

10/25/95

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MEMORANDUM

Subject: Dicofol (List A, Case 0021, Chemical 010501). Product Chemistry Chapter Update and Residue Chemistry Chapter Update for the Reregistration Eligibility Decision Document. DP Barcode D218284, CBRS No. 16001.

From: Stephen Funk, Chemist
Special Review Section I
Chemistry Branch II - Reregistration Support
Health Effects Division (7509C)

Through: Andrew Rathman, Section Head
Special Review Section I
Chemistry Branch II - Reregistration Support
Health Effects Division (7509C)

To: Linda Propst/Judith Loranger, CRM 73
Reregistration Section 3
Reregistration Branch
Special Review and Reregistration Division (7508W)

and

Paula Deschamp and John Redden
Risk Characterization and Assessment Branch
Health Effects Division (7509C)

Attached is an update to the *Product Chemistry Chapter* and the *Residue Chemistry Chapter* for the *Dicofol Reregistration Eligibility Document* (S. Funk, CBRS 13185, DP Barcode D199110, 08/19/94). All significant changes have been redlined.

Additional data are required for the following product chemistry guidelines for dicofol: 61-1; 62-2; 63-14; 63-15; 63-16; 63-19. These data requirements are considered confirmatory.

Additional residue data are required for the following residue chemistry guidelines: 171-3; 171-4(c); 171-4(d); 171-4(k); 165-1. The additional data requirements for all guideline residue chemistry categories are considered confirmatory.

GLN 171-3

Additional label amendments are required. Rotational crop plantback intervals are required. Strawberries must be removed from all EC formulation labels, and the WP/D labels must be amended to conform with the strawberry field trial parameters.

GLN 171-4(c)

A GC method for the determination of dicofol in plant matrices

requires independent laboratory validation. When validated, the method will be submitted for inclusion in PAM for enforcement purposes. The current PAM method is colorimetric. This requirement is considered confirmatory, because multiresidue methods have been shown adequate for recovery of dicofol from plant matrices.

GLN 171-4(d)

A HPLC/GC method for the determination of dicofol and FW-152 in animal commodities requires independent laboratory validation for use as an enforcement method. These requirements are considered confirmatory because PAM contains a HPLC method for the determination of dicofol residues in milk.

GLN 171-4(e)

Dicofol has been shown to be stable in various plant commodities for 1 to 2 years, except in cottonseed (3 months). Dicofol and FW-152 are stable in poultry and cattle tissue, milk, and eggs stored frozen for up to 7 months. No additional data are required.

GLN 171-4(k)

Field trials are required for caneberries and cotton gin byproducts. There are limited data for caneberries to support the existing label use (S. Funk, CBRS 15104, DP Barcode D211756, 03/01/95). Additional trials are required, but are considered confirmatory. The requirement for cotton gin byproduct data is a recent development (*Pesticide Reregistration Rejection Rate Analysis Residue Chemistry: Follow-Up Guidance for Updated Livestock Feeds Tables* (06/94, EPA 738-K-94-001; revised 09/95)), and fulfillment of the requirement will be considered confirmatory.

GLN 171-4(l)

Dicofol has been shown to concentrate in apple pomace, raisins, and plum prunes (S. Funk, CBRS No. 15885, DP Barcode D217490, 08/29/95). This raises issues under the Delaney clause.

GLN 165-1 and 165-2

The registrant will not propose the plantback intervals required by the existing confined rotational crop studies, and will pursue new studies. The data are considered confirmatory, because the plantback intervals may be imposed until new data are evaluated.

Anticipated residues for purposes of dietary exposure assessment have been addressed separately from this document (S. Funk, CBRS 14225, DP Barcode D206745, 09/12/95). Adequate field trial, feeding study, and/or market basket survey data are available for all commodities.

CBRS supports the reregistration of dicofol for use on beans, fruiting vegetable group (eggplant, peppers, pimentos, tomatoes, etc.), cucumbers, melons, pumpkins, squash, citrus, apples,

crabapples, pears, quince, apricots, cherries, nectarines, peaches, nuts (excluding almonds), caneberries, strawberries, cottonseed, hops, tea, and mint. Confirmatory data are required for cotton (gin trash). Additional field trial data are required for dicofol use on caneberries.

Please advise if additional information is needed.

Attachments: *Task 2A: Reregistration Eligibility Document: Product Chemistry Considerations* (06/13/94; revision 10/10/95).

Task 2B: Reregistration Eligibility Document: Residue Chemistry Considerations (06/13/94; revision 10/10/95).

cc: Dicofof List A File, Circ., Subject File, RF, Dynamac Corp., S. Funk, Deborah Hartman- PSPS (7501C).
RDI:A. Rathman:10/10/95:R. Perfetti:10/11/95:E. Zager:10/23/95:
H7509C:CBRS:S.Funk:305-5430:CM#2:RM803:SF(0895.3):09/10/95:10/24/95.

Final Report

DICOFOL

Shaughnessy No. 010501

Case No. 0021

(CBRS No. 13185, DP Barcode D199110)

TASK 2A

**Reregistration Eligibility Decision:
Product Chemistry Considerations**

June 13, 1994. CBRS Update 10/10/95.

Contract No. 68-D2-0053

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
Rockville, MD 20850-3268

DICOFOL

REREGISTRATION ELIGIBILITY DECISION:

PRODUCT CHEMISTRY CONSIDERATIONS

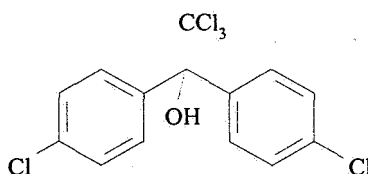
Shaughnessy No. 010501; Case No. 0021

(CBRS No. 13185; DP Barcode D199110)

TASK 2A

DESCRIPTION OF CHEMICAL

Dicofol [1,1-bis(p-chlorophenyl)-2,2,2-trichloroethanol] is a miticide used on terrestrial food crops and non-food sites.



Empirical Formula:	C ₁₄ H ₉ Cl ₅ O
Molecular Weight:	370.5
CAS Registry No.:	115-32-2
Shaughnessy No.:	010501

IDENTIFICATION OF ACTIVE INGREDIENT

Technical dicofol is a reddish-brown extremely viscous nonfree-flowing liquid with a vapor pressure of about 4.0×10^{-7} mm Hg at 25 C. Dicofol is soluble in organic solvents (dichloromethane, methanol, n-heptane, and xylene) and virtually insoluble in water (~1 ppm for the PAI).

MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 3/15/94 identified two dicofol manufacturing-use products (MPs), the Rohm and Haas Company 95.3% technical (T; EPA Reg. No. 707-203) and the Agan Chemical Manufacturers, Ltd. 88% T (EPA Reg. No. 11603-26). The Agan product is repackaged from the Rohm and Haas T. We note that in previous Agency

memoranda the Rohm and Haas T has been identified as an 89% formulation; however, based on the nominal concentration of the active ingredient as presented in recent submissions and the label claim listed in REFs, the product is a 95.3% formulation. We further note that the label claim for the Agan T should be changed from 88% to 95.3% to reflect the nominal concentration of the active ingredient in the source product from which it is repackaged. Because the Agan T is identified as an the 88% T in REFs, it will be referred to as such throughout this RED. The Rohm and Haas and Agan Ts are the only MPs subject to a reregistration eligibility decision.

REGULATORY BACKGROUND

Due to environmental concerns resulting from the presence of DDT and related contaminants (DDTr) in dicofol, Dicofol Special Review was initiated in 1984. As specified in the Dicofol PD 4 (Notice of Intent to Suspend) dated 5/29/86, registrations for dicofol-containing uses faced cancellation unless the upper limit for DDTr was certified at 2.5% of dicofol technical by 1/1/86 and at 0.1% by 7/1/87. The Rohm and Haas 80% T (EPA Reg. No. 707-107), for which data were reviewed in the Dicofol Guidance Document dated 1983, was canceled (6/29/86) because the product did not comply with the Dicofol PD 4 requirements concerning DDTr impurity levels. Rohm and Haas subsequently registered (8/5/87) the current Kelthane® 95.3% T which contains DDTr impurities at 0.1%. Agan fulfilled data requirements for the 88% T containing 2.5% DDTr; however, no data have been provided reflecting a reduction of DDTr impurities to 0.1%.

Although the Guidance Document required additional generic and product-specific product chemistry data for dicofol reregistration, new product chemistry data were necessary for compliance with the DDTr requirements of the Dicofol PD 4. The 1991 Dicofol Reregistration Standard Update summarized data which had been submitted in response to the Guidance Document and the Dicofol PD 4 and which had been reviewed by the Agency. Additional data were required for the Rohm and Haas 95.3% T (EPA Reg. No. 707-203) concerning GLNs 61-1, 61-2, 63-2, 63-4, 63-5, 63-13, 63-14, 63-17, and 63-20. All new product chemistry data were required for the Agan 88% T (EPA Reg. No. 707-203) because the existing database supported a product containing >0.1% DDTr impurities. It was concluded in subsequent Agency reviews that since the current Agan T is repackaged from the Rohm and Haas T, product chemistry data submitted by Rohm and Haas will satisfy data requirements for the Agan product (CBRS No. 11668, D189942, dated 4/28/93, by S. Funk).

The current status of product chemistry data requirements for the Rohm and Haas and Agan Ts is presented in the attached data summary tables. Refer to these tables for listings of the outstanding product chemistry data requirements.

CONCLUSIONS

All generic data requirements are fulfilled for the Rohm and Haas TGAI; however, product-specific data gaps exist for the Rohm and Haas and Agan MPs. Provided that the registrants either certify that the suppliers of starting materials and the manufacturing process for the dicofol products have not changed since the last comprehensive product chemistry review or submit complete updated product chemistry data packages, CBRS has no objections to the reregistration of dicofol with respect to product chemistry data requirements.

EPA MEMORANDA CITED IN THIS DOCUMENT

Subject: Addendum #3 to the Dicofol Registration Standard.
 From: W. Boodee
 To: A. Rispin/J. Ellenberger
 Dated: 7/2/84
 MRID: 00161079

CBRS Nos.: 583, 584, 585, 586, 688, 689, 690, 691
 Subject: Dicofol Data Call-In Product Chemistry and Confidential Statements of Formula.
 From: S. Hummel
 To: E. Allen
 Dated: 3/20/85
 MRID: 00141704

CBRS No.: 1547
 Subject: EPA File Symbol 707-ENG Rohm and Haas Kelthane Technical Product Chemistry Data Supporting New Product Application.
 From: S. Hummel
 To: D. Edwards/B. Kapner
 Dated: 11/21/86
 MRID: None

CBRS No.: 1878
 Subject: EPA File Symbol 707-ENG Rohm and Haas Kelthane Technical Additional Product Chemistry Data Supporting New Product Application
 From: S. Hummel
 To: D. Edwards/B. Kapner
 Dated: 2/17/87
 MRID: None

CBRS No.: 3388
Subject: Rohm and Haas Kelthane Technical Product Chemistry Data Supporting
Amendment to Reduce DDTr Impurities to 0.1%.
From: S. Hummel
To: D. Edwards
Dated: 3/3/88
MRID: 40504501

CBRS No.: 11222
DP Barcode: D186859
Subject: Reregistration of Dicofol. Rohm & Haas Product Chemistry "Final Report -
Series 63 Addendum".
From: K. Dockter
To: L. Propst/J. Loranger
Dated: 2/12/93
MRID: 42514801

CBRS No.: 11668
DP Barcode: D189942
Subject: Dicofol (Kelthane). Makhteshim-Agan (America) Inc. Response to Product
Chemistry DCI.
From: S. Funk
To: L. Propst/J. Loranger
Dated: 4/28/93
MRID: None

CBRS No.: 11338
DP Barcode: D187708
Subject: Reregistration of Dicofol (Chemical No. 010501; List A; Case No. 0021).
Rohm and Haas: Response to the Dicofol Product Chemistry Data
Requirements.
From: F. Toghrol
To: L. Rossi/L. Propst
Dated: 4/28/93
MRID(s): 42633301 and 42633302

CBRS No.: 11944
DP Barcode: D191604
Subject: Reregistration of Dicofol (Chemical No. 010501; List A; Case No. 0021).
Rohm and Haas Protocol for Dicofol MP Product Chemistry
[Oxidation/Reduction (GLN 63-14), Storage Stability (GLN 63-17), and
Corrosion Characteristics (GLN 63-20)].
From: F. Toghrol
To: L. Rossi/L. Propst
Dated: 6/29/93
MRID(s): None

CBRS No.: 12161
DP Barcode: D192702
Subject: Reregistration of Dicofol (Chemical No. 010501; List A; Case No. 0021).
Rohm and Haas: Response to the Dicofol Product Chemistry Data
Requirements (GLN 62-2).
From: F. Toghrol
To: L. Rossi/L. Propst
Dated: 7/22/93
MRID(s): None; CSF dated 10/1/92

CBRS No.: 14500
DP Barcode: D208283
Subject: Product Chemistry for Dicofol. Chemical No. 010501. Case No. 0021.
Registration No. 707-203 (Kelthane® Technical B Miticide).
GLN's 63-17 and 63-20.
From: S. Funk
To: L. Propst/J. Loranger
Dated: 7/20/95
MRID(s): 43383901

CBRS No.: 15299
DP Barcode: D208283
Subject: Dicofol (List A, Case 0021, Chemical 010501). Product Chemistry Chapter
Update for the Reregistration Eligibility Decision Document.
From: S. Funk
To: L. Propst/J. Loranger
Dated: 5/2/95
MRID(s): None

PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

00141704 Rohm & Haas Co. (1984) Product Chemistry: Kelthane Miticides. Unpublished study. 19 p.

00161079 Rohm & Haas Co. (1984) Product Chemistry: Kelthane Technical. Unpublished compilation. 86 p.

40504501 Rohrbach, W.; Nichols, R. (1988) Product Chemistry Section for Kelthane Technical: Project ID No. RWN-88-008. Unpublished study prepared by Rohm and Haas Co. 204 p.

42514801 Batra, R. (1992) Addendum to Product Chemistry of Kelthane Technical (MRID 40504501): Lab Project Number: APR/SH-92-197. Unpublished study prepared by Rohm and Haas Co. 100 p.

42633301 Batra, R. (1992) Addendum to Kelthane Technical B Product Chemistry Series 61: Product Identity and Composition: Lab Chemistry Number Chemistry Series 61: Lab Project Number: APR/SH-92-198. Unpublished study prepared by Rohm and Haas Co. 26 p.

42633302 Verona, D. (1992) Product Chemistry Series 62 Analysis and Certification of Product Ingredients in Kelthane Technical B: Lab Project Number: APR/SH-92-270. Unpublished study prepared by Rohm and Haas Co. 218 p.

43070101 Meyer, A. (1993) Interim Results for Guideline Series 63-17 (Stability) and 63-20 (Corrosion Characteristics) for Kelthane Technical B: Lab Project Number: APR/SH-93-294: 894660-7: 73P-93-35. Unpublished study prepared by Rohm and Haas Co. 69 p.

43383901 (1994) Final Results for Guideline Series 63-17 (Stability) and 63-20 (Corrosion Characteristics) for Kelthane Technical. Unpublished study prepared by Rohm and Haas Co.

Case No. 0021
Chemical No. 010501

Case Name: Dicofol
Registrant: Rohm and Haas Company
Product(s): 95.3% T (EPA Reg. No. 707-203)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ^a	MRID Number ^b
61-1	Product Identity and Disclosure of Ingredients	Y	40504501 <u>42633301</u> CSF dated 10/1/92 ^c
61-2	Starting Materials and Manufacturing Process	Y	40504501 <u>42633301</u>
61-3	Discussion of Formation of Impurities	Y	40504501
62-1	Preliminary Analysis	Y	40504501 <u>42633302</u>
62-2	Certification of Ingredient Limits	Y	40504501 <u>42633302</u> CSF dated 10/1/92 ^c
62-3	Analytical Methods to Verify the Certified Limits	Y	40504501
63-2	Color	Y	42514801 ^d
63-3	Physical State	Y	No MRID ^e
63-4	Odor	Y	42514801 ^d
63-5	Melting Point	Y	42514801 ^d
63-6	Boiling Point	N/A	
63-7	Density, Bulk Density or Specific Gravity	Y	00141704 ^f
63-8	Solubility	Y	00161079 ^g
63-9	Vapor Pressure	Y	00161079 ^g No MRID ^e
63-10	Dissociation Constant	Y	00161079 ^g
63-11	Octanol/Water Partition Coefficient	Y	00161079 ^g
63-12	pH	N/A	
63-13	Stability	Y	42514801 ^d
63-14	Oxidizing/Reducing Action	N ^h	
63-15	Flammability	N ⁱ	
63-16	Explosibility	N ⁱ	
63-17	Storage Stability	Y	43070101; 43383901 ^j
63-18	Viscosity	Y	No MRID ^k
63-19	Miscibility	N ⁱ	
63-20	Corrosion Characteristics	Y ^j	

^a Y = Yes; N = No; N/A = Not Applicable.

^b **Bolded** citations were reviewed under CBRS No. 3388, dated 3/3/88, by S. Hummel; underlined citations were reviewed under CBRS No. 11338, D187708, dated 4/28/93, by F. Toghrol; and all other citations were reviewed as noted.

^c CBRS No. 12161, D192702, dated 7/22/93, by F. Toghrol.

^d CBRS No. 11222, D186859, dated 2/12/93, by K. Dockter.

^e CBRS No. 1878, dated 2/17/87, by S. Hummel.

^f CBRS Nos. 583, 584, 585, 586, 688, 689, 690, and 691, dated 3/20/85, by S. Hummel.

^g Addendum #3 to the Dicofol Registration Standard, dated 7/2/84, by W. Boodee.

^h Rohm and Haas intends to submit an explanation concerning the inapplicability of this property to the active ingredient. CBRS has noted that because this is a product-specific requirement, the oxidizing/reducing potential of each impurity must be considered. This data requirement remains outstanding (CBRS No. 11944, D191604, dated 6/29/93, by F. Toghrol).

ⁱ Data previously accepted for the canceled T (EPA Reg. No. 707-107) are not applicable to this product because this is a product-specific data requirement; new data are required.

^j CBRS No. 14500, D208283, dated 7/20/95, by S. Funk.

^k CBRS No. 1547, dated 11/21/86, by S. Hummel.

Case No. 0021
 Chemical No. 010501

Case Name: Dicofol
 Registrant: Agan Chemical Manufacturers, LTD.
 Product(s): 88% T (EPA Reg. No. 11603-26)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ^a	MRID Number
61-1	Product Identity and Disclosure of Ingredients	N ^b	
61-2	Starting Materials and Manufacturing Process	N/A ^c	
61-3	Discussion of Formation of Impurities	N/A ^c	
62-1	Preliminary Analysis	N/A ^c	
62-2	Certification of Ingredient Limits	N ^b	
62-3	Analytical Methods to Verify the Certified Limits	N/A ^c	
63-2	Color	N/A ^c	
63-3	Physical State	N/A ^c	
63-4	Odor	N/A ^c	
63-5	Melting Point	N/A ^c	
63-6	Boiling Point	N/A ^c	
63-7	Density, Bulk Density or Specific Gravity	N/A ^c	
63-8	Solubility	N/A ^c	
63-9	Vapor Pressure	N/A ^c	
63-10	Dissociation Constant	N/A ^c	
63-11	Octanol/Water Partition Coefficient	N/A ^c	
63-12	pH	N/A ^c	
63-13	Stability	N/A ^c	
63-14	Oxidizing/Reducing Action	N/A ^c	
63-15	Flammability	N/A ^c	
63-16	Explosibility	N/A ^c	
63-17	Storage Stability	N/A ^c	
63-18	Viscosity	N/A ^c	
63-19	Miscibility	N/A ^c	
63-20	Corrosion Characteristics	N/A ^c	

^a Y = Yes; N = No; N/A = Not Applicable.

^b These data do not satisfy the requirements of 40 CFR §158.155 and §158.175 (Guideline Reference Nos. 61-1 and 62-2) concerning product identity and certified limits because a CSF which reflects the nominal concentration and certified limits of the active ingredient in the final product based on the technical source product must be submitted on EPA Form 8570-4 (Rev. 12/90). In addition, the label claim of 88% is not in agreement with the nominal concentration of the active ingredient in the source product. Per PR Notice 91-2 dated 5/2/91, the label for the

product must reflect the nominal concentration of the active ingredient.

° Because this product is repackaged from the Rohm and Haas 95.3% T (EPA Reg. No. 707-203) all product chemistry data requirements will be satisfied by Rohm and Haas (CBRS No. 11668, D189942, dated 4/28/93, by S. Funk).

Final Report

DICOFOL
Shaughnessy No. 010501
Case No. 0021
(CBRS No. 13185, DP Barcode D199110)

TASK 2B
Reregistration Eligibility Decision:
Residue Chemistry Considerations

June 13, 1994. CBRS Update 10/10/95.

Contract No. 68-D2-0053

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
Rockville, MD 20850-3268

DICOFOL

REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

Shaughnessy No. 010501; Case 0021

(CBRS No. 13185; DP Barcode D199110)

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DICOFOL

REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

Shaughnessy No. 010501; Case 0021

(CBRS No. 13185; DP Barcode D199110)

TASK 2B

INTRODUCTION

Dicofol [1,1-bis(4-chlorophenyl)-2,2,2-trichloroethanol and 1-(2-chlorophenyl)-1-(4-chlorophenyl)-2,2,2-trichloroethanol] is a miticide registered for foliar application to a variety of food/feed crops. End-use products registered for use on food/feed crops include emulsifiable concentrates (EC), wettable powders (WP), a flowable concentrate (FIC), and a wettable powder/dust (WP/D) that may be applied as dilute or concentrated ground or aerial sprays.

REGULATORY BACKGROUND

Dicofol was the subject of a Reregistration Standard and Guidance Document dated 12/83 and the Dicofol Reregistration Standard Update dated 9/10/91.

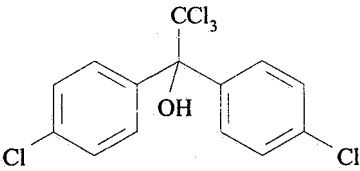
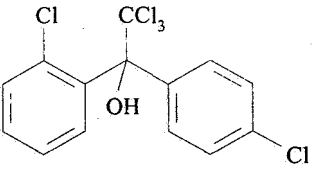
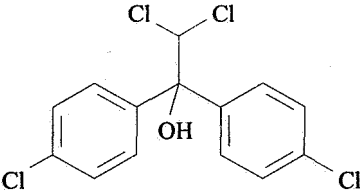
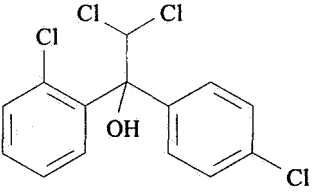
The Dicofol Special Review was initiated in 1984, owing to environmental concerns caused by the presence of DDT and related contaminants (DDTr). Registrations for dicofol-containing uses faced cancellation unless the upper limit for DDTr was certified at 0.1% by 7/1/87.

Tolerances for residues in/on food/feed crops are currently expressed in terms of dicofol *per se* [Source: 40 CFR §180.163]. There are no tolerances established for animal commodities. The HED Metabolism Committee (S. Funk, 9/29/92) determined that dicofol is the only residue of concern in/on plants and that dicofol and its metabolite 1,1-bis (4-chlorophenyl)-2,2-dichloroethanol (FW-152) are the residues of concern in animals. The chemical structures of dicofol and its metabolite FW-152 are depicted in Figure A.

Issues

EPA issued a Final Rule revoking the established tolerance for residues of dicofol in dried tea (59 FR 10993, 3/9/94) to be effective 5/9/94. The Dicofol Task force, consisting of Rohm and Haas Co. and Makhteshim-Agan, Inc., and the National Agricultural Chemical Association filed separate objections to the final rule and EPA stayed the effective date of the final rule (59 FR 23799, 5/9/94). CBTS recommended revocation of the Sec. 409 tolerance for dicofol on dried tea and establishment of a Sec. 408 tolerance for dicofol in/on fresh plucked tea at 30 ppm and of a Sec. 701 maximum residue limit of 50 ppm for dicofol in/on dried tea (W. D. Cutchin, CBTS 1143, DP D212187, 09/12/95).

Figure A. The chemical structures of dicofol and the metabolites of concern.

Structure Metabolite: Chemical name	Structure Metabolite: Chemical name
 <p>p,p'-dicofol: 1,1-bis(4-chlorophenyl)-2,2,2-trichloroethanol</p>	 <p>o,p'-dicofol: 1-(2-chlorophenyl)-1-(4-chlorophenyl)-2,2,2-trichloroethanol</p>
 <p>p,p'-FW-152: 1,1-bis(4-chlorophenyl)-2,2-dichloroethanol</p>	 <p>o,p'-FW-152: 1-(2-chlorophenyl)-1-(4-chlorophenyl)-2,2-dichloroethanol</p>

SUMMARY OF SCIENCE FINDINGS

GLN 171-3: Directions for Use

There are five end-use products currently registered to Rohm and Haas, the primary producer of dicofol. These end-use products are listed below.

EPA Reg. No.	Acceptance		Product Name
	Date	Formulation	
707-201	6/8/89	4 lb/gal FIC	Kelthane 4F Flowable Agricultural Miticide
707-202	8/93	4 lb/gal EC ^a	Kelthane MF Agricultural Miticide
707-204	11/88	1.6 lb/gal EC	Kelthane EC Agricultural Miticide
707-205	8/93	35% WPD ^b	Kelthane 35 Agricultural Miticide
707-229	7/93	50% WP	Kelthane 50 Agricultural Miticide

^a Includes SLN Nos. CA77005300, GA88000600, LA88000700, MS90000400, and TX93001800.

^b Includes SLN Nos. AZ88001000, CA88002900, CA92002600, OR90001500, PA92000400, VA89000500, and WA90002200.

A comprehensive summary of the registered food/feed use patterns of dicofol, based on these product labels, is presented in Table A and reflects revisions proposed by the registrant and reviewed by the Agency (CBRS No. 12732, DP Barcode D196223, 12/21/93, CBRS No. 12734, DP Barcode D196335, 4/14/94, CBRS No. 13521, DP Barcode D201819, 6/23/94, CBRS No. 13520, DP Barcode D201807, 6/23/94, S. Funk, CBRS Nos. 10179 and 10180, DP Barcodes D180337 and D180418, 9/2/92, S. Knizner). A summary of the residue chemistry science assessments for reregistration of dicofol is presented in Table B. The conclusions listed in Table B regarding the reregistration eligibility of dicofol food/feed uses are based on the use patterns registered by the basic producer, Rohm and Haas Co.. When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer labels.

The WP/D labels must be amended such that the application rate and PHI for strawberries are consistent with the field trial parameters (Table A). The EC labels must be amended to delete use on strawberries.

Limited field trial data have been submitted on caneberries (blackberry, raspberry) in the period following the initial *Chemistry Chapter*. The data are adequate to support use on caneberries on an interim basis, but additional confirmatory field trial data are required.

GLN 171-4 (a): Plant Metabolism

The qualitative nature of the residue in plants is adequately understood. Metabolism studies have been conducted with grapefruit, cottonseed, and tomato. Dicofol is not translocated and is not metabolized to an appreciable extent. A study on citrus seedlings indicated that <1% of leaf-applied [¹⁴C]dicofol was translocated from the leaf and <0.05% of soil-applied chemical was taken up by the plant.

In a grapefruit metabolism study, fruit harvested up to 150 days after foliar application of uniformly ring-labeled [¹⁴C]p,p'-dicofol at 4 lb ai/A contained >98% of the radioactivity in the

peel, <1.4% in juice, and <0.6% in pulp. Dicofol accounted for >70% of the radioactivity in peel collected 60 days after treatment and 50-60% in 150-day samples. The metabolite p,p'-dichlorobenzophenone (DCBP) accounted for <2%.

In the cottonseed metabolism study, dicofol comprised ~60% of the radioactivity in whole seeds harvested 15 days following two foliar applications of [¹⁴C]p,p'-dicofol totaling ~5 lb ai/A. DCBP accounted for 15% of the residues in whole cottonseed.

A tomato metabolism study showed dicofol at 86.5% of the radioactive residues in tomato fruits harvested 21 days after two foliar applications of [¹⁴C]p,p'-dicofol at 2.4 lb ai/A. DCBP accounted for ~1% of the residue and evidence of dichlorobenzhydrol (DCBH) at ~1% was detected. In a parallel study with [¹⁴C]o,p'-dicofol, DCBH and DCBP comprised 6.6 and 4.1% of the residue, respectively.

Metabolism in plants proceeds via hydrolysis and oxidation of the trichloroethanol moiety to form dichlorobenzophenone. However, the parent compound remains the predominant residue. The HED Metabolism Committee (S. Funk, 9/29/92) determined that dicofol is the only residue of concern in/on plants.

GLN 171-4 (b): Animal Metabolism

The qualitative nature of the residue in livestock is adequately understood, based on acceptable studies with goats and hens. Goats were dosed with [¹⁴C]dicofol at 15 ppm in the daily diet for 7 days and sacrificed 24 hours later. FW-152 was the major residue, comprising 27-67% of the radioactivity in milk and tissues; dicofol accounted for 10% in kidney and 24-46% in milk, fat, and muscle. Dicofol comprised <1% of the liver residues, whereas DCBP released by base hydrolysis constituted 15%. DCBP also comprised up to 17% of the residues in milk and 18% in fat.

In the poultry metabolism study, hens were dosed with [¹⁴C]dicofol for 7 days at 10 ppm in the daily diet. Dicofol accounted for 13-27% of the residue in whole eggs and 63-77% in fat and muscle. FW-152 constituted up to 17% of the residue in eggs and fat, 22% in muscle, and 33% in liver. DCBP comprised up to 50% of the residues in eggs, but <10% in tissues.

The HED Metabolism Committee (S. Funk, 9/29/92) determined that dicofol and FW-152 are the residues of concern in animals.

GLN 171-4 (c) and (d): Residue Analytical Methods - Plants and Animals

Three colorimetric methods for dicofol determination in/on plants are listed in PAM, Vol. II (Methods A, B, and C). PAM, Vol. II also includes a reference to a GLC method in PAM, Vol. I for the determination of chlorinated hydrocarbons. PAM, Vol. I (Section 211.13H) includes an HPLC method for the determination of dicofol residues in milk. The GC/EC Method TR-310-

86-74 for plant matrices is to be validated by an independent laboratory for inclusion in PAM. An HPLC/GC method for the determination of dicofol and FW-152 in animal commodities, including milk, meat, and eggs, requires an independent laboratory validation.

p,p'-Dicofol and o,p'-dicofol are completely recovered (>80%) using FDA Multiresidue Protocol D (Section 302). p,p'-Dicofol is partially recovered (50-80%) using Multiresidue Protocol E for oily matrices (Section 304), whereas the recovery of the o,p'-isomer using this method is small (<50%). Recovery of both isomers using Protocol E for non-oily matrices (Section 303) is variable [Source: *PESTDATA, PAM, Vol. I Appendix I, 1994*].

GLN 171-4 (e): Storage Stability

Dicofol is stable in apples, string beans, and green peppers stored at -20 C for 24 months. Dicofol is stable in strawberries stored at -20 C for up to 12 months and is stable in melons stored at -20 C for up to 18 months. Dicofol is stable in citrus fruit stored frozen for 2 years and in cottonseed for ~3 months. Dicofol and FW-152 are stable in poultry and cattle tissues, milk, and eggs stored for up to 7 months at frozen temperatures. No additional storage stability data are required.

GLN 171-4 (k): Magnitude of the Residue in Plants

All data requirements for magnitude of the residue in plants have been evaluated and deemed adequate to reassess the tolerances for residues of dicofol in raw plant commodities, with the exception of figs. IR-4 intends to provide data to support the use on caneberries and has submitted one field trial each for blackberries and raspberries; additional confirmatory data are required. The use on figs is not being supported and will be revoked.

CBRS now requires residue data for cotton gin byproducts (commonly called gin trash) which includes burrs, leaves, stems, lint, immature seeds, sand, and dirt. As these data requirements are based on the *Updated Livestock Feeds Tables* for Subdivision O (Residue Chemistry) of the Pesticide Assessment Guidelines (06/94, EPA 738-K-94-001; 09/95 revision), they are considered confirmatory data and will not impede the reregistration process.

GLN 171-4 (l): Magnitude of the Residue in Processed Food/Feed

All data requirements for magnitude of the residue in processed food/feed have been evaluated and deemed adequate to determine the extent to which residues of dicofol concentrate in food/feed items upon processing of the raw agricultural commodity. Residues tend to concentrate in dried, processed feed items (apple pomace) and in raisins, prunes, and citrus oil. Food/feed additive tolerances are required for apple pomace, grape raisins, and plum prunes. Maximum Residue Limits (MRL) are required for citrus oil and dried tea.

GLN 171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

No tolerances have been established for dicofol residues in livestock commodities. However, animal metabolism studies indicate that tolerances are needed for residues of dicofol and FW-152 in meat, milk, poultry, and eggs.

The re-calculated maximum theoretical dietary burdens of dicofol are about 10 ppm for cows and about 17 ppm for beef cattle based on residues in citrus pulp, apple pomace, and cottonseed (seed, meal, hulls). The existing ruminant feeding studies (10, 30, and 100 ppm feeding level) have been recently re-evaluated and found adequate for determining tolerance levels in meat, liver, kidney, meat byproducts, and milk.

The re-calculated maximum theoretical dietary burden of dicofol for poultry is 0.02 ppm, based on residues in cottonseed meal (20% diet X 0.1 ppm residue). The existing poultry feeding studies (0.5 ppm feeding level) have been recently re-evaluated and found adequate for determining tolerance levels in poultry meat, liver, fat, meat byproducts, and eggs.

GLNs 165-1 and 165-2: Confined/Field Rotational Crops

Data on confined rotational crops indicate that no additional data on dicofol rotational crop tolerances are required for rotational crops, provided the registrant revises the product labels to impose a 1-month plantback interval for legume vegetables, a 4-month plantback interval for cereal grains, and a 1-year plantback interval for all other rotated crops. Currently, there are no rotational crop restrictions. The registrant will pursue new confined rotational crop studies. In the interim, the rotational crop restrictions must be added to the labels.

Table A. Use patterns subject to reregistration for: Case 0021, Dicofol. ^a

Site Application Type Application Timing Application Equipment	Form [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Re- treatment Interval (Days)	PHI (Days)	Use Limitations
Apple						
Broadcast or band application Ground or aerial equipment	35% WP/D [707-205]	2.8 lb/A	2	Not specified (NS)	7	No chemigation. Applications may be made in a minimum of 5 gal/A using aerial equipment.
	50% WP [707-229]	3 lb/A	2	NS	7	
	4 lb/gal FIC [707-201]	3 lb/A	2	NS	7	No chemigation. Applications may be made in a minimum of 5 gal/A using aerial equipment. Application to Idared before second cover spray is prohibited. A maximum application rate of 2 lb ai/A for Golden Delicious is in effect.
Bean, dry						
Broadcast or band application Ground or aerial equipment	4 lb/gal EC [707-202]	1.5 lb/A	2	NS	21	No chemigation. Applications may be made in a minimum of 5 gal/A using aerial equipment. The feeding of vines or crop residues to meat or dairy animals is prohibited.
	1.6 lb/gal EC [707-204]					
Bean, succulent						
Broadcast or band application Ground or aerial equipment	4 lb/gal EC [707-202]	1.5 lb/A	2	NS	21	See "Bean, dry."
	1.6 lb/gal EC [707-204]					

(continued; footnotes follow.)

Table A (continued).

Site Application Type Application Timing Application Equipment	Form [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Re- treatment Interval (Days)	PHI (Days)	Use Limitations
Blackberry^b						
Broadcast foliar application Postbloom Ground equipment	35% WP/D [OR90001500] [VA89000500]	1.225 lb/A	NS	NS	2	No chemigation. Application may be made alone or as a tank mix with other pesticides.
	35% WP/D [PA92000400] [WA90002200]	1.225 lb/A	2	NS	7	
Cherry/nectarine/plumcot						
Broadcast or band application Ground or aerial equipment	35% WP/D [707-205] 50% WP [707-229] 4 lb/gal FIC [707-201]	1.5 lb/A	1	NA	7	
Chestnut						
Broadcast or band application Ground or aerial equipment	1.6 lb/gal EC [707-204]	2 lb/A	2	NS	7	No chemigation. Applications may be made in a minimum of 5 gal/A using aerial equipment.
Citrus						
Broadcast or band application Ground or aerial equipment	4 lb/gal EC [707-202] 1.6 lb/gal EC [707-204]	6 lb/A	2	NS	7	No chemigation. Applications may be made in a minimum of 5 gal/A using aerial equipment.

(continued; footnotes follow.)

Table A (continued).

Site Application Type Application Timing Application Equipment	Form [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Re- treatment Interval (Days)	PHI (Days)	Use Limitations
Cotton						
Broadcast or band application Ground or aerial equipment	4 lb/gal EC [707-202]	1.5 lb/A	2	NS	30	No chemigation. Applications may be made in a minimum of 5 gal/A using aerial equipment. The feeding of stalks or trash to meat or dairy animals is prohibited.
	1.6 lb/gal EC [707-204]					
Crabapple						
Broadcast or band application Ground or aerial equipment	35% WP/D [707-205]	2.8 lb/A	2	NS	7	See "Apple."
	50% WP [707-229]	3 lb/A	2	NS	7	See "Apple."
Cucumber (greenhouse grown)						
Broadcast foliar application Ground equipment	35% WP/D [CA88002900]	0.58 lb/A	3	NS	2	Use limited to CA. No chemigation. Applications may be made in 40-100 gal/A using ground equipment. A restricted entry interval of 24 hours is in effect.
Cucurbits (including cantaloupe, cucumber, melon, pumpkin, squash, and watermelon)						
Broadcast or band application Ground or aerial equipment	35% WP/D [707-205]	0.58 lb/A	2	7	2	No chemigation. Applications may be made in a minimum of 5 gal/A using aerial equipment. The feeding of vines, forage, or crop residues to meat or dairy animals is prohibited.
Cucurbits (including cantaloupe, cucumber, melon, pumpkin, squash, and watermelon) (continued)						

(continued; footnotes follow.)

Table A (continued).

Site Application Type Application Timing Application Equipment	Form [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Re- treatment Interval (Days)	PHI (Days)	Use Limitations
Broadcast or band application Ground or aerial equipment	50% WP [707-229]	0.62 lb/A	2	NS	2	No chemigation. Applications may be made in a minimum of 5 gal/A using aerial equipment.
	4 lb/gal FIC [707-201]	0.63 lb/A	2	7	2	No chemigation. Applications may be made in a minimum of 5 gal/A using aerial equipment. The feeding of vines, forage, or crop residues to meat or dairy animals is prohibited.
Broadcast foliar application Aerial equipment	35% WP/D [AZ88001000] [CA92002600]	0.58 lb/A	NS (AZ) 2 (CA)	NS	2	Use limited to AZ and CA. No chemigation. Applications may be made in 5 gal/A (AZ) and 10-20 gal/A (CA) using aerial equipment. Application may be made alone or as a tank mix with other pesticides. The feeding of treated vines, forage, or crop residues to meat or dairy animals is prohibited.
Filbert						
Broadcast or band application Ground or aerial equipment	1.6 lb/gal EC [707-204]	2 lb/A	2	NS	7	See "Chestnut."

(continued; footnotes follow.)

Table A (continued).

Site Application Type Application Timing Application Equipment	Form [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Re- treatment Interval (Days)	PHI (Days)	Use Limitations
Grape						
Broadcast or band application Ground or aerial equipment	35% WP/D [707-205]	1.22 lb/A (WP/D)	2	NS	7	No chemigation. Applications may be made in a minimum of 5 gal/A using aerial equipment.
	50% WP [707-229]	1.2 lb/A (WP and FIC)				
	4 lb/gal FIC [707-201]					
Hickory nut						
Broadcast or band application Ground or aerial equipment	1.6 lb/gal EC [707-204]	2 lb/A	2	NS	7	See "Chestnut."
Hops						
Broadcast or band application Ground or aerial equipment	4 lb/gal EC [707-202]	1.1 lb/A	2	NS	7	No chemigation. Applications may be made in a minimum of 5 gal/A using aerial equipment. The feeding of vines or crop residues to meat or dairy animals is prohibited.
	1.6 lb/gal EC [707-204]	1.1 lb/A	1	Not applicable (NA)	7	
Mint						
Broadcast or band application Ground or aerial equipment	4 lb/gal FIC [707-201]	1.25 lb/A	1	NA	30	No chemigation. Applications may be made in a minimum of 5 gal/A using aerial equipment. The feeding of spent hay or fresh hay to meat or dairy animals is prohibited.
	4 lb/gal EC [707-202]	1.2 lb/A	1	NA	30	
	1.6 lb/gal EC [707-204]	1 lb/A	1	NA	30	

(continued; footnotes follow.)

Table A (continued).

Site Application Type Application Timing Application Equipment	Form [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Re- treatment Interval (Days)	PHI (Days)	Use Limitations
Nectarine (see "Cherry/nectarine/plumcot")						
Peach^c						
Broadcast or band application Ground or aerial equipment	35% WP/D [707-205] 50% WP [707-229]	1.5 lb/A	2	NS	7	
Pear						
Broadcast or band application Ground or aerial equipment	35% WP/D [707-205]	2.8 lb/A	2	NS	7	See "Apple."
	50 % WP [707-229]	3 lb/A	2	NS	7	See "Apple."
Pecan						
Broadcast or band application Ground or aerial equipment	4 lb/gal EC [707-202] 1.6 lb/gal EC [707-204]	2 lb/A	2	NS	7	No chemigation. Applications may be made in a minimum of 5 gal/A using aerial equipment.
Broadcast foliar application Ground equipment	4 lb/gal EC [GA88000600] [LA88000700] [MS90000400] [TX93001800]	2 lb/A	2	NS	7	Use limited to GA, LA, MS, and TX. No chemigation. Applications may be made alone or as a tank mix.

(continued; footnotes follow.)

Table A (continued).

Site Application Type Application Timing Application Equipment	Form [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Re- treatment Interval (Days)	PHI (Days)	Use Limitations
Pepper						
Broadcast or band application Ground or aerial equipment	4 lb/gal EC [707-202]	0.75 lb/A	1	NA	2	No chemigation. Applications may be made in a minimum of 5 gal/A using aerial equipment. The feeding of treated plants, forage, or crop residues to meat or dairy animals.
Plum (see "Peach/plum/prune")						
Plumcot (see "Cherry/nectarine/plumcot")						
Prune (see "Peach/plum/prune")						
Quince						
Broadcast or band application Ground or aerial equipment	35% WP/D [707-205]	2.8 lb/A	2	NS	7	See "Apple."
	50% WP [707-229]	3 lb/A	2	NS	7	See "Apple."
Raspberry ^b						
Broadcast foliar application Postbloom Ground equipment	35% WP/D [OR90001500] [VA89000500]	1.225 lb/A	NS	NS	2	See "Blackberry."
	35% WP/D [PA92000400] [WA90002200]	1.225 lb/A	2	NS	7	

(continued; footnotes follow.)

Table A (continued).

Site Application Type Application Timing Application Equipment	Form [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Re- treatment Interval (Days)	PHI (Days)	Use Limitations
Strawberry						
Broadcast or band application Ground or aerial equipment	35% WP/D [707-205] 50% WP [707-229] 4 lb/gal EC [707-202] ^d 1.6 lb/gal EC [707-204] ^d	1 lb ai/A ^e	2	NS	3 ^e	No chemigation. Applications may be made in a minimum of 5 gal/A using aerial equipment.
— Drench spray or spot treatment — Spring (new growth) or foliar — Ground or aerial equipment^d	4 lb/gal EC [CA77005300]	2.4 lb/A	3	10	2	Use limited to CA. No chemigation. Applications may be made in up to 400 gal/A using ground equipment.
Tomato						
Broadcast or band application Ground or aerial equipment	4 lb/gal EC [707-202]	0.75 lb/A	1	NA	2	See "Pepper."
Walnut						
Broadcast or band application Ground or aerial equipment	4 lb/gal EC [707-202] 1.6 lb/gal EC [707-204]	2 lb/A	2	NS	7	See "Pecan."

^a The use patterns presented are proposed revisions for Rohm and Haas product labels that have reviewed and approved by the Agency (CBRS No. 12732, DP Barcode D196223, S. Funk, 12/21/93; CBRS No. 12734, DP Barcode D196335, S. Funk, 4/14/94; CBRS No. 13521, DP Barcode D201819, S. Funk, 06/23/94), unless otherwise noted.

Table A (continued).

- b These use patterns are not supported currently by adequate residue data. Three additional trials are required, one trial in WA/OR (region 12) and one trial each in region 2 and region 6 for blackberries and/or one trial each in region 1 and in region 5 for raspberries. (CBRS No. 15104, DP Barcode D211756, S. Funk, 03/01/95).
- c The registrant is not supporting use of the EC formulation (707-204; CBRS No. 15168, DP Barcode D212541, S. Funk, 03/23/95).
- d Use on strawberries must be deleted from EC formulation labels. There are no supporting data.
- e Labels must be amended to reflect this use pattern.

Table B. Residue chemistry science assessments for reregistration of dicofol.

GLN: Data Requirements	Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
171-3: Directions for Use		Yes ²	
171-4 (a): Plant Metabolism		No	00004275 00004321 05000993 05004877 05006219 05006528 40042003 ³ 40042004 ³ 40042005 ³ 40953701 40958002 41231901 ⁴ 42971402 ⁵
171-4 (b): Animal Metabolism		No	40042006 ³ 40042007 ³ 40958001 40958003 42276101 ⁶ 42276102 ⁶
171-4 (c/d): Residue Analytical Methods		Yes ⁷	00004420 00004341 00004371 00004426 05004945 05004951 05005141 05005165 05005167 05005274 05005537 05006312 05006330 05017942 05012262 05019781 40042008 ³ 40042030 ⁸ 40042031 ⁸ 40644601 ⁷ 40644603 40644605 40644606 40644607 40644608 40944602 40944603 40944604 41231902 41231903 41231904 41231905 41231906 41231907 41380401 42514802⁹ 42514803 ⁹ 43146501 ¹⁰
171-4 (e): Storage Stability		No	40042009 ⁸ 40042010 ⁸ 40042011 ⁸ 40644605 40644607 40644608 42971403 ⁵ 42971404 ⁵ 42971405 ⁵ 43146503 ¹⁰ 43146504 ¹⁰ 43146505 ¹⁰ 43383904 ¹¹

Table B (continued).

GLN: Data Requirements	Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
171-4 (k): Magnitude of the Residue in Plants			
<u>Legume Vegetables (Succulent/Dried) Group</u>			
- Beans (dry)	5 [§180.163]	No ¹²	00004305 40042017 ⁸ 41231907 41380401
- Beans (succulent)	5 [§180.163]	No ¹³	00004305 00019894 42297201 ¹⁴ 42971407 ⁵ 42971408 ⁵
- Beans (lima)	5 [§180.163]	No ¹⁵	00004305 00019894 42297201 ¹⁴ 42971407 ⁵ 42971408 ⁵
<u>Fruiting Vegetables Group</u>			
- Eggplant	5 [§180.163]	No ¹⁶	00004305
- Peppers	5 [§180.163]	No ¹⁷	00004305 40944602 40944603
- Pimentos	5 [§180.163]	No ¹⁸	00004305 40944602 40944603
- Tomatoes	5 [§180.163]	No ¹⁹	00004305 40944604
<u>Cucurbit Vegetables Group</u>			
- Cantaloupes	5 [§180.163]	No ²⁰	00004305 40042018 ⁸ 40042019 ⁸
- Cucumbers	5 [§180.163]	No ²⁰	00004305 40042020 ⁸ 41231903
- Melons	5 [§180.163]	No ²⁰	00004305 40042018 ⁸ 40042019 ⁸
- Pumpkins	5 [§180.163]	No ²⁰	00004305 40042018 ⁸ 40042019 ⁸
- Summer squash	5 [§180.163]	No ²¹	00004305 40042021 ⁸

Table B (continued).

GLN: Data Requirements	Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
- Watermelons	5 [§180.163]	No ²⁰	00004305 40042018 ⁸ 40042019 ⁸
- Winter squash	5 [§180.163]	No ²⁰	00004305 40042018 ⁸ 40042019 ⁸
<u>Citrus Fruits Group</u>			
- Grapefruit	10 [§180.163]	No ²²	00004305 40042012 ⁸ 40042013 ⁸
- Lemons	10 [§180.163]	No ²²	00004305 40042012 ⁸ 40042013 ⁸ 41231904
- Limes	10 [§180.163]	No ²²	00004305 40042012 ⁸ 40042013 ⁸ 41231904
- Kumquats	10 [§180.163]	No ²²	00004305 40042012 ⁸ 40042013 ⁸
- Oranges	10 [§180.163]	No ²²	00004305 40042012 ⁸ 40042013 ⁸ 41231902
- Tangerines	10 [§180.163]	No ²²	00004305 40042012 ⁸ 40042013 ⁸
<u>Pome Fruits Group</u>			
- Apples	5 [§180.163]	No ²³	00004305 40042014 ⁸ 41231905 43146502 ²⁷
- Crabapples	5 [§180.163]	No ²³	00004305 40042014 ⁸ 41231905
- Pears	5 [§180.163]	No ²⁴	00004305 40042015 ⁸ 40042016 ⁸
- Quinces	5 [§180.163]	No ²³	00004305 40042014 ⁸ 41231905
<u>Stone Fruits Group</u>			
- Apricots	10 [§180.163]	No ²⁵	00004305

Table B (continued).

GLN: Data Requirements	Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
- Cherries	5 [§180.163]	No ²⁶	00004305 42514806 ⁹ 43146504 ¹⁰
- Nectarines	10 [§180.163]	No ²⁵	00004305
- Peaches	10 [§180.163]	No ²⁵	00004305 42514804 ⁹ 43146503 ²⁷ 42975101 ²⁸ 43146503 ¹⁰ 43227803 ²⁹
- Plums/fresh prunes	5 [§180.163]	No ³⁰	00004305 42514805 ⁹
<u>Small Fruits and Berries Group</u>			
- Blackberries	5 [§180.163]	Yes ³¹	00004305
- Boysenberries	5 [§180.163]	Yes ³¹	00004305
- Dewberries	5 [§180.163]	Yes ³¹	00004305
- Grapes	5 [§180.163]	No	00004305 40042024 ⁸
- Loganberries	5 [§180.163]	Yes ³¹	00004305
- Raspberries	5 [§180.163]	Yes ³¹	00004305
- Strawberries	5 [§180.163]	No ³¹	00004305
<u>Tree Nuts Group</u>			
- Bushnuts	5 [§180.163]	No ³²	00004305
- Butternuts	5 [§180.163]	No ³²	00004305
- Filberts	5 [§180.163]	No ³²	00004305
- Hazelnuts	5 [§180.163]	No ³²	00004305
- Hickory nuts	5 [§180.163]	No ³²	00004305
- Pecans	5 [§180.163]	No ³²	00004305 40042022 ⁸

Table B (continued).

GLN: Data Requirements	Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
- Walnuts	5 [§180.163]	No ³²	00004305 40042023 ⁸
<u>Miscellaneous Commodities</u>			
- Cottonseed	0.1 [§180.163]	Yes ³³	00004305 40042025 ⁸ 40042027 ⁸ 41231906 42971406 ⁵
- Figs	5 [§180.163]	No ³⁴	00004305
- Hops	30 [§180.163]	No	00004305 00022895 40944601 42160401 ¹⁴ 42971409 ⁵
- Mint	25 [§180.163]	No	00004272 00004322 00004323 00004324 00021700 00021701
171-4(l): Magnitude of the Residue in Processed Food/Feed			
- Apples	[none]	No ³⁵	40042026 ⁸
- Citrus	[none]	No ³⁶	40042029 ⁸
- Cottonseed	[none]	No ³⁷	40042027 ⁸ 42971410 ⁵
- Grapes	[none]	No ³⁸	40042028 ⁸
- Mint	[none]	No ³⁹	00004321 00021701
- Plums/prunes	[none]	No ⁴⁰	42514805 ⁹ 4314650510
- Tea	45 [§185.410]	No ⁴¹	00021662 ⁴² 00021680 00021682 00021683 00021668 00051013 00051015 42151101 ⁴³ 42214701 ⁴² 42428001 ⁴⁴ 42611901 ⁴⁵
- Tomatoes	[none]	No ⁴⁶	42971411 ⁵

Table B (continued).

GLN: Data Requirements	Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs			
- Fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep	[none]	No ⁴⁷	40042030 ⁸ 40644601 42971405 ⁵
- Milk	[none]	No ⁴⁷	40042030 ⁸ 40644601 42971405 ⁵
- Eggs, and the fat, meat, and meat byproducts of poultry		No ⁴⁸	40042031 ⁸ 40644604 42971404 ⁵
165-1: Rotational Crops (Confined)		Yes ⁴⁹	40042042 ⁵⁰
165-2: Rotational Crops (Field)		Reserved ⁵¹	

1. References in **bold** were reviewed in the Dicofol Update of 9/10/91. Unbolded references were reviewed in the Residue Chemistry Science Chapter of the Reregistration Standard dated 12/83. *Otherwise*, references were reviewed as noted.

2. Rohm and Haas has submitted proposed label revisions for their end-use products (EPA Reg. Nos. 707-201, 707-202, 707-204, 707-205, and 707-229), which were reviewed favorably by CBRS (CBRS No. 12732, DP Barcode D12732, 12/21/93, S. Funk; CBRS No. 15168, DP Barcode D212541, S. 03/23/95, S. Funk; CBRS No. 13521, DP Barcode D201819, 06/23/94, S. Funk; CBRS No. 12734, DP Barcode D196335, 4/14/94, S. Funk). When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer labels.

The registrants must revise the product labels to impose a 1-month plantback interval for legume vegetables, a 4-month plantback interval for cereal grains, and a 1-year plantback interval for all other rotated crops.

The WP and WP/D labels for strawberries must be amended to reflect field trial conditions (2 X 1 lb. a.i./AC, 3 day PHI).

The EC labels must be amended to delete use on strawberries, including the SLN CA77005300. There are no supporting field trial data.

3. CBRS No. 1869, 5/27/87, S. Hummel.

Table B (continued).

4. CBRS No. 13714, DP Barcode D196335, 4/14/94, S. Funk.
~~5. CBRS No. 6084, DP Barcode D196335, 4/14/94, S. Funk.~~
6. CBRS No. 9848, DP Barcode D178183, 8/13/92, S. Funk.
7. The proposed enforcement method for meat, poultry, and milk adequately recovers dicofol and FW-152; this method must undergo independent laboratory validation. Eggs must be included in the validation.

Method TR-310-86-74 for plant matrices must be validated by an independent laboratory.
8. CBRS No. 2578, 10/19/87, S. Hummel.
9. CBRS No. 11263, DP Barcode D186862, 8/27/93, S. Funk.
10. CBRS No. 13379, DP Barcode D200539, 4/14/94, S. Funk.
11. CBRS No. 14499, DP Barcode D208286, 3/23/95, S. Funk.
12. The established tolerance for beans, dry, can be reduced from 5 to 0.5 ppm, based on maximum dicofol residues of 0.46 ppm in/on dry beans (MRID 41231907).
13. The established tolerance for beans, succulent, can be reduced from 5 ppm to 3 ppm, based on maximum dicofol residues of 2.09 ppm in succulent beans following registered use (MRID 42297201).
14. CBRS No. 9968, DP Barcode D178940, 9/23/92, F. Fort.
15. The established tolerance for lima beans should be revoked as lima beans are covered by the tolerance for beans, succulent.
16. The established tolerance for eggplant is supported by tomato and pepper residue data. Based on these data, the established tolerance for eggplant should be lowered from 5 ppm to 2 ppm. An amendment request to add eggplant to the Rohm and Haas Kelthane MF label (707-202) was reviewed favorably. CBRS No. 13520, DP Barcode D201807, 06/23/94, S. Funk.
17. The established tolerance for peppers can be lowered from 5 ppm to 2 ppm, based on a maximum residue of 0.97 ppm in/on peppers (MRIDs 40944602 - 03).
18. The tolerance for pimentos should be revoked, as pimentos are covered by the established tolerance for peppers. 40 CFR §180.34(f)(9)(viii). CBRS No. 13500, DP Barcode D201451, 05/21/94, S. Funk.
19. The established tolerance for tomatoes can be decreased from 5 ppm to 2 ppm, based on maximum residues of 0.46 ppm resulting from registered use (MRID 40944601) and the registrant's request for a fruiting vegetables group tolerance (PP#4E366, CBTS 13900, DP barcode D204684, 2/28/95, M. J. Nelson).

Table B (continued).

20. The established tolerances for cantaloupes, cucumbers, melons, muskmelons, pumpkins, watermelons, and winter squash can be decreased from 5 ppm to 1 ppm, based on maximum residues of 0.45 ppm in/on cucumbers (MRID 40042020), and 0.35 ppm in melons (MRIDs 40042018 and -19) from registered uses. However, to achieve compatibility with the established Codex MRL, CBRS is recommending a tolerance of 2 ppm in/on cucumbers.
21. The established tolerance for summer squash can be lowered from 5 ppm to 2 ppm, based on maximum residues of 1.05 ppm in/on squash (MRID 40042021).
22. The established tolerances for oranges, tangerines, and limes can be lowered from 10 ppm to 5 ppm, based on a maximum residue of 3.55 ppm for oranges. The established tolerance for grapefruit can be lowered from 10 ppm to 6 ppm, based on a maximum field trial residue of 5.26 ppm for dicofol on grapefruit, and the established tolerance for lemons can be lowered from 10 ppm to 2 ppm, based on a maximum field trial residue of 1.34 ppm.
23. The established tolerances for apples, crabapples, and quinces should be increased from 5 ppm to 7 ppm, based on maximum dicofol residues in apples of 6.7 ppm (MRID 40042014).
24. The established 5 ppm tolerance pears should be increased to 12 ppm, based on maximum residues of 10.8 ppm (MRID 40042015 and -16).
25. The established tolerances for peaches, nectarines, and apricots can be lowered from 10 ppm to 5 ppm, based on maximum residues of 3.79 ppm in peaches (MRID 42975101). Residue data submitted for peaches will apply to apricots and nectarines.
26. The established tolerance for cherries can be lowered from 5 to 4 ppm, based on maximum residues of 3.08 ppm (MRID 42514806).
27. CBRS No. 13379, DP Barcode D200539, 4/14/94, S. Funk.
28. CBRS No. 12735, DP Barcode D196290, 3/16/94, S. Funk.
29. CBRS No. 13711, DP Barcode D203428, 6/23/94, S. Funk.
30. The established tolerance for plums (fresh prunes) can be decreased from 5 ppm to 1 ppm, based on maximum residues of 0.84 ppm in plums (MRID 42514805).
31. IR-4 intends to provide residue data on caneberries, and has submitted two field trials from region 12: one each blackberry and raspberry (CBRS No. 15104, DP Barcode D211756, 3/1/95, S. Funk). A minimum of three additional trials is required on blackberry or raspberry in the following geographic regions: region 12 (1), region 2 (1, blackberry), region 6 (1, blackberry), region 1 (1, raspberry), and region 5 (1, blackberry). One trial must be conducted in region 12; the remaining 2 trials may be conducted in any 2 regions indicated.

Adequate field trial data have been submitted for strawberries (CBRS No. 16050, DP Barcode D218452, S. Funk, 09/19/95). The data support use of the D and WP formulations only at 2 X 1lb.a.i./acre, 3 day PHI. The WP/D labels must be revised to reflect this use pattern, and use on strawberries must be deleted from EC labels. The data for pecans and walnuts will apply to bushnuts, butternuts, chestnuts, filberts, hazelnuts, and hickory nuts. The established tolerances for nuts can be decreased from 5 ppm to 0.1 ppm, based on nondetectable residues (<0.01 ppm) in pecans and walnuts (MRIDs 40042022 and -23).

33. CBRS now requires residue data for cotton gin byproducts (commonly called gin trash) which includes burrs, leaves, stems, lint, immature seeds, sand, and dirt. As these data requirements are based on Table II (09/95) for Subdivision O (Residue Chemistry) of the Pesticide Assessment Guidelines, they are considered confirmatory data and should not impede the reregistration process.
34. The use on figs is not being supported. All fig uses must be deleted from product labels and the tolerance must be revoked.
35. Residues concentrated an average of 6.6x in wet apple pomace. This concentration factor applied to the highest average field trial residue value, 2.32 ppm, yields a ready to eat concentration of 15 ppm. A feed additive tolerance of 15 ppm is needed for wet apple pomace, but the DES Proviso precludes establishment of a 409 FAT.
36. Residues concentrated an average of 62.8x in orange oil. This concentration factor applied to the highest average field trial residue value, 3.16 ppm, yields a not ready to eat concentration of 200 ppm. The appropriate dilution factor for ready to eat is 238. Therefore, a Section 701 maximum residue limit of 200 ppm is required for dicofol residues in citrus oil.
37. Food/feed additive tolerances and/or MRL's are not required. CBRS No. 15885, DP Barcode D217490. S. Funk, 08/29/95.
38. Residues concentrated an average of 6.6x in raisins. Application of this concentration factor to the highest average field trial residue, 3.02 ppm, yields a ready to eat concentration of 20 ppm. A Section 409 FAT of 20 ppm is needed for dicofol residues in raisins.
39. A Section 701 maximum residue limit of 30 ppm is required for peppermint and spearmint oils. The average processing factor was 1.6x, and the highest average field trial residue (excluding D formulation) was 17.6 ppm.
40. Dicofol residues concentrated an average of 3.1x in dried prunes. Application of this factor to the highest average field trial residue value, 0.79 ppm, yields a ready to eat residue of 2.5 ppm. Therefore, a food additive tolerance of 3 ppm is needed for prunes.
41. EPA issued a Final Rule revoking the established tolerance (45 ppm) for residues of dicofol in dried tea (59 FR 10993, 3/9/94) to be effective 5/9/94. EPA stayed the effective date of the final rule (59 FR 23799, 5/9/94) owing to objections filed by the Dicofol Task force and the National Agricultural Chemical

Table B (continued).

Association.

Rohm and Haas and Makhteshim-Agan have petitioned (PP#3E4218) for a RAC tolerance on "plucked tea" at 45 ppm. CBTS recommended for a Section 408 tolerance of 30 ppm for dicofol residues in/on plucked tea leaves and for a Section 701 tolerance of 50 ppm for residues of dicofol in dried tea leaves.

42. These studies on tea (MRIDs 00021662 through 00051015) were not cited in the 1983 Guidance Document; these studies were reviewed in conjunction with PP#6H2025.
43. CBRS Nos. 9065/9467/9467/9469, DP Barcodes D171988/D174293/D174319, 4/7/92, J. Smith.
44. CBRS No. 10434, DP Barcode D181848, 9/25/92, S. Funk.
45. CBRS No. 11583, DP Barcode D189175, 4/26/93, S. Funk.
46. No food/feed additive tolerances are needed. CBRS No. 15885, DP Barcode D217490. S. Funk, 08/29/95.
47. The re-calculated ruminant maximum theoretical dietary burden is about 10 ppm for dairy cattle and 17 ppm for beef cattle. The 10 ppm and 30 ppm feeding studies have evaluated (CBRS No. 15513 Addendum, DP Barcode D214974, 08/30/95, S. Funk) for estimating appropriate ruminant tolerance levels. The data indicate that the following tolerances are appropriate for the combined residues of dicofol and FW-152 in ruminant tissues and milk:

Cattle, meat	1 ppm
Cattle, mbyp (excluding liver and kidney)	1 ppm
Cattle, kidney	1 ppm
Cattle, liver	2 ppm
Cattle, fat	20 ppm
Goats, meat	1 ppm
Goats, mbyp (excluding liver and kidney)	1 ppm
Goats, kidney	1 ppm
Goats, liver	2 ppm
Goats, fat	20 ppm
Hogs, meat	1 ppm
Hogs, mbyp (excluding liver and kidney)	1 ppm
Hogs, kidney	1 ppm
Hogs, liver	2 ppm
Hogs, fat	20 ppm
Horses, meat	1 ppm
Horses, mbyp (excluding liver and kidney)	1 ppm
Horses, kidney	1 ppm
Horses, liver	2 ppm
Horses, fat	20 ppm

Table B (continued).

Milk	9.0 ppm (reflecting 0.3 ppm in whole milk)
Sheep, meat	1 ppm
Sheep, mbyp (excluding liver and kidney)	1 ppm
Sheep, kidney	1 ppm
Sheep, liver	2 ppm
Sheep, fat	20 ppm

48. The recalculated maximum theoretical dietary burden for poultry is 0.02 ppm. Using a 0.5 ppm feeding study and adjusting for the difference in theoretical and actual feeding levels, the following tolerances are deemed appropriate for the combined residues of dicofol and FW-152 in poultry tissues (CBRS No. 14225, DP Barcode D206745, S. Funk, 09/12/95):

eggs	0.1 ppm
poultry, fat	0.1 ppm
poultry, liver	0.1 ppm
poultry, mbyp (exc. liver)	0.1 ppm
poultry, meat	0.1 ppm

49. A new confined rotational crop study will be conducted (CBRS 13713, DP Barcode D203431, S. Funk, 06/23/94). Existing data support a 1-month plantback interval for legume vegetables, a 4-month plantback interval for cereal grains, and a 1-year plantback interval for all other rotated crops (CBRS No. 12340, DP Barcode D193933, 2/24/94, S. Funk).

50. CBRS No. 12340, DP Barcode D193933, 2/24/94, S. Funk.
CBRS No. 13713, DP Barcode D203431, 6/23/94, S. Funk.

51. Reserved, pending results of the confined rotational crop study. Plantback intervals in note #49 must be placed on labels.

TOLERANCE REASSESSMENT SUMMARY

Tolerances Listed Under 40 CFR §180.163:

The raw agricultural commodity tolerances listed under 40 CFR §180.163 are currently expressed in terms of dicofol *per se*. The listing of tolerances for residues in/on plant commodities should be designated 40 CFR §180.163(a); as a new section, 40 CFR §180.163(b), must be provided for the listing of animal tolerances expressed in terms of the combined residues of dicofol and its metabolite FW-152. Refer to Table C for modifications in commodity definitions.

Sufficient data are available to ascertain the adequacy of the established tolerances for the following commodities: apples, apricots, beans (dry), beans (succulent), beans (lima), bushnuts, butternuts, cantaloupes, cherries, chestnuts, cottonseed, crabapples, cucumbers, filberts, grapefruit, grapes, hazelnuts, hickory nuts, hops, kumquats, lemons, limes, melons, muskmelons, nectarines, oranges, peaches, pears, pecans, peppermint hay, peppers, pimentos, plums (fresh prunes), pumpkins, quinces, spearmint hay, strawberries, summer squash, tangerines, tomatoes, walnuts, watermelons, and winter squash. Sufficient data exist to support the established tolerance for caneberries, but additional confirmatory data are required, and such will be supplied by IR-4.

There is no registered use for dicofol on figs; this tolerance should be revoked.

The established tolerances for bushnuts, butternuts, chestnuts, filberts, hazelnuts, hickory nuts, pecans, and walnuts can be lowered from 5 ppm to 0.1 ppm, based on nondetectable residues (<0.01 ppm) in/on pecans and walnuts following registered use.

The established tolerance for beans, dry, can be reduced from 5 to 0.5 ppm and the tolerance for beans, succulent, can be reduced from 5 ppm to 3 ppm. Maximum dicofol residues were 0.46 ppm in dry beans and 2.09 ppm in succulent beans following registered use. The established tolerance for lima beans should be revoked as lima beans are covered by the tolerance for beans, succulent.

The established tolerance for summer squash can be lowered from 5 ppm to 2 ppm and the established tolerances for cantaloupes, cucumbers, melons, muskmelons, pumpkins, winter squash, and watermelons can be decreased from 5 ppm to 1 ppm. Maximum residues were 1.05 ppm in/on summer squash, 0.45 ppm in/on cucumbers, and 0.35 ppm in melons from registered uses. However, to achieve compatibility with the established Codex MRL, CBRS is recommending a tolerance of 2 ppm in/on cucumbers.

The established tolerance for peppers can be lowered from 5 ppm to 2 ppm, based on a maximum residue of 1.15 ppm in/on peppers, and the established tolerance for pimentos can be revoked as pimentos are covered by the tolerance on peppers. The established tolerance for tomatoes can be decreased from 5 ppm to 2 ppm, based on maximum residues of 0.46 ppm from registered use. The registrant has requested a group 8 (fruiting vegetable) tolerance, and a value of 2 ppm would

be appropriate (PP#4E4366, CBTS No. 13900, DP Barcode D204684, M. J. Nelson, 02/08/95). This group tolerance would encompass groundcherry, pepinos, and tomatillo. The individual tolerances for tomatoes, peppers, and eggplant should be revoked.

The established tolerances for peaches, nectarines, and apricots can be lowered from 10 ppm to 5 ppm, based on maximum residues of 3.79 ppm in peaches, and the established tolerance for plums (fresh prunes) can be decreased from 5 ppm to 1 ppm, based on maximum residues of 0.84 ppm in plums. The established tolerance for cherries can be lowered from 5 ppm to 4 ppm, based on maximum residues of 3.08 ppm in cherries.

The established tolerance for oranges, tangerines, and limes can be lowered from 10 ppm to 5 ppm, based on a maximum field trial residue of 3.55 ppm for oranges. The established tolerance for grapefruit can be lowered from 10 ppm to 6 ppm, based on a maximum field trial residue of 5.26 ppm for dicofol in grapefruit, and the established tolerance for lemons can be lowered from 10 ppm to 2 ppm, based on a maximum field trial residue of 1.34 ppm.

The established tolerance for apples, crabapples, and quinces should be increased from 5 ppm to 7 ppm, based on maximum dicofol residues in apples of 6.7 ppm. The established 5 ppm tolerance for pears should be increased to 12 ppm, based on maximum residues of 10.8 ppm.

The currently established tolerance for hops is based on data for green hops. However, the Agency now considers the RAC for hops to be hops, dried (PR Notice 93-12, 12/23/93). The available residue data on dried hops (8.5% moisture) indicate dicofol residue levels of 5.52-64.3 ppm (CBRS No. 9968, DP Barcode D178940, 9/23/92, F. Fort). Therefore, the tolerance for hops, dried, as a RAC should be established at 65 ppm.

CBRS now requires residue data for cotton gin byproducts (commonly called gin trash) which includes burrs, leaves, stems, lint, immature seeds, sand, and dirt. As these data requirements are based on the Updated Livestock Feeds Table for Subdivision O (Residue Chemistry) of the Pesticide Assessment Guidelines (9/95), they are considered confirmatory data and should not impede the reregistration process.

The established tolerance for nectarines can be revoked, as nectarines are covered by the tolerance on peaches.

CBTS recommended for establishment of a tolerance of 30 ppm for residues of dicofol on fresh plucked tea leaves and for establishment of a maximum residue limit of 50 ppm for dicofol residues in/on dried tea.

Tolerances needed under 40 CFR §180.163(b). The available livestock feeding studies have been evaluated and the data indicate that tolerances are needed on livestock commodities. The maximum theoretical dietary burdens for cows and beef cattle, based on the reevaluated tolerances (Table C), are calculated to be 10 ppm and 17 ppm respectively. The theoretical diet is composed of apple pomace, citrus pulp, cottonseed, cottonseed meal, and cottonseed hulls.

Apple pomace is the largest contributor to the exposure (87% of cow exposure, 91% of beef exposure).

Maximum Dietary Burden for Cows and Beef Cattle						
Commodity	Reassessed Dicofol Tolerance ¹ (ppm)	% Dry Matter ²	Cow		Beef	
			% in Diet ²	Contribution (ppm)	% in Diet ²	Contribution (ppm)
Apples, pomace, wet	15	40	20	7.5	40	15
Citrus, pulp, dried	5	91	20	1.1	25	1.4
Cottonseed	0.1	88	25	0.03	25	0.03
Cottonseed, meal	0.1	89	15	0.02	10	0.01
Cottonseed, hulls	0.1	90	15	0.02	20	0.02
Cottonseed, cotton gin byproducts	TBD	90	20	-	30	-
Other	-	-	5	0	-	-
TOTAL			100%	8.67	100%	16.4

¹ Includes considerations of policy for revised treatment of processing studies and of need for feed additive tolerances (E. Zager, M. Metzger, 07/17/95 Memorandum).

² Table II Update (06/94) and revisions of 09/95.

Recommendations for ruminant commodity tolerances are based on the 10 ppm and 30 ppm feeding studies (~1 - 3x the maximum theoretical dietary intake). Recommended poultry tolerances are based on data from a 0.5 ppm feeding study (~25x), adjusted for the difference between actual and theoretical feeding levels. A new section designated, 40 CFR §180.163(b), must be added to provide listings for the new tolerances required for the combined residues of dicofol and its metabolite FW-152 in meat, fat, and meat byproducts of cattle, goats, hogs, horses, sheep, and poultry, milk, and eggs. Sufficient data are available to determine appropriate tolerance levels for all animal commodities. The recommended tolerances are presented in Table C.

Tolerances Listed Under 40 CFR §185.410:

The food additive tolerance listed under 40 CFR §185.410 are currently expressed in terms of dicofol *per se*. EPA issued a Final Rule revoking the established food additive tolerance for residues of dicofol in dried tea (59 FR 10993, 3/9/94) to be effective 5/9/94. EPA stayed the effective date of the final rule (59 FR 23799, 5/9/94) owing to objections filed by the Dicofol Task force and the National Agricultural Chemical Association. CBTS has recommended revocation of the food additive tolerance for dried tea (40 CFR §185.410) and the establishment of Section 408 tolerance for plucked tea and a Section 701 maximum residue limit for dried tea.

Additional food additive tolerances needed under 40 CFR §185.410. The available data from processing studies indicate that the following food additive tolerances are needed under 40 CFR §185.410: (i) prunes at 3 ppm, based on the highest average field trial residue of 0.79 ppm for dicofol on plums and an average concentration factor of 3.1x; (ii) raisins at 20 ppm, based on the highest average field trial residue of 3.02 ppm on grapes and an average processing factor of 6.6x.

Feed additive tolerances needed under 40 CFR §186.410. Sufficient data are available to determine that the following feed additive tolerance is needed: (i) apple pomace (wet) at 15 ppm, based on the highest average field trial residue of 2.32 ppm and an average concentration factor of ~6.6x in wet pomace. A new section, 40 CFR §186.410, must be added to provide for the listing of these feed additive tolerances. However, the DES Proviso precludes establishment of a 409 FAT.

Maximum residue limits (MRL) needed. The available data indicate that Section 701 maximum residue limits need to be established for: (i) citrus oil at 200 ppm, based on the highest average field trial residue of 3.16 ppm in oranges, and average processing factor of 62.8x for orange oil, and a dilution factor of 238x for ready to eat; and (ii) dried tea leaves at 50 ppm, based on the highest average field trial residue of 29.1 ppm, an average processing factor of 1.6x, and a ready to eat dilution factor of 77x.

Table C. Tolerance Reassessment Summary

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity/Definition
Tolerances Listed Under 40 CFR §180.163^a			
Apples	5	7	New field trials ^c .
Apricots	10	5	See peach ^c .
Beans (dry form)	5	0.5	<i>Beans, dry.</i> New field trials ^c .
Beans, snap (succulent form)	5	3	<i>Beans, succulent.</i> New field trials ^c .
Beans, lima (succulent form)	5	Revoke	Covered by tolerance for beans, succulent ^c .
Blackberries	5	5	Additional data required.
Boysenberries	5	5	Additional data required.
Bushnuts	5	0.1	See pecan/walnut ^c .
Butternuts	5	0.1	See pecan/walnut ^c .
Cantaloupe	5	1	New field trials ^c .
Cherries	5	4	New field trials ^c .
Chestnuts	5	0.1	See pecan/walnut ^c .
Cottonseed	0.1	0.1	<i>Cotton, seed</i>
Cotton Gin Byproducts	None	TBD ^b	Required by changes in Table II (06/94) ^c .
Crabapples	5	7	See apple ^c .
Cucumbers	5	2	New field trials ^c .
Dewberries	5	5	Additional data required.
Eggplants	5	Revoke	Replaced with Fruiting Vegetables Group Tolerance ^c .
Figs	5	Revoke	No registered use exists ^c .
Filberts/Hazelnuts	5	0.1	See pecan/walnut ^c .
Fruiting Vegetables Group	None	2	Registrant petition and new field trials (tomato, pepper) ^c .
Grapefruit	10	6	New field trials ^c .
Grapes	5	5	
Hickory nuts	5	0.1	See pecan/walnut.
Hops	30	65	<i>Hops, dried.</i> RAC redefined ^c .
Kumquats	10	5	See orange ^c .
Lemons	10	2	New field trials ^c .
Limes	10	5	See orange ^c .
Loganberries	5	5	Additional data required.
Melons	5	1	New field trials (cantaloupes, muskmelon) ^c .

Table C (continued).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity/Definition
Muskmelons	5	1	New field trials ^e .
Nectarines	10	5	See peach ^e .
Oranges	10	5	New field trials ^e .
Peaches	10	5	New field trials ^e .
Pears	5	12	New field trials ^e .
Pecans	5	0.1	New field trials ^e .
Peppermint, tops	25	25	
Peppers	5	Revoke	Replaced with Fruiting Vegetables Group Tolerance ^e .
Pimentos	5	Revoke	Covered by Fruiting Vegetables Group Tolerance ^e .
Plums (fresh prunes)	5	1	New field trials ^e .
Pumpkins	5	1	See squash ^e .
Quinces	5	6	See apple ^e .
Raspberries	5	5	Additional data required.
Spearmint, tops	25	25	
Strawberries	5	5	Labels must be amended to reflect field trials.
Summer squash	5	2	<i>Squash, summer.</i> New field trials ^e .
Tangerines	10	5	See orange ^e .
Tea, plucked leaves	None	30	New RAC definition ^c .
Tomatoes	5	Revoke	Replaced with Fruiting Vegetable Group Tolerance ^e .
Walnuts	5	0.1	New field trials ^e .
Watermelons	5	1	See melons ^e .
Winter squash	5	1	<i>Squash, winter.</i> See summer squash, cucumber, melon ^e .
Tolerances Needed Under 40 CFR §180.163(b)			
Cattle, meat	None	1	Feeding study ^e .
Cattle, mbyp (excluding liver and kidney)	None	1	Feeding study ^e .
Cattle, kidney	None	1	Feeding study ^e .
Cattle, liver	None	2	Feeding study ^e .
Cattle, fat	None	20	Feeding study ^e .
Eggs	None	0.1	Feeding study ^e .

Table C (continued).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity/Definition
Goats, meat	None	1	Feeding study ^e .
Goats, mby (excluding liver and kidney)	None	1	Feeding study ^e .
Goats, kidney	None	1	Feeding study ^e .
Goats, liver	None	2	Feeding study ^e .
Goats, fat	None	20	Feeding study ^e .
Hogs, meat	None	1	Feeding study ^e .
Hogs, mby (excluding liver and kidney)	None	1	Feeding study ^e .
Hogs, kidney	None	1	Feeding study ^e .
Hogs, liver	None	2	Feeding study ^e .
Hogs, fat	None	20	Feeding study ^e .
Horses, meat	None	1	Feeding study ^e .
Horses, mby (excluding liver and kidney)	None	1	Feeding study ^e .
Horses, kidney	None	1	Feeding study ^e .
Horses, liver	None	2	Feeding study ^e .
Horses, fat	None	20	Feeding study ^e .
Milk	None	9.0	Reflecting 0.3 ppm in whole milk corrected by a 30X factor to account for concentration in milk fat. Feeding study ^e .
Poultry, fat	None	0.1	Feeding study ^e .
Poultry, liver	None	0.1	Feeding study ^e .
Poultry, mby (excluding liver)	None	0.1	Feeding study ^e .
Poultry, meat	None	0.1	Feeding study ^e .
Sheep, meat	None	1	Feeding study ^e .
Sheep, mby (excluding liver and kidney)	None	1	Feeding study ^e .
Sheep, kidney	None	1	Feeding study ^e .
Sheep, liver	None	2	Feeding study ^e .
Sheep, fat	None	20	Feeding study ^e .

Tolerances Listed Under 40 CFR §185.410

Table C (continued).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity/Definition
Dried tea	45	Revoke	<i>Tea, dried.</i> Plucked tea added as a RAC; dried tea now is Sec. 701 MRL ^c .
Tolerances Required Under 40 CFR §185.410			
Grapes, raisins	None	20	Processing study ^c .
Prunes	None	3	Processing study ^c .
Tolerances required Under 40 CFR §186.410			
Apples, pomace, wet	None	15	Processing study ^c .
Maximum Residue Limits required under 40 CFR § ?????			
Citrus oil	None	200	Processing study ^c .
Tea, dried leaves	None	50	Processing study ^c .
Mint oil	None	30	Processing study ^c .

- ^a The listing of tolerances for residues in/on plant commodities should be designated 40 CFR §180.163(a), as a new section, 40 CFR §180.163(b), must be provided for the listing of animal tolerances expressed in terms of the combined residues of dicofol and its metabolite FW-152.
- ^b TBD = To be determined when all data requirements are satisfied.
- ^c Reason for tolerance change.

ANTICIPATED RESIDUES

Anticipated residues for dietary risk for acute and chronic exposure have been determined (S. Funk, CBRS 14225, DP Barcode D206745, 09/12/95).

CODEX HARMONIZATION

Several maximum residue limits (MRLs) for dicofol have been established by Codex in various commodities. Codex MRLs and corresponding U.S. tolerances, both currently expressed in terms of dicofol *per se*, are listed in Table D.

Table C (continued).

Table D. Codex MRLs and Applicable U.S. Tolerances.

Commodity	MRL (mg/kg) ^a	U.S. Tolerance (ppm) ^b	Recommendation/ Comments
Cucumber	2	5	A U.S. tolerance of 2 ppm is recommended.
Fruit ^c	5	5; 10	The U.S. tolerances for some fruits cannot be lowered to 5 ppm.
Gherkin	2	None	
Hops (dry)	5	30	The U.S. tolerance cannot be lowered to 5 ppm. Increase to 65 ppm is recommended.
Strawberry	1	5	The U.S. tolerance cannot be lowered to 1 ppm.
Tea, green, black	5	30	The U.S. tolerance (plucked tea) cannot be lowered to 5 ppm.
Tomato	1	2	The U.S. tolerance cannot be lowered to 2 ppm.
Vegetables ^c	5	5	Compatibility currently exists, although lowered U.S. tolerances are recommended for beans, cucurbit vegetables, and fruiting vegetables.

^a All dicofol MRLs are final (CXL). ^b Based on dicofol *per se*.

^c The 22nd CCPR agreed to consider deletion of the general CXL if requested information is not available to the next session (22.268).

The following conclusions can be made regarding efforts to harmonize U.S. tolerances with the Codex MRLs:

Compatibility currently exists between the Codex MRL for "Vegetables" and applicable U.S. tolerances. However, as the CCPR is considering deletion of this general CXL, CBRS is recommending for the lowering of the U.S. tolerances.

Based on the currently registered use pattern, dicofol residues in/on dried hops would exceed the Codex MRL. The U.S. tolerance cannot be lowered to achieve compatibility.

Compatibility currently exists between the Codex MRL for "Fruits" and some of the applicable U.S. tolerances. However, based on the currently registered use pattern, dicofol residues would exceed the Codex MRL in some fruits and these U.S. tolerances cannot be lowered to achieve compatibility.

Compatibility exists between the Codex MRL for tea and the US MRL for dried tea, 50 ppm.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No.: 13379
DP Barcode: D200539
Subject: Upgrades for Peach, Cherry, and Plum/Prune Field trials. Apple Field Trials. Analytical Method for Citrus.
From: S. Funk
To: L. Propst
Dated: 04/14/94
MRID(s): 43146501 through -05

CBRS No.: 12734
DP Barcode: D196335
Subject: Registrant Response to Subject Registration Standard Update
From: S. Funk
To: L. Propst
Dated: 04/14/94
MRID(s): 42971402 and 42971411

CBRS No.: 12735
DP Barcode: D196290
Subject: Enforcement Analytical Method for Animal Commodities. Additional Peach Field Trials.
From: S. Funk
To: L. Propst
Dated: 03/16/94
MRID: 40644601 and 42975101

CBRS No.: 12340
DP Barcode: D193933
Subject: Confined Rotational Crop Study.
From: S. Funk
To: L. Propst and J. Loranger
Dated: 02/24/94
MRID(s): 40042042

CBRS No.: 12732
DP Barcode: D196223
Subject: Reregistration of Dicofol (Kelthane); List A, Case 0021, Chemical 010501
From: S. Funk
To: L. Propst
Dated: 12/21/93
MRID: None

CBRS No.: 11835
DP Barcode: D191011
Subject: Dicofol in/on Plucked Tea. Evaluation of Commodity Definition Change and Residue Data.
From: D. Davis
To: M. Johnson and D. Edwards
Dated: 11/22/93
MRID(s): None

CBRS No.: 11263
DP Barcode: D186862
Subject: Dicofol (Chemical 010501; List A; Case 0021): Plant Analytical Methods (171-4(c)) and Magnitude of the Residue In/On Stone Fruit (171-4(k)).
From: S. Funk
To: L. Propst
Dated: 08/27/93
MRID(s): 42524802 and 42514806

CBRS No.: 11945
DP Barcode: D191597
Subject: Reregistration of Dicofol (Kelthane); List A, Case 0021, Chemical 010501. Registrants' Progress Report and SRRD Requests.
From: S. Funk
To: L. Rossi and L. Propst
Dated: 07/09/93
MRID: 42514800

CBRS No.: 11583
DP Barcode: D189175
Subject: Dicofol: Amendment #1 to Magnitude of the Residue in Black Tea, Green Tea, Instant Tea, and Brewed Tea. Case No. 0021. Chemical No. 010501.
From: S. Funk
To: N. Zahedi and J. McQueen
Dated: 04/26/93
MRID(s): 42611900 and 42611901

CBRS No.: 14499
DP Barcode: D208286
Subject: Dicofol (List A, Case 0021, Chemical 010501). Storage Stability for Apples, Green Beans, Honeydew Melon, Peppers, and Strawberries.
From: S. Funk
To: L. Propst, J. Loranger, J. Redden
Dated: 03/23/95

MRID(s): 43383904
CBRS No.: 15104
DP Barcode: D211756
Subject: Dicofol (List A, Case 0021, Chemical 010501). Canebery Field Trials.
From: S. Funk
To: L. Propst, J. Loranger
Dated: 03/01/95
MRID(s):

CBRS No.: 15885
DP Barcode: D217490
Subject: Dicofol (List A, Case 0021, Chemical 010501). Changes in Food/Feed Additive Tolerances Effected by 07/17/95 Guidance.
From: S. Funk
To: L. Propst, J. Loranger, P. Deschamp, J. Redden
Dated: 08/29/95
MRID(s): None

CBRS No.: 15513 Addendum
DP Barcode: D214974
Subject: Dicofol (List A, Case 0021, Chemical 010501). Resubmittal of Ruminant Feeding Study (171-4(j)). Tolerance Proposals for Ruminant Commodities. Waiver Request for Milk Distribution Study. Dietary Exposure and Risk Assessment.
From: S. Funk
To: L. Propst, J. Loranger
Dated: 08/30/95
MRID(s): 43625300 - 43625304
CBRS No.: None
DP Barcode: None
Subject: The Metabolism Committee Meeting Held on September 2, 1992: Dicofol Plant and Animal Metabolism
From: S. Funk
To: The Metabolism Committee, HED
Dated: 09/29/92
MRID: None

CBRS No.: 15299
DP Barcode: D213282
Subject: Dicofol (List A, Case 0021, Chemical 010501). Product Chemistry Chapter Update for the Reregistration Eligibility Decision Document.
From: S. Funk

To: L. Propst, J. Loranger, J. Redden
Dated: 05/02/95

CBRS No.: 14636
DP Barcode: D208810
Subject: Dicofol (List A, Case 0021, Chemical 010501). Registrant Questions on Unresolved Residue Chemistry Requirements.
From: S. Funk
To: L. Propst, J. Loranger
Dated: 01/31/95
MRID: None

CBRS No.: 15168
DP Barcode: D212541
Subject: Dicofol (List A, Case 0021, Chemical 010501). Registrant Response to Review of Peach Field Trials and Cottonseed Trials.
From: S. Funk
To: L. Propst, J. Loranger, J. Redden
Dated: 03/23/95
MRID: None

CBRS No.: 15187
DP Barcode: D212583
Subject: Dicofol (List A, Case 0021, Chemical 010501). Registrant Tolerance Revision Proposals for Numerous RAC's.
From: S. Funk
To: L. Propst, J. Loranger, J. Redden
Dated: 03/23/95
MRID: 43559001

CBRS No.: 14225
DP Barcode: D212583
Subject: Dicofol (List A, Case 0021, Chemical 010501). Anticipated Residues for Dietary Exposure Risk Analysis.
From: S. Funk
To: L. Propst, J. Loranger, P. Deschamp, J. Redden
Dated: 09/12/95
MRID: None

CBRS No.: None
DP Barcode: None
Subject: Dicofol (List A, Case 0021, Chemical 010501). Use Information.
From: S. Funk

To: Branch Files
Dated: 09/26/95
MRID: None

CBTS No.: 15143
DP Barcode: D212187
Subject: PP#2E04218, Amendment to Petition. Dicofol on Tea Leaves. Change in EPA Policy. Chemical #010501.

From: W. D. Cutchin
To: D. Edwards
Dated: 09/12/95
MRID: 435407

CBRS No.: 10434
Subject: Dicofol: Magnitude of the Residue in Black Tea, Green Tea, Instant Tea, and Brewed Tea.

From: S. Funk
To: A. Sibold and J. Kariya
Dated: 09/25/92
MRID(s): 4242800 and 4242801

CBRS No.: 9968
DP Barcode: D178940
Subject: Dicofol. Case No. 0022. 90-Day Response to the DCI, dated September 30, 1991.

From: F. Fort
To: H. Toma and L. Propst
Dated: 09/23/92
MRID(s): 42160401 and 42297201

CBRS No.: 10179
DP Barcode: D180337
Subject: Dicofol. Amended Label for Kelthane EC.

From: S. Knizner
To: M. Johnson and H. Toma
Dated: 09/02/92
MRID: None

CBRS No.: 10180
DP Barcode: D180418
Subject: Dicofol. Amended Label for Kelthane MF.

From: S. Knizner
To: M. Johnson and H. Toma

Dated: 09/02/92
MRID: None
CBRS No.: 9848
DP Barcode: D178183
Subject: Reregistration of Dicofol. 171-4(b). Nature of the Residue in Laying Hens and Lactating Goats: Supplemental Data.

From: S. Funk
To: L. Rossi
Dated: 08/13/92
MRID(s): 42276100, 42275101, and 42276102

CBRS No.: 9065, 9467-9469
DP Barcode: D171988, D174293, D174319
Subject: Dicofol on Tea. Data from Residue Field Trail Conducted in Japan in 1974; Protocol and Preliminary Data from on-going trails in India; Makhteshim-Agan Response to EPA's proposal to Revoke the Food Additive Tolerance for Dicofol on TEA.

From: J. Smith
To: A. Siebold
Dated: 04/07/92
MRID: 42214701 and 42151101

CBRS No.: None
Subject: Dicofol Product and Residue Chemistry Reregistration Standard Updates.
From: E. Zager
To: L. Rossi and W. Burnam
Dated: 09/10/91
MRID: None

CBRS No.: 6870
Subject: EPA Reg. No. 707-205 Dicofol on Raspberries WA90-00022 24(c) Request for Kelthane 35WP State of Washington Dept. Agriculture Letter of 7/6/90

From: S. Hummel
To: D. Edwards and M. Johnson
Dated: 10/12/90
MRID: None

CBRS No.: 6084
Subject: Rohm and Haas Co. and Makhteshim-Agan (America) Response to the Dicofol Reregistration Standard: Tomato Metabolism Study

From: R. Perfetti
To: R. Engler and L. Rossi

Dated: 05/09/90
MRID(s): 41231900 and 41231901

CBRS No.: 2578
Subject: 010501 - Dicofol. Rohm and Haas Response to Registration Standard
Residue Data and Feeding Studies

From: S. Hummel

To: D. Edwards

Dated: 10/19/87

MRID(s): 40042001 to -02 and -09 to -31

CBRS No.: 1869

Subject: 010501 - Dicofol. Rohm and Haas Response to Registration Standard
Metabolism, Methodology, and Residue Data.

From: S. Hummel

To: D. Edwards

Dated: 05/27/87

MRID(s): 40042001 to -31

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References (used to support established tolerances):

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