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Evaluation of the U.S. EPA Pesticide Product Reregistration Process: Opportunities for Efficiency and Innovation

Promoting Environmental Results Through Evaluation

Table of Contents

List of Exhibits

Acronyms

AD	Antimicrobials Division
AI	Active Ingredient
BEAD	Biological and Economic Analysis Division
BPPD	Biopesticides and Pollution Prevention Division
CBI	Confidential Business Information
CFR	Code of Federal Regulations
CRM	Chemical Review Manager
CRS	Congressional Research Service
CSF	Confidential Statement of Formula
DCI	Data Call-In
EPA	U.S. Environmental Protection Agency
FEAD	Field and External Affairs Division
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
FR	Federal Register
FTE	Full-Time Equivalent
GAO	General Accountability Office
GPRA	Government Performance and Results Act
HED	Health Effects Division
HHDA	Hazard to Humans and Domestic Animals
IRED	Interim Reregistration Eligibility Decision
ISB	Information Services Branch
IMC	Information Management Council
ITRMD	Information Technology and Resource Management Division
MOA	Memorandum of Agreement
MRID	Master Record Identification Number
NRDC	Natural Resources Defense Council
OGC	Office of General Counsel
OIG	Office of Inspector General
OMB	Office of Management and Budget
OPP	Office of Pesticide Programs
OPPIN	Office of Pesticide Programs Information Network
OPPTS	Office of Prevention, Pesticides, and Toxic Substances
PARS	Performance Appraisal and Recognition System
PART	Program Assessment Rating Tool
PDCI	Product-Specific Data Call-in
PM	Product Manager
PPDC	Pesticide Program Dialogue Committee
PPE	Personal Protective Equipment
PPLS	Pesticide Product Label System
PRA	Paperwork Reduction Act
PRB	Product Reregistration Branch
PRIA	Pesticide Registration Improvement Act of 2003
PRN	Pesticide Registration Notice
PSB	Program Support Branch
RCS	Regulatory Coordination Staff
RD	Registration Division
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RUP	Restricted Use Pesticide
SEE	Senior Environmental Employment
SOP	Standard Operating Procedure
SRRD	Special Review and Reregistration Division
TRED	Tolerance Reassessment Eligibility Decision
USDA	U.S. Department of Agriculture
WPS	Worker Protection Standard

Acknowledgments

In Fall 2005 the U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP) entered the EPA Program Evaluation Competition and was selected for an evaluation of its product reregistration process. This competition, jointly sponsored by the Office of Policy, Economics and Innovation and the Office of the Chief Financial Officer, encourages the effective use of program evaluation throughout EPA. As a subcontractor to Industrial Economics, Abt Associates conducted this evaluation under EPA contract EP-W-04-023.

The Abt Associates evaluation team gratefully acknowledges the input and guidance provided by Peter Caulkins, OPP Special Review and Reregistration Division, and Yvonne Watson, EPA Office of Policy, Economics, and Innovation, throughout the design and implementation of the evaluation. We also appreciate the time made available by OPP staff members to meet with the evaluation team, which provided us with critical information on their roles, responsibilities, and perspectives on product reregistration that would not have otherwise been available.

Preface

As a subcontractor to Industrial Economics, Abt Associates conducted this evaluation under EPA contract EP-W-04-023. This report reflects the information made available to Abt Associates either by EPA or through published sources. A substantial amount of the information is qualitative in nature and was collected through a series of interviews with EPA staff. The findings presented in this report are based on the information made available to the evaluation team. Further, the conclusions and recommendations presented in this report are those of the evaluation team and are not necessarily reflective of EPA's position.

Executive Summary

The U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP) conducts a comprehensive review of pesticides initially registered before November 1, 1984, to ensure that they meet contemporary health and safety standards and labeling requirements. After the registrant signals its intent to reregister an active ingredient, EPA conducts science reviews, develops a risk assessment and publishes it for public comment, and issues a Reregistration Eligibility Decision (RED). EPA then must reregister each of the individual pesticide products that contains the active ingredient. This final step in the process – pesticide product reregistration – is the focus of this evaluation.

Product reregistration consists of three basic steps, which are completed by either the OPP Special Review and Reregistration Division (SRRD) or the Registration Division (RD): (1) SRRD sends registrants a Data Call-In (DCI) notice requesting the needed product-specific data. (2) SRRD receives and evaluates the requested studies from the registrants and conducts a preliminary label assessment. (3) RD reregisters a product if it was found to meet its standards by issuing a reregistration notice and stamping a revised label that includes the necessary mitigation.

Evaluation Purpose and Approach

There is considerable interest within EPA to streamline and expedite the product reregistration process. The purpose of this evaluation is to identify potential opportunities for innovation and streamlining of the product reregistration process in order to (1) ensure timelier implementation of the mitigation measures specified in the RED, and (2) make the process as efficient as possible in order to decrease the amount of time needed for product reregistration and use resources in the most effective manner. The evaluation was designed to answer the following questions:

- What components of REDs have caused delays in product reregistration?
- What problems, bottlenecks, or unnecessary duplication of efforts occur in the product reregistration process that are under the control of OPP?
- What innovations or streamlining in process could result in more timely implementation of mitigation specified in the RED and/or more efficient production of outputs?
- What are the pros and cons of each of the proposed innovations or streamlining measures?
- What is the optimal allocation of tasks between the Special Review and Reregistration Division and the Registration Division?
- Are any external entities or considerations impeding the product reregistration process?

The methodology employed several data collection methods, including interviews, document review, reregistration program data, case studies, and subject matter experts.

Product Reregistration Progress

Since beginning reregistration in the late 1980s, EPA has completed reregistration actions for 7,358 products. Reregistration actions for 11,948 products (conventional and antimicrobial)

were pending as of October 2006. Of the pending reregistration actions, the products are distributed through all phases of the pesticide reregistration process. Most of the products (9,088 or 76%) have not yet had the Data Call-in (DCI) approved by the Office of Management and Budget (OMB). The FY2006 REDs resulted in 6,722 products that will require DCIs.

On average, it took more than 54 months to reregister a product. On average, approximately 41 months were needed to transmit the reregistration package to the Product Manager (PM) in RD, and after the reregistration package had been sent to the PM, it took approximately 14 months to complete the reregistration process. The distribution of these data indicated that they are skewed such that the mean (average) is not adequate to represent the average duration of the process; the median time is more informative in this instance. The median time to complete product the product reregistration process was 30 months.

Product Reregistration Delays Associated with REDs

The Registration Eligibility Decisions (REDs) and subsequent activities were found to be a source of delay in product reregistration. REDs were often published before they are complete or before all outstanding issues were properly addressed. These documents represented a "snapshot in time" of the data made available to EPA, and registrants often provided additional data that warrant amending the RED. Some registrants were inclined to challenge the contents of a RED as a way to delay implementing mitigation. Also, some REDs did not represent decisions or included provisions for additional studies, such that product reregistration could not be effectively implemented after the RED was published. REDs sometimes contained small errors, most of which were straightforward and easy to address. The label tables often contained language that RD or SRRD Product Reregistration Branch (PRB) believe could been improved or that is not consistent with labeling for other products. Many of these issues only became apparent at implementation, which was during the product reregistration process.

Post-RED issues were not given high priority in work plans and adequate resources within the four SRRD reregistration branches, as statutory deadlines required continued focus on REDs. Staff from the reregistration branches were often unavailable to assist with post-RED issues. Given the length of time from when a RED was published, to when post-RED issues were addressed, to when product reregistration was conducted, the Chemical Review Manager (CRM) who wrote the RED was often no longer in that position.

Problems, Bottlenecks, and Unnecessary Duplications of Effort

Because of the length of the product reregistration process, as well as the delays that often occur, the mitigation identified in the RED is often not implemented for several years. This delay is particularly troublesome given that the universe of pesticides includes those that were registered prior to November 1, 1984. EPA has made several attempts to implement RED-specified mitigation as soon as possible, including through memoranda of agreement and requests to registrants. Even with regulatory action as a possible consequence of non-response, registrants did not submit amended labels for a substantial number of products.

There is substantial backlog in the number of DCIs that need to be approved by the Office of Management and Budget (OMB) and sent out by OPP so that product reregistration can begin. The review by OMB also results in substantial delay because the approval process takes an

average of nine to ten months. In addition, the format for the justification package has been and continues to be an issue, the needed information is not readily available in a suitable format, and OPP lacks an adequate tracking system for the DCI process.

One of the sources of delay in the product reregistration process are the registrant responses, which require a lot of time for the registrants to prepare and submit, as well as for EPA to receive, track, review, and respond to (if required). During the course of its reregistration program, EPA has initiated several efforts to increase the quality of data it receives from registrants so that data are not deficient, which requires additional time for the registrant to prepare and submit studies and for EPA to review them.

As currently designed, the Special Review and Reregistration Division (SRRD) conducts preliminary label assessments, and the Registration Division (RD) conducts full label reviews. The review by SRRD was intended to focus on mitigation required by the reregistration process, whereas RD focused on label amendments and content more generally. Despite this division of labor, the two reviews are duplicative and RD has not used many of SRRD's label assessments.

Efficient information management is an issue for all aspects of the product reregistration process. In 2000, EPA launched the Office of Pesticide Programs Information Network (OPPIN), which was intended to be an integrated, office-wide system. This system, which replaced existing systems to track reregistration on the product and active ingredient levels, failed to meet the needs of OPP with respect to product reregistration. In response, many staff have created one-off tracking systems in order to get their jobs done, making comprehensive, reliable status updates very difficult to retrieve. OPP again requested improvements to OPPIN in November 2006, but requests to modify OPPIN are often not granted due to competing demands and because OPPIN will be retired in September 2008. It is unclear the extent to which the new information management system, PRISM, will address the needs of product reregistration.

In its FY2007 reregistration work plan, SRRD allocates eight percent of its resources (full-time equivalent (FTE)) to product reregistration. This allocation is roughly equivalent to past staffing levels and SRRD expects the staffing level to remain fairly constant in the short term. SRRD intends to allocate funds to product reregistration at roughly the same level through FY2013. SRRD has predicted that it will complete product reregistration by the end of the 2012 calendar year.

Based on data provided by EPA, Abt Associates developed a conservative estimate as to when it believes OPP might complete product reregistration, assuming that the current level of activity and resource allocation continue. We estimate that product reregistration may not be completed for more than twelve years, or the end of FY2018. This is six years longer than EPA's current prediction, and five years longer than the period for which EPA has budgeted.

External Entities or Considerations

Two divisions of the Office of Pesticide Programs (SRRD and RD) are generally responsible for reregistering conventional pesticide products. However, other divisions participate in the effort, including the Field and External Affairs Division (FEAD) and the Information Technology and Resource Management Division (ITRMD). Both FEAD and the Office of Prevention, Pesticides,

and Toxic Substances Regulatory Coordination Staff participate in the preparation of DCI justification packages and facilitate communication with OMB. FEAD recently developed a streamlined template for the package to improve the process. FEAD also provides scientific and technical staff support to SRRD. ITRMD is responsible for information technology and management. ITRMD receives and responds to requests for data systems improvement, such as those to OPPIN. The science divisions also provide some support for product reregistration, as needed.

The Office of Management and Budget (OMB) reviews and approves DCI justification packages. This review period varies in length and often results in EPA responding to several rounds of questions and issues raised by OMB. A new OMB desk officer was recently assigned to pesticide DCI approvals, so the timeline and procedures for the review of DCI justification packages may change. As needed, the U.S. Department of Agriculture and other federal agencies consult on product reregistration issues.

Finally, the pesticide registrants play a key role in product reregistration and are also a significant source of delay. In response to a DCI, registrants provide both ninety-day and eight-month responses, which include amended labels, waiver requests, and requested studies. In addition to the time provided for response, additional time is required when registrants submit deficient studies that have to be repeated/upgraded. Also, the review of this material and the communication with the registrant consume a significant portion of OPP's time as well.

Recommendations to Streamline or Modify Product Reregistration

The reregistration program has evolved over time and in response to significant policy changes, including the Food Quality Protection Act, Pesticide Registration Improvement Act, and the public participation program. The pesticide reregistration program is required under the Federal Insecticide, Fungicide, Rodenticide Act, but the process is not codified in regulation. Although this arguably has its down sides, for purposes of this evaluation it means that EPA has the flexibility to modify and improve the process to better meet its desired outcomes.

Internally, OPP initiated a dialogue to improve the product reregistration program, including developing a "SWAT Team" approach to expedite product reregistration. In addition, recent management attention has raised the visibility of product reregistration in both RD and SRRD. Based on the results of the evaluation, the following recommendations are presented to further expedite product reregistration and/or implement RED-specified mitigation more quickly:

Recommendations of the Evaluation Team
RED Development
▪ Improve the Transition of Chemical Cases from Reregistration Branches to PRB ▪ Require More Participation by RD in the Development of Label Tables
Implementation of RED-Specified Mitigation
▪ Implement Mitigation in an Expedited Manner When Cost-Effective ▪ Pursue Additional Regulatory Action When Warranted ▪ Further Explore Self-Certified or Electronic Labels
DCI Justifications and Preparation
▪ Ensure that DCIs Are Prepared According to the Package Template ▪ Modify Format of Supporting Data in Risk Assessments
Streamlined Data Requirements
▪ Conduct Additional Analyses to Determine Value of Product-Specific Data ▪ Leverage Related Efforts for Process Improvements ▪ Expand Scope of Batching Approaches to Reduce Number of Requested Studies ▪ Encourage Use of Self-Certified Product Chemistry Data
Registrant Responses
▪ Create Incentives for Registrants to Provide Expedited Responses ▪ Establish Procedures and Pursue Suspensions ▪ Retain Data Review Functions within PRB
Label Reviews and the Role of the Registration Division
▪ Discontinue Label Assessments within SRRD ▪ Improve Transition of Chemical Cases from SRRD to RD
Management, Resources, and Staffing
▪ Reevaluate Allocation of SRRD Resources ▪ Maintain Emphasis on Product Reregistration ▪ Pursue SWAT Teams and Other Strategies to Reduce Backlog ▪ Obtain Support for DCI Preparation
Communication
▪ Improve Internal and External Communication about Product Reregistration
Performance Management
▪ Improve Performance Measures and Strategic Targets ▪ Incorporate Product Reregistration into PARS
Information Management
▪ Continue to Prioritize an Integrated Tracking System ▪ Maintain Web Site as a Repository of Reregistration Decisions

These recommendations are discussed in detail in the body of the report, including applicable pros and cons for each.

1. Introduction

To ensure the safety of older pesticides, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) amendments of 1988 required the U.S. Environmental Protection Agency (EPA) to conduct a comprehensive review of pesticides initially registered before November 1, 1984. Through its pesticide reregistration process, the EPA Office of Pesticide Programs (OPP) ensures that older pesticides meet contemporary health and safety standards and labeling requirements. Reregistration includes approximately 600 active ingredient cases and more than 20,000 pesticide products that contain these active ingredients.

The reregistration process is composed of several steps. After the registrant signals its intent to reregister a pesticide, OPP conducts science reviews, develops a risk assessment and publishes it for public comment, and issues a Reregistration Eligibility Decision RED). After OPP publishes a RED, it then must reregister each of the individual pesticide products that contain the active ingredient. This final step in the process – pesticide product reregistration – is the focus of this evaluation.

1.1 Purpose and Evaluation Questions

Risk assessments and mitigation requirements are incorporated in Reregistration Eligibility Decision documents (REDs) for each active ingredient; however, the mitigation for that active ingredient is not implemented in the field until the individual product labels have been changed. This is accomplished through the product reregistration process that follows the completion of the RED, a process that often spans several years and thus prolongs the implementation of environmentally protective measures specified in REDs. In addition, the recent signature of the REDs for food use pesticides will next require OPP to reregister thousands of individual products. For these and other reasons, there is considerable interest within EPA to streamline and expedite the product reregistration process.

The purpose of this evaluation is to identify potential opportunities for innovation and streamlining of the product reregistration process in order to:

- Ensure timelier implementation of the mitigation measures specified in the RED, and
- Make the process as efficient as possible in order to decrease the amount of time needed for product reregistration and use resources in the most effective manner.

In order to focus the evaluation and establish a clear goal, Abt Associates and EPA identified several specific questions regarding the product reregistration process that were of particular interest. This evaluation was designed to provide the answers to the following questions:

1. What components of REDs have caused delays in product reregistration?
2. What problems, bottlenecks, or unnecessary duplication of efforts occur in the product reregistration process that are under the control of OPP?

3. What innovations or streamlining in process could result in more timely implementation of mitigation specified in the RED and/or more efficient production of outputs?
4. What are the pros and cons of each of the proposed innovations or streamlining measures?
5. What is the optimal allocation of tasks between the Special Review and Reregistration Division and the Registration Division?
6. Are any external entities or considerations impeding the product reregistration process?

1.2 Evaluation Audience

The findings, conclusions, and recommendations of this process evaluation will be of interest largely to the individuals responsible for or who participate in the pesticide product reregistration process. Thus, the primary audiences for this report are EPA managers and staff who will use the results of the evaluation as a management tool to identify issues related to the current process, including the extent/nature of the problems and possible modifications to the product reregistration process. The findings may further serve as a catalyst for innovation within the program, which will increase efficiency and reduce the product reregistration backlog, beyond the scope of what is recommended in this report.

Please note that due to the nature of the evaluation and the information contained within this report, this report and its supporting documentation is considered internal, EPA deliberative material, and therefore should not be cited, quoted, or distributed outside the Office of Pesticide Programs or the Office of Policy, Economics and Innovation unless otherwise approved by both the management of the Office of Pesticide Programs and the EPA Work Assignment Manager, Yvonne Watson.

1.3 Program Description

Product Reregistration for conventional pesticides is largely the responsibility of the EPA Office of Pesticide Programs (OPP) Special Review and Reregistration Division (SRRD), although the final end products – reregistration notices and stamped labels – are dependent upon the Registration Division (RD). In addition to product reregistration, SRRD is also responsible for reregistration eligibility decisions, tolerance reassessments, and special reviews. Reregistration of antimicrobial pesticides or biopesticides is the responsibility of the Antimicrobials Division (AD) and Biopesticides and Pollution Prevention Division (BPPD), respectively. This evaluation focuses only on conventional pesticide products because of the limited time and resources available and because conventional products are most common.

1.3.1 Statutory Framework

The Federal Insecticide, Fungicide, and Rodenticide Act, or FIFRA, as amended in 1988, authorized EPA to conduct a comprehensive pesticide reregistration program. Reregistration involves a complete review of the human health and environmental effects of older pesticides

originally registered before November 1, 1984. The reregistration process is finite and will conclude when all pesticides registered prior to November 1, 1984, have been reregistered (or cancelled). The reregistration requirements of FIFRA are not codified by rulemaking.

FIFRA specified five stages of reregistration and included provisions for collection of reregistration fees. Product reregistration is considered part of phase five, data review and reregistration (FIFRA section 4(b)). According to FIFRA section 4(g)(2)(b):

- Before reregistering a pesticide, EPA shall obtain any needed product-specific data regarding the pesticide and shall review such data within ninety days after its submission.
- EPA shall require that the data be submitted not later than eight months after a determination of eligibility has been made for each active ingredient of the pesticide, unless a longer period is required for the generation of the data (no more than two additional years).
- After reviewing its active ingredient(s) and product-specific data, EPA shall determine whether to reregister a pesticide. If eligible to be reregistered, EPA shall reregister such pesticide within six months after the submission of the product-specific data.

The Pesticide Registration Improvement Act (PRIA) of 2003 established pesticide registration service fees for registration actions. It also included specific deadlines for completion of specific aspects of the reregistration process:

- Complete all REDs for food-use pesticides by August 3, 2006
- Complete all REDs for non-food-use pesticides by October 3, 2008

EPA met its deadline to complete the 231 REDs for food-use pesticides, with the exception of aldicarb.[1] PRIA did not provide deadlines for completion of product reregistration.

Pesticides with food uses must meet the safety standards of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996. EPA must determine that pesticide residues remaining in or on food are safe. As amended by FQPA, FFDCA requires the reassessment of all existing tolerances (pesticide residue limits in or on food).

FQPA also amended FIFRA to require periodic review of pesticide registrations to ensure that all pesticides continue to meet statutory and policy standards over time. FIFRA section 3(g) specifies that EPA establish procedural regulations for conducting registration review on a fifteen-year cycle. This regulatory scheme, called registration review, was proposed for public comment in July 2005[2] and the EPA Administrator signed the final action on August 1, 2006.[3]

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[1] EPA Press Release, "U.S. Pesticide Safety Highest in the World," August 1, 2006, http://www.epa.gov/newsroom/

[2] 40 CFR part 155, Procedural Regulations for Registration Review, Proposed Rule, 70 FR 40251, July 13, 2005

EPA designed the program to address lessons learned from reregistration, including predictable schedules, sound science, transparency and public participation, flexibility, early stakeholder involvement, and using a docket system.[4]

1.3.2 Product Reregistration Process

Pesticides that meet current scientific and regulatory standards may be declared "eligible" for reregistration. To be eligible, an older pesticide must have a substantially complete database, and must not cause unreasonable adverse effects to human health or the environment when used according to EPA-approved label directions and precautions. EPA publishes its reregistration eligibility decision in one of two document types:

- REDs, or Reregistration Eligibility Decisions, for pesticides that have sufficient supporting data and whose risks can be successfully mitigated.
- IREDs, or Interim Reregistration Eligibility Decisions, for pesticides that are undergoing reregistration, require a reregistration eligibility decision, and also must be included in a cumulative assessment under the Food Quality Protection Act (FQPA) of 1996 because they are part of a group of pesticides that share a common mechanism of toxicity.

For pesticides that require tolerance reassessment decisions under FFDCA, but do not require a reregistration eligibility decision, or where the RED was completed prior to the passage of FQPA (1996), EPA publishes a Report on FQPA Tolerance Reassessment Eligibility Decision (TRED).

After EPA declares a pesticide reregistration case conditionally eligible for reregistration (the condition being that RED-specified mitigation is incorporated on the label), the individual end-use products that contain the active ingredient must be reregistered. This concluding part of the reregistration process is called "product reregistration." Product reregistration consists of three basic steps (Figure 1-1):

1. After issuing a RED for an active ingredient, SRRD sends registrants a Data Call-In (DCI) notice requesting any product-specific data needed to complete reregistration for each of the individual pesticide products covered by the RED.

2. SRRD receives and evaluates the requested studies from the registrants. It requests additional information, as needed, and conducts a preliminary label assessment.

3. Based on its review of the data and labeling, RD reregisters a product if it was found to meet FIFRA and FFDCA standards. The primary output of this step is a reregistration notice (issued to the registrant) and the stamped pesticide label, which includes any revised mitigation specified in the RED or during the product reregistration process.

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[3] 40 CFR part 155, Procedural Regulations for Registration Review, Final Rule, 71 FR 45719, August 9, 2006

[4] "Compare Registration Review to Reregistration," Presentation by Susan Lewis, Special Review and Reregistration Division

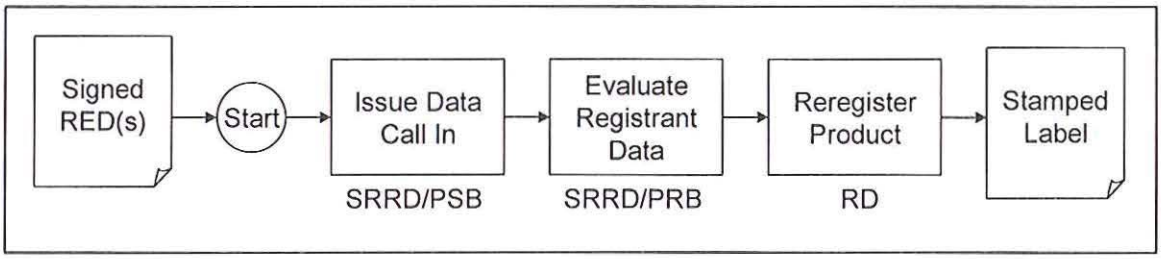


Figure 1-1. Overview of Product Reregistration Process. *(Source: OPP Enterprise Architecture Process Description: Special Review and Reregistration Division Product Reregistration, SRA)*

Issue Data Call-in

After a RED is signed, EPA collects both product-specific data and confirmatory data on the active ingredient as identified in the RED. EPA requests this information through Data Call-ins (DCIs) that are approved by the Office of Management and Budget (OMB) and then issued by EPA to the pesticide registrants. DCIs may either be generic (for confirmatory data) or product-specific (PDCIs). The Program Support Branch in SRRD is responsible for preparing the DCIs.

Evaluate Registrant Data

Registrants must respond to a DCI to indicate whether or not they intend to support a product within ninety days of issuance. If the product will not be supported, EPA publishes a cancellation notice in the *Federal Register*. If a registrant does not respond to the DCI, EPA has the option to initiate a suspension of the registration. Registrants continuing to support a product must submit study data to EPA within eight months of the DCI being issued. The Information Technology and Resource Management Division/Information Services Branch (ITRMD/ISB) reviews the study format, assigns a record number, and sends the studies to the Chemical Review Manager (CRM) in SRRD Product Reregistration Branch (PRB).

The SRRD CRM coordinates and tracks all activities and communication with the registrant. Product chemistry and acute toxicology studies are evaluated within PRB. If a study contains efficacy data, RD conducts the evaluation since PRB does not have in-house expertise in that area. If a study contains deficiencies, the CRM notifies the registrant and requests a corrected study. After all data have been reviewed, PRB conducts a label assessment and then sends the required documentation to RD for a label review and reregistration decision.

Reregister Product

Once RD receives the product reregistration package, the Product Manager (PM) reviews it for completeness and requests any missing data from PRB. In most cases, the label submitted by the registrant with the original reregistration submission is no longer current, so RD requests an updated label from the registrant. Any package inaccuracies are corrected at this time.

Once the amended label has been provided and is acceptable, RD develops a reregistration notice. If a product contains multiple active ingredients, EPA instead issues an amendment to the product's registration; a product with multiple active ingredients is not reregistered until the last active ingredient in its formulation is eligible for reregistration and its label has been

amended. The registrant receives a reregistration notice and a copy of the stamped label. The label is recorded in Pesticide Product Label System (PPLS), which is available on the OPP Web site. This concludes the product reregistration process.

For more information on the product reregistration process, please refer to "OPP Enterprise Architecture Process Description: Special Review and Reregistration Division Product Reregistration," SRA International, September 29, 2005.

1.3.3 Roles in the Product Reregistration Process

This section provides a brief overview of the key OPP divisions that play a role in product reregistration. Other OPP divisions sometimes contribute to product reregistration, as needed and/or requested.

Special Review and Reregistration Division (SRRD) is responsible for pesticide reregistration, tolerance reassessment, and registration review for conventional chemical pesticides.

- Reregistration Branches write the REDs, process confirmatory data on an active ingredient that are submitted in response to a DCI, and address post-RED issues.
- Program Support Branch (PSB) is responsible for preparing DCI justification packages and issuing DCIs.
- Product Reregistration Branch (PRB) tracks ninety-day and eight-month responses to product-specific data call-ins, processes product guidelines and identifies deficiencies, communicates with the registrant, conducts label assessments, and processes packages for RD.

Registration Division (RD) is responsible for product registrations, amendments, registrations, tolerances, experimental use permits, and emergency exemptions for conventional chemical pesticides. With respect to product reregistration, RD conducts label reviews, requests additional label changes (as needed), sends reregistration notices, and stamps (approves) labels.

Information Technology and Resources Management Division (ITRMD) is responsible for information support, dockets, the OPP Web site, computer support, budget, and personnel. With respect to product reregistration, ITRMD receives and processes the ninety-day and eight-month submissions and supports some of the information management databases (e.g., OPPIN).

Field and External Affairs Division (FEAD) is responsible for program policies and regulations; legislation and congressional interaction; regional, state, and tribal coordination and assistance; international and field programs; and communication and outreach activities. With respect to product reregistration, FEAD reviews the DCI justification package and facilitates communication with OMB and other federal agencies.

1.3.4 Product Reregistration Program Logic Model

The evaluation questions (see Section 1.1) were considered relative to the logic model for the pesticide product reregistration program (Figure 1-2). A logic model is a visual, systematic way to represent how a program works by illustrating the relationships between a program's resources, activities, outputs, and short-term, intermediate, and long-term outcomes. The model highlights the key connections between program components and outcomes, as well as providing some context in which the program operates.

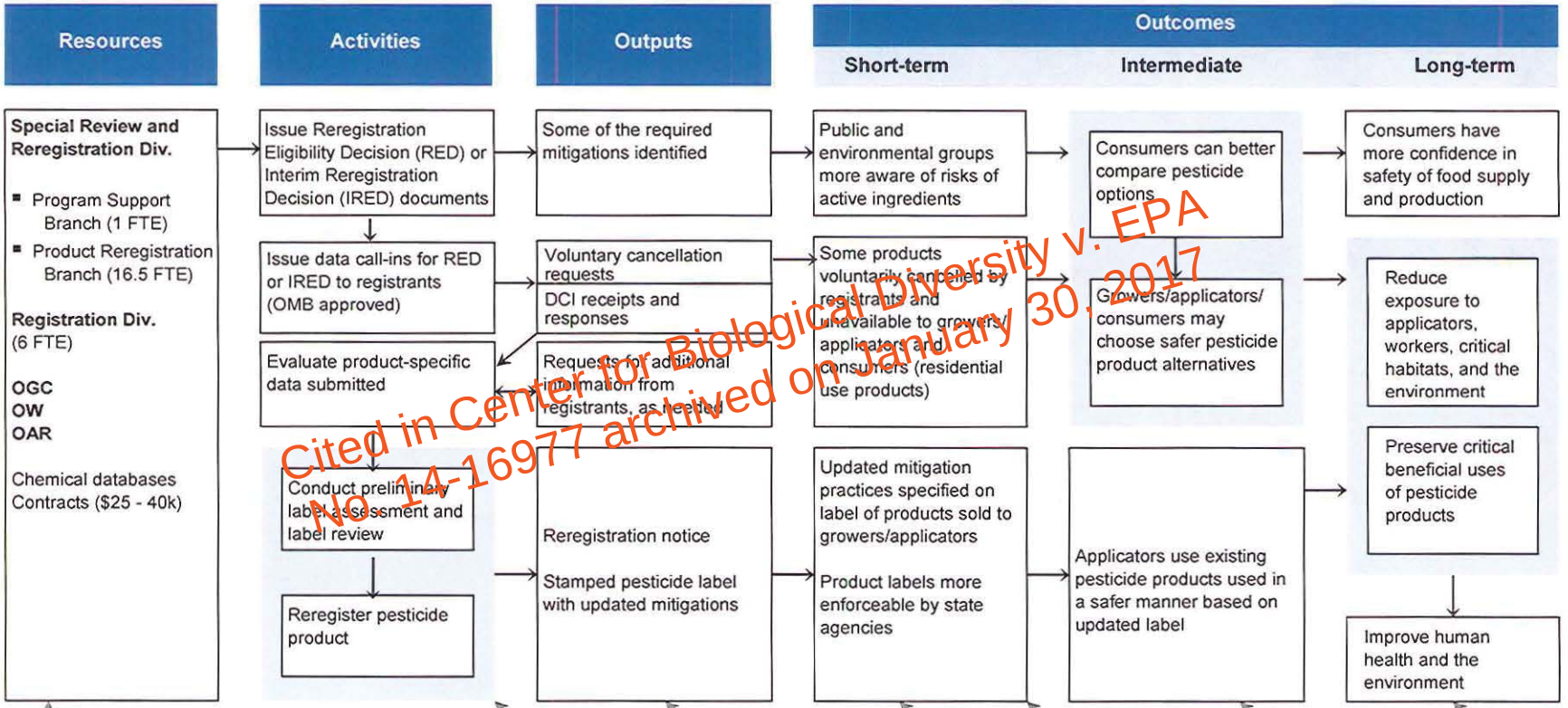
The program's logic model illustrates several key considerations regarding the product reregistration process:

- Issuing the RED does not directly result in mitigations appearing on the label. That is, the program cannot achieve its short-term outcome (updated mitigation practices specified on label of products sold to growers/applicators) until the completion of the entire product reregistration process.
- Product reregistration relies upon registrant-submitted data and receiving that data in a timely manner.
- OPP often has to request additional information from the registrant as it evaluates product-specific data, which results in delays as OPP requests data, the registrant develops the data, and OPP tracks and reviews (or re-reviews) additional submissions.
- Seven entities consult or participate in the product reregistration process, which removes aspects from the direct control of OPP. These organizations include other parts of EPA, other federal agencies, and the pesticide registrants (see "Partners that Consult or Participate").
- Several external factors affect program effectiveness, which influence resources, activities, outputs, and outcomes. These factors affect OPP's regulatory responsibilities, its priorities, the timeliness of information provided, and the resources available to complete product reregistration.
- Product reregistration has a variety of customers with different interests, concerns, and incentives.

Figure 1-2. Logic Model: U.S. EPA Office of Pesticide Programs Product Reregistration

Mission

To improve human and environmental health by ensuring older pesticide products are safe and to effectively manage and mitigate risk based on the best available science. The product reregistration program fulfills this mission by reviewing older pesticide products under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to ensure they meet current scientific and regulatory standards.



Partners that Consult or Participate

- Office of Management and Budget
- U.S. Department of Agriculture
- Regulatory Coordination Staff (EPA OPPTS)
- Field and External Affairs Division (EPA OPP)
- Information Technology and Resource Management Division /Information Services Branch
- Other Federal Agencies (FWS, NMFS, FDA)
- Pesticide Registrants

External Factors Affecting Program Effectiveness

- Oversight of Office of Management and Budget
- Responsiveness of Pesticide Registrants
- Level of budget allocation
- Implications of new legislation and regulations
- FIFRA Scientific Advisory Panel recommendations
- North American Free Trade Agreement requirements
- European Commission regulatory decisions

Customers

Pesticide Registrants develop and produce products

Growers/Applicators purchase, apply, and use products

Agricultural Workers work in areas where products are applied

Environmental Groups advocate a position and raise awareness of environmental issues to the public

General Public use residential products and consume food and other commodities that are treated with pesticides

State Agencies enforce pesticide labels

1.4 Review of Related Evaluations

Numerous entities have commented on reregistration and its shortcomings, though none have focused exclusively on product reregistration. Nonetheless, reviews conducted by the Government Accounting Office (now called the Government Accountability Office), the EPA Office of Inspector General, the Office of Management and Budget, and other entities illustrate the depth of the issues explored later in this report, as well as the striking similarities and marked differences between product reregistration and reregistration generally. In addition, OPP itself has also commented publicly on product reregistration, including in the recent rulemaking for its registration review program.

1.4.1 Funding and Accountability

In 1996, the Congressional Research Service (CRS) reviewed the Food Quality Protection Act, including reregistration and its related funding issues.[5] Reregistration is financed through a combination of appropriated funds and registration "maintenance" fees paid by pesticide registrants. EPA maintains that fee collections have been lower and costs higher than originally anticipated, and as a result maintenance fees have been extended. Pesticide registrants contend that historical funding levels had been adequate, and they questioned whether EPA had managed funds efficiently. One reason for higher than expected costs and reregistration delays has been late and deficient reregistration package submissions, according to EPA, and these problems are being addressed.

EPA requires manufacturers applying to register or reregister a pesticide to submit reports of scientific studies on pesticide toxicity and behavior in the environment. EPA requires that studies conducted by industry conform to EPA standards of scientific quality. Studies that do not meet EPA standards are rejected and must be repeated/upgraded and then reevaluated. Rejected studies contribute to the high cost of registration. While pesticide registrants have argued that EPA's scientific standards are excessive, EPA has insisted that registration decisions should be based on the best available science. Historically, EPA rejected approximately 30 percent of studies submitted. A 1991 analysis of factors contributing to late and deficient study submissions prompted a joint EPA-industry project to improve performance. Because of workshops, guidance, and registrant efforts, the study rejection rate in 1996 was half of what it was in 1993 and many submissions are timelier, according to EPA.

Some have argued that industries have little incentive to submit timely and adequate applications to maintain registrations of older pesticides; while a decision is pending about the safety of the older pesticides, manufacturers may continue to market them.

1.4.2 Reregistration Policy

In 1986, the Natural Resources Defense Council (NRDC) evaluated the reregistration program and related policies.[6] The reregistration process has its roots in the 1972 FIFRA amendments

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[5] CRS Report to Congress: Pesticide Legislation: Food Quality Protection Act of 1996 (P.L. 104-170), 96-759 ENR, September 11, 1996, Linda Jo Schierow, available at http://ncseonline.org/nle/crsreports/pesticides/

[6] "Pesticide Reregistration: An Evaluation of EPA's Progress," Lawrie Mott, Natural Resources Defense Council, San Francisco, California, April 3, 1986

and in its 1986 report NRDC noted, "until recently reregistration was not even a high priority within EPA's pesticide program." Of NRDC's three key findings, one is particularly relevant to the premise of this evaluation: reregistration has not been expeditious. Two of the corresponding recommendations include:

- EPA should immediately issue final regulations establishing procedures for reregistration. Further, NRDC noted, "Without final regulations, EPA's reregistration program is operating on an ad hoc basis. Furthermore, absent a regulatory framework, the public cannot readily follow EPA's process."
- EPA should institute biannual public reports that identify which pesticides have been reregistered, etc. The public has no simple way to determine which pesticides have been reregistered.

Similarly, the Administrative Conference of the United States recommended that EPA adopt, whenever possible, rules setting clear standards for pesticide reregistration data and should communicate those standards to registrants.[7] In 2000, the EPA Office of Inspector General (OIG) concluded that EPA did not consider regulation development a high priority since the pesticide statutes are very prescriptive and the program is highly centralized.[8]

As it developed its registration review program, EPA and industry considered the shortcomings of its reregistration program.[9] In response to its proposal, industry commented that EPA should not implement registration review of end-use products until it fixes the problems with the review of end-use products in reregistration. Registration review and reregistration are likely to be similar and registration review might duplicate the effort of reregistration, especially when a product may undergo product-specific review several times. The commenters were concerned that if EPA does not achieve efficiencies in the review of end-use products, the fifteen-year registration review will extend to forty years.

In response, EPA stated that it expects reregistration to satisfy most product-specific data requirements and achieve many label improvements for end-use products. Although EPA does not expect it will routinely require product-specific data during registration review, it expects that registration review will be an important vehicle for the continuing update of labels. EPA agreed that the review of end-use product labels could benefit from process improvements, and that registrants and other stakeholders can help develop approaches to make this process more efficient.

1.4.3 Information Management

As early as 1980, GAO auditors determined that EPA was behind schedule, lacked a tracking system to identify problems, did not have a formal operating procedure for reregistration, and had not adequately monitored its overall progress in the reregistration program.[10] In 1991, GAO reported on the lengthy delays associated with reregistering pesticides and that such delays

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[7] Recommendations of the Administrative Conference of the United States, 1 CFR part 305, Recommendation 93-5, Procedures for Regulation of Pesticides

[8] Pesticides: Follow-up Report on EPA's Pesticide Program, Report No. 00P00011, March 27,2000, EPA Office of Inspector General

[9] Pesticides; Procedural Regulations for Registration Review, Final Rule, 71 FR 45719, August 9, 2006

[10] Delays and Unresolved Issues Plague New Pesticide Protection Programs, GAO, 1980

stem, in part, from the inadequate support provided by EPA's information systems for reregistering pesticides.[11]

In 1992, GAO reported that after having invested $14 million over three years in data systems development, EPA could not easily assemble accurate, reliable, and complete information on chemicals in its reregistration process.[12] GAO concluded that these information management problems resulted from inadequate systems planning and poor data management. In addition, OPP employed nine separate data base systems to track or manage information about chemicals pending reregistration. Each of these data systems was designed and developed separately without taking into account a way of using them jointly. EPA staff entered information about pesticide studies numerous times into different systems, and data compilation is labor intensive and time consuming.

In 2000, the EPA Office of Inspector General (OIG) published a follow-up report to its 1994 evaluation of the pesticide program.[13] OIG found that the OPP Information Network (OPPIN) had been designed to address most of its information management concerns, but some of the original concerns still exist. OIG noted that OPP had not completed actions to improve information systems that contain inaccurate, incomplete, and duplicate data or that are not integrated.

1.4.4 Performance Management

In FY2005, the Office of Management and Budget (OMB) evaluated the reregistration program using its Program Assessment Rating Tool (PART).[14] The FY2005 Program Assessment indicated that the program was "adequate," and included the following conclusions:

- There is no evidence to indicate that a different program design would be more effective or efficient than what is currently used. The 1996 FQPA changes added clarity to science reviews and introduced higher visibility deadlines, which forced increase effectiveness.
- To help ensure the program is effectively targeted, statues establish criteria for prioritizing reregistration activities and sets specific deadlines and timelines for completion.
- The annual goals are output measures but are acceptable because it is a process-oriented licensing program that results in "products" (i.e., reregistrations).
- The annual output goals reflect activity required to meet statutorily required completion dates. The program did have difficulty meeting annual targets in the past, leading to changes in the statutorily required dates. The targets and baselines for the output measures are adequate.

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[11] Pesticides: EPA's Information Systems Provide Inadequate Support for Reregistration, GAO/T-IMTEC-92-3, October 30, 1991

[12] Pesticides: EPA's Information Systems Provide Inadequate Support for Reregistration, GAO/IMTEC-92-3, October 30, 1991. Pesticides: Information Systems Improvements Essential for EPA's Reregistration Efforts, GAO/IMTEC-93-5, November 23, 1992.

[13] Pesticides: Follow-up Report on EPA's Pesticide Program, Report No. 00P00011, March 27,2000, EPA Office of Inspector General

[14] "Program Assessment: Pesticide Reregistration," expectmore.gov, accessed on July 11, 2006.

- The program uses multiple electronic methods to track information on the progress of reregistration actions and reports on the progress of activities are provided to program management weekly. OPPIN is a central database used to track activity, and it stores history that is easily retrievable.

A performance measure for pesticide product reregistrations was not included in PART, nor was product reregistration considered explicitly when evaluating the reregistration program.

In August 2006, the EPA Office of Inspector General (OIG) issued a critique of the Food Quality Protection Act.[15] OIG commented that although EPA has made progress in implementing the requirements of the FQPA, OPP has primarily measured its success and the impact of FQPA by adherence to its reregistration schedule rather than by reductions in risk to children's health. For FY2005, OPP used the following output measures to assess programs:

- Cumulative percentage of REDs completed
- Number of product reregistrations

OIG commented that the measures used by OPP generally indicate actions taken, instead of environmental or human health outcomes achieved. It concluded that OPP lacks outcome measures to assess the specific impact of those actions on the health of children and others.

1.5 Organization of Report

This report is composed of eight main chapters.

Chapter 1, Introduction, identifies the purpose of the evaluation and its audience, as well as key questions that will be answered. This section also includes a description of the program and a review of related evaluations.

Chapter 2, Methods, summarizes the approach for conducting the evaluation, and is based on the EPA-approved methodology.

Chapter 3, Progress on Product Reregistration, assesses the status of product reregistration and summarizes the duration of the processes.

Chapter 4, Reregistration Eligibility Decisions, discusses the issues associated with this part of the reregistration process that impact product reregistration. This section also discusses three case studies and alternative strategies used by EPA to implement mitigation.

Chapter 5, DCI Justifications and Preparation, addresses the current process for preparation and mail out of the generic and product-specific data call-ins by EPA and approval by the Office of Management and Budget, as well as associated issues and recent changes.

Chapter 6, Data Requirements and Review, summarizes some of the issues associated with registrant responses to the DCI, discusses an analysis of product-specific acute toxicity and product chemistry data, identifies strategies for batching data requirements, and discusses communication and management issues.

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[15] Measuring the Impact of the Food Quality Protection Act: Challenges and Opportunities EPA Office of the Inspector General, Report No. 2006-P-00028, August 1, 2006, http://www.epa.gov/oig/reports/2006/20060801-2006-P-00028.pdf

Chapter 7, Label Assessments and Reviews, addresses the division of labor between SRRD and RD to revise pesticide product labels, discusses workload and other issues, and summarizes the current strategy to expedite product reregistration.

Chapter 8, Suggested Changes to Process Design and Other Recommendations, discusses the project team's recommendations for modifying specific aspects of the product reregistration process based on its findings presented in Chapters 3 through 8. This chapter also identifies specific areas where EPA may wish to modify its current program to better address product reregistration.

2. Methods

The evaluation of the product reregistration program is a process evaluation, which is defined by the Government Accountability Office (GAO) as one that "assesses the extent to which a program is operating as it was intended. It typically assesses program activities' conformance to statutory and regulatory requirements, program design, and professional standards or customer expectations."[16] Therefore, by design, this evaluation does not seek to determine the extent to which OPP achieves its intended outcomes (for instance, reduced exposure to pesticides) but only the activities that contribute to the outcomes.

In preliminary discussions, OPP identified a number of issues and concerns regarding product reregistration, including information management, the division of labor between SRRD and RD, issues in REDs, and information management. Abt Associates sought to examine these concerns and determine the extent of issues, as applicable, as well as identify other issues. This chapter summarizes the data collection methods, data collection approach, and analysis plan.

For more information on the approach taken for this analysis, please see "Identifying Innovations and Streamlining OPP's Product Reregistration Program: Program Evaluation Methodology," July 24, 2006.

2.1 Data Collection Methods

Abt Associates used a variety of methods to collect the information to answer the six evaluation questions. The data collection largely resulted in qualitative data, which we supplemented with quantitative data as needed and as available. Each data collection method used is described below along with the evaluation question(s) it helped answer. Limitations to each approach are identified. The following table summarizes each of the collection methods and the evaluation questions to which they will be applied (Table 2-1).

Table 2-1. Summary of Data Collection Methods

Evaluation Question	Data Collection Method				
	Interviews	Document Review	Program Data	Case Studies	Subject Expert
What components of REDs have caused delays in product reregistration?	•	•		•	•
What problems, bottlenecks, or unnecessary duplication of efforts occur in the product reregistration process that are under the control of OPP?	•	•			•
What innovations or streamlining in process could result in more timely implementation of mitigation specified in the RED and/or more efficient production of outputs?	•	•	•	•	•

[16] U.S. Government Accountability Office, "Performance Measurement and Evaluation: Definitions and Relationships," GAO-05-739SP, May 2005.

Evaluation Question	Data Collection Method				
	Interviews	Document Review	Program Data	Case Studies	Subject Expert
What are the pros and cons of each of the proposed innovations or streamlining measures?			•		•
What is the optimal allocation of tasks between the Special Review and Reregistration Division and the Registration Division?	•				•
Are any external entities or considerations impeding the product reregistration process?	•				•

The information collection activities above are governed by requirements under the Paperwork Reduction Act (PRA). Under PRA, EPA's information collection is limited to nine or fewer non-federal individuals or entities. Requests for similar information and/or similar questions must be limited to nine or fewer non-federal respondents. This evaluation was conducted in compliance with the PRA and other OMB rules on information collection requests.

Interviews

Abt Associates conducted a series of open-ended interviews (i.e., with no pre-determined response options) with numerous EPA staff. These individuals were accessible, have an interest in the results of the evaluation, and have a thorough understanding of the product reregistration process and its issues. In each interview, we characterized an individual's role in the reregistration process and solicited his/her perspective on the process in its entirety. Interviews with management focused more on the overall process, as well as the information flow between OPP divisions. Specific questions were prepared in advance of the interviews to ensure coverage of issues and to manage time (Appendix A).

Interview responses and comments are not referenced/attributed to specific individuals in this report or related discussions and presentations. A list of individuals interviewed or consulted is appended to this report (Appendix B). We believe that this approach increased the honesty of the answers and opinions provided in the interviews. All interviews were audio-recorded (with the permission of the interviewee), and the tapes were used to clarify issues and confirm the evaluator's notes.

This method of data collection was consistent with the statement of work, and also provided the opportunity to identify issues, solicit explanatory information, and understand the general functioning of the product reregistration program. This was appropriate given the process-improvement focus of the evaluation. Abt Associates sought to supplement the information gained in interviews with reregistration status, performance, and tracking data (where available), published documents, and additional information from OPP staff.

Although the perspectives of the registrants and the Office of Management and Budget (OMB) would be a helpful addition to this data collection, we limited our contact to EPA staff because of the limited time and resources available to complete this evaluation. However, in the document review and reregistration program data sections that follow, we identify sources from which we

obtained both published information on the roles of these two groups and their perspectives on product reregistration.

Document Review

Published documents available from EPA, the Government Accountability Office (GAO), the Office of Management and Budget (OMB), industry associations, and environmental groups served as another data source. Abt Associates reviewed these documents to determine the documented issues of reregistration, how reregistration is presented to the registrants and the general public, and how other external auditors perceive the program. These data sources were reviewed and cited, as appropriate, in Chapter 1 to summarize how reregistration has been characterized and/or criticized in the past.

Other documents informed this evaluation, including program descriptions and procedures. Under contract to EPA, SRA International developed a process flow diagram and accompanying report, which details the product reregistration process and its information management practices.[17] These materials summarize the process and its use, identify data sources and applications, describe execution of the process, estimate its duration, and identify potential improvements. The information management issues identified by SRA International were considered relative to other information collected during the evaluation. Abt Associates also reviewed additional documentation provided by EPA, including management briefings, fact sheets, and example tracking reports. These sources provided a further understanding of the process and areas of improvement.

Reregistration Program Data

Abt Associates used existing program data to characterize progress to date on the number of pesticide products reregistered, to establish the length of time it generally takes to reregister a pesticide product, and to consider the value of proposed data streamlining options.

To better define the problem, Abt Associates reviewed available data to determine progress made to date on product reregistration. The background materials developed by SRA International represent educated guesses and ideal conditions of the product reregistration process. For this evaluation, we sought to document in a verifiable manner the timeframe associated with product reregistration. Because of the estimated burden associated with this collection and the lack of a central data source, Abt Associates relied on information available from (1) the quarterly product reregistration briefing for Jim Jones, Director, Office of Pesticide Programs; (2) data pulls from OPP SRRD staff; and (3) Pesticide Reregistration Performance Measures and Goals for FY2005.[18]

As part of the evaluation, Abt Associates reviewed the draft findings of OPP regarding the added value of acute toxicity and product chemistry reviews on mitigation. EPA initiated this review to determine what mitigation is generally added to a product label during these two reviews compared to that specified in the RED. One possible way to streamline product reregistration would be to eliminate or streamline these two aspects of the process; however,

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[17] SRA International, Inc., Support Documentation, "OPP Enterprise Architecture Process Description Special Review and Reregistration Division (SRRD) Product Reregistration: Support Documentation," Task 4: Baseline & Target Architecture Refinement, Task Order Number 5: OPPT Target Architecture Support, September 29, 2005, Contract Number EP-W-05-024

[18] Pesticide Reregistration Performance Measures and Goals for FY2005, 71 FR 36075, June 23, 2006

OPP had no analysis upon which to base this decision. For the draft analysis, EPA selected a random sample of pesticide products and determined the changes made to the mitigation statements as a result of the two review procedures. Because the original data are considered Confidential Business Information (CBI) and because of the time required to collect the data, OPP initiated this portion of the evaluation internally. Abt Associates reviewed the sampling technique and data collection and commented on the adequacy of the sample size. Abt Associates then audited a subset of acute toxicity data to confirm EPA's results. Because product chemistry data is considered CBI, Abt Associates did not audit those results.

Case Studies

EPA requested two types of case studies for evaluation – pesticides for which problems with the RED caused delays in reregistration and pesticides for which reregistration was expedited through Memoranda of Agreement (MOAs). These cases allowed Abt Associates to consider selected pesticides in a more in-depth manner to identify issues and possible solutions. This approach would have been far too resource intensive to complete for all active ingredients. However, this data collection method allowed us to highlight and/or validate perceived successes and failures of the product reregistration program. In order to complete the case studies, we relied on other data collection methods identified in this section, including interviews and document reviews.

By completing the RED case studies, we determined what problems in the REDs caused delays in product reregistration. With this information, OPP may be better informed and could change its procedures to avoid future issues. For the case studies of active ingredients for which an MOA was signed, these case studies illustrated one way that EPA tried to implement mitigation on the label in a timelier manner. The purpose of these studies was to inform recommendations on streamlining the product reregistration process, if possible, but without going to the effort of completing an MOA for each active ingredient. In addition, we considered products for which reregistration was streamlined, such as 2,4-D, by batching data requirements, to determine if this case could be used as a model.

Subject Matter Expert

As Abt Associates planned for the evaluation and developed the methodology, SRRD management provided assistance. Management identified background information and materials, answered questions, and clarified issues or concerns. This feedback allowed Abt Associates to understand issues regarding the product reregistration program prior to collecting information, and helped shape the evaluation questions and the development of the logic model.

This data source is particularly useful when the individual has a unique skill or professional background related to the issue being evaluated that helps the evaluator to better understand the issue and project participants. It is also useful given the internal, process-related orientation of the program evaluation. To ensure that the biases and opinions of a subject matter expert do not influence the data obtained or the conclusions made, Abt Associates challenged assumptions, collected supporting evidence, and/or identified counter-opinions or views.

Similarly, staff from the EPA Office of Policy, Economics, and Innovation served as a resource on evaluation design and implementation, in addition to administering the project.

2.2 Data Collection Approach

This section summarizes how Abt Associates applied each of the above data sources/collection methods to answer the evaluation questions. The data collection largely relied on interviews with OPP staff and managers, which allowed us to gain a full understanding of the product reregistration process and ways in which it could be improved or streamlined. We identified specific areas on which to focus, based on the evaluation questions, a review of background documents, and preliminary conversations with EPA staff.

Problems in REDs (Evaluation Questions 1 and 2)

Abt Associates collected and reviewed information for three case studies on REDs that caused delays in product reregistration: dicofol, captan, and the rodenticide cluster. These cases were selected because EPA is aware of issues with the RED that caused delays in product reregistration. Abt Associates could not make this selection independently, as it requires internal program knowledge and judgment. As the step immediately preceding product reregistration, the RED plays an important role in the information available for product reregistration. In the course of the evaluation, Abt Associates determined how often REDs cause issues in product reregistration by interviewing OPP management and chemical review managers. This review provided perspective for the sample selected for the evaluation.

Abt Associates reviewed RED documentation to become familiar with its contents and conclusions prior to meeting with OPP staff. Because REDs for food-use active ingredients were completed in August 2006, the extent to which RED-associated issues may be addressed in the future is limited. Thus, this part of the evaluation largely documents historical issues that may influence upcoming project work.

Implementation of RED-specified Mitigation (Evaluation Question 3)

Abt Associates reviewed information for two Memoranda of Agreement (MOAs) that allowed mitigation specified in the RED to appear on the label prior to the completion of product reregistration: chlorpyrifos and phosmet. These cases were selected because they are two of approximately ten instances in which EPA signed an MOA to expedite revising labels with mitigation. These set the precedent for implementing RED-specified mitigation prior to the completion of product reregistration and may serve as a model for a voluntary program in the future. Further, these two cases were selected because information is available both in the record and by interviewing staff who participated in the process. Both are organophosphate pesticides. Chlorpyrifos posed serious health risks and revised mitigation was placed on the label within a quick timeframe. Phosmet reregistration is ongoing and highlights the complexity of the issues and the considerations of the product reregistration program.

Abt Associates reviewed the MOA documentation to become familiar with its contents and conclusions prior to meeting with OPP staff. Abt Associates also considered the profile of each of the cases, the level of mitigation specified by the RED, and the number of products impacted. Similarly, OPP initiated a pilot project that uses the MOA as a model for implementing mitigation (propanil). The goal was to have registrants revise the label with the RED-specified mitigation prior to the completion of product reregistration. Abt Associates reviewed available information on propanil and interviewed staff about the success of the approach.

Data Requirements: Batching (Evaluation Questions 2, 3, and 4)

Abt Associates considered the case of 2,4-D as a model for how products may be further batched. Batching is one potential way to reduce the number of data requirements that the registrant needs to fulfill while still making the information available to EPA, as well as reducing the number of studies that OPP needs to review. We interviewed OPP staff to learn their experience with streamlining acute toxicity data requirements by batching products and using existing information about the products for storage stability.

Data Requirements: Acute Toxicity/Product Chemistry (Evaluation Questions 2, 3, and 4)

In order to determine the impact of product-specific acute toxicity reviews and product chemistry reviews conducted during product reregistration on the product label and confidential statement of formula (CSF), OPP analyzed the changes in product labels that resulted from these reviews over the period of its product reregistration activities. OPP initiated this review to determine what mitigation is generally added to a product label during these two reviews. Abt Associates verified the sampling procedure, assisted in data analysis, and audited a subset of OPP's results.

For more information on the approach for the audit, please see "Results of Audit – Evaluation of Acute Toxicity and Product Chemistry Review Findings," Memorandum to Yvonne Watson and Pete Caulkins, U.S. EPA, from Debra Kemp, Albert Acquaye, and Jason Sacks, Abt Associates Inc., January 30, 2007.

Label Reviews (Evaluation Questions 2, 3, 4, and 5)

As currently designed, the product reregistration process often includes label assessments/reviews by both SRRD and RD, which is perceived as a duplication of effort by some staff members. We determined why RD often conducts an extensive second review and identified possible alternatives through interviews of relevant staff.

In addition, a pilot project was designed to determine if the product reregistration process would be more efficient if SRRD conducted only product chemistry and acute toxicity reviews and if RD alone conducted label reviews. To determine this, both SRRD and RD conducted a label review independently of ziram products and determined if the two were consistent. Ziram was selected for this exercise because its products were in the appropriate stage of product reregistration for this pilot.

Relationship between SRRD and RD (Evaluation Question 5)

Although the responsibility of SRRD, RD contributes significantly to the product reregistration process by reviewing labels, issuing reregistration notices, and stamping revised labels. However, the two groups use different systems and have different management and unique cultures. Thus, through interviews we identified issues with the current division of labor and existing issues and proposed alternative means to divide the work, allocate resources, and communicate process information. Abt Associates first reviewed the product reregistration process flow diagram and relevant standard operating procedures (SOPs). We then interviewed staff and managers in both divisions to determine the current division of labor and any associated issues.

DCI Preparation and OMB Approval Process (Evaluation Question 6)

The preparation of the DCI is the first step in the product reregistration process. Despite approved SOPs, the SRRD contended that the DCI process is time-consuming and often evaluated by OMB against varying standards. OMB's approval of a DCI package was believed to be a source of delay in the product reregistration program. Thus, in this evaluation, Abt Associates explored the DCI preparation process and any associated issues.

Information Management (Evaluation Questions 2, 3, and 4)

One of the conclusions of SRA International was that, "EPA and participants of the product reregistration process could very much use an automated method of tracking the numerous products throughout the process. Currently, all tracking is done manually in PRB and only the CRM has direct access to the tracking data." To further support this conclusion, we considered shortcomings in information management, opportunities for improvement, and historical barriers to these improvements. Abt Associates interviewed SRRD, RD, and other OPP staff regarding product-level tracking for reregistration.

Management/Budget (Evaluation Questions 2, 3, and 4)

Although mandated by statute, OPP historically viewed reregistration (and particularly product reregistration) as less important than registration activities. The need to create SRRD in 1989 to focus specifically on reregistration in part reflects this problem. In addition, pesticide reregistration is a politically sensitive and high profile issue with both industry and environmental groups. Abt Associates interviewed OPP management and staff to identify management priorities, budget issues, and external influences.

Timeline for Product Reregistration (Evaluation Question 2)

The premise of this program evaluation was that product reregistration is a time-intensive and lengthy process. Abt Associates validated this assumption with the data available from OPP management briefings, annual reports, and internal databases.

2.3 Data Analysis

Abt Associates compiled and assessed a variety of information, both qualitative and quantitative in nature. For qualitative information obtained from interviews, Abt Associates referred to its notes and interview tapes to summarize the information provided. When and if a discrepancy was identified, we confirmed the information with a third source or with OPP management. As noted in the preface to this report, the findings are reflective of the information provided to the project team.

For quantitative information, Abt Associates used a standard software package and data analysis and presentation techniques to summarize the progress on product reregistration. To the extent that these data sources are limited in utility, we have identified these issues in this report. If data were missing or seemed inconsistent, we confirmed potential data issues with OPP staff.

Abt Associates documented its quality assurance procedures in its Quality Assurance Project Plan, which was approved by Abt Associates, Industrial Economics, and EPA in July 2006.

3. Progress on Product Reregistration

EPA originally estimated that reregistration would include approximately 600 active ingredient cases (consisting of more than 1,100 active ingredients) and approximately 20,000 pesticide products. The exact universe changes as REDs are published and estimates are refined. EPA projects that product reregistration will not likely be completed before the end of calendar year 2012.[19]

3.1 Status of Product Reregistration

Since beginning reregistration in the late 1980s, EPA has completed reregistration actions for 7,358 pesticide products. Reregistration actions for 11,948 products (conventional and antimicrobial) were pending as of October 2006. The overall product reregistration universe, both completed and pending, is presented in Figure 3-1. SRRD will also be responsible for product reregistrations that will follow completion of the 54 remaining, non-food use REDs[20] by October 2008.

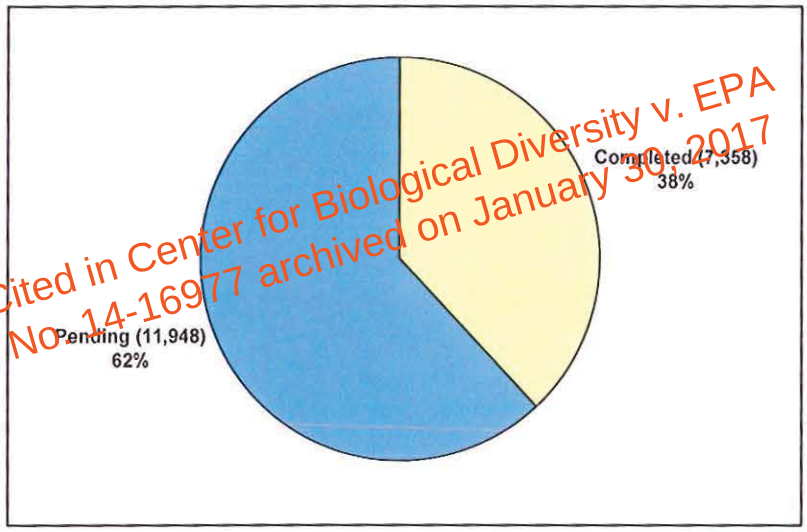

Figure 3-1. Universe of Pesticide Products at End of FY2006

Of the reregistration actions completed through the end of FY2006, the majority of the actions were cancellations (Table 3-1 and Figure 3-2).

[19] Pesticide Reregistration Performance Measures and Goals, Notice, 71 FR 36075, June 23, 2006
[20] http://www.epa.gov/oppsrrd1/reregistration/reregistration_facts.htm

Table 3-1. Cumulative Completed Reregistration Actions through FY2006

Action	Number of Products
Reregistered	2,070
Amended	563
Cancelled	4,695
Suspended	30
Total	**7,358**

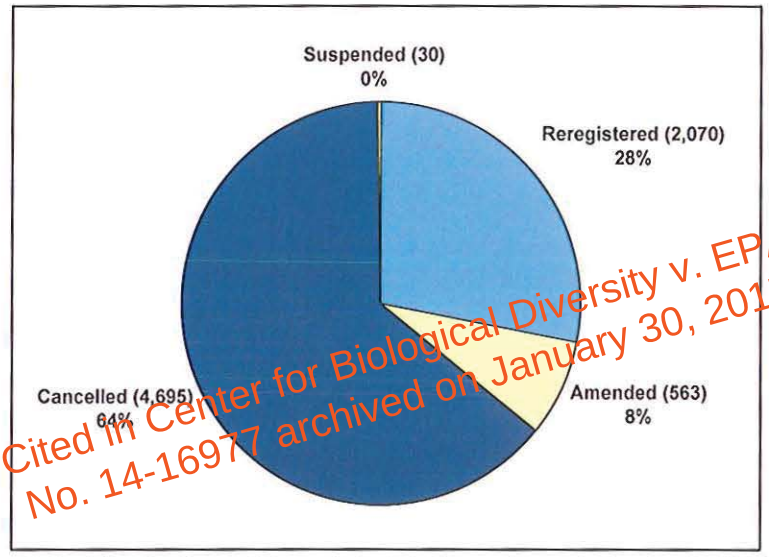

Figure 3-2. Distribution of Completed Actions through the End of FY2006.

Figure 3-3 shows actions (reregistrations, amendments, cancellations) completed from FY2002 through FY2006. (The EPA database was limited to actions completed since 2002, and older data were not readily available.) Note that summing annual actions would result in a greater number of completed actions than reported above since each individual product is potentially subject to multiple actions over time. Figure 3-4 shows actions completed in FY2006.

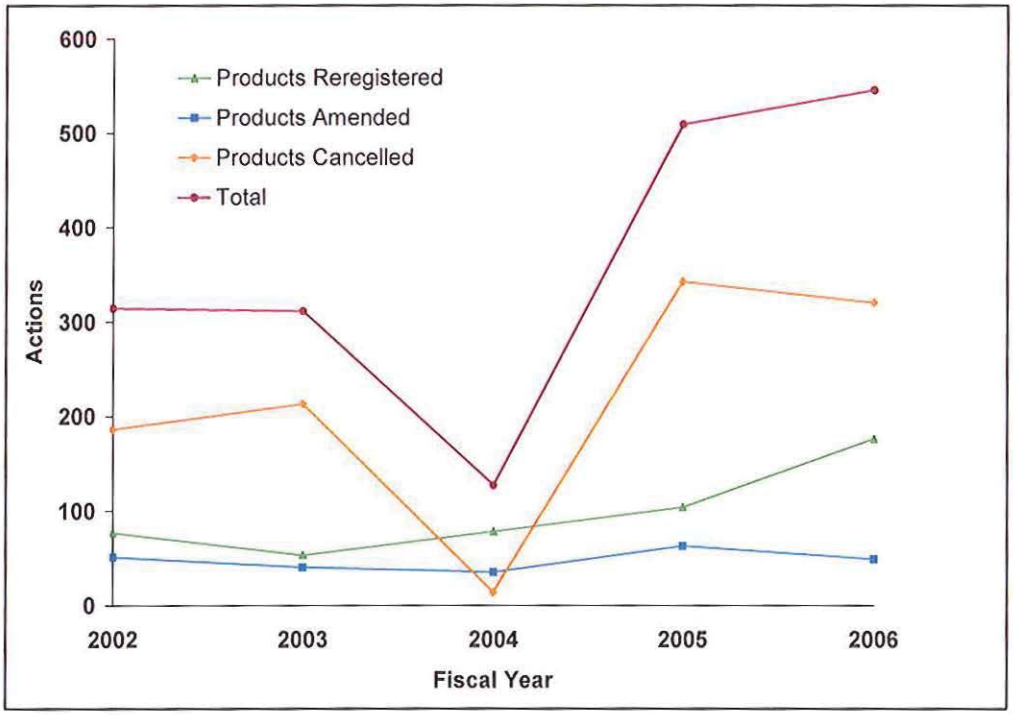

Figure 3-3. Actions Completed from FY2002 through FY2006

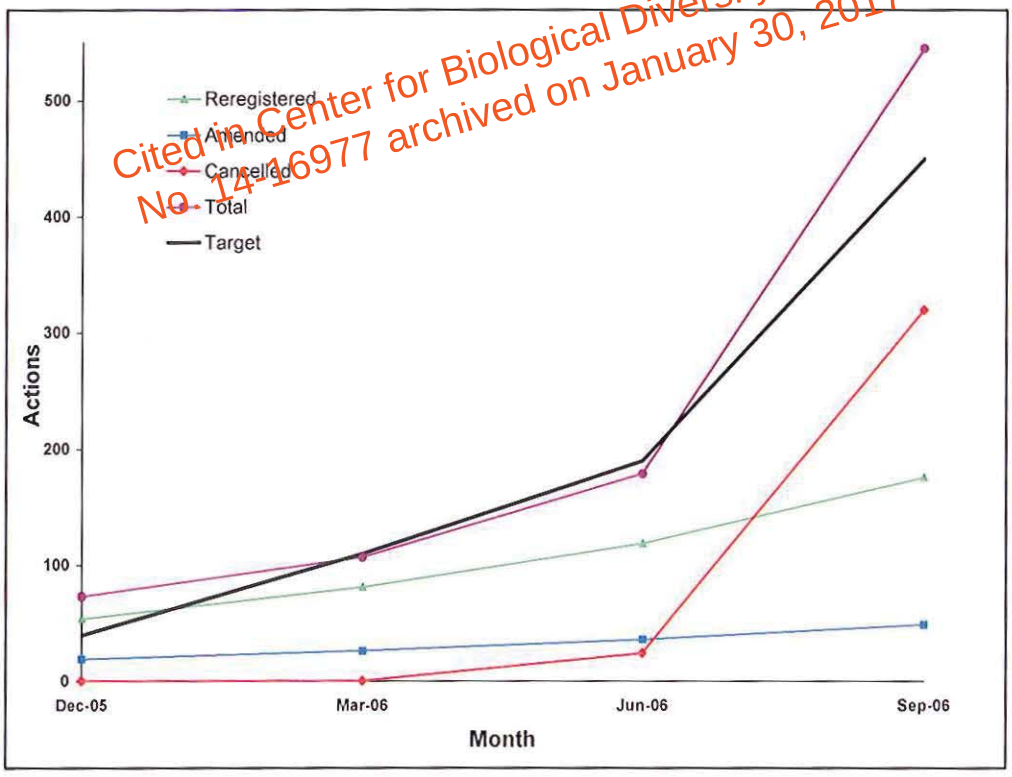

Figure 3-4. Actions Completed in FY2006 Compared to Target

Of the reregistration actions that were pending at the end of FY2006, the products are distributed through all phases of the pesticide reregistration process (Table 3-2). Most of the products (9,088 or 76%) have not yet had the data call-in prepared and/or approved by OMB. This is likely a function of the deadline to complete the REDs for the food-use pesticides by August 3, 2006, which increases the product reregistration backlog. The FY2006 decisions resulted in 6,722 products that will require PDCIs, in addition to remaining decisions from FY2004 and FY2005 that also require PDCIs.

Table 3-2. Products with Actions Pending at the End of FY2006

Location of Products in Process	Number of Products
Awaiting OMB approval – Antimicrobial pesticides	2,229
Awaiting OMB approval – Conventional pesticides	6,859
Awaiting issuance of PDCI – Antimicrobial pesticides	17
Awaiting issuance of PDCI – Conventional pesticides	1,096
Awaiting resolution of post-RED issues (in PRB)	143[a]
Awaiting registrant response to PDCI	318
In PRB process	437
In AD process	24
In BPPD process	53
In RD for reregistration	772
Total	**11,948**

[a] Includes eight products that are also included under "In PRB Process"

The 143 products awaiting resolution of post-RED issues are those for azinphos-methyl and the rodenticide cluster. There are 116 products in PRB and 446 in RD that were awaiting completion of the cumulative risk assessments for the organophosphates and the carbamates. The organophosphate cumulative risk assessment was completed in July 2006.

The FY2006 data source for this section was an internal EPA briefing.[21] These data will be further refined and audited by the EPA Office of Inspector General before being published in the *Federal Register* in 2007. By law, EPA must establish and publish in the *Federal Register* its annual performance measures and goals for pesticide reregistration, tolerance reassessment, and expedited registration. Performance measures and goals were published for FY2005 in the *Federal Register* on June 23, 2006.[22] Data on trends were obtained from OPP Chemical Review Managers.

3.2 Duration of the Product Reregistration Process

SRRD maintains a database, referred to as "STATUS," that includes basic tracking data for products in each of the reregistration cases. Although more detailed information is provided in individual "charts and tables" (in Microsoft Word format), these data are not centralized and

[21] Product Reregistration Quarterly Review, Briefing for Jim Jones, Associate Director of the EPA Office of Pesticide Programs, October 2006

[22] Pesticide Reregistration Performance Measures and Goals, Notice, 71 FR 36075, June 23, 2006

therefore not available for purposes of this analysis. Using the tracking data available, we determined the duration of the product reregistration process. From these data, we can distinguish three points in the reregistration process: (1) when the RED or IRED is issued; (2) when the reregistration package is sent to the product manager (PM) in RD; and (3) when the product is reregistered (decision date). Other milestones, including the date the DCI was sent to OMB, DCI was issued, data were reviewed, etc., are not available in this data source.

In the following tables and figures, we consider 124 REDs covering 1,639 products that were designated in the STATUS database as reregistered (reregistration code 22) and unconditionally reregistered with amendment or conditionally reregistered with amendment (reregistration code 17). Tables 3-3 and 3-4 and Figure 3-5 present the results for a combination of these two reregistration codes.

Table 3-3 shows that, on average, it took 54 months to reregister a product. An average of 41 months was needed to get the reregistration package to the Product Manager (PM) in RD, and after the reregistration package had been sent to the PM, it took an average of 14 months to complete the reregistration process.

With regard to a RED, on average, it took about 47 months to reregister all products covered by a RED. The average maximum time needed for reregistering all products covered by a RED was about 76 months. The average maximum time needed to get the reregistration package to the PM was about 53 months, and on average, once the reregistration package got to the PM, the maximum time to complete the reregistration process was about 33 months.

Table 3-3. Mean Duration of Process for All Products and by RED Case

Group	Mean Duration (months)		
	RED Signed to Sent to PM	Sent to PM to Reregistration Decision	RED Signed to Reregistration Decision
All Products	41	14	54[a]
By RED (case mean)	34	13	47[a]
By RED (case maximum)	53	33	76[b]

[a] Total process duration may not be the sum of the two phases because of rounding.

[b] Total process duration is not the sum of the two phases because we calculated the mean of the maximum length of time in each specific phase and for the entire process.

Table 3-4 presents the mean duration to complete all products for REDs by the number of products. On average, it took 36 months to reregister REDs that covered only one product, and 47 months to reregister all products under REDs that covered more than 70 products. REDs that covered between 14 and 26 products took the longest time (57 months) to complete the product reregistration process. Complete reregistration of the products in these cases also took the longest periods during both phases of the process.

Table 3-4. Mean Duration of Process for RED Case by the Number of Products

Number of Products per RED	Mean Duration (months)		
	RED Signed to Sent to PM	Sent to PM to Reregistration Decision	RED Signed to Reregistration Decision [a]
1	25	12	36
2 – 5	32	12	44
6 – 13	36	17	52
14 – 26	38	18	57
27 – 35	41	14	55
36 – 70	39	9	48
More than 70	40	7	47

[a] Total process duration may not be the sum of the two phases because of rounding.

A closer examination of the distribution of the duration of reregistration of all products shows that the mean does not represent the true picture of the duration of registration. Figure 3-5 depicts the distribution of products by the duration to complete the reregistration process. Figure 3-6 shows the distribution of products by reregistration phase.

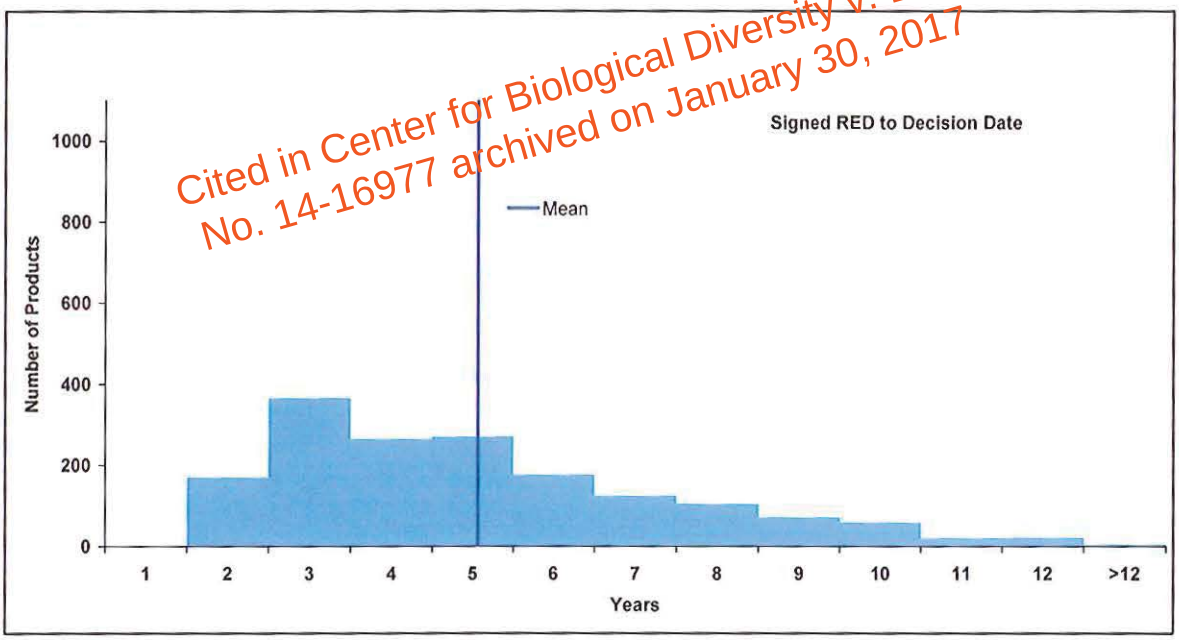

Figure 3-5. Duration of Product Reregistration Process for All Products (Reregistered and Conditional or Unconditional Reregistered Products)

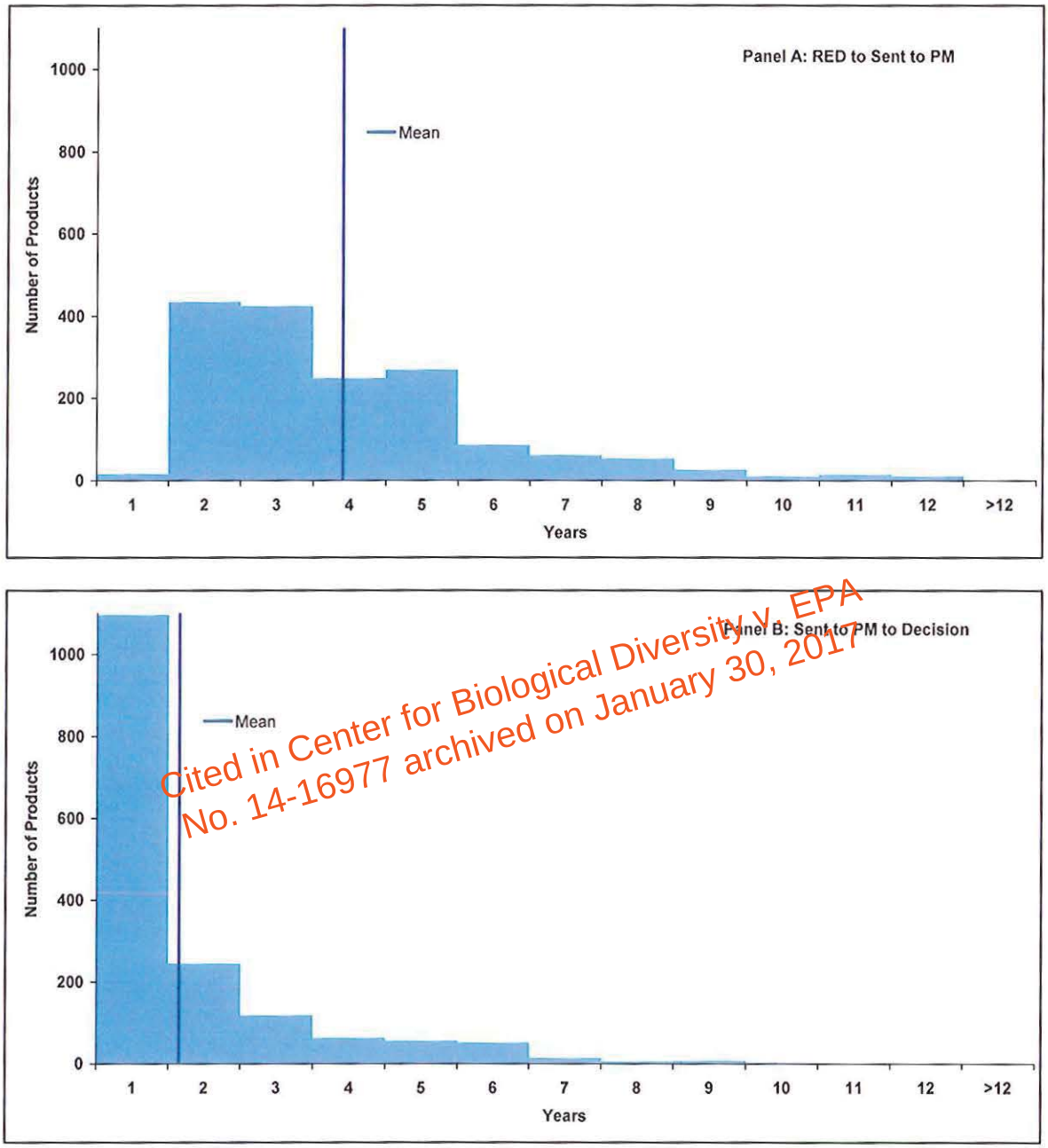

Figure 3-6. Duration of Period from RED Signature to Product Sent to PM (Panel A). Duration of Period from Sent to PM to Decision (Panel B). These graphs include all products (reregistered and conditional or unconditional reregistered products)

Figure 3-5 and 3-6 show that the average (mean statistic) is skewed by a small number of products. More often than not, the duration of the process was less than the mean. This is most obvious for the time needed to reregister a product after it has been sent to the PM. Of the 1,639 products covered in this analysis, 1,155 products, or 70 percent, were reregistered in less than 14 months (the mean time it took to reregister products) after the registration package was sent to the PM (Figure 3-6, Panel B). As such, we present the median time for each of the phases for all the reregistered products in Table 3-5 and the median time by the number of products per RED in Table 3-6 below.

Table 3-5. Median Duration of Process for All Reregistered Products and by RED Case

Group	Median Duration (months)		
	RED Signed to Sent to PM	Sent to PM to Reregistration Decision	RED Signed to Reregistration Decision
All Products	30	7	41
By RED (case mean)	29	9	41
By RED (case maximum)	46	17	69

[a] Total process duration may not be the sum of the two phases because of rounding.
[b] Total process duration is not the sum of the two phases because we calculated the mean of the maximum length of time in each specific phase and for the entire process.

Table 3-6. Median Duration of Process for RED Case by the Number of Products

Number of Products per RED	Median Duration (months)		
	RED Signed to Sent to PM	Sent to PM to Reregistration Decision	RED Signed to Reregistration Decision
1	30	6	35
2 – 5	28	6	39
6 – 13	30	10	37
14 – 26	30	13	57
27 – 35	38	10	55
36 – 70	30	8	36
More than 70	38	5	46

For the universe of products that have not yet completed product reregistration, but that have been sent to the PM in RD, the distribution of the time it took to reach this milestone is presented in Figure 3-7. Since being sent to the PM, the products have remained in RD anywhere from less than one month to more than 11 years. RD staff commented in interviews that many products are sent to them when there are still outstanding issues that need to be addressed.

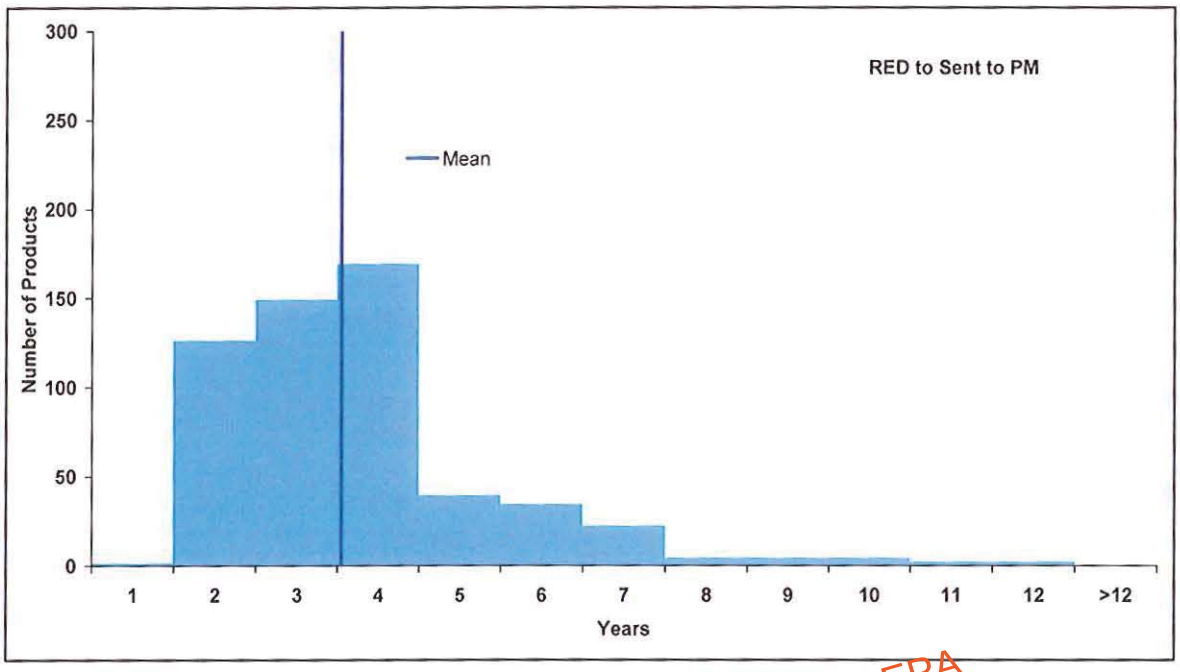

Figure 3-7. Duration of Period from RED Signature to Product Sent to PM for Products that are Not Yet Reregistered

The duration of the period from when the RED is signed to when the product is sent to the PM for reregistration includes several steps, not all of which are the responsibility of SRRD or even EPA. Part of this time includes the preparation and approval of the DCI justification package and the DCIs themselves (see Chapter 5). In addition, this period also includes the time for registrant responses (both ninety-day and eight-month), EPA review of the data submitted, and additional communication with the registrant. Thus, the estimates from the time the RED is signed to when the product reregistration package is sent to the Registration Division (RD) is not indicative of the time that SRRD Product Reregistration Branch (PRB) spends working on product reregistration (i.e., the time from the PDCI issued until the product reregistration package is sent to RD).

For the 755 products pending in PRB at the end of FY2006, SRRD data indicate that:

- 42 percent have been in PRB less than 12 months
- 36 percent have been in PRB between 12 and 24 months
- 20 percent have been in RPB between 24 and 36 months
- 2 percent have been in PRB more than 36 months

Table 3-7 presents the number and percentage of products completed for each fiscal year.

Table 3-7. Product Reregistration Completion Status by Fiscal Year

Fiscal Year	REDs/ IREDs Issued	Associated Products	Products Completed	Products Pending		
				Number	Percent	Location
1991	8	442	422	20	5	RD
1992	20	969	954	15	2	RD, AD, BPPD
1993	10	853	824	29	3	AD, RD
1994	22	729	717	12	2	AD, RD
1995	34	809	772	37	5	AD, RD
1996	42	1,050	970	80	8	AD, RD
1997	28	1,360	1,117	243	18	AD, RD, BPPD, PRB
1998	13	707	560	147	21	RD
1999	14	238	188	50	21	RD
2000	13	195	164	31	16	RD
2001	9	578	270	308	53	RD
2002	15	736	516	220	30	RD
2003	16	1,016	505	511	50	SRRD PRB
2004	17	713	126	587	82	SRRD PSB
2005 [a]	29	1,184	0	1,184	100	SRRD PSB
2006	41	8,693	1	8,692	100	SRRD PSB
Total	**331**	**20,272**	**8,106**	**12,166**	**60**	--

[a] The Fluazifop-p-butyl TRED required a PDCI.

Key: AD = Antimicrobials Division, BPPD = Biopesticides and Pollution Prevention Division, PRB = Product Reregistration Branch, PSB = Program Support Branch, RD = Registration Division, SRRD = Special Review and Reregistration Division.

Source: "Status of Product Reregistration: Pending Products," December 12, 2006.

For purposes of implementing mitigation specified in the RED to reduce risks to human health and the environment, the overall length of the process – from the time EPA signs the RED to the time it stamps the label – is a key metric. However, for purposes of a process evaluation, determining the duration of each individual step becomes critical. Unfortunately, as currently managed, EPA data are of limited value for analyzing the time associated with each step in product reregistration. As explained in later sections, EPA does not track product reregistration data in a centralized database because the main OPP information management system (OPPIN) is not adequate.

4. Reregistration Eligibility Decisions

Reregistration Eligibility Decision (RED) documents include EPA's evaluation of the database for a chemical, its conclusions about 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. A RED also identifies the data and labeling requirements for products eligible for reregistration, as well as any additional confirmatory data needed on the active ingredient. Almost every RED includes some measures or modifications to reduce risks, e.g., declaring certain uses ineligible for reregistration; restricting use of products to certified applicators; limiting the amount or frequency of use; improving use directions and precautions; adding more protective clothing and equipment requirements; employing ground water, surface water, or other environmental and ecological safeguards; and other measures.

The "generic" chemical review managers (CRMs) in the reregistration branches of SRRD develop REDs based on available data and analyses conducted by the OPP science divisions. After a RED is signed, the Program Support Branch (PSB) and the Product Reregistration Branch (PRB) of SRRD initiate product reregistration. The "product" CRMs in PRB provide oversight for product reregistration. As needed, the reregistration branches are responsible for post-RED activities that arise after the RED is published and/or EPA receives product-specific and confirmatory studies.

4.1 Issues with REDs

This evaluation included three case studies where issues in the RED were believed to delay product reregistration. In addition to specific issues, several more general issues regarding the RED-development process became apparent. These include workload management, staffing, and division of labor, all of which are discussed in this section.

The generic CRMs in the four SRRD reregistration branches are responsible for writing a RED for an active ingredient. This part of the reregistration program faces public scrutiny, has ambitious deadlines, and demands a heavy workload. Over the years, this part of the reregistration program has evolved, particularly with respect to the FQPA requirements, scheduling, public participation, and transparency. However, the goal of this part of the process is to publish a RED by the given deadline. As a result, some REDs were published without addressing some outstanding issues. OPP also commented that virtually every RED likely has an issue or a hole because these may not be apparent until the RED is implemented (i.e., during product reregistration). Thus, REDs are sometimes amended to address outstanding issues or to include data that are submitted after the RED is signed. Sometimes EPA still initiates the data call-ins after the RED is signed, even if there are known outstanding issues. In these cases, the registrants are often contacted by both the reregistration branch and PRB.

For those REDs that did not have post-RED issues, generic CRMs indicated that they assumed that product reregistration happened as planned and were unaware of some of the delays and challenges. This is a source of frustration, as years of work to write a RED do not always result in environmental and human health protection as quickly as expected.

Post-RED issues were historically not given high priority in work plans and adequate resources within the four reregistration branches, as statutory deadlines required continued focus on

completing REDs. SRRD often looks to the science divisions for support with post-RED issues. Because there are no deadlines associated with post-RED activities, writing new REDs remain the priority. However, now that the August 2006 deadline to complete food-use REDs has passed, SRRD management has indicated a commitment to addressing post-RED issues (including product reregistration) in FY2007 and beyond.

REDs are not considered legally enforceable; EPA can only enforce DCIs and labels. Some registrants are inclined to challenge the contents of a RED to delay implementation of RED-specified mitigation. As EPA developed a more robust public participation process, registrants are more likely to be aware of upcoming eligibility decisions, which might reduce post-RED issues in the future and speed the product reregistration process.

Given the length of time from when a RED is published, to when post-RED issues are addressed, to when product reregistration is conducted, the CRM who wrote the RED is often no longer in that position. Typically, after about five years CRMs either are promoted or change positions. As staff leave, REDs that are in process need to be transitioned to other staff. As a result, institutional knowledge is often lost and new staff require additional time to become familiar with the issues.

Generic CRMs are responsible for identifying mitigation that needs to be included in revised labels as part of the RED development. Although the CRMs are knowledgeable of the issues of the case, some noted that they are not in the best position to draft label language. CRMs, although trained in writing labeling language, do not perform the task regularly enough to become extremely proficient at it, which sometimes results in problems when developing the label table. Generic CRMs commented that staff members in PRB and/or RD are better suited to determine how the language should read on the RED. Some within OPP believe the most efficient approach to drafting labeling language would consist of the decision-makers – PRB and RD – playing a more active role in the process.

4.2 Case Studies

To better understand how Reregistration Eligibility Decisions (REDs) sometimes cause delays in product reregistration, Abt Associates examined three REDs that were believed to delay product reregistration: the rodenticide cluster, captan, and dicofol. Each case study identified issues and challenges that arise throughout the reregistration process and, in particular, as a result of the contents of a RED.

4.2.1 Rodenticide Cluster

In July 1998, EPA published the RED for the rodenticide cluster, which included six active ingredients.[23] Rodenticides represent EPA's first attempt to cluster active ingredients, an approach that is also being used for fumigants. Since most of the rodenticides share similar use patterns, issuing reregistration decisions for one chemical at a time could shift the rodenticide market, perhaps to chemicals that pose greater risk but may be addressed later in the queue. EPA also intended this approach to maintain a level playing field. Levels of exposure to the varying rodenticides are generally similar, but they differ in toxicities. Thus, EPA expects to

[23] Reregistration Eligibility Decision: Rodenticide Cluster, U.S. EPA Office of Prevention, Pesticides, and Toxic Substances, EPA 738-R-98-007, July 1998

differentiate mitigation measures based on individual toxicities of the chemicals. Although clustering chemicals is more efficient for purposes of analysis, the number of issues and registrants involved complicates actual decisionmaking. In retrospect, EPA commented that it could have published concurrent but separate REDs for each chemical in the cluster and then made decisions for all the cases at the same time. By maintaining separate documents, EPA may have simplified the decision.

The rodenticide RED was incomplete and did not represent final regulatory decisions such that EPA could not implement much of what it included. Outstanding issues included human health (particularly accidental exposure to children) and ecological risks, and the RED included a two-phase approach for mitigating risk. The first phase would put into place short-term measures to identify, decrease, and monitor exposures largely through the use of bittering agents, dyes, and other measures. The second phase sought to reduce exposures in the long term by convening a stakeholder workgroup. EPA commented that the program has matured considerably since the rodenticide RED was published, and it is unclear why the RED was published in its final form. Under today's standards, EPA likely would not publish a document that did not provide actual reregistration eligibility decisions.

After convening a stakeholder workgroup, EPA changed its position on the requirements for bittering agents and dyes in 2004, which was subsequently challenged in a lawsuit. EPA was asked to reconsider this decision and develop a better record. Also, the rodenticide RED predated EPA's formal public participation process for reregistration. EPA is currently addressing the ecological risks of the rodenticide cluster. In January 2003, EPA released a preliminary ecological risk assessment for public comment; a revised assessment was published in September 2004.[24] EPA is formulating a mitigation plan to address these risks that it published for public comment in January 2007.[25]

Because of these outstanding issues, EPA has not yet completed pesticide reregistration for rodenticide products. After the RED was signed in 1998, EPA sent out DCIs, but they were put on hold in light of the outstanding issues. If EPA were to require bittering agents, this would require new product chemistry and acute toxicity studies, which makes it impractical to submit these data until the issue is resolved.

Because of these delays in reregistration, PRB encouraged registrants to voluntarily amend labels to incorporate some of the mitigation specified in the RED in advance of product reregistration. EPA also considered allowing registrants to have a master label that could be used on several different packages. This effort was largely unsuccessful and registrants would not voluntarily amend labels, although some voluntarily added bittering agents. For other reregistration cases, EPA has been successful in having registrants voluntarily amend labels.

Once the ecological risks are addressed through the forthcoming mitigation plan, SRRD expects to issue an amendment to the RED for public comment. EPA will then address any outstanding policy issues or regulatory activities. In the meantime, more than eight years have elapsed since the RED was signed without significant changes to the labels for the rodenticide cluster.

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[24] Rodenticides: Availability of Revised Comparative Ecological Risk Assessment, 69 FR 56756, September 22, 2004

[25] Proposed Risk Mitigation Decision for Nine Rodenticides, January 17, 2007, available at http://www.epa.gov/oppsrrd1/reregistration/rodenticides/rodenticides_mitigation_decision.pdf

This case study illustrates the challenge of clustering active ingredients that might have similar use patterns, but differ in toxicity and other characteristics. EPA staff noted that publishing separate documents concurrently could be a good alternative. This case cautions against publishing a RED without addressing all outstanding issues and not developing a solid record. Lastly, rodenticides shows that registrants are not always amendable to voluntary label changes.

4.2.2 Captan

In November 1999, EPA published the RED for captan, which included a determination that it was a probable human carcinogen based on the properties of a highly reactive but short-lived metabolite.[26] The risk assessment, however, indicated that this classification did not warrant additional mitigation. After EPA published the RED, additional data were submitted during the public comment period that led EPA to amend the RED in November 2004.

The RED pre-dated the formal reregistration public participation process that is in place now, which meant that early opportunities for public comment were more limited. EPA received additional data after the RED was signed that led EPA to recalculate certain re-entry intervals and margins of exposure for specific uses and applications. These new values were included in the RED amendment. The amendment also addressed a few minor inconsistencies that needed to be clarified (e.g., definition of a berry and seed treatment).

Also, after the RED was published in 1999, registrants requested that EPA consider a cancer reclassification for captan, presumably for marketing and other reasons. Because its current cancer classification did not warrant additional mitigation, EPA did not feel it was appropriate to use its limited resources on the analysis. The Captan Task Force, which is composed of captan registrants, voluntarily contracted with an independent body of scientists to review the data to support a mode of action determination for captan. The OPP Health Effects Division (HED) then reviewed this work. Based on the third-party review and subsequent HED review, EPA determined that captan acts through a non-genotoxic threshold mode of action. This determination, however, did not change the risk management conclusions or amend the RED. Overall, it took approximately two years to complete the cancer reclassification.

The cancer reclassification and the amendment to the RED were published for public comment in November 2004.[27] EPA received a modest number of comments, mostly on the cancer reclassification or issues un-related to the RED amendment. The captan amendment was less complex compared to other cases that have been amended. However, the process took considerable effort and was also not given top priority when compared to writing new REDs.

Because of the length of time between completing and subsequently amending the RED, EPA worked with the registrants and the Captan Task Force to amend product labels with RED-specified mitigation as soon as possible. The technical registrants, who were most interested in the cancer reclassification, were able to encourage the product registrants, who were most

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[26] Reregistration Eligibility Decision: Captan, U.S. EPA Office of Prevention, Pesticides, and Toxic Substances, EPA 738-R-99-015, November 1999

[27] Captan; Cancer Reclassification; Amendment of Reregistration Eligibility Decision; Notice of Availability, 69 FR 68357, November 24, 2004

interested in the RED amendment, to revise their labels in an expedited manner. Registrants were also motivated by good environmental stewardship. The SRRD reregistration branch collected the labels in early 2005, which were then sent to the Product Reregistration Branch (PRB) for assessment. However, this approach resulted in confusion because two branches were in contact with registrants, and communication could have been better coordinated. EPA has since completed the product reregistration process for captan products. Reregistration for captan products took seven years from the time the RED was signed.

This case study reiterates that REDs represent the best data and analysis available at the time, and the need to engage registrants in the submission of new data. This case also included a creative solution for a third-party cancer assessment, which saved EPA resources. Lastly, the case illustrates that voluntary label changes can sometimes be successful.

4.2.3 Dicofol

In September 1998, EPA signed the dicofol RED and determined that products containing dicofol may be eligible for reregistration (as specified in the RED) contingent upon results of a dermal toxicity study that was due to EPA in December 1998.[28] In 2005, EPA published an addendum to the RED to establish re-entry intervals (which were not included in the RED) and solicited public comment.[29]

OPP maintains a strict, annual schedule for RED development and signature to meet the statutory deadlines in FQPA, and the deadlines are rarely (if ever) postponed or missed. In order to meet OPP's annual goals, these deadlines often correspond to the end of a fiscal year, which explains why a majority of REDs are signed in September. The dicofol RED was signed, although it lacked information on worker exposure, so that EPA could count dicofol tolerances toward the number of tolerances that were reassessed in FY1998. Staff commented, however, that given the significant data gaps, it would be unlikely that the dicofol RED would be published in that form according to current standards. Despite incomplete information on re-entry intervals, EPA mailed out DCIs in 1998 and received responses and amended labels from the registrant, but label review is pending the resolution of outstanding issues.

To address EPA's concerns with occupational exposure following the signature of the RED, the registrant submitted a dermal toxicity study and a chemical-specific dislodgeable foliar residue study approximately one year after the RED was signed. Given the use of the pesticide and the nature of the study, these data were submitted in a timely manner. However, the data indicate that a substantially longer restricted entry interval (REI) was warranted compared to the REI on the label at the time (more than 3 months compared to 24 hours). These data triggered the involvement of the OPP Biological and Economic Analysis Division (BEAD), who conducted an impact analysis to examine the current market and viable alternatives and met with the registrant. Other more minor issues in the RED, such as updating calculations to be consistent with a revised definition of "short-term exposure" from the OPP Health Effects Division (HED) were also addressed after the RED was signed.

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[28] Reregistration Eligibility Decision: Dicofol, U.S. EPA Office of Prevention, Pesticides, and Toxic Substances, EPA 738-R-98-018, November 1998

[29] Dicofol; Addendum and Closure of Reregistration Eligibility Decision; Notice of Availability, 70 FR 51794, August 30, 2005

Over time, interest in the dicofol case diminished, as other activities within OPP were given a higher priority and staff responsibilities were shifted (several generic CRMs have worked on the dicofol case). When dicofol again became a priority, EPA drafted and published the addendum to the RED for public comment. The growers indicated to EPA that the proposed REIs were unacceptable and maintained that dicofol was a much-needed miticide in the industry. EPA planned to release a second addendum to the dicofol RED after the August 3, 2006, FQPA deadline. This was pushed back further when staff became involved in registration review activities. However, in Summer 2006, the registrant announced that it intends to discontinue dicofol because it does not have sufficient market share.

Given the discrepancy over REI and the registrant's plans to discontinue the product, the registrant did not voluntarily revise its label to include any of the RED-specified mitigation and the labels remain unchanged. More than eight years have elapsed since the RED was signed without significant changes to the labels for dicofol.

The dicofol case study illustrates the issues that result from publishing a RED before it is complete, and that sending DCIs in such situations might not be appropriate. The case also highlights that new data sometimes delay product reregistration and require additional review and consideration.

4.3 Alternative Strategies for Implementing Mitigation

This section reviews two cases where EPA pursued implementation of RED-specified mitigation through signing a memorandum of agreement with registrants, as well as a current pilot project to achieving this same objective without the formal agreement.

4.3.1 Memoranda of Agreement – Chlorpyrifos and Phosmet

EPA uses Memoranda of Agreement (MOAs) as a mechanism by which registrants amend product labels to include RED-specified mitigation in advance of the product reregistration process and may also agree to provide data or take other action. Although used infrequently, EPA has used MOAs in approximately six to twelve instances, including the chlorpyrifos and phosmet cases. The following two cases highlight some of the successes and shortcomings of MOAs. These case studies provide support to the recommendations made later in this report.

In addition to MOAs, EPA has made efforts to amend terms and conditions of registrations to include RED-specified mitigation in a timelier manner. This approach requires fewer resources and does not commit EPA to anything. However, MOAs also provide a mechanism to get data, which is not possible only through amending the terms of conditions of a registration.

Chlorpyrifos

In June 2000, EPA signed an MOA with the chlorpyrifos registrants after several months of negotiation.[30] Under the MOA, registrants requested voluntary cancellation of their existing products and submitted applications for replacement registrations excluding those uses that were canceled (e.g., termite control, residential use). In return, EPA stated that it had no

[30] Memorandum of Agreement between the Environmental Protection Agency and Signatory Registrants Regarding the Registration of Pesticide Products Containing Chlorpyrifos, June 2000

intention to initiate cancellation or suspension proceedings and would act on replacement registrations within ten working days.

EPA was particularly concerned about exposures from residential uses of chlorpyrifos, and estimates that a chlorpyrifos product was in one in four households in the United States. As an organophosphate, chlorpyrifos posed acute risks and exposure and incident data indicated regulatory action was appropriate. In addition, a number of environmental groups published reports on risks of pesticides in food and in the home. This level of concern provided some leverage to convince registrants to take action.

In negotiations, registrants agreed to cancel residential uses. Both EPA and the registrants agreed that a recall of residential-use products was not necessary. There were approximately 10 million pounds of chlorpyrifos in homes, and a recall would pose logistical and disposal problems, including additional environmental and public health concerns. EPA's key objective was to develop an agreement that ensured that mitigation was placed on the label as soon as possible.

Chlorpyrifos is an interesting case because there were originally more than 900 products and extensive mitigation was required. EPA cancelled more than 300 products and amended approximately 100 labels. There are currently about 300 chlorpyrifos products. Because of the complexity of the agreement and the number of labels, EPA developed guidance and communications materials for the regulated community. In order to meet its obligations, EPA assembled a staff of six to eight people from the reregistration branches, PRB, and RD who worked full-time for five to six months on the case to process labels and voluntary cancellations. This work was mostly complete by January 2001, approximately eight months after the MOA was signed.

After having dealt with the residential uses, EPA focused its attention on agricultural uses and remaining regulatory issues, such as the Interim Reregistration Eligibility Decision (IRED) that was published in September 2001. Based on product-specific data, labels had to be reviewed and amended for formal product reregistration, but the product universe was considerably smaller because residential uses had been cancelled.

Several key aspects of the chlorpyrifos case made an MOA a particularly appropriate and successful tool: the registrant was a willing participant in negotiation, EPA was also committed to activities and deadlines, chlorpyrifos received public attention and required swift action, there were numerous products, and residential uses were of concern.

Phosmet

In 2001, EPA signed an MOA with Gowan Company, the only registrant of phosmet.[31] In 2001, EPA also published the IRED for phosmet. Although it is an organophosphate, phosmet does not exhibit the same risk profile of some of the others. There were some residential uses and some incident reports, and Gowan initiated voluntary cancellations for residential uses.

[31] Memorandum of Agreement between the Environmental Protection Agency and Gowan Company Regarding the Registration of Pesticide Products Containing Phosmet, October 2001

Growers expressed to EPA the necessity of phosmet, so EPA pursued an MOA to ensure that mitigation was put in place and worker protection issues were addressed as soon as possible.

The agreement required Gowan to amend all of its phosmet product labels based on the IRED and any modifications EPA considers necessary based on comments received during a sixty-day comment period. After June 30, 2002, products were required to bear labeling approved by EPA in accordance with the agreement. The agreement also required that all registrations of phosmet products labeled for specific crops would include the following terms and conditions:

- After October 30, 2006, products shall bear restricted entry intervals (REIs) specified in the MOA unless prior to that date EPA decided that another REI is appropriate.
- By October 30, 2005, the registrant would submit biomonitoring data, a feasibility study of gloves suitable for field workers, and data reflecting benefits and use patterns of phosmet.

EPA expected to receive revised labels from Gowan in May 2002 so that they could be reviewed and approved in advance of the June 30, 2002, deadline. Because of errors in the submissions, there were several rounds of label reviews and EPA did not approve amended labels until 2005. There were a number of issues that contributed to the delay: SRRD and RD disagreed whether or not the amended labels needed to be complete updates in light of relevant PR notices or if the labels only needed to have the mitigation specified in the IRED included. Note that the MOA stated that "each phosmet product must include on its product label in the Direction for Use section all of the labeling statements identified in the IRED..." SRRD maintained that a complete amendment conflicted with its intent to implement RED-specified mitigation as soon as possible and was beyond the scope of the exercise. Also, due to the substantial number of iterations of labels between OPP and the registrant, it took a long time to finalize the label amendments. There were only a limited number of phosmet labels that were affected by the MOA (ten to twelve) and EPA attempted to prioritize them.

Gowan completed the studies per the agreement and EPA reviewed the data. In 2004, phosmet was the subject of a lawsuit by farmworker organizations that challenged occupational exposure risks. EPA expected that the REIs would need to be lengthened, as was proposed in June 2006, which would require additional label amendments. In January 2007, EPA issued its final decision on nine uses of phosmet that will lengthen most REIs and impose additional mitigation measures. Generic and product-specific DCIs were issued on April 9, 2003. As of October 2006, the majority of phosmet products had not been reregistered.

Several key aspects of the phosmet case made an MOA a particularly appropriate and successful tool: there was only one registrant and there were additional issues beyond label mitigation to be addressed. This case also illustrates that an MOA does not necessarily guarantee timely implementation of all label changes.

4.3.2 Propanil Pilot Project

In an effort to implement the mitigation specified in the RED on the labels in a timelier manner, EPA initiated a pilot project for propanil. EPA published the propanil RED in September 2003 and mailed out DCIs in Spring 2006. SRRD provided the label table to RD at the same time that it issued the PDCI. RD sent a letter to the registrants in May 2006 to request that they

incorporate RED-specified mitigation while SRRD continues with the product reregistration process. This is similar to the approaches for chlorpyrifos and phosmet (above) but without the negotiation and signature of an MOA.

The Propanil Task Force responded to RD's request by questioning why EPA requested the amended label before the registrants responded to the DCI. The Office of General Counsel (OGC) prepared both a specific response to the Propanil Task Force and a generic letter for future use. The letters explained that EPA is working to reduce the amount of time between issuance of the RED and implementation of mitigation required in the RED. Registrants were given ninety days to provide a revised label. In the absence of the required label changes in the RED, EPA stated that the pesticide label does not have sufficient directions for use and/or a precautionary statement to adequately protect health and the environment (and could therefore be considered "misbranded" under Section 2(q) of FIFRA).

As of January 2007, of the 43 products: amended labels for 23 products were submitted to EPA and accepted with comments; 3 were pending in label review; 3 provided no response; and 14 products were voluntarily canceled. On average it took 6 months to receive and accept (with comments) amended labels, not including those that did not respond.

This pilot project illustrates that it is possible to implement RED-specified mitigation, although it will likely require a change in registrant culture as they become familiar with the new process. Given that half of the labels were not submitted, EPA will need to address the consequences of such actions moving forward. In addition, this approach does increase the burden on SRRD, so EPA will need to focus its activities appropriately.

5. DCI Justifications and Preparation

After a RED is signed, the preparation of the generic Data Call-In (DCI) or product-specific Data Call-In (PDCI) notice is the first step in the product reregistration process. Before the DCI can be issued to the registrant, EPA must prepare and receive approval of a DCI justification package from Office of Management and Budget (OMB). This DCI justification package lists all of the product-specific studies, as well as any confirmatory data, that the registrant must submit in order to complete reregistration for each of the individual pesticide products covered by the RED.

Several EPA offices and other agencies are involved in the preparation of a DCI justification package. The Program Support Branch (PSB) is responsible for preparing the DCI justification package and, once approved by OMB, for sending the DCI to the registrant. Several entities assist PSB in the development and review of the DCI justification package, including:

- OPP Field and External Affairs Division (FEAD),
- OPP Science Divisions: Environmental Fate and Effects Division (EFED) and Health Effects Division (HED),
- Office of Prevention, Pesticides, and Toxic Substances (OPPTS) Regulatory Coordination Staff (RCS), and
- SRRD Product Reregistration Branch (PRB).

The U.S. Department of Agriculture (USDA) also assists with DCI justification packages, particularly when high-profile chemicals and/or high-cost studies are involved. To ensure the DCI justification package complies with OMB standards, FEAD and RCS review it before submitting it to OMB.

5.1 Preparation of DCI Justification Package

Despite approved standard operating procedures (SOPs) for developing the DCI justification package, the process is time-consuming and often evaluated by OMB against varying standards. OPP believed that approval of a DCI justification package was a source of delay in the product reregistration program, and we explore this issue in this section.

5.1.1 Template for DCI Justification Package

In an effort to streamline and standardize the DCI justification package based on feedback from OMB on a DCI for the toxics program, RCS initiated changes to the format of the DCI justification packages. Through an iterative process, PSB and RCS re-formulated the template to include "boilerplate" responses for study rationale and intended data use. Despite the intent of streamlining the process, the first package PSB prepared using the template (submitted on May 22, 2006) was much lengthier than previous DCI packages because PSB included both the boilerplate language and standard elements from the old format. The lengths for the most recent packages are:

One year ago:	30 pages long for 26 chemicals
Most recent package:	80 pages long for 21 chemicals

In August 2006, OMB presented EPA with ten questions, which were mostly about process and therefore relatively easy to address (e.g., why is OPP requesting acute toxicity data from the registrant?). OMB approved that particular DCI package in October 2006, five months after it was submitted. It is unclear at this time whether the template changes will help expedite the review and approval of DCI justification packages by OMB.

5.1.2 Supporting Data

A lack of supporting data can lead to several delays in assembling the DCI justification package. First, the manner in which the OPP science divisions write the risk assessments (RAs) is viewed as problematic by several PSB staff. Currently, neither the RAs nor the REDs summarize or clearly identify upfront the rationale for new studies. Often, PSB staff need to review the entire RA to locate necessary information or contact the science divisions to help develop the rationale, both of which can be time consuming.

Second, in conducting the RA, the science divisions may conclude that the registrant needs to conduct "special studies" in order to generate sufficient confirmatory data for product reregistration. In practice, the science divisions delineate the basic parameters of these special studies but do not provide PSB with cost burden estimates. Since special studies fall outside of standard test cost estimates, PSB is responsible for estimating the cost burden for the DCI justification package, despite not being as familiar or knowledgeable as the science divisions about study components.

5.1.3 Tracking

Tracking, as it relates to the DCI preparation process, has several shortcomings. Due to the lack of an integrated tracking system and the multiple players involved in the DCI process, there are at least four tracking systems used by staff to meet different needs: the Office of Pesticide Programs Information Network (OPPIN), a Microsoft Excel-based tracking system, and several Microsoft Word-based tracking systems.

As one of the first steps in the DCI-related tracking process, the generic CRM or product-specific reregistration CRM generates the DCI or PDCI, respectively, in OPPIN. (In practice, PSB, not the generic CRM, typically generates the DCI.) OPPIN is not well suited, however, for detailed tracking of the DCI process because it does not include the needed data fields and reporting functions. Consequently, PSB uses a Word-based system to track the review periods of DCI justification packages by different EPA divisions (i.e., FEAD and RCS) and OMB. It then uses another system to track the return of green cards from registrants. Once PSB processes the product-specific green cards, it forwards them to the product reregistration CRM in PRB who tracks the ninety-day response for the PDCI in Charts and Tables. If the DCI also required generic, confirmatory data, PRB forwards a copy of the green cards to the generic CRM for tracking. The tracking system used for ninety-day and eight-month responses varies among CRMs on the active ingredient level – some use OPPIN; others use separate systems.

OPPIN, which is about five years old, was an attempt at creating a centralized, integrated information management system that would meet the needs of and be accessible to all OPP divisions. Multiple staff expressed dissatisfaction with OPPIN, citing it is not user-friendly, data are not current or complete, and lack of a "report-card" function (guideline status report) to

easily check the status of any given chemical in the post-RED process. CRMS, the predecessor of OPPIN for tracking reregistration of active ingredients, had this functionality, allowing the user to determine where an active ingredient is in the process (e.g., to check the status of submitted studies from a given registrant). Due to its design, CRMS also provided a level of staff accountability that OPPIN does not offer. A new system called PRISM is currently under development and intended to take over the functionality of OPPIN to address currently unmet needs. It is unclear at this time whether PRISM will have the "report card" function or something similar to it.

5.2 Resources and Staff Time

At this time, inadequate staffing in PSB contributes to bottlenecks and delays in the preparation of the DCI justification package. Currently, there are no senior scientists or senior science writers on PSB's staff roster. PSB currently relies on FEAD staff for preliminary reviews of supporting data and documentation. It is not uncommon for FEAD staff members to spend approximately ten percent to twenty percent of their time on DCI preparation and review.

Due to the statutory deadlines for reregistration, generic CRMs begin work on new chemical(s) after the RED is signed. By the time PSB commences the development of the DCI justification package, the CRMs are likely focusing on new chemicals. Consequently, answers to product-specific questions may be difficult to obtain due to the lapse of time between the RED signature and DCI preparation, as well as competing priorities among the CRMs. Moreover, since there are twenty-one CRMs at this time, PSB often must track down the right people to get information.

5.3 Approval of the DCI Justification Package

Since 2003, the total length of time for preparing a DCI (including OMB's review approval) has decreased from an average of 18 to 24 months to an average of 9 to 10 months; the shortest length of time being four months as OPP improved its procedures and developed its relationship with the previous OMB desk officer. A consistent source of delay in the DCI preparation process is OMB's review and approval, which can often span several months. Staff expressed the importance of building a relationship with the OMB officer, so both parties have a mutual understanding of the process. However, the turnover in OMB officers is relatively high: many officers serve for only two to three years.

6. Data Requirements and Review

Key aspects of the product reregistration process are the ninety-day and eight-month responses by the registrant, as well as the review of these data by EPA. Several issues are important to consider relative to the delays and issues with product reregistration, including data management, communication, management priorities, and staffing.

6.1 Data Management of Registrant Responses

Given the number of data guidelines, communications, and other pieces of information that correspond to each product, information management is key to the product reregistration process. Tracking of information is critical for DCI preparation and mail out, ninety-day responses, eight-month responses, data review, label assessment and review, and reregistration decisions. Overall, there are approximately forty-four discrete data elements that must be tracked for each product (i.e., six toxicity studies, twenty-eight product chemistry studies, efficacy studies (if required), waiver requests, study deficiencies, time extensions, and suspensions). Products that are combinations of active ingredients, which may or may not be conducted at the same time, further complicate tracking.

In 2005, SRA International developed a report that described and illustrated the product reregistration process and commented on the adequacy of its tracking systems.[32] SRA concluded, "EPA and participants of the product reregistration process could very much use an automated method of tracking the numerous products throughout the process. Currently, all tracking is done manually in PRB and only the CRM has direct access to the tracking data." Thus, for this evaluation, Abt Associates interviewed several OPP staff members to identify information management issues.

The Office of Pesticide Programs Information Network (OPPIN) was intended to be a centralized system to address the needs of all OPP programs. However, OPPIN is inadequate for purposes of product reregistration because it does not provide the required data fields or reporting functions. It also does not provide PRB the necessary reports to verify the data contained within OPPIN against other data sources, which is critical given the number of tracking systems used for product reregistration. Staff also noted that the concerns with OPPIN extend beyond those of reregistration. SRRD staff have requested modifications to OPPIN to address its shortcomings in tracking reregistration for both active ingredients and end-use products. Generally, requests related to the reregistration of active ingredients have been made more frequently, as many staff believed that those requests were more likely to be granted than those on the product level. OPP staff noted that information management needs for registration review are being addressed to their satisfaction. In addition, staff commented that PRIA actions accounted for most of the OPPIN maintenance budget.

In November 2006, SRRD management again requested several revisions from ITRMD, which reiterated SRRD's priorities from June 2004.[33] These revisions follow in priority order:

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[32] OPP Enterprise Architecture Process Description: Special Review and Reregistration Division Product Reregistration," SRA International, September 29, 2005.

[33] Based on an e-mail message from Pete Caulkins, Associate Director, SRRD, to ITRMD, "Product Reregistration IT Development Projects," September 5, 2006

- RED Outcome Report at the Product Level, which would track by case name and chemical each product, the PDCI issuance date, ninety-day response date, eight-month response date, data review status, date sent to RD, and fields that track RD's interaction with the registrant.
- RED Outcome Summary Report that tracks the total number of products cancelled, reregistered, and amended. A key aspect to this report would be the ability to aggregate these data by chemical, branch, PM, etc.
- Guideline Status Report to track generic studies required by the RED.

These three features were promised to SRRD by ITRMD as part of the next revision to OPPIN.

The first report, RED Outcome Report at the Product Level, was available in the precursor system to OPPIN, which was called PRATS. PRATS was disabled in 2003 after OPPIN was launched. PRATS data are available in read-only format, but PRATS is no longer available for data entry. PRATS included specific fields for tracking product-specific studies (receipt, acceptability, review status, etc.), which is not available in OPPIN.

As a result, EPA has been forced to track outside the centralized system, which is counter to the intent of developing OPPIN. To track product-specific reregistration information, SRRD developed "charts and tables." Charts and tables are a Microsoft Word template that CRMs use to record product reregistration information. They include background information, such as RED date, case, code, PM contact, and number of products, as well as the status of responses in review, products suspended, products canceled, products in label review, products sent to RD, and letters out.[34] For each product, the document includes blowback requested/received, product chemistry data status, toxicity data status, due date for data, date sent to label review, and date sent to RD. It also summarizes contact with the registrant by product and identifies action items. Each CRM has some flexibility to modify the template according to his/her own style, and each file is not available to other CRMs or management because CRMs generally save these files on his/her personal drive. In addition, some CRMs are timelier than others in maintaining their charts and tables.

To provide tracking information to management, SRRD maintains two external databases in either Microsoft Access or Word: (1) STATUS includes information from the "bean sheet," which is a summary report submitted to RD with each reregistration package, and (2) REDS includes the chemical, CRM assignment, number of products, and how many products are reregistered, amended, or cancelled. These databases are only accessible to one SRRD PRB staff member, and serve as the data source for management reports and SRRD's annual performance report. Despite its disadvantages, OPPIN allows SRRD to track RD activities with respect to product reregistration. This helps SRRD maintain its STATUS database. Although there are some similarities between OPPIN and STATUS, OPPIN does not provide the proper reporting features such that PRB can access the needed information in a usable manner.

The third report that was requested, the Guideline Status Report (often referred to as a "report card") has been requested several times by SRRD.[35] This revision would largely benefit the

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[34] Based on charts and tables for Trifluralin, September 15, 2005, provided by Pete Caulkins, Associate Director, SRRD.

[35] "OPPIN Generic Data Management Functionality Assessment," Patrick Dobak, May 2, 2005

reregistration branches that are responsible for tracking confirmatory data for active ingredients, as well as tracking DCI responses. Whereas PRB worked outside the system to develop charts and tables, the effort on the active ingredient side was not as coordinated. As a result, SRRD reregistration branches do not know where confirmatory data are in review nor if the guideline has been satisfied. RD also pursued the development of a database external to OPPIN to track generic data for registration.

Also, on the active ingredient level, staff noted that OPPIN was not well suited for tracking "special studies," which are those that are not included as standard guidelines. Similarly, PRB noted that it does not have a way to track voluntary letters, and Certitrack might be useful for this purpose. Certitrack is a database to track correspondence that was used by some PRB CRMs, but it is a DOS-based program that requires a dedicated printer. OPPIN also does not provide the proper capabilities for data management, as many of the corrections need to be made by a database administrator.

SRRD staff noted that improvements to OPPIN do not seem to be a priority given that OPP is developing PRISM, which will replace OPPIN in September 2008. PRISM, while still in the planning and acquisition phase, intends to use the basic table structures of OPPIN. PRISM, however, will supplement those tables with new and redesigned data structures as it is developed. The primary intention of PRISM is to provide OPP staff and management with an improved presentation layer, integrate currently missing applications and other improved software features, and provide new functional applications. Ultimately PRISM is intended to provide a more stable environment for the entire pesticide industry and coupled with new technologies (Documentum, CDX, and J2EE driven applications), will enhance EPA's ability to meet its strategic goals.[36] Staff noted that OPP has not directly addressed how product reregistration will be addressed in PRISM.

Several staff members expressed that the ultimate success of PRISM hinges upon improved communication between management and staff. In particular, they currently play a mostly responsive role in maintaining and improving OPP tracking needs, e.g., they attend meetings when asked, or provide management with information when requested. These staff members expressed that they would be better able to anticipate and respond to tracking issues if open lines of communication between all staff are maintained. Several staff commented that ITRMD's visibility and involvement in programmatic activities is limited. Because ITRMD has taken a compartmentalized approach when developing both OPPIN and PRISM, staff noted a need to bridge communication within the office. One potential avenue is through the Information Management Council, which is comprised of all OPP division directors and provides a forum to advance IT needs.

As a result of the shortcomings of OPPIN and the current approach to data management, EPA unintentionally created a window of time for which data are not properly tracked because they are not available electronically or not available in a centralized format. The current approach means that PRB is unable to monitor progress in an effective and efficient manner, which wastes a lot of time and things are more likely to fall through the cracks.

[36] http://www.epa.gov/oamhpod1/admin_placement/0610113/qa1.doc

6.2 Acute Toxicity and Product Chemistry Analysis

SRRD conducted an assessment of the impact of product-specific acute toxicity and product chemistry reviews on label mitigation. The SRRD assessment sought to determine the impact of these reviews on revisions made to the product label during reregistration beyond what would be required by the Reregistration Eligibility Decision (RED). SRRD's preliminary analysis indicated that product-specific data had a significant impact on label mitigation. To confirm their findings, Abt Associates conducted an audit of the acute toxicity portion and assessed its utility for the evaluation of the product reregistration program. This section provides background on the data and guidelines and discusses the design of EPA's analysis and our conclusions regarding SRRD's analysis.

For more information on the approach and specific results of the audit, please see "Results of Audit – Evaluation of Acute Toxicity and Product Chemistry Review Findings," Memorandum to Yvonne Watson and Caulkins, U.S. EPA from Debra Kemp, Albert Acquaye, and Jason Sacks, Abt Associates Inc., January 30, 2007.

6.2.1 Background on Acute Toxicity and Product Chemistry Guidelines

The acute toxicity data required on end-use products for product reregistration include the acute oral, acute dermal, and acute inhalation studies, which evaluate systemic toxicity resulting from short-term exposure via the designated route. The remaining acute studies are the primary eye irritation, primary skin irritation, and the dermal sensitization studies. The eye and skin irritation studies assess potential irritation or corrosion from a single exposure, while the dermal sensitization study evaluates allergic contact dermatitis resulting from multiple exposures. These acute studies identify routes of concern, as each study is categorized based on degree of effect (categories I through IV) with Category 1 indicating the most severe effect and Category 4 representing the least severe effect. In addition, each category corresponds with specific label statements or requirements necessary to reduce exposure and protect against acute health effects. The resulting label statements/requirements vary significantly based on product-specific factors such as the formulation type and whether the use pattern is agricultural, occupational/industrial, or residential. Furthermore, label statements for agricultural and occupational use products may vary based on whether the product is subject to the Worker-Protection Standard (WPS).

Acute studies result in hazard communication directly to the user and/or medical professionals through the label sections and/or product classifications listed below.

1. Restricted-Use Pesticide (RUP) Classification
2. Signal Word/Skull and Crossbones Symbol
3. First Aid Statements
4. Note to Physician
5. Hazards to Humans and Domestic Animals (HHDA)
6. Personal Protective Equipment
7. Child-resistant Packaging

The product chemistry data required for product reregistration can be grouped into two categories: (1) product identity, composition, and analysis, and (2) physical and chemical properties. Product identity, composition, and analysis allow EPA to clearly define the product

formulation and identify any inert components of concern. The physical and chemical properties assess potential hazards posed by the formulation (e.g., flammability, corrosivity, and storage stability). Identification of these hazards allows the implementation of preventative measures. Some of the more basic physical and chemical properties evaluated allow EPA to respond to emergency requests for identification of unlabeled pesticides.

6.2.2 Design of Analysis

At the completion of FY2005, SRRD randomly selected a sample of 120 products (7 percent of reregistered products) of the 1,730 products had been reregistered. The sample size of 120 results in one product per RED listed on the OPP Web site with available batching tables at the time this assessment was performed. Abt Associates believes that a larger sample size would be better suited for this analysis, but understands the limited time and resources available to SRRD. SRRD noted that crosschecking labels with the results of the acute toxicity and product chemistry reviews was a lengthy process. Based on its description of how it identified a specific product from each of the 120 REDs, Abt Associates believes that the selection procedure SRRD described was objective and unbiased.

Although Abt Associates confirmed its sampling procedure, we believe that SRRD could have better designed its study and in turn provided a better answer to the issues at hand. For example, we would have suggested that EPA select randomly from among the entire universe of products for which product reregistration was completed or for which labels had been amended. This would have allowed SRRD to confirm that recommendations based on acute toxicity reviews were indeed placed on the final label. In addition, we would have suggested that EPA not constrain itself from sampling one product from each RED given how the number of products vary.

Also, Abt Associates did not believe that EPA's results were presented in a detailed enough manner such that the reader was left with a clear idea of what a "revised statement" means. By establishing criteria for each category or at least providing examples, the reader might have had a clearer idea of how substantive the revisions could be. Similarly, EPA could have made its categories more specific, including multiple categories for signal words (e.g., added, increased, decreased), first aid statements (skin/clothing, eyes, swallowed, inhaled), and individual categories for mitigation statements that appear most frequently and may therefore skew the results (e.g., having container available when calling poison control center, notes about cholinesterase inhibition, etc.).

Finally, the analysis did not provide a comparison of extent of mitigation identified by product-specific data as compared to extent of mitigation identified in the RED. We understand that RED-specified mitigation is generally more substantial. That said, some OPP staff members commented that the product-specific mitigation was negligible. Abt Associates believes that an analysis that identifies the mitigation required by the RED, as well as that specified by product-specific data would be informative.

6.2.3 Audit Conclusions

Although Abt Associates was generally able to confirm the majority of EPA's findings for each of the twelve products included in the audit, the audit revealed several discrepancies and other issues of concern. These discrepancies were identified in the above-referenced memorandum

to EPA. In addition, EPA seemed to be inconsistent in how it characterized Personal Protective Equipment (PPE) in its results. Generally, EPA included the discussion of PPE requirements in the Hazard to Humans and Domestic Animals (HHDA) section of its acute toxicity review memo; however, for purposes of its results sometimes these changes were considered revisions to PPE and sometimes revisions to HHDA.

Often, mitigation specified by the acute toxicity review did not appear on an amended product label. Note, however, that not all products have been reregistered. Similarly, amended labels often included additional mitigation beyond that recommended in the review memo or the label table from the RED. The source (e.g., registrant or RD) of such mitigation is unclear, as well as if mitigation specified by acute toxicity reviews may have otherwise been included on the label (e.g., updates to first aid statements based on current label review standards).

For these reasons as well as the shortcomings identified in the study design, Abt Associates did not feel it was appropriate to include EPA's analysis in its report.

6.3 2,4-D Streamlined Data Requirements

Through batching and citing existing data, OPP can substantially reduce the number of sets of product-specific acute toxicity data to be reviewed for each active ingredient, thus reducing the time required to re-register products. It may be possible to reduce the time required for acute toxicity reviews even further, if the batching process is streamlined. One such example of streamlining may be found in the case of 2,4-D. 2,4-D is an ingredient in more than 600 agricultural and home use products. It comes in multiple chemical forms, and is found in numerous products intended for use in a wide range of uses. The Industry Task Force II on 2,4-D Research Data worked with OPP to reduce product-specific acute toxicity data requirements by using existing data and streamlining the batching process. The Task Force included almost all registrants affected by the 2,4-D reregistration, including every company that had technical registrations for 2,4-D.

Batching allows registrants to use or cite acute toxicity data from a group of similar products to satisfy data requirements. Batching tables are included in the RED and group product formulations that, from an acute toxicity perspective, allow one set of acute data to be used to support the reviews of all products within the batch. Once batching tables are published in the RED, it is the responsibility of registrants to act upon them and submit data to OPP. For instance, after product A submits the required data to EPA, registrants of products B, C, and D that belong to the same batch as product A and want to use (cite) data for product A in support of their products, may pay or offer to pay the registrant of product A to cite its data.

Depending on the chemical and the formulations, OPP may not be able to batch all the acute toxicity data, instead requiring all registrants to submit individual acute toxicity data. This is usually the case for fertilizer products, which may result in individual eye irritation data being required and other acute toxicity data being batched. In many instances, registrants choose not to take advantage of the batches and rather chose to submit their own data, which EPA is obliged to review. Many registrants do not take advantage of the batching because the data already exist, they would prefer to submit their own data, or they do not want to pay data compensation fees. OPP estimates that typically between 20 and 30 percent of registrants take advantage of batching.

6.3.1 2,4-D Batching Approach

The level of success of batching varies from chemical to chemical, since formulations may be quite different. In the case of 2,4-D, a preliminary attempt at batching one of the formulations with the majority of 2,4-D products yielded about 50 to 60 batches. The Industry Task Force II on 2,4-D Research Data submitted a proposed batching scheme, although it was of limited value because it did not include information on inert ingredients, which is confidential business information. The acute data provided by the Task Force, however, were very useful in satisfying the data requirements for individual products and product batches, even though organizing and evaluating such a large volume of data was very time consuming.

This approach did, however, allow PRB to use the existing acute data provided by the Task Force to satisfy some or all data requirements for most of the product batches. This negated the need for a registrant to submit a waiver to cite what was already submitted to EPA. The formation of a task force specifically to address product-specific data requirements will likely result in greater participation in the batching groups by registrants. Also, because Task Force data were available during the batching process, they were used to determine product grouping. In some cases, this allowed for products with a larger range of active ingredient to be grouped together. As a result, EPA asked for only 1,027 acute toxicity studies out of a possible 3,618 studies, which will decrease the burden on the registrants, EPA, and OMB.

6.3.2 2,4-D Storage Stability Requirements

The Industry Task Force II on 2,4-D Research Data approached EPA with information and data to show that different formulations using the chemical are extremely stable under various conditions. For this reason, it was possible to eliminate the storage stability data requirements that are the most expensive ones for registrants and the longest for OPP staff to review. Registrants had over time submitted almost ninety storage stability studies to support registrations or in enforcement cases, all of which indicated that regardless of time, the product remains stable with up to five to seven years of shelf life. As a result, OPP waived the need for any more storage stability studies.

6.3.3 Pros and Cons of this Approach

In general, this approach will save time in reviewing data by identifying good studies that have been conducted properly to support the registration of large groups of products. This batching approach resulted in a 72 percent reduction in the amount of data required compared to getting a six-pack for each of the 603 products.[37] A six-pack for each of these products would have resulted in 3,618 individual studies required, while EPA is asking for 1,027 studies through the current approach. Typically with batching, however, many products use existing data (either from another company within the same batch, or previously generated product-specific data) to support product reregistration. Even if one-third of the 603 products used existing data, this approach would have resulted in a 57 percent reduction in the amount of acute data required.

This approach required registrant participation to determine the studies that may be used to support the reregistration of various product groups. The larger the number of registrants involved in a task force, the greater the degree of participation in batching since the formation of the task force provides an organizational structure to facilitate data sharing and minimize

[37] 2,4-D Batching Project Briefing, provided by Pete Caulkins, February 13, 2007.

registrant costs. Because all 2,4-D registrants were members of the Task Force, they were likely to participate.

Typically OPP would issue the data requirements and shift the responsibility to the registrant. By working with the Task Force, they were able to determine what they needed. OPP has learned from its 2,4-D experience. PRB developed a revised process for working with task forces that does not place as great a burden on its staff. OPP has targeted permethrin (1,185 products), MGK-264 (706 products), and PBO (1,704 products) as candidates for a revised, streamlined approach. This approach appears to be best suited for situations where a task force exists, which can provide the necessary infrastructure to coordinate responses among the various end-use product registrants, ensure their participation, and address data compensation issues.

6.4 Communication

Several entities are involved in product reregistration, including the SRRD reregistration branches following the publication of the RED and the Registration Division after data review is complete. Data collected through interviews indicate that there is a breakdown in communication at the transition of products to and from PRB.

Staff in the reregistration branches often operated on the assumption that the signature of the RED essentially concludes reregistration and that mitigation is implemented in a timely manner. Staff noted that the public and environmental and public health organizations often share this perception. Staff of the SRRD reregistration branches and the Registration Division admitted that they are not as familiar with the process or issues associated with product reregistration as perhaps is warranted.

Further, they recognize that communication with the registrant is not always productive because the registrants lack an incentive for product reregistration. Recently, SRRD has pursued avenues to prevent delays in registrant submissions, which often resulted from submitting comments or inadequate data later in the process. OPP staff also noted that the "stick" associated with product reregistration – suspension – has not been applied recently. SRRD is currently in discussion to reestablish the procedures for that process now that the EPA Office of Compliance is no longer involved in suspension actions.

At the end of each month, SRRD sends a status report to RD that identifies which products are currently with RD for reregistration. This is based on the STATUS tracking database that SRRD maintains external to OPPIN. Several RD staff noted that these reports could provide additional information to make them more useful, and some noted that they did not actively use the report for management purposes.

Whereas reregistration of conventional pesticide products is the responsibility of SRRD, other OPP divisions are responsible for reregistering products under their area of focus. SRRD staff noted the Biopesticides and Pollution Prevention Division (BPPD) has also commented on the inadequacy of OPPIN for product reregistration. However, SRRD staff noted that they were not familiar with the product-specific data tracking procedures within other OPP divisions (BPPD and AD).

6.5 Management and Staffing

As part of the overall reregistration process, product reregistration is only one of the priorities within either SRRD or RD. Historically, writing and publishing REDs was the priority for SRRD and registrations (particularly PRIA actions) were the priority for RD. Recent attention, however, is being focused on product reregistration through pilot projects, quarterly briefings for OPP Director Jim Jones, and regular SRRD/RD meetings on product reregistration. Most recently, the RD Director designed an approach for product reregistration moving forward (see Section 7.5 of this report). OPP management and staff are dedicated to seeing the RED-specified mitigation implemented on product labels, as well as addressing the vulnerability associated with the delays in product reregistration.

Despite attempts within FIFRA to establish deadlines for product reregistration (see Section 1.3.1 of this report), product reregistration has never been pushed and management focused on the front-end of the process. In addition to the impacts on OPP's backlog, a registrant also does not know when it will receive a reregistration decision after submitting an eight-month response. OPP has improved the process by which registrants submit data, including standard formats. OPP staff and management noted that product reregistration is one of the most inefficient processes in OPP, though that is not a result of the people, but the design of the system. To help address performance, SRRD sets goals for product reregistration annually, and these goals are met (see Figure 3-4). SRRD staff noted that because of end of fiscal year deadlines for REDs and other activities, product reregistration gets the most attention in October to January.

In its FY2007 reregistration work plan, SRRD allocates its FTE resources as follows:[38]

- 40 percent to completing non-food-use REDs
- 41 percent to post-RED issues
- 8 percent to product reregistration, which covers both SRRD PRB and RD
- 11 percent to registration review

Over time, a greater percentage of resources will be allocated to registration review. After FY2008, SRRD expects that funds will no longer be allocated for completing REDs, though it will continue to budget for post-RED issues. Funds are allocated for product reregistration through FY2013. The eight percent FTE allocation is roughly equivalent to past staffing levels and SRRD expects the staffing level to remain fairly constant in the short term.

Some staff members commented on the decrease in PRB staffing over time as a result of attrition and retirement. They maintain that it is a challenge for PRB to keep up in light of the workload and reductions in staff. PRB did recently hire a new product chemistry reviewer and a new CRM. Training for new staff is conducted on an ad hoc basis, and written procedures for product reregistration are not available.

[38] Personal communication with Pete Caulkins, January 2007

7. Label Assessments and Reviews

SRRD PRB and RD conduct label assessments and label reviews, respectively. SRRD's preliminary label assessment focuses on comparing the amended label to the label table in the RED to ensure that the label adequately captures the required mitigation. After SRRD's preliminary label assessment, RD reviews the label in its entirety and is responsible for stamping the final, approved version.

A brief overview of the reregistration process as it relates to the label review process is provided below:

- Registrants send OPP a revised label as part of the 90-day response to the DCI to incorporate mitigation on the RED;
- Registrants send OPP product-specific data and/or confirmatory (generic) data over the eight-month response period;
- SRRD evaluates the product-specific data, requests additional information as needed, and determines if additional mitigation is needed;
- After all study reviews are complete, the CRM assembles a label review package for the PRB Label Review Team;
- PRB Label Review Team develops a preliminary label assessment (see Section 7.1);
- The CRM assembles final review package ("clean sheet," all applicable science reviews, the preliminary label assessment, and the draft amended product label) and delivers to Product Manager (PM) in RD; and
- The PM in RD conducts final review of label (see Section 7.2) and requests additional revisions from the registrant, if required. Once approved, the PM stamps the final label and issues a reregistration notice.

7.1 Label Assessment – Special Review and Reregistration Division

The primary purpose of SRRD's preliminary label assessment is to determine whether the draft labels submitted in connection with product reregistration comply with amended labeling language specified in the RED/IRED.[39] To avoid duplication of effort between SRRD's and RD's label reviews, the preliminary label assessment does not comment on other aspects of the label, such as labeling requirements specified in 40 CFR part 156.10, Pesticide Regulation Notices (PRNs), and Criteria and Policy Notices. To assemble the preliminary label assessment and to maintain consistency, SRRD uses a template with the following sections: a scope statement, background, summary of findings (including recommended label changes), and an appendix with a checklist of whether the label changes made by registrants are acceptable or unacceptable.

The preliminary label assessment occurs once the CRM submits the label review package to the SRRD PRB Label Review Team. The label review package consists of the draft label

[39] PRB Preliminary Label Assessment. Memorandum provided to Abt Associates by Larry Schnaubelt, PRB.

submitted by the registrant, SRRD's review of the product-specific data, and the label table, which assists SRRD in comparing the label to the mitigation specified in the RED. The label included in the label review package is the most recent, hardcopy version submitted by the registrant as part of the eight-month response to the DCI. Over this same time period, however, the same registrant may have submitted drafts of amended labels to RD (e.g., to add a new use), and SRRD may be unaware of these label changes. Consequently, the label reviewed by SRRD as part of its preliminary label assessment may not be the most recent version. This problem is magnified by the long timeframes in which label reviews occur, as documented in Chapter 3 of this report. Once completed, the preliminary label assessment is submitted back to the CRM, who then assembles the final review package and delivers it to the appropriate PM in RD.

7.2 Label Review – Registration Division

After receiving the final review package from SRRD, the PM conducts the final label review and stamps the label. It is the responsibility of the PM to identify and address any outstanding labeling issues, including any remaining RED-specific issues, and to obtain the necessary label changes required for final product registration. To do so, the PM typically composes a letter to the registrant specifying necessary labeling revisions.

RD commonly finds issues with the labels that require additional revisions by the registrant (e.g., labels are not compliant with acute toxicity data) or prompt RD to re-conduct the label assessment performed by SRRD. For example, the preliminary label assessments commonly identify labeling issues but do not contain recommended solutions, requiring the PM to duplicate the part of the review related to RED mitigation. Another contributing factor is poor version control of labels between SRRD and RD. As mentioned previously, it is common for PMs to receive old labels as part of the final review package from SRRD, due to the fact that the PRB Label Review Team assesses the amended label submitted by registrants as part of the eight-month response. In these instances, PMs often conduct an entire label review from scratch, since the preliminary label assessment is based on an outdated label.

The OPP Label Review Manual was created as a way to help maintain consistency in RD's label reviews. Despite these guidelines, RD's label reviews are not always conducted in a consistent manner. For example, in instances where a registrant requests the addition of a new use to the label, and the product is still somewhere in the reregistration process, some (but not all) PMs will require that the registrant implement the mitigation stated in the RED at the same time as adding the new use to the label. These PMs will not stamp the new label until the mitigation stated in the RED is incorporated on the label.

Similarly, PMs vary in the way they use SRRD's preliminary label assessment. Several RD Branch Chiefs noted that the label assessments are especially beneficial to new PMs who are not experienced in conducting label reviews or who do not have an extensive knowledge of the product and its regulatory history. The majority of PMs, however, noted that they either entirely disregard the label assessments or only use them as a way to ground-truth their own label reviews.

7.3 Ziram Pilot Project

In Spring 2006, EPA initiated a pilot project using the ziram case where RD and SRRD conducted concurrent, independent label reviews for each of the products to determine how the two divisions assessed label changes. In March 2006, reviews were conducted for three products. There were no differences in the label reviews conducted by the divisions, except that RD had two, minor non-substantive additions that were a result of pesticide notices.[40] Note that two of the products were manufacturing-use products that typically do not require many label changes as a result of the RED.

Also in Spring 2006, SRRD and RD conducted label reviews for sodium acifluorfen using its standard process (i.e., a label assessment in SRRD and a label review in RD). Reviews indicated that the registrant had included a new use on the label, which was caught by both SRRD and RD reviewers.

Although these two reviews indicate the similarities in reviews between the two divisions, our preliminary conclusion is that two pilots are not an adequate sample from which to draw a conclusion. Further, we would have recommended that the reviewers not be told of the pilot project to better represent typical review conditions.

7.4 Workload Management and Other Issues

In some RD branches, products are assigned to PMs and their staffs based on chemical ownership. In other branches, one or two staff members are designated to conduct label reviews on a full-time basis. Many PMs and their staffs are currently juggling label reviews for product reregistration with PRIA and other registration work. Other personnel issues include frequent staff turnover and the likelihood of several PMs retiring in the near future.

With regard to managing workload, the number of review packages delivered by SRRD to RD is highly variable. Branch Chiefs and PMs in RD often do not receive a "heads-up" from SRRD about when to expect review packages. PMs may receive one hundred review packages at a time, or as few as one or two review package every few weeks to a month. The product reregistration backlog is also highly variably among the RD branches. For example, two branches have no backlog while the remaining branches have backlogs of one hundred or more products.

Several PMs expressed preference for receiving all product labels pertaining to one chemical at one time. This is advantageous because it allows the review teams to meet and discuss any issues, thus leading to greater consistency in the label reviews. The downside of batching is that SRRD may hold back a large number of completed packages while completing the remaining products, which delays implementation of mitigation and potentially results in outdated assessments for a significant number of products.

Several staff noted that there is very little collaboration or communication between SRRD and RD on the label assessments and reviews. For example, the PRB Label Review Team rarely

[40] Product Reregistration Quarterly Review, Briefing for Jim Jones, Associate Director of the EPA Office of Pesticide Programs, July 2006

receives feedback nor is asked questions by RD on the preliminary label assessment. Similarly, it is common for there to be little to no interaction between the SRRD CRM and the PM when the final review package is delivered to RD.

To facilitate the handoff of packages between SRRD and RD, OPP recently developed new standard operating procedures (SOPs) to provide RD with streamlined label review packages from PRB.[41] By providing only the critical documents used in PRB's label assessment, OPP expects that RD staff will be able to proceed with reregistering the product with less effort and in a shorter time period. A streamlined package would entail sending RD only the final acceptable review from each discipline (e.g., acute toxicity, product chemistry with acceptable confidential statement of formula, and efficacy), the label assessment, and one copy of the latest draft label (used in the label assessment). Previously, each CRM assembled packages differently and often provided more information than RD required. Both of these issues required RD to spend a significant amount of time reviewing and sorting materials in the package before conducting its label review.

7.5 Current Strategy to Expedite Product Reregistration

Recognizing the backlog in product reregistration, upper management in RD has placed an increased emphasis on product reregistration recently. In Fall 2006, the RD Director developed a plan to expedite product reregistration by forming "SWAT teams," which would include staff from both RD and SRRD and would focus on reducing product reregistration backlog. This is a promising approach because it bridges the divide between RD and SRRD, which will help to facilitate communication between the divisions.

Four categories of products were identified: (1) Products in RD for which the PM has communicated with the registrant but has not yet received a label that is in compliance with the RED, (2) Products in RD for which the PM has not yet taken any action, (3) Products in SRRD PRB for which the DCIs have been issued, and (4) Products in SRRD PRB for which the DCI has not yet been mailed.[42]

Products in Categories 1 and 2 will be addressed by RD staff exclusively. During our interviews, we found that some RD branches had taken the initiative to reduce its product reregistration backlog (as of September 2006), whereas others had not yet addressed products in their branch. Categories 3 and 4 will be addressed by SWAT teams (SRRD and RD).

To address Category 1 products, the PM will send a letter that outlines a registrant's obligations and allow a given amount of time to incorporate these changes before EPA takes action. To address Category 2 products, the PM will send a letter to the registrant requesting label changes as stated in the RED. The registrant must also send a letter that certifies that the only changes on the label were those required by the REDs.

In early October, SWAT teams were established to expedite product registration for Categories 3 and 4. Each team consists of about five SRRD and RD staff, each dedicating full-time, or close to full-time, to product reregistration over the next few months. The SWAT teams will

[41] SOP for Reregistration Packages sent to RD, provided to Abt Associates by Venus Eagle, September 2006

[42] Categories for Products in the SRRD-RD Pipeline, August 2, 2006

conduct label reviews, send letters to registrants about required label revisions, and initiate regulatory action when a registrant does not comply. Each SWAT team will be assigned about one to three active ingredient cases, covering about 100 products in total.[43] RD predicted that the SWAT teams would work for a period of two months.

The SWAT team approach is unique for several reasons:

- It includes ambitious internal deadlines for completing product reregistration
- Product reregistration was made a priority within RD (particularly with respect to products in Categories 1 and 2)
- RD will provide support to SRRD with products that have not yet completed the SRRD portion of the reregistration process.
- It includes strict deadlines for registrant responses, including 30 days for registrants to submit amended labels (Categories 1 and 2). OPP is also considering requiring registrants to amend labels with RED-specified mitigation in advance of product reregistration (Categories 3 and 4).

Preliminary information on the SWAT team approach indicates that each of the RD branches is implementing the approach differently. In any event, the management attention placed on product reregistration will ensure that product reregistration happens in a timelier manner. As the approach is further implemented, EPA will need to assess if the 30-day deadlines are being met, what the role for either division was, and compare number of actions completed in FY2007 to previous years.

[43] Details of Reregistration Process Categories (Draft), provided to Abt Associates by Pete Caulkins, SRRD, September 8, 2006

8. Suggested Changes to Process Design and Other Recommendations

Based on the findings and analysis presented in Chapters 3 through 7 of this report, this chapter presents our recommendations for improving the product reregistration process. As appropriate, we also present pros and cons for each recommendation.

8.1 RED Development

In August 2006, EPA completed the REDs for food-use pesticides as required by the Pesticide Registration Improvement Act. At that time, EPA only had 54 REDs to complete (9 percent). Thus, there are still opportunities to improve non-food-use REDs and to direct more attention to post-RED activities. Based on the case studies discussed in Chapter 4, Abt Associates identified the following issues or problems with REDs that contribute to delays in product reregistration:

- REDs were often published before they are completed or before all outstanding issues were properly addressed.
- The documents represent a "snapshot in time" of the data available to EPA, and registrants often provide additional data that warrant amending the RED.
- Some REDs did not represent reregistration decisions or included provisions for additional studies, such that product reregistration could not be effectively implemented after the RED was published.
- REDs sometimes contained small errors, most of which were straightforward and easy to address.
- The label tables often contained language that RD or PRB felt could be improved or that was not consistent with labeling for other products.
- Staff from the reregistration branches were often unavailable to assist with post-RED issues.
- When a case is transitioned to PRB, staff are often unfamiliar with the RED contents and issues.
- The implementation of REDs was often influenced by other issues, which may not have been directly related to the RED itself (e.g., the cancer reclassification for captan, the registrant's decision to discontinue dicofol, legal challenges, etc.).

With these findings in mind, Abt Associates provides the following recommendations regarding RED development.

8.1.1 Improve Transition of Cases from Reregistration Branches to PRB

The transition of a chemical case from the SRRD reregistration branches to PRB could be improved. One potential way to accomplish this would be to have a "hand-off" meeting that would be attended by the generic CRM, his/her branch chief, the PRB branch chief, and the product CRM. This would be an opportunity for the reregistration branches to brief PRB on the issues, particularly those that are outstanding, and improve the relationship and coordination

within SRRD. This would address the concerns of PRB that reregistration branches do not actively participate in many post-RED issues and also the concerns of the reregistration branches that product reregistration lacks visibility. A meeting would also help delineate roles and responsibilities, and signal a clear transition from one branch to another. Until this meeting occurs, the chemical case would remain the responsibility of the reregistration branches and help encourage them to address post-RED issues.

8.1.2 Require More Participation by RD in the Development of Label Tables

Based on our conversations with both RD and SRRD (reregistration branches and PRB), we believe that the development of the label table in the RED should be improved. This recommendation is based on comments from the reregistration branches that they do not have adequate expertise in labeling. Similarly, both the PRB Label Review Team and the RD PMs noted that label tables often include language that is written in a way that is not suitable for a label or that is inconsistent with other products containing the active ingredient. RD noted that PMs are invited to attend the meetings, but RD does not generally play an active role in the development of the label table. RD Branch Chiefs should ensure that PMs are invited to and attend these meetings. The involvement of both the PM and the RD Team Leader in the RED process will help ensure the quality and thoroughness of the label review as it relates to RED-specified mitigation. In addition, RD should be required to review and approve label tables before they are published to ensure consistency and appropriateness. Note that because of our recommendation to eliminate label assessments within PRB (below), the development and review of the label table would not be a role for PRB.

8.2 Implementation of RED-Specified Mitigation

Based on its review of Memoranda of Agreement (MOAs), pilot projects, and RD's SWAT team approach, Abt Associates identified the following issues or problems related to implementation of RED-specified mitigation:

- Because of the length of the product reregistration process, as well as the delays that often occur, the mitigation identified in the RED is often not implemented for several years. This delay is particularly troublesome given that the universe of pesticides products to be reregistered includes those that were registered prior to November 1, 1984.
- Even with regulatory action as a possible consequence of non-response, several registrants did not submit amended propanil labels to include RED-specified mitigation.
- In the case of phosmet, amended labels were not submitted in an expedited manner as specified in the MOA.

With these findings in mind, Abt Associates provides the following recommendations regarding the implementation of RED-specified mitigation.

8.2.1 Implement Mitigation in an Expedited Manner When Cost-Effective

With the goal of implementing RED-specified mitigation as soon as possible, OPP is considering requiring registrants to amend product labels after a RED is signed to include the required labeling changes. OPP is considering using this approach for all products because OPP

believes that identifying a subset of products would not maintain a level playing field among the registrants. By potentially adding an additional step into the product reregistration process, OPP needs to consider the additional staff time and resources this would require. Not only would OPP need to conduct an additional round of label review, but it would also need to track responses and maintain communication with the registrant.

Although we understand EPA's rationale for applying this policy to the entire universe of end-use products, OPP would have several options available to it if adequate staff and resources were unavailable:

- Identify subset based on risk characteristics based on the attributes of the product (e.g., market share, use patterns) or the level of mitigation required by the RED
- Select REDs that are likely to have issues that might delay product reregistration, including related regulatory activities, etc.

Any rationale for differentiating policies would have to be defensible and be consistent with applicable laws and regulations.

In addition, during the course of product reregistration, both RD and SRRD would be in contact with the registrant. RD would request a label amended with RED-specified mitigation, whereas SRRD would request ninety-day and eight-month responses. OPP would need to ensure that these efforts are consistent and coordinated to reduce confusion on the part of the registrant. Members of the regulated community, particularly smaller companies, are likely to miss the distinction between the two divisions and only focus on the Agency level. Note that this issue arose during the captan reregistration, where both the SRRD reregistration branch and PRB were in contact with the registrants at the same time. Moving forward with the proposed approach, OPP would need to establish better communication and coordination between the RD PM and the SRRD PRB CRM.

Alternatively, although it prolongs implementation of RED-specified mitigation, EPA could require the amended label with the ninety-day response, but instead of holding onto it until the product is ready for label review, PRB could immediately send the label to RD for review. This assumes, however, that the DCI is sent out in a timely manner because RD is considering having a PM send letters to the registrants independently of the DCI. As a benefit, issuing the letters prior to the DCI may allow OPP to identify products that would be cancelled before it goes to the effort of preparing and mailing a DCI.

8.2.2 Pursue Additional Regulatory Action When Warranted

As demonstrated in the cases of propanil and phosmet, several registrants did not submit amended labels despite the consequence of regulatory action or the conditions of the MOA. To ensure that mitigation is consistently implemented and that registrants are aware of the implications of noncompliance, EPA needs to be prepared to pursue the "additional regulatory action" to which it refers in its letters to the registrant. Without this aspect, the success of implementing RED-specified mitigation is limited.

8.2.3 Further Explore Self-Certified or Electronic Labels

As part of its approach to implement RED-specified mitigation sooner, EPA would require registrants to submit a letter that certifies that the only changes that were made to the label were those specified by the RED. Although this issue is outside the scope of this evaluation, Abt Associates suggests that EPA consider requiring a registrant to identify and certify the nature of label changes for all label amendments. This step would increase the transparency, and also reduce the burden on the PM for identifying label changes that may or may not be appropriate. Similarly, several staff noted that OPP has discussed but is not yet actively pursuing an electronic labeling system that would allow EPA to compare label amendments electronically (i.e., in a manner similar to document comparison features in word-processing programs). These two changes to program design would decrease label review burden generally and provide RD with significantly more time to address other issues, including product reregistration.

8.3 DCI Justifications and Preparation

Based on our findings in Chapter 5, Abt Associates identified the following issues or problems associated with developing Data Call-in (DCI) justification packages and mailing out DCIs that contribute to delays in product reregistration:

- The format for the DCI justification package has been and continues to be an issue. Based on the direction provided by the Field and External Affairs Division (FEAD), SRRD used a new streamlined template for the justification package, but it also supplemented the template with a substantial amount of information.
- Risk assessments and REDs often do not provide the necessary information to create the DCI justification package, which requires PSB to spend a significant amount of time collecting additional information.
- As with other parts of the product reregistration process, SRRD does not have the adequate tracking systems available to them and has been forced to develop external systems on an ad hoc basis.

With these findings in mind, Abt Associates provides the following recommendations regarding the preparation of DCI justification packages and DCIs generally.

8.3.1 Ensure that DCIs Are Prepared According to the Package Template

PSB should use the template for the DCI justification package to prepare the DCI package more effectively and efficiently. While it is important to anticipate the needs and questions of OMB, PSB should ensure that the DCI packages provide the essential information, not try to anticipate all of the information that OMB could (but may never) require at a later time. In turn, the DCI justification package template should be revised according to the comments and lessons learned from OMB on an ongoing basis.

8.3.2 Modify Format of Supporting Data in Risk Assessments

The RAs should contain an up-front description of the data gaps and the rationale for new studies so that PSB staff do not have to search for or re-create this information. As part of the

description, the science divisions should include cost burden estimates for "special studies," since they are in the best position to project the requirements and costs of special studies. As a next step, PSB and the science divisions should work together to identify what PSB routinely needs from RAs or REDs in order to construct the DCI justification package, and then how that information can best be presented and summarized going forward.

8.4 Streamlined Data Requirements

Based on EPA's analysis discussed in Section 6.2 of this report, Abt Associates expected to make recommendations for streamlining acute toxicity or product chemistry data requirements based on characteristics of end-use products. However, as described in that section of this report, Abt Associates concluded that the analysis was not designed in a manner that yielded results appropriate for this purpose. Without adequate data on which to base recommendations, Abt Associates is unable to make recommendations for streamlined data requirements. However, based on its research, Abt Associates provides the following recommendations regarding the product-specific data requirements.

8.4.1 Conduct Additional Analyses to Determine Value of Product-Specific Data

In order to provide data to inform an approach for streamlined data requirements, OPP could consider undertaking additional analyses that would be more informative and detailed than the one provided to support this evaluation. Such an analysis would involve randomly selecting from the entire universe of products for which product reregistration was completed or for which labels had been amended. This analysis would also not be limited to sampling one product from each RED. To increase the utility of the results, EPA should identify mitigation resulting from product-specific data in a more detailed manner and record these results in either Microsoft Excel or Access to facilitate analysis. We also believe that a comparison of RED-specified mitigation to that warranted by product-specific data would be informative.

8.4.2 Leverage Related Efforts for Process Improvements

In June 2006, the Pesticide Program Dialogue Committee (PPDC) PRIA Process Improvement Workgroup met to discuss issues with product chemistry studies.[44] The workgroup was formed in reaction to a provision in PRIA on process improvement. The workgroup includes members from EPA and industry, including the director of the Registration Division. Both EPA and registrants have noted that product chemistry studies are often provided as the rationale for extending decisions on registration actions under PRIA. Staff from SRRD participated in the workgroup discussion of product chemistry. Given the common interest in product chemistry studies, Abt Associates recommends that SRRD maintain its participation is these discussions and take full advantage of any procedures, guidance, or calculations that result from this related improvement process. This is also an opportunity for RD and SRRD management to leverage ideas and approaches that are applicable to product reregistration.

8.4.3 Expand Batching Approaches to Reduce Number of Requested Studies

For the case of 2,4-D, EPA worked with the Industry Task Force to identify storage stability studies and to further batch acute toxicity data based on existing studies. For this approach to

[44] http://www.epa.gov/oppfead1/cb/ppdc/pria/june06/june06-minutes.pdf

succeed, all (or almost all) registrants need to be involved. In addition, the number of 2,4-D products also justified the approach.

Due to the unwieldy amount of data received from the Task Force, OPP has decided that future efforts to reduce acute toxicity data requirements will not consider existing data during the batching process. Rather, PRB will provide the Task Force with the batching and allow them to identify acute data that support product batches, after which PRB will evaluate the data for acceptability. The acute toxicity profile and MRIDs for the studies available to support each batch will be identified in the final batching document. EPA should explore ways to engage the registrants early on in the batching process, perhaps by identifying windows of opportunity in the public participation process. This may help to address batching issues in a timelier manner.

EPA is currently considering ways in which product-specific acute toxicity and product chemistry data requirements could be further batched or streamlined for other cases, including PBO (1,704 products), pyrethrins (1,490 products), MGK-264 (706 products), and permethrin (1,185 products).

8.4.4 Encourage Use of Self-Certified Product Chemistry Data

In 1998 OPP issued Pesticide Registration (PR) Notice 98-1, Notice to Manufacturers, Producers, Formulators, and Registrants of Pesticide Products, which allows a "self-certification" program for certain product chemistry data for manufacturing-use products and end-use products. Applicants are allowed to submit a one-page summary of the products physical and chemical properties, but are no longer required to submit the studies upon which the summary is based. Registrants must submit the studies if requested by OPP. Based on our conversations with OPP staff, few registrants take advantage of this option for the purposes of product reregistration. If they did, OPP would likely request the supporting studies, particularly for storage stability. Thus, the benefit of this policy to registrants is not clear because they still need to complete the studies, prepare a summary (that imposes additional burden), and then respond to OPP inquiries. As such, this attempt at streamlining data requirements and submissions does not appear to be an effective one, and EPA should consider if it can provide an incentive for registrants to submit self-certified data or provide guidance that would yield storage stability studies that would not require OPP review.

8.5 Registrant Responses

One of the sources of delay in the product reregistration process is the registrant responses, which require a lot of time for the registrants to prepare and submit, as well as for EPA to receive, track, review, and respond to (if required). During the course of its reregistration program, EPA has initiated several efforts to increase the quality of data it receives from registrants. To ensure that registrants submit responses in a timely manner, or perhaps encourage registrants to submit responses more quickly than required, Abt Associates provides the following recommendations.

8.5.1 Create Incentives for Registrants to Provide Expedited Responses

As appropriate and permissible under applicable laws and regulations, EPA should consider if it could create incentives for registrants to submit data early or signal their intent to cancel a product. One potential approach would be to reduce registration maintenance fees or allow

additional flexibility. EPA would need to consider if these approaches would provide an adequate benefit to OPP relative to the cost (either in dollars or effort). This recommendation is based on the finding that registrants are often unwilling to voluntarily provide data and amend labels. This finding runs counter to the situation in RD where registrants want OPP to process registrations as soon as possible and registrants willingly submit information in a timely manner.

8.5.2 Establish Procedures and Pursue Suspensions

Recently, OPP has not initiated suspensions of product registrations because the procedures are under review. OPP also noted that suspensions require a significant amount of paperwork such that EPA often enters into negotiations instead. It is also difficult to lift a suspension. Because registrants lack an incentive for product reregistration to occur, as they often lose uses or must add additional mitigation to the label, EPA must make an aggressive effort to receive registrant responses. EPA is currently reviewing its procedures and signature authority for suspensions, and should consider suspending registrations of products for which the registrant is not submitting the required information. Despite the effort, this practice will send a clear message to the regulated community.

8.5.3 Retain Data Review Functions within PRB

Until 1989, product reregistration was the responsibility of the Registration Division. SRRD, and PRB specifically, was created specifically to address reregistration because it was not a priority within RD. Some have suggested that given the similarities between the two programs that product reregistration should again be the purview of RD. Although Abt Associates suggests in the next section that the label assessment in PRB should be discontinued, we believe that requesting, managing, and reviewing registrant submissions should remain the responsibility of PRB and be organizationally separate from registration. If these functions were moved to RD, they could be lost when combined with the competing priorities of registration. We believe there is a significant benefit to having dedicated product reregistration reviewers in PRB.

8.6 Label Reviews and the Role of the Registration Division

Based on our findings in Chapter 7, Abt Associates identified the following issues or problems associated with label reviews and assessments that contribute to delays in product reregistration:

- The label assessments are used by some of the registration branches, whereas others do not even consult the documents. Some product mangers commented that PRB information was out of date or inconsistent with related products containing that active ingredient.
- The goal of the PRB label assessment was to consistently implement product reregistration on product labels, but the consistency goal was subsumed by a broader effort for labeling consistency (e.g., Label Review Manual).
- The ziram pilot project did not provide enough information from which to draw conclusions.
- The procedures for the transition between SRRD PRB and RD have helped to streamline the package.

- SRRD and RD staffs generally do not communicate with each other and are generally unaware of the issues and procedures in either division.

With these findings in mind, Abt Associates provides the following recommendations regarding label reviews and the role of RD.

8.6.1 Discontinue Label Assessments within SRRD

While an effort was made to clearly divide roles and responsibilities between RD and SRRD, the preliminary label assessments and label reviews remain duplicative. As such, we recommend that that label review responsibility should reside within RD. This recommendation is based in large part on the finding that many PMs do not consult the preliminary label assessments because they are outdated (i.e., based on an outdated version of the label) or because the PMs regard them as unreliable or incomplete. Given their product-specific knowledge and familiarity with the label review process, PMs are arguably the best-qualified individuals to conduct the label reviews. While a label assessment in SRRD and a full label review in RD ensures that at least two individuals have reviewed the label, we believe that the efforts are redundant. In addition, PRB sometimes defers to RD on labeling decisions anyway (e.g., restricted-use pesticide classifications). Note that this recommendation does not preclude the participation of SRRD staff in the SWAT team approach developed by RD management.

8.6.2 Improve Transition of Cases from SRRD to RD

Better communication and collaboration are needed when SRRD delivers the final review packages to RD. Currently, many CRMs deliver final review packages to PMs without notifying them beforehand or clearly summarizing outstanding issues. We recommend that CRMs and PMs have "hand-off meetings" at this time so any unresolved issues can be flagged and discussed. The scheduling of hand-off meetings will also help PMs to better predict and manage their workloads.

8.7 Management, Resources, and Staffing

Abt Associates drew the following conclusions regarding management, resources, and staffing:

- The resource allocation has remained relatively stable and SRRD expects that will continue.
- The backlog of product reregistration actions to be completed increased after the completion of the food-use REDs in August 2006.
- Recent management attention has raised the visibility of product reregistration in both RD and SRRD.
- The SWAT team approach developed by RD management is a promising approach to accomplishing product reregistration.

With these findings in mind, Abt Associates provides the following recommendations regarding management, resources, and staffing.

8.7.1 Reevaluate Allocation of SRRD Resources

Despite the number of products yet to be completed, particularly following the completion of the food-use REDs in August 2006, Abt Associates believes OPP should reconsider its allocation of resources in FY2007 and in the future. In its FY2007 reregistration work plan, SRRD allocates eight percent of its resource allocation to product reregistration. The eight percent FTE allocation is roughly equivalent to past staffing levels and SRRD expects the staffing level to remain fairly constant in the short term. Funds are allocated to product reregistration at roughly the same level through FY 2013. EPA has predicted that it will complete product reregistration in 2012.

Based on the data presented in Chapter 3, we considered the work that SRRD has yet to complete with respect to product reregistration. In FY2006, EPA completed 545 actions, with 11,948 actions pending. Several active ingredients represent a large number of products: PBO (1,704 products), pyrethrins (1,490 products), MGK-264 (706 products), and permethrin (1,185 products). For purposes of the following calculation, these active ingredients were removed because we expect that EPA will develop unique approaches for these cases such that they may not follow the traditional reregistration process. Thus, we expect that approximately 6,903 actions remain exclusive of these chemical cases. We are working on the assumption that EPA completes 545 actions for FY2007 and beyond, based on stable resource allocation and the potential increased burden that would be associated with implementing RED-specified mitigation in advance of product reregistration. When considering 6,903 products and completing 545 actions per year, we predict that product reregistration may not be completed for more than twelve years, or the end of FY2018. This is six years longer than EPA's current prediction, and five years longer than the period for which EPA has budgeted. We understand that this calculation is rough and that there will also be FTE resources dedicated to the four major active ingredients identified above; however, given this workload and the necessity to complete product reregistration in a timely manner, EPA needs to reconsider its resource allocation.

8.7.2 Maintain Emphasis on Product Reregistration

The attention and emphasis placed on product reregistration by both SRRD and RD management have been critical to the recent improvements. It is important that this emphasis and attention be maintained, particularly as the office has competing priorities (e.g., registration review). In addition, OPP should use all opportunities to elevate issues related to product reregistration to OPP upper management, particularly when it comes to issues of staffing, resources, and policy concerns. Because SRRD and RD both share responsibility for product reregistration, upper management can help align the divisions and establish priorities. This continued emphasis on product reregistration is also important in the event that senior management in either division changes before product reregistration is completed.

8.7.3 Pursue SWAT Teams and Other Strategies to Reduce Backlog

As discussed in Chapter 7, the SWAT team approach developed by RD management is a promising avenue to reduce the product reregistration backlog. After reviewing the materials, Abt Associates believes that the SWAT team approach will be particularly effective at addressing products within Categories I and 2 because the approach requires action by both the PM and the registrant. The changes in process design that correspond to products in

Categories 3 and 4 are more dramatic and longer term. Moving forward, OPP should be mindful of the workload that corresponds to the SWAT team approach, the follow-up required, and the coordination between and roles of SRRD and RD.

Over the long-term, OPP should consider alternative strategies to reduce the product reregistration backlog over the next several years, including a performance-based contract for short-term staff support to assist EPA in the completion of product reregistration actions. The disadvantage of such an approach is that product reregistration requires a lot of internal communication and relies on institutional knowledge. However, some RD staff noted that newer staff or Senior Environmental Employment (SEE) employees are often assigned and successfully complete product reregistration tasks.

8.7.4 Obtain Support for DCI Preparation

The SRRD Program Support Branch (PSB) needs a senior scientist or senior science writer on staff. Although FEAD is a policy-oriented, not science-oriented group, PSB is relying on FEAD expertise in this area to assist in the development of the DCI justification package. This new hire would not only relieve FEAD's time commitment, but would also help expedite the development of the DCI justification package and provide needed scientific expertise. Alternatively, SRRD could shift existing staff to provide additional support in this area, particularly given the number of FY2006 decisions that will require DCIs in the short-term.

8.8 Communication

Based on its research, Abt Associates believes that communication regarding product reregistration could be improved both internally and externally. Elsewhere in this report, we note that the reregistration branches, PRB, and RD are unclear on each other's roles. In addition, PRB used to be physically separated from the rest of SRRD and the new office space seems to have helped facilitate communication. There are, however, opportunities for additional improvements by way of trainings, meetings, and brownbag presentations.

With respect to external communication, product reregistration is not mentioned in many OPP reports, such as the office's annual report.[45] In a recent addition to the EPA Pesticides Web page, "Pesticide Reregistration Facts,"[46] EPA highlighted and acknowledged product reregistration in its summary of the pesticide reregistration process and status. This discussion does not mention product-specific data and leads the reader to assume that product reregistration is a check to confirm that RED-specified mitigation appears on a label. It also notes that EPA "plans to complete the last product reregistration decisions several years after the last REDs are signed." In contrast, there was very little (if any) discussion on the EPA Pesticides Web page previously, and this information was included only within the REDs and *Federal Register* notices. Abt Associates believes that EPA could increase the transparency of the program by explicitly mentioning and addressing product reregistration. For example, to be more explicit and help the regulated community plan better, EPA could add reference to pesticide product reregistration in the "Status of Pesticide Reregistration" Web page along with schedules for REDs and registration review.

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[45] http://www.epa.gov/oppfead1/annual/2005/05annualrpt.pdf
[46] www.epa.gov/oppsrrd1/reregistration/reregistration_facts.htm

8.9 Performance Management

Based on the measures reported under the Government Performance and Results Act (GPRA), Abt Associates believes there are opportunities to make these measures more meaningful for both internal and external stakeholders. Similarly, to address competing priorities within RD, we suggest that OPP incorporate individual performance goals for product reregistration.

8.9.1 Improve Performance Measures and Strategic Targets

As discussed in Section 1.4 of this report, for purposes of GPRA, EPA reports on the number of product reregistration actions completed. However, this type of output measure is not informative because it does not provide a measure of progress relative to the entire universe. Abt Associates recommends that OPP revise this performance measure to use a percentage, which would be more informative. We understand that the universe of pesticide products subject to reregistration is constantly in flux; however, a percentage measure might be more informative for internal purposes. In addition, Abt Associates would suggest that EPA examine its targets for the number of pesticide reregistration actions. Although the targets have increased annually, the targets might not be realistic or ambitious enough to ensure completion of product reregistration within EPA's desired timeframe.

8.9.2 Incorporate Product Reregistration into PARS

In order for the SWAT team approach and other product reregistration process improvements to be most effective, RD should place a continued emphasis on product reregistration. Currently, PMs have to manage their work based on the competing priorities of pesticide registration and reregistration. Until recently, however, RD management has not placed a high priority on product reregistration; for example, PMs have concrete job performance goals related to registration but not to product reregistration. To ensure that RD accomplishes product registration in an efficient, timely manner going forward, RD management should include product reregistration-specific goals in each staff member's Performance Appraisal and Recognition System (PARS). In turn, management should periodically review each PM's workload to make sure that workload is manageable and appropriately distributed among individuals.

8.10 Information Management

Abt Associates drew the following conclusions regarding information management with respect to product reregistration:

- Even though OPPIN was intended to be an integrated system, it has failed to meet the tracking needs of different components of the product reregistration process.
- Many staff have created one-off tracking systems in order to get their jobs done, making reliable status updates very difficult to retrieve.
- The current approach to information management not only contributes to inefficient and inadequate tracking, but also potentially makes EPA vulnerable.
- Information management is an issue in each of the product reregistration sub-processes.

With these findings in mind, Abt Associates provides the following recommendations regarding information management.

8.10.1 Continue to Prioritize an Integrated Tracking System

SRRD should continue to prioritize the development of an integrated tracking system that manages all of the data and information related to the DCI process. For example, the fact that the current tracking system does not adequately track the status of submitted studies and confirmatory data from registrants is a potential liability to EPA.

Assuming that PRISM is the predecessor of OPPIN, SRRD should ensure that PRISM has the necessary data fields and functionality for tracking all components of the DCI process because future programs (e.g., registration review) will use OPP's DCI authority. As an alternative to PRISM, it may be more practical and cost effective to develop a relatively simple tracking system in Access that staff can use for DCI-related tracking. This Access database would track, at a minimum, the following elements of the DCI process: (1) the submission and approval dates of the DCI justification by EPA (FEAD and RCS), (2) submission to and approval by OMB, (3) the outcome of the ninety-day response period whereby registrants specify their intent to comply, seek a waiver, or cancel their product, and (4) the status of submitted studies over the eight month response period. (Item #4, for example, would negate the need for the current "charts and tables" document that is maintained in Word for each PDCI.) Additionally, in developing the DCI tracking system, OPP should consult other EPA offices (e.g. Office of Pollution Prevention and Toxics) that issue DCIs to determine what tracking systems they use, if any, and share lessons learned.

Ideally, OPP would already have in place an integrated, centralized database that would track all remaining aspects of the registration process. Given that product reregistration is a finite process (anticipated completion being 2012), it may not be an effective use of OPP's time and resources to build a sophisticated system such as PRISM for the purposes of product reregistration. Depending on how far along PRISM is in its development phase, we recommend that OPP revisit its tracking needs to determine whether the potential benefits of PRISM will outweigh the negatives (e.g., cost, staff time, limited lifespan), and whether the work already done on PRISM can be transferred towards the creation of a simple, effective Access database. Although the utility of PRISM from strictly a product reregistration standpoint is questionable, PRISM will presumably benefit SRRD's upcoming registration review, which will continue past the complete of product reregistration. The development of any tracking system (whether it be PRISM or an Access database) should involve all relevant staff. CRMs, FEAD, management, and PSB (among others) all have different needs for tracking, and in turn, all groups need the opportunity to provide input on the final system. Since all OPP staff may not be familiar with Access, the database should be created with a user-friendly interface that makes data entry and analysis straightforward.

8.10.2 Maintain Web Site as a Repository of Reregistration Decisions

Both SRRD and RD staff rely on the OPP web site (www.epa.gov/pesticides) as a historical repository of reregistration documentation, including risk assessments, the RED and associated amendments, label tables, and other Federal Register notices. This reliance on the web site is an issue because OPP does not use a docket system for reregistration, nor does OPP publish REDs in hard copy anymore. Because several staff noted that amendments are not often

posted in a timely manner, it is essential that OPP remain attentive to its web site. This type of information is not available in OPPIN, but might be available in the Jacket. The Jackets, however, are not yet available electronically. These records will be critical for registration review.

Appendix A Interview Guide

The following interview guide was used for each of the interviews with OPP staff, including introductions, general questions, issue-specific questions, and conclusions. As appropriate, we also asked questions that arose during the course of the meeting or that related to comments made by the interviewer.

Introductions

"Good morning. I am _____ (introduce self).

This interview is being conducted to get your input about the implementation of the product reregistration program that you have been conducting/involved in. I am especially interested in any problems you have faced or are aware of and recommendations you have."

"If it is okay with you, I will be tape recording our conversation. The purpose of this is so that I can get all the details but at the same time be able to carry on an attentive conversation with you. I assure you that all your comments will remain confidential. I will be compiling a report that will contain a synthesis of all staff comments without any reference to individuals. If you agree to this interview and the tape recording, please sign this consent form."

"I'd like to start by having you briefly describe your responsibilities and involvement thus far with the product reregistration." *(Note to interviewer: You may need to probe to gather the information you need, including length of time individual has worked in the program).*

General Questions

"I'm now going to ask you some questions that I would like you to answer to the best of your ability. If you do not know the answer, please say so."

- In your opinion, what are the biggest challenges faced by product reregistration? How do these challenges influence your role in the process?
- What do you think are the main factors the influence the length of time that product reregistration takes? Which parts of the program are affected?
- How has the program changed over the time you have been here?
- Given your role, what would help you do your job better with respect to product reregistration?
- Which parts of product reregistration do you find the most time consuming? What are your suggestions for streamlining these portions?
- In what ways do you think product reregistration could be improved?
- What do you estimate would be a reasonable amount of time for reregistering a specific product after the RED is signed?

Problems in REDs

- We have been told that the RED for _____ caused delays in product reregistration. Do you agree with this assessment?
- What characteristics of the RED resulted in issues? For example, were parts incomplete, incorrect?

- If appropriate, in what ways was the RED incomplete? Incorrect?
- Did the RED contain any contradictory language?
- Were there any circumstances after the publishing of the RED that delayed product reregistration, for example, data made available, a risk assessment revised?
- How did these factors impact product reregistration? Were all products affected?
- Why do you think that this RED had these issues?
- Is this a high-profile case or of particular interest to the registrant or an environmental group?
- How did you address each of the issues with the RED?
- Who was responsible? What is the estimate of increased burden?
- What was the impact to the registrant?
- Are there ways that the problems with the RED could have been avoided or decreased?
- What needs to change to eliminate the problem?
- How could these changes be accomplished?
- Have you had (or heard of) similar experiences with other REDs? If so, which ones? How often?
- When does this occur (close to a statutory deadline, etc.)?

Implementation of RED-specified Mitigation

- How/why were the cases selected for MOAs? How many MOAs have been signed regarding product reregistration? Do they vary in scope?
- How quickly did mitigation appear on the product label?
- Please characterize communication with the registrant.
- What additional work did this approach require? Can you estimate the additional time?
- How do EPA, environmental groups, and the registrant perceive the case?
- In addition to the MOA, what other factors may be unique to this active ingredient?
- How did this MOA compare to others on which you have worked or about which you have heard?
- How or do you think that this approach could be modified to streamline product reregistration generally?
- What type of products (cases) may lend themselves to such an approach?

Propanil Pilot

- Why were the pilot cases selected?
- How did you approach the registrant? What was his/her reaction?
- What are the legal issues? How are they being overcome?
- Please describe the approach for categorizing products and the rationale for the approach?
- To which categories will EPA apply this option?
- How will these products be considered for product reregistration? Is there any benefit to the registrant for implementing mitigation on the label sooner?

- What is the estimated burden to EPA for this pilot? For the approach generally? What about to the registrant?
- What is the estimate for developing the option? The time required for registrants to respond? To complete the process?

2,4-D Batching

- Who initiated the batching alternative – EPA or the registrants?
- What role did EPA play in the alternative?
- What characteristics of 2,4-D made this alternative appropriate (number of products, etc.)?
- What documentation exists on this case?
- What was required of the registrants collectively?
- How were legal concerns or CBI issues addressed?
- How do registrants view the alternative? Would they characterize it as a positive experience?
- What is the estimated burden savings to EPA or the registrants?
- What are the biggest obstacles to implementing this alternative for other cases?
- In what circumstances would it be appropriate in order to result in the most burden savings?

Label Reviews

- What is the division of labor between SRRD and RD with respect to label reviews?
- How do SRRD and RD approach the task?
- What is the average time a label review takes? Is there a range?
- Knowing that RD stamps the label, what resources are available to RD that might not be available to SRRD as they review the label?
- How useful is the information provided by SRRD?
- What do SRRD and RD look for in the label tables? Could these reviews be reconciled?

Ziram Pilot Project

- Why was the pilot case selected? Were all the ziram products completed or just one?
- What information was given to both divisions? Were they aware that is was for a pilot?
- In your opinion, was this label review treated differently than the average case?
- What differences appeared on each label? How significant are they?
- As an individual, are you comfortable with this streamlining option? Why or why not?
- Do you think this option is a valid approach to streamline reregistration?
- How long did the review take? Is that a typical amount of time?

Relationship between SRRD and RD

- How different are the cultures within the two divisions?
- How is workload and communication coordinated?

- What procedures exist to govern product reregistration?
- What are the priorities for either division? Are they in conflict?
- In what ways could SRRD work better with RD? Vice versa?
- How effective is the SOP for handoff to RD? Pros/Cons?
- What RD resources are available to SRRD – are they coordinated/consistent?

DCI Preparation and OMB Approval Process

- How much time does it take to prepare the DCI? Receive approval?
- Do data exist to support this conclusion?
- Historically, how many DCIs (and DCI packages) are prepared annually? How many active ingredients? Products?
- What issues arise to slow the process?
- What are the issues with OMB? What efforts have been undertaken to address them?
- What tracking issues arise in this part of the product reregistration process?
- In what ways could this part of the process be streamlined?
- To what extent is OPP constrained by OMB in this part of the process?
- How effective are the SOPs in establishing roles and responsibilities for both EPA and OMB?
- When were the SOPs written and how current are they?
- Are there any parts of the process that are not covered by SOPs that should be?

Information Management

- On several occasions, GAO commented on the lack of infrastructure to manage reregistration data. What improvements have been made over the past 10-15 years generally? For products specifically?
- What tracking systems exist for product reregistration?
- Are there shortcomings in the way SRRD tracks product reregistration?
- What are the obstacles to improving this?
- Which data management needs are most important?
- What is the history of requests to improve tracking?
- How is tracking handled in the registration division?
- What is the functionality of OPPIN for product reregistration versus AIs?
- What changes are planned for OPPIN? Will they impact product reregistration?
- On what occasions are data pulls needed? How labor intensive is the process?
- Who needs access to the information?
- What tracking systems are maintained internally? How functional are they? How could it be improved
- What other information management tools have been developed? For what purpose? How could they be improved?

Management/Budget

- How have you seen priorities change within OPP and within the product reregistration program generally over time? How has funding for both OPP and product reregistration changed over time?
- From your perspective, how is product reregistration viewed within OPP? Within the Agency? By the registrants? Environmental and public health groups?
- How and to what extent does political pressure or media attention affect product reregistration?
- Which types of products receive increased scrutiny? Why?
- Are there aspects of product reregistration that receive less attention?
- What types of project planning exercises are completed for product reregistration (e.g., a work plan)? Is there a forecast for completing product reregistration?

Conclusion

- Is there anything else today that I have not directly asked that you think is important for us to consider in our evaluation?
- Is there anyone else that you think we should talk to about these or other issues?

Thank you for your time. We appreciate your thoughts and experiences with product reregistration. Over the coming weeks, we will be compiling responses. If necessary, would it be possible to contact you, if needed, for additional information or clarification?

Appendix B Individuals Interviewed or Consulted

Peter Caulkins	OPP Special Review and Reregistration Division
Pat Dobak	OPP Special Review and Reregistration Division
Venus Eagle	OPP Registration Division, Insecticide-Rodenticide Branch (on detail from SRRD)
Keenan Garvey	OPP Special Review and Reregistration Division
Richard Gebken	OPP Registration Division, Insecticide Branch
Cynthia Giles-Parker	OPP Registration Division, Fungicide Branch
Mike Goodis	OPP Special Review and Reregistration Division, Reregistration Branch 3
Katie Hall	OPP Special Review and Reregistration Division, Reregistration Branch
John Hebert	OPP Registration Division, Insecticide-Rodenticide Branch
Mika Hunter	OPP Biopesticides and Pollution Prevention Division
Marion Johnson	OPP Registration Division, Insecticide Branch
Karen Jones	OPP Special Review and Reregistration Division, Product Reregistration Branch
Dan Kenny	OPP Registration Division, Herbicide Branch
George LaRocca	OPP Registration Division, Insecticide Branch
Meredith Laws	OPP Registration Division, Insecticide-Rodenticide Branch
Susan Lewis	OPP Special Review and Reregistration Division, Reregistration Branch 1
Marianne Lewis	OPP Special Review and Reregistration Division, Product Reregistration Branch
Joanne Miller	OPP Registration Division, Herbicide Branch
Tom Myers	OPP Special Review and Reregistration Division, Reregistration Branch 2
Gary Mullins	OPP Special Review and Reregistration Division, Program Support Branch
Cathryn O'Connell	OPP Special Review and Reregistration Division, Reregistration Branch 2
Mark Perry	OPP Special Review and Reregistration Division, Product Reregistration Branch
Maria Piansay	OPP Special Review and Reregistration Division, Product Reregistration Branch
Linda Propst	OPP Special Review and Reregistration Division, Product Reregistration Branch
Margaret Rice	OPP Special Review and Reregistration Division, Reregistration Branch 2
Larry Schnaubelt	OPP Special Review and Reregistration Division, Product Reregistration Branch
Kelly Sherman	OPP Special Review and Reregistration Division, Reregistration Branch 2
Cameo Smoot	OPP Field and External Affairs Division
Jim Tompkins	OPP Registration Division, Herbicide Branch
Mary Waller	OPP Registration Division, Fungicide Branch

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

Reregistration Eligibility Decision (RED)

1,3-Dichloropropene

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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 [0328] which includes the active ingredient 1,3-Dichloropropene (or trade name Telone). The enclosed Reregistration Eligibility Decision (RED), which was approved on September 30, 1998, contains the Agency's evaluation of the data base of this chemical, 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 also includes requirements for additional data (generic) on the active ingredient 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 the 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 Karen Jones (703) 308-8047. Address any questions on required generic data to the Special Review and Reregistration Division representative, Lisa Nisenson (703) 308-8031.

Sincerely,

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), the RED Fact Sheet, and the Acute Toxicity Batching Tables. 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

1,3-DICHLOROPROPENE (1,3-D)

LIST A

CASE 0328

TABLE OF CONTENTS

REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

John Faulkner	Economic Analysis Branch
Richard Michell	Biological Analysis Branch
Margaret Cogdell	LUIS Representative

Environmental Fate and Effects Risk Assessment

Kevin Poff	Ecological Effects Branch
Estella Waldman	Fate and Monitoring Branch
Jim Carleton	Fate and Monitoring Branch
James Felkel	Ecological Hazard Branch
John Eisenman	Environmental Risk Branch I

Health Effects Risk Assessment

Nancy McCarroll	Toxicology Branch II
Christina Scheltema	Risk Characterization and Analysis Branch
Catherine Eiden	Risk Characterization and Analysis Branch

Registration Support Risk Assessment

Terri Stowe	Fungicide-Herbicide Branch

Risk Management

Lisa Nisenson	Special Review Branch

FEAD

Susan Acree	Communications Branch

Office of General Counsel:

Andrea Medici	Office of General Counsel

Office of Stratospheric Ozone Protection:

Bill Thomas

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
ADD	Average Daily Dose
AADD	Annual Average Daily Dose
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.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP (or EUP)	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
LADD	Lifetime Average Daily Dose
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
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
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.
NAWQA	National Water Quality Assessment - USGS Water sampling Program
NTP	National Toxicology Program
N/A	Not Applicable
NOEC	No Observable Effect Concentration
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
PD	Position Document related to a Special Review
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 (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.
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

Overview

The U.S. Environmental Protection Agency has completed its reregistration eligibility decision for the pesticide 1,3-dichloropropene (1,3-D, or trade name Telone). This decision includes a comprehensive reassessment of the required target data and the use patterns of currently registered products. 1,3-D is a soil fumigant used to control nematodes and certain soil diseases. 1,3-D is registered for use on soils to be planted with all food and feed crops. 1,3-D is classified as a non-food use pesticide when used as a pre-plant soil fumigant and thus there are no tolerances or exemptions from the requirement of a tolerance (for pineapples, 1,3-D is applied at-plant, however there are no residues in food since fruit are not borne until the third year of growth). 1,3-D is a restricted use pesticide and as such can only be applied by certified applicators. There are no homeowner uses of 1,3-D.

1,3-D products are sold in bulk or mini-bulk (1000 gallon) containers and require no mixing prior to loading. All 1,3-D product labels require closed loading systems for transfers between the bulk containers and the specialized application rig, which is tractor-drawn. Most 1,3-D use involves injecting the fumigant into soil at depths from 12-18" deep, followed by soil sealing such as compaction, a water seal or tarp. The soil seal is used to minimize the amount of 1,3-D which volatilizes into the atmosphere after application. There are also four state registrations (known as SLN's) for 1,3-D application through drip irrigation, which is also applied pre-plant.

1,3-D was placed in EPA's Special Review process in 1986 based on cancer concerns for workers. The potential for groundwater contamination and residues in crops grown in treated soils were also cited as concerns to be investigated. In 1991, the Special Review of 1,3-D incorporated risks to residents who live in the vicinity of treated fields for inhalation exposures. Since 1991, the registrant of 1,3-D, Dow AgroSciences, has modified 1,3-D registrations to address worker and residential concerns as detailed below.

The Agency has concluded that 1,3-D, when labeled and used as specified in this Reregistration Eligibility Decision (RED) document, will not cause unreasonable risks to human health or the environment and that all labeled uses are eligible for reregistration. The Agency is requiring data on two degradates, 3-chloroallyl alcohol and 3-chloroacrylic acid, to confirm the Agency's assumption that the acid and alcohol are of equal or less toxicity than 1,3-D.

Recent Label Modifications for Risk Mitigation

In 1992 and in 1996, Dow AgroSciences, requested label changes to reduce levels of 1,3-D which volatilize into the atmosphere during fumigant transfers, application and the post-fumigation time period. Measures added to 1,3-D labels were shut-off valves to prevent 1,3-D from spilling at row turns, closed loading, soil sealing, a 300-foot no-treatment buffer from occupied structures, improved product stewardship, a phase-out of drum delivery, and reduced

application rates. These measures reduced the largest sources of 1,3-D exposures, specifically, the pooling of 1,3-D at row turns when the application "knives" were lifted out of the ground and spills during loading. These measures reduced exposures not only for workers, but for anyone in the vicinity of treated fields.

On September 30, 1998, Dow AgroSciences requested modification of the terms and conditions of 1,3-D registrations to include use prohibition in certain northern tier states (ND, SD, MN, NY, ME, NH, VT, MA, UT, MT, WI) based on ground water concerns, a 100-foot no-treatment buffer around drinking water wells, prohibition of use in areas overlying karst geologies and additional monitoring to confirm that use of 1,3-D does not pose unreasonable risks when used according to product labels. These measures reduce risks for anyone who drinks water from wells in the vicinity of treated fields.

Risk Concerns - Human Health

1,3-D is classified as a B_2 carcinogen by both the oral and inhalation routes of exposure. The 1,3-D risk assessment presents aggregated risks for both routes of exposure. Because EPA does not have toxicity data on the alcohol and acid degradates, EPA assumed carcinogenic and toxicological equivalence to the parent, thus oral exposure and risk estimates are comprised of 1,3-D plus the degradates (unless specifically noted).

Due to 1,3-D's carcinogenicity, environmental fate and use patterns, EPA has concerns that use could result in exposure to residues in air and/or water. EPA's cancer risk estimates for workers who follow label restrictions are in the 10^{-5} to 10^{-6} range. For residents who live near treated fields, lifetime cancer inhalation risk estimates are in the 10^{-5} to 10^{-8} range taking into account a 300 foot no-treatment buffer, but not taking into account other measures (e.g., lowering application rates by 30-65%, soil sealing measures) which were not amenable to quantification under the highly variable field study conditions.

For reregistration, EPA required a prospective ground water study in Wisconsin, which was believed to be highly vulnerable to ground water contamination from 1,3-D use. The registrant also submitted to the agency the results of a prospective ground water study conducted in Florida. Based on the results of these studies and other sampling programs, EPA believes that exposures from well water near treated fields vary depending on factors such as depth to ground water, temperature, soil permeability, and distance from the treated field. Lifetime cancer risk estimates from the Florida study are 4×10^{-6} (on-site wells which do not account for the 100 foot buffer). In Wisconsin, lifetime cancer risks for all age groups, and chronic non-cancer risks for infants and children, were unacceptably high. Cancer risks associated with levels from on-site wells were in the 10^{-3} range. As noted above, the September 30, 1998 modification includes a use prohibition for northern tier states with characteristics similar to the Wisconsin site and will be added to 1,3-D labels as of August 1, 1999.

Both prospective ground water monitoring studies included limited monitoring in off-site wells located down gradient from the treated fields. In the Florida study, time weighted average

(TWA) concentrations of 1,3-D plus its degradates in the on-site wells (10' deep) were 1.15 ppb. TWA concentrations of 1,3-D plus degradates measured in wells located 100 feet down gradient from the treated field were 0.074 ppb. In the Wisconsin study, on-site wells yielded TWA concentrations of 1,3-D and its degradates of 357 ppb while concentrations in a well 65' down gradient from the treated field were 26.6 ppb. Although neither of these studies was designed to quantify offsite exposures; results in both studies indicate that exposures were considerably lower with increasing distance from treated field.

Dow AgroSciences has agreed as a condition of reregistration to conduct tap water monitoring studies to better estimate current concentrations of 1,3-D and degradates in drinking water. Sampling will be targeted to high-use areas and will be initiated once the new labels are in effect in August of 1999. Should residues of 1,3-D and/or the alcohol or acid degradates be detected at levels exceeding the Office of Water Health Advisory of 0.2 ppb, Dow AgroSciences has included, as part of the sampling program, risk reduction measures which would be in place before the next use season. EPA expects to use the results of the sampling program to better characterize risks with the 100' setback and to also see if the sampling program results can be extrapolated in order to characterize risks in other 1,3-D use areas.

The drinking water risk estimates using 1,3-D labels eligible for reregistration is 4×10^{-6}, calculated using on-site wells from the Florida study; the inhalation risk is 6×10^{-6} (using an average of levels monitored from NC, WA and AZ study sites at the 300 foot buffer). Thus the calculated aggregate risk estimate is 1×10^{-5}. This risk estimate does not take into account mitigation from lower application rates, soil sealing measures, increased depth of application, soil moisture and temperature requirements or potential reduction in exposure from the 100 foot drinking water well setback. EPA believes the risk estimates are likely to be in the 10^{-6} range and that risk concerns have been addressed when all of the mitigation measures as specified in this reregistration decision are taken into account.

EPA's risk assessment shows no short-term or acute risks of concern based on current 1,3-D use patterns and that there are no unacceptable developmental or reproductive effects. Infants and children do not appear to have heightened susceptibility to 1,3-D, thus, EPA has determined the extra 10X safety factor is not warranted. EPA looked at whether risks from 1,3-D should be cumulated with risks of a contaminant found in Telone products, 1,2-dichloropropane (1,2-D). For purposes of this reregistration action, EPA has assumed that 1,3-D and 1,2-D do not share a common mechanism of toxicity.

Risk Concerns - Environmental

EPA has received and reviewed all of the data required in the 1986 Registration Standard to assess the environmental risks posed by applications of 1,3-D. 1,3-D is a highly volatile compound, and once in soils, is mobile. 1,3-D's persistence appears to be inversely related to temperature (i.e. high persistence at low temperatures). EPA does not believe there are risks to birds or non-target insects, though there could be risk to aquatic invertebrates and fish, particularly if run-off were to occur. Models suggest that 1,3-D can be transported through run-

off, however, these models are not designed to track volatile soil fumigants. EPA is requiring additional data on the degradates, on estuarine environments and a study to see if 1,3-D enters surface water through runoff.

Based on the results of retrospective ground water monitoring studies and the two prospective studies, EPA believes that the conditions most likely to result in 1,3-D treatment-related ground water contamination are shallow water tables, cold temperatures and high soil permeability, though the studies do not provide enough information to rank these factors. In addition to the ground water monitoring studies, EPA reviewed the results of other sampling programs in 1,3-D use areas and the U.S. Geological Survey's recent water resource monitoring program results. The U.S.G.S. monitoring found no detections of 1,3-D, but did not look for 3-chloroallyl alcohol and 3-chloroacrylic acid.

Other Activities Related to 1,3-D's Reregistration

EPA will be reviewing new information on the carcinogenicity of 1,3-D, specifically, whether EPA will regulate 1,3-D as a non-linear carcinogen. EPA expects this review will take place sometime in 1999; however, no change in EPA's risk assessment, if needed, can take place until the Agency implements final policies on regulation of non-linear carcinogens. EPA also intends to issue a Position Document 2 (PD2) proposing to close out the Special Review for 1,3-D before the end of 1998.

Before reregistering products containing 1,3-D, 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. 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. 1,3-D products which also contain chloropicrin will be eligible for reregistration only when chloropicrin has been found 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" or "EPA") 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 supporting 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 Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA) 21 U.S.C. 301 *et seq.*, and FIFRA 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. As a result, EPA is embarking on an intensive process, including consultation with registrants, States, and other interested stakeholders, to make decisions on the new policies and procedures that will be appropriate as a result of enactment 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. FQPA did not, however, amend any of the existing reregistration deadlines in section 4 of FIFRA. Therefore, the Agency will continue its ongoing reregistration program while it continues to determine how best to implement FQPA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of 1,3-D, including risk to infants and children for any potential dietary, drinking water, dermal, or oral exposures, and cumulative effects as stipulated under FQPA. The document consists of six sections. Section I is the introduction. Section II describes 1,3-D, 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 1,3-D. Section V discusses the reregistration requirements for 1,3-D. Finally, Section VI contains the Appendices which support this Reregistration Eligibility Decision.

II. CASE OVERVIEW

Commercial 1,3-dichloropropene is a mixture of approximately equal proportions of the cis- and trans- isomers. The Telone II formulation contains 94% 1,3-dichloropropene and 6% inert ingredients. The Telone C-17 formulation, which is formulated with 16.5% chloropicrin, contains 77.9% 1,3-dichloropropene and 5.6% inert ingredients. A contaminant, 1,2-dichloropropane may also be present in small quantities (≤0.1%).

A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Decision:

Common Name:	1,3-Dichloropropene
Chemical Name:	1,3-Dichloropropene
Trade and Other Names:	1,3-D, Telone®, Trilone, Pic-Clor, Tri-Form
Chemical Family:	Chlorinated Hydrocarbon
CAS Registry Number:	542-75-6
OPP Chemical Code:	029001
Empirical Formula:	$C_3H_4Cl_2$
Basic Manufacturer:	Dow AgroSciences

Multiple active ingredient products contain: 081501 (chloropicrin)

Registered "Me Too" Products Not Included in Appendix A: 8536-8; 8536-21; 8536-22; 11220-1; 11220-15; 11220-20; 11220-21; 11220-22

B. Use Profile

The following is general information on the current registered uses with an overview of use sites and application methods. A detailed table of these uses of 1,3-D is in Appendix A. Although the Appendix A information only reflects the basic manufacturer's products (i.e. DowAgro Sciences' Telone II and Telone C-17), the 1,3-D uses and use rates for the "me too" products are the same as those of the basic manufacturer's single and multiple active ingredient products, respectively.

TYPE OF PESTICIDE FOR SINGLE ACTIVE INGREDIENT:

Nematicide; Fungicide; Insecticide; Herbicide

MODE OF ACTION:

Soil fumigant, contact poison

USE SITES:

1,3-D is registered for use on all crops to be planted on 1,3-D-treated soils. Thus, the use sites include all vegetable, fruit and nut crops, all forage crops (grasses, legumes and other non-grass forage crops), tobacco, all fiber crops and all nursery crops (ornamental, non-bearing fruit/nut trees and forestry crops).

1,3-D is classified as a non-food use pesticide (and thus there are no tolerances or exemptions from the requirement of a tolerance).

TARGET PESTS FOR SINGLE ACTIVE INGREDIENT:
Plant-Parasitic Nematodes: all types

Plant Diseases: bacterial canker of peaches, sugar beet rhizomania, fusarium wilt of cotton, verticillium wilt of mint

Invertebrates: symphylans (garden centipedes), wireworms

Weeds: Canada thistle, field bindweed (perennial morning glory), quackgrass, and certain other deep-rooted perennial weeds in cropland

TYPES/FORMULATIONS REGISTERED:
End Use Products -

Liquid-Ready to Use - 78.3 to 94.0% (78.3%, and 94.0% multiple and single active ingredient products, respectively)

Note: single and multiple active ingredient "me too" products containing 37.6 to 94.0% 1,3-dichloropropene are also currently registered.

METHODS AND RATES OF APPLICATION:

Types of Treatment: Soil fumigation, broadcast and/or row treatments, and individual tree planting site treatments

Equipment: Soil injection equipment (chisel, Nobel plow, or plow-sole); Deep drip irrigation (6 or more inches deep)

Timing: Preplant (all crops); at planting (pineapple)
Application Rates: See rates listed in Appendix A for the Dow AgroSciences products (62719-12, 62719-32), which reflect the maximum rates of 1,3-D in single and multiple ingredient (i.e., with chloropicrin) formulations, respectively. Maximum rates for uses on vegetable and field crops varies with the soil type. Maximum rates for a given crop are typically slightly higher for the multiple active ingredient product than the single active ingredient product.

USE PRACTICE LIMITATIONS (APPLIES TO ALL 1,3-D PRODUCTS):

1,3-D is a restricted use pesticide (certified handlers only). Label statements include a 300 foot no-treatment buffer zone between treated fields and occupied structures, a five-day restricted entry interval for workers, closed loading, soil sealing immediately following application. In addition, labels suggest waiting at least one week for every gallon of 1,3-D applied before planting due to phytotoxicity.

See section IV. C. (3) for a list of detailed restrictions.

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticidal uses of 1,3-D. These estimates are derived from a variety of published and proprietary sources available to the Agency. The estimates presented in Table 1 are primarily from a 1991 Data Call-In for use and usage.

All 1,3-D is used on agricultural crops; there are no residential uses. The following table estimates 1,3-D use by site:

Table 1. Major 1,3-D Usage Sites

Crop	Acres Treated (000)		% Crop Treated		lbs a.i. applied (000)		States where most usage occurs
	weighted average	estimated maximum	weighted average	estimated maximum	weighted average	estimated maximum	
Crucifers	10	22	4	8	2000	3500	AZ,TX,GA, SC, NC,CA
Peppers	5	10	4	8	400	800	NM,NC,CA
Cucurbits	13	27	2	4	600	1200	TX,AZ,SC, NC,GA,CA
Sugar Beets	45	55	3	4	4000	5500	NE,WY,CO, ID
Cotton	85	150	1	1	2000	6000	AZ,NC,GA, FL,CA
Tobacco	80	102	11	15	7200	9000	NC,SC,GA
Irish Potato	80	95	6	7	1350	1700	WA,ID,OR, CO,ND,MI
Sweet Potato	N/A	N/A	N/A	N/A	N/A	N/A	NC, GA, SC
Peanut	12	25	1	2	900	1900	AL,GA,TX
Fruit/Nut Trees and Grape Vines	27	54	6	13	2400	5000	CA,SC,NC, AZ,GA,NJ
Onions	5	10	5	10	1000	2000	OR,WA,ID
Tomato	2	5	0	1	200	800	GA,FL,AL
Carrots	2	4	2	4	150	250	CA,WA,TX
Pineapple	5	7	14	19	1300	2600	HI
Strawberries	1	4	1	3	80	170	CA,FL,NJ

Usage data covers 1990-1995 for most sites and as early as 1987 for other sites, primarily using data from the 1991 Use Usage and Product Performance DCI. California data is only available for 1994 and 1995 due to the 1991-1993 use permit suspension and limited re-entry program. "Weighted average" weights the more recent years' estimates because they tend to be more reliable estimates than for possibly outdated earlier estimates.

D. Data Requirements and Regulatory History

1,3-D was first registered in 1954 in the United States. A Registration Standard was issued in 1986, along with a Position Document announcing initiation of a Special Review (51 FR 36160) based on cancer concerns for workers. The Standard evaluated the available data with

other relevant information on 1,3-D and required the submission of additional data to maintain the existing registrations and to further refine the risk assessment for the Special Review.

On April 13, 1990, California suspended use permits for 1,3-D because unacceptably high levels of airborne 1,3-D were detected through its air monitoring program. After California suspended the 1,3-D use permits, EPA looked more closely at the risk posed to residents who live in the vicinity of treated fields. In 1992, Dow AgroSciences (at that time DowElanco), agreed to label measures to reduce the amount of 1,3-D that volatilizes into the atmosphere, including closed loading, shut-off valves to prevent 1,3-D from spilling at row turns, improved product stewardship, a phase-out of drum delivery, and reduced application rates. DowElanco also agreed to conduct studies to determine the mitigation value of these and other measures.

In 1996, other measures, including the Worker Protection Standard requirements for Personal Protective Equipment (PPE), were added to 1,3-D labels, including soil sealing, a 300-foot no-treatment buffer from occupied structures and other requirements designed to minimize the amount of 1,3-D that volatilizes (Gibson, 1996). These measures reduced exposures for both workers and anyone else who lives or works in the vicinity of treated fields.

On September 30, 1998, Dow AgroSciences requested modification of the terms and conditions of 1,3-D registrations to include use prohibition in certain northern tier states (ND, SD, MN, NY, ME, NH, VT, MA, UT, MT, WI), a 100-foot no-treatment buffer to drinking water wells, prohibition of use in areas overlying karst geologies and additional monitoring to confirm that use of 1,3-D does not pose unreasonable risks when used according to product labels (Roby, 1998). The benefits of these measures are to reduce risks for anyone who drinks water from wells in the vicinity of treated fields, particularly wells in unconfined aquifers.

Dow AgroSciences is developing confirmatory data for reregistration, to include tap water monitoring in certain 1,3-D use areas, a run-off study and data on the toxicity and environmental fate data for 3-chloroacrylic acid and chloroallyl alcohol.

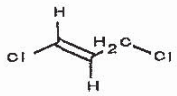
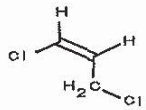
This Reregistration Eligibility Decision reflects an assessment of the data which were submitted in response to the 1986 Registration Standard and the 1991, 1992 and 1996 DCI's.

III. SCIENCE ASSESSMENT

A. Physical and Chemical Properties Assessment

1. Identification of Active Ingredient

The active ingredient 1,3-dichloropropene (1,3-D, or Telone) is a soil fumigant used preplant to control root-knot nematodes and other soil pests and diseases. 1,3-D is a mixture of isomers; in the figures below, the trans isomer is on the left, and cis on the right.

Empirical Formula:	$C_3H_4Cl_2$
Molecular Weight:	110.98
Physical State:	liquid under pressure, volatile
Odor:	sweet, pungent, penetrating
Water Solubility:	2,180 mg/L for cis isomer 2,320 mg/L for trans isomer
Vapor Pressure:	34.3 mmHg for cis isomer at 25°C 23.0 mmHg for trans isomer at 25°C
Boiling Point:	104°C for cis isomer 112.6°C for trans isomer
Specific Gravity:	1.209 g/mL at 25°C

2. Manufacturing and End-Use Product Chemistry

A search of EPA's Reference Files System conducted on September 9, 1998 identified no 1,3-D manufacturing-use products (MPs) under Shaughnessy No. 029001. Although the 1985 1,3-D Reregistration Standard dated identified a single 94% formulation intermediate registered to Dow Chemical Company (EPA Reg. No. 464-511), the product has since been transferred to Dow AgroSciences (EPA Reg. No. 62719-32) and is currently registered as an end-use product (EP). The product jackets for 1,3-D EPs confirms that the Dow AgroSciences 94% EP/MP is the source product for other formulations; therefore, generic (TGAI) and product-specific (MP) data are required to support its use as an MP. Dow AgroSciences has submitted an application to also market their 94% 1,3-D product as a manufacturing use product to reformulators; this application is under review.

3. Conclusions

All pertinent generic data requirements are satisfied for the 1,3-D TGAI except for the new data requirement concerning UV/visible absorption (OPPTS GLN 830.7050). All product-specific data requirements are satisfied for the 94% EP/MP; however, the ingredient certifications (OPPTS GLN 830.1750) must be submitted on EPA Form 8570-4. The data requirements for product chemistry are presented in Appendix D. In addition, the registrant must certify that the suppliers of beginning materials and the manufacturing processes have not changed since the last comprehensive product chemistry review or submit a complete updated product chemistry data package.

B. Human Health Assessment

1. Hazard Assessment

All toxicology guideline studies are fulfilled and the data base for 1,3-D is adequate to support reregistration eligibility. Across the battery of toxicology studies, the Telone test products contained various amounts of 1,3-D depending on the formulation available at the time of testing. Because of this, the toxicity tests were performed with varying percentages of the a.i. EPA does not believe the variations in levels warrants additional testing.

a. Acute Toxicity

The acute toxicity values and categories for 1,3-D are summarized below:

Table 2. Acute Toxicity of 1,3-Dichloropropene

OPP Guideline No.	OPPTS Guideline No.	Study Type	MRID #(S).	Results	Toxicity Category
81-1	870.1100	Acute Oral	40220901	LD_{50} = 300 mg/kg (M) 224 mg/kg (F)	II
81-2	870.1200	Acute Dermal - Rabbit	40220902	LD_{50} = 333 mg/kg	II
81-3	870.1300	Acute Inhalation	40220903	LC_{50} = 3.88 mg/L (M) 4.1 mg/L(F)	IV
81-4	870.2400	Primary Eye Irritation	40220904	Intermediate irritant	II
81-5	870.2500	Primary Skin Irritation	40220905	Slight irritant	III
81-6	870.2600	Dermal Sensitization	40220906	Sensitizer	--
81-8	870.6200	Acute Neurotoxicity	none	None required	--

The oral LD_{50} in the rat was 300 mg/kg in males and 224 mg/kg in females (Toxicity Category II). Clinical signs included diarrhea, lacrimation, chromodacryorrhea, palpebral closure, facial/perineal soiling, labored respiration and rough hair coat. Gross necropsy revealed gastric hemorrhage, watery contents and mucus in the cecum, thickened stomach wall and adhesions between the stomach and abdominal wall (MRID 40220901).

The dermal LD_{50} in the rabbit was 333 mg/kg. Animals exhibited restlessness, squealing, lethargy, transient anorexia, labored respiration and diarrhea. Skin findings were erythema, edema, necrosis and scabs. Gross necropsy revealed mottled skeletal muscles in hind limbs, multifocal erosions and/or ulcers of the stomach and fecal soiling of the perineal area (MRID 40220902).

The inhalation LC_{50} in the rat was 3.88-4.69 mg/L in males and 4.1 mg/L in females (Toxicity Category IV). Animals exhibited tremors, convulsions, salivation, lacrimation, diarrhea and lethargy. Gross necropsy revealed hemorrhaging in multiple lung lobes (MRID 40220903).

Instillation of Telone II (94% a.i.) in rabbit eyes resulted in intermediate irritation (Toxicity Category II). By day 14, all evidence of corneal opacity, iris irritation, conjunctival redness, chemosis and discharge had disappeared (MRID 40220904).

In a rabbit dermal irritation study, very slight erythema and edema were noted (Toxicity Category III). At 72 hours, 5 of 6 animals had well-defined erythema, 1 of 6 exhibited very slight erythema, 2 of 6 exhibited slight edema and 2 of 6 had very slight edema (MRID 40220905).

Telone II (94% a.i.) was a sensitizer in guinea pigs (MRID 40220906).

b. Subchronic Toxicity

(i) Oral

Telone II (96.0% a.i.) was administered to Fischer 344 rats (10/sex/group) at dietary levels of 0, 5, 15, 50 or 100 mg/kg/day for 13 weeks. Body weights and weight gains, as well as food consumption, were reduced at 50 and 100 mg/kg/day in both sexes (questionable reduction in male body weights/gains at 5 and 15 mg/kg/day). Doses of 15, 50 and 100 mg/kg/day caused hyperkeratosis and/or basal cell hyperplasia in the nonglandular portion of the stomach of both sexes. The NOEL was 5 mg/kg/day. The LOEL was 15 mg/kg/day based upon hyperkeratosis and/or basal cell hyperplasia in the nonglandular portion of the stomach of both sexes (MRID 42954802).

In a subchronic study, Telone II (96.0% a.i.) was administered to $B_6C_3F_1$ mice (10/sex/group) at dietary levels of 0, 15, 50, 100 or 175 mg/kg/day for 13 weeks. Body weights and weight gains were lower than the controls in males and females at 50, 100 and 175 mg/kg/day (27, 36, 39 and 58% in males and 7, 22, 30 and 32% in females). The NOEL was 15 mg/kg/day.

The LOEL was 50 mg/kg/day based on lower body weights and body weight gains compared with controls in males and females (MRID 42954801).

The data requirement for a subchronic dog study was waived because a one-year study had been conducted.

(ii) Inhalation

In a 30 day inhalation study, Fischer 344 rats (10/sex/group), were exposed to Telone II ("production grade" - no percentage of a.i. presented) at concentrations of 0, 3, 10 or 30 ppm (0, 0.0136, 0.045 or 0.136 mg/L), 6 hours/day, 5 days/week for 4 weeks. There was no mortality at any dose level. Body weights of male rats at all concentrations were similar to that of the controls. Females exhibited a slight decrease in body weights. There was an increase in the incidence of enlarged peribronchial lymph nodes in males at 3 and 10 ppm, but not at 30 ppm; the incidences were 1, 5, 6 and 2 at 0, 3, 10 and 30 ppm, respectively. Because there was no dose-response as well as lack of an effect on peribronchial lymph nodes at 30 ppm, the NOEL was considered to be 30 ppm (0.136 mg/L, highest dose tested) and the LOEL was > 30 ppm (0.136 mg/L) (MRID 00039685).

In a 30 day inhalation study, CD-1 mice (10/sex/group), were exposed to Telone II ("production grade"- no percentage of a.i. presented) at concentrations of 0, 3, 10 or 30 ppm (0, 0.0136, 0.045 or 0.136 mg/L), 6 hours/day, 5 days/week for 4 weeks. There was no mortality at any dose level. There were no test article related findings at any dose. The NOEL was 30 ppm (0.136 mg/L, highest dose tested) and the LOEL was > 30 ppm (0.136 mg/L) (MRID 00039685).

In a subchronic toxicity study, Fischer 344 rats (10/sex/group) were exposed to Telone II (90.9% a.i.) at concentrations of 0, 10, 30, 90 or 150 ppm (0, 0.045, 0.136, 0.408 or 0.680 mg/L), 6 hours/day, 5 days/week for 13 weeks. Both sexes at 90 and 150 ppm exhibited a significant decrease in body weights while rats at 30, 90 and 150 showed treatment-related histopathological lesions in the nasal turbinates. The NOEL was 10 ppm (0.045 mg/L) and the LOEL was 30 ppm (0.136 mg/L) (MRID 00146461).

In a subchronic toxicity study, $B_6C_3F_1$ mice (10/sex/group) were exposed to Telone II (90.9% ai) at concentrations of 0, 10, 30, 90 or 150 ppm (0, 0.045, 0.136, 0.408 or 0.680 mg/L), 6 hours/day, 5 days/week for 13 weeks. Both sexes at 90 and 150 ppm exhibited a significant decrease in body weights while females showed epithelial degeneration and hyperplasia of the nasal turbinates. The NOEL was 30 ppm (0.045 mg/L) and the LOEL was 90 ppm (0.136 mg/L) (MRID 00146461).

c. Chronic Toxicity/Carcinogenicity

(i) Oral

In a chronic toxicity/carcinogenicity study, Telone II (96% a.i.) was administered as microcapsules by dietary admix to Fischer 344 rats (60/sex/group with 10/sex/group sacrificed at 12 months) at levels of 0, 2.5, 12.5 or 25 mg/kg/day for two years. Body weight gains were decreased for males (8 and 21%) and females (15 and 25%) at 12.5 and 25 mg/kg/day compared to controls. Food consumption was decreased in females at 25 mg/kg/day. There was an increase in liver masses/nodules in males only at 12.5 and 25 mg/kg/day. There was an increased incidence of basal cell hyperplasia of the nonglandular mucosa of the stomach of both sexes at the 12- and 24-month sacrifices at 12.5 and 25 mg/kg/day. For chronic toxicity, the NOEL was 2.5 mg/kg/day and the LOEL was 12.5 mg/kg/day based on a decrease in body weight gain compared with controls and an increase in the incidence of basal cell hyperplasia of the nonglandular mucosa of the stomach. There was evidence of carcinogenicity. The incidences of rats with primary hepatocellular adenomas were as follows respectively (0, 2.5, 12.5 or 25 mg/kg/day): males = 2/50, 1/50, 6/50 and 9/50; females = 0/50, 0/50, 0/50 and 4/50. These data indicate that exposure to 1,3-D increases the incidence of these tumors in males at the two highest doses and in females at the highest dose. The highest dose tested in this study (25 mg/kg/day) was considered adequate to assess the carcinogenic potential of 1,3-D in rats (MRID 43763501). The results of this study were used to establish the oral reference dose (RfD).

In a study reported by the National Toxicology Program (NTP) in 1985, 1,3-D (89.0% a.i.) was administered in corn oil (with 1.0% epichlorohydrin) by gavage to Fischer 344 rats (52/sex/group) at doses of 0, 25 or 50 mg/kg/day three times per week for 104 weeks. Basal cell or epithelial hyperplasia of the forestomach was reported. At 0, 25 and 50 mg/kg/day, squamous cell papillomas of the forestomach (1/52, 1/52 and 9/52 in males respectively; 0/52, 2/52 and 3/52 in females respectively), squamous cell carcinomas of the forestomach (0/52, 0/52 and 4/52 for males) and neoplastic nodules of the liver (1/52, 6/52 and 7/52 for males respectively ; 6/52, 6/52 and 10/52 for females respectively) were seen. The NTP concluded that there was "clear evidence of carcinogenicity" for males and "some evidence" of carcinogenicity for females (MRID 00146469).

In a two-year toxicity/carcinogenicity study in $B_6C_3F_1$ mice (50/sex/group), Telone II (95.8% a.i.) was administered as microcapsules by dietary admix at levels of 0, 2.5, 25 or 50 mg/kg/day. There were no test article effects on clinical signs, mortality, ophthalmology, hematology parameters, organ weights, macroscopic pathology or microscopic pathology. For chronic toxicity, the NOEL was 2.5 mg/kg/day. The LOEL was 25 mg/kg/day for both sexes based on lower body weights and a decrease in weight gains compared with controls. There was no evidence of carcinogenicity (MRID 43757901).

In a study with $B_6C_3F_1$ mice (50/sex/group) reported by NTP in 1985, Telone II (89.0% ai) was administered in corn oil (with 1.0% epichlorohydrin) by gavage at doses of 0, 25 or 50 mg/kg/day three times per week for 104 weeks. The study in males was not considered to be

adequate because of the mortality of controls at weeks 48-51 (25/50, myocarditis) and the 104-week survival for males (8/50, 28/50 and 31/50). Squamous cell papillomas of the forestomach (0/50, 1/50 and 2/50 for females), squamous cell carcinomas of the forestomach (0/50, 0/50 and 2/50 for females), transitional cell carcinomas of the urinary bladder (0/50, 8/50 and 21/48 for females) and alveolar/bronchiolar adenomas (0/50, 3/50 and 8/50 for females) were seen. In males, the study was considered to be inadequate for carcinogenicity (due to mortality of controls). For females, there was "clear evidence of carcinogenicity" (MRID 00146469).

In a chronic toxicity study, beagle dogs (4/sex/group) were administered Telone II (95.8% a.i.) as a dietary admix at levels of 0, 0.5, 2.5 or 15 mg/kg/day for one year. At 15 mg/kg/day, there was: decreased body weight gain; hypochromic, microcytic anemia (increase in erythrocytes along with decreases in hemoglobin, hematocrit, mean corpuscular volume and mean corpuscular hemoglobin); hematopoietic activity in bone marrow and spleen; and a possible increase in absolute liver weights in males. For chronic toxicity, the NOEL was 2.5 mg/kg/day and the LOEL was 15 mg/kg/day based on a decrease in body weight gain compared with controls, microcytic anemia and an increase in hematopoietic activity. The study results also suggested a test-article related increase in absolute liver weights in males compared with controls at the LOEL (MRID 42441001).

(ii) Inhalation

In a chronic toxicity/carcinogenicity study, Fischer 344 rats (50/sex/group plus 10/sex/group to 6- and 12-month exposure groups) were exposed by whole-body inhalation to Telone II (92.1% a.i.) at aerosol concentrations of 0, 5, 20 or 60 ppm (equivalent to approximately 0, 0.023, 0.091 or 0.272 mg/L), 6 hours/day, 5 days/week for a total of 509 days over a two-year period. There was no effect of exposure to 1,3-D on the survival of males or females. Slight (approximately 5% in 60 ppm males and females, as well as 3% in 20 ppm males) decreases in body weight gains were observed (statistically significant, $p<0.05$) but generally only during the first year of the study. The olfactory region of the nasal cavity appeared to be the target tissue as determined by histopathological examination. Males and females having been exposed to 60 ppm (no evidence reported at lower concentrations of 20 or 5 ppm) showed decreased thickness and erosions of the epithelium as well as minimal submucosal fibrosis. For chronic toxicity, the NOEL was 20 ppm (0.091 mg/L)and the LOEL was 60 ppm (0.272 mg/L) based on histopathological changes in nasal tissue as well as the suggestion of decrease in body weight gain compared with controls during the first year of the study. There was no evidence of carcinogenicity (MRID 40312201). The results of this study were used to develop an intermediate residential/bystander inhalation NOEL (see sections III.C.5 and III.D.1).

In a chronic toxicity/carcinogenicity study, $B_6C_3F_1$ mice (50/sex/group plus 10/sex/group to 6- and 12-month exposure groups) were exposed by whole-body inhalation to Telone II (92.1% ai) at aerosol concentrations of 0, 5, 20 or 60 ppm (equivalent to approximately 0, 0.023, 0.091 or 0.272 mg/L) 6 hours/day, 5 days/week for a total of 510 days over a two-year period. There was no effect on survival (at least 80% in each group). There was a statistically significant decrease in body weight gain in 60 ppm males (3-9%) and females (2-11%). Urinary bladder

effects were noted primarily in females at 20 and 60 ppm (slight, moderate or marked roughened, irregular and opaque surfaces were reported in 20/50 at 20 ppm and 30/49 at 60 ppm compared with 3/50 slight in the control group). Hypertrophy and hyperplasia of the nasal respiratory mucosa (very slight/slight) were observed in most 60 ppm mice of both sexes and in 20 ppm females. Degeneration of olfactory epithelium (very slight/slight) was noted in most 60 ppm mice of both sexes. Hyperplasia of the epithelial lining of the nonglandular portion of the stomach was observed in 60 ppm males (0, 5, 20 and 60 ppm: males = 0, 3, 1 and 8; females = 0, 0, 0 and 2 respectively). For chronic toxicity, the NOEL was 5 ppm (0.023 mg/L) and the LOEL was 20 ppm (0.091 mg/L) based on urinary bladder hyperplasia and hypertrophy/hyperplasia of the nasal respiratory mucosa. Hyperplasia of the epithelial lining of the nonglandular portion of the stomach was observed in a higher incidence compared with controls in 60 ppm males and, to a lesser extent, 60 ppm females. There was evidence of carcinogenicity. Bronchioloalveolar adenomas appeared in a higher incidence in 60 ppm males only compared with controls (0, 5, 20 and 60 ppm = 9/50, 6/50, 13/50 and 22/50 respectively). Although the lung tumors noted in this mouse inhalation study were benign, the tumor induction was dose dependent, the tumor incidence was outside the range of historical controls and the tumor type was also seen in the mouse oral bioassay (MRID 40312300).

d. Developmental Toxicity

In a developmental toxicity study, Fischer 344 rats (30 females/group) were exposed during gestation days 6 through 15 to aerosol concentrations of Telone II (90.1% a.i.) at 0, 20, 60 or 120 ppm (equivalent to approximately 0, 0.091, 0.272 or 0.545 mg/L) 6 hours/day. The maternal NOEL was < 20 ppm (< 0.091 mg/L). The maternal LOEL was 20 ppm (0.091 mg/L) based on decreased body weight gains and food consumption compared with controls during the exposure days. The developmental NOEL was 60 ppm (0.272 mg/L). The developmental LOEL was 120 ppm (0.545 mg/L) based on increase in delayed ossification of the vertebral centra. No 1,3-D-related malformations were reported (MRID 00152848).

New Zealand rabbits (17-24 females/group) were exposed to aerosol concentrations of Telone II (90.1% a.i.) at 0, 20, 60 or 120 ppm (equivalent to approximately 0, 0.091, 0.272 or 0.545 mg/L), 6 hours/day during gestation days 6 through 18. The maternal NOEL was 20 ppm (0.091 mg/L). The maternal LOEL was 60 ppm (0.272 mg/L) based on decreased body weight gains compared with controls. The developmental NOEL was 120 ppm (0.545 mg/L). The developmental LOEL was >120 ppm (> 0.545 mg/L, HDT). No 1,3-D related malformations were reported (MRID 00152848).

e. Reproductive Toxicity

In a two-generation inhalation reproduction study, Fischer 344 rats (F_0 adults, 30 males and 40 females/group) were exposed to aerosol concentrations of Telone II (91.2% a.i.) at 0, 10, 30 or 90 ppm (equivalent to approximately 0, 0.045, 0.136 or 0.408 mg/L) 6 hours/day. The durations of exposure (6 hours/day) were as follows: F_0 males and females 5 days/week prior to breeding and 7 days/week during breeding at weeks 11 to 13, then during gestation and lactation;

F_{1a} and F_{1b} generations, dams from gestation day 20 until postpartum day 5; F_1 male and female parents, after weaning (about week 32 of the study) and continued for 12 weeks, but for 5 days per week, 6 hours/day; and F_0 to F_1 until adults were sacrificed. Pregnant females were not exposed to 1,3-D from gestation day 20 to postpartum day 4. Pups were not exposed to 1,3-D (dams separated from pups for 6 hours of exposure/day during lactation days 5 to 28). For parental/systemic toxicity, the NOEL was 30 ppm (0.136 mg/L). The LOEL was 90 ppm (0.408 mg/L) based on a decrease in body weight gain compared with controls, as well as microscopic nonglandular stomach lesions (mainly mucosa) and hyperplasia of the nasal respiratory epithelium with focal degeneration of the olfactory tissue. No reproductive toxicity was seen. For reproductive toxicity, the NOEL was 90 ppm and the LOEL was >90 ppm (HDT) (MRID's 40312401 and 40835301).

f. Mutagenicity

There was a positive effect in the Salmonella assay in strains G46, TA98, TA100 and TA1535 with and without activation and in strains TA1538 and TA1537 with activation. Responses up to approximately 100x and 10x background in strains TA1535 and TA100, respectively, were seen (MRID 00039688). 1,3-D, in the absence of metabolic activation, was positive in the B. subtilis rec-assay only at 1,250 µg/well (MRID 00039688). Up to a toxic concentration of 1,000 µg/plate, no positive results were reported in the E. coli reversion test with or without activation (MRID 00039688). A mouse host-mediated assay with Salmonella typhimurium strain G46 was negative. However, the oral gavage dosing of the mice up to 60 mg/kg may not have been high enough as adequate toxicity was not reported (MRID 00039680). Non-reproducible increases (just at 2x background) were reported in the nonactivated phase of the Chinese hamster ovary (CHO/HGPRT) gene mutation assay at 100, 150, 200, and 250 µM (MRID 00159679). 1,3-D was negative in an unscheduled DNA synthesis (UDS) assay with primary rat hepatocytes up to consistently cytotoxic doses (> 10^{-4} M) (MRID 00146467).

Data from the open literature also indicate that 1,3-D is mutagenic in Salmonella and cultured mouse lymphoma cells and induces chromosomal aberrations, sister chromatid exchange, and DNA strand breaks in several mammalian cell lines in vitro. Overall, the data from somatic cell assays are indicative of a mutagenic concern for 1,3-D and support the weight-of-the-evidence evaluation for carcinogenicity.

1,3-D was also positive for the induction of sex-linked recessive lethal mutations but not reciprocal translocations in Drosophila melanogaster (MRID 00146469). To confirm the results of the Drosophila sex-linked recessive lethal assay, a Data Call In (DCI) was issued for an in vivo alkaline elution assay in testicular cells (following inhalation administration) on June 17, 1996. The Registrant chose to perform an inhalation dominant lethal assay, which is an acceptable substitute. 1,3-D tested negative in this assay. Results from this study show that 1,3-D, administered by inhalation at concentrations up to 150 ppm (≈682 mg/m^3) 6 hours/day, 7 days/week for 10 weeks did not induce a dominant lethal effect in male rat germinal cells (MRID 44302801). The negative findings of this study lessen the concern for germ cell effects; therefore, no further mutagenicity testing is required. Dow AgroSciences is conducting additional

mutagenicity studies for the alcohol and acid degradates; for purposes of this reregistration, EPA is assuming equivalent mutagenic potential to the parent.

g. Metabolism

An oral pharmacokinetics study was conducted in Fischer 344 rats and $B_6C_3F_1$ mice. For the non-protein sulfhydryl studies, the following single oral non-radioactive doses were administered: 0, 1, 5, 25, 50 or 100 mg/kg. Single oral ^{14}C Telone II doses of 0, 1, 50 or 100 mg/kg were administered for the binding studies. The primary route of excretion for both species was the urine. The two major urinary metabolites were identified as 1,3-DCP-mercapturic acid and its sulfoxide (or sulfone) derivative. Following oral administration, most of the radio label was found in the stomach and gastrointestinal tract with lesser amounts in the kidneys, liver, urinary bladder, skin, fat, blood and carcass. Oral administration also depleted the non-protein-sulfhydryl contents of several tissues including the non-glandular stomach (both time- and dose-dependent). Dose-related increases in macromolecular bindings were noted in several organs with the highest binding sites being found in the non-glandular stomach (MRID 00155846).

In another study with Fischer 344 rats, gavage administration of Telone II at 5 mg/kg/day for 14 days resulted in rapid absorption from the gastrointestinal tract with distribution to all tissues examined. Highest concentrations appeared in the non-glandular stomach and urinary bladder. There was rapid elimination in the urine, feces, and as carbon dioxide in expired air. Nine metabolites were isolated from urine with two being identified as 1,3-D-mercapturic acid and the sulfoxide derivative. No parent compound was present in the urine (MRID 40959801).

h. Dermal Absorption

No dermal absorption studies were required. A waiver was granted for the 21-day dermal toxicity study. The current use-pattern does not indicate a concern for potential dermal exposure.

i. Epidemiological Data

The following data bases have been consulted for the poisoning incident data on the active ingredient 1,3-dichloropropene.

(i) OPP Incident Data System (IDS)

The incident data system contains reports of incidents from various sources, including registrants, other federal and state health and environmental agencies, and individual consumers, submitted to OPP since 1992. Reports submitted to IDS represent anecdotal reports or allegations, unless otherwise stated. Typically, no conclusions can be drawn implicating the pesticide as a cause of any of the reported health effects. Nevertheless, with enough cases and/or enough documentation risk mitigation measures may be suggested. No specific information on 1,3-D was found.

(ii) California Department of Food and Agriculture (superseded by the Department of Pesticide Regulation in 1991)

California has collected uniform data on suspected pesticide poisonings since 1982. Physicians are required, by statute, to report to their local health officer all occurrences of illness suspected of being related to exposure to pesticides. The majority of the incidents involve workers. Information on exposure (worker activity), type of illness (systemic, eye, skin, eye/skin and respiratory), likelihood of a causal relationship, and number of days off work and in the hospital are provided.

(iii) National Pesticide Telecommunications Network (NPTN)

NPTN is a toll-free information service supported by OPP. A ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991, inclusive has been prepared. The total number of calls was tabulated for the categories human incidents, animal incidents, calls for information, and others.

(iv) Summary/Conclusions of Epidemiology Data

From the review of California data on suspected 1,3-D poisonings, it appears that a majority of incidents involved illnesses or injuries to workers who applied 1,3-D as a soil fumigant in fields. A large proportion of the cases occurred when workers were preparing, operating, cleaning, or repairing application equipment; however, label changes since 1992 have been adopted which may have prevented reported exposures. Some individuals with inhalation exposures have reported symptoms such as headache, chest pain, fatigue, irritability or difficulty concentrating, persisting for as long as two years after initial exposure.

Accidental ingestion of 1,3-D (concentration and amount unknown) has led to one reported fatality. In a cluster episode, two of nine firemen developed lymphoma six years after exposure to a 1,3-D spill. Other data or evidence from other epidemiologic studies would be needed before an association can be supported.

2. Dose-Response Assessment

a. Determination of Susceptibility to Infants and Children

Under the Food Quality Protection Act (FQPA), P.L. 104-70, which was promulgated in 1996 requires the EPA to "ensure that there is reasonable certainty that no harm will result to infants and children" from aggregate exposure to a pesticide chemical residue. The law further states that in the case of threshold effects, for purposes of providing 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 residues only if, on the basis of reliable data, such margin will be safe for infants and children.

1,3-D is a non-food use pesticide and therefore no tolerances or exemptions from the requirement of a tolerance are required. Although the FQPA's requirements are directed towards tolerance actions, the Agency has reviewed the requirements of FQPA as if 1,3-D were undergoing a tolerance review.

There are no data gaps for the assessment of increased susceptibility to infants and children from exposure to 1,3-D. The Agency has reviewed acceptable prenatal developmental toxicity studies in rats and rabbits and an acceptable two-generation reproduction study in rats following inhalation exposures. The data provided no indication of increased susceptibility in rat or rabbit fetuses following *in utero* exposure to 1,3-D. No developmental toxicity was observed at the highest concentration tested in the pre-natal developmental toxicity studies in rats and rabbits tested. No offspring toxicity was seen at the highest concentration tested in two generation reproduction toxicity study.

The Agency has determined that the 10X additional safety factor for the protection of infants and children (as required by FQPA) is not warranted and has been removed based on the following factors:

i. No evidence of developmental toxicity was seen in the prenatal studies in rats and rabbits and no offspring toxicity was seen in the postnatal toxicity study in rats following inhalation exposure to 1,3-D;

ii. There was no evidence of abnormalities in the development of the fetal nervous system in the pre/post natal studies submitted to the Agency;

iii. The toxicology database is complete;

iv. There is adequate data to conduct exposure assessments.

b. Acute Dietary

EPA has reviewed the available toxicological data for 1,3-D and concluded that the data do not indicate any evidence of significant oral toxicity from a single exposure event. Therefore, the acute dietary risk assessment for a single event high end dietary exposure is not required.

c. Chronic Reference Dose (RfD)

An RfD of 0.025 mg/kg/day was determined based on the NOEL of 2.5 mg/kg/day established in a 2-year dietary admix (microcapsules) study in rats (MRID 43763501) and using

an uncertainty factor of 100. The LOEL of 12.5 mg/kg/day was based on a decrease in body weight gain and an increase in the incidence of basal cell hyperplasia of the nonglandular mucosa of the stomach.

Once a study has been evaluated and the observed effect has been determined to be a threshold effect, EPA generally divides the NOEL from the most appropriate study by an uncertainty factor (usually 100) to determine the RfD. The RfD is a level at or below which daily aggregate exposure over a lifetime is not expected to pose appreciable risk to human health. An uncertainty factor (formerly called "safety factor") of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and also, that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive than other individuals or subgroups. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the studies and determines whether an additional uncertainty factor is warranted. An aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA. Table 9 presents the aggregate exposure and percent RfD.

d. Classification of Carcinogenic Potential

EPA classifies 1,3-D as a Group B_2 (probable human) carcinogen based on oral and inhalation animal studies. This classification was based on NTP studies showing increased tumors in both sexes of rats (Fischer 344) and mice ($B_6C_3F_1$) after oral administration of 1,3-D (MRID 00146469). Tumor types noted included forestomach, liver, mammary, thyroid, adrenal, urinary, and lung. The carcinogenic potency factor (Q_1*) for humans via the oral route is 1.22×10^{-1} using the Multistage Model based on the incidence of combined forestomach, liver, adrenal, and thyroid tumors in male rats and using the 3/4 interspecies scaling factor (Fisher 1994).

EPA has also developed a potency factor (Q_1*) for humans via the inhalation route. This Q_1* is 5.33×10^{-2} based on increased bronchioloalveolar adenomas in male $B_6C_3F_1$ mice from inhalation studies using the linearized low dose extrapolation model and a 3/4 interspecies scaling factor (Fisher 1994; MRID's 40312201, 40312300).

The registrant submitted information as a rebuttal to a draft RED on January 15, 1998 proposing that 1,3-D should be regulated as a non-linear carcinogen (i.e., that there is a "threshold" dose below which there is no risk). While EPA does not believe it is appropriate to delay this reregistration decision, EPA has agreed to reconvene the Carcinogenicity Peer Review Committee sometime in 1999 to consider new information Dow AgroSciences submitted in 1998, particularly that related to whether 1,3-D should be regulated as a non-linear carcinogen. EPA is currently developing policies on regulating non-linear carcinogens and no change to the risk assessment can take place until those polices are officially adopted.

e. Occupational and Residential Exposure

EPA has identified the dose/end points to be used in the risk assessment for occupational and residential exposures. The current use-pattern does not result in exposure through foods grown in 1,3-D-treated soils; however, due to the potential contamination of ground water and consequently drinking water, the Committee has identified doses and endpoints for use in risk assessments for potential ground/drinking water exposures. The current formulations and application methods indicate a potential for occupational or residential exposure primarily via the inhalation route. Little dermal exposure is expected when 1,3-D is used according to label directions, and therefore dermal exposure is not a concern at this time. Doses and endpoints identified are for both drinking water and inhalation exposures (occupational and residential/bystander).

(i) Dermal Absorption

No dermal absorption studies were required. A waiver was granted for the 21-day dermal toxicity study. The current use-pattern does not indicate potential dermal exposure.

(ii) Inhalation Absorption

1,3-D has been tested extensively by the inhalation route. Therefore, inhalation endpoints are available for risk assessment and route to route extrapolation is not necessary. For this risk assessment, EPA assumes inhalation absorption to be 100 percent.

(iii) Acute Dietary

EPA has reviewed the available toxicological data for 1,3-D and concluded that the data do not indicate any evidence of significant oral toxicity from a single exposure event. Therefore, the acute dietary risk assessment for a single event, high-end dietary exposure is not required.

(iv) Short Term Occupational/Residential

EPA has reviewed the available 30-day inhalation studies for 1,3-D and concluded that the data do not indicate any evidence of significant toxicity from repeated exposure of up to 4 weeks duration. No effects were seen in either a rat or a mouse study. Therefore, no endpoint was identified. The short-term occupational/residential risk assessment for 1,3-D is not required.

(v) Intermediate Term Occupational and Residential/Bystander (1 week to several months)

For inhalation, the NOEL of 0.091 mg/L (20 ppm) will be used and is based on histopathological lesions in the olfactory region of the nasal cavity at the LOEL of 0.272 mg/L (60 ppm) in a 2-year combined chronic toxicity/carcinogenicity inhalation study in F344 rats (MRID 40312201). The 90-day (MRID 00146461) and 2-year inhalation studies were used in

conjunction to determine this endpoint. For intermediate term exposures, 90-day tests are generally used; however, the dose selection from the 90-day study (10 ppm, 30 ppm, 90 ppm, 150 ppm) did not allow for selection of an appropriate NOEL when compared to NOEL's seen in other studies. EPA concluded that had the 20 ppm dose been used in the 90-day study, this would likely have been the NOEL, and thus selected the NOEL of 0.091 mg/L (20 ppm) established in the 2-year chronic study.

(vi) Chronic - Occupational and Residential/Bystander

No chronic inhalation exposure is expected for 1,3-D. The current use pattern results in exposure for no more than 3 weeks at a time, generally only once a year. Therefore, no chronic non-cancer endpoint was selected and this risk assessment is not required.

(vii) Office of Water Health Advisory for 1,3-D

EPA's Office of Water has established a Health Advisory for 1,3-D at 0.2 ppb. This is the level that can be consumed daily over a lifetime that is associated with a 1×10^{-6} cancer risk. The Health Advisory, however, is only advisory in nature and is not enforceable. There is no Maximum Contaminant Level (MCL) for 1,3-D.

(viii) Risk Assessment Endpoints for 1,2-Dichloropropane (Impurity)

1,2-Dichloropropane (1,2-D) is of interest because it is an impurity found in Telone products (0.06 to 0.1% by weight) and has been shown to migrate to ground water and persist for many years. EPA has not conducted a formal evaluation of the toxicology database for 1,2-D at this time because 1,2-D is no longer registered as a pesticide. However, 1,2-D has been evaluated by the Office of Research and Development (ORD) to support development of the Drinking Water Criteria Document for the Office of Water (USEPA 1987). ORD evaluated the limited available database for 1,2-D and concluded that the liver was the principal target organ of toxicity. ORD also found effects from acute exposures; the effects were seen in the lungs, liver, kidneys central nervous system and eyes. A more detailed description is on EPA's IRIS data base.

Subchronic oral exposure to 1,2-D resulted in liver congestion, hepatic fatty changes, and liver necrosis in rats receiving 1000 mg/kg/day, 5 days/week for 13 weeks. Mice showed slightly depressed body weight after treatment with 500 mg/kg/day 1,2-D for 5 days/week for 13 weeks.

EPA's Office of Water has established a 10-day health advisory for children of 0.09 mg/L. This health advisory is based on the following assumptions: 10 kg child, consumption of one L/day of water, all exposure comes from water (i.e., no ambient inhalation exposure), and a health advisory value based on 7-30 days of exposure. There is also a Maximum Contaminant Level of 5 ppb established by EPA's Office of Water.

1,2-D has been classified as a Group B_2, probable human carcinogen, with a Q_1* of 3.69 $x10^{-2}$ $(mg/kg/day)^{-1}$ based on the statistically significant increased incidence of hepatocellular adenomas and carcinomas in male and female $B_6C_3F_1$ mice. In addition, a dose-related trend in mammary adenocarcinomas was noted in female F344 rats. This is considered significant because F344 rats have a relatively low background incidence of these tumors (FR 56(20):3540 (January 30, 1991). In addition, 1,2-D was mutagenic in the Salmonella and in Aspergillus nidulans. 1,2-D also induced sister chromatid exchange and chromosome aberrations in Chinese hamster ovary cells.

(ix) Endpoints for Degradates

Two degradates of 1,3-D have been found in groundwater: 3-chloroallyl alcohol and 3-chloroacrylic acid. EPA has determined that the degradates 3-chloroallyl alcohol and 3-chloroacrylic acid should be considered to have toxicological equivalence to the 1,3-D parent in the absence of toxicology data for the degradates (Abbotts 1997). For the water cancer risk assessment, the 1,3-D oral Q_1* will be used to estimate risk for combined exposure to parent and degradates. In addition, the levels of the degradates found in the ground water studies will be combined with 1,3-D levels to calculate non-cancer risks. The oral Q_1* for 1,2-D will be used to calculate cancer risk for this contaminant, but 1,2-D risks will not be added to 1,3-D risks to develop a cumulative risk assessment. A summary of toxicological endpoints for 1,3-D and its degradates of toxicological concern are presented below in Table 3.

Table 3. Summary of Toxicological Endpoints for 1,3-dichloropropene and Related Compounds			
1,3-D			
Exposure Scenario	Toxicological Endpoint for Risk Assessment	Endpoint	Study
Intermediate Residential/Bystander Inhalation Exposure	Inhalation NOEL = 0.091 mg/L	Histopathological lesions of nasal cavity (olfactory region)	2-year combined chronic/ carcinogenicity inhalation study in F344 rats MRID 40312201
Chronic Drinking Water Exposure	RfD = 0.025 mg/kg/day	Decreased body wt gain and increased incidence of basal cell hyperplasia of nonglandular mucosa of stomach	2-year combined chronic /carcinogenicity study in F344 rats (dietary admix, microencapsulated Telone)MRID 43763501
Lifetime Inhalation (Cancer)	$Q_1^* = 5.33 \times 10^{-2}$ $(mg/kg/day)^{-1}$	Lung bronchioloalveolar adenoma tumor rates in male mice, 3/4 scaling factor, Multistage model	2-year combined chronic/ carcinogenicity inhalation study in mice MRID 40312300
Lifetime Drinking Water (Cancer)	$Q_1^* = 1.22 \times 10^{-1}$ $(mg/kg/day)^{-1}$	Combined forestomach, liver, mammary, thyroid, adrenal, urinary, lung tumors, Multistage Model, 3/4 scaling factor	2-year combined chronic/ carcinogenicity study in F344 rats MRID 00146469
Degradates: 3-chloroallyl alcohol and 3-chloroacrylic acid			
Acute Dietary	None	None	None
Lifetime Drinking Water (Cancer)	In lieu of data for degradates, assume potency equivalent to parent, $Q_1^* = 1.22 \times 10^{-1}$ $(mg/kg/day)^{-1}$	Based on combined forestomach, liver, mammary, thyroid, adrenal, urinary, lung tumors, Multistage Model, 3/4 scaling factor	2-year combined chronic/ carcinogenicity study in F344 rats MRID 00146469
1,2-Dichloropropane (Impurity)			
10-Day Health Advisory for Children MCL (adults)	0.09 mg/L 0.005mg/L	Office of Water Value	Office of Water Value
Lifetime Drinking Water (Cancer)	$Q_1^* = 3.69 \times 10^{-2}$ $(mg/kg/day)^{-1}$	Based on incidence of hepatocellular adenomas and/or carcinomas in male mouse, Multistage Model, 3/4 scaling factor	2-year carcinogenicity study in mice and rats, B2 Carcinogen (described in EPA 1990)

3. Dietary Exposure Assessment

a. Dietary Exposure from Food Sources

(I) Directions for Use

All 1,3-D end-use products are registered for use as a preplant soil fumigation for soils to be planted to all vegetable crops, field crops, and fruit and nut crops. Broadcast applications for control of nematodes and garden symphylans can be made at rates up to 332.5 lb a.i./A for vegetable and field crops and up to 344.4 lb a.i./A for fruit and nut crops. Banded applications are permitted at rates not exceeding the per acre broadcast rate. Dow AgroSciences has applied for a new registration for 1,3-D application via sub-surface drip irrigation systems; this application is under review. Special Local Need Registrations (SLN's) OR940038 and WA940038 permit application to potatoes at a maximum rate of 380 lb a.i./A. The worker restricted entry interval (REI) is five days.

A tabular summary of the residue chemistry science assessments for reregistration of 1,3-D is included in Appendix B. The conclusions listed in Appendix A regarding the Reregistration eligibility of 1,3-D uses are based on the use patterns registered by the basic producer, Dow AgroSciences.

(ii) Nature of the Residue in Plants

The qualitative nature of the residue in plants is adequately understood based on soybean, tomato, and sugar beet metabolism studies, and consists of natural plant biochemicals. In studies with tomatoes and soybeans, no residues of the parent, 3-chloroallyl alcohol, or 3-chloroacrylic acid metabolites were detected.

(iii) Nature of the Residue in Livestock

The qualitative nature of the residue in animals is adequately understood based on adequate goat and poultry metabolism studies. The levels of radioactivity observed in tissues and milk at high dosing levels are negligible and suggest that it is unlikely that detectable levels of 1,3-D residues would occur in meat, milk, or eggs. Therefore, no feeding studies or tolerances are required for meat, milk and eggs when 1,3-D is used as a pre-plant soil fumigant in soils planted to feed crops.

(iv) Residue Analytical Methods

No tolerances are to be established for 1,3-D residues in/on plant or animal commodities. As a result of this determination, there is no requirement for the development of enforcement analytical methods for plant or animal commodities.

(v) Multiresidue Method Testing

Because tolerances are not required for soil fumigation uses of 1,3-D, the requirement for multiresidue method testing is waived.

(vi) Storage Stability Data

Because tolerances are not required for soil fumigation uses of 1,3-D, the requirement for storage stability data is waived.

(vii) Magnitude of the Residue in Crop Plants

Because metabolism data show ultimate breakdown of 1,3-D to non-toxic degradates and subsequent re-incorporation into natural plant constituents, tolerances are not to be established for plant commodities and residue data are not required for use as a preplant soil fumigant (Miller 1995).

(viii) Magnitude of the Residue in Processed Food/Feed

Because tolerances are not required for soil fumigation uses of 1,3-D, the requirement for processing studies is waived.

(ix) Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

No tolerances have been established for 1,3-D residues in animal commodities. The requirements for ruminant and poultry feeding studies have been waived.

(x) Magnitude of the Residue in Water, Fish, and Irrigated Crops

1,3-D is presently not registered for direct use on potable water and aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

(xi) Magnitude of the Residue in Food-Handling Establishments

1,3-D is presently not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

(xii) Confined Accumulation in Rotational Crops

An acceptable confined rotational crop study was conducted with wheat, lettuce, and carrots and radishes. The results were in agreement with those from primary plant metabolism

studies, showing extensive incorporation of radiolabelled residues into natural plant biochemical constituents. No plant-back restriction is required.

(xiii) Field Accumulation in Rotational Crops

Given the results of the confined study, field rotational crop studies are not required for 1,3-D.

(xiv) CODEX Harmonization

No Codex MRLs are in effect for 1,3-D residues. Therefore, there are no questions regarding the compatibility of U.S. tolerances and Codex MRLs.

(xv) Conclusions

As noted above, all Reregistration data requirements for residue chemistry have been satisfied, and tolerances are not required for 1,3-D use as a pre-plant soil fumigant. No 1,3-D residues are expected to occur in plants.

b. Dietary Exposure from Drinking Water

(i) Factors Influencing Drinking Water Exposure

The amount of 1,3-D found in either ground or surface water is related to its physical and chemical properties, as well as a number of local environmental conditions, including soil temperature, soil type, and depth to ground water. 1,3-D, once applied, migrates through the soil profile. Transport can take 1,3-D down to ground water, laterally through the soil profile or up from the point of application through volatilization. 1,3-D that is not transported either degrades or is metabolized by soil bacteria.

1,3-D's mobility in soil is measured by soil adsorption coefficients (Kd's) which range from 0.23 in loamy sand to 1.09 in clay. 1,3-D has a low adsorption coefficient in a range of soils and tends to partition preferentially into water over soil (USEPA 1997). 1,3-D is considered to be a mobile chemical.

For this assessment, the half life of a chemical in the environment is presented as two different measurements: (1) the dissipation half-life, which reflects physical transport (i.e. volatilization) and degradation, and (2) the degradation half-life, which reflects degradation via biological and chemical mechanisms only. These measurements can be conducted in both the lab and field.

For 1,3-D, field dissipation studies show half-lives of 1 to 7 days, but laboratory measurements of aerobic soil metabolism show half-lives of up to 54 days. (Because of 1,3-D's high volatility, the aerobic soil metabolism is likely a more accurate measurement of 1,3-D's

degradation half-life in soil.) Hydrolysis studies of 1,3-D show that hydrolysis is independent of pH, but extremely variable with temperatures; longer half-lives are seen with low temperatures (USEPA 1997).

The major degradates of 1,3-D in soil are 3-chloroallyl alcohol and 3-chloroacrylic acid, both of which were detected in the prospective ground water monitoring studies (USEPA 1997). Information on the physical and chemical properties of 1,3-D's degradates, 3-chloroallyl alcohol and 3-chloroacrylic acid, are limited; however, the degradates are not expected to be as volatile as 1,3-D.

1,3-D can migrate to ground water under certain conditions. Extensive ground water monitoring has been conducted for 1,3-D, and detections have been reported from several states. However, no information about past 1,3-D usage is available to correlate with retrospective ground water monitoring data. Results of the Florida ground water prospective monitoring study suggest that 1,3-D may also migrate to surface water via atmospheric transport, i.e., dissolution of 1,3-D vapors in surface waters. Surface water modeling suggests 1,3-D can migrate to surface water via runoff as well. Because of 1,3-D's volatility, it is not expected to persist in surface waters at high concentrations. The stability and persistence of its degradates in surface waters is unclear, but they are likely to be substantially less volatile than the parent, and therefore may be more persistent.

The contaminant 1,2-D has a different environmental fate profile than 1,3-D. 1,2-D is stable and highly persistent in the environment. The degradation of 1,2-D is not temperature dependent, unlike 1,3-D. Laboratory studies also indicate that 1,2-D is also very mobile, and that mobility is inversely proportional to the amount of soil organic matter.

(ii) Drinking Water Standards

1,3-D is not currently regulated under the Safe Drinking Water Act, however a Health Advisory level (HA) of 0.2 ppb has been established for 1,3-D. Because the HA is advisory in nature, public water supply systems are not required to sample and analyze for 1,3-D. The 0.2 ppb represents the level of daily consumption over a lifetime associated with a 1×10^{-6} cancer risk.

The Office of Pesticide Programs has developed drinking water Levels of Comparison (DWLOC's) to capture risk associated with exposure to pesticides in drinking water. A DWLOC, which is not an enforceable standard, is the concentration of a pesticide in drinking water that would be acceptable as an upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses (if any). The DWLOC came about as part of EPA's review of pesticides under the 1996 passage of FQPA, which required EPA to develop a risk assessment tool to take into account these various exposures.

For 1,3-D, EPA has calculated two DWLOC's. For residents who live near treated fields, defined at the 300 feet buffer, the DWLOC for cancer is zero because the inhalation risk estimates are at or greater than 1×10^{-6} for this population. While the cancer risk estimates at distances

between 300 feet up to 800 meters are presented as greater than 1 x 10^{-6} (see Table 13), EPA believes these risks are overstated because the value of all mitigation measures has not been factored into the assessment, and thus a DWLOC of zero may be overly conservative.

For the general population, defined as residents who live at distances greater than 300 feet from 1,3-D treated fields, the DWLOC for cancer has been calculated to be 0.3, which is the level of daily consumption of a pesticide over a lifetime is associated with a 10^{-6} risk (see section vi of this chapter for detailed information on how this number was calculated and its relevance to the 1,3-D risk assessment).

The discrepancy between the Office of Water's HA of 0.2 ppb and OPP's DWLOC of 0.3 ppb is explained by the two offices different approaches to risk assessment. In general, the Office of Water assumes a different exposure level and a higher cancer potency estimate for 1,3-D. In addition, the DWLOC was generated using cancer data which was developed since the establishment of the 1987 HA. OPP, OW and EPA's Office of Research and Development are planning to share the information developed from the Cancer Peer Review (planned for 1999) in order to coordinate reviews based on the best and most up-to-date data on 1,3-D. OPP has, however, decided to use the 0.2 ppb HA as the trigger for implementation of risk mitigation in the tap water monitoring program because it is an established reference point and because it affords an extra level of protection should the monitoring program detect 1,3-D and/or the degradates.

The contaminant 1,2-D is regulated under the Safe Drinking Water Act. It has a maximum contaminant level (MCL) of 5 ppb, and a maximum contaminant level goal (MCLG) of 0 because it is a B_2 carcinogen (USEPA 1990). In addition, the Office of Water has established a Health Advisory for 1,2-dichloropropane: the 10-day Health Advisory for a 10-kg child is 0.09 mg/L. The drinking water concentration associated with a 10^{-6} cancer risk for a 70-kg adult is 0.06 mg/L (USEPA 1996).

The Office of Water did not establish a 1-day health advisory for 1,2-D because there were insufficient toxicological data on acute effects. In 1979, the National Academy of Sciences recommended an acceptable level of 0.3 mg/L for a 70 kg adult exposed to 1,2-D for a week.

(iii) Groundwater Monitoring

EPA has reviewed available groundwater monitoring data for 1,3-D (USEPA 1997). The Pesticides in Groundwater Database (EPA 1992) indicates detections of 1,3-D in Florida, New York, and Washington following normal field use. This database also reports detections in California due to point source pollution, and 1,3-D has also been detected in California following normal use. Small scale retrospective monitoring conducted by the registrant showed detections in studies conducted in Nebraska, but not in California or North Carolina. There was an unverified detection in a Washington study and a fifth study in Florida was terminated after a sink hole collapsed near the study site. More information on the Pesticides in Groundwater Database

and the retrospective studies can be found in section III. E.2. EPA believes that the best information for assessing human exposure through contaminated ground water is derived from two prospective ground water studies from Wisconsin and Florida, which are discussed below.

Prospective ground water study sites are located where a pesticide has never been used and follows a pesticide's movement from application forward in time through the unsaturated zone into ground water at a study site. The advantage over retrospective studies is that one can rule out detections from prior treatments and that application and environmental conditions can be tracked and evaluated against any detection (or lack of detection).

Wisconsin Site -- In Wisconsin, results show that 1,3-D was detected in an aquifer used for drinking water at concentrations ranging from 0.05 to 579 ppb. The Wisconsin study was still in progress as of printing of this RED, thus levels are presented up to 337 days following 1,3-D application of the two year study. In the Wisconsin study, ground water monitoring was conducted in on-site wells and one offsite well cluster following application of Telone II at a rate 28 gal/acre (283 lbs a.i./acre, typical rate). Depth to ground water ranged from 15-22 feet from the surface throughout the first 337 days of the study.

The study tracked results from eight on-site wells and the off-site well located 65 feet downgradient. The registrant requested that a 100 foot buffer from drinking water wells be added to labels after the study was well underway, therefore, the Agency was not able to modify the study to include how this buffer would affect human exposures with the 100 foot buffer. Although there was one off-site well, these levels can only be used as indicative of a trend, but cannot be used for quantitative risk assessment. For on-site wells, the peak 1,3-D concentration was 579 ppb, the time-weighted concentration (over an 11 month sampling period) was 134 ppb for 1,3-D alone and 357 ppb with 1,3-D plus the two degradates. The peak level of 1,3-D found in the downgradient offsite well was 173 ppb and a time-weighted average of parent plus degradates in this well was 26.6 ppb (Carleton 1998, Eiden 1998). The contaminant 1,2-D was found in all of the onsite shallow and deep wells at concentrations up to 3.9 ppb, and in the offsite well at concentrations up to 0.9 ppb.

Florida Site -- The Registrant volunteered to conduct small scale monitoring in southern Florida because of concerns for groundwater contamination due to the high water table and soil porosity, and in order to assess whether Telone products could be used without causing unreasonable adverse effects as an alternative to methyl bromide.

The Florida study design also evaluated on-site and off-site shallow and deep wells. In Florida, the majority of residents obtain drinking water from public supplies, which tap into the deep Floridian aquifer. However, approximately 20 percent of the population in Florida (up to 80% in certain Florida counties) tap private wells into the shallow, unconfined aquifers.

1,3-D was detected in the Florida prospective study at concentrations ranging from 0.05 to 21.6 ppb in shallow wells (screened at a 10 feet depth) not used for drinking water and up to one ppb in wells that tap into a confined aquifer (screened at a 70 feet depth) which could be

used for drinking water. In Florida, total 1,3-D residues (parent + degradates) in ground water were detected up to 43.9 ppb in the shallow wells (10 feet deep), and up to 8.9 ppb in the deeper wells (70 feet deep). The time-weighted averages (1,3-D plus degradates) were 1.15 ppb in wells at 10 feet from the surface and 0.17 ppb in wells 70 feet from the surface. For off-site wells, the time weighted average (1,3-D plus degradates) was 0.074 ppb.

(iv) Surface Water

Limited surface water monitoring data are available for 1,3-D. Ambient surface water monitoring was conducted concurrent with the Florida prospective ground water study. Monitoring was performed at four sampling sites along two perimeter ditches around a 1,3-D-treated field. 1,3-D was detected above a detection limit of 0.05 ppb in 14 of 20 samples collected from the two ditches in the first five days post-application (prior to the first runoff event). Concentrations ranged from 0.07 to 1.8 ppb. The maximum concentration of 1.8 ppb was the only detection > 1 ppb. No 1,3-D was detected in samples collected from the ditches after five days post-application. The degradate, 3-chloroacrylic acid, was detected in four of the 20 samples collected from the two ditches in the first five days post-application at concentrations ranging from 0.09 to 0.15 ppb. The degradate, 3-chloroallyl alcohol, was detected at a concentration of 0.78 ppb in one sample collected from the north ditch nine days post-application. No detections were noted after the first rainfall event. No rainfall events of sufficient magnitude to generate runoff occurred during the ditch water monitoring.

EPA believes that the 1,3-D found in surface water might have resulted from dissolution of volatilized compound from the air. A second possible pathway is that the levels in surface water resulted from a ground water-surface water interaction.

EPA also used computer modeling to see if 1,3-D use could contaminate surface water through runoff. EPA used Tier 2 (PRZM/EXAMS) modeling to estimate concentrations of 1,3-D, 3-chloroallyl alcohol, and 3-chloroacrylic acid in surface water in a small pond one hectare by 2 meters deep, adjacent to a 10-hectare field. EPA assumed that 1,3-D was incorporated to a depth of 25 cm below the soil surface. The model simulation included a decay rate from the parent compound (1,3-D) to the alcohol and acid degradates. Because the environmental fate data on the degradates is incomplete, EPA used assumptions based on 1,3-D's environmental fate in generating estimates in surface water through modeling.

EPA compared a variety of modeled and monitored results to test the veracity of the model. The maximum reported concentrations of 1,3-D, 3-chloroallyl alcohol, and 3-chloroacrylic acid detected in the Florida ground water monitoring study were: 21.6 ppb, 13.5 ppb, and 8.79 ppb, respectively. Maximum surface water concentrations of 1,3-D and 3-chloroallyl alcohol/ 3-chloroacrylic acid (combined) estimated from the PRZM/EXAMS model were: 1390, and 24 ppb, respectively. The average annual surface water concentrations (based on a 36 year mean) of 1,3-D and its degradates estimated from the PRZM/EXAMS model were 0.801 and 0.340 ppb, respectively. Average annual concentrations of 1,3-D and its degradates in

ditch water from the Florida small-scale prospective monitoring study could not be calculated from the limited monitoring duration (the maximum concentration of 1,3-D was 1.8 ppb).

The discrepancy between model estimates of the maximum concentrations in surface water and the monitoring data reflect, in part, the fact that they address different transport pathways. However, the larger problem with the models is that they are not well-suited to track volatile soil incorporated fumigants through the soil to air and water resources. Based on the data base as a whole, EPA believes once 1,3-D enters surface water, it degradess rapidly due to its chemical properties. Thus, the fate and concentrations of the degradates become of primary concern. EPA does not have a complete data base to determine whether run-off is a significant pathway, and thus Dow AgroSciences is conducting a run-off study to track whether 1,3-D is available for run-off. It should be noted that concentrations of the material in the ditch water fell below detection limits within five days after application in the Florida study; however, the presence of 1,3-D in the ditches was not reflective of the run-off process, since no run-off generating rainfall events occurred prior to its appearance in the ditch water.

(v) Drinking Water Exposure Estimates

EPA is using the results of the Florida and Wisconsin studies to derive ground water concentrations to quantify exposure to 1,3-D and its degradates in drinking water. EPA has estimated dietary exposure to 1,3-D via drinking water using these study results and a daily water consumption value of 2 L/day for adult males and females with bodyweights of 70 kg and 60 kg, respectively, and 1 L/day consumption for infants and children with a 10 kg bodyweight. The following equation used to estimate exposure to 1,3-D through drinking water for adult males is provided as an example of how EPA calculated exposure to 1,3-D and its degradates in drinking water:

$$\text{Exposure (mg/kg/day) (Adult male)} = \frac{(\text{conc'n, } \mu\text{g/L})(2 \text{ L/day})(0.001 \text{ mg/}\mu\text{g})}{70 \text{ kg adult body weight}}$$

Chronic exposure estimates for 1,3-D, its degradates and 1,2-D based on time-weighted mean concentrations detected in ground water from small-scale prospective studies are provided in Table 4 below.

Table 4. Chronic Exposure Estimates for 1,3-D, Degradates, and 1,2-D based on Time-Weighted Mean Concentrations (TWMC) from Prospective Ground Water Studies. Exposures are presented in mg/kg/day.

Populations	Compound	FLORIDA PROSPECTIVE STUDY (365 days)						WISCONSIN PROSPECTIVE STUDY (after 337 days, on-site wells)	
		10-ft wells		70-ft wells		10-ft wells, 100' off-site		shallow aquifer (15-22 ft)	
		TWMC µg/L	Exposure	TWMC µg/L	Exposure	TWMC µg/L	Exposure*	TWMC µg/L	Exposure
Adult males	1,3-D	0.30	8.6×10^{-6}	0.04	1.1×10^{-5}	0.026		134	3.8×10^{-3}
Adult females			1×10^{-5}		1.3×10^{-5}				4.5×10^{-3}
Infants & Children			3×10^{-5}		4×10^{-5}				1.3×10^{-2}
Adult males	3-chloroacrylic alcohol	0.31	8.8×10^{-6}	0.11	3.1×10^{-5}	0.025		87	2.5×10^{-3}
Adult females			1×10^{-5}		3.6×10^{-5}				2.9×10^{-3}
Infants & Children			3×10^{-5}		1×10^{-4}				8.7×10^{-3}
Adult males	3-chloroacrylic acid	0.54	1.5×10^{-5}	0.03	8.6×10^{-7}	0.023		136	3.9×10^{-3}
Adult females			1.8×10^{-5}		1×10^{-6}				4.5×10^{-3}
Infants & Children			5.4×10^{-5}		3×10^{-6}				1.4×10^{-2}
Adult males	1,3-D + Degradates	1.15	3.3×10^{-5}	0.17	4.9×10^{-6}	0.074		357	1×10^{-2}
Adult females			3.8×10^{-5}		5.6×10^{-6}				1.2×10^{-2}
Infants & Children			1.2×10^{-4}		1.7×10^{-5}				3.6×10^{-2}
Adult males	1,2-D	0.22	6.3×10^{-6}	0.06	1.7×10^{-5}	NA		1.69	4.9×10^{-5}
Adult females			7.3×10^{-6}		2×10^{-6}				5.6×10^{-5}
Infants & Children			2.2×10^{-5}		6×10^{-6}				1.7×10^{-4}

* - note these wells were not used for risk assessment purposes, therefore, TWMC values are only presented to compare to levels found in other wells.

Limited surface water monitoring data from the Florida prospective study suggest that 1,3-D may migrate to surface water by transport pathways other than run-off. However, because information regarding potential 1,3-D migration to surface water is limited, and because 1,3-D is a volatile fumigant not well suited to the PRZM/EXAMS model, the concentrations of 1,3-D and its degradates derived from the model will be compared to drinking water levels of comparison. That is, they will not be used to quantify a drinking water risk associated with residues of 1,3-D and its degradates in surface water.

As noted previously, the Office of Pesticide Programs developed drinking water Levels of Comparison (DWLOC's) as a way to evaluate the concentration of a pesticide in drinking water that would be acceptable as an upper limit (i.e. no greater than 1×10^{-6} lifetime cancer risk or 100% RfD) in light of total aggregate exposure to that pesticide from food, water, and residential uses (if any). While there are no exposures from food or residential uses, EPA has decided it is

appropriate to aggregate inhalation and oral (drinking water) exposures. EPA calculated DWLOC values for chronic (RfD) and cancer (Q_1*) endpoints.

(vi) DWLOC/1,3-D plus Degradates

The RfD for 1,3-D (plus degradates) was used to calculate a Drinking Water Level of Comparison (DWLOC) for non-cancer, chronic effects. The $DWLOC_{chronic}$ is the concentration of 1,3-D in drinking water consumed daily over a lifetime that, as part of the aggregate chronic exposure from all sources (food, water and residential), occupies no more than 100% of the RfD. The $DWLOC_{chronic}$ for 1,3-D plus the degradates is 875 ppb for the total US population, 750 ppb for females 13+ years old, and 250 ppb for children. Note there is not an inhalation component because no chronic, non-cancer endpoint was identified and thus no risk assessment was required.

The **$DWLOC_{chronic}$** for 1,3-D plus degradates was calculated using the following formula:

$$DWLOC_{chronic} = \frac{\text{chronic water exposure (1,3-D + degradates) (mg/kg/day)(body weight,kg)}}{\text{(water consumption, L/day)}(10^{-3}\ \text{mg/µg})}$$

where chronic water exposure = RfD (because there is no exposure to 1,3-D via food); water consumption is two L/day for adults and one L/day for children; and body weight is 70 kg for total US population, 60 kg for females 13+ years old, and 10 kg for children 1 to 6 years old.

The oral Q_1* for 1,3-D was used to calculate a DWLOC for cancer effects associated with exposures to 1,3-D plus the degradates. The $DWLOC_{cancer}$ is the concentration of 1,3-D in drinking water consumed daily over a lifetime that is associated with a 1×10^{-6} cancer risk from all exposures. As noted previously in this document, EPA has developed two DWLOC's for 1,3-D (plus degradates). Because the cancer risk associated with inhalation exposures at the 300 feet buffer is above 1×10^{-6}, the DWLOC for water exposure is zero. Although calculated inhalation risk estimates for residents who live near treated fields are above 1×10^{-6}, EPA believes these estimates are overstated because all mitigation measures which are on 1,3-D labels have not been factored into the assessment.

For the general population (those living more than 300 feet from treated fields), the $DWLOC_{cancer}$ for 1,3-D is 0.3 µg/L (ppb). Because there is no dietary (food) exposure to 1,3-D, individuals could be exposed to 8.2×10^{-6} mg/kg/day of 1,3-D in drinking water before EPA's level of concern (1×10^{-6} cancer risk) would be exceeded. See section III.D. iv for an explanation of how EPA calculated risk estimates for cancer and how levels found in the ground water studies compare to the DWLOC for cancer. As explained in section III. B.3 b., there is an Office of Water Health Advisory of 0.2 ppb which differs from the DWLOC of 0.3 ppb.

The **$DWLOC_{cancer}$** for 1,3-D was calculated using the following formula:

$$DWLOC_{cancer} = \frac{\text{(chronic water exposure (1,3-D + degradates), mg/kg/day)(body weight)}}{\text{(µg/L)(water consumption, L/day)}(10^{-3}\ \text{mg/µg})}$$

where chronic water exposure = $\frac{1 \times 10^{-6}}{\text{oral } Q_1^* \text{ of } 1.22 \times 10^{-1} \text{ (mg/kg/day)}^{-1}}$,

water consumption is 2 L/day, and body weight is 70 kg.

(vii) DWLOC/1,2-D.

The oral Q_1^* for 1,2-dichloropropane was used to calculate a DWLOC for cancer effects caused by 1,2-D. The $DWLOC_{cancer}$ for 1,2-dichloropropane is 1 ug/L. The inhalation exposure studies did not monitor for levels of 1,2-D in air, therefore, the DWLOC only estimates oral exposures.

The **$DWLOC_{cancer}$ for 1,2-dichloropropane** was calculated using the following formula:

$$DWLOC_{chronic} \text{ (µg/L)} = \frac{\text{(chronic water exposure, mg/kg/day)(body weight)}}{\text{(water consumption, L/day)}(10^{-3} \text{ mg/µg})}$$

where chronic water exposure = $\frac{1 \times 10^{-6}}{\text{oral } Q_1^* \text{ of } 3.69 \times 10^{-2} \text{ (mg/kg/day)}^{-1}}$,

water consumption is 2 L/day, and body weight is 70 kg.

DWLOC's can also be compared to model estimates as a surrogate way to estimate and characterize risks. Using PRZM/EXAMS as a model, EPA devised three scenarios to give 36-year mean concentrations for 1,3-D and its degradates in pond water and compared those to the DWLOC's for chronic (RfD) toxicity endpoints. DWLOC values were calculated for chronic (non-cancer) effects for three subpopulations (U.S. population, adult females, and children and infants), and calculated for cancer effects for the general U.S. population. Table 5 below provides a comparison of the model estimates for three scenarios from Idaho, Mississippi and Georgia to the DWLOC values for the general population..

Table 5. Estimated Concentrations of 1,3-D, 3-chloroallyl alcohol, and 3-chloroacrylic acid in Pond Water (PRZM/EXAMS).

Subgroup	DWLOC chronic (ug/L)	36-Year Mean (ug/L)		
		Potatoes (ID)	Tobacco (GA)	Cotton (MS)
US Population	875	0.045	0.357	0.801
Females	750	0.016	0.081	0.340
Children & Infants	250	0.061	0.438	1.141

Note the DWLOC for the cancer endpoint is 0.3 ppb, which would be exceeded for all groups from the MS scenario and for all but females in the GA scenario.

However, EPA does not expect 1,3-D concentrations to persist in surface waters long enough to provide chronic exposures and recognizes that PRZM/EXAMS is not well suited to tracking volatile fumigants. Estimated average concentrations of 1,3-D and its degradates, alone or in total, are well below the DWLOC's for chronic, non-cancer effects for the subpopulations of concern. Estimated concentrations of 1,3-D, *per se*, are greater than the DWLOC for cancer effects in two of the scenarios modeled. EPA has some concern that the degradates, being less volatile than the parent compound, may persist in surface waters. Dow AgroSciences is developing environmental fate and run-off data to show whether the degradates persist to pose chronic risks.

C. Occupational and Residential Exposure

1. Summary of Use Pattern and Application Methods

There are no homeowner products containing 1,3-D. 1,3-D is a restricted-use pesticide and thus only certified handlers are allowed to load and apply 1,3-D.

1,3-D is applied by injection below the soil surface at least 12 inches. The liquid 1,3-D then diffuses through the soil spaces. 1,3-D may be degraded while in the soil or it may volatilize or migrate to groundwater. Occupational and residential/bystander inhalation exposure occurs as a result of 1,3-D volatilization. Inhalation is the primary route of exposure for workers. The rate of 1,3-D volatilization is affected by application method, soil sealing method, soil composition (e.g, amount of clay and organic matter), and soil moisture, temperature and a variety of other local environmental factors.

1,3-D is applied to soil by two methods: row and broadcast. With both methods, 1,3-D is injected 12-18 inches below the final sealed soil surface. The broadcast method uses one chisel, Nobel (sweep) plow or plow-sole application equipment with one or more fumigant outlets. The broadcast method requires the formation of a raised bed after the application. The row method consists of either one or two chisels per plant row to treat a band of soil where the crop is to be planted. The row method involves forming beds at the time of application so that the fumigant is placed at least 12 inches from the nearest soil/air interface.

1,3-D products do not require mixing, and are loaded into tanks which are attached to tractors or application rigs directly from a bulk or mini-bulk container. Bulk loading from tanker trucks is the predominant practice where custom applicators are the biggest users (e.g., the Pacific Northwest). Mini-bulk systems are portable 1000-gallon "traveler" cylinders with dry disconnects to prevent 1,3-D leaks. After applying 1,3-D, the user returns the mini-bulk container and any remaining 1,3-D to the local distributor, who then sells the remainder or returns the mini-bulk container for cleaning (note: cleaning and maintenance of bulk and mini-bulk containers are regulated by OSHA and are not included in this exposure assessment).

2. Exposure Mitigation Measures in Effect

Since 1992, numerous mitigation measures have been added to all 1,3-D product labels. Specific mitigation measures for workers and area residents are described below.

a. Workers

The following table presents label measures that are in effect to reduce exposures to workers through the dermal and inhalation routes of exposure. The largest sources of worker exposure, through leaks and spills, were addressed by the use of closed loading, equipment to shut off 1,3-D flow at row-turns and respirators.

Table 6. Summary of 1,3-D Label Restrictions that Impact **Worker** Exposures

Regulatory Action (effective date)	Label Requirements
Registration Standard (1986)	Precautionary Statements; Cancer Hazard Warning; Classification Change to Restricted Use Pesticide; Reentry increased to 72 Hours*; Clothing for Applicators and Handlers (Coveralls*, Chemical-resistant Gloves and Boots, Liquid-proof Hat).
1992 Label Amendments (1992/1993)	Lowered Maximum Rates; Deletion of Selected Use Sites; Revised Respirator Requirements*; Closed Loading Requirements; Technology to Minimize 1,3-D Spillage during Application, Improved Product Stewardship Materials
Worker Protection Standard (August 1992 see 57 FR 38102)	Coveralls Over Short-sleeved Shirt and Short Pants; Chemical-resistant Gloves and Footwear; Chemical-resistant Apron (for Direct Handlers).
1995 Label Amendments (1996)	A Respirator Requirement for All 1,3-D Handlers (Except Those in Certain Closed Cabs); Restricted Entry Increased to 5 Days; Soil Moisture and Soil Sealing Requirements; Modified Application Techniques and Lower Maximum Use Rates.

* Superceded or modified by later label measures.

b. Residents/Bystanders

1,3-D labels require a 300 foot buffer zone between treated fields and an occupied structure where 1,3-D applications are prohibited. Other measures listed in the table above, including use of the "traveler" mini-bulk loading system, reduced application rates, increased injection depth, soil sealing, and soil moisture requirements, are also expected to reduce exposure to residents and bystanders, although exposure reduction cannot be quantified (Carleton 1996a).

3. Factors Influencing 1,3-D Exposure

The label measures described above reduce, but do not do not completely prevent, 1,3-D releases into the atmosphere. EPA believes that the greatest potential for release under current labels is through the chisel trace that is left as 1,3-D is applied, and through off-gassing that occurs for several days after application. For this route, local environmental conditions greatly influence inhalation exposure to agricultural workers and residents/bystanders. Local soil conditions, such as soil type, moisture, organic content, and soil temperature all influence the rate of 1,3-D volatilization and subsequent exposure to workers or residents. 1,3-D product application methods, including soil sealing, injection depth, and placement of injection shanks influence the volatilization of 1,3-D. Local meteorological conditions, such as prevailing wind, also influence air concentrations and exposure potential. Application rates may also influence 1,3-D volatilization, although a quantitative relationship between application rate and air concentration has not been established. In addition, 1,3-D air concentrations may vary with time after application. Peak 1,3-D volatilization generally occurs over the first 72 hours following 1,3-D application, although detectable levels are still present 14 days following application.[1] 1,3-D exposure also varies with distance from treated fields. 1,3-D air concentrations measured 125 meters from treated fields were 45 to 72 percent lower than air concentrations measured five meters from treated fields (Carleton 1996).

4. Exposure Monitoring Studies

Dow AgroSciences performed exposure monitoring studies for both workers and for residents who live near treated fields. Most of these studies were required by the 1992 DCI. An additional worker study on 1000 gallon mini-bulk "travelers" was submitted by Dow AgroSciences in 1995, which was incorporated into the worker risk assessment, but not the residential assessment. Studies used for the EPA Worker and Resident/Bystander Risk Assessments are summarized below.

a. Worker Monitoring Studies

Personal air monitoring was conducted for product loaders, applicators, and re-entry workers (MRID's 42946201, 42845602, and 4880401). Air samples were drawn through activated carbon sorbent tubes, using battery operated pumps to collect air from the breathing zones of the workers at a measured flow rate. Samples were subsequently desorbed in an organic solvent and analyzed by GC-ECD or GC-FID. For the loaders and applicators, two kinds of samples were collected: four hour samples, and task-specific short duration (4 to 46 minutes) samples. The four hour samples provided inherently time-weighted average air concentrations over a major fraction of a work day, while the task-specific samples measured the air concentrations associated only with high-contact activities. For product loaders, these activities were the actual loading events. The 4-hour loader samples included the loading events, and the

[1] In two of three residential exposure studies, peak Telone air concentrations occurred within 72 hours of application.

time spent on site between loading events. In the Ainger, NC worker monitoring study, only short-term task specific samples were collected. Sampling occurred only when workers were actively engaged in loading. Worker monitoring studies are described below and the data from these studies are summarized in Tables 7 and 8.

- **Moses Lake, WA Worker Study**. October and November, 1992. Telone II was applied at the maximum application rate of 25 gal/acre (252.5 lbs a.i./acre) on a field used for potatoes; soil type was sandy loam. Bulk loading was used, with dry disconnects, which are common practice in the region. Application was by the broadcast method.

- **Buckeye, AZ Worker Study.** March 3-10, 1993. Telone II was applied by the row method at the maximum rate of 12 gal/acre (121.2 lbs a.i./acre) to a field used to grow cotton; soil type was loamy sand. Bulk loading was used, with dry disconnects. (The study also collected samples without dry disconnects, but these data were not used for Reregistration because dry disconnects are now a label requirement.)

- **Ainger, NC Worker Study.** April 3-5, 1995. Telone C-17 (1,3-D plus chloropicrin) was applied by the row method at a rate of approximately 10 gal/acre (82 lbs a.i./acre) to a field used to grow tobacco. Soil type was not specified. This study utilized the mini-bulk delivery system, Dow AgroSciences' portable 1000-gallon "traveler" cylinders, which utilize dry disconnects. End row spill control was also used in this study.

Not all available worker monitoring data were used for exposure assessment. Only data reflecting the label requirements current at the time of testing were used (e.g., respirators, dry disconnects, end-row spill control).

Biological exposure monitoring was also conducted on both sedentary human volunteers (controlled study) and on workers performing typical tasks. Urinalysis was used to detect the major 1,3-D metabolites (Levy 1993, McMahon 1993). These studies are described in detail in the worker exposure assessment for 1,3-D (Mehta 1994b). The biological monitoring data were not used in this risk assessment because an accurate correlation between urinary metabolite excretion and the air monitoring data could not be made to estimate absorbed dose (McMahon 1993). The biomonitoring data showed 1,3-D absorption in the range of 72-82 percent; these absorption estimates were determined to be minimum values after comparison with field trial data. Absorption via the inhalation route was assumed to be 100 percent for the purposes of this risk assessment.

b. Resident/Bystander Monitoring Studies

The NC, AZ and WA studies (MRID 42845601) included off-site monitoring to assess exposures to residents who live near treated fields. Residential/bystander monitoring studies

involved air sampling for 14 days at various stations 5, 25, 125, 500 and 800 meters from a 1,3-D-treated field (and additional sampling stations at 1200 and 1600 feet for the AZ site). Prior to the initiation of the treatment, baseline air samples were collected at sampling stations located 500 meters from the treatment sites. The applications were conducted utilizing standard cultural practices and equipment at the time of the study. Fields that were selected and treated were isolated from all other known 1,3-D handling activities. Air sampling was conducted in all four compass directions. EPA analyzed data for samples taken downwind from treated fields, as well as for pooled data from all four directions (to account for shifts in wind direction). Air sampling was conducted around the clock to account for day and night exposures. Greater 1,3-D ambient air concentrations and volatilization rates were found at night (Mehta 1994a). However, only the 24-hour, time-weighted average air concentrations were used to estimate residential/bystander exposures, due to a lack of individual time activity data on time spent in and around the house at day and night.

Air monitoring was conducted directly above the treated field, and at distances of 5, 25, 125, 500, and 800 meters from the edge of the field, in each of four orthogonal directions (i.e. N,S,E,W). All samples were taken approximately five feet above the ground, using battery operated pumps to draw air through activated carbon sorbent tubes at a measured flow rate. Samples were collected during the 1,3-D application at all sampling locations, except directly above the fields. After the application was finished, sampling began at all locations, and continued for 14 days post application. The first 24 hour period following application was divided into six 4-hour samples. 1,3-D air concentrations were at their peak during the first 24-hours. The next 48 hours were divided into four 12-hour samples. The remaining 11 day period was divided into 24-hour samples, one for each day.

At the Washington study site, the presence of a nearby cattle stockyard prevented the collection of a sample 800 meters south of the treated field. However, at the Arizona site, samples were collected at 1200 and 1600 meters from the field in all four directions, in addition to the distances listed above.

Residential/bystander monitoring studies are described below.

- **Phase 1. Moses Lake, WA.** October 26 to November 9, 1992. Air monitoring was conducted at 20 monitoring locations surrounding a 20 acre plot treated with Telone II using the broadcast method at the maximum rate of 25 gal/acre (252.5 lbs a.i./acre). Prior to the initiation of the treatment, baseline air samples were collected at sampling stations located 500 meters from the treatment site. The 800 meter south samples could not be collected because a cattle stockyard was located to the south of the treated field. The soil type was characterized as loamy sand.

- **Phase 2. Harquahala Valley, AZ.** February 16 to March 2, 1993. Telone II was applied using the row method at a rate of 12 gal/acre (121.2 lbs a.i./acre), imitating an application for a melon field. Air monitoring was conducted at 28 monitoring

locations surrounding the 20 acre plot treated with Telone II. The soil type was characterized as a sandy loam.

- **Phase 3. Hookerton, North Carolina**. December 7-21, 1992. Air monitoring was conducted at 20 monitoring locations surrounding a 12 acre plot that had been treated with Telone C-17. Telone C-17 was applied using the broadcast method at a maximum label rate of 20 gal/acre (164 lbs a.i./acre) for tobacco. The soil type was characterized as a sandy loam.

Monitoring data from these studies are summarized in Table 7 below. Off-site monitoring results are presented at various distances from treated fields. The monitoring data showed that 1,3-D air concentrations peaked during the first three days following treatment and then declined over a period of 14 days following treatment, which was the duration of the air monitoring. Data from the resident/bystander study are presented in a way that captures this peak. Data are presented as (1) the maximum 4-hour air concentration during the study, measured during the first few days of treatment, (2) mean 24 hour air concentrations, (3) mean 7-day air concentrations, and (4) mean 15-day air concentrations.

For each sampling station, the time weighted average (TWA) air concentration was calculated for the appropriate sampling period. This consisted of the arithmetic mean of the mean daily air concentrations. For all except the on-site samples, this calculation included the concentrations measured during the application process. For each distance from a treated field, the mean TWA over all four directions (N, S, E, W) was calculated for the appropriate monitoring period. The data for all three sites was then pooled, and an overall average for each distance was calculated for the entire data set.

Table 7. 1,3-D Air Concentration Monitoring Data for Agricultural Workers

Activity	Sample Duration	Study sites	Total reps.	Air Concentration (µg/m³)		
				Range	Mean	Median
Loading [a]	4 hr	WA, AZ	10	177-5932	1,631	623
Loading [a]	task only	WA,AZ	10	526-32490	10,833	4,860
Loading [a]	task only	NC	12	52-1180	464	442
Application[b]	4 hr & task	WA, AZ, NC	28	43-6581	1,359	1,150

[a] With use of dry disconnects
[b] With use of end-row spill control

Table 8. Offsite Air Monitoring data

Distance from treated field (m)	Study Site	Max. 4-hour conc. (µg/m³)	Max conc. 24 hour TWA (µg/m³)	Mean conc. 7 day (µg/m³) **numbers in bold indicate mean levels at that distance for the 3 studies**	Mean conc. 15 day (µg/m³) **numbers in bold indicate mean levels at that distance for the 3 studies**
1600	AZ	90.9	23.3	3.2	2.4
1,200	AZ	157.7	46.0	5.6	3.8
800	AZ	215.9	62.9	9.7	6.5
	WA	171.9	79.7	21.0	14.6
	NC	63.2	10.8	1.4	1.3
				10.7	**7.5**
500	AZ	482.2	140.4	18.6	11.8
	WA	183.0	91.7	24.1	17.2
	NC	92.1	16.0	2.2	1.5
				15.0	**10.2**
125 Edge of buffer zone	AZ	1709.5	579.3	92.0	55.6
	WA	521.3	278.2	55.0	40.2
	NC	281.0	58.0	10.4	6.0
				52.5	**33.9**
25	AZ	3573.6	1807.0	196.0	112.4
	WA	317.7	212.2	74.9	62.1
	NC	394.3	222.9	26.2	15.1
				99.0	**63.2**
5	AZ	1592.6	1278.2	184.8	104.7
	WA	351.0	235.5	91.7	73.6
	NC	671.2	343.7	38.3	21.7
				104.9	**66.7**
onsite	AZ	2316.4	1067.1	315.4	171.1
	WA	351.0	266.2	151.3	115.5
	NC	339.9	261.9	75.6	40.4
				180.8	**109.0**

5. Exposure Estimates Used for Risk Assessment

EPA based its risk assessment on 1,3-D air concentrations measured in the monitoring studies described above. Only inhalation exposure was estimated; dermal exposure is expected to be negligible because of 1,3-D's volatility and the protective measures on 1,3-D product labels.

Because the number of monitored replicates at each site was small (5 to 13), EPA pooled the results from different sites to obtain the largest possible sample sizes for each exposure scenario. Tables 7 and 8 present a summary of the pooled data on air concentrations from these studies.

For intermediate-term worker exposure, the 4-hour samples were used to calculate the mean air concentrations over all pooled replicates. Separate inhalation exposure estimates are provided for custom loaders and applicators, because different individuals perform these tasks. However, for growers, EPA assumed that the same person conducts both loading and application of 1,3-D. Since growers presumably spend most of their work day engaged in application rather than loading, intermediate-term exposures estimates for growers were based on the air concentration for application rather than loading. All worker air concentration estimates were adjusted using a protection factor of 0.10 for respirators.

For intermediate-term residential/bystander exposure, a time weighted average (TWA) air concentration was calculated for the first eight days of exposure only (day of application and the first seven days of a 14-day study). These are the mean 7-day air concentrations in Table 8, which were used to calculate intermediate term MOE's.

For lifetime residential/bystander exposure, the TWA air concentration was calculated for the entire sampling period for each monitoring station. This time weighted average was the arithmetic mean of the mean daily air concentrations. For all but the on-site samples, this calculation included the air concentrations measured during the application process. This value was normalized over a 24 hour period, and incorporated into an overall 15 day TWA (the day of application plus the 14 days following). Since samples were not collected above the fields during the application process, the on-site TWA covered only the 14 day period after application.

For each distance from a treated field, the mean TWA over all four directions (N, S, E, W) was calculated for the entire monitoring period. The data for all three sites were then pooled, and an overall average for each distance was calculated for the entire data set. These values appear in Table 8 under the heading of "Mean conc. 15 day" air concentrations. Subsequent cancer calculations took account of the differing numbers of days used in calculating the mean air concentrations at the different distances, by assuming 14 days of exposure for the on-site concentration, and 15 days for all the others.

To calculate intermediate-term exposures, a similar calculation was performed, except that for each distance, a TWA air concentration was calculated for the first eight days only (day of application plus the seven days following). These values appear in Table 8 under the heading of "Mean conc. 7 day" air concentrations. Intermediate-term MOE's were estimated as the intermediate-term inhalation NOEL of 0.091 mg/L (see Table 3) divided by the "mean 7 day" 1,3-D air concentration.

Exposures to agricultural handlers entering treated fields after the five day REI were also calculated using the on-site air monitoring data from the residential/bystander studies. For each of

the three monitored sites, the TWA 1,3-D air concentration was calculated for the period consisting of days 6-14 post-application. The resulting concentration was used to estimate cancer risks to handlers entering treated fields.

Chronic, lifetime exposures to workers and area residents were expressed as lifetime average daily dose (LADD). The LADD of 1,3-D was calculated according to the following formula:

$$\text{LADD (mg/kg/day)} = \frac{[(\text{air concentration, } \mu g/m^3)(\text{mg}/1000\ \mu g)(\text{ventilation rate, } m^3/hr)(hr/day)(\text{days/yr})(1\ yr/365\ \text{days})(\text{yrs exposed}/70\ \text{yrs})]}{70\ \text{kg body wt}}$$

using the following values for workers and residents/ bystanders:

	Workers	Residents/Bystanders
Ventilation rate	1.74 m^3/h (light work)	0.81 m^3/h
Lifetime Exposure	30 years, grower, 20 years, commercial	30 years
Average Lifetime	70 years	70 years
Exposure Duration	crop specific	16 h/day
Exposure Frequency	crop specific	13 days/event, 1 events/yr

LADD's for commercial "for-hire" handlers were calculated by first estimating average daily doses (ADD's) in mg/kg/day, from the air concentrations. Information on days per year and hours per day were obtained for each crop, state by state, from Dow AgroSciences' Use and Usage Summary Report. However, for loaders, the report lists only the total hours per day spent actively engaged in loading (0.5 to 1.25 hour/day), not total hours spent on site. To estimate ADD's, the Agency therefore assumed loaders to be on site for the same number of hours per day as the applicators (5 to 10 hour/day, depending on state and crop).

LADD's for growers assumed that the majority of the work day is spent applying 1,3-D, and only as much time as is required to load the tank is spent engaged in loading. Therefore, the 4-hour samples were used in the calculation of the portion of the exposure resulting from application, and the task-specific samples were used to calculate the exposure incurred while loading (because 4-hour samples were not collected for the mini-bulk study, the Agency made the assumption that for the use of mini-bulk cylinders, the task-specific loader air concentrations are experienced for the duration of a work cycle). The loading and application exposures were then added to estimate the total exposure for these individuals. Information on hours per day and days per year for each activity were obtained from the Dow AgroSciences' Use and Usage Summary Report. For growers, the Agency assumed that the same person conducts both loading and application of 1,3-D.

Exposure estimates for residents/bystanders were based on pooled data to account for random shifts in wind directions. For residents/bystanders, the Agency also assumed 16 hours/day spent in and around the house. EPA assumed 1,3-D air concentrations to be the same indoors and outdoors, in the absence of indoor air monitoring data. Exposure estimates for residents/bystanders are provided for individuals who remain at a fixed distance from a treated field. The LADD for workers was adjusted using a protection factor of 0.10 for respirators.

D. Risk Assessment

EPA expects both occupational and residential/bystander exposure from the use of 1,3-D. Residents and bystanders near Telone-treated fields are exposed via ambient air. Dietary exposure may occur through drinking water, but is not expected from food sources. Exposure can occur by the inhalation and oral (drinking water) routes, but not is not expected from the dermal route of exposure based on use patterns and label requirements for 1,3-D use.

1. Dietary Risk and Characterization

a. Food Source

No dietary risk assessment was performed for 1,3-D, because no residues are found in foods. Telone products are pre-plant fumigants which break down in the soil and thus are not available for uptake by plants. The at-plant treatment for pineapples shows that the fruit, which are borne three years later, do not contain 1,3-D treatment-related residues.

b. Drinking Water Source

(i) Acute Drinking Risk

No acute toxicological endpoints were identified for 1,3-D exposure for acute or subchronic time duration. Therefore, no acute or subchronic drinking water risk assessment was conducted.

For 1,2-D, EPA's Office of Water has a children's 10-day health advisory of 0.09 mg/L (90 µg/L or 90 ppb). The maximum concentration of 1,2-D found was 1.3 µg/L (0.0013 mg/L) in the Florida study and 3.9 µg/L (0.0039 mg/L) in the Wisconsin study. Because the maximum concentration of 1,2-D found in the prospective ground water monitoring studies does not exceed the 10-day health advisory for children, it is not considered to be of concern.

The Maximum Contaminant Level (MCL) for 1,2-D is 0.005 mg/L (5 µg/L). The maximum concentration of 1,2-D in the Florida study on-site wells was 1.3 µg/L in shallow wells and in the Wisconsin study was 3.9 µg/L. Therefore, the levels of 1,2-D found in the prospective studies do not exceed the MCL and are not considered to be of concern.

(ii) Short and Intermediate Term Drinking Water Risk

For 1,2-D, EPA's Office of Water has established a 10-day health advisory; the concentrations of 1,2-D in the water monitoring studies were compared to the 10-day health advisory for 1,2-D. Concentrations of 1,2-D in groundwater did not exceed the 10-day Health Advisory of 0.09 mg/L or the MCL of 0.005 mg/L and are not of concern. In the Florida study, the peak groundwater concentration in on-site wells of 1,2-D was 1.3 µg/L (0.0013 mg/L). In the Wisconsin monitoring study, the peak groundwater concentration of 1,2-D was reported to be 3.9 µg/L (0.0039 mg/L).

(iii) Chronic Drinking Water Risk as % RfD

For 1,3-D, EPA has determined that the oral RfD should be 0.025 mg/kg/day, based on a NOEL of 2.5 mg/kg/day from a 2-year chronic/carcinogenicity study in rats and an uncertainty factor of 100.

The chronic drinking water risk is calculated as a percent of the RfD taken up by drinking water. As stated previously, groundwater is expected to be the only source for chronic drinking water exposure to 1,3-D.

The following calculation was used:

$$\% \text{ RfD} = \frac{(\text{Drinking Water Exposure, mg/kg/day})}{\text{RfD of 0.025 mg/kg/day}} \times 100\%$$

Time-weighted average ground water concentrations from the prospective ground water monitoring studies were used to estimate risk as a percentage of the RfD. Chronic drinking water exposure was compared to the RfD for the total U.S. population (as represented by adult males), adult females, and infants/children. For the exposure scenario using ground water monitoring data from the Wisconsin prospective ground water monitoring study, chronic exposure to 1,3-D for the total US population is 40 percent of the RfD, for adult females chronic exposure is 48 percent of the RfD, and for infants/children (the most highly exposed sub-population) chronic exposure is 144 percent of the RfD. Dietary and drinking water exposures below 100 percent of the RfD are generally considered not to be of concern. Chronic (non-cancer) risk estimates based on exposure to 1,3-D in drinking water are presented in Table 9 below.

Risk estimates for drinking water associated with chronic, non-cancer effects were not calculated for surface water because the available monitoring information on 1,3-D and its degradates in surface water is inadequate (does not provide a long-term average concentration value, i.e., a time-weighted mean concentration or information on whether run-off would contribute to surface water levels). No RfD was available for 1,2-D; therefore, a chronic drinking water risk assessment was not performed.

Table 9- Risk Estimates for Chronic Effects (non-cancer) of 1,3-D and 1,3-D + Degradates as a %RfD based on Maximum Exposure Calculated from the Wisconsin (up to day 337 from on-site wells of 2-Year Study) and Florida Prospective Ground Water Study Data.			
Wisconsin Prospective Ground Water Study (15-22 feet deep wells)			
Populations	Compound	Exposure (mg/kg/day)	% RfD
Adult males	Telone + degradates	1×10^{-2}	40
Adult females		1.2×10^{-2}	48
Infants & Children		3.6×10^{-2}	144
Florida Prospective Ground Water Study (10 feet deep wells on site)			
Populations	Compound	Exposure (mg/kg/day)	% RfD
Adult males	Telone + degradates	3.3×10^{-5}	<1.0
Adult females		3.8×10^{-5}	<1.0
Infants & Children		1.2×10^{-4}	<1.0
Florida Prospective Ground Water Study (70 feet deep wells on site)			
Adult males	Telone + degradates	4.9×10^{-6}	<1.0
Adult females		5.6×10^{-6}	<1.0
Infants & Children		1.7×10^{-5}	<1.0

(iv) Carcinogenic Risk from Drinking Water

The Agency estimated cancer risks associated with dietary exposure to 1,3-D via drinking water from ground water sources. Appropriate and reliable monitoring data for surface water were not available. Cancer risks were estimated for the total US population only, because the Agency has insufficient information to estimate lifetime drinking water consumption (or cancer risk) for subpopulations of varying ages and reproductive status.

Cancer risk estimates were calculated using the following equation:

Cancer risk = (chronic drinking water exposure, mg/kg/day) x Q_1*, $(mg/kg/day)^{-1}$

Chronic drinking water exposure values are derived from time-weighted mean concentrations of 1,3-D, its degradates, and 1,2-D detected in the Wisconsin and Florida prospective monitoring studies.

The oral Q_1* is 1.22×10^{-1} $(mg/kg/day)^{-1}$ for 1,3-D and 3.69×10^{-2} $(mg/kg/day)^{-1}$ for 1,2-D. Note there is a separate Q_1* for 1,3-D via the inhalation route of exposure, which is discussed in the following section.

Cancer risk estimates were derived from both the Florida and the Wisconsin study based on total concentration of 1,3-D and the degradates, 3-chloroallyl alcohol and 3-chloroacrylic acid (assuming that the degradates have cancer potency equivalent to 1,3-D). Lifetime cancer risk estimates from wells located on-site are estimated to be from 4×10^{-6} (Florida) to 1.2×10^{-3} (Wisconsin). The new 1,3-D labels prohibit use within 100 feet of a drinking water well, so these risks are likely overestimates.

Both prospective ground water monitoring studies included limited monitoring in off-site wells located down gradient from the treated fields. The studies were underway when the registrant proposed the 100' no-treatment buffer from drinking water wells, and as such, the study could not be modified to assess human exposures with this buffer. In the Florida study, time weighted average (TWA) concentrations of 1,3-D plus its degradates in the on-site wells (10' deep) were 1.15 ppb. TWA concentrations of 1,3-D plus degradates measured in wells located 100 feet down gradient from the treated field were 0.074 ppb. In the Wisconsin study, on-site wells yielded TWA concentrations of 1,3-D and its degradates of 357 ppb while concentrations in a well 65' down gradient from the treated field were 26.6 ppb. Although neither of these studies was designed to quantify offsite exposures, results in both studies indicate that exposures were lower with increasing distance from treated field.

Dow AgroSciences has agreed as a condition of reregistration to conduct tap water monitoring studies to better estimate current concentrations of 1,3-D and degradates in drinking water. Sampling will be targeted to high-use areas and will be initiated once the new labels are in effect in August of 1999. EPA expects the sampling program will allow better characterization of risks including the 100' setback required from drinking water wells now required on the label.

Drinking water cancer risks were not calculated for surface water because the available monitoring information on 1,3-D and/or its degradates in surface water is inadequate (since it does not provide a long-term average concentration value, i.e., a time-weighted mean concentration) for use in a chronic exposure assessment to estimate cancer risks. The Agency believes that continued chronic exposure to 1,3-D is unlikely because 1,3-D is likely to dissipate rapidly from surface water via volatilization, making chronic surface water exposure unlikely. The potential for chronic exposure to the degradates is expected to be greater, since they are likely to be less volatile than the parent. As mentioned in the previous section, Dow AgroSciences is conducting a run-off study to investigate whether there is a potential for substantial exposures via surface water. Drinking water cancer risk estimates based on ground water data for the contaminant 1,2-D range from 6.3×10^{-8} to 1.8×10^{-6}. Cancer risk estimates for on-site drinking water wells are summarized in Table 10 below.

Table 10. Chronic Exposures and Cancer Risk Estimates for 1,3-D, its Degradates, and 1,2-D based on Time-Weighted Mean Concentrations from Prospective Ground Water Monitoring Studies									
Compound	Florida Ground water Monitoring Data (on-site wells)						Wisconsin Ground water Monitoring Data (on-site wells)		
	10 ft deep wells			70 ft deep wells			shallow aquifer (15-22 ft)		
	Conc'n, µg/L	Estimated Exposure, mg/kg/day	cancer risk	Conc µg/L	Estimated Exposure, mg/kg/day	cancer risk	Conc µg/L	Estimated Exposure, mg/kg/day	cancer risk
1,3-D	0.30	8.57×10^{-6}	1.0×10^{-6}	0.04	1.1×10^{-6}	1.4×10^{-7}	134	3.8×10^{-3}	4.7×10^{-4}
3-chloroacrylic alcohol	0.31	8.86×10^{-6}	n/a	0.11	3.1×10^{-6}	n/a	87	2.5×10^{-3}	n/a
3-chloroacrylic acid	0.54	1.54×10^{-5}	n/a	0.03	8.6×10^{-7}	n/a	136	3.9×10^{-3}	n/a
1,3-D + Degradates	1.15	3.17×10^{-5}	4.0×10^{-6}	0.17	4.9×10^{-6}	5.9×10^{-7}	357	1.0×10^{-2}	1.2×10^{-3}
1,2-Dichloropropane	0.22	6.3×10^{-6}	2.3×10^{-7}	0.06	1.7×10^{-6}	6.3×10^{-8}	1.69	4.8×10^{-5}	1.8×10^{-6}

*Cancer risk estimates were calculated using the following equation:
Cancer risk = (drinking water exposure, mg/kg/day) X Q_1* (mg/kg/day)-1
Where oral Q_1 * = 1.22×10^{-1} (mg/kg/day)$^{-1}$ for 1,3-D and 3.69×10^{-2} (mg/kg/day)$^{-1}$ for 1,2-D

c. Dietary Risk Characterization

The dietary risk assessment is based solely on exposures through levels in ground water; no exposure is expected from foods planted in 1,3-D-treated soils and there is insufficient data to quantify whether surface water could contribute to dietary risk. Based on the results of the prospective ground water studies in Florida and Wisconsin, the Agency believes that 1,3-D, its degradates, and 1,2-D can migrate to ground water under certain conditions. 1,3-D levels can persist in colder areas and levels of the degradates persist even in warmer areas. In estimating cancer risks, the Agency is making the assumption that Telone and its degradates' concentrations are of equal toxicity (and carcinogenicity).

The results of the prospective ground water study in Wisconsin confirmed EPA's hypothesis that 1,3-D could pose unreasonable risks under certain conditions where temperatures are low. The Wisconsin site was chosen based on its higher-end vulnerability characteristics (ground water less than 20 feet from the surface, porous soils and very cold climate). Levels of 1,3-D plus its degradates in wells located within the field were associated with lifetime cancer risk estimates of 1×10^{-3} and levels in the off-site well were elevated even after a year. Given this high estimate, EPA has determined that nothing short of a prohibition will protect areas similar to the Wisconsin site. As of October 1, 1999, all 1,3-D labels will bear prohibitions in certain northern tier states where ground water is less than 50 feet from the surface and where soils are porous (Hydrological Type A). Dow AgroSciences has committed to develop tap water monitoring in Michigan and Connecticut, which are cold areas, but with vulnerability characteristics that are less extreme than those at the Wisconsin site.

EPA believes that areas of Florida are also vulnerable to ground water contamination from 1,3-D use. Based on the prospective ground water study conducted in Florida, EPA believes that residents who tap wells into shallow aquifers in the vicinity of treated fields are most at risk. The study results show that on-site wells with levels of 1,3-D and its degradates were associated with risk estimates of 4×10^{-6} to 3×10^{-5} in shallow wells. The off-site well was located approximately 100 feet from the treated fields and showed levels considerably less than those found in the on-site wells (1.15 ppb onsite compared to 0.074 ppb off-site). To confirm the results of the prospective ground water monitoring studies, Dow AgroSciences has committed to conducting tap water monitoring in two distinct agricultural areas in Florida: northern Florida and in the Biscayne Aquifer (Dade and Broward counties) once use expands to that area.

EPA also looked at other sources of ground water monitoring to determine whether additional prospective ground water monitoring studies should be required. Based on the EPA Pesticides in Ground Water database and the USGS NAWQA study, EPA believes that 1,3-D does not present risk of widespread ground water contamination. Rather, the data base on ground water monitoring supports developing label restrictions to prevent localized contamination. Dow AgroSciences is conducting additional tap water monitoring in the Pacific Northwest, the Southeast, Nebraska and Florida to support 1,3-D registrations under labeling as specified in this document.

Based on 1,3-D's chemical properties and pattern of use (i.e. soil injected), exposure from surface water is not expected to be significant. However, various models, as well as the results of the Florida study showing detectable levels in nearby ditches, support the need for a run-off study. Dow AgroSciences is also conducting other data on the environmental fate and ecotoxicity of the degradates, together with the run-off study to confirm that surface water residues are not a concern, or to provide data that allows EPA to characterize and address any potential concerns.

The Agency notes that the models used to estimate surface water levels are not suitable for tracking volatile soil fumigants through the environment; thus, EPA views the model results as highly uncertain. See sections III.E. 1. and 2. for more details on these models and the water-related studies assessing 1,3-D levels in the environment.

d. Occupational and Residential/Bystander Inhalation Risk Characterization

Estimates of intermediate-term systemic risks and excess individual lifetime cancer risk for custom operators, growers, and area residents/bystanders are given in Tables 11, 12, and 13.

(i) Risks from Intermediate Term Inhalation Exposure

For intermediate-term worker MOE's, the 4-hour samples were used to calculate mean air concentrations over all pooled replicates. Tables 11 and 12 present commercial "for-hire" handlers and private handler (grower) exposure and risk estimates, respectively, derived using these values.

Table 11 presents the exposure and risk estimates for commercial handlers who handle 1,3-D, based upon the air concentration values listed in Table 7. Intermediate-term MOE's for commercial handlers were calculated as the ratio of the intermediate-term inhalation NOEL to the mean air concentration (adjusted by a 90 percent protection factor for wearing a respirator).

(ii) Cancer Risks from Lifetime Inhalation Exposure

Cancer risks for commercial "for-hire" handlers were calculated by first estimating average daily doses (ADD's) in mg/kg/day, from the air concentrations. Information on days per year and hours per day were obtained for each crop, state by state, from Dow AgroSciences' Use and Usage Summary Report. However, for loaders, the report lists only the total hours per day spent actually engaged in loading (0.5 to 1.25 hour/day), not total hours spent on site. Therefore, to estimate their ADD's, the Agency therefore assumed loaders to be on site for the same number of hours per day as the applicators (5 to 10 hour/day, depending on state and crop).

Table 12 presents exposure and risk estimates for growers who handle 1,3-D, based upon the air concentration values listed in Table 7. For growers, the Agency assumed that the same person conducts both loading and application of 1,3-D products. Since growers presumably spend most of their work day engaged in application, rather than loading, intermediate-term risks

(MOE's) for growers were estimated using the air concentration for application rather than loading.

Cancer risks for growers assumed that the majority of the work day is spent applying 1,3-D and only as much time as is required to load the tank is spent actually engaged in loading. Therefore, the 4-hour samples were used in the calculation of the portion of the exposure resulting from application, and the task-specific samples were used to calculate the exposure incurred while loading (because 4-hour samples were not collected for the mini-bulk study, the Agency assumed that the task-specific loader air concentrations are experienced for the duration of a work cycle). The loading and application exposures were then added to estimate the total exposure for these individuals.

Cancer risk estimates were calculated using the following formula:

Excess cancer risk = Q_1^* X LADE

where $Q_1^* = 5.3 \times 10^{-2}$ (mg/kg/day)$^{-1}$

and LADE = $\frac{\text{exposure (mg/kg/yr)}}{\text{365 days/year}} \times \frac{\text{20 (custom) or 30 (grower) years}}{\text{70 years}}$

The excess individual lifetime cancer risk estimates for occupational exposure range from 7.0×10^{-6} to 6.1×10^{-5} for custom handlers and 5.1×10^{-6} to 3.0×10^{-5} for private growers. These values may be overestimates because they do not reflect certain mitigation measures which are expected to reduce risk, but can not be quantified. Generally, the Agency considers risks of 10^{-6} or lower not to be of concern and carefully examines risks in the range of 10^{-4} to 10^{-6} to seek ways of reducing risks prior to reregistration (Barolo, 1996). Risks that fall closer to 10^{-4} where no additional mitigation is available are judged against the benefits of the pesticide's use. For 1,3-D, worker risks have been mitigated to extent feasible and are considered to be overestimates given that some label measures' mitigation value cannot be quantified and included in the risk estimate. In addition, the Agency considers the benefits of 1,3-D use to be high. Based on EPA's policy, the cancer risks of 1,3-D use for workers under current labels are considered to be acceptable.

Table 11. 1,3-D Custom Handler Intermediate-Term and Cancer Risks										
			Conc.			Doses (mg/kg/day)[a]			Cancer	Int.-Term
Delivery Method	Example Crop	Task	µg/m³	hr/d	d/yr	ADD	AADD	LADD	Risk	MOE[a]
Bulk	Cotton, AZ	Loader	1631	10	36	0	4.0e-03	1.1e-03	6.1×10^{-5}	560
		Applicator	1359	10	20	3.4e-02	1.9e-03	5.3e-04	2.8×10^{-5}	670
Bulk	Potatoes, WA	Loader	1631	8	24	3.2e-02	2.1e-03	6.1e-04	3.2×10^{-5}	560
		Applicator	1359	8	24	2.7e-02	1.8e-03	5.1e-04	2.7×10^{-5}	670
Mini-bulk	Tobacco, NC	Loader	464	5	10	5.8e-03	1.6e-04	4.5e-05	2.4×10^{-6}	1960
		Applicator	1359	5	10	1.7e-02	4.6e-04	1.3e-04	7.0×10^{-6}	670

a Adjusted for wearing of respirator or use of enclosed tractor cab (PF= 0.1)

Table 12. 1,3-D Grower Intermediate-Term and Cancer Risks											
		Loading		Application:							
		Conc.		Conc.			Doses (mg/kg/day)[a]			Cancer	Int.-Term
Delivery Method	Example Crop	µg/m³	hr/d	µg/m³	hr/d	d/yr	ADD	AADD	LADD	Risk	MOE[a]
Bulk	Cucurbits, TX	10833	0.25	1,359	6	05	2.7e-02	1.1e-03	6.3e-04	3.4×10^{-5}	670
Bulk	Pineapples, HI	10833	1.45	1359	6	11	5.4e-02	1.6e-03	9.3e-04	5.0×10^{-5}	670
Mini-bulk	Tobacco, NC	464	0.5	1359	5	3.5	1.7e-02	-2	-10	5.1×10^{-6}	670
Mini-bulk	Peanuts, GA	464	1	1359	3	5	1.1e-02	1.5e-04	8.8e-05	4.7×10^{-6}	670

a Adjusted for wearing of respirator or use of enclosed tractor cab (PF= 0.1)

Table 13 presents exposure estimates for residents who live near treated fields.

Table 13. Residential/Bystander Exposure

Distance from treated field (m)	Study Site(s)	Doses (mg/kg/day)		Cancer Risk	Int.-Term MOE
		ADD	LADD		
1600	AZ	7.6 e-07	-3	$1.7x\ 10^{-8}$	2800
1200	AZ	2.9e-05	-1	$6.6x\ 10^{-7}$	1600
800	overall	5.7e-05	-2	$1.3x\ 10^{-6}$	8500
500	overall	7.7e-05	-3	$1.8x\ 10^{-6}$	6100
125	overall	2.6e-04	-1	$5.9x\ 10^{-6}$	1700
25	overall	4.8e-04	-2	$1.1x\ 10^{-5}$	920
5	overall	5.1e-04	-2	$1.2x\ 10^{-5}$	870
onsite	overall	8.3e-04	-4	$1.9x\ 10^{-5}$	500

Shading denotes edge of buffer zone required 300 ft from an occupied structure.

A buffer zone of 300 feet (approximately 125 meters) is required between all occupied structures and any field where 1,3-D is used to mitigate cancer risks to area residents whose homes are adjacent to treated fields.

The resident/bystander cancer risks may represent overestimates because individuals are not likely to spend 16 hours/day at a fixed distance for 30 years. Most people in regions where 1,3-D is used are not part of this subpopulation (i.e. do not live at the edge of a buffer zone), and are therefore presumed to be at somewhat lower risk. Also, the population of area residents living at the edge of the buffer zone is expected to be small, according to limited 1992 population survey data from Dow AgroSciences (Mehta 1994c). The population survey of states comprising 95 percent of 1,3-D usage showed that there were approximately 1088 residences in the 17 states where 1,3-D is used within one mile of 1,3-D treated fields (Mehta 1994c). There are no data on the number of people actually residing within 300 feet of treated fields.

Other risk-mitigation measures, including reduced application rates, increased injection depth, mandatory soil sealing, and soil moisture requirements may also reduce exposure to residents and bystanders, although the magnitude of this reduction cannot be quantified and therefore cancer risk estimates are likely to be overstated.

(iii) Aggregate Exposure and Cumulative Risk

EPA has aggregated inhalation and oral exposures to 1,3-D. For 1,3-D, the aggregate risk estimate would be calculated as follows:

cancer risk $_{\text{inhalation exposure}}$ + cancer risk $_{\text{water exposure}}$ = aggregate lifetime cancer risk

In calculating aggregate risk, EPA has determined that a reasonable worst-case exposure scenario would be comprised of the inhalation risk at the 300 foot buffer, derived from the average of three air monitoring studies, and water exposure risk from the on-site concentrations from the Florida study. EPA did not use the Wisconsin study values because as of August 1, 1999, use in areas similar to this site will be prohibited. Thus the aggregate risk would be:

6×10^{-6} $_{\text{inhalation exposure}}$ + 4×10^{-6} $_{\text{water exposure}}$ = 1×10^{-5}

This aggregate cancer risk estimate, however, is based on assessments which contain numerous uncertainties from both the inhalation and water routes of exposure. Those uncertainties are detailed in section e. below.

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 consider "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, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA 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 for 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 common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether 1,3-D has a common mechanism of toxicity with 1,2-D or other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this reregistration decision, EPA has assumed that 1,3-D and 1,2-D do not have a common mechanism of toxicity.

e. Uncertainties in the Risk Assessment and Risk Characterization Summary for 1,3-D

The Agency estimated cancer risk to growers, custom loaders/applicators, and residents/bystanders exposed to 1,3-D. Exposures via the dermal route were assumed to be negligible due to 1,3-D's high volatility and PPE requirements. Inhalation data were available and deemed appropriate for quantitative risk assessment, and thus, route to route extrapolation was not necessary for risk assessment. Oral and inhalation exposures were aggregated to develop risk estimates for residents/bystanders.

There are numerous uncertainties associated with the studies used to develop exposure estimates. Although the air monitoring studies were designed to evaluate exposures under normal use conditions, the influence of local environmental conditions, such as wind, soil type and weather patterns coupled with 1,3-D's volatility, resulted in mixed results. Results varied widely not only between sites, but also within sites on a day-by-day basis. The inhalation exposure estimates provided in this assessment are derived from a limited number of monitoring studies per site, which further increases the uncertainty.

Where possible, the Agency has incorporated label mitigation measures into the risk assessment. However, not all mitigation measures can be quantified. For example, the following mitigation measures are likely to further reduce worker and residential exposures to 1,3-D and associated cancer risk: reduced maximum application rates by 30-65% depending on the crop, increased soil injection depth from 10" to 12", soil sealing, and shank placement. The actual impact of these specific mitigation measures on reducing risk cannot be quantified with the available data.

Some air monitoring data need to be considered carefully, since the results did not show a reduction in exposure levels with certain mitigation measures, including use of enclosed cabs and dry disconnects, measures which are known to reduce exposures. The monitoring data did not show enclosed cabs to provide any reduction in exposure, possibly because applicators frequently left the enclosed cab to perform various tasks during the application process. Therefore, the 1,3-D labels were modified to require a respirator if the worker leaves the enclosed cab during application for any reason.

Dry disconnects, which are couplers designed to prevent leaks and emissions during fumigant transfers, appear to offer some exposure mitigation. Exposure reduction with dry disconnects could be quantified with the short-term sampling data but not with the 4-hour sampling data. The 4-hour sampling data suggest an increase in exposure with the use of dry disconnects, which is counter-intuitive. The reasons are likely due to a low number of sampling replicates and inherent variability in the study conditions.

There are uncertainties regarding practices of commercial operators. Exposure and risk estimates provided assume that commercial operators treat only one crop. Risk may be underestimated for commercial operators treating specialty crops in the Pacific Northwest. However, the Agency also believes that custom operators are in a better position to train personnel and maintain and update equipment, which results in better control over exposures to 1,3-D.

Some use practices have changed since the early studies were conducted, as have the laws governing agriculture. Just as local environmental conditions affect 1,3-D volatilization, individual growers' decisions on application rate, application method, injection depth, and soil sealing measures vary. For example, some growers use different application rates from year to year depending on the level of nematode infestation. Actual land use is unpredictable, and is ultimately driven by weather conditions, pests, and market pressures. Therefore, the inhalation exposure estimates and assumptions used represent a simplification of real-world exposures.

The residential risk assessment is based on an average for the three sites monitored (N.C., WA, AZ), though 1,3-D air levels were quite different among the three sites. In addition, the monitoring at the N.C. site was conducted using drum loading, which was the predominant use at the time of the study, but which has since been phased out in favor of mini-bulk containers. Air levels with drum loading are expected to be higher than the mini-bulk containers since closed loading and dry disconnects (to prevent release of vapors) were not used with drums and since loading 1,3-D into the tractor-drawn tank was more frequent because the 55-gallon drums were smaller than the 1000 gallon mini-bulk. A mini-bulk study was submitted in 1996, but was only designed to measure worker exposures. Although higher levels were seen at the AZ and WA sites, EPA expects that the levels from the N.C. site, and thus the average overall, would have been lower had the mini-bulk system been used in the off-site monitoring.

For the water exposure component of the aggregate risk estimate, levels monitored from on-site wells were used in the assessment. As of August 1, 1999, however, there will be a 100 foot no-treatment buffer between treated fields and drinking water wells. The prospective ground water monitoring studies included limited off-site monitoring, which showed decreasing levels with increasing distance from 1,3-D treated fields. However, studies with more sampling and a study design to look specifically at levels in off-site wells would have to be conducted in order to quantify any relationship between distance to treated field and levels in wells used for drinking water.

Despite the limitations discussed in this section, EPA believes that the air and ground water monitoring are suitable for risk assessment. The studies were specifically designed to assess exposures to 1,3-D, taking into account the unique chemical qualities of 1,3-D, as well as the specialized 1,3-D loading and application techniques. However, the influence of a variety of environmental factors, particularly in the air monitoring studies, confounded many results. Even if additional data were required to address some of the shortcomings discussed above, EPA believes it would be unlikely that the additional effort would significantly improve the assessment given that confounding factors, such as wind and precipitation, could not be controlled under actual field test conditions.

E. Environmental Assessment

1. Environmental Fate and Transport

1,3-D dissipates primarily through volatilization, leaching, abiotic hydrolysis, and aerobic soil metabolism. Field volatility studies have shown that approximately 25 percent of the applied 1,3-D volatilizes during the two weeks after an application. Hydrolysis is temperature dependent and there is an increase in stability at lower temperatures. At 2°C, for both pH 5.5 and 7.5, the half-life of the parent was 90 to 100 days. Under aerobic conditions, half-lives ranging from 12 to 54 days were reported for the parent. The 3-chloroallyl alcohol is expected to be the main hydrolytic degradation product and 3-chloroacrylic acid the major aerobic metabolite. Laboratory mobility data, in addition to ground-water monitoring information, has clearly demonstrated that 1,3-D is highly mobile in soil. The Freundlich adsorption coefficients for 1,3-D were: K_d= 0.23 in loamy sand, K_d= 0.32 in sand; and in clay, K_d= 0.42 and 1.09.

a. Environmental Fate Assessment of 1,2-D

The formulated 1,3-D product contains from 0.1 to 0.06 percent 1,2-D. 1,2-D has a vapor pressure of 42 mm Hg at 20°C, has a water solubility of 2700 ppm at 20°C, is fairly stable to hydrolysis with a half-life of 77 days at pH 5.5, and has variable aerobic soil half-lives (41 to 69 days on four soils but stable in a sandy loam and a loam). With 1,2-D, photoreactions are also minimal with a half-life of 313 days with respect to the (OH) radical and stable with respect to ozone. Mobility studies give a strong indication of the extreme mobility of 1,2-D. Freundlich adsorption coefficients for 1,2-D were K_d=0.12, K_d=0.16, K_d=0.05, K_d=0.87 for the Fuquay loamy sand, Metz sandy loam, Hanford loam, and the Wahiawa sandy clay loam soils, respectively. In column leaching experiments using a Fuquay loamy sand with 0.64% organic carbon, a total of 85.8% of the applied 1,2-D leached from the soil column. For the Wahiawa sandy clay loam column with 2.32% organic carbon, a total of 73.2% of the applied was found in the leachate. Thus, mobility was somewhat inversely proportional to organic matter content.

b. Degradation

Hydrolysis. In buffered solutions at pH values of 5, 7, 9, the half-life of 1,3-D was 13.5 days at 20°C. A supplemental study at pH's 5.5 and 7.5 showed that the half-life of 1,3-D was 90

to 100 days at 2°C; 11 to 13 days at 15°C; and 2 days at 29°C. The chloroallyl alcohol is expected to be the main hydrolytic product (MRID 00158442).

Another supplemental study gave these results: at pH values of 5, 7, and 9, the half-life of 1,2-D was 51 days at 10°C; 10 to 13 days at 20°C; and 3 to 5 days at 30°C. The chloroallyl alcohol reached maximum concentrations of 32%, 72%, and 78% at 10°, 20°, and 30°C, respectively, and appeared to be stable to further hydrolysis. Hydrolysis of 1,3-D is pH independent and temperature dependent (MRID 00117050).

Photodegradation in Air. Both cis and trans 1,3-D (purity ≥ 94.8%) at 0.035 to 0.050 μg/ml did not degrade in borosilicate glass vials irradiated continuously for 30 days with a xenon arc lamp at 25°C and ambient humidity. After 30 days of irradiation, 95% to 98% of the applied radioactivity was recovered, as 1,3-D and no degradates were detected. In the dark control at 30 days post-treatment, 86% to 92% of the applied was recovered as 1,3-D and no degradates were observed. The study indicates that under these conditions, direct photolysis in air is not an important degradative mode for 1,3-D (MRID 40390101).

Reactions of 1,3-D and 1,2-D with ozone (O_3) and OH radicals were studied. The half-lives of 1,3-D with respect to the OH radical were seven and 12 hours for the trans and cis isomers, respectively. The observed degradation products were formyl chloride and chloroacetaldehyde. The half-lives of the trans and cis isomers of 1,3-D with respect to ozone were 12 and 52 days, respectively. The observed products were formyl chloride and chloroacetaldehyde, chloroacetic acid, HCl, CO, CO_2, and formic acid. The rate of photolysis alone seems insignificant (as was shown in the above 161-4 experiment) relative to the reactions of 1,3-D with ozone and the OH radicals. For 1,2-D the experiments also indicated that the only significant loss in the atmosphere would be a reaction with the OH radical. The half-life with respect to the OH radical was 313 days. A half-life of 313 days for 1,2-D would indicate the compound is sufficiently stable for worldwide long-distance transport (Tuazon, 1984).

Aerobic Soil Metabolism. The reported half-lives were 12 days in Catlin silt loam soil and 54 days in Fuquay loamy sand soil. These major nonvolatile degradates were isolated from the soils: cis/trans-3-chloroprop-2-en-1-ol (3-chloroallyl alcohol) and cis/trans-3-chloroprop-2-enoic acid (3-chloroacrylic acid). Numerous naturally-occurring carboxylic acids were also identified as degradates (MRID 42642301).

Anaerobic Soil Metabolism. In a silty clay loam soil at 15°C, the half-life of 1,3-D was reported to be 9.1 days. In a sandy loam soil at 15°C, the half-life was 7.7 days. In both a silty clay loam and sandy loam soil, at 25°C, the half-life was 2.4 days. The observed degradates were chloroacrylic acid, propionic acid, and an unknown (MRID 40025901)

c. Mobility

Column Leaching. The calculated Freundlich adsorption coefficients for 1,3-D were: loamy sand K_d= 0.23; sand K_d= 0.32; clay K_d= 0.42 and 1.09. The average maximum K_{oc} values

were 20 for sand, 25 for loamy sand, and 41 and 42 for two clay soils. In 30-cm columns of sand, loamy sand, and Florida clay, 1-3-D leached when more than 25 inches of water were applied. A total of 1.9% to 4.6% of the applied (unaged) radioactivity remained in the soils and 70% to 84% was found in the leachate (MRID 40538901).

Aged Column Leaching. Aged (31 days) 1,3-D residues were very mobile, with 25.6% to 32.0% of the applied radioactivity in the leachates of 30-cm columns of loamy sand soil. 1,3-D and the degradates 3-chloroallyl alcohol, chloroacrylic acid, and composite carboxylic acids (including acetic acid, oxalic acid, and propionic acid) were detected in both the leachates and the upper 2-cm soil segment extracts.

Batch Equilibrium (1,2-D). Freundlich adsorption coefficients for 1,2-D were 0.12 (n=1.13), 0.16 (n=1.13), 0.05 (n=1.63), and 0.87 (n=1.07), with corresponding K_{oc}'s of 18.8, 23.5, 10.4, 37.5 for the Fuquay loamy sand, Metz sandy loam, Hanford loam, and the Wahiawa sandy clay loam, respectively. The Freundlich desorption coefficients were 1.54 (n=0.99), 0.93 (n=1.22), 0.45 (n=1.52), and 3.45 (n=1.13), with corresponding Koc's of 241, 137, 93.8 and 149 for the Fuquay loamy sand, Metz sandy loam, Hanford loam, and Wahiawa sandy clay loam (MRID 42868501).

Column Leaching (1,2-D). The column leaching experiments indicated that for the Fuquay loamy sand, a total of 85.8% of the applied 1,2-D leached from the soil column. 1,2-D was distributed evenly throughout the column. For the Wahiawa sandy clay loam column, a total of 73.2% of the applied was found in the leachate. 1,2-D was not evenly distributed throughout the column and concentrations were highest near the final soil segment. Sorption coefficients estimated from the column leaching studies were 0.09 and 0.43 for the Fuquay and Wahiawa soils with corresponding Koc's of 14.1 and 18.5 (MRID 42868501).

Field Volatility. The factors influencing the volatility of 1,3-D from a field plot include, but are not limited to, soil organic matter, wind speed, soil moisture content, depth of incorporation-injection, soil temperature and soil porosity. Approximately 25 percent of the applied 1,3-D had volatilized by 14 days post-treatment (the final sampling interval). The volatilization of 1,3-D increased to 35.1 mg/m^2·hour by 3 days post-treatment using the aerodynamic flux method with 33- and 90-cm sampling levels at the plot center. Volatilization ranged from 8.13 to 22.3 mg/m^2·hour at 4-6 days, 4.6 to 17.5 mg/m^2·hour at 7-9 days, 3.31 to 7.78 mg/m^2·hour at 10-12 days, and 1.28 to 4.93 mg/m^2·hour at 12-14 days (MRID 42545101).

1,3-D was soil injected at 12-14 inches at 346 lb. a.i. per acre into fields of sandy loam, loamy sand, and muck soils. At six to 12 hours post-treatment, 1,3-D reached a maximum concentration of 0.09 to 4.4 ppm at the 0.5-foot height above the soil surface. 1,3-D concentrations decreased to $\leq$ 0.03 ppm in all air samples from all locations by seven days post-treatment. It was not detected above the loamy sand and sandy loam soils by 14 days or above the muck soil by 21 days. Volatilization rates appeared to be inversely proportional to the amount of soil organic matter and proportional to soil porosity (MRID 41057701).

Telone II was applied at approximately 12.8 gallons per acre (121 lbs a.i./acre) to a fallow plot in Nevada and monitored over 7 days for airborne concentrations directly above the field and at locations up to one-half mile away (no MRID, EFGWB #91-0910). The average value of 1,3-D at a 6-inch height above the field during 7 days was 465.31 $\mu g/m^3$; at a 5-foot height at the edge of the field it was 94.81 $\mu g/m^3$; at a 5-foot height 100 feet from the field it was 39.39 $\mu g/m^3$; at a 5-foot height 1/4 mile from the field it was 5.17 $\mu g/m^3$; and at a 5-foot height one-half mile from the field it was 3.88 $\mu g/m^3$. Wind was a major factor in the dispersion of 1,3-D as higher concentrations were measured at night. During the day, the increase in wind velocity also increased vapor dispersion and lowered the measurable amount of material (Houtman et al., 1991).

In general, it is difficult to correlate soil moisture content with volatilization but Glotfelty and Schomberg (1989) and Lyman et al. (1982) suggest that the extreme drying of soil during drought will greatly decrease volatilization. Addition of moisture to dry soils will generally increase volatilization rates to a point beyond which additional moisture may have little effect or may start to decrease volatilization. The effect of changes in soil moisture on the volatilization of organics from soils with intermediate moisture contents is difficult to predict and depends upon the chemical, soil type, and the initial soil moisture content. In general, soil chisel incorporation of 1,3-D is accompanied by capping off the soil injection cores and/or by covering the field with plastic to minimize volatilization. Deeper injection minimizes the total amount of material that volatilizes and maximizes the amount of time from injection until volatiles are observed at the soil/air interface because of the increased soil distance through which the pesticide must diffuse.

d. Field Dissipation

Terrestrial Field Dissipation. Cis and trans 1,3-D applied at 345 lb a.i./A dissipated with an observed initial half-life of approximately one day and a second half-life of approximately seven days in the surface 24-inches of a bare-ground loamy sand soil (MRID 40855501).

1,3-D was applied at 342 lb a.i./A to a sand soil field plot in California. 1,3-D residues declined from a maximum of 130,000 ppb in the 0.3- to 0.45-meter layer of soil immediately after treatment to less than 10 ppb (detection limit) in any soil layer at 71 days. The degradate 3-chloroallyl alcohol declined from a maximum of 410 ppb in the 0.66 to 0.81 meter layer of soil at seven days posttreatment to less than 10 ppb in any soil layer at 71 days (MRID 40403301); additional data 3/24/89). The half-life is approximately seven days assuming a linear dissipation rate.

2. Water Resources

a. Ground Water

High-quality data indicate that 1,3-D leaches to ground water as a result of normal agricultural use. The 1986 Registration Standard and Special Review position document both

noted that the Agency has concerns for the potential for ground water contamination based on limited ground water monitoring data and laboratory data on the mobility of 1,3-D.

(i) Occurrence of 1,3-D in Ground Water

Monitoring information collected since 1983 indicates that 1,3-D has been detected in ground water in seven states in different regions of the U.S. with detected levels up to 800 ppb. Note from the previous section that the average daily concentration associated with a 10^{-6} lifetime risk is 0.3 ppb. 1,3-D has also been detected in ground water in The Netherlands in potato and flower bulb fields. Because an MCL has not been established for 1,3-D, no monitoring for this chemical is required under the Safe Drinking Water Act.

1,2-D has been detected in ground water in California, Connecticut, Florida, Hawaii, Massachusetts, Maryland, Nebraska, New York, Oregon, Washington, and Wisconsin. The MCL for 1,2-D is 5 ppb. Dow AgroSciences's information indicates an estimated HAL of 1.2 ppb. This section describes the data base used by EPA in developing its human health and environmental risk assessment for 1,3-D

(ii) Small-Scale Retrospective Monitoring

In 1986, the Agency requested that the registrant evaluate the impact of 1,3-D on ground water in varied environments with different use patterns. From 1989 to 1992, Dow AgroSciences conducted retrospective ground-water monitoring studies at Grant County, Washington; Merced County, California; Monterey County, California; Wayne County, North Carolina; and Scotts Bluff County, Nebraska. A sixth study in Florida was terminated when a nearby sinkhole collapsed and interfered with monitoring. Although there were significant problems with the study designs and sampling, results indicated that 1,3-D can leach to ground water.

Nebraska. 1,3-D concentrations in ground water ranged from 0.23 ppb to 3.86 ppb using a detection limit of 0.05 ppb. In this sugar beet study, maximum residues were seen in ground water eight months after application. The cis isomer was detected fourteen months after the 1,3-D application.

Washington. In the Washington potato study, the cis isomer of 1,3-D was detected at 0.03 ppb in two ground-water samples from two of the 50-foot wells on the site approximately one month after application.

North Carolina and California. No residues of 1,2-D; 1,3-D or its degradates were detected in ground water in the North Carolina tobacco study, the Merced County, California sweet potato study or the Monterey County, California carrot study.

(iii) State Ground-Water Monitoring Studies

The Pesticides in Ground Water Database (EPA, 1992) indicates detections of 1,3-D in three states -- Florida, New York, and Washington -- because of normal field use. The database also reports detections of 1,3-D in California because of point source problems (i.e., misuse or a spill). Additional monitoring in Hawaii, Massachusetts, Mississippi, and Oregon has not yielded any detections of 1,3-D.

California. In 1987, 1988, and 1991, 1,3-D was detected in six wells in Del Norte, Fresno, and Santa Clara counties. Using a method detection limit of 0.5 ppb, concentrations ranged from 0.89 to 1.9 ppb. No information is available about the source of the detections. 1,3-D was not detected in 9,915 wells sampled from May 1979 to June 1996 using detection limits ranging from 0.02 to 100 ppb (Bartkowiak, 1997).

In Riverside, California, illegal use of 1,3-D in 1986 and 1987 resulted in six detections in one irrigation well ranging from 6.8 to 31 ppb (EPA, 1992).

Florida. From 1987 to 1996, a total of 9,505 wells were monitored for 1,3-D residues. The present detection limit is 0.0850 ppb, but has varied in the past (Fisher, 1997). Although 1,3-D was detected in three wells at concentrations ranging from 0.28 to 8 ppb, these are probably most likely 1,2-D detections (Riotte, 1997).

Hawaii. The Hawaii Department of Health monitors for 1,3-D in ground water because of its use as a soil fumigant in the pineapple industry. From 1979 to 1987, samples were analyzed from 54 wells and no residues were found (Giambelluca, 1988).

Massachusetts. In the summer and fall of 1985, several Massachusetts agencies analyzed samples from 239 wells in tobacco-growing areas. Using a detection limit of 1.0 ppb, no 1,3-D was found. No samples were analyzed for degradates (Massachusetts Interagency Task Force, 1986).

Mississippi. In Mississippi, a statewide drinking-water ambient monitoring survey was designed to sample for pesticides. 1,3-D is not widely used in Mississippi (Landreth, 1997), and the reported monitoring may not have been conducted in areas where 1,3-D has been used. To date, 348 deep wells have been sampled and analyzed for cis and trans 1,3-D. No residues have been detected using a detection limit of 0.10 ppb for the parent.

New York. Although monitoring for 1,3-D is not usually done by the State, several studies have been done by researchers to determine the leaching potential of 1,3-D in Suffolk County, New York. In one of the studies done in 1983, 1,3-D was detected in ground water at concentrations ranging from 37 to 270 ppb in one well over a period of three months. The detection limit used in this study was 2 ppb (Loria et al., 1986). In another study, no 1,3-D was detected in nine wells located near fields where 1,3-D was applied. The detection limit used here was also two ppb (Kotcon and Loria, 1987).

Oregon. In Oregon, a standard analytical screen that includes 1,3-D is performed for every well that is sampled. Many of these wells are not in agricultural areas or 1,3-D use areas. Some 1,3-D has been found using a detection limit of 0.5 ppb. However, problems with data retrieval make it impossible to determine how much or how many times 1,3-D has been detected (McLaughlin, 1997).

Washington. From 1990 through 1996, the Washington State Department of Ecology analyzed 196 wells for cis and trans 1,3-D. The trans isomer was found on April 30, 1991 in three wells at concentrations of 0.10, 0.11, and 0.11 ppb. The same three wells were re-sampled in February 1992 (10 months later) and no 1,3-D was detected (Larsen, 1997).

(iv) Small-Scale Prospective Monitoring

Wisconsin. The Agency required that Dow AgroSciences conduct a small-scale prospective ground-water monitoring study in a northern climate because of the concern for 1,3-D persistence in cold climates. Dow AgroSciences conducted site selection in Idaho, Nebraska, Wyoming, Michigan, Minnesota, North Dakota and Wisconsin. The site selection criteria required shallow ground water, porous soils, minimal slope, no impeding layer (such as a clay barrier) between the treatment zone and ground water, no prior usage of 1,3-D and no concurrent usage of 1,3-D in the vicinity of the test site. Potato-growing areas in these states were targeted since potatoes are a major use site for 1,3-D use. The site in Wisconsin met all of EPA and Dow AgroScience's selection criteria and was thus selected to represent a vulnerable site in a northern use area.

On September 9, 1997, Telone II was applied to a sugar beet field at 28 gallons per acre (266 lb ai/acre). Levels peaked at 579 ppb in on-site wells after one year of monitoring. In the off-site well located 65 feet down gradient, 1,3-D levels peaked at 173 ppb.

1,2-D was detected in all eight of the onsite shallow wells and four of the onsite deep wells at concentrations ranging from trace levels to 3.9 ppb using a quantitation limit of 0.05 ppb.

Dow AgroSciences also submitted, though with insufficient information to allow formal EPA review, results to predict 1,3-D levels at further distances off-site. Using the program ModFlow, which looked at concentrations of 1,3-D only, downgradient concentrations reached 0.3 ppb at 1100 feet after 2.5 years. The same model predicts a time-weighted concentration at 100 feet downgradient of 8.4 ppb after the first year and 13.4 ppb after the second year. Given the levels and trends seen in the modeling and monitoring, EPA does not believe that the 100 feet buffer alone would provide sufficient mitigation for human health risks.

Florida. In 1993, Dow AgroSciences initiated a small-scale prospective monitoring study in southern Florida. Because of concerns for potential ground-water contamination, EPA and the State of Florida became involved in the study design and review. On December 13, 1995, Telone C-17 was applied to a pepper field at approximately 22.5 gallons per acre. Study results showed

detections of 1,3-D, 1,2-D and both the 3-chloroacrylic acid and 3-chloroallyl alcohol degradates in ground water.

Most Floridian soils are porous with shallow water tables. While most residents of the state obtain water from public systems which tap aquifers that are not surficial, there are areas where 20% or more of the residents obtain water from private wells that tap surficial aquifers (in some counties up to 80%). Some areas have a spodic horizon between the surficial and deeper aquifers, while other areas overlay karst geology (highly permeable, rocky soils). Note that as of August 1, 1999, the 1,3-D labels prohibit use in areas of karst geology. In order to support agriculture in certain areas of Florida, perimeter ditches are used to either raise the availability of water serving the field, or to divert excess rainfall. There can be extensive interaction between these ditches, surface water and surficial ground water aquifers. Because of the warmer temperatures, EPA expected the rate of degradation to be relatively higher than in areas with lower temperatures.

In the uppermost part of the aquifer (one to two foot wells which were not used in the drinking water assessment) 1,3-D was detected in all eight of the onsite wells. Detections peaked at 833 ppb and declined to 0.19 ppb by 110 days after application. These wells also contained 3-chloroallyl alcohol at concentrations ranging from trace levels to 360 ppb and 3-chloroacrylic acid at concentrations ranging from trace levels to 424 ppb. 1,2-D was detected at concentrations ranging from trace levels to 11.5 ppb. Five offsite wells also contained 1,3-D residues at concentrations ranging from trace levels to 0.23 ppb.

At a depth of 10 feet from the surface, 1,3-D was detected in all eight of the onsite wells. Concentrations ranged from trace levels (0.05 ppb) to 21.6 ppb. These wells also contained 3-chloroallyl alcohol at concentrations ranging from trace levels to 13.5 ppb and 3-chloroacrylic acid at concentrations ranging from trace levels to 8.79 ppb. 1,2-D was detected at concentrations ranging from trace levels to 1.28 ppb.

Early in the study, 1,3-D was briefly detected in the deep part of the aquifer (70 feet), however, the concurrent water blanks from the bailers used to sample the deep wells contained similar 1,3-D concentrations. Also, the bromide tracer did not reach these deep wells during the study, suggesting these detections were the result of inadvertent sample contamination. However, the information submitted is as follows: 1,3-D was detected in two of the three onsite wells in the Lower Tamiami Aquifer with concentrations ranging from 0.05 to 1.03 ppb. These wells also contained 3-chloroallyl alcohol at concentrations ranging from trace levels to 7.85 ppb and chloroacrylic acid at trace concentrations. 1,2-D was detected at concentrations ranging from trace levels to 0.07 ppb. No 1,3-D residues were found in the offsite deep well; 1,2-D was detected in this well at trace levels in all but one sampling event.

(v) The National Water Quality Assessment Program

In 1991, the U.S. Geological Survey initiated the National Water Quality Assessment program (NAWQA) to study national water quality. The monitoring, which is being conducted in

four parts, will assess more than 50 of the largest river basins and aquifers (study units) and cover the drinking water sources of about 70 percent of the U.S. population.

NAWQA included 1,3-D (both isomers) and 1,2-D among the compounds tested. Areas of the country with the highest 1,3-D use are covered, at least in part, by 10 study units. None of the reports released to date have shown detections of 1,3-D in wells or other water resources. The summary reports, however, do not allow the Agency to assess whether 1,3-D use took place in the vicinity of water sampling locations and did not sample for the acid and alcohol degradates.

Nonetheless, the information in the NAWQA reports is useful. Although no information in the reports directly links 1,3-D use to the monitored wells, the absence of detections suggests that 1,3-D use does not result in widespread aquifer contamination.

b. Modeling and Occurrence of 1,3-D in Surface Water

A mixture of the cis and trans isomers of 1,3-D is typically applied at a rate of several hundred pounds per acre at a depth of approximately one foot below the soil surface. It then moves through the soil profile, with some escaping up through the treatment zone to the atmosphere. One study (MRID 42545101) showed that approximately 25 percent of applied 1,3-D volatilizes, however, environmental and soil conditions will affect the actual amount. The 1,3-D isomers undergo fairly rapid dissipation in soil via volatilization and to a lesser extent degradation. Also, only chemical molecules that have diffused into the top one to two centimeters of soil at the time a runoff event occurs would likely be susceptible to runoff. Such factors should somewhat limit the runoff potential of the 1,3-D isomers. However, extremely high application rates of several hundred pounds per acre coupled with low soil/water partitioning, indicate some potential for runoff.

In addition to runoff, another route of 1,3-D transport to surface water could be by dissolution of volatilized compound from the air. Dow AgroSciences has proposed this route to explain 1,3-D residues in perimeter ditches of a treated field in Florida (see previous discussion on the Florida prospective ground-water monitoring study) prior to any runoff events. Dow AgroSciences postulates that during conditions of low wind, volatilized 1,3-D will move close to the ground due to its higher density than air, and that some of the 1,3-D passing over surface water will be transported from the air to the water and dissolved. Another possibility is that in Florida, ground water may be contributing to residues in surface water through ground and surface water interactions. Both the 3-chloroallyl alcohol and 3-chloroacrylic acid were detected in surface water along with 1,3-D in the prospective ground-water monitoring study in Florida.

1,3-D will probably undergo rapid rates of dissipation in most surface waters due to volatilization and, to a lesser extent, by abiotic hydrolysis and possibly biodegradation. Volatilization rates will be highest for shallow turbulent water and decrease with increasing depth and decreasing turbulence. Isomer mixture soil/water partition coefficients of 0.23 in a loamy sand, 0.32 in a sand, 0.42 and 1.09 in two clay soils indicate that the concentration of 1,3-D in sediment pore water will be comparable to that adsorbed to suspended and bottom sediment.

Concentrations in the water column will be less than in the sediment pore water, but should still be somewhat comparable to concentrations adsorbed to sediment. The low octanol/water partitioning of 1,3-D indicates that its bioaccumulation potential is probably low.

c. Drinking Water Exposure Assessment

Please refer back to section III. B.3. for a full discussion of the levels used for the drinking water exposure and risk assessment.

3. Ecological Assessment

a. Toxicity to Terrestrial Animals

(i) Birds, Acute and Subacute

An acute oral (LD_{50}) study using the technical grade of the active ingredient (TGAI) were submitted to establish the toxicity of 1,3-D to birds. The result of the Northern bobwhite test is presented in Table 14.

Table 14. Avian Acute Oral Toxicity

Species	% ai	LD_{50} (mg/kg)	Toxicity Category	MRID No. Author/Year	Study Classification[1]
Northern bobwhite *(Colinus virginianus)*	92	152	moderately toxic	00118938 Wildlife International /1982	Core

[1] Core (study satisfies guideline), Supplemental (study is scientifically sound, but does not satisfy guideline)

Since the LD_{50} falls in the range of 51 to 500 mg/kg, 1,3-D is moderately toxic to avian species on an acute oral basis (MRID 00118938).

Two subacute dietary studies on the Mallard duck and Northern bobwhite using the TGAI were submitted to establish the toxicity of 1,3-D to birds. The avian acute dietary LC_{50} test is a subacute, eight-day dietary laboratory study designed to determine the dietary concentration of toxicant that is likely to cause 50 percent mortality in a test population of birds. The TGAI is administered to juvenile birds' diets for five days, followed by three days of "clean" diet. Results of these tests are presented in Table 15.

Table15 Avian Subacute Dietary Toxicity

Species	% ai	LC_{50} (ppm)	Toxicity Category	MRID No. Author/Year	Study Classification
Northern bobwhite *(Colinus virginianus)*	92	>10,000	Practically Nontoxic	STEODI03 Fink, 1975	Core
Mallard duck *(Anas platyrhynchos)*	92	>10,000	Practically Nontoxic	00120908 Fink, 1975	Core

The LC_{50} is higher than 2,000 ppm. This toxicity value indicates that 1,3-D is practically nontoxic to birds on a subacute dietary basis; however, this result is inconsistent with the acute oral test. The subacute dietary results could be explained by the fact that the length of time to perform the test is long and, because 1,3-D is highly volatile, it may not remain in the food. Therefore, the birds may have received an inadequate dose resulting in a low dose response. Field study data indicate that volatility is the primary route of 1,3-D dissipation with dispersal increasing to 35.1 mg/m^2/hour by three days. Therefore, the weight of evidence indicates that 1,3-D is moderately toxic to birds (LD_{50} = 157 mg/kg) (MRID's STEODI03 and 00120908).

(ii) Birds, Chronic

Avian reproduction studies using the TGAI were not required for 1,3-D in the 1986 Registration Standard. Since the field dissipation half-life is roughly one week and generally only one application is made per year, birds are not expected to be exposed to repeated or continuous residues of 1,3-D.

(iii) Mammals, Acute and Chronic

The toxicity values for mammals are presented in Table 16 (USEPA, 1997). Results indicate that 1,3-D is slightly toxic to toxic to small mammals on an acute oral basis (640 mg/kg) (MRID #0039693).

Table 16. Mammalian Toxicity

Species	Test Material	Test Type	Toxicity Value	Affected Endpoints	MRID No.
Laboratory mouse *(Mus musculus)*	Telone II	Acute Oral	LD_{50} 640 mg/kg (M&F)	Mortality	00039683
Laboratory rat *(Rattus norvegicus)*	1,3-dichloropropene	Acute Inhalation	LC_{50} 729 ppm/4 hours	Mortality	235350
Laboratory mouse *(Rattus norvegicus)*	1,3-dichlorpropene	Chronic Inhalation	NOEL Systemic 730 ppm	No systemic effects observed at 730 ppm	00039685
Laboratory rat *(Rattus norvegicus)*	90% ai cis + trans	Developmental - Inhalation	NOEL Maternal 20 ppm NOEL Developmental 60 ppm	Maternal - body weight loss and reduced food consumption Developmental - delayed ossification of vertebral centra	00144715 00152848
Laboratory rat *(Rattus norvegicus)*	96% ai cis + trans	13 Week Feeding	NOEL 5 mg/kg/day LOEL15 mg/kg/day	Body weight, hyperkeratosis and/or basal cell hyperplasia of the non-glandular portion of the stomach	42954802

(iv) Insects

A honeybee acute contact study using the typical end-use product was not required in the 1986 Registration Standard. The registered application method via soil injection prior to planting should not result in honeybee exposure. However, exposure in adjacent habitats could occur because of 1,3-D's volatility and the probability of the chemical drifting offsite.

Results from a study submitted for contact toxicity on honeybees are presented in Table 17, and indicate that 1,3-D is moderately toxic to bees on an acute contact basis (MRID's 00028772 and 00018842).

Table 17. Non-target Insect Acute Contact Toxicity

Species	% ai	LD_{50} (μg/bee)	Toxicity Category	MRID No. Author/Year	Study Classification
Honey bee *(Apis mellifera)*	TGAI	6.6	Moderately toxic	00028772/ Atkins/1972	Core
Honey bee *(Apis mellifera)*	Formulation	6.6	Moderately toxic	00018842/ Atkins/1969	Core

b. Terrestrial Field Testing

Based on the application method and use pattern, terrestrial field testing of 1,3-D has not been requested or submitted to support reregistration.

c. Toxicity to Freshwater Aquatic Animals

(i) Freshwater Fish and Amphibians, Acute

Freshwater fish toxicity studies using the TGAI were submitted to establish the toxicity of 1,3-D to fish and amphibians. Results of these tests are presented in Table 18. Since the LC_{50} falls in the range of 1 to 10 ppm, 1,3-D is moderately toxic to freshwater fish on an acute basis. (MRID's 00039692 and STE0DI02). The registrant is also conducting additional studies on the degradates as confirmatory data.

Table 18. Freshwater Fish Acute Toxicity

Species/ (Flow-through or Static)	% ai	96-hour LC_{50} (ppm) (measured/nominal)	Toxicity Category	MRID No. Author/Year	Study Classification
Walleye *(Stizostedion vitreum)* static	100	1.08 (measured)	Moderately Toxic	40098001/ Mayer & Ellersieck/ 1986	Core
Largemouth Bass *(Micropterus salmoides)* static	100	3.65 (measured)	Moderately Toxic	40098001/ Mayer & Ellersieck/ 1986	Core
Rainbow Trout *(Salmo gairdneri)* static	92	3.9 (measured)	Moderately Toxic	00039692/ Bentley/ 1975	Core
Fathead Minnow *(Pimephales promelas)* static	100	4.1 (measured)	Moderately Toxic	40098001/ Meyer & Ellersieck/ 1986	Core
Rainbow Trout *(Salmo gairdneri)* static	92	5.9 (unknown)	Moderately Toxic	STE0DI01 USEPA 1977	Core
Bluegill Sunfish *(Lepomis macrochirus)* static	≥80	6.1 (nominal)	Moderately Toxic	00117043/ Buccafusco/ 1981	Supplemental [1]
Bluegill Sunfish *(Lepomis macrochirirus)* static	92	6.7 (unknown)	Moderately Toxic	STE0DI02 USEPA 1977	Core
Bluegill Sunfish *(Lepomis macrochirirus)* static	92	7.1 (measured)	Moderately Toxic	00039692/ Bentley/ 1975	Core

[1] Rated supplemental because the dose levels were not high enough to calculate an LD_{50}.

(ii) Freshwater Fish, Chronic

Dow AgroSciences will conduct a freshwater fish early life-stage study (72-4) using Rainbow trout as confirmatory data. As stated previously in this document, EPA believes that 1,3-D will undergo rapid rates of dissipation in most surface waters due to volatilization and, to a lesser extent, by abiotic hydrolysis and possibly biodegradation. However, given the high acute

LC_{50} value and a half-life of 13.5 days, the Agency is interested in comparing the results to the run-off study to gage possible exposures to freshwater fish on a chronic basis.

(iii) Freshwater Invertebrates, Acute

Results of the freshwater invertebrate acute studies are presented in Table 19.

Table 19. Freshwater Invertebrate Acute Toxicity

Species/(Static or Flow-through)	% ai	48-hour LC50/ EC50 (ppm) (measured/nominal)	Toxicity Category	MRID No. Author/Year	Study Classification
Waterflea *(Daphnia magna)*	100	0.09	Highly Toxic	40098001/ Mayer & Ellersieck/ 1986	Core

Since the LC50/EC50 is less than 0.1 ppm, 1,3-D is considered very highly toxic to aquatic invertebrates on an acute basis. The guideline (72-2) is fulfilled (MRID 40098001). The registrant is also conducting the 72-2(a) study on the degradates to compare to the assumption in the risk assessment that the degradates are of equal or less toxicity to 1,3-D.

(iv) Freshwater Invertebrate, Chronic

Dow AgroSciences has agreed to conduct a freshwater invertebrate chronic study (72-4(b)) using *Daphnia magna*.

The data at hand on acute levels show that the LC_{50} for aquatic invertebrates (0.09 ppm) is less than 0.1 ppm. Also, at all registered application rates, initial, 21-day, and 90-day surface-water EECs, as calculated by GENEEC, are less than one percent of the lowest LC_{50} for freshwater invertebrates. However, because GENEEC is not suitable for tracking soil fumigants and since EPA expects rapid rates of dissipation in most surface waters, EPA is less concerned about chronic risks than for acute risks for aquatic invetebrates.

(v) Freshwater Field Studies

A freshwater field study using the TGAI is not required for 1,3-D.

d. Toxicity to Estuarine and Marine Animals

(i) Estuarine and Marine Fish, Acute

The 1986 Registration Standard did not require estuarine and marine studies. Use of 1,3-D, however, is expected to expand into areas, namely Florida, that could impact estuarine and marine environments. The registrant has committed to submit by June 1, 1999 a study on 1,3-D for acute estuarine and marine fish using the sheepshead minnow. Studies on estuarine and

marine fish for the degradates are reserved pending the outcome of this 1,3-D acute study and other studies.

(ii) Estuarine and Marine Fish, Chronic

Chronic tests of estuarine/marine fish test using the TGAI are not required for 1,3-D at this time. This requirement will be re-evaluated after reviewing the freshwater fish toxicity information.

(iii) Estuarine and Marine Invertebrates, Acute

The registrant is conducting confirmatory studies on the mysid shrimp (72-3(c)) and Eastern oyster (72-3(b)) to test the toxicity of 1,3-D on estuarine and marine invertebrates. As noted above, 1,3-D use is expected to increase in areas and could impact estuarine and marine environments.

(iv) Estuarine and Marine Invertebrate, Chronic

Chronic tests of estuarine and marine invertebrates using the TGAI are not required for 1,3-D at this time. This requirement will be re-evaluated after examining the results of the chronic freshwater invertebrate, acute marine/estuarine studies and the run-off study.

(v) Estuarine and Mayane Field Studies

A field study in estuarine/marine environments using the TGAI is not required for 1,3-D.

e. Toxicity to Aquatic and Terrestrial Plants

The registrant has committed to conducting Tier I and Tier II tests for aquatic and terrestrial plants using the TGAI. These studies are being conducted because 1,3-D is labeled for use as an herbicide and has phytotoxicity warnings. The registrant has also committed to conducting Tier I and Tier II tests for aquatic plants for the degradates (3- chloroacrylic acid and 3-chloroallyl alcohol).

f. Toxicity of Degradation Products and Manufacturing Impurities

No data were available to conduct a full ecological assessment for 1,2-D, 3-chloroallyl alcohol or 3-chloroacrylic acid. All of these chemicals are considered at least as toxic as the parent. As noted throughout this section, the registrant is conducting various environmental fate and ecotoxicity studies on the degradates.

4. Exposure and Risk Characterization

a. Explanation of the Risk Quotient (RQ) and the Level of Concern (LOC)

Risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. The quotient method is used to integrate the results of exposure and ecotoxicity data. In this method, risk quotients (RQ's) are calculated by dividing exposure estimates by both acute and chronic ecotoxicity values.

RQ = EXPOSURE/TOXICITY

RQ's are then compared to EPA's levels of concern (LOC's). These LOC's are criteria used by EPA to indicate potential risk to non-target organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on non-target organisms. LOC's currently address the following risk presumption categories: (1) **acute high** - potential for acute risk is high and regulatory action may be warranted in addition to restricted use classification; (2) **acute restricted use** - the potential for acute risk is high but may be mitigated through restricted use classification; (3) **acute endangered species** - the potential for acute risk to endangered species is high and regulatory action may be warranted; and (4) **chronic risk** - the potential for chronic risk is high and regulatory action may be warranted. Currently, the Agency does not conduct assessments for chronic risk to plants, acute or chronic risk to non-target insects, or chronic risk from granular/bait formulations to mammalian or avian species.

The 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: LC50 (fish and birds), LD50 (birds and mammals), EC50 (aquatic plants and aquatic invertebrates) and EC25 (terrestrial plants). Examples of toxicity test effect levels derived from the results of long-term laboratory studies assessing chronic effects are: LOEC (birds, fish, and aquatic invertebrates), NOEC (birds, fish and aquatic invertebrates) and MATC (fish and aquatic invertebrates). For birds and mammals, the NOEC 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 NOEC and LOEC) is used as the ecotoxicity test value in assessing chronic effects to fish and aquatic invertebrates. However, the NOEC is used if the measurement endpoint is reproduction or survival. Risk presumptions, along with the corresponding RQ's and LOC's are listed in Table 20.

Table 20. 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 < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC50 or LD50/sqft or LD50/day	0.1
Chronic Risk	EEC/NOEC	1
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 < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC50 or LD50/sqft or LD50/day	0.1
Chronic Risk	EEC/NOEC	1

[1] abbreviation for Estimated Environmental Concentration (ppm) on avian/mammalian food items
[2] $\frac{\text{mg/ft}^2}{\text{LD50 * wt. of bird}}$ [3] $\frac{\text{mg of toxicant consumed/day}}{\text{LD50 * wt. of bird}}$

Table 21. 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 NOEC	1

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

Table 22. Risk Presumptions for Plants

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

[1] EEC = lbs ai/A
[2] EEC = (ppb/ppm) in water

For pesticides applied as nongranular products (e.g., liquids, dusts applied via broadcast methods, etc.), the EECs on food items following product application are compared to toxicity values to assess risk (Fletcher et al., 1994). However, the Agency currently does not have routinely used methods for predicting EECs for soil fumigants. When available, risk determinations can be made when actual concentrations have been reported in terrestrial field dissipation studies or other studies submitted in support of reregistration.

b. Field Data Used for Risk Assessment

In this assessment, post-application 1,3-D residues detected in soil, water, and air samples are compared to toxicity values. It should be noted that this risk assessment relies on very little data, measured or predicted. It should also be noted that the reported field studies were conducted with lower application rates than allowed on some crops. 1,3-D concentrations in soil, water, and air will be higher with corresponding higher application rates. However, the risk quotients calculated from the environmental data do provide information about the potential risk of 1,3-D application to non-target species. In some instances, extrapolations were made to higher application rates, however, these levels are a simplification of what actual levels may be. Environmental fate and air monitoring study results have not established a correlation between the level of applied product and subsequent levels in the environment.

Two terrestrial field dissipation studies (MRID's 40403305 and 40855501) provided 1,3-D residue concentrations in treated soil and subsequent dissipation rates. A prospective ground-water monitoring study in Florida yielded 1,3-D concentrations in water collected from ditches adjacent to treated fields (MRID 44005201). Three field volatility studies evaluated atmospheric concentrations of 1,3-D under field conditions (MRID's 42545101, 41057701 and EFGWB 91-0910).

c. Exposure and Risk to Non-target Terrestrial Animals

1,3-D is used on over half a million acres of cropland each year (see Table 1). For orchard trees and grapevines, approved rates are as high as 556 lbs a.i./A. However, because the application method reduces terrestrial exposure and because of the relatively low toxicity to mammals, its use is not expected to result in large incidents of mortality. No avian mortality incidents have been reported in relation to 1,3-D applications. Telone C-17 contains chloropicrin, which is a contact irritant to humans and serves as a warning to applicators. It is assumed this product could affect birds and wild mammals in the same manner, resulting in avoidance and thereby reducing the risk of exposure.

The Agency does not have a standard protocol for conducting terrestrial risk assessments on terrestrial organisms when chemicals are applied via soil injection methods. Instead, in this risk assessment, animals were assumed to be exposed through dietary intake of contaminated soil. Beyer et al. (1994) analyzed scat samples from a variety of vertebrate species to determine the percent of soil in the diet. His work showed that the quantity of soil in animal diets can range from less than two percent up to 30 percent. Animals can ingest soil intentionally to provide

missing minerals or unintentionally through preening and grooming activities or by particles adhering to food items such as roots, tubers or foliage. Many species of birds also inadvertently ingest soil when probing soft soils for food. For the purpose of calculating risk quotients, it was assumed that 100 percent of the soil in an animal's diet comes from the treated field.

(i) Birds

Because of the application method, 1,3-D use in chemical soil fumigation operations is not expected to present a significant hazard to avian species. However, birds could be exposed through both dietary and inhalation routes. The available toxicity information allowed an acute risk determination through dietary routes. However, no information is available on acute inhalation toxicity to birds but the acute risk associated with this type of exposure is probably insignificant.

Risk quotients were calculated from the field dissipation residue data submitted to the Agency in support of reregistration. The Northern bobwhite LD_{50} was chosen to calculate the following risk quotients because of the wide range between the avian LD_{50} and the two avian LC_{50}'s determined for this chemical. The discrepancy between the two endpoints is believed to be the result of the difficulty of keeping 1,3-D concentrations constant on the test diets considering 1,3-D's volatility. The following equation was used to determine the avian acute risk quotients:

$$LD_{50}s/day = \frac{EEC * (\%\ daily\ food\ consumption * \%\ soil\ in\ diet)}{LD_{50}}$$

The results of these calculations are presented in Table 23.

Table 23. Risk Quotients for Acute Avian Exposure --based upon an Avian LD_{50} of 152 mg/kg and a mean and range of soil consumption rates[1] of 10.6% (>2% to 30%) of the total daily food intake and a daily food consumption rate of 18% of total body weight. EECs are taken from a field dissipation study submitted to the Agency (MRID 40403301).

Application Rate and Injection Depth (MRID #)	EEC (ppm)	Avian LD_{50} (mg/kg)	Daily Soil Ingestion Rate[1]	RQ
342 lbs ai/acre (13-15 inches) (404033-01)	130	152	Mean = 10.6% Range = >2 to 30%	Mean =0.02 Range = <0.003 to 0.05

[1] Soil consumption values are taken from Beyer et al. 1995.

From Table 20, the LOC's for avian species are: 0.5 (acute high risk); 0.2 (acute restricted use); 0.1 (acute endangered species); and 1 (chronic risk). An evaluation of the above risk quotients shows that no LOC's are exceeded for avian species. If it assumed that the concentration in soil is directly proportional to the application rate, the EEC would be 208 ppm at the highest rate of 556 lbs a.i./acre. At this concentration, no LOC's were exceeded. At this soil concentration, a 100-gm bird with an LD_{50} of 152 mg/kg would need to consume 72 grams of soil to attain this equivalent dose. This evaluation indicates that 1,3-D use should not result in significant acute mortality to avian species under any application scenario.

No avian chronic test data were required to support reregistration. Since 1,3-D is generally only applied once per growing season and because it has a relatively short field dissipation half-life, it is not expected to result in long-term exposure or subsequent chronic effects.

(ii) Mammals

Because of the application method, the use of 1,3-D in chemical soil fumigation operations is not expected to present a significant hazard to mammals. However, exposure could occur through both dietary and inhalation routes. No incidents of mammalian mortality have been reported due to the application of 1,3-D.

Risk quotients were calculated from field dissipation data and laboratory mouse LD_{50} data using the following equation:

$$LD_{50}s/day = \frac{EEC * (\%\ daily\ food\ consumption * \%\ soil\ in\ diet)}{LD_{50}}$$

The results of these calculations are presented in Table 24.

Table 24. Risk Quotients for Acute Mammalian Exposure -- based upon a mammalian LD_{50} of 640 mg/kg and a mean and range of soil consumption rates[1] of 4.4% (>2% to 17%) of the total daily intake and a daily food consumption rate of 5% of total body weight. EECs are from a field dissipation study submitted to the Agency (MRID 40403301).

Application Rate and Injection Depth (MRID #)	EEC (ppm)	Mammalian LD_{50} (mg/kg)	Daily Soil Ingestion Rate[1]	RQ
342 lbs ai/acre (13-15 inches) (404033-01)	130	640	Mean = 4.4% Range = >2 to 17%	Mean =0.008 Range = <0.003 to 0.03

[1] Soil consumption values are taken from Beyer et al. 1995.

From Table 20, the LOC's for mammal are as follows: 0.5 (acute high risk); 0.2 (acute restricted use); 0.1 (acute endangered species); and 1 (chronic risk). Evaluation of the above risk quotients show that no LOC's are exceeded for mammalian species. If it is assumed that the concentration in soil is directly proportional to the application rate, the EEC would be 208 ppm at the highest rate of 556 lbs a.i./acre. At this soil concentration, a 20-gram mouse with an LD_{50} of 640 mg/kg would need to consume 61 grams of soil (three times its body weight) to attain this equivalent dose. Therefore, 1,3-D use should not result in significant acute mortality to mammalian species via dietary exposure under any application scenario.

Acute inhalation toxicity was assessed by comparing mammalian inhalation data to the amount of volatilized chemical found above the treated fields. Using an application rate of 346 lbs a.i./acre, 1,3-D concentrations at a height of 6 inches above the soil surface never exceeded 4.4 ppm. This value is less than 0.01 percent of the mammalian inhalation LD_{50} of 713 mg/kg.

Even if 1,3-D concentrations in the air are directly proportional to the application rate, atmospheric concentrations are not expected to reach toxic levels. This result also indicates that 1,3-D use should not result in significant acute mortality to mammalian species via inhalation exposure under any application scenario.

Chronic toxicity is normally assessed through dietary routes of exposure and soil can be a substantial portion of the diet. Using the assumptions of the acute assessment and substituting the reproductive effect NOEL of > 90 ppm for the LD_{50}, the chronic LOC is not exceeded. Chronic risk can also be assessed by using the NOEL of 5 mg/kg/day derived in the 13-week rat feeding study. The following assumptions are used for this calculation:

- a mouse weighs approximately 20 grams, so the NOEL per mouse would be 0.1 mg/day;
- a mouse eats the equivalent of 18 percent of its body weight per day and a maximum of 17 percent of the diet is soil, which equates to 612 mg of soil per day;
- if soil 1,3-D concentrations were 208 mg/kg soils at an application rate of 556 lbs a.i./acre, each gram of soil would contain 0.208 mg. 1,3-D; and
- following these assumptions, a mouse would consume 0.127 mg of 1,3-D per day.

Using the above scenario, the chronic RQ is 1.3, which exceeds the LOC. However, this model uses maximum exposure condition. If factors such as the average concentration of 1,3-D over a 13 week period (32 ppm at a seven day field dissipation half-life) or soil consumption rates more typical of small mammals are used, the LOC is no longer exceeded. Since 1,3-D is applied generally only once per growing season and because it has a relatively short dissipation half-life, EPA does not expect long-term exposures.

(ii) Terrestrial Insects

The Agency currently does not assess risk to non-target insects. Results of acceptable studies are used for recommending appropriate label precautions.

d. Exposure and Risk to Non-target Freshwater Aquatic Animals

Exposure of pesticides to aquatic non-target organisms is possible through surface water runoff, soil erosion, off-target drift, and movement from ground water to surface water. Risk via exposure to 1,3-D concentrations in surface-water was assessed by using aquatic EEC's predicted using the program GENEEC (see Table 21) and from actual residues in ditch water found during a ground-water study. These estimates of environmental levels were then compared to known toxicity reference values.

(i) Freshwater Fish

Acute and chronic risk quotients are presented in Table 25.

Table 25. Risk Quotients for Freshwater Fish --Based on a (Walleye) LC50 of 1.08 ppm. Chronic risk quotients could not be evaluated due to the lack of chronic toxicity information.

Site/ Application Method/ Rate in lbs ai/A	LC50 (ppm)	NOEC/ MATC (ppm)	EEC Initial/Peak (ppm)	EEC 90-Day Ave.[1] (ppm)	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOEC or MATC)
177	1.08	nd	0.685	0.006	0.63	nc
253	1.08	nd	0.980	0.008	0.91	nc
354	1.08	nd	1.380	0.012	1.27	nc
404	1.08	nd	1.570	0.013	1.45	nc
556	1.08	nd	2.160	0.018	2.00	nc

[1] 56 day concentration was not modeled.
nd = no data
nc = not calculated

From Table 21, the LOC's for aquatic animals areas follows: 0.5 (acute high risk); 0.1 (restricted use); 0.005 (acute endangered species); and 1 (chronic). The results of the GENEEC model indicate that aquatic acute high risk, restricted use, and endangered species levels of concern are exceeded for freshwater fish at application rates equal to or above 177 lbs a.i./acre. Chronic risk could not be determined because of the lack of chronic toxicity data.

Because GENEEC is not suitable for tracking soil fumigants, EPA believes that actual residues may be a better indicator of exposure and risk. The freshwater fish LC_{50} (1.08 ppm) was compared to actual residues detected in perimeter ditches adjacent to fields treated at an application rate of 182 lbs a.i./acre (MRID #44005201). Concentrations ranged from 0.34 ppb to 1.8 ppb. The resulting risk quotient ranges from 0.002 to 0.0003 which does not exceed any LOC. If residues in ditch water are assumed to be directly proportional to the application rate, then at 556 lbs ai/acre, concentrations in ditch water would reach 5.5 ppb. At this concentration no LOC's are exceeded.

Concentrations of 1,3-D in ground water four feet below the surface in Florida reached a maximum of 833 ppb. At this concentration, the acute high risk LOC for fish would be exceeded by 1,3-D alone by 1.5 times. This assessment does not account for the additional toxicity presented by the two degradates that were also found in ground water in Florida. Note that there can be considerable interaction between surface and ground water, thus, the levels found in ground water are relevant in a discussion of exposures to fish.

(ii) Freshwater Invertebrates

The acute and chronic risk quotients are presented in Table 26.

Table 26. Risk Quotients for Freshwater Invertebrates --Based on a Daphnia LC50 of 0.09 ppm. Chronic risk quotients could not be evaluated due to the lack of chronic toxicity information.

Site/ Application Method/ Rate in lbs ai/A	LC50 (ppm)	NOEC/ MATC (ppm)	EEC Initial/Peak (ppm)	EEC 21-Day Ave. (ppm)	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOEC or MATC)
177	0.09	nd	0.685	0.025	7.61	nc
253	0.09	nd	0.980	0.035	10.89	nc
354	0.09	nd	1.380	0.05	15.33	nc
404	0.09	nd	1.570	0.055	17.44	nc
556	0.09	nd	2.160	0.080	24.00	nc

nd = no data
nc = not calculated

From Table 21, the LOC's for aquatic animals areas follows: 0.5 (acute high risk; 0.1 (restricted use); 0.005 (acute endangered species); and 1 (chronic). The results indicate that aquatic acute high risk, restricted use, and endangered species levels of concern are exceeded for freshwater invertebrates at application rates equal to or above 177 lbs a.i./acre from the GENEEC model. Chronic toxicity could not be determined due to a lack of toxicity information.

When the LC_{50} (0.09 ppm) is compared to actual residues (MRID #44005201) detected in perimeter ditches adjacent to fields in Florida treated at an application rate of 182 lbs a.i./acre ranged from 1.8 ppb to 0.34 ppb. The resulting risk quotients range from ranges from 0.02 to 0.004, which do exceed the endangered species LOC. If residues in ditch water are assumed to be directly proportional to the application rate, then at 556 lbs a.i./acre, concentrations in ditch water would reach 1.04 to 5.5 ppb. At concentrations above 4.5 ppb, endangered species LOCs are exceeded.

Concentrations of 1,3-D in ground water four feet below the surface at the application site in Florida reached a maximum of 833 ppb. At this concentration, the acute high risk LOC for invertebrates would be exceeded. This does not account for the additional toxicity presented by the two degradates that were also found in this ground water. Additionally, concentrations remained at potentially toxic levels for approximately 60 days. In addition to 1,3-D movement in aquatic environments through ground and surface water interaction, shallow ground water is itself inhabited by aquatic invertebrates.

e. Exposure and Risk to Estuarine and Marine Animals

No toxicity information for estuarine and marine animals were required in the 1986 Registration Standard. Consequently, no risk analysis could be conducted for these types of organisms.

The registrant is conducting several estuarine and marine studies on 1,3-D. The tests are estuarine/marine invertebrates with the mysid shrimp (72-3(c)) and the Eastern oyster (72-3(b)) and estuarine/marine fish using the Sheepshead minnow (72-3(a)). Should the results of these studies and other toxicity studies on the degradates show a potential for ecotoxicity from the degradates, EPA will also require studies on the degradates for estuarine and marine animals.

f. Exposure and Risk to Non-target Plants

No toxicity information for non-target plants were required in the 1986 Registration Standard. Consequently, no risk analysis could be conducted for these types of organisms. The registrant has committed to conducting Tier I and Tier II studies for 1,3-D (aquatic and terrestrial) and its degradates (aquatic). These studies are scheduled to be submitted by October 1, 2000.

g. Endangered Species

The Endangered Species Protection Program is expected to be finalized in the future. Limitations in the use of 1,3-D will be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. EPA 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.

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 are eligible for reregistration. The Agency has previously identified and required the submissions of generic (i.e. active ingredient specific) data required to support reregistration of products containing 1,3-D. The Agency has completed its review of these generic data and has determined that the data are sufficient to support reregistration of 1,3-D. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of 1,3-D, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of 1,3-D. The Agency has determined that 1,3-D products, when used as specified in this document (i.e. only pre-plant soil fumigant uses and according to label requirements to include the pending restrictions listed in Table 31), do not result in unreasonable adverse effects to human health or the environment. Therefore, the Agency finds that products containing 1,3-D as the active ingredient are eligible for reregistration. The reregistration of

particular products is addressed in Section V. of this document. Note that products which also contain chloropicrin will not be deemed eligible for reregistration until the reregistration of that active ingredient has been completed.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. Although the Agency has found that all uses of 1,3-D are eligible for reregistration when used according to specifications in this document, 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 1,3-D if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change. This includes the results of the studies now underway on the degradates, the run-off study, and the tap water monitoring program.

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient 1,3-D, as well as other data generated for the 1,3-D Special Review, the Agency has sufficient information on the health effects of 1,3-D and on its potential for ground water contamination. The Agency has determined that 1,3-D products, labeled and used as specified in this Reregistration Eligibility Decision document, will not pose unreasonable adverse effects to humans or the environment. Therefore, the Agency concludes that all products containing 1,3-D, when used under the conditions specified in this document, are eligible for reregistration.

C. Regulatory Position

The following is a summary of the regulatory positions and rationales for managing risks associated with the use of 1,3-D. Where the registrant has committed to labeling revisions that are not yet on 1,3-D labels, specific language is set forth in Section V. of this document.

1. Summary of 1,3-D's Carcinogenicity

EPA has classified 1,3-D as a B_2 carcinogen by both the oral and inhalation routes of exposure. Dow AgroSciences has submitted information in support of having EPA regulate 1,3-D as a non-linear carcinogen. EPA conducted a preliminary review of the information and expects to reconvene the Cancer Peer Review sometime in 1999 to consider the information. EPA will not, however, reconsider the 1,3-D risk assessment until all EPA policies regarding the regulation of non-linear carcinogens are finalized.

2. Summary of EPA's Approach to the 1,3-D Risk Assessment

a. Tolerances, Codex Harmonization and Dietary Risk

EPA has determined that 1,3-D, when applied as a pre-plant soil fumigant, is a non-food use pesticide and therefore, tolerances or exemptions from the requirement of a tolerance, are not required. (There is one exception for pineapples, which are treated at plant but show no residues since fruit are not borne until three years later). Therefore, a review of tolerance actions under the safety standard established under section 408(b)(2)(D) of the Federal Food, Drug and Cosmetics Act, as amended by FQPA, is not required. 1,3-D is regulated under the safety standard established under Section 3 of FIFRA, which requires that no unreasonable adverse effects to human health or the environment be associated with use of a pesticide. Nonetheless, EPA has reviewed the data base for 1,3-D to determine whether infants and children are particularly susceptible to toxic effects from exposures to 1,3-D residues and whether aggregate and cumulative exposures pose unreasonable risks.

No tolerances or Codex MRLs have been established; therefore, there are no issues regarding the compatibility of MRLs and tolerances.

Although there is no dietary risk from foods, EPA's risk assessment assumes dietary exposures to come from water sources (ground water). Results from the Florida study suggest that 1,3-D may enter surface water as volatilized residues in the air, settle into surface water and then dissolve. This route, however, is considered insignificant and the registrant is conducting studies to confirm that surface water is not a significant source of exposure.

EPA also looked to see if infants and children have increased susceptibility to the toxic effects of 1,3-D. In making its determination, EPA considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed and other information. Based on the current data requirements, 1,3-D has a complete database for developmental and reproductive toxicity. Therefore, EPA has concluded that an extra uncertainty factor of 10 is not warranted in order to protect infants and children.

No acute toxicological endpoints were identified for 1,3-D exposure for any population sub-group under labeling as specified in this document. For 1,2-D, the levels found in the ground water studies were 20 to 30 times lower than the Office of Water's 10-day Health Advisory for children.

Dow AgroSciences is developing data for reregistration on the toxicological profile, including developmental toxicity, for the alcohol and acid degradates. For purposes of reregistration, the Agency assumed that the degradates possess the same toxicological profile as the parent.

b. Aggregate and Cumulative Risk

EPA considers the main sources of 1,3-D exposure to be inhalation and drinking water from contaminated wells, especially for residents who live near treated fields. Aggregated cancer risks (inhalation plus water) for residents who live near treated fields based only on the information that allowed quantification of exposure are approximately 1×10^{-5}. This estimate does not include all of the mitigation measures to reduce inhalation risk, nor does it take into account a 100 foot no-treatment buffer from drinking water wells. While there are no data to assess the potential for risk from surface water residues, EPA believes this would be an insignificant source of exposure. Based on use patterns, dermal exposure is considered to be insignificant. EPA also looked at whether the Agency should also provide estimates of cumulative risks with the contaminant, 1,2-D. EPA does not have available data to determine whether 1,3-D has a common mechanism of toxicity with 1,2-D or other substances. For purposes of this reregistration action, EPA has assumed that 1,3-D and 1,2-D do not have a common mechanism of toxicity. EPA has determined that exposures under the current use patterns meet the safety standards set by FFDCA and FIFRA.

c. Effects to the Endocrine System

EPA is required to develop a screening program to determine whether certain substances (including all active ingredient pesticides and inerts) "may have an effect in humans that is similar to an effect predicted 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 three 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.

In deciding to continue to make reregistration determination during the early stages of FQPA implementations, 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 determination described in this RED are no longer appropriate. In this case, the Agency will consider itself free to pursue whatever action may be appropriate including, but not limited to, reconsideration of any portion of this RED.

2. Summary of 1,3-D's Benefits

1,3-D is one of the few remaining registered soil fumigants used to control nematodes. Nematodes are microscopic soil worms that live in the soil spaces. Nematodes cause damage by damaging the roots themselves (thereby doing the most damage to root crops such as carrots and potatoes), by reducing yields and by creating opportunities for other soil pathogens to enter the plant. 1,3-D is also used to control wireworms and rhizomania. The combination product of 1,3-D and chloropicrin is also used to treat nematodes and fungi.

The benefits of 1,3-D use are expected to increase with the phase-out of methyl bromide, mainly for use on tomatoes and strawberries. Additional research may find alternative uses for 1,3-D, or it is possible that other nematicides are identified or developed to replace both methyl bromide and 1,3-D.

3. Summary of Risk Management Decisions

a. Human Health

(i) Dietary

The Agency has determined that dietary exposure and risk associated with the use of 1,3-D under current labeling are negligible.

Exposure through Foods Grown in Treated Soils. Data show that no residues of 1,3-D or its degradates of toxicological concern are found in crops grown in treated soils, as long as 1,3-D is applied as a pre-plant soil fumigant. 1,3-D labels suggest a waiting period of one week for every 10 gallons of 1,3-D applied between soil treatment and planting, based on phytotoxicity concerns. For fall fumigation, 1,3-D is applied several months before planting. 1,3-D either volatilizes, leaches below the root zone, or breaks down in the soil, and thus is generally not available for uptake.

Dow AgroSciences has indicated interest in at- and post-plant applications of 1,3-D to orchard crops and grapevines. Before acting on these registrations, the Agency will require data on whether there are residues in treated crops and whether tolerances, or exemptions from the requirement of a tolerance, will be needed to support these uses.

Exposure through Water. Based on ground water monitoring, the Agency has concluded there can be dietary exposure to 1,3-D through contaminated ground water. 1,3-D is mobile, and in some areas, persistent, though these properties vary according to environmental conditions such as temperature, soil type and soil porosity.

There are numerous ground water data bases available to the Agency, including a survey of EPA's own monitoring, the USGS NAWQA Program and state data. The best information for assessing human health impacts are two prospective ground water monitoring studies conducted

in Florida and Wisconsin. The Agency believes that these two study sites represent vulnerable environments for ground water contamination from 1,3-D use.

The Florida site is vulnerable in that the soils are porous and the water table is shallow. The Agency is particularly concerned about the potential for increased use in these vulnerable environments because 1,3-D has been identified by USDA as an adequate alternative to methyl bromide, which is used heavily in Florida tomato production. Dow AgroSciences has agreed to conduct tap water monitoring in both traditional 1,3-D use areas in the north of the state and in south Florida once 1,3-D use expands to that region. Risks associated with levels found in shallow, on-site wells were as high as 4×10^{-6} (though the labels which are to take effect in August of 1999 will prohibit 1,3-D use within 100' of drinking water wells).

The Wisconsin site is also vulnerable. The ground water level is high and soils are porous; in addition, risk appears to be exacerbated by low soil and water temperatures. In the Wisconsin study, risks associated with lifetime exposures to levels found in on-site wells were in the 10^{-3} range, and measurable levels persisted for more than 12 months.

Both prospective ground water monitoring studies included limited monitoring in off-site wells located down gradient from the treated fields. In the Florida study, time weighted average (TWA) concentrations of 1,3-D plus its degradates in the on-site wells (10' deep) were 1.15 ppb. TWA concentrations of 1,3-D plus degradates measured in wells located 100 feet down gradient from the treated field were 0.074 ppb. In the Wisconsin study, on-site wells yielded TWA concentrations of 1,3-D and its degradates of 337 ppb while concentrations in a well 65' down gradient from the treated field were 26.6 ppb. Although neither of these studies was designed to quantify offsite exposures, results in both studies indicate that exposures were considerably lower with increasing distance from treated field.

Dow AgroSciences has agreed as a condition of reregistration to conduct tap water monitoring studies to better estimate current concentrations of 1,3-D and degradates in drinking water. Sampling will be targeted to high-use areas and will be initiated once the new labels are in effect in August of 1999. Should residues of 1,3-D and/or the alcohol or acid degradates be detected at levels exceeding the Office of Water Health Advisory of 0.2 ppb, Dow AgroSciences has included, as part of the sampling program, risk reduction measures which would be in place before the next use season. EPA expects to use the results of the sampling program to better characterize risks with the 100' setback and to also see if the sampling program results can be extrapolated in order to characterize risks in other 1,3-D use areas.

The Agency has evidence that degradation of 1,3-D is temperature dependent. For this reason, the Agency believes that once 1,3-D contaminates ground water in certain colder areas, residues can persist for long periods of time at levels that pose unreasonable risks. For this reason, Dow AgroSciences amended their labels to prohibit use in certain northern tier states where soils are porous and water tables are 50 feet or less. Although 1,3-D is used infrequently, or not at all in these areas, the Agency believes the label statement is appropriate. Based on the levels and persistence seen in the Wisconsin study, one application could result in unreasonable

lifetime risks. Dow AgroSciences is also conducting tap water monitoring in Michigan and Connecticut to confirm that the label prohibition to be added as of August 1, 1999 covers all vulnerable cold environments.

EPA is also aware of other data bases which show only a few detects out of tens of thousands of samples nationwide. The NAWQA sampling showed no detections of 1,3-D out of 21 study units, the locations of which coincide with some of the counties with heaviest 1,3-D use. The main weakness in interpreting these data is that there is no information in the summary reports to determine whether 1,3-D was used in proximity of tested wells. A second weakness is that NAWQA did not test for the presence of the two degradates of toxicological concern (3-chloroacrylic acid and 3-chloroallyl alcohol). Nonetheless, the NAWQA summary reports do provide a qualitative sense that 1,3-D use does not result in widespread aquifer contamination.

In summary, the Agency believes it has mitigated risks in the most vulnerable areas and is focusing resources now on developing confirmatory data in additional areas of high 1,3-D use. All 1,3-D labels bear a ground water advisory to alert users to ground water contamination risk and as of August 1, 1999, there will be a 100 foot buffer between drinking water wells and treated fields. Although the buffer is expected to provide some protection to drinking water, the actual mitigation on a site-by-site basis cannot be quantified since this will depend on a variety of local factors (such as soil type, subsurface hydrogeology, etc.). The tap water monitoring will be designed to allow EPA to take further regulatory action if study results indicate a problem. EPA is also committed to following trends in usage should 1,3-D use increase significantly, especially in areas which may be vulnerable.

(ii) Residential Exposure

The Agency has determined that exposures and risk to residents who live near 1,3-D-treated fields has been mitigated to the extent feasible. Data developed for reregistration and the Special Review show that about 25 percent of applied 1,3-D volatilizes from treated soils into the atmosphere and that atmospheric levels decrease with increasing distance from treated fields. These studies were less clear as to the value of a variety of measures added to 1,3-D labels.

In 1994, 1,3-D labels were modified to add a 300 foot buffer between occupied structures and treated fields. Three air monitoring studies in different environments show an approximate 30 percent overall reduction in air levels at this distance, however, the amount varied by site. In addition, there are label measures designed to minimize the amount of 1,3-D that volatilizes out of treated fields, such as soil sealing, engineering controls for loading and application and lowered rates. As mentioned above, the risk reduction value of several of these measures cannot be quantified with the data available, and would be difficult to obtain based on numerous uncontrollable variables that ultimately influence exposure to 1,3-D.

In addition to not including (in a quantitative sense) all mitigation measures, there are also uncertainties related to the data used to derive the residential exposure estimates. For example, although levels are generally expected to decrease with increasing distance, at the Washington

site, levels at 125 meters were approximately 70% **higher** than at 25 meters (see Table 8). Although the studies were carefully designed to assess actual exposures, the variety and influence of local environmental factors (such as wind, soil type, temperature) were quite large. These factors not only varied from test site to test site, but even day by day at the individual test sites. In addition, the small number of replicates per site are likely to have contributed to the mixed results. The assessment also assumes that a person is 300 feet from the edge of the field for 16 hours a day, 15 days a year for 30 years. EPA believes it is reasonable to use this as a "worst-case" exposure scenario, though this is likely to overstate most residents' exposure.

In addition, a weakness in the residential exposure assessment is in the use of the North Carolina data using 55-gallon drums of Telone C-17. While a later study using the mini-bulk system was used to replace the worker exposures, that study could not be used for residential exposure assessment. The N.C. data was combined with the Washington state and Arizona data to get an average exposure, so the contribution of the N.C. values is expected to overstate exposures because of the higher air levels associated with drum loading.

Dow AgroSciences has indicated interest in developing systems that apply 1,3-D at sub-surface soil depths, instead of at the 12 inch depth required by current labels. The Agency believes that this new method could provide lower exposures since the delivery system would not leave a chisel trace. This chisel trace is thought to be the main path for 1,3-D movement to the atmosphere. The Agency will require air monitoring with any registration application which requests depth of application of less than 12 inches.

There are no residential uses of 1,3-D; thus, there is no exposure from home-based applications.

(iii) Aggregate and Cumulative Risks

The calculated drinking water risk estimates using 1,3-D labels eligible for reregistration is 4×10^{-6} (using on-site wells from the Florida study); the inhalation risk is 6×10^{-6} (using an average of levels monitored from NC, WA and AZ study sites at the 300' buffer). Thus the calculated aggregate risk estimate is 1×10^{-5}. This risk estimate does not take into account mitigation from lower application rates, soil sealing measures, increased depth of application, soil moisture and temperature requirements or potential reduction in exposure from the 100 foot drinking water well setback. EPA believes the risk estimates are likely to be in the 10^{-6} range and that risk concerns have been addressed when all of the mitigation measures as specified in this reregistration decision are taken into account. The Agency has not cumulated risks with the impurity 1,2-D or other chemicals since no determination has been made that these chemicals share a common mode of toxicity.

(iv) Occupational Exposure

The Agency has determined that existing label measures are sufficient to mitigate worker exposures to 1,3-D. Several label changes have been made since the 1986 Registration Standard,

including closed loading systems, engineering controls to prevent 1,3-D spillage at row-turns, the phase-out of drum delivery, respiratory requirements, the use of closed cabs, increasing the restricted entry interval from three to five days and protective clothing.

While the data developed for estimating worker risks is of high quality, there are uncertainties. From Table 7, the studies used to test the efficacy of dry disconnects (shut-off valves for closed loading systems) gave mixed results, even suggesting that exposures were higher with the dry disconnects. Another uncertainty is assessing the potential risk to workers based on the methyl bromide phase-out. Increased 1,3-D risks would occur if a worker who currently applies methyl bromide replaces that methyl bromide use with 1,3-D. Based on conversations with grower groups and the registrant, this is unlikely since there is very little, if any, tandem use of the two fumigants. The phase-out of methyl bromide will likely increase the numbers of workers who are exposed to 1,3-D, but will not likely increase the lifetime cancer risk of an individual worker.

According to data developed for the Special Review and reregistration, the risks for custom applicators, custom loaders and for growers (who are assumed to both load and apply 1,3-D) is in the 10^{-5} to 10^{-6} range. Note that 1,3-D is a restricted use pesticide based on cancer concerns for worker risks. Because of this there are certain training and reporting requirements. The 1,3-D product stewardship goes beyond this training to provide manuals, videos and technical support in the field.

EPA's policy on worker risk sets a goal of no greater than 10^{-6} lifetime risks for workers. If, however, there are not measures available to do so, then risks that are somewhat higher will be considered acceptable. Risks that are higher than 10^{-4} are generally not seen as acceptable unless extremely high benefits of the use of the pesticide outweigh these risks.

In summary, the Agency believes that worker risks have been adequately mitigated with current label measures and are in accordance with current worker risk policies. The Agency's determination takes into account expected increases in usage of 1,3-D with the methyl bromide phase out.

b. Environmental/Ecological Effects

The Agency believes that use of 1,3-D as specified in this document will not pose unreasonable risks to the environment. However, certain properties of 1,3-D and its degradates justify the on-going monitoring program underway to confirm this position.

Specifically, 1,3-D and its degradates have been detected in both retrospective and prospective ground water monitoring studies. 1,3-D is considered mobile and persistent, with these properties varying depending on environmental conditions. Studies show that the rate of 1,3-D degradation is proportional to temperature, and thus 1,3-D is expected to be more persistent in colder environments. Limited data suggest that the degradates of 1,3-D, in particular 3-chloroacrylic acid, are more persistent than 1,3-D and the influence of temperature on

persistence is less than for the parent. For this reason, the registrant is generating data on the toxicity and environmental fate of the degradates. For this RED, the Agency has assumed that the degradates' toxicity and exposure parameters are equal to the parent; this is considered a conservative estimate.

The results of the prospective studies and information developed by USGS demonstrate that 1,3-D levels in ground water decrease with increasing distance from treated fields. The NAWQA found no detections of 1,3-D in any of its 21 Phase 1 monitoring study units around the country, suggesting that 1,3-D does not pose a widespread contamination risk to aquifers. Rather, the Agency believes the highest risks to the environment are in localized areas close to treated fields. The label statement to prohibit use in areas similar to the Wisconsin study site (i.e., cold climates with shallow ground water and permeable soils) is expected to lessen the potential for environmental risk as well as risks to human health.

For ecological effects, the available acute toxicity data on the TGAI indicate that 1,3-D is slightly toxic on an acute oral basis to small mammals, moderately toxic on an acute oral basis to birds, moderately toxic to acutely toxic to freshwater fish and bees, and very highly toxic to freshwater invertebrates. Toxicity testing has not been conducted on estuarine or marine organisms.

Because 1,3-D degradation appears to be related to temperature, organisms living in cooler climates (where degradation is slower) would be at greater risk than those in warm climates. Applications to cool climate crops may pose the greatest acute and chronic risks. Alternatively, although use in Florida may present a substantial risk to freshwater and estuarine organisms, the potential for chronic effects may be shortened because of the rapid degradation in warm climates.

1,3-D application methods (soil injection and subsurface drip irrigation) greatly reduce the risk to terrestrial birds. Since application is primarily to bare fields prior to planting, terrestrial organisms could be at risk through three routes of exposure: ingestion of contaminated soil, ingestion of contaminated water or inhalation of 1,3-D vapors.

Birds. Soil residue levels found in field samples were used to estimate risk to birds. Acute risk quotients did not exceed any LOC even at the maximum application rates. No data are available to conduct a chronic risk assessment. However, given the relatively short field dissipation half-life, chronic exposure is not anticipated.

Mammals. Using soil and air concentrations from field studies, acute risk quotients did not exceed any LOC. These results indicate the use of 1,3-D should not result in significant acute mortality to mammalian species via dietary or inhalation exposure under any application scenario. The chronic LOC was not exceeded based on reproductive effects data. It was exceeded slightly in a rat feeding study, but given 1,3-D's relatively short dissipation half-life and one application per year, EPA does not expect chronic effects.

Aquatic Organisms. Using GENEEC information, application rates equal evaluated (at or above 177 lbs. a.i. per acre) exceed the acute high risk LOC's for freshwater fish and freshwater invertebrates. Using measured residues found in ditch water adjacent to treated fields at 182 lbs. ai/acre, the LOC for endangered species was exceeded. Concentrations in four foot deep ground water in Florida were higher than the LOC for aquatic invertebrates. No data were available to assess chronic risk.

It should be noted again that the computer model GENEEC is a screening model designed only to help determine if substantial risks are unlikely. It should not be used to determine if substantial risks are likely. The determination of whether risks actually exceed the LOC's depends on data generated from higher-tier exposure and risk assessments and/or additional monitoring information.

Estuarine and Marine Organisms. No estuarine or marine toxicity data were required for reregistration in the 1986 Registration Standard, and as such, no acute or chronic risk analysis could be conducted. The registrant is generating acute data for estuarine and marine organisms since 1,3-D use is expected to expand to these areas.

Plants. No toxicity information for non-target plants has been submitted. Consequently, no risk analysis has been conducted. However, 1,3-D is registered as a herbicide and has phytotoxicity warnings and, therefore, is a candidate for both terrestrial and aquatic plant testing.

c. Restricted Use Classification

Based on 1,3-D's high acute inhalation toxicity, potential carcinogenicity and its use patterns, the Agency is maintaining the Restricted Use classification for all 1,3-D products that are currently so classified.

d. Endangered Species Statement

The Agency has developed a program (the "Endangered Species Protection Program") to identify pesticides which may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that will eliminate the adverse impacts. At present, the program is being implemented on an interim basis as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989), and is providing information to pesticide users to help them protect these species on a voluntary basis. As currently planned, the final program will call for label modifications referring to required limitations on pesticide uses, typically as depicted in county-specific bulletins or by other site-specific mechanism as specified by state partners. A final program, which may be altered from the interim program, will be described in a future Federal Register notice. The Agency is not imposing label modifications through this RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

e. Labeling Rationale

The Agency is maintaining its current label restrictions and is basing its reregistration eligibility decision on these measures and other label measures that will be added as of August 1, 1999. There are on-going studies, reviews and data collection which are being conducted to confirm the Agency's position that 1,3-D, when used as specified in this document, does not pose unreasonable adverse effects to humans or the environment. Should the results of those confirmatory data provide information to change the Agency's current risk assessment and position, EPA will consider further label changes to maintain the registration of products containing 1,3-D.

(i) Labeling Requirements for Handlers (Including Re-Entry)

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) and changes to 1,3-D labels in 1992 and 1996 established worker protection requirements to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) and research uses on farms, forests, nurseries and greenhouses to produce agricultural plants (including food, feed and fiber plants, trees, turf grass, flowers, shrubs, ornamentals and seedlings). Uses within the scope included not only uses on plants but also uses on the soil or planting medium the plants are (or will be) grown in.

The Personal Protective Equipment (PPE) requirements under the WPS, as well as the process for complying with the WPS are found in PR notice 93-7. For products containing 1,3-D, a supplement, entitled, "Supplement Four-D, Labeling Guidance for 1,3-Dichloropropene Fumigant Products" was issued with specific working for all 1,3-D product labels. A separate supplement, "Supplement Four-E, Labeling guidance for 1,3-Dichloropropene Plus Chloropicrin Fumigant Products" was also issued.. Some of the PPE requirements in the WPS were further refined in 1995. The requirements for 1,3-D handlers are specified below (note these are requirements for 1,3-D only):

Handlers Performing Direct Contact Tasks (e.g., includes equipment repair and calibration, fumigant transfers, clean-up of small spills) -
- Coveralls over short-sleeved shirt and short pants,
- Chemical-resistant gloves (barrier laminate (EVAL) or viton)
- Chemical resistant footwear plus socks
- Face-sealing goggles, unless full face respirator is worn
- Chemical resistant headgear for overhead exposure
- Chemical-resistant apron
- Respirator with organic-vapor-removing cartridge or canister approved for pesticides

Handlers in Enclosed Cabs
- Coveralls
- Shoes and socks

- A half-face respirator with an organic-vapor-removing cartridge or canister approved for pesticides
- A respirator is NOT required if occupants are within an enclosed cab equipped with a vapor-adsorptive filter (activated charcoal). HOWEVER, PPE for direct handlers must be worn if applicator within cab leaves the cab and re-enters.

Post Application/Re-entry Handlers in Treated Area within REI - Five Days after Application
- Coveralls
- Chemical-resistant gloves (barrier laminate (EVAL) or viton)
- Chemical-resistant footwear and socks
- Respirator with organic-vapor-removing cartridge or canister approved for pesticides

Handlers Exposed to High Concentrations (e.g., clean-up of large spills)
- Chemical resistant suit
- Chemical resistant gloves (barrier laminate (EVAL) or viton)
- Chemical-resistant footwear plus socks
- Chemical-resistant headgear
- Supplied air respirator

The Agency is retaining the WPS requirements, as well as all other PPE and engineering controls which are as follows:

Table 27. Summary of 1,3-D Label Restrictions that Affect Worker Exposures

Regulatory Action (effective date)	Label Requirements
Registration Standard (1986)	Precautionary Statements; Cancer Hazard Warning; Classification Change to Restricted Use Pesticide; Reentry increased to 72 Hours*; Clothing for Applicators and Handlers (Coveralls*, Chemical-resistant Gloves and Boots, Liquid-proof hat).
1992 Label Amendments (1992/1993)	Lowered Maximum rates; Deletion of Selected Use Sites; Revised Respirator Requirements*; Closed Loading Requirements; Technology to Minimize 1,3-D Spillage during Application, Improved Product Stewardship Materials
Worker Protection Standard (August 1992 see 57 FR 38102)	Coveralls over short-sleeved shirt and short pants; Chemical-resistant gloves and footwear; Chemical-resistant Apron (for direct handlers).
1995 Label Amendments (1996)	A Respirator Requirement for all 1,3-D handlers (except those in certain closed cabs); Restricted Entry increased to 5 days; Soil moisture and soil sealing requirements; Modified application techniques and Lower maximum use rates.

* - measures which were superceded or modified by subsequent label changes

(ii) Labeling Requirements that Affect Residential Exposure

There are no residential uses of 1,3-D. However, the Agency has concerns for inhalation risks to residents who live near 1,3-D treated fields, and an additional concern for residents who obtain drinking water from private wells in the proximity of treated fields.

Residential risks were not included in the 1986 Registration Standard. In 1990, California suspended 1,3-D use permits based on unexpectedly high levels of 1,3-D in the atmosphere following treatment. EPA used the Special Review process to obtain additional data and risk mitigation (through label amendments) to mitigate inhalation exposures.

EPA is also retaining requirements for measures to mitigate risks from exposure through ground water. The following table summarizes label statements which are required for 1,3-D labels to protect residents who live near treated fields.

Table 28. Measures to Reduce Risks to Residents who Live Near Treated Fields

	Label Measures
Measures Designed to Reduce Inhalation Risk	300' No-treatment Buffer; Lowered application rates; Loading Requirements; Technology to Minimize 1,3-D Spillage during Application, Soil moisture and soil sealing requirements; Modified application techniques
Measures to Reduce Dietary Risk via Potential Ground Water Exposure	100' buffer between drinking water wells and treated fields (as of 8/1/99); lowered application rates, ground water advisory; prohibition of use in certain states with shallow ground water and vulnerable soils (as of 8/1/99); prohibition in areas overlying karst geology (as of 8/1/99)

(iii) Other Labeling Requirements

Because the end-use product Telone II is also reformulated into other products, EPA is requiring that any product containing 1,3-D bear a label statement to require that all measures on the Telone label are also required on any other product containing 1,3-D. This measure is designed to cover all reformulated products, whether the 1,3-D source is Dow AgroScience's Telone product or from some other producer or reformulator.

V. ACTIONS REQUIRED OF REGISTRANTS

A. Amendments to Current 1,3-D Registrations

This section specifies the data requirements and responses necessary for the reregistration of products containing 1,3-D.

B. Requirements for 1,3-D Products

1. Additional Generic Data Requirements

On September 30, 1998, Dow AgroSciences requested changes to the terms and conditions of their 1,3-D registrations to include modified labels and study requirements (Roby, 1998). All 1,3-D products must be relabeled by August 1, 1999 to include the amended labeling.

In addition to the label changes, the registrant has agreed to conduct the following studies:

a. Studies to be performed as a result of modified terms and conditions of registration -- Studies on 3-chloroacrylic acid and 3-chloroallyl alcohol

Table 29 - Study on 3-chloroacrylic acid and 2-chloroallyl alcohol	OPP Guideline Number	Study Due Date
Acute oral-rat	81-1	June 1, 1999
Acute dermal toxicity - rabbit/rat	81-2	June 1, 1999
Primary eye irritation - rabbit	81-4	June 1, 1999
Primary dermal irritation	81-5	June 1, 1999
dermal sensitization	81-6	June 1, 1999
mutagenicity (Ames assay)	84-2A	October 1, 1999
mouse micronucleus	84-2	October 1, 1999
pharmacokinetics/balance of metabolism	85-1	October 1, 2000
mouse lymphoma	84-2	October 1, 1999
in vitro chromosomal aberration in Chinese Hamster lung	84-2	October 1, 1999
developmental toxicology	83-3A	January 1, 2000
subchronic 90-day feeding study	82-1A	January 1, 2000
aquatic aerobic metabolism	162-4	October 1, 1999

Table 29 - Study on 3-chloroacrylic acid and 2-chloroallyl alcohol	OPP Guideline Number	Study Due Date
adsorption/desorption	163-1	October 1, 1999
hydrolysis	161-1	October 1, 1999
vapor pressure	68-9	October 1, 1999
Henry's Law Constant	NA	October 1, 1999
acute fish toxicity- rainbow trout	72-1	June 1, 1999
acute aquatic invertebrate toxicity- Daphnia magna	72-2(a)	June 1, 1999
Tier I and Tier II aquatic plant	122-2/123-2	June 1, 1999

b. Studies to be performed as a result of modified terms and conditions of registration - 1,3-D

Table 30 - Study on 1,3-D	Guideline Number	Due Date
Freshwater fish early life stage - rainbow trout	72-4(a)	October 1, 1999
Freshwater aquatic invertebrate life cycle - Daphnia magna	72-4(b)	October 1, 1999
Estuarine/marine fish LC 50- sheepshead minnow	72-3(a)	June 1, 1999
Estuarine/marine invertebrate LC50-mysid shrimp	72-3(b)	June 1, 1999
Estuarine/marine invetebrate LC50-eastern oyster	72-3(b)	June 1, 1999
Tier I and Tier II aquatic plant	122-2/123-2	June 1, 1999
Seed germination and seedling emergence	122-1(a)	October 1, 1999
Vegetative vigor	122-1(b)	October 1, 1999
Tier I and Tier II terrestrial plants	122-1 and 123-1	October 1, 2000
Aerobic aquatic metabolism	162-4	October 1, 1999

c. Studies to be performed as a result of modified terms and conditions of registration with tiered requirements - Run-off Study and Studies on Ecotoxicity

Dow AgroSciences will conduct a run-off study to assess whether run-off is a significant pathway for movement of 1,3-D in the environment. If studies show that 1,3-D and/or its degradates can enter surface water in unacceptably high amounts as a result of run-off, then the battery of studies for 3-chloroacrylic acid and 3-chloroallyl alcohol for estuarine/marine animals (sheepshead minnow, mysid shrimp, eastern oyster) will be required.

In addition, EPA may require an avian acute oral study on the degradates pending the results of the environmental fate studies on the degradates. As noted in section E.4.c., the application method, of 1,3-D is not expected to result in high exposures to birds. If, however, the environmental fate study results show that concentrations of concern may be present, then EPA will require an acute avian oral study.

d. Product Chemistry 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. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies.. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The product-specific data requirements are listed in Appendix D, "Product Specific Data Call-In."

2. Formulation Changes

There are no requirements for formulation changes to products containing 1,3-D at this time.

3. Time frames

Revised labeling is scheduled to be borne by all products by August 1, 1999. The time frames for the additional studies are listed in the Tables 29 and 30 above.

4. Labeling Requirements for End-Use Products

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

Table 31: Summary of Required Labeling Changes for 1,3-Dichloropropene		
Description	**Required Labeling**	**Placement on Label**
All Products Containing the Active Ingredient 1,3-Dichloropropene		
This statement must be added to 1,3-D labels to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	FORMULATOR USE OF 1,3-DICHLOROPROPENE: Labeling for end use products containing 1,3-Dichloropropene that are prepared and sold by formulators must comply with all labeling for precautionary statements, use precautions, environmental hazards, handling and protective equipment requirements, maximum application rates, and other exposure mitigation measures specified in this product labeling.	General Use Precautions in Directions for Use
On labels as of August 1, 1999	"Do not apply within 100 feet of any well used for potable water." "Do not apply in areas overlying karst geology." "The following restriction applies only in North Dakota, South Dakota, Wisconsin, Minnesota, New York, Maine, New Hampshire, Vermont, Massachusetts, Utah and Montana: Where ground water aquifers exist at a depth of 50 feet or less from the surface, do not apply this product where soils are Hydrologic Group A."	

C. Existing Stocks

The existing stocks time frames have been set for products containing 1,3-D. The label changes which are referred to above in Table 32 are to be on all products which are sold or distributed by Dow AgroSciences or any reformulator by August 1, 1999.

VI. APPENDICES

Appendix A - Table of Use Patterns Subject to this RED

Appendix A is 23 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 0328 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 0328 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 1,3-Dichloropropene

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	all	40163301
61-2A	Start. Mat. & Mnfg. Process	all	40163301
61-2B	Formation of Impurities	all	40163301
62-1	Preliminary Analysis	all	40398501
62-2	Certification of limits	all	40504201, 40398501
62-3	Analytical Method	all	40504201, 40398501
63-2	Color	all	40483801, 40483802, 40483803, 40483804, 40483805, 40483806,40163301
63-3	Physical State	all	40483801, 40483802, 40483803, 40483804, 40483805, 40483806,40163301
63-4	Odor	all	40163301, 40483801, 40483802, 40483803, 40483804, 40483805, 40483806
63-5	Melting Point	all	40163301, 40483801, 40483802, 40483803, 40483804, 40483805, 40483806
63-6	Boiling Point	all	40163301, 40163301, 40483801, 404838702, 40483803, 40483804, 40483805, 40483806
63-7	Density	all	40163301, 40163301, 40483801, 40483802, 40483803, 40483804, 40483805, 40483806

Data Supporting Guideline Requirements for the Reregistration of 1,3-Dichloropropene

REQUIREMENT		USE PATTERN	CITATION(S)
63-8	Solubility	all	40483801, 40483802, 40483803, 40483804, 40483805, 40483806
63-9	Vapor Pressure	all	40483801, 40483802, 40483803, 40483804, 40483805, 40483806
63-10	Dissociation Constant	all	40483801, 40483802, 40483803, 40483804, 40483805, 40483806
63-11	Octanol/Water Partition	all	40483801, 40483802, 40483803, 40483804, 40483805, 40483806
63-12	pH	all	40483801, 40483802, 40483803, 40483804, 40483805, 40483806
63-13	Stability	all	40483804, 40483801, 40483802, 40483803, 40483805, 40483806
63-17	Storage stability	all	00162145
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral - Quail/Duck	A,B,C	261149
71-1B	Acute Avian Oral - Quail/Duck TEP	A,B,C	waived
71-2A	Avian Dietary - Quail	A,B,C	00120908
71-2B	Avian Dietary - Duck	A,B,C	STEOD103
71-3	Wild Mammal Toxicity	A,B,C	waived
71-5B	Actual Field Study	A,B,C	waived
72-1A	Fish Toxicity Bluegill	A,B,C	STOD102
72-1B	Fish Toxicity Bluegill - TEP	A,B,C	waived

Data Supporting Guideline Requirements for the Reregistration of 1,3-Dichloropropene

REQUIREMENT		USE PATTERN	CITATION(S)
72-1C	Fish Toxicity Rainbow Trout	A,B,C	00039692
72-1D	Fish Toxicity Rainbow Trout- TEP	A,B,C	waived
72-2A	Invertebrate Toxicity	A,B,C	40098001
72-2B	Invertebrate Toxicity - TEP	A,B,C	waived
72-3A	Estuarine/Marine Toxicity - Fish	A,B,C	see footnote
72-3B	Estuarine/Marine Toxicity - Mollusk	A,B,C	see footnote
72-3C	Estuarine/Marine Toxicity - Shrimp	A,B,C	see footnote
72-4A	Early Life Stage Fish	A,B,C	see footnote
122-1A	Seed Germination/Seedling Emergence	A,B,C	see footnote
122-1B	Vegetative Vigor	A,B,C	see footnote
122-2	Aquatic Plant Growth	A,B,C	see footnote
123-1A	Seed Germination/Seedling Emergence	A,B,C	see footnote
123-1B	Vegetative Vigor	A,B,C	see footnote
123-2	Aquatic Plant Growth	A,B,C	see footnote
124-1	Terrestrial Field	A,B,C	waived
124-2	Aquatic Field	A,B,C	see footnote
141-1	Honey Bee Acute Contact	A,B,C	00028772
141-2	Honey Bee Residue on Foliage	A,B,C	000188423

TOXICOLOGY

Data Supporting Guideline Requirements for the Reregistration of 1,3-Dichloropropene

REQUIREMENT		USE PATTERN	CITATION(S)
81-1	Acute Oral Toxicity - Rat		40220901
81-2	Acute Dermal Toxicity - Rabbit/Rat		40220902
81-3	Acute Inhalation Toxicity - Rat		40220903
81-4	Primary Eye Irritation - Rabbit		40220904
81-5	Primary Dermal Irritation - Rabbit		40220905
81-6	Dermal Sensitization - Guinea Pig		40220906
82-1A	90-Day Feeding - Rodent		42954801, 42954802
82-1B	90-Day Feeding - Non-rodent		43763501
82-2	21-Day Dermal - Rabbit/Rat		waived
82-4	90-Day Inhalation - Rat		00039685
83-1A	Chronic Feeding Toxicity - Rodent		40312201, 40312301
83-1B	Chronic Feeding Toxicity - Non-Rodent		42922301, 42441001
83-2A	Oncogenicity - Rat		434653501, 40312201
83-2B	Oncogenicity - Mouse		40312301
83-2B	Oncogenicity - Mouse		40312301
83-3A	Developmental Toxicity - Rat		00152848
83-3B	Developmental Toxicity - Rabbit		00152848
83-4	2-Generation Reproduction - Rat		40835301
84-2A	Gene Mutation (Ames Test)		44302801

Data Supporting Guideline Requirements for the Reregistration of 1,3-Dichloropropene

REQUIREMENT		USE PATTERN	CITATION(S)
84-2B	Structural Chromosomal Aberration		00259101
85-1	General Metabolism		40959801, 161151
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
133-3	Dermal Passive Dosimetry Exposure		waived
133-4	Inhalation Passive Dosimetry Exposure		waived
ENVIRONMENTAL FATE			
161-1	Hydrolysis		00158442, 262730
161-4	Photodegradation		40330101
162-1	Aerobic Soil Metabolism		42642301
162-2	Anaerobic Soil Metabolism		40025901
162-3	Anaerobic Aquatic Metabolism		waived
162-4	Aerobic Aquatic Metabolism		see footnote
163-1	Leaching/Adsorption/Desorption		42868501, 425155501, 40538901
163-3	Volatility - Field		42845601, 42845602, 42545101, 42774201
164-1	Terrestrial Field Dissipation		41385701, 40155501
164-2	Aquatic Field Dissipation		waived
164-5	Long Term Soil Dissipation		waived
165-1	Confined Rotational Crop		43140201
165-2	Field Rotational Crop		waived

Data Supporting Guideline Requirements for the Reregistration of 1,3-Dichloropropene

REQUIREMENT		USE PATTERN	CITATION(S)
166-1	Ground Water - Small Prospective		44227701, 44318701, 44258901, 44226901, 44270201, 44005201
166-2	Ground Water - Small Retrospective		43428301, 42914301, 42452901, 42536401, 42354201
166-3	Ground Water - Irrigated Retrospective		inapplicable
RESIDUE CHEMISTRY			
171-4A	Nature of Residue - Plants		42845401, 42894201, 42784201, 42760801, 42709401
171-4B	Nature of Residue - Livestock		43083301, 42946401
171-4C	Residue Analytical Method - Plants		waived
171-4D	Residue Analytical Method - Animal		waived
171-4E	Storage Stability		42354201
171-4F	Magnitude of Residues - Potable H2O		waived
171-4G	Magnitude of Residues in Fish		waived
171-4H	Magnitude of Residues - Irrigated Crop		waived
171-4I	Magnitude of Residues - Food Handling		waived
171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg		waived
171-4K	Crop Field Trials		waived

Data Supporting Guideline Requirements for the Reregistration of 1,3-Dichloropropene

REQUIREMENT		USE PATTERN	CITATION(S)
171-4L	Processed Food		waived
171-5	Reduction of Residues		waived
171-6	Proposed Tolerance		waived
171-7	Support for Tolerance		waived
171-13	Analtyical Reference Standard		waived

Note- Requirements for these studies were not included in the 1986 Registration Standard, however, based on expected increases in usage to sensitive environments, the registrant is conducting these studies, which are to be submitted by October 1, 1999 (except for 122-1 and 123-1, which are due October 1, 2000).

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 3(c)(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.

BIBLIOGRAPHY

MRID **CITATION**

Table 1 - Citations with MRID Numbers Assigned

00030385 Glas, R.D. (1979) Determination of Residues of Cisand Trans 1,3Dichloropropene in Plant Materials: ACR 79.15. Method dated Nov 30, 1979. (Unpublished study received Feb 7, 1980 under 464511; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL: 241761-B)

00033255 McKinney, W.J.; Wendt, M.B.; Abbott, R.; et al. (1978) [Residues in Sugarbeets]: TIR-24-355-76. (Unpublished study including TIR24-355-76-B, received Jun 25, 1980 under 464-511; prepared by Shell Development Co., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:242726-A)

00033256 McKinney, W.J.; Wendt, M.B.; Fries, F.A.; et al. (1978) [Residues in Cabbage]: TIR-24-160-78-A. (Unpublished study including TIR24-195-78B and TIR-24-195-78, received Jun 25, 1980 under 464511; prepared by Shell Development Co., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:242726-B)

00033257 McKinney, W.J.; Wendt, M.B. (1978) [Residues in Potatoes]: TIR-24172-78-A. (Unpublished study including TIR-24-172-78-B, received Jun 25, 1980 under 464-511; prepared by Shell Development Co., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL: 242726-C)

00033258 McKinney, W.J.; Fries, F.A.; Wendt, M.B.; et al. (1978) [Residues in Cauliflower]: TIR-24-180-78. (Unpublished study including TIR-24-180-78-B, received Jun 25, 1980 under 464-511; prepared by Shell Development Co., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:242726-D)

00033259 McKinney, W.J.; Fries, F.A.; Wendt, M.B.; et al. (1978) [Residues in Lettuce]: TIR-24-191-78A. (Unpublished study including TIR24-191-78-B, TIR-24-192-78A and TIR-24-192-78-B, received Jun 25, 1980 under 464-511; prepared by Shell Development Co., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:242726-E)

00033260 McKinney, W.J.; Fries, F.A.; Bierman, B.; et al. (1979) [Residues in Watermelon]: TIR-24-227-78B. (Unpublished study including TIR-24-227-78, TIR-24-244-78-B and TIR-24-244-78, received Jun 25, 1980 under 464-511;

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific 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 5; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of product specific 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, Data Call-In Response Form, as well as 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 03-31-99).

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 - Product-Specific Data Call-In Response Form (Insert A)
3 - Requirements Status and Registrant's Response Form (Insert B)
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 and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form (Insert B). Depending on the results of the studies required in this Notice, additional 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 Insert B, Requirements Status and Registrant's Response Form (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 (tel: 703-487-4650).

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 160.3(a)(6)].

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

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for 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

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 chose 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. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These 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 Form 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) must be submitted for each product listed on the Data Call-In Response Form (Insert A) unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form(Insert A). 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), 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.

1. **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 the Data Call-In Response Form (Insert B). If you choose this option, this is the only form 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.

2. **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 5 on the Requirements Status and Registrant's Response Form(Insert A) and item numbers 7a and 7b on the Data Call-In Response Form(Insert B). Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. **Request for Product Specific Data Waivers.** Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on 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.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form (Insert A) that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form (Insert A) 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 A). 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 -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced here in 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.

The time frames in the Requirements Status and Registrant's Response Form (Insert A) are the time frames that the Agency is allowing for the submission of completed study reports. 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 -- 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. 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 -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. 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 do 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 your 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 EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. 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 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 burdens 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 will normally 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(j) "'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(k), 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 must also certify at the time of submitting 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 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 are usually 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 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 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.

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.

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 should also 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 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 8570-34, Certification with Respect to Citations of Data (in PR Notice 98-5).

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), as appropriate.

III-D. REQUESTS FOR DATA WAIVERS

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 Requirements Status and Registrant's Response Form. 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.

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 CANCELED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or canceled 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 would generally 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 suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also 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 canceled products containing an active ingredient for which the Agency has particular risk concerns will be determined on 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 (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form (Insert A) and a completed Requirements Status and Registrant's Response Form (Insert B) for 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 Data Call-In Response Form (Insert A) need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), 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

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form (Insert A)
3 - Requirements Status and Registrant's Response Form (Insert B)
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

1,3-DICHLOROPROPENE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing 1,3-Dichloropropene.

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 0328. 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).

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for 1,3-Dichloropropene are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on 1,3-Dichloropropene 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 1,3-Dichloropropene 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 Karen Jones at (703) 308-8047.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Karen Jones
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: **1,3-Dichloropropene**

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INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORM (INSERT A) FOR PRODUCT SPECIFIC DATA

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes.**" If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **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.

Item 7a. 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.**" 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. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. 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.

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INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM (INSERT B) FOR PRODUCT SPECIFIC DATA

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the 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. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.

Item 9. **Enter only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (**Developing Data**). 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. By the specified due date, I will also submit: (1) a completed **"Certification with Respect to Citations of Data (in PR Notice 98-5)" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA 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. By the specified due date, I will also

submit: (1) a completed **"Certification with Respect to Citations of Data (in PR Notice 98-5)" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4).**

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. 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 also submitting a completed **"Certification of Attempt to Enter into an Agreement with other Restraints for Development of Data " (EPA Form 8570-32).** 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 (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4).**

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4).**

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4).**

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If 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 EPA 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)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). 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 and Registrant's Response" Form indicating 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. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. 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.

EPA'S BATCHING OF TELONE (1,3-DICHLOROPROPENE) 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 **Telone** (1,3-dichloropropene) 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 is generated or existing data is 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 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.

Ten products were found which contain Telone as the active ingredient. These products have been placed into four batches in accordance with the active and inert ingredients and type of formulation.

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	62719-32	94.0	LIQUID
	11220-01	94.0	LIQUID

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
2	8536-21	1,3-dichloropropene ... 79.9 chloropicrin ... 15.0	LIQUID
	11220-20	1,3-dichloropropene ... 79.9 chloropicrin ... 15.0	LIQUID
	62719-12	1,3-dichloropropene ... 78.3 chloropicrin ... 16.5	LIQUID

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
3	8536-22	1,3-dichloropropene ... 65.8 chloropicrin ... 29.7	LIQUID
	11220-21	1,3-dichloropropene ... 65.8 chloropicrin ... 29.7	LIQUID
	11220-22	1,3-dichloropropene ... 61.1 chloropicrin ... 34.65	LIQUID

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
4	8536-08	1,3-dichloropropene ... 37.6 chloropicrin ... 59.4	LIQUID
	11220-15	1,3-dichloropropene ... 35.3 chloropicrin ... 58.8	LIQUID

The following summarizes acute data requirement by batch:

- Registrants with products in Batch 1 need to cite/submit all acute data on one of the subject products.
- Registrants with products in Batch 2 need to cite/submit all acute data on one of the subject products.
- Registrants with products in Batch 3 need to cite/submit all acute data on one of the subject products.
- Registrants with products in Batch 4 need to cite/submit all acute data on one of the subject products.

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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:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf.
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-32	Certification of Attempt to Enter into an Agreement with other Restraints for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf.
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.
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.

8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf.
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf.
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf.
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf.
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf.
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.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
   b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
   c. Antimicrobials Division Organizational Structure/Contact List
   d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
   e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
   f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
   g. 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.

Documents Associated with this RED

The following is a list of available documents for 1,3-Dichloropropene 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 Lisa Nisenson at (703) 308-8031.

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 1,3-Dichloropropene.

The following documents are part of the Administrative Record for 1,3-Dichloropropene and may be 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.

APPENDIX A REPORT

THE FOLLOWING WERE THE REGISTERED USES AS OF JANUARY 27, 1997
ALL USES ARE ELIGIBLE FOR REREGISTRATION SUBJECT TO RISK MITIGATION MEASURES

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop	/year	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
FOOD/FEED USES													
AGRICULTURAL CROPS/SOILS (UNSPECIFIED)			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	404 lb A	*	NS	NS	NS	NS	NS	NS	OP		C92, CAS
	RTU	NA	404 lb A	*	NS	NS	NS	NS	NS	NS	WA		C46, C92, CAS
ALFALFA			Use Group: TERRESTRIAL FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
ALMOND			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
APPLE			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
APRICOT			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
ASPARAGUS			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
BANANA			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS

APPENDIX A REPORT

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps /crop /year	Max. Rate	Max. Dose (AI unless noted otherwise)/Al /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)													
BARLEY			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
BEANS			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
BEETS			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
BLACKBERRY			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
BLUEBERRY			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
BOYSENBERRY			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
BROCCOLI			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
BRUSSELS SPROUTS			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS

APPENDIX A REPORT

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop	/year	Max. Dose ((AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)													
BUCKWHEAT			Use Group: TERRESTRIAL FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
CABBAGE			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
CARROT (INCLUDING TOPS)			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
CASHEW			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
CAULIFLOWER			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
CELERY			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
CHARD, SWISS			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
CHERRY			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS

APPENDIX A REPORT

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop	/year	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)													
CHESTNUT			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
CITRUS FRUITS			Use Group: TERRESTRIAL FOOD+FEED CROP										
Broadcast, Preplant, Plowsole or chisels	RTU	NA	UC 369 lb A	* *	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
Soil band treatment, Preplant, Chisel	RTU	NA	8.4375 lb 1K linear ft	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
CLOVER			Use Group: TERRESTRIAL FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
COLLARDS			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
CORN (UNSPECIFIED)			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
CORN, POP			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
COTTON (UNSPECIFIED)			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS

APPENDIX A REPORT

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop	/year	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)													
COWPEA/BLACKEYED PEA			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
COWPEAS			Use Group: TERRESTRIAL FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
CRANBERRY			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
CUCUMBER			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
CURRANT			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
DATE			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
DECIDUOUS FRUIT TREES (UNSPECIFIED)			Use Group: TERRESTRIAL FOOD+FEED CROP										
Broadcast, Preplant, Plowsole or chisels	RTU	NA	373.69 lb A	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
Soil band treatment, Preplant, Chisel	RTU	NA	9.748 lb 1K linear ft	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU

APPENDIX A REPORT

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)													
DEWBERRY			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
EGGPLANT			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
ENDIVE (ESCAROLE)			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
FIELD CROPS (UNSPECIFIED)			Use Group: TERRESTRIAL FOOD+FEED CROP										
Broadcast, Preplant, Plowsole or chisels	RTU	NA	192.24 lb A	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
Soil band treatment, Preplant, Chisel	RTU	NA	5.013 lb A / Linear ft	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	181.8 lb A	*	NS	NS	NS	NS	NS	5 d			C13, C46, C92, CAS
FIG			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
FILBERT (HAZELNUT)			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
FLAX			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS

APPENDIX A REPORT

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps /crop	/year	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)													
FRUITS (UNSPECIFIED)			Use Group: TERRESTRIAL FOOD+FEED CROP										
Broadcast, Preplant, Plowsole or chisels	RTU	NA	369.6 lb A	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
Soil band treatment, Preplant, Chisel	RTU	NA	8.4375 lb 1K linear ft	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	353.5 lb A	*	NS	NS	NS	NS	NS	5 d			C13, C46, C92, CAS
GARLIC			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
GOOSEBERRY			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
GRAPEFRUIT			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
GRAPES			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
GRASS FORAGE/FODDER/HAY			Use Group: TERRESTRIAL FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
HICKORY NUT			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS

APPENDIX A REPORT

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop	/year	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)													
HOPS				Use Group: TERRESTRIAL FOOD+FEED CROP									
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
HORSERADISH				Use Group: TERRESTRIAL FOOD CROP									
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
HUCKLEBERRY				Use Group: TERRESTRIAL FOOD CROP									
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
KALE				Use Group: TERRESTRIAL FOOD CROP									
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
KOHLRABI				Use Group: TERRESTRIAL FOOD CROP									
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
KUMQUAT				Use Group: TERRESTRIAL FOOD+FEED CROP									
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
LEEK				Use Group: TERRESTRIAL FOOD CROP									
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
LEMON				Use Group: TERRESTRIAL FOOD+FEED CROP									
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS

APPENDIX A REPORT

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps Max. Rate /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)											
LESPEDEZA			Use Group: TERRESTRIAL FEED CROP								
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS NS	NS NS	NS	3 d			C13, C46, C92, CAS
LETTUCE			Use Group: TERRESTRIAL FOOD CROP								
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS NS	NS NS	NS	3 d			C13, C46, C92, CAS
LIME			Use Group: TERRESTRIAL FOOD+FEED CROP								
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS NS	NS NS	NS	3 d			C13, C46, C92, CAS
LOGANBERRY			Use Group: TERRESTRIAL FOOD CROP								
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS NS	NS NS	NS	3 d			C13, C46, C92, CAS
MELONS			Use Group: TERRESTRIAL FOOD CROP								
Soil fumigation, Preplant, Drip irrigation	RTU	NA	90.9 lb A	*	NS NS	NS NS	NS	3 d	AZ		C92, CAS
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS NS	NS NS	NS	3 d			C13, C46, C92, CAS
MELONS, CANTALOUPE			Use Group: TERRESTRIAL FOOD CROP								
Soil fumigation, Preplant, Drip irrigation	RTU	NA	90.9 lb A	*	NS NS	NS NS	NS	3 d	AZ		C92, CAS
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS NS	NS NS	NS	3 d			C13, C46, C92, CAS
MELONS, HONEYDEW			Use Group: TERRESTRIAL FOOD CROP								

APPENDIX A REPORT

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

SITE Application Type, Application Timing, Application Equipment – Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop	/year	Max. Dose [(AI unless noted otherwise)/AI /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)													
MELONS, HONEYDEW (con't)			Use Group: TERRESTRIAL FOOD CROP (con't)										
Soil fumigation, Preplant, Drip irrigation	RTU	NA	90.9 lb A	*	NS	NS	NS	NS	NS	3 d	AZ		C92, CAS
MELONS, MUSK			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Drip irrigation	RTU	NA	90.9 lb A	*	NS	NS	NS	NS	NS	3 d	AZ		C92, CAS
MELONS, WATER			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Drip irrigation	RTU	NA	90.9 lb A	*	NS	NS	NS	NS	NS	3 d	AZ		C92, CAS
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
MILLET (FOXTAIL)			Use Group: TERRESTRIAL FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
MILLET, PROSO (BROOMCORN)			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
MINT			Use Group: TERRESTRIAL FOOD+FEED CROP										
Broadcast, Preplant, Plowsole or chisels	RTU	NA	277.92 lb A	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
Soil band treatment, Preplant, Chisel	RTU	NA	5.012 lb 1K linear ft	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	595.9 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS

APPENDIX A REPORT

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop	/year	Max. Dose [(AI unless noted otherwise)/AI] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)													
MUSTARD			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
NECTARINE			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
OATS			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
OKRA			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
OLIVE			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
ONION			Use Group: TERRESTRIAL FOOD CROP										
Broadcast, Preplant, Plowsole or chisels	RTU	NA	267.12 lb A	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
Soil band treatment, Preplant, Chisel	RTU	NA	6.964 lb 1K linear ft 262.8 lb A	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
	RTU	NA	252.5 lb A	*	NS	NS	NS	NS	NS	5 d			C13, C46, C92, CAS

APPENDIX A REPORT

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

SITE Application Type, Application Timing, Application Equipment – Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop	/year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)													
ORANGE				Use Group: TERRESTRIAL FOOD+FEED CROP									
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
PARSNIP				Use Group: TERRESTRIAL FOOD+FEED CROP									
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
PASTURES				Use Group: TERRESTRIAL FEED CROP									
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
PEACH				Use Group: TERRESTRIAL FOOD CROP									
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
PEANUTS (UNSPECIFIED)				Use Group: TERRESTRIAL FOOD+FEED CROP									
Broadcast, Preplant, Plowsole or chisels	RTU	NA	192.24 lb A	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
Soil band treatment, Preplant, Chisel	RTU	NA	5.012 lb 1K linear ft	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
PEAR				Use Group: TERRESTRIAL FOOD CROP									
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
PEAS (UNSPECIFIED)				Use Group: TERRESTRIAL FOOD+FEED CROP									
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS

APPENDIX A REPORT

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps Max. Rate /crop /year Max. Dose cycle	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)												
PECAN			Use Group: TERRESTRIAL FOOD CROP									
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS NS	NS	NS	NS	3 d			C13, C46, C92, CAS
PEPPER			Use Group: TERRESTRIAL FOOD CROP									
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS NS	NS	NS	NS	3 d			C13, C46, C92, CAS
PERSIMMON			Use Group: TERRESTRIAL FOOD CROP									
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS NS	NS	NS	NS	3 d			C13, C46, C92, CAS
PIMENTO			Use Group: TERRESTRIAL FOOD CROP									
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS NS	NS	NS	NS	3 d			C13, C46, C92, CAS
PINEAPPLE			Use Group: TERRESTRIAL FOOD+FEED CROP									
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS NS	NS	NS	NS	3 d			C13, C46, C92, CAS
PLUM			Use Group: TERRESTRIAL FOOD CROP									
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS NS	NS	NS	NS	3 d			C13, C46, C92, CAS
POMEGRANATE			Use Group: TERRESTRIAL FOOD CROP									
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS NS	NS	NS	NS	3 d			C13, C46, C92, CAS
POTATO, WHITE/IRISH			Use Group: TERRESTRIAL FOOD+FEED CROP									
Broadcast, Preplant, Plowsole or chisels	RTU	NA	UC 267.12 lb A	*	NS NS	NS	NS	NS	5 d			C13, C46, CAL, CAU

APPENDIX A REPORT

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop	/year	Max. Dose [(AI unless noted otherwise)/AI /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)													
POTATO, WHITE/IRISH (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)										
Soil band treatment, Preplant, Chisel	RTU	NA	6.964 lb 1K linear ft	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
Soil fumigation, Preplant, Chisel	RTU	NA	255 lb A	*	NS	NS	NS	NS	NS	NS	ID		
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
	RTU	NA	252.5 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
PRUNE			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
PUMPKIN			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
QUINCE			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
RADISH			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
RASPBERRY (BLACK, RED)			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS

APPENDIX A REPORT

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop	/year	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)													
RUTABAGA			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
RYE			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
SAFFLOWER			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
SALSIFY			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
SHALLOT			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
SORGHUM			Use Group: TERRESTRIAL FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
SORGHUM (UNSPECIFIED)			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS

APPENDIX A REPORT

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps Max. Rate @ Max. Dose /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)											
SOYBEANS (UNSPECIFIED)			Use Group: TERRESTRIAL FOOD+FEED CROP								
Broadcast, Preplant, Plowsole or chisels	RTU	NA	UC 189.6 lb A *	*	NS NS	NS NS	NS	5 d			C13, C46, CAL, CAU
Soil band treatment, Preplant, Chisel	RTU	NA	4.289 lb 1K linear ft *	*	NS NS	NS NS	NS	5 d			C13, C46, CAL, CAU
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A *	*	NS NS	NS NS	NS	3 d			C13, C46, C92, CAS
SPINACH			Use Group: TERRESTRIAL FOOD CROP								
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A *	*	NS NS	NS NS	NS	3 d			C13, C46, C92, CAS
SQUASH (SUMMER)			Use Group: TERRESTRIAL FOOD CROP								
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A *	*	NS NS	NS NS	NS	3 d			C13, C46, C92, CAS
SQUASH (WINTER)			Use Group: TERRESTRIAL FOOD CROP								
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A *	*	NS NS	NS NS	NS	3 d			C13, C46, C92, CAS
STRAWBERRY			Use Group: TERRESTRIAL FOOD CROP								
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A *	*	NS NS	NS NS	NS	3 d			C13, C46, C92, CAS
SUGAR BEET			Use Group: TERRESTRIAL FOOD+FEED CROP								
Broadcast, Preplant, Plowsole or chisels	RTU	NA	UC 189.6 lb A *	*	NS NS	NS NS	NS	5 d			C13, C46, CAL, CAU
Soil band treatment, Preplant, Chisel	RTU	NA	4.289 lb 1K linear ft 4.211 lb A *	*	NS NS	NS NS	NS	5 d			C13, C46, CAL, CAU

APPENDIX A REPORT

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop	/year	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)													
SUGAR BEET (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	181.8 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
SUGARCANE			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
SWEET POTATO			Use Group: TERRESTRIAL FOOD CROP										
Broadcast, Preplant, Plowsole or chisels	RTU	NA	265.5 lb A	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
Soil band treatment, Preplant, Chisel	RTU	NA	5.977 lb [illegible] linear [illegible] 456.7 lb A	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
TANGELO			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
TANGERINES			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
TOMATO			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
TREE NUTS			Use Group: TERRESTRIAL FOOD+FEED CROP										
Broadcast, Preplant, Plowsole or chisels	RTU	NA	373.68 lb A	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU

APPENDIX A REPORT

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	# Max. Rate /crop cycle	# Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)													
TREE NUTS (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)										
Soil band treatment, Preplant, Chisel	RTU	NA	9.748 lb 1K linear ft	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	353.5 lb A	*	NS	NS	NS	NS	NS	5 d			C13, C46, C92, CAS
TREFOIL			Use Group: TERRESTRIAL FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
TURNIP			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
VEGETABLES (UNSPECIFIED)			Use Group: TERRESTRIAL FOOD+FEED CROP										
Broadcast, Preplant, Plowsole or chisels	RTU	NA	252.5 lb A	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
Soil band treatment, Preplant, Chisel	RTU	NA	6.964 lb 1K linear ft	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	252.5 lb A	*	NS	NS	NS	NS	NS	5 d			C13, C46, C92, CAS
VETCH			Use Group: TERRESTRIAL FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
WALNUT (ENGLISH/BLACK)			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS

APPENDIX A REPORT

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)													
WHEAT			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
YOUNGBERRY			Use Group: TERRESTRIAL FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
NON-FOOD/NON-FEED													
FOREST TREES (ALL OR UNSPECIFIED)			Use Group: FORESTRY										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
KENAF			Use Group: TERRESTRIAL NON-FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
ORNAMENTAL AND/OR SHADE TREES			Use Group: TERRESTRIAL NON-FOOD CROP										
Broadcast, Preplant, Plowsole or chisels	RTU	NA	587.52 lb A	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
Soil band treatment, Preplant, Chisel	RTU	NA	15.32 lb 1K linear ft 392.85 lb A	* *	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	1030.2 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS
	RTU	NA	555.5 lb A	*	NS	NS	NS	NS	NS	5 d			C13, C46, C92, CAS
ORNAMENTAL HERBACEOUS PLANTS			Use Group: TERRESTRIAL NON-FOOD CROP										
Broadcast, Preplant, Plowsole or chisels	RTU	NA	587.52 lb A	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU

APPENDIX A REPORT

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop	/year	Max. Dose (AI unless noted otherwise)/A /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
NON-FOOD/NON-FEED (con't)													
ORNAMENTAL HERBACEOUS PLANTS (con't)			Use Group: TERRESTRIAL NON-FOOD CROP (con't)										
Soil band treatment, Preplant, Chisel	RTU	NA	15.32 lb 1K linear ft 392.85 lb A *	NS	NS	NS	NS	NS	5 d				C13, C46, CAL, CAU
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A *	NS	NS	NS	NS	NS	3 d				C13, C46, C92, CAS
	RTU	NA	555.5 lb A *	NS	NS	NS	NS	NS	5 d				C13, C46, C92, CAS
ORNAMENTAL LAWNS AND TURF			Use Group: TERRESTRIAL NON-FOOD CROP										
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A *	NS	NS	NS	NS	NS	3 d				C13, C46, C92, CAS
ORNAMENTAL NONFLOWERING PLANTS			Use Group: TERRESTRIAL NON-FOOD CROP										
Broadcast, Preplant, Plowsole or chisels	RTU	NA	587.52 lb A *	NS	NS	NS	NS	NS	5 d				C13, C46, CAL, CAU
Soil band treatment, Preplant, Chisel	RTU	NA	15.32 lb 1K linear ft 392.85 lb A *	NS	NS	NS	NS	NS	5 d				C13, C46, CAL, CAU
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	555.5 lb A *	NS	NS	NS	NS	NS	5 d				C13, C46, C92, CAS
ORNAMENTAL WOODY SHRUBS AND VINES			Use Group: TERRESTRIAL NON-FOOD CROP										
Broadcast, Preplant, Plowsole or chisels	RTU	NA	587.52 lb A *	NS	NS	NS	NS	NS	5 d				C13, C46, CAL, CAU
Soil band treatment, Preplant, Chisel	RTU	NA	15.32 lb 1K linear ft 392.85 lb A *	NS	NS	NS	NS	NS	5 d				C13, C46, CAL, CAU
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A *	NS	NS	NS	NS	NS	3 d				C13, C46, C92, CAS
	RTU	NA	555.5 lb A *	NS	NS	NS	NS	NS	5 d				C13, C46, C92, CAS

APPENDIX A REPORT

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. # Apps @ Max. Rate /crop cycle	Max. # Apps @ Max. Rate /year	Max. Dose (AI unless noted otherwise)/A /crop cycle	Max. Dose (AI unless noted otherwise)/A /year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
NON-FOOD/NON-FEED (con't)													
TOBACCO			Use Group: TERRESTRIAL NON-FOOD CROP										
Broadcast, Preplant, Plowsole or chisels	RTU	NA	192.24 lb A	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
Soil band treatment, Preplant, Chisel	RTU	NA	5.012 lb 1K linear ft	*	NS	NS	NS	NS	NS	5 d			C13, C46, CAL, CAU
Soil fumigation, Preplant, Plowsole or chisels	RTU	NA	363.6 lb A	*	NS	NS	NS	NS	NS	3 d			C13, C46, C92, CAS

APPENDIX A REPORT

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

LEGEND

Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	: Minimum dose for a single application to a single site. System calculated. Antimicrobial claims only.
Max. Appl. Rate (AI unless noted otherwise)	: Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose	: Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate	: Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A]	: Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days)	: Minimum Interval between Applications (days)
Re-Entry Intv.	: Reentry Intervals
PRD Report Date	: LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

*	: Non-specific
C	: Coarse
M	: Medium
F	: Fine
O	: Others

FORMULATION CODES

RTU	: LIQUID-READY TO USE

ABBREVIATIONS

AN	: As Needed
NA	: Not Applicable
NS	: Not Specified (on label)
UC	: Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE

DCNC	: Dosage Can Not be Calculated
No Calc	: No Calculation can be made
W	: PPM calculated by weight
V	: PPM Calculated by volume
U	: Unknown whether PPM is given by weight or by volume

APPENDIX A REPORT

Case 0328 [Telone] Chemical 029001 [1,3-Dichloropropene]

APPLICATION RATE (CONT.)
cwt : Hundred Weight
nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES
C13 : Groundwater restriction.
C46 : Do not apply through any type of irrigation system.
C92 : For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.
CAL : Do not contaminate water, food or feed.
CAS : Do not contaminate food or feed.
CAU : Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES
AZ : Arizona
ID : Idaho
OR : Oregon
WA : Washington

REENTRY INTERVAL ABBREVIATIONS
d : day(s)

UNIT DESCRIPTIONS
A : acre
lb : pound
linear ft : linear foot

Pesticides Home
Regulating Pesticides Home
Reregistration Home
About Reregistration
Product Reregistration
Public Participation
Reregistration Status
Progress & Status Reports

Updated RED Fact Sheet: 1, 3-Dichloropropene (1, 3-D)

August 2008

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 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 that describe 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 meet current human health and safety standards and can be used without posing unreasonable risks to human health and the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document.

The 1, 3-D RED was completed in 1998. However, for comparative purposes revised risk assessments for 1, 3-D were completed concurrently with the other fumigants (methyl bromide, chloropicrin, metam sodium/metam potassium, and dazomet) as these fumigants went through the reregistration process. The Agency evaluated these soil fumigants at the same time to ensure that human health risk assessment approaches are consistent, and that risk tradeoffs and economic outcomes were considered appropriately in reaching risk management decisions. This review is part of EPA's program to ensure that all pesticides meet current health and safety standards.

The following is the mitigation required from the 1998 1, 3-D RED and previous negotiations:

- Lowered maximum application rates (rate decrease depends on the crop)
- Deletion of selected use sites
- Closed loading requirements
- Technology to minimize spillage during the application
- Improved product stewardship materials
- Additional PPE: coveralls over short-sleeved shirt and short pants, chemical resistant gloves and footwear, chemical resistant apron (for direct handlers), respirator requirements for all handlers except those in certain closed cabs
- Restricted entry interval increased to 5 days
- Soil moisture and sealing requirements
- Modified application techniques
- 300 foot buffer from occupied structures
- Loading requirements
- Ground water advisory
- Prohibition of use in northern tier states, ND, SD, WI, MN, NY, ME, NH, VT, MA, UT, MT with shallow groundwater and vulnerable soils
- 100 foot buffer between drinking water wells and treated fields
- Prohibition of use in areas overlaying karst geology

Since the 1998 RED, the following changes have been made:

- The prohibition of use in areas overlying karst geology was changed to prohibit application

within 100 feet of karst topographical features.
- The 300 foot buffer from occupied structures was changed to 100 feet from occupied structures for some products.
- A tolerance was established in/on grape at 0.018 ppm when 1, 3-D is applied via drip irrigation in established vineyards.

The Agency believes that mitigation required as part of the 1998 RED and the subsequent changes address the risks of concern for 1, 3-D. Although no new risks of concern have been identified for 1, 3-D, due to the complex nature of soil fumigation, the Agency believes that mitigation currently being required for the other fumigants in the group, for example fumigant management plans, handler training, emergency preparedness and response, may also be appropriate for 1, 3-D and will consider whether to add these measures to 1, 3-D products.

EPA plans to reevaluate the soil fumigants as a group again beginning in 2013 as part of the registration review program. EPA may also consider additional mitigation measures during other regulatory reviews of 1, 3-D.

The RED requirements for the other soil fumigants are not currently applicable to products that contain 1, 3-D only. However for 1, 3-D products that contain chloropicrin, the labels must be revised to reflect the mitigation required in the chloropicrin RED.

For More Information

An electronic version of the 1, 3-D RED is available at https://www.epa.gov/pesticides/reregistration/telone/. Supporting documents are also available in the 1, 3-D docket, EPA-HQ-OPP-2005-0124 at http://www.regulations.gov. For more information about EPA's pesticide reregistration program, please contact the Special Review and Reregistration Division (7508P), Office of Pesticide Programs, 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 Pesticide Information Center (NPIC). Call toll-free 1-800-858-7378, from 6:30 am to 4:30 pm Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, Monday through Saturday. The NPIC internet address is http://npic.orst.edu.