United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508C)

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EPA

Reregistration Eligibility Decision (RED)

Dicofol

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508C) | EPA-738-F-98-016 November 1998

EPA R.E.D. FACTS

DICOFOL

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0021, dicofol.

Use Profile

Dicofol is an organochlorine miticide/pesticide used for foliar applications, mostly on cotton, apples, and citrus crops. Other crops include: strawberries, mint, beans, peppers, tomatoes, pecans, walnuts, stonefruit, cucurbits, and non-residential lawns/ornamentals. Formulations registered for use on food/feed crops include emulsifiable concentrates, and wettable powder formulations. These formulations may be applied as concentrated or dilute sprays using aircraft, duster, groundboom, and sprayer.

Regulatory History

Dicofol was first registered as a pesticide in the U.S. in 1957. EPA issued a Registration Standard for dicofol on December 30, 1983. Data Call-Ins on September 30, 1991, March 3, 1995, and October 13, 1995 required additional residue and ecological effects data.

Currently, 32 dicofol products are registered, including end use and manufacturing use products.

Human Health Assessment

Toxicity

Exposure to pesticidal residues of dicofol to the U.S. population can occur via diet through its usage on a wide array of crops, such as apples and citrus. Occupational exposure to dicofol occurs to pesticide workers via its agricultural application.

The Agency has calculated the chronic dietary reference dose (RfD) for dicofol, the amount of pesticide believed not to cause adverse effects if consumed daily over a 70 year lifetime, at 0.004 mg/kg/day based on hormonal toxicity seen in both sexes of an oral chronic dog study.

EPA has calculated an acute dietary reference dose for dicofol, the amount of a pesticide which can be consumed in one day and believed not to cause adverse effects, of 0.05 mg/kg/day based on neurotoxic effects observed after a single oral dose in a rat acute neurotoxicity study.

For the purpose of determining short-term and intermediate term worker risk, the endpoints of concern were selected for developmental and hormonal toxicity observed in rabbit and rat studies.

For the purposes of precautionary language for the registered product labels, dicofol has been found to be toxicity category III (the second lowest of four categories) for acute oral toxicity, acute dermal toxicity, acute eye irritation, and acute dermal irritation. Dicofol has been found to be toxicity category IV (lowest category) for acute inhalation.

Dietary Exposure

People may be exposed to residues of dicofol through the diet. Tolerances or maximum residue limits have been established for dicofol. (See 40 CFR §180.163). The raw agricultural commodity tolerances listed under 40 CFR §180.163 are currently expressed in terms of dicofol *per se*, with no animal tolerances established. The dicofol RED recommends that the listing of tolerances for residues in/on plant commodities be designated 40 CFR §180.163(a), and that a new section, 40 CFR §180.163(b), be provided for the listing of animal tolerances expressed in terms of the combined residues of dicofol and its metabolite FW-152.

The dicofol RED recommends that dicofol tolerances be revised as follows: 1 tolerance level is recommended to be revoked, 4 tolerances are recommended to remain unchanged, 3 tolerances are recommended to be raised, 45 new tolerances are recommended to be established, and 33 tolerance levels are recommended to be moved to a crop grouping. In most cases, tolerance levels being moved to a crop grouping are also having their tolerance levels lowered, based on new field trial data.

Chronic dietary food exposure is calculated at 38% of the RfD in the most at-risk population (children, 1-6 years), not enough to cause concern. Acute dietary exposure estimates, while higher (90% of RfD in the most at-risk

population, non-nursing infants, less than 1 years old), still do not exceed the Agency's Level of Concern.

When possible exposure to pesticidal residues of dicofol through drinking water, taken from conservative modeling estimates, are included in the dietary assessment, the Agency still does not have a risk concern for any population subgroup with either acute or chronic dietary exposure.

Occupational and Residential Exposure

The risk assessment in this RED raises some strong concerns for dicofol mixers/loaders/applicators, and field workers. The endpoint of concern is hormonal and developmental toxicity. At the present time, most short term and all intermediate term scenarios result in Margin of Exposures (MOEs) which exceed the Agency's level of concern, even with engineering controls. However, the Agency believes that the default assumptions used to arrive at this conclusion may have led to an overestimation of that risk (i.e. the default assumption of 100% dermal absorption and a initial Dislodgeable Foliar Residue (DFR) level at 20% of the application rate and assuming residue dissipation of 10% per day). To improve our estimation of dicofol risk, the registrants have initiated a dermal toxicity study, which is due to the Agency on December 31, 1998. In addition, as a result of a Data Call In from October 13, 1995, the registrants are also completing a DFR study, due in October, 1998. EPA will consider results of these studies in a revised risk assessment. In the interim, while this data is being developed and evaluated, the registrants have agreed to undertake risk mitigation measures (described in the Risk Mitigation section of this Fact Sheet) to address the occupational risks identified in this RED.

EPA will revise the Restricted Entry Interval (REI) based upon results of the dermal toxicity study and DFR study.

Because all residential uses are being voluntarily canceled by the registrants, residential risk is not a concern.

FQPA Considerations

EPA conducted additional risk analyses using available data in response to the new FQPA requirements. Based upon data evaluated by the Agency, the 10X FQPA safety factor is being reduced to 3X for all population subgroups for both chronic and acute dietary risk.

The Agency has not made a determination whether dicofol or any other pesticide has a common mechanism of toxicity for either cancer or non-cancer effects and require a cumulative risk assessment. For the purposes of this RED, EPA has considered only the risks from dicofol. If required, cumulative risks will be assessed when methodologies for determining common mechanism of toxicity and for performing cumulative risk assessments are finalized.

Environmental Assessment

Environmental Fate

Dicofol has a short to intermediate half-life (days to months) in laboratory studies. Major routes of dissipation are hydrolysis in neutral and alkaline environments and microbial-mediated degradation. Dicofol is likely to be more persistent in acidic than neutral or alkaline soils or waters and in drier conditions. Laboratory and field data suggest that dicofol is not very mobile, and neither leaching nor volatility are expected to play an important role in the dissipation of dicofol.

Ecological Effects

Dicofol is moderately to slightly toxic on an acute basis to terrestrial animals and slightly toxic to honey bees. Dicofol has also been shown to cause reproductive effects in avian and mammalian species. For avian species, laboratory studies suggest that reproductive sensitivity varies greatly, with raptors apparently the most sensitive. Dicofol is highly to very highly toxic to all aquatic organisms tested, including fish, invertebrates, and estuarine/marine organisms.

Ecological Effects Risk Assessment

Acute risks to non-target mammals from exposure to dicofol may occur for citrus, apples, pears, nuts, and quince uses from exposure to short grass food sources. Because many small mammal species primarily feed on short grass, acute hazard from these use patterns is possible. For avian species, exposure to dicofol in short grass exceeds the Level of Concern (LOC), based on current uses. Since few if any avian species feed solely or even primarily on short grass, the acute hazard from this use does not present an unacceptable risk.

Chronic hazard, in the form of reproductive impairment to mammalian and avian species, can occur for all currently registered use patterns.

For certain avian species, numerous reproductive parameters may be adversely affected by exposure to dicofol. Greatest risk appears to be from citrus. Laboratory data suggest that, for certain avian species, numerous reproductive parameters may be adversely affected by exposure to dicofol, based on present uses.

In aquatic environments, fresh and salt water fish, shellfish, and invertebrates are potentially at risk from direct contamination of dicofol to the water. Indirect contamination is also a concern

Labeling and other risk mitigation measures recommended in Chapters 4 and 5 of the dicofol RED are sufficient to address these environmental risk concerns.

Risk Mitigation

To address risks to homeowners, residents, and children:

- All residential uses have been eliminated from labels and will be voluntarily canceled.

To address risks to handlers:

- Mixers/loaders/applicators must wear additional personal protective equipment (PPE), as specified in the labeling specifics in Chapter 5 of the RED, and use enclosed cabs and cockpits.
- All wettable powder formulations produced after December 31, 1998 must be produced in water soluble packaging (WSP).
- Application with handheld equipment is eliminated for liquid formulations.
- Liquid formulations produced after December 31, 1998 must bear labeling requiring closed mixing systems for dry beans.

To address risks to workers (persons entering treated areas following applications of dicofol):

- A revised REI will be set, based on DFR data being submitted in October, 1998, and on a dermal toxicity study being submitted in December, 1998.

To protect the environment and wildlife:

- Dicofol applications are limited to no more than one per year. Previously, for some uses, the number of applications allowed per year was either unrestricted or limited to 2 or 3 applications per year.
- Dicofol applications on citrus will not exceed 3 pounds a.i./acre per year. This has been reduced from 8 pounds a.i./acre per year.
- Dicofol applications on strawberries will not exceed 2 pounds a.i./acre per year. This has been reduced from 2.4 pounds a.i./acre per year.
- Additionally, as a result of previous agreements with the registrants, applications will not exceed:

  3 lb ai/acre for apples and pears (reduced from 4 lb ai/acre);

  2 lb ai/acre for pecans and walnuts (reduced from 4 lb ai/acre);

  1.5 lb ai/acre for cotton (reduced from 1.6 lb ai/acre);

  1.3 lb ai/acre for grapes (reduced from 1.5 lb ai/acre);

  0.63 lb ai/acre for cucurbits (reduced from 1.5 lb ai/acre);

  0.75 lb ai/acre for tomatoes and peppers (reduced from .8 lb ai/acre);

1.5 lb ai/acre for stonefruits;

1.5 lb ai/acre for beans; and

0.55 lb ai/acre for nonresidential lawns and ornamentals.

- A spray drift and Runoff Caution Statement is being added to the label. Also, a statement prohibiting application directly to water is being added to the label.

Additional Data Required

All dicofol products must comply with EPA's current pesticide product labeling requirements. For a comprehensive list of labeling requirements, see Chapter 5 of the dicofol RED document.

EPA is requiring the following additional generic studies for dicofol to confirm its regulatory assessments and conclusions: a UV/visible absorption study, DFR study, dermal toxicity study, and postnatal developmental neurotoxicity study in addition to other confirmatory studies listed in Chapter 5 of the dicofol RED.

The Agency also is requiring product-specific data including revised Confidential Statements of Formula (CSFs) and revised labeling for reregistration. In addition, the Agency is requiring certain confirmatory data, as detailed in Chapter 4 of the dicofol RED document.

Product Labeling Changes Required

All dicofol end-use products must comply with EPA's current pesticide product labeling requirements. For a comprehensive list of labeling requirements, please see the dicofol RED document, chapter 5.

Regulatory Conclusion

EPA has determined that products containing dicofol may be eligible for reregistration, as specified in the dicofol RED, contingent upon results of a dermal toxicity study due to the Agency in December 1998.

The registrants have agreed to a voluntary cancellation of all dicofol products, which will go into effect if, after a review of the dermal toxicity study, MOEs remain unacceptable. In addition, the registrants have agreed to the risk mitigation measures discussed in the Risk Mitigation section of this Fact Sheet. Moreover, a restricted entry interval (REI) will be set, based on the dermal toxicity study and a DFR study to be submitted to EPA in October 1998.

If results of the dermal toxicity study and DFR study show dicofol to be acceptable, based upon review by the Agency's science peer review committees and EPA management approval, dicofol products will then be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA. Products which contain active ingredients in addition to dicofol will be reregistered when all of their other active ingredients also are eligible for reregistration.

While the current occupational risk assessment indicates possible unacceptable risk levels, EPA has found that it is not appropriate to declare dicofol ineligible at this time. One key consideration is the fact that the registrants are submitting a study which may be a more appropriate study for regulatory purposes but which the Agency has not yet received. Although the Agency would not normally delay a decision for a study voluntarily conducted by a registrant outside the RED timeframe, two factors make this appropriate here. First, the registrants have committed to significant risk mitigation measures to be implemented immediately. Second, the registrants have committed to a process that would result in automatic and voluntary cancellation of any use which continues to have unacceptable risk after EPA completes its review of the incoming new study, in a timeframe that is comparable or more rapid than what EPA could achieve through its own regulatory process.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for dicofol during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone (703) 305-5805.

Electronic copies of the RED and this fact sheet and this fact sheet are available on the Internet. See http:www.epa.gov/REDs.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone (513) 489-8190, fax (513) 489-8695.

Following the comment period, the dicofol RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone (703) 605-6000.

For more information about EPA's pesticide reregistration program, the dicofol RED, or reregistration of individual products containing dicofol, please contact the Special Review and Reregistration Division (7508C), OPP, US EPA, Washington, DC 20460, telephone (703) 308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free (800) 858-7378, between 9:30 am and 7:30 pm Eastern Standard Time, Monday through Friday.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

NOV 25 1998

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case dicofol which includes the active ingredients 1,1-bis(chlorophenyl)-2,2,2-trichloroethanol 1-(2-chlorophenyl)-1-(4-chlorophenyl)-2,2,2-trichloroethanol. The enclosed Reregistration Eligibility Decision (RED), which was approved on September 30, 1998, contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses is due 90 days from the receipt of this letter. The second set of required responses is due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

Please note that the Food Quality Protection Act of 1996 (FQPA) became effective on August 3, 1996, amending portions of both pesticide law (FIFRA) and the food and drug law (FFDCA). This RED takes into account, to the extent currently possible, the new safety standard set by FQPA for establishing and reassessing tolerances. However, it should be noted that in continuing to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA. Rather, these early determinations

will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and any rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Venus Eagle at (703) 308-8045. Address any questions on required generic data to the Special Review and Reregistration Division representative, Phil Budig at (703) 308-8029.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, a DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the **product specific** response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may, but are not required to, delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must

comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By Express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

Dicofol

LIST A

CASE 0021

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION

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DICOFOL REREGISTRATION ELIGIBILITY DECISION TEAM

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
DWLOC	Drinking Water Level of Comparison
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur..
HDT	Highest Dose Tested
IR4	Interregional Research Project No. 4
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
μg/L	Micrograms per liter
mg/L	Milligrams Per Liter

GLOSSARY OF TERMS AND ABBREVIATIONS

MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NOEC	No Observable Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24 © of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency (hereafter referred to as "the Agency") has completed its reregistration eligibility decision of the pesticide active ingredient 1,1-bis(4-chlorophenyl)-2,2,2-trichloroethanol and 1-(2-chlorophenyl)-1-(4-chlorophenyl)-2,2,2-trichloroethanol, also known as dicofol. This reregistration decision includes a comprehensive reassessment of the required data and use patterns of currently registered products. Dicofol is a miticide used 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.

This reregistration decision considered the requirements of the "Food Quality Protection Act of 1996" (FQPA) which amended the Federal Food Drug and Cosmetic Act and the Federal Insecticide Fungicide and Rodenticide Act, the two Federal statutes that provide the framework for pesticide regulation in the United States. FQPA became effective immediately upon signature and all reregistration eligibility decisions (REDs) signed subsequent to August 3, 1996 are accordingly being evaluated under the new standards imposed by FQPA.

In establishing or reassessing tolerances, FQPA requires the Agency to consider aggregate exposures to pesticide residues, including all anticipated dietary exposures and other exposures for which there is reliable information, as well as the potential for cumulative effects from a pesticide and other compounds with a common mechanism of toxicity. The Act further directs EPA to consider the potential for increased susceptibility of infants and children to the toxic effects of pesticide residues, and to develop a screening program to determine whether pesticides produce endocrine disrupting effects.

In summary, based on the data reviewed by EPA, dicofol does not present an acute or chronic dietary risk to the U.S. populations at large, or any subgroups. This analysis includes the contribution from food and water. The agency has determined that dicofol may present serious concerns in occupational and residential settings. The toxicity endpoint of concern in these settings is hormonal toxicity (inhibition of ACTH stimulated cortisol). The Agency has also determined that dicofol may present an ecological risk.

However, the Agency believes that the default assumptions used in the occupational risk assessment may have led to an overestimation of that risk (i.e. the default assumption of 100% dermal absorption and an initial Dislodgeable Foliar Residue (DFR) level at 20% of the application rate and assuming residue dissipation of 10% per day). To improve our estimation of dicofol occupational risk, the registrants have initiated a dermal toxicity study, which is due to the Agency on December 31, 1998. In addition, as a result of a Data Call In from October 13, 1995, the registrants are also completing a DFR study, due in October, 1998. These data will be used to develop revised margins of exposure (MOE) and restricted entry intervals (REI). In the interim, while this data is being developed and evaluated, the registrants have also agreed to undertake several risk mitigation measures to address the occupational risks identified in this RED (described below and in Chapters

IV and V). Additionally, to address the Agency's residential and ecological risk concerns, the registrants have agreed to voluntarily cancel residential uses of dicofol and to adopt ecological risk mitigation.

The Agency will conclude that dicofol is eligible for reregistration if, after consideration of dermal toxicity data submitted by the registrants, the revised MOEs are found to be acceptable (i.e., MOEs above 100). The registrants have submitted a request to voluntarily cancel all uses/products which are found to have unacceptable MOEs after consideration of the new data and if risks cannot be mitigated to acceptable levels.

While the registrants' DFR and dermal exposure studies data are being developed, the following interim measures have been taken, or will be taken, to reduce risk from dicofol to humans and the environment:

1. All residential uses have been deleted from labels and will be voluntarily canceled.
2. Mixer/loader/applicators will be required to wear additional personal protective equipment (PPE) and use enclosed cabs and cockpits.
3. Application with handheld equipment is eliminated for liquid formulations.

d. All wettable powder formulations produced after December 31, 1998 must be produced in water soluble packaging (WSP).

e. Liquid formulations produced after December 31, 1998 must bear labeling requiring closed mixing systems for dry beans.

f. Applications of dicofol will be limited to no more than one per year. Previously, in some uses, the number of applications allowed per year was either unrestricted or limited to two or three applications per year.

7. Citrus application levels have been reduced from 8 lbs. a.i. per acre to 3 lbs. a.i. per acre. Further reductions will be made, if required, based on the results of the ongoing dermal study, within one year of the publication date of this RED.
8. Application rate for wettable powders on strawberries has been reduced to 2 lbs. a.i. per acre, reduced from 2.4 lbs. a.i. per acre.
9. A spray drift and Runoff Caution Statement is being added to the label. Also, a statement prohibiting application directly to water is being added to the label.

While the current occupational risk assessment indicates possible unacceptable risk levels, EPA has found that it is not appropriate to declare dicofol ineligible at this time. One key consideration is the fact that the registrants are submitting a study which may be a more appropriate study for regulatory purposes but which the Agency has not yet received. Although the Agency would not normally delay a decision for a study voluntarily conducted by a registrant outside the RED timeframe, two factors make this appropriate here. First, the registrants have committed to significant risk mitigation measures to be implemented immediately. Second, the registrants have committed to a process that would result in automatic and voluntary cancellation of any use which continues to have unacceptable risk after EPA completes its review of the incoming new study, in a timeframe that is comparable or more rapid than what EPA could achieve through its own regulatory process.

Before reregistering the products containing dicofol, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF), and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. Additionally, except for cases where the basic registrants have made commitments for label changes in 1999, revised labeling must also be submitted within eight months of the issuance of this document. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

On August 3, 1996, the President signed the "Food Quality Protection Act of 1996" (FQPA) (Public Law 104-170), which amended the Federal Food Drug and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Among other things, the FQPA requires the Agency to consider the special sensitivity of infants and children to a pesticide, aggregate exposure of a pesticide from dietary, drinking water, and non-occupational exposures, and cumulative effects from other compounds with a common mode of toxicity when establishing or reassessing tolerances. As a result, EPA is embarking on an intensive process, including consulting with registrants, States, and other interested stakeholders, to make decisions on the new policies and procedures necessary for implementation of FQPA. This process will include a more in-depth analysis of the new safety standard and how it should be applied to both food and non-food pesticide applications. However, FQPA did not amend any of the existing reregistration deadlines in Section 4 of FIFRA. Therefore, the Agency will continue its ongoing registration program while it continues to determine how best to implement the FQPA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of dicofol. The document consists of six sections.

Section I is the introduction.
Section II describes dicofol, its uses, data requirements and regulatory history.
Section III discusses the human health and environmental assessment based on the data available to the Agency.
Section IV presents the reregistration decision for dicofol.
Section V discusses the reregistration requirements for dicofol.
Section VI contains the Appendices which support this Reregistration Eligibility Decision.

Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

Dicofol is a member of the organochlorine class of pesticides. Other members of this class include DDT, methoxychlor, chlorobenzilate, and ethylan. Less closely related members of the class include lindane, dieldrin, endrin, chlordane, heptachlor, aldrin, endosulfan, kepone, and toxaphene (George W. Ware, Fundamentals of Pesticides, Thomson Publications, 1982).

The following active ingredient is covered by this Registration Eligibility Decision (RED).

- **Common Name:** dicofol
- **Chemical Name:** 1,1-bis(chlorophenyl)-2,2,2-trichloroethanol
  1-(2-chlorophenyl)-1-(4-chlorophenyl)-2,2,2-trichloroethanol
- **Chemical Family:** organochlorine
- **CAS Registry Number:** 115-32-2
- **OPP Chemical Code:** 010501
- **Empirical Formula:** $C_{14}H_9Cl_5O$
- **Trade and Other Names:** Kelthane
- **Basic Manufacturers:** Rohm and Haas Company and Makhteshim-Agan

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of the uses of dicofol is in Appendix A

Use Sites: **Terrestrial Food/Feed Crops**

Apple; Apricot; Beans; Beans, dried-type; Beans, succulent (lima); Beans, succulent (snap); Bermuda grass; Blackberry; Boysenberry; Cherry; Chestnut; Citrus fruits; Cotton; Crabapple; Cucumber; Dewberry; Filbert (hazelnut); Grapefruit; Grapes; Hickory nut; Hops; Kumquat; Lemon; Lime; Loganberry; Melons; Melons, cantaloupe; Melons, musk; Melons, water; Mint/peppermint/spearmint; Nectarine;

Orange; Peach; Pear; Pecan; Pepper; Plum; Prune; Pumpkin; Quince; Raspberry (black, red); Squash (all or unspecified); Squash (summer); Squash (winter); Strawberry; Tangelo; Tangerines; Tomato; and Walnut (English/black).

Terrestrial Non-Food

Christmas tree plantations, nonagricultural outdoor buildings and structures, ornamentals

Greenhouse Non-Food

Ornamentals

Greenhouse Food Crop

Cucumber

Indoor Food

Agricultural farm premises, nonagricultural outdoor buildings and structures

Target Pests

Dicofol is used to control numerous species of mites feeding on or found on the above listed sites.

Formulations Types Registered

Technical grade; dust; emulsifiable concentrate; flowable concentrate; wettable powder

Method and Rate of Application

Method- Dip treatment; Dust application; High volume spray (dilute); Low volume spray (concentrate); Outdoor general surface spray; Spot treatment

Equipment- Fixed wing aircraft; Dip tank; Duster; Groundboom; Helicopter; High volume ground sprayer; Low volume ground sprayer; Low volume sprayer; Power sprayer; Sprayer; Tank-type sprayer

Timing- Foliar; Nursery stock; Preharvest; Postharvest; When needed

Rates- see Appendix A

C. Estimated Usage of Pesticide

Based on available pesticide survey usage information for the years of 1987 through 1996, total annual domestic agricultural usage of dicofol averaged about 860,000 pounds active ingredient (a.i.) for about 720,000 acres treated. Most of the acreage is treated with 2 pounds a.i. or less per application, and the average acre is treated with about 1.2 pounds a.i. per year. Fruits tend to have the highest application rates.

The largest markets for dicofol in terms of total pounds active ingredient are cotton (over 50%) and citrus (almost 30%). Although only about 4% of the cotton acres grown are treated with dicofol, over 60% of all crop acres treated with dicofol are cotton acres. The remaining usage is primarily on other fruits and vegetables. Most of the usage is in California and Florida.

Registered nonagricultural sites not listed above nor included in the table below are not covered by EPA data sources. Registered crops not covered by EPA data include crabapples, quinces, and tea.

Table 1 QUANTITATIVE USAGE ANALYSIS--1987-96**

Site	Acres Grown (000)g1	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb ai/ acre/yr	#appl / yr	lb ai/ A/appl	(% of total lb ai used on this site)
Strawberries	51	5	7	10%	13%	10	23	2.0	2.1	0.9	CA FL OR 86%
Other berries	-	-	-	-	5%	-	-	-	-	-	
Oranges	867	59	112	7%	13%	150	305	2.5	1.2	2.1	FL 83%
Grapefruit	194	25	42	13%	22%	89	284	3.6	1.5	2.3	FL TX AZ 100%
Lemons	63	1	3	2%	5%	3	5	1.8	1.0	1.8	AZ 89%
Citrus, Other*	51	3	6	6%	12%	6	14	2.0	1.1	1.7	FL 97%
Apples	572	11	23	2%	4%	14	34	1.3	1.1	1.2	VA IN NY CA MI ME 63%
Pears	78	1	3	1%	4%	2	4	1.6	1.4	1.1	PA CA OR NY 83%
Crabapples	-	-	-	-	-	-	-	-	-	-	
Quinces	-	-	-	-	-	-	-	-	-	-	

Site	Acres Grown (000)g1	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb ai/ acre/yr	#appl / yr	lb ai/ A/appl	(% of total lb ai used on this site)
Peaches	212	0	1	0%	0%	0	1	1.6	1.4	1.2	MA NY CA 82%
Cherries	128	0	0	0%	0%	0	0	1.0	1.0	1.0	CA MI 100%
Plums & Prunes	140	0	0	0%	0%	0	0	0.6	1.7	0.3	CA OH 100%
Stone Fruit, Other*	189	1	5	0%	3%	0	2	0.5	1.0	0.5	CA 100%
Grapes	825	17	33	2%	4%	18	30	1.1	1.1	1.0	CA 96%
Pecans	488	10	31	2%	6%	17	69	1.7	1.7	1.0	GA 80%
Walnuts	205	1	3	1%	1%	3	6	1.9	1.0	1.8	CA 100%
Nut Trees, Other*	712	11	32	2%	5%	17	68	1.6	1.6	1.0	GA CA 95%
Cantaloupes	113	32	55	28%	49%	12	23	0.4	1.0	0.4	CA 100%
Watermelons	258	11	20	4%	8%	7	14	0.6	1.0	0.6	CA AZ 89%
Cucurbits*	285	1	6	0%	2%	2	4	1.5	1.2	1.3	TX CA 89%

Site	Acres Grown (000)g1	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb ai/ acre/yr	#appl / yr	lb ai/ A/appl	(% of total lb ai used on this site)
Tomatoes	500	15	29	3%	6%	9	25	0.6	1.1	0.5	CA SC 82%
Peppers	115	3	12	3%	10%	4	25				
Beans/Peas, Green	723	4	11	1%	2%	5	9	1.2	1.0	1.1	CA 91%
Beans/Peas, Dry	2,181	33	140	2%	6%	38	150	1.1	1.0	1.1	CA 82%
Cotton	12,689	460	586	4%	5%	440	618	1.0	1.0	1.0	CA AZ 90%
Hops	40	2	3	6%	8%	2	3	1.0	1.0	1.0	OR ID 89%
Mint	154	11	16	7%	10%	13	20	1.2	1.0	1.2	ID OR 87%
Tea	-	-	-	-	-	-	-	-	-	-	
Total Agriculture	**21,833**	**719**	**949**			**859**	**1,298**				
Average				0.033	0			1.195			
Lots/Farmsteads/ etc	24,815	-	497	-	2%	-	649	-	-	-	
Woodland	62,825	-	5	-	0%	-	2	-	-	-	

Site	Acres Grown (000)g1	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb ai/ acre/yr	#appl / yr	lb ai/ A/appl	(% of total lb ai used on this site)
Nurseries	-	14	-	-	-	20	30	-	-	-	
Commercial	-	-	-	-	-	5	-	-	-	-	
Recreational	-	-	-	-	-	1	-	-	-	-	
Residential Outdoor	-	-	-	-	-	35	-	-	-	-	

COLUMN HEADINGS

Wtd Avg = Weighted average--the most recent years and more reliable data are weighted more heavily.
Est Max = Estimated maximum, which is estimated from available data.
Average application rates are calculated from the weighted averages.

NOTES ON TABLE DATA

Usage data primarily covers 1987 - 1996. Calculations of the above numbers may not appear to agree because they are displayed as rounded
to the nearest 1000 for acres treated or lb. a.i. (Therefore 0 = < 500)
to the nearest whole percentage point for % of crop treated. (Therefore 0% = < 0.5%)
A dash (-) indicates that information on this site is NOT available in EPA sources or is insufficient.

*** Other/Crop Groups**

Citrus, Other includes kumquats, limes, tangelos, and tangerines.
Cucurbits includes cucumber, squash, and pumpkin.
Nut Trees, Other includes chestnuts, filberts, and hickory nuts.
Stone Fruit, Other includes apricots, and nectarines.

**SOURCES: EPA data, 1987-96; USDA NASS, 1990-96; and National Center for Food and Agricultural Policy, 1992.

D. Data Requirements

Data requested in the December 30, 1983, Registration Standard for dicofol include studies on product chemistry, residue chemistry, environmental fate, toxicity, and ecological effects. These data were required to support the uses listed in the Registration Standard. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

Due to environmental concerns resulting from the presence of dichloro-diphenyl-trichloro-ethane (DDT) and related contaminants (DDTr) in dicofol, a Dicofol Special Review was initiated in 1984. As specified in the Dicofol PD 4 (Notice of Intent to Suspend) dated May 29, 1986, registrations for dicofol-containing uses faced cancellation, unless the upper limit for DDTr was certified at 2.5% of dicofol technical by January 1, 1986 and at 0.1% by July 1, 1987. 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 (June 29, 1986) because the product did not comply with the Dicofol PD 4 requirements concerning DDTr impurity levels. Rohm and Haas subsequently registered (August 5, 1987) the current Kelthane® 95.3% T which contains DDTr impurities at 0.1%. Makhteshim-Agan fulfilled data requirements for the 88% T containing >1% DDTr. However, no data have been provided reflecting a reduction of DDTr impurities to 0.1%. It was concluded in subsequent Agency reviews that product chemistry data submitted by Rohm and Haas will satisfy data requirements for the Agan product (CBRS No. 11668, D189942, dated April 28, 1993, by S. Funk).

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. 11603-26) because the existing database supported a product containing >0.1% DDTr impurities. Data remain outstanding for 63-14, 63-15, 63-16, and 63-19. All these data are considered confirmatory.

A Data-Call-In (DCI) for chemical-specific post-application exposure and/or environmental fate data (as regulated by Series 875.2100, 875.2400, and 875.2500) was issued October 13, 1995, and is due in October 1998. In lieu of these data, a surrogate range-finder post-application exposure assessment was performed for occupational or residential settings.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

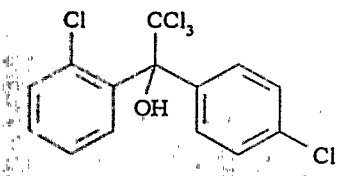
Additional data are required for the following product chemistry guidelines for dicofol: 830.1550; 830.6314; 830.6315; 830.6316; 830.6319; 830.7050. These data requirements are considered confirmatory.

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, the Agency has no objections to the reregistration of dicofol with respect to product chemistry data requirements.

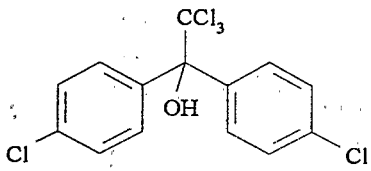
1. Description of Chemical

Dicofol [1,1-bis(4-chlorophenyl)-2,2,2-trichloroethanol and 1-(2-chlorophenyl)-1-(4-chlorophenyl)-2,2,2-trichloroethanol] is a miticide used on terrestrial food crops and non-food sites. Dicofol is structurally similar to DDT. Dicofol differs from DDT by the replacement of the hydrogen (H) on C-1 with hydroxyl (OH).

o, p'-dicofol



p, p'-dicofol



Empirical Formula:	$C_{14}H_9Cl_5O$
Molecular Weight:	370.5
CAS Registry No.:	115-32-2
Shaughnessy No.:	010501

2. 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 relatively insoluble in water (~1 ppm for the PAI).

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base on dicofol is adequate to support reregistration eligibility.

a. Acute Toxicity

The following table summarizes the acute toxicity values and categories for technical dicofol.

Table 2: Acute Toxicity of Technical Dicofol.

TEST	RESULTS	CATEGORY
Oral LD_{50} - Rat	587 mg/kg	III
Dermal LD_{50} - Rabbit	2 - 5 g/kg	III
Inhalation LC_{50} - Rat	>4.2 mg/L	IV
Eye Irritation - Rabbit	Moderate irritation	III
Dermal Irritation- Rabbit	Moderate irritation	III
Dermal Sensitization - Guinea pig	Not sensitizing	NA

Based on a LD_{50} value of 587 mg/kg in CRCD rats, dicofol was placed in Toxicity Category III for acute oral toxicity (guideline 81-1; MRID 40731204).

An acute dermal toxicity test with CRCD rats reported the dermal LD_{50} to be greater than 5.0 g/kg, placing dicofol in Toxicity Category IV for dermal toxicity (guideline 81-2; MRID 40731205). When tested in New Zealand white rabbits for dermal toxicity, the LD_{50} was between 2 and 5 g/kg, placing dicofol in Toxicity Category III (guideline 81-2; MRID 40731205).

The acute inhalation LC_{50} was greater than 4.2 mg/L in one study and greater than 5 mg/L in another study. Based on these results in rats, dicofol was placed in Toxicity Category IV (guideline 81-3; MRID 00256514; 40731202).

A primary eye irritation study with rabbits indicated dicofol to be a moderate eye irritant, placing it in Toxicity Category III (guideline 81-4; 256589). A primary dermal irritation study in rabbits showed dicofol to be a moderate irritant, placing it in Toxicity Category III (guideline 81-5; 256589). Dicofol was shown to be a non-sensitizer in guinea pigs (guideline 81-6; MRID 40048506).

b. Subchronic Toxicity

In a subchronic oral toxicity study in rats, groups of Crl:CD (SD)BR rats (10/sex/dose) received dicofol at dietary concentrations of 1, 10, 100, 500, and 1,500 ppm for 90 days (0.07, 0.64, 6.49, 32.01, and 95.84 mg/kg/day for males, and 0.08, 0.78, 7.84, 36.11, and 105.91 mg/kg/day for females, respectively). The controls received an untreated diet. Under the conditions of the study,

dicofol produced a wide range of effects in both sexes of rats. At 1,500 ppm dicofol produced death and clinical signs such as lethargy and ataxia prior to death. Reduced body weights and food consumption were seen in 500 and 1,500 ppm rats of both sexes. Most of the other effects were associated with toxicity seen in the liver (increased liver weights, enhanced hepatic Mixed Function Oxidase (MFO) activity, and hepatocellular hypertrophy), adrenals (diffuse adrenal cortical cell vacuolation and decreased corticosterone levels), thyroid (hypertrophy of the thyroid follicular epithelium), and stomach (focal chief-cell hyperplasia in the fundic mucosa). Effects on the liver and thyroid were seen in dose levels as low as 100 ppm and 10 ppm, respectively. However, at 1 ppm, dicofol did not produce an effect in any of the parameters examined in this study. The NOAEL was 1 ppm (0.07 mg/kg) and the LOAEL was 10 ppm (0.64 mg/kg), based on an increase in the incidence of hypertrophy of the thyroid follicular epithelium (MRID No.47015801).

This study is classified as **acceptable** and satisfies the data requirements for a subchronic feeding study in rodents (Guideline No. 82-1a). The Registrants, however, are requested to submit data on the analyses of the tissue residues of the test compound.

In a 90-day feeding study in mice, groups of Crl:CD^{R}-1 (ICR) BR mice (10/sex/group) were fed diets containing dicofol at concentrations of 10, 125, 250, 500, or 1000 ppm (1.6, 18.2, 38.2, 84.4, or 178.4 mg/kg for males and 2.1, 29.3, 56.2, 108.0, or 188.4 mg/kg for females, respectively) for 13 weeks. Under the conditions of this study dicofol did not produce any compound-related effects in 10 ppm male or female mice. Dicofol produced dose-related effects on the body weights, the liver (increased liver weights, hepatic MFO activity, hepatocellular hypertrophy associated with necrosis and vacuolation), kidney (decrease in weight, granular and dilated kidneys, dilation and degeneration of cortical tubules of kidneys), and the adrenal glands (diffuse hypertrophy of adrenal cortical cells), at dose levels as low as 125 ppm, 250 ppm and 500 ppm, respectively. Effects seen in 1,000 ppm were more severe than any lower dose levels. The NOAEL was 10 ppm (1.6 mg/kg) and the LOAEL was 125 ppm (18.2 mg/kg) based on a decrease in body weights, increased hepatic MFO activity, and an increase in liver weights (MRID No. 40042044).

This study is classified as **acceptable**, although a subchronic feeding study in mice is not required.

In a subchronic oral toxicity study in dogs, groups of beagle dogs (6/sex/dose) received dicofol at dietary concentrations of 0, 10, 100, 300, or 1,000 ppm (0, 0.29, 3.3, 9.9, or 26 mg/kg for males and 0, 0.31, 3.4, 9.8, or 27 mg/kg for females) for three months. The NOAEL was 10 ppm (0.29 mg/kg/day) and the LOAEL was 100 ppm (3.3 mg/kg/day), based on a decrease in cortisol release in response to adrenocorticotropic (ACTH) administration, an increase in relative liver weights, and oligospermatogenesis in males. There were effects also on survival, testes, prostate, liver, gastrointestinal tract, and heart at the LOAEL and higher doses (MRID No.40042043).

This study is classified as **acceptable** and satisfies the data requirements for a subchronic feeding study in non-rodents (Guideline No. 82-1b).

In a 28-day dermal toxicity study, groups of CD rats (6/sex/dose) received repeated dermal applications of dicofol (44.8%) at doses of 0 (water control), 0 (formulation blank), 1.0, 2.5, 4.0, and 40.0 mg a.i./kg, 6 hours/day, 5 days/week for 4 weeks. Each animal received 1 ml/kg of the test article. Under conditions of the study, dicofol did not produce a treatment-related increase in clinical signs or mortality, and did not affect food consumption, hematology, and clinical chemistry parameters. Dicofol produced a slight decrease in body weights and body weight gains in the highest dose males and an increase in the incidence of hepatocellular centrilobular hypertrophy. The increase in the incidence of liver hypertrophy in 40.0 mg/kg rats could be considered as an adaptive effect, while the slight decrease in body weights and body weight gains appeared to be equivocal results. Under conditions of this study, the highest dose (40 mg a.i./kg) could be conservatively considered as the NOAEL was 4.0 mg/kg/day and the LOAEL was 40.0 mg/kg/day (MRID No.44099201).

In a 28-day dermal toxicity study (MRID No. 41077001), groups of New Zealand white rabbits (6/sex/dose) received repeated dermal applications of Kelthane MF miticide (43.6% a.i) at doses of 0 (water control), 0 (formulation control), 4.1, 10.2, or 61.1 mg a.i./kg, 6 hours/day, 5 days/week for 4 weeks. The test material caused dermal irritation at all dose level including the water control. The degree of dermal irritation and incidences of acanthosis and hyperkeratosis in treated skin were similar in the formulation control and in the high dose animals. Therefore, the dermal irritation was attributed to the formulation vehicle. Systemic toxicity was manifested as statistically significantly decreased body weight in males at the mid and high doses and in females at the high dose. For systemic toxicity, the NOAEL of 4.1 mg/kg/day and the LOAEL was 10.2 mg/kg/day

These studies are classified as **acceptable** and satisfy the data requirements for 21-day dermal toxicity study (Guideline No. 82-2).

c. Chronic Toxicity/Carcinogenicity

In a one-year chronic toxicity study in dogs, groups of beagle dogs (6/sex/dose) were fed diets containing dicofol (93.3%) at doses of 0, 5, 30, or 180 ppm for 52 weeks. These doses corresponded to 0, 0.12, 0.82, or 5.71 mg/kg for males, and 0, 0.13, 0.85, or 5.42 mg/kg for females, respectively. The NOAEL was 5 ppm (0.12 mg/kg/day in males and 0.13 mg/kg/day in females), and the LOAEL was 30 ppm (0.85 mg/kg/day in females and 0.82 mg/kg/day in males), based on inhibition of ACTH-stimulated cortisol release in both sexes. There was increased mortality, increased alkaline phosphatase levels, increased liver weights, and hepatocyte hypertrophy in males and females at the high dose (MRID 40997101).

This study is classified as **acceptable** and satisfies the data requirements for a chronic feeding study in non-rodents (Guideline No. 83-1).

In a chronic toxicity/carcinogenicity study in rats, groups of CRL:CD^{R} BR rats (60/sex/dose) received dicofol at dietary levels of 0, 5, 50, or 250 ppm (0, 0.22, 2.23, or 11.34 mg/kg/day for males and 0.27, 2.69, or 14.26 mg/kg/day for females, respectively) for 24 months. For chronic toxicity, the NOAEL was 5 ppm (0.27 mg/kg/day in females, 0.22 mg/kg/day in males), and the LOAEL was 50 ppm (2.69 mg/kg/day in females, 2.23 mg/kg/day in males), based on decreased food

consumption, decreased body weight gain, reduced triglyceride levels, and increased hepatic mixed function oxidase activity, seen at or before 12 months. There were also histological changes: the liver showed centrilobular hepatocyte hypertrophy, vacuolation, and areas of necrosis in 50 and 250 ppm males and females, and the adrenal glands showed cortical cell vacuolation in 250 ppm males and females. No compound-related increases in tumor incidence were observed in this study (MRID No.41150001).

This study is classified as **acceptable** and satisfies data requirements for a chronic feeding/carcinogenicity study (Guideline No. 83-5).

Carcinogenic bioassays of dicofol were also carried out by the National Cancer Institute in rats and mice[1]. In the rat study, groups of Osborne-Mendel rats (50/sex/dose; control, 20/sex) were fed 0, 471, or 942 ppm (equivalent to 0, 23.6 or 47.1 mg/kg/day) in males and 0, 380, or 760 ppm (equivalent to 0, 19, or 38 mg/kg/day) in females for 78 weeks, followed by 34 weeks without treatment. Dose-related body weight depression was found in both sexes. No compound-related tumors were observed at either dose (MRID 41037801).

In the NCI mouse carcinogenicity study, groups of B6C3F1 mice (50/sex/dose; control, 20/sex) were given dicofol at dietary concentrations of 0, 264, or 528 ppm in males (equivalent to 0, 39.6, or 79.2 mg/kg/day) and 0, 122, or 243 ppm (equivalent to 0, 18.3 or 36.5 mg/kg/day) in females for 45 weeks, followed by 14-15 weeks without treatment. High dose females had decreased body weights. Incidences of hepatocellular adenomas and hepatocellular adenomas/carcinomas combined were significantly increased in males at both dose levels (39.6 and 79.2 mg/kg/day) (MRID 41037801).

d. Developmental Toxicity

In a developmental toxicity study in rats, groups of pregnant Crl:COBS CD rats (25/dose group) received oral administration of dicofol (95.6%) at doses of 0, 0.25, 2.5, or 25 mg/kg/day on gestation days 6-15. For maternal toxicity, the NOAEL was 0.25 mg/kg/day, and the LOAEL was 2.5 mg/kg/day based on salivation, reduced food consumption and body weight gain, and increased relative liver weight accompanied by centrilobular hepatocyte hypertrophy. No developmental toxicity was observed. For developmental toxicity, the NOAEL was greater than 25 mg/kg/day (MRID 40042046). The lack of developmental toxicity seen in this study is also confirmed by the results of a published developmental toxicity study in normal and malnourished pregnant Wistar rats exposed to dicofol at 10 mg/kg/day on gestation days 4 to 15 (Lemonica et al., 1993).

This study is classified as **acceptable** and satisfies the data requirements for a prenatal developmental toxicity study in rats (Guideline No. 83-3a).

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[1] The dietary concentrations for the NCI rat and mouse carcinogenicity studies (discussed below) indicate time-weighted concentrations.

In a developmental toxicity study in rabbits, groups of artificially inseminated New Zealand white rabbits (20/dose group) received dicofol (95.6%) by gavage at doses of 0, 0.4, 4, or 40 mg/kg/day on gestation days 7-19. For maternal toxicity, the NOAEL was 4 mg/kg/day and the LOAEL was 40 mg/kg/day, based upon findings of abnormal feces, reduced food consumption and body weight gain, and increased relative liver weight associated with hepatocyte cytoplasmic hyalinization and vacuolation. For the developmental toxicity, the NOAEL was 4 mg/kg/day and the LOAEL was 40 mg/kg/day, based on an increased incidence of abortions in the does (MRID No 40042047).

This study is classified as **acceptable** and satisfies the data requirements for a prenatal developmental toxicity study in rabbits (Guideline No. 83-3b).

e. Reproductive Toxicity

In a two-generation reproduction study, groups of Crl:CD BR rats (25/sex/group) were fed diets containing Dicofol (93.3%) at dose levels of 0, 5, 25, 125 or 250 ppm (equivalent to 0.4, 1.9, 9.5, or 18.9 mg/kg/day for males and 0.4, 2.1, 10.5, or 20.5 mg/kg/day for females, respectively). One litter was produced in the first generation, and two litters were produced in the second generation (MRID No. 41606601).

For parental systemic toxicity, the NOAEL was 5 ppm (0.4 mg/kg/day) and the LOAEL was 25 ppm (1.9/2.1 mg/kg/day for M/F) and above based upon histopathological changes in P and F1 livers (hypertrophy of centrilobular hepatocytes with associated vacuolation) and F1 ovaries (increased vacuolation). In addition, at 250 ppm (18.9/20.5 mg/kg/day in M/F), hypertrophy /vacuolation of the adrenal glands was observed in P and F1 females (MRID No. 41606601).

For reproductive toxicity, the NOAEL was 5 ppm (0.4 mg/kg/day) and the LOAEL was 25 ppm (1.9/2.1 mg/kg/day in M/F), based on the ovarian vacuolation in the F1 females, which was judged to be an effect on reproductive physiology.

For offspring toxicity, the NOAEL could be defined at 25 ppm (1.9/2.1 mg/kg/day for M/F) and the LOAEL at 125 ppm (9.5/10.5 mg/kg/day for M/F), based on decreased F2 pup viability (increased numbers of stillborn pups, postnatal day 0-4 pup deaths, and total litter loss). Additionally, at 250 ppm (18.9/20.5 mg/kg/day in M/F), viability of F1 pups and F1 and F2a pup weight (Days 7 and 14) were decreased.

In a special one-generation postnatal toxicity study in Sprague-Dawley rats (30/sex/group), 96.4% Dicofol was administered at dietary concentrations of 5, 25, or 125 ppm (0, 0.3, 1.7, and 8.7 mg/kg/day for males, and 0, 0.4, 2.0, and 9.8 mg/kg/day for females, respectively, during premating). Parental animals were treated for 10 weeks, then mated. Selected F1 rats were weaned and maintained on treated diets until 70-100 days of age. A satellite group (10 treated F0 females/dose), which were mated with F0 males from the main study to produce F1 offspring, were used for evaluation of test material and metabolite residues in serum during the premating phase of the study, in milk on days 2 and 12 postpartum, in prenursing neonate tissue, and in serum from weanling pups. The animals were adequately exposed to the test material during all phases of the study as shown by

quantifiable levels of the Dicofol and metabolites in adult serum, milk, prenursing neonate tissue, and weanling serum (MRID No. 44253801).

For parental systemic toxicity, the NOAEL was 25 ppm (1.7/2.0 mg/kg/day in M/F), and the LOAEL was 125 ppm (8.7/9.8 mg/kg/day in M/F), based on increased absolute and relative liver weights and on histopathologic findings in the liver of adult F0 and F1 male and female rats (centrilobular hypertrophy of hepatocytes with increased cytoplasmic eosinophilia).

For offspring toxicity, the NOAEL was also 25 ppm (1.7/2.0 mg/kg/day in M/F) and the LOAEL was 125 ppm (8.7/9.8 mg/kg/day in M/F), based on histopathologic findings in the liver of F1 weanlings (vacuolization of centrilobular hepatocytes in both sexes and hypertrophy of centrilobular hepatocytes with or without increased cytoplasmic eosinophilia in females).

No treatment-related effects were observed on the number of stillborns, mean litter sizes at birth, sex ratio, viability, clinical signs, or body weight of offspring. No treatment-related effects were observed on parameters of reproductive function or performance: length of estrous cycle; epididymal sperm count, concentration, motility, and morphology; testicular spermatid count and concentration; sexual maturation as evidenced by age of vaginal opening in females and preputial separation in males; mean precoital interval; mating and fertility indices; and median gestation length. For reproductive toxicity, the NOAEL was >125 ppm.

In the two-generation reproduction study, vacuolation of the ovary was observed in F1 females. In the one-generation study, further examination of female reproductive function included evaluation of estrous cyclicity. Vaginal smears were examined to determine the number of estrous cycles attained within a 21-day period. Study results indicated that the mean number of estrous cycles in the F0 rats ranged from 5.2 in the control group to 5.4 in the high-dose group. In F1 females, the mean number of estrous cycles ranged from 4.6 for controls to 5.3 for the high-dose group. In addition, presentation of the cyclicity data in the study report indicated that there was only one F0 low-dose female that remained in diestrus for $\geq$6 days and no females of either generation remained in estrus for $\geq$6 days. Based upon these findings, the study author concluded that there was no effect on estrous cyclicity. However, it was noted by the reviewer that the criterion of $\geq$6 days of estrus is an high-end value for abnormality of this single phase of the estrous cycle. A more appropriate and sensitive analysis of the data should address the number of females with $\geq$4 days of diestrus or $\geq$3 days of estrus, which are considered definitions of abnormality in the estrous cyclicity of the rat. Individual data presented in the study report for either generation did not allow for a further analysis of the cycle periodicity in this manner.

An expanded presentation of the cyclicity data, which includes the number of females with $\geq$4 days of diestrus or $\geq$3 days of estrus, is required. This information will be used to support or refute the conclusion of the study report, i.e., that dicofol does not affect the estrous cycle in female rats under the conditions of this study.

Data in the study report indicate inconsistencies in the evaluation of ovarian follicle count in female rats following dicofol exposure. Variations in the follicle counts obtained in two separate readings of the ovarian sections were not resolved in the study report.

The technique used in the analysis of primordial follicle count was consistent with a 1995 draft of proposed revisions to the EPA guideline for reproduction and fertility effects (OPPTS 870.3800). The study protocol specified that one ovary would be serial sectioned and every tenth section would be examined. However, this very likely resulted in the evaluation of ovarian sections from the outer 1/3 of each side of the ovary, where few if any primordial follicles would generally be expected. Depending upon the number of sections that originated in these areas of the ovary, the numerical follicle count values for each rat could be substantially disparate and not representative of the actual follicular population of the animal. It is suspected that the source of the differences between the duplicate follicle counts could be attributed at least in part to this technical aspect.

Ovarian histopathology samples should be reexamined to more adequately evaluate the follicle count data and to attempt to resolve inconsistencies in the study results. Depending on the methods and procedures used in the registrants' histopathology laboratory, sections of each ovary may have been preserved in such a manner so as to enable performing a reevaluation, using only those sections that originated in the inner 1/3 of the ovary. It is imperative that the number of sections evaluated provide sufficient statistical power to adequately support the conclusions. It is further suggested (based upon information presented at an ILSI/HESI Workshop on Evaluation and Interpretation of Reproductive Endpoints for Human Health Risk Assessment, November, 1997) that, in the reanalysis, growing and primordial follicles can be combined in the counting procedure, and that the number of antral follicles need not be counted.

f. Mutagenicity

Dicofol at doses ranging from 5 to 5000 µg/plate did not cause mutations in an Ames assay (MRID No.40042048). In addition, dicofol did not induce mutations in the *in vitro* Chinese hamster ovary cell HGPRT assay which tested concentrations of 3.0 to 6.0 µg/ml without metabolic activation and 4.5 to 20 µg/ml with metabolic activation. (MRID No.40042049).

This study is classified as **acceptable** and satisfies the data requirements for a gene mutation study (Guideline No. 84-2a).

There were no indications that dicofol at concentrations ranging from 7.5 to 20 µg/ml (without metabolic activation) and 7.5 to 22.5 µg/ml (with metabolic activation) induced structural chromosomal aberrations in an *in vitro* cytogenetic assay using Chinese hamster ovary cells (MRID No.40042051).

This study is classified as **acceptable** and satisfies the data requirements for a structural chromosomal aberration assay (Guideline No. 84-2b).

In an *in vivo* cytogenetic assay, groups of CRL:COBS-CD(SD) rats (30 males/dose) received dicofol at doses of 47.8, 191.2, or 478.0 mg/kg. Dicofol did not induce a clastogenic response in the chromosomes of bone marrow cells of the test animals ((MRID No. 40042050).

This study is classified as **acceptable** and satisfies the data requirements for a structural chromosomal aberration assay (Guideline No. 84-2b).

Since the initial battery of mutagenicity studies (discussed above) demonstrate no mutagenic activity, additional mutagenicity testing on dicofol is not required.

g. Neurotoxicity

In an acute neurotoxicity screening study, groups of Crl:CD^{R}BR VAF/Plus^{R} rats (10/sex/group) received a single oral administration of dicofol 95.5%) at doses of 0, 15, 75, or 350 mg/kg. At 350 mg/kg/day, dicofol produced an increase in the incidence of ataxia and of uncoordinated landing in females. The 350 mg/kg/day females also showed signs of being asleep. Dicofol did not cause any histopathological changes in the central or peripheral nervous systems. The NOAEL was 15 mg/kg/day and the LOAEL was 75 mg/kg/day, based on decreases in body weights and reduced food consumptions (MRID No. 42633303).

This study is classified as **acceptable** and satisfies the data requirements for an acute neurotoxicity study in rats (Guideline No. 81-8).

In a subchronic neurotoxicity study, groups of Crl:CD^{R}BR VAF/Plus^{R} rats (10/sex/group) were fed diets containing dicofol (95.1%) at concentrations of 0, 5, 100, or 500 ppm, (0, 0.3, 5.6, or 27.8 mg/kg for males and 0, 0.3, 6.5, or 31.3 mg/kg for females, respectively). Dicofol did not cause any histopathological changes in the central or peripheral nervous systems. The NOAEL was 5 ppm (0.3 mg/kg/day) and the LOAEL was 100 ppm (5.6 mg/kg/day), based on the decreased motor activity and the increased liver weight (MRID No. 42971401).

This study is classified as **acceptable** and satisfies the data requirements for a subchronic neurotoxicity study in rats (Guideline No. 82-7).

h. Metabolism

Metabolism studies in male and female Sprague Dawley rats used a single oral dose of 50 mg/kg of ^{14}C-dicofol. The radiolabel was eliminated mainly in the feces and to a lesser extent in the urine. The parent compound was preferentially stored in adipose tissue. Also, when ^{14}C-dicofol was administered to female rats every day for 16 days at a dose of 0.5 mg/kg/day, the compound was eliminated mainly in feces and stored in adipose tissue (MRID No. 43070104). The metabolic pathways for dicofol were deduced, with the major one involving reductive halogenation to dichlorodicofol (DCD) and oxidation to dichlorobenzophenone (DCBP), dichlorobenzoic acid (DCBA), and dichlorobenzil (DCBH). This metabolic pathway is consistent with that proposed by Brown and Casida (1987). Analysis of metabolites revealed that, at most, 0.2% of the radioactive residue was DDE which could be contributed by the presence of DDT (0.2%) and DDE (0.01%) in the test material. The data indicated that dicofol metabolized differently from that of DDT, which is metabolized to the purported carcinogen, DDE (guideline 85-1; MRID No.00400420). This conclusion is also supported by the data of Brown and Casida (1987).

In two comparative disposition studies in rats which received orally equal doses of (0.5 mg/kg) dicofol and DDT, dicofol is consistently eliminated more rapidly than DDT in the test animals. Tissue concentrations of radiolabel in fat, gonads, liver, adrenals, and muscle are not significantly different between dicofol- and DDT-treated rats which were given (by gavage) multiple doses of dicofol or

DDT (MRID No. 43070104). However, in another study rats received a single oral high dose (50 mg/kg) of either DDT or dicofol. More DDT was found in fat and adrenals than dicofol (MRID No. 43070103). In the blood, the radioactivity level is consistently higher in dicofol-treated rats than that in DDT-treated ones (MRID No. 43070104).

A metabolism study comparing o,p'-dicofol and p,p'-dicofol was conducted in female rats. Test animals received a single dose (50 mg/kg) by gavage. More radioactivity was eliminated by the o,p'-^{14}C-dicofol treated rats than that by the p,p'-^{14}C-dicofol treated rats. In general, the $t_{1/2}$ for the tissue elimination of radiolabel was greater in p,p'-^{14}C-dicofol treated rats than in the o,p'-^{14}C-dicofol treated group. At 10 days after dosing more ^{14}C-label was retained in the bodies of p,p'-^{14}C-dicofol females (≈22%) than in o,p'-^{14}C-dicofol treated ones (1%). Most sequestered ^{14}C was found in the fat (MRID No.43070105).

i. Dermal Absorption

Currently, there is no acceptable dermal absorption study. In the absence of an acceptable dermal absorption study, the default absorption rate of 100% will be assumed for the present time. However, the Agency believes this is an overestimation of actual dermal absorption of dicofol, as discussed in Chapter 4 of this document. The registrants are submitting a new dermal toxicology study, which is due in December 1998.

The available dermal absorption study (MRID No. 44099202), which showed a dermal absorption of 60%, was determined to be unacceptable because:

1. the dose was improperly applied (i.e., the 100 µL dose was applied to an unrestricted area of 4 cm^2);
2. only females were tested. A dermal absorption study employing female rats will lead to a higher absorption factor because, in general, female rats have greater skin permeability to chemicals than male rats. Since male rats already have skin which is more permeable than humans, the Series 875 Guidelines recommends the use of male rats, which provides more accurate data for assessing dermal absorption for human risk assessments; and
3. The experimental design was unacceptable (i.e., rats were dosed for 6 hours, washed, and then maintained on test for 7 days before termination, thus grossly overestimating the availability of dicofol for systemic toxicity).

In addition, the Agency has recommended that the Registrants conduct a 90-day dermal toxicity study in dogs to specifically evaluate the whether the most sensitive endpoint (inhibition of ACTH stimulated cortisol release) observed in the most sensitive species (dogs) following oral exposure will also occur following dermal exposure. The dermal absorption factor may be derived by comparing doses that caused this effect following the oral and dermal exposures. The Agency has been informed that the Registrants are conducting this study.

j. Special Studies/Other Toxicological Considerations

Reproductive effects in alligators: A study of the effects of organochlorine contamination on alligators in Lake Apopka, Florida, is available. The study is contained in the report on Testimony

to U.S. House of Representatives Subcommittee on Health and the Environment (Guillette, 1993). In 1980, the Tower Company, which was adjacent to Lake Apopka, had a chemical spill. One of the major products in the spill was Kelthane^{R} (dicofol), which contained DDT at concentrations as high as 15%, and DDT's metabolites, DDD, DDE, and chloro-DDT. Guillette testified that, in his investigations, alligator eggs and neonates from Lake Apopka differ from other Lakes in many significant ways. The following observations are most significant:

1. Embryos and neonates within the first 10 days of life from Lake Apopka had high mortality rates.

2. The ratio of estradiol to testosterone was substantially higher in neonates from Lake Apopka than those from other lakes in Florida (estradiol level was higher than the normal level, while testosterone level was lower than the normal concentration).

3. The increase in estradiol level corresponded to differences in the histological appearance of the gonads. "Females from Lake Apopka exhibit ovaries containing large numbers of polyovular follicles and polynuclear oocytes. Testes from males show poorly organized seminiferous tubules." (Guillette's testimony).

4. Alligator eggs from Lake Apopka were found to contain significant levels of DDE. When alligator eggs were experimentally injected with DDE, an abnormal testicular steroidogenesis was seen. Males produced elevated concentrations of estradiol and abnormally low levels of testosterone.

A published article (Heinz, Percival, and Jennings, 1991) showed elevated levels of several organochlorines in alligator eggs from Lake Apopka collected in 1985. In those eggs, DDE was the most commonly found organochlorine, but dicofol itself was not detected.

In the registrant's April 20, 1998 rebuttal, Rohm and Haas suggested that a source other than dicofol may be the cause of the reproductive effects seen in alligators, and that possible co-contamination with dibromochloropropane and/or ethylene dibromide may be responsible. However, no data were submitted to substantiate the registrant's claim that these other chemicals could be responsible.

2. Dose Response Assessment

a. Determination of Susceptibility to Infants and Children

Under the Food Quality Protection Act (FQPA), Public Law 104-170, which was promulgated in 1996 as an amendment to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA), the Agency was directed to "ensure that there is a reasonable certainty that no harm will result to infants and children" from aggregate exposure to a pesticide chemical residue. The law further directs that, in the case of threshold effects, for purposes of establishing this reasonable certainty of no harm, "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of data with

respect to exposure and toxicity to infants and children. Notwithstanding this requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide residue only if, on the basis of reliable data, such margin will be safe for infants and children." (FQPA 1996)

Determination of Susceptibility

The Hazard Identification Assessment Review Committee (HIARC)) determined that data provided no indication of increased susceptibility of rats or rabbits fetuses following *in utero* exposures in the prenatal developmental toxicity studies, or following postnatal exposure in the two-generation reproduction toxicity study (Memorandum: J. Rowland to B. Madden, dated December 17, 1997).

Adequacy of Database

There are no data gaps for the standard Guideline 870 requirements for a food-use chemical by 40 CFR Part 158. However, the HIARC determined that a postnatal developmental neurotoxicity study in rats is required for dicofol. This decision was based on the following factors:

1. evidence of neurobehavioral effects in the acute and subchronic neurotoxicity studies;
2. endocrine toxicity (adrenal and thyroid) was seen throughout the database;
3. ovarian toxicity, consistent with enhanced steroidogenic activity, was seen in the two-generation reproduction study in rats;
4. structural activity concern (i.e., dicofol is structurally related to DDT, a neurotoxicant, and DDE, an endocrine disrupter) (Memorandum: J. Rowland to B. Madden, dated December 17, 1997); and
5. Uncertainty of the involvement of dicofol in the reproductive failure of alligator population following accidental spill into the Lake Apopka, Florida.

Determination of the FQPA Safety Factor

The decision to apply an additional safety factor to ensure the protection of infants and children from exposure to dicofol, as required by FQPA, was elevated to the OPP Division Directors, who discussed the dicofol FQPA Safety Factor on April 9, 1998. It was determined that the additional 10X Safety Factor for the protection of infants and children should be reduced to 3X (Tarplee and Rowland, 1997).

Rationale for Selection of the FQPA Safety Factor

Although no increased susceptibility was seen in the prenatal developmental and post natal developmental toxicity studies, it was determined that an FQPA Safety Factor is necessary for the protection of infants and children. It was determined that the 10X Safety Factor can be reduced to 3X based on the following factors:

- Data show no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to dicofol in the developmental and reproductive toxicity studies.

- There are no data gaps for the Guideline 870 requirements. However, the Agency (HED HIARC Committee, December 17, 1997) has determined that a developmental neurotoxicity study in rats is required, since dicofol produced neurotoxic effects in adult rats in the submitted acute and subchronic neurotoxicity.

- Although dicofol was shown to inhibit ACTH-stimulated cortisol release in dogs, no evidence of endocrine toxicity was noted in the offspring in the one-generation reproductive study in rats with a postnasal exposure phase.

Identification of Population Subgroups

Acute Dietary:

The FQPA Safety Factor will be applied to all population subgroups because:

1. the dose and endpoint is based on neurotoxicity for this risk assessment;
2. there is a data gap for the developmental neurotoxicity study; and
3. an endpoint appropriate for acute dietary risk assessment may be identified from the developmental neurotoxicity study.

Chronic Dietary Risk Assessment:

The Agency's FQPA Safety Factor of 3X will be applied to all population subgroups because:

1. the dose and endpoint for this risk assessment is based on inhibition of adrenal cortical trophic hormone (ACTH) stimulated release of cortisol in male and female of dogs; and
2. there is a data gap for the developmental neurotoxicity study.

Residential Risk Assessments: Residential uses are being voluntarily canceled by the registrants.

b. Chronic Reference Dose (RfD)

The Agency (HED RfD/Peer Review Committee (RFD PRC; January 27, 1994)) recommended an RfD of 0.0012 mg/kg/day based on the NOAEL of 0.12 mg/kg/day established in a chronic feeding study in dogs and an Uncertainty Factor of 100 to account for inter-species variation (10X) and intra-species extrapolation (10X). The NOAEL was based on the inhibition of adrenal cortical trophic hormone (ACTH)-stimulated cortical release in both sexes of dogs at 0.82 mg/kg/day (LOAEL).

On May 23, 1997, the RfD/Peer Review reviewed the additional information submitted by the registrants, which included results from the 1-year and the 90-day toxicity studies in dogs, along with the special reproduction study. It was concluded that:

1. the inhibition of cortisol release in females at 52 weeks was just as great as that which occurred in the 12-week examination period.
2. The 90 minute cortisol level in females control rats at 25 weeks appeared to be low when

compared to the cortisol levels in female control rats at pretest, weeks 12 and 52..

3. There was a slight inhibition of the ACTH stimulated cortisol release at 10 ppm (≈0.3 mg/kg/day) in both males and females of the 90-day feeding study in dogs, although the inhibition was not statistically significant. In addition, using the data from a chronic feeding study in dogs is also more relevant in terms of the duration of exposure.

Additional confirmatory data considered by the Agency (RfD PRC) include organ weight findings from a postnatal study with dicofol (MRID 44253801, 44253802, & 44253803). The members of the Committee believed that the significant perturbations in organ weights seen in the confirmatory studies are indicative of endocrine disruption, even at the lowest level tested (5 ppm equivalent to 0.3 mg/kg/day), where no other histological or toxicological findings were reported. Therefore, the evidence of endocrine disruption at 0.3 mg/kg/day in this postnatal study in rats is supportive of the position of the Committee that the NOAEL, which is most appropriate to use in establishing the RfD, and which is based on the inhibition in ACTH stimulated cortisol release, is at 5 ppm (0.12 mg/kg/day) from the chronic dog study, rather than at 10 ppm (0.3 mg/kg/day) from the subchronic toxicity study in dogs. Using a weight of the evidence approach, the Committee decided that revising the NOAEL from 30 ppm to 5 ppm in the 1-year feeding study in dogs was appropriate, and applying the NOAEL of 5 ppm (0.12 mg/kg/day) for establishing a RfD was reasonable (Memorandum, RFD Peer Review Report, January 27, 1994).

In December, 1997, the Agency (Hazard Identification Assessment Review Committee (HIARC)) reassessed the RfD pursuant to FQPA. The HIARC concurred with the dose (NOAEL=0.12 mg/kg/day), endpoint (inhibition of ACTH stimulated release of cortisol) and study (chronic dog), but recommended an Uncertainty Factor of 300 (10X for inter-species variation, 10X for intra-species extrapolation, and 3X for FQPA (Memorandum: J. Rowland to B. Madden, dated December 17, 1997).

The FQPA Safety Factor of 3X, recommended by the Agency's HIARC, was concurred by the FQPA Safety Factor Committee and this factor is applied for chronic dietary risk assessment.

c. Carcinogenic Classification

The Agency (HED Carcinogenicity Peer Review Committee (CPRC)) has classified dicofol as a nonquantifiable **"Group C," possible human carcinogen.** This classification was based on the increase in the incidence of liver adenomas and combined liver adenomas and carcinomas in male mice (MRID 41037801). The Agency recommended that, for the purpose of risk assessment, the **RfD approach** be used for quantification of chronic human risk. The RfD approach was used to assess dietary cancer risk, and a quantitative dietary cancer risk assessment was not performed. Dietary risk concerns, due to long-term consumption of dicofol residues, are adequately addressed by the DRES chronic exposure analysis using the RfD.

d. Dermal Absorption

The dermal absorption study was determined to be not appropriate for use in dermal risk assessments. Therefore, a dermal absorption factor of 100% (default value) will be used in occupational risk assessments. For details see Section III.B.1.i.

e. Summary of Toxicological Endpoints for Use in Human Risk Assessment

The Hazard Identification Assessment Committee (HIARC) selected the doses and toxicological endpoints for use in dietary and non-dietary (dermal and inhalation) in risk assessments.

i. Dietary: Acute Reference Dose

To estimate acute (one day) dietary risk, the endpoint chosen was neurotoxicity observed following a single oral dose in an acute neurotoxicity study in rats (MRID No. 42633303). The NOAEL was 15 mg/kg/day and the LOAEL was 75 mg/kg/day, based on decreased body weight and reduced food consumption. The NOAEL is divided by an Uncertainty Factor of 300 (10X for inter-species variation, 10X for intra-species extrapolation, and 3X for FQPA), resulting in an **acute RfD of 0.05 mg/kg/day**. The FQPA Safety Factor of 3X is applied to the acute dietary risk assessment for all population subgroups.

ii. Dietary: Chronic Reference Dose

To estimate chronic dietary risk, the endpoint chosen was hormonal toxicity observed in a chronic toxicity study in dogs (MRID 40997101). The NOAEL was 0.12 mg/kg/day and the LOAEL was 0.82 mg/kg/day, based on inhibition of adrenal cortical trophic hormone (ACTH) stimulated release of cortisol in both sexes of dogs. The NOAEL is divided by an Uncertainty Factor of 300 (10X for inter-species variation, 10X for intra-species extrapolation, and 3X for FQPA), resulting in the **chronic RfD of 0.0004 mg/kg/day**. The FQPA Safety Factor of 3X is applied to the chronic dietary risk assessment for all population subgroups.

iii. Dietary: Carcinogenic

To estimate the carcinogenic risk, the Agency (CPRC) recommended the RfD approach for quantification of chronic human risk. Therefore, a quantitative dietary cancer risk assessment was not performed. Dietary risk concerns due to long-term consumption of dicofol residues are adequately addressed by the DRES chronic exposure analysis using the chronic RfD.

iv. Dermal Absorption

In the absence of an acceptable dermal absorption study, the use of a 100% (default value) is required since oral NOAELs were selected for occupational dermal risk assessments. For details see Section III.B.1.i.

v. Dermal: Short-Term Occupational Exposure (1-7 Days)

To estimate short term dermal risk, an oral dose (NOAEL) from a prenatal developmental toxicity study in rabbits was used (MRID No.40042047). The NOAEL was 4.0 mg/kg/day and the endpoint of concern was an increased frequency of abortions, at 40 mg/kg/day (LOAEL). Since an oral NOAEL was chosen, a dermal absorption rate of 100% should be used for route-to-route

extrapolations for risk assessments. A Margin of Exposure (MOE) of 100 is adequate for occupational exposure. There are no residential uses at the present time.

Although 28-day dermal toxicity studies were available in rats and rabbits with formulation products (44% active ingredient), the Agency's Hazard Identification Committee selected an oral dose because:

1. the effects (abortions) seen after a treatment of short duration (11 days), which is appropriate for this exposure period (1-7 days);
2. the NOAEL (4 mg/kg/day) was identical via the oral and the dermal routes in the same species (rabbits), indicating credible dermal absorption via the route;
3. developmental effects are not evaluated in dermal studies; and
4. the oral NOAEL will provide adequate protection for pregnant workers.

Therefore, the Committee considered the 28-day dermal toxicity studies to be co-critical.

In the 28-day dermal toxicity study in rats, the NOAEL was 4 mg/kg/day and the LOAEL was 40 mg/kg/day, based on slight decreases in body weights and body weight gains, as well as an increase in the incidence of liver hypertrophy, which was also seen at this dose. Although this was considered as an adaptive effect, liver effects were also seen in rabbits via the oral route (MRID No. 44099201).

In the 28-day dermal toxicity study in rabbits, the NOAEL was 4.1 mg a.i/kg/day and the LOAEL was 10.2 mg a.i/kg/day, based on decreased body weight gain (MRID No. 41077001).

vi. Dermal: Intermediate-Term Occupational Exposure (1-Week to Several Months)

To estimate intermediate-term dermal risk, an oral dose (NOAEL) was selected from a 90-day oral toxicity study in dogs (MRID 40042047). The NOAEL was 0.29 mg/kg/day and the endpoint of concern was inhibition of ACTH stimulated cortisol release and oligospermatogenesis observed at 3.3. mg/kg/day (LOAEL). The Agency did not use the 28-day dermal studies because:

1. The endpoint of concern (i.e., hormonal toxicity) was seen both in the subchronic and chronic feeding studies in the sensitive species (dogs) at comparable doses (0.29 mg/kg/day in the subchronic study and 0.12 mg/kg/day in the chronic study); and
2. this developmental endpoint is not measured in the dermal toxicity studies. The use of a dermal absorption factor is required since an oral NOAEL was selected for this dermal risk assessment. In the absence of an acceptable dermal absorption study, the default rate of 100% was used.

A Margin of Exposure (MOE) of 100 is adequate for occupational exposure. There are no residential uses at the present time.

vii. Dermal: Long-Term Occupational Exposure (Several Months to Life Time)

Based on use patterns of dicofol included in this RED, the agency has determined that long-term (chronic) exposure, or continuous exposure over several months, is unlikely. Therefore, dermal risk assessments were not conducted.

viii. Inhalation: Any Time Period

Except for an acute inhalation toxicity study, for which Dicofol is placed in Toxicity Category IV (LC_{50} = >4.2 mg/L), no other toxicity studies are available via this route. Therefore, in order to estimate inhalation exposure, the HIARC selected the oral NOAELs of 4 mg/kg/day, 0.29 mg/kg/day, and 0.12 mg/kg/day for the Short-, Intermediate-, and Long-Term, inhalation risk assessments, respectively. Since oral doses were selected, route-to-route extrapolations should be as follows:

Step I. Convert the inhalation exposure value (µg/lb a.i/L) using a 100% absorption rate (default value), application rate, and acres treated to an equivalent oral dose (mg/kg/day).

Step II. Convert the dermal exposure component (mg/kg/day) using a 100% dermal absorption rate (default), application rate and acres treated to an equivalent oral dose.

Step III. Combine the oral equivalent doses in Steps I and II to obtain a total dose (dermal + inhalation).

Step IV Compare the total oral equivalent dose to calculate the MOEs for:

short-term MOE =	NOAEL of 4 mg/kg/day
intermediate term MOE=	NOAEL of 0.29 mg/kg/day

The toxicological endpoints selected for various exposure scenarios are summarized in Table 3.

TABLE 3: Summary of Toxicological Endpoints for Use in Human Risk Assessment

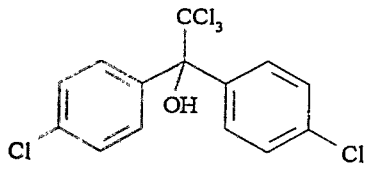
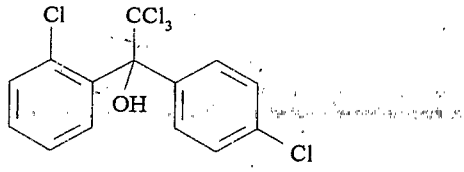
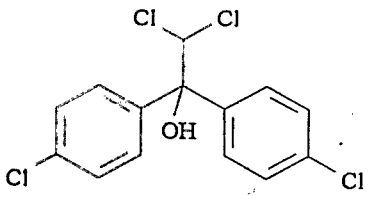
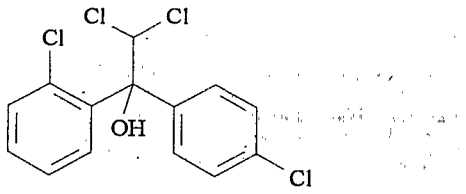
Exposure Route	Duration	Population Subgroup	Critical Study (MRID No.)	NOAEL (mg/kg/day)	LOAEL (mg/kg/day)	Endpoint for Risk Assessment	Acceptable MOE or RfD
Dietary (includes drinking water and food sources)	Acute Risk	General population, including infants and children	Acute neurotoxicity in rats (42633303)	15	75	Decreases in body weights and food consumption;	Acute RfD= 0.05 mg/kg/day
	Chronic Risk	General population, including infants and children	Chronic dog (40997101)	0.12	0.82	Inhibition of adrenal cortical trophic hormone (ACTH) release in both sexes of dogs	Chronic RfD= 0.004 mg/kg/day
	Carcinogenic Risk	General population, including infants and children	Carcinogenicity study in mice (MRID No. 41037801	The RfD approach was used to assess dietary cancer risk, and a quantitative dietary cancer risk assessment was not performed. Dietary risk concerns due to long-term consumption of dicofol residues are adequately addressed by the DRES chronic exposure analysis using the RfD.			
Dermal and Inhalation Exposure[a]	Short-Term	Adult-Occupational	Developmental Toxicity in-rabbit (40042047)	4.0	40.0	Increase in frequency of abortions	A MOE of 100 is adequate for occupational dermal and inhalation exposures.
The exposure concern is only occupational since there are no residential uses at the present time.	Intermediate-Term	Adult-Occupational	90-day oral dog 40042043	0.29	3.3	Inhibition of ACTH stimulated cortisol release and oligospermatogenesis	A MOE of 100 is adequate for occupational dermal and inhalation exposures.

a = Since oral NOAELs were used for dermal and inhalation exposures, appropriate route-to-route extrapolations should be used for dermal absorption (100%, default) and inhalation absorption (100%, default) factors.

3. Dietary Exposure and Risk Assessment/Characterization

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 Agency (HED Metabolism Committee; September 29, 1992) determined that dicofol is the only residue of concern in/on plants and that dicofol and its metabolites 1,1-bis (4-chlorophenyl)-2,2-dichloroethanol and 1-(2-chlorophenyl)-1-(4-chlorophenyl)-2,2,-dichloroethanol (FW-152) are the residues of concern in animals. The chemical structures of dicofol and metabolite FW-152 are depicted below in Figure A.

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

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

a. Registered Food Uses

For a list of use sites and application rates, refer to Appendix A.

b. Summary of Science Findings

Summary of Residue Chemistry Guidelines

Residue chemistry data are adequate for the purposes of this RED. Additional residue confirmatory data are listed in Chapter 5.

OPPTS 860.1200: Directions for Use

A comprehensive summary of the registered food/feed use patterns of dicofol, based on these product labels, is presented in Appendix A and reflects revisions proposed by the registrants and reviewed by the Agency. A summary of the residue chemistry science assessments for reregistration of dicofol is presented in Table 4. Conclusions listed in Table 45 regarding the reregistration eligibility of dicofol food/feed uses are based on the use patterns registered by the basic producers, Rohm and Haas and Makhteshim-Agan. When end-use product DCIs are developed (e.g., at issuance of the RED), the Agency should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended so they are consistent with the basic producer labels.

Limited field trial data have been submitted on caneberries (blackberry, raspberry). Data are adequate to support use on caneberries on an interim basis, but additional confirmatory field trial data are required.

The Wettable Powder/Dust (WP/D) formulation labels must be amended such that the application rate and PHI for strawberries are consistent with the field trial parameters (Appendix A). The crop field trials used to support the dicofol tolerance on strawberries was conducted using only wettable powder formulations. Therefore, the Agency presently does not have the data to support the use of emulsifiable concentrate formulations of dicofol on this commodity.

OPPTS GLN 860.1300: Plant Metabolism

The qualitative nature of residue in plants is adequately understood. Metabolism in plants proceeds via hydrolysis and oxidation of the trichloroethanol moiety to form dichlorobenzophenone. However, the parent compound remains the predominant residue. The Agency (HED Metabolism Committee; September 29, 1992) determined that dicofol is the only residue of concern in/on plants. 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 [^{14}C]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 [^{14}C]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 [^{14}C]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 [^{14}C]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 [^{14}C]o,p -dicofol, DCBH and DCBP comprised 6.6 and 4.1% of the residue, respectively.

OPPTS GLN 860.1300: Animal Metabolism

The qualitative nature of residue in livestock is adequately understood, based on acceptable studies with goats and hens. The Agency (HED Metabolism Committee; September 29, 1992) determined that dicofol and FW-152 are the residues of concern in animals. Goats were dosed with [^{14}C]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 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 [^{14}C]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.

OPPTS GLN 860.1340: Residue Analytical Methods-Plants and Animals

Three colorimetric methods for dicofol determination in/on plants are listed in Pesticide Assessment Methods (PAM), Vol. II (Methods A, B, and C). PAM, Vol. II also includes a reference to a gas/liquid chromatography (GLC) method in PAM, Vol. I, for the determination of chlorinated hydrocarbons. PAM, Vol. I (Section 211.13H) includes an high performance liquid chromatography (HPLC) method for the determination of dicofol residues in milk. The GC/EC Method TR-310-86-74 for plant matrices must be validated for cottonseed, tomatoes, and stone fruit by an independent laboratory for inclusion in PAM. An acceptable independent laboratory validation (ILV) for cottonseed, tomatoes, oranges, and stonefruit has been submitted. After successful validation, the method will be validated by the Agency and will be submitted for inclusion in PAM for enforcement purposes. The current PAM method is colorimetric. This requirement is considered confirmatory, because multi residue methods have been shown adequate for recovery of dicofol from plant matrices.

An HPLC/GC method for the determination of dicofol and FW-152 in animal commodities has been validated by an independent laboratory for use as an enforcement method. The method will be subjected to Agency validation and then submitted for publication in PAM as an enforcement method. PAM contains a HPLC method for the determination of dicofol in milk.

p,p -dicofol and o,p -dicofol are completely recovered (>80%) using FDA Multi residue Protocol D (Section 302). p,p -dicofol is partially recovered (50-80%) using Multi residue 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).

OPPTS GLN 860.1380: 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, cottonseed, apples, string beans, and green peppers stored frozen for two years. Dicofol and FW-152 are stable in poultry and cattle tissues, milk, and eggs stored for up to seven months at frozen temperatures. No additional storage stability data are required.

OPPTS GLN 860.1480: 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 maximum theoretical dietary burden for dairy cattle is 22 ppm and for beef cattle 41 ppm. The existing ruminant feeding studies (10, 30, or 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 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.

OPPTS GLN 860.1500: 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. Interregional Program 4 (IR4) 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. Use of dicofol on figs is not being supported by the registrants.

Field trials are required for caneberries and cotton gin byproducts. There are limited data for caneberries to support the existing label use. 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.

OPPTS GLN 860.1520: 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. Dicofol has been shown to concentrate in apple pomace, citrus oil, mint oil, dried tea, citrus pulp, cottonseed oil, raisins, and plum prunes. Tolerances will be needed for these processed commodities.

OPPTS 860.1850 and 860.1900 Confined/Field Rotational Crops

Based on the review of recently submitted data on confined rotational crops treated with dicofol, the Agency recommends that plantback intervals not be required for crops rotated with dicofol-treated crops, since there was no quantifiable residue level at any interval. The Agency further recommends that tolerances not be required for inadvertent residues on crops rotated with dicofol-treated crops.

For purposes of the reregistration of dicofol, the data requirements for OPPTS 860.1850 and 860.1900 are fulfilled.

c. Anticipated Residues

As part of the Reregistration Eligibility Decision process for dicofol, anticipated residues of 1,1-bis(4-chlorophenyl)-2,2,2-trichloroethanol and 1-(2-chlorophenyl)-1-(4-chlorophenyl)-2,2,2-trichloroethanol in/on raw agricultural commodities and of these compounds, plus the dicofol metabolites FW-152, isomers 1,1-bis(4-chlorophenyl)-2,2-dichloroethanol and 1-(2-chlorophenyl)-1-(4-chlorophenyl)-2,2-dichloroethanol, in animal commodities must be determined in order to perform dietary risk analyses. Table 4 lists anticipated residues of dicofol in all DRES food items resulting from raw agricultural commodities with label uses for dicofol. Commodities with canceled registrations are not included. Table 4 also lists the anticipated residues of dicofol plus the metabolite FW-152 in meat, milk, poultry, and eggs, resulting from the use of dicofol on animal feed items. US FDA monitoring data (1991 - mid 1994), USDA PDP survey data (1991 -1994), field trial and processing data, and/or reassessed tolerances were used in arriving at the values. Quantitative usage information (percent crop treated based on acreage) was obtained from the sources indicated in footnote #2 of Table 4.

Anticipated residues for chronic (cancer and non-cancer) dietary exposure considerations are based on survey data where an adequate sample size is available (> ca. 200 samples). Average value of all domestic and foreign FDA surveillance monitoring and all PDP monitoring samples is used for chronic risk analysis anticipated residue value. In the absence of sufficient survey data, the average of all relevant field trial residues, corrected for percent crop treated, is used as anticipated residue for chronic dietary risk analysis. In the absence of both survey and field trial data, such as for raw agricultural commodities covered by translation of data from a very similar crop, the tolerance value, corrected for percent crop treated, is used as the anticipated residue.

For determination of anticipated residues in livestock commodities for chronic dietary risk, average residues from monitoring data were used as the basis for estimation of the dietary exposure of the livestock. Reasonable livestock diets were also used. For example, apple pomace and citrus pulp were not fed simultaneously. The practical dietary burden for dairy cattle was calculated to be 0.055 ppm, and for beef cattle, 0.11 ppm. These burdens were compared with the results of the cattle feeding study to estimate residues in milk, meat, fat, and meat by-products.

Dicofol (two isomers) alone is considered in the determination of anticipated residues in plant commodities. However, dicofol and the FW-152 metabolite (two isomers) are considered by the Agency in arriving at the anticipated residues for animal commodities.

Anticipated residues for dietary risk for acute and chronic exposure have been determined (S. Funk, CBRS 14225, DP Barcode D206745, 09/12/95) and subsequently refined (S. Funk, 03/18/96; S. Funk, 04/30/96; S. Funk, DP Barcode D235741, CBRS No. 17911, 06/03/97; S. Funk, DP Barcode D236612, 07/01/97; S. Funk DP Barcode D246234, 6/11/98). For purposes of incorporating the various changes and refinements, the anticipated residues are summarized in Table 4.

Dietary Risk Assessment Assumptions

Apple juice anticipated residue was based on the average processing factor (0.018), which is the average of five processing studies (0.015, 0.010, 0.030, 0.012, and 0.020) and the monitoring data average for apples (0.014 ppm) multiplied by a processing factor of 0.018. Anticipated residue is:

$$0.014 \text{ ppm} \times 0.018 = 0.00025 \text{ ppm}.$$

Previously, DRES concentration factors were applied to the citrus raw agricultural commodity values (survey data or field trial data or tolerance values) to arrive at anticipated residues in citrus juices. The registrants maintain that this is inappropriate, because there are processing studies for oranges to show that residues decline from the raw agricultural commodity to the juice. The Agency agrees that studies do show a reduction in residue and that use of the default DRES factors are not, therefore, appropriate.

Two processing studies were conducted in 1986 in California. Oranges with field-weathered residues of dicofol, 3.79 and 4.46 ppm, were processed into juice, molasses, oil, and peel. In both instances, total dicofol residue in the juice was <0.01 ppm, corresponding to residue reduction factors of 379X and 446X, respectively, with an average factor of 413X. Using this factor of 0.0024 based on the processing studies (1/413), and the RAC field trial, tolerance, or survey values (S. Funk, January 21, 1998, DP D240042), the following chronic anticipated residues are calculated:

grapefruit-juice: 0.012 ppm [PDP + FDA survey mean, n = 1626] X 0.0024 = 0.000029 ppm.

limes- juice: 6 ppm [group tolerance] X 0.0024 = 0.014 ppm

lemon- juice: 0.6 ppm [field trial average] X 0.0024 = 0.0014 ppm

oranges- juice: 0.012 ppm [PDP + FDA survey mean, n = 2825] X 0.0024 = 0.000029 ppm

tangerines- juice: 0.012 ppm [orange] X 0.0024 = 0.000029 ppm.

Acute anticipated residues would also be reduced through use of the orange processing factor to 0.03 ppm for grapefruit juice (highest field trial X 0.005), 0.007 ppm for lemon juice (highest field trial X 0.005), 0.03 ppm for lime and tangerine juices (6 ppm group tolerance X 0.005), and 0.02 ppm for orange juice (highest field trial X 0.005).

Rohm and Haas Company maintains that more reasonable residue values can be obtained for *processed grape fractions* through the use of survey data and processing factors, rather than field trial data and processing data. There were 2,237 PDP grape samples and 3,121 FDA grape samples analyzed in 1991 - 1994, with an average residue of 0.016 ppm. Applying the average processing factors of 4.7X for raisins and 0.25X for juice, the chronic anticipated residues are 0.075 ppm in raisins and 0.004 ppm in juice. The registrants use a factor of 0.027X for juice, but the data indicate factors of 0.1X and 0.4X, average 0.25X (Table I-42; S. Funk, DP D206745, 08/95).

The previous DRES calculation concentrated dicofol residues in both the fat and non-fat fractions of *milk*. This is not possible. The whole milk residue value of 0.0015 ppm (S. Funk, D236612, 07/01/98) would represent a conservative estimate for non-fat fractions. The 0.04 ppm value of Table 4 (S. Funk, 01/21/98, DP D240042) applies as stated to milk fat (only). The estimated concentration factor from whole milk to milk fat is 30X.

The anticipated residues indicated in Table 4 represent new estimates for citrus juices, apple juice, grape juice, raisins, and non-fat milk fractions. These new anticipated residues were used in DRES calculations.

Table 4: Anticipated Residues of Dicofol in Plant Commodities and of Dicofol Plus FW-152 in Animal Commodities for Dietary Risk Assessment

Food Item	Food Code	Residue Data Source		% Crop Treated[2,3]	Chronic Anticipated Residue (ppm)	Acute Anticipated Residue (ppm)
		Chronic	Acute			
Apples	04001AA	Survey	Field Trial	4	0.014	7
Apples-dried[4]	04001DA	Survey[4]	Field Trial[4]	4	0.11	56
Apples-juice	04001JA	Survey/ Processing	Field Trial/ Processing	4	0.00025	0.05
Apricots	05001AA	Tolerance	Tolerance	1	5	5
Apricots-dried	05001DA	Tolerance[5]	Tolerance[5]	1	30	30
Beans-dry-Great Northern	15001AA	Field Trial	Tolerance	2	0.1	0.5
Beans-dry-Kidney	15001AB	Field Trial	Tolerance	2	0.1	0.5
Beans-dry-Lima	15001AC	Field Trial	Tolerance	2	0.1	0.5
Beans-dry-Navy	15001AD	Field Trial	Tolerance	2	0.1	0.5
Beans-dry- other	15001AE	Field Trial	Tolerance	2	0.1	0.5
Beans-dry-Pinto	15001AF	Field Trial	Tolerance	2	0.1	0.5
Beans, dry-hyacinth (mature seed)	15030AA	Field Trial	Tolerance	2	0.1	0.5
Peas, black-eyed	15031AA	Field Trial	Tolerance	2	0.1	0.5
Beans-dry-garbanzo (chick pea)	15032AA	Field Trial	Tolerance	2	0.1	0.5
Beans, lima, succulent	15002AA	Survey	Tolerance	2	0.01	3
Beans, snap-succulent-green	15003AA	Survey	Tolerance	2	0.01	3
Beans- succulent-other	15003AB	Survey	Tolerance	2	0.01	3
Beans-succulent-yellow wax	15003AC	Survey	Tolerance	2	0.01	3
Beans-succulent-broadbeans (immature seed)	15022AB	Survey	Tolerance	2	0.01	3

Food Item	Food Code	Residue Data Source		% Crop Treated[2,3]	Chronic Anticipated Residue (ppm)	Acute Anticipated Residue (ppm)
		Chronic	Acute			
Beans-succulent-hyacinth (young pods)	15030AB	Survey	Tolerance	2	0.01	3
Blackberries	01002AA	Survey	Tolerance	1	0.023	5
Boysenberries	01003AA	Tolerance	Tolerance	1	5	5
Butternuts	03010AA	Tolerance	Tolerance	2	0.1	0.1
Cantaloupes-pulp	10002AB	Survey	Field Trial	30	0.004	1
Casabas	10003AA	Survey	Tolerance	30	0.004	1
Cattle, MBYP (exc. kidney & liver)	53001BA	Feeding Study	Tolerance	N/A	0.005	3
Cattle, fat	53001FA	Feeding Study	Tolerance	N/A	0.05	50
Beef- kidney	53001KA	Feeding Study	Tolerance	N/A	0.004	3
Beef-liver	53001LA	Feeding Study	Tolerance	N/A	0.01	5
Cattle, meat	53001MA	Feeding Study	Tolerance	N/A	0.005	3
Cherries	05002AA	Survey	Field Trial	1	0.01	4
Cherries-dried	05002DA	Survey[6]	Field Trial[6]	1	0.04	16
Cherries-juice	05002JA	Survey[7]	Field Trial[7]	1	0.015	6
Chestnuts	03004AA	Tolerance	Tolerance	2	0.1	0.1
Chicken-MBYP	55015BA	Feeding Study	Tolerance	N/A	0.002	0.1
Chicken-flesh (+skin, w/o bones)	55015MB	Feeding Study	Tolerance	N/A	0.008	0.1
Chicken-flesh (w/o skin, w/o bones)	55015MA	Feeding Study	Tolerance	N/A	0.002	0.1
Chicken-giblets (liver)	55015LA	Feeding Study	Tolerance	N/A	0.002	0.1
Crenshaws	10004AA	Survey	Tolerance	30	0.004	1
Grapefruit-pulp	02002AA	Survey	Field Trial	16	0.012	6

Food Item	Food Code	Residue Data Source		% Crop Treated[2,3]	Chronic Anticipated Residue (ppm)	Acute Anticipated Residue (ppm)
		Chronic	Acute			
Grapefruit-juice	02002JA	Survey/ Processing	Field Trial/ Processing	16	0.000029	0.03
Kumquats	02003AA	Tolerance	Tolerance	16	10	10
Lemons-pulp	02004AB	Field Trial	Field Trial	16	0.6	1.5
Lemons-juice	02004JA	Field Trial/ Processing	Field Trial/ Processing	16	0.0014	0.007
Limes	02005Ab	Tolerance	Tolerance	16	6	6
Limes-juice	02004JA	Tolerance/ Processing	Tolerance/ Processing	16	0.014	0.03
Oranges-pulp	02006AB	Survey	Field Trial	16	0.012	4
Oranges-juice	02006JA	Survey /Processing	Field Trial/ Processing	16	0.000029	0.02
Tangerines	02008AA	Survey (orange)	Field Trial	16	0.012	5
Tangerines-juice	02008JA	Survey (orange) /Processing (orange)	Tolerance /Processing (orange)	16	0.000029	0.03
Citrus, oil	90999AB	Field Trial /Processing (orange)	Tolerance/ Processing	16	200	200
Cotton, seed, meal	27003WA	Field Trial/ Processing	Field Trial/ Processing	10	0.03	0.03
Cotton, seed, oil	270030A	Filed Trial/ Processing	Field Trial/ Processing	10	0.3	0.3
Crabapples	04002AA	Tolerance	Tolerance	4	10	10
Cucumbers	10010AA	Survey	Field Trial	1	0.003	0.5
Dewberries	01004AA	Tolerance	Tolerance	100	5	5
Eggplant	11001AA	Survey	Tolerance	100	0.01	2
Eggs	55014AA	Feeding Study	Tolerance	N/A	0.002	0.05
Filberts (Hazelnuts)	03005AA	Tolerance	Tolerance	2	0.1	0.1

Food Item	Food Code	Residue Data Source		% Crop Treated[2,3]	Chronic Anticipated Residue (ppm)	Acute Anticipated Residue (ppm)
		Chronic	Acute			
Peppers, Bell	11003AA	Survey	Survey/ Tolerance	5	0.007	2
Peppers, Chili	11003AB	Survey	Survey/ Tolerance	5	0.007	2
Peppers, Other	11003AD	Survey	Survey/ Tolerance	5	0.007	2
Pimentos	11004AA	Survey	Survey/ Tolerance	5	0.007	2
Tomatoes	11005AA	Survey	Field Trial	3	0.004	1
Tomatoes-juice	11005JA	Field Trial/ Processing	Tolerance/ Processing	3	0.07	0.2
Tomatoes-puree	11005RA	Field Trial/ Processing	Tolerance/ Processing	3	0.3	1
Tomatoes-paste	11005TA	Field Trial/ Processing	Tolerance/ Processing	3	0.6	2
Tomatoes-catsup	11005UA	Field Trial/ Processing	Tolerance/ Processing	3	0.4	1.2
Goats, MBYP (exc. kidney & liver)	53002BA	Feeding Study	Tolerance	N/A	0.005	3
Goats, fat	53002FA	Feeding Study	Tolerance	N/A	0.05	50
Goats, kidney	53002KA	Feeding Study	Tolerance	N/A	0.004	3
Goats, liver	53002LA	Feeding Study	Tolerance	N/A	0.01	5
Goats, meat (boneless, lean)	53002HA	Feeding Study	Tolerance	N/A	0.005	3
Grapes-fresh	01014AA	Survey	Field Trial	3	0.016	3.5
Grapes-raisins	01014DA	Survey/ Processing	Tolerance	3	0.075	20
Grapes-juice	01014JA	Survey/ Processing	Tolerance/ Processing	3	0.004	1.3
Hickory Nuts	03006AA	Tolerance	Tolerance	2	0.1	0.1

Food Item	Food Code	Residue Data Source		% Crop Treated[2,3]	Chronic Anticipated Residue (ppm)	Acute Anticipated Residue (ppm)
		Chronic	Acute			
Meat By-Products (MBYP) (exc. kidney & liver)	53006BA	Feeding Study	Tolerance	N/A	0.005	3
Hogs, fat	53006FA	Feeding Study	Tolerance	N/A	0.05	50
Hogs, kidney	53006KA	Feeding Study	Tolerance	N/A	0.004	3
Hogs, liver	53006LA	Feeding Study	Tolerance	N/A	0.01	5
Hogs, meat	53006MA	Feeding Study	Tolerance	N/A	0.005	3
Honeydew Melons	10005AA	Survey	Field Trial	24	0.004	1
Hops, dried	08020AA	Field Trial	Tolerance	6	25	65
Horses, MBYP (exc. kidney & liver)	53003AA	Feeding Study	Tolerance	N/A	0.005	3
Horses, fat	53003AA	Feeding Study	Tolerance	N/A	0.05	50
Horses, kidney	53003AA	Feeding Study	Tolerance	N/A	0.004	3
Horses, liver	53003AA	Feeding Study	Tolerance	N/A	0.001	5
Horses, meat	53003AA	Feeding Study	Tolerance	N/A	0.005	3
Loganberries	01005AA	Tolerance	Tolerance	100	5	5
Milk, fat	50000FA	Feeding Study	Tolerance	N/A	0.04	22
Milk, non-fat		Feeding Study	Tolerance Derived	N/A	0.0015	0.75
Mint, oil, peppermint	28080AA	Field Trial/ Processing	Tolerance	30	30	30
Mint, oil, spearmint	28081AA	Field Trial/ Processing	Tolerance	30	30	30
Nectarines	05003AA	Survey	Tolerance	100	0.01	5

Food Item	Food Code	Residue Data Source		% Crop Treated[2,3]	Chronic Anticipated Residue (ppm)	Acute Anticipated Residue (ppm)
		Chronic	Acute			
Peaches	05004AA	Survey	Field Trial	1	0.013	4
Peaches-dried	05004DA	Survey[8]	Field Trial[8]	1	0.091	28
Pears	04003AA	Survey	Field Trial	4	0.01	10
Pears-dried	04003DA	Survey[9]	Field Trial[9]	4	0.05	45
Pecans	03008AA	Tolerance	Tolerance	2	0.1	0.1
Persian Melons	10007AA	Survey	Tolerance	24	0.004	1
Plums	05005AA	Survey	Field Trial	1	0.01	1
Plums, Prunes-dried	05005DA	Field Trial/ Processing	Field Trial/ Processing	1	2.5	3
Plums, Prune-juice	05005JA	Survey[10]	Field Trial[10]	1	0.02	1.4
Poultry, other byproducts	55013BA	Feeding Study	Tolerance	N/A	0.002	0.1
Poultry, other-giblets (liver)	55013LA	Feeding Study	Tolerance	N/A	0.002	0.1
Poultry, other-flesh (+skin, w/o bones)	55013MA	Feeding Study	Tolerance	N/A	0.002	0.1
Pumpkins	10011AA	Field Trial	Field Trial	2	1	1
Quinces	04004AA	Field Trial	Field Trial	4	7	7
Raspberries	01006AA	Tolerance	Tolerance	1	5	5
Sheep, MBYP	53005BA	Feeding Study	Tolerance	N/A	0.005	3
Sheep, kidney	53005KA	Feeding Study	Tolerance	N/A	0.004	3
Sheep, liver	53005LA	Feeding Study	Tolerance	N/A	0.012	5
Sheep, fat	53005FA	Feeding Study	Tolerance	N/A	0.05	50
Sheep, meat	53005MA	Feeding Study	Tolerance	N/A	0.005	3
Squash, summer	10013AA	Survey	Field Trial	1	0.004	1
Squash, winter	10014AA	Survey	Field Trial	1	0.004	1
Strawberries	01016AA	Survey	Tolerance	10	0.014	10

Food Item	Food Code	Residue Data Source		% Crop Treated[2,3]	Chronic Anticipated Residue (ppm)	Acute Anticipated Residue (ppm)
		Chronic	Acute			
Tea	07003AA	Tolerance/ Brewing Study	Tolerance	10	0.005	45
Turkey-MBYP	55008BA	Feeding Study	Tolerance	N/A	0.008	0.1
Turkey-flesh (w/o skin, w/o bones)	55008MA	Feeding Study	Tolerance	N/A	0.002	0.1
Turkey-giblets (liver)	55008LA	Feeding Study	Tolerance	N/A	0.002	0.1
Walnuts	03009AA	Tolerance	Tolerance	2	0.1	0.1
Watermelons	10008AA	Survey	Field Trial	11	0.004	1
Wine and Sherry	43058AA	Field Trial/ Processing	Tolerance/ Processing	6	0.3	0.5

[1] Dicofol is a mixture of 1,1-bis(4-chlorophenyl)-2,2,2-trichloroethanol and 1-(2-chlorophenyl)-1-(4-chlorophenyl)-2,2,2-trichloroethanol. FW-152 is a mixture of 1,1-bis(4-chlorophenyl)-2,2-dichloroethanol and 1-(2-chlorophenyl)-1-(4-chlorophenyl)-2,2-dichloroethanol.

[2] Percent crop treated differs from that published in Table 1. The percent crop treated presented in Table 1 is based on a QUA developed by OPP's Biological and Economics Analysis Division (BEAD). For this table, most percent crop treated data were not obtained from BEAD, but were obtained from: *Pesticide Use in U.S. Crop Production*, National Center for Food and Agricultural Policy, 02/95; *Battelle Worldwide Pesticide Program, Insecticides IV*, 1990, from *Agricultural Chemical Usage, Vegetables*; USDA, 06/93; USDA Agricultural Statistics 1991; SRI International, *Deciduous Tree and Vine Crop Markets: U.S. Pacific States, 1990; 1988 Specialty Crop Pesticide Study- Fruit, Grapes, and Nuts*, Doane Marketing Research, Inc. Where conflicting numbers were found, the highest percent crop treated value was used. Data for peaches, apricots, cotton, mint, plums, grape wine, cherries, tea, blackberries, and raspberries were from a 11/05/92 Memorandum, John Faulkner (BEAD), listing 1990 usage information. If no data were available, 100% crop treated was assumed.

[3] Per cent crop treated should be used in the DRES analysis of chronic anticipated residues ONLY where the entry is redlined (in the original memo).

[4] Apple average residue value multiplied by the processing factor (0.018).

[5] Apricot rac values multiplied by the DRES concentration factor (6).

[6] Cherry rac values multiplied by the DRES concentration factor (4).

[7] Cherry rac values multiplied by the DRES concentration factor (1.5).

[8] Peach rac values multiplied by the DRES concentration factor (7).

[9] Pear rac values multiplied by the DRES concentration factor (4.4).

[10] Plum rac values multiplied by the DRES concentration factor (1.4).

d. Dietary Risk from Food Sources

Residues

Tolerances for dicofol residues in/on food and feed crops are published in 40 CFR Section 180.163. There are no tolerances established for animal commodities. Tolerances for animal commodities are now needed and have been included in the chronic analysis. Default concentration factors were generally not used for this analysis, because specific anticipated residues were given for most food forms.

Chronic Exposure:

A summary of the residue information considered in the chronic analysis was previously presented in Table 4. Although some of the percent crop treated values recorded in this table differ slightly from those presented in Table 1, in general they are overestimates and therefore represent a more conservative exposure assessment.

A DRES chronic exposure analysis was performed using anticipated residues and percent of crop treated, if applicable. Estimated chronic dietary risk for the U.S. general population and the highest subgroups are given in the table below.

Table 5: Chronic Dietary Food Exposure and Risk Estimate to Dicofol (from food alone)

Population	Exposure (mg/kg/day)	Percent of the RfD
U.S. Population	0.000076	19
Non-Nursing Infants(< 1 year)	0.000129	32
Children (1-6 years)	0.000150	38
Children (7-12 years)	0.000104	26

Estimated chronic dietary risk for the U.S. general population and all subgroups are below the Agency's level of concern for food alone. However, this estimate does not include the contribution of drinking water to dietary risk (which is discussed below in Section e, "Dietary Risk from Drinking Water Sources"). Dietary exposures from almost all food commodities were based on refined residues, such as anticipated residues or tolerance level residues corrected for percent of crop treated information applied. These estimates are not worst-case and are not expected to represent gross over-estimates of chronic dietary risk to dicofol. The FQPA Safety Factor of 3X has been applied to the RfD for this analysis (RfD = 0.0004 mg/kg/day), because the RfD is based on inhibition of adrenal cortisol trophic hormone (ACTH) stimulated-release. Generally, the Agency is not concerned about dietary risk if the risk estimate results in less than 100% of the RfD.

Acute Exposure:

The percentage of the acute reference dose is a measure of how close the acute exposure comes to the Reference Dose, and is calculated as the ratio of acute exposure (mg/kg/day) to the acute RfD (mg/kg/day). In this case, because the endpoint is based on neurotoxicity, the FQPA Safety Factor of 3X has been incorporated into the acute RfD for use with the dietary risk assessment for all population subgroups. The resulting acute RfD is 0.05 mg/kg/day. Generally, acute dietary risk estimates greater than 100% of the Acute RfD exceed the Agency's level of concern.

Rohm and Haas has provided a probabalistic acute dietary Monte Carlo (MC) analysis (MRID 44636501). The MC includes percent-crop treated data, and a distribution of residues obtained from field trial data. The analysis was reviewed and found to be acceptable. Acute dietary estimates at the 99.9th percentile exposure, are summarized in Table 6. The acute dietary risk estimates based on this highly refined exposure assessment do not exceed the Agency's level of concern.

Table 6: Dicofol Acute Dietary Exposure Estimates at the 99.9th Percentile (from food alone)

Population	Exposure (mg/kg/day)	% of Acute RfD
US Population	0.017523	35
Non-nursing infants (<1 year old)	0.044923	90
Children (1-6 years old)	0.034919	70
Children (7-12 years old)	0.024705	49

e. Dietary Risk from Drinking Water Sources

There is no established Maximum Contaminant Level (MCL) for residues of dicofol in drinking water. No health advisory levels for dicofol in drinking water have been established.

Ground Water

A tier 1 assessment that provides estimates of the concentration of dicofol in ground water was conducted. This tier 1 assessment used SCI-GROW, an empirical model based on actual ground-water monitoring data from small-scale prospective ground-water monitoring studies, to estimate upper bound concentrations of a chemical in vulnerable ground water. The SCI-GROW model estimated a 90-day peak average concentration of 0.069 ug/l for dicofol in ground water. This value was compared to drinking water levels of comparison (DWLOCs) calculated for both acute and chronic effects of dicofol. Because the concentration of pesticides in ground water is not expected to fluctuate widely, a single value was selected for acute and chronic exposure assessments.

Surface Water

The Agency calculated tier 2 (PRZM-EXAMS) estimated environmental concentrations (EECs) for dicofol in potential surface water sources. The EEC's are based on the environmental fate data for p,p'-dicofol, since it occurs in the greatest proportion (4.5:1 ratio with o,p'-dicofol) and is the more persistent of the two isomers. The EEC's were revised in June, 1998 to reflect the overall mean EECs for surface water. The Agency has characterized the surface water estimates by stating that further revision and refinement of the numbers would not result in lower values, and that even the available monitoring data is in the same general range as the model estimates. Estimated overall mean concentration of dicofol in surface water is 0.5 ug/l.

Drinking Water Risk

The Agency has calculated drinking water levels of comparison for acute and chronic exposures to dicofol in drinking water for the adult general U.S. population and non-nursing infants (< 1 year old), respectively.

Acute Dietary Risk from Drinking Water

For acute exposure to dicofol, the drinking water level of comparison (DWLOC) for the U.S. population is 1,140 ug/l; for non-nursing infants (<1 yr. old): 50 ug/l; for children 1-6 years old: 150 ug/l; and for children 7-12: 250 ug/l.

For acute exposure to the U.S. population, excluding infants and children, the Agency uses a body weight of 70 kg and 2 liters consumption of water per day for adults. For infants and children, the Agency uses a body weight of 10 kg and 1 liter consumption of water per day.

As stated previously, the estimated overall mean concentration of dicofol in surface water (from PRZM-EXAMS) is **0.5 μg/L** and **0.069 μg/L** for ground water (from SCI-GROW). The estimated average concentration of dicofol in either surface or ground water is less than the Agency's drinking water levels of comparison for dicofol for the adult U.S. general population, and all population subgroups. Therefore, the Agency does not have an acute dietary risk concern from exposure to dicofol to the US population.

Chronic Dietary Risk from Drinking Water

For chronic exposure to dicofol, the drinking water level of comparison (DWLOC) for the U.S. population is 11.34 ug/l; for non-nursing infants (<1 yr. old): 2.5 ug/l; for children 1-6 years old;2.71 ug/l; and for children 7-12: 2.96 ug/l.

For chronic exposure to the U.S. population excluding infants and children, the Agency uses a body weight of 70 kg and 2 liter consumption of water per day for adults and a body weight of 10 kg and 1 liter consumption of water for infants and children.

The estimated average concentration of dicofol in either surface or ground water (**0.5 μg/L** and **0.069 μg/L,** respectively) is less than the Agency's drinking water levels of comparison for dicofol the adult U.S. general population, and all population subgroups. Therefore, the Agency does not have a chronic dietary risk concern from exposure to dicofol to the US population.

4. Occupational and Residential Exposure and Risk Characterization

An occupational and/or residential exposure assessment is required for an active ingredient if:

1. certain toxicological criteria are triggered and
2. there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete.

However, because the registrants have removed these residential uses from the technical label, these uses will be canceled on these products. All other products containing dicofol are intended solely for non-residential uses.

a. Use Pattern and Formulation Summary

Applications of dicofol can be made using either ground-based or aerial equipment. Ground-based application methods include high volume sprays, low volume sprays, and spot treatments, among others. Aerial application methods include low volume sprays only. Soil incorporation is not required for any of these uses. The timing of applications is generally not restricted to specific time periods during the growing season of each crop/target with the exception of any previously established pre-harvest intervals. Based on the types of crops/targets to which dicofol can be applied, the use of several types of application equipment is possible. Application rates for the emulsifiable concentrate and flowable concentrate formulations can range up to 4 lb ai/acre (air and ground-based) while the application rate for the wettable powder formulations can range up to 3 lb ai/acre. Ground-based application volumes range from 20 to 1,600 gallons per acre while aerial application volumes range from 3 to 10 gallons per acre.

The registrants have proposed the following reduced maximum application rates (Rohm and Haas rebuttals dated 6/18/96 and 4/20/98): 6 lb ai/acre for citrus (since reduced to 3 lb ai/acre); 3 lb ai/acre for apples and pears; 2 lb ai/acre for pecans and walnuts; 1.5 lb ai/acre for cotton; 2.4 lb ai/acre for strawberries (since reduced to 2.0 lb ai/acre); 1.3 lb ai/acre for grapes; 1.5 lb ai/acre for stonefruits; 0.63 lb ai/acre for cucurbits; 1.5 lb ai/acre for beans; 0.75 lb ai/acre for tomatoes and peppers; and 0.55 lb ai/acre for nonresidential lawns and ornamentals.

Based on the use patterns and potential exposures described above, 14 major exposure scenarios were identified for dicofol:

1. mixing/loading wettable powder for aerial application;
2. mixing/loading wettable powder for ground-based application;

3. mixing/loading liquid for aerial application;
4. mixing/loading liquid for ground-based application;
5. mixing/loading liquids for high pressure handwand application;
6. applying the liquid formulation with groundboom;
7. applying the liquid formulation with aerial equipment;
8. applying the liquid formulation with airblast sprayer;
9. applying the liquid formulation with high pressure handwand sprayer;
10. applying sprays with a handgun (lawn) sprayer ;
11. flagging during the application of the liquid formulation with aerial equipment;
12. mixing, loading, and applying the liquid formulation with backpack sprayer;
13. mixing, loading, and applying the liquid formulation with hose-end sprayer; and
14. mixing, loading, and applying the liquid formulation with low pressure handwand sprayer.

The Agency has determined that there is potential exposure to persons entering sites previously treated with dicofol. Postapplication exposures may occur to agricultural workers following applications to the crops identified in the use summary during routine hand-labor crop-production tasks, such as hoeing, thinning, and harvesting activities, as well as non-hand-labor tasks, such as crop-advisor and irrigation-related activities.

b. Assumptions

Total exposure was calculated by summing the oral dose equivalents of inhalation and dermal exposure, then compared with the appropriate NOAEL for risk assessment. Application rates, daily maximum area treated, and daily baseline exposure (for workers wearing baseline protection: long pants, long sleeved shirt, shoes, and socks) are provided in Table 8 below. Crop-specific application rates and acreage information were provided by Rohm and Haas in order to determine a more refined, accurate exposure assessment (6/97). Unit exposure data were derived from the Pesticide Handlers Exposure Database (PHED), Version 1.1. Exposure scenario details, such as level of confidence, PPE, engineering controls, and standard assumptions are presented in Tables 7-12.

The PHED was developed by Health Canada, The American Crop Protection Association, and EPA. PHED was initially released for public use in 1992. PHED is a generic/surrogate exposure database containing a large number of measured values of dermal and inhalation exposure for pesticide workers (e.g., mixers, loaders, and applicators) involved in handling and applying pesticides. The database currently contains data for over 2,000 monitored exposure events. Use of surrogate or generic data is appropriate, since it is generally believed that the physical parameters of the handling and application process (e.g., the type of formulation used, the method of application, and the type of clothing worn), not the chemical properties of the pesticide, control the amount of dermal and inhalation exposure. Thus, PHED typically allows exposure and risk assessments to be conducted with a much larger number of observations than are normally available from a single exposure study.

PHED also contains algorithms that allow the user to complete surrogate task-based exposure assessments beginning with one of the four main data files contained in the system (i.e., mixer/loader, applicator, flagger, and mixer/loader/applicator). Users select data from each file and construct exposure scenarios that are representative of the use of the chemical. The Agency, in conjunction with the PHED task force, has evaluated all of the data currently in PHED, and developed a surrogate exposure table that contains a series of standard exposure estimates for various scenarios. These standard unit exposure values are the basis for this assessment. The standard exposure values (i.e., the unit exposure values included in the exposure and risk tables) are based on the "best fit" values calculated by PHED. PHED calculates "best fit" exposure values by assessing the distributions of exposures for each body part included in data sets selected for the assessments (e.g., chest or forearm), and then calculates a composite exposure value representing the entire body. PHED categorizes distributions as normal, lognormal, or "other." Generally, most data contained in PHED are lognormally distributed or fall into the PHED "other" distribution category. If the distribution is lognormal, the geometric mean for the distribution is used in the calculation of the "best fit" exposure value. If the data are an "other" distribution, the median value of the data set is used in the calculation of the "best fit" exposure value. As a result, the surrogate unit exposure values that serve as the basis for this assessment generally range from the geometric mean to the median of the selected data set.

The Agency's first step in performing a handler exposure assessment is to complete a baseline exposure assessment. The baseline scenario generally represents a handler wearing long pants, a long-sleeved shirt, and no chemical-resistant gloves. If the level of concern is met or exceeded, then increasing levels of risk mitigation, such as PPE (personal protective equipment) and engineering controls, are used to recalculate the MOE's, until the exposure is sufficiently reduced to achieve an appropriate margin of exposure.

Handler Exposure Data

Data for the dicofol handler exposure assessment was obtained from the Pesticide Handlers Exposure Database (PHED), Version 1.1. Confidence levels in the available data (ranging from low to high) and other details are provided in Table 12.

Handler (Mixer/Loader/Applicator) Exposure Scenarios

The Agency has determined that there is a potential exposure to mixers, loaders, applicators, or other handlers during usual use-patterns associated with dicofol. In particular, the Agency is concerned about exposures to handlers during the treatment of crops by ground and aerial equipment, and during treatment of ornamentals using hand-held equipment.

Exposure Calculations

The following calculations are used to assess the risk to handlers.

Daily Exposure (mg ai/day) is calculated using the following equation:

Daily Systemic Dose due to Dermal Exposure (mg/kg/day) is calculated using the following formula:

$$Daily\ Systemic\ Dose\left(\frac{mg}{Kg\ Day}\right) = Daily\ Exposure\left(\frac{mg}{Day}\right)\ \left(\frac{1}{Body\ Weight\ (Kg)}\right)\ Dermal\ Absorption$$

Short Term and Intermediate Term Risk/Margin of Exposure (MOE) was calculated using the following formula:

$$MOE = \frac{NOEL\left(\frac{mg}{kg\ day}\right)}{Absorbed\ Daily\ Dose\left(\frac{mg}{kg\ day}\right)}$$

Exposure and risk for the short term and intermediate term uses of dicofol are summarized in the tables below. Short-term occupational risk was calculated using the endpoint of 4.0 mg/kg/day, with an MOE of at least 100 required. Intermediate-term occupational risk was calculated using the 0.29 mg/kg/day NOAEL (EPA, Hazard Identification Assessment Review Committee Report, December 17, 1997) with a required MOE of 100 or more. The Agency (HED Metabolism Committee; September 29, 1992) determined that dicofol and FW-152 are the residues of concern in animals.

Exposure was calculated under the assumption of 100% dermal absorption and therefore *may result in an overestimation of risk.*

Postapplication Exposure Data

Significant potential for exposure exists for workers after application of dicofol. Chemical-specific post-application exposure or environmental fate data (as regulated by Series 875) have not been submitted in support of the reregistration of dicofol. Therefore, a surrogate range-finding post-application exposure assessment was performed for occupational settings. In this assessment, dislodgeable foliar residue (DFR) are assumed to be 20% of the application rate and dissipation is assumed at 10% per day. Environmental fate data were not reviewed for the surrogate assessment. The study indicates that prolonged restricted-entry intervals are necessary to protect workers. Although exposure at residential sites is likely to be lower than for occupational use sites, a post-application residential risk assessment was not conducted because restricted entry intervals are not feasible in residential settings. The Agency has concerns regarding post-application exposure for occupational use sites, and requests that the registrants submit the required data (see Section 4) as soon as possible. A new DFR study is being conducted by the registrants and is due in October 1998.

Until these data are submitted and evaluated, the post-application use scenarios remain a concern.

c. Occupational Handler (Mixer/Loader and Applicator) Exposure and Risk Assessment/Characterization

The registrants have agreed to risk reduction measures, including revised use patterns, application rates, water soluble packaging for all wettable powder formulation products, and additional personal protective equipment.

Another suggestion made by the registrants in the rebuttal (MRID 44552801) was to add gloves, coveralls, and respirators to labels for mixer/loaders using water soluble packets. In response, the Agency has stated that it has reservations about requiring additional PPE, **other than gloves**, such as double layers of clothing and respirators, in addition to engineering controls, (closed mixing loading systems, such as water-soluble packet) and **does not recommend that particular mitigation measure.**

Short-term estimated risks, based on the exposure values in Table 7 are presented in Table 8 for workers with baseline clothing and with additional PPE. Intermediate-term estimated risks, based on the exposure values in Table 7 are presented in Table 9 for workers wearing baseline clothing in addition to PPE. Tables 10 and 11 present the estimated risk for workers when engineering controls are implemented in addition to PPE.

The registrants have committed to move to water soluble packaging for all wettable powder formulations in an effort to reduce exposure. Therefore, risk to mixer/loaders when handling wettable powder formulations of dicofol was only calculated for workers using water soluble packaging, a closed system (engineering controls), so the risk estimates for these workers appears only in Tables 10 and 11. Water soluble mixing will be in place for all wettable powder systems in 1999.

Occupational Handler Risk Estimates

With the agency's current assumption of 100% dermal absorption, estimated risks for short-term and intermediate-term exposure for all handlers wearing baseline personal protective equipment (long sleeved shirt, long pants, shoes, and socks), all show MOEs of less than 100 and, therefore, exceed the Agency's **level of concern**.

With additional PPE consisting of a double layer of clothing, chemical resistant gloves, and an organic vapor-removing respirator, workers have reduced exposure but risks for some short-term and intermediate-term use scenarios still result in MOE's below 100.

Only the following short-term use scenarios result in acceptable MOE's above 100 and do not exceed the Agency's level of concern for occupational risk with additional PPE consisting of a double layer of clothing, chemical resistant gloves, and an organic vapor-removing respirator: (from Table 8):

- Mixing/loading Liquids for Groundboom Application to Peppers and Tomatoes

- Groundboom Application to Beans, Strawberries, and Peppers and Tomatoes
- High Pressure Handwand Application to Lawns/Ornamentals
- Flagging for Application to Grapes, Cucurbits, and Tomatoes and Peppers

All other short-term exposure scenarios result in MOE's below 100 and exceed the Agency's level of concern.

There are no <u>intermediate-term</u> use scenarios which result in acceptable MOE's above 100 (from Table 9).

With engineering controls consisting of closed mixing/loading systems (water soluble packaging for wettable powders and enclosed delivery systems for liquids) and closed cabs for all application and flagging scenarios, workers have exposure reduced further, but the risks for some short-term and intermediate-term use scenarios result in MOE's below 100.

Only the following <u>short-term</u> use scenarios for workers using engineering controls result in MOE's above 100 and **do not exceed the Agency's level of concern** for occupational risk (from table 10):

- Mixing/Loading Wettable Powders for Groundboom Application to Peppers and Tomatoes.
- Mixing/Loading Liquids for Aerial Application to Cucurbits and Peppers and Tomatoes.
- Mixing Loading Liquids for Groundboom Application to Strawberries, Mint, and Beans
- All Groundboom Application Scenarios.
- Aerial Application to Pecans/Walnuts, Grapes, Stonefruit, Cucurbits, and Peppers and Tomatoes.
- All Airblast Application Scenarios.
- All Flagging Scenarios.
- All Other Scenarios With MOE's Above 100 as Mentioned Above.

All other use scenarios result in MOE's below 100 and exceed the Agency's level of concern.

Only the following <u>intermediate-term</u> use scenarios for workers using engineering controls result in acceptable MOE's above 100 and do not exceed the Agency's level of concern for occupational risk (from Table 11):

- All Flagger Use Scenarios, except citrus.
- All Other Scenarios With MOE's Above 100 as Mentioned Above.

All other intermediate-term use scenarios result in MOE's below 100 and exceed the Agency's level of concern.

The Agency assumes that by wearing an organic vapor removing cartridge respirator, workers can reduce inhalation exposure by an estimated 90 percent. Likewise, the Agency assumes that fabric coveralls worn over baseline protection can reduce dermal exposure by 50 percent. The PHED exposure data used to calculate risk estimates for handlers wearing baseline clothing, with PPE, and with engineering controls, varies from poor quality ("low confidence") to high quality ("high confidence"). Generally, if at least 15 PHED data records are available and the data quality are graded A and/or B, the source is considered with high confidence. If fewer than 15 PHED data records are available or the data quality is low, the source is considered with low confidence.

The registrants asserted in their April 20, 1998 rebuttal that, "Dicofol users will not be handling this product exclusively on an all-day basis for more than a few days at most in any given season." The Agency agrees and acknowledges that the occupational handler risk assessment is conducted using assumptions which attempt to account for the inherent variability in use practices and human behavior. Some of the assumptions used in the handler risk assessment may be too conservative for the typical applicator, but are reasonable for a commercial applicator. Other assumptions, such as the dermal absorption rate of 100% or the number of acres treated per day must be used in the absence of real data in order to be protective of public health.

TABLE 7. HANDLER AND FLAGGER EXPOSURE FOR DICOFOL

Exposure Scenario (Scenario #)	Baseline Dermal Unit Exposure[a] (mg/lb ai)	Baseline Inhalation Unit Exposure[b] (µg/lb ai)	Crop[c]	Proposed Maximum Application Rate[c] (lb ai/acre)	Daily Max. Treated[d] (acres)	Daily Dermal Exposure[e] (mg/day)	Daily Inhalation Exposure[f] (mg/day)	Daily Total Exposure[g] (mg/day)
Mixer/Loader								
Mixing/Loading Wettable Powder for Aerial Application (1)	3.8	43.4	Citrus	3	480	See Engineering Controls-Tables 10 and 11		
			Apples/Pears	3	200			
			Pecans/Walnuts	2	200			
			Cotton	1.5	480			
			Strawberries	2.0	250			
			Grapes	1.3	250			
			Stonefruit	1.5	250			
			Cucurbits	0.63	320			
			Beans	1.5	320			
			Tomatoes/Peppers	0.75	320			
Mixing/Loading Wettable Powder for Groundboom Application (2)	3.8	43.4	Cotton	1.5	200	See Engineering Controls-Tables 10 and 11		
			Strawberries	2.0	90			
			Mint	1.3	140			
			Beans	1.5	90			
			Peppers/Tomatoes	0.75	90			
Mixing/Loading Liquid for Aerial Application (3)	2.9	1.2	Citrus	3	480	4200	1.7	4200
			Apples/Pears	3	200	1700	0.72	1700
			Pecans/Walnuts	2	200	1200	0.48	1200
			Cotton	1.5	480	2100	0.86	2100
			Strawberries	2.0	250	1500	0.60	1500
			Grapes	1.3	250	910	0.38	910
			Stonefruit	1.5	250	1100	0.45	1100
			Cucurbits	0.63	320	580	0.24	580
			Beans	1.5	320	1400	0.58	1400
			Tomatoes/Peppers	0.75	320	700	0.29	700
Mixing/Loading Liquid for Groundboom Application (4)	2.9	1.2	Cotton	1.5	200	870	0.36	870
			Strawberries	2.0	90	520	0.22	520
			Mint	1.3	140	510	0.21	510
			Beans	1.5	90	390	0.16	390
			Peppers/Tomatoes	0.75	90	200	0.081	200
Mixing/Loading Liquid for High Pressure Handwand Application (5)	2.9	1.2	Lawn/Ornamental	0.55	10 (H)	16	0.007	16
					20 (O)	32	0.013	32
Applicator Exposure								
Groundboom (6)	0.015	0.7	Cotton	1.5	200	4.5	0.21	4.7
			Strawberries	2.0	90	2.7	0.13	2.8

TABLE 7: HANDLER AND FLAGGER EXPOSURE FOR DICOFOL

Exposure Scenario (Scenario #)	Baseline Dermal Unit Exposure[a] (mg/lb ai)	Baseline Inhalation Unit Exposure[b] (μg/lb ai)	Crop[c]	Proposed Maximum Application Rate[c] (lb ai/acre)	Daily Max. Treated[d] (acres)	Daily Dermal Exposure[e] (mg/day)	Daily Inhalation Exposure[f] (mg/day)	Daily Total Exposure[g] (mg/day)
			Mint	1.3	140	2.6	0.12	2.7
			Beans	1.5	90	2.0	0.095	2.1
			Peppers/Tomatoes	0.75	90	1.0	0.047	1.1
Aerial (7)	See Engineering Controls		Citrus	3	480	See Engineering Controls- Tables 10 and 11		
			Apples/Pears	3	200			
			Pecans/Walnuts	2	200			
			Cotton	1.5	480			
			Strawberries	2.0	250			
			Grapes	1.3	250			
			Stonefruit	1.5	250			
			Cucurbits	0.63	320			
			Beans	1.5	320			
			Tomatoes/Peppers	0.75	320			
Airblast (8)	0.4	4.5	Citrus	3	24	29	0.32	29
			Pecans/Walnuts	2	60	48	0.54	49
			Hops	1.2	64	31	0.35	31
			Stonefruit	1.5	64	38	0.43	39
			Grapes	1.3	24	12	0.14	12
			Cucurbits	0.63	90	23	0.26	23
High Pressure Handwand (9)	1.8	79	Ornamentals	0.03 lbs/1000ft^2	1000 ft^2	0.05	0.002	0.052
Applying sprays with a handgun (lawn) sprayer (10)	See PPE	1.4	PCO Lawns	0.55	5	See PPE Tables 8, 9	0.0039	See PPE Tables 8, 9
Flagger								
Flagging (11)	0.01	0.3	Citrus	3	480	14	0.43	14
			Apples/Pears	3	200	6	0.18	6.2
			Pecans/Walnuts	2	200	4	0.12	4.1
			Cotton	1.5	480	7.2	0.22	7.4
			Strawberries	2.0	250	5.0	0.15	5.2
			Grapes	1.25	250	3.1	0.094	3.2
			Stonefruit	1.5	250	3.8	0.11	3.9
			Cucurbits	0.63	320	2	0.06	2.1
			Beans	1.5	320	4.8	0.14	4.9
			Tomatoes/Peppers	0.75	320	2.4	0.072	2.5
Mixer/Loader/Applicator								
Backpack Sprayer (12)	4.99	30	Non Residential Lawns/Ornamentals	0.01 lb/1000 ft^2 or 0.55	(O) 5	14	0.083	14

TABLE 7: HANDLER AND FLAGGER EXPOSURE FOR DICOFOL								
Exposure Scenario (Scenario #)	Baseline Dermal Unit Exposure[a] (mg/lb ai)	Baseline Inhalation Unit Exposure[b] (μg/lb ai)	Crop[c]	Proposed Maximum Application Rate[c] (lb ai/acre)	Daily Max. Treated[d] (acres)	Daily Dermal Exposure[e] (mg/day)	Daily Inhalation Exposure[f] (mg/day)	Daily Total Exposure[g] (mg/day)
Hose-End (13)	30.55	9.5	Non-Residential Lawns/Ornamentals	0.55	(O) 5	84	0.026	84
Low Pressure Handwand Sprayer (14)	103	31	Non-Residential Lawns/Ornamentals	0.01 lb/1000 ft^2 or 0.55	(O) 5	280	0.085	280

(H) = homeowner; (O) = occupational

a Baseline Protection = Long pants, long sleeve shirts, no gloves, shoes and socks, open mixing/loading, open cockpit, open cab tractor; see Table 12 for details.

b Baseline Protection = No respirator; see Table 12 for details.

c Proposed crops and maximum application rates are based on Rohm and Haas (Susan S. Hurt) rebuttal dated June 18, 1996. Tables have now been further reduced to 3 lb ai/acre.

d Values represent the maximum area which can be used in a single day based on Rohm and Haas Company's (Susan S. Hurt) rebuttal dated June 18, 1996.

e Daily dermal exposure (mg/day) = Exposure (mg/lb ai) * Max. Appl. Rate (lb ai/acre) * Max. Treated

f Daily inhalation exposure (mg/day) = Exposure (μg/lb ai) * (1mg/1,000 μg) conversion * Max Appl Rate (lb ai/A) * Max Treated

g Daily total exposure (mg/day) = Daily dermal exposure + Daily inhalation exposure

TABLE 8: SHORT TERM RISK FOR DICOFOL HANDLERS AND FLAGGERS WITH BASELINE AND ADDITIONAL PPE

Exposure Scenario (Scenario #)	Crop	Baseline Total Dose (mg/kg/day)[a]	Baseline Total MOE[b]	Risk Mitigation Measure					
				Additional PPE[c]					
				Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (μg/lb ai)	Daily Dermal Dose (mg/kg/day)[d]	Daily Inhalation Dose (mg/kg/day)[e]	Daily Total Dose (mg/kg/day)[a]	Total MOE[b]
Mixer/Loader Risk									
Mixing/Loading Wettable Powder for Aerial Application (1)	Citrus	See Engineering Controls Tables 10 and 11							
	Apples/Pears								
	Pecans/Walnuts								
	Cotton								
	Strawberries								
	Grapes								
	Stonefruit								
	Cucurbits								
	Beans								
	Tomatoes/Peppers								
Mixing/Loading Wettable Powder for Groundboom Application (2)	Cotton								
	Strawberries								
	Mint								
	Beans								
	Peppers/Tomatoes								
Mixing/Loading Liquid for Aerial Application (3)	Citrus	70	0.06	0.025	0.12	0.6	0.029	0.60	7
	Apples/Pears	29	0.14			0.25	0.012	0.25	16
	Pecans/Walnuts	19	0.21			0.17	0.0080	0.18	22
	Cotton	35	0.11			0.30	0.014	0.31	13
	Strawberries	25	0.16			0.21	0.0010	0.21	19
	Grapes	15	0.26			0.13	0.0065	0.14	29
	Stonefruit	18	0.22			0.16	0.0075	0.17	24
	Cucurbits	9.7	0.41			0.083	0.0040	0.087	46
	Beans	23	0.17			0.20	0.0096	0.21	19
	Tomatoes/Peppers	12	0.34			0.10	0.0048	0.10	40
Mixing/Loading Liquid for Groundboom Application (4)	Cotton	15	0.28			0.13	0.00060	0.13	32
	Strawberries	8.7	0.46			0.075	0.00036	0.075	53
	Mint	8.5	0.47			0.073	0.00036	0.073	55
	Beans	6.5	0.61			0.056	0.00027	0.056	71
	Peppers/Tomatoes	3.3	1.2			0.028	0.00014	0.028	140

TABLE 8: SHORT TERM RISK FOR DICOFOL HANDLERS AND FLAGGERS WITH BASELINE AND ADDITIONAL PPE

Exposure Scenario (Scenario #)	Crop	Baseline Total Dose (mg/kg/day)[a]	Baseline Total MOE[b]	Risk Mitigation Measure					
				Additional PPE[c]					
				Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (μg/lb ai)	Daily Dermal Dose (mg/kg/day)[d]	Daily Inhalation Dose (mg/kg/day)[e]	Daily Total Dose (mg/kg/day)[a]	Total MOE[b]
Mixing/Loading Liquid for High Pressure Handwand Application (5)	Lawn/Ornamentals @10 acres	0.23	17	N/A	N/A	N/A	N/A	N/A	N/A
	@20 acres	0.46	9						
Applicator Risk									
Groundboom (6)	Cotton	0.079	51	0.01	0.07	0.05	0.00035	0.050	79
	Strawberries	0.047	85			0.030	0.00021	0.030	130
	Mint	0.046	87			0.030	0.00021	0.030	130
	Beans	0.035	113			0.023	0.00016	0.023	170
	Peppers/Tomatoes	0.018	226			0.011	0.000079	0.011	360
Aerial (7)	See Engineering Controls Table for all crops								
Airblast (8)	Citrus	0.48	8.3	0.12	0.45	0.14	0.00054	0.14	29
	Pecans/Walnuts	0.81	4.9			0.24	0.00090	0.24	17
	Hops	0.52	7.7			0.15	0.00058	0.15	26
	Stonefruit	0.65	6.2			0.19	0.00072	0.19	21
	Grapes	0.2	20			0.06	0.00023	0.06	66
	Cucurbits	0.39	10.3			0.11	0.00043	0.11	36
High Pressure Handwand (9)	Lawns/Ornamentals	0.17	23	0.31	7.9	0.028	0.00072	0.029	140
		0.34	12			0.056	0.0014	0.057	70
Applying Sprays with a handgun (lawn) sprayer (10)	PCO Lawns	See PPE		0.19	1.4 (no respirator)				
Flagger Risk									
Flagging (11)	Citrus	0.23	17	0.007	0.03	0.17	0.00072	0.17	24
	Apples/Pears	0.1	39			0.070	0.00030	0.070	57
	Pecans/Walnuts	0.069	58			0.047	0.00020	0.047	85
	Cotton	0.12	32			0.084	0.00036	0.084	47
	Strawberries	0.087	46			0.058	0.00025	0.058	69
	Grapes	0.054	75			0.036	0.00016	0.036	110
	Stonefruit	0.064	62			0.044	0.00019	0.044	91
	Cucurbits	0.034	120			0.023	0.00010	0.023	170
	Beans	0.082	49			0.056	0.00024	0.056	71
	Tomatoes/Peppers	0.041	97			0.028	0.00012	0.028	140
Mixer/Loader/Applicator									
Backpack Sprayer (12)	Lawns/Ornamentals	(O) 0.23	17	1.3	3	0.058	0.00014	0.058	69
Hose-End (13)	Lawns/Ornamentals	(O) 1.4	2.9	4.6	0.95	0.21	0.000044	0.21	19

TABLE 8: SHORT TERM RISK FOR DICOFOL HANDLERS AND FLAGGERS WITH BASELINE AND ADDITIONAL PPE

Exposure Scenario (Scenario #)	Crop	Baseline Total Dose (mg/kg/day)[a]	Baseline Total MOE[b]	Risk Mitigation Measure: Additional PPE[c]					
				Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (μg/lb ai)	Daily Dermal Dose (mg/kg/day)[d]	Daily Inhalation Dose (mg/kg/day)[e]	Daily Total Dose (mg/kg/day)[a]	Total MOE[b]
Low Pressure Handwand (14)	Lawns/Ornamentals	(O) 4.7	0.85	3.2	3.1	0.15	0.00014	0.15	27

(O) = occupational; Use of dicofol on residential lawns is no longer a use site.

a Baseline total dose = (daily dermal exposure + daily inhalation exposure)/60 kg. (Note: Exposure values are from Table 7.)

b Total MOE = NOAEL (short-term NOAEL = 4 mg/kg/day) / daily total dose (mg/kg/day).

c Additional PPE = Double layer of clothing, chemical resistant gloves, and an organic/vapor removing respirator. Unit inhalation exposures for respirators are based on the unit inhalation exposures on Table 7 adjusted by a 10-fold protection factor.

d Daily dermal dose = Dermal unit exposure (mg/lb ai) x Appl. rate (lb ai/A) x Acres/60 kg. (Note: Appl. rate and acres treated are from Table 7)

e Daily Inhalation Dose (mg/kg/day) = Inhalation unit exposure (μg/lb ai) x $\left(\frac{1\ mg}{1{,}000\ \mu g\ conversion}\right)$ x Appl. rate (lb ai/A) x Acres/60 kg. (Note: Appl. rate and acres treated are from Table 7)

N/A - Not applicable; homeowners are not required to use PPE.

TABLE 9: INTERMEDIATE-TERM RISK FOR HANDLERS AND FLAGGERS FOR DICOFOL WITH BASELINE AND ADDITIONAL PPE

Exposure Scenario (Scenario #)	Crops	Baseline Total Dose (mg/kg/day)[a]	Baseline Total MOE[b]	Risk Mitigation Measure					
				Additional PPE[c]					
				Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (ug/lb ai)	Daily Dermal Dose (mg/kg/day)[d]	Daily Inhalation Dose (mg/kg/day)[e]	Daily Total Dose (mg/kg/day)[a]	Total MOE[b]
Mixer/Loader Risk									
Mixing/Loading Wettable Powder for Aerial Application (1)	Citrus	See Engineering Controls Tables 10 and 11							
	Apples/Pears								
	Pecans/Walnuts								
	Cotton								
	Strawberries								
	Grapes								
	Stonefruit								
	Cucurbits								
	Beans								
	Tomatoes/Peppers								
Mixing/Loading Wettable Powder for Groundboom Application (2)	Cotton								
	Strawberries								
	Mint								
	Beans								
	Peppers/Tomatoes								
Mixing/Loading Liquid for Aerial Application (3)	Citrus	70	0.004	0.025	0.12	0.6	0.0029	0.6	0.5
	Apples/Pears	29	0.01			0.25	0.012	0.25	1.2
	Pecans/Walnuts	19	0.016			0.17	0.0080	0.18	1.8
	Cotton	35	0.0086			0.30	0.014	0.31	1
	Strawberries	25	0.01			0.21	0.0010	0.21	1.4
	Grapes	15	0.02			0.13	0.0065	0.14	2.3
	Stonefruit	18	0.017			0.16	0.0075	0.17	1.9
	Cucurbits	9.7	0.031			0.083	0.0040	0.087	3.6
	Beans	23	0.013			0.20	0.0096	0.21	1.5
	Peppers/Tomatoes	12	0.026			0.10	0.0048	0.10	3
Mixing/Loading Liquid for Groundboom Application (4)	Cotton	15	0.021	0.025	0.12	0.13	0.00060	0.13	2.4
	Strawberries	8.7	0.033			0.075	0.00036	0.075	3.9
	Mint	8.5	0.035			0.073	0.00036	0.073	4.1
	Beans	6.5	0.046			0.056	0.00027	0.056	5.3
	Peppers/Tomatoes	3.3	0.092			0.028	0.00014	0.028	11
Mixing/Loading Liquids for High Pressure Handwand Application (5)	Lawn/Ornamentals @10 acres	0.23	1.3	N/A	N/A	N/A	N/A	N/A	N/A
	@20 acres	0.46	0.63						

TABLE 9: INTERMEDIATE-TERM RISK FOR HANDLERS AND FLAGGERS FOR DICOFOL WITH BASELINE AND ADDITIONAL PPE

Exposure Scenario (Scenario #)	Crops	Baseline Total Dose (mg/kg/day)[a]	Baseline Total MOE[b]	Risk Mitigation Measure: Additional PPE[c]					
				Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (μg/lb ai)	Daily Dermal Dose (mg/kg/day)[d]	Daily Inhalation Dose (mg/kg/day)[e]	Daily Total Dose (mg/kg/day)[a]	Total MOE[b]
Applicator Risk									
Groundboom (6)	Cotton	0.079	4	0.01	0.07	0.050	0.00035	0.050	6
	Strawberries	0.047	6			0.030	0.00021	0.030	9.7
	Mint	0.046	7			0.029	0.00021	0.029	10
	Beans	0.035	8			0.023	0.00016	0.023	13
	Peppers/Tomatoes	0.018	17			0.011	0.000079	0.011	26
Aerial (7)	See Engineering Controls Table for All Crops								
Airblast (8)	Citrus	0.48	0.6	0.12	0.45	0.14	0.00054	0.14	2.1
	Pecans/Walnuts	0.81	0.37			0.24	0.00090	0.24	1.2
	Hops	0.52	0.58			0.15	0.00058	0.15	1.9
	Stonefruit	0.65	0.46			0.19	0.00072	0.19	1.6
	Grapes	0.2	1.5			0.06	0.00023	0.06	5
	Cucurbits	0.39	10.3			0.11	0.00043	0.11	2.6
High Pressure Handwand (9)	Ornamentals	0.17	1.7	0.31	7.9	0.028	0.00072	0.029	10
		0.34	0.87			0.056	0.0014	0.057	5.2
Applying Sprays with a handgun (lawn) sprayer (10)	PCO Lawns	See PPE	See PPE	0.19	1.4 (no respirator)				
Flagger Risk									
Flagging (11)	Citrus	0.23	1.3	0.007	0.03	0.17	0.00072	0.17	1.8
	Apples/Pears	0.1	2.9			0.070	0.00030	0.070	4.3
	Pecans/Walnuts	0.069	4.4			0.047	0.00020	0.047	6.4
	Cotton	0.12	2.4			0.084	0.00036	0.084	3.6
	Strawberries	0.087	3.3			0.058	0.00025	0.058	5
	Grapes	0.054	5.6			0.036	0.00016	0.036	8.2
	Stonefruit	0.064	4.7			0.044	0.00019	0.044	6.8
	Cucurbits	0.034	8.7			0.023	0.00010	0.023	13
	Beans	0.082	3.6			0.056	0.00024	0.056	5.3
	Tomatoes/Peppers	0.041	7.3			0.028	0.00012	0.028	11
Mixer/Loader/Applicator									
Backpack Sprayer (12)	Lawns/Ornamentals	(O) 0.23	1.3	1.3	3	0.058	0.00014	0.058	5.2
Hose-End (13)	Lawns/Ornamentals	(O) 1.4	0.21	4.6	0.95	0.21	0.000044	0.21	1.4
Low Pressure Handwand (14)	Lawns/Ornamentals	(O) 4.7	0.064	3.2	3.1	0.15	0.00014	0.15	2

(O) = occupational; Homeowner use of dicofol for ornamentals is not expected to occur for seven or more consecutive days and is therefore excluded.

a Baseline total dose = (daily dermal exposure + daily inhalation exposure)/60 kg. (Note: Exposure values are from Table 7.)

b Total MOE = NOAEL (intermediate-term NOAEL = 0.29 mg/kg/day) / daily total dose (mg/kg/day). The NOAEL of 0.29 mg/kg/day was rounded to 0.3 mg/kg/day.

c Additional PPE = Double layer of clothing, chemical resistant gloves, and an organic/vapor removing respirator. Unit inhalation exposures for respirators are based on the unit inhalation exposures on Table 7 adjusted by a 10-fold protection factor.

d Daily dermal dose = Dermal unit exposure (mg/lb ai) x Appl. rate (lb ai/A) x Acres/60 kg. (Note: Appl. rate and acres treated are from Table 7.)

e Daily Inhalation Dose (mg/kg/day) = Inhalation unit exposure (μg/lb ai) x $\left(\frac{1\ mg}{1{,}000\ \mu g}\right)$ x Appl. rate (lb ai/A) x Acres/60 kg. (Note: Appl. rate and acres treated are from Table 7.)

N/A - Not applicable; homeowners are not required to use PPE.

TABLE 10: SHORT-TERM RISK FOR DICOFOL WITH ENGINEERING CONTROLS								
Exposure Scenario (Scen. #)	Crop	Proposed Maximum Application Rate (lb ai/acre)	Risk Mitigation Measure: Engineering Controls[a]					
			Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (μg/lb ai)	Daily Dermal Dose (mg/kg/day)[b]	Daily Inhalation Dose (mg/kg/day)[c]	Daily Total Dose (mg/kg/day)[d]	Total MOE[e]
Mixer/Loader Risk								
Mixing/Loading Wettable Powder for Aerial Application (1)	Citrus	3	0.02	0.2	0.48	0.0048	0.48	8.3
	Apples/Pears	3			0.20	0.0020	0.2	20
	Pecans/Walnuts	2			0.13	0.0013	0.13	30
	Cotton	1.5			0.24	0.0024	0.24	17
	Strawberries	2			0.17	0.0017	0.17	24
	Grapes	1.3			0.1	0.0010	0.11	38
	Stonefruit	1.5			0.13	0.0013	0.13	32
	Cucurbits	0.63			0.067	0.00067	0.067	59
	Beans	1.5			0.16	0.0016	0.16	25
	Tomatoes/Peppers	0.75			0.08	0.0008	0.081	50
Mixing/Loading Wettable Powder for Groundboom Application (2)	Cotton	1.5			0.10	0.0010	0.10	40
	Strawberries	2			0.060	0.0006	0.061	66
	Mint	1.3			0.058	0.00058	0.059	68
	Beans	1.5			0.045	0.00045	0.045	88
	Peppers/Tomatoes	0.75			0.023	0.00023	0.023	180
Mixing/Loading Liquid for Aerial Application (3)	Citrus	3	0.009 (Gloves)	0.08	0.22	0.0019	0.22	18
	Apples/Pears	3			0.09	0.00080	0.091	44
	Pecans/Walnuts	2			0.06	0.00053	0.061	66
	Cotton	1.5			0.11	0.00096	0.11	37
	Strawberries	2			0.075	0.00067	0.076	53
	Grapes	1.3			0.047	0.00043	0.047	85
	Stonefruit	1.5			0.056	0.00050	0.057	70
	Cucurbits	0.63			0.03	0.00027	0.03	130
	Beans	1.5			0.072	0.00064	0.073	55
	Tomatoes/Peppers	0.75			0.036	0.00032	0.036	110
Mixing/Loading Liquid for Groundboom Application (4)	Cotton	1.5	0.009 (Gloves)	0.08	0.045	0.00040	0.045	88
	Strawberries	2			0.027	0.00024	0.027	150
	Mint	1.3			0.026	0.00024	0.026	150
	Beans	1.5			0.020	0.00018	0.020	200
	Peppers/Tomatoes	0.75			N/A	N/A	N/A	N/A

TABLE 10: SHORT-TERM RISK FOR DICOFOL WITH ENGINEERING CONTROLS								
Exposure Scenario (Scen. #)	Crop	Proposed Maximum Application Rate (lb ai/acre)	Risk Mitigation Measure					
			Engineering Controls[a]					
			Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (μg/lb ai)	Daily Dermal Dose (mg/kg/day)[b]	Daily Inhalation Dose (mg/kg/day)[c]	Daily Total Dose (mg/kg/day)[d]	Total MOE[e]
g125 Mixing/Loading Liquids for High Pressure Handwand Application (5)	Lawn/Ornamentals	0.55	N/A	N/A	N/A	N/A	N/A	N/A
Applicator Risk								
Groundboom (6)	Cotton	1.5	0.0067	0.04	0.034	0.00020	0.034	120
	Strawberries	NA			NA	NA	NA	NA
	Mint	NA			NA	NA	NA	NA
	Beans	NA			0.015	0.00009	0.015	267
	Peppers/Tomatoes	NA			NA	N/A	NA	NA
Aerial (7)	Citrus	3	0.005	0.068	0.12	0.0016	0.12	33
	Apples/Pears	3			0.05	0.00068	0.051	79
	Pecans/Walnuts	2			0.033	0.00045	0.034	120
	Cotton	1.5			0.060	0.00082	0.061	66
	Strawberries	2			0.042	0.00057	0.043	93
	Grapes	1.3			0.026	0.00037	0.026	150
	Stonefruit	1.5			0.031	0.00043	0.031	129
	Cucurbits	0.63			0.017	0.00023	0.017	240
	Beans	1.5			0.040	0.00054	0.041	99
	Tomatoes/Peppers	0.75			0.020	0.00027	0.020	200
Airblast (8)	Citrus	3	0.016 (Gloves)	0.4	0.019	0.00048	0.019	210
	Pecans/Walnuts	2			0.032	0.00051	0.033	120
	Hops	1.2			0.020	0.00064	0.021	190
	Stonefruit	1.5			0.026	0.00021	0.026	150
	Grapes	1.3			0.008	0.00021	0.0082	490
	Cucurbits	0.63			0.015	0.00038	0.015	266
High Pressure Handwand (9)	Lawns/Ornamentals	0.55	N/A	N/A	N/A	N/A	N/A	N/A
Applying Sprays with a Handgun (lawn) Sprayer (10)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Flagger Risk								
Flagging (11)	Citrus	3	0.0002	0.006	0.0048	0.00014	0.0049	820
	Apples/Pears	3			0.0020	0.000060	0.0021	1900
	Pecans/Walnuts	2			0.0013	0.000040	0.0013	3100
	Cotton	1.5			0.0024	0.000072	0.0025	1600

TABLE 10: SHORT-TERM RISK FOR DICOFOL WITH ENGINEERING CONTROLS								
Exposure Scenario (Scen. #)	Crop	Proposed Maximum Application Rate (lb ai/acre)	Risk Mitigation Measure: Engineering Controls[a]					
			Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (μg/lb ai)	Daily Dermal Dose (mg/kg/day)[b]	Daily Inhalation Dose (mg/kg/day)[c]	Daily Total Dose (mg/kg/day)[d]	Total MOE[e]
	Strawberries	2			0.0017	0.00005	0.0017	2400
	Grapes	1.25			0.0010	0.000031	0.0010	4000
	Stonefruit	1.5			0.0013	0.000038	0.0013	3100
	Cucurbits	0.625			0.00067	0.000020	0.00069	5800
	Beans	1.5			0.0016	0.000048	0.0016	2400
	Tomatoes/Peppers	0.75			0.00080	0.000024	0.00082	4900
Mixer/Loader/Applicator								
Backpack Sprayer (12)	Lawns/Ornamentals	0.55	N/A	N/A	N/A	N/A	N/A	N/A
Hose-End (13)	Lawns/Ornamentals	0.55	N/A	N/A	N/A	N/A	N/A	N/A
Low Pressure Handwand (14)	Lawns/Ornamentals	0.55	N/A	N/A	N/A	N/A	N/A	N/A

N/A Not applicable since previous MOE was over 300 or engineering controls not possible (e.g., backpack sprayer).

a Engineering Controls = Single layer clothing; no gloves, and no respirator while using water soluble packets for WP, closed mixing/loading systems for liquid formulations, and enclosed cockpit/cabs for aerial, groundboom, airblast, and flaggers. Note: The liquid closed mixing/loading and airblast applicator scenarios include chemical resistant gloves because the no glove scenarios are not available. The only data available for aerial applicators are for enclosed cockpits.

b Daily dermal dose = Dermal unit exposure (mg/lb ai) x Appl. rate (lb ai/A) x Acres/60 kg. (Note: Appl. rate and acres treated are from Table 7.)

c Daily Inhalation Dose (mg/kg/day) = Inhalation unit exposure (μg/lb ai) x $\left(\frac{1\ mg}{1{,}000\ \mu g}\right)$ x Appl. rate (lb ai/A) x Acres/60 kg. (Note: Appl. rate and acres treated are from Table 7)

d Total Dose = (daily dermal dose + daily inhalation dose)

e Total MOE = NOAEL (intermediate-term NOAEL = 4 mg/kg/day) / daily total dose (mg/kg/day)

TABLE 11: INTERMEDIATE-TERM RISK FOR DICOFOL WITH ENGINEERING CONTROLS								
Exposure Scenario (Scenario #)	Crop	Proposed Maximum Application Rate (lb ai/acre)	Risk Mitigation Measure					
			Engineering Controls[a]					
			Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (μg/lb ai)	Daily Dermal Dose (mg/kg/day)[b]	Daily Inhalation Dose (mg/kg/day)[c]	Daily Total Dose (mg/kg/day)[d]	Total MOE[e]
Mixer/Loader Risk								
Mixing/Loading Wettable Powder for Aerial Application (1)	Citrus	3	0.02	0.2	0.48	0.0048	0.48	0.6
	Apples/Pears	3			0.2	0.0020	0.2	1.5
	Pecans/Walnuts	2			0.13	0.0013	0.13	2.2
	Cotton	1.5			0.24	0.0024	0.24	1.2
	Strawberries	2			0.17	0.0017	0.17	1.7
	Grapes	1.3			0.1	0.0010	0.11	2.9
	Stonefruit	1.5			0.13	0.0013	0.13	2.4
	Cucurbits	0.63			0.067	0.00067	0.067	4.5
	Beans	1.5			0.16	0.0016	0.16	1.9
	Tomatoes/Peppers	0.75			0.08	0.0008	0.081	3.7
Mixing/Loading Wettable Powder for Groundboom Application (2)	Cotton	1.5			0.1	0.0010	0.1	3
	Strawberries	2			0.060	0.0006	0.061	4.8
	Mint	1.3			0.058	0.00058	0.059	5.1
	Beans	1.5			0.045	0.00045	0.045	6.6
	Peppers/Tomatoes	0.75			0.023	0.00023	0.023	13
Mixing/Loading Liquid for Aerial Application (3)	Citrus	3	0.009 (Gloves)	0.08	0.72	0.0019	0.22	1.4
	Apples/Pears	3			0.09	0.00080	0.091	3.3
	Pecans/Walnuts	2			0.06	0.00053	0.061	5
	Cotton	1.5			0.11	0.00096	0.11	2.8
	Strawberries	2			0.075	0.00067	0.076	3.8
	Grapes	1.3			0.047	0.00043	0.047	6.3
	Stonefruit	1.5			0.056	0.00050	0.057	5.3
	Cucurbits	0.63			0.03	0.00027	0.03	9.9
	Beans	1.5			0.072	0.00064	0.073	4.1
	Tomatoes/Peppers	0.75			0.036	0.00032	0.036	8.3
Mixing/Loading Liquid for Groundboom Application (4)	Cotton	1.5	0.009 (Gloves)	0.08	0.045	0.00040	0.045	6.6
	Strawberries	2			0.027	0.00024	0.027	11
	Mint	1.3			0.026	0.00024	0.026	11
	Beans	1.5			0.02	0.00018	0.020	15
	Peppers/Tomatoes	0.75			0.01	N/A	0.01	29

TABLE 11: INTERMEDIATE-TERM RISK FOR DICOFOL WITH ENGINEERING CONTROLS

Exposure Scenario (Scenario #)	Crop	Proposed Maximum Application Rate (lb ai/acre)	Risk Mitigation Measure: Engineering Controls[a]					
			Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (μg/lb ai)	Daily Dermal Dose (mg/kg/day)[b]	Daily Inhalation Dose (mg/kg/day)[c]	Daily Total Dose (mg/kg/day)[d]	Total MOE[e]
Mixing/Loading Liquids for High Pressure Handwand Application (5)	Lawn/Ornamentals	0.55	N/A	N/A	N/A	N/A	N/A	N/A
Applicator Risk								
Groundboom (6)	Cotton	1.5	0.0067	0.04	0.034	0.00020	0.034	8.9
	Strawberries	2			0.020	0.00012	0.020	15
	Mint	1.3			0.02	0.00012	0.020	15
	Beans	1.5			0.015	0.00009	0.015	20
	Peppers/Tomatoes	0.75			0.0075	N/A	0.0075	40
Aerial (7)	Citrus	3	0.005	0.068	0.12	0.0016	0.12	2.5
	Apples/Pears	3			0.05	0.00068	0.051	5.9
	Pecans/Walnuts	2			0.033	0.00045	0.034	8.9
	Cotton	1.5			0.06	0.00082	0.061	4.9
	Strawberries	2			0.042	0.00057	0.043	6.7
	Grapes	1.3			0.026	0.00037	0.026	11
	Stonefruit	1.5			0.031	0.00043	0.031	9.7
	Cucurbits	0.63			0.017	0.00023	0.017	18
	Beans	1.5			0.04	0.00054	0.041	7.4
	Tomatoes/Peppers	0.75			0.02	0.00027	0.020	15
Airblast (8)	Citrus	3	0.016 (Gloves)	0.4	0.019	0.00048	0.019	16
	Pecans/Walnuts	2			0.032	0.00051	0.033	9.1
	Hops	1.2			0.02	0.00064	0.021	14
	Stonefruit	1.5			0.026	0.00021	0.026	11
	Grapes	1.3			0.008	0.00021	0.0082	37
	Cucurbits	0.63			0.015	0.00038	0.015	19.3
High Pressure Handwand (9)	Lawns/Ornamentals	0.55	N/A	N/A	N/A	N/A	N/A	N/A
Applying Sprays with a Handgun (lawn) Sprayer (10)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Flagger Risk								
Flagging (11)	Citrus	3	0.0002	0.006	0.0048	0.00014	0.0049	61
	Apples/Pears	3			0.002	0.000060	0.0021	150
	Pecans/Walnuts	2			0.0013	0.000040	0.0013	230
	Cotton	1.5			0.0024	0.000072	0.0025	120
	Strawberries	2			0.0017	0.00005	0.0018	160
	Grapes	1.25			0.0010	0.000031	0.0010	300

TABLE 11: INTERMEDIATE-TERM RISK FOR DICOFOL WITH ENGINEERING CONTROLS								
Exposure Scenario (Scenario #)	Crop	Proposed Maximum Application Rate (lb ai/acre)	Risk Mitigation Measure					
			Engineering Controls[a]					
			Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (μg/lb ai)	Daily Dermal Dose (mg/kg/day)[b]	Daily Inhalation Dose (mg/kg/day)[c]	Daily Total Dose (mg/kg/day)[d]	Total MOE[e]
	Stonefruit	1.5			0.0013	0.000038	0.0013	230
	Cucurbits	0.625			0.00067	0.000020	0.00069	440
	Beans	1.5			0.0016	0.000048	0.0016	180
	Tomatoes/Peppers	0.75			0.0008	0.000024	0.00082	360
Mixer/Loader/Applicator								
Backpack Sprayer (12)	Lawns/Ornamentals	0.55	N/A	N/A	N/A	N/A	N/A	N/A
Hose-End (13)	Lawns/Ornamentals	0.55	N/A	N/A	N/A	N/A	N/A	N/A
Low Pressure Handwand (14)	Lawns/Ornamentals	0.55	N/A	N/A	N/A	N/A	N/A	N/A

N/A Not applicable since previous MOE was over 300 or engineering controls not possible (e.g., backpack sprayer).

a Engineering Controls = Single layer clothing; no gloves, and no respirator while using water soluble packets for WP, closed mixing/loading systems for liquid formulations, and enclosed cockpit/cabs for aerial, groundboom, airblast, and flaggers. Note: The liquid closed mixing/loading and airblast applicator scenarios include chemical resistant gloves because the no glove scenarios are not available. The only data available for aerial applicators are for enclosed cockpits.

b Daily dermal dose = Dermal unit exposure (mg/lb ai) x Appl. rate (lb ai/A) x Acres/60 kg. (Note: Appl. rate and acres treated are from Table 7)

c Daily Inhalation Dose (mg/kg/day) = Inhalation unit exposure (μg/lb ai) x $\left(\frac{1\ mg}{1{,}000\ \mu g}\right)$ x Appl. rate (lb ai/A) x Acres/60 kg. (Note: Appl. rate and acres treated are from Table 7)

d Baseline Total Dose = (daily dermal dose + daily inhalation dose)

e Total MOE = NOAEL (intermediate-term NOAEL = 0.29 mg/kg/day) / daily total dose (mg/kg/day). The NOAEL of 0.29 mg/kg/day was rounded to 0.3 mg/kg/day.

TABLE 12: EXPOSURE SCENARIO DESCRIPTIONS FOR USES OF DICOFOL

Exposure Scenario (Number)	Data Source	Comments[a]
Mixer/Loader Exposure		
Mixing Wettable Powder (1,2)	PHED Version 1.1	**Baseline:** Dermal and inhalation acceptable grades. Dermal = 7 to 24 replicates; Inhalation = 44 replicates; Low confidence in dermal data; Medium confidence inhalation data. **PPE:** Dermal A, B, C grades and inhalation acceptable grades. Dermal = 22 to 45 replicates; Inhalation = 44 replicates; Medium confidence in dermal and inhalation data. **Engineering Control:** Dermal grades acceptable; inhalation all grades. Dermal = 5 to 15 replicates. Inhalation = 15 replicates. PHED data used for baseline and engineering controls no PFs were necessary. Maximum PPE values calculated from PHED data using 50% PF for the addition of coveralls. 90% PF for the addition of organic vapor removing (O/V) respirator.
Mixing / Loading Liquids (3,4,5)		**Baseline:** Dermal and inhalation acceptable grades. Dermal = 53 to 122 replicates; Inhalation = 85 replicates; high confidence in both dermal and inhalation data. **PPE:** Dermal and inhalation acceptable grades. Dermal = 59 to 122 replicates; Inhalation = 85 replicates; high confidence in dermal and inhalation data. **Engineering Control:** Dermal and inhalation grades acceptable; Dermal = 0 to 22 replicates. Inhalation = 27 replicates. Low confidence in dermal data; high confidence in inhalation data. PHED data used for baseline and engineering controls no PFs were necessary. Maximum PPE values calculated from PHED data using 50% PF for the addition of coveralls, 90% PF for the addition of O/V respirator.
Applicator Exposure		
Groundboom (6)	PHED Version 1.1	**Baseline:** Dermal and inhalation acceptable grades. Dermal = 23 to 42 replicates; Inhalation = 22 replicates; High confidence in dermal and inhalation data. **PPE:** Dermal and inhalation acceptable grades. Dermal = 8 to 42 replicates; Inhalation = 85 replicates; high confidence in inhalation data and low confidence in dermal data. **Engineering Control:** Dermal and inhalation grades acceptable; Dermal = 5 to 16 replicates. Inhalation = 16 replicates. Low confidence in dermal data; high confidence in inhalation data. PHED data used; no PFs were necessary, except a 90% PF for O/V respirator.

TABLE 12: EXPOSURE SCENARIO DESCRIPTIONS FOR USES OF DICOFOL		
Exposure Scenario (Number)	Data Source	Comments[a]
Aerial equipment (liquids) (7)		**Baseline:** Dermal grades A, B, C; inhalation all grades. Dermal = 1 to 17 replicates; Inhalation = 17 replicates. Low confidence for dermal and inhalation data. **PPE:** Dermal and inhalation acceptable grades. Dermal = 59 to 122 replicates; Inhalation = 85 replicates; high confidence in dermal and inhalation data. **Engineering Control:** Dermal and inhalation grades acceptable; Dermal = 0 to 22 replicates. Inhalation = 27 replicates. Low confidence in dermal data; high confidence in inhalation data. PHED data used for baseline, no PFs were necessary. For PPE a 50% PF was used for coveralls.
Airblast (8)		**Baseline:** Dermal and inhalation acceptable grades. Dermal = 22 to 49 replicates; Inhalation = 47 replicates; High confidence in dermal and inhalation data. **PPE:** Dermal and inhalation acceptable grades. Dermal = 18 to 49 replicates; Inhalation = 47 replicates; High confidence in dermal and inhalation data. **Engineering Control:** Dermal grades acceptable; inhalation all grades. Dermal = 5 to 15 replicates. Inhalation = 9 replicates. Low confidence in dermal and inhalation data. PHED data used for baseline and engineering controls no PFs were necessary. 90% PF for the addition of O/V respirator.
High Pressure Handwand (9)		**Baseline:** Dermal and inhalation all grades. Dermal = 2 to 11 replicates; Inhalation = 11 replicates; Low confidence in dermal and inhalation data. **PPE:** Dermal and inhalation all grades. Dermal = 9 to 11 replicates; Inhalation = 11 replicates; Low confidence in dermal and inhalation data. PHED data used for baseline; no PFs were necessary. Maximum PPE values calculated from PHED data using 50% PF for the addition of coveralls. 90% PF for the addition of O/V respirator.
Applying Sprays with a Handgun (lawn) Sprayer (10)		

TABLE 12: EXPOSURE SCENARIO DESCRIPTIONS FOR USES OF DICOFOL		
Exposure Scenario (Number)	Data Source	Comments[a]
Flagger		
Liquids (11)	PHED Version 1.1	**Baseline:** Dermal and inhalation grades acceptable. Dermal = 16 to 18 replicates; inhalation = 18 replicates. High confidence in dermal data and inhalation data. **PPE:** Dermal and inhalation acceptable grades. Dermal = 59 to 122 replicates; Inhalation = 85 replicates; high confidence in dermal and inhalation data. **Engineering Control:** Dermal and inhalation grades acceptable; Dermal = 0 to 22 replicates. Inhalation = 27 replicates. Low confidence in dermal data; high confidence in inhalation data. PHED data used for baseline values, no PFs were necessary. For PPE a 50% PF was used for coveralls, while a 90% PF was used for chemical resistant gloves.
Mixer/Loader/Applicator		
Backpack Sprayer (12)	PHED Version 1.1	**Baseline and PPE:** Dermal grades A, B, C and inhalation acceptable grades. Dermal = 9 to 11 replicates; Inhalation = 11 replicates; Low confidence in dermal and inhalation data. PHED data used for baseline. Maximum PPE values calculated from PHED data using 50% PF for the addition of coveralls. 90% PF for the addition of O/V respirator.
Hose-End Sprayer (13)	PHED Version 1.1	**Baseline and PPE:** Dermal all grades and inhalation C grade. Dermal = 8 replicates; Inhalation = 8 replicates; Low confidence in dermal and inhalation data. PHED data used for baseline. Maximum PPE values calculated from PHED data using 50% PF for the addition of coveralls. 90% PF for the addition of O/V respirator.
Low Pressure Handwand (14) Sprayer		**Baseline and PPE:** Dermal and inhalation all grades. Dermal = 25 to 96 replicates; Inhalation = 96 replicates; Low confidence in dermal and inhalation data. PHED data used for baseline. Maximum PPE values calculated from PHED data using 50% PF for the addition of coveralls. 90% PF for the addition of O/V respirator.

"Acceptable grades," as defined by HED SOP for meeting Subdivision U Guidelines are grades A and B. All grades that do not meet HED's SOP are listed individually.

d. Occupational Post Application Exposure and Risk Assessment/ Characterization

Post Application Summary

The Agency is concerned about postapplication exposure and risk to agricultural workers following applications to the crops identified in the use summary (Appendix A) during routine hand-labor crop-production tasks, such as hoeing, thinning, and harvesting activities and non-hand-labor tasks, such as crop-advisor and irrigation-related activities.

A Data-Call-In (DCI) for chemical-specific post-application exposure data (as regulated by Series 875.2100, 875.2400, and 875.2500) was issued October 13, 1995, and is due in October 1998. In lieu of these data, a surrogate range-finder post-application exposure assessment was performed for occupational or residential settings.

The range finder assessment in Table 13 is based on the minimum and maximum application rates of 0.63 lb ai/A and 3 lb ai/A, respectively. The transfer coefficients (TC) range from low exposure potentials (500 cm^2/hr), such as hoeing, to high exposure potentials (10,000 cm^2/hr), such as citrus harvesting. The restricted entry interval (REI) ranges from 44 days to 79 days.

Table 13: Dicofol Intermediate-Term Postapplication Agricultural Surrogate Assessment (Range Finder)

DAT[a]	DFR ($\mu g/cm^2$)[b]		Dermal Dose (mg/kg/day)[c]				MOE[d]			
			Min. Rate		Max. Rate		Min. Rate		Max. Rate	
	Min. Rate	Max. Rate	Low	High	Low	High	Low	High	Low	High
0	1.41	8.97	0.094	1.88	0.598	11.96	3	<1	<1	<1
44	0.014	0.087	0.001	0.018	0.006	0.116	318	16	50	3
65	0.001	0.010	N/A	0.002	0.001	0.013	N/A	145	460	23
72	0.001	0.005	N/A	0.001	N/A	0.006	N/A	303	N/A	48
94	N/A	0.002	N/A	N/A	N/A	0.003	N/A	N/A	N/A	100

a DAT = Days after treatment.

b DFR ($\mu g/cm^2$) = Appl. rate (lb ai/A) x 11.209 (μg per cm^2/lb ai per acre conversion) x 0.2 (fraction of ai retained on foliage). Dissipation is assumed at 10% per day (environmental fate data were not reviewed for this surrogate assessment).

c Dermal Dose (mg/kg/day) = DFR ($\mu g/cm^2$) x T_c (cm^2/hr) x 1 mg/1000 μg conversion) x 1 (100% dermal absorption) x 8 (hrs/day) / 60 kg BW. Where LOW = 500 cm^2/hr and High = 10,000 cm^2/hr.

d MOE = NOAEL (mg/kg/day) / Dermal Dose (mg/kg/day). Where NOAEL = 0.29 mg/kg/day.

Based on results of this analysis, several scenarios had MOEs below 100. Therefore, the Agency has concerns regarding post-application exposure. The DFR data is currently being generated in response to the October 1995 Data Call-In. Until these data are submitted from the postapplication exposure study, and evaluated, post-application use scenarios remain a concern. A final REI will be set based the DFR Data which will be submitted to the Agency in October, 1998. However, in the interim, EPA will set an REI of 24 hours.

e. Residential and Other Non-Occupational Exposures and Risks

The registrants have voluntarily canceled all residential turf uses; therefore, the Agency did not include estimated risks to homeowners from residential exposure in the exposure and risk tables (Tables 7-12).

Additionally, the registrants have voluntarily canceled all residential ornamental uses of dicofol. Therefore, the risk from this use was not calculated.

f. Incidence Reports

Cases of dicofol poisonings were reported to the following data bases as of October 10, 1995.

OPP Incident Data System: Nine incidents involving dicofol have been received since the inception of the data base in 1992. Eight of these involved exposure to multiple pesticides; the specific pesticide responsible for the reported illnesses (mostly dermal irritation) could not be determined. The only incident in which dicofol was used alone involved fish and wildlife effects.

California Department of Food and Agriculture (CDFA): A total of 38 incidents involving exposure to dicofol alone were reported from the years 1982-1992, inclusively. The following types of illnesses were reported for these cases: systemic - 19 (50%); skin - 10 (26%); eye - 8 (21%); and eye/skin - 1 (3%). One person was hospitalized as a result of dicofol related illness. Applicators and field workers were the most frequently exposed workers. The number of incidents per 1000 applications of dicofol for the years 1990-1992, inclusively, was calculated. (As of 1990, information is available for all agricultural uses; prior to that, only data on restricted use applications were required to be reported.) The number of incidents/1000 applications for all illnesses ranged from 0.11 to 0.21. The number of systemic illnesses/1000 applications ranged from 0.09 to 0.11. These values are about one-half the median of those reported for 28 organophosphate and carbamate pesticides involved in a Data Call-In (DCI) for pesticides of risk to agricultural workers. Based on these recent data, it appears that dicofol represents a relatively low risk to farm workers and handlers in California.

National Pesticide Telecommunications Network (NPTN): This database collected reports from 1984 to 1991 (inclusive) showing 91 human, 9 animal, and 31 other poisoning incidents for a total of 131 incidents involving dicofol from 571 phone calls made to the hotline.

5. Food Quality Protection Act Considerations

a. Cumulative Effects

Section 408(b)(2)(D)(v) of the Food Quality Protection Act requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency considers "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, the Agency does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. the Agency has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that results of this pilot process will increase the Agency's scientific understanding of this question such that the Agency will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical-specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case, the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case, a common mechanism of activity will be assumed).

Dicofol is a member of the organochlorine class of pesticides. Other members of this class include DDT, methoxychlor, chlorobenzilate and ethylan. Less closely related members of the class include lindane, dieldrin, endrin, chlordane, heptachlor, aldrin, endosulfan, kepone, and toxaphene (George W. Ware, Fundamentals of Pesticides, Thomson Publications, 1982).

At this time, the Agency does not have available data to determine whether dicofol has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action. Therefore the Agency has not assumed that dicofol has a common mechanism of toxicity with other substances.

b. Endocrine Disrupter Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect..." The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed until August 3, 1999 to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

c. Special Sensitivity of Infants and Children

For an evaluation of special sensitivity of infants and children, see section III-B-2-a.

d. Aggregate Risk

In examining aggregate exposure, FQPA directs EPA to take into account available information concerning exposures from pesticide residues in food and other exposures for which there is reliable information. These other exposures include drinking water and non-occupational exposures (e.g., to pesticides used in and around the home). Risk assessments for aggregate exposure consider both short-term and long-term (chronic) exposure scenarios, considering the toxic effects which would likely be seen for each exposure duration.

Acute Aggregate Risk

Acute aggregate risk assessment for dicofol include risks associated with dietary exposure through food and drinking water only. Estimates of exposures to dicofol from food sources through highly refined probalistic analysis do not exceed the Agency's levels of comparison.

DWLOCs, for residues of dicofol in drinking water therefore are relatively high (50 ppb for non-nursing infants, the most sensitive subgroup) compared to conservative modeling estimates of dicofol concentrations (Tier II/Prizm Exams). Therefore, the Agency concludes with reasonable certainty that acute aggregate exposure to pesticidal dicofol does not exceed the Agency's level of concern.

Chronic Aggregate Risk

The chronic aggregate risk assessment for dicofol includes risks associated with dietary exposure through food, water, and any registered residential uses with the potential for chronic exposure. Anticipated residues and percent crop-treated data for commodities with published tolerances result in an exposure to dicofol through food which represents 19% of the RfD for the U.S. general population. The highest subgroup, children (1-6 years), occupies 38% of the RfD. Dietary risk for non-nursing infants occupies 32% of the RfD, and dietary risk for children (1-7 years) occupies 26% of the RfD. Tier 2 estimated average concentrations in ground water (0.069 ppb) or

surface water (0.5 ppb) do not exceed drinking water levels of comparison (DWLOCs) for the general U.S. population or any of the population subgroups. The registered residential uses of dicofol do not present a chronic residential exposure scenario. The Agency thus concludes that aggregate chronic exposure and risk estimates do not exceed the Agency's level of concern.

Short Term and Intermediate Term Aggregate Risk

There are no residential exposures. Therefore, an aggregate risk assessment is not required.

C. Environmental Assessment

1. Exposure Characterization

The Agency has adequate data to assess the hazards of dicofol to nontarget terrestrial organisms.

a. Environmental Fate Assessment

Laboratory and field studies show that dicofol isomers have a short to intermediate half-life (days to months) and are moderately persistent in the environment as a result of normal label uses. In ecological monitoring studies conducted in New York, Florida, and California, dicofol dissipated from the soil surface with a half life ranging from two to four months. The major routes of dissipation appear to be hydrolysis in neutral and alkaline pHs and microbially-mediated degradation. o,p'-Dicofol dissipates more rapidly than p,p'-dicofol. o,p'-Dicofol hydrolyzes rapidly and is somewhat susceptible to photolysis in water. Photolysis does not play a role in the degradation of p,p'-dicofol. Mobility and volatilization do not significantly contribute to the dissipation of the dicofol isomers.

Dicofol and DDT are similar in chemical structure. However, important differences in chemistry separate these two organochlorine pesticides. Dicofol has an environmentally significant water solubility providing dicofol with a pathway for degradation; DDT does not. Dicofol has an environmental half-life of weeks compared to years for DDT. While dicofol has some ability to accumulate, DDT has a much greater ability to do so. Most importantly, dicofol does not degrade to DDE, but to degradates less toxic than dicofol, whereas DDT degrades to DDE which has been identified as the toxic moiety.

For dicofol, evidence for endocrine disruption is suggestive, but not definitive. It clearly has reproductive effects in some species, although they appear to differ somewhat from its close analogues, DDT and/or DDE. Whether the difference is due to the ability of dicofol to be metabolized to less toxic chemicals, its relatively short half-life, or the reduced potency of the parent, is not known at this time. It is clear, however, that dicofol does not present the enormous bioaccumulation potential of DDT/DDE and for that reason alone may be deemed of lesser concern than DDT/DDE.

i. Degradation and Metabolism

Dicofol is relatively insoluble in water (1.32 ppm @ 25°C) and partitions with organic solvents (K_{ow}=1.1x10^6). It is not likely to volatilize extensively (vapor pressure=3.9x10^{-7} mm Hg at 25° C, calculated Henry's Constant 1.44x10^{-7} atm m^2/mol). Dicofol contains <0.1% DDT and its residues in its current formulation.

o,p'-dicofol and p,p'-dicofol hydrolyze relatively quickly at neutral and alkaline pH's. Both isomers are stable under acidic conditions. o,p'-dicofol hydrolyzed with half-lives of 47 days at pH 5, 8 hours at pH 7, and 9 minutes at pH 9 (MRID 40042033). p,p'-dicofol hydrolyzed with half-lives of 85 days at pH 5, 64 hours at pH 7, and 26 minutes at pH 9 (MRIDs 40042032 and 40460105). The major degradate in both studies, the o,p'- and p,p'-isomers of dichlorobenzophenone (DCBP), appeared to resist further degradation. Chlorobenzoic acid (CBA) was also observed in the pH 7 solution in the o,p'- study; other minor degradates were isolated, but not identified in the p,p'- study.

In acidic (pH 5) water, o,p'-dicofol photolyzes moderately rapidly, while p,p'-dicofol does not. o,p'-dicofol photodegraded with a half-life of 15 days in a pH 5 solution (MRID 40849702). The major degradate was o,p'-DCBP. In contrast, o,p'-dicofol degraded with a half-life of 32-33 days in the dark control. p,p'-dicofol photodegraded with a half-life of 92 days in a pH 5 solution (MRID 40849701). The major degradate was p,p'-DCBP. The half-life of the dark control was 149-246 days.

Photolysis on soil is not an important route of degradation for dicofol, possibly due to binding on the soil and lack of solubility in soil water. o,p'-dicofol degraded with a half-life of 30 days while p,p-dicofol degraded with a half-life of 21-30 days on silt loam soil irradiated with artificial light that does not simulate natural sunlight (MRIDs 40042036 and 40042037). The major degradates identified in the studies were the o,p' and p,p' isomers of DCBP.

Aerobic soil metabolism plays an important part in the degradation of o,p'-dicofol; it is less important for p,p'-dicofol. o,p'-Dicofol degraded with a half-life of 8 days in a loam soil (MRID 41094201). The major metabolites were 1,(2-chlorophenyl)-1-(4'-chlorophenyl)-2,2-dichloroethanol (o,p'-FW-152), o,p'-DCBP, 2-chlorobenzoic acid (2-CBA), 3-hydroxy-2,4-dichlorobenzophenone (OH-o,p'-DCBP), and 2,4'-dichlorobenzhydrol (o,p'-DCBH). Unextracted residues comprised 57-61% of the applied amount after 12 months, while volatile residues were <4%. p,p'-Dicofol degraded with a half-life of 43 days in a silt loam soil (MRID 41050701). The major metabolites were 1,1-(ρ-chlorophenyl)-2,2-dichloroethanol (p,p'-FW-152), p,p'-DCBP, and 3-hydroxy-4,4'-dichlorobenzophenone (3-OH-p,p'-DCBP). Volatile residues were 21-22% of the applied and unextractable residues were 10-15% of the applied after 12 months.

The o,p'-isomer of dicofol apparently will not persist long in anaerobic soils. o,p'-Dicofol degraded with a half-life of 6 days from a flooded silt loam soil under anaerobic conditions (MRID 43908701). The major degradates were o,p'-FW-152 (averaging 43% of the applied 30 days after flooding) and o,p'-DCBH (averaging 15% of the applied 30 days after flooding). Samples were aged aerobically for 3 days before flooding. p,p'-Dicofol declined during 60 days of anaerobic incubation,

with a half-life of <30 days (MRID 40042039). Major degradates were p,p'-FW 152 and 4,4'-dichlorobenzhydrol (p,p'-DCBH).

ii. Mobility

Both isomers of dicofol show moderate to low mobility in batch equilibrium and column leaching studies, with little potential to leach to ground water. o,p'-dicofol showed low mobility in sand, sandy loam, and clay loam soil column leaching experiments (MRID 41509802). Of the applied radioactivity, 75 to 98% remained in the upper 1 or 2 inches of the columns. Less than 3% of the applied radioactivity was in the leachate. The degradate o,p'-DCBP was present at 1-11% of the recovered radioactivity in the soil columns. In batch equilibrium studies, mobility of p,p'-dicofol was moderate in sand (Freundlich K_{ads} and K_{oc} values were 8.4 and 8383, respectively) and low in sandy loam (K_{ads} of 64.6; K_{oc} of 8073), silt loam (K_{ads} of 70; K_{oc} of 5868), and clay loam (K_{ads} of 82.8; K_{oc} of 5917) soil slurries (MRID 41509801). The K_{des} values ranged from 29.3 to 335.

Two supplemental leaching studies conducted on p,p'-dicofol suggest that the chemical does not significantly leach under the testing conditions (IDs GS0021002 and GS0021007). No data are available on the mobility of aged dicofol or on the mobility of the major degradates of dicofol. Based on the results of the terrestrial field dissipation studies, it appears that dicofol metabolites are not very mobile under normal use conditions.

iii. Bioaccumulation

p,p'-dicofol residues accumulated in bluegill sunfish with bioconcentration factors of 6,600, 17,000, and 10,000X in fillet, viscera, and whole fish, respectively, during 28 days of exposure (Acc. No. 265330). The estimated elimination half-life was 33 days. No information is available on the bioaccumulation in fish for o,p'-dicofol. Little information is available on bioaccumulation in other fish species. However, since o,p'-dicofol hydrolyzes quickly ($t_{½}$=8 hrs at pH 7), it may not be available under normal aquatic conditions to bioaccumulate in fish.

A supplemental confined rotational crop study suggests that dicofol may accumulate in plants and therefore be available to mammals (MRID 43958701). Persistence data indicate that dicofol, especially the p,p'-isomer, has the potential to accumulate in the soil for a short period of time. However, estimated bioconcentration factors suggest that dicofol is not expected to bioconcentrate significantly[2].

Supplemental monitoring studies (see vi below) show that dicofol residues may be found in low concentrations in different matrices, including soil, crop foliage, earthworms, aquatic habitats, and selected bird species. However, dicofol residue levels were lower than those of background DDE levels, often by 1 to 2 orders of magnitude.

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[2] Howard, P.H. (Ed.). 1991. *Handbook of Fate and Exposure Data for Organic Chemicals. Vol. III - Pesticides.* Lewis Publ.

iv. Field Dissipation

Although supplemental, several terrestrial field dissipation studies confirm the results of the laboratory persistence and mobility studies. These studies suggest that dicofol does not persist in the field for long periods (on an order of several days to several weeks). In a dissipation study on cotton in California (MRID 41381801), half of dicofol residues dissipated in less than 7 days (DT_{50} value, which is the length of time required for 50% of the parent to dissipate from the surface 6-inches of the soil). In another dissipation study on strawberries in California (MRID 42118601), the rate of dissipation was slower (DT_{50}s of 22 days for o,p'-dicofol and 72 days for p,p'-dicofol). Differences in dissipation rates were related to greater amounts of irrigation in the cotton study. Results of these studies suggest that metabolism is the dominant route of dissipation in the field. Neither dicofol nor its residues moved significantly below 6 inches in either study. The major degradates observed in these field studies -- o,p' and p,p'-DCBP, o,p'-DCBH, 4-CBA, and p,p'-FW 152 -- are not the same as those associated with DDT.

v. Spray Drift

No dicofol-specific studies were reviewed. Droplet size spectrum (201-1) and drift field evaluation (202-1) studies were required, since the different products may be applied by aircraft and due to the concern for potential risk to nontarget aquatic organisms. To satisfy these requirements, the registrants, in conjunction with other registrants, formed the Spray Drift Task Force (SDTF). The SDTF has completed and submitted to the Agency its series of studies which are intended to characterize spray droplet drift potential due to various factors, including application methods, application equipment, meteorological conditions, crop geometry, and droplet characteristics. EPA has evaluated those studies associated with aerial spray applications, and will evaluate those studies associated with ground spray applications in the near future. This assessment of dicofol used simplified off-target drift rates of 1% of the applied spray volume from ground applications and 5% from aerial and orchard air blast applications at 100 feet downwind. After its review of the new studies, the Agency will determine whether a reassessment of the potential risks from the application of dicofol to nontarget organisms is warranted.

vi. Monitoring Studies

Comprehensive ecological monitoring studies of dicofol residues were conducted for three years in California cotton fields (1990-92; MRIDs 41785102, 41857301, and 42285503), Florida citrus groves (1989-91; (MRIDs 41785103, 41845605, 42091501, and 42437301), and New York apples orchards (1989-91; (MRIDs 41845604, 42285501, and 42721301). Areas and crops selected had a previous history of heavy dicofol use and a high likelihood for exposure to nontarget organisms. Application rates typified those most commonly used by the growers and not necessarily the maximum label rates. Dicofol residues were monitored in soil, adjacent waters, plant foliage, fish, mammals, reptiles, amphibians, earthworms, birds, and bird eggs. In these studies, the overall half-lives for the residues of p,p'-dicofol in soils vary from 58 days in California to 113 days in Florida. In New York, it was not possible to calculate a half-life in the 90-day observation period. In all studies, o,p-dicofol was present at much smaller concentrations than p,p'-dicofol.

Residues of p,p'-dicofol were detected in the foliage of crops and dissipated with a half-life ranging from 9 days (cotton) to 61 days (citrus crops). Dicofol was found at a concentration of 1-2 ppm in earthworms in New York. Less than 1% of water samples from adjacent aquatic habitats had dicofol residues greater than the detection limit (0.005 ppm). However, no water chemistry, location, or weather data was provided to determine whether residues reached water or if they dissipated in the waters. While dicofol residues were detected in the various sampled compartments, including eggs of different species, concentrations of DDE were much greater (often by 1 to 2 orders of magnitude).

Although the monitoring studies had data gaps that would have aided in interpreting the environmental concentrations in various compartments, results lend support to laboratory studies which suggest that while dicofol is likely to persist in the monitored environments with half lives ranging from 2 to 4 months, it is not as persistent as DDT or DDE. The results of this study have been used to compare modeled estimated environmental exposures to concentrations of dicofol that may be expected under "typical" use conditions and were helpful in the characterization of the risk associated with dicofol use.

b. Terrestrial Exposure Assessment

Table 14 estimates the maximum estimated environmental exposures (EECs) likely to occur on mammalian and avian foods immediately following application. This exposure estimate is based on the methods of Hoerger and Kenaga (1972)[3] as modified by Fletcher et al. (1994)[4].

Table 14: Estimated Environmental Concentrations on Avian and Mammalian Food Items (ppm) Following a Single Application at 1 lb. ai/A (Hoerger and Kenaga, 1972, as modified by Fletcher et al, 1994)

Food Items	*EEC (ppm) Predicted Maximum Residue*	*EEC (ppm) Predicted Mean Residue*
Short grass	240	85
Tall grass	110	36
Broadleaf plants and small insects	135	45
Fruits, pods, seeds, and large insects	15	7

[3] Hoerger, F., and E.E. Kenaga. 1972. Pesticide residues on plants: Correlation of representative data as a basis for estimation of their magnitude in the environment. In F. Coulston and F. Korte, eds., *Environmental Quality and Safety: Chemistry, Toxicology, and Technology,* Georg Thieme Publ, Stuttgart, West Germany, pp. 9-28.

[4] Fletcher, J.S., J.E. Nellessen, and T.G. Pfleeger. 1994. Literature review and evaluation of the EPA food-chain (Kenaga) nomogram, an instrument for estimating pesticide residues on plants. Environ. Tox. Chem. 13:1383-1391.

Uncertainties in the terrestrial EECs are primarily associated with a lack of data on interception and subsequent dissipation from foliar surfaces. Based on these estimates, maximum exposures range from 96 to 1,920 ppm on short grass, 44 to 880 ppm on long grass, 54 to 1,080 ppm on broadleaf plants, and 6 to 120 ppm for fruits and seeds. Highest exposures occur on citrus, while the lowest typically occur from the lawn and turf use.

Comparison of Modeled EECs With Field Residue Monitoring Data

Table 15 summarizes the highest geometric mean concentrations of p,p'-dicofol in eight matrices, foliage, grass, soil, small mammals, terrestrial invertebrates, reptiles/amphibians, birds, and fish, collected over three years of testing in the field monitoring studies.

Table 15: Three-year mean p,p'-dicofol concentrations (ppm)[1] in selected biotic and abiotic matrices.

State	*Site*[2]	*Foliage*	*Grass*	*Soil*	*Mammal*	*Terr. Invert.*	*Herps*	*Birds*	*Fish*
CA	C	92	NG[3]	0.3	0.8	3.9	0.9	NT[4]	NT
	NC	0.6	0.5	0.1	0.1	0.2	0.6	0.1	0.04
FL	C	74	78	0.5	1.4	2.1	3.8	NT	NT
	NC	5.9	9.7	0.1	0.1 (7d)	0.8	0.5 (7d)	0.9	0.5 (7d)
NY	C	97	48	0.6 (21d)	1.1	1.7	2.2 (7d)	NT	NT
	NC	5.2	5.2	<0.1	0.3 (7d)	0.5	0.4 (21d)	0.1	0.2 (7d)

1 All means are calculated from 0-day concentrations, except where noted in parentheses after the mean.
2 C= crop area; NC= non-crop area
3 NG= Not collected because no grass present on treated area.
4 NT= Not taken for crop areas.

In general, p,p'-dicofol concentrations in treated crop and adjacent non-crop areas were considerably lower than those predicted by Fletcher et al. (1994). Residue concentrations were variable and declined exponentially after application. The highest mean concentrations were typically found immediately following application on the treated area, usually on the treated crop foliage, except for the Florida citrus site. Residues of p,p'-dicofol on the non-crop area were typically 1 to 2 orders of magnitude below those found in the crop areas. In the crop areas, the highest mean concentration of p,p'-dicofol measured in the abiotic matrices were 97 ppm for foliage (New York), 78 ppm on grass (Florida) and 0.56 ppm for soil (New York). The highest mean concentration of p,p'-dicofol measured in the abiotic matrices for the non-crop area were 9.7 ppm for grass (Florida), 5.9 ppm on foliage (Florida), and 0.1 ppm for soil (California and Florida).

Foliage residues in the crop areas declined from 3-year means of 92, 97 and 74 ppm immediately after application, to 0.05, 16 and 24 ppm 90 days later for cotton, orchards, and citrus, respectively. Dissipation half-lives for cotton, orchard, and citrus foliage were 9, 41, and 61 days, respectively. Grass residues declined from 3-year means of 48 and 78 ppm immediately after

application, to 0.15 and 2.3 ppm 90 days later for orchards and citrus, respectively. Dissipation half-lives of p,p'-dicofol on orchard and citrus grass were 12 and 21 days, respectively.

Foliage residues in non-crop areas declined from 3-year means of 0.6, 5.2, and 5.9 ppm immediately after application to 0.09, 0.9, and 0.55 ppm after 90 days for cotton, orchards, and citrus, respectively. Mean grass residues declined from 0.47, 5.1, and 9.7 ppm immediately after application, to 0.04, 0.08, and 0.54 ppm 90 days later for cotton, orchards, and citrus, respectively.

In crop areas, the highest mean concentrations of p,p'-dicofol measured in the biotic matrices were 1.4 ppm for small mammals (Florida), 3.9 ppm for terrestrial invertebrates (California), and 3.8 ppm for reptiles/amphibians (Florida). In non-crop areas, highest mean concentrations were 0.3 ppm for small mammals (New York), 0.76 ppm for terrestrial invertebrates (Florida), 0.38 ppm for reptiles/amphibians (Florida), 0.9 ppm for birds (Florida), and 0.26 ppm for fish (Florida).

c. Water Resource Assessment

i. Ground Water Assessment

Laboratory data suggest that dicofol, with moderate to low mobility and moderate persistence, is not expected to leach significantly. This is supported by the two terrestrial field dissipation studies conducted in California. While mobility data for dicofol degradates/metabolites are not available, no movement of the major degradates was observed in the field studies. The weight of evidence from the environmental fate and transport data suggest that dicofol is not expected to leach extensively to groundwater under normal use conditions.

The EPA *Pesticides in Ground Water Data Base*[5] shows no detections of dicofol in limited sampling in California, Georgia, Hawaii, and Texas (1,634 wells sampled between 1979-1991). Howard (1991) refers to a report of dicofol concentrations of 0.2-1.8 ppb in ground water wells from a hazardous waste site in Dade County, Florida. This incident may have been the result of point source contamination rather than pesticide use.

ii. Surface Water Assessment

Dicofol can contaminate surface water from spray drift applications. Substantial fractions of dicofol may be available for runoff for several days to weeks after application, depending on the isomer and field soil conditions. Intermediate soil/water partitioning of dicofol indicates that the chemical will move in runoff, both dissolved in runoff water and adsorbed to eroding soil.

Once dicofol reaches surface waters, it will be susceptible to rapid hydrolysis in neutral to alkaline waters, even water bodies such as ponds where water turnover is slow. However, dicofol

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5. Pesticides in Ground Water Database A Compilation of Monitoring Studies: 1971-1991 National Summary. Published in September 1992. EPA 734-12-92-001.

is stable to hydrolysis in acidic waters and is only moderately susceptible to biodegradation under aerobic and anaerobic conditions. Volatility and Henry's Law constant data suggest that dicofol has a low potential to volatilize from water. Because of these characteristics, dicofol may be substantially more persistent in acidic than neutral or alkaline waters, particularly where water turnover is slow and microbial populations are low.

An intermediate soil/water partitioning coefficient suggests that substantial fractions of dicofol will be adsorbed to suspended and bottom sediment. While the concentration of dicofol in suspended and bottom sediment will be greater than the concentration in the water column, the mass of dicofol in the water column will generally be greater in the sediment. The reported BCFs for p,p'-dicofol in the bluegill sunfish indicate that dicofol has significant bioaccumulation potential.

Limited fate data on the major transformation products of dicofol, primarily terrestrial field dissipation studies, indicate these products may exhibit intermediate to high soil/water partitioning. Consequently, adsorption to eroding soil probably represents a major component of degradate runoff. The importance of dissolution in runoff water to overall losses of dicofol degradates due to runoff will probably vary from substantial, for any with intermediate soil/water partitioning, to little for any with high soil/water partitioning.

In the three-year, three-state monitoring studies (see *a. vi.* above), less than 1% of water samples collected from aquatic habitats adjacent to treated fields contained p,p'-dicofol residues above the reporting limit (0.005 ppm). Maximum dicofol concentrations reported for sampled surface water adjacent to treated citrus groves in Florida ranged from 21 ppb at the time of application to 140 ppb 7 days after application, and up to 52 ppb 90 days after application. The annual time-weighted average geometric mean concentrations for the surface waters in all 3 study areas (California, Florida, and New York) ranged from 0.4 to 1.1 ppb. Low level of residues of p,p'-dicofol were measured in fish. The monitoring studies were not specifically designed to determine EEC's extent for drinking water assessments on a national scale. In particular, the frequency of sampling is not adequate to provide peak concentrations for acute risk assessments. However, the study results are useful in evaluating the screening-model assessment. In this case, model results are compandable (in the same range) to the monitoring data.

In a South Florida Water Management District[6] study of samples collected regularly from 27 surface water sites between 1988 and 1993, dicofol was not detected (above detection limits generally ranging from 0.002 to 0.18 ppm) in any of the samples. The Agency does not have any other data on dicofol in surface waters.

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[6] Miles, C. J. and R. J. Pfeuffer. 1994. Pesticide Residue Monitoring in Sediment and Surface Waters. Technical Publication-December, 1994. South Florida Water Management District.

d. Aquatic Exposure Assessment

Based on laboratory data, the Agency has characterized dicofol as very highly toxic to both cold and warm water fish species and aquatic invertebrates. As such, the Agency is concerned about any direct and/or indirect contamination of aquatic environments from the use of dicofol.

i. Direct Contamination

All current dicofol labels allow for aerial application. Because many registered uses of dicofol are grown in close proximity to aquatic habitats, and because of the variety of topographical and geographical features under which many of these crops are grown, the Agency believes it is reasonable to assume that direct contamination to aquatic environments will occur. The aquatic estimated environmental concentrations (EECs) likely to occur in a 6 inch layer of water that is directly exposed to an application of dicofol are based on the Dewitt nomograph. EEC range from a high of 2.94 ppm for nut trees to 0.25 ppm for the lawn and turf use pattern. These EECs were used to calculate acute risk quotients for fish resulting from exposure to a direct application of dicofol to a surface water body.

ii. Indirect Contamination (Runoff/Drift)

GENEEC is a screening model that provides an upper-bound EEC on a high exposure site. The program uses basic environmental fate values and pesticide label information to calculate EECs in a 1-hectare, 2-meter deep pond following treatment of a 10-hectare field. The runoff event occurs two days after the last application. . GENEEC takes into account adsorption to the soil or sediment, incorporation of the pesticide, degradation in soil before runoff, and degradation within the water body. Dicofol fate parameters used in the model were soil K_{OC} (6.0), solubility (1.32 ppm), and half-lives for aerobic soil metabolism (43 days), hydrolysis (64 hrs), water photolysis (4 days), and aquatic metabolism (stable). The model assumes direct deposition of 5% of the application rate for aerial spray applications and 1% for ground spray applications.

Table 16 lists the aquatic EECs likely to occur from runoff and drift, as predicted by the GENEEC model. Based on the maximum label application rates, and assuming 2 applications with an average 30-day interval between applications, peak EECs (i.e., a rain immediately following application) range from 2.4 ppb on turf to 28.6 ppb on nuts. The GENEEC model also predicts that dicofol residues will decline fairly rapidly and that by day 56, aquatic residues will be less than 2 ppb. Apples, citrus, pears, and quince, with label application rates of 3 lb ai/acre, applied twice at 30-day intervals, had peak EECs of 18.3 ppb and 56-day EECs of 1.1 ppb.

Table 16: Aquatic EECs of dicofol by crop, as predicted by the GENEEC model.

Crop	*Rate (lb ai/A)*	*No. (Days)*	*Interv.*	*Peak GEEC (ppb)*	*4 Day GEEC (ppb)*	*21Day GEEC (ppb)*	*56 Day GEEC (ppb)*
Apples	3.0	2	30	18.3	11.9	2.9	1.1
Beans(Cal).	1.5	2	30	9.2	6.0	1.4	0.5
Beans	0.5	2	30	3.0	2.0	0.5	0.2
Citrus	3.0	2	30	18.3	11.9	2.9	1.1
Cotton	1.5	2	30	10.7	7.2	1.8	0.7
Cucurbits	0.625	2	30	3.8	2.5	0.6	0.2
Grapes	1.165	2	30	7.1	4.6	1.1	0.4
Hops	1.165	2	30	8.3	5.6	1.4	0.5
Lawn/Turf	0.4	2	30	2.4	1.6	0.4	0.1
Mint	1.25	1		4.2	2.7	0.6	0.2
Nuts	4.0	2	30	28.6	19.1	4.8	1.8
Ornamental	0.45	2	30	2.8	1.8	0.4	0.2
Pears	3.0	2	30	18.3	11.9	2.9	1.1
Peppers	0.75	2	30	4.6	3.0	0.7	0.3
Quince	3.0	2	30	18.3	11.9	2.9	1.1
Strawberry	2.4	2	30	14.6	9.5	2.3	0.9
Tomatoes	0.75	2	30	4.6	3.0	0.7	0.3

2. Ecological Effects Characterization

The Agency has adequate data to assess the hazard of dicofol to nontarget terrestrial organisms.

Toxicity testing reported in this section does not represent all species of bird, mammal, or aquatic organism. Only two surrogate species for both freshwater species and birds are used to represent all freshwater fish (2,000+) and bird (680+) in the United states. For mammals, acute studies are usually limited to the Norway rat or the house mouse. Estuarine/marine testing is usually limited to a crustacean, a mollusk, and a fish. Also, neither reptiles nor amphibians are tested. The assessment of risk or hazard makes the assumption that avian and reptilian toxicity are similar. The same assumption is used for fish and amphibians.

a. Toxicity to Terrestrial Animals

i. Birds, Acute and Subacute

In order to establish the toxicity of dicofol to birds, the following tests are required using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); two subacute dietary studies (LC_{50}) on one species of waterfowl (preferably the mallard duck), and one species of upland game bird (preferably bobwhite quail).

Dicofol is moderately toxic to avian species on an acute oral basis and slightly toxic on a subacute dietary basis. The guideline requirements are fulfilled.

Table 17: Avian Acute Oral Toxicity Findings

Species	*% A.I.*	*LD_{50} mg/kg*	*MRID No. Author/Year*	*Toxicity Category*	*Fulfills Guideline Requirement*
Ring-necked pheasant	87.8	265	Hudson et al. 1984 160000	moderately toxic	yes

Table 18: Avian Subacute Dietary Toxicity Findings

Species	*% A.I.*	*LC_{50} ppm*	*MRID No. Author/Year*	*Toxicity Category*	*Fulfills Guideline Requirement*
Northern Bobwhite	99	3010	GS0021007 Hill et al. 1975	slightly toxic	yes
Mallard	99	1651	GS0021007 Hill et al., 1975	slightly toxic	yes
Pheasant	99	2126	GS0021007 Hill et al., 1975	slightly toxic	yes

ii. Birds, Chronic

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. Because dicofol is persistent and has the potential to bioaccumulate in the environment, chronic reproduction testing is required.

Table 19: Avian Reproduction Findings

Species	*% A.I.*	*NOAEC[1] ppm*	*LOAEC[1] ppm*	*Endpoints affected*	*MRID No. Author/Year*	*Fulfills Guideline Requirement*
Northern Bobwhite	93	120	120	no effects	40042055; 42003501	yes
Mallard Duck	93.3	<10	10	cracked eggs, shell strength	41231301	yes
American kestrel	93	1	3	thinned egg shells; reduced shell thickness	41934001; 42268701	yes
Screech-Owl	93	<10	10	egg shell weight and thickness	Wiemeyer et al., 1989	yes
Ring-Dove	98.8	<40	40	egg-shell thickness; cracked eggs; egg production	Schwarzbach et al., 1988	yes
Mallard Duck	Tech.?	10	10	no effects	Hill, Heath & Spann, 1975 GS 002007	Supplemental

1 NOAEC = No Observed Adverse Effect Concentration; LOAEC = Lowest Observed Adverse Effect Concentration

Avian Reproduction Data Overview

Schwartzbach et al.(1988) fed dicofol (or its metabolites) contaminated feed to ring doves (Streptopelia risoria) for 90 consecutive days. They found that dicofol concentrations in egg yolks ranged from 2.62 to 22.58 ppm and that dietary concentrations as low as 40 ppm caused statistically significant differences in egg-shell thickness, cracked eggs, and egg production and that treated birds produced a mean of 1.88 eggs per clutch as compared to 1.97 eggs per clutch produced by the control birds. In addition, 16.9% of all eggs produced by the treated group were either broken or cracked, as compared to 5.7% of eggs produced by the control group. The principle metabolite of dicofol, DCD, did not produce thinning of eggshells and did not metabolize well to DCBP or DCBH. The authors also reported that egg-shell thickness became progressively thinner with increasing time of exposure to the dicofol diets and that concentrations of dicofol in ring dove eggs were significantly correlated with egg-shell thinning.

Wiemeyer et al. (1989) found that egg-shell weight and thickness were adversely affected in screech-owls fed dicofol-treated diets at levels as low as 10 ppm. However, no statistically significant differences existed between controls and treated birds for other reproductive parameters.

Beavers et al. (1989) conducted a one generation reproduction study with mallard ducks and found that dicofol significantly reduced egg shell strength at 40 ppm, but caused no statistically

significant differences in other parameters, such as eggs laid, eggs hatched, and 14-day survivors (MRID 41231301). However, Heath and Spann (1973) found that dicofol (Kelthane) had no effect on the number of eggs laid, the number of eggs cracked, or the number eggs embryonated and 3-week embryos, when mallard ducks were fed 5 and 10 ppm in their diets (GS0021014). Based on these data, Heath and Spann concluded that relatively low levels of Kelthane (5 and 10 ppm) had no significant effect on mallard reproduction.

Frank et al. (1986) conducted a one generation (19-week exposure) reproduction study with bobwhite quail fed dietary concentrations of dicofol at 30 and 120 ppm (MRID 40042055). Some of the reproductive parameters measured included the number of eggs laid, cracked eggs, shell thickness, eggs set, viable embryos, hatchlings, and 14-day survivors. No statistically significant effects, relative to the control birds, were found for any of the reproductive parameters measured.

On the other hand, Clark et al. (1990) studied the effects of dicofol on American kestrel reproductive parameters through two breeding seasons (MRID 41934001) and found that dicofol caused egg-shell thinning, lowered the thickness index at dietary concentrations of 3 ppm, and reduced shell weight at 10 ppm. All changes were dose-related. However, although these parameters were affected, there was no evidence that these changes had any serious effects on the production of young. These authors concluded that dicofol was equal to or less effective than DDE as a shell-thinning agent. These same authors also concluded that before it was possible to fully determine the ecological effects of dicofol, actual field studies on wild bird populations must be conducted.

Avian reproductive studies indicate that dicofol, at least for certain species, can affect such avian reproductive parameters as shell strength, shell thickness, and egg production. The guideline requirements are fulfilled.

Some of these studies may have been conducted with dicofol material, which still had higher levels of DDT (greater than the current requirement to have less than 0.1% DDTr impurities).

iii. Avian Field Studies

Based on its structural similarity to DDT, its persistence, and its potential to bioaccumulate, and several laboratory studies that showed dicofol caused eggshell thinning at very low levels of dietary exposure, the Agency presumed that dicofol could cause reproductive impairment to avian species. This presumption of hazard prompted the Agency to issue a Data Call-In (DCI) in order to collect residue data and other information that could be used to assess the hazard and potential risk to avian species under actual field conditions.

In multi-year, multi-crop field residue monitoring studies in California, New York and Florida, dicofol residues were analyzed in various biotic and abiotic matrices on treated crop areas and adjacent habitats. Eggs were collected from thirteen avian species and were analyzed for residues and eggshell thickness (MRIDs 41764801, 41764802, 41845601, 41845602, 41845603, 42285501, 42285505, and 42721302). These data were compared with the nesting success for these species.

Yearly geometric mean p,p'-dicofol residues ranged from 0.0027 ppm (several species in California) to 0.46 ppm (American robin eggs in New York). Yearly means were highest in New York (0.01-0.46 ppm), and lowest in California (<LOD to 0.02 ppm). Yearly geometric means for p,p'-FW152 residues ranged from 0.002 ppm (mourning dove in California) to 0.218 ppm (eastern screech owl in Florida). Three year means exceeded 0.03 ppm only in eggs of the eastern screech owls in Florida and robins in New York (0.0947 ppm). Yearly geometric means for p,p'-DCBP residues ranged from 0.004 ppm (starling in California) to 0.1651 ppm (eastern screech owl in Florida). Three year means exceeded 0.03 ppm only in eggs of eastern screech owls in Florida and New York (0.1093 and 0.0648 ppm, respectively), New York robins (0.0374 ppm), and Florida mockingbirds (0.0431 ppm). Except for p,p'-FW152 concentrations in the eastern screech owl in Florida, geometric mean metabolite residue concentrations were generally lower than for p,p'-dicofol. None of the yearly geometric means for dicofol, p,p'-FW152, or p,p'-DCBP exceeded 0.5 ppm.

In comparison, background concentrations of p,p'-DDE were widespread and about one order of magnitude greater than that of p,p'-dicofol and its metabolites. Yearly geometric means p,p'-DDE concentrations ranged from 0.03 ppm (mourning dove in Florida) to 19.3 ppm (American robin in NewYork). All yearly geometric mean residues of p,p'-DDE were greater than 0.03 ppm.

An analysis of eight different bird species (in which greater than 10 nests were studied) found no significant difference in mean eggshell thickness between successful and unsuccessful nests. This strongly indicates that unsuccessful nesting was not related to decreased eggshell thinning. Geometric mean concentrations of both p,p'-dicofol and p,p'-DDE did not differ significantly between eggs from successful and unsuccessful nests for most species. The exception was the New York robin, where residues of p,p'-dicofol were significantly higher ($p<0.05$) in unsuccessful nests. Geometric mean concentrations of p,p'-dicofol (0.54 ppm) were 30-fold lower than those for p,p'-DDE (16.3 ppm). Cause-effect relationships cannot be determined from this study.

iv. Mammals, Acute and Chronic

Wild mammal testing is required on a case-by-case basis, depending on the results of lower tier studies, such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. In most cases, however, an acute oral LD_{50} from the Agency's Health Effects Division (HED) is used to determine toxicity to mammals. This LD_{50} is reported below.

Dicofol is moderately toxic to small mammals on an acute oral basis.

Table 20: Mammalian Acute Oral Toxicity Findings

Species	*LD_{50} mg/kg*	*MRID #*	*Toxicity Category*
Rat (small mammal surrogate)	587	40731202	slightly toxic

The mammalian reproductive study indicates that dicofol had an effect on mammalian reproductive physiology and on offspring.

Table 21: Mammalian Reproduction Findings

Species	*% A.I.*	*NOAEL[1] ppm*	*LOAEL[1] ppm*	*Endpoints affected[2]*	*MRID No. Author/Year*	*Fulfills Guideline Requirement*
Rat	93	5	25	A,B,C,D,E,F	41806601	Yes

1 NOAEL = No Observed Adverse Effect Level; LOAEL = Lowest Observed Adverse Effect Level

2 A: reduced viability of pups; B: increased number of stillborn pups; C: pup deaths; D: total litter loss; E: weight reduction; F: vacuolation in ovaries.

v. Insects

A honey bee acute contact LD_{50} study is required if the proposed use will result in honey bee exposure.

Dicofol is slightly toxic to bees. The guideline requirement is fulfilled.

Table 22: Nontarget Insect Acute Contact Toxicity Findings

Species	*% AI*	*LD_{50} µg a.i./bee*	*MRID No. Author/Year*	*Toxicity Category*	*Fulfills Guideline Requirement*
Honey Bee	Tech.	>50	ID05001991	slightly toxic	yes

b. Toxicity to Aquatic Animals

i. Freshwater Fish

In order to establish the toxicity of a pesticide to freshwater fish, the minimum data required on the technical grade of the active ingredient are two freshwater fish toxicity studies. One study should use a cold water species (preferably the rainbow trout), and the other should use a warm water species (preferably the bluegill sunfish).

Results of the 96-hour acute toxicity studies indicate that dicofol is highly toxic to freshwater fish. The guideline requirements are fulfilled.

Table 23: Freshwater Fish Acute Toxicity Findings

Species	*% A.I.*	*LC_{50} ppm a.i.*	*MRID No.*	*Toxicity Category*	*Fulfills Guideline Requirement*
Rainbow trout	93.3	0.124	41695401;42468201	highly toxic	yes
Bluegill sunfish	Tech.	0.51	GS0021004	highly toxic	yes
Channel Catfish	Tech.	0.36	GS0021003	highly toxic	yes
Fathead Minnow	93.3	0.50	GS0021018	highly toxic	yes

Data from fish early life-stage tests or life-cycle tests with aquatic invertebrates (on whichever species is most sensitive to the pesticide as determined from the results of the acute toxicity tests) are required if the product is applied directly to water or expected to be transported to water from the intended use site, and when the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity; or if any acute LC_{50} or EC_{50} is greater than 1 mg/L; or if the EEC in water is equal to or greater than 0.01 of any acute EC_{50} or LC_{50} value; or if the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any acute EC_{50} or LC_{50} value and any of the following conditions exist: studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected, physicochemical properties indicate cumulative effects, or the pesticide is persistent in water (e.g. half-life greater than 4 days).

Results indicate that dicofol can affect the early life-stages of freshwater fish. The guideline requirement is fulfilled.

The fish life cycle test is required when an end use product is intended to be applied directly to water or is expected to transfer to water from the intended use site when any of the following conditions apply: the EEC is equal to or greater than one-tenth of the NOAEL in fish early life stage or invertebrate life cycle test or if studies of other organisms indicate reproductive physiology of fish may be affected.

Table 24: Fish Early Life-Stage Toxicity Findings

Species	*% A.I*	*NOAEC (ppb)*	*LOAEC (ppb)*	*MATC[1] (ppb)*	*MRID No.*	*Endpoints Affected*	*Fulfills Guideline Requirement*
Freshwater: Rainbow trout	93.3	1.0		>4.4 <7.9	42000601; 42063001	growth	Supplemental
Freshwater: Rainbow Trout	>95.5	4.6	9.1	6.5	43383902	growth	Yes

1 MATC = Maximum Allowed Toxic Concentration, defined as the geometric mean of the NOAEC and LOAEC.

Dicofol can affect the reproductive physiology of the fathead minnow at levels as low as 5.5 ppb (mean hatching success). The guideline requirement is fulfilled.

Table 25: Fish Life-Cycle Toxicity Findings

Species	*% A.I.*	*NOAEC (ppb)*	*LOAEC (ppb)*	*MATC (ppb)*	*MRID No*	*Endpoints Affected*	*Fulfills Guideline Requirement*
Fathead minnow	93.3	2.75	5.5	6.31	42628901; 43162001	growth; spawning; hatchability	yes

ii. Freshwater Invertebrates

Minimum testing required to assess the hazard of a pesticide to freshwater invertebrates is a freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges.

There is sufficient information to characterize dicofol as highly toxic to aquatic invertebrates. The guideline requirement is fulfilled.

Table 26: Freshwater Invertebrate Toxicity Findings

Species	*% A.I.*	*EC_{50} (mg/l)*	*MRID NO. Author/Year*	*Toxicity Category*	*Fulfills Guideline Requirement*
Daphnia magna	93.3	0.14	40042057; 40098001; 42003502	highly toxic	yes

iii. Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is intended for direct application to the marine/estuarine environment or is expected to reach this environment in significant concentrations. Because use of dicofol on apples, citrus, and cotton may result in exposure to the estuarine environment, testing of estuarine and marine organisms is appropriate.

The requirements under this category include a 96-hour LC_{50} for an estuarine fish, a 96-hour LC_{50} for shrimp, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study with oysters.

There is sufficient information to characterize dicofol as being highly to very highly toxic to estuarine/marine organisms.

Table 27: Estuarine/Marine Acute Toxicity Findings

Species	*% A.I.*	*LC_{50}/EC_{50}*	*MRID No. Author/Year*	*Toxicity Category*	*Fulfills Guideline Requirement*
Eastern oyster embryo larvae	93.3	96-hour EC_{50}=15.1 ppb	41026701	very highly toxic	yes
Mysid Shrimp	93.3	96-hour EC_{50}=0.14ppm	42003503; 40042059; 40042060	very highly toxic	yes
Sheepshead minnow	93.3	96-hour LC_{50}=0.37 ppm	41695402	highly toxic	yes

c. Toxicity to Plants

Plant testing is not required for pesticides other than herbicides except on a case-by-case basis (e.g., label bears phytotoxicity warnings incident data or literature demonstrates phytotoxicity).

3. Environmental Risk Assessment

A means of integrating the results of exposure and ecotoxicity data is called the quotient method. For this method, risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic.

RQ = EXPOSURE/TOXICITY

RQs are then compared to OPP's levels of comparison (LOCs). These LOCs are criteria used by OPP to indicate potential risk to nontarget organisms and the need to consider regulatory action. Criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. LOCs currently address the following risk presumption categories:

1. **acute high** - potential for acute risk is high, regulatory action may be warranted in addition to restricted use classification.
2. **acute restricted use** - potential for acute risk is high, but this may be mitigated through restricted use classification.
3. **acute endangered species** - potential for acute risk to endangered species is high, regulatory action may be warranted.
4. **chronic risk** - potential for chronic risk is high, regulatory action may be warranted.

Currently, EFED does not assess chronic risk to plants, acute or chronic risks to nontarget insects, or chronic risk from granular/bait formulations to mammalian or avian species.

Ecotoxicity test values (i.e., measurement endpoints) used in the acute and chronic risk quotients are derived from the results of required studies. Examples of ecotoxicity values derived from the results of short-term laboratory studies that assess acute effects are:

1. LC_{50} (fish and birds),
2. LD_{50} (birds and mammals,
3. EC_{50} (aquatic plants and aquatic invertebrates), and
4. EC_{25} (terrestrial plants).

Examples of toxicity test effect levels derived from the results of long-term laboratory studies that assess chronic effects are:

1. LOAEC (birds, fish, and aquatic invertebrates),
2. NOAEC (birds, fish, and aquatic invertebrates), and
3. MATC (fish and aquatic invertebrates).

For birds and mammals, the NOAEC value is used as the ecotoxicity test value in assessing chronic effects. Other values may be used when justified. Generally, the MATC (defined as the geometric mean of the NOAEC and LOAEC) is used as the ecotoxicity test value in assessing chronic effects to fish and aquatic invertebrates. However, the NOAEC is used if the measurement end point is production of offspring or survival.

Tables 28-30 show how the RQs are calculated for each representative group (birds, mammals, fish, aquatic invertebrates, and plants) and provides the levels of comparison used in the subsequent evaluations.

Table 28: RQ Calculations, LOCs and Risk Presumptions for Terrestrial Animals

Risk Presumption	*RQ*	*LOC*
	Birds	
Acute High Risk	EEC[1]/LC50 or LD50/sqft[2] or LD50/day[3]	0.5
Acute Restricted Use	EEC/LC50 or LD50/sqft or LD50/day (or LD50	0.2
Acute Endangered Species	< 50 mg/kg)	0.1
Chronic Risk	EEC/LC50 or LD50/sqft or LD50/day	1
	EEC/NOAEC	
	Wild Mammals	
Acute High Risk	EEC/LC50 or LD50/sqft or LD50/day	0.5
Acute Restricted Use	EEC/LC50 or LD50/sqft or LD50/day (or LD50	0.2
Acute Endangered Species	< 50 mg/kg)	0.1
Chronic Risk	EEC/LC50 or LD50/sqft or LD50/day	1
	EEC/NOAEC	

[1] abbreviation for Estimated Environmental Concentration (ppm) on avian/mammalian food items

[2] $\frac{mg/ft^2}{LD50 * wt. of bird}$ [3] $\frac{mg\ of\ toxicant\ consumed/day}{LD50 * wt. of bird}$

Table 29: RQ Calculations, LOCs and Risk Presumptions for Aquatic Animals

Risk Presumption	*RQ*	*LOC*
Acute High Risk	EEC[1]/LC50 or EC50	0.5
Acute Restricted Use	EEC/LC50 or EC50	0.1
Acute Endangered Species	EEC/LC50 or EC50	0.05
Chronic Risk	EEC/MATC or NOAEC	1

[1] EEC = (ppm or ppb) in water

Table 30: RQ calculations, LOCs, and risk assumptions for Plants

Risk Presumption	*RQ*	*LOC*
	Terrestrial and Semi-Aquatic Plants	
Acute High Risk	EEC[1]/EC25	1
Acute Endangered Species	EEC/EC05 or NOAEC	1
	Aquatic Plants	
Acute High Risk	EEC[2]/EC50	1
Acute Endangered Species	EEC/EC05 or NOAEC	1

[1] EEC = lbs ai/A

[2] EEC = (ppb/ppm) in water

For this ecological risk assessment, results of the ecotoxicity data are compared first with modeled estimated environmental concentrations (EECs) derived from terrestrial exposure (see *1.b* in this chapter) and aquatic exposure (see *1.d* in this chapter). This provides a screening-level assessment of the potential for the use of dicofol, at maximum application rates, to pose a risk to the assessed organisms. The ecotoxicity data are also compared with results of a multi-year ecological monitoring data conducted on citrus in Florida, cotton in California, and apples in New York. The levels of dicofol found in this study represent likely concentrations of dicofol under typical use conditions in these areas. The differences between these comparisons and the implications on the ecological risk assessment are discussed in the risk characterization that follows this section.

a. Exposure and Risk to Nontarget Terrestrial Animals

i. Avian Hazard Assessment

Table 31 shows maximum and minimum avian dietary risk quotients for all currently registered uses of dicofol. Both acute and chronic dietary risk quotients are presented.

Table 31: Maximum and minimum estimated environmental concentrations and avian dietary risk quotients for dicofol.

Crop	*Rate (lb ai/A)*	*LC50 (ppm)[1]*	*LOAEC (ppm)[2]*	*Max. EEC (ppm)[2]*	*Min. EEC (ppm)[3]*	*Max. Acute RQ EEC/ LC50*	*Min. Acute RQ EEC/ LC50*	*Max. Chronic RQ EEC/ LOAEC*	*Min. Chronic RQ EEC/ LOAEC*
Apple	3	1651	3	720	21	0.44	0.01	240	7.0
Beans	0.5	1651	3	120	3.5	0.07	0.00	40	1.2
Beans (CA)	1.5	1651	3	360	10.5	0.22	0.01	120	3.5
Citrus	3	1651	3	720	21	0.44	0.01	240	7.0
Cotton	1.5	1651	3	360	10.5	0.22	0.01	120	3.5
Cucurbits	0.625	1651	3	150	4.375	0.09	0.00	50	1.5
Grapes	1.165	1651	3	279.6	8.155	0.17	0.00	93.2	2.7
Hops	1.165	1651	3	279.6	8.155	0.17	0.00	93.2	2.7
Lawn & Turf	0.4	1651	3	96	2.8	0.06	0.00	32	0.9
Mint	1.25	1651	3	300	8.75	0.18	0.01	100	2.9
Nuts	4	1651	3	960	28	0.58	0.02	320	9.3
Ornamentals	0.4	1651	3	96	2.8	0.06	0.00	32	0.9
Pears	3	1651	3	720	21	0.44	0.01	240	7.0
Peppers	0.75	1651	3	180	5.25	0.11	0.00	60	1.8

Table 31: Maximum and minimum estimated environmental concentrations and avian dietary risk quotients for dicofol.

Crop	*Rate (lb ai/A)*	*LC50 (ppm)*[1]	*LOAEC (ppm)*[2]	*Max. EEC (ppm)*[2]	*Min. EEC (ppm)*[3]	*Max. Acute RQ EEC/ LC50*	*Min. Acute RQ EEC/ LC50*	*Max. Chronic RQ EEC/ LOAEC*	*Min. Chronic RQ EEC/ LOAEC*
Quince	3	1651	3	720	21	0.44	0.01	240	7.0
Strawberries	0.8	1651	3	192	5.6	0.12	0.00	64	1.9
Tomatoes	0.75	1651	3	180	5.25	0.11	0.00	60	1.8

1 LC50 value for mallard duck (GS0021007).
2 LOAEC value for American kestrel (MRID#s 41934001; 42268701)
3 Maximum EECs on avian food items based on Fletcher et al (1994) for short grass (see Table 14).
4 Minimum EECs on avian food items based on Fletcher et al (1994) for fruits and seeds (see Table 14).

(a) Avian Acute Risk

Maximum risk quotients (based on short-grass EECs) ranged from 0.06 for lawn and turf use to 0.58 for use on nut trees. No minimum acute risk quotients (which were based on EECs for fruit and seeds) exceeded 0.02. Only nut tree use, at an application rate of 4 lb a.i./acre, exceeded the maximum acute high risk LOC of 0.5. Based on these risk quotients, the only use patterns that exceed the LOC to non-target avian species, on an acute dietary basis, are citrus and nuts.

In general, Table 31 shows that acute risk (in the form of direct mortality) to non-target avian species from exposure to dicofol only exceeds the LOC (0.5) from exposure to short grass. Since few avian species feed solely on short grass, the likelihood for any large scale hazard to numerous species appears unlikely. Still, certain species (i.e., geese and ducks) may be at risk because of their feeding habits.

(b) Avian Chronic Risk Based on Laboratory Data

Chronic risk quotients in Table 31 were determined by establishing a ratio between the maximum and minimum EEC and the lowest observed adverse effect level (LOAEC) as determined in the avian reproductive tests (in this case, 3 ppm for the kestrel). Maximum risk quotients ranged from 32 for the lawn and turf and ornamental uses, to 320 for the nut tree use. Minimum risk quotients ranged from 0.9 for the lawn and turf and ornamentals use, to 9.3 for nut tree use.

In summary, the risk quotients suggest that chronic hazard, in the form of reproductive impairment to avian species, is expected to exceed the Agency's LOC (1.0) for all the currently registered dicofol use patterns.

(c) Avian Chronic Risk Based on Field Data

Results of the avian reproductive studies, conducted under laboratory conditions, suggest that effects of dicofol on avian reproductive parameters vary greatly. For example, NOAEC values for the five avian species tested ranged from 1 ppm for the American kestrel (MRID #s 41934001, 2268701) to 120 ppm for the Northern bobwhite quail (MRID #s 40042055, 42003501). Similarly, LOAEC values ranged from 3 ppm for the American kestrel to 120 ppm for the bobwhite quail. If this variation occurs under laboratory conditions, it is only reasonable to assume that it may also occur under field conditions.

A comparison of the laboratory data with dicofol concentrations in the field studies suggests that adverse avian reproductive effects from dicofol, in the form of egg-shell thinning, could occur. However, correlations between egg-shell thickness and dicofol residue levels in the eggs were either positive or near zero. In addition, egg-shell thickness from unsuccessful nests was actually greater than that in successful nests in 9 of 12 species/regions. These data indicate that actual field exposure/food chain contamination is either less than exposure regimes found in the laboratory to cause adverse effects or that the effects are somehow being either mitigated or masked in the field.

Laboratory studies on kestrels (Clark et al., 1990) report adverse effects on eggs at dietary levels of 1.7 ppm. Although measured field residue concentrations of p,p'-dicofol in the California and New York monitoring studies were greater than 3 ppm, geometric mean egg residue levels were at or below 0.02 ppm. No statistical correlation was found between dicofol residues and shell thickness. At the levels of exposure measured in New York and California, no adverse reproductive effects to American kestrels can be attributed to dicofol or any other chemical.

Wiemeyer et al. (1989) reported adverse impacts on egg-shell weight and thickness in screech-owls fed dicofol-treated diets at levels as low as 10 ppm (9.2 ppm wet wt.). Field residue levels of dicofol in Florida citrus ranged from 0.5 to 74 ppm in the cropped area and 0.1 to 9.7 ppm in the non-crop area, high enough to affect both egg-shell weight and thickness in screech-owls utilizing this area. In the 45 eastern screech owl eggs collected in Florida, eggshell thickness and weight decreased significantly as p,p'-dicofol residues increased. However, eggshell thickness was greater in unsuccessful screech-owl nests than in successful nests, suggesting that nesting success was not adversely affected by eggshell thickness.

Geometric mean concentrations of p,p'-dicofol in eggs and eggshell thickness for eight species of birds from California, Florida, and New York were similar in both successful and unsuccessful nests. In fact, egg-shell thickness for the unsuccessful nests was actually greater in 9 of the 12 species/regions while the geometric mean residues of p,p'-dicofol in eggs from successful nests was greater than unsuccessful nests for 6 of the 12 species/regions. These data suggest that exposure to p,p'-dicofol residues did not result in eggshell thinning and had no other adverse reproductive impact in the avian populations studied. The only statistically significant difference ($p<0.05$) in the geometric mean egg residues between successful and unsuccessful nests was for the American Robin in New

York. However, no significant correlations existed between p,p'-dicofol levels in eggs and eggshell thickness. All correlation coefficients were very close to zero.

While actual effects were not demonstrated in the field monitoring study, the study was designed to measure dicofol concentrations in various environmental compartments, not to test for effects. The only conclusion that can be drawn from the study is that, in some instances, the concentrations of dicofol found in egg residues exceeded those levels that were found to cause reproductive problem in laboratory studies.

ii. Mammalian Hazard Assessment

Table 32 shows the maximum and minimum mammalian dietary risk quotients for all the currently registered uses of dicofol (based on data for the meadow vole). Both acute and chronic dietary risk quotients are presented.

Table 32: Maximum and minimum EECs and acute and chronic risk quotients for meadow vole exposure to dicofol.

Crop	*Rate (lb ai/A)*	*LC50 (ppm)[1]*	*NOEC (ppm)[2]*	*Max. EEC (ppm)[3]*	*Min. EEC (ppm)[4]*	*Max. Acute RQ EEC/ LC50*	*Min. Acute RQ EEC/ LC50*	*Max. Chronic RQ EEC/ NOEC*	*Min. Chronic RQ EEC/ NOEC*
Apple	3	1005	25	720	21	0.72	0.02	28.80	0.84
Beans	0.5	1005	25	120	3.5	0.12	0.00	4.80	0.14
Beans (CA)	1.5	1005	25	360	10.5	0.36	0.01	14.40	0.42
Citrus	3	1005	25	720	21	.72	0.02	28.80	.84
Cotton	1.5	1005	25	360	10.5	0.36	0.01	14.40	0.42
Cucurbits	0.625	1005	25	150	4.375	0.15	0.00	6.00	0.18
Grapes	1.165	1005	25	279.6	8.155	0.28	0.01	11.18	0.33
Hops	1.165	1005	25	279.6	8.155	0.28	0.01	11.18	0.33
Lawn/Turf	0.4	1005	25	96	2.8	0.10	0.00	3.84	0.11
Mint	1.25	1005	25	300	8.75	0.30	0.01	12.00	0.35
Nuts	4	1005	25	960	28	0.96	0.03	38.40	1.12
Ornamentals	0.4	1005	25	96	2.8	0.10	0.00	3.84	0.11
Pears	3	1005	25	720	21	0.72	0.02	28.80	0.84
Peppers	0.75	1005	25	180	5.25	0.18	0.01	7.20	0.21
Quince	3	1005	25	720	21	0.72	0.02	28.80	0.84

Table 32: Maximum and minimum EECs and acute and chronic risk quotients for meadow vole exposure to dicofol.

Crop	*Rate (lb ai/A)*	*LC50 (ppm)[1]*	*NOEC (ppm)[2]*	*Max. EEC (ppm)[3]*	*Min. EEC (ppm)[4]*	*Max. Acute RQ EEC/ LC50*	*Min. Acute RQ EEC/ LC50*	*Max. Chronic RQ EEC/ NOEC*	*Min. Chronic RQ EEC/ NOEC*
Strawberries	0.8	1005	25	192	5.6	0.19	0.01	7.68	0.22
Tomatoes	0.75	1005	25	180	5.25	0.18	0.01	7.20	0.21

1 Based on rat LD50 value adjusted for the body weight and food consumption for the meadow vole (MRID 40731202).
2 Based on rat NOAEC of 25 ppm.
3 Maximum EECs on avian food items based on Fletcher et al (1994) for short grass. See Table 15
4 Minimum EECs on avian food items based on Fletcher et al (1994) for fruits and seeds. See table 15.

(a) Acute Mammalian Risk

Maximum risk quotients ranged from 0.10 for the lawn and turf use to 0.96 for use on nut trees. No minimum risk quotients exceeded 0.12. The use of dicofol at maximum application rates on citrus, apples, nuts, pears, and quince exceeded the acute high risk LOC of 0.5 for non-target mammalian species.

In general, acute risk in the form of direct mortality to non-target mammalian species from exposure to dicofol exceeds the LOC for citrus, apples, pears, nuts, and quince, and then only from exposure from short grass. Because numerous small mammal species primarily feed on short grass, acute hazard from these use patterns is possible.

(b) Chronic Mammalian Risk

Chronic risk quotients in Table 32 were determined by establishing a ratio between the maximum and minimum EECs and the lowest effect level (LOAEL) as determined in the mammalian reproductive tests (in this case, 25 ppm for the rat). Maximum risk quotients ranged from 3.84 for lawn, turf, and ornamental uses, to 38.4 for use on nut trees. Minimum risk quotients ranged from 0.11 for lawn, turf and ornamentals, to 1.12 for nut trees.

Based upon risk quotients derived from laboratory data and the EEC of dicofol, chronic hazard (in the form of reproductive impairment) to mammalian species exceeds the LOC for all currently registered use patterns. There are no mammalian field study data available for reproductive effects.

b. Exposure and Risk to Nontarget Freshwater and Marine Aquatic Animals

Based on laboratory data, dicofol is characterized as very highly toxic to both cold and warm water fish species, aquatic invertebrates, and marine and estuarine organisms. As such, the Agency

is concerned about any direct and/or indirect contamination of both fresh and salt water environments from the use of dicofol. Because all current dicofol labels allow for aerial application of dicofol to many crops that are in close proximity to various types of aquatic environments, the Agency believes it is reasonable to assume that some direct contamination of aquatic environments is possible from the use of dicofol.

i. Aquatic Acute Risk From Direct Contamination to Water

Table 33 shows the maximum acute risk quotients for fresh water fish, aquatic invertebrates, shellfish, and salt water fish, respectively, resulting from direct contamination of dicofol to water.

Table 33: Acute risk quotients for aquatic organisms from direct contamination of dicofol to a 6 inch layer of water (Based on DeWitt nomograph).

Crop	*Applic. Rate (lb a.i./A)*	*EEC (ppm) (6" layer)*	*Fresh water Fish[1]*		*Invertebrates[2]*		*Shellfish[3]*		*Salt water Fish[4]*	
			LC50 (ppm)	*RQ*	*LC50 (ppm)*	*RQ*	*LC50 (ppm)*	*RQ*	*LC50 (ppm)*	*RQ*
Apples	3.0	2.20	0.124	17.7	0.14	15	0.015	146	0.37	5.9
Beans (CA)	1.5	1.10	0.124	8.9	0.14	7	0.015	73	0.37	3.0
Beans	0.5	0.36	0.124	2.9	0.14	2	0.015	24	0.37	1.0
Citrus	3.0	2.20	0.124	17.7	0.14	15	0.015	146	0.37	5.9
Cotton	1.5	1.10	0.124	8.9	0.14	7	0.015	73	0.37	3.0
Cucurbits	0.625	0.47	0.124	3.8	0.14	3	0.015	31	0.37	1.3
Grapes	1.165	0.85	0.124	6.9	0.14	6	0.015	56	0.37	2.3
Hops	1.165	0.85	0.124	6.9	0.14	6	0.015	56	0.37	2.3
Lawn & Turf	0.4	0.29	0.124	2.3	0.14	2	0.015	19	0.37	0.8
Mint	1.250	0.91	0.124	7.3	0.14	6	0.015	60	0.37	2.5
Nuts	4.0	2.94	0.124	23.7	0.14	21	0.015	196	0.37	7.9
Ornamentals	0.45	0.33	0.124	2.7	0.14	2	0.015	22	0.37	0.9
Pears	3.0	2.20	0.124	17.7	0.14	15	0.015	146	0.37	5.9
Peppers	0.75	0.55	0.124	4.4	0.14	3	0.015	36	0.37	1.5
Quince	3.0	2.20	0.124	17.7	0.14	15	0.015	146	0.37	5.9
Strawberries	2.4	1.76	0.124	14.2	0.14	12	0.015	117	0.37	4.8
Tomatoes	0.75	0.55	0.124	4.4	0.14	3	0.015	36	0.37	1.5

1 LC50 for freshwater fish is based on rainbow trout.
2 LC50 for invertebrates is based on Daphnia magna.
3 LC50 for shellfish is based on eastern oyster.
4 LC50 for salt water fish is based on sheepshead minnow.

Maximum risk quotients for aquatic organisms from the direct contamination of dicofol to a 6" layer of water were greatest on nut tree uses and lowest for lawn and turf uses. Risk quotients ranged from 23.7 to 2.3 for freshwater fish, 21 to 2.1 for aquatic invertebrates, 196 to 19.3 for shellfish, and 7.9 to 0.8 for salt water fish.

For fresh water fish, aquatic invertebrates and shellfish, all of the risk quotients exceed the LOC for acute risk. The only risk quotient that does not exceed the LOC is for salt water fish for the lawn, turf, and ornamental use patterns.

ii. Aquatic Acute Risk From Indirect Contamination to Water (Runoff/Drift)

Table 34 shows maximum acute risk quotients for fresh water fish, aquatic invertebrates, shellfish, and salt water fish, respectively, resulting from indirect contamination of dicofol to water by spray drift during application and runoff after the pesticide has been applied. EECs are estimated using GENEEC (see the Aquatic Exposure Assessment of the Exposure Characterization).

Table 34: Acute risk quotients for aquatic organisms from indirect contamination of dicofol to a pond via spray drift and runoff (using peak EECs estimated using GENEEC).

Crop	*Applic. Rate (lb a.i./A)*	*peak EEC (ppb)*	*Fresh water Fish[1]*		*Invertebrates[2]*		*Shellfish[3]*		*Salt water Fish[4]*	
			LC50 (ppb)	*RQ*	*LC50 (ppb)*	*RQ*	*LC50 (ppb)*	*RQ*	*LC50 (ppb)*	*RQ*
Apples	3.0	155	124	1.25	140	1.11	15.1	10.3	370	0.42
Beans	0.5	25.9	124	0.21	140	0.18	15.1	1.71	370	0.07
Beans (CA)	1.5	77.6	124	0.63	140	0.55	15.1	5.14	370	0.21
Citrus	3.0	155	124	1.25	140	1.11	15.1	10.3	370	0.42
Cotton	1.5	77.6	124	0.63	140	0.55	15.1	5.14	370	0.21
Cucurbits	0.625	38.8	124	0.31	140	0.28	15.1	2.57	370	0.10
Grapes	1.165	60.3	124	0.49	140	0.43	15.1	3.99	370	0.16
Hops	1.165	60.3	124	0.49	140	0.43	15.1	3.99	370	0.16
Lawn & Turf	0.4	20.7	124	0.17	140	0.15	15.1	1.37	370	0.06
Mint	1.250	64.7	124	0.52	140	0.46	15.1	4.28	370	0.17
Nuts	4.0	206	124	1.66	140	1.47	15.1	13.6	370	0.56
Ornamentals	0.45	20.6	124	0.17	140	0.15	15.1	1.36	370	0.06
Pears	3.0	155	124	1.25	140	1.11	15.1	10.3	370	0.42
Peppers	0.75	38.9	124	0.31	140	0.28	15.1	2.58	370	0.11
Quince	3.0	155	124	1.25	140	1.11	15.1	10.3	370	0.42

Crop	Applic. Rate (lb a.i./A)	peak EEC (ppb)	Fresh water Fish[1]		Invertebrates[2]		Shellfish[3]		Salt water Fish[4]	
			LC50 (ppb)	RQ	LC50 (ppb)	RQ	LC50 (ppb)	RQ	LC50 (ppb)	RQ
Strawberries	2.4	41.4	124	0.33	140	0.30	15.1	2.74	370	0.11
Tomatoes	0.75	38.8	124	0.31	140	0.28	15.1	2.57	370	0.10

1 LC50 for freshwater fish is based on rainbow trout.
2 LC50 for invertebrates is based on Daphnia magna.
3 LC50 for shellfish is based on eastern oyster.
4 LC50 for salt water fish is based on sheepshead minnow.

Maximum risk quotients from indirect contamination of aquatic habitats by drift and run-off were greatest for nut tree use and lowest for lawn and turf uses. Risk quotients ranged from 1.66 to 0.17 for freshwater fish, 1.47 to 0.15 for aquatic invertebrates, 13.6 to 1.36 for shellfish, and 0.56 to 0.06 for salt water fish.

For freshwater fish and aquatic invertebrates, application rates equal to or greater than 1.25 lbs. a.i./A exceed the LOC. All application rates exceed the LOC for shellfish, while only the application rate of 4 lbs. ai./acre for nut trees exceeds the LOC for salt water fish species.

iii. Aquatic Chronic Risk to Fish

Table 35 shows the risk quotients for fresh water fish from chronic exposure to dicofol. The maximum risk quotient is 0.33 for use on nut trees while the lowest is 0.03 for beans (California), lawn, turf, and ornamental uses. No use patterns exceed the chronic LOC (1.0) for fish.

Table 35: Risk quotients for fish from chronic exposure to dicofol using GENEEC-derived EECs.

Crop	Applic. Rate (lb a.i./A)	56-day EEC (ppb)	LOAEC[1] (ppb)	Max. RQ EEC/LOAEC
Apples	3.0	1.1	5.5	0.20
Beans	0.5	0.5	5.5	0.10
Beans (CA)	1.5	0.2	5.5	0.03
Citrus	3.0	1.1	5.5	0.20
Cotton	1.5	0.7	5.5	0.12
Cucurbits	0.625	0.2	5.5	0.04
Grapes	1.165	0.4	5.5	0.08
Hops	1.165	0.5	5.5	0.09
Lawn & Turf	0.4	0.1	5.5	0.03
Mint	1.25	0.2	5.5	0.04

Crop	Applic. Rate (lb a.i./A)	56-day EEC (ppb)	LOAEC[1] (ppb)	Max. RQ EEC/LOAEC
Nuts	4.0	1.8	5.5	0.33
Ornamentals	0.45	0.2	5.5	0.03
Pears	3.0	1.1	5.5	0.20
Peppers	0.75	0.3	5.5	0.05
Quince	3.0	1.1	5.5	0.20
Strawberries	2.4	0.9	5.5	0.16
Tomatoes	0.75	0.3	5.5	0.05

1 LOAEC for fathead minnow life-cycle study (MRID 42628901; 43162001).

c. Exposure and risk to Endangered Species

The endangered species level of concern from the use of dicofol is exceeded for fish and aquatic invertebrates at all label application rates; for birds at application rates greater than 0.75 lb a.i./acre, and for mammals at application rates greater than 0.4 lb a.i./acre. The Endangered Species Protection Program is expected to become final in the future. Limitations in the use of dicofol will be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. The Agency anticipates that a consultation with the Fish and Wildlife Service will be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

4. Risk Characterization

Available field data suggest that dicofol does not pose significant adverse effects on avian reproduction and does not present an unreasonable risk to ecosystems. However, the potential for such effects, based on laboratory data, is great for certain species. Because of uncertainties surrounding the relationship between the laboratory and field data, the Agency believes it is prudent to impose risk reduction measures to reduce the likelihood of unacceptable risk as much as possible. Mitigation and labeling measures presented in chapter 4 should be put in place.

Data Gaps:

The environmental fate and transport database for dicofol is largely complete. The ecological toxicity data base is adequate to assess the hazard of dicofol to nontarget terrestrial organisms.

a. Environmental Fate and Exposure Assessment

Dicofol has a short to intermediate half-life (days to months) in laboratory studies. The chemical is likely to be more persistent in acidic than neutral or alkaline soils or waters and in drier

conditions. Major dissipation routes are hydrolysis under neutral and alkaline pHs and aerobic and anaerobic soil metabolism, with the p,p'-isomer being more persistent. Laboratory and field data suggest that dicofol is not very mobile, and neither leaching nor volatility are expected to play an important role in the dissipation of dicofol. Terrestrial field dissipation studies conducted in California suggest that the persistence of dicofol is highly dependent on field and environmental conditions. Metabolism appears to be the dominant mode of dissipation in the field, with dissipation half-lives for the dominant p,p'-isomer ranging from a less than a week to greater than two months. The more rapid dissipation was associated with greater inputs of water by irrigation.

In a three-year monitoring study, the dissipation half-life for dicofol in soil was on the order of two months in California and four months in Florida. Dicofol concentrations in soil in New York remained at a similar level throughout the study period. Factors such as differing pHs of soil and water (both tend to be in the neutral to alkaline range in California and in the acidic range in New York, although no field data was provided to assess this), timing and amount of rainfall and irrigation, and different agronomic practices (including liming) are likely to influence the persistence of dicofol in the environment.

Major degradates of dicofol are the o,p'- and p,p'- isomers of diclorobenzophenone (DCBP), chlorobenzoic acid (CBA), 1,1-(chlorophenyl)-2,2-dichloroethanol (FW-152), hydroxy-DCPB, and dichlorobenzhydrol (DCBH). DCBP is a degradate in hydrolysis, photolysis, and metabolism, while the other compounds result from metabolic processes.

Ground Water Assessment

Dicofol is not expected to leach extensively to ground water under label use conditions. Available data demonstrate low solubility in water, relatively high binding capacity to soils (K_ds of 8.4 to 82.8), and little or no movement of the parent compound. While mobility data for dicofol degradates are not available, no movement of the major degradates was observed in the field studies. No detections of dicofol in ground water are reported in the EPA *Pesticides in Ground Water Data Base*.

Surface Water Assessment

Dicofol can contaminate surface water via spray drift during application. Substantial fractions of applied dicofol could be available for runoff for several days to weeks after application. Because of susceptibility to hydrolysis with increasing pH, dicofol is not likely to persist in neutral to alkaline waters, even with long hydrologic residence times. Dicofol may be substantially more persistent in some acidic waters, particularly in those with relatively long hydrological residence times and low microbiological populations.

b. Environmental Hazard Assessment

Toxicity to Terrestrial Organisms:

Dicofol is moderately to slightly toxic on an acute basis to terrestrial animals and slightly toxic to honey bees. For avian species, the results of the laboratory studies suggest that the reproductive sensitivity of avian species to dicofol varies greatly. Raptors appear to be the most sensitive and non-raptors the least. For example, NOAEC (No Observed Adverse Effect Concentration) values for five avian species ranged from 1 ppm for the American kestrel to 120 ppm for the Northern bobwhite quail. LOAEC (Lowest Observed Adverse Effect Concentration) values ranged from 3 ppm for the American kestrel to >120 ppm for the bobwhite quail. The reproductive parameters affected included egg-shell thickness, shell strength, egg production, and hatchability.

Using the rat as a surrogate for terrestrial mammals, the NOAEL for reproductive effects is 5 ppm and the LOAEL is 25 ppm. Reproductive effects included reduced viability of pups, increased number of stillborns, pup death, total litter loss, weight reduction, and vacuolation in ovaries.

Toxicity to Aquatic Organisms

Dicofol is highly to very highly toxic to all aquatic organisms tested, including fish, invertebrates, and estuarine/marine organisms.

Dicofol is highly toxic on an acute basis to both cold and warm water species of fish. It also causes early life stage toxicity at levels of 19 ppb for fathead minnow and 1 ppb for rainbow trout. Dicofol is highly toxic on an acute basis to the freshwater invertebrate species, *Daphnia magna,* with an EC_{50} of 0.14 mg/l. Dicofol is classified as highly to very highly toxic to marine and estuarine organisms.

c. Environmental Risk Assessment

Risk to Terrestrial Organisms:

Acute risk, in the form of direct mortality, to non-target mammalian species from exposure to dicofol exceed the level of concern (LOC) for citrus, apples, pears, nuts, and quince only from exposure from short grass. Because numerous small mammal species primarily feed on short grass, acute hazard from these use patterns is possible. For avian species, the acute LOC is exceeded only in exposure to short grass. Except for the few avian species, such as geese or ducks, which may feed primarily on short grass, the acute hazard from this use does not present an unacceptable risk.

Maximum and minimum chronic Risk Quotient (RQs) values exceed the LOCs for both mammalian and avian species for all registered uses of dicofol. Chronic hazard, in the form of reproductive impairment to mammalian and avian species, can occur for all currently registered use patterns. The highest exposure is predicted to occur on nut trees and the lowest on lawn and turf.

Uncertainties in the modeled terrestrial EECs used to calculate the RQs result from a lack of data on interception and subsequent dissipation from foliar surfaces. A comparison of the EECs with levels measured in the three year, three state monitoring study show that concentrations predicted by the model are two to ten times greater than levels measured in the crop areas (Table 36). The non-crop areas had substantially less residue than the crop areas.

Table 36. Comparison of three-year average geometric mean residue values of p,p'-dicofol with EEC values estimated using the method by Fletcher et al (1994).

State	*Site (Crop)*	*Foliage EEC (ppm)*	*Foliage Measured (ppm)*	*Grass EEC (ppm)*	*Grass Measured (ppm)*
California	C (Cotton)	203	92	165-360	NG
"	NC		0.6		0.5
Fla.	C (Citrus)	1080	74	880-1920	78
"	NC		5.9		9.7
New York	C (Apples)	405	97	330-720	48
"	NC		5.2		5.2

C= crop area; NC= non-crop area
NG= Not collected, because no grass present on treated area

Residues of dicofol were found in terrestrial species in each of the locations, both crop and non-crop areas, for each of the study years in the field monitoring study. For mammals, dicofol levels ranged from 2.6 ppm in Florida to 0.6 ppm in New York and California. For terrestrial invertebrates, dicofol levels ranged from 4.2 ppm in Florida to 1.3 ppm in New York. Dicofol levels found in reptiles and amphibians in Florida ranged from 0.02 ppm to 6.6 ppm. In all cases, levels of DDE (a primary degradate of DDT, known to cause reproductive effects in a number of species) found in the terrestrial species were one to two orders of magnitude lower than those for dicofol.

Comparisons between estimated environmental concentrations (EECs) and laboratory data suggest that, for certain avian species, numerous reproductive parameters may be adversely affected by exposure to dicofol. However, under conditions present in the field studies, adverse avian reproductive effects in the form of egg-shell thinning were not detected. But it should be noted that detectable levels of dicofol were found in the birds in all states, but levels of DDE were either equal to or greater than levels of dicofol.

Risk to Aquatic Organisms:

All current dicofol labels allow for aerial application. Many of the crops on which dicofol is registered for use may be grown in close proximity to aquatic habitats or in areas in which runoff to water bodies may occur. Therefore, the potential exists for risk to aquatic organisms from exposure to dicofol through direct contamination or indirect contamination by spray drift or runoff. For direct contamination, all RQs exceed the LOC for fresh and salt water fish, invertebrates, and shellfish. For indirect contamination (i.e., runoff or spray drift) all application rates exceeded the LOC for shellfish.

For fresh water fish and aquatic invertebrates, application rates equal to or greater than 1.25 lb a.i./A exceeded the LOC; for salt water fish, application rates equal to or greater than 4 lb a.i./A exceeded the LOC. None of the use patterns exceed the LOC for chronic risk to fish.

EECs used to calculate RQs are upper-bound estimates based on hydrolysis, photolysis, and metabolism in neutral water. Dicofol is likely to be more persistent in acidic waters and less persistent in alkaline waters. In the monitoring studies, geometric mean residue levels of p,p'-dicofol in water adjacent to the treated areas ranged from 1.5 ppb in Florida to 0.4 ppb in New York. While the model overestimates peak environmental concentrations for acute effects, it correctly predicts concentrations below a chronic concern. However, the studies did not provide sufficient information to determine whether reported residue concentrations reflect typical conditions. Such an evaluation would need information on water chemistry, particularly pH (the fate of dicofol is pH-dependent), flow rates, residence time in water, type and location of the receiving water, application and sampling dates, and the duration and timing of rainfall events.

Peak concentrations of dicofol residue in fish in the monitoring studies ranged from 0.3 - 0.6 ppm in Florida and New York to 0.1 ppm in California. The lowest levels were in the 0.01 ppm range in all states. In contrast to terrestrial mammals and invertebrates, DDE levels in fish were approximately equal to or greater than the dicofol levels.

Laboratory studies show that dicofol has some potential to bioaccumulate in fish, with bioaccumulation factors in bluegill sunfish of 6,600, 17,000, and 10,000X in fillet, viscera, and whole fish, respectively, during the 28-day exposure period. However, dicofol residues depurated relatively quickly, with an estimated elimination half-life of 33 days.

d. Comparison of Dicofol to DDT and DDE

Dicofol and DDT are similar in chemical structure. However, important differences in chemistry separate these two organochlorine pesticides. Dicofol has an environmentally significant water solubility, providing dicofol with a pathway for degradation; DDT does not. Dicofol has an environmental half-life of weeks compared to years for DDT. While dicofol has some ability to accumulate, DDT has a much greater ability to do so. Most importantly, dicofol does not degrade to DDE, but to degradates less toxic than dicofol, whereas DDT degrades to DDE which has been identified as the toxic moiety.

For dicofol, evidence for endocrine disruption is suggestive, but not definitive. It clearly has reproductive effects in some species, although they appear to differ somewhat from its close analogues, DDT and/or DDE. Whether the difference is due to the ability of dicofol to be metabolized to less toxic chemicals, its relatively short half-life, or the reduced potency of the parent, is not known at this time. It is clear, however, that dicofol does not present the enormous bioaccumulation potential of DDT/DDE and, for that reason alone, may be deemed of lesser concern than DDT/DDE.

e. Inferences from Field Monitoring Studies

Laboratory data suggest dicofol concentrations in excess of 3 ppm will adversely affect reproductive outcomes in sensitive avian species; levels at or above 25 ppm will similarly affect mammalian species. Exposure modeling using maximum application rates predict dicofol concentrations equal to or in excess of these levels. In contrast, the monitoring study indicates that these models may overestimate exposure concentrations in some instances by several orders of magnitude. Although the residue monitoring study is handicapped by the limitations previously discussed, it does provide a "snapshot in time" of environmental levels of dicofol in biotic and abiotic mediums in three diverse geographical areas and three different crops.

Analysis of monitoring data suggest:

- limited potential to accumulate in soils;

- detectable residues in fish at levels lower than DDE residues;

- detectable residues in all terrestrial species at levels greater than DDE;

- detectable residues in avian species at levels lower than DDE;

- detectable residues in eggs, with egg-shell thinning in some species;

- egg-shell thinning is not always correlated with dicofol concentrations.

It is worthwhile to emphasize that all mediums monitored contained detectable levels of dicofol in some or all of the samples. Although dicofol was detected in only 50% of the surface water samples, fish presumably taken from those surface waters did contain detectable levels of dicofol. For the most part, residue levels exhibited a cyclic pattern--rising from a background level to a peak concentration at 7 or 21 days after application and then falling to or near to the previous background level. Whether these levels are increasing or will increase with time in any of the compartments is not possible to determine in the context of this monitoring study.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient dicofol are eligible for reregistration. The Agency has previously identified and required the submission of dicofol data required to support reregistration of products containing dicofol. The Agency has completed its review of these data. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of dicofol, and lists the submitted studies that the Agency found acceptable.

Data identified in Appendix B were sufficient for the Agency to assess the registered uses of dicofol and to determine that dicofol might be used without resulting in unreasonable adverse effects to humans and the environment, contingent upon results of dermal toxicity and Dislodgeable Foliar Residue (DFR) studies that will be submitted by the registrants (see section B below). Therefore, the Agency finds that all products containing dicofol as the active ingredient may be eligible for reregistration, subject to the conditions in this RED, if revised MOEs, which will be calculated in consideration of the revised dermal toxicity study, are acceptable (this is further described in Section B below). The reregistration of particular products is addressed in Section V of this document.

The Agency will make its reregistration eligibility determination based upon the target data base required for reregistration, the dermal toxicity study currently being conducted by the registrants, current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc., and data identified in Appendix B. Although the Agency has found that all uses of dicofol might be eligible for reregistration under currently defined conditions, as defined in this RED, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing dicofol, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

Before reregistering products containing dicofol, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF), and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. Additionally, except for cases where the basic registrants have made commitments for label changes in 1999, revised labeling must also be submitted within eight months of the issuance of this document. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

B. Determination of Eligibility Decision

Based on the reviews of the generic data for the active ingredient dicofol, the Agency has sufficient information on the health effects of dicofol and on its potential for causing adverse effects in fish and wildlife and the environment. The risk assessment in this RED raises some strong concerns for occupational dermal exposure. However, the Agency believes that the assumptions used to arrive at this conclusion may have led to an overestimation of risk (i.e. the assumptions of 100% dermal absorption, a Dislodgeable Foliar Residue (DFR) level of 20% at the application rate, and a residue dissipation rate of 10% per day). To refine our estimation of dicofol risk, the registrants have initiated a dermal toxicity study, which is due to the Agency on December 31, 1998. In addition, as a result of a Data Call In from October 13, 1995, the registrants are also completing a DFR study, due in October, 1998. In order to address the occupational risks identified in this RED while the new data are being developed and evaluated, the registrants have also agreed to undertake several interim risk mitigation measures (described in section C of this chapter and Chapter 5). Additionally, the registrants have agreed to several risk mitigation measures to address ecological and residential risk.

The Agency will conclude that dicofol is eligible for reregistration if, after consideration of the dermal toxicity data submitted by the registrants, the revised MOEs are found to be acceptable (i.e., MOEs above 100). The registrants have submitted a request to voluntarily cancel all uses/products which are found to have unacceptable MOEs after consideration of the new data and if risks cannot be mitigated to acceptable levels.

The Agency has determined that dicofol products, labeled and used as specified in this Reregistration Eligibility Decision, may not pose unreasonable risks or adverse effects to humans or the environment, contingent on the results of the dermal toxicity and DFR studies currently being conducted by the registrants. Under the Food Quality Protection Act of 1996, the Agency has determined with a reasonable certainty that no harm will result to infants and children or to the general population from aggregate exposure to dicofol. The Agency concludes that products containing dicofol might be eligible for reregistration for all uses, as specified in this RED, contingent upon results of the dermal toxicity and DFR studies

C. Regulatory Position

As currently calculated in this document, the risk to workers from occupational dermal exposure exceeds acceptable levels (i.e., current MOEs are less than 100. See table 11). However, the Agency believes that the assumption of 100% dermal absorption, used in the absence of acceptable data, may have led to an overestimation of occupational risk. As a result, EPA has found that it is not appropriate to declare dicofol ineligible at this time. One key consideration is the fact that the registrants will submit a study by December 31, 1998, which may be a more appropriate study for regulatory purposes. Although the Agency would not normally delay a decision for a study voluntarily conducted by registrants outside the RED timeframe, two factors make this appropriate here. First, the registrants have committed to significant risk mitigation measures to be implemented immediately. Second, the registrants have committed to a process that would result in automatic and voluntary cancellation of any use which continues to have unacceptable risk after EPA completes its review of the incoming new study, in a timeframe that is comparable or more rapid than what EPA could achieve through its own regulatory process.

The registrants have agreed to conduct a dermal toxicity study, which will be submitted to the Agency by December 31, 1998. The registrants will also be submitting DFR data in October 1998. Results of these studies will be evaluated in conjunction with other toxicity studies and a decision will be made on the use of these studies for dermal risk assessment.

The registrants has submitted a request to voluntarily cancel all dicofol uses/products that are found to have unacceptable MOEs after consideration of the new data and if risks cannot be mitigated to acceptable levels.

To further address risk mitigation during the interim period between the issuance of this RED and evaluation of the dermal toxicity and DFR studies, the Agency is requiring and the registrants have agreed to the following:

To address risks to homeowners, residents, and children:

- All residential uses have been deleted from labels and will be voluntarily canceled.

To address risks to mixers/loaders/applicators:

- Mixers/loaders/applicators will be required to wear additional personal protective equipment (PPE), as specified in the labeling specifics in Chapter 5, and use enclosed cabs and closed cockpits.
- All wettable powder formulations produced after December 31, 1998 must be produced in water soluble packaging (WSP).
- Application with handheld equipment is prohibited for liquid formulations.
- All liquid formulations produced after December 31, 1998 must bear labeling requiring closed mixing systems for dry beans.

To address risks to workers (persons entering treated areas following applications of dicofol):

- A revised REI will be set, based on DFR data being submitted in October, 1998, and on a dermal toxicity study being submitted in December, 1998.

To protect the environment and wildlife:

- Dicofol applications are limited to no more than one per year. Previously, for some uses, the number of applications allowed per year was either unrestricted or limited to 2 or 3 applications per year.
- Dicofol applications on citrus will not exceed 3 pounds a.i./acre per year. This has been reduced from 8 pounds a.i./acre per year.
- Dicofol applications on strawberries will not exceed 2 pounds a.i./acre per year. This has been reduced from 2.4 pounds a.i./acre per year.
- Additionally, as a result of previous agreements with the registrants, applications will not exceed:
  - 3 lb ai/acre for apples and pears (reduced from 4 lb ai/acre);
  - 2 lb ai/acre for pecans and walnuts (reduced from 4 lb ai/acre);
  - 1.5 lb ai/acre for cotton (reduced from 1.6 lb ai/acre);
  - 1.3 lb ai/acre for grapes (reduced from 1.5 lb ai/acre);
  - 0.63 lb ai/acre for cucurbits (reduced from 1.5 lb ai/acre);
  - 0.75 lb ai/acre for tomatoes and peppers (reduced from .8 lb ai/acre);
  - 1.5 lb ai/acre for stonefruits;
  - 1.5 lb ai/acre for beans; and
  - 0.55 lb ai/acre for nonresidential lawns and ornamentals.

- A spray drift and Runoff Caution Statement is being added to the label. Also, a statement prohibiting application directly to water is being added to the label.

1. Tolerance Reassessment

Tolerances for plant commodities should be expressed in terms of the combined residue of 1,2-bis(4-chlorophenyl)-2,2,2-trichloroethanol and 1-(2-chlorophenyl)-1-(4-chlorophenyl)-2,2,2-trichloroethanol. The listing should be designated 40 CFR §180.163(a).

Tolerances for animal commodities should be expressed as the combined residue of 1,1-bis(4-chlorophenyl)-2,2,2-trichloroethanol, 1-(2-chlorophenyl)-1-(4-chlorophenyl)-2,2,2-trichloroethanol, 1,1-bis(4-chlorophenyl)-2,2-dichloroethanol, and 1-(2-chlorophenyl)-1-(4-chlorophenyl)-2,2,-dichloroethanol. The listing should be designated 40 CFR §180.163(b) (Table 38).

2. Tolerance Revocations and Import Tolerances

As part of EPA's reregistration eligibility decision for dicofol, several feed/food uses have been voluntarily canceled. Once a pesticide use is no longer registered in the United States, the related pesticide residue tolerance and/or food/feed additive regulation may be no longer needed. It is EPA policy to propose revocation of a tolerance, and/or food/feed additive regulation, following the deletion of a related food use from a registration, or following the cancellation of a related food use regulation. EPA has the responsibility under the Federal Food, Drug, and Cosmetic Act (FFDCA) to revoke a tolerance/regulation on the grounds that the Agency cannot conclude that the tolerance/regulation is protective of the public health.

However, the Agency recognizes that interested parties may want to retain a tolerance and/or food/feed regulation in the absence of a U.S. registration, to allow legal importation of food to the U.S. To assure that all food marketed in the U.S. is safe, under FFDCA, EPA requires the same technical chemistry and toxicology data for such import tolerances (tolerances without related U.S. registrations) as are required to support U.S. food use registrations and any resulting tolerances. See 40 CFR, § 158 for EPA's data requirements to support domestic use of a pesticide and establishment and maintenance of a tolerance and/or food/feed regulation. In addition, EPA requires residue chemistry data (crop field trials) that are representative of growing conditions in exporting countries in the same manner that EPA requires representative residue chemistry data from different U.S. regions to support domestic use of the pesticide and the tolerance and/or regulation. Additional guidance on the Agency's import tolerance policy will be published in an upcoming *Federal Register* Notice.

Changes to Tolerances

The raw agricultural commodity tolerances listed under 40 CFR §180.163 are currently expressed in terms of dicofol *per se*. However, 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 38 for modifications in commodity definitions.

In many of the following paragraphs, EPA plans to propose revocation of specific tolerances for administrative reasons, rather than risk (e.g., creation of group tolerances and elimination of single tolerance).

Tolerances Needed Under 40 CFR §180.163(a):

Sufficient data are available to ascertain the adequacy of the established tolerances for the following commodities: apples, apricots, beans (dry), beans (succulent), beans (lima), beechnuts, butternuts, cantaloupes, cherries, chestnuts, cottonseed, crabapple, 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 IR4.

There is no registered use for dicofol on figs; this tolerance will be proposed for revocation.

The established tolerances for beechnuts, 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 will be proposed for revocation, as lima beans are covered by the tolerance for beans, succulent.

The established tolerances for summer squash, cantaloupes, cucumbers, muskmelons, pumpkins and watermelons can be replaced by a cucurbit group tolerance of 2 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.

The registrants have requested a Group 8 (fruiting vegetable) tolerance, and a value of 2 ppm would be appropriate (PP 4E4366, 2/8/95). This group tolerance would encompass groundcherry, pepinos and tomatillos. The individual tolerances for tomatoes, peppers, and eggplant will be proposed for revocation. The maximum residue in/on peppers was 1.15 ppm.. The maximum residue in/on tomatoes from registered use was 0.46 ppm.

A stone fruit crop group tolerance of 5 ppm will be established, and the individual commodity tolerances (peach, nectarine, apricot, and plum) should be proposed for revocation. The maximum residues in/on peaches was 3.79 ppm. The maximum residue in/on plums (fresh prunes) was 0.84 ppm. The maximum residue found in/on cherries was 3.08 ppm.

Established tolerance for oranges, tangerines, limes, and other citrus fruits can be replaced with a citrus crop group tolerance of 6 ppm. The maximum residue in/on oranges was 3.55 ppm and the maximum residue in/on grapefruit was 5.26 ppm. The maximum field trial for lemons was 1.34 ppm.

The established tolerance for apples, crabapple, pears, and quinces can be proposed for revocation and replaced with a pome fruit crop group tolerance of 10 ppm. The maximum field trial residue in/on apples was 6.7 ppm. The maximum residue found in/on pears was 10.8 ppm. This value was one of two duplicate samples. The other sample had a value of 6.8 ppm dicofol. The PHI was 6 days, whereas the label specifies 7 days, and three applications were made, whereas the label specifies a maximum of two applications per season. The group tolerance will adequately cover pears.

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 an RAC will be established at 65 ppm.

The established tolerance for strawberries will be raised from 5 ppm to 10 ppm to reflect the findings of new field trials.

The agency 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 recently issued OPPTS Residue Chemistry Test Guidelines, 860.1000, Table 1, they are considered confirmatory data and should not impede the reregistration process.

The Agency recommended for establishment of a tolerance of 30 ppm for residues of dicofol on fresh plucked tea leaves and for 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 37), are calculated to be 22 ppm and 41 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 (86% of cow exposure, 93% of beef exposure).

Table 37: 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	38	40	20	19	40	38
Citrus, pulp, dried	12	91	20	2.6	25	3.3
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	-	-
Other	-	-	5	0	-	-
TOTAL			100%	22	100%	41

[1] Includes considerations of policy for revised treatment of processing studies and of need for feed tolerances (E. Zager, . 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 (~ 0.5 - 1.4X the maximum theoretical dietary intake for dairy cattle, 0.7X for beef cattle). 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.

Tolerances Listed Under 40 CFR §185.410:

The food additive tolerances 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. The Agency recommended revocation of the food additive tolerance for dried tea (40 CFR §185.410) and the establishment of tolerances for plucked tea and dried tea.

Additional tolerances needed for processed commodities:

The available data from processing studies indicate that the following tolerances are needed:

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;
iii. 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;
iv. 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;
v. peppermint oil and spearmint oil at 30 ppm, based on the highest average field trial residue of 17.6 ppm and an average processing factor of 1.6X; and cottonseed oil; and
vi. cottonseed oil at 0.5 ppm, based on the concentration factor of 4.9X and the highest average field trial residue of 0.06 ppm.

Sufficient data are available to determine that the following feed tolerances are needed:

i. apple pomace (wet) at 38 ppm, based on the highest average field trial residue of 5.54 ppm and an average concentration factor of ~6.6X in wet pomace; and
ii. citrus pulp (dried) at 12 ppm, based on the highest average field trial residue of 3.16 ppm (orange) and an average concentration factor of 3.7X.

Table 38: Tolerance Reassessment Summary for Dicofol

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct *Commodity/Definition*
Tolerances Listed Under 40 CFR §180.163 [a]			
Apples	5	Propose Revocation	Replace with pome fruit tolerance (10 ppm.). New field trials[c].
Apricots	10	Propose Revocation	Replace with stone fruit tolerance (5 ppm.). See peach[c].
Beans (dry form)	5	0.5	*Beans, dry.* New field trials[c].
Beans, snap (succulent form)	5	3	*Beans, succulent.* New field trials[c].
Beans, lima (succulent form)	5	Propose Revocation	Covered by tolerance for beans, succulent[c].
Blackberries	5	Propose Revocation	Additional data required. Replace with caneberry tolerance (5 ppm.).
Boysenberries	5	Propose Revocation	Additional data required. Replace with caneberry tolerance (5 ppm).
Beechnuts	5	0.1	See pecan/walnut[c].
Butternuts	5	0.1	See pecan/walnut[c].
Cantaloupe	5	Propose Revocation	New field trials[c]. Replace with cucurbit tolerance (2 ppm).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct *Commodity/Definition*
Caneberry	none	5	Crop group tolerance. Additional field trials required.
Cherries	5	Propose Revocation	New field trials[c]. Replace with stone fruit tolerance (5 ppm).
Chestnuts	5	0.1	See pecan/walnut[c].
Citrus fruits	None	6	Crop group tolerance.
Cottonseed	0.1	0.1	*Cotton, seed*
Cotton Gin Byproducts	None	TBD[b]	OPPTS Guidelines 860; Table I
Crabapple	5	Propose Revocation	See apple[c]. Replace with pome fruit tolerance (10 ppm).
Cucumbers	5	Propose Revocation	New field trials[c]. Replace with cucurbit tolerance (2 ppm).
Cucurbit Vegetables	None	2	Crop group tolerance.
Dewberries	5	Propose Revocation	Additional data required. Replace with caneberry tolerance (5 ppm.).
Eggplants	5	Propose Revocation	Replace with fruiting vegetables tolerance (2 ppm)[c].
Figs	5	Propose Revocation	No registered use exists[c].
Filberts/Hazelnuts	5	0.1	See pecan/walnut[c].
Fruiting Vegetables Group	None	2	Crop group tolerance[c].
Grapefruit	10	Propose Revocation	New field trials[c]. Replace with citrus tolerance (6 ppm).
Grapes	5	5	
Hickory nuts	5	0.1	See pecan/walnut.
Hops, dried	30	65	*Hops, dried*. RAC redefined[c].
Kumquats	10	Propose Revocation	See orange[c]. Replace with citrus tolerance (6 ppm).
Lemons	10	Propose Revocation	New field trials[c]. Replace with citrus tolerance (6 ppm.).
Limes	10	Propose Revocation	New field trials[c]. Replace with citrus tolerance (6 ppm).
Loganberries	5	Propose Revocation	Additional data required. Replace with caneberry tolerance (5 ppm).
Melons	5	Propose Revocation	New field trials (cantaloupes, muskmelon)[c]. Replace with cucurbit tolerance (2 ppm).
Muskmelons	5	Propose Revocation	New field trials[c]. Replace with cucurbit tolerance (2 ppm).
Nectarines	10	Propose Revocation	See peach[c]. Replace with stone fruit tolerance (5 ppm.).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct *Commodity/Definition*
Oranges	10	Propose Revocation	New field trials[c]. Replace with citrus tolerance (6 ppm).
Peaches	10	Propose Revocation	New field trials[c]. Replace with stone fruit tolerance (5 ppm.).
Pears	5	Propose Revocation	New field trials[c]. Replace with pome fruit tolerance (10 ppm.).
Pecans	5	0.1	New field trials[c].
Peppermint, tops	25	25	
Peppers	5	Propose Revocation	Replace with fruiting vegetables tolerance (2 ppm)[c].
Pimentos	5	Propose Revocation	Replace with fruiting vegetables tolerance (2 ppm) [c].
Plums (fresh prunes)	5	Propose Revocation	New field trials[c]. Replace with stone fruit tolerance (5 ppm).
Pome fruits	None	10	Crop group tolerance.
Pumpkins	5	Propose Revocation	See squash[c]. Replace with cucurbit tolerance (2 ppm).
Quinces	5	Propose Revocation	See apple[c]. Replace with pome fruit tolerance (10 ppm).
Raspberries	5	Propose Revocation	Additional data required. Replace with caneberry tolerance (5 ppm).
Spearmint, tops	25	25	
Stone fruits	None	5	Crop group tolerance.
Strawberries	5	10	New field trials[c].
Summer squash	5	Propose Revocation	New field trials[c]. Replace with cucurbit tolerance (2 ppm).
Tangerines	10	Propose Revocation	See orange[c]. Replace with citrus tolerance (6 ppm).
Tea, plucked leaves	None	30	New RAC definition[c].
Tomatoes	5	Propose Revocation	New field trials[c]. Replace with fruiting vegetable tolerance (2 ppm).
Walnuts	5	0.1	New field trials[c].
Watermelons	5	Propose Revocation	See melons[c]. Replace with cucurbit tolerance (2 ppm.).
Winter squash	5	Propose Revocation	See summer squash, cucumber, melon[c]. Replace with cucurbit tolerance (2 ppm.).
Tolerances Needed Under 40 CFR §180.163(b)			
Cattle, meat	None	3	Feeding study[c].

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct *Commodity/Definition*
Cattle, mbyp (excluding liver and kidney)	None	3	Feeding study[c].
Cattle, kidney	None	3	Feeding study[c].
Cattle, liver	None	5	Feeding study[c].
Cattle, fat	None	50	Feeding study[c].
Eggs	None	0.05	Feeding study[c]. Established at 0.05 for compatibility with Codex
Goats, meat	None	3	Feeding study[c].
Goats, mbyp (excluding liver and kidney)	None	3	Feeding study[c].
Goats, kidney	None	3	Feeding study[c].
Goats, liver	None	5	Feeding study[c].
Goats, fat	None	50	Feeding study[c].
Hogs, meat	None	3	Feeding study[c].
Hogs, mbyp (excluding liver and kidney)	None	3	Feeding study[c].
Hogs, kidney	None	3	Feeding study[c].
Hogs, liver	None	5	Feeding study[c].
Hogs, fat	None	50	Feeding study[c].
Horses, meat	None	3	Feeding study[c].
Horses, mbyp (excluding liver and kidney)	None	3	Feeding study[c].
Horses, kidney	None	3	Feeding study[c].
Horses, liver	None	5	Feeding study[c].
Horses, fat	None	50	Feeding study[c].
Milk	None	22	Reflecting 0.75 ppm in whole milk corrected by a 30X factor to account for concentration in milk fat. Feeding study[c].
Poultry, fat	None	0.1	Feeding study[c].
Poultry, liver	None	0.1	Feeding study[c].
Poultry, mbyp (excluding liver)	None	0.1	Feeding study[c].
Poultry, meat	None	0.1	Feeding study[c].
Sheep, meat	None	3	Feeding study[c].

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct *Commodity/Definition*
Sheep, mbyp (excluding liver and kidney)	None	3	Feeding study[c].
Sheep, kidney	None	3	Feeding study[c].
Sheep, liver	None	5	Feeding study[c].
Sheep, fat	None	50	Feeding study[c].
Processed Commodity Tolerances			
Apples, pomace, wet	None	38	Processing study[c].
Citrus pulp, dried	None	12	Processing study[c].
Citrus oil	None	200	Processing study[c].
Cottonseed, oil, refined	None	0.5	Processing study[c].
Grapes, raisins	None	20	Processing study[c].
Mint oil	None	30	Processing study[c].
Prunes	None	3	Processing study[c].
Tea, dried leaves	45	50	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.

3. 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*, for plant commodities and dicofol plus FW-152 for animal commodities are listed in Table 39, which follows.

The harmonization of Codex MRLs and US tolerances has been updated. The tolerance for eggs should be lowered to 0.05 ppm for compatibility with Codex.

Table 39: Codex MRLs and Applicable U.S. Tolerances			
Commodity[1]	MRL (mg/kg)[2]	U.S. Tolerance (ppm)[3]	Recommendation/Comment
Beans (dry)	0.1	0.5	Data do not support a lower US tolerance, with field trial residues as great as 0.4 ppm.
Cattle meat	3	3	
Cherries	5	5	U.S. tolerance is for stone fruit.
Citrus fruits	5	6	Data do not support a lower U.S. tolerance.
Common bean (pods and/or immature seeds)	2	3	Data indicate that a tolerance of 2 ppm for succulent beans is not acceptable, maximum field trial residue of 2.09 ppm.
Cotton seed	0.1	0.1	Compatible
Cotton seed oil, Edible	0.5	0.5	Compatible
Cucumber	0.5	2	U.S. tolerance is for the cucurbit crop group. Data do support a 0.5 ppm tolerance for cucumber per se.
Eggs	0.05	0.05	Compatible
Fruits (except as otherwise noted)	5	5 caneberries 5 stone fruits 10 pome fruits 6 citrus fruits	The 1992 JMPR proposed withdrawal.
Grapes	5	5	Compatible
Hops, Dry	50	65	Data indicate that the tolerance cannot be decreased.
Melons, except watermelon	0.2	2	U.S. tolerance is for the cucurbit crop group. The maximum residue on melons was 0.35 ppm.
Milks	0.1	22	U.S. tolerance is based on milk fat. The corresponding value for whole milk is 0.75 ppm.
Peach	5	5	U.S. tolerance is for stone fruit.

Table 39: Codex MRLs and Applicable U.S. Tolerances			
Commodity[1]	MRL (mg/kg)[2]	U.S. Tolerance (ppm)[3]	Recommendation/Comment
Pecan	0.01	0.1	U.S. tolerance is set at the demonstrated limit of quantitation.
Peppers	1	2	U.S. tolerance is for the fruiting vegetables group. Field trial data for peppers indicate that a 1 ppm tolerance would not be adequate.
Plums (including prunes)	1	5	U.S. tolerance is for stone fruit. Data support a 1 ppm tolerance for plums per se.
Pome fruits	5	10	Apple data require a tolerance >5 ppm; maximum residue 6.7 ppm. Other pome fruits are adequately covered by a 10 ppm tolerance.
Poultry meat	0.1	0.1	Compatible
Prunes	3	5	Data support a tolerance of 3 ppm, but prunes are covered by the stone fruit group tolerance, at 5 ppm.
Squash, Summer	1	2	Data indicate that the maximum residue slightly exceeded 1 ppm.
Tea (dried leaves)	50	50	Data do not support a lower tolerance.
Tomato	1	2	Tolerance is for the fruiting vegetables group. A tolerance of 1 ppm would be adequate for tomatoes per se.
Walnuts	0.01	0.1	Tolerance is based on the demonstrated limit of quantitation (residue less than 0.01 ppm).

[1] Commodity definition is that of Codex.
[2] Only final MRLs (CXL) are listed.
[3] Revised proposed tolerances per the RED.

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

- 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 (e.g. fruits, pome), and these U.S. tolerances cannot be lowered to achieve compatibility.

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

4. Food Quality Protection Act Findings

a. Determination of Safety for U.S. Population

EPA has determined that established tolerances for dicofol with amendments and changes specified in this document meet the safety standards under FQPA amendments to section 408(b)(2)(D) requiring a reasonable certainty of no harm for the general population. In reaching this determination, EPA has considered available information on aggregate exposures (both acute and chronic) from food and drinking water.

The aggregate risk assessment for dicofol concludes that acute dietary exposure to dicofol residues, including drinking water, does not pose a risk to any population subgroup.

The aggregate risk assessment for dicofol concludes that chronic dietary exposure to dicofol residues, including drinking water, does not pose a risk to any population subgroup.

Since all residential uses of dicofol are being eliminated, no dermal or inhalation exposure is expected in or around the home and, therefore, the risk assessment is not required.

b. Determination of Safety for Infants and Children

EPA has determined that established tolerances for dicofol, with amendments and changes as specified in this document, meet safety standards under the FQPA amendments to section 408(b)(2)(C) for infants and children and that there is a reasonable certainty of no harm to infants and children. The safety determination for infants and children considers factors noted above for the general population but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of dicofol residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from dicofol residues, EPA considers the completeness of the database for developmental and reproductive effects, the nature and severity of the effects observed, and other information.

As noted in Section III, B-2, the Agency has determined that for dicofol, the 10X safety factor required by FQPA to account for enhanced sensitivity of infants and children can be reduced to 3X. This reduction is based on data results for dicofol and is explained in Section III, B-2.

In deciding to continue to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early case by case decisions, EPA does not intend to set broad precedents for the application of FQPA to its regulatory determinations. Rather, these early decisions will be made on a case by case basis and will not bind EPA as it proceeds with further policy development and rulemaking that may be required.

EPA may determine, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate. In this case, the Agency will take such action as may be appropriate including, but not limited to, reconsideration of any portion of this RED.

5. Summary of Risk Management Decisions

a. Human Health

EPA believes that, given the weight of the evidence, dietary risk from dicofol to all US population subgroups does not exceed the Agency's level of concern (LOC) and is therefore not cause for concern.

Acute Dietary

The acute aggregate risk from food and drinking water through highly refined probabalistic analysis do not exceed the Agency's LOC. Therefore, no risk reduction or risk mitigation steps are necessary.

Chronic Dietary

Chronic dietary risk from food sources and drinking water is measured at well below the Agency's LOC. Highest risk population from food exposure are children (1-6 years old), at 38% of the RfD, based on a DRES chronic exposure analysis. The addition of drinking water exposure to dicofol is not significant enough to cause concern. Therefore, no risk reduction or risk mitigation steps are necessary for this route of exposure.

Occupational and residential

The risk assessment in this RED raises some strong concerns for dicofol mixers/loaders/ applicators, and field workers. The endpoint of concern is hormonal toxicity. At the present time, most short term and all intermediate term scenarios result in Margin of Exposures (MOEs) which exceed the Agency's level of concern, even with engineering controls. However, the Agency believes that the default assumptions used to arrive at this conclusion may have led to an overestimation of that risk (i.e. the default assumption of 100% dermal absorption and a initial Dislodgeable Foliar Residue (DFR) level at 20% of the application rate and assuming residue dissipation of 10% per day). To improve our estimation of dicofol risk, the registrants have initiated a dermal toxicity study, which is due to the Agency on December 31, 1998. In addition, as a result of a Data Call In from October 13, 1995, the registrants are also completing a DFR study, due in October, 1998. EPA will consider results of these studies in a revised risk assessment. In the interim, while this data is being developed and evaluated, the registrants have agreed to undertake risk mitigation measures (described below) to address the occupational risks identified in this RED.

EPA will revise the Restricted Entry Interval (REI) based upon results of the dermal toxicity study and DFR study.

Because all residential uses are being voluntarily canceled by the registrants, residential risk is not a concern.

Endocrine Disrupter Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect on humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect..." The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, and industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

b. Environmental

Based on the risk assessment and risk characterization, the Agency has concluded that there are environmental concerns due to dicofol which must be addressed through risk reduction and/or risk mitigation. The following risk reduction/risk mitigation measures are being taken to specifically address environmental concerns noted in this section:

- Applications of dicofol will be limited to no more than one per year. Previously, in some uses, the number of applications allowed per year was either unrestricted or limited to two or three applications per year.
- Citrus application levels have been reduced from 8 lbs. a.i. per acre to 3 lbs. a.i. per acre. Further reductions will be made, if required, based on the results of the ongoing dermal

study, within one year of the publication date of this RED.

- Application rate for wettable powders on strawberries has been reduced to 2 lbs. a.i. per acre, reduced from 2.4 lbs. a.i. per acre.
- A spray drift and Runoff Caution Statement is being added to the label. Also, a statement prohibiting application directly to water is being added to the label.
- Additionally, as a result of previous agreements with the registrants, applications will not exceed:

  3 lb. ai/acre for apples and pears (reduced from 4 lb. ai/acre);
  2 lb. ai/acre for pecans and walnuts (reduced from 4 lb. ai/acre);
  1.5 lb. ai/acre for cotton (reduced from 1.6 lb. ai/acre);
  1.3 lb. ai/acre for grapes (reduced from 1.5 lb. ai/acre);
  0.63 lb. ai/acre for cucurbits (reduced from 1.5 lb. ai/acre);
  0.75 lb. ai/acre for tomatoes and peppers (reduced from .8 lb. ai/acre);
  1.5 lb. ai/acre for stonefruits;
  1.5 lb. ai/acre for beans; and
  0.55 lb. ai/acre for nonresidential lawns and ornamentals.

i. Avian

Acute

Acute risk to avian species is considered low. The only acute avian exposure to dicofol which exceeds the Agency's level of concern is to short grasses. Since few avian species feed primarily on short grasses, that risk is not considered unacceptable. Therefore, no risk reduction and/or risk mitigation measures are necessary.

Chronic

Laboratory tests have shown dicofol can have adverse reproductive effects on birds, specifically egg shell thickness, weight, and strength, egg production, and hatchability. Field monitoring found that, in some instances, the concentrations of dicofol in egg residues exceeded those levels found to cause reproductive problems in laboratory studies. While actual effects were not demonstrated in the field monitoring study, the study was designed to measure dicofol concentrations in various environmental compartments, not to test for effects. Therefore, the agency has concluded that measures to reduce such potential risk, as detailed above, are warranted.

ii. Mammals

Acute

Acute risk to mammals, including threatened and endangered species, from exposure to dicofol, is considered moderate. These risks exceed the Agency's level of concern for citrus, apples, pears, nuts, and quince, only from exposure to short grass. To protect various small mammals which primarily feed on short grass, the Agency recommends application reductions and other risk mitigation measures detailed above for these use patterns.

Chronic

As with avian species, dicofol has been shown to have an effect on mammalian reproductive physiology and offspring, exceeding the Agency's LOC for all currently registered use patterns. Risk reduction/mitigation measures for all use patterns, as noted at the beginning of this section, are appropriate to address reproductive concerns.

iii. Insects

Dicofol is considered slightly toxic to bees. Recommended risk mitigation steps will address this.

iv. Freshwater Fish, invertebrates, and estuarine/marine organisms

Acute

Dicofol is very highly toxic to fresh- and salt-water fish, shellfish, and aquatic invertebrates. These aquatic habitats are potentially at risk from direct contamination of dicofol to water or indirect contamination via spray drift or runoff. Exposure from indirect or indirect contamination exceeds several Agency levels of concern. Risk reduction and/or mitigation measures, as listed at the beginning of this section, are appropriate to address acute risk concerns.

Chronic

No dicofol use patterns currently registered exceed the Agency's chronic LOC for fish. Therefore, no risk reduction and/or risk mitigation measures are necessary to reduce chronic risk to fish.

v. Nontarget Plants

Plant testing is not required for pesticides other than herbicides.

vi. Surface Water

Dicofol can contaminate surface water via spray drift during application and by runoff for several days to weeks after application. Once it reaches surface waters, dicofol is not likely to persist in neutral to alkaline waters, but may be substantially more persistent in some acidic waters, particularly in those with relatively long hydrological residence times and low microbiological populations. Appropriate labeling and other risk mitigation measures to reduce the risk of runoff are being added to labels, including the labeling statement prohibiting applications directly to water. These label changes are noted in Chapter 5.

vii. Ground Water

Because dicofol has low to moderate mobility and moderate persistence, it is not expected to leach extensively to ground water under normal use conditions. Field trials showed no movement of dicofol degradates/metabolites into ground water. Risk of dicofol contamination in groundwater is considered low. Therefore, no risk mitigation and/or risk reduction steps are necessary in this area.

6. Occupational Labeling Rationale/Risk Mitigation

At this time, all products containing dicofol are intended solely for occupational use (i.e. mixed, loaded, and applied by commercial applicators only; not available to homeowners). No registered uses will involve applications at residential sites.

a. The Worker Protection Standard

EPA's Worker Protection Standard for Agricultural Pesticides (WPS) affects all pesticide products whose labeling reasonably permits use in the commercial or research production of agricultural plants on any farm, forest, nursery, or greenhouse. In general, WPS products had to bear WPS-complying labeling when sold or distributed after April 21, 1994. The WPS labeling requirements pertaining to personal protective equipment (PPE), restricted-entry intervals (REI), and notification are interim. These requirements are to be reviewed and revised, as appropriate, during reregistration and other Agency review processes.

Many uses of dicofol are outside the WPS scope.

b. Requirements for Handlers

For each end-use product, personal protective equipment and engineering control requirements for pesticide handlers are set during reregistration as follows:

- Based on risks posed to handlers by the active ingredient, EPA may establish active-ingredient specific (a-i specific) handler requirements for end-use products containing that active ingredient. If such risks are minimal, EPA may choose not to establish a-i specific handler requirements.

- EPA establishes handler PPE requirements for most end-use products, based on each product's acute toxicity characteristics.

- If a-i specific requirements have been established, they must be compared to the PPE specified for the end-use product. The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product. Engineering controls are considered more stringent than PPE requirements.

EPA is establishing a-i specific requirements for all occupational handlers for dicofol. EPA calculated that margins of exposure (MOE) were very low and a serious concern for all occupational mixers, loaders, and applicators. Wettable powder formulations produced after December 31, 1998 will be required to be formulated in water-soluble packaging. Applicators using aerial or mechanical ground equipment will be required to be in enclosed cabs or enclosed cockpits and flaggers for aerial applications will be required to use enclosed cabs. All other handlers will be required to wear chemical-resistant gloves, footwear, and headgear (if overhead exposure), double-layer of body protection, and a respirator. In addition, a chemical-resistant apron will be required for mixers, loaders, cleaners of equipment, and handlers applying dicofol as a dip. Use patterns and PPE are specified in Chapter 5. Handheld application equipment is prohibited for liquid formulations. Application of liquid formulations on dry beans must be done using closed mixing systems.

Since potential handler exposure is similar for WPS and nonWPS uses, the a-i specific handler requirements (specified in Section V) are the same for WPS and nonWPS occupational uses of dicofol end-use products.

c. Homeowner Use Products

Because all residential uses are canceled for dicofol, no homeowner use requirements are necessary.

d. Post-Application Entry restrictions

Occupational-Use Products (WPS Uses)

Restricted-entry intervals, early-entry PPE, and "double" notification:

The interim Worker Protection Standard (WPS) restricted-entry intervals (REI's) for agricultural workers are based solely on the acute dermal toxicity and skin and eye irritation potential of the active ingredient. In addition, the WPS retains two types of REI's established by the Agency before the promulgation of the WPS: (1) product-specific REI's established on the basis of adequate data, and (2) interim REI's that are longer than those that would be established under the WPS.

The WPS prohibits routine entry to perform hand labor tasks during the REI and requires PPE to be worn for other early-entry tasks that require contact with treated surfaces.

"Double" notification is the statement on the labels of some WPS pesticide products requiring employers to notify workers about pesticide-treated areas orally as well as by posting of the treated areas. The interim WPS "double" notification requirement is imposed if the active ingredient is classified as toxicity category I for acute dermal toxicity or skin irritation potential.

During the reregistration process, EPA establishes REI's, early-entry PPE, and double notification requirements based on consideration of all available relevant information about the active ingredient, including acute toxicity, other adverse effects, epidemiological information, and post-application data. EPA will establish a restricted-entry interval for dicofol upon completion of analysis

of the dermal toxicity and DFR studies. The DFR study is due to EPA in October 1998 and the dermal toxicity study is due to EPA in December 1998.

Occupational-Use Products (NonWPS Uses)

Since EPA has concerns about post-application exposures to persons after nonWPS occupational uses of dicofol, it is establishing entry restrictions for all nonWPS occupational uses of dicofol end-use products. The Agency has determined that restricting entry into treated areas after liquid applications until sprays have dried is a prudent safety practice applicable at the nonWPS use-sites where dicofol will be applied.

e. Other Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing dicofol. For the specific labeling statements, refer to Section V of this document.

7. Restricted Use Classification

Dicofol does not require and is not being considered for restricted use.

8. Endangered Species Statement

The Endangered Species Protection Program is expected to become final in the future. Limitations in the use of dicofol will be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. The Agency anticipates that a consultation with the Fish and Wildlife Service will be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

9. Spray Drift Advisory

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation to develop the best spray drift management practices. The Agency is now requiring interim measures that must be placed on product labels/labeling as specified in Section V. Once the Agency completes its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, the Agency may impose further refinements in spray drift management practices to further reduce off-target drift and risks associated with this drift.

V. ACTIONS REQUIRED OF REGISTRANTS AND OTHERS

This section specifies the conditions (data requirements, label changes, and other responses) necessary for the reregistration of both manufacturing use and end use products.

A. Manufactured Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of dicofol for the uses covered in this RED has been reviewed and determined to be substantially complete.

The following confirmatory data are required:

- Additional confirmatory data are required to support the established tolerances for the crop group caneberries, 860.1500 (171-4K). A minimum of 3 additional trials are required on blackberries or raspberries from three different geographical regions. IR4 is expected to supply these data. (See Appendix B)

- Field trials are required for cotton gin byproducts, 860.1500 (171-4L). The requirement for cotton gin byproduct data is a recent development under new OPPTS guidelines. (Series 860.1000) (*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)).

- Additional data are required for the following product chemistry guidelines for dicofol: 830.1550 (158.155); 830.6314 (63-14); 830.6315 (63-15); 830.6316 (63-16); 830.6319 (63-19); and 830.1750 (158.175). (See Appendix B)

- Data are required for 830.7050, UV/visible absorption. This is a new end use product requirement in conjunction with OECD (OECD number 101).

- The registrants must 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.

- With regard to the subchronic feeding study in rodents (Guideline No. 82-1, 870.3150) data on the analyses of the tissue residues of the test compound should be submitted (MRID 47015801).

- The Agency is waiting for data regarding post-application exposure for occupational use sites. The DFR data is due in October, 1998, in response to the Agricultural Reentry Data Call-In (1995). Until these data are submitted and evaluated, the post-application use scenarios remain a concern.

- The Wettable Powder/Dust (WP/D) formulation labels must be amended such that the application rate and PHI for strawberries are consistent with the requirements specified in this RED. The Emulsifiable Concentrate (EC) labels which still contain strawberry use must be amended to delete that crop (Guideline No. 171-3) (860.1200) (Appendix B).

- For 860.1340 (Guideline No. 171-4C, D), Residue Analytical Methods, method TR-310-86-74 for plant matrices must be validated by an independent laboratory (ILV) (Appendix B).

- Tolerances are needed for ruminant and poultry commodities.

- The registrants must submit a developmental neurotoxicity study in rats, Guideline No. 83-6 (870-6300). This study is now required since dicofol produces neurotoxic effects in adult rats.

- As a result of a Data Call In from October 13, 1995, the registrants must also submit a DFR study, due in October, 1998.

Required Occupational/Residential Exposure Studies and Recommendations

Handler (mixer/loader and/or applicator) exposure data were required from a previous DCI (March 3, 1995 and October 30, 1995). This data is being developed by the Ag Reentry Task Force. Rohm and Haas is a member of this task force and the Agency will review that data when it is received.

2. Labeling Requirements for Manufacturing Use products

To remain in compliance with FIFRA, manufacturing use (MP) labeling must be revised to comply with all current EPA regulations, PR notices, and application policies. The MP labeling must bear the labeling contained in Table 40 at the end of this section.

B. End Use Products

1. Additional Product Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. While the Agency has not yet determined dicofol to be eligible, these product specific data requirements can be found in Appendix D, the Generic and Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure they meet current EPA acceptance criteria (Appendix D, Generic and Product Specific Data Call Notice) and, if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards,

then the study MRID numbers should be cited according to the instructions in the requirement Status and registration Response Form provided for each product.

2. Labeling Requirements for End Use Products

All end use product labels should be amended so they are in compliance with basic producer labels.

All end-use products should have clear, concise and complete labeling instructions in accordance with Table 40. Proper labels can improve reader understanding, thereby reducing misuse and the potential for incidents. Towards this end, the Agency is requiring the following:

Directions for Use:

Directions for Use must be stated in terms that can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. It must be presented in a format that is easy to understand and follow. The Directions for Use section of a pesticide label must provide the necessary information to answer four major questions regarding the use of the pesticide. These four questions are:

1. Why is the pesticide being used? (For what pest(s) or problem?)
2. Where is the pesticide applied? (Where should it not be applied?)
3. How is the pesticide applied? (What special precautions must the user take? How much should they use?)
4. When should the pesticide be applied?

In addition, the Agency encourages the use of graphic symbols whenever possible, to clarify the written label.

National Pesticide Telecommunications (NPTN) Hotline Number

All dicofol labels must refer consumers to the NPTN number for additional information. This reference must bear the labeling contained in Table 40 at the end of this section.

First Aid (Statement of Practical Treatment)

The Agency is requiring that all labels with Statement of Practical Treatment sections be amended so that these sections are entitled, "First Aid." First aid statements must be brief, clear, simple and in straightforward language (conforming to the labeling required by the Agency) so that the average person can easily and quickly understand the instructions. These statements should be appropriate for all ages or, when necessary, should include distinctions between the treatments for different ages.

Table 40 summarizes the labeling requirements being imposed by this RED for all dicofol products. Any use instructions on current labels that conflict with those listed below should be removed.

For **sole-active-ingredient** end-use products that contain dicofol:

- Revise the product labeling to adopt the mixer/loader/applicator personal protective equipment/engineering control requirements set forth in this section.
- Revise the product labeling to adopt the entry restrictions which will be set after the Agency reviews DFR data and dermal toxicity data, due in October 1998, and December 1998, respectively.

For **multiple-active-ingredient** end-use products that contain dicofol:

- Compare the mixer/loader/applicator personal protective equipment/engineering control requirements set forth in this section to the requirements on the current labeling.
- Retain the more protective requirements. (For guidance on which requirements are considered more protective, see PR Notice 93-7.)
- Compare the entry restrictions which will be set to the entry restrictions on the current labeling.
- Retain the more protective restrictions. (A specific time period in hours or days is considered more protective than "sprays have dried" or "dusts have settled.")

The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient specific personal protective equipment specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Table 40: Summary of Required Labeling Changes for Dicofol Products		
Description	**Required Labeling**	**Placement**
Manufacturing Use		
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"Only for formulation into a insecticide for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."	Directions for Use
	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	
Environmental Hazards Statements	"This chemical is toxic to aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA."	

End Use Products Intended for Occupational Use (WPS and Non-WPS))		
Worker Protection Requirements for Products Subject to WPS	Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS)," and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7," which reflect the requirements of EPA's labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.	Precautionary Labeling Under Hazards to Humans and Domestic Animals
PPE Requirements	Default PPE is established on the basis of acute toxicity category of the end-use products in accordance with PR Notice 93-7.	Precautionary Labeling Under Hazards to Humans and Domestic Animals
Personal Protective Equipment (PPE)	"Personal Protective Equipment (PPE): Applicators and other handlers must wear: Coveralls over long sleeve shirt and pants. Chemical resistant gloves. Chemical resistant footware plus socks. Chemical resistant headgear for overhead exposure. Chemical resistant apron when cleaning equipment , mixing or loading, or applying as a dip. For exposure in enclosed areas, use a respirator with either an organic vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) . For exposure outdoors, use a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)	Precautionary Statements Hazards to Humans and Domestic Animals
User Safety Requirements	"Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash separately from other laundry."	Precautionary Statements Hazards to Humans and Domestic Animals (Immediately following PPE)

End Use Products Intended for Occupational Use (WPS and Non-WPS))		
Engineering Controls	"Engineering Controls Applicators using aircraft must be located in enclosed cockpits and applicators using mechanical ground equipment and all flaggers must be located in enclosed cabs that meet the specifications provided in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(5-6). While in enclosed cabs or cockpits, handlers are permitted to wear reduced personal protective equipment as specified in the WPS. When handlers use closed systems in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4.), the handler PPE requirements may be reduced or modified as specified in the WPS."	Precautionary Statements Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
Engineering Controls for all wettable powder formulations	"Water-soluble packets when used correctly qualify as a closed loading system under the WPS. Handlers handling this product while it is enclosed in intact water-soluble packets are permitted to wear long-sleeved shirt, long pants, shoes and socks, chemical-resistant gloves, and chemical-resistant apron, provided the other required PPE is immediately available in case the bag is opened."	Precautionary Statements Hazards to Humans and Domestic Animals *(Immediately following PPE and User Safety Requirements.)*
User Safety Recommendations	"User Safety Recommendations Users should: 1. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. 2. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. 3. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	*Precautionary* Statements Hazardous to Humans and Domestic Animals (Immediately following Engineering Controls. Statement must be placed in a box on label.)

End Use Products Intended for Occupational Use (WPS and Non-WPS))		
Environmental Hazards Statements	"This pesticide is toxic to fish and wildlife. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water, to areas where surface water is present or to intertidal areas below mean high water mark. Do not contaminate water when disposing of equipment or washwaters. This chemical can contaminate surface water through drift from spray application. Under some conditions, dicofol may runoff into surface water for several weeks after application. These conditions include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas overlaying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and highly erodible soils cultivated using poor agricultural practices such as conventional tillage and down the slope plowing."	Precautionary Statements Environmental Hazards
Entry restrictions for non-WPS uses that are applied as sprays.	"Do not enter or allow others to enter the treated area until sprays have dried."	**If no WPS uses are on the label** -- Place the Non WPS entry restrictions in the Directions for Use, under the heading "Entry Restrictions." **If WPS uses are also on label** -- Follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box, and place the appropriate Non WPS entry restrictions in that box.
Application Restrictions for all dicofol products in liquid formulations.	"Hand-held equipment is prohibited for applications. This product must be applied only with mechanical ground or aerial application equipment. "	Directions for Use General Precautions and Restrictions

End Use Products Intended for Occupational Use (WPS and Non-WPS))		
Application Restrictions for all Dicofol Products	"Do not apply this product by any method not specified on this label." "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application." "Applications of dicofol will be limited to no more than one per year on any one field" "Do not apply to residential sites." "Do not apply by ground equipment within 25 feet, or by air within 150 feet of lakes, reservoirs, rivers, permanent streams, marshes, natural ponds, estuaries, or commercial fish farm ponds. Increase the buffer zone to 450 feet when ultra low volume (ULV) application is made." "Do not cultivate within 10 feet of the aquatic area so as to allow growth of a vegetative buffer strip."	Directions for Use, General Precautions and Restrictions
Application restrictions for Dicofol products	"Applications of this product on citrus may not exceed 3 lbs a.i./acre per application." "Applications of this product on strawberries may not exceed 2 lbs a.i./acre per application."	Directions for Use, General Precautions and Restrictions
Application restrictions for Dicofol products	"Applications of this product on apples and pears may not exceed 3 lbs a.i./acre per application." "Applications of this product on pecans and walnuts may not exceed 2 lbs a.i./acre per application." "Applications of this product on cotton may not exceed 1.5 lbs a.i./acre per application." "Applications of this product on grapes may not exceed 1.3 lbs a.i./acre per application." "Applications of this product on stonefruits may not exceed 1.5 lbs a.i./acre per application." "Applications of this product on cucurbits may not exceed .63 lbs a.i./acre per application." "Applications of this product on beans may not exceed 1.5 lbs a.i./acre per application." "Applications of this product on tomatoes and peppers may not exceed .75 lbs a.i./acre per application." "Applications of this product on nonresidential lawns and ornamentals may not exceed .55 lbs a.i./acre per application."	Directions for Use, General Precautions and Restrictions

End Use Products Intended for Occupational Use (WPS and Non-WPS))		
The following language must be placed on each product that can be applied aerially:	"Aerial Spray Drift Management" "Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions."	Directions for Use
The following language must be placed on each product that can be applied aerially:	"The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations. 1.The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor. 2.Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees. Where states have more stringent regulations, they should be observed. The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information."	Directions for Use
The following language must be placed on each product that can be applied aerially:	"Aerial Drift Reduction Advisory" "This section is advisory in nature and does not supersede the mandatory label requirements." "INFORMATION ON DROPLET SIZE" "The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions)."	Directions for Use

End Use Products Intended for Occupational Use (WPS and Non-WPS))		
The following language must be placed on each product that can be applied aerially:	"CONTROLLING DROPLET SIZE" "•Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets. •Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure. •Number of nozzles - Use the minimum number of nozzles that provide uniform coverage. •Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential. •Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift."	Directions for Use
The following language must be placed on each product that can be applied aerially:	"BOOM LENGTH" "For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width."	Directions for Use
The following language must be placed on each product that can be applied aerially:	"APPLICATION HEIGHT" "Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind."	Directions for Use

End Use Products Intended for Occupational Use (WPS and Non-WPS)		
The following language must be placed on each product that can be applied aerially:	"SWATH ADJUSTMENT" "When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)"	Directions for Use
The following language must be placed on each product that can be applied aerially:	"WIND" "Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift."	Directions for Use
The following language must be placed on each product that can be applied aerially:	"TEMPERATURE AND HUMIDITY" "When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry."	Directions for Use
The following language must be placed on each product that can be applied aerially:	"TEMPERATURE INVERSIONS" "Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing."	Directions for Use

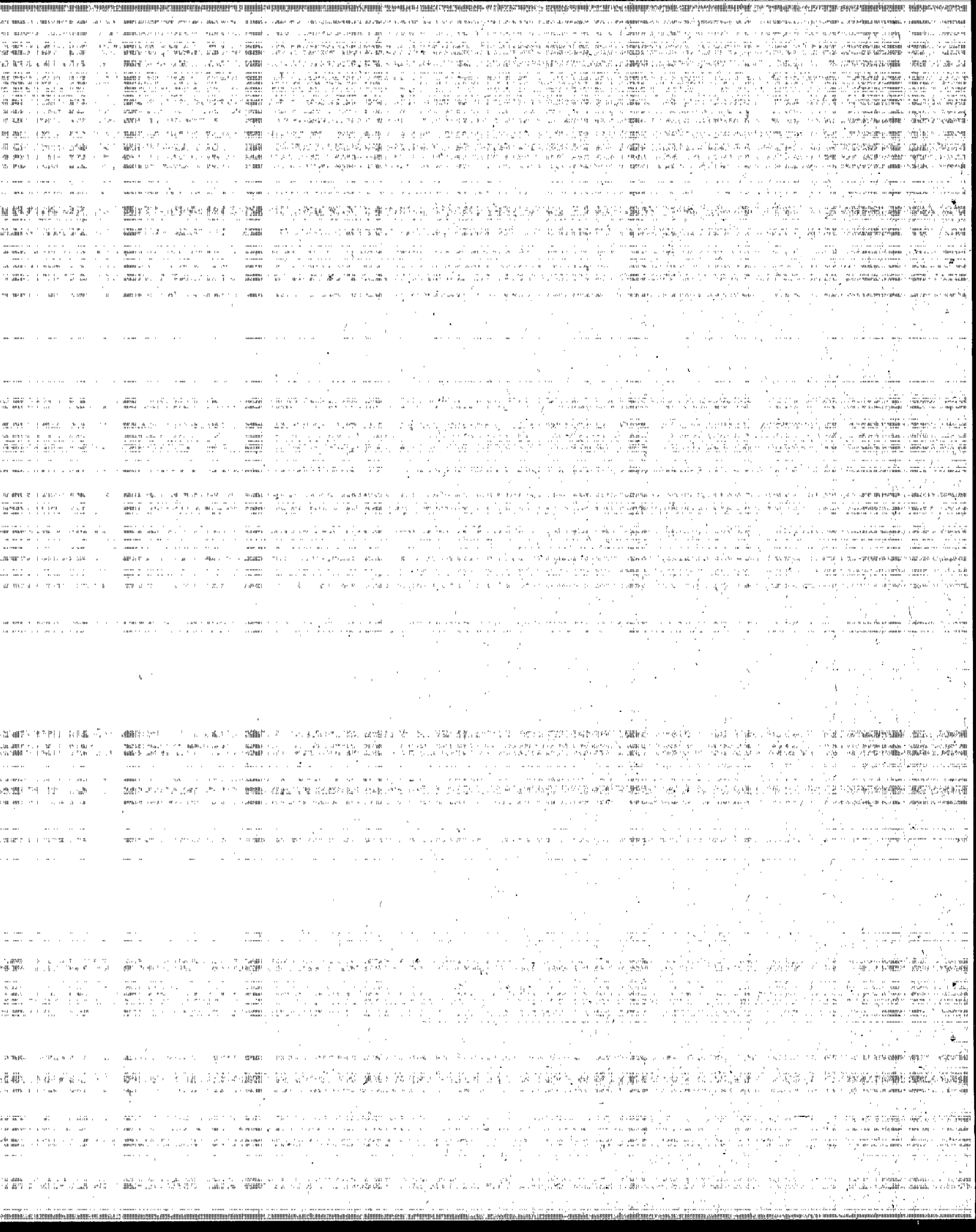
End Use Products Intended for Occupational Use (WPS and Non-WPS))		
The following language must be placed on each product that can be applied aerially:	"SENSITIVE AREAS" "The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas)."	Directions for Use

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case by case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy;" Federal register, Volume 56, No. 123, June 26, 1991.

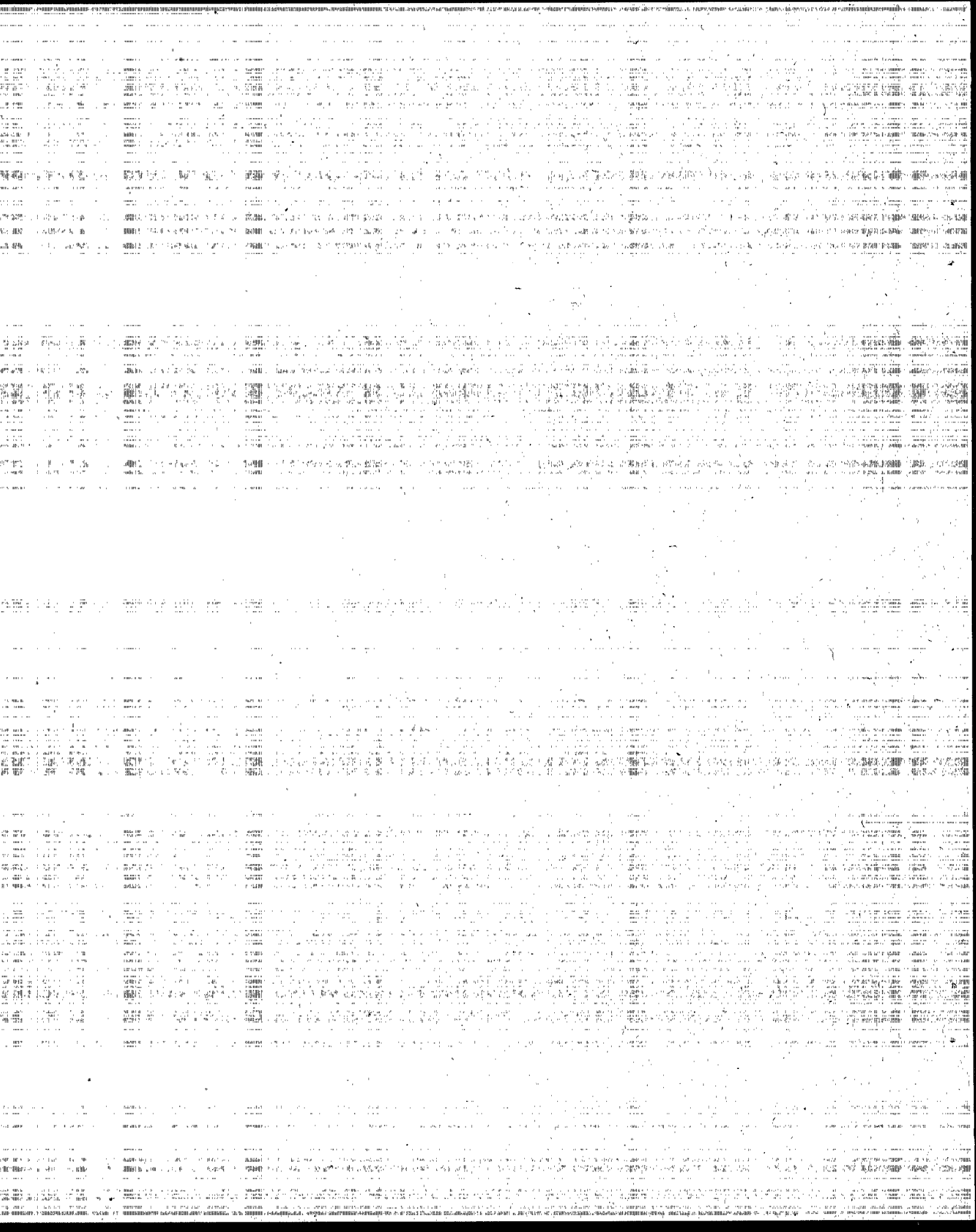
The Agency has determined that registrants may distribute and sell dicofol products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant remain obligated to meet preexisting Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES



Appendix A - Table of Use Patterns Subject to this RED

Appendix A is 46 pages long and is not being included in this RED. Copies of Appendix A are available upon request per the instructions in Appendix E.



GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 0021 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 0021 in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Dicofol

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	All	40504501, 42633301
61-2A	Start. Mat. & Mnfg. Process	All	00142595, 00145489, 00149734, 00150402, 00161079, 00162966, 00164070, 40001201, 40004801, 40297201, 40504501, 42633301
61-2B	Formation of Impurities	All	00143708, 00150402, 00151575, 00154969, 00161079, 00164070, 40297201, 40504501, 42633301
62-1	Preliminary Analysis	All	00149734, 00151576, 00154970, 00161079, 00162966, 00163337, 00164070, 00164383, 40504501, 42633301, 40779201, 40004801, 40001201
62-2	Certification of limits	All	40504501, 42633302
62-3	Analytical Method	All	40504501
63-2	Color	All	42514801
63-3	Physical State	All	00004358
63-4	Odor	All	00150402, 00151207, 00154969, 00161079, 00164070, 42514801
63-5	Melting Point	All	42514801
63-6	Boiling Point	All	00151207, 00154969, 00161079, 00164070
63-7	Density	All	00141704, 00004358
63-8	Solubility	All	00143715, 00150402, 00151207, 00151577, 00154969, 00161079, 00163338, 00164070

Data Supporting Guideline Requirements for the Reregistration of Dicofol

REQUIREMENT		USE PATTERN	CITATION(S)
63-9	Vapor Pressure	All	00151059, 00151207, 00151577, 00154971, 00161079, 00164070
63-10	Dissociation Constant	All	00151207, 00154969, 00161079, 00164070
63-11	Octanol/Water Partition	All	00141578, 00151207, 00154969, 00161079, 40042001, 40042002
63-13	Stability	All	00151207, 00154969, 00161079, 00164070
63-14[7]	Oxidizing/Reducing Action	All	DATA GAP
63-15[8]	Flameability	All	DATA GAP
63-16[2]	Explodability	All	DATA GAP 00141704
63-17	Storage stability	All	43070101, 43383901
63-19[2]	Miscibility	All	DATA GAP 00141704
63-20	Corrosion characteristics	All	43070101, 43383901
158.155[9]	Product Identity and Composition	All	DATA GAP

ECOLOGICAL EFFECTS

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7 Rohm and Haas intends to submit an explanation concerning the inapplicability of this property to the active ingredient. This data requirement remains outstanding.

8 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.

9 These data do not satisfy the requirements of 40 CFR §158.155 and §158.175 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.

Data Supporting Guideline Requirements for the Reregistration of Dicofol

REQUIREMENT		USE PATTERN	CITATION(S)
70-1	Environmental Monitoring	A,B,C,H,I	41764801, 41764802, 41785101, 41845601, 41845602, 41845603, 41845604, 41845605, 41857301, 42091501, 42285501, 42285502, 42285503, 42285504, 42285505, 42437301, 42721301, 42721302
71-1B	Acute Avian Oral - Quail/Duck TEP	A,B,C	160000
71-2A	Avian Dietary - Quail	A,B,C	GS0021007
71-2B	Avian Dietary - Duck	A,B,C	GS0021007
71-3	Wild Mammal Toxicity	A,B,C	40731202
71-4A	Avian Reproduction - Quail	A,B,C	40042055, 41231301, 41934001, 42003501, 42268701, 42975102, 42975103, 42975104, Wiemeyer et al., 1985, Schwarzbach et al. 1988, 0021007
71-4B	Avian Reproduction - Duck	A,B,C	41231301
71-5B	Actual Field Study	A,B,C	41764801, 41764802, 41785101, 41785102, 41785103, 41845601, 41845602, 41845603, 41845604, 41845605, 41857301, 42091501, 42285501, 42285502, 42285503, 42285504, 42285505, 42437301, 42721301, 42721302
72-1A	Fish Toxicity Bluegill	A,B,C	40042056, 41695401, 41985701, 42468201
72-1C	Fish Toxicity Rainbow Trout	A,B,C	41695401, 42468201, GS0021003, GS0021004, GS0021018
72-2B	Invertebrate Toxicity - TEP	A,B,C	40042057, 40098001, 42003502
72-3A	Estuarine/Marine Toxicity - Fish	A,B,C	40042058, 41695402

Data Supporting Guideline Requirements for the Reregistration of Dicofol

REQUIREMENT		USE PATTERN	CITATION(S)
72-3B	Estuarine/Marine Toxicity - Mollusk	A,B,C	40042059, 40042060, 40042061, 41026701, 41695402, 42003503
72-3C	Estuarine/Marine Toxicity - Shrimp	A,B,C	40042059, 40042060, 42003503
72-4A	Early Life Stage Fish	A,B,C	42000601, 42063001, 42468201, 42468202, 43127501, 43383902
72-5	Life Cycle Fish	A,B,C	42628901, 43162001
72-6	Aquatic Organism Accumulation	A,B,C	265330
TOXICOLOGY			
81-3	Acute Inhalation Toxicity - Rat	A,B,C,H,I	00256514, 40048503, 40731202, 40731204
81-4	Primary Eye Irritation - Rabbit	A,B,C,H,I	256589a
81-5	Primary Dermal Irritation - Rabbit	A,B,C,H,I	256589b
81-6	Dermal Sensitization - Guinea Pig	A,B,C,H,I	40048506, 40731201, 43146506
81-8-SS	Acute Neurotoxicity Study	A,B,C,H,I	42633303
81-9-SS	Developmental Toxicity	A,B,C,H,I	Reserved
82-1A	90-Day Feeding - Rodent	A,B,C,H,I	40042044, TRID 470158014
82-1B	90-Day Feeding - Non-rodent	A,B,C,H,I	40042043, 40042047, 40997101
82-2	21-Day Dermal - Rabbit/Rat	A,B,C,H,I	41077001, 44099201
83-1A	Chronic Feeding Toxicity - Rodent	A,B,C,H,I	41150001
83-1B	Chronic Feeding Toxicity - Non-Rodent	A,B,C,H,I	40997101
83-2A	Oncogenicity - Rat	A,B,C,H,I	40997101, 41150001
83-2B	Oncogenicity - Mouse	A,B,C,H,I	41037801

Data Supporting Guideline Requirements for the Reregistration of Dicofol

REQUIREMENT		USE PATTERN	CITATION(S)
83-3A	**Developmental Toxicity - Rat**	A,B,C,H,I	40042046, 44253801
83-3B	**Developmental Toxicity - Rabbit**	A,B,C,H,I	40042047
83-4	**2-Generation Reproduction - Rat**	A,B,C,H,I	41806601
83-5	**Combined Chronic Toxicity/Carcinogenicity**	A,B,C,H,I	41150001
83-6	**Developmental Neurotoxicity Study**	A,B,C,H,I	DATA GAP
84-2A	**Gene Mutation (Ames Test)**	A,B,C,H,I	40042048, 40042049, 42852401
84-2B	**Structural Chromosomal Aberration**	A,B,C,H,I	40042050, 40042051, 43070102, 43383903
84-4	**Other Genotoxic Effects**	A,B,C,H,I	40042052
85-1	**General Metabolism**	A,B,C,H,I	00400420, 40042053, 40042054, 43070103, 43070104, 43070105
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	**Foliar Residue Dissipation**	A,B,C	DATA GAP
158.175[10]	**Certified Limits of Ingredients**	A,B,C,H,I	DATA GAP
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	A,B,C,H,I	00141580, 40042032, 40042033, 40460105
161-2	**Photodegradation - Water**	A,B,C	40042034, 40042035, 40849701, 40849702, 41375401, 43182601

[10] These data do not satisfy the requirements of 40 CFR §158.155 and §158.175 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.

Data Supporting Guideline Requirements for the Reregistration of Dicofol

REQUIREMENT		USE PATTERN	CITATION(S)
161-3	**Photodegradation - Soil**	A,B,C	40042036, 40042037, 40460101, 40460103
161-4	**Photodegradation - Air**	A,B,C,H,I	waived
162-1	**Aerobic Soil Metabolism**	A,B,C,H,I	40042038, 41050701, 41094201
162-2	**Anaerobic Soil Metabolism**	A,B,C,H,I	40042039, 43070106, 43908701
163-1	**Leaching/Adsorption/Desorption**	A,B,C,H,I	41509801, 41509802, GS0021002, GS0021007
164-1	**Terrestrial Field Dissipation**	A,B,C	40042040, 40042041, 41299901, 41381801, 42118601, 43227801, 43227802
164-5	**Long Term Soil Dissipation**	A,B,C	41785102, 41785103, 41857301, 41845604, 42091501, 42285501, 42285503, 42437301, 42721301, 48145605
165-1	**Confined Rotational Crop**	A	40042042, 43847601, 43958701
165-2	**Field Rotational Crop**	A	Reserved
165-4	**Bioaccumulation in Fish**	A,B	265330
165-5	**Bioaccumulation - Aquatic NonTarget**	A,B,C	41785102, 41785103, 41845604, 41845605, 41857301, 42091501, 42285501, 42285503, 42437301
201-1	**Droplet Size Spectrum**	A,B,C	DATA GAP
202-1	**Drift Field Evaluation**	A,B,C	DATA GAP

Data Supporting Guideline Requirements for the Reregistration of Dicofol

REQUIREMENT		USE PATTERN	CITATION(S)
RESIDUE CHEMISTRY			
171-3[11]	**Directions for Use**	A,B,C,H,I	DATA GAP
171-4A	**Nature of Residue - Plants**	A,B,H	00004275, 00004321, 00143704, 05006528, 40042003, 40042004, 40042005, 40953701, 40958002, 41231901, 42971402
171-4B	**Nature of Residue - Livestock**	A,B,H	42276101, 42276102, 40042006, 40042007, 40958001, 40958003, 001465184

[11] Rohm and Haas has submitted proposed label revisions for their end-use products (EPA Reg. Nos. 707-201707-202, 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). The registrant has also submitted label revisions as part of a mitigation effort. 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 EC labels must be amended to delete use on strawberries, including the SLN CA77005300. There are no supporting field trial data.

Data Supporting Guideline Requirements for the Reregistration of Dicofol

REQUIREMENT		USE PATTERN	CITATION(S)
171-4C[12]	**Residue Analytical Method**	A,B,H	DATA GAP 00004341, 00004371, 00004420, 00004426, 05004945, 05004951, 05005141, 05005165, 05005167, 05005274, 05005537, 05006312, 05006330, 05012262, 05017942, 05019781, 40042008, 40042030, 40042031, 40644601, 40644603, 40644605, 40644606, 40644607, 40644608, 40812101, 40944603, 40944604, 41231902, 41231903, 41231904, 41231905, 41231906, 41231907, 41380401, 42514802, 42514803, 43146501, 43908703, 43908704
171-4D[6]	**Residue Analytical Method**	A,B,H	DATA GAP 40042030, 40042031, 40644601, 40644604, 40812101, 43908702, 43908705
171-4E	**Storage Stability**	A,B,C,H,I	40042009, 40042010, 40042011, 42514804, 42971403, 42971404, 42971405, 43146503, 43146504, 43146505, 43227803, 43383904
171-4F	**Magnitude of Residues - Potable H2O**		Reserved
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	A,B,H	40042030, 40042031, 40644601, 40644604, 40731901, 42971404, 42971405
	Fat, meat, and meat byproducts of cattle, goats, hogs horses and sheep	A,B,H	40042030, 40644601, 42971405
	Milk	A,B,H	40042030, 40644601, 42971405
	Eggs and the fat, meat, and meat byproducts of poultry	A,B,H	40042031, 40644604, 42971404

[12] Method TR-310-86-74 for plant matrices must be validated by an independent laboratory.

Data Supporting Guideline Requirements for the Reregistration of Dicofol

REQUIREMENT		USE PATTERN	CITATION(S)
171-4K[13]	**Crop Field Trials**	A,B,H	
	Legume vegetables		
	Beans (dry)	A,B,H	00004305, 40042017, 41231907, 41380401, 42297201, 42971408
	Beans (succulent)	A,B,H	00004305, 42297201, 42971407, 42971408
	Beans (lima)	A,B,H	00004305, 42297201, 42971407, 42971408
	Fruiting Vegetables Group		
	Eggplant	A,B,H	00004305
	Peppers	A,B,H	00004305, 40944602, 40944603
	Pimentos	A,B,H	00004305, 40944602, 40944603
	Tomatoes	A,B,H	00004305, 40944604
	Cucurbit Vegetables Group		
	Cantaloupes	A,B,H	00004305, 40042018, 40042019, 40644603
	Cucumbers	A,B,H	00004305, 40042020, 40644603, 41231903
	Melons	A,B,H	00004305, 40042018, 40042019
	Pumpkins	A,B,H	00004305, 40042018, 40042019

[13] For blackberries, boysenberries, dewberries, loganberries, and raspberries:

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 formulation only at 2 X 2.4 lb..a.i./acre, 3 day PHI. Use on strawberries must be deleted from EC labels. The tolerance for residues of dicofol in/on strawberries must be increased to 10 ppm.

Data Supporting Guideline Requirements for the Reregistration of Dicofol

REQUIREMENT	USE PATTERN	CITATION(S)
Summer squash	A,B,H	00004305, 40042021, 40644603
Watermelons	A,B,H	00004305, 40042018, 40042019
Winter squash	A,B,H	00004305, 40042018, 40042019, 40042021, 40644603
Citrus Fruits Group		
Grapefruit	A,B,H	00004305, 40042012, 40042013
Lemons	A,B,H	00004305, 40042012, 40042013, 40644603, 41231902, 41231904
Limes	A,B,H	00004305, 40042012, 40042013, 41231904
Kumquats	A,B,H	00004305, 40042012, 40042013
Oranges	A,B,H	00004305, 40042012, 40042013, 41231902
Tangerines	A,B,H	00004305, 40042012, 40042013
Pome Fruits Group		
Apples	A,B,H	00004305, 40042014, 41231905, 43146502
Crabapples	A,B,H	00004305, 40042014, 41231905
Pears	A,B,H	00004305, 40042015, 40042016
Quinces	A,B,H	00004305, 40042014, 41231905
Stone Fruits Group		
Apricots	A,B,H	00004305
Cherries	A,B,H	00004305, 42514806, 43146504
Nectarines	A,B,H	00004305
Peaches	A,B,H	00004305, 42514804, 42975101, 43227803

Data Supporting Guideline Requirements for the Reregistration of Dicofol

REQUIREMENT	USE PATTERN	CITATION(S)
Plums/Fresh Prunes	A,B,H	00004305, 42514805, 43146505
Small Fruits and Berries		
Blackberries	A,B,H	DATA GAP 00004305, 43529901
Boysenberries	A,B,H	DATA GAP 00004305, 43529901
Dewberries	A,B,H	DATA GAP 00004305, 43529901
Grapes	A,B,H	00004305, 40042024
Loganberries	A,B,H	DATA GAP 00004305, 43529901
Raspberries	A,B,H	DATA GAP 00004305, 43529901
Strawberries	A,B,H	00004305, 43752801
Tree Nuts group		
Bushnuts	A,B,H	00004305
Butternuts	A,B,H	00004305
Filberts	A,B,H	00004305
Hazelnuts	A,B,H	00004305
Hickory Nuts	A,B,H	00004305
Pecans	A,B,H	00004305, 40042022
Walnuts	A,B,H	00004305, 40042022, 40042023
Miscellaneous Commodities		
Cottonseed	A,B,H	00004305, 40042025, 40042027, 41231906, 42971406, 42971410
Figs	A,B,H	00004305

Data Supporting Guideline Requirements for the Reregistration of Dicofol

REQUIREMENT		USE PATTERN	CITATION(S)
	Hops	A,B,H	00004305, 00022895, 40944601, 42160401, 42971409
	Mint	A,B,H	00004272, 00004322, 00004323, 00004324, 00021700, 00021701
171-4L[14]	**Processed Food**		
	Apples	A,B,H	40042026
	Citrus	A,B,H	40042029
	Cottonseed	A,B,H	40042027, 42971410
	Grapes	A,B,H	40042028
	Hops	A,B,H	42160401
	Mint	A,B,H	00021701, 00004321
	Plums/Prunes	A,B,H	40042026, 42514805, 43146505
	Tea	A,B,H	00021662, 00021668, 00021680, 00021683, 00051013, 00051015, 42151101, 42214701, 42428001, 42611901
	Tomatoes	A,B,H	42971411

[14] 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 this is a recent change (OPPTS Test Guidelines, 860.1000, Table 1), the data requirement is considered confirmatory data and should not impede the reregistration process.

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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00004321	Rohm and Haas Company (1964) Kelthane in Mint Oil. Includes four undated methods. (Unpublished study received Jan 28, 1966 under 6F0472; CDL:090524-K)
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC AND PRODUCT SPECIFIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3 (for both generic and product specific data), the Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 5).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this

information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-99).

This Notice is divided into six sections and six Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I -Why You are Receiving this Notice
Section II -Data Required by this Notice
Section III -Compliance with Requirements of this Notice
Section IV -Consequences of Failure to Comply with this Notice
Section V -Registrants' Obligation to Report Possible Unreasonable Adverse Effects
Section VI -Inquiries and Responses to this Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms(Insert A) with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms (Insert B) with Instructions
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredient(s).

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms (Insert B) (for both generic and product specific data requirements). Depending on the results of the studies required in this Notice, additional studies/testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in the Requirements Status and Registrant's Response Forms (Insert B) within the time frames provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (Telephone number: 703-605-6000).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

You must use the correct forms and instructions when completing your response to this Notice. The type of Data Call-In you must comply with (Generic or Product Specific) is specified in item number 3 on the four Data Call-In forms (Attachments 2 and 3).

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for generic and product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data Requirements

The options for responding to this Notice for generic data requirements are: (a) voluntary cancellation, (b) delete use(s), (c) claim generic data exemption, (d) agree to satisfy the generic data requirements imposed by this Notice or (e) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the generic data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

Two forms apply to generic data requirements, one or both of which must be used in responding to the Agency, depending upon your response. These two forms are the Data-Call-In Response Form(Insert A), and the Requirements Status and Registrant's Response Form((Insert B).

The Data Call-In Response Forms(Insert A) must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms(Insert B) also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms(Insert A) and the Requirements Status and Registrant's Response Forms(Insert B) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation -

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit completed Generic and Product Specific Data Call-In Response Forms(Insert A), indicating your election of this option. Voluntary cancellation

is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice, which are contained in Section IV-C.

b. Use Deletion -

You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form (Insert B), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 under item 9 in the instructions for the Requirements Status and Registrant's Response Forms (Insert B). You must also complete a Data Call-In-Response Form(Insert A) by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, is allowed only if the product bears an amended label.

c. Generic Data Exemption -

Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient if the active ingredient in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

(i). The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;

(ii). Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

(iii). You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form(Insert A), Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form(Insert A). If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form (Insert A). Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

d. Satisfying the Generic Data Requirements of this Notice

There are various options available to satisfy the generic data requirements of this Notice. These options are discussed in Section III-C.1. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the Requirements Status and Registrant's Response Form(Insert B) and item 6b on the Data Call-In Response Form (Insert A). If you choose item 6b (agree to satisfy the generic data requirements), you must submit the Data Call-In Response Form(Insert A) and the Requirements Status and Registrant's Response Form(Insert B) as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "GENERIC" in item number 3.

e. Request for Generic Data Waivers.

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for the Requirements Status and Registrant's Response Form(Insert B). If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

2. Product Specific Data Requirements

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this Notice or (c) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form(Insert A), and the Requirements Status and Registrant's Response Form(Insert B), for product specific data. The Data Call-In Response Form (Insert A) must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form(Insert B) also must be submitted for each product listed on the Data Call-In Response Form(Insert A) unless the voluntary cancellation option is selected. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form(Insert A) and Requirements Status and Registrant's Response Form (Insert B) (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form(Insert A), indicating your election of this option. Voluntary cancellation is item number 5 on both the Generic and Product Specific Data Call-In Response Forms(Insert B). If you choose this option, you must complete both Data Call-In response forms. These are the only forms that you are required to complete.

If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

b. Satisfying the Product Specific Data Requirements of this Notice.

There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the product specific Requirements Status and Registrant's Response Form(Insert B) and item numbers 7a and 7b (agree to satisfy the product specific data requirements for an MUP or EUP as applicable) on the product specific Data Call-In Response Form(Insert A). Note that the options available for addressing product specific data requirements differ slightly from those options for fulfilling generic data requirements. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Decision document.

c. Request for Product Specific Data Waivers.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's

Response Form(Insert B). If you choose this option, you must submit the Data Call-In Response Form(Insert A) and the Requirements Status and Registrant's Response Form(Insert B) as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form(Insert A) that you agree to satisfy the generic data requirements (i.e. you select item number 6b), then you must select one of the six options on the Generic Requirements Status and Registrant's Response Form(Insert B) related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide you to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified timeframe (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data

If you choose to develop the required data it must be in conformance with Agency guidelines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG) and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form(Insert B) and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost share or agreeing to share in the cost of developing that study. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the Requirements Status and Registrant's Response Form(Insert B) are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2. Agreement to Share in Cost to Develop Data

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3. Offer to Share in the Cost of Data Development

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you did not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept the offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed Certification with Respect to Citations of Data (in PR Notice 98-5) (EPA Form 8570-34) . In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost-sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed to or, failing agreement, to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form(Insert A) and a Requirements Status and Registrant's Response Form(Insert B) committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant normally will be subject to initiation of suspension proceedings, unless you commit to submit, and do submit, the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4. Submitting an Existing Study

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3, *Raw data* means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3, means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information pursuant to the requirements of 40 CFR Part 160. Registrants also must certify at the time of submission of the existing study that such GLP information is available for post May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both documents available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data usually are not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such a study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5 entitled "Standard Format for Data Submitted under FIFRA".

Option 5. Upgrading a Study

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5 entitled "Standard Format for Data Submitted under FIFRA."

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option also should be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally, your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria, as well as a certification regarding protocol compliance with Agency requirements.

Option 6. Citing Existing Studies

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable, or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as

"core-guideline" or "core-minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option, you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form No. 8570-34, Certification with Respect to Citations of Data.

2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form(Insert A) that you agree to satisfy the product specific data requirements (i.e. you select option 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form(Insert B) related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form(Insert B). These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time-frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option.

Option 3. Offer to Share in the Cost of Data Development --The same requirements for generic data (Section III.C.I., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

Option 4. Submitting an Existing Study -- The same requirements described for generic data (see Section III.C.1., Option 4) apply to this option for product specific data.

Option 5. Upgrading a Study -- The same requirements described for generic data (see Section III.C.1., Option 5) apply to this option for product specific data.

Option 6. Citing Existing Studies -- The same requirements described for generic data (see Section III.C.1., Option 6) apply to this option for product specific data.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form(Insert A) and the Requirements Status and Registrant's Response Form(Insert B), and in the generic data requirements section (III.C.1.), as appropriate.

III-D. REQUESTS FOR DATA WAIVERS

1. Generic Data

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are not appropriate for your product.

a. Low Volume/Minor Use Waiver

Option 8 under item 9 on the Requirements Status and Registrant's Response Form(Insert B). Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume/minor use pesticides. In implementing this provision, EPA considers low volume pesticides to be only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver, the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume/minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of

the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume/minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

(i). Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

(ii) Provide an estimate of the sales (pounds and dollars) of the active ingredient for each major use site. Present the above information by year for each of the past five years.

(iii) Total direct production cost of product(s) containing the active ingredient by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

(iv) Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient, such as costs of initial registration and any data development.

(v) A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vi) A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vii) For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the

reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume/minor use waiver will result in denial of the request for a waiver.

b. Request for Waiver of Data

Option 9, under Item 9, on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You also must submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice are not appropriate to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

2. Product Specific Data

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the product specific Requirements Status and Registrant's Response Form(Insert B). Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver

request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A. NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

   a. Inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form(Insert A) and a Requirements Status and Registrant's Response Form(Insert B).

b. Fulfill the commitment to develop and submit the data as required by this Notice; or

c. Otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1) EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2) EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3) EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C. EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding generally would not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be

clearly demonstrating to EPA that granting such permission would be consistent with the Act. You also must explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden, the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on a case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due, unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3-year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

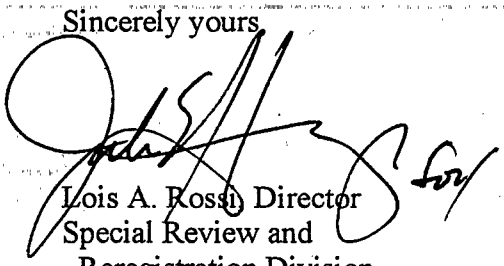
If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice must include completed Data Call-In Response Forms (Insert A)and completed Requirements Status and Registrant's Response Forms (Insert B), for both

(generic and product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Generic and Product Specific Data Call-In Response Forms(Insert A) need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours



Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

DICOFOL DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing Dicofol.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of 0021. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), and (5) a list of registrants receiving this DCI (Attachment 5). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for Dicofol are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Dicofol are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible Dicofol products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Venus Eagle at (703) 308-8045.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Venus Eagle
Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508C
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **Dicofol**

Dicofol DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing Dicofol.

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Dicofol. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), and (4) a list of registrants receiving this DCI (Attachment 5). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for Dicofol are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional product chemistry data on Dicofol are needed. These data are needed to fully complete the reregistration of all eligible Dicofol products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Phil Budig at (703) 308-8029.

All responsades to this Notice for the generic data requirements should be submitted to:

Phil Budig, Chemical Review Manager
Special Review Branch
Special Review and Registration Division (H7508W)
Office of Pesticiafde Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Dicofol

Instructions For Completing The "Data Call-In Response Forms" For The Generic And Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" (Insert A) and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Data Call-In Response Forms."(Insert A) Only registrants responsible for generic data have been sent the generic data response form. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

Although the form is the same for both generic and product specific data, instructions for completing these forms are different. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 4 have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2137, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS (INSERT A)

Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS**: This item identifies your company name, number and address.

Item 2. **ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. **ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

Item 4. **ON BOTH FORMS:** This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. **ON BOTH FORMS:** Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms (Insert B)

Item 6a. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

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United States Environmental Protection Agency
Washington, D.C. 20460

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03/31/99

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary

1. Company name and Address 000707
ROHM & HAAS CO
ATTN: ROBERT H. LARKIN
100 INDEPENDENCE MALL WEST
PHILADELPHIA PA 19106

2. Case # and Name
0021 Dicofol
Chemical # and Name 010501
Bis(chlorophenyl)-2,2,2-trichloroethanol

3. Date and Type of DCI
GENERIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
707-203					

8. Certification

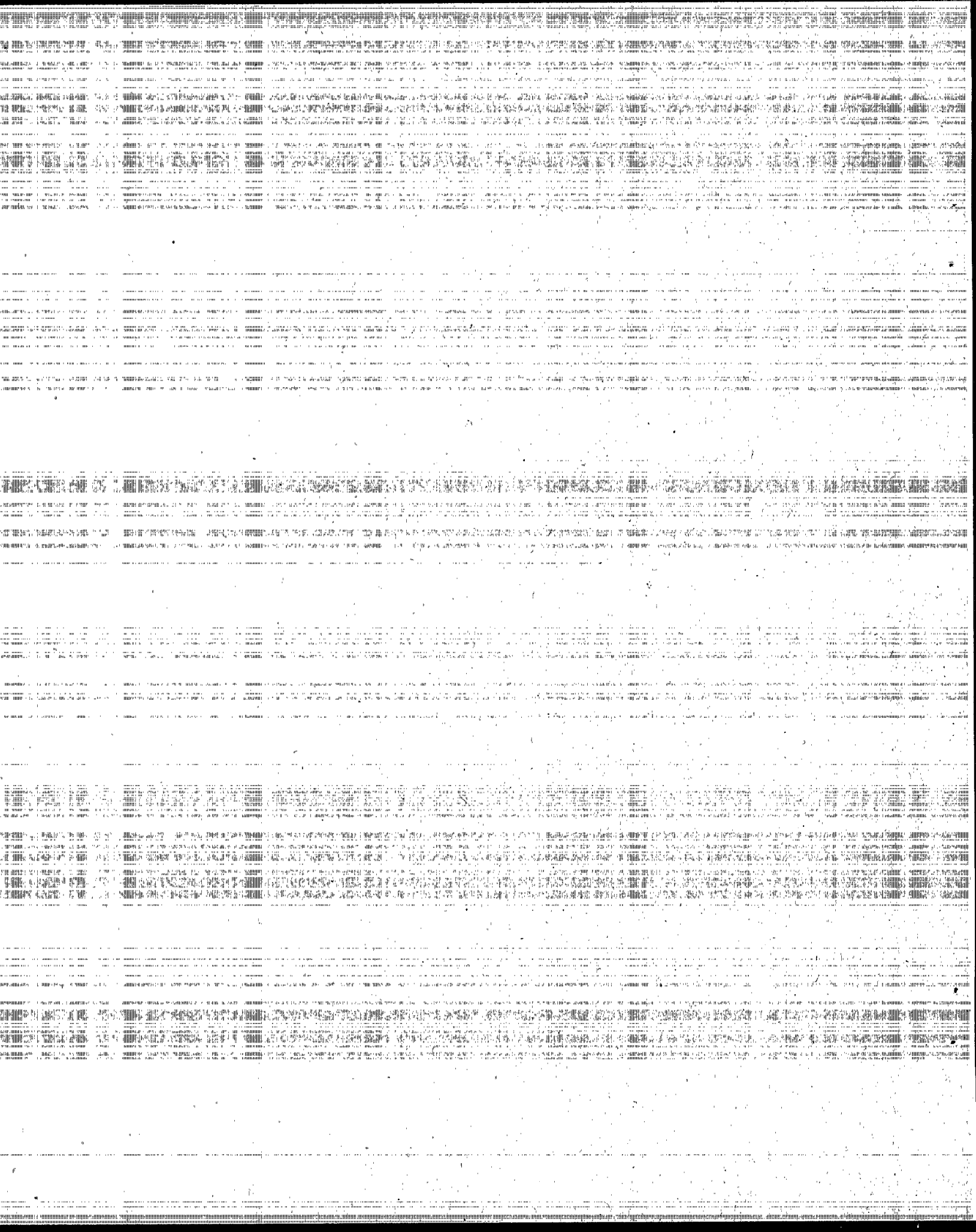
I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative _____

9. Date

10. Name of Company Contact

11. Phone Number



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United States Environmental Protection Agency
Washington, D.C. 20460

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03/31/99

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary

1. Company name and Address 011603
AGAN CHEM MFG, LTD
MAKHTESHIM-AGAN OF N AMERICA INC
551 FIFTH AVE SUITE 1100
NEW YORK NY 10176

2. Case # and Name
0021 Dicofol
Chemical # and Name 010501
Bis(chlorophenyl)-2,2,2-trichloroethanol

3. Date and Type of DCI
GENERIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
11603-26					

8. Certification

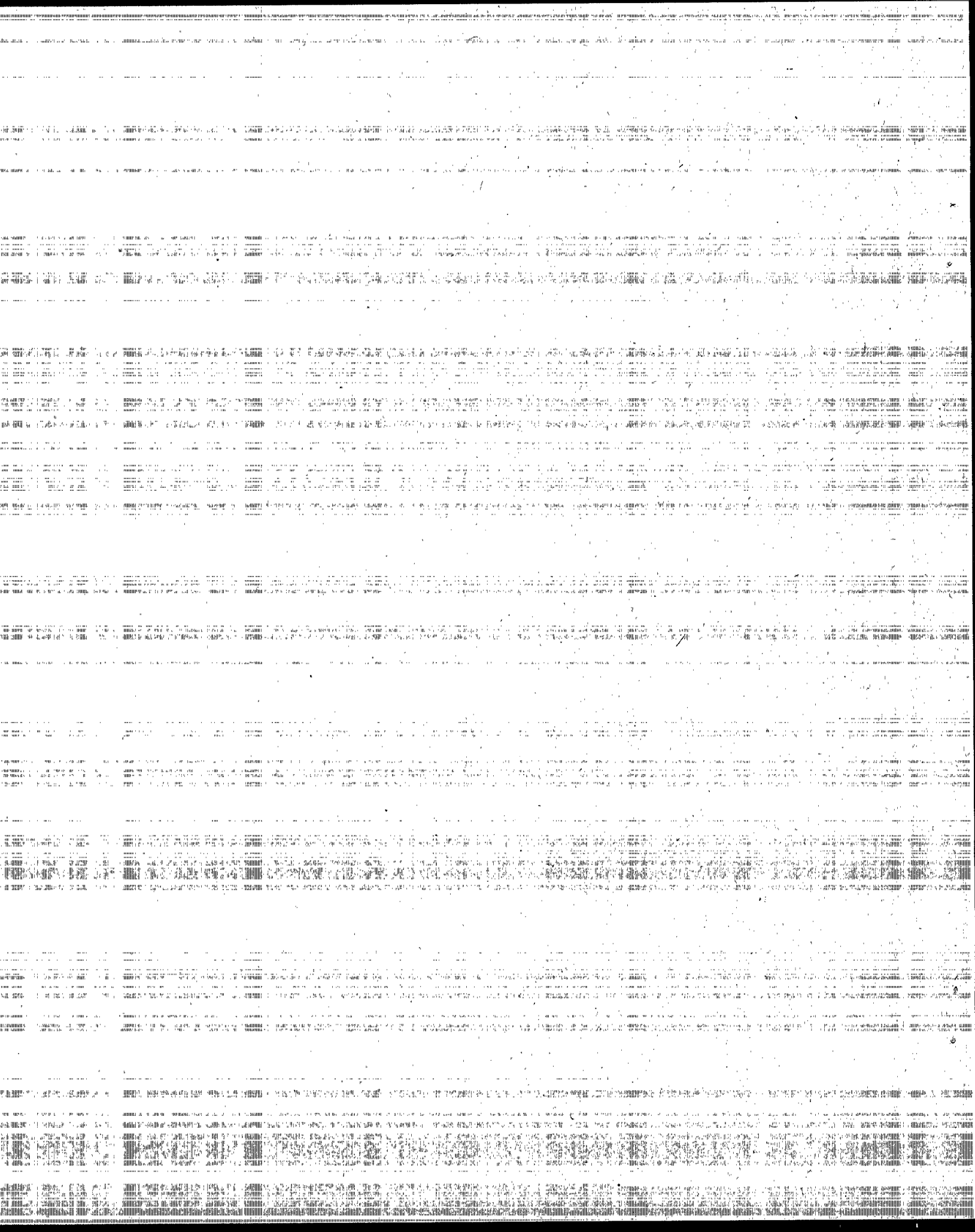
I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative _____

9. Date

10. Name of Company Contact

11. Phone Number



DRAFT COPY

United States Environmental Protection Agency
Washington, D. C. 20460

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-99

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0021 Dicofol	PRODUCT SPECIFIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
NNNNNN-NNNNN		N.A.	N.A.		

8. Certification

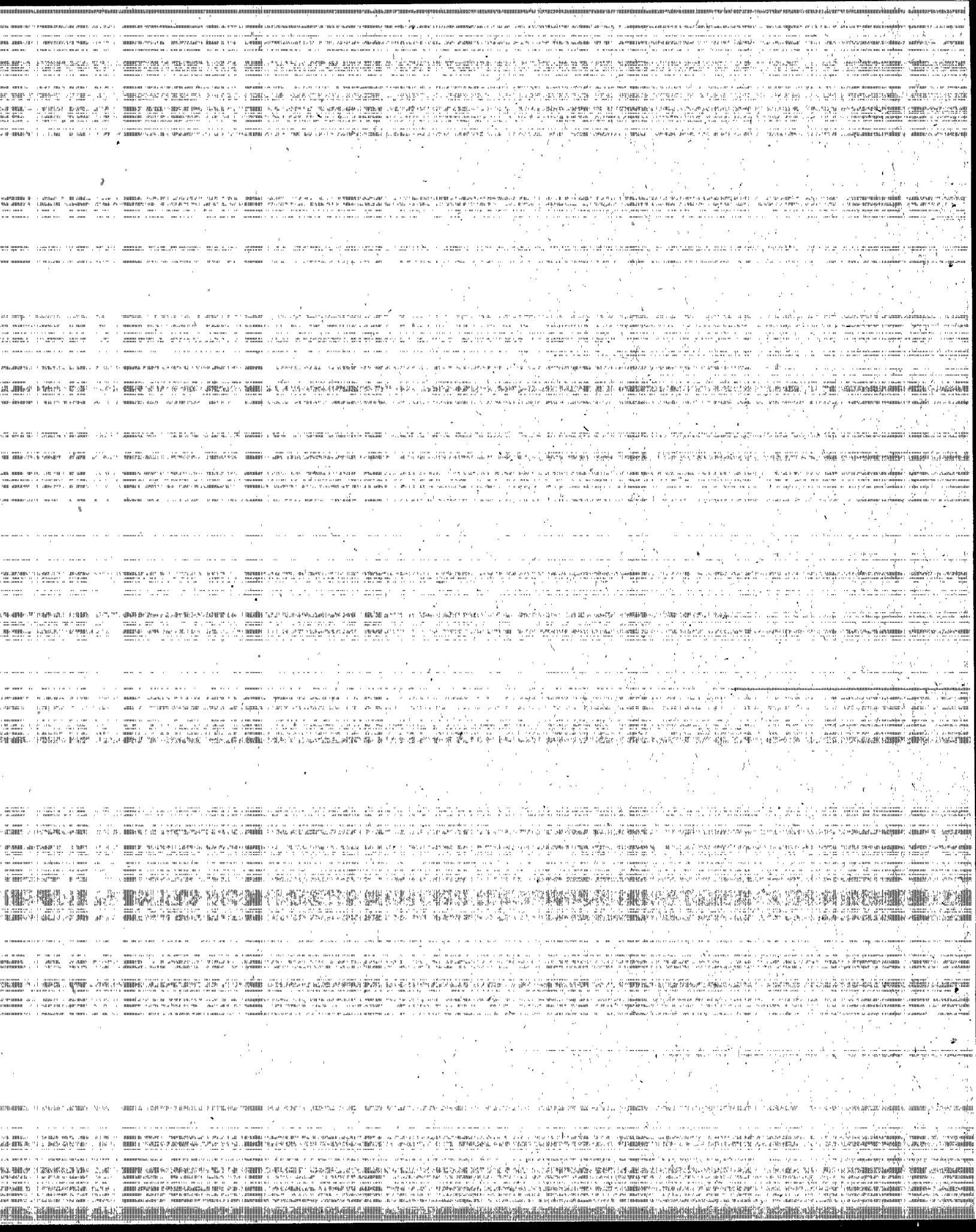
I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number



INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS (INSERT B)

Generic and Product Specific Data Call-In

Item 6b. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the Requirements Status and Registrant's Response Form(Insert B) that indicates how you will satisfy those requirements.

NOTE: **Item 6a and 6b are not applicable for Product Specific Data.**

Item 7a. **ON THE PRODUCT SPECIFIC DATA FORM:** For each manufacturing use product (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

Item 7b. For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do not complete the Requirements Status and Registrant's Response form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver.

NOTE: **Item 7a and 7b are not applicable for Generic Data.**

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS (INSERT B) CONTINUED

Generic and Product Specific Data Call-In

Item 8. **ON BOTH FORMS:** This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialed and dated in the space provided for the certification.

Item 9. **ON BOTH FORMS:** Enter the date of signature.

Item 10. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 11. **ON BOTH FORMS:** Enter the phone number of your company contact.

Note: You may provide additional information that does not fit on this form in a signed letter that accompanies your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

Instructions For Completing The "Requirements Status and Registrant's Response Forms" (Insert B) For The Generic and Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Requirements Status and Registrant's Response Forms." Only registrants responsible for generic data have been sent the generic data response forms. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms to include certain information unique to this chemical. DO NOT use these forms for any other active ingredient.

Items 1 through 8 have been preprinted on the form. Item 9 must be completed by the registrant as appropriate. Items 10 through 13 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2137, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS" (Insert B)

Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.

Item 2. **ON THE GENERIC DATA FORM:** This item identifies the case number, case name, EPA chemical number and chemical name.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the case number, case name, and the EPA Registration Number of the product for which the Agency is requesting product specific data.

Item 3. **ON THE GENERIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the type of Data Call-In. The date of issuance is also date stamped. Note the unique identifier number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.

Item 5. **ON BOTH FORMS:** This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form(Insert B).

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS" (Insert B) continued

Generic and Product Specific Data Call-In

Item 6. **ON BOTH FORMS:** This item identifies the code associated with the use pattern of the pesticide. In the case of efficacy data (product specific requirement), the required study only pertains to products which have the use sites and/or pests indicated. A brief description of each code follows:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food crop
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

Item 7. **ON BOTH FORMS:** This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

EUP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Indredient or Pute Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP ___%	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled

TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*	See: guideline comment

Item 8. This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5.

ON THE GENERIC DATA FORM: The time frame runs from the date of your receipt of the Data Call-In notice.

ON THE PRODUCT SPECIFIC DATA FORM: The due date for submission of product specific studies begins from the date stamped on the letter transmitting the Reregistration Eligibility Decision document, and not from the date of receipt. However, your response to the Data Call-In itself is due 90 days from the date of receipt.

Item 9. **ON BOTH FORMS:** Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

Option 1. **ON BOTH FORMS:** (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocols and progress reports required in item 5 above.

Option 2. **ON BOTH FORMS:** (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

However, for Product Specific Data, I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency indicates in an attachment to this notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

Option 3. **ON BOTH FORMS:** (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. I am submitting evidence that I have made an

offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice apply as well.

However, for Product Specific Data, I understand that this option is available only for acute toxicity or certain efficacy data and only if the Agency indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option.

Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

Option 5. **ON BOTH FORMS:** (Upgrading a Study) I will submit by the specified due date, or will cite data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

Option 6. **ON BOTH FORMS:** (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.

However, for Product Specific Data, I am citing another registrant's study. I understand that this option is available **ONLY** for acute toxicity or certain efficacy data and **ONLY** if the cited study was conducted on my product, an identical product or a product which the Agency has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

FOR THE GENERIC DATA FORM ONLY: The following three options (Numbers 7, 8, and 9) are responses that apply only to the "Requirements Status and Registrant's Response Form" (Insert B) for generic data.

Option 7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

Option 8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Option 9. (Request for Waiver of Data) I have read the statements concerning data waivers other than lowvolume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

FOR PRODUCT SPECIFIC DATA: The following option (number 7) is a response that applies to the "Requirements Status and Registrant's Response Form" (Insert B) for product specific data.

Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days-of my receipt of the Agency's written decision, submit a revised "Requirements Status" form specifying the option chosen. I also understand that the deadline for submission of data as specified by the original Data Call-In notice will not change.

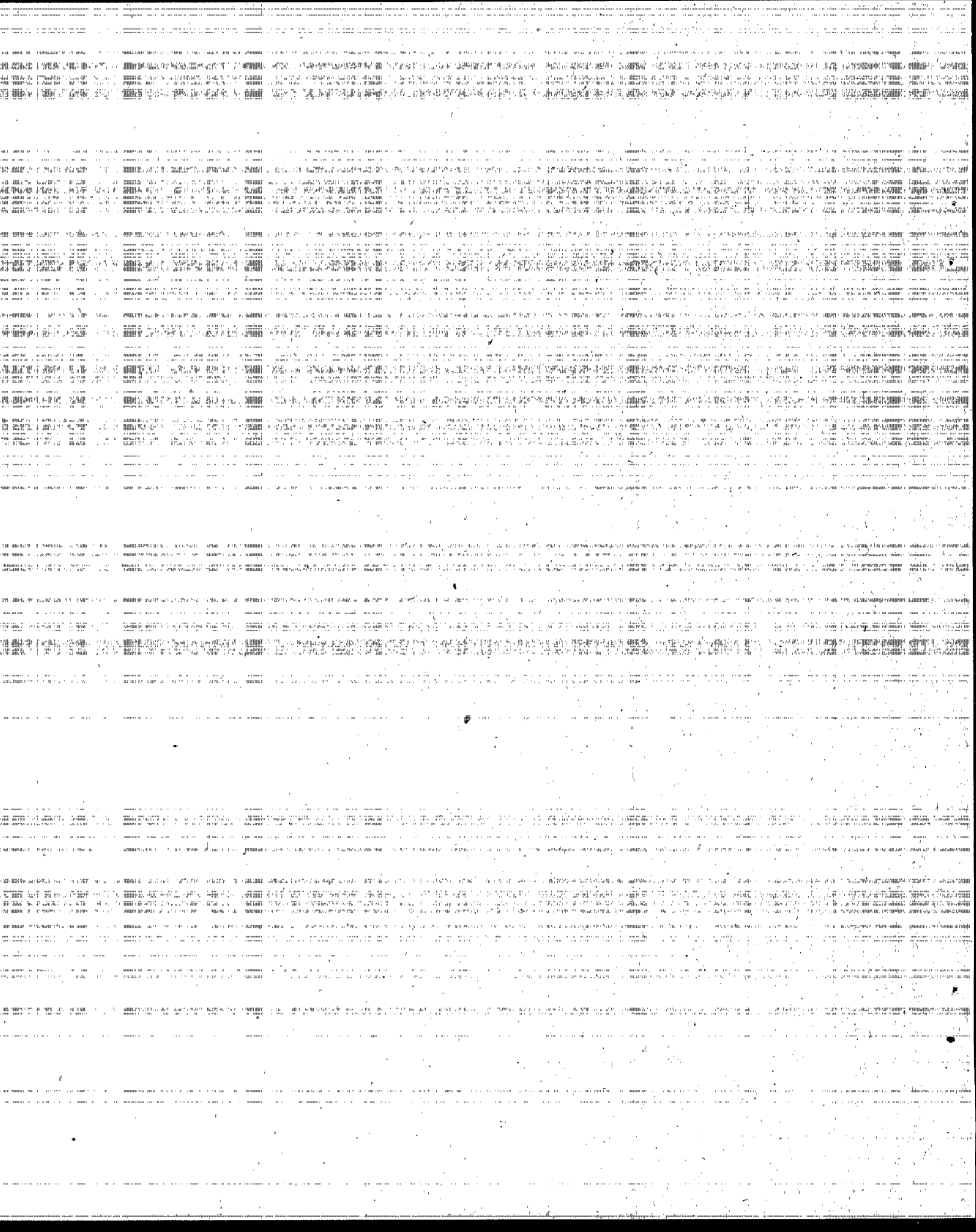
Item 10. **ON BOTH FORMS:** This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. **ON BOTH FORMS:** Enter the date of signature.

Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that the Agency can ensure that its records are correct.



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United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03/31/99

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary

1. Company name and Address 000707
ROHM & HAAS CO
ATTN: ROBERT H. LARKIN
100 INDEPENDENCE MALL WEST
PHILADELPHIA PA 19106

2. Case # and Name
0021 Dicofol
Chemical # and Name 010501
Bis(chlorophenyl)-2,2,2-trichloroethanol

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
830.7050 *	U/V Visable Absorption					ABCHI	TGAI	12 mos.	
83-6 *	Developmental Neurotoxicity		Y			ABCHI	TGAI	24 mos.	

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative _____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D.C. 20460

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0021 Dicofol
Chemical # and Name
010501 Bis(chlorophenyl)-2,2,2-trichloroethanol

GUIDELINE	COMMENT
830.7050	This is a new end use product requirement in conjunction with OECD.
83-6	The EPA Hazard Identification Assessment Review Committee determined that this study is required for the following reasons: 1. evidence of neurobehavioral effects in the acute and subchronic studies. 2. endocrine toxicity (adrenal and thyroid) was seen throughout the database. 3. ovarian toxicity, consistant with enhanced steroidgenic activity was seen in the two-generation reproduction study in rats. 4. structural activity concern (i.e.. dicifol is structurally related to DDT, a neurotoxicant, and DDE, an endocrine disrupter). 5. Uncertainty over the involvement of dicofol in the reproductive failure of alligator population following accidental spill into Lake Apopka, Florida.

List of All Registrants Sent This Data Call-In Notice

Case # and Name

0021 Dicofol

Chemical # and Name

010501 Bis(chlorophenyl)-2,2,2-trichloroethanol

Company Number	Company Name	Additional Name	Address	City & State	Zip
000707	ROHM & HAAS CO	ATTN: ROBERT H. LARKIN	100 INDEPENDENCE MALL WEST	PHILADELPHIA PA	19106
011603	AGAN CHEM MFG, LTD	MAKHTESHIM-AGAN OF N AMERICA INC	551 FIFTH AVE SUITE 1100	NEW YORK NY	10176

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-99

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0021 Dicofol EPA Reg. No. NNNNNN-NNNNN	PRODUCT SPECIFIC ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
61-1	Product identity & composition (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(a)	Descriptn starting materials, (1,2) productn & formulatn process					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(b)	Discussion of formation of impurities (1,3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-1	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-2	Color (17)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-3	Physical state					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-4	Odor (17)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-7	Density					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-13	Study not required for product							8 mos.	

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-99

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0021 Dicofol EPA Reg. No. NNNNNN-NNNNN	PRODUCT SPECIFIC ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	specific reregistration.									
63-14	Oxidizing or reducing action	(10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-15	Flammability	(11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-16	Explodability	(12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability	(18)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity	(13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility	(14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage	(15)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
	Acute Toxic - Regular Chemical									
81-1	Acute oral toxicity-rat	(1,36,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-2	Acute dermal toxicity-rabbit/rat	(1,2,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-3	Acute inhalation toxicity-rat	(3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-4	Primary eye irritation-rabbit	(2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-5	Primary dermal irritation	(1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-6	Dermal sensitization	(4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-99

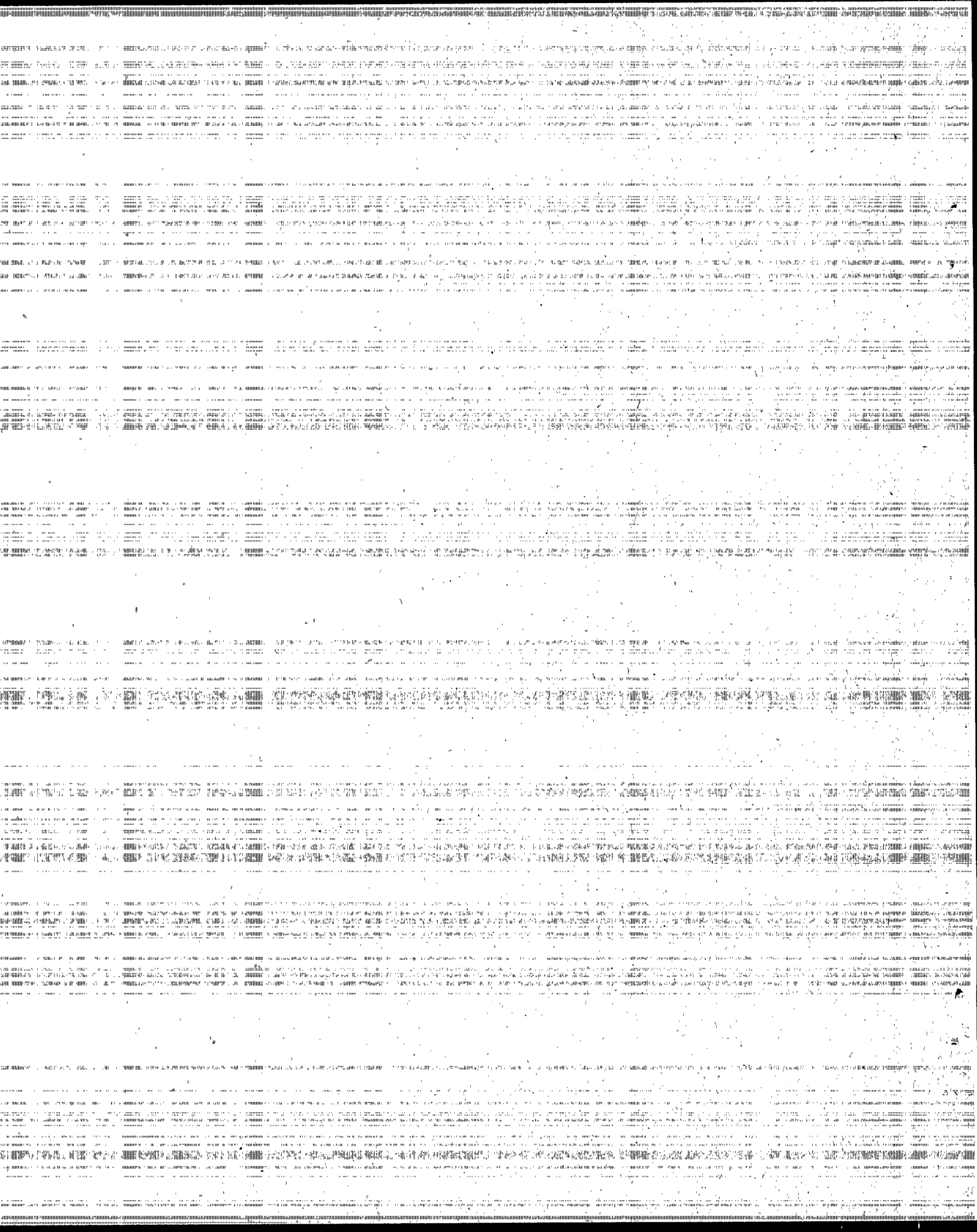
INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0021 Dicofol EPA Reg. No. NNNNNN-NNNNN	PRODUCT SPECIFIC ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Efficacy - Invertebrate Control Agents								
	Ornamental Plants								
95-4,5	Efficacy evaluation (1,5)					HI K	EP	8 mos.	
95-4,5	Comparative field test (1,2)					HI K	EP	8 mos.	
	Shade, Forest Trees, Lawns and Turf								
95-6,7	Efficacy evaluation (1,3,4)					A C JK	EP	8 mos.	
95-6,7	Comparative field test (1,2)					A C JK	EP	8 mos.	
	Domestic Animals and Their Manmade Premises								
95-8,9	Laboratory evaluation (1,3,4,6)					LM O	EP	8 mos.	
95-8,9	Comparative field test (1,2)					LM O	EP	8 mos.	
	Mosquito, Blackfly, Biting Midge Treatments								
95-10	Laboratory efficacy evaluation (1,3,4)					A CDE JK	EP	8 mos.	
95-10	Comparative field test (1,2)					A CDE JK	EP	8 mos.	
	Premises Treatments								
95-11	Laboratory efficacy evaluation (1,3,4)					KLM O	EP	8 mos.	
95-11	Comparative field test (1,2)					KLM O	EP	8 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date



United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0021 Dicofol

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product. [NOTE: If a product is a 100 percent repackage of another registered product, registrants are not subject to any data requirements identified in the tables.]; TEP = typical end-use product; TGAI = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

Use Categories Key:

A - Terrestrial food crop	B - Terrestrial food feed crop	C - Terrestrial nonfood crop	D - Aquatic food crop	E - Aquatic nonfood outdoor
F - Aquatic nonfood Industrial	G - Aquatic nonfood residential	H - Greenhouse food crop	I - Greenhouse nonfood crop	J - Forestry
K - Residential outdoor	L - Indoor food	M - Indoor nonfood	N - Indoor Medical	O - Indoor residential

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

Prod Chem - Regular Chemical

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).

2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.

3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.

4 To support registration of an MP or EP, whether produced by an integrated system or not, the technical grade of Active Ingredient must be analyzed. If the technical grade of Active Ingredient cannot be isolated, a statement of composition of the practical equivalent of the technical grade of Active Ingredient must be submitted. Data on EPs or MPs will be required on a case-by-case basis.

5 Certified limits are not required for inert ingredients in products proposed for experimental use.

9 Required if test substances are dispersible with water.

10 Required if product contains an oxidizing or reducing agent.

11 Required if product contains combustible liquids.

12 Required if product is potentially explosive.

13 Required if product is a liquid.

14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.

15 Required if end-use product is liquid and is to be used around electrical equipment.

17 Not required unless efficacy data are required.

18 Required for MP and EP but should not be submitted for EP unless (a) efficacy data are required to be submitted, (b) the storage stability data show that the active ingredient(s) is (are) not within the certified limits or toxicologically significant degradates are detected, or (c) product instability is suspected or incidents of instability are reported. Refer to PR Notice 92-5 for more information.

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.

2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0021 Dicofol

Footnotes (cont.):

of potential eye and dermal irritation effects.

3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).

4 Required unless repeated dermal exposure does not occur under conditions of use.

36 Special testing (acute, subchronic, and/or chronic) is required for organophospates, and may be required for other cholinesterase inhibitors and other pesticides which have demonstrated a potential to adversely affect the visual system. Registrants should consult with the agency for development of protocols and methodology prior to initiation of studies.

37 Testing of the EP dilution in addition to the EP or MP is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

Efficacy - Invertebrate Control Agents

1 The agency has waived all requirements to submit efficacy data for invertebrate control agents for nonpublic health uses. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commenly accepted pest control practices. The registrant must develop and maintain the relevant data upon which the determination of efficacy is based. The Agency reserves the right to require, on a case-by-case basis (e.g., significant new uses or benefits data in cases of special reviews) submission of efficacy data for any pesticide product, registered or proposed for registration when necessary.

2 Comparative product performance data are required to be developed and maintained in the registrant's file and must be submitted to the Agency on a case-by-case basis for risk/benefit analyses such as for public interest findings and cases of special review.

3 Efficacy evaluations can be conducted under laboratory, greenhouse, or field conditions.

4 Required to be developed and maintained in the Reggistrant's file for all pests claimed on the label when resistance to the pestcide has been demonstrated.

5 Ornamental Plants includes greenhouse floriculture crops and foliage crops, and all outdoor ornamental plants.

6 Pets and Domestic Animals includes livestock, poultry, fur-, and wool-bearing animals as well as household pets.

EPA'S BATCHING OF DICOFOL PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources, and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing **Dicofol** as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition, and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar," since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data are generated or existing data are referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In (DCI) Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1); Submitting an Existing Study (Option 4); Upgrading an Existing Study (Option 5); or, Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2); Offers to Cost Share (Option 3); or, Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5, or 6. However, a

registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Fourteen (14) products were found which contain **Dicofol** as the active ingredient. These products have been placed into three batches and a "no batch" category, in accordance with the active and inert ingredients and type of formulation. Furthermore, the following bridging strategies are deemed acceptable for this chemical:

- Product 34704-513 in the "No Batch" Group may be supported by the products in Batch 2, with the exception of Eye Irritation Test data.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

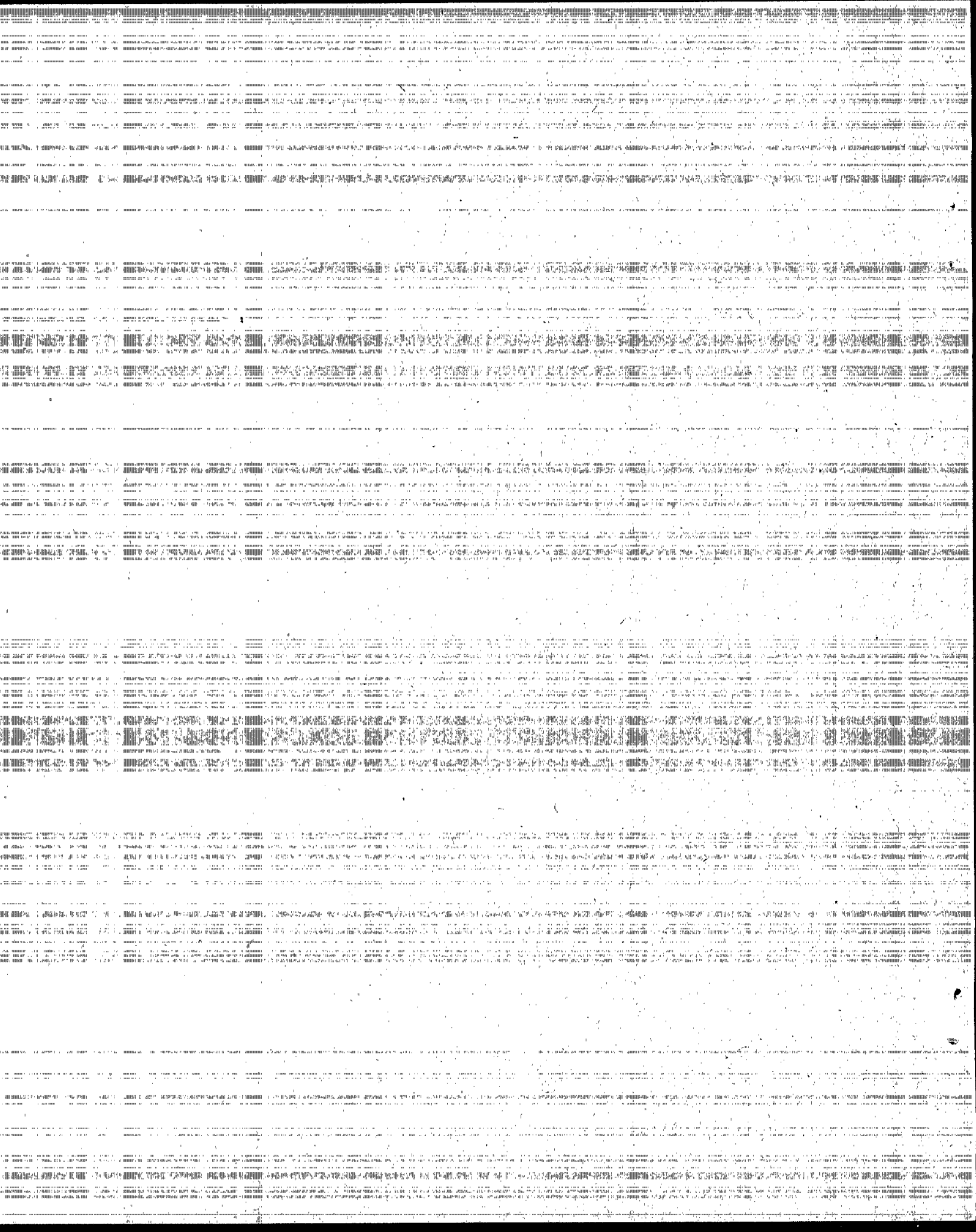
Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	707-203	95.3%	Powder
	11603-26	88.0%	Powder

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
2	707-202	42.0	Liquid
	66222-21	42.0	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
3	707-204	18.5	Liquid
	10163-96	18.5	Liquid

No Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	707-229	50.0	Powder
	51036-75	42.0	Liquid

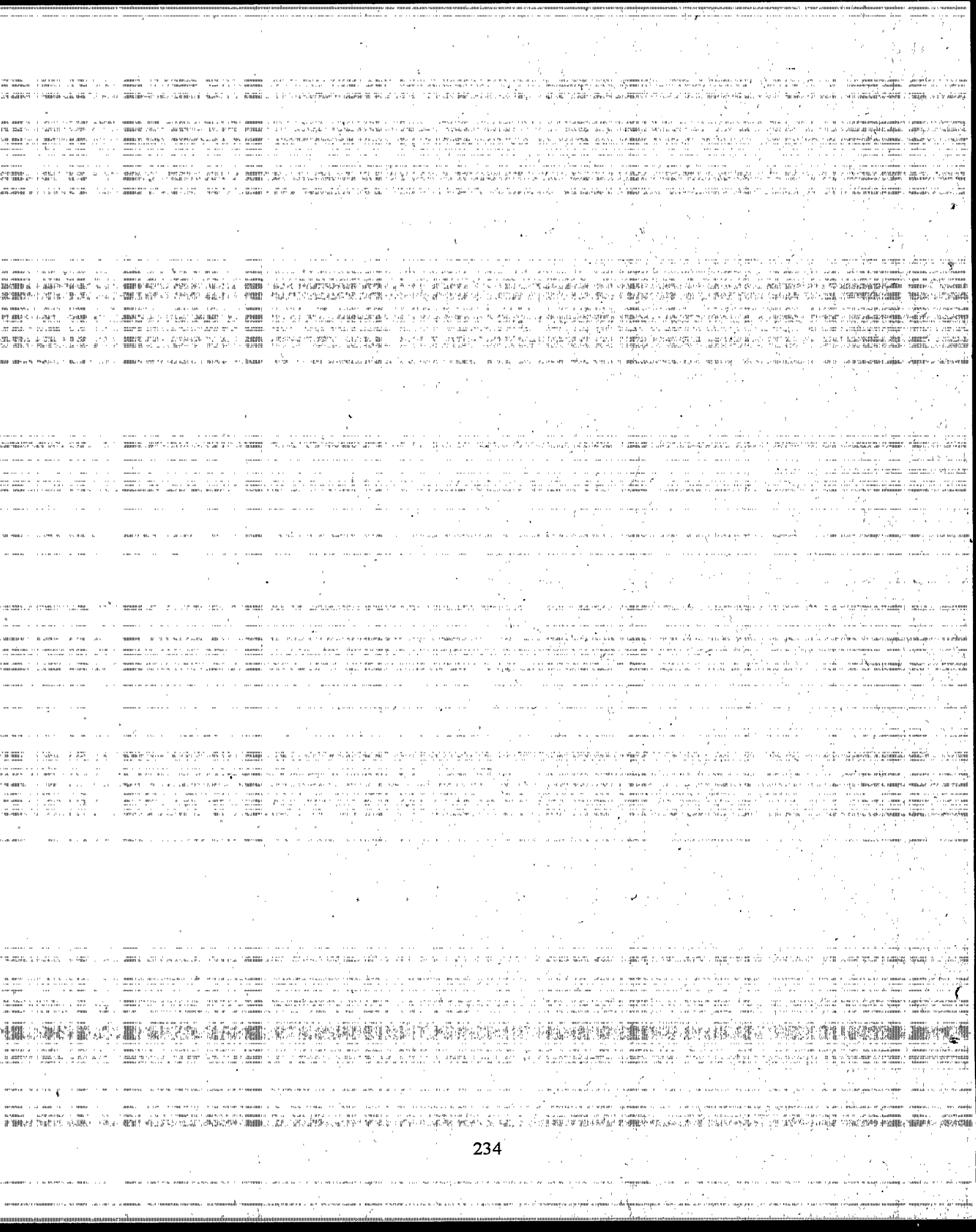
No Batch	EPA. Reg. No.	% Active Ingredient	Formulation Type
	34704-513	41.1	Liquid
	707-201	41.0	Liquid
	707-205	35.0	Solid
	239-2574	3.0, plus 4.00% Orthene 3.25% Triforine	Liquid
	239-2575	3.0, plus 8.00% Orthene	Liquid
	10163-234	3.0	Powder



List of All Registrants Sent This Data Call-In Notice

Case # and Name
0021 Dicofol
Chemical # and Name
010501 Bis(chlorophenyl)-2,2,2-trichloroethanol

Company Number	Company Name	Additional Name	Address	City & State	Zip
000707	ROHM & HAAS CO	ATTN: ROBERT H. LARKIN	100 INDEPENDENCE MALL WEST	PHILADELPHIA PA	19106
011603	AGAN CHEM MFG, LTD	MAKHTESHIM-AGAN OF N AMERICA INC	551 FIFTH AVE SUITE 1100	NEW YORK NY	10176



LIST OF AVAILABLE RELATED DOCUMENTS AND ELECTRONICALLY AVAILABLE FORMS

Pesticide Registration Forms are available at the following EPA internet site:

http://www.epa.gov/opprd001/forms/.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet: at the following locations:

a) Form 8570-1 Application for Pesticide Registration/Amendment- *http://www.epa.gov/opprd001/ forms/8570-1.pdf.*

b) Form 8570-4 Confidential Statement of Formula - *http://www.epa.gov/opprd001/forms/8570-4.pdf.*

c) Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data - *http://www.epa.gov/opprd001/forms/8570-32.pdf.*

d) Form 8570-34 Certification with Respect to Citations of Data (in PR Notice 98-5) - *http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.*

e) Form 8570-35 Data Matrix (in PR Notice 98-5) - *http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.*

f) Form 8570-36 Summary of the Physical/Chemical Properties (in PR Notice 98-1) - *http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.*

g) Form 8570-37 Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1) - *http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.*

Pesticide Registration Kit *www.epa.gov/pesticides/registrationkit/.*

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.
2. Pesticide Registration (PR) Notices
   a. 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

   Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.
3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)
   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement
   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
   e. EPA Form No. 8570-35, Data Matrix
4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)
   a. Registration Division Personnel Contact List
      Biopesticides and Pollution Prevention Division (BPPD) Contacts
      Antimicrobials Division Organizational Structure/Contact List
   b. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
   c. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
   d. 40 CFR Part 158, Data Requirements for Registration (PDF format)
   e. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) the following address:

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at 1-800-858-7378 or through their Web site.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
the Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.

List of Available Related Documents

The following is a list of available documents for Dicofol that may further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic

File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies are available on our website at www.epa.gov/REDs, or contact Phil Budig at (703) 308-8029.

1. PR Notice 86-5.

2. PR Notice 91-2 (pertains to the Label Ingredient Statement).

3. A full copy of this RED document.

4. A copy of the fact sheet for Dicofol.

The following documents are part of the Administrative Record for Dicofol and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.

2. Detailed Label Usage Information System (LUIS) Report.

3. Appendix A - Table of Use Patterns Subject to Reregistration

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.

2. EPA Acceptance Criteria