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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: Carbofuran. Storage Stability in Various Crops, Magnitude of the Residue in

Non-bell Peppers and Sorghum, and Magnitude of the Residue in/on Processed

Commodities of Sorghum and Sugar Beets.

DP Barcodes: D221465, D221469, D221473, D221476, D223210; CBRS Nos. 16638, 16694, 16695, 16914, and 17452; MRID Nos.: 438425-01, 438428-01,

438519-01, 438522-01, and 439071-01; Case No. 0101.

FROM: David J. Miller, HSO, US Public Health Service

Chemistry Pilot Review Team

Chemistry Branch II--Reregistration Support

Health Effects Division (7509C)

THRU: R.B. Perfetti, Ph.D., Acting Branch Chief

Chemistry Branch II--Reregistration Support

Health Effects Division (7509C)

TO: Paula Deschamp, Section Head

Reregistration Branch

Risk Characterization and Analysis Branch (7509C)

Attached is a review of storage stability, field trial, and processing studies for carbofuran. The studies were submitted by FMC Corporation. This information was reviewed by Dynamac Corporation under the supervision of CBRS/HED. The data assessment has undergone secondary review in the Branch and has been revised to reflect Agency policies.

CBRS makes the following conclusions with respect to the submitted studies:

- The submitted data are inadequate to fulfill reregistration requirements for sorghum because field trials were not conducted at the maximum registered rate. The registrant must either modify existing product labels or submit additional field trial data reflecting existing label application rates as detailed in the attached review.
- The submitted data are inadequate to fulfill reregistration data requirements for non-bell peppers because the field trials were not conducted at the maximum registered use pattern of carbofuran and geographic representation was inadequate. The registrant must either modify the existing product labels to reflect the use pattern used in the submitted field trials, or submit additional field trial data reflecting the maximum registered use pattern as detailed in the attached review.
- Although the submitted <u>sorghum processing data</u> indicate that individual residues of carbofuran metabolites of concern may concentrate in bran, no sorghum processed commodities are considered to be significant food/feed items (Table 1, OPPTS 860.1000) and therefore no tolerances for sorghum processed commodities are required.
- The submitted <u>sugar beet processing study</u> is adequate to satisfy reregistration data requirements. The study indicates that the combined residues of carbofuran and its metabolites do not concentrate in dried pulp and refined sugar processed from sugar beet root samples. Although the data indicate that combined residues may concentrate in molasses, the present 0.1 ppm sugar beet root tolerance is expected to adequately cover residues of carbofuran in this commodity.

If you need additional information, please advise.

cc: RF, SF, List A Rereg. File, Circ., DJM. RDI: Pilot Team: 1/23/97;RPerfetti:1/28/97.

CARBOFURAN

Shaughnessy No. 090601; Case No. 0101

(CBRS No. 16638; DP Barcode D221473)

(CBRS No. 16694; DP Barcode D221469)

(CBRS No. 16695; DP Barcode D221465)

(CBRS No. 16914; DP Barcode D223210) (CBRS No. 17452; DP Barcode D221476)

REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

BACKGROUND

In response to the Carbofuran Reregistration Standard Update, dated 1/9/91, and the EPA Data Call-In (DCI) Notice, dated 3/9/92, FMC Corporation submitted data depicting the magnitude of carbofuran residues in/on non-bell peppers (1995; MRID 43852201), sorghum raw agricultural commodities (1994; MRID 43842801), sorghum processed commodities (1994; MRID 43842501), and sugar beet processed commodities (1995; MRID 43851901). In addition, storage stability data for the acid hydrolysates of various crops (1992; MRID 43907101) have been submitted. Data from these submissions are evaluated herein for adequacy in fulfilling residue chemistry data requirements for the reregistration of carbofuran. The Conclusions and Recommendations stated below pertain only to the above submissions. All other residue chemistry data requirements stated in the Carbofuran Update and the Carbofuran DCI Notice are not addressed herein. Since the issuance of the Carbofuran Update, most uses of granular carbofuran have been discontinued (56 FR 64621, 12/11/91) because of adverse effects to avian species. The use of the flowable concentrate (FIC) formulation on peppers, sorghum, and sugar beets is permitted under FIFRA Section 24(c).

The qualitative nature of carbofuran residues in plants is not adequately understood; additional data regarding the components in an extract of soybean hay are required. The qualitative nature of the residue of carbofuran in animals is adequately understood based on acceptable studies conducted on ruminants and poultry. CBRS tentatively concluded, pending receipt of the outstanding plant metabolism data, that the residues of concern in plant and animal commodities are the residues which are currently regulated, i.e., parent carbofuran and its

metabolites 3-hydroxy-carbofuran, 7-phenol-carbofuran, 3-hydroxy-7-phenol carbofuran, and 3-keto-7-phenol-carbofuran. The HED Metabolism Committee has concluded that field trials must include analysis for the regulated metabolites as well as the metabolite 3-ketocarbofuran.

Tolerances are established [40 CFR §180.254 (a), (b), and (c), §185.600, and §186.600] for the combined residues of carbofuran (2,3-dihydro-2,2-dimethyl-7-benzofuranyl-*N*-methylcarbamate), its carbamate metabolite 3-hydroxy carbofuran (2,3-dihydro-2,2-dimethyl-3-hydroxy-7-benzofuranyl-*N*-methylcarbamate), and its phenolic metabolites 7-phenol carbofuran (2,3-dihydro-2,2-dimethyl-7-benzofuranol), 3-keto-7-phenol carbofuran (2,3-dihydro-2,2-dimethyl-3-oxo-7-benzofuranol), and 3-hydroxy-7-phenol carbofuran (2,3-dihydro-2,2-dimethyl-3,7-benzofurandiol), in or on various raw agricultural commodities, food, and feed items. All tolerances, except bananas, sugar beets, coffee beans, rice, sorghum grain, and sugarcane, specify a maximum level for carbamate residues in or on the commodity.

Analytical methods are available for the determination of carbofuran and its regulated metabolites. These methods (Methods I through X and Methods A through C) are located in PAM Vol. II Section 180.254.

Codex MRLs are expressed as the sum of carbofuran and 3-hydroxy carbofuran. Issues pertaining to compatibility of U.S. tolerances with Codex MRLs will be addressed at the issuance of the RED.

CONCLUSIONS AND RECOMMENDATIONS

Storage Stability

1. The submitted data reflecting the stability of carbofuran and its carbamate and phenol metabolites in the acid hydrolysates of alfalfa forage and hay, corn grain, silage, and stover, and sugar beet roots and tops during cold storage (~8 C) are adequate. The data are sufficient to allow CBRS to conclude that carbofuran and its carbamate metabolites are stable in the acid hydrolysates of plant commodities for up to 8 months of refrigerated storage and that carbofuran phenol metabolites are stable in acid hydrolysates of plant commodities during up to 6 months of frozen storage. CBRS has no storage stability concerns associated with the present study.

Magnitude of the Residue in Plants

2. Non-bell peppers: The submitted data are inadequate to fulfill reregistration data requirements because the field trials were not conducted at the maximum registered use pattern of carbofuran on non-bell peppers (a maximum of two sequential applications at 2 and 3 lb ai/A with a 21-day PHI) and geographic representation was inadequate. The registrant must either modify the existing product labels (SLNs AZ910001 and TX930011) to reflect the use pattern used in the submitted field trials (including a 2-3

month retreatment interval), or submit additional field trial data reflecting the maximum registered use pattern. If the registrant wishes to rely on the submitted data, an additional field trial with non-bell peppers must be conducted in Region 8 for adequate geographic representation. If instead registrant wishes to support a shorter retreatment interval, an additional two field trials must be performed, one in region 8 and the other in region 9 or 10.

- 3a. Sorghum: The submitted data are inadequate to fulfill reregistration requirements because field trials were not conducted at the maximum registered rate (some SLN labels allow at-planting application to be made at up to 2.5 lb ai/A with a 16-inch row spacing). The registrant must either (i) modify existing product labels to specify that the maximum at-planting application rate is 1 lb ai/A with a PTI of 60 days or (ii) submit field trial data reflecting at-planting application at 2.5 lb ai/A followed by two foliar applications at 0.5 lb ai/A/application.
- 3b. If the registrant chooses to modify the existing label such that application rate instructions coincide with those tested in the present trials (Option (i), above), the submitted data indicate that the combined carbofuran residues of concern in/on sorghum grain will not exceed the established 0.1-ppm tolerance, but that the established 3-ppm tolerance (of which no more than 0.5 ppm is carbamate) for sorghum forage and fodder may be too low. Based on the results of the current study and a previous 1984 submission, CBRS would recommend tolerances of 0.1 ppm for sorghum grain, and 10 ppm for sorghum forage/silage and fodder (of which no more than 2 ppm can consist of carbamate residues) provided that the existing product label is modified to specify that the maximum at-planting application rate is 1 lb ai/A with a PTI of 60 days.
- 3c. We note that 16 SLNs are currently registered for use on sorghum, and that recent policy allows a maximum of 5 SLN registrations per crop. The registrant must either apply for a federal registration of the 4 lb/gal FlC formulation on sorghum, or cancel all but 5 of the SLN registrations. These SLNs or the proposed federal registration <u>must</u> be supported by appropriate field trial data.
- 3d. The registrant has previously received a waiver for aspirated grain fraction study data requirements. This was granted in a Greybeard decision dated 3/6/93 based, in part, on the registrant's statement in a March 3, 1993 letter that "Furadan's use patterns do not permit applications after head formation (any foliar applications must be made before the head emerges from the boot). Provided all labels are changed to reflect this requirement, CBRS will not require that any aspirated grain fraction studies be performed for sorghum.

Magnitude of the Residue in Processed Food/Feed

- 4. Sorghum: The submitted sorghum processing data indicate that individual residues of carbofuran metabolites of concern concentrated up to 2x in bran and that individual residues of carbofuran metabolites of concern did not concentrate in sorghum decorticated seeds or grits processed from sorghum grain bearing detectable residues of 3-OH carbofuran and 3-OH-7-Ph carbofuran following treatment at an exaggerated rate. Because no sorghum processed commodities are considered to be significant food/feed items (Table 1, OPPTS 860.1000), tolerances for sorghum processed commodities are not required.
- 5. Sugar beet: The submitted sugar beet processing study is adequate to satisfy reregistration data requirements. The study indicates that the combined residues of carbofuran and its metabolites do not concentrate in dried pulp and refined sugar processed from sugar beet root samples bearing detectable residues (3-OH-7-Ph carbofuran only). The data indicate that combined residues may concentrate in molasses. However, residues in molasses concentrate by only a factor of 2. Since the study was performed at a 3x application rate (maximum tolerable rate) and residues concentrated by only 2x, a separate tolerance for molasses is not necessary; instead, the present 0.1 ppm sugar beet root tolerance is expected to adequately cover residues of carbofuran in molasses.

DETAILED CONSIDERATIONS

Residue Analytical Methods

The raw agricultural and processed commodity samples from the current submissions were analyzed by FMC Corporation (Princeton, NJ) for residues of carbofuran (3-hydroxy-carbofuran (3-OH), and 3-keto-carbofuran (3-keto) using an HPLC method with fluorescence detection, and for residues of 7-phenol-carbofuran (7-Ph), 3-hydroxy-7-phenol-carbofuran (3-OH-7-Ph), and 3-keto-7-phenol-carbofuran (3-keto-7-Ph) using a GC method with mass selective detection.

Briefly, samples were ground, acid hydrolyzed (in 0.25 N HCl at reflux for 1 hour), and stored under refrigeration (~5-8 C) until separately analyzed for carbamates and phenols. For the determination of carbamates, the hydrolysate was applied to a C₁₈ solid phase extraction (SPE) column coupled to an amino-propyl SPE cartridge. Residues were eluted with 1% methanol in dichloromethane (DCM), evaporated to dryness, and redissolved in acetonitrile (ACN) for analysis by HPLC using a C-18 column, a gradient mobile phase of ACN and water, a postcolumn reactor specific for carbamates, and a fluorescence detector. The limits of quantitation (LOQ) for carbamates were 0.05 ppm (non-bell peppers), 0.1 ppm (sorghum forage, silage, hay, and fodder), and 0.03 ppm (sorghum grain and the processed commodities of sorghum and sugar beets). The limits of detection (LOD) for carbamates were 0.01 ppm

(non-bell peppers, sorghum grain, and the processed commodities of sorghum and sugar beets), 0.02 ppm (sorghum forage, silage, hay, and fodder), 0.04 ppm (corn silage), 0.05 ppm (sugar beet tops and roots), 0.1 ppm (alfalfa forage), and 0.2 ppm (alfalfa hay and corn grain and stover).

For the determination of phenolic metabolites, the hydrolysate was applied to a C₁₈ SPE cartridge. Residues were eluted with 5% ethanol (EtOH) in DCM and partitioned twice with 0.25 N sodium hydroxide. Residues were then derivatized with pentafluorobenzyl bromide (PFBB) in isopropanol and partitioned twice with hexane. The hexane fraction was dried with sodium sulfate, EtOH was added, and the hexane was evaporated. The EtOH was acidified with concentrated HCl to ethylate the 3-hydroxy-7-phenol PFB derivative. After the addition of water, the ethylated mixture was repartitioned with hexane three times. Residues were concentrated and redissolved in EtOH prior to analysis by GC/MS using a DB-5 fused silica capillary column. The limits of quantitation (LOQ) of phenols were 0.05 ppm (non-bell peppers), 0.5 ppm (sorghum forage, silage, hay, and fodder), and 0.03 ppm (sorghum grain and the processed commodities of sorghum and sugar beets). The limits of detection (LOD) for phenols were 0.01 ppm (non-bell peppers, sorghum grain, and the processed commodities of sorghum and sugar beets), 0.04 ppm (corn silage), 0.05 ppm (sugar beet tops and roots), 0.1 ppm (alfalfa forage and sorghum forage, silage, hay, and fodder), and 0.2 ppm (alfalfa hay and corn grain and stover).

Concurrent method recovery analyses were conducted by FMC Corporation (Princeton, NJ) to determine the suitability of the methods for residue data collection purposes. Untreated samples of RACs from the field trials and storage stability studies, and processed fractions from the processing studies were separately fortified with carbamates and phenols at various levels. Residues of carbofuran and its carbamate and phenolic metabolites were nondetectable in/on all samples of untreated RACs and processed fractions. Representative chromatograms, sample calculations, and standard curves were provided. The recovery data are presented in Table 1. These data suggest that the methods are adequate for data collection for carbofuran and its carbamate and phenolic metabolite residues in/on alfalfa (forage and hay), corn silage, grain, and stover, sugar beet tops and roots, non-bell peppers, sorghum forage, silage, hay, fodder, and grain and sorghum processed commodities, and sugar beet processed commodities.

Table 1. Concurrent method recoveries of carbofuran and its carbamate and phenol metabolites from fortified samples of various commodities from the submitted storage stability and field trial studies.

•	Fortification	n Level			Percen	t Recovery	<u>,</u>	
	(ppm)	C	Carbamates		-	Phenois	
Commodity	Carbamates	Phenois	Carbofuran	3-keto	3-OH	7-Ph	3-keto-7-Ph	3-OH-7-Ph
Alfalfa, forage	0.50	0.50	93-114 (11); 122	81-116 (12)	86-111 (12)	68; 76-117 (11)	79-112 (11); 122	64; 77-112 (11)
Alfalfa, hay	1.00	1.00	78-116 (Ì2)	81-109 (12)	84-109 (12)	77-114 (12)	· 72-111 (12)	70-110 (11); 122
Corn, silage	1.00	1.00	85-118 (11); 131	85-117 (10); 125, 126	85-115 (10); 121, 125	82-110 (12)	75-115 (11); 121	77-115 (11); 123
Corn, grain	0.20	0.20	87-116 (11); 128	77-110 (12)	75-106 (11); 123	66, 67; 78-114 (4); 121- 143 (3)	80-117 (9)	65; 80-110 (7); 129
Corn, stover	1.00	1.00	70-118 (10); 121, 124	77-114 (12)	76-114 (12)	70-107 (12)	73-117 \ (10); 123, 130	62-64 (3); 83- 118 (9)
Pepper, non-	0.05	0.05	94	82	94	69	91	96
bell	0.1	0.5	71	76	. 82	93	102	116
	*-			·		66	88	70
Sorghum, forage	0.1	0.5	74-85 (7)	83-116 (7)	74-96 (7)	65, 66, 69; 73-90 (6)	68, 68; 75-103; 121 (6)	67, 68; 72- 104 (6)
	1.0		67; 79	73, 86	76, 87			
Sorghum, silage	0.1	0.5	71-87 (6)	74-97 (6)	84-96 (6)	66; 70-84 (5)	69; 78-109 (5)	70-110 (6)
Sorghum, hay	0.1	0.5-0.6	65; 75-95 (6)	67; 77-99; 122 (6)	68; 78-97 (6)	66, 69; 71-80 (7)	71-114 (7)	61; 72-116; 123 (7)
Sorghum, fodder	0.1	0.5	74-82 (5)	72-83 (5)	79-87 (5)	64, 65, 65, 65; 71 (5)	74-106 (5)	74-95 (5)
Sorghum, grain	0.03	0.03	71-89 (9)	73-105 (9)	73-100 (9)	64, 65, 65, 65, 68; 72-88 (9)	82-119; 122 (9)	72-113; 125 (9)
	0.1	0.1	75, 89	84, 99	83, 90	66, 83	77, 111	70, 90
Sorghum,	0.03	0.03	77	83	82	70	83	84
decorticated seed	0.1	0.1	61	66	68 ·	82	97	89
Sorghum, grits	0.03	0.03	88	85	79	85	81	86
	0.1	0.1	77	76	77	86	93	93
Sorghum, bran	0:03	0.03	88	95	109	87	82	73
	0.1	0.1	81	79	80	75	71	61
Sugar beet, tops	0.25	0.25	90-114 (10); 121, 122	90-114 (11); 121	83-108 (12)	67; 70-96 (10)	64; 74-115 (9)	57, 67; 70- 108 (9)
Sugar beet,	0.03	0.03	88, 91	84, 105	93, 103	77, 81	99, 105	77, 128
root	0.1	0.1	90, 94	89, 107	98, 105	68, 82	91, 101	68, 122
	0.25	0.25	84-108 (12)	80-106 (12)	74-114 (12)	54, 59, 65, 67; 70-100 (8)		65; 72-99 (10); 120

Table 1 (continued).

•	Fortificatio	n Level	Percent Recovery								
	(ppm	1)		Carbamates		Phenois					
Commodity	Carbamates	Phenols	Carbofuran	3-keto	3-ОН	7-Ph	3-keto-7-Ph	3-OH-7-Ph			
Sugar beet,	0.03	0.03	104	85	94	94	97	107			
molasses	0.1	0.1	88	86	98	76	83	76			
Sugar beet, wet	0.03	0.03	96	85	77	71	113	92			
pulp	0.1	0.1	84	96	73	63	93	99			
Sugar beet,	0.03	0.03	80	80	72	90	124	74			
dried pulp	0.1	0.1	66	72	78	85	106	69			
Sugar beet,	0.03	0.03	95	73	68	50	95	77			
refined sugar	0.1	0.1	92	96	86	55	97	83			

Each recovery value represents one sample unless otherwise indicated in parentheses; recovery values outside the acceptable 70-120% range are listed separately.

Storage Stability Data

The RAC samples from the field trials were promptly frozen after harvest, shipped frozen to FMC Corporation (Princeton, NJ) where they were stored frozen until homogenized and acid hydrolyzed. Following acid hydrolysis, hydrolysates were stored in a refrigerator (~5-8 C) until residue analysis. Samples collected for the processing studies were frozen after harvest and then shipped frozen to the processing facilities, where samples were stored frozen for 5 days (sugar beets) or 125 days (sorghum) until processing. All samples of processed commodities were stored frozen and shipped to the analytical laboratory where they were stored frozen until acid hydrolysis. Following hydrolysis, samples were stored in a refrigerator (~5 to 8 C) prior to residue analysis. With the exception of one sample, all samples were acid hydrolyzed within 2-37 days of collection; one sample of sorghum grain from the processing study was stored frozen for 143 days prior to hydrolysis. The storage intervals between acid hydrolysis and carbamate analysis were 2-140 days and the storage intervals between acid hydrolysis and phenol analysis were 5-181 days. Data pertaining to the stability of carbofuran and its metabolites in frozen plant commodities were discussed in the Carbofuran Update; these data indicated that residues were generally stable for up to 11 months of frozen storage.

The registrant has submitted (1992; MRID 43907101) storage stability data for the acid hydrolysates of various raw agricultural commodities in support of the field trial-studies. The following substrates were chosen to be representative commodities for crop field trials requiring storage stability data: alfalfa forage and hay; corn silage, grain, and stover; and sugar beet tops and roots (root crop).

Samples were acid hydrolyzed and fortified with carbamates or phenols at 0.20-1.00 ppm. The fortified and unfortified samples were stored at ~8 C. Samples were extracted and

analyzed after 0, 1, 3, 6 (for phenols) or 8 months (for carbamates) of cold storage. Samples were analyzed using the methods described in "Residue Analytical Methods." The results of the storage stability study are presented in Table 2. The registrant stated that the averages of the fortified recovery analyses were used to correct the residue levels in storage stability samples. Because the actual recovery values used to correct the storage stability results could not be determined by the study reviewer, only the corrected storage stability recovery results are presented in Table 2.

Table 2. Storage stability of residues of carbofuran and its metabolites in the acid hydrolysates of fortified samples of alfalfa, corn, and sugar beet commodities during storage at ~8 C.

Analyte	Commodity	Fortification Level (ppm)	Storage Period (Months)	Corrected Recovery in Stored Samples (%) ^a
Carbofuran	Alfalfa, forage	0.50	0	82-94 (4)
. 17		·	1.	84-114 (3)
		, [3	102-108 (3)
			6	104-106 (3)
Carbofuran	Alfalfa, hay	1.00	0	93-102 (4)
			1	104-113 (3)
+ 2		Ī	3	99-112 (3)
		·	8	95-98 (3)
Carbofuran	Corn, silage	1.00	0	95-108 (4)
			1	91-99 (3)
			3	87-105 (3)
·		-	8	74-113 (3)
Carbofuran	Corn, grain	0.20	0	85-105 (4)
			1	95-110 (3)
		1 4	3	85-90 (3)
			8	95-105 (3)
Carbofuran	Corn, stover	1.00	0	101-108 (4)
			. 1	95-99 (3)
			3	93-100 (3)
			8	96, 98
Carbofuran	Sugar beet, tops	0.25	0	96-112 (4)
			1	96-108 (3)
			3	88-100 (3)
			8	100-120 (3)
Carbofuran	Sugar beet, roots	0.25	0	104-116 (4)
en e		*	1	96-104 (3)
	*, *		3	88-108 (3)
			8	88-96 (3)
3-Keto	Alfalfa, forage	0.50	0	86-96 (4)
•			· 1	94-108 (3)
			3	102-110 (3)
y		l t	. 6	100-108 (3)
3-Keto	Alfalfa, hay	1.00	0	95-104 (4)
			1	102-115 (3)
			3	94-111 (3)
		l t	8	100-108 (3)

Table 2 (continued).

Analyte	Commodity	Fortification Level (ppm)	Storage Period (Months)	Corrected Recovery in Stored Samples (%) ^a
3-Keto	Corn, silage	1.00	0	92-104 (4)
	,		1	93-94 (3)
			3	84-102 (3)
		· •	8	104-117 (3)
3-Keto	Corn, grain	0.20	0	85-105 (4)
			1	95-115 (3)
			3	85-90 (3)
	*	. [8	90-105 (3)
3-Keto	Corn, stover	1.00	0	99-111 (4)
		ļ-	ì	95-100 (3)
8		· -	3	90-100 (3)
		-	8	95, 98
3-Keto	Sugar beet, tops	0.25	0	96-104 (4)
			1	108-112 (3)
			3	80-92 (3)
· ·		1	8	92-100 (3)
3-Keto	Sugar beet, roots	0.25	0	104-112 (4)
1			. 1	96-112 (3)
		1	3	88-100 (3)
e de la companya de l			8	100-104 (3)
3-OH	Alfalfa, forage	0.50	0	90-100 (4)
3 011			1	94-118 (3)
6.			. 3	100-110 (3)
		ľ	6	100-120 (3)
3-OH	Alfalfa, hay	1.00	0	98-104 (4)
3-011	111111111111111111111111111111111111111		1	100-113 (3)
	·		3	88-108 (3)
	,		8	101-106 (3)
3-OH	Corn, silage	1.00	0	82-102 (4)
J-Q11	Com, shugo	1.00	. 1	88-98 (3)
			3	92-113 (3)
*			8	97-127 (3)
3-OH	Corn, grain	0.20	0	90-105 (4)
J-OH	Com, gram	0.20	1	90-105 (3)
			3	85-105 (3)
·			8	95-105 (3)

Table 2 (continued).

Analyte	Commodity	Fortification Level (ppm)	Storage Period (Months)	Corrected Recovery in Stored Samples (%) a
3-ОН	Corn, stover	1.00	0	101-112 (4)
•			1	91-95 (3)
			3	87-105 (3)
		7	8	97, 102
3-ОН	Sugar beet, tops	0.25	0	96-108 (4)
			1	96-112 (3)
			3	100-104 (3)
2.011			8	88-132 (3)
3-ОН	Sugar beet, roots	0.25	0	108-116 (3); 124
	*		1	80-92 (3)
*	•		3	92-124 (3)
7.81			8	88-100 (3)
7-Ph	Alfalfa, forage	0.50	0	100-106 (3)
			1	80-108 (3)
		1	3	88-108 (3)
7 701	-		6 .	88-100 (3)
7-Ph	Alfalfa, hay	1.00	0	95-109 (3)
			1	103-120 (3)
			3	89-102 (3)
			6	95-109 (3)
'-Ph	Corn, silage	1.00	0	101-106 (3)
			1	88-101 (3)
			3	74-87 (3)
			6	92-106 (3)
-Ph	Corn, grain	0.20	0	90-110 (3)
			1	100-105 (3)
			3	70-105 (3)
			6	NA b
-Ph	Corn, stover	1.00	0	92-110 (3)
			1	93-107 (3)
,	1.		3	71-93 (3)
DI.			6	87-94 (3)
-Ph	Sugar beet, tops	0.25	0	88-100 (3)
			1	68; 88, 104
,			3	92-108 (3)
and the second s			6	80-96 (3)

Table 2 (continued).

Analyte	Commodity	Fortification Level (ppm)	Storage Period (Months)	Corrected Recovery in Stored Samples (%) ^a
7-Ph	Sugar beet, roots	0.25	0	56; 104.(2)
		-	1	100-112 (3)
-			3	84-100 (3)
			6	76-100 (3)
3-Keto-7-Ph	Alfalfa, forage	0.50	0	102-108 (3)
			1	82-98 (3)
			3	84-106 (3)
			6	84-106 (3)
3-Keto-7-Ph	Alfalfa, hay	1.00	0	91-108 (3)
4			1	107, 112; 122
			3	88-102 (3)
	· · · · · · · · · · · · · · · · · · ·	ľ	6	94-110 (3)
3-Keto-7-Ph	Corn, silage	1.00	0	95-99 (3)
			1	94-103 (3)
	-	1 4	3	74-93 (3)
	•		6	100-110 (3)
3-Keto-7-Ph	Corn, grain	0.20	0	85-110 (3)
			1	80-120 (3)
			. 3	70-100 (3)
			6	NA ^b
3-Keto-7-Ph	Corn, stover	1.00	0	86-111 (3)
			1	98-103 (3)
			3	88-105 (3)
			6	93-101 (3)
3-Keto-7-Ph	Sugar beet, tops	0.25	0	80-96 (3)
			1	84-96 (3)
			3	96-108 (3)
		·	6	84-100 (3)
3-Keto-7-Ph	Sugar beet, roots	0.25	0	84-104 (3)
3 12000 1 1-			1	100-108 (3)
•			3	88-96 (3)
		· ·	6	84-100 (3)
3-OH-7-Ph	Alfalfa, forage	0.50	0	96-108 (3)
2 011 1 14	1		1	66; 90, 98
			3	86-104 (3)
			6	78-96 (3)

Table 2 (continued).

•		Fortification	Storage Period	Corrected Recovery in
Analyte	Commodity	Level (ppm)	(Months)	Stored Samples (%) a
3-OH-7-Ph	Alfalfa, hay	1.00	0	92-99 (3)
			1	106-110 (3)
			3	83-105 (3)
			6	83-94 (3)
3-OH-7-Ph	Corn, silage	1.00	. 0	82-102 (3)
* .			1	87-107 (3)
*			3	74-84 (3)
			6	94-104 (3)
3-OH-7-Ph	Corn, grain	0.20	0	100-115 (3)
			1	80-115 (3)
	,		3	70-115 (3)
			6	N/A b
3-OH-7-Ph	Corn, stover	1.00	0	78-98 (3)
*	·	1	1	102-112 (3)
		. 4 4	3	58; 89, 102
	i e e		6	78-99 (3)
3-OH-7-Ph	Sugar beet, tops	0.25	0	80-96 (3)
			1	64; 92, 108
• 2			3	76-112 (3)
	4		6	76-100 (3)
3-OH-7-Ph	Sugar beet, roots	0.25	0	48; 84, 108
			1	92-112 (3)
			· 3	84-88 (3)
	,		. 6	76-92 (3)

^a Number of samples in parentheses. Storage stability results were corrected by the registrant using the average of the fortified recovery analyses.

Study summary: The submitted data reflecting the stability of carbofuran and its carbamate and phenol metabolites in the acid hydrolysates of alfalfa forage and hay, corn grain, silage, and stover, and sugar beet roots and tops during cold storage (~8 C) are adequate. The data are sufficient to allow CBRS to conclude that carbofuran and its carbamate metabolites are stable in the acid hydrolysates of plant commodities during up to 8 months of refrigerated storage and that carbofuran phenol metabolites are stable in acid hydrolysates of plant commodities during up to 6 months of cold storage.

The registrant stated that results were not available due to unacceptable recoveries and an insufficient amount of remaining hydrolysate.

Magnitude of the Residue in Plants

Non-bell Peppers

Established tolerance: A tolerance of 1 ppm (of which no more than 0.2 ppm is carbamate) has been established for the combined residues of carbofuran, its carbamate metabolite, and its phenolic metabolites in/on peppers [40 CFR §180.254(a)].

Registered use patterns: The 4 lb/gal FIC formulation is registered for use limited to AZ and TX on peppers at 5 lb ai/A/season. A maximum of two applications per season can be made, the first (2 lb ai/A) as an in-furrow application during planting and the second (3 lb ai/A) as a sidedress 4-6 weeks later. A PHI of 21 days is in effect. These use directions were obtained from EPA SLN Nos. AZ910001 and TX930011, with parent EPA Reg. No. 279-2876; the parent product is not registered for use on peppers.

Discussion of the data: FMC Corporation has submitted data (1995; MRID 43852201) from 2 trials conducted in CA and NM depicting residues of carbofuran and its carbamate metabolites (3-keto and 3-OH), and its phenolic metabolites (7-Ph, 3-keto-7-Ph, and 3-OH-7-Ph) in/on non-bell peppers. Mature non-bell peppers were harvested 28 days following the last of two applications, at a 55- or 110-day retreatment interval, of the 4 lb/gal FIC formulation (EPA Reg. No. 279-2876) at a total of 2.5 lb ai/A/season. The first application was made at planting as an in-furrow treatment at 1.0 lb ai/A followed by a sidedress application at 1.5 lb ai/A using ground equipment. Applications were made in 3.4-21.6 gal/A of water.

One control and duplicate treated samples were collected from each test site. Residues of carbofuran and its carbamate and phenolic metabolites in/on treated and untreated non-bell peppers were determined using the HPLC and GC/MS methods described above. Residues were less than the LOD (<0.01 ppm) in/on two untreated samples of non-bell peppers. Residues in/on treated samples are presented in Table 3.

Table 3. Residues of carbofuran and its carbamate and phenolic metabolites in/on non-bell peppers harvested 28 days following two applications of the 4 lb/gal FlC formulation at 1.0 and 1.5 lb ai/A/application (2.5 lb ai/A/season).

	•	. Residues (ppm) *										
2		Carbam	ates									
Test Location	Carbofuran	3-keto	3-OH	Total b	7-Ph	3-keto-7-Ph	3-OH-7-Ph	Total	Combined b			
CA	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.02 <0.02	(0.01) (0.02)	<0.01 <0.01	<0.01 <0.01	<0.03 <0.04	<0.05 <0.06			
NM	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.02 <0.02	0.05 (0.04)	(0.02) (0.03)	(0.02) (0.01)	0.09 0.08	<0.11 <0.10			

Residues in/on treated samples were not corrected for concurrent recovery. Residue values in parentheses are estimates; ≥ LOD (0.01 ppm) but ≤ LOQ (0.05 ppm).

Total does not include residues of 3-keto-carbofuran which is not a residue of concern of carbofuran.

Geographic representation is inadequate to support the registered SLN uses in AZ and TX because field trials were conducted in CA and NM. The registrant stated that they intend to pursue a federal registration (Section 3) of the 4 lb/gal FlC formulation on non-bell peppers. The subject field trials were conducted in Regions 9 (NM) and 10 (CA). A minimum of three field trials is required for a federal registration on non-bell peppers (OPPTS 860.1500, Tables 1 and 4). To fulfill geographic representation requirements for the registered SLN uses and for any future federal registration, an additional field trial with non-bell peppers must be conducted in TX (Region 8).

Study summary (1995; MRID 43852201): The submitted data indicate that the combined carbofuran residues of concern were <0.05-<0.11 ppm [including <0.02 ppm carbamates] in/on non-bell peppers harvested 28 days following the last of two applications, with a 55- or 110-day retreatment interval, of the 4 lb/gal FIC formulation at 1.0 and 1.5 lb ai/A/application (2.5 lb ai/A/season) in ~3-22 gal of water/A using ground equipment. The submitted data do not reflect the maximum registered use pattern of carbofuran on non-bell peppers (a maximum of two sequential applications at 2 and 3 lb ai/A with a 30 day retreatment interval and a 21-day PHI). The registrant must either modify the existing product labels (SLNs AZ910001 and TX930011) to reflect the use pattern used in the submitted field trials (including a 2-3 month retreatment interval and 28 day PHI), or submit additional field trial data reflecting the maximum registered use pattern. If the registrant wishes to rely on the submitted data, an additional field trial with non-bell peppers must be conducted in Region 8 for adequate geographic representation. If instead registrant wishes to support a shorter retreatment interval and/or a shorter PHI, an additional two field trials must be performed, one in region 8 and the other in region 9 or 10.

Sorghum

Established tolerances: Tolerances have been established for the combined residues of carbofuran, its carbamate metabolite, and its phenolic metabolites in/on sorghum grain at 0.1 ppm, sorghum forage at 3 ppm (of which no more than 0.5 ppm is carbamate), and sorghum fodder at 3 ppm (of which no more than 0.5 ppm is carbamate) [40 CFR §180.254(a)].

Registered use patterns: The 4 lb/gal FIC formulation is registered for use limited to AL, AR, KS, LA, MO, MS, NE, NM, OK, TN, and TX on sorghum. Soil in-furrow, band, or injection applications may be made at planting at 1 lb ai/13,000 linear ft of row (1 lb ai/A with 40-inch row spacing). Some labels specify that up to 2.5 lb ai/A may be applied based on a 16-inch row spacing. In addition, foliar applications may be made at 0.5 lb ai/A as a directed spray in a minimum of 20 gal/A using ground equipment or as a broadcast spray using ground or aerial equipment (minimum of 2 gal/A for air). A maximum of two foliar applications may be made per season (except NM780015, TN840004, and TX780004 for a which no maximum seasonal rate is listed). Grazing of treated fields or cutting for silage or forage is prohibited (AR810051, MO790006, and OK810012). Grazing of treated fields or cutting for silage or forage within 30 days following treatment is prohibited (KS880001 and

NE880003). Grazing of treated fields or cutting for silage or forage within 75 days following treatment is prohibited (KS880002, LA910018, MO810024, MS820020, NE920009, NM780015, TN840004, TX780004, and TX810006). Applications after heads emerge from the boot are prohibited (KS880001, LA910018, MO790006, MS820020, NE880003, NM780015, OK810012, TN840004, TX780004, and TX810006). Application to grain sorghum prior to rogueing is prohibited (LA910018, NM780015, TN840004, and TX780004). These use directions were obtained from the following SLN (24c) product labels: AL880003, AR810051, AR810052, KS880001, KS880002, LA910018, MO790006, MO810024, MS820020, NE880003, NE920009, NM780015, OK810012, TN840004, TX780004, and TX810006, with parent EPA Reg. No. 279-2876; the parent product is not registered for use on sorghum.

According to REFS, 16 SLNs are currently registered for use on sorghum; these SLNs cover the major sorghum-growing regions of the U.S. Recent Registration Division policy allows a maximum of 5 SLN registrations per crop. The registrant must either apply for a federal registration of the 4 lb/gal FIC formulation on sorghum, or cancel all but 5 of the SLN registrations. We note that the Agency does not consider prohibitions against the grazing of treated fields or cutting for silage or forage to be practical for sorghum.

Discussion of the data: FMC Corporation has submitted data (1994; MRID 43842801) from six trials conducted in KS, MO, NE, OK, SD, and TX depicting residues of carbofuran and its carbamate metabolites (3-keto and 3-OH), and its phenolic metabolites (7-Ph, 3-keto-7-Ph, and 3-OH-7-Ph) in/on sorghum forage, silage, hay, grain, and fodder. Sorghum forage was harvested 37 to 60 days following the first application (immediately prior to the second application) and sorghum silage, hay, grain, and fodder were harvested 27 to 91 days following the last of three applications of the 4 lb/gal FIC formulation (EPA Reg. No. 279-2876) at a total rate of 2.0 lb ai/A. The first application was made at planting as an in-furrow treatment at 1.0 lb ai/A. This application was followed by two postemergence broadcast applications [prior to flag leaf emergence (Vanderlip stage 3), 37 to 60 days after the first application, and at flag leaf emergence (Vanderlip stage 4), 7 to 16 days after the second application] at 0.5 lb ai/A/application. Applications were made in ~5-26 gal/A of water using ground equipment.

One control and duplicate treated samples were collected from each test site. Forage was sampled just prior to flag leaf emergence, silage (fresh, unfermented) and hay (field-dried silage) were sampled at the dough stage, and grain and fodder were sampled at maturity. Fresh silage as sampled in this study is defined as "sorghum forage" in Table 1 (OPPTS 860.1000). Fodder and hay samples were allowed to dry in the field up to 3 and 6 days, respectively. The registrant stated that fodder and grain samples from the SD site were not analyzed because they did not mature due to unusually cold weather. Residues of carbofuran and its carbamate and phenolic metabolites in/on treated and untreated sorghum forage, silage, hay, grain, and fodder were determined using the HPLC and GC/MS methods described above. Apparent residues of carbamates were less than the LOD (<0.02 ppm) in/on six untreated samples each of sorghum forage, silage, and hay and five untreated samples of

sorghum fodder, and less than the LOD (<0.01 ppm) in/on five untreated samples of sorghum grain. Apparent residues of phenols were less than the LOD (<0.1 ppm) in/on six untreated samples each of sorghum forage, silage, and hay and five untreated samples of sorghum fodder, and less than the LOD (<0.01 ppm) in/on five untreated samples of sorghum grain. Residues in/on treated samples are presented in Table 4.

The registrant stated that the high residue values in/on the forage samples from TX may have been due to a small sampling size. Statistical analyses conducted by the registrant determined these residue values to be outliers (Thompson outlier test). Nevertheless, previous studies have been reviewed by Chemistry Branches (as reflected in the Registration Standard Update dated 1/9/91) in which higher residues were seen following similar treatment practices. Specifically, FMC previously submitted data (MRID 00145685) in which sorghum fodder was harvested 67-85 days following the last of three applications of the 10% G formulation and 4 lb/gal FlC formulations for a total of 3 lb ai/A (2 lb ai/A at planting followed by two foliar applications at 0.5 lbs ai/A each). This was reviewed by Dietary Exposure Branch (C. Deyrup, 12/17/84, DEB No. 229) which cited combined residues of up to 8.11 ppm (of which 0.98 ppm was carbamate).

Residues of carbofuran and its carbamate and phenolic metabolites in/on sorghum forage harvested 37 to 60 days following an at-planting application of the 4 lb/gal FlC formulation at 1.0 lb ai/A, and in/on sorghum silage, hay, fodder, and grain harvested 27-91 days following an additional two applications of the 4 lb/gal FlC formulation at 0.5 lb ai/A/application (2.0 lb ai/A/season).

						Residue	s (ppm) *			
Test	PTI		Carbam	ates			Ph	enols		
Location	(days)	Carbofuran	3-keto	3-OH	Total b	7-Ph	3-keto-7-Ph	3-OH-7-Ph	Total	Combined ^b
					Sorghum	forage				
KS	40	<0.02 <0.02	<0.02 <0.02	<0.02 <0.02	<0.04 <0.04	<0.1 <0.1	<0.1 <0.1	<0.1 <0.1	<0.3 <0.3	<0.34 <0.34
мо	37	(0.04) (0.06)	<0.02 <0.02	(0.05) (0.05)	0.09 0.11	(0.21) (0.19)	(0.11) (0.10)	(0.11) <0.1	0.43 <0.39	<0.52 <0.50
NE	39	<0.02 <0.02	<0.02 <0.02	<0.02 <0.02	<0.04 <0.04	<0.1 <0.1	<0.1 <0.1	<0.1 <0.1	<0.3 <0.3	<0.34 <0.34
ОК	37	<0.02 <0.02	<0.02 <0.02	0.13 0.13	<0.15 <0.15	(0.15) (0.13)	<0.1 <0.1	(0.10) <0.1	<0.35 ≰0.33	<0.50 <0.48
SD	60	<0.02 <0.02	<0.02 <0.02	<0.02 <0.02	<0.04 <0.04	<0.1 <0.1	<0.1 <0.1	<0.1 <0.1	<0.3 <0.3	<0.34 <0.34
TX	44	0.47 0.46	(0.09) (0.08)	. 0.65 0.59	1.12 1.05	(0.30) (0.25)	(0.11) (0.10)	(0.43) (0.35)	0.84 0.70	1.96 1.75
				*	Sila	ģe				
KS	51	(0.02) <0.02	<0.02 <0.02	(0.02) (0.03)	0.04 <0.05	(0.11) (0.14)	<0.1 <0.1	<0.1 <0.1	<0.31 <0.34	<0.35 <0.39
МО	52	<0.02 <0.02	<0.02 <0.02	(0.03) (0.03)	<0.05 <0.05	(0.16) (0.17)	<0.1 <0.1	<0.1 <0.1	<0.36 <0.37 .	<0.41 <0.43
NE	46	<0.02 <0.02	<0.02 <0.02	(0.06) (0.06)	<0.08 <0.08	(0.18) (0.18)	<0.1 <0.1	(0.10) <0.1	<0.38 <0.38	<0.46 <0.46
ОК	38	(0.02) <0.02	<0.02 <0.02	0.13 0.13	0.15 <0.15	(0.35) (0.38)	(0.14) (0.15)	(0.25) (0.24)	0.74 0.77	<0.89 <0.92
SD	37	<0.02 <0.02	<0.02 <0.02	(0.06) (0.06)	<0.08 <0.08	(0.12) (0.12)	<0.1 <0.1	<0.1 <0.1	<0.32 <0.32	<0.40 <0.40
TX	27	(0.02) (0.02)	<0.02 <0.02	0.11 (0.09)	0.13 0.11	(0.16) (0.12)	<0.1 <0.1	(0.12) <0.1	<0.38 <0.32	<0.51 <0.43
					Н	ау				· · · · · · · · · · · · · · · · · · ·
KS	51	<0.02 <0.02	<0.02 <0.02	(0.02) (0.02)	<0.04 <0.04	<0.1 <0.1	<0.1 <0.1	<0.1 <0.1	<0.3 <0.3	<0.34 <0.34
МО	52	<0.02 <0.02	<0.02 <0.02	<0.02 <0.02	<0.04 <0.04	<0.1 <0.1	<0.1 <0.1	<0.1 <0.1	<0.3 <0.3	<0.34 <0.34
NE	46	<0.02 <0.02	<0.02 <0.02	(0.04) (0.04)	<0.06 <0.06	(0.13) (0.12)	<0.1 <0.1	<0.1 <0.1	<0.33 <0.32	<0.39 <0.38
ОК	38	(0.02) (0.04)	<0.02 <0.02	0.18 0.22	0.20 0.26	0.52 (0.48)	(0.23) (0.22)	(0.27) (0.25)	1.02 0.95	<1.22 <1.21
SD	37	<0.02 <0.02	<0.02 <0.02	(0.05) (0.07)	<0.07 <0.09	(0.16) (0.16)	<0.1 <0.1	(0.11) (0.10)	<0.37 <0.36	<0.44 <0.45
TX	27	<0.02 <0.02	<0.02 <0.02	(0.06) (0.04)	<0.08 <0.06	(0.12) (0.10)	<0.1 <0.1	<0.1 <0.1	<0.32 <0.30	<0.40 <0.36 ‡

Table 4 (continued).

•						Residue	s (ppm) *			
Test	PTI		Carbam	ates			Ph	enols	4	
Location	(days)	Carbofuran	3-keto	3-OH	Total b	7-Ph	3-keto-7-Ph	3-OH-7-Ph	Total	Combined b
					Gra	in				
KS	79	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.02 <0.02	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.03 <0.03	<0.05 <0.05
МО	80	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.02 <0.02	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.03 <0.03	<0.05 <0.05
NE	66	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.02 <0.02	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.03 <0.03	<0.05 <0.05
OK	.59:	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.02 <0.02	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.03 <0.03	<0.05 <0.05
TX	63	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.02 <0.02	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.03 <0.03	<0.05 <0.05
					Fod	der				
KS	79	<0.02 <0.02	<0.02 <0.02	<0.02 <0.02	<0.04 <0.04	<0.1 <0.1	<0.1 <0.1	<0.1 <0.1	<0.3 <0.3	<0.34 <0.34
МО	80	<0.02 <0.02	<0.02 <0.02	<0.02 <0.02	<0.04 <0.04	<0.1 <0.1	<0.1 <0.1	<0.1 <0.1	<0.3 <0.3	<0.34 <0.34
NE	66	<0.02 <0.02	<0.02 <0.02	(0.06) (0.07)	<0.08 <0.09	(0.23) (0.23)	<0.1 <0.1	(0.11) (0.10)	<0.44 <0.43	<0.52 <0.52
OK	59	<0.02 <0.02	<0.02 <0.02	0.18 0.20	<0.20 <0.22	(0.43) (0.36)	(0.20) (0.18)	(0.33) (0.29)	0.96 0.83	<1.16 <1.05
TX	63	<0.02 <0.02	<0.02 <0.02	(0.05) (0.06)	<0.07 <0.08	(0.14) (0.12)	<0.1 <0.1	(0.11) <0.1	<0.3 9 <0.32	<0.42 <0.40

Residues in/on treated samples were not corrected for concurrent recovery. Residue values in parentheses are estimates; ≥ LOD but ≤ LOQ. Forage, Silage, Háy, and Fodder: Carbamates: LOQ=0.1 ppm and LOD=0.02 ppm; Phenols: LOQ=0.5 ppm and LOD=0.10 ppm. Grain: Carbamates: LOQ=0.03 ppm and LOD=0.01 ppm; Phenols: LOQ=0.03 ppm and LOD=0.01 ppm.

Does not include residues of 3-keto-carbofuran which is not a residue of concern of carbofuran.

Geographic representation of the submitted residue data is adequate. The test states of KS(30%), MO(6%), NE(15%), OK(2%), SD(2%), and TX(31%) accounted for 86% of the 1991 U.S. sorghum grain production (1992 USDA Agricultural Statistics).

Study summary (1994; MRID 43842801): The submitted data are inadequate to fulfill reregistration requirements because field trials were not conducted at the maximum registered rate; some SLN labels allow at-planting application to be made at up to 2.5 lb ai/A (with a 16-inch row spacing). The registrant must either (i) modify existing product labels to specify that the maximum at-planting application rate is 1 lb ai/A with a PHI of 60 days or (ii) submit field trial data reflecting at-planting application at 2.5 lb ai/A followed by two foliar applications at 0.5 lb ai/A/application. We note that 16 SLNs are currently registered for use on sorghum, and that recent Registration Division policy allows a maximum of 5 SLN registrations per crop. The registrant must either apply for a federal registration of the 4 lb/gal FIC formulation on sorghum, or cancel all but 5 of the SLN registrations. These SLNs or the proposed federal registration must be supported by appropriate field trial data.

The submitted data indicate that the combined carbofuran residues of concern in/on sorghum grain will not exceed the established 0.1-ppm tolerance, but that the established 3-ppm tolerance (of which no more than 0.5 ppm is carbamate) for sorghum forage and fodder may be too low. The combined residues of carbofuran and its metabolites in/on sorghum forage harvested 37-60 days following a single application of the 4 lb/gal FIC formulation at 1.0 lb ai/A/application were <0.36-1.96 ppm (of which <0.04-1.12 ppm were carbamates). The combined residues in/on sorghum silage (forage) harvested 27-52 days following the last of three applications, at 7- to 60-day retreatment intervals, of the 4 lb/gal FIC formulation at 1.0, 0.5, and 0.5 lb ai/A/application (2.0 lb ai/A/season) were <0.35-<0.89 ppm (of which 0.04-0.15 ppm were carbamates). The combined residues of carbofuran and its metabolites in/on sorghum grain harvested 59-91 days following the same treatment were <0.05 ppm (of which <0.02 ppm were carbamates). The combined residues of carbofuran and its metabolites in/on sorghum fodder were <0.34-<1.16 ppm (of which <0.04-<0.22 ppm were carbamates).

Based on the results of the current study and the previously submitted study, CBRS would recommend tolerances of 0.1 ppm for sorghum grain, and 10 ppm for sorghum forage/silage and fodder (of which no more than 2 ppm can consist of carbamate residues) provided that the existing product label is modified to specify that the maximum at-planting application rate is 1 lb ai/A with a PHI of 60 days.

Although the submitted sorghum processing study (discussed below) indicates that carbofuran residues of concern concentrate (1.4x) in sorghum bran and Residue Chemistry Test Guidelines (860.1000) require an aspirated grain fraction study if a processing study shows concentration of residues of regulatory concern concentrate in an outer seed coat, the registrant has previously received a waiver for aspirated grain fraction study data requirements. This was granted in a Greybeard decision dated 3/6/93 based, in part, on the registrant's statement in a March 3, 1993 letter that "Furadan's use patterns do not permit applications after head formation (any foliar applications must be made before the head emerges from the boot). Provided all labels are changed to reflect this requirement, CBRS will not require that any aspirated grain fraction studies be performed.

Magnitude of the Residue in Processed Commodities

Sorghum Processed Commodities

Established tolerances: Tolerances have been established for the combined residues of carbofuran, its carbamate metabolite, and its phenolic metabolites in/on sorghum grain at 0.1 ppm, sorghum forage at 3 ppm (of which no more than 0.5 ppm is carbamate), and sorghum fodder at 3 ppm (of which no more than 0.5 ppm is carbamate) [40 CFR §180.254(a)]. No tolerances have been established for residues of carbofuran in any sorghum processed commodities.

Registered use patterns: See "Registered use patterns" under "Sorghum" (page 16).

Discussion of the data: FMC Corporation submitted data (1994; MRID 443842501) pertaining to the potential for concentration of residues of carbofuran and its carbamate and phenolic metabolite in the processed commodities of sorghum. In two tests conducted in KS and TX sorghum grain was harvested 63 or 87 days following the last of three applications of the 4 lb/gal FlC formulation (EPA Reg. No. 279-2876) at a total rate of 8.0 lb ai/A. The first application was made at planting as an in-furrow treatment at 3.0 lb ai/A (1.2x the maximum registered rate for this type of application). This application was followed by two postemergence applications [prior to flag leaf emergence (Vanderlip stage 3), 40 to 44 days following the first application, and at flag leaf emergence (Vanderlip stage 4), 8 to 15 days following the second application] at 2.5 lb ai/A/application (5x the maximum rate for this type of application). Applications were made in ~6-18 gal/A of water using ground equipment.

At crop maturity, a bulk sample of sorghum grain was separated from the rest of the plant and frozen. A subsample of the bulk grain sample was sent directly to FMC Corporation (Princeton, NJ) for residue analysis. The remainder of the bulk sorghum grain sample was shipped frozen by refrigerated truck to the processor (Food Protein R&D Center, Texas A&M University, Bryan, TX) where it was processed into decorticated seed, grits, and bran. Only grain samples from the TX trial were processed because after an initial analysis, residue levels were slightly higher.

Sorghum grain was processed according to simulated commercial procedures into decorticated seed, grits, and bran. Briefly, sorghum grain was dried and cleaned by aspiration and screening. Cleaned grain was abrasively milled to separate the **bran** from the seed. This process also produced **decorticated seed** as well as small and large **grits**. The registrant submitted adequate descriptions and material balance sheets for the processing procedures.

The processed fractions were shipped frozen on dry ice to the analytical laboratory (FMC Corporation, Princeton, NJ). Residues of carbofuran and its carbamate and phenolic metabolites in/on treated and untreated sorghum grain and sorghum processed commodities were determined using the HPLC and GC/MS methods described above. The results of the sorghum processing study are presented in Table 5. Apparent residues of carbofuran and its carbamate and phenolic metabolites were nondetectable (<0.01 ppm each) in/on two samples of untreated sorghum grain, and one sample each of decorticated seed, grits, and bran processed from untreated sorghum grain.

Table 5. Residues of carbofuran and its carbamate and phenolic metabolites in/on sorghum processed from sorghum grain treated with three applications, with 8- to 44-day retreatment intervals, of the 4 lb/gal FIC formulation at 3.0, 2.5, and 2.5 lb ai/A/application (8.0 lb ai/A/season; 4x).

Sorghum		Carba	mates						
Commodity	Carbofuran	3-keto	3-OH	Total *	7-Ph	3-keto-7-Ph	3-OH-7-Ph	Total	Combined *
Residues (ppm) ^b								
Grain (field)	<0.01	<0.01	<0.01	<0.02	<0.01	<0.01	(0.01)	<0.03	<0.05
Grain (processor)	<0.01	<0.01	(0.01)	<0.02	<0.01	<0.01	(0.01)	<0.03	<0.05
Decorticated seed	<0.01	<0.01	<0.01	<0.02	<0.01	<0.01	<0.01	<0.03	<0.05
Grits	<0.01	<0.01	<0.01	<0.02	<0.01	<0.01	<0.01	<0.03	<0.05
Bran	<0.01	<0.01	<0.01	<0.02	(0.02)	<0.01	(0.02)	<0.05	< 0.07
Concentration	Reduction Fact	ors							
Decorticated seed	·		<1x	<1x	-		<1x	<1x	<1x
Grits			<1x	<la><lx< li=""></lx<></la>			<lx< td=""><td><1x</td><td><1x</td></lx<>	<1x	<1x
Bran			<1x	<1x	2x		2x	2x	1.4x

Does not include residues of 3-keto-carbofuran which is not a residue of concern of carbofuran.

Study summary (1994; MRID 43842501): The submitted sorghum processing data indicate that individual residues of carbofuran metabolites of concern may concentrate in bran and that individual residues of carbofuran metabolites of concern did not concentrate in sorghum decorticated seeds or grits processed from sorghum grain bearing detectable residues of 3-OH carbofuran and 3-OH-7-Ph carbofuran following treatment at an exaggerated rate. Because no sorghum processed commodities are considered to be significant food/feed items (Table 1, OPPTS 860.1000), tolerances for sorghum processed commodities are not required.

Sugar Beet Processed Commodities

Established tolerances: Tolerances have been established for the combined residues of carbofuran, its carbamate metabolite, and its phenolic metabolites in/on sugar beets at 0.1 ppm and sugar beet tops at 2 ppm (of which no more than 1 ppm is carbamate) [40 CFR §180.254(a)]. No food/feed additive tolerances have been established for residues of carbofuran in any sugar beet processed commodities.

Registered use patterns: The 4 lb/gal FlC formulation is registered for use limited to ID, OR, and TX on sugar beets as a single soil band treatment at 2 lb ai/A in a minimum of 10 gal of finished spray/A. A PHI of 90 days is in effect. These use directions were obtained from the following SLN (24c) product labels: SLN Nos. ID920002, OR920014, and TX930011 with parent EPA Reg. No. 279-2876; the parent product is not registered for use on sugar beets. In addition, the 4 lb/gal FlC formulation is also registered for use limited to NE on sugar

Each residue value represents a single sample. Residue values in parentheses are estimates; ≥ LOD (0.01 ppm) but ≤ LOQ (0.03 ppm).

beets as a single soil band treatment made at planting through the six leaf stage at 0.075 lb ai/1,000 feet of row. A PHI of 90 days is in effect. These use directions were obtained from EPA SLN No. NE950001 with parent EPA Reg. No. 279-2876.

Discussion of the data: FMC Corporation submitted data (1995; MRID 43851901) pertaining to the potential for concentration of residues of carbofuran and its carbamate and phenolic metabolite in the processed commodities of sugar beets. In one test conducted in CO sugar beets were harvested 92 days following a single postemergence application of the 4 lb/gal FlC formulation (EPA Reg. No. 279-2876) at 6.0 lb ai/A/application (3x the maximum application rate). Application was made as a banded spray in ~20 gal/A of water using ground equipment (CO₂ backpack sprayer). The registrant indicated that 3x the intended use rate was determined to be the highest possible exaggerated rate which could be applied without excessive crop phytotoxicity.

At crop maturity, a bulk sample of sugar beets was harvested from the control and treated plots. A subsample of sugar beet roots was removed from the bulk sample and shipped frozen to FMC Corporation (Princeton, NJ) for residue analysis. The remainder of the bulk sugar beet root samples were shipped frozen by aircraft to the processor (Wm. J. Englar and Associates; Moses Lake, WA).

At the processing facility, sugar beet root samples were processed into wet and dried pulp, molasses, and refined sugar using procedures which simulated normal commercial processing conditions. Briefly, the roots were washed in water and sliced into cossettes. The sliced cossettes were placed in a counter current diffuser with a mixture of fresh water and pulp press water. Sugar from cossettes was extracted into water and the extract (raw juice) was purified by the addition of lime and carbon dioxide and heated at 84-87 C. Impurities in the extract were precipitated by the addition of a settling aid. The clear liquid was filtered, carbonated with carbon dioxide gas, heated at 93 C, and filtered again. The thin juice was concentrated by evaporation to produce thick juice and frozen until further processing. Once thawed, the thick juice was heated at 80 C in a vacuum pan and centrifuged to separate the sugar from the molasses. The sugar was then washed with hot water and dried with hot air to produce refined sugar. The beet pulp left over from the sugar extraction was pressed and a subsample removed to produce wet pulp. The remainder was dried to produce dried pulp. The registrant submitted adequate descriptions and material balance sheets for the processing procedures.

The processed fractions were shipped frozen to the analytical laboratory (FMC Corporation, Princeton, NJ). Residues of carbofuran and its carbamate and phenolic metabolites in/on treated and untreated sugar beets and sugar beet processed commodities were determined using the HPLC and GC/MS methods described above. The results of the sugar beet processing study are presented in Table 6. Apparent residues of carbofuran and its carbamate and phenolic metabolites were nondetectable (<0.01 ppm each) in/on two samples of untreated sugar beet roots, and in one sample each of molasses, wet and dried pulp, and refined sugar processed from untreated sugar beet roots.

Table 6. Residues of carbofuran and its carbamate and phenolic metabolites in/on sugar beet and its processed commodities treated with a single postemergence application of the 4 lb/gal FlC formulation at 6.0 lb ai/A/application (3x).

Sugar Beet		Carba	mates			Ph	enols		
Commodity	Carbofuran	3-keto	3-OH	Total *	7-Ph	3-keto-7-Ph	3-OH-7-Ph	Total	Combined *
Residues (ppm)	b								
Root (field)	<0.01	<0.01	<0.01	<0.02	<0.01	<0.01	(0.01)	<0.03	<0.05
Root (processor)	<0.01	<0.01	<0.01	<0.02	<0.01	<0.01	(0.02)	<0.04	<0.06
Molasses	<0.01	<0.01	<0.01	<0.02	(0.02)	<0.01	0.07	< 0.10	<0.12
Wet pulp	<0.01	<0.01	<0.01	<0.02	<0.01	<0.01	<0.01	<0.03	<0.05
Dried pulp	<0.01	<0.01	<0.01	<0.02	<0.01	<0.01	(0.01)	<0.03	<0.05
Sugar	<0.01	<0.01	<0.01	<0.02	<0.01	<0.01	<0.01	<0.03	<0.05
Concentration/	Reduction Fact	ors							
Molasses					>2x		7x	№3 x	>2x
Wet pulp					:		<1x	<1x	<1x
Dried pulp							<1x	<1x	<1x
Sugar	-						<1x	<1x	<1x

Does not include residues of 3-keto-carbofuran which is not a residue of concern of carbofuran.

Study summary (1995; MRID 43851901): The submitted sugar beet processing study is adequate to satisfy reregistration data requirements. The study indicates that the combined residues of carbofuran and its metabolites do not concentrate in dried pulp and refined sugar processed from sugar beet root samples bearing detectable residues (3-OH-7-Ph carbofuran only). The data indicate that combined residues may concentrate in molasses. However, residues in molasses concentrate by only a factor of 2. Since the study was performed at a 3x application rate (maximum tolerable rate) and residues concentrated by only 2x, a separate tolerance for molasses is not necessary; instead, the present 0.1 ppm sugar beet root tolerance is expected to adequately cover residues of carbofuran in molasses. Therefore, no tolerances are required for any sugar beet processed commodity is not required.

MASTER RECORD IDENTIFICATION NUMBERS

43842501 Shevchuk, N. (1994) Magnitude of the Residue of Carbofuran and its Carbamate and Phenolic Metabolites in/on Processed Parts from Sorghum Treated with Furadan 4F: Lab Project Number: 078SOR93R2: P-2919: 93CGR23. Unpublished study prepared by FMC Corp. 94 p.

43842801 Shevchuk, N. (1994) Magnitude of the Residue of Carbofuran and its Carbamate and Phenolic Metabolites in/on Sorghum Treated with Furadan 4F: Lab Project Number: P-2918: 078SOR93R1. Unpublished study prepared by FMC Corp. 139 p.

b Each residue value represents a single sample. Residue values in parentheses are estimates; ≥ LOD (0.01 ppm) but ≤ LOQ (0.03 ppm).

43851901 Brooks, M. (1995) Magnitude of the Residue of Carbofuran and Its Carbamate and Phenolic Metabolites in/on Sugar Beets with Furadan 4F Insecticide: Lab Project Number: P-3010:078SBE94R1. Unpublished study prepared by FMC Corp. 112 p.

43852201 Kim, I. (1995) Magnitude of the Residue of Carbofuran and Its Carbamate and Phenolic Metabolites in/on Non-Bell (Hot) Pepper Treated with Furadan 4F: Lab Project Number: P-3032:078PNB94R1. Unpublished study prepared by FMC Corp. 73 p.

43907101 Barros, A. (1992) Sub-Ambient Storage Stability of Carbofuran and Its Carbamate and Phenolic Metabolites in the Acid Hydrolysates of Various Crop Matrices: Lab Project Number: 078CSS91R4: P-2706. Unpublished study prepared by FMC Corp. 121 p.