United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508C)
EPA 738-R-98-021
December 1998

Reregistration Eligibility Decision (RED)

Methomyl

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 methomyl. The enclosed Reregistration Eligibility Decision (RED), which was approved on September 29, 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 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 Bonnie Adler (703) 308-8523. Address any questions on required generic data to the Special Review and Reregistration Division representative Tom Myers (703) 308-8589.

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) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; otherwise, your product may be suspended.**

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

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

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

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

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

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

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

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

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

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

By U.S. Mail:

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

By Express:

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

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

REREGISTRATION ELIGIBILITY DECISION

METHOMYL

LIST A

CASE 0028

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

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METHOMYL REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

William Gross	Biological Analysis Branch
Jihad Alsadek	Economic Analysis Branch

Environmental Fate and Effects Risk Assessment

Jose Melendez	Environmental Risk Branch IV
Nick Federoff	Environmental Risk Branch IV
Richard Felthousen	Environmental Risk Branch IV
Nelson Thurman	Environmental Risk Branch IV
Ann Stavola	Environmental Risk Branch IV

Health Effects Risk Assessment

Yung Yang	Toxicology Branch I
John Leahy	Chemistry and Exposure Branch I
Brian Steinwand	Chemistry and Exposure Branch I
Cathy Eiden	Risk Characterization and Analysis Branch

Registration Support Risk Assessment

Tom Harris	Insecticide-Rodenticide Branch

Risk Management

Tom Myers	Reregistration Branch II

GLOSSARY OF TERMS AND ABBREVIATIONS

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.
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
FRSTR	Final Registration Standard and Tolerance Reassessment
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
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
MUP	Manufacturing-Use Product
MPI	Maximum Permissible Intake

GLOSSARY OF TERMS AND ABBREVIATIONS

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

EXECUTIVE SUMMARY

Background

This Reregistration Eligibility Decision (RED) document addresses the reregistration eligibility of the pesticide methomyl, S-methyl N-((methylcarbamoyl)oxy) thioacetimidate. Methomyl is a carbamate registered on a wide variety of sites including field, vegetable, and orchard crops; turf (sod farms only); livestock quarters; commercial premises; and refuse containers. Methomyl acts as an insecticide against Lepidopterous, suppresses Coleopterous and some Hemipterous insect pests. Methomyl acts as an ovicide against cotton bollworms and budworms.

Methomyl was first registered in the United States in October, 1968. All methomyl products, except the 1% bait formulations, are classified as restricted use pesticides. A Registration Standard issued in April, 1989 required additional testing, modified tolerances, and required label modifications related to applicator safety, reentry intervals, and environmental hazards.

Reregistration Eligibility

EPA has completed its reregistration eligibility decision of the pesticide methomyl. This decision includes a comprehensive reassessment of the required target data and the use patterns of currently registered products. This decision considered the requirements of the “Food Quality Protection Act of 1996" (FQPA, Public Law 104-170) that amended the Federal Food Drug and Cosmetic Act and the Federal Insecticide, Fungicide and Rodenticide Act. These are the two Federal statutes that provide the framework for pesticide regulation in the United States. FQPA became effective immediately upon signature. All reregistration eligibility decisions signed after August 3, 1996 are, accordingly, being evaluated under the new standards imposed by FQPA.

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

In determining whether to retain, reduce, or remove the 10x FQPA safety factor for infants and children, EPA uses a weight of evidence approach taking into account the completeness and adequacy of the toxicity data base, and the nature and severity of the effects observed in pre- and post-natal studies. Although the data provided no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to methomyl, data gaps exists for the acute and subchronic neurotoxicity studies. These studies would have yielded cholinesterase inhibition and field observation behavior data, as well as histopathology of the

central and peripheral nervous system which are not presently available for evaluation. The Agency determined that the 10x safety factor to account for increased sensitivity of infants and children should be reduced from 10x to 3x. Regarding aggregate exposure, the Agency only considered dietary exposure from food and water because there are no homeowner uses of methomyl.

The Agency has determined that methomyl is a degradate of thiodicarb, which is a registered pesticide. Therefore, methomyl residues resulting from applications of both thiodicarb and methomyl have been considered in an aggregate risk assessment and compared to appropriate toxicological endpoints for methomyl.

The Agency does not have, at this time, available data to determine whether methomyl has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this assessment, therefore, the Agency has not assumed that methomyl has a common mechanism of toxicity with other substances.

The Agency has determined that methomyl, labeled and used as specified in this Reregistration Eligibility Decision document, will not cause unreasonable risks to humans or the environment and that these uses are eligible for reregistration. The Agency is requiring additional data for toxicology, ecological effects, and residue chemistry that are expected to confirm the risk assessment.

Health Effects

Methomyl was classified by the HED/RfD/Peer Review Committee as Group E, that is, not likely to be carcinogenic to humans via relevant routes of exposure.

The RfD for methomyl was calculated to be 0.008 mg/kg/day from a two-year feeding study in dogs with a NOEL of 2.5 mg/kg/day for males and females. The LOEL was 10 mg/kg/day based on histopathological effects in the kidney. An uncertainty factor (UF) of 100 was applied to account for intraspecies variability and interspecies extrapolation together with a safety factor of 3x for FQPA, based on the lack of acute and subchronic neurotoxicity studies (data gaps).

The results of the Monte Carlo acute dietary exposure analyses, for methomyl only, indicate that there are adequate margins of exposure for the general U.S. population (MOE=958), children 1 to 6 years of age (MOE=417), and infants (MOE=1117) from the application of methomyl. For this analysis, percent crop treated information and field trial residue data were utilized for all commodities.

The results of the acute aggregate exposure analyses for food, for thiodicarb and methomyl, were compared to the methomyl acute dietary NOEL of 6 mg/kg/day. There are adequate margins of exposure for the general U.S. population (MOE=912), children 1 to 6 years

of age (MOE=417) and infants (MOE=756). This analysis used a Monte Carlo simulation which included anticipated residues and percent crop treated information for all commodities.

The results of the chronic dietary risk evaluation system (DRES) analyses, for methomyl only, indicate that the anticipated residue contribution for infants occupies 67% of the RfD. For children 1-6 years old 62.6% of the RfD is occupied and for the general U.S. population, 35% of the RfD is occupied. For this analysis, anticipated residues were determined for only five of the approximately 70 commodities and percent crop treated information was used for all commodities.

Results of the chronic aggregate exposure analyses for food, for thiodicarb and methomyl, show that the most significantly exposed subpopulation is infants (<1 year old) with 6.5% of the RfD occupied. For children 1-6 years old 2.7% of the RfD is occupied. For the general U.S. population, only 1.9% of the RfD is occupied. For this aggregate exposure analysis, anticipated residues and percent crop treated information were utilized for all of the approximately 70 commodities, which is why the numbers are lower when compared to the analysis for methomyl alone, where anticipated residues were used for only 5 commodities.

The Agency has calculated drinking water levels of concern for acute exposure to methomyl in surface and ground water for the U.S. population and children (1-6 yrs.). They are 470 and 56 ppb, for the U.S. population and children, respectively. For chronic (non-cancer) exposure to methomyl in surface and ground water, the drinking water levels of concern are 275 and 78 ppb for U.S. population and children (1-6 yrs old), respectively.

Estimated maximum (acute exposure) concentrations of methomyl in surface and ground water are 30 and 20 ppb, respectively. The estimated average (chronic exposure) concentration of methomyl in surface water is 26 ppb. Average concentrations in ground water are not expected to be higher than the maximum concentrations. The maximum estimated concentrations of methomyl in surface and ground water are less than the Agency's levels of concern for methomyl in drinking water as a contribution to acute aggregate exposure. The estimated average concentrations of methomyl in surface and ground water are less than the Agency's levels of concern for methomyl in drinking water as a contribution to chronic aggregate exposure.

Therefore, the Agency concludes that aggregate exposure to all sources of methomyl does not exceed the Agency's risk concerns.

To minimize the risks of potential systemic toxicity to mixers/loaders the Agency is requiring the use of personal protective equipment and/or the use of engineering controls.

Environmental Fate and Ecological Effects

Laboratory studies indicate that methomyl is moderately persistent and highly mobile. It is stable to hydrolysis at lower pH's (neutral to acidic) and degrades slowly in alkaline conditions.

Methomyl photolyzes quickly in water but more slowly in soils. It is moderately stable to aerobic soil metabolism but degrades more rapidly under anaerobic conditions. In laboratory studies, methomyl does not readily adsorb to soil and has the potential to be very mobile. Field studies show varying dissipation rates of the chemical in soils. Dissipation rates were related primarily to differences in soil moisture content, which may affect the microbial activity, and rainfall/irrigation, which could influence leaching.

Methomyl has been detected in ground water in a prospective ground water monitoring study and in other reported incidences. While it may reach ground water under certain conditions, methomyl will not likely persist under many conditions. Methomyl can contaminate surface water as a result of spray drift during application or by runoff from treated sites. Methomyl would not be expected to persist in clear, shallow waters because of its susceptibility to photolysis.

The major concerns for non-target organisms are chronic risks to non-target mammalian and freshwater invertebrate organisms. Risks to aquatic invertebrates from exposure to methomyl are likely to occur wherever methomyl is used. Accumulation of methomyl from repeated applications contributes to the chronic risks.

Risk to non-target mammalian and freshwater invertebrate organisms have been addressed by reducing the highest seasonal use rates between 11 to 20 percent on eight crops. These crops are generally the crops for which most methomyl is sold. The highest single application rate will be reduced by 50 percent (from 1.8 pounds to 0.9 pounds). No crop will have a single application rate above 0.9 pounds of methomyl per acre. These measures will result in less loading of methomyl in the environment. Reductions in risk to non-target aquatic organisms is also expected from measures that reduce the potential for spray drift during aerial or ground applications. Risk mitigation through spray drift control requirements and buffer zones was imposed. In addition, label statements are required to minimize the potential for ground water and surface water contamination. A statement supporting the use of an Integrated Pest Management (IPM) plan will also be added to the labels.

Product Reregistration

Before reregistering the products containing methomyl, 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 and acute toxicity testing for each registration. After reviewing these data and the revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

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

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

On August 3, 1996, the 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 the Federal Insecticide, Fungicide, and Rodenticide Act (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. The FQPA did not, however, amend any of the existing reregistration deadlines in section 4 of FIFRA. The Agency, will therefore, 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 methomyl. The document consists of six sections. Section I is the introduction. Section II describes methomyl, 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 methomyl. Section V discusses the reregistration requirements for methomyl. Finally, Section VI contains the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Methomyl
- **Chemical Name:** S-methyl N-((methylcarbamoyl)oxy) thioacetimidate
- **Chemical Family:** Carbamate
- **CAS Registry Number:** 16752-77-5
- **OPP Chemical Code:** 090301
- **Empirical Formula:** $C_5H_{10}N_2O_2S$
- **Trade and Other Names:** Lannate
- **Basic Manufacturer:** E.I. du Pont de Nemours and Company Inc.

B. Use Profile

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

Type of Pesticide: carbamate insecticide and molluscicide

Use Sites:

TERRESTRIAL FOOD CROP
leafy vegetables, cucumber, cucurbit vegetables, melons, melons (cantaloupe), melons (water), pumpkin, squash (summer), eggplant, beets, groundcherry (strawberry tomato/tomatillo), pepper, broccoli, broccoli raab, broccoli (chinese), brussels sprouts, cabbage, cabbage (chinese), cauliflower, celery, chard (swiss), chicory, collards, dandelion, endive (escarole), fennel, kale, lettuce, lettuce (head), lettuce leaf (black seeded simpson, salad bowl, etc.), parsley, spinach, avocado, pomegranate, asparagus, onions (green and bulb), pecan, pear, artichoke (Jerusalem), beets (roots and tops), carrot (roots and tops), garlic, horseradish, radish, sweet potato, blueberry, strawberry, nectarine, peach, grapefruit, lemon, orange, tangelo, tangerines, mint, peppermint, spearmint, tomato, barley, oats, rye, wheat, corn (field), corn (pop), corn (sweet), corn (unspecified), cotton (unspecified), peanuts (unspecified), sorghum (unspecified), soybeans (unspecified), mustard (greens), turnip (greens), apple, potato (white/Irish), onion, beans (dried-type), beans (succulent), lentils, peas (field), peas (succulent), peas (unspecified), grapes, sugar beet.

TERRESTRIAL FEED CROP
bermudagrass, alfalfa, lentils, sugar beets (including tops).

TERRESTRIAL NON-FOOD CROP
commercial/institutional/industrial premises/equipment (outdoor), manure, cattle/swine feedlots and surrounding areas, recreational areas, refuse/solid waste sites (outdoor), tobacco, animal kennels/sleeping quarters (commercial), turf sod farms, tree nuts (non-bearing), deciduous fruit trees (non-bearing).

INDOOR FOOD
agricultural/farm structures/buildings and equipment, dairy farm milk handling facilities and equipment, livestock, food/meat/dairy/poultry processing plant, premises/equipment, food/grocery marketing/storage/distribution.

INDOOR NON-FOOD
agricultural/farm structures/buildings and equipment, silos, commercial/industrial/institutional premises and equipment, commercial storages/warehouses premises (indoor), eating establishments, egg handling facilities and equipment, fur and wool bearing animals, fur farm equipment/premises, rabbits, animal kennels/sleeping quarters (commercial), horses (show/race/special/ponies), incinerators.

Target Pests:

Invertebrates (insects and related organisms, molluscs, fouling organisms and miscellaneous invertebrates). Including: alfalfa blotch leafminer, alfalfa caterpillar, alfalfa looper, alfalfa weevil (larvae), aphids, apple aphid, armyworm and eggs, asparagus beetle, aster leafhopper, avocado leafroller, avocado looper, bean leaf beetle, beet armyworm and larvae, beet webworm, black bean aphid, black cutworm, blueberry budmoth, blueberry leafhopper, blueberry leafroller, blueberry maggot, bollworm and eggs/larvae, budworms, cabbage looper, cabbageworms, carrion beetle, catfacing insects, cereal leaf beetle, chaff scale, cherry fruitworm, citrus cutworm, climbing cutworms, codling moth,corn earworm and larvae/eggs, corn rootworm beetles (adult), corn rootworms (adult), cotton aphid, cotton fleahopper, cotton leaf perforator (larvae), cotton leafworm, cranberry fruitworm, crickets, cucumber beetles, cutworms, darkling ground beetles, diamondback cabbage moth, diamondback moth, egyptian alfalfa weevil (larvae), european corn borer and eggs/larvae, fall armyworm and larvae, flea beetles and larvae, forest tent caterpillar, fruittree leafroller, fruitworms, glover scale, granulate cutworm, grape berry moth, grape leaffolder, grapeleaf skeletonizer, grasshoppers, green cloverworm, green fruitworm, green peach aphid, hornworms, house fly, imported cabbageworm,leafhoppers, lesser appleworm, loopers, lygus bugs (adults and nymphs), melon aphid, melonworm, mexican bean beetle, mint flea beetle, obliquebanded leafroller, omnivorous leafroller, omnivorous leaftier, omnivorous looper, orange tortrix, oriental fruit moth, pea aphid, peach twig borer, pickleworm, picnic beetle, plant bugs, potato leafhopper, potato tuberworm, purple scale, redbacked cutworm, redbanded leafroller, rosy apple aphid, saltmarsh caterpillar, sawflies (larvae), sharpnosed leafhopper, silverspotted skipper, sod webworms, soft brown scale, sorghum midge, sorghum webworm, southern armyworm, soybean looper and larvae, spirea aphid, spotted asparagus beetle, spotted cucumber beetle, spruce budworm (larvae), stink bugs, striped grass loopers, tarnished plant bug, tentiform leafminers, thrips, tobacco budworm and eggs/larvae, tomato fruitworm, tomato hornworm, tomato pinworm, tubeworms, tufted apple bud moth, tussock moths, variegated cutworm, variegated leafroller, velvetbean caterpillar, weevils, western flower thrips, western tent caterpillar, western tussock moth, western yellowstriped armyworm, white apple leafhopper, white cutworm, whiteflies, yellow scale and yellowstriped armyworm.

Types/Formulations Registered:
Manufacturing product, bait/solid, dust, granular, soluble concentrate/liquid and solid.

Methods and Rates of Application:
Types of Treatment: Bait application; Band treatment; Broadcast; Brush-on; Dust; Feed lot treatment; Foliar treatment; Ground spray; High volume spray (dilute);

Low volume spray (concentrate); Outdoor premise treatment; Soil band treatment; Spray; Ultra low volume spray.

Equipment: Aircraft; bait box; brush; cup; duster; glove; granule applicator; ground; high volume ground sprayer; low volume ground sprayer; package applicator; scoop; shaker can; shaker jar; sprayer; ultra low volume sprayer

Rates: See Appendix A

Timing: Normally applied when pest pressure is highest on a "When Needed" basis. With fruit crops during the bloom, petal fall, prebloom and leaf stages. On corn, can be applied during the whorl/foliar stages. With other crops, application is during the foliar or leaf stages of the crop.

Use Practice Limitations: (these do not apply to all uses on all products)
Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes).
Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.
Do not apply directly to water.
Do not apply in residential areas.
Do not apply through any type of irrigation system.
Do not apply to food or feed contact surfaces.
Do not apply where runoff is likely to occur.
Do not contaminate food or feed.
Do not contaminate water, food or feed.
Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority (POTW).
Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).
Do not discharge into lakes, streams, ponds, or publicwater unless in accordance with NPDES Permit.
Do not make more than _____ applications per crop cycle (10, 3).
Do not place in locations accessible to children, pets or domestic animals.
Do not store or use in or around the home or home garden.
Do not use in homes.
Do not use in milking stalls, milking parlors, or milk houses.
Endangered species restriction.
Keep out of lakes, streams, and ponds.
Keep out of lakes, streams, ponds, tidal marshes, and estuaries.
Preharvest interval not located on the label.
Proper ventilation required
Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas.

__ day(s) prefeeding interval (10, 12, 3).
__ day(s) pregrazing interval (10, 3).
__ day(s) preharvest interval (1, 10, 14, 15).

Site/Application Limitations: (these apply to specific methods and rates of application)
Do not make more than _____ applications per crop cycle (6, 10).
__ day(s) pregrazing interval (3, 5, 7, 10, 14, 30).
Do not graze livestock in treated areas.
__ day(s) prefeeding interval (3, 7, 10, 12, 14, 21, 30).
Do not feed to livestock.
Do not feed or graze animals on treated areas.
Do not feed treated forage to livestock.
Do not feed treated vines to livestock
__ day(s) preharvest interval. (0, 1, 2, 3, 4, 5, 6, 7, 10, 14, 15, 21, 25, 30, 40, 65, 80)

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticidal uses of methomyl. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability that results from using data from various information sources.

An estimated 2.5 to 3.5 million pounds active ingredient of methomyl are applied annually in the U.S. Almost 100 percent of lettuce, artichokes, asparagus, okra, oriental vegetables, and rhubarb are treated. Almost 75 percent of pomegranates are treated. Between 50 and 60 percent of peppers (sweet), sweet corn and sweet corn (fresh) are treated. Between 40 to 50 percent of cabbbage, cole crops, eggplants/peppers and tomatoes (fresh) are treated.

The table on the following pages shows the estimated typical annual usage of methomyl.

COLUMN HEADINGS

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

NOTES ON TABLE DATA

Usage data primarily covers 1987 - 1995.
Calculations of the numbers may not appear to agree because they are displayed as rounded:
to the nearest 1000 for acres treated or lb. a.i. (Therefore 0 = < 500)
to the nearest whole percentage point for % of crop treated. (Therefore 0% = < 0.5%)

0 = Available EPA sources indicate that no usage is observed in the reported data for this site, which implies that there is little or no usage.

Definition of Crop Groups

Citrus, Other includes kumquats, limes, tangelos, and tangerines.
Cole Crops includes broccoli, Brussels sprouts, cabbage, cauliflower, mustard greens, collards, bok choy, and chard.
Cucurbits includes cucumber, squash, and pumpkin.
Leafy Vegetables, Other includes celery, kale, parsley, and spinach.
Melons includes cantaloupe, watermelon, honeydew, muskmelon, and winter melon.
Nut Trees, Other includes chestnuts, filberts, hazelnuts, hickory nuts, macadamia nuts, pistachios, lychie nuts, and palm.
Pome-Like Fruit, Other includes figs, kiwifruit, persimmons, pomegranates, carambolas, and papaya.
Root and Tuber Crops includes red beets, carrots, horseradish, parsnips, radish, rutabagas, sweet potatoes, turnips, and yams.
Stone-Like Fruit, Other includes apricots, avocados, dates, nectarines, olives, coconuts, mangoes, and feijoa.
Vegetables, Other includes, artichokes, aspargus, okra, oriental vegetables, rhubarb, and truck garden.
Other Crops includes ornamentals, popcorn, rapeseed/canola, and safflower.

SOURCES: EPA data, USDA, and National Center for Food and Agricultural Policy

Table 1 - Estimated Typical Annual Usage of Methomyl

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb ai/ acre/yr	#appl / yr	lb ai/ A/appl	(% of total lb ai used on this site)
Alfalfa	23,949	215	410	1%	2%	94	186	0.4	1.0	0.4	CA AZ NM 83%
Almonds	429	0	0	0%	0%	0	0	1.3	1.0	1.3	CA 100%
Apples	572	132	245	23%	43%	80	150	0.6	1.0	0.6	MI PA VA NY WV MD 86%
Beans, Lima, Fresh	6	1	2	16%	38%	1	2	1.1	2.3	0.5	GA 100%
Beans/Peas, Dry	2,051	13	53	<1%	3%	6	26	0.5	1.0	0.5	OR CA TX 80%
-Beans, Dry	1,802	11	45	1%	0.03	5	20	0.5	1.0	0.5	CA 100%
-Peas ,Dry	249	2	8	1%	0.03	1	6	0.7	1.0	0.7	CA 92%
Beans, Green	304	57	103	19%	34%	25	45	0.4406	1.0	0.44065	FL DE CA GA VA 82%
Beans, Snap, Fresh	81	22	40	28%	49%	23	41	1.0	2.6	0.4	FL 86%
Peas, Green	386	14	43	4%	11%	6	18	0.4	1.0	0.4	WA CA NY 92%
Berries	121	37	72	31%	60%	66	133	1.8	1.0	1.8	CA FL NJ LA 86%
-Blueberries	59	22	43	37%	73%	19	39	0.9	2.0	0.4	MI NJ 99%
-Raspberries	11	0	0	0%	4%	0	1	1.8	1.0	1.8	OH 100%
-Strawberries	51	15	29	29%	57%	47	93	3.2	6.4	0.5	FL CA 100%
Cabbage, Fresh	84	31	54	37%	64%	61	106	2.0	3.9	0.5	FL GA TX CA 87%
Cabbage	85	37	65	44%	76%	77	133	2.1	5.5	0.4	FL GA TX CA 88%
Cherries	128	1	2	1%	2%	1	3	1.4	1.0	1.4	MI PA 85%

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb ai/ acre/yr	#appl / yr	lb ai/ A/appl	(% of total lb ai used on this site)
Citrus, Other	51	0	1	1%	2%	0	1	1.0	1.0	1.0	CA AZ FL 100%
Cole Crops	313	151	238	48%	76%	81	131	0.5	1.0	0.5	CA FL AZ TX NC LA 76%
-Broccoli	114	26	52	23%	46%	26	53	1.0	1.6	0.6	CA AZ 94%
-Brussels Sprouts	3	0	0	1%	7%	0	0	0.6	1.0	0.6	CA 100%
-Cauliflower	58	13	26	23%	45%	25	50	1.9	1.8	1.1	CA 82%
-Collards	11	2	5	19%	48%	3	7	1.4	1.0	1.4	AZ GA CA 84%
Corn	72,284	181	458	0%	1%	69	181	0.4	1.0	0.4	TX FL SC GA MO NM 67%
Corn Continuous	27,111	65	198	0%	1%	21	55	0.3	1.0	0.3	FL MA AZ NY LA CA 70%
Cotton	12,689	781	1,627	6%	13%	260	572	0.3	1.0	0.3	MS TX AR LA AZ AL 77%
Cucurbits	261	41	77	16%	30%	46	93	1.1	1.0	1.1	FL TX LA 81%
-Cucumbers	172	27	45	16%	26%	37	81	1.4	1.0	1.4	FL GA NC 85%
--Cucumbers, Fresh	55	14	20	25%	36%	30	64	2.1534	4.1	0.52466	FL 89%
--Cucumbers, Proc.	117	13	25	11%	21%	12	24	0.9	2.2	0.4	FL TX 87%
-Squash	53	12	26	22%	48%	18	40	1.6	1.0	1.6	FL 93%
-Pumpkins	36	2	6	6%	16%	2	5	0.8	1.0	0.8	CA 100%
Eggplant	4	1	3	38%	77%	3	5	1.9	4.9	0.4	FL 85%
Eggplant/Peppers	119	59	119	49%	100%	30	56	0.5	1.0	0.5	FL CA TX LA NC AL 80%
Garlic	25	3	8	13%	31%	1	2	0.2	1.0	0.2	CA 100%

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb ai/ acre/yr	#appl / yr	lb ai/ A/appl	(% of total lb ai used on this site)
Grapefruit	194	2	4	1%	2%	2	3	0.9	1.0	0.9	AZ TX 90%
Grapes	825	59	139	7%	17%	45	102	0.8	1.0	0.8	CA WA 83%
Grapes, Raisin	267	5	21	2%	8%	3	12	0.6	1.0	0.6	CA 100%
Grapes, Table	76	5	12	6%	16%	4	11	0.9	1.0	0.9	
Greens	2	1	2	47%	100%	2	5	1.7	3.1	0.6	AZ 100%
Hay, Other	33,427	17	41	0%	0%	6	19	0.3	1.0	0.3	NC MS FL CA 84%
Lemons	63	5	10	8%	16%	3	5	0.5	1.0	0.5	AZ 94%
Lettuce	519	519	519	100%	100%	350	501	0.7	1.0	0.7	AZ CA 96%
Lettuce, Head	212	157	212	74%	100%	230	387	1.5	2.3	0.6	CA AZ 97%
Lettuce, Other	47	24	41	51%	89%	25	44	1.1	1.7	0.6	CA AZ 99%
Lots/Farmsteads/etc	24,815	3	6	0%	0%	1	2	0.4	1.0	0.4	NM FL AR GA AL LA 66%
Cantaloupes	113	9	15	8%	13%	4	6	0.4	1.0	0.4	CA 80%
Watermelons	258	41	60	16%	23%	33	66	0.8	1.0	0.8	FL GA TX SC CA 82%
Melons, Honeydew	27	3	5	11%	17%	1	3	0.5	1.3	0.4	CA TX 100%
Mint	154	16	38	10%	25%	16	38	1.0	1.0	1.0	IN WI 89%
Nut Trees	712	7	30	1%	4%	3	11	0.4	1.0	0.4	GA 83%
Nut Trees, Other	100	0	4	0%	5%	0	4	1.0	1.0	1.0	PA 100%
Oats	4,525	5	192	0%	4%	3	90	0.5	1.0	0.5	TX NC CA 89%

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb ai/ acre/yr	#appl / yr	lb ai/ A/appl	(% of total lb ai used on this site)
Onions, Dry	157	33	60	21%	38%	48	87	1.4	3.4	0.4	TX CA 93%
Onions, Green	14	2	6	14%	43%	1	4	0.6	1.0	0.6	CA 100%
Oranges	867	18	31	2%	4%	14	28	0.8	1.0	0.8	CA 82%
Pasture	86,960	18	36	0%	0%	9	18	0.5	1.0	0.5	NC 92%
Peaches	212	12	27	6%	13%	8	15	0.7	1.0	0.7	PA CA TX NJ AL GA 64%
Peanuts	1,610	145	344	9%	21%	65	132	0.4	1.0	0.4	GA AL FL 82%
Pears	78	2	4	2%	5%	1	2	0.6	1.0	0.6	CA NY MI PA GA IN 71%
Pecans	488	8	34	2%	7%	3	15	0.4	1.0	0.4	GA AL 93%
Peppers, Bell	55	27	53	49%	97%	57	114	2.1	5.5	0.38446	FL TX 87%
Peppers, Hot	23	0	2	1%	7%	0	1	0.7	1.0	0.7	CA 100%
Peppers, Sweet	77	41	77	52%	100%	84	174	2.1	2.1	1.0	FL NJ TX 83%
Plums & Prunes	140	3	14	2%	10%	3	10	0.8	1.0	0.8	CA AL MI 80%
Pomegranates	3	2	3	69%	100%	2	5	0.9	1.0	0.9	CA 100%
Pome-Like Fruit, Other	29	4	9	13%	30%	3	9	0.9	1.0	0.9	CA FL 100%
Potatoes	1,421	39	124	3%	9%	18	62	0.5	1.0	0.5	FL CA AL PA 88%
Rice	2,921	1	5	0%	0%	0	2	0.4	1.0	0.4	AR CA 100%
Roots/Tubers	244	28	47	11%	19%	18	40	0.7	1.0	0.7	FL CA 83%

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb ai/ acre/yr	#appl / yr	lb ai/ A/appl	(% of total lb ai used on this site)
-Beets	12	1	2	6%	14%	0	1	0.5	1.0	0.5	CA 100%
-Carrots	107	7	15	7%	14%	4	8	0.5	1.3	0.4	CA FL 84%
-Radishes	37	13	23	34%	61%	11	20	0.9	1.0	0.9	FL 100%
-Sweet Potatoes	85	0	4	1%	5%	0	4	0.9	1.0	0.9	CA 100%
Sorghum	11,280	75	211	1%	2%	25	63	0.3	1.0	0.3	TX FL AR LA SC GA 78%
Soybeans	62,879	135	316	0%	1%	44	113	0.3	1.0	0.3	MS GA LA TN NC TX 74%
Spinach, Fresh	19	4	8	22%	43%	3	7	0.8	1.5	0.5	TX CA AZ MD 82%
Stone-Like Fruit, other	189	8	23	4%	12%	7	21	0.9	1.0	0.9	CA 83%
Nectarines	29	10	20	36%	69%	10	19	0.9	1.0	0.9	CA 100%
Sugar Beets	1,415	62	138	4%	10%	33	74	0.5	1.0	0.5	CA ID 95%
Sugarcane	852	6	13	1%	2%	2	4	0.3	1.0	0.3	FL 100%
Summer Fallow	29,040	11	889	0%	3%	5	387	0.4	1.0	0.4	GA 99%
Sunflower	2,745	8	95	0%	3%	5	57	0.6	1.0	0.6	FL 100%
Sweet Corn	784	446	784	57%	100%	180	373	0.4	1.0	0.4	FL GA AR CA WA NJ 71%
Sweet Corn, Fresh	233	134	228	58%	98%	380	643	2.8	8.5	0.3	FL GA CA 85%
Sweet Corn, Proc.	544	18	47	3%	9%	10	25	0.5	1.8	0.3	MN WA IL 100%
Tobacco	695	135	228	19%	33%	61	104	0.5	1.0	0.5	GA KY NC SC 85%

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb ai/ acre/yr	#appl / yr	lb ai/ A/appl	(% of total lb ai used on this site)
Tomatoes	500	255	445	51%	89%	130	190	0.5	1.0	0.5	CA FL AL 88%
Tomatoes, Fresh	136	62	85	45%	62%	110	170	1.8	3.5	0.5	FL CA 94%
Vegetables, Bulb	198	42	80	21%	40%	20	37	0.5	1.0	0.5	TX NM NY 85%
Celery	37	21	29	56%	78%	32	44	1.5	2.2	0.7	CA FL MI 89%
Parsley	2	0	1	19%	80%	0	1	0.6	1.0	0.6	CA 100%
Vegetables, Other	286	286	286	100%	100%	190	355	0.7	1.0	0.7	AZ CA TX FL NM NJ 77%
Asparagus	88	13	25	15%	28%	6	11	0.5	1.0	0.5	CA WA 90%
Walnuts	205	0	0	0%	0%	0	0	0.3	1.0	0.3	CA 100%
Wheat	62,407	94	2,680	0%	4%	42	1,206	0.5	1.0	0.5	MD NC VA 88%
Wheat, Winter	45,854	35	119	0%	0%	20	72	0.6	1.0	0.6	AR NC VA MD 82%
Woodland	62,825	0	0	0%	0%	0	0	1.0	1.0	1.0	FL MI 100%

D. Data Requirements

In addition to data requirements imposed to obtain the original registration of this active ingredient, data were required in the April 1989 Registration Standard for methomyl. Data required included studies on ecological effects, environmental fate, residue chemistry, and mammalian toxicity. Appendix B includes all data requirements identified by the Agency for currently registered uses.

E. Regulatory History

Methomyl was first registered in the United States in October, 1968 by E. I. Dupont de Nemours and Co. for use as an insecticide in commercial plantings of chrysanthemums (use in home planting was specifically prohibited). Cabbage, broccoli, and cauliflower were added on June 18, 1969. Additional sites and pests have been added to the labels over the years. Currently, methomyl is registered on a wide variety of sites including field, vegetable, and orchard crops; turf (sod farms only); livestock quarters; commercial premises; and refuse containers. All uses are agricultural, industrial, or commercial. There are no residential uses of methomyl.

In 1978 all methomyl products were classified as restricted use pesticides except the 90% soluble bag formulations (which became restricted use pesticides in 1989) and 1% bait formulations (which are currently not restricted use products).

The Registration Standard issued in April, 1989 required, in addition to testing, modifying tolerances, and label modifications related to applicator safety, reentry intervals, and environmental hazards.

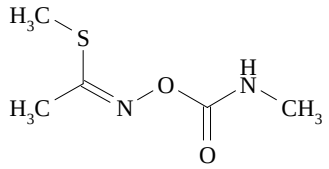
In 1995 as part of a risk mitigation plan, limitations on fly baits were imposed including restricting use to certain commercial agricultural production areas where children would not be present, incorporating an embittering agent into the formulation, using only colors unattractive to children for the final bait formulation, and (for selected uses only) requiring the use of bait stations instead of scattering the bait.

The ornamental and greenhouse uses were voluntarily cancelled in July 1998.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

The following figure shows the chemical structure of methomyl.



Empirical Formula:	$C_5H_{10}N_2O_2S$
Molecular Weight:	162.2
CAS Registry No.:	16752-77-5
OPP Code No.:	090301

Identification of Active Ingredient

Technical methomyl is a white crystalline solid with a slightly sulfurous odor and melting point of 78-79 C. Methomyl is soluble in water (5.8 g/100 g) and in most organic solvents (100 g/100 g methanol; 72 g/100 g acetone; 42 g/100 g ethanol; 22 g/100 g isopropanol; and 3 g/100 g toluene). Methomyl decomposes slowly in water. The rate of degradation increases with temperature, alkalinity, aeration, and sunlight.

Manufacturing-Use Products

There are two methomyl manufacturing-use products (MPs) registered under Shaughnessy No. 090301: the E. I. du Pont de Nemours and Company, Inc. 98% technical (T; EPA Reg. No. 352-366) and 90% formulation intermediate (FI; EPA Reg. No. 352-361). Only the du Pont MPs are subject to a reregistration eligibility decision.

Product Chemistry Data Requirements

All pertinent data requirements are satisfied for the du Pont 98% T and the 90% FI; except for Guideline 830.7050 pertaining to UV/visible absorption for the pure active ingredient. This guideline is required. In addition, the registrant must certify that the suppliers of the beginning materials and the manufacturing processes for the methomyl MPs have not changed since the last comprehensive product chemistry review or submit complete updated product chemistry data packages.

B. Human Health Assessment

1. Toxicology Assessment

The available toxicological database for methomyl is adequate and will support a reregistration eligibility determination. No data are available on the acute and subchronic neurotoxicity of methomyl. Since methomyl is a carbamate and neurotoxic signs have been observed in two species (dogs and rabbits) by two different exposure routes (oral and dermal), acute and subchronic neurotoxicity studies are required.

a. Acute Toxicity

The following table summarizes the results of the acute mammalian toxicity studies conducted with technical methomyl.

Table 2 - Summary of Methhomyl Acute Mammalian Toxicity Studies.

Route	Species	Results	Tox Category
Oral	Rat	LD_{50} (m) = 34 mg/kg LD_{50} (f) = 30 mg/kg	I
Dermal	Rabbit	LD_{50} >2000 mg/kg	III
Inhalation	Rat	LC_{50} = 0.258, mg/L (male and female)	II
Eye Irritation[a]	Rabbit	Corneal opacity	I
Skin Irritation[a]	Rabbit	No Irritation	IV
Dermal Sensitization[a]	Guinea Pig	Not a skin sensitizer	N/A
Delayed Neurotoxicity	Hen	Negative	N/A

[a] Not required for TGAI, however, presented here for informational purposes.

The oral LD_{50} values for methomyl based on rat studies, were 34 and 30 mg/kg in males and females, respectively (Toxicity Category I). Clinical signs observed in all treatment groups of both sexes included tremors, low posture and salivation. (MRID 42140101).

The dermal LD_{50} value for methomyl in rabbits was greater than 2000 mg/kg for both sexes (Toxicity Category III) (MRID 42074602).

The acute inhalation LC_{50} for methomyl was 0.258 mg/L in rats for both sexes (Toxicity Category II), based on a four-hour exposure (nose only) to technical grade methomyl aerosol. (MRID 42140102).

Methomyl is highly toxic *via* ocular exposure. In a primary eye irritation study, a female rabbit treated with 15 mg of technical methomyl (92.4%) died 20 minutes after the treatment with typical cholinergic symptoms indicative of neurotoxicity. Animals treated with 10 mg of methomyl exhibited similar clinical signs of neurotoxicity but survived. At

this dose, corneal opacity and iritis were observed at 1 hour after the treatment and completely reversed by 7 days (MRID 41964001). Another primary eye irritation study in rabbits using a 30.5% methomyl formulation showed corneal opacity and conjunctivitis from 7 to 14 days in washed and unwashed eyes, respectively (MRID 00053407). Primary eye irritation for methomyl is considered to be in Toxicity Category I.

A primary dermal irritation study with technical methomyl in rabbits showed no erythema or edema (Toxicity Category IV) (MRID 42074603). A dermal sensitization study in guinea pigs using technical methomyl showed that the compound is not a skin sensitizer (MRID 42074605).

An acute delayed neurotoxicity study with methomyl in atropine-pretreated hens, using the LD_{50} dose (28 mg/kg) as well as higher doses, was negative. No treatment related effects were observed over the duration of the study (MRID 00008827).

b. Subchronic Toxicity

The following table summarizes the results of the sub-chronic toxicity studies for methomyl.

Table 3 - Summary of Methomyl Sub-Chronic Toxicity Studies

GLN#	Type of Study	NOEL mg/kg/day	LOEL mg/kg/day	Toxic Effects
82-1a	90-day feeding - rat	6.25	12.5	Inhibited body weight gain in both sexes and erythroid hyperplasia in the bone marrow of males.
82-1b	90-day feeding - dog[1]	14.68 males 12.5 females	not established	No apparent treatment-related effects at highest dose tested.
82-2	21-day dermal - rabbit	5	50	Brain and plasma ChE inhibitions.
82-2	21-day dermal - rabbit[2]	90	not established	Lack of toxicologically significant plasma, RBC or brain ChE inhibition at the doses tested.

[1] This study was classified as unacceptable due to deficiencies in the study. However, it is not necessary to repeat the study because sufficient data from a chronic toxicity study in dogs are available.

[2] The NOEL from this study was used as the short term and intermediate term dermal occupational endpoints for risk assessments.

In a 90-day feeding study in rats, Charles River CD rats (10/sex/group) were fed methomyl at dietary levels of 0, 0.5, 2.5 or 12.5 mg/kg/day for 13 weeks. An additional group received 6.25 mg/kg/day of the test material for 6 weeks and 25 mg/kg/day for the remaining 7 weeks. Treatment did not cause increased mortalities. No inhibition of

cholinesterase activity was observed in any treated group. The NOEL is 6.25 mg/kg/day and the LOEL is 12.5 mg/kg/day based on inhibited body weight gain in both sexes and erythroid hyperplasia in the bone marrow of males (MRID 00007190).

In a 90-day feeding study in dogs, beagle dogs (4/sex/group) were fed methomyl at dietary levels of 0, 1.44, 3.18 or 14.68 mg/kg/day, in males and 0, 1.45, 3.01 and 12.5 mg/kg/day, in females. The examination of body weights, food consumption, hematology, clinical chemistry, urinalysis and gross examinations in all treated animals as well as microscopic examinations in control and high-dose dogs did not reveal any apparent treatment-related effects. The NOEL is 14.68 and 12.5 mg/kg/day, respectively, for males and females. These are the highest doses tested. This study is unacceptable because the purity of the test substance and its stability and actual concentration in the diet were not determined and many tissues were not examined microscopically (MRID 00009010). However, since sufficient data from a chronic toxicity study are available, an additional subchronic toxicity study in dogs is not required.

In a 21-day dermal toxicity study, New Zealand White rabbits were dermally exposed to methomyl (98.35%, a.i.) for 21 days at dose levels of 0, 5, 50 or 500 mg/kg/day. Clinical signs included hyperactivity (increased reaction to stimuli-noise) at the high-dose in both sexes. At Day 21, mid- and high-dose males and high-dose females displayed significantly lower plasma cholinesterase (ChE) activity. Mean RBC ChE activity was also decreased, but only slightly, at the high-dose (both sexes). Brain ChE activity was significantly decreased at the high-dose (both sexes). At the mid-dose, although not statistically significant, inhibition of brain ChE activity was indicated (3/5 males and 4/5 females exhibited brain ChE inhibition when compared with controls). The NOEL for systemic toxicity is 5 mg/kg/day and the LOEL is 50 mg/kg/day based on brain and plasma ChE inhibitions. No dermal irritation was observed (MRID 41251501).

In another 21-day dermal toxicity study conducted for better characterization of cholinesterase inhibition, groups of New Zealand White rabbits (6/sex/group) received repeated dermal applications of methomyl (98.6%) at dose levels of 0, 15, 30, 45, or 90 mg/kg/day, 6 hours/day, 7 days/week for 21 consecutive days. No treatment-related deaths or clinical signs of toxicity were observed. Body weight and food consumption were not affected by the treatment. Hematology and clinical chemistry parameters were not measured. Gross pathological examination did not reveal significant effects from the treatment. Histopathological examination was not conducted. There were no statistically or biologically significant differences in plasma or RBC cholinesterase inhibition. Statistically significant decreases were observed in brain ChE in males at doses of $\geq$30 mg/kg/day and in females at 90 mg/kg/day.

However, the Agency did not attribute the statistically significant decreases observed in brain ChEI to treatment, for the following reasons: 1) lack of dose-response in either sex; 2) the values approached the level of sensitivity of the assay itself; 3) there was

concern about inherent variability; 4) lack of convincing evidence in the other two compartments (RBC and plasma) at this dose; 5) lack of clinical signs in this dermal study as opposed to the observance of clinical signs in the oral study in the same species; and 6) lack of toxicity via the dermal route (LD_{50}=2000 mg/kg) when compared to the oral route (NOEL=16 mg/kg/day) in the developmental rabbit study. Therefore, the NOEL was established at 90 mg/kg/day (HDT) for plasma, RBC and brain ChE and a LOEL for ChE was not established in this study (MRID 44436301).

c. Chronic Toxicity and Carcinogenicity

Based on the available chronic toxicity and carcinogenicity studies which demonstrated no evidence of carcinogenicity, methomyl was classified as a Group E, not likely to be carcinogenic to humans via relevant routes of exposure (HED/RfD/ Peer Review Committee document dated October 25, 1996). The following table summarizes the results of the chronic/carcinogenicity toxicity studies for methomyl.

Table 4 - Summary of Methomyl Chronic/Carcinogenicity Toxicity Studies

GLN#	Type of Study	NOEL mg/kg/day	LOEL mg/kg/day	Toxic Effects
83-1a and 83-2a	2-year chronic/ carcinogenicity- rat	5	20	Depressed body weight gain in both male and females rats. No evidence of carcinogenicity from the test material.
83-1b[1]	2-year chronic - dog[1]	2.5	10	Histopathological effects in the kidneys.
83-2b	mice 104-week carcinogenicity	not established	not established	No evidence of carcinogenicity from the test material.

[1] The NOEL from this study was used to calculate the methomyl reference dose (RfD), multiplied by the uncertainty factor of 300.

In a combined chronic toxicity and carcinogenicity study, Charles River CD rats (80/sex/group) were fed diets containing methomyl (99+%) for two years at dose levels of 0, 50, 100 or 400 ppm (0, 2.5, 5.0 or 20.0 mg/kg/day, respectively, based on the standard conversion ratio). No significant toxicity was observed. The NOEL is 100 ppm (5 mg/kg/day) and the LOEL is 400 ppm (20 mg/kg/day) based on depressed body weight gain. Methomyl was not considered carcinogenic because there was no evidence that the test material increased the incidence of any neoplastic lesion. (MRID 00078361).

In a chronic toxicity study, beagle dogs (4/sex/group) were fed diets containing methomyl (90%) at dose levels of 0, 50, 100, 400 or 1000 ppm (0, 1.25, 2.5, 10, or 25 mg/kg/day, respectively, based on the standard conversion ratio) for 24 months. Two males at the 1000 ppm group exhibited tremors, salivation, incoordination, and circling movements during the 13th week of the study. One female in the 1000 ppm group died in the 9th week of the study. A replacement dog exhibited repeated convulsive seizures after

17 days of dosing and died on day 18. There were no significant differences among treatment and the control groups for RBC and plasma ChE activities which were measured at week 9 and week 13 (high dose only) of the study. The NOEL is 100 ppm (2.5 mg/kg/day) and the LOEL is 400 ppm (10.0 mg/kg/day) based on histopathological effects in kidneys manifested as swollen/irregular epithelial cells of the proximal convoluted tubules as well as an increase in the amount of pigment in the cytoplasm of these cells (MRID 00007091).

In a carcinogenicity study, CD-1 mice (80/sex/group) were fed diets containing methomyl (99+%) initially at levels of 0, 7.5, 15 or 120 mg/kg/day. Due to increased mortality, the high dose level was decreased to 60 mg/kg/day at week 28; further, the high and mid dose levels were reduced to 30 and 11.25,mg/kg/day respectively, at week 39 for the same reason. These levels (7.5, 11.25 and 30 mg/kg/day) were maintained for the remainder of the 104 week treatment period. The highest dose level tested in this study was considered to be adequate for carcinogenicity testing based on increased mortality. The treatment did not alter the spontaneous tumor profile in this strain of mice under the test conditions (MRID 00078423).

Other Carcinogenic Issues

Methomyl is a metabolite of and is structurally-related to thiodicarb, a pesticide that was classified as a B2 carcinogen. Although thiodicarb appears to have some carcinogenic concerns, thiodicarb would not be found as a result of application of methomyl. There are two animal metabolites acetamide and acetonitrile. Acetamide, a metabolite of methomyl, has been evaluated by the the Agency and classified as a Group C, possible human carcinogen. However, after a thorough investigation, the Agency concluded that the ingestion of methomyl and acetamide in the diet should not represent a significant carcinogenic hazard to the consuming public based on the following: 1) the conversion rate of methomyl to acetamide is low, approximately 2-3 percent, therefore, residue levels of acetamide in edible meat should be low, 2) carcinogenicity studies with methomyl in two rodent species indicated no increase in any type of tumor under the test conditions, 3) the product is comprised of 98.7 percent syn-isomer and 0.092 percent anti-isomer, syn-isomer must be converted to anti-isomer before acetamide is formed, and 4) acetamide induced liver tumors in rats only when administered at very high dosages, i.e. more than 1000 mg/kg/day. Ingestion of acetonitrile from application of methomyl would not represent a significant carcinogenic hazard because it is volatile, residues are small, it has little or no cancer potential, and since it is a rat metabolite its toxicity was accounted for in the toxicity studies.

d. Developmental and Reproductive Toxicity

The following table summarizes the results of the developmental and reproductive toxicity studies for methomyl.

Table 5 - Summary of Methomyl Developmental and Reproductive Toxicity Studies.

GLN#	Type of Study	NOEL mg/kg/day	LOEL mg/kg/day	Toxic Effects
83-3(a)	developmental - rat	maternal; 9.4 developmental; 33.9 (HDT)	maternal 33.9	Decreased body weight gain and food consumption during gestation.
83-3(b)	developemental - rabbit	maternal; 6 developmental; 16, (HDT)	maternal; 16	Based on mortalities and clinical signs.
83-4	2-generation - rat	offspring; 3.75 parental; 3.75	offspring; 30 parental; 30	Decrease in mean number of live pups and body weights of offspring Decreased body weight and food consumption and altered hematology parameters.

In a developmental toxicity study in rats, methomyl (99%) was administered in the diet to 25 presumed pregnant Charles River-CD (ChR-CD) rats per group at concentrations of 0, 4.9, 9.4 and 33.9 mg/kg/day on gestation days 6 through 16. The data did not reveal any apparent developmental toxicity. The NOEL for maternal toxicity is 9.4 mg/kg/day and the LOEL is 33.9 mg/kg/day based on decreased body weight gain and food consumption during gestation. The NOEL for developmental toxicity is 33.9 mg/kg/day, the highest dose tested (MRID 00008621).

In a developmental toxicity study in rabbits, methomyl (98.7%) was administered *via* stomach tube to 20 presumed pregnant New Zealand white (DLI:NZW) rabbits per group (19 in the high-dose group) at dosages of 0, 2, 6 and 16 mg/kg/day on gestation days 7 through 19. Clinical signs indicated neurotoxic effects in high-dose rabbits. There was no evidence of developmental toxicity in this study. The NOEL for developmental toxicity is 16 mg/kg/day. The NOEL for maternal toxicity is 6 mg/kg/day and the LOEL is 16 mg/kg/day based on mortalities and clinical signs (MRID 00131257).

In a 2-generation reproduction study, Sprague-Dawley rats in the F_0 parental generation were fed methomyl at dose levels of 0, 3.75, 30, or 60 mg/kg/day. The F_1 offspring were treated at the same dosages. There was a dose-related increase in clinical signs involving the nervous system during the first few weeks of the study and the incidence of alopecia was increased in the 30 and 60 mg/kg/day group animals. The NOEL for parental systemic toxicity is 3.75 mg/kg/day and the LOEL is 30 mg/kg/day based on decreased body weight and food consumption and altered hematology parameters. The NOEL for offspring toxicity is 3.75 mg/kg/day and the LOEL is 30

mg/kg/day based on decreases in both the mean number of live pups and mean body weights of offspring (MRIDs 43250701, 43769401).

The data provided no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to methomyl. In the prenatal developmental toxicity studies in rats and rabbits and the two-generation reproduction study in rats, effects in the offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity. There was no assessment of potential susceptibility in the area of functional development.

e. Mutagenicity

Sufficient data are available to satisfy data requirements for mutagenicity testing. Technical methomyl did not induce a genotoxic response in any of the tests listed below.

In a Chinese hamster ovary cells HGPRT forward gene mutation assay, methomyl was negative up to cytotoxic levels ($\geq$40 mM = 6.5 mg/mL -S9; $\geq$150 µM = 0.24 mg/mL +S9) (MRID 00161887).

In a mouse micronucleus assay, methomyl was negative in ICR mice up to an overtly toxic dose (12 mg/kg) administered once by oral gavage. There was no evidence of a cytotoxic effect on the target tissue (MRID 44047703).

An *in vivo* bone marrow cytogenetic assay indicated that the test was negative in Sprague Dawley rats up to an overtly toxic level (20 mg/kg) administered once by oral gavage. Target tissue cytotoxicity was not observed (MRID 00161888).

Methomyl was found to be inactive in a series of USEPA-sponsored mutagenicity studies which included: *Salmonella typhimurium/ Escherichia coli* reverse gene mutation assays, DNA damage studies in bacteria, yeast and human lung fibroblasts, and a *Drosophila melanogaster* sex-linked recessive lethal assay (MRID 00124901).

f. Metabolism

In a metabolism study, male and female CD rats were given a single oral dose of 5 mg/kg of radiolabelled methomyl. Results indicated that methomyl was rapidly absorbed (>95%) and metabolized in both sexes. Approximately 53% of the dose was eliminated in the urine, 22-23% in expired air as $^{14}CO_2$, 12-13% in expired air as ^{14}C-acetonitrile while only 2-3% was eliminated in the feces. The levels found in the carcass and tissues were 8-9% of the dose. The overall elimination half-life was about 5 hours. One major metabolite found in the urine was mercapturic acid derivative of methomyl (approximately 18% of the dose). More than 10 additional minor metabolites were also found including acetonitrile ($\approx$2%), acetate ($\approx$2%), a sulfate conjugate of methomyl oxime ($\approx$4%) and acetamide (0.2-

0.4%). Three major metabolic pathways were discussed in the study. One involves the displacement of the S-methyl moiety of methomyl with glutathione which is then transformed *in vivo* to the corresponding mercapturic derivative. Another major metabolic pathway involves cleavage of the carbamate ester to release the oxime portion of the molecule which may be rapidly metabolized or conjugated. The third pathway involves *in vivo* isomerization of methomyl to the anti-methomyl isomer and then a Beckman re-arrangement and elimination reaction to form acetonitrile which is mostly eliminated in expired air (MRID 42021301).

Another metabolism study was conducted to determine whether or not methomyl undergoes biotransformation to acetamide in a species more closely related to humans. Male cynomolgus monkeys were given a single oral dose (4.8-5.4 mg/kg) of radiolabelled methomyl. Recovery of radioactivity in 48 hours amounting to 64.52-76.2% of the dose in urine, volatiles, and tissues indicated appreciable absorption of methomyl from the GI tract. Approximately 23.5-34.9% of the dose was eliminated in urine and 2.6-4.6% of the dose was eliminated in feces. Elimination in expired air at 48 hours amounted to 3.6-6.8% of the dose as acetonitrile and 31.2-38.2% of the dose as CO_2. After seven days, total radioactive residue in tissue was 4.02-5.4% of the dose. Acetamide excretion in 24-hour urine was 0.3-0.5% of the dose (MRIDs 42379001, 42816701).

2. Dose-Response Assessment

a. Potential Risk to Infants and Children and FQPA Safety Factor

In determining whether to retain, reduce, or remove the 10x FQPA safety factor for infants and children, EPA uses a weight of evidence approach taking into account the completeness and adequacy of the toxicity data base, the nature and severity of the effects observed in pre- and post-natal studies, and other information such as epidemiological data.

For purposes of assessing the pre- and post-natal toxicity of methomyl, EPA has evaluated two developmental studies and one reproduction study. Based on current toxicological data requirements, the data base for methomyl, relative to pre- and post-natal toxicity is complete. The effects observed in the methomyl developmental and reproduction studies are summarized in Table 5, section II, B,d.

The data provided no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to methomyl. In the prenatal developmental toxicity studies in rats and rabbits and the two-generation reproduction study in rats, effects in the offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity.

Although the data provided no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to methomyl, data gaps exists for the acute and subchronic neurotoxicity studies. These studies would have yielded cholinesterase inhibition and field observation behavior data, as well as histopathology of the central and peripheral nervous system which are not presently available for evaluation. These studies are considered data gaps because methomyl has exhibited neurotoxic signs in two species (dogs and rabbits) by two different routes of exposure (oral and dermal). The Agency has determined that the need for a developmental neurotoxicity study should be placed in reserve status pending receipt and review of the acute and subchronic neurotoxicity studies.

FQPA Safety Factor

The 10x Safety Factor for increased susceptibility to infants and children (as required by FQPA) was reduced to 3x (FQPA Safety Factor Committee, April 6, 1998).

In determining whether to retain, reduce, or remove the 10x FQPA safety factor for infants and children, EPA uses a weight of evidence approach taking into account the completeness and adequacy of the toxicity data base, and the nature and severity of the effects observed in pre- and post-natal studies. Although the data provided no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to methomyl, data gaps exists for the acute and subchronic neurotoxicity studies. These studies would have yielded cholinesterase inhibition and field observation behavior data, as well as histopathology of the central and peripheral nervous system which are not presently available for evaluation. The Agency determined that the 10x safety factor to account for increased sensitivity of infants and children should be reduced from 10x to 3x.

The FQPA Safety Factor (3x) should be applied for acute and chronic dietary risk assessments for the General Population including infants and children. Application of the FQPA Safety Factor is appropriate for these risk assessments because of the lack of data on the neurotoxic potential of methomyl following single and repeated exposures (i.e., acute and subchronic neurotoxicity studies).

b. Reference Dose

An RfD was established based on a two-year feeding study in dogs with a NOEL of 2.5 mg/kg/day for males and females. The LOEL was 10 mg/kg/day for males and females, based on histopathological efffects in the kidney (MRID 00007091). An uncertainty factor (UF) of 100 was applied to account for intraspecies variability and interspecies extrapolation together with a safety factor of 3x for the FQPA safety factor based on the lack of acute and subchronic neurotoxicity studies (data gaps). On this basis, the RfD was calculated to be 0.008 mg/kg/day.

Methomyl has been reviewed by the FAO/WHO Joint Committee Meeting (1989) on Pesticide Residues (JMPR) which established an acceptable daily intake (ADI) of 0.03 mg/kg/day.

c. Carcinogenicity Classification and Risk Quantification

The Agency has classified methomyl as a Group E, not likely to be carcinogenic to humans via relevant routes of exposure based on the results of the chronic toxicity and carcinogenicity studies conducted with methomyl which showed no evidence of carcinogenicity (HED/RfD/ Peer Review Committee, 1996).

d. Toxicological Endpoints

The following toxicological endpoints were selected for methomyl (Hazard Identification Assessment Review Committee, March 3, 1998).

Dermal Absorption

A dermal absorption factor is not applicable since a dermal NOEL was selected for short- and intermediate-term dermal risks assessments. The current use pattern does not warrant long-term dermal risk assessments.

Acute Dietary (1 day)

The maternal NOEL of 6 mg/kg/day from a developmental toxicity study in the rabbit is the endpoint used for the risk assessment. This is based on deaths in dams on days 1-3 after dosing at 16 mg/kg/day (LOEL). An uncertainty factor (UF) of 100 was applied to account for intraspecies variability and interspecies extrapolation. The FQPA safety factor of 10x to account for potential increased susceptibility of infants and children was reduced to 3x. The 3x was due to the lack of acute and subchronic neurotoxicity studies (MRID 00131257).

Short Term Dermal Occupational or Residential Exposure (1-7 days)

For short-term dermal occupational or residential exposure, the NOEL of 90 mg/kg/day from a rabbit 21-day dermal toxicity study was the endpoint selected to be used in risk assessments. No treatment-related deaths or clinical signs of toxicity were observed at the doses tested. Body weight and food consumption were not affected by the treatment. There were no statistically or biologically significant differences in plasma or RBC cholinesterase inhibition (ChEI) at the doses tested. Two 21 day dermal toxicity studies were available for consideration. After review of the results of both studies together, it was determined that the most recent study provided a better characterization of cholinesterase inhibition (MRID 44436301).

Intermediate Term Dermal Occupational or Residential Exposure (several days to several months)

See Short Term exposure (above).

Long-Term Occupational or Residential Exposure (several months to lifetime)

Based on the use patterns there is minimal concern for long-term dermal exposure or risk.

Inhalation Exposure (any time period)

For short, intermediate, and long term inhalation exposure, mortality and clinical signs of neurotoxicity at 0.137 mg/L (NOEL) from an acute inhalation study in rats (MRID# 42140102) was selected as the endpoint. This risk assessment was performed only for those scenarios where inhalation exposure is greater than 1% of total dermal and inhalation exposure. The risks due to dermal and inhalation exposure were combined because of a common endpoint (i.e., clinical signs of neurotoxicity seen following dermal and inhalation exposures). The combined risk resulting from dermal and inhalation exposure to methomyl may be calculated by combining MOEs for these routes. The following equation was used to calculate a total MOE ($\mathbf{MOE_T}$):

$$MOE_T = \frac{1}{\frac{1}{MOE_{dermal}} + \frac{1}{MOE_{inhalation}}}$$

(John E. Whalan and Hugh M. Pettigrew. Route-Specific vs. Route-To-Route Procedures in Margin of Exposure (MOE) Calculations for Inhaled Pesticides, and the Combining of MOEs. Draft Interim Policy. September 16, 1996. Page 7.)

3. Exposure Assessment

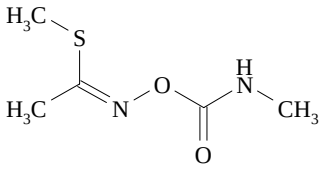
a. Dietary Exposure (food sources)

The residue chemistry database includes information on the types of pesticide residues found in plants and animals, the levels of detected pesticide residues, and a description of the analytical methods used. Residue chemistry data are used by the Agency to determine the residues of concern and to establish tolerances in food and feed. Tolerances are pesticide residue levels that should not be exceeded in or on a raw agricultural commodity in the channels of interstate commerce. Tolerances for residues of methomyl are currently expressed in terms of methomyl *per se*, in/on plant raw agricultural commodities (RACs) [40 CFR §180.253 (a) and (b)]. Tolerances on plant commodities range from 0.1 ppm to 40 ppm. A food/feed additive tolerance has been established for

methomyl residues in imported dried hops (12 ppm) [40 CFR §185.4100]. Adequate methods are available for the enforcement of established tolerances, as currently defined.

The Agency has determined that residues of acetamide and acetonitrile resulting from the application of methomyl are not residues of concern in animals and will not be regulated (See discussion under B.1.c. "Chronic Toxicity and Carcinogenicity"). The residue of concern in plants and animals is methomyl. The chemical name and structure of methomyl is depicted in the following table.

Table 6 - Chemical name and structure of methomyl

Common Name/Chemical Name	Chemical Structure
Methomyl *S*-methyl *N*-[(methylcarbamoyl)oxy] thioacetimidate	

The Agency has updated the Livestock Feeds Table [Table 1 in the Residue Chemistry Test Guidelines, OPPTS Series 860, August 1996]. Additional residue data are now required for some commodities as a result of these changes in Table 1; these data requirements have been incorporated into this document. The need for additional tolerances and for revisions to exposure/risk assessments will be determined upon receipt of the required residue chemistry data.

Summary of Science Findings

OPPTS GLN 860.1200 (formerly 171-1): Directions for Use

There are two methomyl end-use products (EPs) with food/feed uses registered to E. I. du Pont de Nemours & Company, Inc. These EPs are presented below (Reference Files System, September 23, 1996).

EPA Reg No.	Label Acceptance Date	Formulation Class	Product Name
352-342 [a]	9/96	90% SC/S	DuPont Lannate® SP Insecticide
352-384 [b]	9/96	2.4 lb/gal SC/L	DuPont Lannate® LV Insecticide

[a] Includes SLN Nos. CA770495, CA780136, CA850052, CA860059, CA880014, CA900034, CA910010, CA910011, DE800009, FL780004, FL780037, FL780055, FL820014, LA950016, NC820011, NJ940009, PA930002, TX930022, and WV930003.

[b] Includes SLN Nos. FL880004, IL830019, LA950017, and TX920011.

A review of the above labels and supporting residue data indicate that the following label amendments are required:

A 14-day preharvest interval (PHI) is specified for beet tops under use directions for "Beets (Table)" and a 10-day PHI is specified for beet tops under use directions for "Leafy Green Vegetables." Use directions should be amended to specify a single PHI for beet tops. The available data support a 10-day PHI.

Label directions for sweet corn should be amended to include a PHI for sweet corn stover, which is listed as a regulated feed item. The available corn fodder (stover) data support a 21-day PHI.

Label directions for cotton state "Do not graze or feed treated cotton to livestock." This restriction should be deleted from the labels because cotton gin trash is a regulated livestock feed item that is not under the grower's control.

Directions for garlic specify a maximum single application rate of 0.45 lb ai/A and a maximum of six applications per crop, which would result in a maximum seasonal rate of 2.7 lb ai/A. However, the currently labeled seasonal rate is 3.6 lb ai/A/crop. The seasonal use rate should be amended to be no higher than the total resulting from the maximum number of applications at the maximum rate.

A 7-day PHI is specified for bermudagrass forage. However, current Agency Guidelines (Table 1, OPPTS Guideline 860.1000) require 0-day PHIs for grass forages. Concomitant with developing zero day residue data for bermudagrass forage, the registrant should amend product labels to list a 0-day PHI for bermudagrass forage.

Since lentil forage and hay are no longer considered to be significant livestock feed items, PHIs for these commodities can be deleted from the use directions for lentils.

Use directions for peppers list a maximum seasonal use rate of 4.05 lb ai/A. This rate appears to be a typographical error. The maximum seasonal rate should be 4.5 lb ai/A/crop. The registrant should clarify the maximum seasonal rate for peppers.

For sorghum, the registrant should either specify a 0-day PHI for forage and submit supporting residue data or amend labels to restrict the use only to grain sorghum.

Label directions for soybeans specify PHIs for forage and hay that depend upon whether the last application was made at <0.45 lb ai/A or at 0.45-0.9 lb ai/A. Because the current federally registered maximum use rate is 0.45 lb ai/A, these label directions are confusing. The use directions should be amended to specify PHIs of 3 and 12 days for forage and hay, respectively, regardless of the application rate. These PHIs are supported by the available data.

Use directions for sugar beets should be amended to specify a 21-day PHI for both sugar beet roots and tops concomitant with establishing the proposed tolerance for sugar beet tops.

OPPTS GLN 860.1300 (formerly 171-4a): Nature of the Residue in Plants

The qualitative nature of the residue in plants is adequately understood based on cabbage, corn, and tobacco metabolism studies. The residue of concern in plants is methomyl.

OPPTS GLN 860.1300 (formerly 171-4b): Nature of the Residue in Livestock

The qualitative nature of the residue in animals is adequately understood based upon acceptable ruminant and poultry metabolism studies. The Agency has determined that residues of acetamide and acetonitrile resulting from the application of methomyl to crops are not residues of concern in animals and will not be regulated. (See discussion under B.1.c. "Chronic Toxicity and Carcinogenicity"). The residue of concern in animals is methomyl, *per se*. The Agency concluded that there is no reasonable expectation of finite methomyl residues in ruminant and poultry commodities [180.6(a)(3)]. Therefore, tolerances for methomyl are not required for meat, milk, poultry, and eggs.

OPPTS GLN 860.1340 (formerly 171-4c,d): Residue Analytical Methods

Adequate analytical methodology is available for data collection and enforcing tolerances of methomyl. Method I in the Pesticide Analytical Manual (PAM), Vol. II, is a GLC/ sulfur microcoulometric detection method that has undergone a successful EPA method validation on corn, leafy vegetables, and fruiting vegetables. This method involves solvent extraction, clean-up by liquid-liquid partitioning, and a base hydrolysis of methomyl residues to methomyl oxime. Acidified residues of methomyl oxime are then partitioned into an organic solvent and determined by GLC using a sulfur microcoulometric detector. The limit of detection is 0.02 ppm for plant commodities.

A HPLC/fluorescence detection method (Method AMR 3015-94) has also been proposed as an enforcement method. For this method, methomyl residues are extracted into water:acetone, solvent partitioned, and cleaned up using a Florisil column. Residues of methomyl are then quantified by HPLC using post-column hydrolysis and derivatization with *o*-phthalaldehyde followed by fluorescence detection. This method has recently undergone a successful EPA method validation using dry pea seeds, sorghum hay, and sugar beet foliage. The validated limit of quantitation is 0.02 ppm.

Data from analysis of methomyl residues in plants have been collected using Method I or modifications of Method I, which included modifications to the clean-up procedures and/or use of a flame photometric detector with a sulfur filter (FPD-S) instead

of the microcoulometric detector. Data have also been collected using variations of the adequate HPLC/fluorescence detection method.

Data from the recent ruminant feeding study were collected using a modification of the above HPLC/fluorescence detection method. Methomyl residues were extracted and purified using solid-phase extraction and liquid-liquid partitioning. Residues were then quantified by HPLC/fluorescence detection following post-column derivatization. The reported limit of quantitation was 0.01 ppm in milk and meat commodities. Since tolerances are not required for animal commodities, an enforcement method for animal commodities is also not required.

OPPTS GLN 860.1360 (formerly 171-4m): Multiresidue Method Testing

The FDA PESTDATA database indicates that methomyl is completely recovered using FDA Multiresidue Protocols A and D (PAM I Sections 242.2 and 232.4).

OPPTS GLN 860.1380 (formerly 171-4e): Storage Stability Data

Requirements for storage stability data are satisfied for purposes of reregistration, with the exception of the need for storage stability data on residues of methomyl in potato tubers, onions, dry bean and pea seeds, pea hay, peanut nutmeats, soybean hay, and sorghum forage and hay.

The available data indicate that methomyl is stable in apples, broccoli, corn, oranges (halves) stored at -20 C for up to 24 months; grapes stored at -20 C for up to 27 months; succulent beans stored at -18 C for up to 30 months; beets and beet foliage stored at -10 C for ~1 year; milk stored at -20 C for up to 22 months; mint hay stored at -10 C up to 6 months; mint oil stored at -20 C up to 5 months; and tobacco leaves stored at -18 C for up to 83 days.

Data submitted with a ruminant feeding study indicate that methomyl is stable at <-70 C in liver for 5.4 months and in muscle and milk for 6 months.

Methomyl declined in fortified chopped oranges stored at -20 C by 30% within 6 months, ~60% within 12 months, and by >80% within 24 months.

OPPTS GLN 860.1500 (formerly 171-4k): Magnitude of the Residue in Crop Plants

For purposes of reregistration, requirements for magnitude of the residue in plants are fulfilled for the following crops/commodities: alfalfa, fennel, apple, asparagus, avocado, barley, beans (succulent), beet (table), bermudagrass hay, blueberry, broccoli, Brussels sprouts, cabbage (incl. Chinese cabbage), carrot, cauliflower, celery, chicory roots, citrus fruits, corn (field, pop, and sweet), cottonseeds, cowpea forage, cucumber, eggplant, garlic, grape, green onions, lettuce, melons, mint hay, nectarine, peach, oats,

peanut, pear, pea vines, peas (succulent), pecan, peppers, pomegranate, pumpkin, rye, soybean, spinach, summer squash, strawberry, sugar beet (roots and tops), sweet potato, tomato, tomatillo, tobacco, and wheat. Adequate field trial data depicting methomyl residues following applications made according to the maximum or proposed federally registered use patterns have been submitted for these commodities. Geographical representation is adequate and a sufficient number of trials reflecting representative formulation classes were conducted.

Once the registrant provides acceptable storage stability data on methomyl residues in dry beans and peas, pea hay, onions (dry bulb), potatoes, soybean hay, and sorghum fodder (stover) and hay, adequate residue data would also be available for these commodities.

Residue data on dry bulb onions can be translated to support the use on garlic; and residue data on celery can be translated to support a similar use on anise (fennel). Residue data on green onions can be translated to support use on leeks. Residue data from tomatoes will be translated to support use on tomatillos.

Although residue data do not exist or are incomplete for beet tops, collards, dandelions, kale, mustard, greens, parsley, and Swiss chard, the Agency has previously determined that residue data on spinach can be translated to support similar uses on these commodities. Residue data on lettuce can be translated to support use on endive (escarole).

The available data on carrots, potatoes, sugar beets, and table beets adequately support a crop group tolerance of 0.2 ppm for the Root Vegetables Crop Group provided adequate storage stability data are submitted. There is no federally registered use on the representative commodity radish and no residue data are available on radish. For purposes of a crop group tolerance, residue data on table beets can be substituted for data on radishes, as these crops are culturally similar.

In November 1987 the Methomyl Final Registration Standard and Tolerance Reassessment, (FRSTR) previously concluded that the available residue data on dry beans would be translated to support the use on lentils. However, label directions for lentils more closely approximate the proposed use on dried peas. Therefore, residue data on dried peas will be translated to support the use on lentils once storage stability issues pertaining to dried bean and pea seeds are resolved.

For purposes of reregistration, additional residue data and/or label amendments are required on chicory tops, radishes, turnips (greens), sorghum forage, bermudagrass forage, and cotton gin byproducts as explained in detail below.

For chicory tops, data are required from a single test in Region 2 depicting methomyl residues in/on chicory leaves following multiple applications at the maximum

labeled rate. Leaves should be harvested at the proposed 30-day PHI. Based upon the residue data, the registrant should propose an appropriate tolerance for chicory tops (leaves) and amend labels to include a 30-day PHI for chicory leaves.

For radishes, data are required depicting methomyl residues in/on tops (leaves) harvested 3 days following the last of two foliar applications of methomyl each at 0.9 lb ai/A. These data are required to support SLN No. CA770495. As per OPPTS Guideline 860.1500, the registrant can conduct three tests for radish at 1x the maximum rate at three separate sites in CA (two samples per test), or 1x and 2x tests for radish at two separate sites in CA (one sample per test). Alternatively, the registrant may elect to cancel this use on radishes. Residue data from carrots can be translated to cover radish roots.

Turnip greens appears on the current labels under the crop grouping Leafy Green Vegetables. The registrant must remove turnip greens from the labels. If the registrant wishes to keep turnip greens on the labels then they would be required to do so under the new crop groupng "Leaves of Root and Tuber Vegetables". Then the registrant is required to generate data depicting residues of methomyl in/on turnip tops (leaves) as per whatever the established maximum application and minimum PHI for turnip greens on the labels would be. The registrant cannot translate data from existing data on leafy green vegetables to turnip greens. Turnip greens (tops) are no longer included in the new crop group for Leafy Green Vegetables (Crop Group 4). Turnip tops are considered a representative commodity under the crop grouping for Leaves of Root and Tuber Vegetables (Crop Group 2). If the registrant wishes to keep turnip tops on the labels, they must submit the required residue data, and then along with existing data on sugar beet tops, they could propose a crop group tolerance for Leaves of Root and Tuber Vegetables (Crop Group 2).

In accordance with current Agency guidance (Residue Chemistry Test Guidelines, OPPTS 860 series), zero-day residue data are required on grass forages. Therefore, zero-day residue data are required on bermudagrass forage. Data are required depicting methomyl residues in/on bermudagrass forage harvested the same day as an application at 0.9 lb ai/A. A total of 12 trials are required in regions of the country in which bermudagrass is grown for forage. Grass forages include forage sorghums. Therefore, data are required on methomyl residues in/on sorghum forage harvested the same day as the last of two applications of methomyl each at 0.45 lb ai/A (for a toal seasonal application of 0.9 lb ai/A). Residue data from the bermuda grass trials can be translated to support the sorghum forage uses. Alternatively, the registrant may amend their labels to restrict the use of methomyl to only grain sorghum, in which case the available sorghum forage data (14-day PHI) are adequate. In addition, if the use is restricted to grain sorghum, then a tolerance would not be required for sorghum hay.

Data are required depicting methomyl residues in/on cotton gin byproducts ginned from cotton harvested 15 days after the last of multiple foliar applications of methomyl at the maximum labeled rate and totaling 1.8 lb ai/A/season. The cotton must be harvested

by commercial equipment (stripper and mechanical picker) to provide an adequate representation of plant residue from the ginning process. At least three field trials for each type of harvesting (stripper and picker) are needed, for a total of six field trials.

OPPTS GLN 860.1520 (formerly 171-4l): Magnitude of the Residue in Processed Food/Feed

The reregistration requirements for magnitude of the residue in processed food/feed commodities are fulfilled for apple, citrus, corn, cottonseed, grape, mint, peanut, potato, sorghum, soybean, sugar beet, tomato, and wheat. Based on the available processing studies, a separate tolerance is only required for dried citrus pulp.

Methomyl residues did not concentrate in any processed commodities except wheat bran (1.9x) and dried citrus pulp (2.9x). The Agency has concluded that separate tolerances are not required for bran of barley, rye, or wheat. Based upon HAFT residues of 0.7 ppm for small grain field trials and the 1.9x concentration factor, the maximum expected residues in bran would be 1.3 ppm, which is not significantly higher than the 1 ppm RAC tolerance.

Based upon HAFT residues of 0.53 ppm for citrus fruits and the observed 2.9x concentration factor, the maximum expected methomyl residues in dried citrus pulp would be 1.54 ppm. Because the RAC tolerance for citrus fruits is being reassessed to 1 ppm, the registrant should propose a tolerance of 2.0 ppm for methomyl residues in dried citrus pulp.

OPPTS GLN 860.1480 (formerly 171-4j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

No tolerances have been established for methomyl residues in livestock commodities. The requirement for a poultry feeding study has been waived. The Agency believes this to be a 180.6(a)(3) situation, that is no reasonable expectation of finite residues, based upon the results of the poultry metabolism study, which used a 45x feeding level.

Adequate ruminant metabolism and feeding studies are available. Residues of methomyl were not detected in milk and meat of livestock. The Agency concluded that there is no reasonable expectation of finite methomyl residues in ruminant commodities [180.6(a)(3)]. Therefore, no tolerances will be required for livestock commodities.

OPPTS GLN 860.1850 (formerly 165-1): Confined Accumulation in Rotational Crops

The application rate used in the study was not the appropriate maximum seasonal rate (1X) for the individual crops tested. This study must be conducted at the 1X rate. Beets, sunflower seeds, and cabbage planted at 30- and 120-days posttreatment contained

total radioactive residues (TRR) ranging from 0.04-2.0 ppm. A 12-month plantback interval was not included in the study. Although the registrant stated the belief that residues of methomyl *per se* were <0.01 ppm, no definitive anlayses for methomyl *per se* were conducted. Based on all of the above, a new confined rotational crop study is required. (See OPPTS Test Guidelines Series 860 Residue Chemistry Section 860.1850).

OPPTS GLN 860.1900 (formerly 165-2): Field Accumulation in Rotational Crops

The Agency reserves the requirement of this study until the results of the confined rotational crop study are received and reviewed.

b. Dietary Risk Assessment and Risk Characterization

The Agency has determined that methomyl is a degradate of a registered pesticide, thiodicarb. Therefore, where relevant, methomyl residues resulting from applications of both thiodicarb and methomyl will be considered in an aggregate risk assessment and compared to appropriate toxicological endpoints for methomyl.

Chronic (Non-Cancer) Risk - Methomyl Alone (food source only)

Chronic dietary risk from food sources is not a concern. A Dietary Risk Evaluation System (DRES) chronic exposure analysis for the US Population and 22 subgroups was performed using percent crop treated data for all commodities and anticipated residue data for only 5 commodities. Tolerance level residues were used for the other commodities.

Existing tolerances result in an anticipated residue contribution (ARC) which represents 34.6% of the RfD for the U.S. general population. The highest subgroup, Non-Nursing Infants (<1 year old) occupies 67% of the RfD and Children (1-6 years old) occupies 62% of the RfD.

Increasing the rye tolerance from 1 to 10 ppm, and the increase in the lentil tolerance from 0.1 ppm to 0.2 ppm and the deletion of watercress results in an ARC of 35% of the RfD for the U.S. general population, 67% for Non-Nursing Infants (<1 year old) and 63% for Children (1-6 years old).

This chronic analysis for methomyl is not a worst case estimate of dietary exposure with most residues at tolerance level although, some refinements such as percent crop treated data and anticipated residues for 5 commodities have been incorporated. Based on the risk estimates calculated in this analysis, it appears that chronic dietary risk from food sources is not of concern.

Chronic (Non-Cancer) Risk - Methomyl and Thiodicarb Combined (food source only)

Chronic exposures to methomyl residues from both thiodicarb and methomyl applications were combined and compared to the methomyl reference dose. The aggregated chronic exposure is shown in the table below (MRIDs 44327202, 44360702).

Table 7 - Chronic Aggregate Risk - Methomyl and Thiodicarb Combined

Population Subgroup	Dietary %RfD[a]
U. S. General	1.9
Children (1 to 6 years)	2.7
Infants	6.5

[a] Dietary %RfD includes methomyl residues from application of thiodicarb and methomyl

Results of the chronic exposure analysis show that no single subpopulation exceeded 7% of the RfD. For the subpopulations, infants (<1 year old) and children (1- 6 years old), 6.5% and 2.7% of the RfD is occupied, respectively. For the general U.S. population, only 1.9% of the RfD was occupied. In this analysis anticipated residue data were used for all 70 commodities (as opposed to only 5 in the analysis for methomyl alone). Percent crop treated information was used for all commodities. This refinement accounts for the lower numbers in this assessment compared to the assessment for methomyl alone.

Cancer Risk

Methomyl is classified as a Group E. The chemical is not likely to be carcinogenic to humans via the relevant routes of exposure.

No aggregate cancer risk assessment is required because methomyl is not a carcinogen.

Acute Dietary Risk - Methomyl Alone (food source only)

To estimate acute dietary exposure to the residues of methomyl, the registrant conducted Monte Carlo simulations which utilized residues from the application of methomyl. For this analysis, percent crop treated information and field trial residue data were used for all commodities (MRIDs 44327201, 44360701).

Acute exposure estimates to methomyl were compared to the methomyl maternal NOEL of 6 mg/kg/day from a rabbit developmental study based on deaths in dams on days 1-3 after dosing at 16 mg/kg/day. The acute exposure analysis was calculated for the overall U.S. population, children 1 to 6 years of age, and infants.

For calculating the Margin of Exposure (MOE) for methomyl, the FQPA safety factor to account for any special sensitivity to infants and children has been reduced from 10x to 3x to account for the lack of acute and subchronic neurotoxicity studies. Therefore, a MOE of at least 300 is considered acceptable.

Table 8 - Acute Exposure MOEs for Methomyl.

Group of Concern	Exposure	NOEL	MOE[1]
U.S. Population	0.006261	6 mg/kg/day	958
Children 1 to 6 years	0.014399	6 mg/kg/day	417
Infants	0.005370	6 mg/kg/day	1117

[1] 99.9 percentile

The results of the acute exposure analyses indicate that there are adequate margins of exposure for the overall U.S. population, children 1 to 6 years of age and infants.

Acute Risk - Methomyl and Thiodicarb Combined (food source only)

The registrant provided and the Agency has found acceptable, an acute dietary Monte Carlo distributional risk assessment which utilized combined residues of methomyl from the application of thiodicarb and residues of methomyl from the application of methomyl. For this analysis, percent crop treated information and field trial residue data were used for all commodities. The methomyl acute dietary NOEL of 6 mg/kg/day was used to calculate the MOEs. The estimated MOEs are shown in the table below. Again, an MOE of at least 300 is considered acceptable (MRIDs 44327202, 44360702).

Table 9: EPA-calculated Margins of Exposure (MOEs) for Various U.S. Subpopulations Based on Acute Effects and 24-hour intervals (NOEL = 6 mg/kg BW/day).		
Population Group	Food	
	24 hour interval	
	mg/kg BW/day	MOE
U.S. Population		
95th percentile	0.000349	17192
99th percentile	0.001099	5460
99.9th percentile	0.006577	912
Infants		
95th percentile	0.000215	27907
99th percentile	0.000874	6865
99.9th percentile	0.007940	756
Children 1-6 years		
95th percentile	0.000482	12448
99th percentile	0.002108	2846
99.9th percentile	0.014396	417

Although refined using percent crop treated data, these estimates are still likely to be a conservative estimate of the Margin of Exposure. For example, they assume that residues, when present, are present as a result of application at the maximum permitted level and observance of the minimum PHI. No reduction as a result of transport time from farm gate to consumer is assumed to occur. Also, no further reduction of residues through washing, peeling, or cooking at the producer or consumer level is assumed to occur. The Agency concludes that sufficient margins of exposure exist at the 99.9th percentile value.

c. Aggregate Exposure

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

Methomyl is a food use chemical. There are no residential uses of methomyl; therefore the considerations for aggregate exposure are those from food and drinking water.

d. Drinking Water Assessment

OPP has calculated drinking water levels of concern (DWLOCs) for methomyl in surface and ground water for the U.S. population and children 1 to 6 years old (Standard Operating Procedures for Drinking Water Exposure and Risk Assessments, 11/26/97 and Interim Guidance for Conducting Drinking Water Exposure Estimates, 12/2/97). For acute exposures, they are 470 and 56 ppb, for the U.S. population and children (1 - 6 yrs old), respectively. For chronic (non-cancer) exposure they are 275 and 78 ppb for the U.S. population and children (1-6 years old), respectively.

To calculate the DWLOC for acute exposure relative to the acute toxicity endpoint, the acute dietary food exposure (from the combined thiodicarb and methomyl Monte Carlo analysis) was subtracted from the ratio of the acute NOEL (used for acute dietary assessments) to the "acceptable" MOE for aggregate exposure to obtain the acceptable acute exposure to methomyl in drinking water. To calculate the DWLOC for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from DRES) was subtracted from the RfD to obtain the acceptable chronic (non-cancer) exposure to methomyl in drinking water. DWLOCs were then calculated using default body weights and drinking water consumption figures.

Estimated concentrations of methomyl in surface water are from PRZM/Exams modeling. The estimated maximum (acute exposure) concentration is 30 ppb and the estimated average (chronic exposure) concentration is 26 ppb. The estimated maximum concentration of methomyl in ground water is 20 ppb based on the Agency's Pesticides in Ground Water Database. Average concentrations in ground water are not expected to be higher than the maximum concentrations. These estimated concentrations of methomyl in surface and ground water are less than the Agency's levels of concern for methomyl in drinking water as a contribution to acute and chronic aggregate exposure. Therefore, taking into account the present uses, the Agency concludes with reasonable certainty that residues of methomyl in drinking water when considered along with other sources of exposure for which the Agency has reliable data would not result in levels of aggregate human health risk that exceed levels of concern.

The estimates of methomyl in surface and ground waters are derived from models that use conservative assumptions (health-protective) regarding the pesticide transport from the point of application to surface and ground water. Because the Agency considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of concern in drinking water may vary as those uses change. If new uses are added in the future, the Agency will reassess the potential impacts of methomyl on drinking water as a part of the aggregate risk assessment process.

Endocrine Disruption

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

e. Cumulative Risk

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 methomyl has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, therefore, EPA has not assumed that methomyl has a common mechanism of toxicity with other substances.

4. Occupational and Residential

a. Occupational and Residential Exposure

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete.

Occupational-use products and homeowner-use products

At this time, products containing methomyl are intended primarily for occupational use only and not for homeowner use. Therefore, no residential risk assessment is required.

Epidemiological Information

In 1993 EPA issued a Data Call-In for Poison Control Center Data for 28 organophosphate and carbamate insecticides, and identified methomyl as one of five candidates for immediate action under the Acute Worker Risk Strategy. Use of methomyl products in California from 1982 - 1989 resulted in the second highest total number of agricultural worker poisoning incidents, and the highest number of agricultural related hospitalizations of all the chemicals reviewed.

The Agency has evaluated incident data for methomyl in two recent documents: "Review of 1982 - 1989 Poison Control Center Data Call In,", dated December 5, 1994; and "Review of 1990 - 1994 Poisoning Data for Aldicarb, Azinphosmethyl, Carbofuran, Methamidophos, and Methomyl,"dated June 26, 1996. The second memorandum was an update of the first, and summarizes the limited available data from the OPP Incident Data System (IDS) and California data from the Pesticide Illness Surveillance System for five insecticides ranked among the top six in the 1994 review.

In the 1994 review, methomyl ranked twelth among the 28 pesticides on most measures of hazard where methomyl was clearly identified as the cause of the incident. It was ranked fourth out of the five reviewed pesticides based on handler poisoning per 1,000 applications in California. Methomyl is the most widely used chemical in California of the 28 reviewed. Exposures to methomyl ranked third in terms of percentage of occupational cases requiring medical treatment among pesticides with a sufficient number

of cases reported. For non-occupational cases, it also ranked third for percent life-threatening cases. Methomyl had the third highest ratio of Poison Control Center (PCC) poisonings, health care referrals, and hospitalizations per 1,000 pounds reported used in agriculture. The ratio of childhood exposures and poisonings per 1,000 applications reported in U.S. homes was ranked third for methomyl.

In the 1996 review, cases reported to the IDS and the California Pesticide Illness Surveillance System were considered. Most of the cases reported to the IDS occurred in California. The review concluded that application, mixing/loading, and spray drift appeared to be roughly equally involved in undue exposures to methomyl. Improper use of water soluble bags continued to be a problem although it seemed likely that this type of poisoning would decline as workers become more familiar with this type of container. Serious cases occurred when backpack sprayers were left unattended and when methomyl was stored in improper containers. The backback sprayer issue was resolved during the development of the Acute Worker Risk Strategy which required that methomyl can only be applied to crops using mechanical ground and aerial application equipment.

In 1995, the Agency met with the registrants of methomyl and mitigation measures were adopted to reduce incidents for the fly bait formulations. For the fly bait products the use was limited to commercial agriculture production where children would not be present. In addition, the bait stations are required to be placed four feet above the ground, an embittering agent was added to all fly bait stations, and the color of the formulations was limited to earth-tones or other dark unattractive colors.

In 1996, the Agency met with the registrants of methomyl and developed an Acute Worker Risk Strategy. The measures adopted to reduce worker risks included, but were not limited to: the addition to the label of generic spray drift language, and label language prohibiting the application of this product in a way that will contact workers or other persons, either directly or through drift; an agreement to require closed systems if warranted by the risk assessments; the use of only mechanical ground or aerial application equipment when applying methomyl to crops; the use of additional PPE or engineering controls based on WPS requirements; and chemical resistant apron and footwear for cleaners and repairers. A pictogram was added to water soluble bag packaging demonstrating no cutting, ripping or tearing of the bag. A safe use educational program was initiated and the registrant is required to provide California incident data for methomyl directly to the Agency as it becomes available.

As each set of mitigation measures were put into effect the number of incidents reported from the use of methomyl has been decreasing.

Handlers

Exposures and Assumptions

EPA has determined that there are potential exposures to mixers, loaders, applicators, and other handlers as the result of usual use patterns associated with methomyl. Based on the use patterns, 15 major exposure scenarios were identified for methomyl: (1a) mixing/loading wettable powders for aerial application; (1b) mixing/ loading wettable powders for groundboom application; (1c) mixing/loading wettable powders for airblast application; (2a) mixing/loading liquids for aerial application; (2b) mixing/loading liquids for groundboom application; (2c) mixing/loading liquids for airblast application; (3a) loading granulars for tractor-drawn/mechanical spreader application; (3b) loading granulars for tractor-drawn bait application; (3c) loading granulars for aerial bait application; (3d) loading granulars for bait station application; (4) applying sprays with a fixed-wing aircraft; (5) applying sprays with a helicopter; (6) applying sprays with groundboom equipment; (7a) applying granulars with a tractor-drawn spreader; (7b) applying baits with a tractor-drawn spreader; (8) applying baits with aerial equipment; (9) applying baits by hand; (10) applying dust with various dust application equipment; (11) applying liquids with an airblast sprayer; (12) applying pastes with a paint brush; (13) loading/applying granular bait with a belly-grinder spreader; (14) flagging aerial bait applications; and (15) flagging for aerial spray applications.

No data are available for the following scenarios: dust application; mixing pelleted baits with water for paint brush applications or mixing pastes (which are assumed to be the same worker as the applicator, however, only applicator data are available); and flagging for aerial bait applications. Risk estimates will be made by extrapolation from other data.

Short-term and intermediate-term dermal and inhalation exposure estimates (developed using PHED Version 1.1 surrogate data) are presented in Table 10. No chemical-specific data were submitted. Where appropriate, multiple application rates are used to represent crops with differing maximum application rates. The maximum rates for most crops are (1) 0.45 lb ai/acre (e.g., barley, garlic); (2) 0.9 lb ai/acre (e.g., citrus, melons), or (3) 1.8 lbs ai/acre (e.g., sod farm turf, peaches). These calculations of handlers' daily dermal and inhalation exposure to methomyl are used to calculate the daily doses to those handlers. Table 11 presents the dermal risk assessment for both short-term and intermediate-term exposures together with risk estimates utilizing PPE and engineering controls. Table 12 presents the inhalation risk assessment. Table 13 presents combined dermal and inhalation MOEs for scenarios where inhalation exposure exceeded 1% of the dermal exposure. Table 13 also notes the minimum level of mitigation considered to achieve MOEs greater than 100. Table 14 summarizes the caveats and parameters specific to each exposure scenario and corresponding risk assessment.

The following assumptions were made:

1) Average body weight of an adult handler is 70 kg; 2) area treated in each scenario: 350 acres for aerial applications (including flaggers supporting aerial applications), 80 acres for groundboom applications and granular tractor drawn/mechanical spreader applications, 40 acres for airblast sprayer applications, 1 acre for belly-grinder applications, 10 lbs. of product for paint brush applications, and 0.25 acres for granular bait station applications (based on EPA Reg. No. 5871-3, 0.25 lb product (1 percent ai) per 500 ft^2; which assumes 0.25 acre maximum likely treatment area).

Since inhalation absorption data are not available, 100% inhalation absorption was assumed.

Table 10: Short-term and Intermediate-term Dermal and Inhalation Exposures to Methomyl (Engineering controls are in Table 11)

Exposure Scenario (Scen.#)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (μg/lb ai)[b]	Application Rate (lb ai/acre)[c]	Daily Acres Treated[d]	Daily Dermal Exposure (mg/day)[e]	Daily Inhalation Exposure (mg/day)[f]
Mixer/Loader Exposure						
Mixing/Loading Wettable Powder for Aerial Application (1a)	3.8	43.4	(1) 0.45	350	599	6.84
			(2) 0.9		1,197	13.67
			(3) 1.8		2,394	27.34
Mixing/Loading Wettable Powder for Groundboom Application (1b)			(1) 0.45	80	137	1.56
			(2) 0.9		274	3.12
			(3) 1.8		547	6.25
Mixing/Loading Wettable Powder for Airblast Application (1c)			(1) NA	40	NA	NA
			(2) 0.9		137	1.56
			(3) 1.8		274	3.12
Mixing/Loading Liquids for Aerial Application (2a)	2.9	1.2	(1) 0.45	350	457	0.19
			(2) 0.9		914	0.38
			(3) 1.8		1827	0.76
Mixing/Loading Liquids for Groundboom Application (2b)			(1) 0.45	80	104	0.043
			(2) 0.9		209	0.086
			(3) 1.8		418	0.17
Mixing/Loading Liquids for Airblast Application (2c)			(1) NA	40	NA	NA
			(2) 0.9		104	0.043
			(3) 1.8		209	0.086
Loading Granulars for Tractor-Drawn/Mechanical Spreader Application (3a)	0.0076	1.7	0.15	80	0.091	0.02
Loading Granulars for Tractor-Drawn Bait Applications (3b)			0.9	80	0.547	0.122
Loading Granulars for Aerial Bait Applications (3c)			0.9	350	2.394	0.536
Loading Granulars for Bait Station Application (3d)			0.2175	0.25 (44 bait stations)	0.0004	0.000092

Table 10: Short-term and Intermediate-term Dermal and Inhalation Exposures to Methomyl [Engineering controls are in Table 11] (continued)

Exposure Scenario (Scen.#)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (μg/lb ai)[b]	Application Rate (lb ai/acre)[c]	Daily Acres Treated[d]	Daily Dermal Exposure (mg/day)[e]	Daily Inhalation Exposure (mg/day)[f]
Applicator Exposure						
Applying Sprays with a Fixed-Wing Aircraft (4)	See Engineering Controls	See Engineering Controls	(1) 0.45	350	See Engineering Controls	See Engineering Controls
			(2) 0.9			
			(3) 1.8			
Applying Sprays with a Helicopter (5)	See Engineering Controls	See Engineering Controls	(1) 0.45	350	See Engineering Controls	See Engineering Controls
			(2) 0.9			
			(3) 1.8			
Applying Sprays with a Groundboom Sprayer (6)	0.015	0.7	(1) 0.45	80	0.54	0.025
			(2) 0.9		1.08	0.05
			(3) 1.8		2.16	0.1
Applying Granulars with a Broadcast Spreader (Tractor) (7a)	0.01	1.2	0.15	80	0.12	0.014
Applying Baits with Tractor-Drawn Spreader (7b)			0.9	80	0.72	0.086
Applying Baits with Aerial Equipment (8)	See Eng. Controls	See Eng. Controls	0.9	350	See Eng. Controls	See Eng. Controls
Applying Baits by Hand (9)	No data--See PPE	468	0.2175	0.25	See PPE	0.025
Applying Dust with Dust Application Equipment (10)	No data	No data	1.0	No data	No data	No data
Applying Liquids with an Airblast Sprayer (11)	0.36	4.5	(1) NA	40	NA	NA
			(2) 0.9		12.96	0.16
			(3) 1.8		25.92	0.32
Applying Paste with a Brush (12) (Note: No mixer/loader data available, though likely to be same worker. No information available about area covered by paste.)	182	284	0.01 lb ai / lb product, 0.25 lbs product/4 oz H_20	10 lbs product	18.2	0.028
Mixer/Loader/Applicator Exposure						
Loading/Applying Granular Bait with a Belly Grinder (13)	10.4	61.8	0.2175	1	2.26	0.013

Exposure Scenario (Scen.#)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (μg/lb ai)[b]	Application Rate (lb ai/acre)[c]	Daily Acres Treated[d]	Daily Dermal Exposure (mg/day)[e]	Daily Inhalation Exposure (mg/day)[f]
Flagger Exposure						
Flagging Aerial Bait (granular) Applications (14)	No data	No data	0.9	350	No data	No data
Flagging Aerial Spray Applications (15)	0.01	0.28	(1) 0.45	350	1.58	0.044
			(2) 0.9		3.15	0.088
			1.8		6.3	0.18

[a] Baseline dermal unit exposure represents long pants, long sleeved shirt, no gloves, open mixing/loading, open cab tractor. Baseline data are not available for aerial application or applying baits by hand.

[b] Baseline inhalation exposure represents no respirator.

[c] Application rates are maximum values found in the Methomyl labels. In some scenarios, a range of maximum application rates were used as follows: (1) low rate (e.g., barley, garlic), (2) medium rate (e.g., citrus, melons), (3) high rate (e.g., peaches, sod farm turf).

[d] Daily acres treated values are estimates of acreage that could be treated in a single day for each exposure scenario of concern. For Scenario 12, no information is available to estimate area treated with pastes mixed from bait pellets. EPA estimates that 10 lbs of product could be handled per day (yielding roughly 2 gallons of paste). Note that no mixer/loader data are available from which to estimate exposure, and that the mixer/loader would likely apply the paste, too. Thus, resulting MOEs would be somewhat lower than are estimated in Tables 11 - 13.

[e] Daily dermal dose (mg/day) = Exposure (mg/lb ai) * Appl. rate (lb ai/acre) * Acres treated.

[f] Daily inhalation exposure (mg/day) = Exposure (μg/lb ai) * (1mg/1000μg) conversion * Appl. Rate (lb ai/A) * Acres Treated.

Table 11: Short-term and Intermediate-term Dermal Risks of Methomyl

Exposure Scenario (Scen #)	Baseline Dermal Dose (mg/kg/day)[a]	Baseline Dermal MOE[b]	Risk Mitigation Measures					
			Additional PPE[c]			Engineering Controls[d]		
			PPE Dermal Unit Exp. (mg/lb ai)	PPE Daily Dermal Dose (mg/kg/day)[a]	PPE Dermal MOE[b]	Eng. Controls Dermal Unit Exposure (mg/lb ai)	Eng. Controls Dermal Daily Dose (mg/kg/day)[a]	Eng. Controls Dermal MOE[b]
Mixer/Loader Risk								
Mixing/Loading Wettable Powder for Aerial Application (1a)	(1) 8.6	10	0.13	0.29	310	0.02	NA	NA
	(2) 17.1	5		0.59	150		NA	NA
	(3) 34.2	3		1.17.	77		0.18	500
Mixing/Loading Wettable Powder for Groundboom Application (1b)	(1) 2.0	45	0.16	0.08	1100		NA	NA
	(2) 3.9	23		0.16	560		NA	NA
	(3) 7.8	12		0.33	270		NA	NA
Mixing/Loading Wettable Powder for Airblast Application (1c)	(1) NA	NA		NA	NA		NA	NA
	(2) 2.0	45		0.08	1100		NA	NA
	(3) 3.9	23		0.16	560		NA	NA
Mixing/Loading Liquids for Aerial Application (2a)	(1) 6.5	14	0.043	0.10	900	NA	NA	NA
	(2) 13.1	7		0.20	450		NA	NA
	(3) 26.1	3		0.39	230		NA	NA
Mixing/Loading Liquids for Groundboom Application (2b)	(1) 1.5	60		0.02	4,500		NA	NA
	(2) 3.0	30		0.04	2,300		NA	NA
	(3) 6.0	15		0.09	1,000		NA	NA
Mixing/Loading Liquids for Airblast Application (2c)	(1) NA	NA	0.043	NA	NA		NA	NA
	(2) 1.5	60		0.02	4,500			
	(3) 3.0	30		0.04	2,300			
Loading Granulars for Tractor-Drawn/Mechanical Spreader Application (3a)	0.0013	69,000	NA	NA	NA	NA	NA	NA
Loading Granulars for Tractor-Drawn Bait Applications (3b)	0.0078	12,000	NA	NA	NA	NA	NA	NA
Loading Granulars for Aerial Bait Applications (3c)	0.0342	2,600	NA	NA	NA	NA	NA	NA
Loading Granulars for Bait Station Application (3d)	5.7×10^{-6}	1.5×10^{7}	NA	NA	NA	NA	NA	NA
Applicator Risk								
Applying Sprays with a Fixed-Wing Aircraft (4)	See Engineering Controls	See Engineering Controls	See Engineering Controls	See Engineering Controls	See Engineering Controls	0.005	0.011	8,200
							0.023	3,900
							0.045	2,000
Applying Sprays with a Helicopter (5)	See Engineering Controls	See Engineering Controls	See Engineering Controls	See Engineering Controls	See Engineering Controls	0.0021	0.005	18,000
							0.009	10,000
							0.019	4,700
Applying Sprays with a Groundboom Sprayer (6)	(1) 0.008	11,000	NA	NA	NA	NA	NA	NA
	(2) 0.015	6,000						
	(3) 0.03	3,000						
Applying Granulars with a Broadcast Spreader (Tractor) (7a)	0.0017	53,000	NA	NA	NA	NA	NA	NA
Applying Baits with Tractor-Drawn Spreader (7b)	0.010	9,000	NA	NA	NA	NA	NA	NA

Exposure Scenario (Scen #)	Baseline Dermal Dose (mg/kg/day)[a]	Baseline Dermal MOE[b]	Risk Mitigation Measures					
			Additional PPE[c]			Engineering Controls[d]		
			PPE Dermal Unit Exp. (mg/lb ai)	PPE Daily Dermal Dose (mg/kg/day)[a]	PPE Dermal MOE[b]	Eng. Controls Dermal Unit Exposure (mg/lb ai)	Eng. Controls Dermal Daily Dose (mg/kg/day)[a]	Eng. Controls Dermal MOE[b]
Applying Baits with Aerial Equipment (8)	See Engineering Controls	See Engineering Controls	See Engineering Controls	See Engineering Controls	See Engineering Controls	0.0016	0.007	13,000
Applying Baits by Hand (9)	No data-- See PPE	No data-- See PPE	71.3	0.06	1,500	NA	NA	NA
Applying Dust with Dust Application Equipment (10)	No data	No data	No data	No data	No data	No data	No data	No data
Applying Liquids with an Airblast Sprayer (11)	(1) NA	NA	NA	NA	NA	NA	NA	NA
	(2) 0.19	470		NA	NA		NA	NA
	(3) 0.37	240		NA	NA		NA	NA
Applying Paste with a Brush (12) Note: No mixer loader data available.	0.26	350	NA	NA	NA	NA	NA	NA
Mixer/Loader/Applicator Risk								
Loading/Applying Granular Bait with a Belly Grinder (13)	0.032	2,800	NA	NA	NA	NA	NA	NA
Flagger Risk								
Flagging Aerial Bait (granular) Applications (14)	No data	No data	No data	No data	No data	No data	No data	No data
Flagging Aerial Spray Applications (15)	(1) 0.023	3,900	NA	NA	NA	NA	NA	NA
	(2) 0.045	2,000		NA	NA		NA	NA
	(3) 0.09	1,000		NA	NA		NA	NA

Note: Application rates are maximum values found in the Methomyl labels. In some scenarios, a range of maximum application rates were used as follows: (1) low rate (e.g., barley, garlic), (2) medium rate (e.g., citrus, melons), (3) high rate (e.g., peaches, sod farm turf).

[a] Dermal Dose (mg/kg/day) = Dermal Exposure (mg/day) / Body weight (70 kg).

[b] Dermal MOE = NOEL (90 mg/kg/day) / Daily Dermal Dose (mg/kg/day). Values are rounded to 2 significant figures. PPE daily doses rounded to nearest hundredth.

[c] Additional PPE:

Scenarios 1a: Double layer of clothing and chemical resistant gloves.
Scenarios 1b, 1c Single layer of clothing and chemical resistant gloves.
Scenarios 2a, 2b, 2c: Single layer of clothing and chemical resistant gloves.
Scenario 9: Single layer of clothing and chemical resistant gloves (no data for no gloves scenario).

[d] Engineering Controls:

Scenario 1a: Water soluble packets, single layer of clothing, no gloves.
Scenario 4: Enclosed cockpit, single layer of clothing, no gloves (no data for open cockpit scenario).
Scenario 5: Enclosed cockpit, single layer of clothing, no gloves (no data for open cockpit scenario).
Scenario 8: Enclosed cockpit, single layer of clothing, no gloves (no data for open cockpit scenario).

Table 12: Inhalation Risks of Methomyl (any duration)

Exposure Scenario (Scen #)	Baseline Inhalation Dose (mg/kg/day)[a]	Baseline Inhalation MOE[b]	Risk Mitigation Measures					
			Additional PPE[c]			Engineering Controls[d]		
			PPE Inhalation Unit Exp. (μg/lb ai)	PPE Daily Inhalation Dose (mg/kg/day)[a]	PPE Inhalation MOE[b]	Eng. Controls Inhalation Unit Exposure (μg/lb ai)	Eng. Controls Inhalation Daily Dose (mg/kg/day)[a]	Eng. Controls Inhalation MOE[b]
Mixer/Loader Risk								
Mixing/Loading Wettable Powder for Aerial Application (1a)	(1) 0.098	380	8.68 (dust/mist respirator)	NA	NA	0.24	NA	NA
	(2) 0.20	190		0.039	950		NA	NA
	(3) 0.39	95		0.078	470		0.002	18,500
Mixing/Loading Wettable Powder for Groundboom Application (1b)	(1) 0.022	1,700	NA	NA	NA		NA	NA
	(2) 0.045	820					NA	NA
	(3) 0.089	420					NA	NA
Mixing/Loading Wettable Powder for Airblast Application (1c)	(1) NA	NA	NA	NA	NA		NA	NA
	(2) 0.022	1,700					NA	NA
	(3) 0.045	820					NA	NA
Mixing/Loading Liquids for Aerial Application (2a)	<1 percent of dermal dose	NA	NA	NA	NA	NA	NA	NA
Mixing/Loading Liquids for Groundboom Application (2b)	(1) 0.0006	62,000	NA	NA	NA	0.08	NA	NA
	(2) 0.0012	31,000					NA	NA
	(3) 0.0024	15,000					NA	NA
Mixing/Loading Liquids for Airblast Application (2c)	<1 percent of dermal dose	NA	NA	NA	NA	NA	NA	NA
Loading Granulars for Tractor Drawn/ Mechanical Spreader Application (3a)	<1 percent of dermal dose	NA	NA	NA	NA	NA	NA	NA
Loading Granulars for Tractor-Drawn Bait Applications (3b)	0.002	19,000	NA	NA	NA	NA	NA	NA
Loading Granulars for Aerial Bait Applications (3c)	0.008	4,600	NA	NA	NA	NA	NA	NA
Loading Granulars for Bait Station Application (3d)	<1 percent of dermal dose	NA	NA	NA	NA	NA	NA	NA
Applicator Risk								
Applying Sprays with a Fixed-Wing Aircraft (4)	See Engineering Controls	See Engineering Controls	See Engineering Controls	See Engineering Controls	See Engineering Controls	0.068	0.0002	190,000
							0.0003	120,000
							0.0006	61,000
Applying Sprays with a Helicopter (5)	See Engineering Controls	See Engineering Controls	See Engineering Controls	See Engineering Controls	See Engineering Controls	<1 percent of dermal dose	NA	NA
Applying Sprays with a Groundboom Sprayer (6)	(1) 0.0004	93,000	NA	NA	NA	NA	NA	NA
	(2) 0.0007	53,000						
	(3) 0.0014	26,000						
Applying Granulars with a Tractor Drawn Spreader Rate = 0.15 lbs ai/A) (7a)	0.0002	190,000	NA	NA	NA	NA	NA	NA

Exposure Scenario (Scen #)	Baseline Inhalation Dose (mg/kg/day)[a]	Baseline Inhalation MOE[b]	Risk Mitigation Measures					
			Additional PPE[c]			Engineering Controls[d]		
			PPE Inhalation Unit Exp. (μg/lb ai)	PPE Daily Inhalation Dose (mg/kg/day)[a]	PPE Inhalation MOE[b]	Eng. Controls Inhalation Unit Exposure (μg/lb ai)	Eng. Controls Inhalation Daily Dose (mg/kg/day)[a]	Eng. Controls Inhalation MOE[b]
Applying Baits with a Tractor-Drawn Spreader (7b)	0.001	37,000	NA	NA	NA	NA	NA	NA
Applying Baits with Aerial Equipment (8)	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	1..32	0.006	6,200
Applying Baits by Hand (9)	0.0004	93,000	NA	NA	NA	NA	NA	NA
Applying Dust with Dust Application Equipment (10)	No data	No data	No data	No data	No data	No data	No data	No data
Applying Liquids with an Airblast Sprayer (11)	(1) NA	NA	NA	NA	NA	0.4	NA	NA
	(2) 0.0023	16,000					0.0002	190,000
	(3) 0.0046	8,000					0.0004	93,000
Applying Paste with a Brush (12)	< 1 percent of dermal dose	NA	NA	NA	NA	NA	NA	NA
Mixer/Loader/Application Risk								
Loading/Applying Granular Bait with a Belly Grinder (13)	<1 percent of dermal dose	NA	NA	NA	NA	NA	NA	NA
Flagger Risk								
Flagging Aerial Bait (granular) Applications (14)	No data	No data	No data	No data	No data	No data	No data	No data
Flagging Aerial Spray Applications (15)	(1) 0.0006	62,000	NA	NA	NA	0.0056	NA	NA
	(2) 0.0013	28,000					NA	NA
	(3) 0.0026	14,000					0.00005	740,000

Note: Application rates are maximum values found in the Methomyl labels. In some scenarios, a range of maximum application rates were used as follows: (1) low rate (e.g., barley, garlic), (2) medium rate (e.g., citrus, melons), (3) high rate (e.g., peaches, sod farm turf).

[a] Inhalation dose (mg/kg/day) = Inhalation Exposure (mg/day) / Body Weight (70 kg)

[b] Inhalation MOE = NOEL (mg/kg/day) / Inhalation Dose (mg/kg/day), where NOEL = 0.137 mg/L; route-to-route extrapolation = [(0.0048 mg/L/day * 1 * 8.46 L/hr * 6 hr * 1) / (0.190 kg)] = NOEL of 37 mg/kg/day.

[c] Additional PPE:

(1a) Dust/mist respirator (5 fold protection factor)

[d] Engineering Controls:

(1a) Water soluble packets
(4) Enclosed cockpit
(5) Enclosed cockpit
(8) Enclosed cockpit

Note: For Scenario 1a, PPE and Engineering Controls inhalation MOEs were calculated at the 0.9 and 1.8 lb ai/acre rates (although inhalation MOEs were acceptable at baseline and PPE respectively) so that the dermal and inhalation MOEs could be combined in Table 11.

Table 13: Combined Short-term and Intermediate-term Dermal and Inhalation Risks of Methomyl

Exposure Scenario (Scen #)	Dermal MOE[a]	Inhalation MOE[b]	Combined Dermal and Inhalation MOE[c]
Mixer/Loader Risk			
Mixing/Loading Wettable Powder for Aerial Application (1a)	(1) 310 PPE	380 Baseline	170 PPE (double layers, gloves, no respirator)
	(2) 150 PPE	950 PPE	130 PPE (double layers, gloves, dust/mist respirator)
	(3) 500 PPE	< 1 percent of dermal dose	500 Eng. Controls (water soluble packets, single layer, no gloves or respirator)
Mixing/Loading Wettable Powder for Groundboom Application (1b)	(1) 1100 PPE	1,700 Baseline	670 PPE (single layer, gloves)
	(2) 560 PPE	820 Baseline	330 PPE (single layer, gloves)
	(3) 270 PPE	420 Baseline	160 PPE (single layer, gloves)
Mixing/Loading Wettable Powder for Airblast Application (1c)	(1) NA (0.45 lb ai/A rate not used)	NA	NA (0.45 lb ai/A rate not used)
	(2) 1,100 PPE	1,700 Baseline	660 PPE (single layer, gloves)
	(3) 560 PPE	820 Baseline	330 PPE (single layer, gloves)
Mixing/Loading Liquids for Aerial Application (2a)	(1) 900 PPE	<1 percent of dermal dose	900 PPE (single layer, gloves)
	(2) 450 PPE		450 PPE (single layer, gloves)
	(3) 230 PPE		230 PPE (single layer, gloves)
Mixing/Loading Liquids for Groundboom Application (2b)	(1) 4500 PPE	62,000 Baseline	4200 PPE (single layer, gloves)
	(2) 2300 PPE	31,000 Baseline	2100 PPE (single layer, gloves)
	(3) 1000 PPE	15,000 Baseline	930 PPE (single layer, gloves)
Mixing/Loading Liquids for Airblast Application (2c)	(1) NA (0.45 lb ai/A rate not used)	<1 percent of dermal dose	NA (0.45 lb ai/A rate not used)
	(2) 4500 PPE		4500 PPE (single layer, gloves)
	(3) 2300 PPE		2300 PPE (single layer, gloves)
Loading Granulars for Tractor Drawn/Mechanical Spreader Application (3a)	69,000 Baseline	<1 percent of dermal dose	69,000 Baseline
Loading Granulars for Tractor-Drawn Bait Applications (3b)	12,000 Baseline	19,000 Baseline	7,400 Baseline
Loading Granulars for Aerial Bait Applications (3c)	2600 Baseline	4600 Baseline	1,700 Baseline
Loading Granulars for Bait Station Application (3d)	880,000 Baseline	<1 percent of dermal dose	880,000 Baseline
Applicator Risk			
Applying Sprays with a Fixed-Wing Aircraft (4)	(1) 8200 Eng. Cntrls.	190,000 Eng. Cntrls.	7,900 Eng. Cntrls. (Closed cockpit)
	(2) 3900 Eng. Cntrls.	120,000 Eng. Cntrls.	3,800 Eng. Cntrls. (Closed cockpit)
	(3) 2000 Eng. Cntrls.	61,000 Eng. Cntrls.	1,900 Eng. Cntrls. (Closed cockpit)

Exposure Scenario (Scen #)	Dermal MOE[a]	Inhalation MOE[b]	Combined Dermal and Inhalation MOE[c]
Applying Sprays with a Helicopter (5)	(1) 18,000 Eng. Cntrls.	<1 percent of dermal dose	18,000 Eng. Cntrls. (Closed cockpit)
	(2) 10,000 Eng. Cntrls.		10,000 Eng. Cntrls. (Closed cockpit)
	(3) 4700 Eng. Cntrls.		4,700 Eng. Cntrls. (Closed cockpit)
Applying Sprays with a Groundboom Sprayer (6)	(1) 1100 Baseline	93,000 Baseline	9,800 Baseline
	(2) 6000 Baseline	53,000 Baseline	5,400 Baseline
	(3) 3000 Baseline	26,000 Baseline	2,700 Baseline
Applying Granulars with a Broadcast Spreader (Tractor) (7a)	53,000 Baseline	190,000 Baseline	42,000 Baseline
Applying Baits with Tractor-Drawn Spreader (7b)	9000 Baseline	37,000 Baseline	7,200 Baseline
Applying Baits with Aerial Equipment (8)	13,000 Eng. Controls	6,200 Eng Cntrls.	4,200 Eng. Cntrls. (Closed cockpit)
Applying Baits by Hand (9)	1500 PPE	93,000 Baseline	1,500 PPE (single layer, gloves)
Applying Dust with Dust Application Equipment (10)	No data	No data	No data
Applying Liquids with an Airblast Sprayer (11)	(1) NA (0.45 lb ai/acre rate not used)	NA	NA
	(2) 470 Baseline	16,000 Baseline	460 Baseline
	(3) 240 Baseline	8,000 Baseline	230 Baseline
Applying Paste with a Brush (12)	350 Baseline	<1 percent of dermal dose	350 Baseline
Mixer/Loader/Application Risk			
Mixing/Loading/Applying Granular Bait for Belly Grinder Application (13)	2800 Baseline	<1 percent of dermal dose	2,800 Baseline
Flagger Risk			
Flagging Aerial Bait Applications (14)	No data	No data	No data
Flagging Aerial Spray Applications (15)	(1) 3900 Baseline	62,000 Baseline	3,700 Baseline
	(2) 2000 Baseline	28,000 Baseline	1,900 Baseline
	(3) 1000 Baseline	14,000 Baseline	930 Baseline

Note: Application rates are maximum values found in the Methomyl labels. In some scenarios, a range of maximum application rates were used as follows: (1) low rate (e.g., barley, garlic), (2) medium rate (e.g., citrus, melons), (3) high rate (e.g., peaches, sod farm turf).

[a] Dermal MOEs and levels of PPE and Eng. Cntrl. descriptions are listed in Table 11.

[b] Inhalation MOEs are listed in Table 12.

[c] Combined MOE (formula from Methomyl Hazard ID, dated 3/3/98) = $\frac{1}{\frac{1}{MOE_D} + \frac{1}{MOE_I}}$

Table 14: Exposure Scenario Descriptions for the Use of Methomyl

Exposure Scenario (Number)	Data Source	Standard Assumptions (8-hr work day)	Comments
Mixer/Loader Descriptors			
Mixing/Loading Wettable Powder Formulations (1a, 1b and 1c)	PHED V1.1	350 acres for aerial, 80 acres for groundboom, 40 acres for airblast.	**Baseline:** "Best Available" grades: Hands= all grades, dermal = acceptable grades, inhalation = ABC grades. Hands 28 replicates; dermal = 7 to 24 replicates; inhalation = 44 replicates. Low confidence in dermal data; medium confidence for inhalation data. **PPE:** "Best Available" grades: Hands, dermal, and inhalation = ABC grades. Hands 24 replicates; dermal = 22 to 45 replicates; inhalation = 44 replicates. Medium confidence in hands, dermal and inhalation data. **Engineering Controls:** "Best Available" grades: Dermal acceptable grades; hands and inhalation = all grades. Hands 5 replicates; dermal = 6 to 15 replicates; inhalation = 15 replicates. Low confidence in dermal and inhalation data. PHED data used for baseline no Protection Factors (PFs) were necessary. A 50% PF was used for PPE to represent double layer of clothing (dermal exposure excluding head and hands). A 5-fold PF was used for the PPE scenario for the addition of a dust/mist respirator.
Mixing/Loading Liquid Formulations (2a, 2b and 2c)	PHED V1.1	350 acres for aerial, 80 acres for groundboom, 40 acres for airblast.	**Baseline:** "Best Available" grades: Hands, dermal, and inhalation acceptable grades. Hands = 53 replicates; Dermal = 25 to 122 replicates; Inhalation = 85 replicates. High Confidence in dermal and inhalation data. **PPE:** "Best Available" grades: Hands and dermal acceptable grades. hands = 59 replicates: Dermal = 25 to 122 replicates. High confidence in dermal data. PHED data used for baseline no PFs were necessary.
Loading Granular Formulations (3a, 3b, 3c, and 3d)	PHED V1.1	350 acres for aerial, 80 acres for row planters and tractor-drawn spreaders. 0.25 acres for bait stations (equivalent to 44 bait stations).	**Baseline:** "Best Available" grades: Hands = all grades; dermal and inhalation acceptable grades. Hands = 10 replicates; dermal = 29 to 36 replicates; inhalation = 58 replicates. Low confidence in dermal data; high confidence for inhalation data. PHED data used for baseline, no PFs were necessary.

Exposure Scenario (Number)	Data Source	Standard Assumptions (8-hr work day)	Comments
Applicator Descriptors			
Applying Sprays with a Fixed-wing Aircraft (4)	PHED V1.1	350 acres.	**Engineering Controls:** "Best Available" grades: Hands = acceptable grades; dermal, and inhalation ABC grades. Hands = 34 replicates; dermal = 24 to 48 replicates; inhalation = 23 replicates. Medium Confidence in dermal and inhalation data. PHED data used no PFs were necessary.
Applying Sprays with a Helicopter (5)	PHED V1.1	350 acres.	**Engineering Controls:** "Best Available" grades: Hands, dermal and inhalation acceptable grades. Hands = 2 replicates; dermal = 3 replicates; inhalation = 3 replicates. Low confidence in dermal and inhalation data. PHED data used no PFs were necessary.
Applying Sprays with a Groundboom Sprayer (6)	PHED V1.1	80 acres.	**Baseline:** "Best Available" grades: Hands, dermal, and inhalation acceptable grades. Hands = 16 replicates; dermal = 16 to 18 replicates; inhalation = 18 replicates. High confidence in dermal and inhalation data. PHED data used no PFs were necessary.
Applying Granulars and Pelleted Baits with a Tractor-Drawn Spreader (7a and 7b)	PHED V1.1	80 acres.	**Baseline:** "Best Available" grades: Hands, dermal, and inhalation = acceptable grades. Hands = 5 replicates; dermal = 1 to 5 replicates; inhalation = 5 replicates. Low confidence in dermal and inhalation replicates. PHED data used no PFs were necessary.
Applying Baits with Aerial Equipment (8)	PHED V1.1	350 acres.	**Engineering Controls**: "Best Available" grades: Hands, dermal, and inhalation all grades. Hands = 4 replicates, dermal and inhalation = 13 replicates. Low confidence in dermal and inhalation data. PHED data used no PFs were necessary.
Applying Baits by Hand (9)	PHED V1.1	0.25 acres.	**PPE:** "Best Available" grades: Hands, dermal, and inhalation = acceptable grades ABC. Hands = 15 replicates; dermal and inhalation = 16 replicates. Medium confidence in dermal and inhalation data. (Baseline data not available.) PHED data used no PFs were necessary.
Applying Dust with Dust Applicator Equipment (10)	No data	No data.	No data
Applying Liquids with an Airblast Sprayer (11)	PHED V1.1	40 acres.	**Baseline:** "Best Available" grades: Hands, dermal, and inhalation = acceptable grades. Hands = 22 replicates; dermal = 32 to 49 replicates; inhalation = 47 replicates. High confidence in dermal and inhalation data. PHED used for baseline data, no PFs necessary.

Exposure Scenario (Number)	Data Source	Standard Assumptions (8-hr work day)	Comments
Applying Paste with a Brush (12)	PHED V1.1	10 lbs. End-use product, or about 2 gallons of paste.	**Baseline:** "Best Available" grades: Hands and dermal = ABC grades, inhalation = C grade. Hands, dermal, and inhalation = 15 replicates. Medium confidence in dermal data and inhalation data. PHED data used for baseline, no PFs were necessary.
Mixer/Loader/Applicator Descriptors			
Mixing/Loading/Applying Granular Bait with a Belly-Grinder (13)	PHED V1.1	1 acre.	**Baseline:** "Best Available" grades: Hands and dermal = ABC grades, inhalation = acceptable grades. Hands = 23 replicates, dermal = 29 to 45 replicates, inhalation = 40 replicates. Medium confidence in dermal data, high confidence for inhalation data. PHED data used for baseline, no PFs were necessary.
Flagger Descriptors			
Flagging Aerial Bait (Granular) Applications (14)	No data	350 acres.	No data
Flagging Aerial Spray Applications (15)	PHED V1.1	350 acres.	**Baseline:** "Best Available" grades: Hands, dermal, and inhalation acceptable grades. Hands = 16 replicates: dermal = 16 to 18 replicates; inhalation = 18 replicates. High confidence in dermal and inhalation data. PHED data used for baseline, no PFs were necessary.

[a] Standard Assumptions based on an 8-hour work day. BEAD data were not available.

[b] "Best Available" grades are defined by OREB SOP for meeting Subdivision U Guidelines. Best available grades are assigned as follows: matrices with grades A and B data and a minimum of 15 replicates; if not available, then grades A, B and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality and number of replicates. Data confidence are assigned as follows:

High = grades A and B and 15 or more replicates per body part
Medium = grades A, B, and C and 15 or more replicates per body part
Low = grades A, B, C, D and E or any combination of grades with less than 15 replicates

b. Occupational Risk Estimates

Estimates of exposure and risk indicate that, for several scenarios, measures to reduce handlers exposures should be considered. Table 13 shows the levels of mitigation needed to attain MOEs greater than 100, while Table 14 describes the data quality and confidence level for each scenario. Options to reduce handlers' exposures and risk range from personal protective equipment (double layer of clothing and chemical resistant gloves) to engineering controls (water soluble packets).

Combined Dermal and Inhalation Risk from Occupational Handler Exposure

The calculations of combined dermal and inhalation risk indicate that the MOEs are acceptable (100 or greater) at baseline (long pants, long sleeved shirt) for the following scenarios:

- (3a thru 3d) loading granulars for ground, air, and bait applications;
- (6) applying sprays with groundboom sprayers;
- (7a and 7b) applying granulars and baits with tractor-drawn broadcast spreaders;
- (11) applying liquids with an airblast sprayer;
- (12) applying pastes with a brush;
- (13) mixing/loading/applying granular baits for belly grinder applications; and
- (15) flagging aerial spray applications.

The calculations of combined dermal and inhalation risk indicate that the MOEs are acceptable (100 or greater) with the noted additional PPE for the following scenarios:

- (1a) Mixing/loading wettable powders for aerial applications at the 0.45 lb. a.i./A rate requires double layer of clothing and chemical resistant gloves. At the 0.9 lb. a.i./A rate double layer of clothing, chemical resistant gloves, and a dust/mist respirator are required. At the 1.8 lb. a.i./A rate water soluble bags and single layer of clothing are required. However, if water soluble packaging is used for all rates for wettable powders then only a single layer of clothing (long-sleeved shirt, long pants, and shoes plus socks) is required;
- (1b) Mixing/loading wettable powders for groundboom applications requires single layer of clothing and chemical resistant gloves;
- (1c) Mixing/loading wettable powders for airblast applications requires single layer of clothing and chemical resistant gloves; and
- (2a, 2b, and 2c) Mixing/loading liquids for aerial, groundboom and airblast applications requires single layer of clothing and chemical resistant gloves;
- (9) applying baits by hand requires single layer of clothing and chemical resistant gloves.

In the regulatory section this information has been integrated with other considerations based on epidemiological information and handler incident data to determine the final PPE requirements.

The calculations of combined dermal and inhalation risk indicate that the MOEs are acceptable (100 or greater) with the noted engineering controls for the following scenarios:

- (1a) mixing/loading wettable powders for aerial application at the 1.8 lb rate requires water soluble bags;
- (4) applying sprays with fixed-wing aircraft (baseline and PPE not available) requires an enclosed cockpit;
- (5) applying sprays with a helicopter (baseline and PPE not available) requires an enclosed cockpit; and
- (8) applying baits with aerial equipment (baseline and PPE not available) requires an enclosed cockpit.

However, when estimated MOEs for closed-cockpit exposure scenarios are an order of magnitude larger than the uncertainty factor (i.e., the acceptable MOE), then this scenario would also be acceptable using an open-cockpit plane. For methomyl, an occupational MOE of 100 or higher is required to be above the Agency's level of concern. The combined dermal and inhalation MOEs for enclosed cockpits range from 1900 to 18000. Therefore, an enclosed cockpit is not required for scenarios 4, 5, and 8 above.

The combined dermal and inhalation risks for the following scenarios were not calculated because the inhalation dose was less than 1 percent of the dermal dose:

- (2a) mixing/loading liquids for aerial application;
- (2c) mixing/loading liquids for airblast application;
- (3a and 3d) mixing/loading granulars for tractor drawn spreaders;
- (5) applying sprays with a helicopter;
- (12) applying paste with a brush; and
- (13) mixing/loading/applying granular bait for belly grinder application.

There are data gaps for the following scenarios:

- (10) applying dust with dust application equipment; and
- (14) flagging aerial bait applications

There are no data that can be used to assess the risk associated with the use of dust formulations. Therefore, a maximum level of PPE is required until appropriate exposure data are developed for risk assessment and the assessment justifies removal of PPE. Mixers and loaders are required to wear long-sleeve shirt, long pants, chemical resistant apron, chemical resistant gloves, chemical resistant footwear plus socks, and a respirator. Applicators are required to wear coveralls over long-sleeve shirt, long pants, chemical resistant gloves, chemical resistant footwear plus socks, chemical resistant headgear for overhead exposure, and a respirator.

There are no data that can be used to assess the risk associated with flagging for aerial bait applications. Therefore, the PPE requirements are the same as those for flagging for aerial spray applications and consist of long-sleeve shirt, long pants, and shoes plus socks.

There are no data that can be used to assess the risk associated with mixing pelleted baits or pastes for paint brush applications. Therefore, the minimum PPE requirements are long-sleeve shirt, long pants, chemical resistant apron, chemical resistant gloves and a respirator.

c. Post-Application

Exposure & Assumptions

Dermal

Grapes Reentry Exposure Study (app. Rate 0.9 lb a.i./A)

Among the postapplication data developed for methomyl, the Agency has selected a study which monitored residues resulting from applications to grapes as the best available for assessing potential exposure to reentry workers. The Agency has used the data from this study to estimate exposure and risk for workers following methomyl applications in a variety of scenarios. Also, the Agency has excluded data developed for canceled sites (e.g., greenhouse, ornamentals). In the grape study both foliage and soil dislodgeable residues as well as worker reentry exposure were measured. Grapes were treated with a single application of methomyl at a rate of 0.9 lb ai/acre using an airblast sprayer. Dislodgeable foliar residue (DFR) measurements were conducted before treatment, and on days after treatment (DAT) 1, 2, 3, 5, 7, 10, and 14. Replicate soil samples were collected on the day of reentry. Workers reentered seven sites treated with methomyl between DAT 7 and 11 (MRID 41032301).

The Best Fit DFR data in the following table were derived by averaging the DFRs from six study sites. The seventh site, Del Rey, CA, was not used because of insufficient data points. The transfer coefficient used in the following table (27,021 cm^2/hr) was obtained by averaging the transfer coefficients obtained from three sites where reentry to perform grape girdling took place. (The three site-specific transfer coefficients for girdling were 9,757 cm^2/hr; 13,192 cm^2/hr; and 58,114 cm^2/hr.) The table below presents the dose, exposure, and MOEs for workers girdling grapes.

Table 15: Worker (Girdling) Reentry Exposure to Methomyl Residues Following Application to Grapes

Days After Treatment	Best Fit DFR ($\mu g/cm^2$)[a]	Tc (cm^2/hr)[b]	Exposure (mg/day)[c]	Dose (mg/kg/day)[d]	MOE[e]
0	0.5432	27,021	117.42	1.68	54
1	0.4361	27,021	94.27	1.35	67
2	0.3516	27,021	76.00	1.09	83
3	0.2845	27,021	61.50	0.88	100

[a] The average foliar dislodgeable residues from the grape study at an application rate of 0.9 lb a.i./A (MRID 41032301). DFR ($\mu g/cm^2$) was derived by converting the measured DFR data into lognormal then running a linear regression equation to estimate the dissipation over time.

[b] Transfer coefficients calculated by averaging three girdling activity study sites.

[c] Exposure (mg/day) = [(Best Fit DFR x Transfer Coefficient (27,021 cm^2/hr)) / 1,000 $\mu g/mg$] x 8 hrs/day]

[d] Dose (mg/kg/day) = Exposure (mg/day) / 70 kg (assumed weight of worker).

[e] MOE = NOEL (90 mg/kg/day) / Dose (mg/kg/day). MOEs are rounded to 2 significant figures.

Other Crops with Similar Maximum Application Rates

For other crops with similar maximum rates, the Agency has used the grape DFR data combined with a range of estimated transfer coefficients to assess potential postapplication dermal exposure to workers. The Agency has estimated 1,000 cm^2/hr to represent the transfer coefficient for crops with potentially low dermal transfer during routine postapplication activities ("low exposure crops"), and 10,000 cm^2/hr to represent the transfer coefficient for crops with potentially high dermal transfer during routine postapplication activities ("high exposure crops"). The Agency believes these transfer coefficients are reasonable estimates for these crop types.

Low Exposure Crops: Alfalfa, fennel, asparagus, barley, beans (lima, snap), beets, broccoli, Brussels sprouts, cabbage, carrot, cauliflower, celery, chard, chicory, collards, cucumber, cucurbit vegetables, dandelion, eggplant, endive, garlic, groundcherry, horseradish, kale, lentils, lettuce, melons, mint, mustard, oats, onion, parsley, peanuts, pea, pecan, pepper, peppermint, potato, pumpkin, radish, rye, sorghum, spinach, squash, sugar beet, sweet potato, turnip, and wheat.

High Exposure Crops: Apple, artichoke, avocado, blueberry, cotton, corn, grapes (activities other than girdling), grapefruit, lemon, nectarine, orange, peach, pear, pomegranate, tangelo, tangerine, tobacco, tomato, tree nuts, sod farm turf (cutting/rolling).

Using the DFR data from the grape study and estimated transfer coefficients, the table below presents the dermal exposure, dose, and MOEs for the low and high exposure crops.

Table 16: Worker Reentry Exposure to Methomyl Residues for Low and High Exposure Crops

Days After Treatment	Best Fit DFR (μg/cm^2)[a]	Tc (cm^2/hr)[b]	Exposure (mg/day)[c]	Dose (mg/kg/day)[d]	MOE[e]
0	0.5432	1,000 (Low)	4.35	0.062	1500
		10,000 (High)	43.46	0.62	150
1	0.4361	1,000 (Low)	3.49	0.05	NA
		10,000 (High)	34.89	0.50	NA
2	0.3516	10,000	28.13	0.40	NA

[a] The average foliar dislodgeable residues from the grape study at an application rate of 0.9 lb a.i./A (MRID 41032301). DFR (μg/cm^2) was derived by converting the measured DFR data into lognormal then running a linear regression equation to estimate the dissipation over time. The application rate in the study was 0.9 lbs. active ingredient per acre.

[b] Transfer coefficients: 10,000 cm^2/hr for crops with potentially high dermal transfer; and 1,000 cm^2/hr for crops with potentially low dermal transfer.

[c] Exposure (mg/day) = [(Best Fit DFR x Transfer Coefficient (cm^2/hr)) / 1,000 μg/mg] x 8 hrs/day

[d] Dose (mg/kg/day) = Exposure (mg/day) / 70 kg (assumed weight of worker).

[e] MOE = NOEL (90 mg/kg/day) / Dose (mg/kg/day). MOEs are rounded to 2 significant figures.

Crops with Other Maximum Application Rates

Lower Rates: Several crops/sites have application rates lower than that used in the grape study. For these crops, the values reflected in the table above are assumed to represent the high-end of potential exposures. Actual exposures are likely to be lower due to lower application rates and lower resulting DFRs.

Higher Rates: Peaches and sod farm turf have application rates which exceed the 0.9 lbs ai/acre that was used in the grape study. For these crops, the DFRs resulting from applications made at higher rates would likely result in higher exposures than those reflected in the last table. Both peaches and turf are in the "high exposure crop" category. If the DFRs were assumed to be twice as high for turf and peaches based on the application rate being double that used in the grape study (i.e., 1.8 lbs ai/acre versus 0.9 lbs ai/acre), MOEs would still exceed 100 on DAT 2. The table below presents these estimates.

Table 17: Estimated Worker Reentry Exposure to Methomyl Residues Following Application to Peaches and Turf

Days After Treatment	Estimated DFR ($\mu g/cm^2$)[a]	Tc (cm^2/hr)[b]	Exposure (mg/day)[c]	Dose (mg/kg/day)[d]	MOE[e]
0	1.0864	10,000	86.91	1.24	73
1	0.8722	10,000	69.78	1.00	90
2	0.7032	10,000	56.26	0.80	110

[a] The average foliar dislodgeable residues from the grape study MRID 41032301; DFR ($\mu g/cm^2$) was derived by converting the measured DFR data into lognormal then running a linear regression equation to estimate the dissipation over time. The values in this table are double those derived from the grape data based on the maximum application rate for peaches and turf being double the rate used in the study.

[b] Transfer coefficient estimated to be: 10,000 cm^2/hr for crops with potentially high dermal transfer.

[c] Exposure (mg/day) = [(Best Fit DFR x Transfer Coefficient (10,000 cm^2/hr)) / 1,000 $\mu g/mg$] x 8 hrs/day]

[d] Dose (mg/kg/day) = Exposure (mg/day) / 70 kg (assumed weight of worker).

[e] MOE = NOEL (90 mg/kg/day) / Dose (mg/kg/day). MOEs are rounded to 2 significant figures.

Baits, Dusts, and Pastes

There are currently no data from which to estimate postapplication exposure following application of dusts, baits, and pastes using aerial and ground equipment, and paint brushes. Risk estimates were made by extrapolation from other data.

Inhalation

Although methomyl has an inhalation endpoint of 37 mg/kg/day, no postapplication inhalation risk assessment has been completed. The postapplication risk assessment quantified only dermal exposures. This is because of the relatively high vapor pressure of methomyl (1×10^{-5} mM Hg), historical data which indicate that dermal expsoure is the predominant exposure route and the low inhalation risk estimates for applicators.

d. Post-Application Risks

The calculations of postapplication exposure and risk in Tables 15, 16, and 17 indicate that for certain crops, restricted-entry intervals (REIs) based on the short and intermediate term dermal toxicological endpoint should be considered. MOEs for grape girdlers do not reach 100 until the third day after application, indicating at least a 3-day REI. Estimates of exposure and risk for peach and commercial sod harvesters indicate that MOEs exceed 100 on the second day after application, indicating at least a 2-day REI. For other crops and sites, no additional postapplication mitigation is indicated based on the short and intermediate term dermal endpoint. For these other crops and sites the REI should be based on the acute toxicity of methomyl. Since methomyl is in acute toxicity category 1 for primary eye irritation, a 48 hour REI is indicated. In

the regulatory section this information has been integrated with other considerations based on epidemiological information and incident data to determine the required REIs.

For early entry into treated areas (i.e., during the REI) that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, reentry workers should wear the clothing and PPE consistent with the acute toxicity categories of the active ingredient (i.e., long sleeved shirt, long pants, shoes and socks, chemical resistent gloves, and protective eyewear).

No data are available for estimating worker's dermal exposures to methomyl following applications of baits. However, EPA recognizes that dermal exposures to methomyl following application of baits are likely to be significantly lower than would result from workers' contact with treated foliage. Therefore, EPA believes that dermal risk from bait applications would not exceed the risks estimated above for foliar contact in "low exposure" crops.

Postapplication risk assessments were not completed for dusts, pastes, and paintbrush applications of methomyl. Dust use scenarios were not addressed due to lack of appropriate data and the similarity with other postapplication agricultural scenarios (i.e., a postapplication exposure assessment for sprays on various crops may be used to crudely assess risks from dusts given the uncertainty associated with the extrapolation). Pastes and paintbrush postapplication exposure assessments were not completed because of a lack of data and because these scenarios are believed to have a low potential for exposure (i.e., dermal contact with treated surfaces is likely minimal or nonexistent given the use pattern).

e. Non-Occupational Exposures and Risks

Non-Occupational Exposure

Dermal: Based on current labels and information provided by the registrants, EPA believes that the following three scenarios represent potential non-occupational postapplication exposure for methomyl:

1. Non-Occupational dermal exposure to methomyl-treated "U-Pick" peaches.

This is believed to be a worst-case scenario for non-occupational postapplication exposure to methomyl. DFR data from the grape study were used in combination with the SOPs for Residential Exposure Assessments (draft, December 18, 1997) to estimate non-occupational postapplication exposure.

The following scenario was used for children. A youth, 10 - 12 years of age, is assumed to have 2 hours of exposure, a transfer coefficient of 5,000 cm^2/hr, and weigh 39.1 kg. Because the pre-harvest interval for peaches treated with methomyl is 4 days, the best fit DFR values (from Table 12) for DAT 4 were used, and doubled to represent the maximum rate of 1.8 lbs ai/acre for

peaches. A child's exposure picking peaches is thus estimated as: DFR (0.4628μg/cm^2) x Tc (5,000 cm^2/hr) x Duration (2 hrs) x Conversion μg/mg (1/1,000) = 4.6 mg/day. Daily dose is estimated by dividing the exposure by the body weight: 4.6 mg per day / 39.1 kg = 0.12 mg/kg/day.

The resulting MOE is calculated using the 90 mg/kg/day dermal NOEL as: 90 (NOEL) / 0.12 (Dose) = 750.

The following scenario was used for adults picking peaches: an adult is assumed to have 4 hours of exposure, a transfer coefficient of 10,000 cm^2/hr, with a body weight of 71.8 kg. The adult exposure is estimated to be 18.5 mg/day, with a daily dose of 0.26 mg/kg/day.

The resulting MOE is calculated as, 90 (NOEL) / 0.26 (Dose) =350.

To further limit exposure, a statement has been added to the agricultural labels prohibiting the use of methomyl in home plantings and on any commercial crop that is turned into a "U-Pick", "Pick Your Own" or similar operation.

2. Incidental dermal exposure following application of bait pellets in public access areas (such as trash disposal areas associated with commercial establishments).

No data are available to quantify potential exposures and risks. However, based on the above estimates for occupational and residential exposures to treated peach foliage, which would be expected to be much higher than for incidental dermal exposures to baits, EPA believes that potential non-occupational dermal exposures to baits is below that which would present a risk concern.

3. Ingestion of bait pellets by children mistaking them for food or candy.

No data are available for quantifying such potential exposures. However, the issue of accidental ingestion by children was addressed through mitigation agreed upon between the registrants and the Agency in 1995 for the fly bait formulations. For the fly bait products, the use was limited to commercial agriculture production where children would not be present. The bait stations are required to be placed four feet above the ground. An embittering agent has been added to all fly bait stations and the color of the formulations are limited to earth-tones or other dark, unattractive colors. The Agency believes that when baits are applied according to label instructions, potential for children's accidental oral exposure would not present a significant risk.

Summary of Non-Occupational Risk

Estimates of dermal exposure and risk, presented above, indicate that MOEs exceed 100 for both adults and children for the scenario considered to represent a worst case, harvesting treated peaches at a U-Pick farm. The adult MOE at day 4 is 350, and the MOE for children is

750. Methomyl-specific DFR data from the grape study were used with the SOPs for Residential Exposure Assessment, to derive these results. Because the pre-harvest interval (PHI) for peaches is 4 days, DAT 4 DFR values were selected. EPA believes these estimates are conservative and represent the high end of potential non-occupational dermal exposures. Since the U-Pick scenario has been prohibited on the label and because the bait pellets are not a significant use of methomyl these uses will not be added to the aggregate risk assessment.

Additional Occupational/Residential Exposure Studies

Handler Studies

Based on the risk assessment of the current uses of methomyl, additional handler exposure studies are not required at this time.

Post-Application Studies

Based on the risk assessment of the current uses of methomyl, additional post-application exposure studies are not required at this time.

C. Environmental Assessment

The Agency has adequate data to assess the hazard of methomyl to nontarget terrestrial organisms. However, an estuarine/marine fish early life-cycle study (72-4a), and an estuarine/marine invertebrate life-cycle study (72-4b) are required as confirmatory information.

1. Toxicity to Terrestrial Animals

a. Birds, Acute and Subacute

An acute oral toxicity study using the technical grade of the active ingredient (TGAI) is required to establish the toxicity of methomyl to birds. The preferred test species is either mallard duck (a waterfowl) or bobwhite quail (an upland gamebird). Results of the tests are tabulated below.

Table 18: Avian Acute Oral Toxicity

Species	*% ai*	*LD50 (mg/kg)*	*Toxicity Category*	*MRID No. Author/Year*	*Study Classification*[1]
Northern bobwhite quail *(Colinus virginianus)*	98.7	24.2	highly toxic	00161886 Beavers, 1983	core
Mallard duck *(Anas platyrhynchos)*	90	15.9	highly toxic	00160000 Tucker, 1970	core
Ring-necked Pheasant *(Phasianus colchicus)*	90	15.4	highly toxic	00160000 Tucker, 1970	core

[1] Core (study satisfies guideline).

The LD_{50} for methomyl falls in the 10-50 mg/kg range, which is considered highly toxic to avian species on an acute oral basis. The guideline (71-1) is fulfilled (MRID 00161886, 00160000).

Two subacute dietary studies using the TGAI are required to establish the toxicity of methomyl to birds. The preferred test species are mallard duck and bobwhite quail. Results of these tests are tabulated below.

Table 19 - Avian Subacute Dietary Toxicity

Species	*% ai*	*5-Day LC50 (ppm)*	*Toxicity Category*	*MRID No. Author/Year*	*Study Classification*
Northern bobwhite quail *(Colinus virginianus)*	>95	1100	slightly toxic	#22923 Hill et al.,1975	core
Mallard duck *(Anas platyrhynchos)*	>95	2883	slightly toxic	#22923 Hill et al., 1975	core
Ring-necked pheasant *(Phasianus colchicus)*	>95	1975	slightly toxic	#22923 Hill et al., 1975	core

The LC_{50} for methomyl falls in the 1001-5000 ppm range, which is considered slightly toxic to avian species on a subacute dietary basis. The guideline (71-2) is fulfilled. (MRID# 22923).

b. Birds, Chronic

Avian reproduction studies using the TGAI are required for methomyl because birds may be subject to repeated or continuous exposure to the pesticide, especially preceding or during the breeding season. The preferred test species are mallard duck and bobwhite quail. Results of these tests are tabulated below.

Table 20 - Avian Reproduction

Species/ Study Duration	*% ai*	*NOEC[1] (ppm)*	*LOEC Endpoints*	*MRID No. Author/Year*	*Study Classification*
Northern bobwhite quail *(Colinus virginianus)*	98.35	150	fewer eggs laid and eggs set	41898602 Beavers et al., 1990	core
Mallard duck *(Anas platyrhynchos)*	98.35	150	female weight change (loss)	41898601 Beavers et al.,1990	core

[1]NOEC = No Observed Effect Concentration

The results indicate that methomyl does not affect avian reproduction at 150 ppm. The guideline (71-4) is fulfilled. (MRID 41898602, 41898601).

c. Mammals, Acute and Chronic

Wild mammal testing is required on a case-by-case basis, depending on the results of lower tier laboratory mammalian studies, intended use pattern and pertinent environmental fate characteristics. In most cases, rat or mouse toxicity values obtained from the Agency's Health Effects Division (HED) substitute for wild mammal testing. Results of these tests are tabulated below.

Table 21: Mammalian Toxicity

Species	*% ai*	*Test Type*	*Toxicity Value mg/kg*	*Affected Endpoints*	*MRID No.*
laboratory rat *(Rattus rattus)*	90	LD50	17-24 mg/kg	mortality	00009227
Laboratory rat (*Rattusrattus)*	98.35	LD50	30-34 mg/kg	mortality	421401-01
Laboratory rat (*Rattusrattus)*	98	Repro.	NOEC 75 ppm LOEC 600 ppm	body weight	432507-01
Laboratory rat (*Rattusrattus)*	97.5	Repro.	NOEC 100 ppm LOEC >100 ppm	no effects	MRO-00007093
Mule deer (*Odocoileus hemionus*)	90	LD50	11.0-22.0	mortality	Tucker, 1970 00160000

The results indicate that methomyl is very highly toxic to mammals on an acute oral basis. There is no guideline requirement.

d. Insects

Honey bee acute contact and toxicity of residues on foliage studies using the TGAI are required for methomyl because its use will result in honey bee exposure. Results of this test are tabulated below.

Table 22: Nontarget Insect Acute Contact Toxicity

Species	*% ai*	*LD_{50} (μg/bee)*	*Toxicity Category*	*MRID. No. /Year*	*Study Classification*
Honey bee *(Apis mellifera)*	90	< 0.5	highly toxic	00014715 / 1971	Supplemental

An analysis of the results indicates that methomyl is categorized as highly toxic to bees on an acute contact basis. Although the study (MRID 00014715) is supplemental and does not fulfill the guideline (141-1) requirements, a new study is not required.

2. Toxicity to Aquatic Animals

a. Freshwater Fish, Acute

Two freshwater fish toxicity studies using the TGAI are required to establish the toxicity of methomyl to fish. The preferred test species are rainbow trout (a coldwater fish) and bluegill sunfish (a warmwater fish). Results of these tests are tabulated below.

Table 23 - Freshwater Fish Acute Toxicity

Species/ (Flow-through or Static)	*% ai*	*96-hr LC_{50} (ppm) (mea./ nominal)*	*Toxicity Category*	*MRID No. Author/Year*	*Study Classification*
Rainbow trout *(Oncorhynchus mykiss)*	95-98	1.6	moderately toxic	Johnson,1980 40094602	core
Bluegill sunfish *(Lepomis macrochirus)*	95-98	1.05	moderately toxic	Johnson,1980 40094602	core
Brook Trout *(Salvelinus* fontinalis)	95-98	1.5	moderately toxic	Johnson,1980 40094602	core
Cutthroat trout *(Salmo clarki)*	95-98	6.8	moderately toxic	Johnson,1980 40094602	core
Channel catfish *(Ictalurus punctatus)*	95-98	0.53	highly toxic	Johnson,1980 40094602	core
Largemouth bass *(Micropterus salmoides)*	95-98	1.25	moderately toxic	Johnson, 1980 40094602	core
Atlantic salmon (Salmo salar)	95-98	1.12	moderately toxic	Johnson, 1980 40094602	core
Fathead minnow (Pimephales promelas)	95-98	2.8	moderately toxic	Johnson,1980 40094602	core
Channel catfish (Ictalurus punctatus)	29	0.32	highly toxic	Johnson, 1980 40094602	core
Bluegill sunfish *(Lepomis macrochirus)*	29	0.67	highly toxic	Johnson,1980 40094602	core
Rainbow Trout *(Onchoryhncus mykiss)*	29	1.2	moderately toxic	Johnson, 1980 40094602	core
Fathead minnow (*Pimephales promelas*)	29	1.5	moderately toxic	Johnson, 1980 40094602	core
Rainbow trout (*Onchoryhncus mykiss*)	24	1.2	moderately toxic	Johnson, 1980 40094602	core
Atlantic salmon (*Salmo salar*)	24	1.4	moderately toxic	Johnson, 1980 40094602	core
Brook trout (*Salvilinus fontinalis*)	24	2.2	moderately toxic	Johnson, 1980 40094602	core
Bluegill sunfish (*Lepomis macrochirus*)	24	0.7	highly toxic	Johnson, 1980 40094602	core
Bluegill sunfish (*Lepomis macrochirus*)	degradate	462	practically non-toxic	Schneider, 1976 00009061	core

Because the 96-hour LC_{50} for the technical grade material falls in the range of 0.5 ppm to 6.8 ppm, methomyl is considered to be moderately to highly toxic to freshwater fish on an acute basis. The guideline (72-1) is fulfilled (MRID 40094602). Since the 96-hour LC_{50} falls between 0.32 and 2.2, the formulated products of methomyl are also considered to be moderately toxic to highly toxic to freshwater fish on an acute basis. (MRID 40094602). The toxicity of the degradate thiolacetohydroxamic acid, 5-methyl ester, was found to be 462 ppm. This degradate is considered to be practically non-toxic to freshwater fish (MRID 00009061).

b. Freshwater Fish, Chronic

A freshwater fish early life-stage test using the TGAI is required for methomyl because the end-use product may be transported to water from the intended use site, and the following conditions are met: (1) methomyl is intended for use such that its presence in water is likely to be continuous or recurrent, (2) it has aquatic acute LC_{50}s or EC_{50}s of less than 1 mg/l, and (3) the EEC in water is equal to or greater than 1 percent of an acute LC_{50} or EC_{50} value. The preferred test species is rainbow trout. Results of this test are tabulated below.

Table 24: Freshwater Fish Early Life-Stage Toxicity Under Flow-through Conditions

Species/ Study Duration	*% ai*	*NOEC (ppb)*	*MATC/ LOEC[1] (ppb)*	*Endpoints Affected*	*MRID No. Author/Year*	*Study Classification*
Fathead Minnow *(Pimephales promelus)*	>99	57	82/117	larvae survival	00131255 Driscoll, 1982	core

[1] MATC = Maximum Allowed Toxic Concentration, defined as the geometric mean of the NOEC and LOEC.

The data indicate that methomyl significantly reduced larvae survival at concentrations greater than 117 ppb. The guideline (72-4) is fulfilled.(Acc. # 00118512).

A freshwater fish life-cycle test using the TGAI is required for methomyl because the end-use product may be transported to water from the intended use site and the EEC is equal to or greater than one-tenth of the NOEL in the fish early life-stage and invertebrate life-cycle tests. The preferred test species is fathead minnow. Results of this test are tabulated below.

Table 25: Freshwater Fish Life-Cycle Toxicity Under Flow-through Conditions

Species	*% ai*	*NOEC/LOEC (ppm)*	*MATC[1] (ppm)*	*Endpoints Affected*	*MRID*	*Study Classification*
Fathead minnow *(Pimephales promelas)*	98.4	0.076/0.142	0.104	growth	43072101	Core

[1] Defined as the geometric mean of the NOEC and LOEC.

The data indicate that methomyl affected the growth of fathead minnows at concentrations of 0.142 ppm. The guideline (72-5) is fulfilled (MRID 43072101).

c. Freshwater Invertebrates, Acute

A freshwater aquatic invertebrate toxicity test using the TGAI is required to establish the toxicity of methomyl to aquatic invertebrates. The preferred test species is *Daphnia magna*. Results of these tests are tabulated below.

Table 26 - Freshwater Invertebrate Acute Toxicity

Species	*% ai*	*48-hour LC50/ EC50 (ppb)*	*Toxicity Category*	*MRID No. Author/Year*	*Study Classification*
Waterflea *(Daphnia magna)*	>99	31.7	very highly toxic	00019977 Goodman,1978	core
Waterflea *(Daphnia magna)*	95-98	8.8 EC50	very highly toxic	Johnson & Finney, 1980; 40094602	core
Waterflea *(Daphnia magna)*	24	7.6	very highly toxic	Johnson & Finney, 1980; 40094602	core
Waterflea *(Daphnia magna)*	>99	28.7	very highly toxic	00131254	core
Scuds *(Gammarus pseudolimnaeus)*	24	1,050	highly toxic	Mayer, 1986 40098001 Johnson & Finney, 1980; 40094602	core
Skwala	24	343	very highly toxic	Johnson & Finney, 1980; 40094602	core
Pteronarcella	24	69	very highly toxic	Johnson & Finney, 1980; 40094602	core

Because the LC_{50}/EC_{50} of the TGAI falls in the range of 8.8 to 31.7 ppb, methomyl is considered to be highly to very highly toxic to aquatic invertebrates on an acute basis. The guideline (72-2) is fulfilled (MRID# 00019977, 40094602). The LC_{50}/EC_{50} for the 24% formulated product ranges from 7.6 to 1,050 ppb (MRID# 40098001, 40094602) . Therefore, the formulated product is also considered to range from highly to very highly toxic to aquatic invertebrates.

d. Freshwater Invertebrates, Chronic

A freshwater aquatic invertebrate life-cycle test using the TGAI is required for methomyl because the end-use product may be transported to water from the intended use site, and the following conditions are met: (1) methomyl is intended for use such that its presence in water is likely to be continuous or recurrent, (2) it has aquatic acute LC_{50}s or EC_{50}s of less than 1 mg/l, and (3) the EEC in water is equal to or greater than 1 percent of an acute LC_{50} or EC_{50} value. The preferred test species is *Daphnia magna*. Results of this test are tabulated below.

Table 27: Freshwater Aquatic Invertebrate Life-Cycle Toxicity

Species	*% ai*	*21-day NOEC (ppb)*	*MATC[1] (ppb)*	*Endpoints Affected*	*MRID No. Author/Year*	*Study Classification*
Waterflea *(Daphnia magna)*	>99	>0.4	0.6	number of young /adult	00118512 Britelli, 1982	core

[1] Maximum Allowed Toxic Concentration, defined as the geometric mean of the NOEC and LOEC.

The data indicate that methomyl significantly reduced the number of young produced at concentrations greater than 0.4 ppb. The guideline (72-4) is fulfilled. (Acc# 00118512).

e. Estuarine and Marine Fish, Acute

Acute toxicity testing with estuarine/marine fish using the TGAI is required for methomyl because the active ingredient is expected to reach this environment due to its use in coastal counties. The preferred test species is sheepshead minnow. Results of this test are tabulated below.

Table 28 - Estuarine/Marine Fish Acute Toxicity

Species	*% ai*	*96-hour LC50 (ppb) (measured/ nominal)*	*Toxicity Category*	*MRID No. Author/Year*	*Study Classification*
Sheepshead minnow *(Cyprinodon variegatus)*	98.35	1,160	moderately toxic	41441202	core

Since the LC_{50} falls in the range of >1-10 ppm, methomyl is considered to be moderately toxic to estuarine/marine fish on an acute basis. The guideline (72-3a) is fulfilled (MRID# 41441202).

f. Estuarine and Marine Fish, Chronic

An estuarine/marine fish early life-stage toxicity test using the TGAI is required for methomyl because the end-use product may be transported to estuarine/marine waters from the intended use site and the following conditions are met: (1) methomyl is intended for use such that its presence in water is likely to be continuous or recurrent, and (2) the EEC in water is equal to or greater than 1 percent of an acute LC_{50} or EC_{50} value. The preferred test species is sheepshead minnow. This guideline (72-4a) is not fulfilled.

An estuarine/marine fish life-cycle test using the TGAI may be required for methomyl because the end-use product is expected to reach this environment due to its use in coastal counties and the following conditions are met: (1) the EEC is equal to or greater than one-tenth of the NOEC in the fish early life-stage or invertebrate life-cycle test, or, (2) studies of other organisms indicate the reproductive physiology of fish may be affected. The preferred test species is sheepshead minnow. The requirement for this study is deferred until a valid estuarine fish early life-stage study is submitted and reviewed.

g. Estuarine and Marine Invertebrates, Acute

Acute toxicity testing with estuarine/marine invertebrates using the TGAI is required for methomyl because the end-use product may reach this environment because of its use in coastal counties. The preferred test species are mysid shrimp and eastern oyster. Results of these tests are tabulated below.

Table 29 - Estuarine/Marine Invertebrate Acute Toxicity

Species	*% ai.*	*96-hr LC50/EC50 (ppm) (mea/nominal)*	*Toxicity Category*	*MRID No. Author/Year*	*Study Classification*
Eastern oyster (shell deposition) *(Crassostrea virginica)*	98.35	EC50>140	practically non-toxic	42074601 Ward, 1991	core
Mysid *(Mysidopsis bahia)*	98.35	0.23	highly toxic	41441201 Ward, 1989	core
Grass *(Palaemonetes vulgaris)*	24	0.13	highly toxic	00009230 Bentley,1973	supplemental
Fiddler crab *(Uce pugilator)*	24	2.38 (TL50)	moderately toxic	00009230 Bentley,1973	supplemental
Grass shrimp *(Palaemonetes vulgaris*)	90	0.049 (TL50)	very highly toxic	Sleight, 1973 00009134	core
Pink Shrimp (*Penaeus duorarum*)	90	0.019 (TL50)	very highly toxic	Sleight, 1973 00009134	core
Mud crab (*Neopanope texana*)	90	0.410 (TL50)	highly toxic	Sleight, 1973 00009134	supplemental

An LC_{50} in the range of 0.019 to 0.23 ppm suggests that methomyl has the potential to be very highly toxic to marine shrimp species (TGAI and formulation). A study used to evaluate oyster shell deposition (short term growth) produced an EC_{50} of greater than 140 ppm, which suggests practically no toxicity to adult oysters. The guideline (72-3b and 72-3c) is fulfilled (MRID#s 41441201, 42074601). The LC_{50} for the 24% formulation ranges from 0.13 to 2.38 (TL50) indicating that this product is moderately to highly toxic to estuarine invertebrates.

h. Estuarine and Marine Invertebrates, Chronic

An estuarine/marine invertebrate life-cycle toxicity test using the TGAI is required for methomyl because the end-use product may be transported to the estuarine/marine environment from the intended use site, and the following conditions are met: (1) the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity, (2) it has an aquatic acute LC_{50} or EC_{50} of less than 1 mg/l, and (3) the EEC in water is equal to or greater than 1

percent of an acute LC_{50} or EC_{50} value. The preferred test species is mysid shrimp. This Guideline (72-4b) is not fulfilled.

3. Toxicity to Plants

a. Terrestrial

Currently, terrestrial plant testing is not required for pesticides, other than herbicides, except on a case-by-case basis. It is not required for methomyl.

b. Aquatic

Currently, aquatic plant testing is not required for pesticides, other than herbicides and fungicides, except on a case-by-case basis. It is not required for methomyl.

D. Environmental Fate

1. Environmental Fate Assessment

Laboratory studies indicate that methomyl is moderately persistent and highly mobile. It is stable to hydrolysis at lower pH's (neutral to acidic) and degrades slowly in alkaline conditions. Methomyl photolyzes quickly in water but more slowly in soils. It is moderately stable to aerobic soil metabolism but degrades more rapidly under anaerobic conditions. In laboratory studies, methomyl does not readily adsorb to soil and has the potential to be very mobile. Field studies show varying dissipation rates of the chemical in soils. Dissipation rates were related primarily to differences in soil moisture content, which may affect the microbial activity; and rainfall/irrigation, which could influence leaching.

Degradation and Metabolism

Methomyl is stable to hydrolysis at pH 5 and 7 and slowly degrades in pH 9 buffered solutions (half-life, $t_{1/2} \approx 30$ days). The major hydrolysis degradate is S-methyl-N-hydroxythioacetimidate (41-44% of the applied after 30 days) (MRID 00131249). Methomyl photodegrades quickly in water ($t_{1/2}$ of 1 day), but more slowly on soils ($t_{1/2}$ of 34 days). The major photolysis degradate, acetonitrile, peaked at 66% of the applied after 15 days in water and 40% of the applied after 30 days on soil (MRID 00161885).

Methomyl degraded with a half-life of 30-45 days in an aerobic silt loam soil and 10.5 days in an aerobic loam soil. The major degradate was $^{14}CO_2$ (22.5% of the applied after 45 days in the silt loam soil, and 75% of the applied at 3 months in the loam soil). Nonextractable residues peaked at 26% of the applied after 45 days in the silt loam soil and 25% of the applied in the loam soil. A minor degradate, S-methyl-N-hydroxythioacetimidate, accounted for $\leq$2% of the applied (MRID 00008568).

Under anaerobic conditions, methomyl degraded with a half-life of 14 days in static conditions (nitrogen atmosphere) and <7 days in dynamic conditions (flowing nitrogen atmosphere) on a loam soil following 14 days of aerobic incubation. In the dynamic system, the major degradate was $^{14}CO_2$, which comprised 30% of the applied during the 14 days of aerobic incubation, and an additional 23% after 60 days of anaerobic incubation. Unextracted residues peaked at 36% of the applied after 7 days of anaerobic incubation. More rapid degradation under anaerobic conditions may be catalyzed by the presence of dissolved (ferrous) iron (MRID 43708806; open literature).

In a supplemental aquatic metabolism study, methomyl degraded with estimated half-lives of 4-5 days from two water-sediment systems that were not completely aerobic or anaerobic. Acetonitrile averaged a maximum of 17% of the applied at 7 days, and acetamide accounted for up to 14% of the applied at day 7. After 102 days, volatilized acetonitrile totaled up to 27% of the applied and $^{14}CO_2$ was up to 46% of the applied (MRID 43325402).

The only nonvolatile degradate found in the laboratory studies was S-methyl-N-hydroxythioacetimidate. It was present at high concentrations in the alkaline hydrolysis study but was only a minor degradate in the aerobic soil metabolism, anaerobic soil metabolism, and photolysis in water studies ($\leq$3% of the applied at all test intervals) (MRID 43325403).

Mobility

Methomyl and its degradate S-methyl-N-hydroxythioacetimidate are very mobile in soils, as demonstrated by soil TLC (R_f values 0.46-0.82 and 0.86-0.93, respectively). Results of the batch equilibrium studies show methomyl has a low affinity to bind to soil (K_{ads} 0.23-1.4, K_{oc} 19-34; K_{des} 0.5-2.8, $K_{oc(des)}$ 37-48), further indicating that the chemical will be mobile. Methomyl is a highly soluble chemical (5.47 g/100 g water). Its vapor pressure ($5x10^{-5}$ mm Hg) and Henry's Law Constant ($1.8x10^{-10}$ atm m^3/mol) suggest a low potential to volatilize from water (MRIDs 00044306 and 00161884).

Bioaccumulation

The low octanol/water partition coefficient (1.29 to 1.33) suggests that the chemical will have a low tendency to accumulate in fish.

Field Dissipation

Five terrestrial field dissipation studies are available on methomyl (MRIDs 00008844, 00009324, 00009326, 41623901, and 41623902). Although the studies were found acceptable, some have deficiencies that increase the level of uncertainty in the results. Dissipation half-lives from the surface soil ranged from 4 to 52 days. Such variations can be expected in the terrestrial field dissipation studies because of the large number of processes that occur simultaneously and the large number of variables present in the field.

The moderate persistence of methomyl appears to be tied to the soil conditions. In a muck soil (52% organic matter content), no methomyl was detected 7 days after treatment. A quick dissipation in a soil with such a high organic matter content may be related to microbial activity or rapid permeability. Two other studies conducted in sand and silt loam soils show extensive dissipation ($\geq$82% of the applied) after 1-3 months, with the remaining radioactivity recovered in the upper 8-15 inches of soil. No dissipation half-lives could be calculated in these studies because only a few sampling intervals are available.

In two recent studies conducted in cropped cabbage fields, the dissipation half-life from the surface ranged from 4-6 days in Mississippi to 54 days in California. Two factors may explain the differences in dissipation between the two sites. Soil moisture content, which may affect the level of biological activity, varied between the two sites (moisture contents ranged from 2.5 to 17% in the CA soils and averaged 16% over the first 15 days in the MS soils). The MS site received more rainfall, which may have led to more leaching out of the surface. In both studies the majority of the methomyl residues were found in the upper 30 cm of soil.

Spray Drift

No methomyl-specific studies were reviewed. Droplet size spectrum (201-1) and drift field evaluation (202-1) studies were required since the products may be applied aerially and the concern exists for potential risk to nontarget aquatic organisms. To satisfy these requirements the registrant is part of the Spray Drift Task Force (SDTF). The SDTF has completed and submitted to the Agency its series of studies which are intended to characterize spray droplet drift potential due to various factors, including application methods, application equipment, meteorological conditions, crop geometry, and droplet characteristics. After its review of the new studies the Agency will determine whether a reassessment is warranted of the potential risks from the application of methomyl to nontarget organisms.

2. Terrestrial Exposure Assessment

The terrestrial exposure assessment is based on the methods of Hoerger and Kenaga (1972)[1] as modified by Fletcher et al. (1994)[2]. Terrestrial estimated environmental concentrations (EECs) were derived from maximum application rates. For multiple applications they incorporate dissipation rates for methomyl. The Agency used a foliar dissipation rate of 4 days, which was the maximum rate reported in the field residue monitoring studies submitted by the registrant. Uncertainties in the terrestrial EECs are primarily associated with a lack of data on interception by and subsequent

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

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

dissipation from foliar surfaces. The estimated EECs in this table are the basis for the exposure estimates for birds and mammals in the terrestrial risk assessments.

Table 30: Estimated Environmental Concentrations (EECs) on Avian and Mammalian Food Items for Selected Uses, Based on Hoerger and Kenaga (1972), Modified by Fletcher et al (1994).

Site / Use	*Application Rate (lb ai/ac) x No.of Apps./Interval (da) = Max. Seasonal Rate (lb ai/ac)*	*Short grass*	*Tall grass*	*Broadleaf plants, small insects*	*Fruits, pods, seeds, large insects*
		Maximum / Mean EECs (ppm) [1]			
Baseline	Single App, 1 lb/A	240 / 85	110 / 36	135 / 45	15 / 7
Corn	0.45 x 16/1 = 7.2	636 / 225	292 / 95	358 / 119	40 / 19
Cotton	0.6 x 3/3 = 1.8	281 / 99	129 / 42	158 / 53	18 / 8
Lettuce	0.9 x 10/2 = 9.0	714 / 253	327 / 107	402 / 134	45 / 21
Peaches	1.8 x 3/5 = 5.4	690 / 244	316 / 104	388 / 129	43 / 20
Citrus	0.9 x 3/5 = 2.7	345 / 122	158 / 52	194 / 65	22 / 10

1 For multiple applications, a foliar dissipation half-life of 4 days, based on field residue monitoring studies, was incorporated.

3. Water Resource Assessment

Ground Water Assessment

Available data suggest that methomyl is moderately persistent in soils, highly soluble in water, and very mobile in soils. Such properties are characteristic of chemicals that are known to leach to ground water. A prospective ground water monitoring study conducted in a vulnerable area in Georgia (1992-1994) detected methomyl in ground water at concentrations ranging from 0.110 to 0.428 ppb. The monitoring study was conducted with a total application rate of 11.25 lb ai/ac, approximately 1.5 times the maximum label rate for corn. Although sampling continued for 27 months after application, no methomyl was detected after approximately 4 months. In addition, the Pesticides in Ground Water Database indicates that methomyl has been detected in three other states (Missouri, New York, and New Jersey) at concentrations up to 20 ppb.

The available information shows that in some of its use area, methomyl has the potential to leach to ground water. However, as illustrated by the prospective study conducted in Georgia, this degradation of ground-water quality will probably be short-lived.

Surface Water Assessment

Methomyl can contaminate surface water as a result of spray drift during application or runoff from treated sites. Substantial fractions of methomyl may be available for runoff for several days to weeks after application. Most of the methomyl reaching surface waters will be dissolved in

the runoff water rather than adsorbed to eroding soil. The rapid direct aqueous photolysis of methomyl should greatly limit its persistence in clear shallow waters. Its susceptibility to biodegradation should also limit the persistence of methomyl in waters with microbiological activity. Due to its resistance to abiotic hydrolysis, it will be more persistent in deeper and/or unclear waters with low microbiological populations and long hydrologic residence time.

The low soil/water partitioning coefficient of methomyl indicates that it will readily move into the water body. Dissolved concentrations of methomyl in sediment pore water and the water body will be comparable to concentrations adsorbed to sediment. The low octanol/water coefficient of methomyl indicates that its bioaccumulation potential is probably low.

The South Florida Water Management District (SFWMD) collected samples every two to three months from 27 surface water sites within the SFWMD from November 1988 through November 1993 and analyzed them for multiple pesticides. Methomyl was detected (detection limits ranging from 1.9 to 20 μg/L) in one sample at a concentration of 1.9 μg/L. In 1994, Washington state collected surface water samples in April, June, and October from 8 sites (24 total samples) and analyzed them for multiple pesticides including methomyl. Methomyl was not detected in any of the samples above an approximate quantification limit of 0.04 ug/L. However, methomyl was detected at a concentration of 0.088 ug/L in a 1993 sample collected from a site (Salmon Creek) not resampled in 1994. Neither study indicated whether the samples were taken in major methomyl use areas and whether detections are related to actual methomyl usage.

A search of STORET for methomyl in surface water revealed 9 detections in 3849 samples collected over 37 states. Detections were reported in California (5 detects ranging from 0.13 to 0.67 ug/L), Texas (3 detects ranging from 0.12 to 1 ug/L), Pennsylvania (0.19 ug/L), and Washington (0.9 ug/L). Most of the detection limits were below 1 ug/L.

The reported monitoring data provide supplemental information on methomyl concentrations in surface water. However, these data were not used for determining ecological risks or drinking water concentrations because of uncertainties in sample collection and location (particularly the association with actual use areas), methods of analysis, limits of detection, and quality control.

The relatively low soil/water partitioning of methomyl indicates that it will probably not be effectively removed by the primary sediment removal treatment processes employed by many surface water supply systems. Methomyl is not regulated under the Safe Drinking Water Act (SDWA) and has no established MCL. However, the Office of Drinking Water has established one- and ten-day Health Advisory Levels (HALs) of 300 ug/L and a lifetime HAL of 200 ug/L for methomyl. The annual mean concentrations of high use pesticides with fate characteristics comparable to methomyl, such as atrazine and metolachlor, rarely exceed several ug/L. Consequently, it is unlikely annual mean methomyl concentrations will exceed the lifetime HAL of 200 ug/L. However, peak concentrations of high use pesticides with similar fate characteristics do occasionally exceed 100 ug/L. Therefore, the possibility exists for peak methomyl concentrations to occasionally fall within range of the 300 ug/L 1-day and ten-day HALs.

4. Aquatic Exposure Assessment

Preliminary aquatic EECs are estimated using GENEEC, a screening model that provides an upper-bound estimate of EECs on a high exposure site. The GENEEC program uses basic environmental fate values (adsorption to soil, degradation in soil before runoff and in water) and pesticide label information (rates, intervals, incorporation, method of application) to estimate the EECs in a one-hectare, two-meter deep pond following the treatment of a 10 ha field. The runoff event occurs two days after the last application. The model accounts for direct deposition of spray drift onto the water body (assuming 5% of the application rate for aerial spray applications and 1% for ground spray applications). When risk quotients (RQs) for aquatic organisms are exceeded, refined aquatic EECs are calculated using PRZM/EXAMS.

Table 31: Environmental fate parameters used to predict methomyl EECs.

Parameter	Methomyl
water solubility (ppm)	58,000
Koc (avg):	24 - 42[1]
aerobic soil metabolism, t1/2	45 da[2]
hydrolysis t1/2, pH 7	stable
aerobic aquatic metabolism, t1/2	n/a
aqueous photolysis t1/2	1 da

[1] The K_{OC} value for methomyl is 42. The value used in the calculations was 24 (corrected for organic matter). Given the variability inherent in the parameters and the level of sensitivity of the existing models, the new value will not change the assessment or the bottom line substantially.

[2] The 90% upper confidence interval for the three reported half-lives of 10.5, 30, and 45 days (mean of 28.5; standard deviation of 14.1) is 44 days.

The Pesticide Root Zone Model (PRZM2.3) simulates pesticides in field runoff on daily time steps, incorporating runoff, infiltration, erosion, and evapotranspiration. The model calculates foliar dissipation and runoff, pesticide uptake by plants, microbial transformation, volatilization, and soil dispersion and retardation. The Exposure Analysis Modeling System (EXAMS II) simulates pesticide fate and transport in an aquatic environment (one hectare body of water, two meters deep). The modeled scenarios were selected on the basis of major uses (cotton, corn, lettuce), high application rates (peaches), and variations in label rates (lettuce). The Table below shows the EECs calculated from each method.

Table 32: Estimated Environmental Concentrations (EECs) For Aquatic Exposure from Aerial Application on Selected Uses Using GENEEC and PRZM2.

Site	*Application Rate x No/ Interval (da)*	*Peak EEC (ppb)*	*21-day avg. EEC (ppb)*	*56-day avg. EEC (ppb)*	*90-day avg. EEC (ppb)*	*90% Upper EEC (ppb)*
GENEEC						
Peaches	1.8 lb/A x 3/5	260	246	223	--	--
Lettuce	0.9 lb/A x 10/2	409	386	350	--	--
Corn (Sweet)	0.45 lb/A x 16/1	334	315	286	--	--
Lettuce	0.225 lb/A x 15/2	143	135	122	--	--
PRZM2/EXAM II						
Corn	0.45 lb/A x 16/1	60	59	54	50	18
Cotton	0.6 lb/A x 3/3	55	52	47	43	10
Lettuce	0.225 lb/A x 15/2	30	28	26	24	8
Lettuce	0.9 lb/A x 10/2	88	84	81	76	24
Peaches	1.8 lb/A x 3/5	99	95	85	79	23

Monitoring Studies for Methomyl

Aquatic residue monitoring studies for various use patterns were conducted on sweet corn in Illinois and Georgia, apples in Michigan, lettuce and tomatoes in Florida, and cantaloupe in California.

The dissipation half-life from the soil surface ranged from 4 days (FL lettuce) to 26 days (MI apple orchard during a dry period). In at least one study, the dissipation rate increased greatly after rainfall events, suggesting that leaching may be a major route of dissipation. Foliar dissipation half-lives ranged from a few hours (on corn) to 4 days (on apples). Peak concentrations in adjacent water bodies ranged from 2 to 175 ppb. Such variations would be expected because of differences in site characteristics, weather conditions, and cropping practices. At least under the conditions of the monitoring studies, spray drift appeared to be the primary source of methomyl residues reaching the surface waters. Runoff may be more of a contributing factor under site, soil, and weather characteristics that favor runoff.

Except for the Georgia sweet corn study, peak methomyl concentrations in adjacent water bodies were similar to or lower than those estimated by the Agency in Table 32. However, scenarios used in the models differed from the actual field conditions, so direct comparisons should be interpreted with caution. Predicted and measured concentrations were generally similar in magnitude

and pattern of dissipation for those sites that were both modeled and monitored. This supports the use of PRZM/EXAMS to provide a reasonable estimate of methomyl concentrations in adjacent surface waters. For risk assessment purposes, the modeled data, which incorporates 36 years of weather data and provides a 90% upper bound estimate based on variations in weather patterns, was used. Under actual use conditions, a chemical such as methomyl, which is moderately persistent but highly mobile, is likely to be susceptible to variations in rainfall amounts and patterns (MRIDs 43569301, 43599801, 43708807).

E. Environmental Risk Assessment

The results of exposure and ecotoxicity data are integrated using the quotient method. For this method, risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, for both acute and chronic effects.

RQ = EXPOSURE/TOXICITY

RQs are then compared to OPP's levels of concern (LOCs). These LOCs are criteria used by OPP to indicate potential risk to nontarget 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 nontarget organisms. LOCs currently address the following risk presumption categories: (1) acute high - potential for acute risk is high, regulatory action may be warranted in addition to restricted use classification, (2) acute restricted use - the potential for acute risk is high, but this may be mitigated through restricted use classification, (3) acute endangered species - the potential for acute risk to endangered species is high, regulatory action may be warranted, and (4) chronic risk - the potential for chronic risk is high, regulatory action may be warranted. Currently, the Agency does not perform assessments for chronic risk to plants, acute or chronic risks to nontarget insects, or chronic risk to mammalian or avian species from granular/bait formulations.

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: (1) LC50 (fish and birds), (2) LD50 (birds and mammals, (3) EC50 (aquatic plants and aquatic invertebrates), and (4) EC25 (terrestrial plants). Examples of toxicity test effect levels derived from the results of long-term laboratory studies that assess chronic effects are: (1) LOEC (birds, fish, and aquatic invertebrates), (2) NOEC (birds, fish and aquatic invertebrates) and (3) 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 effect is production of offspring or survival.

Risk presumptions, along with the corresponding RQs and LOCs are tabulated below.

Table 33 - 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[2] or LD50/day (or LD50 < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC50 or LD50/sqft[2] or LD50/day	0.1
Chronic Risk	EEC/NOEC	1.0
Wild Mammals		
Acute High Risk	EEC/LC50 or LD50/sqft[2] or LD50/day	0.5
Acute Restricted Use	EEC/LC50 or LD50/sqft[2] or LD50/day (or LD50 < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC50 or LD50/sqft[2] or LD50/day	0.1
Chronic Risk	EEC/NOEC	1.0

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

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

Table 34 - 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	1.0

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

1. Exposure and Risk to Nontarget Terrestrial Animals

Birds

For pesticides applied as a nongranular product (e.g., liquid, dust), the estimated environmental concentrations (EECs) on food items following product application are compared to LC50 values to assess risk. The predicted 0-day maximum and mean residues of a pesticide that may be expected to occur on selected avian or mammalian food items can be found in the following Tables. The tables also show the risk quotients for avian species.

Non-granular Products

The acute risk quotients for broadcast applications of nongranular products are tabulated below.

Table 35: Avian Acute Dietary Risk Quotients for a Range of Single Application Rates for Nongranular Products (Broadcast) Based on a bobwhite quail LC50 of 1100 ppm.

Single App. Rate (lbs ai/A)	*Food Items*	*Maximum EEC (ppm)*	*LC50 (ppm)*	*Acute RQ (EEC/ LC50)*
0.225	Short Grass	54	1100	0.05
	Tall grass	25	1100	0.02
	Broadleaf plants/Insects	30	1100	0.03
	Seeds	3	1100	<0.01
0.45	Short Grass	108	1100	0.10*
	Tall grass	50	1100	0.05
	Broadleaf plants/Insects	61	1100	0.06
	Seeds	7	1100	0.01
0.9	Short grass	216	1100	0.20**
	Tall grass	99	1100	0.09
	Broadleaf plants/Insects	122	1100	0.11*
	Seeds	14	1100	0.01
1.8	Short grass	432	1100	0.39**
	Tall grass	198	1100	0.18*
	Broadleaf plants/Insects	243	1100	0.22**
	Seeds	27	1100	0.02

* exceeds acute endangered species LOCs. ** exceeds acute restricted and acute endangered species LOCs.

The acute restricted use LOC (0.2) is exceeded for all use patterns with application rates greater than or equal to 0.9 lbs. a.i./acre. The endangered species LOC (0.1) is exceeded for all use patterns with application rates greater than or equal to 0.45 lbs. a.i./acre. There are no reported field incidents involving methomyl and any avian species.

Chronic risk quotients were calculated using the peak (maximum) and average residues on food items. Average residues are calculated from multiple pesticide applications degrading over time from the first to after the last application. The following Table presents avian chronic risk quotients based on both peak and average residues for multiple, broadcast applications of non-granular products.

Table 36: Avian Chronic Risk Quotients for Multiple Broadcast Applications of Nongranular Products Based on a mallard duck NOEC of 150 ppm .

Site/App. Method Rate (lb ai/A) x # of Apps. Interval (days)	*Food Items*	*EEC[1] (ppm)*		*NOEC (ppm)*	*Chronic RQ (EEC/ NOEC)*	
		Maximum	*Average*		*Maximum*	*Average*
Corn / Aerial 0.45 x 16 (1 da) 7.2 lb/ac max	Short grass Tall Grass Broadleaf plants/Insects Seeds	636 292 358 40	225 95 119 19	150	4.24 + 1.94 + 2.38 + 0.26	1.50 + 0.63 0.79 0.12
Citrus / Aerial 0.9 x 3 (5) 2.7 lb/ac max.	Short grass Tall Grass Broadleaf plants/Insects Seeds	345 158 194 22	122 52 65 10	150	2.30 + 1.05 + 1.30 + 0.14	0.81 0.34 0.43 0.06
Lettuce, Cole Crops / Aerial 0.9 x 10 (2 da) 9.0 lb/ac max.	Short Grass Tall Grass Broadleaf plant/Insect Seeds	714 327 402 45	253 107 134 21	150	4.76 + 2.18 + 2.68 + 0.30	1.68 + 0.71 0.89 0.14
Cotton / Aerial 0.6 x 3 (3 da) 1.8 lb/ac max	Short Grass Tall Grass Broadleaf plant/Insect Seeds	281 129 158 18	99 42 53 8	150	1.87 + 0.86 1.05 + 0.12	0.66 0.28 0.35 0.05
Peaches / ground 1.8 x 3 (5 da) 5.4 lb/ac max	Short grass Tall grass Broadleaf plants/Insects Seeds	690 316 388 43	244 104 129 20	150	4.60 + 2.10 + 2.58 + 0.28	1.62 + 0.69 0.86 0.13

1 Assumes dissipation using the FATE program and foliar dissipation data from the residue monitoring studies (half-life = 4 days).

+ exceeds chronic risk LOC for reproductive effects.

For multiple broadcast applications of nongranular products the avian chronic level of concern, for maximum residue concentrations, is exceeded at a multiple total rate equal to or above 0.45 lbs. a.i./A. For average residue concentrations, chronic LOCs are exceeded at rates greater than 1.0 lbs. a.i./A applied at least 3, times or lower rates applied more than 3 times.

Granular Products (Sweet Corn in Georgia and Florida)

Birds may ingest granular pesticide formulations when foraging for food or grit. They also may be exposed by other routes, such as walking on exposed granules or drinking water contaminated by granules. The number of lethal doses (LD_{50}s) that are available within one square foot immediately after application ($LD_{50}s/ft^{2)}$ is used as the acute risk quotient for granular/bait products. Risk quotients are calculated for three separate weight classes of birds: 1000 g (e.g., waterfowl), 180 g (e.g., upland gamebird) and 20 g (e.g., songbird). The results are tabulated in the following table.

Table 37: Avian risk quotients for granular products broadcast on corn and not incorporated, based on a ring-necked pheasant LD50 of 15.4 mg/kg.

Site/ Application Method/ Rate in lbs ai/A	*% Pesticide Left on Surface*	*Body Weight (g)*	*LD50 (mg/kg)*	*Acute RQ[1] (LD50/ft²)*
0.15	5	20	15.4	0.26**
0.15	5	180	15.4	0.03
0.15	5	1000	15.4	0.51

[1] RQ = $\frac{0.05 * \text{App. Rate (lbs ai/A)} * (453{,}590 \text{ mg/lbs}/43{,}560 \text{ ft}^2/\text{A})}{\text{LD50 mg/kg} * \text{Weight of Animal (g)} / 1000 \text{ g/kg}}$

** exceeds endangered species and restricted use LOCs

For broadcast applications of granular products, levels of concern are exceeded only for songbird species or small birds (e.g., juveniles). However, mitigating factors may greatly reduce the potential for hazard even to these species. For example, the methomyl 5G granule is not only extremely small (0.08 mg compared to an average of 0.34 mg for granules) but also is shaped more like a flake than a typical grit. In addition, application directions specify that the product is to be applied directly to the whorls of the corn plant rather than broadcast over the crop. This greatly reduces the amount of product likely to be applied to the ground. These factors make the selection of such granules very unlikely by avian species, greatly reducing the hazard. Therefore, no avian acute levels of concern are exceeded at any registered application rates for broadcast applications of granular products. There are no banded or in-furrow applications for any of the granular registrations. Currently, the Agency does not have a standard procedure for assessing chronic risk to avian species for granular products.

Mammals

The estimated potential for adverse effects to wild mammals is based on the Agency's draft 1995 SOP for mammalian risk assessments and the methods of Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994). The concentration of methomyl in the diet that is expected to be acutely lethal to 50% of the test population (LC_{50}) is determined by dividing the LD_{50} value (usually rat LD_{50}) by the % (decimal of) body weight consumed. A risk quotient is then determined by dividing the EEC by the derived LC_{50} value. Risk quotients are calculated for three separate weight classes of mammals (15, 35, and 1000 g), each presumed to consume four different kinds of food (grass, forage, insects, and seeds).

Non-granular Products

The following table presents the acute risk quotients for herbivores/insectivores from single broadcast applications of nongranular products of methomyl.

Table 38: Mammalian (Herbivore/Insectivore) Acute Risk Quotients for a Range of Single Application Rates for Nongranular Products (Broadcast) Based on a rat LD50 of 32 mg/kg.

Appl. Method/ Rate in lbs ai/A	*Body Wt. (g)*	*% Body Weight Consumed*	*Rat LD50 (mg/ kg)*	*EEC (ppm) Short Grass*	*EEC (ppm) Forage/ Insects*	*EEC (ppm) Large Insects*	*Acute RQ[1] Short Grass*	*Acute RQ Forage & Small Insects*	*Acute RQ Large Insects*
aerial/ .225	15	95	32	54	30	3	1.60***	0.89***	0.12*
	35	66					1.11***	0.62***	0.06
	1000	15					0.25**	0.14*	0.01
aerial/ .45	15	95	32	108	61	7	3.21***	1.81***	0.21**
	35	66					2.23***	1.26***	0.14*
	1000	15					0.51***	0.29**	0.03
aerial/ 0.9	15	95	32	216	122	14	6.40***	3.63***	0.42**
	35	66					4.46***	2.52***	0.29**
	1000	15					1.01***	0.57***	0.07
ground/ 1.8	15	95	32	432	243	27	12.83***	7.21***	0.80**
	35	66					8.97***	5.01***	*
	1000	15					2.03***	1.14***	0.56**
									*
									0.13*

[1] RQ = EEC (ppm) / LD50 (mg/kg)/ % Body Weight Consumed

* exceeds endangered species LOC

** exceeds endangered species and restricted use LOC

*** exceeds endangered species, restricted use and acute high risk LOCs

Single broadcast applications at rates equal to or greater than 0.225 lbs. a.i./A exceed endangered species, acute restricted use and high acute risk LOCs for herbivores and insectivores.

The following table presents the acute risk quotients for granivores from single broadcast applications of nongranular products of methomyl.

Table 39: Mammalian (Granivore) Acute Risk Quotients for Single Application of Nongranular Products (Broadcast) Based on a rat LD50 of 32 mg/kg.

Site/ Applic. Meth/ Rate	*Body Weight (g)*	*% Body Weight Consumed*	*Rat LD50 (mg/kg)*	*EEC (ppm) Seeds*	*Acute RQ[1] Seeds*
Lettuce/aerial .45 lb ai/ac	15	21	32	7	0.05
	35	15			0.03
	1000	3			<0.01
Citrus/aerial 0.9 lb ai/ac	15	21	32	14	0.09
	35	15			0.06
	1000	3			0.01
Peaches/ground 1.8 lb ai/ac	15	21	32	27	0.17 *
	35	15			0.12 *
	1000	3			0.02

[1] RQ = $\frac{\text{EEC (ppm)}}{\text{LD50 (mg/kg)/ \% Body Weight Consumed}}$ * exceeds endangered species LOC

Single broadcast applications at maximum application rates greater than 0.9 lbs. a.i./A exceed the endangered species LOC for granivores.

The following table presents the acute risk quotients for herbivores/insectivores from multiple broadcast applications of nongranular products of methomyl.

Table 40: Mammalian (Herbivore/Insectivore) Acute Risk Quotients for Multiple Applications of Nongranular Products (Broadcast). Based on a rat LD50 of 32 mg/kg.

Site/ App. Method/ Rate in lbs ai/A (No. of Apps.) (Interval)	*Body Weight (g)*	*% Body Weight Consumed*	*Rat LD50 (mg/kg)*	*EEC (ppm) Short Grass*	*EEC (ppm) Forage/ Insects*	*EEC (ppm) Large Insect*	*Acute RQ[1] Short Grass*	*Acute RQ Forage & Small Insects*	*Acute RQ Large Insects*
Cotton/aerial 0.6 x 3 (3) 1.8 lb./A max.	15	95	32	281	158	18	8.34***	4.69 ***	0.53***
	35	66					5.80 ***	3.26***	0.37 **
	1000	15					1.32 ***	0.74 ***	0.08
Corn / aerial 0.45 x 16 (1) 7.2 lb./A max.	15	95	32	636	358	40	18.88 ***	10.63 ***	1.19 ***
	35	66					13.12 ***	7.38 ***	0.83 ***
	1000	15					2.98 ***	1.68 ***	0.19 *
Lettuce / aerial 0.9 x 10 (2 da) 9.0 lb./A max.	15	95	32	714	402	45	21.20 ***	11.93 ***	1.34 ***
	35	66					14.73 ***	8.29 ***	0.93 ***
	1000	15					3.35 ***	1.88 ***	0.21 **

Table 40: Mammalian (Herbivore/Insectivore) Acute Risk Quotients for Multiple Applications of Nongranular Products (Broadcast). Based on a rat LD50 of 32 mg/kg.

Site/ App. Method/ Rate in lbs ai/A (No. of Apps.) (Interval)	*Body Weight (g)*	*% Body Weight Consumed*	*Rat LD50 (mg/kg)*	*EEC (ppm) Short Grass*	*EEC (ppm) Forage/ Insects*	*EEC (ppm) Large Insect*	*Acute RQ[1] Short Grass*	*Acute RQ Forage & Small Insects*	*Acute RQ Large Insects*
Citrus/aerial 0.9 x 3 (10) 2.7 lb./A max.	15	95	32	345	194	22	10.24 ***	5.76 ***	0.65 ***
	35	66					7.12 ***	4.00 ***	0.45 **
	1000	15					1.62 ***	0.91 ***	0.10 *
Peaches/aerial 1.8 x 3 (5) 5.4 lb./A max.	15	95	32	690	388	43	20.48 ***	11.52 ***	1.28 ***
	35	66					14.23 ***	8.00 ***	0.89 ***
	1000	15					3.23***	1.82***	0.20 **

[1] RQ = EEC (ppm) / LD50 (mg/kg)/ % Body Weight Consumed

* exceeds endangered species LOC.
** exceeds acute restricted use and endangered species LOC.
*** exceeds endangered species, acute restricted use and acute high risk LOC.

Multiple broadcast applications at all rates and intervals of application exceed the endangered species, acute restricted use and acute high risk LOCs for herbivores and insectivores.

The following table presents the acute risk quotients for granivores from multiple broadcast applications of nongranular products of methomyl.

Table 41: Mammalian (Granivore) Acute Risk Quotients for Multiple Applications of Nongranular Products (Broadcast) Based on a rat LD50 of 32 mg/kg.

Use/ App. Meth./ Rate lbs ai/A (# apps)	*Body Wt. (g)*	*% Body Weight Consumed*	*Rat LD50 (mg/kg)*	*EEC (ppm) Seeds*	*Acute RQ[1] Seeds*
Cotton / aerial 0.6 x 3 (3 da) 1.8 lb./A max.	15	21	32	18	0.12*
	35	15			0.08
	1000	3			0.02
Corn / aerial 0.45 x 16 (1 da) 7.2 lb./A max.	15	21	32	40	0.26**
	35	15			0.19*
	1000	3			0.04
Citrus /aerial 0.9 x 3 (5 da). 2.7 lb. A max.	15	21	32	22	0.14*
	35	15			0.10*
	1000	3			0.02
Lettuce / aerial 0.9 x 10 (2 da) 9.0 lb./A max.	15	21	32	45	0.30**
	35	15			0.21**
	1000	3			0.04
Peaches/aerial/ 1.8 x 3 (5 da) 5.4 lb./A max.	15	21	32	43	0.28**
	35	15			0.20**
	1000	3			0.04

[1] RQ = EEC (ppm) / LD50 (mg/kg)/ % Body Weight Consumed

* exceeds endangered species LOC
** exceeds endangered species and restricted use LOCs

Multiple broadcast applications of nongranular products at application rates equal to or greater than 5.4 lbs a.i./A exceed the endangered species and acute restricted use LOC for granivores. At multiple total application rates less than 5.4 lbs. a.i./A, only the LOC for endangered species is exceeded.

Chronic mammalian RQs were based on multiple broadcast applications of nongranular products. Results are tabulated below.

Table 42: Mammalian Chronic Risk Quotients for Multiple Applications of Nongranular Products (Broadcast) Based on a laboratory rat NOEC of 75 ppm in a reproductive study.

Site/App. Method Rate (lb ai/A) x No of Apps. Interval (days)	*Food Items*	*EEC[1] (ppm)*		*NOEC (ppm)*	*Chronic RQ (EEC/ NOEC)*	
		Maximum	*Average*		*Maximum*	*Average*
Corn / Aerial 0.45 x 16 (1 da) 7.2 lb/ac max	Short grass	636	225	75	8.48 +	3.00 +
	Tall Grass	292	95		3.89 +	1.26 +
	Broadleaf plants/Insects	358	119		4.77 +	1.58 +
	Seeds	40	19		0.53	0.25
Citrus / Aerial 0.9 x 3 (5) 2.7 lb/ac max.	Short grass	345	122	75	4.60 +	1.62 +
	Tall Grass	158	52		2.10 +	0.69
	Broadleaf plants/Insects	194	65		2.58 +	0.01
	Seeds	22	10		0.29	0.13
Lettuce, Cole Crops / Aerial 0.9 x 10 (2 da) 9.0 lb/ac max.	Short Grass	714	253	75	9.52 +	3.37 +
	Tall Grass	327	107		4.36 +	1.42 +
	Broadleaf plant/Insect	402	134		5.36 +	1.78 +
	Seeds	45	21		0.60	0.28
Cotton / Aerial 0.6 x 3 (3 da) 1.8 lb/ac max	Seeds Short Grass	25 281	10 99	75	3.74 +	1.32 +
	Tall Grass	129	42		1.72 +	0.56
	Broadleaf plant/Insect	158	53		2.10 +	0.70
	Seeds	18	8		0.24	0.10
Peaches / ground 1.8 x 3 (5 da) 5.4 lb/ac max	Short grass	690	244	75	9.20 +	3.25 +
	Tall grass	316	104		4.21 +	1.38 +
	Broadleaf plants/Insects	388	129		5.17 +	1.72 +
	Seeds	43	20		0.57	0.26

1 Assumes dissipation using FATE program and foliar dissipation data from the aquatic residue monitoring studies (half-life = 4 days).
+ exceeds chronic risk LOC for reproductive effects.

For multiple broadcast applications of nongranular products, the mammalian chronic LOC is exceeded at all rates and intervals of applications for both maximum and average residues.

Granular Products (Sweet Corn in Georgia and Florida)

Mammalian species may be exposed to granular/bait pesticides by ingesting granules. They also may be exposed by other routes, such as by walking on exposed granules and drinking water contaminated by granules. The number of lethal doses (LD50's) that are available within one square foot immediately after application can be used as a risk quotient (LD50's/ft^2)for the various types of

exposure to bait pesticides. Risk quotients are calculated for three separate weight classes of mammals: 15 g, 35 g and 1000 g. Results are tabulated below.

Table 43: Mammalian Acute Risk Quotients for Granular Products (Broadcast and Unincorporated on Corn) Based on a Rat LD50 of 32 mk/kg.

Site/ Application Method/ Rate in lbs ai/A	*Fraction of pesticide Left on the Surface*	*Body Weight (g)*	*Rat LD50 (mg/kg)*	*Acute RQ[1] (LD50/ft^2)*
0.15	5	15	32	0.16*
0.15	5	35	32	0.07
0.15	5	1000	32	<0.01

[1] RQ = $\frac{0.05 * \text{App. Rate (lbs ai/A)} * (453{,}590 \text{ mg/lbs}/43{,}560 \text{ ft}^2/\text{A})}{\text{LD50 mg/kg} * \text{Weight of Animal (g)} / 1000 \text{ g/kg}}$ * exceeds endangered species LOC

For broadcast granular products, mammalian acute high risk LOCs are not exceeded. Although the endangered species level of concern is exceeded at a registered maximum application rate equal to or greater than 0.15 lbs. a.i./A, other factors greatly reduce the potential for hazard even to these species. For example, the methomyl 5G granule is an extremely small granule (0.08 mg as compared to an average size granule that weighs 0.34 mg). In addition, the shape of the methomyl 5G granule is quite different than the typical grit. The methomyl 5G granule is shaped more like a flake rather than the typical granular structure. These factors greatly reduce the likelihood of exposure to non-target organisms. Therefore, for broadcast applications of granular products, no mammalian acute levels of concern are exceeded at any registered application rates. There are no banded or in-furrow applications for any of the granular registrations. Currently, EPA does not have a standard procedure for assessing chronic risk to mammalian species from granular products.

Insects

Currently, EPA does not assess risk to nontarget insects. Results of the honey bee acute contact study have used for recommending appropriate label precautions.

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

Acute risk assessments are based on the maximum (peak) EEC values (see Aquatic Exposure Assessment). For chronic risk, 21-day EECs are used for invertebrates and 60-day EECs are used for fish. The EPA believes that, because of their proximity to aquatic environments, citrus uses will result in the direct application of methomyl to aquatic environments. For citrus use patterns, EPA assumes simple dilution of the amount applied to a surface acre of water 6 inches deep.

Freshwater Fish

Preliminary RQs calculated using EECs from the GENEEC model all exceeded aquatic endangered species, acute restricted use, and chronic risk LOCs. Therefore, refined EECs, generated by PRZM/EXAMS, were used to calculate the RQs in the Table below.

Table 44: Risk Quotients for Freshwater Fish based on a channel catfish LC50 of 500 ppb and a fathead minnow NOEC of 57 ppb of methomyl.						
Site/ Application Method/ Rate in lbs ai/A (No. of Apps.)	*LC50 (ppb)*	*NOEC/ MATC (ppb)*	*EEC Initial/ Peak (ppb)*	*EEC 21-Day Ave. (ppb)*	*Acute RQ (EEC/LC50)*	*Chronic RQ (EEC/NOEC or MATC)*
Refined EECs based on PRZM/EXAMS Modeling						
Peaches/aerial / 1.8 (3)	500	57	99	95	0.20 **	1.67 +
Lettuce/aerial / 0.9 (10)	500	57	88	84	0.18 **	1.47 +
Corn/aerial / 0.45 (16)	500	57	60	59	0.12 **	1.04
Lettuce/aerial / 0.225 (15)	500	57	30	28	0.06 *	0.49
EECs based on Direct Application to a 6" layer of water						
Citrus/aerial / 0.9 (3)	500	57	130	111	0.26**	1.95 +

+ Exceeds chronic risk LOC

* Exceeds endangered species LOC

** Exceeds endangered species and acute restricted use LOC

Based on refined EECs for peaches, lettuce, and corn, acute aquatic endangered species LOCs are exceeded for freshwater fish at application rates equal to or greater than 0.225 lbs. a.i./A. Endangered species, and acute restricted use LOCs are exceeded at application rates equal to or greater than 0.45 lbs.a.i./A. Chronic risk LOCs for freshwater fish are exceeded at multiple application rates greater than 0.45 lbs. a.i./A. For citrus use, direct application of methomyl to water at an application rate equal to or greater than 0.9 lbs. a.i./acre exceeds LOCs for endangered species and acute restricted use and the chronic risk LOC for freshwater fish.

Freshwater Invertebrates

The acute and chronic risk quotients are tabulated below.

Table 45: Risk Quotients for Freshwater Invertebrates. Based on a Daphnia LC50 of 8.8 ppb and a Daphnia NOEC/MATC of 0.6 ppb.						
Site/ Applic. Method/ Rate in lbs ai/A (No. of Apps.)	*LC50 (ppb)*	*NOEC/ MATC (ppb)*	*EEC (ppb) Peak*	*EEC (ppb) 21-Day Avg*	*Acute RQ (EEC/LC50)*	*Chronic RQ (EEC/NOEC or MATC)*
Refined EECs based on PRZM/EXAMS Modeling						
Peaches / aerial / 1.8 (3)	8.8	0.6	99	95	11.25***	158.3 +
Lettuce / aerial / 0.9 (10)	8.8	0.6	88	84	10.00***	140 +
Corn / aerial / 0.45 (16)	8.8	0.6	60	59	6.82***	98 +
Lettuce / aerial / 0.225 (15)	8.8	0.6	30	28	3.41***	46.6 +
EECs based on Direct Application to a 6" layer of water						
Citrus / aerial / 0.9 (3)	8.8	0.6	130	123	14.77***	205 +

+ Exceeds the chronic LOC.
*** Exceeds the acute high risk, acute restricted use and endangered species LOCs.

Results using refined EECs for peaches, lettuce, and corn indicate aquatic acute high risk, restricted use, and endangered species levels of concern are exceeded for freshwater invertebrates at application rates equal to or above 0.225 lbs. a.i./A. Multiple applications at rates greater than or equal to 0.225 lbs a.i./acre result in chronic hazard to freshwater invertebrates.

For citrus uses, acute high risk, acute restricted use, endangered species, and chronic risk LOCs are exceeded for freshwater invertebrates from the direct application of methomyl to a 6 inch layer of water at the maximum application rate of 0.9 lbs. a.i./acre. Based on these results, mitigation agreed to in 1993 between the Agency and the registrants, limited the citrus use to Arizona and California only. Methomyl is no longer allowed on Florida citrus. However, application to shallow bodies of water such as irrigation ditches and canals in California is possible for this use pattern.

Estuarine and Marine Animals

Estuarine Fish

The following table shows the risk quotients for estuarine/marine fish.

Table 46: Risk Quotients for Estuarine/Marine Fish Based on a Sheepshead minnow LC50 of 1,160 ppb. Based on refined EECs using PRZM/EXAMS.			
Site/ Applic. Method/ Rate in lbs ai/A (No. of Apps.)	*LC50 (ppb)*	*EEC Initial/ Peak (ppm)*	*Acute RQ (EEC/LC50)*
Peaches / aerial / 1.8 (3)	1160	99	0.09*
Lettuce / aerial / 0.9 (10)	1160	88	0.08*
Corn / aerial / 0.45 (16)	1160	60	0.05*
Lettuce / aerial / 0.225 (15)	1160	30	0.03

* exceeds acute endangered species LOC

Acute endangered species levels of concern are exceeded for estuarine fish at maximum application rates above 0.225 lbs. a.i./A.

Estuarine Aquatic Invertebrates

The following table shows the risk quotients for estuarine/marine invertebrates.

Table 47: Risk Quotients for Estuarine/Marine Aquatic Invertebrates Based on a pink shrimp species) TL50 of 49 ppb. Based on refined EECs using PRZM/EXAMS.			
Site/ Application Method Rate in lbs ai/A (No. of Apps.)	*LC50 (ppb)*	*EEC Initial/ Peak (ppb)*	*Acute RQ (EEC/LC50)*
Peaches / aerial / 1.8 (3)	19	99	5.21*
Lettuce / aerial / 0.9 (10)	19	88	4.63*
Corn / aerial / 0.45 (16)	19	60	3.15*
Lettuce / aerial / 0.225 (15)	19	30	1.58*

*exceeds acute endangered species, restricted use and acute high risk LOC.

Acute high risk, restricted use, and endangered species levels of concern are exceeded for estuarine invertebrates at maximum application rates equal to or above 0.225 lbs. a.i./A.

Exposure and Risk to Aquatic Organisms Based on Residue Monitoring Data

The following tables summarize the residue monitoring data collected from the aquatic field studies and uses these results for the EECs. The tables include either the peak, median or maximum reported residues that occurred in ponds and the drainage/irrigation canals that were located either within or adjacent to the treated fields.

Freshwater Fish

The following table shows the risk quotients for freshwater fish using monitoring estimates for EECs.

Table 48: Risk Quotients for Freshwater Fish based on a channel catfish LC50 of 500 ppb and a fathead minnow NOEC of 57 ppb of methomyl. EECs derived from residue monitoring data.

Site/ Application Method/ Rate in lbs ai/A (No. of Apps.)[1]	*LC50 (ppb)*	*NOEC/ MATC (ppb)*	*Initial Peak/Max Res. (ppb)*	*21-Day Ave. Res. (ppb)*	*Acute RQ (EEC/LC50)*	*Chronic RQ (EEC/NOEC or MATC)*
Apples/air blast / 1.35 (5)	500	57	13.3	7.6	0.03	0.13
Corn/aerial / 0.45 (28)	500	57	15.75	5.8	0.03	0.10
Corn/aerial / 0.3-0.5 (29)	500	57	7.0	4.2	0.01	0.07
Lettuce/aerial / 0.225 (15)	500	57	65.5	38.3	0.13*	0.67
Cantaloupe/aerial / 0.9 (6)	500	57	96	9	0.19*	0.16

*exceeds endangered species LOC.

1 Application rates and number of applications are from the actual monitoring studies and may not necessarily coincide with maximum label applications.

The use of methomyl, at least for certain use patterns, exceeds the endangered species acute LOCs for freshwater fish. The chronic LOC was not exceeded for any of the use patterns.

Freshwater Invertebrates

The following table shows the risk quotients for invertebrates using monitoring estimates for EECs.

Table 49: Risk Quotients for Freshwater Invertebrates (based on a Daphnia LC50 of 8.8 ppb and a NOEC of 0.4 ppb of methomyl). EEC derived from residue monitoring data.

Site/ Application Method/ Rate, lbs ai/A (# of Apps.)[1]	*LC50 (ppb)*	*NOEC/ MATC (ppb)*	*Initial Peak/Max Res. (ppb)*	*21-Day Ave. Res. (ppb)*	*Acute RQ (EEC/LC50)*	*Chronic RQ (EEC/NOEC or MATC)*
Apples/air blast / 1.35 (5)	8.8	0.4	13.3	7.6	1.51***	19.00 +
Corn/aerial / 0.45 (28)	8.8	0.4	15.75	5.8	1.79***	14.50 +
Corn/aerial / 0.3-0.5 (29)	8.8	0.4	7.0	4.2	0.80***	10.50 +
Lettuce/aerial / 0.225 (15)	8.8	0.4	65.5	38.3	7.44***	95.75 +
Cantaloupe/aerial / 0.9 (6)	8.8	0.4	96	9	10.91***	22.50 +

1 Application rates and number of applications are from the actual monitoring studies and may not necessarily coincide with maximum label applications.

+ Exceeds chronic LOC for aquatic invertebrates

*** Exceeds acute endangered species, acute restricted use and acute high risk LOCs.

The use of methomyl in all of the field-tested use patterns exceeded the acute endangered species, acute restricted use and acute high risk LOCs for freshwater invertebrates. Chronic LOCs for freshwater invertebrates were also exceeded for all of the use patterns tested.

3. Exposure and Risk to Endangered Species

The Endangered Species Protection Program is expected to become final in the future. Limitations in the use of methomyl may 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 may be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county bulletins.

4. Environmental Risk Characterization

Fate and Exposure

Methomyl appears to be moderately persistent and highly mobile. The dominant routes of dissipation appear to be metabolism (biologically-mediated degradation), leaching, and photolysis in clear waters. Site-specific factors affecting the persistence of methomyl include aerobicity, organic matter and soil moisture content, exposure to sunlight, pH, climate (especially rainfall) and crop management factors that influence leaching and runoff.

Methomyl photolyzes quickly in water but slowly in soils. It is moderately stable to aerobic soil metabolism but degrades more rapidly under anaerobic conditions. While methomyl becomes more susceptible to hydrolysis as the pH increases above neutral, this is not expected to be a major route of dissipation under most circumstances. Laboratory studies show that methomyl does not readily adsorb to soil and has the potential to be very mobile. Dissipation from the soil surface occurs by a combination of chemical breakdown and movement. Field studies show that the varying dissipation rates for methomyl were related primarily to differences in soil moisture content, which may affect the microbial activity, and rainfall/irrigation, which could influence leaching. The major degradate in most metabolism studies was CO_2. Another degradate, S-methyl-N-hydroxythioacetamidate, primarily appears to be a product of alkaline hydrolysis.

Ground Water Assessment: Methomyl has been detected in ground water in a prospective ground water monitoring study and in other reported incidences. The potential for ground water contamination is greatest with highly permeable soils, shallow depths to ground water, and an excess of water (from precipitation and/or irrigation) moving through the soil to carry the chemical with it. While it may reach ground water under certain conditions, methomyl will not likely persist under many conditions.

Surface Water Assessment: Methomyl can contaminate surface water as a result of spray drift during application or by runoff from treated sites. Methomyl would not be expected to persist in clear, shallow waters because of its susceptibility to photolysis. However, it may persist longer in waters

where sunlight penetration is limited (such as in deeper waters or waters with a significant sediment load or population of organisms such as algae). Monitoring studies suggest that spray drift is likely to be a major source of methomyl in surface waters. Under certain conditions, runoff may be a source of methomyl contamination. Runoff vulnerability is likely to be greater in high rainfall areas (eastern and southeastern U.S.) than in semi-arid to arid areas (in large areas of the southwest and western U.S.). Other avenues of methomyl movement include irrigation and drainage ditches/channels/lines and lateral subsurface flow.

Inferences From Field Monitoring Studies

The dissipation half-lives of methomyl from the soil surface in monitoring studies conducted in California, Illinois, Michigan, Georgia, and Florida were similar in range to those measured in the terrestrial field dissipation studies. In at least one study, the dissipation rate increased greatly after rainfall events, suggesting that leaching may be a major route of dissipation. Foliar dissipation half-lives ranged from a few hours (on corn) to 4 days (on apples). These data were similar to foliar half-lives reported for cotton leaves.

Predicted (using PRZM/EXAMS) and measured concentrations of methomyl in water were generally similar in magnitude and pattern of dissipation for those sites that were both modeled and monitored. This provides supporting evidence that PRZM/EXAMS can provide a reasonable estimate of methomyl concentrations in adjacent surface waters under the tested conditions. For risk assessment and screening purposes, EPA used the modeled data, which incorporates 36 years of weather data and generally provides a 90% upper bound estimate based on variations in weather patterns. A chemical such as methomyl, which is moderately persistent but highly mobile, is likely to be susceptible to variations in rainfall amounts and patterns.

Environmental Risk

Non-target Terrestrial Organisms

Because of its versatility in controlling a wide variety of insects, methomyl can be, and is, used throughout the U.S. As such, the potential for exposure to numerous non-target birds, mammals, and beneficial insects that directly utilize these crops for nesting, feeding, cover, and other activities is likely. In addition, indirect exposure from drift is likely to contaminate a wide variety of ecosystems and possibly adversely affect non-target organisms utilizing these habitats.

Laboratory studies show that methomyl is highly toxic and very highly toxic to avian and mammalian species, respectively, on an acute oral basis but only slightly toxic to avian species on a subacute dietary basis. However, avian acute dietary risk quotients (RQs) indicate that acute restricted and acute endangered species Levels of Concern (LOC) are exceeded only from exposure to short grass and large insects. Since short grass or similar vegetative material does not constitute a major portion of many avian diets, most birds are not expected to be at risk on a subacute dietary basis. However, other species (e.g, ducks, geese and swans) that tend to graze on short grass are at greater risk. Risks to birds that eat mainly insects are expected to occur within the acute restricted use LOC range, at the highest application rate of 1.8 lbs. a.i./A.

Avian chronic LOCs (based on avian reproductive toxicity data) are exceeded for both average and maximum EECs from multiple applications even at the lowest application rate of 0.225 lbs. a.i./A. RQs suggest that seed eating birds are at less risk than insectivores or birds that feed on short grass or other herbaceous material. Seed-eaters are not at risk from multiple applications at the highest application rate of 1.8 lbs. a.i./A on peaches.

Mammalian acute dietary RQs are considerably greater than avian RQs and exceed the LOCs for endangered species, acute restricted use and acute high risk for herbivores and insectivores for all application rates. This is especially the case for multiple applications. However, for granivores (seed eaters) only acute RQs at the highest single application rate exceed the endangered species LOCs. Multiple applications only exceed the acute endangered species and acute ristricted use LOCs at application rates equal to or greater than 0.45 pounds a.i./A. Unlike avian species, many small rodents and other mammals consume copious amounts of grass and herbaceous material. As such, the likelihood that mammals, especially herbivores and insectivores, will be adversely affected is considerably greater than for birds.

Mammalian chronic RQs based on reproductive toxicity data suggest that even from a single application, the chronic LOC is exceeded at registered maximum application rates equal to or greater than 0.45 lbs. a.i./A for herbivores (based on residues for short grass). However, chronic LOCs for insectivores are only exceeded at application rates greater than or equal to 0.90 lbs. a.i./A. Chronic LOCs are not exceeded for seed-eaters at any application rate for either single or multiple applications.

Based strictly on the RQs derived from laboratory toxicity data and EECs it can be concluded that methomyl poses acute and chronic risks to numerous non-target wildlife species, including threatened and endangered species. However, “real world” factors, both biotic and abiotic, reduce the potential for this risk. Data suggest that physical abrasion, rainfall, and spray irrigation remove most of the product from the plant surface which reduces the risk to non-targets that may feed on either the treated crops and/or other contaminated vegetation in adjacent habitats.

Non-target Aquatic Organisms

Laboratory toxicity data show that methomyl and its formulated products are moderately to highly toxic to freshwater fish and moderately toxic to estuarine fish on an acute basis. However, results from a chronic early life-stage study show that methomyl significantly reduced fish larvae survival under flow through conditions.

Methomyl and its formulated products are highly to very highly toxic to freshwater invertebrates on an acute basis. Acute toxicity studies on estuarine/marine invertebrates show very high toxicity to several shrimp species while short-term oyster shell growth appeared to be practically unaffected from methomyl exposure. Chronic toxicity from exposure to methomyl at concentrations greater than 0.4 ppb can reduce the number of young freshwater invertebrates produced. In general, the toxicity data suggest that aquatic invertebrates are much more sensitive to methomyl contamination than either fresh or salt water fish species.

RQs generated by PRZM/EXAMS indicate that acute endangered species LOCs are exceeded for freshwater fish at application rates equal to or greater than 0.225 lbs a.i./A and for estuarine fish at application rates equal to or greater than 0.45 lbs. a.i./A. Acute restricted use LOCs for freshwater fish are only exceeded at maximum application rates equal to or greater than 0.45 lbs a.i./A. Chronic risk LOCs for freshwater fish (based on a fathead minnow early life stage study) are exceeded at multiple application rates greater than 0.45 lbs. a.i./A.

Finally, the direct application of methomyl to a 6 inch layer of water (as is likely to occur from spraying citrus groves) at an application rate equal to or greater than 0.9 lbs. a.i./acre will result in chronic hazard to freshwater fish as well as exceeding the LOCs for acute endangered species and acute restricted use.

RQs generated by PRZM/EXAMS indicate that acute endangered species, acute restricted use and acute high risk LOCs are exceeded for freshwater and estuarine invertebrates at application rates equal to or greater than 0.225 lbs. a.i./A. Chronic risk LOCs (based on a daphnia life-cycle study) for freshwater invertebrates are exceeded at multiple application rates greater than 0.225 lbs. a.i./A. These chronic RQs range from 46.6 (multiple applications of 0.225 lbs.a.i./A for lettuce) to 158.3 (multiple applications of 1.8 lbs. a.i./A for peaches).

Finally, the direct application of methomyl to a 6 inch layer of water (as is likely to occur from spraying citrus groves) at an application rate equal to or greater than 0.9 lbs. a.i./acre exceeds the acute endangered species, acute restricted use and acute high risk LOCs as well as the chronic LOC for freshwater invertebrates.

RQs for freshwater fish, based on actual field monitoring data, indicate that only the endangered species LOCs are exceeded even at application rates equal to 1.35 lbs. a.i./acre. Results from these studies also indicate that chronic LOCs for aquatic invertebrates are not exceeded at any application rate.

Therefore, based strictly on the risk quotients derived from laboratory toxicity data and model-generated EECs, methomyl poses acute and chronic risk to numerous non-target aquatic organisms, especially aquatic invertebrates, including threatened and endangered species. The refined EECs generated using PRZM/EXAMS are based on high runoff potential sites in actual crop use areas. The values used are based on 1 in 10 year runoff events, which are dependent on the amount and timing of precipitation (typically generated from 24 to 36 years of actual precipitation data). On sites which are less prone to runoff and in years in which weather patterns do not favor high runoff, the actual aquatic environmental concentrations are likely to be less than those predicted and used for this risk assessment.

The results of the field monitoring studies conducted in various crops at different geographical locations provide snap shots of the potential toxicity of methomyl to aquatic organisms under actual use conditions. Since modeled concentrations based on individual site and weather data were similar to measured concentrations, the EPA concludes that PRZM/EXAMS provides a reasonable estimate of methomyl concentrations in water. Results of the monitoring studies illustrate the range in methomyl concentrations in water that may occur under a variety of site conditions and

weather patterns. It is most likely that actual risks are somewhere between those predicted with PRZM/EXAMS and those found in the monitoring studies.

Using these measured residue concentrations, freshwater fish RQs showed that, even at the highest application rates, only the endangered species LOCs were exceeded. Chronic LOCs were not exceeded for any of the use patterns. However, endangered species, acute restricted use and acute high risk LOCs were exceeded for aquatic invertebrates even at the lowest application rates. These results clearly show that the greatest hazard to non-target aquatic organisms is to aquatic invertebrates.

An outdoor microcosm study was conducted to evaluate the fate of methomyl in tank water and hydrosoil and the effects on populations of zooplankton, phytoplankton, macroinvertebrates and bluegill sunfish from exposure to methomyl. Results of the study show no apparent methomyl-related treatment effects to either bluegill sunfish or phytoplankton populations. Decreases in abundance in the Cladocera zooplankton populations occurred; however, other zooplankton populations (Copepoda and Rotifera) actually increased in abundance (probably as a result of decreased competition with reduced populations of Cladocera) during the study. Macroinvertebrate (Ephemeroptera) abundance clearly decreased in the two highest treatment groups. In addition, results also show a decrease in abundance for Chironomidae; however, these decreases were very short-lived, were not dose related, and could not be solely attributable to treatment. This study summary is based on a cursory review of the study and is not the result of a critical analysis of the study design, data, or interpretations of results (MRID 43744402).

Results of an apple orchard monitoring study conducted in Michigan showed that nearly 44 percent of the application rate never reached the ground because of the wind conditions. Drift cards placed in an adjacent pond indicated that 2 to 44 percent of the application rate may have drifted into the pond. The data from this and other monitoring studies indicate that the broad scale use of methomyl on sites adjacent to or near aquatic habitats may result in methomyl reaching aquatic environments on an annual basis.

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 ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing methomyl active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing methomyl. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of methomyl, 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 methomyl and to determine that methomyl can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing methomyl as the active ingredient, labeled and used as specified in this Reregistration Eligibility Decision document, are eligible for reregistration. The reregistration of particular products is addressed in Section V. of this document.

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. and the data identified in Appendix B. Although the Agency has found that all uses of methomyl, labeled and used as specified in this Reregistration Eligibility Decision document, are eligible for reregistration, 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 methomyl, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient methomyl, the Agency has sufficient information on the health effects of methomyl and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that methomyl products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that products containing methomyl for all uses, labeled and used as specified in this Reregistration Eligibility Decision document, are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of methomyl, labeled and used as specified in this Reregistration Eligibility Decision document, are eligible for reregistration.

C. Regulatory Position

The following is a summary of the regulatory positions and rationales for methomyl. Where labeling revisions are imposed, specific language is set forth in Section V. of this document.

1. Food Quality Protection Act Findings

Determination of Safety for U.S. Population

The Agency has determined that established tolerances with amendments and changes as specified in this document for methomyl meet the safety standards under the FQPA amendments to section 408(b)(2)(D) for the general population. In reaching this determination the Agency has considered the available information on aggregate exposures, both acute and chronic, from food and water as well as the possibility of aggregate effects from methomyl and thiodicarb since thiodicarb degrades rapidly to methomyl.

Since there are no residential or lawn uses of methomyl, no dermal or inhalation exposure is expected in and around the home.

The results of the acute aggregate exposure analyses for food, for thiodicarb and methomyl, demonstrate that there are adequate margins of exposure for the general U.S. population (MOE=912). Estimated acute water exposures do not exceed the drinking water level of concern.

Results of the chronic aggregate exposure analyses for food, for thiodicarb and methomyl, show that for the general U.S. population, only 1.9% of the RfD is occupied. Estimated chronic water exposures do not exceed the drinking water level of concern.

Determination of Safety for Infants and Children

The Agency has determined that established tolerances with amendments and changes as specified in this document for methomyl meet the safety standards under the FQPA amendments to section 408(b)(2)(D) for infants and children. In reaching this determination the Agency has considered the available information on the aggregate exposures, both acute and chronic, from food and water as well as the possibility of aggregate exposure from methomyl and thiodicarb since thiodicarb degrades rapidly to methomyl.

In determining whether to retain, reduce, or remove the 10x FQPA safety factor for infants and children, EPA uses a weight of evidence approach taking into account the

completeness and adequacy of the toxicity data base, the nature and severity of the effects observed in pre- and post-natal studies, and information on exposure.

For purposes of assessing the pre- and post-natal toxicity of methomyl, EPA has evaluated two developmental studies and one reproduction study. Based on current toxicological data requirements, the data base for methomyl, relative to pre- and post-natal toxicity is complete. The data provided no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to methomyl. In the prenatal developmental toxicity studies in rats and rabbits and the two-generation reproduction study in rats, effects in the offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity. There was no assessment of potential susceptibility in the area of functional development.

There are however, data gaps for acute and subchronic neurotoxicity studies in rats. These studies are considered data gaps because methomyl has exhibited neurotoxic signs in two species (dogs and rabbits) by two different routes of exposure (oral and dermal). The Agency has determined that the need for a developmental neurotoxicity study should be placed in reserve status pending receipt and review of the acute and subchronic neurotoxicity studies.

Based on these considerations, the 10x Safety Factor for increased susceptibility to infants and children (as required by FQPA) was reduced to 3x.

The results of the acute aggregate exposure analyses for food, for thiodicarb and methomyl, demonstrate that there are adequate margins of exposure for children 1 to 6 years of age (MOE=417) and infants (MOE=756). Estimated acute water exposures do not exceed the drinking water level of concern.

Results of the chronic aggregate exposure analyses for food, for thiodicarb and methomyl, show that the most significantly exposed subpopulation is infants (<1 year old) with 6.5% of the RfD occupied. For children 1-6 years old, 2.7% of the RfD is occupied. Estimated chronic water exposures do not exceed the drinking water level of concern.

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

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

Endocrine Disruption

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

Cumulative Risk

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).

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

2. Tolerance Reassessment

Tolerance Reassessment Summary

As a result of FQPA, pesticide residues are no longer regulated under section 409 of FFDCA. Consequently, all tolerances will eventually be placed in 40 CFR section 180. However, because methomyl tolerances still exist under sections 185 and 186, references to these sections are still used in this document. The Agency will issue a Federal Register Notice moving all methomyl tolerances listed under sections 185 and 186 to 40 CFR §180.253.

Tolerances for residues of methomyl in/on plant RACs are currently expressed in terms of methomyl [40 CFR §180.253 (a) and (b)]. A food/feed additive tolerance has been established for residues of methomyl in dried hops [40 CFR §185.4100].

A summary of the methomyl tolerance reassessment and recommended modifications in commodity definitions are presented in Table 50.

Tolerances Listed Under 40 CFR §180.253(a):

Sufficient data are available to ascertain the adequacy of the established tolerances on all listed commodities except for dry beans, bermudagrass forage, lentils, sorghum forage, and turnips (greens).

Additional residue data and/or label amendments are required before the adequacy of tolerances can be determined on bermudagrass forage, sorghum forage, radishes, and turnips (greens); and supporting storage stability data are required before tolerances can be reassessed on dry beans and lentils. Because the use on lentils is similar to the proposed use on dry peas, data on dried pea seeds will be translated to support the tolerance on lentils. Provided acceptable storage stability data are submitted, residue data on dry peas indicate that the tolerance on lentils should be increased to 0.2 ppm.

Tolerances on barley forage, bean forage, peanut hulls, and rye hay will be revoked because the Agency no longer considers these commodities to be significant livestock feed items due to revisions in Table 2. (Table 1 in OPPTS Guideline 860.1000).

In accordance with 40 CFR §180.1 (h), the tolerance on green onions covers leeks and the tolerance on peaches covers nectarines. Therefore, individual tolerances on leeks and nectarines will be revoked.

Tolerances will also be revoked for the outdated listings on leafy vegetables (exc. beet tops, broccoli, . . . etc.) and root crop vegetables. Tolerances either already exist for individual members of these outdated crop groups or sufficient data are available to establish new tolerances. In addition, the tolerance on Brassica (cole) leafy vegetables should be revoked because individual tolerances ranging from 2 to 6 ppm have been established on all brassica vegetables having registered uses.

Individual tolerances have been established on peppers (2 ppm) and tomatoes (1 ppm), and the available data support a 0.2 ppm tolerance in/on eggplants. Concomitant with establishing a tolerance on eggplant, the tolerance on fruiting vegetables must be revoked.

The available residue data on oranges, grapefruits, tangerines, and lemons adequately support a crop group tolerance for citrus fruits. Methomyl residues were <0.02-0.53 ppm in/on citrus fruits harvested 1 day following application(s) of methomyl at $\leq$1x the maximum labeled rate. Therefore, a 1 ppm tolerance must be established on the citrus fruits crop group. Concomitant with establishing the crop group tolerance, individual tolerances for grapefruit, lemon, orange, and tangerines should be revoked.

Since there are no registered uses on watercress, the tolerance on watercress should be revoked.

Tolerances Listed Under 40 CFR §180.253 (b):

Sufficient data are available to ascertain the adequacy of the established 4 ppm tolerance with a regional registration on pears.

Tolerances Listed Under 40 CFR §185.4100:

Sufficient data are available to ascertain the adequacy of the established 12.0 ppm tolerance on imported dried hops. In accordance with PR Notice 93-12 (12/93), dried hops are now regulated as a RAC. A permanent tolerance will be established on dried hops cones, and the food additive tolerance will be revoked.

New Tolerances Needed Under 40 CFR §186.253 (a):

Sufficient data are available to determine appropriate tolerances for aspirated grain fractions (grain dust), the citrus fruits crop group, dried citrus pulp, cowpea forage, eggplant, dried hops cones, and sugar beet tops. Grain dust data generated using treated wheat and sorghum indicate that a 25 ppm tolerance is needed for methomyl residues in/on aspirated grain fractions. The available residue data support methomyl tolerances of 1 ppm in/on citrus fruits, 10 ppm in/on cowpea forage, 0.2 ppm in/on eggplants, 10 ppm in/on dried hops cones, and 2 ppm in/on sugar beet tops.

Before tolerances can be established on cowpea hay, bulb onions, pea seeds, field pea seeds and hay, root and tuber vegetables, sorghum stover and hay, and soybean hay, storage stability data are required to support the available residue data.

Provided the registrant submits acceptable storage stability data, the available residue data also support methomyl tolerances of 0.2 ppm on the root and tuber vegetables crop group, 0.2 ppm in/on onion bulbs, 0.2 ppm in/on pea seeds and field pea seeds, 2 ppm in/on field pea hay, 10 ppm in/on cowpea hay, 0.2 ppm in/on soybean hay, 4 ppm in/on sorghum stover, and 1 ppm in/on sorghum hay.

Tolerances are required for methomyl residues in/on chicory tops, radish tops, and cotton gin byproducts. Appropriate tolerances will be determined once residue data are submitted.

The following table provides a tolerance reassessment summary for methomyl.

Table 50 - Tolerance Reassessment Summary for Methomyl.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR §180.253 (a):			
Alfalfa	10	10	Separate tolerances each at 10 ppm should be established for *alfalfa, forage* and *alfalfa, hay*.
Apples	1	1	*Apple*
Asparagus	2	2	
Avocados	2	2	*Avocado*
Barley, forage	10	Revoke	No longer considered to be a significant feed item.
Barley, grain	1	1	
Barley, hay	10	10	
Barley, straw	10	10	
Beans, dry	0.1 (N)	0.1 [a]	Storage stability data are required to support the reassessed tolerance. *Bean, seed*
Beans, forage	10	Revoke	No longer a regulated feed item.
Beans, succulent	2	2	*Bean, succulent*
Beets, tops	6	6	*Beets, tops (leaves)*
Blueberries	6	6	*Blueberry*
Brassica (cole) leafy vegetables	6	Revoke	Individual tolerances ranging from 2 to 6 ppm have been established for brassica vegetables with registered uses.
Broccoli	3	3	
Brussels sprouts	2	2	
Cabbage	5	5	
Cabbage, Chinese	5	5	
Cauliflower	2	2	
Celery	3	3	
Citrus Fruits Crop Group	None	1	The available data support a 1 ppm tolerance for the *Citrus Fruits Crop Group*
Collards	6	6	
Corn, fodder	10	10	
Corn, forage	10	10	
Corn, fresh (inc. sweet) (K+CWHR)	0.1 (N)	0.1	*Corn, sweet (K+CWHR)*
Corn, grain (inc. pop)	0.1 (N)	0.1	*Corn, grain*
Cottonseed	0.1 (N)	0.1	*Cotton, seed, undelinted*
Cucurbits	0.2 (N)	0.2	*Cucurbit Vegetables Crop Group*
Dandelions	6	6	
Endive (escarole)	5	5	

Table 50 *(continued)*.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Grapefruit	2	Revoke	Tolerance should be revoked once a 1 ppm tolerance is established for the *Citrus Fruits Crop Group*.
Grapes	5	5	*Grape*
Grasses, Bermuda	10	TBD [b]	Additional data are required. *Grass, Bermuda, forage*
Grasses, Bermuda, hay (dry, dehydrated)	40	40	*Grass, Bermuda, hay*
Kale	6	6	
Leeks	3	Revoke	In accordance with 40 CFR §180.1 (h), residues in/on leeks are covered by the tolerance on green onions.
Lemons	2	Revoke	Tolerance should be revoked once a 1 ppm tolerance is established for the *Citrus Fruits Crop Group*.
Lentils	0.1	0.2 [a]	Once supporting storage stability data are provided for dried legume seeds, data on dry pea seed, which will be translated to support the use on lentils. These data indicate that the tolerance should be increased to 0.2 ppm. *Lentil, seed.*
Lettuce	5	5	
Mint, hay	2	2	Separate tolerances each at 2 ppm should be established for *peppermint, tops* and *spearmint, tops*.
Mustard, greens	6	6	
Nectarines	5	Revoke	In accordance with 40 CFR §180.1 (h), residues in/on nectarines are covered by the tolerance on peaches.
Oats, forage	10	10	
Oats, grain	1	1	
Oats, hay	10	10	
Oats, straw	10	10	
Onion, green	3	3	
Oranges	2	Revoke	Tolerance should be revoked once a 1 ppm tolerance is established for the *Citrus Fruits Crop Group*.
Parsley	6	6	
Peaches	5	5	*Peach*

Table 50 *(continued)*.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Peanuts	0.1 (N)	0.1	*Peanut, nutmeat*
Peanuts, hulls	0.1 (N)	Revoke	No longer a regulated feed item.
Peas	5	5	*Pea, succulent*
Peas, vines	10	10	Vines of pea cultivars used for human food are no longer considered to be a significant feed item; only vines of field pea cultivars grown for livestock feeding are regulated. The current tolerance should be changed to *Pea, field, vines*.
Pecans	0.1	0.1	*Pecan*
Peppers	2	2	*Pepper, bell and non-bell*
Pomegranates	0.2 (N)	0.2	
Rye, forage	10	10	
Rye, grain	1	1	
Rye, hay	10	Revoke	No longer considered to be a significant feed item.
Rye, straw	10	10	
Sorghum, forage	1	TBD	A label amendment or additional data are required.
Sorghum, grain	0.2 (N)	0.2	
Soybeans	0.2 (N)	0.2	*Soybean, seed*
Soybean, forage	10	10	
Spinach	6	6	
Strawberries	2	2	*Strawberry*
Swiss chard	6	6	
Tangerines	2	Revoke	Tolerance should be revoked once a 1 ppm tolerance is established for the *Citrus fruits Crop Group*.
Tomatoes	1	1	*Tomato*
Turnips, greens, tops	6	TBD	Additional data are required unless the registrnat removes turnip greens, tops from the federal labels.
Vegetables, fruiting	0.2 (N)	Revoke	Tolerance should be revoked once a 0.2 ppm tolerance is established for *Eggplants*. Separate tolerances are already established on tomatoes and peppers.

Table 50 *(continued)*.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Vegetables, leafy (exc. beets(tops), broccoli, Brussels sprouts, cabbage, cauliflower, celery, Chinese cabbage, collards, dandelions, endive (escarole), kale, lettuce, mustard greens, parsley, spinach, Swiss chard, turnip greens (tops), and watercress)	0.2 (N)	Revoke	The outdated tolerance for leafy vegetables should be revoked because separate tolerances have been established for leafy vegetables commodities with registered uses.
Vegetables, root crop	0.2 (N)	Revoke	The outdated tolerance for root crop vegetables should be revoked once a tolerance is established for the *Root and Tuber Vegetables Crop Group*
Watercress	6	Revoke	There are no registered uses on watercress.
Wheat, forage	10	10	
Wheat, grain	1	1	
Wheat, hay	10	10	
Wheat, straw	10	10	
Tolerances with A Regional Registration listed under 40 CFR §180.253 (b):			
Pears	4	4	*Pear*
Food Additive Tolerances listed under 40 CFR §185.4100 :			
Hops, dried	12	Revoke	In accordance with PR Notice 93-12 (12/93), dried hops are now regulated as a RAC. A section 408 tolerance should be established on *Hops cones, dried*.
Tolerances needed under 40 CFR §186.253 (a):			
Aspirated grain fractions	None	25	The available data indicate that a 25 ppm tolerance should be proposed for *Aspirated grain fractions*.
Chicory, tops (leaves)	None	TBD	Additional data are required.
Citrus, pulp, dried	None	2	The available data indicate that the registrant should propose a 2 ppm tolerance for *Citrus pulp, dried*.
Cotton gin byproducts	None	TBD	Data are required.

Table 50 *(continued)*.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Cowpea, forage	None	10	Cowpea is the only bean foliage crop the Agency considers to be a significant livestock feed item. The available bean forage and hay data support equivalent tolerances on cowpea forage and hay. Tolerances should be proposed for *Cowpea, forage* and *Cowpea, hay*.
Cowpea, hay	None	10 [a]	
Eggplant	0.2 [c]	0.2	The registrant should propose a 0.2 ppm tolerance for *Eggplant*.
Onions, bulb	0.2 [d]	0.2 [a]	Once acceptable storage stability data are available, the registrant should propose a 0.2 ppm for *Onions, bulb*.
Pea, seed	None	0.2 [a]	Once acceptable storage stability data are available, the available data support the proposed tolerances.
Pea, field, hay	None	2 [a]	Once acceptable storage stability data are available, the registrant should propose tolerances for *Pea, field, seed* and *Pea, field, hay*, which are supported by the available dry pea data.
Pea, field, seed	None	0.2 [a]	
Hops cones, dried	None	10	As per PR Notice 93-12 (12/93), a section 408 RAC tolerance should be established for *Hops cones, dried*. In addition, a review of the available residue data indicate that the import tolerance can be lowered to 10 ppm to achieve compatibility with the Codex MRL.
Radish, tops (leaves)	None	TBD	Data are required.
Root and Tuber Vegetables Crop Group	None	0.2 [a]	Once supporting storage stability data are available for potato, adequate data will be available to support a crop group tolerance for the *Root and Tuber Vegetables Crop Group*
Sorghum, stover	None	4 [a]	Storage stability data are required to support the proposed tolerances.
Sorghum, hay	None	1 [a]	

Table 50 *(continued)*.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Soybean, hay	None	0.2 [a]	Based upon the proposed 12-day PHI, the available residue data support a 0.2 ppm tolerance. Once supporting storage stability data are available the registrant should propose a revised tolerance on *Soybean, hay*.
Sugar beet, tops	0.2 [e]	2	The available data indicate that the tolerance should be increased to 2 ppm. *Beets, sugar, tops (leaves)*.

[a] Reassessed tolerance is tentative pending submission of supporting storage stability data.
[b] TBD = To be determined. Tolerance cannot be determined at this time because additional data are required.
[c] Tolerance as part of the outdated fruiting vegetables crop group.
[d] Tolerance as part of the outdated root crop vegetables group.
[e] Tolerance as part of the outdated leafy vegetables crop group.

Codex Harmonization

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for methomyl residues in/on various plant and animal commodities (see *Guide to Codex Maximum Limits For Pesticide Residues, Part A.1, 1995*). Codex has combined MRLs for thiodicarb and methomyl into a single listing. Codex MRLs and U.S. tolerances are not presently compatible because the U.S. tolerance expression currently includes only methomyl, whereas the Codex MRL residue definition includes methomyl and methomyl oxime (methyl hydroxythioacetimidate).

A comparison of the Codex MRLs and the corresponding U.S. tolerances is presented in Table 51.

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

- If the Codex MRL residue definition for methomyl is amended to include only methomyl, U.S. tolerances and Codex MRLs would be compatible for the following crops/commodities: alfalfa, asparagus, beans (dry and succulent), cabbage, cauliflower, citrus fruits, cucumbers, eggplants, grapes, hops, lettuce (head), melons, mint hay, onions (bulb), pea vines, peaches/nectarines, peanuts, peas (succulent), sorghum, soybeans, soybean forage, summer squashes, tomatoes, and watermelons. In addition, the MRL and tolerance for sorghum forage would be compatible if the registrant chooses to restrict the U.S. use to only grain sorghum.

- Based upon the use patterns registered in the U.S. and the available residue data, compatibility of U.S. tolerances and Codex MRLs is not possible for the following

crops/commodities: celery, cottonseeds, kale, maize (field corn), oats, welsh onion, peppers, pome fruits, potato, spinach, sugar beet, sweet corn, and wheat.

Table 51 - Codex MRLs for methomyl and applicable U.S. tolerances.

Codex			Reassessed U.S. Tolerance (ppm)	Recommendation and Comments
Commodity (As Defined)	MRL (mg/kg)	Step		
Alfalfa forage (green)	10	CXL	10	
Asparagus	2	CXL	2	
Barley	0.5	CXL	1	U.S. residue data indicate that higher tolerances are required.
Barley straw and fodder, dry	5	CXL	10	
Beans (dry)	0.1	CXL	0.1	
Cabbages, head	5	CXL	5	
Cauliflower	2	CXL	2	
Celery	2	CXL	3	U.S. residue data indicate that the higher tolerance is required.
Citrus fruits	1	CXL	1	
Common bean (pods and/or immature seeds)	2	CXL	2	
Cotton seed [a]	0.5	CXL	0.1	U.S. residue data indicate that a lower tolerance is acceptable.
Cucumber	0.2	CXL	0.2	Covered by U.S. tolerance for the Cucurbit Vegetables Crop Group.
Egg plant	0.2	CXL	0.2	
Grapes	5	CXL	5	
Hops, dry	10	CXL	10	
Kale	5	CXL	6	U.S. residue data indicate that the higher tolerance is required.
Lettuce, head	5	CXL	5	
Maize [a]	0.05 * [b]	CXL	0.1	U.S. residue data indicate that the higher tolerance is required.
Maize fodder [a]	50 fresh wt.	CXL	10	U.S. residue data indicate that a lower tolerance is acceptable.
Maize forage [a]	50 fresh wt.	CXL	10	
Meat (from mammals other than marine mammals)	0.02 *	CXL	None	The Agency has determined that residues in meat represent a 40 CFR §180.6(a)(3) situation; therefore U.S. tolerances are not required.

Table 51 *(continued)*.

Codex			Reassessed U.S. Tolerance (ppm)	Recommendation and Comments
Commodity (As Defined)	MRL (mg/kg)	Step		
Melons, except watermelon	0.2	CXL	0.2	Covered by U.S. tolerance for the Cucurbit Vegetables Crop Group
Milks	0.02 *	CXL	None	The Agency has determined that residues in milk represent a 40 CFR §180.6(a)(3) situation; therefore a U.S. tolerance is not required.
Mint hay	2	CXL	2	
Nectarine	5	CXL	None	Covered by 5.0 ppm U.S. tolerance on peaches.
Oat straw and fodder, dry	5	CXL	10	U.S. residue data indicate that the higher tolerance is required.
Oats	0.5	CXL	1	U.S. residue data indicate that the higher tolerance is required.
Onion, bulb	0.2	CXL	0.2	
Onion, Welsh	0.5	CXL	3	Covered by U.S. tolerance for green onions; U.S. residue data indicate that a higher tolerance is required.
Pea vines (green)	10	CXL	10	
Peach	5	CXL	5	
Peanut	0.1	CXL	0.1	
Peanut forage (green)	5	CXL	None	U.S. label directions prohibit feeding of treated peanut vines to livestock.
Peas (pods and succulent=immature seeds)	5	CXL	5	Succulent podded and shelled peas are covered by a single U.S. tolerance.
Peas, shelled (succulent)	0.5	CXL		
Peppers	1	CXL	2	U.S. residue data indicate that a higher tolerance is required.
Pineapple	0.2	CXL	None	Not registered for this use in the U.S.
Pome fruits	2	CXL	None	Separate U.S. tolerances have been established for apples at 1.0 ppm and pears at 4.0 ppm
Potato	0.1	CXL	0.2	Cover by U.S. tolerance for the Root and Tuber Vegetables Crop Group; U.S. residue data indicate that a higher tolerance is required.
Sorghum	0.2	CXL	0.2	

Table 51 *(continued)*.

Codex			Reassessed U.S. Tolerance (ppm)	Recommendation and Comments
Commodity (As Defined)	MRL (mg/kg)	Step		
Sorghum forage (green)	1	CXL	TBD [c]	Additional residue data are required to support the U.S. tolerance, or the current 1.0 ppm tolerance could be compatible if the registrant restricts the use to only grain sorghum.
Soya bean (dry) [a]	0.2	CXL	0.2	U.S. tolerance for soybeans does not distinguish between immature and mature seeds.
Soya bean (immature bean)	0.1	CXL		
Soya bean forage (green)	10	CXL	10	
Spinach	5	CXL	6	U.S. residue data indicate that a higher tolerance is required.
Squash, summer	0.2	CXL	0.2	Covered by U.S. tolerance for the Cucurbit Vegetables Crop Group.
Sugar beet	0.1	CXL	0.2	Covered by U.S. tolerance for the Root and Tuber Vegetables Crop Group; U.S. residue data indicate that a higher tolerance is required.
Sweet corn (corn-on-the-cob) [a]	2	CXL	0.1	U.S. residue data indicate that a lower tolerance is acceptable.
Tomato [a]	1	CXL	1	
Watermelon	0.2	CXL	0.2	Covered by U.S. tolerance for the Cucurbit Vegetables Crop Group
Wheat	0.5	CXL	1	U.S. residue data indicate that a higher tolerance is required.
Wheat straw and fodder, dry	5	CXL	10	

[a] MRL is based upon thiodicarb use.
[b] An asterisk (*) signifies that the MRL was established at or about the limit of detection.
[c] To be determined; additional residue data are required.

3. Summary of Risk Management Decisions

Human Health

The Agency concludes that there are no acute dietary concerns associated with potential residues of methomyl from application of thiodicarb and methomyl in food. Based on Monte Carlo analysis with the level of concern being an MOE of 300, sufficient margins of exposure exist [U.S. population (MOE=912), children 1 to 6 years of age (MOE=417) and

infants (MOE=756)] at the high-end percentile exposure level of interest (99.9th percentile value).

Results of the chronic exposure analysis show that no single subpopulation exceeded 7% of the RfD. For the subpopulations, non-nursing infants (<1 year old) and children (ages 1- 6 years old), 6.5% and 2.7% of the RfD is occupied, respectively. For the general U.S. population, only 1.9% of the RfD was occupied.

Estimated concentrations of methomyl in surface and ground water are less than the Agency's levels of concern for methomyl in drinking water as a contribution to acute and chronic aggregate exposure. Therefore, the Agency concludes that aggregate exposure to all sources of methomyl does not exceed the Agency's risk concerns.

To minimize the risks of potential systemic toxicity to mixers/loaders the Agency is requiring the use of personal protective equipment and/or the use of engineering controls (water soluble bags).

Environmental Fate and Effects

Laboratory studies indicate that methomyl is moderately persistent and highly mobile. It is stable to hydrolysis at lower pH's (neutral to acidic) and degrades slowly in alkaline conditions. Methomyl photolyzes quickly in water but more slowly in soils. It is moderately stable to aerobic soil metabolism but degrades more rapidly under anaerobic conditions. In laboratory studies, methomyl does not readily adsorb to soil and has the potential to be very mobile. Field studies show varying dissipation rates of the chemical in soils. Dissipation rates were related primarily to differences in soil moisture content, which may affect the microbial activity, and rainfall/irrigation, which could influence leaching.

Methomyl has been detected in ground water in a prospective ground water monitoring study and in other reported incidences. While it may reach ground water under certain conditions, methomyl will not likely persist under many conditions. Methomyl can contaminate surface water as a result of spray drift during application or by runoff from treated sites. Methomyl would not be expected to persist in clear, shallow waters because of its susceptibility to photolysis.

The major concerns for non-target organisms are the chronic risks posed by the use of methomyl to non-target mammalian and freshwater invertebrate organisms. Risks to aquatic invertebrates from exposure to methomyl are likely to occur wherever methomyl is used. Accumulation of methomyl from repeated applications contributes to the chronic risks.

4. Ecological Risk Mitigation for Methomyl

To lessen ecological and potential water risks posed by methomyl, EPA is requiring the following mitigation from registrants of methomyl containing products.

1) The registrant will revise end use product labels to reduce the maximum seasonal use rates as noted in the table below;

Table 52 Revised Maximum Seasonal Use Rates

Crop	From Present Season Rate (lb ai)	To New Season Rate (lb ai)	Percent Decrease
Broccoli	7.2	6.3	12.5
Cabbage	9.0	7.2	20
Cauliflower	9.0	7.2	20
Celery	9.0	7.2	20
Chinese cabbage	8.1	7.2	11.1
Corn, sweet	7.2	6.3	12.5
Lettuce, head	9.0	7.2	20
Tomato	7.2	6.3	12.5

These measures will result in less loading of methomyl in the environment.

2) The registrant will reduce the single maximum per acre application rate of methomyl by 50% from 1.8 pounds to 0.9 pounds on peaches and commercial sod farms. No methomyl crop use will exceed a single application rate of 0.9 pounds of methomyl per acre.

3) The following statement supporting the use of an Integrated Pest Management (IPM) plan must be added to the labels.

"This product should be used as part of an Integrated Pest Management (IPM) program which can include biological, cultural, and genetic practices aimed at preventing economic pest damage. Application of this product should be based on IPM principles and practices including field scouting or other detection methods, correct target pest identification, population monitoring and treating when target pest populations reach locally determined action thresholds. Consult your state cooperative extension service, professional consultant or other qualified authorities to determine appropriate action threshold levels for treating specific pest/crop systems in your area."

4) Based on the environmental risk assessment for methomyl, the following advisories are required to be on the label for methomyl: a labeling statement for potential ground water contamination, a labeling statement to minimize the potential for surface water contamination and labeling statements are required on manufacturing use products and end use products based on the toxicity to nontarget organisms. A bee hazard statement is also required.

5) The following spray drift label requirement for products with aerial applications is required to be on the label for methomyl: "Do not apply by ground equipment within 25 feet, or by air within 100 feet of lakes, reservoirs, rivers, estuaries, commercial fish ponds and natural, permanent streams, marshes or natural, permanent ponds. Increase the buffer zone to 450 feet from the above aquatic areas when ultra low volume application is made."

5. Restricted Use Classification

Based on its acute toxicity and use patterns, the Agency is maintaining Restricted Use classification for all methomyl products that are currently so classified.

6. Endangered Species Statement

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures to address the adverse impacts. The program would require use restrictions to protect endangered and threatened species at the county level. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register and have available voluntary county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

7. Labeling Rationale

At this time, all products containing methomyl are intended primarily for occupational use (e.g. mixed, loaded, and applied by occupational applicators only; generally not available to homeowners). No registered use is likely to involve applications at residential sites.

The Worker Protection Standard (WPS)

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

At this time some of the registered uses of methomyl are within the scope of the WPS and some uses are outside the WPS scope.

Requirements for Handlers

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

- Based on risks posed to handlers by the active ingredient, EPA may establish active-ingredient-specific ("a.i. specific") handler requirements for end-use products containing that active ingredient. If the risks to handlers posed by the active ingredient are minimal, EPA may establish no a.i. specific handler requirements.

- Based on the acute toxicity characteristics of the end-use product, EPA usually establishes handler PPE requirements for each end-use product.

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

Occupational-Use Products

EPA is establishing a.i. specific requirements for some occupational handlers of methomyl. In determining the a.i. specific requirements for handlers of methomyl, the Agency considered the exposure and risk assessment for occupational handlers and the available epidemiological information about methomyl.

The MOE's for combined dermal and inhalation exposure were less than 100 for some occupational mixers and loaders handling wettable powder and liquid formulations. The MOEs were greater than 100 for persons mixing and loading wettable powder to support aerial applications only when engineering controls (i.e., water soluble packaging) are employed for the 1.8 lb a.i./A. However, the registrant has agreed to reduce this rate to 0.9 lb a.i./A for the remaining uses of peaches and commercial sod farms. No methomyl crop use will exceed a single application rate of 0.9 lb a.i./A. At the 0.45 lb a.i./A rate, double layering of clothing, and chemical resistent gloves are required. At the 0.9 lb a.i./A rate, double layering of clothing, chemical resistant gloves and a respirator are required. However, if water soluble packaging is used for the 0.45 and 0.9 lb a.i./A rates for wettable powders then only a single layer of clothing (long-sleeved shirt, long pants, and shoes plus socks) is required. The MOEs are greater than 100 for (1) handlers mixing/loading wettable powder formulations to support ground applications and (2) handlers mixing/loading liquid formulations to support aerial, chemigation, and ground applications only when personal protective equipment (i.e., chemical-resistant gloves) is worn. Due to lack of data for baseline scenarios, MOEs are greater than 100 for applications of baits by hand only when chemical resistent gloves are worn. The Agency is requiring active-ingredient-based protection for handlers of methomyl in this exposure situation.

In 1993 EPA issued a Data Call-In for Poison Control Center Data for 28 organophosphate and carbamate insecticides and identified methomyl as one of five candidates for immediate action under the Acute Worker Risk Strategy. Use of methomyl products in California from 1982 - 1989 resulted in the second highest total number of agricultural worker poisoning incidents, and the highest number of agricultural related hospitalizations of all the chemicals reviewed.

In 1995, the Agency met with the registrants of methomyl and mitigation measures were adopted to reduce incidents for the fly bait formulations. For the fly bait products the use was limited to commercial agriculture production where children would not be present. The bait stations are required to be placed four feet above the ground. Also, an embittering agent is required to be added to all fly bait stations and the color of the formulations are limited to earth-tones or other dark unattractive colors.

In 1996, the Agency and the registrants of methomyl adopted measures to reduce handler poisoning incidents. These measures included (1) the use of only mechanical ground or aerial application equipment when applying methomyl to crops, and (2) the use of chemical resistant apron and footwear for cleaners and repairers of equipment. In addition, wettable powder formulations must be formulated in water soluble packaging that has a pictogram depicting that the bags should not be cut, ripped, or torn.

As each set of mitigation measures were put into effect the number of handler incidents from the use of methomyl has been decreasing. Therefore, EPA has determined to retain the risk reduction measures already in place. In addition, based on the exposure and risk assessment and concerns about handler incidents, EPA is imposing additional personal protective equipment requirements as identified in Section V, Actions Required by Registrants, Table 53, Summary of Required Label Changes for Methomyl Products.

There are no data that can be used to assess the risk associated with the use of dust formulations. Therefore, a maximum level of PPE is required until appropriate exposure data are developed for risk assessment and the assessment justifies removal of PPE. Mixers and loaders are required to wear long-sleeve shirt, long pants, chemical resistant apron, chemical resistant gloves, chemical resistant footwear plus socks, and a respirator. Applicators are required to wear coveralls over long-sleeve shirt, long pants, chemical resistant gloves, chemical resistant footwear plus socks, chemical resistant headgear for overhead exposure, and a respirator.

There are no data that can be used to assess the risk associated with flagging for aerial bait applications. Therefore, the PPE requirements are the same as those for flagging for aerial spray applications and consist of long-sleeve shirt, long pants, and shoes plus socks.

There are no data that can be used to assess the risk associated with mixing pelleted baits or pastes for paint brush applications. Therefore, the minimum PPE requirements are long-sleeve shirt, long pants, chemical resistant apron, chemical resistant gloves and a respirator.

For applicators using fixed- and rotary-wing aircraft to apply methomyl, the risks are acceptable (i.e., ranging from 1900 to 18,000) when enclosed cockpits are assumed. Since the Pesticide Handlers Exposure Database does not contain sufficient data to estimate exposure to applicators using aircraft with open cockpits, only exposure for aerial applicators using engineering controls, (i.e., enclosed cockpits) was estimated. However, an enclosed cockpit is not required for methomyl if estimated MOEs for enclosed cockpit exposure are an order of magnitude larger than the uncertainty factor (i.e., the acceptable MOE). For methomyl, an occupational MOE of 100 or higher is required to be above the Agency's level of concern. The enclosed cockpit MOEs range from 1900 up to 18000. Therefore, the Agency does not have concerns for handlers who may apply methomyl using aircraft with open cockpits.

WPS and NonWPS Uses:

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

Post-Application/Entry Restrictions

Occupational-Use Products (WPS Uses)

Restricted-Entry Intervals, Early-Entry PPE, and "Double" Notification:

The interim Worker Protection Standard (WPS) restricted-entry intervals (REIs) for agricultural workers are based solely on the acute dermal toxicity and skin and eye irritation potential of the active ingredient. In addition, the WPS retains two types of REI's established by the Agency prior to the promulgation of the WPS: (1) product-specific REI's established on the basis of adequate data, and (2) interim REI's that are longer than those that would be established under the WPS. The WPS prohibits routine entry to perform hand labor tasks during the REI and requires PPE to be worn for other early-entry tasks that require contact with treated surfaces. "Double" notification is the statement on the labels of some WPS pesticide products requiring employers to notify workers about pesticide-treated areas orally as well as by posting of the treated areas. The interim WPS "double" notification requirement was imposed if the active ingredient is classified as toxicity category I for acute dermal toxicity or skin irritation potential.

During the reregistration process, EPA establishes REIs, early-entry PPE, and double notification requirements based on consideration of all available relevant information about the active ingredient, including acute toxicity, other adverse effects, epidemiological information, and post-application data.

In determining the post-application requirements for methomyl, EPA considered the exposure and risk assessment for post-application workers and the available post-application epidemiological information about methomyl.

Estimates of postapplication exposure and risk indicate that for certain crops, restricted-entry intervals (REIs) based on the short and intermediate term dermal toxicological endpoint are necessary. MOEs for grape girdlers do not reach 100 until the third day after application, requiring at least a 3-day REI. Estimates of dermal exposure and risk for peach and commercial sod harvesters indicate that MOEs exceed 100 on the second day after application, requiring at least a 48 hour REI. For other crops and sites, estimates of dermal exposure and risk indicate that MOEs exceed 100 on the day of application after sprays have dried (i.e., 12 hours following application). However, since methomyl is in acute toxicity category 1 for primary eye irritation, a 48 hour REI is required.

Based on the epidemiological information analyzed for the Acute Worker Risk Strategy and on previous post-application risk assessments of methomyl, the Agency has established crop-specific restricted-entry intervals for methomyl for the following crops: apple, cotton, grapefruit, lemon, nectarine, oranges, tangelo, tangerine (3 days), peaches (4 days), grapes (7 days). The Agency has determined that these crop-specific REIs should be retained.

For early entry into treated areas (i.e., during the REI) that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, early-entry workers should wear the clothing and PPE consistent with the toxicity of the active ingredient and with the incidents associated with post-application exposures. The Agency has determined that the appropriate early-entry attire for dermal protection is coveralls, shoes plus socks, and chemical-resistant gloves. In addition, protective eyewear must be worn, since methomyl is classified as category I for eye irritation potential.

Since the restricted-entry interval for grapes is 7 days, the Agency is requiring double notification for uses of methomyl on grapes.

Occupational-Use Products (NonWPS Uses)

At this time, EPA is not establishing entry restrictions of a specific length for nonWPS occupational uses of methomyl end-use products, since the anticipated frequency, duration, and degree of exposure following nonWPS occupational applications do not warrant special risk mitigation measures. However, EPA will prohibit entry into treated areas (such as rights-of-way, hedgerows, fencerows, and drainage areas) until sprays have dried, due to concerns about dermal and inhalation exposures immediately after application and as a prudent safety practice.

Other Labeling Requirements

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

8. Spray Drift Advisory

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

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of methomyl for the above eligible uses has been reviewed and determined to be substantially complete. The following studies are required for methomyl.

81-8 Acute neurotoxicity - rat
82-7 Subchronic neurotoxicity - rat
72-4(a) Estuarine/marine fish early life stage test
72-4(b) Estuarine/marine invertebrate life-cycle test
830.7050 UV/visible absorption spectrum
860.1380 Storage Stability Data (formerly 171-4e)
860.1500 Magnitude of the Residue in Crop Plants (formerly 171-4k)
860.1850 Confined Accumulation in Rotational Crop (formerly 165-1)

Additional Residue Chemistry Data

For those crops with reduced application rates, new residue data must be submitted in support of lower tolerances. The Agency is willing to discuss ways to reduce the number of field trials necessary to support appropriate tolerances.

Additional storage stability data are required to depict the stability of methomyl residues in frozen storage in/on dry beans and peas, bean and pea hay, onions (dry bulb), potatoes, soybean hay, and sorghum fodder (stover) and hay.

Additional residue data and/or label amendments are required on chicory tops, radishes, turnips (greens), sorghum forage, bermudagrass forage, and cotton gin byproducts.

For chicory tops, data are required from a single test in Region 2 depicting methomyl residues in/on chicory leaves following multiple applications at the maximum labeled rate. Leaves should be harvested at the proposed 30-day PHI. Based upon the residue data, the registrant should propose an appropriate tolerance for chicory tops (leaves) and amend labels to include a 30-day PHI for chicory leaves.

For radishes, data are required depicting methomyl residues in/on tops (leaves) harvested 3 days following the last of two foliar applications of methomyl each at 0.9 lb ai/A. These data are required to support SLN No. CA770495. As per OPPTS Guideline 860.1500, the registrant can conduct three tests for radish at 1x the maximum rate at three separate sites in CA (two samples per test), or 1x and 2x tests for radish at two separate sites in CA (one sample per test). Alternatively, the registrant may elect to cancel this use on radishes. Residue data from carrots can be translated to cover radish roots.

Turnip greens appear on the current labels under the crop grouping Leafy Green Vegetables. The registrant must remove turnip greens from the labels. If the registrant wishes to keep turnip greens on the labels then they would be required to do so under the new crop grouping Leaves of Root and Tuber Vegetables. In that case the registrant is required to generate data depicting residues of methomyl in/on turnip tops (leaves) as per whatever the established maximum application and minimum PHI for turnip greens on the labels would be. The registrant cannot translate data from existing data on leafy green vegetables to turnip greens. Turnip greens (tops) are no longer included in the new crop group for Leafy Green Vegetables (Crop Group 4). Turnip tops are considered a representative commodity under the crop grouping for Leaves of Root and Tuber Vegetables (Crop Group 2). If the registrant wishes to keep turnip tops on the labels, they must submit the required residue data, and then along with existing data on sugar beet tops, they could propose a crop group tolerance for Leaves of Root and Tuber Vegetables (Crop Group 2).

In accordance with current Agency guidance (Residue Chemistry Test Guidelines, OPPTS 860 series), zero-day residue data are required on grass forages. Therefore, zero-day residue data are required on bermudagrass forage. Data are required depicting methomyl residues in/on bermudagrass forage harvested the same day as an application at 0.9 lb ai/A. A total of 12 trials are required in regions of the country in which bermudagrass is grown for forage. Grass forages include forage sorghums. Therefore, data are required on methomyl residues in/on sorghum forage harvested the same day as the last of two applications of methomyl each at 0.45 lb ai/A (for a total seasonal application of 0.9 lb ai/A). Residue data from the bermuda grass trials can be translated to support the sorgum forage uses. Alternatively, the registrant may amend their labels to restrict the use of methomyl to only

grain sorghum, in which case the available sorghum forage data (14-day PHI) are adequate. In addition, if the use is restricted to grain sorghum, then no tolerance would be required for sorghum hay.

Data are required depicting methomyl residues in/on cotton gin byproducts ginned from cotton harvested 15 days after the last of multiple foliar applications of methomyl at the maximum labeled rate and totaling 1.8 lb ai/A/season. The cotton must be harvested by commercial equipment (stripper and mechanical picker) to provide an adequate representation of plant residue from the ginning process. At least three field trials for each type of harvesting (stripper and picker) are needed, for a total of six trials.

2. Labeling Requirements for Manufacturing-Use Products and End-Use Products

To remain in complaince with FIFRA, manufacturing use product (MUP) and end use product (EUP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies as noted in the following table.

Table 53 Summary of Required Labeling Changes for Methomyl Products		
Description	**Required Labeling**	**Placement**
Manufacturing Use Products		
One of these statements may be added to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"Only for formulation into an [fill blank with Insecticide, Herbicide or the applicable term which describes the type of pesticide use(s)] for the following use(s) [fill blank only with those uses that are being supported by the MP registrant]."	Directions for Use
	"This product may be used to formulate product for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with the U.S. EPA submission requirements regarding support of such use(s)."	
	"This product may be used to formulate product for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with the U.S. EPA submission requirements regarding support of such use(s)."	
Environmental Hazards Statement	"This pesticide is toxic to fish, aquatic invertebrates, and mammals. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements Environmental Hazards
End Use Products Intended for Occupational Use (WPS and non-WPS)		

Table 53 Summary of Required Labeling Changes for Methomyl Products		
Worker Protection Requirements for Products Subject to WPS	Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS)", and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7", which reflect the requirements of EPA' s labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.	
PPE Requirements	Default PPE is established on the basis of acute toxicity category of the end-use products in accordance with PR Notice 93-7.	Precautionary Labeling Under Hazards to Humans and Domestic Animals
PPE Requirements for wettable powder formulations	Mixers, loaders, others exposed to the concentrate, and cleaners/repairers of equipment must wear: --coveralls over long-sleeve shirt and long pants, --chemical-resistant gloves*, --chemical-resistant footwear plus socks, --chemical-resistant apron, --a respirator dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C). Applicators, flaggers, and others exposed to the dilute must wear: --long-sleeve shirt and long pants, and --shoes plus socks. *For the glove statement, use the statement established for methomyl through the instructions in Supplement Three of PR Notice 93-7.	Precautionary Labeling Under Hazards to Humans and Domestic Animals

Table 53 Summary of Required Labeling Changes for Methomyl Products		
PPE Requirements for liquid formulations	Mixers, loaders, others exposed to the concentrate, and cleaners/repairers of equipment must wear: --long-sleeve shirt and long pants, --shoes plus socks, --chemical-resistant gloves*, --chemical-resistant apron. Applicators, flaggers, and others exposed to the dilute must wear: --long-sleeve shirt and long pants, --shoes plus socks. *For the glove statement, use the statement established for methomyl through the instructions in Supplement Three of PR Notice 93-7.	Precautionary Labeling Under Hazards to Humans and Domestic Animals
PPE Requirements for bait formulations that include directions for application by hand-held equipment	Mixers, loaders, applicators, and other handlers must wear: --long-sleeved shirt and long pants, --chemical resistant gloves*, --shoes plus socks. Flaggers, and others exposed to the bait must wear: --long-sleeve shirt and long pants, --shoes plus socks. *For the glove statement, use the statement established for methomyl through the instructions in Supplement Three of PR Notice 93-7.	Precautionary Labeling Under Hazards to Humans and Domestic Animals
PPE Requirements for mixers of pelleted baits or pastes for paint brush applications	Mixers of pelleted baits or pastes for paint brush applications must wear: --long-sleeved shirt and long pants, --chemical resistant gloves*, --chemical resistant apron, --shoes plus socks, --a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C). *For the glove statement, use the statement established for methomyl through the instructions in Supplement Three of PR Notice 93-7.	Precautionary Labeling Under Hazards to Humans and Domestic Animals

Table 53 Summary of Required Labeling Changes for Methomyl Products		
PPE Requirements for dust formulations	Mixers, loaders, others exposed to the dust, and cleaners/repairers of equipment must wear: --long-sleeve shirt and long pants, --chemical-resistant gloves*, --chemical-resistant apron, --chemical resistant footwear plus socks, --a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C). Applicators, and others exposed to the dust must wear: --coveralls over long-sleeve shirt and long pants, --chemical-resistant gloves*, --chemical resistant footwear plus socks, --a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), --chemical resistant headgear for overhead exposure. *For the glove statement, use the statement established for methomyl through the instructions in Supplement Three of PR Notice 93-7.	Precautionary Labeling Under Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Labeling Under Hazards to Humans and Domestic Animals, Following PPE
User Safety Requirements for all products that specify coveralls in the PPE	"Discard clothing or other materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Labeling Under Hazards to Humans and Domestic Animals, Following PPE
Engineering Controls	"Engineering Controls" "When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."	Precautionary Statements Under Hazards to Humans and Domestic Animals, Following Use Safety Requirements

Table 53 Summary of Required Labeling Changes for Methomyl Products		
Engineering Controls For Wettable Powder Formulatiuons	The following Engineering Controls are required in addition to those specified above: All wettable powder products must be formulated in water-soluble packaging, the outside of which contains a pictogram depicting that users should not cut, rip, or tear the bag. "Water-soluble packets when used correctly qualify as a closed loading system under the WPS. Handlers handling this product while it is enclosed in intact water-soluble packets are permitted to wear long-sleeved shirt, long pants, shoes plus socks, chemical-resistant gloves, and chemical-resistant apron, provided the other required PPE is immediately available in case the bag is opened."	Precautionary Statements Under Hazards to Humans and Domestic Animals, Following Use Safety Requirements
User Safety Recommendations	"User Safety Recommendations" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Labeling Under Hazards to Humans and Domestic Animals, Following Engineering Controls

Table 53 Summary of Required Labeling Changes for Methomyl Products		
Environmental Hazards, Ground and Surface Water Statements	"This pesticide is toxic to fish, aquatic invertebrates, and mammals. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high-water mark. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate." "This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area." "This chemical is known to leach through soil into ground water under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination." "This chemical can contaminate surface water through spray drift. Under some conditions, it may also have a high potential for runoff into surface water for several days to weeks after application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas overlaying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain to surface water."	Precautionary Statements Environmental Hazards
Restricted Entry Interval for WPS Uses	The restricted-entry intervals are: apple, cotton, grapefruit, lemon, nectarine, oranges, tangelo, tangerine --3 days, peaches -- 4 days, grapes -- 7 days, all other WPS uses -- 48 hours.	Directions for Use Agricultural Use Requirements Box and associated with each crop/use as specified by Supplement Three of PR Notice 93-7.
Early-Entry PPE for WPS Uses	The PPE required for early entry is: --coveralls, --chemical-resistant gloves*, --shoes plus socks, --protective eyewear. *For the glove statement, use the statement established for methomyl through the instructions in Supplement Three of PR Notice 93-7.	Directions for Use Agricultural Use Requirements Box as specified by Supplement Three of PR Notice 93-7.

Table 53 Summary of Required Labeling Changes for Methomyl Products		
Double Notification for labels with directions for use on grapes	The following statement must be added to all end-use product labeling that contains directions for use on grapes: "Notify workers of the application to grapes by warning them orally and by posting warning signs at entrances to treated areas."	Directions for Use Agricultural Use Requirements Box as specified by Supplement Three of PR Notice 93-7.
Entry restrictions for non-WPS uses that are applied as sprays	"Do not enter or allow others to enter the treated area until sprays have dried."	**If no WPS uses are on the label -** - Place the Non WPS entry restrictions in the Directions for Use, under the heading "Entry Restrictions." **If WPS uses are also on label --** Follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box, and place the appropriate Non WPS entry restrictions in that box.
General Application Restrictions	"Do not apply by ground equipment within 25 feet, or by air within 100 feet of lakes, reservoirs, rivers, estuaries, commercial fish ponds and natural, permanent streams, marshes or natural, permanent ponds. Increase the buffer zone to 450 feet from the above aquatic areas when ultra low volume application is made." "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application." "Use only in commercial and farm plantings. Not for use in home plantings nor on any commercial crop that is turned into a "U-Pick", "Pick Your Own" or similar operation."	General Precautions and Restrictions section in Directions for Use.
Application Restrictions for products with directions for applications to crops	"Hand-held equipment is prohibited for applications to crops. This product must be applied to crops only with mechanical ground or aerial application equipment."	General Precautions and Restrictions section in Directions for Use.
Application rate restrictions for products with directions for application on Brocolli	Directions for application to brocolli must be amended to specify a maximun seasonal application rate of 6.3 lbs ai/acre.	Directions For Application section in Directions for Use

Table 53 Summary of Required Labeling Changes for Methomyl Products		
Application rate restrictions for products with directions for application on Cabbage	Directions for application to cabbage must be amended to specify a maximun seasonal application rate of 7.2 lbs ai/acre.	Directions For Application section in Directions for Use
Application rate restrictions for products with directions for application on Cauliflower	Directions for application to cauliflower must be amended to specify a maximun seasonal application rate of 7.2 lbs ai/acre.	Directions For Application section in Directions for Use
Application rate restrictions for products with directions for application on Celery	Directions for application to celery must be amended to specify a maximun seasonal application rate of 7.2 lbs ai/acre.	Directions For Application section in Directions for Use
Application rate restrictions for products with directions for application on Chinese Cabbage	Directions for application to chinese cabbage must be amended to specify a maximun seasonal application rate of 7.2 lbs ai/acre.	Directions For Application section in Directions for Use
Application rate restrictions for products with directions for application on Sweet Corn	Directions for application to sweet corn must be amended to specify a maximun seasonal application rate of 6.3 lbs ai/acre.	Directions For Application section in Directions for Use
Application rate restrictions for products with directions for application on Head Lettuce	Directions for application to head lettuce must be amended to specify a maximun seasonal application rate of 7.2 lbs ai/acre.	Directions For Application section in Directions for Use
Application rate restrictions for products with directions for application on Tomatoes	Directions for application to tomatoes must be amended to specify a maximun seasonal application rate of 6.3 lbs ai/acre.	Directions For Application section in Directions for Use
Application rate restrictions for products with directions for application on peaches	Directions for application to peaches must be amended to specify a single maximun per acre application rate of 0.9 lbs ai/acre.	Directions For Application section in Directions for Use
Application rate restrictions for products with directions for application on commercial sod farms	Directions for application to commercial sod farms must be amended to specify a single maximun per acre application rate of 0.9 lbs ai/acre.	Directions For Application section in Directions for Use
Preharvest intervals (PHI) for products with directions for application on beet tops.	Directions for application to beet tops must be amended to specify a preharvest interval (PHI) of 10 days.	Directions For Application section in Directions for Use
Preharvest intervals (PHI) for products with directions for application on Sweet Corn	Directions for application to sweet corn must be amended to specify a preharvest interval (PHI) of 21 days for sweet corn stover.	Directions For Application section in Directions for Use
Grazing restrictions for products with directions for application on Cotton	Label directions for cotton state "Do not graze or feed treated cotton to livestock." This restriction should be deleted from the labels because cotton gin trash is a regulated livestock feed item that is not under the grower's control.	Directions For Application section in Directions for Use

Table 53 Summary of Required Labeling Changes for Methomyl Products		
Application rate restrictions for products with directions for application on Garlic	Directions for garlic specify a maximum single application rate of 0.45 lb ai/A and a maximum of six applications per crop, which would result in a maximum seasonal rate of 2.7 lb ai/A. However, the currently labeled seasonal rate is 3.6 lb ai/A/crop. The seasonal use rate should be amended to be no higher than the total resulting from the maximum number of applications at the maximum rate.	Directions For Application section in Directions for Use
Preharvest interval (PHI) for products with directions for application on Bermudagrass Forage	A 7-day PHI is specified for bermudagrass forage. However, current Agency Guidelines (Table 1, OPPTS Guideline 860.1000) require 0-day PHIs for grass forages. Concomitant with developing zero day residue data for bermudagrass forage, the registrant should amend product labels to list a 0-day PHI for bermudagrass forage.	Directions For Application section in Directions for Use
Preharvest interval for products with directions for application on lentil forage and hay	Since lentil forage and hay are no longer considered to be significant livestock feed items, PHIs for these commodities can be deleted from the use directions for lentils.	Directions For Application section in Directions for Use
Application rate restrictions for products with directions for application on peppers	Use directions for peppers list a maximum seasonal use rate of 4.05 lb ai/A. This rate appears to be a typographical error. The maximum seasonal rate should be 4.5 lb ai/A/crop. The registrant should clarify the maximum seasonal rate for peppers.	Directions For Application section in Directions for Use
Preharvest interval for products with directions for application on soybeans forage and hay	Label directions for soybeans specify PHIs for forage and hay that depend upon whether the last application was made at <0.45 lb ai/A or at 0.45-0.9 lb ai/A. Because the current registered maximum use rate is 0.45 lb ai/A, these label directions are confusing. The use directions should be amended to specify PHIs of 3 and 12 days for forage and hay, respectively, regardless of the application rate. These PHIs are supported by the available data.	Directions For Application section in Directions for Use
Preharvest interval for products with directions for application on sorghum	For sorghum, either specify a 0-day PHI for forage and submit supporting residue data or amend labels to restrict the use only to grain sorghum.	Directions For Application section in Directions for Use
Preharvest interval for products with directions for application on sugar beets	Use directions for sugar beets should be amended to specify a 21-day PHI for both sugar beet roots and tops concomitant with establishing the proposed tolerance for sugar beet tops.	Directions For Application section in Directions for Use

Table 53 Summary of Required Labeling Changes for Methomyl Products		
The following statement supporting the use of an Integrated Pest Management (IPM) plan must be added.	"This product should be used as part of an Integrated Pest Management (IPM) program which can include biological, cultural, and genetic practices aimed at preventing economic pest damage. Application of this product should be based on IPM principles and practices including field scouting or other detection methods, correct target pest identification, population monitoring and treating when target pest populations reach locally determined action thresholds. Consult your state cooperative extension service, professional consultant or other qualified authorities to determine appropriate action threshold levels for treating specific pest/crop systems in your area."	
Spray Drift Label Requirements for Product with Aerial Applications	Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions. The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations. 1. The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor. 2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees. Where states have more stringent regulations, they should be observed. The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information.	
Aerial Drift Reduction Advisory Information. (This section is advisory in nature and does not supersede the mandatory label requirements.)	**INFORMATION ON DROPLET SIZE** The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions below).	

Table 53 Summary of Required Labeling Changes for Methomyl Products		
	CONTROLLING DROPLET SIZE ! Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets. ! Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure. ! Number of nozzles - Use the minimum number of nozzles that provide uniform coverage. ! Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential. ! Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.	
	BOOM LENGTH For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width.	
	APPLICATION HEIGHT Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.	
	SWATH ADJUSTMENT When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)	

Table 53 Summary of Required Labeling Changes for Methomyl Products		
	WIND Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.	
	TEMPERATURE AND HUMIDITY When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.	
	TEMPERATURE INVERSIONS Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.	
	SENSITIVE AREAS The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas).	

B. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established on a case-by-case basis, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell methomyl products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

APPENDIX A - TABLE OF USE PATTERNS SUBJECT TO THIS RED

Appendix A is 72 pages long and is not being included in this RED. Copies of Appendix A are available upon request per 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 methomyl covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to methomyl 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 Methomyl

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
830.1550 (formerly 61-1)	Product Identity and Disclosure of Ingredients	All	41402104, 41402105, 41505201, 42003802, 42476801
830.1600 (formerly 61-2a)	Starting Materials and Manufacturing Process	All	41402104, 41402105, 42003801, 42003802
830-1670 (formerly 61-2b)	Discussion of Formation of Impurities	All	41402104, 41402105, 42003801, 42003802
830.1700 (formerly 62-1)	Preliminary Analysis	All	41505201, 42476801, 42671401
830.1750 (formerly 62-2)	Certification of Ingredient Limits	All	41402105, 41505201, 42003802, 42476801
830.1800 (formerly 62-3)	Analytical Methods to Verify the Certified Limits	All	41505201, 42476801, 42671401
830.6302 (formerly 63-2)	Color	All	41402103, 41402106, 42003803
830.6303 (formerly 63-3)	Physical State	All	41402103
830.6304 (formerly 63-4)	Odor	All	41402103
830.6313 (formerly 63-13)	Stability	All	41402103
830.7000 (formerly 63-12)	pH	All	41402103
830.7050	UV/Visible Absorption	All	Data Gap
830.7200 (formerly 63-5)	Melting Point/Melting Range	All	41402103
830.7300 (formerly 63-7)	Density/Relative Density /Bulk Density	All	41402103
830.7370 (formerly 63-10)	Dissociation Constant in Water	All	41402103

REQUIREMENT		USE PATTERN	CITATION(S)
830.7550 (formerly 63-11)	Partition Coefficient Octanol/Water	All	41402102, 41402103
830.7840 (formerly 63-8)	Water Solubility	All	41402103
830.7950 (formerly 63-9)	Vapor Pressure	All	41402103
ECOLOGICAL EFFECTS			
71-1a	Acute Avian Oral	A,B,C,I,J	00160000, 00161886
71-2a	Avian Dietary - Quail	A,B,C,I,J	22923
71-2b	Avian Dietary - Duck	A,B,C,J	22923
71-4a	Avian Reproduction - Quail	A,B,C,J	41898602
71-4b	Avian Reproduction - Duck	A,B,C,J	41898601
72-1a	Fish Toxicity Bluegill	A,B,C,J	00009061, 40094602
72-1c	Fish Toxicity Rainbow Trout	A,B,C,I,J	40094602
72-2a	Invertebrate Toxicity	A,B,C,I,J	00131254, 00019977, 40094602, 40098001
72-3a	Estuarine/Marine Toxicity - Fish	A,B,C,J	41441202
72-3b	Estuarine/Marine Toxicity - Mollusk	A,B,C,J	42074601
72-3c	Estuarine/Marine Toxicity - Shrimp	A,B,C,J	41441201, 00009230, 00009134
72-4a	Early Life Stage Fish - Freshwater	A,B,C,J	00131255
72-4a	Early Life Stage Fish - Estuarine/Marine	A,B,C,J	Data Gap
72-4b	Life Cycle Invertebrate - Freshwater	A,B,C,J	00118512
72-4b	Life Cycle Invertebrate - Estuarine/Marine	A,B,C,J	Data Gap
72-5	Fish Life Cycle	A,B,C,J	43072101
141-1	Honey Bee Acute Contact	A,B,C,J	00014715

Data Supporting Guideline Requirements for the Reregistration of Methomyl

REQUIREMENT		USE PATTERN	CITATION(S)
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	All	42140101
81-2	Acute Dermal Toxicity -Rabbit	All	42074602
81-3	Acute Inhalation Toxicity - Rat	All	42140102
81-4	Primary Eye Irritation - Rabbit	All	00053407, 41964001
81-5	Primary Dermal Irritation - Rabbit	All	42074603
81-6	Dermal Sensitization - Guinea Pig	All	42074605
81-7	Acute Delayed Neurotoxicity - Hen	A,B,C,I,J	00008827
81-8	Acute Neurotoxicity - Rat	A,B,C,I,J	Data Gap
82-1a	90-Day Feeding - Rodent	A,B,C,I,J	00007190
82-1b	90-Day Feeding - Non-rodent	A,B,C,I,J	00009010
82-2	21-Day Dermal - Rabbit		41251501, 44436301
82-7	Subchronic Neurotoxicity - Rat	A,B,C,I,J	Data Gap
83-1a	Chronic Feeding Toxicity - Rodent	A,B,C,I,J	00078361
83-1b	Chronic Feeding Toxicity - Non-Rodent	A,B,C,I,J	0007091
83-2a	Oncogenicity - Rat	A,B,C,I,J	00078361
83-2b	Oncogenicity - Mouse	A,B,C,I,J	00078423
83-3a	Developmental Toxicity - Rat	A,B,C,I,J	00008621
83-3b	Developmental Toxicity - Rabbit	A,B,C,I,J	00131257
83-4	2-Generation Reproduction - Rat	A,B,C,I,J	43250701
84-2a	Gene Mutation (Ames Test)	All	00124901

Data Supporting Guideline Requirements for the Reregistration of Methomyl

REQUIREMENT		USE PATTERN	CITATION(S)
84-2b	Structural Chromosomal Aberration	All	00161887
84-4	Other Genotoxic Effects	All	00161888, 44047703
85-1	General Metabolism	A,B,C,I,J	42021301, 42379001
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1a	Foliar Residue Dissipation	A,B,C,I,J	00009185, 41032301, 42271701 (in review)
133-3	Dermal Passive Dosimetry Exposure	A,B,C,I,J	Ag. Reentry Task Force
133-4	Inhalation Passive Dosimetry Exposure	A,B,C,I,J	Waived
ENVIRONMENTAL FATE			
160-5	Chemical Identity	All	41402104
161-1	Hydrolysis	A,B,C,I,J	00131249
161-2	Photodegradation - Water	A,B,C,J	00161885, 43823305
161-3	Photodegradation - Soil	A,B,C,J	00163745
162-1	Aerobic Soil Metabolism	A,B,C,I,J	00008586, 43217901
162-2	Anaerobic Soil Metabolism	A,B,C	00073214, 43217902
162-3	Anaerobic Aquatic Metabolism	A,B,C,J	43325401, 43325402, 43325403, 43708806
163-1	Leaching/Adsorption/ Desorption	A,B,C,I,J	00044306, 00161884
164-1	Terrestrial Field Dissipation	A,B,C	00009324, 00009326, 00008844, 41623901, 41623902, 42288001, 43217903, 42345601

Data Supporting Guideline Requirements for the Reregistration of Methomyl

REQUIREMENT		USE PATTERN	CITATION(S)
164-2	Aquatic Field Dissipation	A,B,C	43708801, 43708802, 43708803, 43708804, 43708805, 43708806, 43744401, 43744402, 43823302, 43823303, 43823304
166-1	A Small Scale Prospective Groundwater Monitoring Study with Methomyl	A,B,C	43568301, 43599801, 43708807,
201-1	Droplet Size Spectrum	A,B,C,J	Spray Drift Task Force
202-1	Drift Field Evaluation	A,B,C,J	Spray Drift Task Force
RESIDUE CHEMISTRY			
860.1300 (formerly 171-4a)	Nature of the Residue - Plants	A,B	00044069, 00135794, 00158689, 05008206
860.1300 (formerly 171-4b)	Nature of the Residue - Livestock	A,B	00063418, 41048301, 41513001, 41903001, 42421401, 43144601, 43741801
860.1340 (formerly 171-4c,d)	Residue Analytical Method	A,B	00007132, 00008837, 00009009, 00009074, 00085367, 41040401, 41048301, 41402107, 41721502, 41801201, 43432002, 43432003
860.1360 (formerly 171-4m)	Multiresidue method	A,B	41402107

Data Supporting Guideline Requirements for the Reregistration of Methomyl

REQUIREMENT		USE PATTERN	CITATION(S)
860.1380 (formerly 171-4e)	Storage Stability	A,B	00007071, 00007044, 00007948, 00063421, 00073259, 00144617, 00126579, 05008453, 41801201, 42827201, 42827202, 43081601, 43081602, 43157801, 43188101, 43188102, 43188103, 43188104, 43188105, 43188106, 43334401, 43833301, and Data Gap for other crops
860.1480 (formerly 171-4j)	Magnitude of the Residue in Meat,Milk,Poultry, and Eggs	A,B	00008832, 00009365, 41801201, 42291005, 43833301
860.1500 (formerly 171-4k)	Magnitude of the Residue Crop Field Trials	A,B	

REQUIREMENT	USE PATTERN	CITATION(S)
Root and Tuber Vegetables Group:		
- Beets, garden		00073259
- Carrots		00007837
- Chicory		00009063
- Horseradish		carrot data
- Potatoes		00006997, 00007801, 00008295, 00008862
- Radishes		Data Gap
- Sugar beets		00007004, 00007161, 00008044, 00008863
- Sweet potatoes		42118205
- turnips		Data Gap
Leaves of Root and Tuber Vegetables Group:		
- Beet, tops		00073259
- Chicory, tops (leaves)		41853201, Data Gap
- Radish, tops (leaves)		Data Gap
- Turnip, greens (tops)		00008362, Data Gap
- Sugar beet, tops		00007004, 00008044, 41701302, 42291004, 43346801
Bulb Vegetables (Allium spp.) Group:		
- Garlic		dry bulb onion data
- Leeks		00144617
- Onions, dry bulb		00007192, 41693503, 42291003
- Onions, green		00007192, 00073261

REQUIREMENT	USE PATTERN	CITATION(S)
Leafy Vegetables (Except Brassica Vegetables)Group:		
- Celery		00007136, 00008061, 00008679, 00008803, 00055457, 42118209
- Dandelions		spinach data
- Endive (escarole)		lettuce data
- Lettuce		00007039, 00007168, 00007175, 00007715, 00008679, 00008803, 00007992, 00008264, 00008964, 42118208
- Parsley		spinach data
- Spinach		00007001, 00007002, 00007003, 00007185, 00007862, 00055457
- Swiss chard		spinach data
Brassica (Cole) Leafy Vegetables Group:		
- Broccoli		00007604, 00008043, 00008789, 00055457, 42118207
- Brussels sprouts		00008043, 00008061, 00055457
- Cabbage		00007039, 00007168, 00007715, 00007928, 00008679, 00008964, 42118206
- Cabbage, Chinese		cabbage data
- Cauliflower		00007605, 00008043, 00008789, 00055457, 42118207, 43415201
- Collards		00008359, 00008535
- Kale		00008360
- Mustard greens		00008361

REQUIREMENT	USE PATTERN	CITATION(S)
Legume Vegetables (Succulent or Dried) Group:		
- Beans, dry		00007134, 00009154, 42118201
- Beans, succulent		00007134, 00007135, 00007168, 00008264, 00008436, 00009154, 42118202
- Lentils		dried peas data
- Peas, dry		42118204, 43432001
- Peas, succulent		00007683, 00007999, 00008154, 00009079
- Soybeans		00007008, 00008264, 00008411, 00008602, 00008998, 00009083, 00142925
- Cowpea, forage		00007134, 00007168, 00008264, 00009154, 42118201, 42118202, 42514301
- Peas, vines		00007683, 00007999, 00008154, 00009079, 42118204, 42514301, 43432001
- Soybeans, hay		00007008, 00008264, 00008411, 00008602, 00008998, 00009084, 00142925, 42514301, 43358901
Fruiting Vegetables (Except Cucurbits) Group:		
- Eggplant		00007094, 00009000
- Peppers		00006995, 00006996, 00007094, 00007626, 00144827
- Tomatoes		00007007, 00007039, 00007094, 00007626, 00008742, 00156940, 05009890
- Tomatillos		tomato data

REQUIREMENT	USE PATTERN	CITATION(S)
	Cucurbit Vegetables Group:	
	- Cucumbers	00007970, 00009076, 00009291
	- Melons	00007970, 00009291, 00144827
	- Squash	00007970, 00144827
	Citrus Fruits Group:	
	- Grapefruit	00007137, 00009070, 44047701
	- Lemons	00007138, 00009070, 44047701
	- Oranges	00007139, 00009070, 44047701
	- Tangerines	00007140, 00009070, 44047701
	Pome Fruits Group:	
	- Apples	00007077, 00007610, 00008182, 00009803, 41701301, 42867601
	- Pears	00063419, 00063421, 41693501, 42291001
	Stone Fruits Group:	
	- Nectarines	00007672, 00007832, 44047702
	- Peaches	00007832, 00038316, 00144827, 00156939, 44047702
	Berries Group:	
	- Blueberries	00008334
	Tree Nuts Group:	
	- Pecans	00008919

REQUIREMENT	USE PATTERN	CITATION(S)
Cereal Grains Group:		
- Barley, grain		00007612
- Corn, (inc. Sweet)(K+CWHR)		00007142, 42118203
- Corn, grain (inc. pop)		00007039, 00007659, 00008838, 42118203
- Oats, grain		00007612
- Rye, grain		00007612
- Sorghum, grain		00008233, 00009366, 00006998
- Wheat, grain		00007612, 00156941
Forage, Fodder, and Straw of Cereal Grains Group:		
- Barley forage, hay, straw		00007612
- Corn forage and fodder		00007039, 00007142, 00008838, 00073260, 42118203
- Oats forage, hay, straw		00007612
- Rye forage, hay, straw		00007612
- Sorghum forage		00008233, 00009366, 41721501, 42324901, 42918201, 43807401, 44073001 and data gap
- Wheat forage, hay, straw		00007612, 00156941
Grass Forage, Fodder, and Hay Group:		
- Grasses, Bermuda		00019996, 00050461, 00050462, 00050463, 00078359, and data gap
- Grasses, Bermuda, hay		00019996, 00050461, 00050462, 00050463, 00078359
Nongrass Animal Feeds (Forage, Fodder, Straw, and Hay) Group:		
- Alfalfa		00007133, 00007159, 00008039, 00008984, 43756601

REQUIREMENT	USE PATTERN	CITATION(S)
Herb and Spices Group:		
- fennel (anise)		00019983
Miscellaneous Commodities:		
- Asparagus		00008938
- Aspirated grain fractions		43359401, 43359402
- Avocados		00161144
- Cottonseed		00007690, 00007989, 00009075, 00009135, 00009378 and data gap
- Grapes		00007634, 00007991, 00144827, 00156937, 41693502, 42291002
- Hops, dried		40056901, 41040401, 41313101
- Mint, hay		00007043, 00007044, 00007996
- Peanuts		00007081, 00007713, 00007997, 00007998, 00008666, 00009078, 00028735, 00028736
- Peanuts, hulls		00007081, 00007713, 00007997, 00007998, 00008666, 00009078, 00028735, 00028736
- Pomegranates		00009002, 00009003
- Strawberries		00008847, 00009004
- Tobacco		00007005, 00008964, 00157373, 05008453, 05013872, 42142701

Data Supporting Guideline Requirements for the Reregistration of Methomyl

REQUIREMENT		USE PATTERN	CITATION(S)
860.1520 (formerly 171-4l)	Magnitude of the Residues in Processed Food/Feed	A,B	
	- Apple		00007070
	- Citrus		00009070, 41898608
	- Corn		41898606
	- Cottonseed		00007925, 41898604
	- Grape		00007657
	- Mint		00007043, 00007044, 00007996 41898603
	- Peanut		41898609
	- Potato		41914801
	- Sorghum		41902901
	- Soybean		41898607
	- Tomato		00007601, 41898605
	- Wheat		
860.1850 (formerly 165-1)	Confined Accumulation in Rotational Crop	A,B,C	00019947 and Data Gap
860.1900 (formerly 165-2)	Field Accumulation in Rotational Crop	A,B,C	Data Gap
Special Studies	Chronic and Acute Dietary Exposure Assessment	A,B,C	44327201, 44327202, 44360701, 44360702

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

    a. Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

    b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

    c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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Moran, D. 1991. Pesticide Monitoring in Suffolk County, New York, Department of Health Services, Bureau of Drinking Water, Hauppauge, New York.

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00006995	Shell Chemical Company (1976) 1975--Residue Data for Nudrin® Insecticide in Bell Peppers Resulting from the Application of Nudrin, a California Study: TIR-24-240-75. (Unpublished study received Jun 29, 1976 under 201-347; CDL:232402-A)
00006996	Shell Chemical Company (1976) 1975--Residue Data for Nudrin® Insecticide in Green Peppers Resulting from the Application of Nudrin, an Iowa Study: TIR-24-268-75. (Unpublished study received Jun 29, 1976 under 201-347; CDL:232402-B)
00006997	Shell Chemical Company (1968?) Residue Data: Methomyl in Potatoes. (Unpublished study received Jun 29, 1976 under 201-347; CDL:232402-C)
00006998	Shell Chemical Company (1976) 1975-Residue Data for Nudrin® Insecticide in Grain Sorghum Resulting from the Application of Nudrin, a Texas Study: TIR-24-350-75. (Unpublished study received Jun 29, 1976 under 201-347; CDL:232402-D)
00007001	Shell Chemical Company (1976) 1975--Residue Data for Nudrin® Insecticide in Spinach Resulting from the Application of Nudrin from Modesto, California: TIR-24-137-75. (Unpublished study including TIR-24-280-75, received Jun 29, 1976 under 201-347; CDL:232402-I)
00007002	Shell Chemical Company (1975) 1974--Residue Data for Nudrin® Insecticide in Spinach Following Application of Nudrin from Yakima, Washington: TIR-24-147-74. (Unpublished study received Jun 29, 1976 under 201-347; CDL:232402-J)
00007003	Shell Chemical Company (1976) 1975--Residue Data for Nudrin® Insecticide in Spinach Resulting from the Application of Nudrin, a Tennessee Study: TIR-24-363-75. (Unpublished study received Jun 29, 1976 under 201-347; CDL:232402-K)
00007004	Shell Chemical Company (1975) 1974--Residue Data for Nudrin® Insecticide in Sugar Beets Following Application of Nudrin from Williams, California: TIR-24-177-74. (Unpublished study including TIR-24-184-74 and TIR-24-247-74, received Jun 29, 1976 under 201-347; CDL:232402-L)

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44047702	Kennedy, C.; Tomic, D. (1994) Magnitude of Residues of Methomyl Insecticide in Peach and Nectarine When Applied at the Maximum Proposed Use Pattern and Sampled Over Time: Lab Project Number: AMR 1968-91: 1968-91: LAN-1968-91. Unpublished study prepared by E.I. du Pont de Nemours and Co. and McKenzie Laboratories,Inc. 182 p.
44047703	Bentley, K. (1995) Mouse Bone Marrow Micronuclues Assay of DPX-X1179-394: Lab Project Number: 10210-001: 413-95: HLR 413-95. Unpublished study prepared by E.I. du Pont de Nemours and Co. 22p.
44073001	Kennedy, C. (1996) Magnitude of Residues of Methomyl in Grain Sorghum Fodder Following Application of Lannate LV Insecticide at Maximum Label Rates: Lab Project Number: AMR 3298-95: ML95-0578-DUP. Unpublished study prepared by Dupont Ag Products and Morse Labs., Inc. 143 p.
44327201	Kidwell, J.; Barraj, L. (1997) Chronic and Acute Dietary Exposure Assessment: Methomyl: Lab Project Number: METHOMYL 97-01. Unpublished study prepared by Novigen Sciences, Inc. 221 p.
44327202	Kidwell, J.; Barraj, L. (1997) Chronic and Acute Dietary Exposure Assessment: Combined Thiodicarb and Methomyl Residues: Lab Project Number: THIODICARB/METHOMYL 97-01. Unpublishedstudy prepared by Novigen Sciences, Inc. 79 p.
44360701	Kidwell, J. (1997) Supplemental Report: Chronic and Acute Dietary Exposure Assessment: Methomyl: Lab Project Number: METHOMYL 97-01-SUPPLEMENTAL REPORT. Unpublished study prepared by Novigen Sciences, Inc. 93 p.
44360702	Kidwell, J. (1997) Supplemental Report: Chronic and Acute Dietary Exposure Assessment: Thiodicarb and Methomyl Combined Residues: Lab Project Number: THIODICARB/METHOMYL 97-01A-- SUPPLEMENTAL REPORT. Unpublished study prepared by Novigen Sciences, Inc. 52 p.
44436301	Finlay, C. (1997) Methomyl Technical: 21-Day Repeated Dose Dermal Toxicity Study in Rabbits: Lab Project Number: 11586: HL-1997-00913: 11586-001. Unpublished study prepared by Haskell Laboratory. 145 p.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC AND PRODUCT SPECIFIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3 (for both generic and product specific data), the Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 5).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this

information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-99).

This Notice is divided into six sections and six Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I	-	Why You are Receiving this Notice
Section II	-	Data Required by this Notice
Section III	-	Compliance with Requirements of this Notice
Section IV	-	Consequences of Failure to Comply with this Notice
Section V	-	Registrants' Obligation to Report Possible Unreasonable Adverse Effects
Section VI	-	Inquiries and Responses to this Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms(Insert A) with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms (Insert B) with Instructions
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredient(s).

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms (Insert B) (for both generic and product specific data requirements). Depending on the results of the studies required in this Notice, additional studies/testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in the Requirements Status and Registrant's Response Forms (Insert B) within the time frames provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (Telephone number: 703-605-6000).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

You must use the correct forms and instructions when completing your response to this Notice. The type of Data Call-In you must comply with (Generic or Product Specific) is specified in item number 3 on the four Data Call-In forms (Attachments 2 and 3).

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for generic and product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data Requirements

The options for responding to this Notice for generic data requirements are: (a) voluntary cancellation, (b) delete use(s), (c) claim generic data exemption, (d) agree to satisfy the generic data requirements imposed by this Notice or (e) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the generic data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

Two forms apply to generic data requirements, one or both of which must be used in responding to the Agency, depending upon your response. These two forms are the Data-Call-In Response Form(Insert A), and the Requirements Status and Registrant's Response Form((Insert B).

The Data Call-In Response Forms(Insert A) must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms(Insert B) also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms(Insert A) and the Requirements Status and Registrant's Response Forms(Insert B) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation -

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit completed Generic and Product Specific Data Call-In Response Forms(Insert A), indicating your election of this option. Voluntary cancellation

is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice, which are contained in Section IV-C.

b. Use Deletion -

You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form (Insert B), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 under item 9 in the instructions for the Requirements Status and Registrant's Response Forms (Insert B). You must also complete a Data Call-In Response Form(Insert A) by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, is allowed only if the product bears an amended label.

c. Generic Data Exemption -

Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient if the active ingredient in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

(i). The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;

(ii). Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

(iii). You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form(Insert A), Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form(Insert A). If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form (Insert A). Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

d. Satisfying the Generic Data Requirements of this Notice

There are various options available to satisfy the generic data requirements of this Notice. These options are discussed in Section III-C.1. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the Requirements Status and Registrant's Response Form(Insert B) and item 6b on the Data Call-In Response Form (Insert A). If you choose item 6b (agree to satisfy the generic data requirements), you must submit the Data Call-In Response Form(Insert A) and the Requirements Status and Registrant's Response Form(Insert B) as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "GENERIC" in item number 3.

e. Request for Generic Data Waivers.

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for the Requirements Status and Registrant's Response Form(Insert B). If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

2. Product Specific Data Requirements

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this Notice or (c) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form(Insert A), and the Requirements Status and Registrant's Response Form(Insert B), for product specific data. The Data Call-In Response Form (Insert A) must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form(Insert B) also must be submitted for each product listed on the Data Call-In Response Form(Insert A) unless the voluntary cancellation option is selected. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form(Insert A) and Requirements Status and Registrant's Response Form (Insert B) (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form(Insert A), indicating your election of this option. Voluntary cancellation is item number 5 on both the Generic and Product Specific Data Call-In Response Forms(Insert B). If you choose this option, you must complete both Data Call-In response forms. These are the only forms that you are required to complete.

If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

b. Satisfying the Product Specific Data Requirements of this Notice.

There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the product specific Requirements Status and Registrant’s Response Form(Insert B) and item numbers 7a and 7b (agree to satisfy the product specific data requirements for an MUP or EUP as applicable) on the product specific Data Call-In Response Form(Insert A). Note that the options available for addressing product specific data requirements differ slightly from those options for fulfilling generic data requirements. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Decision document.

c. Request for Product Specific Data Waivers.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's

Response Form(Insert B). If you choose this option, you must submit the Data Call-In Response Form(Insert A) and the Requirements Status and Registrant's Response Form(Insert B) as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form(Insert A) that you agree to satisfy the generic data requirements (i.e. you select item number 6b), then you must select one of the six options on the Generic Requirements Status and Registrant's Response Form(Insert B) related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide you to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified timeframe (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data

If you choose to develop the required data it must be in conformance with Agency guidelines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG) and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form(Insert B) and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost share or agreeing to share in the cost of developing that study. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the Requirements Status and Registrant's Response Form(Insert B) are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2. Agreement to Share in Cost to Develop Data

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3. Offer to Share in the Cost of Data Development

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you did not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept the offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed Certification with Respect to Citations of Data (in PR Notice 98-5) (EPA Form 8570-34) . In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost-sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed to or, failing agreement, to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form(Insert A) and a Requirements Status and Registrant's Response Form(Insert B) committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant normally will be subject to initiation of suspension proceedings, unless you commit to submit, and do submit, the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4. Submitting an Existing Study

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3, *Raw data* means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3, means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information pursuant to the requirements of 40 CFR Part 160. Registrants also must certify at the time of submission of the existing study that such GLP information is available for post May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both documents available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data usually are not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such a study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5 entitled "Standard Format for Data Submitted under FIFRA".

Option 5. Upgrading a Study

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5 entitled "Standard Format for Data Submitted under FIFRA."

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option also should be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally, your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria, as well as a certification regarding protocol compliance with Agency requirements.

Option 6. Citing Existing Studies

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable, or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as

"core-guideline" or "core-minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option, you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form No. 8570-34, Certification with Respect to Citations of Data.

2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form(Insert A) that you agree to satisfy the product specific data requirements (i.e. you select option 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form(Insert B) related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form(Insert B). These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time-frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option.

Option 3. Offer to Share in the Cost of Data Development --The same requirements for generic data (Section III.C.I., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

Option 4. Submitting an Existing Study -- The same requirements described for generic data (see Section III.C.1., Option 4) apply to this option for product specific data.

Option 5. Upgrading a Study -- The same requirements described for generic data (see Section III.C.1., Option 5) apply to this option for product specific data.

Option 6. Citing Existing Studies -- The same requirements described for generic data (see Section III.C.1., Option 6) apply to this option for product specific data.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form(Insert A) and the Requirements Status and Registrant's Response Form(Insert B), and in the generic data requirements section (III.C.1.), as appropriate.

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are not appropriate for your product.

a. Low Volume/Minor Use Waiver

Option 8 under item 9 on the Requirements Status and Registrant's Response Form(Insert B). Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume/minor use pesticides. In implementing this provision, EPA considers low volume pesticides to be only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver, the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume/minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a

registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume/minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

(i). Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

(ii) Provide an estimate of the sales (pounds and dollars) of the active ingredient for each major use site. Present the above information by year for each of the past five years.

(iii) Total direct production cost of product(s) containing the active ingredient by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

(iv) Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient, such as costs of initial registration and any data development.

(v) A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vi) A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vii) For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the

reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume/minor use waiver will result in denial of the request for a waiver.

b. Request for Waiver of Data

Option 9, under Item 9, on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You also must submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice are not appropriate to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

2. Product Specific Data

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the product specific Requirements Status and Registrant's Response Form(Insert B). Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that

submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

   a. Inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form(Insert A) and a Requirements Status and Registrant’s Response Form(Insert B).

b. Fulfill the commitment to develop and submit the data as required by this Notice; or

c. Otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1) EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2) EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3) EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding generally would not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be 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 also must explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden, the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on a case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due, unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3-year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice must include completed Data Call-In Response Forms (Insert A)and completed Requirements Status and Registrant's Response Forms (Insert B), for both

(generic and product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Generic and Product Specific Data Call-In Response Forms(Insert A) need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

METHOMYL DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing methomyl.

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 methomyl. 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 methomyl are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on methomyl 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 methomyl 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 Bonnie Adler at (703) 308-8523.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Bonnie Adler
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: **Methomyl**

METHOMYL DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing methomyl.

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of methomyl. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), and (4) a list of registrants receiving this DCI (Attachment 5).

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for methomyl are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional product chemistry data on methomyl are needed. These data are needed to fully complete the reregistration of all eligible methomyl products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Tom Myers at (703) 308-8589.

All responsades to this Notice for the generic data requirements should be submitted to:

Tom Myers, Chemical Review Manager
Reregistration Branch II
Special Review and Registration Division (7508C)
Office of Pesticiafde Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: Methomyl

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Instructions For Completing The "Data Call-In Response Forms" For The Generic And Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" (Insert A) and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Data Call-In Response Forms."(Insert A) Only registrants responsible for generic data have been sent the generic data response form. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

Although the form is the same for both generic and product specific data, instructions for completing these forms are different. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 4 have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2137, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
INSERT A
Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS**: This item identifies your company name, number and address.

Item 2. **ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. **ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

Item 4. **ON BOTH FORMS:** This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. **ON BOTH FORMS:** Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms (Insert B)

Item 6a. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
INSERT A
Generic and Product Specific Data Call-In

Item 6b. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the Requirements Status and Registrant's Response Form(Insert B) that indicates how you will satisfy those requirements.

NOTE: **Item 6a and 6b are not applicable for Product Specific Data.**

Item 7a. **ON THE PRODUCT SPECIFIC DATA FORM:** For each manufacturing use product (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

Item 7b. For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do not complete the Requirements Status and Registrant's Response form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver.

NOTE: **Item 7a and 7b are not applicable for Generic Data.**

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
INSERT A CONTINUED
Generic and Product Specific Data Call-In

Item 8. **ON BOTH FORMS:** This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialed and dated in the space provided for the certification.

Item 9. **ON BOTH FORMS:** Enter the date of signature.

Item 10. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 11. **ON BOTH FORMS:** Enter the phone number of your company contact.

Note: You may provide additional information that does not fit on this form in a signed letter that accompanies your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

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Instructions For Completing The "Requirements Status and Registrant's Response Forms" (Insert B) For The Generic and Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Requirements Status and Registrant's Response Forms." Only registrants responsible for generic data have been sent the generic data response forms. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms to include certain information unique to this chemical. DO NOT use these forms for any other active ingredient.

Items 1 through 8 have been preprinted on the form. Item 9 must be completed by the registrant as appropriate. Items 10 through 13 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2137, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS" (Insert B)

Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.

Item 2. **ON THE GENERIC DATA FORM:** This item identifies the case number, case name, EPA chemical number and chemical name.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the case number, case name, and the EPA Registration Number of the product for which the Agency is requesting product specific data.

Item 3. **ON THE GENERIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the type of Data Call-In. The date of issuance is also date stamped. Note the unique identifier number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.

Item 5. **ON BOTH FORMS:** This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form(Insert B).

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS" (Insert B) continued

Generic and Product Specific Data Call-In

Item 6. **ON BOTH FORMS:** This item identifies the code associated with the use pattern of the pesticide. In the case of efficacy data (product specific requirement), the required study only pertains to products which have the use sites and/or pests indicated. A brief description of each code follows:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food crop
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

Item 7. **ON BOTH FORMS:** This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

EUP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Indredient or Pute Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP ___%	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites

TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*	See: guideline comment

Item 8. This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5.

ON THE GENERIC DATA FORM: The time frame runs from the date of your receipt of the Data Call-In notice.

ON THE PRODUCT SPECIFIC DATA FORM: The due date for submission of product specific studies begins from the date stamped on the letter transmitting the Reregistration Eligibility Decision document, and not from the date of receipt. However, your response to the Data Call-In itself is due 90 days from the date of receipt.

Item 9. **ON BOTH FORMS:** Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

Option 1. **ON BOTH FORMS:** (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocols and progress reports required in item 5 above.

Option 2. **ON BOTH FORMS:** (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

However, for Product Specific Data, I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency indicates in an attachment to this notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

Option 3. **ON BOTH FORMS:** (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice apply as well.

However, for Product Specific Data, I understand that this option is available only for acute toxicity or certain efficacy data and only if the Agency indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option.

Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

Option 5. **ON BOTH FORMS:** (Upgrading a Study) I will submit by the specified due date, or will cite data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

Option 6. **ON BOTH FORMS:** (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum,

or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.

However, for Product Specific Data, I am citing another registrant's study. I understand that this option is available **ONLY** for acute toxicity or certain efficacy data and **ONLY** if the cited study was conducted on my product, an identical product or a product which the Agency has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

FOR THE GENERIC DATA FORM ONLY: The following three options (Numbers 7, 8, and 9) are responses that apply only to the "Requirements Status and Registrant's Response Form" (Insert B) for generic data.

Option 7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

Option 8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Option 9. (Request for Waiver of Data) I have read the statements concerning data waivers other than lowvolume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

FOR PRODUCT SPECIFIC DATA: The following option (number 7) is a response that applies to the "Requirements Status and Registrant's Response Form" (Insert B) for product specific data.

Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must

be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days-of my receipt of the Agency's written decision, submit a revised "Requirements Status" form specifying the option chosen. I also understand that the deadline for submission of data as specified by the original Data Call-In notice will not change.

Item 10. **ON BOTH FORMS:** This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. **ON BOTH FORMS:** Enter the date of signature.

Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that the Agency can ensure that its records are correct.

EPA'S BATCHING OF PRODUCTS CONTAINING METHOMYL AS THE ACTIVE INGREDIENT 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 the active ingredient S-Methyl N-((methylcarbamoyl) oxy) thioacetimidate, the Agency has batched products which can be considered similar in terms of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), product form (liquid, paste, solid, etc.), and labeling (e.g., signal word, precautionary labeling, etc.).

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. Registrants have the option of participating with all or some other registrants of products in their product's batch, to deal 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 or 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 or she may do so provided that the data base is complete and valid by today's standards (see the attached acceptance criteria), 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. Registrants may not support their product using data conducted on a product from a different batch. EPA must approve any new or canceled formulations (that were presented to the Agency after the publication of the RED) before data derived from them can be used to cover other products in a batch. 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 or 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 or 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 or 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 or her studies and offering to cost share (Option 3) those studies.

Table 1 displays the batches for the active ingredient methomyl.

Table 1.

Batch	Registration Number	Percent Active Ingredient	Form
1	352-342	methomyl ... 90%	solid
	352-361	methomyl ... 90%	solid
	352-366	methomyl ... 98.7%	solid
	CA77030800	methomyl ... 90%	solid
	CA77049500	methomyl ... 90%	solid
	CA78013600	methomyl ... 90%	solid
	CA81000700	methomyl ... 90%	solid
	CA81000701	methomyl ... 90%	solid
	CA81000702	methomyl ... 90%	solid
	CA85005200	methomyl ... 90%	solid
	CA86005900	methomyl ... 90%	solid
	CA88001400	methomyl ... 90%	solid
	CA90003400	methomyl ... 90%	solid
	CA91001000	methomyl ... 90%	solid
	CA91001100	methomyl ... 90%	solid
	DE80000900	methomyl ... 90%	solid
	FL78003700	methomyl ... 90%	solid

Batch	Registration Number	Percent Active Ingredient	Form
	FL78005500	methomyl ... 90%	solid
	FL82001400	methomyl ... 90%	solid
	LA95001600	methomyl ... 90%	solid
	NJ94000900	methomyl ... 90%	solid
	OR78000400	methomyl ... 90%	solid
	PA93000200	methomyl ... 90%	solid
	TX93002200	methomyl ... 90%	solid
	WV93000300	methomyl ... 90%	solid
2	352-384	methomyl ... 29%	liquid
	FL88000400	methomyl ... 29%	liquid
	IL83001900	methomyl ... 29%	liquid
	LA95001700	methomyl ... 29%	liquid
	TX92001100	methomyl ... 29%	liquid
3	270-255	methomyl ... 1.000%	solid
	1203-69	methomyl ... 1.225%	solid
	2724-274	methomyl ... 1.000%	solid
	7319-6	methomyl ... 1.000%	solid
	53871-3	methomyl ... 1.000%	solid
	67517-25	methomyl 1.000%	solid

Batch	Registration Number	Percent Active Ingredient	Form
4	34704-301	methomyl ... 2.000%	solid
	45735-15	methomyl ... 2.00%	solid
5	9779-331	methomyl ... 5%	solid
	57242-2	methomyl ... 5%	solid

Table 2 lists the products in the "No Batch" group. These products can not be batched because they were not considered to be similar to other the products in terms of acute toxicity. The registrant of this product is responsible for meeting the acute toxicity data requirements for it individually. These products may not cite acute toxicity/ irritation data derived from any other products in this RED. The registrant may cite pre-existing data conducted on their individual product (or data cited in this RED for the technical product) if it exists and it meets current Agency standards.

Table 2.

Registration Number	Percent Active Ingredient	Product Type
352-270	methomyl ... 24%	liquid
5481-2802	methomyl ... 2%	solid
*5905-487	methomyl ... 2%	solid
10163-218	methomyl ... 1.5%	solid

*Reg. no. 5905-487 was placed into the "No Batch" group because of a lack of information concerning the inert ingredient portion of this product. EPA encourages the registrant to submit information on the inerts of this product to determine if this product can be placed into a batch with other products.

This page has been inserted as a place marker and is replaced by an electronically generated PDCI List of Registrants page number 1 in the actual Printed version of the Red document

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:

Forms Required for Responding to the RED:		
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.
Other Pesticide Registration Forms:		
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 Methomyl 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 Tom Myers at (703) 308-8589.

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 Methomyl.

The following documents are part of the Administrative Record for Methomyl 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.