Meeting could not with confidence relate the data to the GAP of other countries. Further, new data on peel and pulp residues in Spanish trials did not include important information, precluding a determination of whether the data reflected Spanish GAP (which is itself still in question). If future submissions show that all of the Spanish data reflect GAP, maximum whole fruit residues of <0.05 mg/kg carbosulfan and 0.3 mg/kg carbofuran plus 3-hydroxy-carbofuran would be indicated, assuming a peel to pulp ratio of 30:70. Re-submitted Brazilian data (<0.05 mg/kg carbosulfan, carbofuran, or 3-hydroxy-carbofuran) could not be related to the Brazilian GAP information provided.

The only data that could be related to GAP with some confidence were from Italian trials reviewed in 1984 which could be compared to Spanish GAP and Israeli data which could be compared to Israeli GAP. The Italian trials according to Spanish GAP resulted in maximum residues of 0.7 mg/kg carbosulfan and 1.7 mg/kg for the sum of carbofuran and 3-hydroxy-carbofuran. Maximum residues reflecting Israeli GAP were 0.05 mg/kg carbosulfan and 0.4 mg/kg for the sum of carbofuran and 3-hydroxy-carbofuran, although requested information on the interval from sampling to analysis to give greater confidence in the results was not provided.

Because the requested clarification of GAP and the sampling-to-analysis intervals still have not been supplied, because only a relatively small data base is available which can be compared to GAP, and because of a large discrepancy between the two sets of results which were comparable to GAP, the Meeting concluded that insufficient information had been provided to support a citrus limit for carbosulfan or carbofuran. The Meeting was informed that additional supervised citrus trials would be conducted in Spain, Brazil and Mexico.

Hops. German data for green and dry hops, spent hops and beer that were reviewed by the 1984 JMPR were re-submitted to the Meeting, together with GAP for Spain and Germany. No GAP information was provided to the 1984 Meeting. The data indicate that dry hop residues are unlikely to exceed 3 mg/kg for carbosulfan and 7 mg/kg for combined residues of carbofuran and 3-hydroxy-carbofuran after the 28-day Spanish PHI from the 37.5 g ai/hl used in the supervised trials. No data were available for the maximum 75 g ai/hl reported to be Spanish GAP. Maximum residues 21 days (German GAP PHI) after 6 applications at 37.5 ai/hl resulted in carbosulfan residues of 0.04-3.4 mg/g in dry hops and 0-2.2 mg/kg in green hops. Corresponding residues of carbofuran plus 3-hydroxy-carbofuran were 1.4-11.3 mg/kg in dry hops and 1-9.9 mg/kg in green hops. Because 6 applications were used, compared to GAP of one application, the Meeting was unable to estimate a limit for hops.

Melons. Data (indoor) were available from only two trials in one country (two results at the GAP PHI) with only one trial at the maximum application rate. No analyses were conducted for 3-hydroxy-carbofuran and critical

supporting information on sample storage conditions and the interval from sampling to analysis were lacking. It was therefore concluded that the data were insufficient to support an MRL for melons. The Meeting was informed that supervised trials on melons are being conducted in Spain.

Pome fruit. The 1984 JMPR reviewed data on apples and pears from three countries, but did not estimate a limit for pome fruit because the data base could not be related to available GAP and critical supporting information (e.g. storage conditions and intervals) was not provided. Summaries of some of the data reviewed by the 1984 JMPR were provided to the present Meeting as well as additional summary data not previously reviewed. Because only summary information was provided, because most of the old and new data could not be compared to the available Spanish GAP, and because the desirable critical supporting information still had not been provided, the Meeting concluded that the data were insufficient to support limits for pome fruit.

Potatoes. Fairly extensive data from Italy, France and the UK were reviewed by the 1984 JMPR. Summaries of these data were provided to the Meeting, but 11 of the 13 trials did not reflect the (Spanish) GAP PHI of 28 days. A discussion document and selected pages from a sugar beet metabolism study were provided in response to the 1984 JMPR requirement for a root metabolism study from both foliar and soil treatments. The Meeting concluded that data reflecting GAP were not adequate to recommend an MRL and that submission of the complete metabolism study would be needed before that requirement could be regarded as satisfied.

Stone fruit. Summary data from a substantial number of trials were available, but were not adequately reported and many of the trials did not reflect GAP PHIs for use in recommending MRLs. The trials most adequately reported were based on an 83-day PHI, whereas GAP is 28 days. The Meeting concluded that data reflecting GAP were inadequate and inadequately reported to recommend MRLs.

Sugar beet. Extensive data were reviewed by the 1984 JMPR but critical supporting information was sketchy or in some cases missing, data were not relevant to available GAP information and a root metabolism study was required. Information provided to the Meeting indicated that Spanish GAP was similar to that used in the French and UK trials reviewed in 1984, except that the Spanish PHI is 60 days whereas most of the trials results were at ≥ 104 days. Summary discussion information and selected pages from a sugar beet root metabolism study provided to the Meeting did not meet a 1984 JMPR root metabolism requirement. The full reports need to be submitted. Summary Italian data from trials at application rates greater than the Spanish GAP rates and at longer intervals than the minimum Spanish PHI were also provided. The Meeting concluded that data reflecting GAP were still inadequate to support an MRL for sugar beets. When the complete metabolism study and the detailed Italian data are provided a Meeting can reconsider the position.

Metabolism. The Meeting was informed that metabolism studies on oranges, rats, and goats and an animal transfer study on cows are being conducted.

RECOMMENDATIONS

On the basis of information provided to the Meeting, and in view of the lack of complete critical supporting studies requested since 1984 and of adequate data reflecting GAP, the Meeting recommended that the temporary limit for carbosulfan in citrus fruits should be withdrawn.

Definition of the residue: carbosulfan.

CCN	Crop	Maximum Residue Limit (mg/kg)	
		New	Previous

FC 00001	Citrus	Withdrawn	2 T
----------	--------	-----------	-----

REFERENCES

FMC. 1983. Determination of Residual Concentrations of FMC 35001 and its Metabolites, Carbofuran and 3-Hydroxy Carbofuran, in Oranges From Spain (Pulp and Peel). Unpublished FMC report FCC40B/82584, submitted by the Spanish government.

FMC. 1984. The Determination of Concentrations of FMC 35001 and its Metabolites, Carbofuran and 3-Hydroxycarbofuran in Oranges From Israel. Project No. FCC 63. 1984. Submitted to the 1991 and 1993 JMPRs. Unpublished report.

FMC. 1993. Volumes 1 and 2 submitted to the 1993 JMPR by FMC Corporation.

Volume 1 - Carbosulfan/Citrus Residue Data, Supplemental Information, JMPR-1993. Tab 10 - 1985 Brazilian supervised trials data. Tab 11 - Determination of Concentrations of FMC 35001 and its Metabolites, Carbofuran and 3-Hydroxy Carbofuran in Oranges From Israel. Unpublished FMC report FCC 63, 1984.

Volume 2 -JMPR Response Carbosulfan. Includes FMC discussion and comments and selected tables and text from various reports in response to 1984 and 1991 requirements and desirables:

Cold studies - Cow tissues (Tilka, 1982 Report RAN-007); in milk (Leppert, 1982, Report RAN-0058); carbosulfan phenolic residues in cow milk and tissue (Witkonton, 1982a, Report P-0496); residues of dibutylamine residue in cow milk and tissues (Witkonton, 1982b, Report P-0516) and methods of analysis for dibutylamine in milk and tissues (Witkonton, 1982c, Report P-0501).

Label studies: ruminant tissues and milk (Wu, 1982a, Report M-4854) and carbosulfan (Wu, 1982b, Report M4875); eggs (Markle,1982, Report RAN-0050).

Metabolism Study on Sugar Beets (Robinson, 1982, Report P-0498).

Spain. 1993. Spanish GAP and Residues Studies in Apples (8), Oranges (2), Nectarines (4), Peaches (12), Melon (2), Potatoes (13), Sugar Beet (3), Hops (26).

Report Numbers

apple	73/39; 73/25; 73/6; 73/26
oranges	FCC40A/82583;
peaches	E88-312, 314
melons	Facultad de Ciencias, Universidad de Murcia
potatoes	FCC24/28/42 821050(G); FCC 26; FCC 24/1;
Beer/hops	73/40; 73/36; 73/32B; 73/32A; 73/32; 73/21; 73/22; 73/31;

73/12

73/12

30 June 1993 submission of the Spanish government. Most of the information was also submitted, but not reviewed, in 1991.