United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508C)

EPA 738-R-05-XXX
August 2005

Reregistration Eligibility Decision (RED) for

Maneb

Reregistration Eligibility Decision

for

Maneb

List B
Case No. 0644

Approved By:

_____
Debra Edwards, Ph.D.
Director, Special Review and
Reregistration Division

_____
Date

TABLE OF CONTENTS

MANEB REREGISTRATION ELIGIBILITY DECISION TEAM i

GLOSSARY OF TERM AND ABBREVIATIONS ii

EXECUTIVE SUMMARY iv

I. INTRODUCTION 1

II. CHEMICAL OVERVIEW 2
A. Regulatory History 2
B. Chemical Identification 3
1. Maneb 3
2. Ethylene thiourea (ETU) 4
C. Use Profile 4
D. Estimated Usage of Maneb 7

III. SUMMARY OF METIRAM RISK ASSESSMENTS 9
A. Human Health Risk Assessment 9
1. Toxicity Assessment of Maneb 10
a. Acute Toxicity Profile for Maneb 10
b. FQPA Safety Factor Considerations for Maneb 11
c. Toxicological Endpoints for Maneb 12
2. Toxicity Assessment of ETU 14
a. Acute Toxicity Profile for ETU 14
b. FQPA Safety Factor Considerations for ETU 15
c. Toxicological Endpoints for ETU 16
3. Metiram and ETU Carcinogenicity 17
4. Metiram and ETU Endocrine Effects 18
5. Dietary Risk from Food 18
a. Exposure Assumptions 18
b. Population Adjusted Dose 19
1) Acute Dietary Risk from Food 19
2) Chronic Dietary Risk from Food 20
3) Cancer Dietary Risk from Food 21
6. Dietary Exposure from Drinking Water 22
a. Surface Water 22
b. Ground Water 23
7. Residential Exposure and Risk 23
8. Aggregate Risks from Food, Drinking Water and Residential Uses 25
a. Acute Aggregate 26
b. Short-Term Aggregate 27
c. Chronic (Non-Cancer) Aggregate 28
d. Cancer Aggregate 28

9. Occupational Risks 28
a. Occupational Handler Exposure 29
1) Agricultural and Greenhouse Handler Risks 30
2) Handler Risk for Potato Seed-Piece Treatment 35
b. Post-Application Assessments 39
c. Human Incident Data 43
B. Environmental Risk Assessment 43
1. Environmental Fate and Transport 44
2. Ecological Risk Presumptions 44
3. Risk to Terrestrial Species 46
a. Birds and Mammals Exposure and Toxicity 46
b. Birds and Mammals Risk 47
c. Non-Target Plant Risk 48
d. Non-Target Insect Risk 49
4. Risk to Aquatic Species 49
a. Fish and Invertebrate Exposure and Toxicity 49
b. Fish and Invertebrate Risk 51
c. Non-Target Aquatic Plant Risk 52
5. Risk to Federally Listed Endangered and Threatened Species 55
6. Ecological Incidents 53

IV. RISK MANAGEMENT, REREGISTRATION AND TOLERANCE REASSESSMENT 54
A. Determination of Reregistration Eligibility 54
B. Public Comments and Responses 55
C. Regulatory Position 55
1. Food Quality Protection Act Findings 55
a. "Risk Cup" Determination 55
b. Determination of Safety for U.S. Population (including Infants and Children) 55
c. Endocrine Disruptor Effects 56
d. Cumulative Risks 56
2. Tolerances Reassessment Summary 57
a. Tolerances Currently Listed Under 40 CFR § 180.110 57
b. Tolerances Listed Under 40 CFR § 180.110 (a) 57
c. Tolerances To Be Proposed Under 40 CFR § 180.110 (a) 58
d. Tolerance Listed Under 40 CFR § 180.110 (b) 58
e. Codex Harmonization 61
D. Regulatory Rationale 61
1. Human Health Risk Management 62
a. Dietary (Food) Risk Mitigation 62
b. Dietary (Drinking Water) Risk Mitigation 62
c. Residential Risk Mitigation 62
d. Aggregate Risk Mitigation 62
e. Occupational Risk Mitigation 63
1) Agricultural and Greenhouse Handler Risk Mitigation . . . 63
2) Potato Seed-Piece Treatment Mitigation 66

3 Post-Application Risk Mitigation 67
2. Environmental Risk Mitigation 67
a. Terrestrial Species Mitigation 67
b. Aquatic Species Mitigation 68
3. Significance of the EBDCs 68
4. Summary of Risk Mitigation Measures 70
E. Other Labeling Requirements 70
1. Endangered Species Considerations 70
2. Spray Drift Management 71

V. WHAT REGISTRANTS NEED TO DO 71
A. Manufacturing Use Products 72
B. End-Use Products 73
C. Labeling Changes Summary Table 74

VI. Appendices 85

MANEB REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment
Richard Michell, Plant Pathologist
Bill Phillips, Agronomist
Arnet (Skee) Jones, Branch Chief
David Donaldson, Economist
Tim Keily, Economist
David Widawsky, Branch Chief

Environmental Fate and Effects Risk Assessment
Ronald Parker, RAPL
Gabe Patrick, Eco Tox Risk Assessor
Mohammed Ruhman, Eco Fate
Jean Holmes, Team Leader
Mah Shamim, Branch Chief

Endangered Species
Arty Williams, Acting Associate Director

Health Effects Risk Assessment
Tim Dole, ORE Assessor
Christine Olinger, Residue Chemist
Felicia Fort, Residue Chemist
Kit Farwell, Toxicologist
Linda Taylor, Toxicologist
Michael Metzger, Branch Chief

Registration Support
Lisa Jones, Senior Reviewer
Mary Waller, PM, Team 21
Cynthia Giles-Parker, Branch Chief

Risk Management
Tawanda Spears, Maneb CRM
Kimberly Nesci, Team Leader
Michael Goodis, Branch Chief

Office of General Counsel
Kevin Minoli
Michele Knorr

GLOSSARY OF TERMS AND ABBREVIATIONS

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CCA	Comparative Cholinesterase Assay
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EC	Engineering Control
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
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.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment

NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1^*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24©) of FIFRA)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UF_{db}	Database Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

EPA has completed its review of public comments on the revised maneb risk assessments and is issuing its risk management decision for maneb. There are currently 40 tolerances being reassessed for maneb. The revised risk assessments are based on the Agency's review of the required data supporting the use patterns of currently registered maneb products and additional information and comments received. After considering the risks identified in the revised risk assessment, public comments, and mitigation suggestions from interested parties, EPA developed its risk management decision for uses of maneb that pose risks of concern. As a result, the Agency has determined that maneb-containing products are eligible for reregistration provided that data needs are addressed, risk mitigation measures are adopted, and labels are amended accordingly. The decision is discussed fully in this document.

Maneb was first registered in the United States in 1962 as a broad spectrum fungicide. Maneb is used on a wide variety of food/feed crops, including fruit and nut crops, vegetable crops, field and forage crops, grapes, field crop seeds, and others; ornamental plants in nurseries and greenhouses; and sod farms. There are no residential labels, and no agricultural uses that could result in exposure to maneb in residential settings; however, because transplanted turf from sod farms can result in potential residential exposure, a post-application scenario from this use was assessed. Approximately 2.5 million pounds of maneb are used annually, mostly on almonds, lettuce, peppers, and walnuts.

Maneb is a member of the ethylene bisdithiocarbamate (EBDC) group of fungicides, which includes the related active ingredients mancozeb and metiram. This document summarizes risk estimates for both maneb and its metabolite and environmental degradate ethylene thiourea (ETU). Maneb and two other EBDC fungicides, mancozeb and metiram, are all metabolized to ETU in the body and all degrade to ETU in the environment. Therefore, EPA has considered the aggregate or combined risks from food, water and non-occupational exposure resulting from maneb alone, ETU resulting from maneb use, and ETU from all sources (i.e., the other EBDC fungicides: mancozeb and metiram). The aggregate risk from ETU from all sources must be considered to reassess the tolerances for maneb, metiram and mancozeb.

Overall Risk Summary

Maneb dietary risks from food and drinking water sources are low and not of concern. Although there are no registered residential uses of maneb, assessed toddler exposure to transplanted turf is of concern. There are risk concerns for some occupational handlers, which will be mitigated with additional personal protective equipment (PPE) and use restictions. In addition, some application restrictions are to be added to product labels in order to maintain a 24 hour restricted entry interval (REI). For ecological risks, maneb poses some chronic risk to birds and mammals, and acute risk to aquatic species.

Dietary Risk

Acute, chronic, and cancer dietary (food only) risk from maneb, maneb-derived ETU, and ETU from all sources are low and below the Agency's level of concern. The drinking water exposure assessment for maneb addresses concentrations of ETU only, since maneb is not expected to remain in drinking water long enough to reach a location that would supply water for human consumption, whether from surface or groundwater sources. Estimated concentrations of ETU, for both surface and ground water sources of drinking water, are low and not of concern.

Residential Risk

There are no current labeled uses for residential applications of maneb. The only potential residential exposure to maneb is from residues remaining on transplanted turf from sod farms.

EPA's original analysis indicated risks above levels of concern for toddler exposure to transplanted turf for maneb. Recognizing that potential risk, the maneb registrants voluntarily agreed to reduce the maximum application rate and/or extend the time between treatment and harvesting of sod from one to three days (i.e., a 3 day PHI for transplanted turf). The reduced application rate and/or extended PHI, combined with the logistics of transplanting turf and installation restrictions, effectively reduced the potential contribution from this use pattern to a level not of concern to the Agency.

Aggregate Risk/ETU

Aggregate risk refers to the combined risk from food, drinking water, and residential exposures (as a result of residential exposures to ETU from mancozeb and maneb uses). In addition, aggregate risk can result from one-time (acute), short-term and/or chronic (non-cancer and cancer) exposures, and considers exposures from maneb-derived ETU and ETU from all sources, depending upon the scenario assessed. Acute, short-term, and chronic (non-cancer) aggregate risks are low and not of concern. Aggregate cancer risk estimates are within a negligible risk range, and therefore no mitigation measures are needed.

Occupational Risk

Workers can be exposed to maneb and maneb-derived ETU through mixing, loading, and/or applying (handlers) the pesticide to agricultural crops and ornamental plants, or re-entering treated sites. To address predicted risks from these exposures, the registrant has agreed to voluntarily cancel maneb use on sweet corn, grapes, apples, and Kadota figs; reduce the application rate on turf; and restrict against the use of wettable powder formulation products for aerial and chemigation application methods. Moreover, additional personal protective equipment (PPE), such as a PF5 (dust/mist) respirator are required for some mixer/loader and/or applicator scenarios, whereas for other scenarios only single layer clothing is required. Engineering controls are also required for commercial potato seed-piece treatment (dust collection equipment) and aerial applications (enclosed cockpits).

At the current restricted entry interval (REI) of 24 hours and use patterns on current labels, predicted maneb and ETU exposures exceed standard levels of concern for post-application high-end exposure scenarios for turf, sweet corn, grapes, Kadota figs, and apples. To address these risks, the Agency is requiring that the application rate to turf be reduced. In addition, maneb use on sweet corn, grapes, Kadota figs, and apples have since been cancelled. The Agency plans to maintain the current 24 hour REI for the remaining uses.

Ecological Risk

For terrestrial species, maneb acute risks are low to mammals, birds, and non-target insects. However, the screening-level ecological risk assessment for terrestrial species indicates some risk quotient (RQ) exceedance of the chronic levels of concern (LOCs), especially from maneb applications to turf, almonds, and apples. In the aquatic environment, there is a potential acute risk to freshwater/estuarine/marine fish and invertebrates. Currently, there are no data available to assess chronic risks to freshwater invertebrates, estuarine/marine fish, or estuarine/marine invertebrates. The Agency is requiring additional toxicity data as part of this RED to address these data gaps. Therefore, to be more protective of these species that may be exposed to maneb, the technical registrant has agreed to cancel some uses and to make some additional label changes to reduce potential risk, such as reducing the maximum application rate for some uses.

Endangered Species

Based on available screening level information, there is a potential concern for maneb's acute effects on listed freshwater and estuarine/marine animals and chronic effects on listed birds and mammals should exposure actually occur. The Agency expects that maneb poses a low acute risk to nontarget insects because maneb is practically nontoxic to honeybees (acute contact LD50 > 12 μg/bee). However, the Agency does not assess risk to bees using RQs because a screening-level RQ assessment method for estimating the risk to bees is not available. The Agency does not currently have enough data to quantify risks for maneb at the screening-level and cannot preclude potential direct effects to the following taxinomic groups: listed nontarget terrestrial plants and vascular aquatic plants, freshwater invertebrates, and estuarine/marine fish. These findings are based solely on EPA's screening-level assessment and do not constitute "may affect" findings under the Endangered Species Act (ESA) for any listed species. If the Agency determines use of metiram "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402).

Mitigation Summary

To address assessed risks of concern, the following mitigation measures will be implemented:

Maneb-All Formulations

- Sweet Corn - Cancel Use
- Grapes - Cancel Use
- Apples - Cancel Use

- Kadota Figs - Cancel Use
- Seed Treatment to Rice and Peanuts - Cancel Use
- Oats Seed Treatment - Reduce maximum application rate from 0.0031lb ai/lb seed to 0.0021 lb ai/lb seed
- Almonds- Reduce maximum seasonal rate from 25.6 to 19.2 lbs ai/acre/season and retain maximum application rate of 6.4 lbs ai/acre.
- Sod Farm Turf - Reduce maximum application rate from 17.4 lbs ai/acre to 8.7 lbs ai/acre, limit maximum seasonal rate to 34.8 lbs ai/acre/season and add a 3 day pre-harvest interval. Handlers mixing/loading of dry flowables and liquids for aerial or chemigation application, add a PF5 Respirator.
- Cut Flowers - Limit number of applications per year to 20
- Commercial Potato Seed-Piece Treatment (dust) - require engineering controls (e.g. dust collector equipment)

Maneb- Wettable Powder Formulation Only

- Sod Farm Turf - Cancel Use
- Chemigation/Aerial Applications - Delete Application Method
- For mixing/loading all remaining uses add PF 5 Respirator.

Regulatory Decision

The Agency has determined that most uses of the active ingredient maneb are eligible for reregistration provided that (1) current data gaps and confirmatory data needs identified herein are addressed and (2) the risk mitigation measures outlined in this document are adopted, and labels are amended to reflect these measures. The following uses of maneb are not eligible for reregistration and are being voluntarily canceled by registrants and deleted from all maneb labels: sweet corn, grapes, apples, and kadota figs.

Next Steps

The Agency provided several opportunities for public comment and interaction as this decision was being developed. Therefore, the Agency is issuing this RED document for maneb without a formal public comment period, as announced in a Notice of Availability published in the ***Federal Register***. However, the docket remains open, and any comments submitted in the future will be placed in this public docket and addressed by the Agency, as appropriate.

EPA will issue a generic DCI for additional data necessary to confirm the conclusions of this RED for the active ingredient maneb. EPA will also issue a product-specific DCI for data necessary to complete product reregistration for products containing maneb.

I. INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks 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 or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA) to require reassessment of all existing tolerances for pesticides in food. FQPA also requires EPA to review all tolerances in effect on August 3, 1996 by August 3, 2006. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. When a safety finding has been made that aggregate risks are not of concern and the Agency concludes that there is a reasonable certainty of no harm from aggregate exposure, the tolerances are considered reassessed. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment will be accomplished through the reregistration process.

As mentioned above, FQPA requires EPA to consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity" when considering whether to establish, modify, or revoke a tolerance. Potential cumulative effects of chemicals with a common mechanism of toxicity are considered because low-level exposures to multiple chemicals causing a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any one of these individual chemicals. Maneb belongs to a group of pesticides called dithiocarbamates, which also includes two other ethylene bis-dithiocarbamate (EBDC) fungicides metiram and mancozeb. For the purposes of this reregistration eligibility decision (RED), EPA has concluded that maneb does not share a common mechanism of toxicity with other substances. The Agency reached this conclusion after a thorough internal review and external peer review of the data on a potential common mechanism of toxicity. For more information, please see the December 19, 2001 memorandum, *"The Determination of Whether Dithiocarbamate Pesticides Share a Common Mechanism of Toxicity,"* which is available on the internet at http://www.epa.gov/oppsrrd1/cumulative/dithiocarb.pdf. However, the EBDCs share a common metabolite and degradate, ethylene thiourea (ETU), which is considered in this RED.

This document presents EPA's revised human health and ecological risk assessments, its progress toward tolerance reassessment, and the reregistration eligibility decision for maneb. The document consists of six sections. Section I contains the regulatory framework for

reregistration/tolerance reassessment. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and environmental effects risk assessments based on data, public comments, and other information received in response to the preliminary risk assessments. Section IV presents the Agency's reregistration eligibility and risk management decisions. Section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV. Section VI contains the Appendices, which list related information, supporting documents, and studies evaluated for the reregistration decision. The preliminary and revised risk assessments for maneb are available in the Office of Pesticide Programs (OPP) Public Docket, under docket numbers OPP-2004-0078 and OPP-2005-0178, respectively, on the Agency's web page, http://www.epa.gov/edockets.

II. CHEMICAL OVERVIEW

A. Regulatory History

Maneb was first registered in the United States in1962 for use on food and ornamental crops to prevent crop damage in the field and to protect harvested crops from deterioration in storage or transport. Maneb is a member of the ethylene bisdithiocarbamate (EBDC) group of fungicides, which includes the related active ingredients mancozeb and metiram. Moreover, it has been determined that the EBDCs share the common degradate ethylenethiourea (ETU). The EBDCs have been the subject of two Special Reviews. In 1977, the Agency initiated a Special Review for products containing EBDCs based on evidence suggesting that the EBDCs and ETU, a contaminant, metabolite and degradation product of these pesticides, posed potential risks to human health and the environment. In 1982, the Agency concluded this Special Review by issuing a Final Determination (PD 4) which required risk reduction measures to prevent unreasonable adverse effects pending development and submission of additional data needed for improved risk assessment.

In 1987, EPA issued a second Notice of Initiation of Special Review of the EBDC pesticides because of health concerns caused by ETU, including potential carcinogenic, developmental and thyroid effects. The Special Review's Preliminary Determination (PD 2/3) was published on 12/20/89 (54 FR 52158) and the Final Determination (PD 4) on 3/2/92 (57 FR 7484). The Agency concluded that the dietary risks of EBDCs exceeded the benefits for the following food/feed uses for which one or more of the EBDC pesticides were registered: apricots, carrots, celery, collards, mustard greens, nectarines, peaches, rhubarb, spinach, succulent beans, and turnips. Accordingly, EPA canceled all maneb and other EBDC products registered on the above-listed food/feed crops.

The Maneb Registration Standard dated 8/22/86 required additional product chemistry data concerning maneb. Addendum No. 1 to the Maneb Reregistration Standard dated 3/31/87 included the review of data not available at the time of the original registration standard and required additional product chemistry data. A comprehensive Data-Call-In (DCI) was issued 4/1/87 to all registrants of maneb concerning product chemistry data requirements. The Product Chemistry Chapter of the Maneb Registration Standard Update dated 5/13/88 included a review of data submitted in response to the 4/1/87 DCI with regard to adequacy in fulfilling product chemistry requirements. A Guidance Document for maneb was issued 10/88. Product chemistry data submitted in response to the

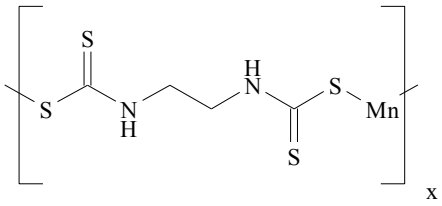
Guidance Document were reviewed in the Maneb Registration Standard Update dated 8/11/92, and additional data were required for the registration of maneb.

The 1992 Special Review decision initially set the pre-harvest interval (PHI) for use on potatoes at fourteen (14) days for most states. The only exceptions to the 14 day PHI were Connecticut, Florida, Maine, Massachusetts, New Hampshire, New York, Pennsylvania, Vermont, and Wisconsin, where EPA determined that disease pressures caused by late blight justified a 3 day PHI. Subsequently, presented with evidence of late blight in additional states, EPA extended the 3 day PHI to Delaware, Michigan, Rhode Island and Ohio. Recently, EPA received requests for amendments to several EBDC product registrations and a petition to amend the 1992 cancellation order to allow for a three day PHI in all states, due to an alleged increase in the occurrence of late blight nationwide. EPA has not determined whether the petition warrants a hearing under 40 C.F.R. § 164 nor has it determined whether it will grant the attendant registration amendment requests. Although EPA has not reached any conclusions on the merits of the petition or the amendment requests, potential risks that would result from a nationwide reduction in the PHI for potatoes to 3 days have been considered in this RED. That consideration is for informational purposes only and cannot be interpreted as an indication of the Agency's position on the petition or amendment requests.

B. Chemical Identification

1. Maneb

Chemical Structure:



Common Name: Maneb

Chemical Name: Manganese ethylene- 1,2-bisdithiocarbamate

Trade Name: Manex, Dithane-22

Chemical Family: Dithiocarbamate

Case Number: 0642

CAS Registry Number: 12427-38-2

OPP Chemical Code: 014505

Moleculer weight: $(265.3)_x$

Empirical Formula: $(C_4H_6MnN_2S_4)_x$

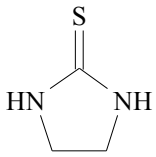
Basic Manufacturers: Cerexagri, Inc.

Technical maneb is a yellow powder which decomposes at 135 °C, and has a density of 0.4-0.5 kg/L; it has a negligible vapor pressure of $<10^{-7}$ mbar at 20 °C. Maneb is moderately soluble in water (0.417 g/L at 22-24 °C), and is practically insoluble in organic solvents (<0.0010g/L in toluene, 0.0033 g/L in hexane, 0.0137 g/L in dichloromethane, and 0.133 g/L in methanol at 22-24 °C). Maneb decomposes with heat and under acidic conditions.

2. Ethylene thiourea (ETU)

Ethylene thiourea (ETU) is a metabolite, environmental degradate, and cooking byproduct of maneb and the other EBDC fungicides, metiram and mancozeb. Chemical information is provided for ETU because many of the risk concerns for maneb and the other EBDCs are driven by risk from ETU.

Chemical Structure:



Chemical Name: Ethylene thiourea

CAS Registry Number: 96-45-7

OPP Chemical Code: 600016

Molecular Weight: 102.2

Empirical Formula: $C_3H_6N_2S$

Technical ethylene thiourea (ETU) is a crystalline solid with a white to pale green color, and a faint amine odor. It has a melting point of 203-204°C. ETU has an octanol/water partition coefficient of 0.22. ETU is considered soluble in water, with a water solubility of 20,000 ppm at 30°C, but it is also slightly soluble in methanol, ethanol, ethylene glycol, pyridine, acetic acid and naphtha. When ETU is heated to decomposition, nitrogen and sulfur oxides are emitted.

C. Use Profile

The following is information on the currently registered uses including an overview of use

sites and application methods. A detailed table of the uses of maneb eligible for reregistration is contained in Appendix A.

Type of Pesticide: Fungicide

Target pest(s): Typical diseases targeted include various downy mildews, late blights, leaf spots, root rots, twig and blossom blights, seedling diseases, fruit molds/rots, root rots, and leaf/stem blights.

Mode of action: Contact (non-systemic)

Use Sites:

- Food/Feed Uses: Maneb is registered for foliar applications to food/feed crops including almond, apple, banana, bean (dry), broccoli, Brussels sprout, cabbage (including Chinese cabbage), cauliflower, collard, corn (sweet and pop), cranberry, cucumber, eggplant, endive, fig, garlic, grape, kale, kohlrabi, lettuce (head and leaf), melon (cantaloupe, casaba, crenshaw, honeydew, and watermelon), mustard greens, onion (dry bulb and green), papaya, pepper, potato, pumpkin, squash (summer and winter), sugar beet, tomato, and turnip grown for greens. Maneb is additionally registered for seed treatment of barley, corn (field), cotton, flaxseed, oat, potato, rice, rye, safflower, sorghum, and wheat.

- Non-Food & Residential Uses: Horticultural use is permitted on ornamental plants in nurseries and greenhouses and on sod farms. There are no residential labels, and no agricultural uses that could result in exposure to maneb in residential settings. The registrant has agreed to modify labels for turf use to specify, "*For Use on Sod Farms Only*." However, because transplanted turf from sod farms can result in potential residential exposure, a residential post-application scenario is included in the risk assessment.

- Public Health Uses: None.

Use Classification: General Use

Formulation Types: Maneb formulations include dust, emulsifiable concentrate (EC), liquid and dry flowable (water soluble granules) (DF), flowable concentrate (FC), and ready-to-use (RTU) solution.

Application Methods: Application methods include aerial, airblast, groundboom, chemigation, and hand application using low-pressure handwand and backpack sprayers. The application methods for seed and seed-piece treatment include commercial stationary equipment, on-farm stationary equipment, and tractor-drawn planter boxes.

Application Rates: There are currently 30 active maneb labels and 1 FIFRA Section 24(c) Special Local Need (SLN) registration. The application rates in agriculture range from 1.2 pounds of active ingredient per acre (lbs ai/A) for corn to 6.4 lbs ai/A for almonds. Multiple applications are permitted per season, ranging from 3 for cranberries to 15 for sweet corn, with application intervals of 7 to 14

days. Some uses (e.g., grapes) have separate rates for eastern and western regions. The application rates in horticulture are 1.2 lb ai/A for most ornamentals up to 17.4 lb ai/A for turf. Horticulture and turf applications are allowed as much as once weekly with no annual limit.

Application Timing: Maneb is applied at foliar, pre-bloom, and pre-bloom through foliar stages and also as a seed-piece treatment.

EBDCs Maximum Application Rates: As a result of Special Review, the Agency set usage limitations on the EBDC fungicides (mancozeb, maneb, and metiram) to establish consistency between the EBDCs registrations and Market Basket Survey data. The total poundage of all of the EBDC fungicides (mancozeb, maneb, and metiram) used on each crop must not exceed the maximum seasonal application rate for any one of these fungicides. The maximum season rate for all of the EBDCs used is the same for most of the crops regardless of which EBDC is used, with the exception of cucurbits (cucumbers, melons, and summer and winter squash), for which the maximum rate per season depends upon which EBDC is used. The current maximum seasonal application rates for the EBDCs, by crop, are summarized in Table 1.

Table 1. Maximum Label Application Rates for the EBDC Fungicides

Crop Group	Crop(s)	EBDC Used MZ = Mancozeb MN = Maneb MT = Metiram	Maximum Label Application Rates (lb ai/acre)	
			Per Application	Total EBDC Per Season
Field Crops	Barley, Oats, Rye, Triticale, Wheat	MZ	1.6	4.8
Field Crops	Beans, Dry	MN	1.6	9.6
Field Crops	Corn: hybrid seedcorn	MZ, MN	1.2	12
Field Crops	Corn: field	MZ	1.2	12
Field Crops	Cotton	MZ	1.6	6.4
Field Crops	Peanuts	MZ	1.6	12.8
Field Crops	Sugar Beets	MZ, MN	1.6	11.2
Fruits	Bananas	MZ, MN	2.4	24
Fruits	Cranberries	MZ, MN	4.8	14.4
Fruits	Figs, Kodota	MN	2.4	2.4
Fruits	Grapes - West	MZ, MN	2	6
Fruits	Grapes- East	MZ, MN	3.2	19.2
Fruits	Papayas	MZ, MN	2	28
Fruits	Plantains	MZ	2.4	24
Miscellaneous	Christmas Trees, Douglas Fir	MZ	3.2	NA
Non-Food	Tobacco fields	MZ	1.5	6
Non-Food	Tobacco seedlings	MZ	2	No Max
Nut Crops	Almonds	MN	6.4	25.6
Ornamentals	Ornamentals, Pachysandra	MZ	13 -14	NA
Ornamentals	Ornamentals, Variety	MZ, MN	1.2 - 1.6	NA
Pome Fruits	Apples	MZ, MN, MT	2.4 or 4.8	16.8 or 19.2

Table 1. Maximum Label Application Rates for the EBDC Fungicides				
Crop Group	**Crop(s)**	**EBDC Used MZ = Mancozeb MN = Maneb MT = Metiram**	**Maximum Label Application Rates (lb ai/acre)**	
			Per Application	**Total EBDC Per Season**
Pome Fruits	Pears, Crabapples, Quince	MZ	2.4 or 4.8	16.8 or 19.2
Turf	Sod Farm	MZ, MN	16.3 - 19	NA
Turf	Golf Course, Athletic Fields	MZ	16.3 - 19	NA
Vegetables	Asparagus	MZ	1.6	6.4
Vegetables	Brassica	MN	1.6	9.6
Vegetables	Corn: sweet/pop/seed: East of Miss.	MZ, MN	1.2	18
Vegetables	Corn: sweet/ pop/seed: West of Miss.	MZ, MN	1.2	6
Vegetables	**Cucumbers**	**MZ, MN**	**MZ = 2.4 MN = 1.6**	**MZ = 19.2 MN = 12.8**
Vegetables	Fennel	MZ	1.6	12.8
Vegetables	Gourds: Edible	MZ	2.4	19.2
Vegetables	Lettuce	MN	1.6	6.4 (CA), 9.6 (US)
Vegetables	**Melons**	**MZ, MN**	**MZ = 2.4 MN = 1.6**	**MZ = 19.2 MN = 12.8**
Vegetables	Onions: Dry Bulb, Garlic	MZ, MN	2.4	24
Vegetables	Onions: Green	MN	2.4	11.2
Vegetables	Peppers	MN	1.6 (w), 2.4 (e)	9.6 (w), 14.4 (e)
Vegetables	Potatoes	MZ, MN, MT	1.6	11.2
Vegetables	Pumpkins	MN	1.6	12.8
Vegetables	Shallots	MZ, MN	2.4	24
Vegetables	**Squash (winter) Squash (summer)**	**MN MZ, MN**	**MZ = 2.4 MN = 1.6**	**MZ = 19.2 MN = 12.8**
Vegetables	Tomatoes	MZ, MN	2.4 (w), 1.6 (e)	6.4 (w), 16.8 (e)
Vegetables	Watermelons	MZ, MN	2.4	19.2

Note - Crops in bold have different rates depending upon which EBDC is used. Also, the not applicable (NA) reference is because the use was not a part of Special Review.
(w) - West
(e) - East

D. Estimated Usage of Maneb

Table 2 below summarizes the best available estimates for the pesticide usage of maneb. Based on Agency data, the average total annual domestic usage of maneb is approximately 2½ million pounds. Agricultural uses are concentrated in (but not limited to) the following states: Florida, Maine, Minnesota, North Dakota, New Jersey, Rhode Island, Texas, and Wisconsin.

Table 2. Maneb Crop Usage Summary			
Crop	**Pounds of Active Ingredient (lbs. a.i.) / Year**	**% Crop Treated**	
		Average	**Maximum**
Almonds	300,000	10	15
Apples	40,000	<1	5
Beans, Dry	10,000	<1	<2.5
Beans, Green	8,000	5	15
Broccoli	20,000	5	15
Brussels Sprouts (*CA)	1,000	25	35
Cabbage	40,000	15	15
Cantaloupes	3,000	<1	<2.5
Carrots	3,000	<1	5
Cauliflower	5,000	5	10
Celery	3,000	5	5
Collards	4,000	10	25
Corn (Field)	<500	<1	5
Cucumber	30,000	5	5
Dry Beans/Peas	20,000	<1	<2.5
Eggplant	7,000	55	65
Garlic	30,000	25	25
Grapes	20,000	<1	5
Greens, Mustard	2,000	5	5
Kale	1,000	5	5
Lettuce	600,000	65	75
Onions	70,000	10	20
Pears	5,000	<1	<2.5
Peppers	200,000	30	45
Potatoes	100,000	5	10
Pumpkins	4,000	5	5
Spinach	10,000	15	45

Table 2. Maneb Crop Usage Summary			
Crop	Pounds of Active Ingredient (lbs. a.i.) / Year	% Crop Treated	
		Average	Maximum
Squash	10,000	5	15
Sugar Beets	40,000	<1	5
Sweet Corn	10,000	<1	<2.5
Tomatoes	100,000	5	10
Walnuts	300,000	30	35
Watermelons	20,000	5	10

III. SUMMARY OF MANEB RISK ASSESSMENTS

The following is a summary of EPA's human health and ecological effects risk findings and conclusions for the non-systemic fungicide maneb, as presented fully in the documents: *Maneb. Revised Health Effects Division (HED) Human Health Risk Assessment to Support Reregistration,* dated June 8, 2005; *ETU from EBDCs: Health Effects Division (HED) Human Health Risk Assessment of the Common Metabolite/Degradate ETU to Support Reregistration,* dated June 8, 2005; and *Environmental Fate and Ecological Risk Assessment for Maneb, Section 3 Reregistration for Control of Fungal Diseases on Numerous Crops, Ornamental Plantings, and Turf (Phase 3 Response),* dated June 21, 2005; hereafter referred to as the Environmental Fate and Effects Risk Assessment.

The purpose of this section is to summarize the key features and findings of the risk assessments in order to help the reader better understand the conclusions reached in the assessments. Risks summarized in this RED document are those that result only from the use of maneb. While the risk assessments and related addenda are not included in this RED, they are available from the Office of Pesticide Programs (OPP) Public Docket: OPP-2004-0178 and may also be accessed on the Agency's website at http://www.epa.gov/edockets. Hard copies of these documents may be found in the OPP public docket under this same docket number. The OPP public docket is located in Room 119, Crystal Mall II, 1801 South Bell Street, Arlington, VA, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

A. Human Health Risk Assessment

EPA released its preliminary risk assessments for maneb for public comment on November 24, 2004 for a 90 day public comment period (Phase 3 of the public participation process). The preliminary risk assessments may be found in the OPP public docket at the address given above and in EPA's electronic docket under docket number OPP-2004-0078. In response to comments received and new studies submitted during Phase 3, the risk assessments were updated and refined. The risk assessments were revised again in June 2005 to incorporate comments and additional studies

submitted by the registrant. Revised risk assessments may be found in the OPP dockets under docket number OPP-2005-0178. Major revisions to the maneb human health risk assessment include the following:

- Reduction of the database uncertainty factor from 10 to 1 for chronic dietary exposures, incidental oral exposures, and dermal exposures.
- Modification of residue values for tomatoes and leaf lettuce.
- Assessment of toddler turf exposure at the existing label rate and the proposed reduced rate.

This document summarizes risk estimates for both maneb and its metabolite and environmental degradate ethylene thiourea (ETU). Maneb and two other EBDC fungicides, metiram and mancozeb, are all metabolized to ETU in the body and all degrade to ETU in the environment. Therefore, EPA has considered the aggregate or combined risks from food, water and non-occupational exposure resulting from maneb alone, ETU resulting from maneb use, and ETU from all sources (i.e., the other EBDC fungicides: metiram and mancozeb). The aggregate risk from ETU from all sources must be considered to reassess the tolerances for metiram, maneb and mancozeb, in accordance with FQPA.

1. Toxicity Assessment of Maneb

Toxicity assessments are designed to predict if a pesticide could cause adverse health effects in humans (including short-term or acute effects such as skin or eye damage; and lifetime or chronic effects such as cancer, development and reproduction deficiencies, etc.) and the level or dose at which such effects might occur. The Agency has reviewed all toxicity studies submitted for maneb and has determined that the toxicological database is sufficient for reregistration.

For more details on the toxicity and carcinogenicity of maneb see the *Maneb: HED Toxicology Chapter for the Reregistration Eligibility Decision Document (RED),* dated December 23, 1999 and the *Maneb-Revised Report of the Hazard Identification Assessment Review Committee,* dated April 2, 2003, which are available at http://www.epa.gov/edockets under docket number OPP-2004-0078.

a. Acute Toxicity Profile of Maneb

Maneb demonstrates low acute toxicity via the oral (Toxicity Category IV), dermal (Toxicity Category III) and inhalation (Toxicity Category III) routes of exposure. Because maneb is not irritating to the eyes or the skin, it is in Toxicity Category III for both routes. However, maneb is a skin sensitizer. The acute toxicity profile for maneb is summarized in Table 3.

Table 3. Acute Toxicity Profile for Maneb

Guideline No.	Study Type	MRID	Results	Toxicity Category
870.1100	Acute Oral - rat	41975601	LD_{50} = >5000 mg/kg	IV

Table 3. Acute Toxicity Profile for Maneb				
Guideline No.	**Study Type**	**MRID**	**Results**	**Toxicity Category**
870.1200	Acute Dermal - rabbit	41975602	LD_{50} = >2000 mg/kg	III
870.1300	Acute Inhalation - rat	41975603	LC_{50} = >1.3 mg/L	III
870.2400	Primary Eye Irritation	41975604	not an eye irritant	III
870.2500	Primary Skin Irritation	41975605	not a skin irritant	III
870.2600	Dermal Sensitization	41975606	a dermal sensitizer	N/A
* LD50 or LC50 = Median Lethal Dose or Concentration. A statistically derived single dose or concentration that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation).				

b. FQPA Safety Factors Considerations for Maneb

The Federal Food Drug and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act (FQPA) directs the Agency to use an additional tenfold (10X) safety factor to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. FFDCA authorizes the Agency to modify the tenfold safety factor only if reliable data demonstrate that the resulting level of exposure would be safe for infants and children.

Special FQPA Safety Factor. The Agency concluded that there is qualitative indication of increased sensitivity to infants and children based on the results of the rat developmental toxicity study in which decreased fetal viability was observed at a dose level that produces decreased body-weight gain/food consumption in the maternal rat. The decreased fetal viability is considered more adverse than decreased body weight/food consumption. An adequate developmental toxicity study in rabbits is not available with which to assess susceptibility. The Agency considered the degree of concern for susceptibility within the context of all available toxicity data, and concluded there is low concern for the observed qualitative susceptibility based on the following:

- The doses selected for overall risk assessment address concerns seen in the prenatal developmental toxicity study;
- The dose-response in the rat developmental study was well-characterized;
- There was a clear NOAEL/LOAEL (No/Lowest Observed Adverse Effect Level) for maternal and developmental toxicity; and
- The doses selected for risk assessment also address concerns for thyroid toxicity.

Since there are no residual uncertainties for pre- and/or post-natal toxicity, the Special FQPA Safety Factor was removed (reduced to 1X) for maneb.

Database Uncertainty Factor. The Agency concluded there is a concern for developmental neurotoxicity following exposure to maneb. Evidence of neurotoxicity and neuropathology has been seen in rats following oral exposure to maneb in both subchronic and chronic studies. The

metabolite/degradate ETU has been shown to be a teratogen in rats, with effects seen in the central nervous system, urogenital and skeletal systems. In addition, neurotoxic effects have been observed in studies with another EBDC, metiram. Therefore, the Agency will be requiring a developmental neurotoxicity study (DNT) for maneb.

A comparative thyroid study in young and adult animals had previously been required for maneb and the other EBDC fungicides, as well as their common metabolite/degradate ETU. Cerexagri, Inc. suggested that the comparative thyroid study be conducted with ETU and evaluated prior to any similar testing with maneb, because ETU is believed responsible for thyroid toxicity occurring in the EBDC toxicity studies.

As a result, the Agency has decided it is appropriate for the comparative thyroid study to be conducted with ETU. ETU is a direct-acting thyroid toxicant which inhibits thyroid peroxidase enzyme and is believed to be responsible for the thyroid toxicity with the EBDCs. The comparative thyroid study should be conducted using ETU and requirement for a comparative thyroid study with maneb, as well as the other EBDC fungicides, is reserved.

A dose analysis was conducted on maneb in order to determine the need for and size of a database uncertainty factor (UF_{DB}) in the absence of a submitted developmental neurotoxicity study (DNT) for maneb. Assuming the doses tested in the required DNT will be similar to those in the available 2-generation reproduction study, the doses will be 5/6, 21/24, and 83/100 mg/kg/day. The assumed NOAEL (5/6 mg/kg/day) for offspring effects in the DNT is compared to the doses selected for risk assessment, resulting in only the doses selected for the acute dietary endpoints exceeding the assumed DNT NOAEL.

The Agency determined that a 10X database uncertainty factor (UF_{DB}) is needed for acute dietary exposures only to account for the lack of DNT study, however, the above analysis supports reduction or removal of the 10X UF_{DB} to 1X for chronic dietary exposures, incidental oral exposures, dermal exposures, and inhalation exposures because the doses did not exceed the assumed DNT NOAEL.

c. Toxicological Endpoints for Maneb

The toxicological endpoints used in the human health risk assessment for maneb are listed in Table 4. The safety factors used to account for interspecies extrapolation, intraspecies variability, the potential for special susceptibility to infants and children (FQPA 10X), and database uncertainties related to FQPA Safety Factor considerations are also described in Table 4 below.

Table 4. Toxicological Endpoints for Maneb.

Exposure Scenario	Dose, Uncertainty Factors (UFs), and Safety Factors (SFs)	Population Adjusted Dose (PAD) or Target Margin of Exposure (MOE)	Study and Toxicological Effects
Maneb Dietary Exposures			

Table 4. Toxicological Endpoints for Maneb.			
Exposure Scenario	**Dose, Uncertainty Factors (UFs), and Safety Factors (SFs)**	**Population Adjusted Dose (PAD) or Target Margin of Exposure (MOE)**	**Study and Toxicological Effects**
Acute Dietary Females 13 - 49	NOAEL = 20 mg/kg/day UF=100X (inter and intraspecies) FQPA SF = 1X FQPA UF=$10X_{database}$ Total UF=1000X Acute RfD = 0.02 mg/kg/day	aPAD= $\frac{\text{Acute RfD}}{\text{FQPA SF}}$ aPAD= 0.02 mg/kg/day	Developmental Toxicity (Rat) LOAEL=100 mg/kg/day, based on increased post-implantation loss and resorptions, decreased fetal viability
Acute Dietary General Population	NOAEL=1000 mg/kg/day UF=100X (inter and intraspecies) FQPA SF = 1X FQPA UF=$10X_{database}$ Total UF=1000X Acute RfD=1.0 mg/kg/day	aPAD= $\frac{\text{Acute RfD}}{\text{FQPA SF}}$ aPAD=1.0 mg/kg/day	Acute Neurotoxicity (Rat) LOAEL=2000 mg/kg/day, based on slight impairment of forelimb grip strength
Chronic Dietary General Population	NOAEL=5 mg/kg/day UF=100X (inter and intraspecies) FQPA SF = 1X Total UF=100X Chronic RfD = 0.05 mg/kg/day	cPAD = $\frac{\text{Chronic RfD}}{\text{FQPA SF}}$ cPAD = 0.05 mg/kg/day	Subchronic toxicity, Rat LOAEL=24 mg/kg/day based on thyroid effects [increased thyroid weight and follicular cell hypertrophy in males and decreased T_4 in females]
Maneb Incidental Oral Exposures (Residential, Postapplication)			
Any Duration [1-30 days] [>30 days to 6 mos.]	NOAEL = 5 mg/kg/day UF=100X (inter and intraspecies)	Residential MOE=100	Subchronic toxicity, Rat LOAEL=24 mg/kg/day based on thyroid effects [increased thyroid weight and follicular cell hypertrophy in males and decreased T_4 in females]

Table 4. Toxicological Endpoints for Maneb.			
Exposure Scenario	**Dose, Uncertainty Factors (UFs), and Safety Factors (SFs)**	**Population Adjusted Dose (PAD) or Target Margin of Exposure (MOE)**	**Study and Toxicological Effects**
Maneb Dermal Exposures			
Any Duration [1-30 days] [>30 days to 6 mos.] [>6 mos.]	Dermal NOAEL=300 mg/kg/day UF=100X (inter and intraspecies) 2% dermal absoprtion observed in the rat; thus adsorbed dose = 6.	Residential MOE=100 Occupational MOE=100	21-day Dermal Toxicity, Rabbit LOAEL = 1000 mg/kg/day, based on microscopic thyroid changes [follicular cell hypertrophy] in both sexes and increased thyroid weights in males.
Maneb Inhalation Exposure			
Any Duration [1-30 days] [>30 days to 6 mos.] [>6 mos.]	NOAEL=5 mg/kg/day UF=100X (inter and intraspecies) Inhalation Absorption =100%	Residential MOE=100 Occupational MOE=100	Subchronic toxicity, Rat LOAEL=24 mg/kg/day based on thyroid effects [increased thyroid weight and follicular cell hypertrophy in males and decreased T_4 in females]
NOAEL- No Observable Adverse Effect Level, the highest dose at which no adverse health effect is observed. **LOAEL** - Lowest Observable Adverse Effect Level, the lowest dose at which an adverse health effect is observed. **aPAD/cPAD** - acute and chronic, respectively, population adjusted dose (PAD), a reference dose which has been adjusted to account for the FQPA safety factor.			

2. Toxicity Assessment of ETU

As previously mentioned, some of the toxicity of the parent EBDCs is attributed to their common metabolite, ETU. The toxicology database for ETU contains a limited number of FIFRA guideline studies; therefore, the Agency has relied on a combination of literature studies and unpublished studies conducted according to the OPPTS testing guidelines. The thyroid is a target organ for ETU, and thyroid toxicity as a result of ETU exposure has been noted in subchronic and chronic rat, mouse, and dog studies. Overt liver toxicity was observed in one chronic dog study. Developmental defects in the rat developmental study included hydrocephaly and related lesions, skeletal system defects, and other gross defects. These defects showed increased susceptibility to fetuses because they occurred at a dose that only caused decreased maternal food consumption and body weight gain.

For more details on the toxicity and carcinogenicity of ETU, see the *ETU- 3rd Report of the Hazard Identification Assessment Review Committee,* dated May 28, 2003, which is available on the internet and in the public docket.

a. Acute Toxicity Profile for ETU

ETU demonstrates low acute toxicity via dermal (Toxicity Category III) and inhalation (Toxicity Category IV) routes of exposure. Because ETU is not irritating to the eyes or the skin, it is in Toxicity Category IV for both routes. However, acute oral and dermal sensitization studies with ETU were not available to determine acute toxicity. The acute toxicity profile for ETU is summarized in Table 5.

Table 5. Acute Toxicity Profile for ETU

Guideline No.	Study Type	MRID Nos.	Results	Toxicity Category
870.1100	Acute Oral - rat	N/A	N/A	N/A
870.1200	Acute Dermal - rabbit	458881-01	LD_{50} > 2000 mg/kg	III
870.1300	Acute Inhalation - rat	458881-02	LC_{50} > 10.4 mg/L	IV
870.2400	Primary Eye Irritation	458881-04	No irritation	IV
870.2500	Primary Skin Irritation	458881-03	No irritation	IV
870.2600	Dermal Sensitization	N/A	N/A	N/A

b. FQPA Safety Factor Considerations for ETU

Special FQPA Safety Factor. Since there is evidence of increased susceptibility of fetuses following exposure to ETU in the rat developmental studies, the Agency evaluated the level of concern for the effects observed when considered in the context of all available toxicity data. In addition, the Agency evaluated the database to determine if there were residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors to be used in the ETU risk assessment. The Agency determined that the degree of concern for the susceptibility seen in ETU developmental studies was low because:

- The teratogenic effects have been well-characterized in numerous studies in the published literature, as well as in a guideline study submitted by the registrant;
- There is a clear NOAEL for these effects and the dose-response relationship, although steep, is well-characterized in the numerous developmental studies in rats;
- The developmental endpoint with the lowest NOAEL was selected for deriving the acute RfD; and
- The target organ toxicity (thyroid toxicity) was selected for deriving the chronic RfD as well as endpoints for non-dietary exposures (incidental oral, dermal, and inhalation).

Since the ETU doses selected for overall risk assessments will address the concern for developmental and thyroid toxicity, there are no residual uncertainties with regard to pre- and/or post-natal toxicity. The Agency concluded that the Special FQPA Safety Factor could be reduced to 1X for ETU.

Database Uncertainty Factor. The Agency concluded a developmental neurotoxicity study for ETU is required, based on severe central nervous system defects observed in the developmental toxicity study in rats. In addition to the developmental neurotoxicity study, the following data gaps were identified:

- Developmental toxicity study in rabbits
- 2-Generation reproduction study in rats
- A study evaluating the comparative thyroid toxicity in adults and offspring

The Agency determined that a 10x database uncertainty factor (UF_{DB}) is needed to account for the lack of these studies since the available data provide no basis to support reduction or removal of the 10X UF_{DB}.

c. Toxicological Endpoints for ETU

The toxicological endpoints used in the human health risk assessment for ETU are listed in Table 6. The safety factors used to account for interspecies extrapolation, intraspecies variability, the potential for special susceptibility to infants and children (FQPA 10X), and database uncertainties related to FQPA saftey factor considerations are also described in Table 6 below.

Table 6. ETU Toxicological Endpoints for Use in Human Health Risk Assessment

Exposure Scenario	Dose, Uncertainty Factors (UFs), and Safety Factors (SFs)	Population Adjusted Dose (PAD) or Target Margin of Exposure (MOE)	Study and Toxicological Effects
ETU Dietary Exposures			
Acute Dietary Females 13 - 50	NOAEL = 5 mg/kg/day UF = 100X (inter and intraspecies) FQPA SF = 1X FQPA UF = $10X_{database}$ Total UF = 1000X Acute RfD = 0.005 mg/kg/day	aPAD = $\frac{\text{Acute RfD}}{\text{FQPA SF}}$ aPAD = 0.005 mg/kg/day	Developmental Rat Toxicity (Khera Study, MRID 45937601) LOAEL = 10 mg/kg/day, based on developmental defects of brain.
Acute Dietary General Population	Not Applicable	No appropriate endpoint attributable to a single exposure (dose) was identified.	
Chronic Dietary	NOAEL = 0.18 mg/kg/day UF=100X (inter and intraspecies) FQPA SF = 1X FQPA UF = $10X_{database}$ Total UF = 1000X Chronic RfD=0.0002 mg/kg/day	cPAD = $\frac{\text{Chronic RfD}}{\text{FQPA SF}}$ cPAD = 0.0002 mg/kg/day	Dog Chronic Oral Toxicity (MRID No. 42338101) LOAEL= 1.99 mg/kg/day based on thyroid toxicity

Table 6. ETU Toxicological Endpoints for Use in Human Health Risk Assessment			
Exposure Scenario	**Dose, Uncertainty Factors (UFs), and Safety Factors (SFs)**	**Population Adjusted Dose (PAD) or Target Margin of Exposure (MOE)**	**Study and Toxicological Effects**
ETU Incidental Oral Exposures [Residential/Postapplication]			
Short-Term [1-30 days] Intermediate-Term [>30 days to 6 months]	NOAEL = 7 mg/kg/day UF = 100X (inter and intraspecies) FQPA UF = $10X_{database}$ FQPA SF = 1X	Residential MOE = 1000 Occupational MOE = N/A	4-week range-finding dog study LOAEL= 34 mg/kg/day based thyroid toxicity
ETU Dermal Exposures			
Short-Term [1-30 days] Females 13-49 Intermediate-Term [30 days - 6 months]	NOAEL = 5 mg/kg/day UF = 100X (inter and intraspecies) FQPA UF = $10X_{database}$ FQPA SF = 1X Dermal Absorption = 26%	Residential MOE = 1000 Occupational MOE = 100	Same as above for acute dietary exposures.
Long-Term [> 6 months]	NOAEL = 0.18 mg/kg/day UF = 100X (inter and intraspecies) FQPA UF = $10X_{database}$ FQPA SF = 1X Dermal Absorption = 26%	Residential MOE = 1000 Occupational MOE = 100	Same as above for chronic dietary exposures.
ETU Inhalation Exposures			
Short-Term [1-30 days] Females 13-49 Intermediate-Term [30 days - 6 months]	NOAEL = 5 mg/kg/day UF = 100X (inter and intraspecies) FQPA UF = $10X_{database}$ FQPA SF = 1X Inhalation Absorption = 100%	Residential MOE = 1000 Occupational MOE = 100	Same as above for acute dietary exposures.
Long-Term [>6 months]	NOAEL = 0.18 mg/kg/day UF = 100X (inter and intraspecies) FQPA UF = $10X_{database}$ FQPA SF = 1X Inhalation Absorption = 100%	Residential MOE = 1000 Occupational MOE = 100	Same as above for chronic dietary exposures.
NOAEL- No Observable Adverse Effect Level, the highest dose at which no adverse health effect is observed. **LOAEL** - Lowest Observable Adverse Effect Level, the lowest dose at which an adverse health effect is observed. **aPAD/cPAD** - acute and chronic, respectively, population adjusted dose (PAD), a reference dose which has been adjusted to account for the FQPA safety factor.			

3. Maneb and ETU Carcinogenicity

In assessing the carcinogenicity of pesticides, the Agency first evaluates evidence that the pesticide is a carcinogen. If there is evidence, such as tumor formation, and the pesticide is classified as a carcinogen, a quantitative assessment is conducted using a Q_1* (non-threshold) or a Margin of Exposure (threshold) approach. The mechanism of the tumor formation determines whether or not a threshold or non-threshold assessment is conducted. Table 7 below provides a comparison of tumor data for ETU, mancozeb, maneb, and metiram.

Table 7. Tumor Incidence in EBDC/ETU Carcinogenicity Studies in Rats and Mice

Species	ETU	Mancozeb	Maneb	Metiram
Rats	Thyroid follicular cell adenomas and carcinomas at 83 & 250 ppm	Thyroid follicular cell adenomas and carcinomas at 750 ppm (HDT) [56 ppm ETU]	No increase in tumor of any type at 1000 ppm (HDT) [75 ppm ETU]	No increase in tumor of any type at 320 ppm (HDT) [24 ppm ETU]
Mice	Thyroid follicular cell adenomas and carcinomas, pituitary adenomas, hepatocellular adenomas and carcinomas at 1000 ppm	No increase in tumor of any type at 1000 ppm (HDT) [75 ppm ETU]	Increased incidence of hepatocellular adenomas and alveogenic adenomas in the lungs at 2400 ppm [180 ppm ETU]	No increase in tumor of any type at 1000 ppm [75 ppm ETU]

HDT - Highest Dose Tested
[Numbers in brackets represent ETU "dose" levels based on a 7.5% conversion of parent EBDC to ETU]

Historically, it has been assumed that maneb's potential for carcinogenicity (as well as that of the other EBDCs, metiram and mancozeb) is due to the formation of the metabolite ETU, which is classified as a probable human carcinogen (B2), with a cancer potency factor (Q_1^*) of 0.0601 $(mg/kg/day)^{-1}$ for risk assessment. On this basis, maneb cancer risk has been calculated by estimating exposure to maneb-derived ETU (including the metabolic conversion) and using the ETU cancer potency factor to provide a quantitative estimate of risk. In a 1999 Review, the Agency concluded that cancer risk for maneb and the other EBDCs should continue to be evaluated in this way.

4. Maneb and ETU Endocrine Effects

The available human health and ecological effects data for maneb suggest possible thyriod effects, which may indicate potential endocrine disruption. EPA has considered these effects in the human health risk assessment by selecting endpoints based on thyroid effects. To further address these effects, EPA is requiring a confirmatory comparative thyroid toxicity study for maneb. Data on ecological effects suggest possible hormonal effects to birds and mammals. These effects will be addressed when the Agency's Endocrine Disruptor Screening and Testing Advisory Committee develops appropriate screening and/or testing protocols. At that time, maneb may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

5. Dietary Risk from Food

a. Exposure Assumptions

EPA conducted acute, chronic, and cancer dietary (food) risk assessments for maneb and its metabolite ETU using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 1.3), which incorporates consumption data from USDA's Continuing Survey of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. Because ETU is both a metabolite and environmental degradate of maneb and the other two EBDC fungicides, it was considered in the dietary risk assessment. The Agency conducted a dietary risk assessment for ETU from all sources, because ETU can be derived from mancozeb, maneb, or metiram.

The acute and chronic dietary (food) risk analyses were conducted using anticipated residue values from field trial and market basket survey data. The 1989-1990 market basket survey for EBDCs and ETU was the largest of its kind, with 6000 samples (300 samples for each of 10 crops and food forms). Processing factors, cooking factors, and estimated percent crop treated information were also incorporated into the dietary risk assessment. EPA derived anticipated residues for ETU from market basket survey data, ETU formed from the parent EBDCs during processing, and ETU formed by metabolic conversion of the parent EBDCs.

b. Population Adjusted Dose

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic dietary assessments, the risk is expressed as a percentage of a level of concern (i.e., the dose predicted to result in no unreasonable adverse health effects to any human sub-population, including sensitive members of such sub-populations). This level of concern is referred to as the Population Adjusted Dose (PAD). Dietary risk is characterized in terms of the PAD, which reflects the Reference Dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA Safety Factor.

Estimated dietary (food) risks less than 100% of the Population Adjusted Dose (PAD), either acute (aPAD) or chronic (cPAD), are not of concern to the Agency. The aPAD is the dose at which a person could be exposed at any given day with no adverse health effects expected. The cPAD is the dose at which an individual could be exposed over the course of a lifetime with no adverse health effects expected. Risk estimates from maneb and ETU residues in food are summarized below.

1) Acute Dietary Risk from Food

As previously mentioned, the acute dietary (food) risk assessment for maneb was conducted using the DEEM-FCID™ computer model, anticipated residues, processing and cooking factors, and estimates of percent crop treated. A highly refined, probabilistic acute dietary assessment was conducted using a distribution of residue data for nonblended and partially blended commodities. The Agency has high confidence in this assessment. Acute dietary risk values for maneb, ETU resulting from maneb use, and ETU from all sources (that is, ETU resulting from the application of all

three EBDC compounds, mancozeb, metiram, and maneb) are presented in Table 8. *(For the acute dietary endpoints see Table 4 for maneb and Table 6 for ETU)*

Table 8. Summary of Acute Dietary Exposure Analysis						
Population Subgroup	Maneb[a]		Maneb-Derived ETU[b]		ETU from All Sources[b]	
	99.9th Percentile Exposure (mg/kg/day)	% aPAD	99.9th Percentile Exposure (mg/kg/day)	% aPAD	99.9th Percentile Exposure (mg/kg/day)	% aPAD
U.S. Population	0.014	1.4	Not Applicable		Not Applicable	
Females 13 to 49 years	0.018	89	0.003	52	0.0026	55
[a] aPAD is 1.0 mg/kg/day (general population) and 0.02 mg/kg/day (females 13 to 49) [b] aPAD is 0.005 mg/kg/day						

For maneb *per se*, the acute dietary risk is below the Agency's level of concern. Dietary exposure at the 99.9th percentile comprises 89% of the aPAD for females age 13-49, the population subgroup with the highest exposure. Dietary exposure for the general U.S. population and all other population subgroups, including infants and children, comprised <2% of the aPAD.

For maneb-derived ETU, the estimated acute dietary risk for ETU is below the Agency's level of concern. Dietary exposure comprises 52% of the aPAD for females 13-49 years of age.

For ETU from all sources, the estimated acute dietary risk for total ETU is also below the Agency's level of concern. Dietary exposure comprises 55% of the aPAD for females 13-49 years old.

2) Chronic Dietary Risk from Food

Chronic (non-cancer) dietary risk from food is calculated by using the average consumption value for foods and average residue values on those foods over a 70-year lifetime. The chronic dietary (food) risk assessment was conducted using the DEEM-FCID™ computer model, anticipated residues, processing and cooking factors, and estimates of percent crop treated. The chronic assessment used deterministic methodology to provide point estimates of risk. Chronic dietary risk values for maneb, maneb-derived ETU, and ETU from all sources are presented in Table 9. *(For the chronic dietary endpoints see Table 4 for the maneb and Table 6 for the ETU)*

Table 9. Summary of Chronic (Non-Cancer) Dietary Exposure Analysis						
Population Subgroup	Maneb [a]		Maneb-Derived ETU [b]		ETU from All Sources [b]	
	Exposure (mg/kg/day)	% cPAD	Exposure (mg/kg/day)	% cPAD	Exposure (mg/kg/day)	% cPAD
Children (1- 2)	0.000076	<1	0.000029	14	0.000108	54

Table 9. Summary of Chronic (Non-Cancer) Dietary Exposure Analysis						
Population Subgroup	Maneb [a]		Maneb-Derived ETU [b]		ETU from All Sources [b]	
	Exposure (mg/kg/day)	% cPAD	Exposure (mg/kg/day)	% cPAD	Exposure (mg/kg/day)	% cPAD
Females 13 - 49	0.000103	<1	0.000015	7.5	0.000027	14
U.S. population	0.000081	<1	0.000016	7.9	0.000031	16
[a] cPAD is 0.05 mg/kg/day [b] cPAD is 0.0002 mg/kg/day						

Maneb *per se* dietary risk estimates are all below the Agency's level of concern. The highest exposed subgroup was females age 13-49, whose chronic dietary exposure comprised <1% of the cPAD. Dietary exposure for the general U.S. population comprised <1% of the cPAD.

For maneb-derived ETU, the most exposed subgroup was children 1-2 years old, whose chronic dietary exposure comprised 14% of the cPAD, which is below the Agency's level of concern. For the general U.S. population, dietary exposure to maneb-derived ETU residues comprised 7.9% of the cPAD.

For ETU from all sources, the estimated chronic dietary risk is also below the Agency's level of concern. The dietary exposure from ETU from all sources comprises 54% of the cPAD for children 1-2 years old, the most highly exposed population subgroup.

3) Cancer Dietary Risk from Food

Cancer dietary risk from food is calculated by using the average consumption values for food and average residue values for those foods over a 70-year lifetime. The chronic exposure value is multiplied by a linear low-dose, or Q_1*, based on animal studies, to determine the lifetime cancer risk estimate. For cancer dietary exposure, risk estimates within the range of an increased cancer risk of 1 x 10^{-6} (one in a million) are generally not of concern to the Agency.

As mentioned above, maneb's potential for carcinogenicity has been based on its metabolite ETU. The ETU cancer potency factor has been used for assessing cancer risk associated with maneb uses.

The Agency evaluated the carcinogenicity potential of ETU and classified ETU as a "probable human carcinogen" (group B2). Based upon female mouse liver tumors in a National Toxicology Program (NTP) study, the Q_1* for ETU, using a 3/4 scaling factor to account for body weight ratio from animal to human, was determined to be 6.01 x 10^{-2} mg/kg/day^{-1}. On this basis, maneb estimated cancer risk has been calculated by estimating exposure to maneb-derived ETU (including the metabolic conversion of 0.075) and using the ETU cancer potency factor. Cancer dietary risk values are listed in Table 10.

The cancer risk for maneb-derived ETU is approximately 9.6 x 10^{-7}, which is less than 1 x 10^{-}

[6] and therefore is not considered to be of concern to the Agency. The cancer risk for ETU from all sources is approximately 1.86 x 10^{-6}, which is within the negligible risk range of 10^{-6} and not considered to be of concern.

Table 10. Cancer Dietary Exposure and Risk Summary for Maneb-derived ETU and ETU from all Sources.

Population	Maneb-derived ETU		ETU from All Sources	
	Chronic Dietary Exposure (mg/kg/day)	Cancer Risk Estimate*	Chronic Dietary Exposure (mg/kg/day)	Cancer Risk Estimate**
General U.S. Population	0.000016	9.6 x 10^{-7}	0.000031	1.86 x 10^{-6}

*Major contributors to this risk are mango and milk.
**Major contributors to this risk are lettuce and milk.

6. Dietary Exposure from Drinking Water

Drinking water exposure to pesticides can occur through surface and ground water contamination. EPA considers acute (one day) and chronic (lifetime) drinking water risks and uses either modeling and/or monitoring data, if the latter is available and of sufficient quality, to estimate those exposures. Risks from exposure to ETU in drinking water are further discussed in the section titled "Aggregate Exposure and Risk."

The Agency prepared a drinking water exposure assessment for ETU only. The parent EBDC fungicides were not assessed because they are very short-lived in soil and water, and are not expected to reach water used for human consumption, whether from surface water or groundwater sources. ETU, however, is highly water soluble, and moderately mobile, and may reach both surface and groundwater under some conditions. ETU has an aerobic soil half-life of about 3 days; in the absence of data, the aerobic aquatic metabolism half-life was assumed to be about 6 days, or double the soil half-life. The measured anaerobic aquatic metabolism half-life, however, is substantially longer (149 days), which may lead to the periodic detections in groundwater. The ETU estimated drinking water concentrations (EDWCs) were generated using data from both monitoring and modeling. Table 9 shows the EDWCs used to assess exposure to ETU in drinking water from surface water and groundwater.

Table 11. ETU Surface Water and Groundwater Estimated Drinking Water Concentrations (EDWC)

Drinking water source	Duration	EDWC (ppb)	Data Source
Surface Water	Acute (Peak)	25.2	Modeling
	Chronic/Cancer	0.1	Monitoring
Groundwater	All Durations	0.21	Monitoring

a. Surface Water

Monitoring data for ETU from a targeted surface water monitoring study conducted by the ETU Task Force and representing vulnerable and high EBDC use sites were available for use in the risk assessment. In the study, none of the tested surface water samples had concentrations above the limit of detection of 0.1 ppb. Therefore, the chronic/cancer EDWC was assigned the value of 0.1 ppb of ETU. The monitoring value of 0.1 ppb of ETU was also assigned to be the lower limit of the acute EDWC. In addition, the Agency decided that a higher limit for the acute value is necessary because monitoring samples were taken every 14 days during the application season and peak values may have been missed. In order to obtain this value, the Agency performed PRZM/EXAMS simulation modeling for 22 crop scenarios. In modeling, the Agency considered the use patterns for all of the EBDCs and chose the highest application rate and lowest application intervals. Modeling results showed the highest one-in-ten year acute surface water EDWC to be 25.2 ppb based on application of EBDCs to peppers crop in Florida. Therefore, a range of acute EDWCs was established with a lower limit, based on monitoring and an upper limit based on the PRZM/EXAMS modeling described above. The established range of acute Estimated Drinking Water Concentration (EDWC) values for surface water, at the national level, is expected to be between the detection limit of 0.1 ppb (from monitoring) and the highest peak value 25.2 ppb (from modeling after adjustment by the 0.87 national percent crop area factor or PCA). In summary, the Agency used a combined approach to assess drinking water exposure using both targeted surface water monitoring and simulation modeling to bracket the expected acute concentrations of ETU in drinking water between 0.1 and 25.2 ppb. Chronic surface water values were set conservatively at 0.1 ppb, the detection limit for the monitoring data.

b. Ground Water

A groundwater EDWC was selected from a targeted monitoring study conducted in 2001 to 2003 for seven states chosen to represent the high historic EBDC use areas in the US. Based on the monitoring results, the highest measured value in a public drinking water well was 0.210 ppb in Lee County, Florida. Therefore, the groundwater EDWC is assigned the value of 0.21 ppb of ETU. In this study, ETU was not detected in any of the treated community drinking water sampled from the monitored 84 sites even when it was detected in the raw water. The absence of ETU in potable water from community water supplies may be related to its rapid degradation resulting from aeration and chemical treatment.

7. Residential Exposure and Risk

Residential exposure assessments consider all potential non-occupational pesticide exposure, other than exposure due to residues in foods or in drinking water. There are no current labeled uses for residential applications of maneb on residential areas or home gardens. The only potential residential exposure to maneb is from residues remaining on transplanted turf from sod farms. Risk to toddlers, the most sensitive sub-population, was evaluated for four post-application routes of exposure: dermal exposure; incidental oral exposure from children putting their hands in their mouth after touching treated turf (hand-to-mouth); children mouthing a handful of treated turf (object-to-mouth); and children eating soil from treated sod (soil ingestion).

To estimate residential risks, the Agency calculates a margin of exposure (MOE), which is the ratio of the NOAEL selected for risk assessment to the exposure. This MOE is compared to a level of concern which is the same value as the uncertainty factor (UF) applied to a particular toxicity study. The standard UF is 100x (10x to account for interspecies extrapolation and 10x for intraspecies variation), plus any additional FQPA safety factor retained due to concerns unique to the protection of infants and children. For maneb, the Agency does not have risk concerns for MOEs greater than 100 for dermal and incidental oral exposures. For ETU, the target MOE is 1000 for dermal and incidental oral exposures.

Although maneb is not registered for residential use, EPA has considered residential post-application risk to transplanted sod treated with maneb on sod farms. EPA evaluated post-application exposure and risk only for toddlers because they comprise the most sensitive subpopulation. MOEs are presented on day 3 after application (the first day of potential exposure) and on the day when the MOE is no longer of concern, which is the recommended pre-harvest interval (PHI). These risk estimates and PHIs for toddlers will be protective of all other subpopulations.

Table 12. Maneb Post-Application Risks for Toddlers Exposed to Turf

Exposure Pathway	Label Application Rate of 17.4 lb ai/A		Proposed Label Rate of 8.7 lbs ai/A	
	MOE on Day 3 (PHI = 1 day*)	PHI Needed to Reach an MOE of 100 (days)	MOE on Day 3 (PHI = 1 day*)	PHI Needed to Reach an MOE of 100 (days)
Dermal	48	3	96	2
Hand-to-Mouth (HTM)	62	3	124	1
Object-to-Mouth (OTM)	250	0	500	0
Soil Ingestion	62000	0	124000	0
Total MOE**	**24**	**5**	**49**	**3**

* The current "PHI" is one day because the REI is 24 hours.
** Total MOE = 1/[(1/Dermal MOE) + (1/HTM MOE) + (1/OTM MOE) + (1/Soil MOE)]

For maneb, the MOE for almost each exposure scenario is of risk concern on the first day of potential exposure at the current label rate of 17.4 lbs ai/A with the exception of soil ingestion. However, as residues decline over time, MOEs reach acceptable levels. Likewise, the total MOE, or sum of risk for all potential exposure scenarios is of concern on the first day of potential exposure but reaches an acceptable level over time. Further, the total MOE for toddlers reaches 100 with a PHI of 3 days at a reduced maximum application rate of 8.7 lbs ai/A proposed by the technical registrant and 5 days at the current label rate, as shown above in Table 12.

Table 13. Maneb-Derived ETU Post-Application Risks for Toddlers Exposed to Turf				
Exposure Pathway	**Label Application Rate of 17.4 lb ai/A**		**Proposed Label Rate of 8.7 lbs ai/A**	
	MOE on Day 3 (PHI = 1 day*)	**PHI Needed to Reach an MOE of 100 (days)**	**MOE on Day 3 (PHI = 1 day*)**	**PHI Needed to Reach an MOE of 1000 (days)**
Dermal	460	3	920	2
Hand-to-Mouth (HTM)	1100	1	2200	0
Object-to-Mouth (OTM)	3600	0	7200	0
Soil Ingestion	24000	0	48000	0
Total MOE**	**300**	**5**	**600**	**3**
* The current "PHI" is one day because the REI is 24 hours. ** Total MOE = 1/[(1/Dermal MOE) + (1/HTM MOE) + (1/OTM MOE) + (1/Soil MOE)]				

For maneb-derived ETU, the MOE for dermal exposure is 460 at the current label rate and 920 at the reduced maximum application rate on the first potential day of exposure. MOEs for incidental oral exposure are all greater than 1000 and not of concern. The MOE for total post-application exposure to ETU is 300 and increases to 600 with the proposed label rate of 8.7 lbs ai/A on the first day of exposure. As ETU residues decline over time, MOEs reach 1000. A PHI of 5 days at the current rate and 3 days at the proposed rate is necessary for the MOE from total exposure to reach a MOE of 1000, as shown above in Table 13.

8. Aggregate Risks from Food, Drinking Water and Residential Uses

The FQPA amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there is reliable information." Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure.

In accordance with the FQPA, the Agency must consider and aggregate pesticide exposures and risks from three major sources or pathways: food, drinking water and, if applicable, residential or other non-occupational exposures. For maneb, the Agency conducted a refined aggregate risk assessment that combines exposures across all pathways. The Agency included acute, chronic and cancer EDWCs directly in the dietary exposure assessments to calculate aggregate dietary (food + drinking water) risk. This is done by using the relevant PRZM-EXAMS value as a residue for drinking water (all sources) in the dietary exposure assessment conducted using the DEEM-FCID™ model. The principal advantage of this approach is that the actual individual body weight and water consumption data from the CSFII are used, rather than assumed weights and consumption estimates

for broad age groups.

Short-term residential and other non-occupational exposure assessments consider all potential pesticide exposure, other than exposure due to residues in food and/or in drinking water. Each route of exposure (i.e., oral, dermal, inhalation) is assessed, where appropriate, and risk is expressed as a Margin of Exposure (MOE), which is the ratio of estimated exposure to an appropriate NOAEL dose. An MOE greater than or equal to the target MOE is considered adequately protective and not a risk of concern. The target MOE is 100 for residential exposures to maneb, and the target MOE is 1000 for exposure to ETU.

Risk estimates from all relevant pathways (i.e., food, drinking water, and residential or non-occupational) for maneb *per se*, maneb-derived ETU, and ETU from all sources were calculated to assess aggregate risks. When aggregating exposure and risk from various sources, both the route and duration of exposure are considered. Exposure to multiple sources that are expected to co-occur are detailed below.

Since exposure to maneb *per se* is not expected from the drinking water pathway, aggregate exposure and risk for maneb *per se* are limited to combined food and residential exposures (i.e., transplanted turf that has been treated with maneb at a sod farm). The contribution from potential exposures to maneb in food is insignificant relative to the contribution from exposure to maneb on transplanted turf; therefore, the aggregate risk estimate is equivalent to the estimated risk from transplanted turf (see Section III.A.7).

For ETU resulting from maneb use, the Agency assessed the following aggregate exposure scenarios:

- acute aggregate (food + water)
- non-cancer chronic aggregate (food + water)
- cancer aggregate (food + water)

For ETU from all sources, the Agency assessed the following aggregate exposure scenarios:

- acute aggregate (food + water)
- short-term aggregate (food + water + residential [as a result of the residential uses of mancozeb])
- chronic (non-cancer) aggregate (food + water)
- cancer aggregate (food + water + residential [as a result of the residential uses of mancozeb])

a. Acute Aggregate

Acute aggregate (food + drinking water) risk for maneb-derived ETU from both groundwater and surface water sources of drinking water, when combined with exposure through food, is below the Agency's level of concern. The acute aggregate risk for maneb-derived ETU is 86% of the aPAD at the 99.9th percentile, which is less than 100% of the aPAD, as shown in Table 14.

Table 14. Acute DWLOC Calculations for Maneb-Derived ETU				
Population Subgroup	aPAD (mg/kg/day)	Estimated Drinking Water Concentration EDWC (ppb)	99.9 Percentile	
			Exposure (mg/kg/day	% aPAD
Females 13 - 49	0.005	25.2	0.004321	86

Similarly, acute aggregate (food + drinking water) risk for ETU from all sources is also calculated to be below the Agency's level of concern. The acute aggregate risk for ETU from all sources is 87% of the aPAD at the 99.9th percentile, which is less than 100% of the aPAD.

b. Short-Term Aggregate

Short-term aggregate (food + drinking water + residential [as a result of residential exposures from mancozeb uses]) risk for ETU from all sources is below the Agency's level of concern for residential handlers, and children and adults exposed to ETU from re-entry activities. Short-term aggregate risks were calculated for adults by aggregating chronic food exposure, chronic drinking water exposure and post-application golfing or gardening exposures. Short-term aggregate MOEs are significantly greater than the target MOE of 1000 (see Table 15).

EPA's original ETU analysis indicated risks above levels of concern for toddler exposure to transplanted turf treated with maneb. Recognizing that potential risk, the maneb registrants agreed to reduce the maximum application rate and/or extend the time between treatment and harvesting of sod from one to three days (i.e., 3 day pre-harvest interval [PHI]). Additionally, given the typical one to three day installation window following harvesting, the minimum time that would elapse between treatment and installation of sod in a residential setting would be within the range of four to six days. Further, the frequent and long duration of watering of newly installed sod and the need to restrict foot traffic for several weeks after planting should also minimize children's exposure to residues on transplanted turf. The reduced application rate and/or extended PHI, combined with the logistics of transplanting turf and installation restrictions, effectively reduced the potential contribution from this use pattern to a level not of concern to the Agency. The Agency has determined that aggregate risk assessments for transplanted turf exposure scenarios are not necessary, because such exposures are expected to be rare events.

Table 15. Short-Term Aggregate Post-Application Risk Estimates for ETU from All Sources.	
Exposure Scenario	Short-Term MOEs
Golfing	6200
Home Garden Handler (Handwand)	62000
Home Garden Post-Application	14450

c. Chronic (Non-Cancer) Aggregate

Chronic aggregate (food + drinking water) risk to maneb-derived ETU is below the Agency's level of concern. The aggregate chronic risks to maneb-derived ETU were calculated using food and drinking water only, because the potential residential exposure to ETU from maneb use is considered a short-term exposure scenario. The chronic aggregate risk estimate of 18% (groundwater) and 16% (surface water) of the cPAD for the most highly exposed population subgroup, children 1-2 years old, is less than 100% of the cPAD and not of risk concern.

Chronic aggregate (food + drinking water) risk to ETU from all sources is also below the Agency's level of concern. The chronic aggregate risk was calculated using food and drinking water exposure only, because golfing, athletic field and toddler transplanted turf exposure scenarios for ETU from all sources were considered to occur only on a short-term basis. The chronic aggregate risk estimate of 56% (surface water) and 58% (groundwater) of the cPAD for the most highly exposed population subgroup, children 1 to 2 years old, is less than 100% of the cPAD and not of risk concern.

d. Cancer Aggregate

Cancer aggregate (food + drinking water) risk to maneb-derived ETU for the general U.S. population 1.2×10^{-6}, and considered to be negligible. In addition, aggregate cancer risk estimates for exposure to ETU from all sources are in the range of 2×10^{-6} and considered to be negligible. The cancer risks were aggregated using the food and drinking water exposure estimates for the general population and the food, water and recreational exposure estimates for golfers, home gardeners and athletes. Note that the recreational contribution to this risk estimate is a result of the application of mancozeb.

9. Occupational Risks

Workers can be exposed to maneb and maneb-derived ETU through mixing, loading, and/or applying the pesticide to fruit and nut crops; vegetable crops; field and forage crops; grapes; sod farms; potato seed pieces; field crop seeds; and ornamental trees, shrubbery, annual plants, and perennial plants; or re-entering treated sites. Some of these exposures are expected to occur in greenhouses as a result of use in tomato production and on cut flowers. Occupational non-cancer risk to workers is measured by a Margin of Exposure (MOE), which determines how close the occupational exposure comes to a NOAEL. However, the occupational assessment does not consider an FQPA SF for sensitive populations (infants or children), nor is it affected by the FQPA database uncertainty factor being applied to dietary exposures for maneb. Thus, the target MOE for occupational risk is 100, and MOEs greater than 100 do not exceed the Agency's level of concern. For occupational cancer risks, as for dietary cancer risk and as described above in Section III.A.5., risk estimates within the range of an increased cancer risk of 1×10^{-6} (one in a million) generally do not exceed the Agency's level of concern. When occupational MOE are less than 100 or occupational cancer risks exceed the range of an increased cancer risk of 1×10^{-6}, EPA strives to reduce worker cancer risks through the use of personal protective equipment and engineering controls or other mitigation measures. The Agency generally considers occupational cancer risks within the

range of an increased risk of 1 x 10^{-6} or less to be negligible, but will consider risks as high as 10^{-4} when all mitigation measures that are feasible have been applied, and when evaluating the advantages associated with the use of the pesticide. The cancer risks for application of maneb to agricultural crops are as a result of exposure to ETU, and calculated by estimating 30 days of exposure per year.

References to ETU in the occupational risk section of this document refer to maneb-derived ETU from three sources, ETU formed in tank mixes, ETU formed in the body by metabolic conversion, and ETU formed in the environment through degradation. For both handler and post-application assessments, the maneb dose considered ETU from metabolic conversion of maneb to ETU and from maneb converted to ETU in tank mixes. Handler assessments addressed combined dermal and inhalation exposures, but post-application risks were derived solely from dermal exposure.

Occupational risk is assessed based on exposures at the time of application (termed "handler" exposure) and following application, or post-application exposure. Application parameters are generally defined by the physical nature of the formulation (e.g., formula and packaging), by the equipment required to deliver the chemical to the use site, and by the application rate required to achieve an efficacious dose. Post-application risk is assessed for activities such as scouting, irrigating, pruning, and harvesting and is based primarily on dermal exposure estimates. Note that occupational risk estimates are intended to represent pesticide workers, and on this basis assumptions are made concerning acres treated per day and the seasonal duration of exposure.

For more information on the assumptions and calculations of potential risks to workers handling maneb or working in maneb treated areas, see the *Maneb: Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document* dated June 8, 2005, which is available in the public docket (OPP-2005-0178).

a. Occupational Handler Exposure

For handlers, most exposures were considered to be short-term (1-30 days) or intermediate-term (1-6 months) in duration, with the exception of greenhouse uses, which may result in chronic (>180 days) exposure. For handler assessments that consider exposure to ETU, non-cancer short-term and intermediate-term risks were the same, but chronic risks were assessed using a different toxicological dose and endpoint. For both the maneb handler assessments and the ETU non-cancer assessments, dermal and inhalation exposures were combined, since the endpoints selected as the basis for risk assessment (thyroid effects) were similar.

No chemical-specific handler exposure studies were submitted in support of the reregistration of maneb, so Pesticide Handler Exposure Database (PHED, Version 1.1, 1998) data were used to calculate unit exposure values to estimate occupational handler exposures to maneb and ETU during application to crops and ornamentals. There are no recent or adequate data (either chemical-specific or in PHED) that reflect the specifics of the potato seed-piece treatment scenario; therefore, PHED data for other scenarios were extrapolated to approximate seed-piece treatment. Moreover, standard assumptions were used for the number of acres treated, body weight, hours worked, etc. for most handler scenarios. For the potato seed-piece use, assumptions were based on conversations with

experts in the potato industry.

Occupational handler assessments are conducted using increasing levels of protection. The Agency typically evaluates all exposures with minimal protection and then considers additional protective measures using a tiered approach (going from minimal to maximum levels of protection) in an attempt to assess reduction in exposure achieved by each protective measure. The lowest tier is represented by the baseline clothing scenario (i.e., single layer clothing, socks, and shoes), followed by, if MOEs are of concern, increasing levels of risk mitigation, such as personal protective equipment (PPE) and engineering controls (EC). End-use product PPE will be assessed on a product-by-product basis. Maneb labels currently require double layer PPE and a chemical-resistant apron for mixing/loading; double layer PPE without the apron for applying; and a respirator for use of the dust formulation for potato seed treatment.

1) Agricultural and Greenhouse Handler Risks

To assess occupational agricultural and greenhouse handler risks, the Agency conducted the following risk assessments:

- Maneb - Agricultural and Greenhouse Handlers (Non-cancer; combined dermal and inhalation MOEs)
- ETU - Agricultural and Greenhouse Handlers (Non-cancer; combined dermal and inhalation MOEs)
- ETU - Agricultural and Greenhouse Handlers (Cancer)

To simplify this occupation risk summary, only maneb short/intermediate-term MOEs are presented in this section. Short/intermediate-term maneb risks for occupational agricultural and greenhouse handlers are summarized in Table 16. In addition, only ETU long-term MOEs are presented, and are summarized in Table 17. Measures to mitigate the risks presented in Tables 16 and 17 will also address risks from short/intermediate-term exposures to ETU and long-term exposures to maneb. ETU cancer risks for agricultural and greenhouse use are summarized in Table 18.

Table 16. Summary of Maneb Short/Intermediate-Term Combined MOEs for Agricultural Crops

Exposure Scenario	Crop Type	Application Rate (lb ai/acre)	Acres Treated/Day	Base-line	Single Layer	Single Layer + PF5	Double Layer + PF5	Double Layer + PF10	Eng. Controls
Mixer/Loader (M/L)									
M/L Wettable Powder (WP) for Aerial Application or Chemigation	turf: sod farms fruits and nuts field crops,vegetables	17.4 2.0 to 6.4 1.2 to 2.4	350	**0.55** **≥1.5** **≥4.0**	**1.3** **≥3.4** **≥9.1**	**5** **≥14** **≥36**	**5.3** **≥15** **≥39**	**8.9** **≥24** **≥64**	140 ≥390 >1000

Table 16. Summary of Maneb Short/Intermediate-Term Combined MOEs for Agricultural Crops

Exposure Scenario	Crop Type	Application Rate (lb ai/acre)	Acres Treated/Day	Base-line	Single Layer	Single Layer + PF5	Double Layer + PF5	Double Layer + PF10	Eng. Controls
M/L WP for Ground-boom	turf: sod farms cranberries, grapes field crops, vegetables ornamentals	17.4 2.0 to 4.8 1.2 to 2.4 1.2	80	**2.4** **≥8.7** **≥17** **70**	**5.5** **≥20** **≥40** 160	**22** **≥80** ≥160 640	**23** **≥85** ≥170 680	**39** **≥**140 ≥280 >1000	620 >1000 >1000 >1000
M/L WP for Airblast	fruits and nuts	2.0 to 6.4	40	**≥13**	**≥30**	≥120	≥130	≥210	>1000
M/L WP for HP Handwand	ornamentals, tomatoes	1.2 to 2.4	10	≥140	>300	>1000	>1000	>1000	>1000
M/L Dry Flowable (DF) for Aerial Application or Chemigation	turf: sod farms fruits and nuts field crops, vegetables	17.4 2.0 to 6.4 1.2 to 2.4	350	**31** **≥84** ≥220	**31** **≥84** ≥220	**46** ≥130 >300	**62** ≥170 >300	**67** ≥180 >300	ND ND ND
M/L DF for Groundboom	turf: sod farms All other crops	17.4 1.2 to 4.8	80	130 >400	130 >400	200 >700	270 >900	290 >1000	ND ND
M/L DF for Airblast	fruits and nuts	2.0 to 6.4	40	>700	>700	>1000	>1000	>1000	ND
M/L DF for HP Handwand	ornamentals, tomatoes	1.2 to 2.4	10	>1000	>1000	>1000	>1000	>1000	ND
M/L Liquids for Aerial Application or Chemigation	turf: sod farms fruits and nuts field crops, vegetables	17.4 2.0 to 6.4 1.2 to 2.4	350	**1.2** **≥3.2** **≥8.4**	**36** **≥**99 ≥260	92 ≥250 ≥670	110 >300 >800	110 >300 >1000	250 >600 >1000
M/L Liquids for Groundboom	turf: sod farms all other crops	17.4 1.2 to 4.8	80	**5.1** **≥18**	160 >500	400 >1000	480 >1000	620 >1000	>1000 >1000
M/L Liquids for Airblast	fruits and nuts	2.0 to 6.4	40	**≥28**	>800	>1000	>1000	>1000	>1000
M/L Liquids for HP Handwand	ornamentals, tomatoes	1.2 to 2.4	10	≥290	>1000	>1000	>1000	>1000	>1000
Applicator									
Aerial Application	turf: sod farms All other crops	17.4 1.2 to 6.4	350	NA - It was assumed that only closed cockpit aircraft are used.					380 >1000
Groundboom Application	turf: sod farms All other crops	17.4 1.6 to 4.8	80	260 >900	260 >900	660 >1000	750 >1000	980 >1000	>1000 >1000
Airblast Application	fruits and nuts	2.0 to 6.4	40	≥130	≥160	≥280	≥300	≥330	>1000
HP Handwand Application	ornamentals, tomatoes	1.2 to 2.4	10	>500	>1000	>1000	>1000	>1000	>1000
Mixer/Loader/Applicator (M/L/A)									
M/L/A WP with LP Handwand	tomatoes, ornamentals	1.2 to 2.4	0.4	No Data	≥290	>1000	>1000	>1000	N/A
M/L/A WP with Backpack Sprayer				No Data					

Table 16. Summary of Maneb Short/Intermediate-Term Combined MOEs for Agricultural Crops

Exposure Scenario	Crop Type	Application Rate (lb ai/acre)	Acres Treated/Day	Base-line	Single Layer	Single Layer + PF5	Double Layer + PF5	Double Layer + PF10	Eng. Controls
M/L/A DF with LP Handwand or Backpack Sprayer				No Data					
M/L/A Liquids with LP Handwand				≥210	>1000	>1000	>1000	>1000	>1000
M/L/A Liquids with Backpack Sprayer				No Data	>1000	>1000	>1000	>1000	>1000
Flagger									
Flag Aerial Applications	turf: sod farms All other crops	17.4 1.2 to 6.4	350	110 ≥290	100 ≥280	210 ≥580	230 >600	260 >700	>1000 >1000

***MOEs in bold are less than 100 and are of concern.**

Crop Groups

Fruits and nuts- includes almonds, cranberries, grapes and pome fruits.
Field crops - includes corn, dry beans, potatoes and sugar beets.
Vegetables - includes brassicca, curcurbits, garlic, greens, lettuce, onions, peppers and tomatoes

PPE Levels

Baseline - includes long pants and long sleeve shirts without gloves.
Single Layer (SL) - includes baseline PPE with chemical resistant gloves
Double Layer (DL) - includes coveralls over baseline PPE and chemical resistant gloves - typically required by the labels
PF5 - Filtering facepiece respirator (i.e. a dustmask) with a protection factor of 5
PF10 - Half face cartridge respirator with a protection factor of 10
EC - Engineering control - includes water soluble bags , closed loading systems and enclosed cabs.

Table 17. Summary of ETU Long-Term Combined MOEs for Agricultural Crops

Exposure Scenario	Crop Type	Application Rate (lb ai/acre)	Acres Treated per Day	Base-line	Single Layer	Single Layer + PF5	Single Layer + PF10	Double Layer + PF10	Eng. Controls
Mixer/Loader									
Mix/Load WP for HP Handwand	tomatoes (east) tomatoes (west) ornamentals	2.4 1.6 1.2	10 10 10	49 73 97	140 220 290	520 780 1000	780 >1000 >1000	880 >1000 >1000	>1000 >1000 >1000
Mix/Load DF for HP Handwand	ornamentals, tomatoes	1.2 to 2.4	10	>1000	>1000	>1000	>1000	>1000	No Data
Mix/Load Liquids for HP Handwand	tomatoes (East) tomatoes (West) ornamentals	2.4 1.6 1.2	10	88 130 180	>1000	>1000	>1000	>1000	>1000
Applicator									
HP Handwand Application	tomatoes (East) tomatoes (West) ornamentals	2.4 1.6 1.2	10	120 180 240	350 520 700	420 630 840	430 640 860	570 860 >1000	No Data
Mixer/Loader/Applicator									

Table 17. Summary of ETU Long-Term Combined MOEs for Agricultural Crops

Exposure Scenario	Crop Type	Application Rate (lb ai/acre)	Acres Treated per Day	Base-line	Single Layer	Single Layer + PF5	Single Layer + PF10	Double Layer + PF10	Eng. Controls
Mix/Load/Apply WP with LP Handwand	tomatoes (East) tomatoes (West) ornamentals	2.4 1.6 1.2	0.4	No Data	110 170 230	300 450 590	370 560 750	470 710 940	N/A
Mix/Load/Apply WP with Backpack Sprayer	ornamentals, tomatoes	1.2 to 2.4	0.4	No Data					
Mix/Load/Apply DF with LP Handwand or Backpack	ornamentals, tomatoes	1.2 to 2.4	0.4	No Data					
Mix/Load/Apply Liquids with LP Handwand	tomatoes (East) tomatoes (West) ornamentals	2.4 1.6 1.2	0.4	43 64 85	>1000	>1000	>1000	>1000	N/A
Mix/Load/Apply Liquids with Backpack Sprayer	tomatoes (East) tomatoes (West) ornamentals	2.4 1.6 1.2	0.4	ND	>1000	>1000	>1000	>1000	N/A

ND = No Data
N/A = Engineering Controls are Not Applicable

PPE Levels
Baseline - includes long pants and long sleeve shirts without gloves.
Single Layer (SL) - includes baseline PPE with chemical resistant gloves
Double Layer (DL) - includes coveralls over baseline PPE and chemical resistant gloves - typically required by the labels
PF5 - Filtering facepiece respirator (i.e. a dustmask) with a protection factor of 5
PF10 - Half face cartridge respirator with a protection factor of 10
EC - Engineering control - includes water soluble bags , closed loading systems and enclosed cabs.

Note: Ornamentals include carnations, chrysanthemums, dahlias, dogwood, gladiolus, lillies, pansies, peonies, roses, snapdragons, zinnias

Maneb Non-Cancer Risks. Several short/intermediate-term MOEs for maneb are of concern to the Agency at the current level of PPE (Table 16). For example, handlers mixing and loading wettable powders for aerial or chemigation applications to any crop; handlers mixing and loading wettable powders for groundboom application to turf; and handlers mixing and loading dry flowable for aerial or chemigation application to turf all require engineering controls to achieve MOEs >100. The remaining scenarios are acceptable with the addition of varying levels of PPE. The long-term maneb MOEs for all scenarios for which there are data are all 100 or greater at baseline PPE; therefore, these are not of concern to the Agency and not presented in a table in this document.

ETU Non-Cancer Risks: The short/intermediate-term MOEs for ETU are all greater than the maneb short/intermediate-term MOEs discussed above; therefore, these risk estimates are not presented in a table in this document. Any mitigation necessary to address the maneb short/intermediate-term risk will also adequately address the ETU short/intermediate term risks. The long-term MOEs for ETU are all 100 or greater for all of the scenarios listed at single layer PPE (Table 17); therefore, these are not of concern to the Agency

Table 18. Summary of ETU Cancer Risks for Agricultural Handlers

Exposure Scenario	Crop Type	Application Rate (lb ai/acre)	Acres Treated per Day	Base-line	Single Layer	Double Layer	Double Layer + PF5	Double Layer + PF10	Eng. Controls
Mixer/Loader (M/L)									
M/L WP for Aerial Application or Chemigation	turf: sod farms fruits and nuts field crops, vegetables	17.4 1.8 to 3.6 1.2 to 2.4	350	**2e-03** **<5e-04** <3e-04	**8e-04** <2e-04 <1e-04	**8e-04** <2e-04 <1e-04	2.e-04 <4e-05 <3e-05	1e-04 <3e-05 <2e-05	8e-06 <2e-06 <1e-06
M/L WP for Ground-boom	turf: sod farms grapes, cranberries field crops, vegetables ornamentals	17.4 1.8 to 3.0 1.2 to 2.4 1.2	80	**5e-04** <9e-05 <7e-05 2e-05	2e-04 <3e-05 <3e-05 6e-06	2e-04 <3e-05 <2e-05 6e-06	5e-05 <8e-06 <6e-06 2e-06	3e-05 <5e-06 <4e-06 1e-06	2e-06 <3e-07 <3e-07 7e-08
M/L WP for Airblast	fruits and nuts	1.9 to 3.6	40	<6e-05	<2e-05	<2e-05	<5e-06	<3e-06	<2e-07
M/L WP for HP Handwand	ornamentals, tomatoes	1.2 to 1.4	10	<6e-06	<2e-06	<2e-06	<5e-07	<3e-07	<2e-08
M/L DF for Aerial Application or Chemigation	turf: sod farms fruits and nuts field crops, vegetables	17.4 1.8 to 3.6 1.2 to 2.4	350	4e-05 <9e-06 <6e-06	4e-05 <9e-06 <6e-06	3e-05 <7e-06 <5e-06	2e-05 <5e-06 <3e-06	2e-05 <5e-06 <3e-06	ND ND ND
M/L DF for Groundboom	turf: sod farms All other crops	17.4 1.2 to 3.0	80	1e-05 <2e-06	1e-05 <2e-06	8e-06 <1e-06	5e-06 <9e-07	5e-06 <9e-07	ND ND
M/L DF for Airblast	fruits and nuts	1.8 to 3.6	40	<1e-06	<1e-06	<8e-07	<5e-07	<5e-07	ND
M/L DF for HP Handwand	ornamentals, tomatoes	1.2 to 1.4	10	<1e-07	<1e-07	<8e-08	<6e-08	<5e-08	ND
M/L Liquids for Aerial App or Chemigation	turf: sod farms fruits and nuts field crops, vegetables	17.4 1.8 to 3.6 1.2 to 2.4	350	**1e-03** <3e-04 <2e-04	3e-05 <6e-06 <4e-06	3e-05 <6e-06 <4e-06	1e-05 <2e-06 <2e-06	9e-06 <2e-06 <1e-06	5e-06 <1e-06 <7e-07
M/L Liquids for Groundboom	turf: sod farms All other crops	17.4 1.2 to 3.0	80	3e-04 <5e-05	7e-06 <1e-06	6e-06 <1e-06	3e-06 <5e-07	2e-06 <4e-07	1e-06 <2e-07
M/L Liquids for Airblast	fruits and nuts	1.8 to 3.6	40	<3e-05	<7e-07	<6e-07	<3e-07	<2e-07	<1e-07
M/L Liquids for HP Handwand	ornamentals, tomatoes	1.2 to 1.4	10	<3e-06	<7e-06	<7e-08	<3e-08	<2e-08	<1e-08
Applicator (App)									
Aerial App	turf: sod farms all other crops	17.4 1.2 to 3.6	350	No Data (ND)					5e-06 <9e-07
Groundboom App	turf: sod farms all other crops	17.4 1.2 to 3.0	80	5e-06 <9e-07	5e-06 <9e-07	5e-06 <8e-07	2e-06 <4e-07	2e-06 <3e-07	9e-07 <2e-07
Airblast App	fruits and nuts	1.8 to 3.6	40	<7e-06	<6e-06	<5e-06	<4e-06	<4e-06	<4e-07
HP Handwand Application	ornamentals, tomatoes	1.2 to 1.4	10	<2e-06	<8e-07	<6e-07	<5e-07	<5e-07	N/A

Table 18. Summary of ETU Cancer Risks for Agricultural Handlers

Exposure Scenario	Crop Type	Application Rate (lb ai/acre)	Acres Treated per Day	Base-line	Single Layer	Double Layer	Double Layer + PF5	Double Layer + PF10	Eng. Controls
Mixer/Loader/Applicator (M/L/A)									
M/L/A WP with LP Handwand	tomatoes, ornamentals	1.2 to 1.4	0.4	ND	<2e-06	<2e-06	<8e-07	<6e-07	N/A
M/L/A WP with Backpack , M/L/A DF with LP Handwand M/L/A DF with Backpack				No unit exposure data are available for these scenarios.					
M/L/A Liquids with LP Handwand	tomatoes, ornamentals	1.2 to 1.4	0.4	<7e-06	<8e-08	<8e-08	<3e-08	<3e-08	N/A
M/L/A Liquids with Backpack	tomatoes, ornamentals	1.2 to 1.4	0.4	ND	<2e-07	<2e-07	1e-07	<1e-07	N/A
Flagger									
Flag Aerial Applications	turf: sod farms all other crops	17.4 1.2 to 3.6	350	1e-05 <3e-06	1e-05 <3e-06	1e-05 <3e-06	8e-06 <2e-06	7e-06 <1e-06	2e-07 <4e-08

***Cancer Risks in Bold Equal or Exceed 1e-04 which is equivalent to 1 x 10^{-4}**

Crop Groups
Fruits and nuts- includes almonds, cranberries, grapes and apples.
Field crops - includes corn, dry beans, potatoes and sugar beets.
Vegetables - includes brassicca, curcurbits, garlic, greens, lettuce, onions, peppers and tomatoes

PPE Levels
Baseline - includes long pants and long sleeve shirts without gloves.
Single Layer (SL) - includes baseline PPE with chemical resistant gloves
Double Layer (DL) - includes coveralls over baseline PPE and chemical resistant gloves
PF5 - Filtering facepiece respirator (i.e. a dustmask) with a protection factor of 5
PF10 - Half face cartridge respirator with a protection factor of 10
EC - Engineering control

ETU Cancer Risks: The cancer risks for handlers mixing and loading wettable powders for aerial or chemigation application to any crop are greater than the risk range of 10^{-4} at the labeled PPE (double layer). Of these scenarios, risk estimates decrease within the range of an increased cancer risk of 1 x 10^{-6} considering the use of engineering controls (except handlers mixing and loading wettable powders for aerial or chemigation application to turf, with a cancer risk estimate of 8 x 10^{-6} with engineering controls). All other scenarios have risks less than the 10^{-4} range at the labeled level of PPE (double layer), and each of these decrease to within the range of an increased cancer risk of 1 x 10^{-6} with some level of PPE or engineering controls (except handlers mixing and loading liquids for aerial or chemigation application to turf). The ETU cancer risks are summarized in Table 18 above.

2) Handler Risk for Potato Seed-Piece Treatment

To assess occupational handler potato seed-piece treatment risks, the Agency conducted risk assessments, the results of which are summarized below. Long-term risks were not calculated for the seed-piece treatment scenarios, because the scenarios only occur for a few weeks or months at a time and do not occur on a year round basis.

- Maneb - Potato Seed-Piece Treatment (Non-cancer - short/intermediate-term combined dermal and inhalation MOEs)
- ETU - Potato Seed-Piece Treatment (Non-cancer - short/intermediate-term combined dermal and inhalation MOEs)
- ETU - Potato Seed-Piece Treatment (Cancer)

Table 19. Maneb Combined Short/Intermediate Term MOEs for Potato Seed-Piece Treatment

Exposure Scenario	Treatment Rate	Amount Treated per Day	Base-line	Single Layer	Single Layer + PF5	Single Layer + PF10	Double Layer + PF10	Eng Controls
Mix/Load								
Load Dusts for Commercial Seed-Piece Treatment	0.08 lb ai/cwt	10,000 cwt	**4.2**	**9.5**	**38**	**61**	**68**	1100
Load Dusts for On-Farm Seed-Piece Treatment	0.08 lb ai/cwt	800 cwt	**52**	120	480	770	850	14000
Applicator								
Apply Dusts During Commercial or On-Farm Seed-Piece Treatment	0.08/cwt	10,000 cwt	There is no unit exposure data available for this scenario.					
Secondary Handler Exposure								
Load Treated Seed Pieces for Planting	1.6 lb ai/acre	40 acres	3000	3000	12000	19000	24000	No Data
Plant Treated Seed Pieces	1.6 lb ai/acre	40 acres	4000	4100	15000	23000	29000	22000

Maneb Non-Cancer Risks: Risks of concern are indicated for handlers mixing and loading maneb dust formulations for commercial potato seed-piece treatment, and would require a closed-capture (engineering control) system to exceed the target MOE of 100. Risks of concern are also indicated for handlers mixing and loading dusts for on-farm potato seed-piece treatment, and would require the addition of gloves (single layer PPE). There is no unit exposure data to assess risks to applicators applying dusts; however, the Agency believes that these risks will not be greater than for handlers mixing and loading dusts. There are no risks to secondary handlers handling the treated seed-pieces at baseline PPE (Table 19).

ETU Non-Cancer Risks: The short/intermediate term ETU non-cancer MOEs for seed-piece treatment are greater than the corresponding maneb non-cancer MOEs presented in Table 19 above and are above 100 for all of the scenarios if gloves are worn. As such, these MOEs are not tabulated in this document.

Table 20. ETU Cancer Risks from Maneb Potato Seed-Piece Treatment

Exposure Scenario	Typical Application Rate	Amount Treated Daily	Single Layer	Single Layer + PF5	Single Layer + PF10	Double Layer + PF10	Eng Controls
Mixer/Loader							
Load Dusts for Commercial Seed-Piece Treatment	0.098 lb ai/cwt	10000 cwt	1e-04	3e-05	1e-05	7e-06	1e-06
Load Dusts for On-Farm Seed-Piece Treatment	0.098 lb ai/cwt	800 cwt	8e-06	2e-06	8e-07	6e-07	9e-08

Table 20. ETU Cancer Risks from Maneb Potato Seed-Piece Treatment							
Exposure Scenario	**Typical Application Rate**	**Amount Treated Daily**	**Single Layer**	**Single Layer + PF5**	**Single Layer + PF10**	**Double Layer + PF10**	**Eng Controls**
Applicator							
On-Farm Seed-Piece Treatment - Apply Dusts	0.098	No Data	No unit exposure data are available for this scenario.				
Secondary Handler Exposure							
Load Treated Seed Pieces for Tractor Planting	1.6 lb ai/acre	40 acres	3e-07	9e-08	6e-08	5e-08	No Data
Tractor Plant Treated Seed Pieces			2e-07	8e-08	3e-08	2e-08	5e-08

ETU Cancer Risks: The cancer risks for loading dusts for commercial seed piece treatment are 10^{-4} at single layer PPE. Engineering controls would be needed for this scenario to achieve a cancer risk within the range of 10^{-6}. The cancer risk for loading dusts for on-farm seed-piece treatment is greater than 10^{-6} at single layer PPE; the addition of a dust/mist respirator is needed to mitigate these risks. As stated above, no data are available to assess risks to applicators; however the Agency believes that risks to applicators will not be greater than risks to handlers mixing and loading dusts for seed treatment. The cancer risks of handling the treated seed pieces are less than 10^{-6} with single layer PPE (Table 20).

Occupational Handler for Seed Treatment

To assess occupational handler seed treatment risks, the Agency conducted the risk assessments listed below. Long term risks were not calculated for the seed treatment scenarios, because the scenarios only occur for a few weeks or months at a time and do not occur on a year round basis.

- Maneb - Seed Treatment (Non-cancer - combined short/intermediate-term dermal and inhalation MOEs)
- ETU - Seed Treatment (Non-cancer - combined short/intermediate-term dermal and inhalation MOEs)
- ETU - Seed Treatment (Cancer)

Table 21. Maneb Short/Intermediate-Term Combined MOEs for Seed Treatment									
Exposure Scenario	**Seed Type**	**Application Rate (lb ai/lb seed)**	**Amount Treated (lb seed/day)**	**Baseline**	**Single Layer**	**Single Layer + PF5**	**Single Layer + PF10**	**Double Layer + PF10**	**Eng Control**
Loader/Applicator (1)	cotton (adl)	0.0015	160000	ND	1900	3200	3500	4300	ND
	tomato	0.004	88000	ND	1300	2200	2400	2900	ND
	flax	0.0035	160000	ND	810	1400	1500	1800	ND
	safflower	0.001	718000	ND	630	1100	1200	1400	ND
	peanuts	0.008	120000	ND	470	790	860	1100	ND
	wheat	0.0016	718000	ND	390	660	720	900	ND
	barley, rice, rye	0.002	718000	ND	320	530	580	720	ND
	corn (field)	0.0027	550000	ND	300	510	560	700	ND
	sorghum	0.0023	718000	ND	270	460	500	630	ND
	oats	0.0031	718000	ND	200	340	370	460	ND
Bagger (2)	Same as above			Baseline MOEs are 500 or greater					
Sewer (3)	Same as above			Baseline MOEs are 470 or greater					

Table 21. Maneb Short/Intermediate-Term Combined MOEs for Seed Treatment									
Exposure Scenario	**Seed Type**	**Application Rate (lb ai/lb seed)**	**Amount Treated (lb seed/day)**	**Baseline**	**Single Layer**	**Single Layer + PF5**	**Single Layer + PF10**	**Double Layer + PF10**	**Eng Control**
Multiple Activities (4)	cotton (adl)	0.0015	160000	ND	630	1400	1700	ND	ND
	tomato	0.004	88000	ND	430	970	1200	ND	ND
	flax	0.0035	160000	ND	270	610	730	ND	ND
	safflower	0.001	718000	ND	210	480	570	ND	ND
	peanuts	0.008	120000	ND	160	360	420	ND	ND
	wheat	0.0016	718000	ND	130	300	350	ND	ND
	barley, rice, rye	0.002	718000	ND	110	240	280	ND	ND
	corn (field)	0.0027	550000	ND	100	230	270	ND	ND
	sorghum	0.0023	718000	ND	**92**	210	250	ND	ND
	oats	0.0031	718000	ND	**68**	150	180	ND	ND
Planter Box Seed Treatments Using Dusts (5a)	corn	0.0017	1440	ND	660	660	660	ND	ND
	rye	0.0011	6720	ND	220	220	220	ND	ND
	barley	0.0013	7200	ND	170	170	170	ND	ND
	wheat	0.0010	9600	ND	170	170	170	ND	ND
	oats	0.0020	7200	ND	110	110	110	ND	ND
Planter Box Seed Treatments Using Liquids (5a)	tomato	0.0042	80	ND	4800	4800	4800	ND	ND
	safflower	0.0011	1600	ND	910	910	910	ND	ND
	cotton adl	0.0015	1200	ND	890	890	890	ND	ND
	sorghum	0.0023	1200	ND	580	580	580	ND	ND
	field corn	0.0027	1440	ND	410	410	410	ND	ND
	flax	0.0035	3360	ND	140	140	140	ND	ND
	rye	0.0018	6720	ND	130	130	130	ND	ND
	barley	0.0021	7200	ND	110	110	110	ND	ND
	wheat	0.0016	9600	ND	100	100	100	ND	ND
	oats	0.0031	7200	ND	**72**	**72**	**72**	ND	ND
	rice	0.0021	12000	ND	**64**	**64**	**64**	ND	ND
	peanuts	0.008	11200	ND	**18**	**18**	**18**	ND	ND
Plant Treated Seeds (6)	Same as above.		80 to 30000	ND	Single layer MOEs are 520 or greater.				

Maneb Non-Cancer Risks: Most of the maneb short/intermediate-term combined MOEs for handlers treating seeds or handlers planting treated seed exceed the target MOE of 100 with single layer PPE. Handlers performing multiple activities to treat sorghum seeds and oat seeds with maneb exceed the Agency's level of concern, and a dust/mist respirator is needed to mitigate those risks. Handlers using liquid maneb formulation in planter box seed treatment to treat oats, rice, and peanut seeds exceed the Agency's level of concern, even considering the use of additional PPE, and additional mitigation measures (e.g., decreasing rates or cancelling the use) must be considered (Table 21).

ETU Non-Cancer Risks. The short/intermediate term ETU MOEs for seed treatment are greater than the corresponding maneb MOEs and are above 100 for all of the scenarios. As such, these MOEs are not tabulated in this document.

Table 22. ETU Cancer Risks from Maneb Seed Treatment									
Exposure Scenario	**Seed Type**	**Application Rate (lb ai/lb seed)**	**Amount Treated (lb seed/day)**	**Baseline**	**Single Layer**	**Single Layer + PF5**	**Single Layer + PF10**	**Double Layer + PF10**	**Eng Control**
Commercial Seed Treatment									
Loader/Applicator (1)	cotton (adl)	0.0015	160000	ND	7e-07	4e-07	4e-07	3e-07	ND
	tomato	0.004	88000	ND	1e-06	7e-07	6e-07	5e-07	ND
	flax	0.0035	160000	ND	2e-06	1e-06	1e-06	8e-07	ND
	safflower	0.001	718000	ND	2e-06	1e-06	1e-06	1e-06	ND
	peanuts	0.008	120000	ND	3e-06	2e-06	2e-06	1e-06	ND
	wheat	0.0016	718000	ND	3e-06	2e-06	3e-06	2e-06	ND
	barley, rice, rye	0.002	718000	ND	4e-06	3e-06	3e-06	2e-06	ND
	corn (field)	0.0027	550000	ND	4e-06	3e-06	3e-06	2e-06	ND
	sorghum	0.0023	718000	ND	5e-06	3e-06	3e-06	2e-06	ND
	oats	0.0031	718000	ND	6e-06	4e-06	4e-06	3e-06	ND
Bagger (2)	Same as above			Baseline Cancer Risks are 2e-06 or less.					
Sewer (3)	Same as above			Baseline Cancer Risks are 2e-06 or less.					
Multiple Activities (4)	Same as above			ND	<2e-05	<9e-06	<8e-06	ND	ND
On-Farm Seed Treatment									
Planter Box Seed Treatment Using Dusts (5a)	corn	0.0017	1440	ND	8e-07	8e-07	8e-07	ND	ND
	rye	0.0011	6720	ND	2e-06	2e-06	2e-06	ND	ND
	barley	0.0013	7200	ND	3e-06	3e-06	3e-06	ND	ND
	wheat	0.0010	9600	ND	3e-06	3e-06	3e-06	ND	ND
	oats	0.0020	7200	ND	5e-06	5e-06	5e-06	ND	ND
Planter Box Seed Treatments Using Liquids (5b)	tomato	0.0042	80	ND	1e-07	1e-07	1e-07	ND	ND
	safflower	0.0011	1600	ND	6e-07	6e-07	6e-07	ND	ND
	cotton adl	0.0015	1200	ND	6e-07	6e-07	6e-07	ND	ND
	sorghum	0.0023	1200	ND	9e-07	9e-07	9e-07	ND	ND
	field corn	0.0027	1440	ND	1e-06	1e-06	1e-06	ND	ND
	flax	0.0035	3360	ND	4e-06	4e-06	4e-06	ND	ND
	rye	0.0018	6720	ND	4e-06	4e-06	4e-06	ND	ND
	barley	0.0021	7200	ND	5e-06	5e-06	5e-06	ND	ND
	wheat	0.0016	9600	ND	5e-06	5e-06	5e-06	ND	ND
	oats	0.0031	7200	ND	7e-06	7e-06	7e-06	ND	ND
	rice	0.0021	12000	ND	8e-06	8e-06	8e-06	ND	ND
	peanuts	0.008	11200	ND	3e-05	3e-05	3e-05	ND	ND
Planting Treated Seed									
Plant Treated Seeds (6)	Same as above.		80 to 30000	ND	Single layer Cancer risks are 8e-07 or less.				

ETU Cancer Risks: The cancer risks for handlers treating seeds (commercially or on farm) or handlers planting treated seed are all equal to or less than 2×10^{-5} at single layer PPE. Cancer risks associated with most scenarios are within the range of 1×10^{-6} with the addition of PPE including a respirator with a protection factor of 10.

b. Post-Application Assessments

The post-application occupational risk assessment considers exposure to chemical maneb and maneb-derived ETU from entering treated fields, sod farms, orchards, and greenhouses. Given the nature of activities in these locations and that maneb is applied at various times during plant growth, contact with treated surfaces is likely. A variety of post-application exposure scenarios were identified by the type of activity involved and by the range of exposure expected, i.e., low, medium and high exposure activities. Examples of low exposure activities include irrigation and scouting; medium exposure activities may involve scouting of mature plants, or in greenhouses, hand pinching

flowers. Potential high exposure activities include hand harvesting, and thinning and pruning apples, and very high exposure activities include sweet corn hand harvesting. In the Worker Protection Standard, a Restricted-Entry Interval (REI) is defined as the duration of time which must elapse before residues decline to a level so entry into a previously treated area and engaging in any task or activity would not result in exposures which are of concern.

Post-Application Exposures and Assumptions

Six chemical-specific dislodgeable foliar residue (DFR) studies were submitted for maneb, and four of these were used, along with typical HED transfer coefficients, to estimate post-application exposure and risk for all crops/ornamentals potentially treated with maneb. The six DFR studies were conducted on apples in New York and Washington State, tomatoes in California and Florida, and grapes in California. One of the apple studies (New York) is not being used because no field fortification data were collected, and one of the Florida tomato studies is not being used because of low field recovery and weak correlation. The DFR studies were extrapolated to other crops on which maneb is used by considering the effects of application method, crop morphology, and climate. No Turf Transferable Residue (TTR) studies were submitted for maneb, therefore, a mancozeb TTR study was used as a source of surrogate data.

Maneb Non-Cancer Post-Application Risks: Current maneb label requirements specify a 24 hour REI. Most of the short/intermediate-term maneb MOEs exceed 100 on day 0, and are not of concern to the Agency. However, for workers reentering treated corn fields, tree fruit orchards, and grape orchards to conduct high exposure activities, the time needed to achieve maneb MOEs of 100 ranges up to 26 days, with the longest time needed for reentering grape orchards for training and tying in the West (Table 23).

Table 23. Maneb Short/Intermediate-Term Post-Application Non-Cancer Risks

Crop Group	Application Rate (lb a.i/acre)	MOE on Day 0 (Days when MOE > 100)			
		Low	Medium	High	Very High
Berry, low (Cranberry)	4.8	220	NA	NA	NA
Bunch/bundle (Banana)	2.4	4000	300	200	NA
Field/row crops, Low/Medium - West Field/row crops, Low/Medium - East	1.6 1.6	8200 5900	550 400	NA NA	NA NA
Field/Row crop, tall (Corn) - West Field/Row crop, tall (Corn) - East	1.2 1.2	NA NA	2700 2000	1100 790	64 (5) 46 (11)
Flowers, cut	1.2	NA	NA	160	NA
Ornamental Plants	1.2	7200	4500	2000	NA
Tree, fruit, deciduous - West Tree, fruit, deciduous - East	2..4	260 180	NA	86 (5) 58 (6)	NA
Tree, fruit, evergreen (Papaya)	2	470	160	NA	NA
Tree, nut (Almond)	6.4	190	NA	NA	NA

Table 23. Maneb Short/Intermediate-Term Post-Application Non-Cancer Risks					
Crop Group	**Application Rate (lb a.i/acre)**	**MOE on Day 0 (Days when MOE > 100)**			
		Low	**Medium**	**High**	**Very High**
Turf - California Turf - North Carolina Turf - Pennsylvania	17.4 17.4 17.4	18000 32000 41000	NA NA NA	550 960 1200	NA NA NA
Vegetable, Brassica - West Vegetable, Brassica - East	1.6 1.6	410 300	210 150	160 120	NA NA
Vegetable, Cucurbit - West Vegetable, Cucurbit - East	1.6 1.6	1600 1200	550 400	330 240	NA NA
Vegetable, fruiting - West Vegetable, fruiting - East	1.6 2.4	1600 790	1200 560	820 400	NA NA
Vegetables, leafy - West Vegetables, leafy - East	1.6 1.6	1600 1200	550 400	330 240	NA NA
Vegetable, root - West Vegetable, root - East	2.4 2.4	1800 1300	370 260	220 160	NA NA
Vine/trellis (Grapes) - West Vine/trellis (Grapes) - East	2.0 3.2	590 260	290 130	**59 (26)** **26 (14)**	NA NA

ETU Non-Cancer Post-Application Risks (Short/Intermediate Term): Current maneb label requirements specify a 24 hour REI. Most of the short/intermediate-term ETU MOEs exceed 100 on day 0, and are not of concern to the Agency. However, for workers reentering treated tree fruit orchards, and grape orchards in the East to conduct high exposure activities, the time needed to achieve ETU MOEs of 100 ranges up to 19 days, with the longest time needed for reentering tree fruit orchards in the West for pruning, training, tying, and thinning (Table 24).

Table 24. ETU from Maneb Post-Application Non-Cancer Risks (Short/Intermediate Term)					
Crop Group	**Application Rate (lb a.i./acre)**	**MOE on Day 0 (Days when MOE > 100)**			
		Low	**Medium**	**High**	**Very High**
Berry, low (Cranberry)	4.8	200	NA	NA	NA
Bunch/bundle (Banana)	2.4	32000	2500	1600	NA
Field/row crops, Low/Medium - West Field/row crops, Low/Medium - East	1.6 1.6	52000 49000	3500 3200	NA NA	NA NA
Field/Row crop, tall (Corn) - West Field/Row crop, tall (Corn) - East	1.2 1.2	NA NA	17000 16000	6900 6500	410 380
Flowers, cut	1.2	NA	NA	1300	NA
Ornamental Plants	1.2	59000	37000	16000	NA
Tree, fruit, deciduous - West	2.4	150	NA	**49 (19)**	NA
Tree, fruit, deciduous - East	2.4	160	NA	**54 (8)**	NA
Tree, fruit, evergreen (Papaya)	2	3900	1300	NA	NA
Tree, nut (Almond)	6.4	110	NA	NA	NA

Table 24. ETU from Maneb Post-Application Non-Cancer Risks (Short/Intermediate Term)					
Crop Group	**Application Rate (lb a.i./acre)**	**MOE on Day 0 (Days when MOE > 100)**			
		Low	**Medium**	**High**	**Very High**
Turf - California	17.4	14000	NA	410	NA
Turf - North Carolina	17.4	81000	NA	2500	NA
Turf - Pennsylvania	17.4	110000	NA	3400	NA
Vegetable, Brassica - West	1.6	2600	1300	1000	NA
Vegetable, Brassica - East	1.6	2400	1200	970	NA
Vegetable, Cucurbit - West	1.6	10000	3500	2100	NA
Vegetable, Cucurbit - East	1.6	9700	3200	1900	NA
Vegetable, fruiting - West	1.6	10000	7400	5200	NA
Vegetable, fruiting - East	2.4	6500	4600	3200	NA
Vegetables, leafy - West	1.6	10000	3500	2100	NA
Vegetables, leafy - East	1.6	9700	3200	1900	NA
Vegetable, root - West	2.4	12000	2300	1400	NA
Vegetable, root - East	2.4	11000	2200	1300	NA
Vine/trellis (Grapes) - West	2.0	4500	2100	430	NA
Vine/trellis (Grapes) - East	3.2	240	120	**24 (17)**	NA

ETU Non-Cancer Post-Application Risks (Chronic): The chronic ETU MOEs presented in Table 25 for greenhouse tomatoes, ornamental plants, and cut flowers exceed 100 on day 0 and are not of concern to the Agency.

Table 25. ETU from Maneb Post-Application Non-Cancer Risks (Chronic)				
Crop Group	**Application Rate (lb ai/acre)**	**Long term MOE on Day 0 (Days when MOE >100)**		
		Low	**Medium**	**High**
Greenhouse Cut Flowers	1.2	NA	NA	100
Greenhouse Ornamental Plants	1.2	2500	1500	680
Greenhouse Tomatoes	2.4	270	190	140

ETU Cancer Post-Application Risks: All ETU cancer risks are less than or in the range of 10^{-4} on the day of application for all of the scenarios. The risks for many of the remaining high exposure scenarios decline to within the range of less than 1 x 10^{-6} several weeks after application, with the longest taking greater than 80 days (grapes in the West).

Table 26. ETU from Maneb Post-Application Cancer Risks					
Crop Group	**Application Rate (lb a.i./acre)**	**Cancer Risk on Day 0**			
		Low	**Medium**	**High**	**Very High**
Berry, low (Cranberry)	3	3e-05	NA	NA	NA
Bunch/bundle (Banana)	2.4	0	4e-06	7e-06	NA

Table 26. ETU from Maneb Post-Application Cancer Risks					
Crop Group	**Application Rate (lb a.i./acre)**	**Cancer Risk on Day 0**			
		Low	**Medium**	**High**	**Very High**
Field/row crops, Low/Medium - West Field/row crops, Low/Medium - East	1.6 1.6	2e-07 2e-07	3e-06 3e-06	NA NA	NA NA
Field/Row crop, tall (Corn) - West Field/Row crop, tall (Corn) - East	1.2 1.2	NA NA	6e-07 7e-07	2e-06 2e-06	3e-05 3e-05
Flowers, cut	1.2	NA	NA	4e-06	NA
Ornamental Plants	1.2	2e-07	3e-07	7e-07	NA
Tree, fruit, deciduous - West	3.6	1e-04	NA	2e-04	NA
Tree, fruit, deciduous - East	3.6	1e-04	NA	2e-04	NA
Tree, fruit, evergreen (Papaya)	2	3e-06	8e-06	NA	NA
Tree, nut (Almond)	3.1	5e-05	NA	NA	NA
Turf - California Turf - North Carolina Turf - Pennsylvania	17.4 17.4 17.4	8e-07 1e-07 9e-08	NA NA NA	3e-05 4e-06 3e-06	NA NA NA
Vegetable, Brassica - West Vegetable, Brassica - East	1.6 1.6	4e-06 4e-06	8e-06 9e-06	1e-05 1e-05	NA NA
Vegetable, Cucurbit - West Vegetable, Cucurbit - East	1.6 1.6	1e-06 1e-06	3e-06 3e-06	5e-06 6e-06	NA
Vegetable, fruiting - West Vegetable, fruiting - East	1.4 1.4	1e-06 1e-06	1.2e-06 1.3e-06	2e-06 2e-06	NA NA
Vegetables, leafy - West Vegetables, leafy - East	1.6 1.6	1e-06 1e-06	3e-06 3e-06	5e-06 6e-06	NA NA
Vegetable, root - West Vegetable, root - East	2.4 2.4	9.2e-07 9.8e-07	5e-06 5e-06	8e-06 8e-06	NA NA
Vine/trellis (Grapes) - West Vine/trellis (Grapes) - East	1.8 2.1	2e-06 3e-05	5e-06 6e-05	2e-05 3e-04	NA NA

c. Human Incident Data

The most recent assessment of maneb incidents was completed in 2002. Information sources consulted included the OPP Incident Data System (IDS), the Poison Control Centers (1993 to 1998), and the California Pesticide Illness Surveillance Program (1982 to 1999). There were no incidents reported in the OPP Incident Data System from 1992 to 2001. There were 37 exposures reported to the Poison Control Centers (1993-1998) and 24 received follow-up to determine medical outcome. Ten experienced no symptoms and 14 experienced minor symptoms, primarily nausea and diarrhea. There were four reports of dermal effects and three were considered to be related to their exposure. There were 18 cases reported in the California Pesticide Illness Surveillance Program (1982-1999) in which maneb was used alone or was judged to be responsible for the health effects. Twelve of these cases involved post-application exposure to field residues and the most common effect was skin rashes. The reports in the literature also indicated that maneb causes skin sensitization.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. For detailed discussions of all aspects of the environmental risk assessment refer to the following document: *Environmental Fate and Ecological Risk Assessment for Maneb, Section 3 Reregistration for Control of Fungal Diseases on Numerous Crops, Ornamental Plantings, and Turf (Error Correction Response)*, dated June 21, 2005, which is available on the internet and in the public docket.

1. Environmental Fate and Transport

Maneb is a high molecular weight polymer composed of repeating single units containing manganese ions/salts. Parent maneb is insoluble in water but is expected to decompose rather quickly, by hydrolytic reactions, into a multi-species residue (maneb complex) consisting of transient species and degradates including the degradate of concern ETU. Most of the species present in the maneb residue are expected to partition into the soil/sediment particles; with varied strength of bonding. These soil associated materials are not largely affected by abiotic degradation, but are susceptible to very slow bio-degradation possibly further producing degradates, including ETU, at a very slow rate.

Due to rapid hydrolytic decomposition, parent maneb is expected to exist in the natural environment for a short duration (<1 day) when moisture is available. Parent maneb appears to be stable in alkaline (3 hours at pH 9), neutral (3 hours at pH 7) and acidic (4 hours at pH 5) conditions. In dry conditions and in soils with very low water holding capacity parent maneb decomposition is slow. Maneb has low octanol/water partition coefficients (K_{ow}) suggesting that it would not be significantly bio-concentrated by aquatic organisms. Furthermore, maneb has a very low vapor pressure, thus indicating that volatilization is not an important dissipation pathway. This rate is largely dependent on moisture availability and, therefore, in dry conditions and in soils with very low water holding capacity, parent maneb will persist.

The degradate of concern (ETU) is predicted to be susceptible to leaching due to its high solubility and mobility. In the soil environment, ETU lacks stability which can limit its leaching; however, its possible slow and steady formation from maneb complex can overcome the lack of stability and make it available for leaching at low concentrations. ETU has an aerobic soil half-life of about 3 days; in the absence of data, the aquatic aerobic metabolism half-life was assumed to be about 6 days, or double the soil half life. The measured anaerobic aquatic metabolism half-life, however, is substantially longer (149 days) possibly leading to the periodic detections in ground water. ETU is highly soluble in water (20,000 ppm), highly vulnerable to indirect photolysis (half-life= 1 day), and moderately mobile (288 L/kg). It also has a high vapor pressure, but high solubility reduces the possibility of losses from surface water due to volatilization.

2. Ecological Risk Presumptions

The pesticide use profile, exposure data, and toxicity information are used to determine risk estimates to non-target terrestrial and aquatic organisms. The EECs are used to calculate RQs. An RQ is the estimated ratio of exposure concentration to the toxicity endpoint. The calculated RQs use

the EECs that are based on the maximum single application rate of maneb, which would yield the maximum maneb exposure estimates. The RQ is then compared to the LOC to predict whether exposure to maneb and its degradates could pose a risk to non-target organisms. Table 27 outlines the Agency's LOCs and the corresponding risk presumptions.

Table 27. Agency's LOCs and Risk Presumptions

If RQ > LOC value given below.....			Then EPA presumes .....
Terrestrial Organisms	**Aquatic Organisms**	**Plants**	**Risk Presumption**
0.5	0.5	1	**Acute Risk -** there is potential for acute risk; regulatory action may be warranted in addition to restricted use classification.
0.2	0.1	N/A	**Acute Restricted Use -** there is potential for acute risk, but may be mitigated through restricted use classification.
0.1	0.05	1	**Acute Endangered Species -** endangered species may be adversely affected; regulatory action may be warranted.
1	1	N/A	**Chronic Risk -** there is potential for chronic risk; regulatory action may be warranted.

Note that the following ecological risks are based on parent maneb only. EPA did not estimate ETU exposure or potential ecological risk from ETU as a result of use of maneb. The Agency expects ecological ETU exposure and risk resulting from maneb's uses to be encompassed by ETU exposure and risk resulting from mancozeb's uses because the EBDCs share similar application patterns. The Agency chose ETU from mancozeb uses as a surrogate assessment to determine exposure and risk from any ETU because mancozeb has the broadest use pattern of the EBDCs, thus providing a comprehensive view of risks posed by ETU. ETU exposure and risk as a result of mancozeb application are addressed in the mancozeb RED.

In summary, chronic mammalian ETU RQs exceed the LOC for most of mancozeb's use patterns, especially for small- and medium-sized mammals. ETU is practically acutely nontoxic to mammals, and EPA does not expect acute risks to mammals from ETU exposure. EPA does not have any toxicity data to evaluate ETU's toxicity to birds. In aquatic habitats, RQs are less than the LOCs for ETU's acute risk to freshwater fish, freshwater invertebrates, and nonvascular plants from use of mancozeb. The Agency does not have data to evaluate ETU's acute risks to estuarine/marine fish and invertebrates, and vascular aquatic plants. Overall, based on available toxicity data, the ETU ecological risks assessed for mancozeb use are less than the corresponding maneb parent risks. As such, measures to address ecological risk from maneb parent, as part of this RED, will address potential maneb-derived ETU exposures as well.

3. Risk to Terrestrial Organisms

a. Birds and Mammals Exposure and Toxicity

The Agency assessed exposure to terrestrial organisms by first predicting the amount of maneb residues found on animal food items and then, using information on typical food consumption by various species of birds and mammals, to predict the amount of pesticide that could be consumed. The amount of residues on animal feed items are based on the Fletcher nomogram which is a model developed by Hoerger and Kenaga (1972) and modified by Fletcher (1994). Thus, EPA modeled the maximum and mean residues of maneb, immediately following a single application at 1 lb ai/A. EPA's estimates of maneb residues on various wild animal food items are summarized in Table 28. EPA used these EECs and standard food consumption values to estimate dietary exposure levels for maneb to birds and mammals.

Table 28. Estimated Environmental Concentrations on Avian and Mammalian Food Items

Food Items	EEC (ppm) Predicted Maximum Residue[1]	EEC (ppm) Predicted Mean Residue[1]
Short grass	240	85
Tall grass	110	36
Broadleaf/forage plants and small insects	135	45
Fruits, pods, seeds, and large insects	15	7

[1] Predicted maximum and mean residues are for a 1 lb ai/a application rate and are based on Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994).

Maneb is categorized as practically nontoxic to avian species and small mammals on an acute oral and subacute dietary basis. The acute toxicity profile for birds and mammals is summarized in Table 29.

Table 29. Maneb Acute Toxicity Endpoints for Birds and Mammals

Toxicity Study	Test Species	% a.i.	Endpoint	Toxicity Category	MRID Author Year
Acute (Single dose by gavage)					
Avian Oral	Bobwhite Quail	86	LD50 = >2,150 mg/kg/day	Practically nontoxic	40657001 D. Fletcher 1988
Mammalian Oral	Laboratory Rat	Unknown	LD50 = >5,000 (male & female) mg/kg/day	Practically nontoxic	41975601
Subacute (Five days of treated feed)					
Avian Dietary	Bobwhite Quail	assumed 100%	LC50 = >10,000 ppm ai	Practically nontoxic	00104264 R. Fink 1975

Table 29. Maneb Acute Toxicity Endpoints for Birds and Mammals					
Toxicity Study	**Test Species**	**% a.i.**	**Endpoint**	**Toxicity Category**	**MRID Author Year**
Avian Dietary	Mallard Duck	86 (doses were adjusted to 100%)	LC50 = >5,000 ppm ai	Practically nontoxic	40657002 D. Fletcher 1988

In a maneb avian reproduction study using the mallard duck, chronic toxic effects were seen which included a reduction in the number of hatchlings as percentages of eggs laid, eggs set, and live 3-week old embryos, and a reduction in the number of 14-day old survivors as a percentage of eggs set. Results from chronic 2-generation reproduction study for maneb in laboratory rats show parental and fetal toxicity at a LOAEL of 300 ppm with parental toxicity resulting in significant increase in lung weight (both generations) and liver weight in F1 (one generation removed from the original parent generation) and an increased incidence of diffuse follicular epithelial hypertrophy/hyperplasia (lesions on the organs' surfaces) in F1. Fetal toxicity at this test concentration (300 ppm) was also noted based on a slight delay in the startle response in the offspring. These endpoint are summarized in Table 30.

Table 30. Maneb Chronic Toxicity Endpoints for Birds and Mammals					
Test Species	**% a.i**	**NOAEC or NOAEL (ppm)**	**LOAEC or LOAEL (ppm)**	**Effects at LOAEC or LOAEL**	**MRID**
Mallard Duck	91	20	100	Reduced hatchling survival at 14 days	43586502
Laboratory Rat	87.3	75	300	Paternal - Increased lung (both generations) and liver weight and increased lesions on organs' surface Fetal - Delay in the startle response	42049401
NOAEC / LOAEC = No Observable Adverse Effect Concentration, the highest dose at which no adverse health effect is observed./ Lowest Observable Adverse Effect Concentration, the lowest dose at which an adverse health effect is observed. **NOAEL / LOAEL**= No Observable Adverse Effect Level, the highest dose at which no adverse health effect is observed / Lowest Observable Adverse Effect Level, the lowest dose at which an adverse health effect is observed.					

b. Birds and Mammals Risk

The acute risk to terrestrial animals from maneb's use are a low risk concern since maneb has been determined to be practically nontoxic to birds and mammals on an acute basis. Therefore, acute RQs were not generated for birds or mammals. The Agency expects chronic risk to birds and mammals from maneb's uses. Avian and mammalian RQs exceed the chronic LOCs for almost all use maneb modeled exposures. Based on multiple applications, the chronic RQs for birds range from a high of 265 on turf to a low of 0.4 on collards, turnips, and mustards (Georgia and Tennessee only) using a half-life value of 3.2 days. Table 31 summarizes the avian chronic RQs from multiple applications of maneb.

Table 31. Avian Chronic RQs from Maneb Application			
Crop	**Maximum Application Rate (lbs a.i./A)**	**Avian Chronic RQs (NOAEC= 20 ppm)**	
		Based on maximum EECs	**Based on mean EECs**
		Range = Shortgrass - Seeds	
Turf	17.4	265 - 17	94 - 8
Almonds	6.4	98 - 6	35 - 3
Apples	4.8	74 - 5	26 - 2
Potatoes (MN only)	1.6	29 - 2	10 - 1
Mustard, Collards & Turnips (GA & TN only)	1.2	15 - 1	5 - 0.4

Chronic RQs for mammals ranged from a high of 71 on turf to a low of 0.1 on collards, turnips, and mustards (Georgia and Tennessee only). The Agency expects risk to maneb to be below the LOC for acute risk to mammals, because maneb is practically nontoxic (rat LD_{50} > 5,000 mg/kg/day) to mammals on an acute basis. Thus, RQs for acute mammalian exposure were not calculated. Table 32 summarizes the mammalian chronic RQs from multiple applications of nongranular maneb products.

Table 32. Mammalian Chronic RQs from Maneb Application			
Crop	**Maximum Application Rate (lbs a.i./A)**	**Chronic RQs (NOAEL= 75 ppm)**	
		Based on maximum EECs	**Based on mean EECs**
		Range = Shortgrass - Seeds	
Turf	17.4	71 - 4	25 - 2
Almonds	6.4	26 - 2	9 - 1
Apples	4.8	20 - 1	7 - 1
Potatoes (MN only)	1.6	8 - 0.5	3 - 0.2
Mustard, Collards & Turnips (GA & TN only)	1.2	4 - 0.3	1 - 0.1

c. Non-Target Plant Risk

Terrestrial plants inhabiting dry and semi-aquatic areas may be exposed to pesticides from direct applications via runoff, spray drift, or volatilization. RQs could not be calculated because toxicity data for plants are not available. The potential for acute risks to non-endangered, endangered and/or threatened terrestrial plants at use sites is unknown. Currently, the Agency does not perform chronic risk assessments for terrestrial plants.

d. Non-Target Insects Risk

Maneb is practically nontoxic to honeybees from acute exposure (LD_{50} > 12 µg/bee). The Agency does not expect maneb exposure to pose acute risk to non-target insects because maneb is practically nontoxic to honeybees and there are no incident data reporting adverse effects to honeybees.

4. Risk to Aquatic Species

a. Fish and Invertebrate Exposure and Toxicity

The Agency expects maneb to reach aquatic environments through drift and runoff since maneb is not labeled for direct application to aquatic environments. Maneb is insoluble in water but the Agency expects it to decompose rather quickly, by hydrolytic reactions, into a multi-species residue (maneb complex) consisting of transient species and degradates, including the degradate of concern, ETU. Once maneb reaches the aquatic environment, the Agency believes the maneb complex will be the portion of the maneb that is biologically available to aquatic organisms. The Agency expects most of the transient species present in the maneb complex to partition into the sediment particles with varied strength of bonding. Over time, ETU is the dominant transformation product of the metiram complex. These metiram complex residues are short-lived in aquatic media, but ETU is persistent in this media unless it is subjected to rapid degradation by microbes and/or indirect photolysis.

Unlike the drinking water assessment described in the human health risk assessment section of this document, the ecological water resource assessment does not include the Index Reservoir (IR) and Percent-Crop Area (PCA) factor refinements. The IR and PCA factors represent a drinking water reservoir, not the variety of aquatic habitats, such as ponds adjacent to treated fields, relevant to a risk assessment for aquatic animals. Therefore, the EEC values used to assess exposure to aquatic animals are not the same as the values used to assess human dietary exposure from drinking water sources.

EECs were estimated using tier II modeling, the linked PRZM and EXAMS models (PRZM/EXAMS). In modeling, maneb uses on apples, peppers, potatoes, and tomatoes were chosen. Apples, peppers, potatoes, and tomatoes were chosen because they are the major uses for maneb and PRZM-EXAMS modeling scenarios exist for these uses. The EECs are used for assessing acute and chronic risks to aquatic organisms. Acute risk assessments are performed using peak EEC values for single and multiple applications. Chronic risk assessments are performed using the 21-day EECs for invertebrates and 60-day EECs for fish. Table 33 summarizes the aquatic EECs for maneb.

Table 33. Tier II Estimated Environmental Concentrations (EECs) of Maneb in Surface Water (ppb)

Crop	Rate (lbs ai/Acre)	Number of Applications	Interval	Peak	96 Hour	21 Day	60 Day	Annual Average
Apples (NC)	4.8	4	7	84.0	14.4	4.1	1.8	0.3
Peppers (FL)	1.6	6	7	113.0	16.7	5.4	2.1	0.4

Table 33. Tier II Estimated Environmental Concentrations (EECs) of Maneb in Surface Water (ppb)								
Crop	**Rate (lbs ai/Acre)**	**Number of Applications**	**Interval**	**Peak**	**96 Hour**	**21 Day**	**60 Day**	**Annual Average**
Potatoes (ME)	1.6	7	5	47.6	6.7	2.1	1.0	0.2
Tomatoes (FL)	1.6	7	7	197.9	31.6	9.2	4.0	0.7

Acutely, maneb is very highly toxic to cold water freshwater fish (LC_{50} = 42 ppb), highly toxic to slightly toxic to warm water freshwater fish (LC_{50} = 170 - 68,000 ppb) and highly toxic to estuarine/marine fish (LC_{50} = 180 ppb). Acute toxicity values for aquatic invertebrates suggest that maneb is highly toxic to freshwater invertebrates (Daphnia EC_{50} = 120 ppb) and highly to very highly toxic to estuarine/marine invertebrates (mysid shrimp EC_{50} = 3 ppb), as summarized in Table 34.

Table 34. Acute Toxicity Endpoints for Aquatic Species					
Toxicity Study	**Test Species**	**% a.i.**	**LC_{50} or EC_{50} (ppb)**	**Toxicity Category**	**MRID**
Freshwater Fish (96-hr)	Rainbow Trout	84.8	42	Very Highly Toxic	40706001
Estuarine/Marine Fish (flow-through 96-hr)	Atlantic Silverside	84.8	180	Highly Toxic	40943101
Freshwater Invertebrate (static 48-hr)	Daphnid	84.8	120	Highly Toxic	40749402
Estuarine/Marine Invertebrate (flow-through 96-hr)	Mysid shrimp	84.8	3	Very Highly Toxic	41000002

Early life-stage chronic freshwater fish NOAEC and LOAEC values were determined to be 6.1 and 12 ppb, respectively, with reduced hatchability, fish survival and length of fry being the endpoints affected. Chronic freshwater fish toxicity data is summarized in Table 35.

Table 35. Maneb Chronic Toxicity Endpoints for Freshwater Fish						
Toxicity Study	**Test Species**	**% a.i**	**NOAEC (ppb)**	**LOAEC (ppb)**	**Effects at LOAEC**	**MRID**
Freshwater Fish Early Life-Stage	Fathead minnow	87.3	6.1	12	Reduced hatchability	41346301
NOAEC / LOAEC = No Observable Adverse Effect Concentration, the highest dose at which no adverse health effect is observed./ Lowest Observable Adverse Effect Concentration, the lowest dose at which an adverse health effect is observed.						

b. Fish and Invertebrates Risk

There are potential acute risks to freshwater/estuarin/marine fish and invertebrates. Currently,

there are no data available to assess chronic risks to freshwater invertebrates, estaurine/marine fish, or estaurine/marine invertebrates. The Agency is requiring additional data acute and chronic toxicity data as a part of this RED. Maneb acute and chronic RQs for freshwater fish, acute RQs for freshwater invertebrates and estuarine/marine fish and invertebrates are summarized below in Table 36, 37, and 38, respectively.

Table 36. Acute and Chronic RQs for Freshwater Fish from Maneb Application

Crop	Maximum Single Application Rate (lbs a.i./A)	Peak EEC (ppb)	Freshwater Fish RQs	
			Acute (LC_{50}= 42 ppb)	Chronic (NOAEC= 6.1 ppb)
Apples	4.8	84	2	0.30
Pepper	1.6	113	2.69	0.34
Potatoes (Maine Only)	1.6	47.6	1.13	0.16
Tomato	2.4	197.9	4.71	0.66

Table 37. Acute RQs for Freshwater Invertebrates from Maneb Application

Crop	Maximum Single Application Rate (lbs a.i./A)	Peak EEC (ppb)	Freshwater Invertebrates Acute RQs (LC_{50}= 120 ppb)
Apples	4.8	84	0.70
Pepper	1.6	113	0.94
Potatoes (Maine Only)	1.6	47.6	0.40
Tomato	2.4	197.9	1.65

Table 38. Acute RQs for Estuarine/Marine Fish and Invertebrates from Maneb Application

Crop	Maximum Single Application Rate (lbs a.i./A)	Peak EEC (ppb)	Estuarine/Marine Acute RQs	
			Fish (LC_{50}= 180 ppb)	Invertebrates (LC_{50}= 3 ppb)
Apples	4.8	84	0.47	28
Pepper	1.6	113	0.63	38
Potatoes (Maine Only)	1.6	47.6	0.26	16
Tomato	2.4	197.9	1.10	66

c. Non-Target Aquatic Plants Risk

Like terrestrial plants, non-target aquatic plants may be exposed to pesticide from run-off, spray drift or volatization of maneb. Available information suggest that maneb may be toxic to non-vascular aquatic plants. The EC_{50} for freshwater green algae was 13 ppb based on growth inhibition, and a nominal NOAEC of 5.0 ppb. The potential for acute risks to terrestrial, semi-aquatic and aquatic vascular plants exposed to maneb at use sites is unknown due to lack of data. EPA will require plant data to assess acute risks to terrestrial, semi-aquatic and aquatic plants. Acute aquatic plant data are usually conducted for aquatic vascular plants using the surrogate duckweed *Lemna gibba*. Currently, the Agency is not assessing chronic effects on aquatic plants.

Exposure to non-target aquatic plants may occur through runoff or spray drift from adjacent treated sites. Runoff and drift exposure is computed from PRZM-EXAMS. The risk quotient is determined by dividing the pesticide's initial or peak concentration in water by the plant EC_{50} value. Acute risk quotients for freshwater, non-vascular plants based on green algae (*Ankistrodesmus bibraianus*) data are presented in Table 39. The results indicate that the non-vascular, non-target plant acute risk LOC of 1 is exceeded for maneb's assessed use patterns.

Table 39. Acute RQs for Aquatic Non-Vascular Plants from Maneb Application

Crop	Maximum Single Application Rate (lbs a.i./A)	Peak EEC (ppb)	Aquatic Non-Vascular Plants Acute RQs (LC_{50}= 13.4 ppb)
Apples	4.8	84	6.27
Pepper	1.6	113	8.43
Potatoes (Maine Only)	1.6	47.6	3.55
Tomato	2.4	197.9	14.77

5. Risk to Federally Listed Endangered and Threatened Species

Based on available screening-level information there is a potential concern for maneb's acute effects on listed freshwater and estuarine/marine animals and chronic effects on listed birds and mammals should exposure actually occur. The Agency expects maneb poses a low acute risk to nontarget insects because maneb is practically nontoxic to honeybees (acute contact LD50 > 12 μg/bee). However, the Agency does not assess risk to bees using RQs because a screening- level RQ assessment method for estimating the risk to bees is not available. The Agency does not currently have enough data to quantify risks for maneb at the screening-level and cannot preclude potential direct effects to the following taxonomic groups: listed nontarget terrestrial plants and vascular aquatic plants, freshwater invertebrates, and estuarine/marine fish (acute basis), and listed mammals and birds (chronic basis). These findings are based solely on EPA's screening-level assessment and do not constitute "may affect" findings under the Endangered Species Act (ESA) for any listed species.

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on federally listed endangered and threatened species, and to implement mitigation measures that address these impacts. The ESA requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs and considers ecological parameters, pesticide use information, the geographic relationship between specific pesticide uses and species locations and biological requirements and behavioral aspects of the particular species. When conducted, this analysis will consider regulatory changes recommended in this RED that are being implemented at that time. A determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, or consultations with the Fish and Wildlife Service or National Marine Fisheries Service as appropriate. If the Agency determines use of maneb "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). Until that species specific analysis is completed, the risk mitigation measures being implemented through this RED will reduce the likelihood that endangered and threatened species may be exposed to maneb at levels of concern.

6. Ecological Incidents

The Ecological Incident Information System (EIIS) reported maneb in three fish kill incidents. An incident, occurring in August 1973 and reported by the Oregon Department of Agriculture showed some fish in a 15 acre pond had been killed. Presumably drift from an aerial application of maneb and endosulfan to potatoes caused the kill. No analysis of the dead fish were provided. Both maneb and endosulfan are very highly toxic to freshwater fish [maneb rainbow trout LC_{50} = 42.0 ppb and endosulfan rainbow trout LC_{50} = 0.37 ppb (Endosulfan RED, 2001) and both pesticides could have been responsible for the fish kill, if in fact the kill was pesticide related. However, the inadequate information provided with this reported incident and the lack of laboratory analyzes make it difficult to charge this fish kill to either pesticide.

The second maneb related incident occurred in June 1994 and was reported by the North Carolina Department of Agriculture. The owner of a 2.5 acre commercial fishpond filed a complaint of a fish kill in the pond because of drift from applications of maneb, trifluralin, imazaquin, pendimethalin, and acephate aerially applied to corn and soybean fields near the pond. The owner felt the fish kill was a result of drift from these pesticides. The North Carolina Department of Agriculture investigated this complaint and took samples for analysis but the sampling evidence did not confirm the presence of maneb or the other pesticides listed in the samples taken. Based on the investigation and the analysis of samples, it is unlikely that maneb contributed to this fish kill.

The final maneb related incident occurred in August1994 and was reported by the Maine Department of Agriculture. In this incident, roughly 10,000 newly released brook trout were killed in a pond that borders New Brunswick, Canada and Maine. Three pesticides (maneb, esfenvalerate, and chlorothalonil) recently applied to potatoes surrounding this pond were suspected in this fish kill. Tissue samples of the fish confirmed the presence of all three pesticides (maneb at 169 ppb, esfenvalerate at 4.2 ppb, and chlorothalonil at 20 ppb) in the fish. These fish samples were taken

from both the pond and brooks feeding the pond. Again, as in the first incident, all three of these pesticides are very highly toxic to freshwater fish. Maneb's rainbow trout LC_{50} is 42.0 ppb, esfenvalerate's rainbow trout LC_{50} is 0.26 ppb (Hicks, L., 1995) and chlorothalonil's rainbow trout LC_{50} is 42.3 ppb (Chlorothalonil RED, 1998). The submitter of the incident report pointed out there were severe thunderstorms in the area preceding the fish kill which suggest pesticide runoff was a cause in this kill. Based on sampling evidence, the Agency believes maneb was a contributory cause in this fish kill.

IV. RISK MANAGEMENT, REREGISTRATION, AND TOLERANCE REASSESSMENT

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of generic (i.e., active ingredient-specific) data to support reregistration of products containing maneb as an active ingredient. 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 maneb.

The Agency has completed its assessment of the dietary, occupational, residential (as a result of exposures from mancozeb and maneb only), and ecological risk associated with the use of pesticide products containing the active ingredient maneb, including maneb-derived ETU and ETU from all sources. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient maneb, the Agency has sufficient information on the human health and ecological effects of maneb to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that maneb containing products are eligible for reregistration provided that: (i) current data gaps and confirmatory data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. Label changes are described in Section V. Appendix A summarizes the uses of maneb that are eligible for reregistration. Appendix B identifies the generic data requirements necessary as part of the Agency's determination of reregistration eligibility of maneb, and lists the submitted studies that the Agency reviewed and found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of maneb, the Agency has determined that maneb products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA and FQPA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of maneb. If all changes outlined in this document are incorporated into the product labels, then all current risks for maneb will be adequately mitigated for the purposes of this reregistration determination.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked extensively with stakeholders and the public to reach its regulatory decisions for maneb. During the public comment period on the risk assessments, which closed on February 22, 2005, the Agency received comments from the registrant, growers and grower groups. These comments in their entirety and the Agency's response are available in the public docket (OPP-2005-0078) at http://www.epa.gov/edockets.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide. EPA has determined that aggregate risk from exposure to maneb is within acceptable levels, provided that the mitigation measures stipulated in this document are implemented. Because maneb and the other EBDC fungicides (metiram and mancozeb) degrade to ETU in the environment and metabolize to ETU in the body, an aggregate assessment for ETU derived from both maneb and other EBDCs was also done. The Agency has determined that the human health risks from these combined exposures to both maneb and ETU are within acceptable levels, provided the mitigation measures stipulated in this document are implemented. In other words, EPA has concluded that the tolerances for maneb meet FQPA safety standards.

b. Determination of Safety to U.S. Population (including Infants and Children)

The Agency has determined that the established tolerances for maneb, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of maneb. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of maneb and its ETU metabolite and degradate. EPA has also considered information on the aggregate exposure to ETU, resulting both from the use of maneb and from the use of the other EBDC fungicides.

As discussed in Section III of this document, acute, chronic and cancer dietary (food alone) risks from maneb are not of concern. Aggregate risk, which combined food, drinking water and residential exposures, where applicable, from maneb, maneb-derived ETU, and ETU from all sources are also not of concern. The aggregate risk assessment for ETU considers residential scenarios, because mancozeb has uses that may result in residential exposure to ETU.

c. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to

determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

The available human health and ecological effects data for maneb suggest possible thyroid effects, which may indicate potential endocrine disruption. EPA has considered these effects in the human health risk assessment by selecting endpoints based on thyroid effects. To further address these effects, EPA is requiring a confirmatory comparative thyroid toxicity study for maneb. Data on ecological effects suggest possible hormonal effects to birds, mammals, and aquatic organisms. These effects will be addressed when the Agency's Endocrine Disruptor Screening and Testing Advisory Committee develops appropriate screening and/or testing protocols. At that time, maneb may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

d. Cumulative Risks

Risks summarized in this document are those that result only from the use of maneb and its metabolite, ETU. The FFDCA, as amended by FQPA, requires that 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 reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Maneb belongs to a group of pesticides called dithiocarbamates, which also includes the EBDC fungicides metiram and mancozeb. For the purposes of this RED, EPA has concluded that maneb does not share a common mechanism of toxicity with other substances. The Agency reached this conclusion after a thorough internal review and external peer review of the data on a potential common mechanism of toxicity. For more information, please see the December 19, 2001 memorandum, *"The Determination of Whether Dithiocarbamate Pesticides Share a Common Mechanism of Toxicity,"*which is available on the internet at http://www.epa.gov/oppsrrd1/cumulative/dithiocarb.pdf.

2. Tolerance Reassessment Summary

a. Tolerances Currently Listed Under 40 CFR §180.110

Maneb tolerances are established under 40 CFR §180.110(a) and §180.110(b). The permanent tolerances listed under 40 CFR §180.110(a) are expressed in terms of the residues of the

fungicide maneb (manganese ethylenebisdithiocarbamate), calculated as zinc ethylenebisdithiocarbamate. The time-limited tolerance listed in 40 CFR §180.110(b) is currently expressed in terms of the residues of maneb and its metabolite ethylenethiourea (ETU).

The only established maneb tolerances are for plant commodities. No maneb tolerances have yet been established in livestock or processed food/feed commodities. The Agency is now recommending that maneb tolerances also be established in livestock commodities. Based on a reevaluation of the available plant and livestock metabolism studies, the Agency has reaffirmed that the residues of toxicological concern to be included in risk assessment are the parent EBDC (including maneb) and ETU. For regulatory/enforcement purposes, the Agency recommends that tolerances in plant and livestock commodities at 40 CFR §180.110(a) be established for residues of maneb *per se*. The Agency recommends that the EBDC (including maneb) tolerances be calculated as carbon disulfide rather than as zineb.

Since issuance of the Maneb Update in 1992, the Agency has updated the list of raw agricultural commodities (RACs) and processed commodities and feedstuffs derived from crops. As a result of change to the livestock feeds table, to maneb tolerances for certain RACs that have been removed from the livestock feeds table need to be revoked. Also, some commodity definitions must be corrected. A summary of maneb tolerance reassessments is presented in Table 40.

b. Tolerances Listed Under 40 CFR §180.110 (a)

Sufficient data are available (or were translated when appropriate) to reassess the established tolerances in/on the following commodities, pending label amendments for some crops including: almonds; beans (dry form); broccoli; Brussels sprouts; cabbage; cauliflower; cucumbers; eggplant; kohlrabi; melons; onions (bulb); pumpkins; sugar beet tops; summer squash; winter squash; and tomatoes.

Although additional data are required to confirm the existing tolerance levels in/on the following commodities, the Agency has no dietary, drinking water or residential risk concerns associated with these tolerances and considers them reassessed: bananas; Chinese cabbage; collards; cranberries; endive (escarole); kale; lettuce; mustard greens; onions (green); papayas; peppers; potatoes; and turnip tops.

The established tolerances in/on the following commodities should be revoked since maneb uses on certain crops were disallowed for reregistration as per EBDC Final Determination (PD 4) on March 2, 1992 (57 FR 7484): apricots; beans (succulent form); carrots; celery; nectarines; and peaches. Further, for apples, grapes, figs, and sweet corn, the registrant has requested voluntary cancellation. Receipt of this request will be published in the near future.

A maneb tolerance for garlic has also not been established and need not be proposed. In accordance with 40 CFR §180.1, the reassessed tolerance for onions (dry bulb) may apply to garlic, since the registered use patterns of maneb on garlic and onions (dry bulb) are identical.

c. Tolerances To Be Proposed Under 40 CFR §180.110 (a)

A tolerance should be established in 40 CFR§180.110(a) for "beet, sugar, roots" based on the available field trial data. Tolerances should also be established in 40 CFR§180.110 (a) for the following commodities after adequate field trial data have been submitted and evaluated: almond, hulls; corn, pop, grain; corn, pop, stover; corn, sweet, forage; and corn, sweet, stover.

Based on the results of an acceptable sugar beet processing study, a tolerance for "beet, sugar, pulp, dried" should be established. The processing studies submitted for grapes and tomatoes indicate that residues of maneb and ETU did not concentrate in the respective processed commodities of these crops.

Field residue data and tolerances in/on cowpea forage and hay will not be required provided labels are amended such that maneb use on beans specifically exclude cowpeas.

Tolerances in eggs, milk, and the fat, meat byproducts, and meat of cattle, goats, hogs, horses, poultry, and sheep should be established based on the results of reviewed livestock metabolism studies.

Tolerances must be proposed that reflect either the maximum expected residue levels or, if no measurable residues are detected, the limit of quantization of the analytical method.

d. Tolerances Listed Under 40 CFR §180.110 (a) and (b)

Sufficient data have been submitted to reassess the established time-limited tolerance in walnuts associated with a Section 18 registration. The available data support establishment of a permanent tolerance in walnuts currently proposed.

Table 40. Tolerance Reassessment Summary for Maneb.

Commodity	Established Tolerance (ppm)	Reassessed Tolerance [1] (ppm)	Comment *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR §180.110 (a)			
Almond	0.1	0.1	[*Almond, nutmeat*]
Apple	2	Revoke [4]	Registrant has requested voluntary cancellation.
Apricot	10	Revoke	Disallowed for reregistration.
Bananas (not more than 0.5 ppm) shall be in the pulp after peel is removed and discarded (preharvest application only)	4	TBD	Additional banana field trial data and submissions of foreign labels are required. [*Bananas, whole (Pre-H)*]
Bean (dry form)	7	2.5	[*Bean, dry*]
Bean, succulent	10	Revoke	Disallowed for reregistration.
Broccoli	10	6	Field trial data support the reduced tolerance level

Table 40. Tolerance Reassessment Summary for Maneb.			
Commodity	**Established Tolerance (ppm)**	**Reassessed Tolerance [1] (ppm)**	**Comment** ***[Correct Commodity Definition]***
Brussels sprouts	10	6	Translated from broccoli data.
Cabbage	10	21	Field trial data support the increased tolerance level
Cabbage, Chinese	10	TBD	Additional field trial data are required.
Carrot, roots	7	Revoke	Disallowed for reregistration.
Cauliflower	10	6	Translated from broccoli data.
Celery	5	Revoke	Disallowed for reregistration.
Collards	10	TBD	Additional field trial data on collards are required.
Cranberry	7	TBD	Additional cranberry field trial data are required.
Cucumber	4	2.0	Field trial data support the reduced tolerance level
Eggplant	7	2.5	Translated from tomato data.
Endive (escarole)	10	TBD	To be translated from data requested for leaf lettuce.
Fig	7	Revoke[4]	Registrant has requested voluntary cancellation.
Grape	7	Revoke[4]	Registrant has requested voluntary cancellation.
Kale	10	TBD	Additional field trial data on kale are required
Kohlrabi	10	6	Translated from broccoli data.
Lettuce	10	TBD	Additional field trial data on head lettuce are required. [*Lettuce, head*]
Lettuce	10	TBD	Additional field trial data on leaf lettuce are required. [*Lettuce, leaf*]
Melon	4	3	Field trial data support the reduced tolerance level
Mustard greens	10	TBD	Additional field trial data on mustard greens are required.
Nectarine	10	Revoke	Disallowed for reregistration.
Onion	7	6	[*Onion, bulb*]
		TBD	[*Onion, green*]
Papaya	10	TBD	Additional papaya field trial data are required.
Peach	10	Revoke	Disallowed for reregistration.
Pepper	7	TBD	Additional field trial data on non-bell peppers are required. [*Pepper, bell and non-bell*]
Potato	0.1	TBD	Additional potato field trial data are required.
Pumpkin	7	3	Translated from melon data.

Table 40. Tolerance Reassessment Summary for Maneb.			
Commodity	**Established Tolerance (ppm)**	**Reassessed Tolerance [1] (ppm)**	**Comment** ***[Correct Commodity Definition]***
Beet, sugar, tops	45	120	Field trial data support the increased tolerance level
Squash, summer	4	2.0	Translated from cucumber data.
Squash, winter	4	3	Translated from melon data.
Sweet corn, kernel plus cob with husks removed	5	Revoke[4]	[*Corn, sweet, kernel plus cob with husks removed*]
Tomato	4	2.5	Field trial data support the reduced tolerance level
Turnip, greens	10	TBD	Additional field trial data on turnip tops are required.
Turnip, roots	7	Revoke	Turnips grown for roots may not be treated.
Tolerances To Be Proposed Under 40 CFR §180.110 (a) [3]			
Almond, hulls	None	TBD	Additional field trial data on almond hulls are required.
Beet, sugar, root	None	1.2	
Beet, sugar, pulp, dried	None	2.5	
Cattle, fat	None	0.02	
Cattle, mbyp	None	0.02	
Cattle, meat	None	0.02	
Eggs	None	0.02	
Cattle, fat	None	0.02	
Cattle, mbyp	None	0.02	
Cattle, meat	None	0.02	
Goats, fat	None	0.02	
Goats, mbyp	None	0.02	
Goats, meat	None	0.02	
Hogs, fat	None	0.02	
Hogs, mbyp	None	0.02	
Hogs, meat	None	0.02	
Horses, fat	None	0.02	
Horses, mbyp	None	0.02	
Horses, meat	None	0.02	
Milk	None	0.02	
Poultry, fat	None	0.02	
Poultry, mbyp	None	0.02	
Poultry, meat	None	0.02	
Sheep, fat	None	0.02	
Sheep, mbyp	None	0.02	
Sheep, meat	None	0.02	

Table 40. Tolerance Reassessment Summary for Maneb.			
Commodity	**Established Tolerance (ppm)**	**Reassessed Tolerance [1] (ppm)**	**Comment** ***[Correct Commodity Definition]***
Tolerance Listed Under 40 CFR §180.110 (b)			
Walnut	0.05	0.03	Expiration/revocation date 12/31/07 associated with a Sec.18

[1] The reassessed tolerances are for the residues of maneb expressed as carbon disulfide *per se*, and are contingent upon the recommended label revisions.
[2] TBD = To be determined. Reassessment of tolerance(s) cannot be made at this time because additional data are required.
[3] Does not include tolerances that may be required from use of maneb on crops with seed or propagation stock treatments.
[4] The Agency intends to follow-up to the registrant's request with a Request for Voluntary Cancellation Notice in the Federal Register which announces receipt of the request.

e. Codex Harmonization

There are no established or proposed Codex MRLs for residues of maneb *per se*; however, Codex limits for dimethyldithiocarbamates fungicides are grouped under dithiocarbamates. The maximum residue limits (MRLs) for dithiocarbamates are established for several commodities resulting from the use of mancozeb, maneb, metiram, propineb, thiram, and ziram and are currently expressed as ppm carbon disulfide. When the tolerance reassessments are finalized U.S. tolerances will be harmonized with Codex MRLs with respect to residue definition. A numerical comparison of the Codex MRLs and the corresponding reassessed U.S. tolerances for maneb are presented on the internet at the Food and Agricultural Organization database website: http://faostat.fao.org/faostat/collections?version=ext&hasbulk=0.

D. Regulatory Rationale

The following is a summary of the rationale for the mitigation measures necessary for reregistration eligibility and for managing risks associated with the use of maneb. Where labeling revisions are warranted, specific language is set forth in the summary table of Section V (Table 43 of this RED document).

1. Human Health Risk Management

a. Dietary (Food) Risk Mitigation

Acute, chronic, and cancer dietary (food only) exposure and risk from maneb, maneb-derived ETU, and ETU from all sources are below the Agency's level of concern. Since there are no acute, chronic, cancer dietary (food only) risks of concern, no mitigation measures are necessary.

b. Drinking Water Risk Mitigation

The drinking water exposure assessment for maneb addresses concentrations of ETU only,

since maneb is not expected to remain in drinking water long enough to reach a location that would supply water for human consumption whether from surface or ground water. Estimated concentrations of ETU, for both surface and ground water sources of drinking water, are low and not of concern; therefore, no mitigation is needed.

c. Residential Risk Mitigation

The only potential residential exposure to maneb is from residues remaining on transplanted turf from sod farms. Risk to toddlers, the most sensitive sub-population, was evaluated for post-application exposure, and is of concern on the first day of potential exposure at the current maximum label rate. However, as residues decline over time and/or application rates are reduced, MOEs reach acceptable levels. To address risk concerns for toddlers who may be playing on transplanted sod previously treated with maneb, the registrant has agreed to a 3-day pre-harvest interval (PHI). This measure effectively prohibits maneb application to turf grown on sod farms for 3 days prior to harvest of sod, thereby mitigating the short-term risk for toddlers who may play on transplanted sod. To further address potential residential post-application exposure from turf, the registrant has agreed to reduce maximum application rate for sod farm turf from 17.4 lbs ai/A to 8.7 lbs ai/A, and limit the maximum seasonal rate to 34.8 lbs ai/A/season.

d. Aggregate Risk Mitigation

Aggregate risk refers to the combined risk from food, drinking water, and residential (as a result of residential exposures from mancozeb uses) exposures. In addition, aggregate risk can result from one-time (acute), short-term and/or chronic (non-cancer and cancer) exposures. Below is a discussion of the risk for each duration of exposure and any risks of concern.

Acute Aggregate: Since residues of maneb *per se* are not expected in drinking water, acute aggregate risks for maneb consist of acute exposures to maneb-derived ETU and ETU from all sources. Potential concentrations of maneb-derived ETU and ETU from all sources in drinking water, when combined with exposure through food, are below Agency's level of concern for acute aggregate risk (see Table 12). No mitigation measures are necessary for acute aggregate risk.

Short-term Aggregate: Short-term aggregate (food + drinking water + residential [as a result of residential exposures from mancozeb uses]) risk for ETU from all sources is below the Agency's level of concern for residential handlers, and children and adults exposed to ETU from re-entry activities (see Section III.A.8.b and Table 15). Therefore, no mitigation is required.

Chronic (Non-Cancer) Aggregate: The chronic aggregate risks to maneb-derived ETU and ETU from all sources were calculated using food and drinking water exposures only, because residential and recreational exposure scenarios were considered to occur only on a short-term basis. Aggregate (food + drinking water) chronic risks to maneb-derived ETU and ETU from all sources are below the Agency's level of concern; therefore, no mitigation is required.

Cancer Aggregate: Aggregate (food + drinking water) cancer risk to maneb-derived ETU for the general U.S. population is below the Agency's level of concern. The cancer risk from ETU from

all sources was aggregated using food, drinking water and residential/recreational (as a result of mancozeb uses) exposures. This risk estimate is 2 x 10^{-6}, with the food exposure being the largest contributor of cancer risk, followed by drinking water from groundwater sources. The Agency considers cancer risks as high as 3 in 1 million are within the negligible risk range; thus, cancer aggregate risks are not of concern. Therefore, the Agency believes no further mitigation is required for maneb.

e. Occupational Risk Mitigation

It is the Agency's policy to mitigate occupational risk to the greatest extent necessary and feasible. Mitigation measures may include reducing application rates, reducing the use of hazardous formulations, and the use of engineering controls, such as closed cabs and water soluble packaging. In cases when such measures are not feasible or do not reduce risks to acceptable levels, then personal protective equipment (PPE) requirements are added to end product labels. A wide range of factors is considering in making risk management decisions for worker risks. These factors include estimated margins of exposure (MOEs), cancer risk estimates, incident data, the nature and severity of adverse effects observed in animal studies, uncertainties in the risk assessment, alternative registered pesticides, the importance of the chemical in integrated pest management (IPM) programs, and other similar factors. Maneb is an EBDC fungicide of significant importance to agriculture, as described in Section IV.D.3. of this document. Thus, in certain scenarios described below, no additional mitigation has been deemed necessary by the Agency, though risk estimates slight exceed general levels of concern.

1) Agricultural and Greenhouse Handler Risk Mitigation

Handler exposure assessments are completed by EPA considering the use of baseline PPE, and, if warranted, increasing levels of PPE and engineering controls in order to estimate their potential impact on exposure. The target MOE for occupational risk is 100, and MOEs greater than 100 do not exceed the Agency's level of concern. For occupational cancer risks, estimates in the general range of 1 x 10^{-6} (one in a million) generally do not exceed the Agency's level of concern. When occupational MOE are less than 100 or occupational cancer risks exceed the general range of 1 x 10^{-6}, EPA strives to reduce worker risks through the use of personal protective equipment and engineering controls or other mitigation measures. The Agency generally considers occupational cancer risks in the range of 1 x 10^{-6} or less to be negligible, but may accept estimated risks as high as 1 x 10^{-4} (1 in 10,000) when all mitigation measures that are feasible have been applied, and in particular, when there are critical pest management needs associated with the use of the pesticide. Levels of PPE considered are described below:

- Baseline - long-sleeved shirt, long pants, and shoes and socks
- Single layer - baseline plus gloves
- Double layer - baseline plus gloves and coveralls
- PF5 - a dust/mist filtering respirator
- PF10 - a half face respirator with appropriate cartridges

Non-Formulation-Specific Mitigation

In addition to the mitigation measures specific to each formulation of maneb being presented below, the technical registrant has agreed to cancel maneb use on sweet corn, grapes, apples, and kadota figs and reduce the maximum application rate on turf by half to 8.7 lb ai/A.

Wettable Powder Formulations

As described in Section III.A.6. of this document, non-cancer risks to handlers mixing and loading wettable powder formulations for aerial or chemigation application are of concern at the maximum PPE (double layer and a PF10 respirator). MOEs ranged from 9 to 64, depending on the crop. In addition, risks to handlers mixing and loading wettable powders for turf application are above the Agency's level of concern at maximum PPE, with a MOE of 39. The registrant has agreed to prohibit the use of wettable powders for aerial or chemigation application, and prohibit the use of wettable powders for use on turf in order to mitigate this risk concern.

For all other handlers mixing and loading maneb in wettable powder formulations, the Agency is requiring the use of single layer PPE and a PF5 respirator, as explained further in the paragraphs below.

With the use of single layer PPE and a PF5 respirator, maneb short/intermediate-term MOEs for handlers mixing and loading wettable powder for groundboom applications range from 640 to 80 and cancer risk estimates range from 9×10^{-6} to 2×10^{-6}. For the majority of use sites, risk estimates are in the 1×10^{-6} range. The use on cranberries results in the short/intermediate term MOE of 80 and the cancer risk estimate of 9×10^{-6}; these risk estimates slightly exceed the Agency's level of concern. No further mitigation measures are needed.

With the use of single layer PPE and a PF5 respirator, the maneb short/intermediate-term MOEs for handlers mixing and loading wettable powders for airblast application to fruits and nuts are greater than 120 and the cancer risk estimates are less than 5×10^{-6}. MOEs are not of concern to the Agency, and cancer risk estimates are in the general range of 1×10^{-6}. No further mitigation measures are needed.

With the use of single layer PPE and a PF5 respirator, maneb MOEs for handlers mixing and loading wettable powders for high-pressure handwand application to ornamental plants and tomatoes are all greater than 500 (short/intermediate-term and long-term) and cancer risk estimates are in the general range of 1 x 10-6. Risk estimates are not of concern to the Agency at the necessary level of PPE.

With the use of single layer PPE and a PF5 respirator, maneb MOEs for handlers mixing, loading, and applying wettable powders with a low-pressure handwand to ornamental plants and tomatoes are all greater than 300 (short/intermediate-term and long-term), and cancer risk estimates are in the general range of 1×10^{-6}. Risk estimates could not be calculated for handlers mixing, loading, and applying wettable powders with a backpack sprayer; however, these risk estimates are not expected to be greater than for handlers mixing, loading, and applying with a low pressure

handwand since these application scenarios are similar. Risk estimates are not of concern to the Agency at the necessary level of PPE.

Dry Flowable Formulations

For handlers mixing and loading dry flowable formulations of maneb for aerial or chemigation application on sod farms, the Agency is requiring the use of single layer PPE and a PF5 respirator. With the use of the proposed PPE and the decrease in application rates, the maneb MOE is 92 and the cancer risk estimate is approximately 1×10^{-5}. These risk estimates slightly exceed the Agency's level of concern. No further mitigation measures are needed at this time.

For handlers mixing and loading dry flowable formulations of maneb for all other uses, the Agency is requiring the use of single layer PPE. Considering this mitigation, short/intermediate term risk estimates for most uses do not exceed the Agency's level of concern with MOEs ranging from 130 to greater than 1000; however, MOEs for handlers mixing and loading dry flowable for aerial or chemigation application to fruits and nuts slightly exceed the Agency's level of concern (MOE is 84 at the highest application rate). In addition, considering this mitigation, cancer risk estimates range from 1×10^{-5} to significantly less than 1×10^{-6}; the scenarios for which cancer risk estimates slightly exceed the Agency's level of concern are handlers mixing and loading for the following uses: groundboom application to turf and aerial or chemigation application to other crops. No further mitigation is needed.

Risk estimates could not be calculated for handlers mixing, loading, and applying dry flowable formulations with a backpack sprayer or a low pressure handwand; however, these risk estimates are expected to be much lower than for handlers mixing, loading, and applying wettable powders in the same manner (with a MOE of greater than 290 and a cancer risk estimate in the general range of 1×10^{-6}) because dry flowable formulations are much less dusty than wettable powder formulations and result in less inhalation exposure to handlers. Therefore, these scenarios are not of concern to the Agency.

Liquid Formulations

For handlers mixing and loading liquid formulations of maneb for aerial or chemigation application to sod farms, the Agency is requiring the use of single layer PPE and a PF5 respirator, which results in a maneb MOE of 184 and a cancer risk estimate of 5×10^{-6}. These risk estimates slightly exceed the Agency's level of concern. No further mitigation measures are needed at this time.

For handlers mixing and loading, and for handlers mixing, loading, and applying liquid formulations of maneb for all other uses, the Agency is requiring the use of single layer PPE). With the proposed PPE, all short/intermediate term risk estimates are not of concern to the Agency; MOEs range from 99 to greater than 1000. In addition, with the proposed PPE, cancer risk estimates range from 7×10^{-6} to 8×10^{-8}. The scenarios for which cancer risk estimates slightly exceed the Agency's level of concern are handlers mixing and loading for the following uses: groundboom application to turf; aerial or chemigation application to other crops; and high pressure handwand application to

ornamentals and tomatoes. No further mitigation is needed at this time.

Applicators - All Formulations

For wettable powder formulations, the registrant has agreed to prohibit aerial and chemigation applications. For handlers applying wettable powder formulations by any other application method, the Agency is requiring the use of single layer PPE and a PF5 respirator. With the use of this PPE, applicator MOEs range from 660 to greater than 1000 and are therefore below the Agency's level of concern. Cancer risk estimates for applicators range from 4×10^{-6} to 2×10^{-8}. Some of these cancer risk estimates slightly exceed the Agency's level of concern (for handlers applying via groundboom to turf and via airblast to fruits and nuts). No further mitigation measures are needed at this time.

For aerial application of dry flowable or liquid formulations, the Agency is requiring the use of engineering controls (closed cockpits). For handlers applying dry flowable or liquid formulations by any other method to any crop, the Agency is requiring the use of single layer PPE. With the use of this PPE, applicator MOEs range from 260 to greater than 1000 and are therefore below the Agency's level of concern. Applicator cancer risk estimates range from 9×10^{-6} to 4×10^{-8}. Some of these cancer risk estimates slightly exceed the Agency's level of concern (for handlers applying via groundboom to turf and via airblast to fruits and nuts). No further mitigation measures are needed at this time.

2) Potato Seed-Piece Treatment Mitigation

As described in Section III of this document, risks to handlers loading dust formulation for potato seed piece treatment are of concern to the Agency at baseline PPE. As such, the Agency is requiring and the technical registrant has agreed to the use of engineering controls (dust collection equipment) for commercial potato seed-piece treatment (maneb MOE of 1100 and cancer risk estimate of 1×10^{-6} with engineering controls), and the use of single layer PPE for on-farm potato seed-piece treatment (maneb MOE of 120 and cancer risk estimate of 8×10^{-6}). There is no data available to assess risk to applicators applying dusts, however, the Agency believes that this risk will not be greater than risk to mixer/loaders since applicators are handling the same amount of material. The dust collection equipment requirement will protect applicators as well. The cancer risk slightly exceeds the Agency's level of concern. No further mitigation is necessary.

For all seed treatment, the Agency is requiring the use of single layer PPE. As described in Section III of this document, risks to handlers performing multiple activities to treat oat seeds and handlers using liquid formulations to treat oat, rice, and peanut seed exceed the Agency's level of concern at single layer PPE; however, all other seed treatment activities are not of concern to the Agency. To mitigate this risk, the technical registrant has agreed to cancel seed treatment on rice and peanuts, and is reducing the oat seed treatment rate to 0.0021 lb ai/lb seed from 0.0031 lb ai/lb seed. Based on the decrease in rate on oats, and the use of single layer PPE, the MOEs previously of concern become ~90, which is not significantly different than 100 and not of concern to the Agency. Cancer risk estimates range from 2×10^{-5} to 8×10^{-7}, based on the use of single layer PPE and slightly exceed the Agency's level of concern for some seeds. Risks will be lower with reduced application rates; therefore, no further mitigation is necessary.

3) Post-Application Risk Mitigation

When preparing post-application risk assessments, EPA considers dislodgeable foliar residue (DFR) data, application rates, transfer coefficients based on crop type and exposure scenario (low, medium, or high contact activities), and assumptions about average occupational workdays and adult body weight. In the case of maneb, both maneb and its degradate ETU were considered in the assessment. For the ETU cancer risk assessment, the Agency assumed that workers would be exposed for 30 days each year.

At the current REI of 24 hours, for high-end exposure scenarios, there are maneb risks of concern for workers reentering treated grape and tree fruit orchards. As such, the technical registrant has agreed to cancel use on deciduous tree fruit (apples and Kadota figs) and grapes. In addition, the registrant is cancelling use on corn, which has a risk estimate of 3×10^{-5} for very high activities at day 0. The registrant is also decreasing the application rate for turf (risk estimate of 3×10^{-5}) by half, from 17.4 lb ai/A to 8.7 lb ai/A. Cancer risks for the remaining uses are between 5×10^{-5} (almonds) and 9×10^{-8} at day 0, and slightly exceed the Agency's level of concern for some crops. No further mitigation is needed at this time.

2. Environmental Risk Mitigation

It is the Agency's policy to mitigate ecological risks to the greatest extent necessary and feasible. Mitigation measures may include lowering application rates, reducing the number of applications, restricting the timing of applications, minimizing runoff potential, and others.

a. Terrestrial Species Mitigation

From a short-term or acute maneb exposure, the Agency expects low risk to mammals and birds. However, the screening-level ecological risk assessment indicates some exceedance of the chronic screening LOCs for risk to birds and small mammals. In particular, the highest chronic RQs result from maneb use on turf and almonds. With an assessed total of three applications at a rate of 17.4 lbs ai/A to turf, the corresponding avian chronic RQs based on mean EECs range from 94 to 8 and the mammalian chronic RQs range from 25 to 2. Predicted exposures from maneb on almonds also exceed screening levels of concern for birds and mammals, with RQs based on mean EECs ranging from 35 to 3 for birds and 9 to 1 for mammals. Use on apples also results in high RQs ranging from 26 to 2 for birds and 7 to 1 for mammals. These RQs are screening level estimates, incorporating modeled estimated environmental concentrations. Nevertheless, to be more protective of terrestrial species that may be exposed on a chronic basis, the technical registrant has agreed to additional label changes to reduce potential risk. For example, the maximum application rate to turf is being reduced from 17.4 to 8.7 lbs ai/A and the maximum number of applications is also being reduced for almonds from 4 times to 3 per year thus reducing the seasonal total amount of maneb being applied. Moreover, the use on apples is being voluntarily cancelled. Refer to Table 41 for summary of revisions to use site parameters.

The Agency does not expect maneb exposure to pose acute risk to non-target insects, because maneb is practically nontoxic to honeybees and there are no incident data reporting adverse effects to

honeybees. Therefore, no bee precautionary labeling is required on maneb product labeling.

b. Aquatic Species Mitigation

There are predicted acute risks to aquatic species (freshwater/estuarine/marine fish and invertebrates) from maneb use. Currently, there are no toxicity data available to assess chronic risks to freshwater invertebrate, estuarine/marine fish or estuarine/marine invertebrates. The Agency is requiring additional toxicity data as part of this RED to address these data gaps.

Although the assessed acute and chronic RQs to aquatic species are relatively low, some LOC exceedances exist. The same mitigation measures addressing terrestrial risks will also reduce these risks, including reducing single maximum application rates, reducing maximum number of applications per year and maximum seasonal application rates and voluntarily cancelling uses. Refer to Table 41 for summary of revisions to use site parameters.

Table 41. Revised Use Site Parameters and Requirements for Maneb

Crop	Single Application Rates (lb ai/A)		Minimum Retreatment Interval (days)	Maximum Number of Applications Per Year		Yearly Maximum Rate (lb ai/A)	
	Previous	Revised		Previous	Revised	Previous	Revised
Almonds	6.4	6.4	7	4	3	25.6	19.2
Turf	17.4	8.7	7	Unlimited	4	Unlimited	34.8
Cut Flowers	1.2	1.2	7	Unlimited	20	Unlimited	24

3. Significance of the EBDCs

As mentioned above, EPA received many comments in response to the Federal Register Notice published on November 24, 2004 (OPP-2004-0078) announcing the availability of the EBDC risk assessments and requests for risk reduction options. The majority of the comments supported the continued use of the EBDC products and data supporting the usefulness of the EBDCs to control plant diseases. The Agency also obtained information from internal expertise, USDA's Office of Pesticide Management and Policy (OPMP), and proprietary sources on several use sites.

Based on the information provided by a variety of resources, the Agency has determined that the EBDCs are a class of fungicides that are particularly significant to agriculture and integrated pest management (IPM) programs due to the use of the EBDCs in disease resistance management programs. The EBDCs have a multi-site mode of action, and, as such, are not considered susceptible to resistance development. This is supported by the fact that there has been no confirmed case of fungal resistance to the EBDCs after over 50 years of use. Because of these characteristics, the EBDCs are important resistance management partner chemicals for tank mixing or rotation with newer and lower risk fungicides that have single-site modes of action such as the sterol inhibitors and the strobilurins. This property helps to prolong the life of the newer and lower risk fungicides.

The Agency is committed to long-term pest resistance management strategies, and an important pesticide resistance management strategy is to avoid the repeated use of pesticides with the same or similar mode/target site of action in the same field (OPP PR Notice 2001-5). Because of this, the Agency has considered the advantages from the use of EBDCs as an important tool in fungicide resistance management programs while making its reregistration decision for all 3 EBDCs, mancozeb, maneb, and metiram.

Further, comparing the cost per treatment of EBDCs with other fungicides, cost information demonstrated that the EBDCs are generally lower. The following paragraphs are summaries for specific use sites.

Potatoes

Mancozeb, maneb, and metiram are used to control early blight and late blight as well as several potato seed-piece diseases. The alternative fungicides include strobilurins (e.g. azoxystrobin, trifloxystrobin), chlorothalonil, propamocarb, dimethomorph, cymoxanil, copper, triphenylin hydoxide (TPTH), iprodione, and zoxamide fluazinam. However, there is no one alternative fungicide registered to control all the potato diseases for which EBDCs are registered. Because there has been reduced sensitivity of the strobilurins towards early blight on potatoes in some areas, rotational applications of strobilurins with fungicides with a different mode of action are required after every application.

Along with the EBDCs, chlorothalonil has been considered the standard early blight and late blight treatments for years. However, EBDCs are needed for use when the seasonal allowance of chlorothalonil per acre has been reached. Copper and tin products are less efficacious for early blight in some areas. Lastly, applications of TPTH may result in injury to foilage of sensitive varieties, but injury is reduced and efficacy is improved when TPTH is combined with an EBDC fungicide.

Tomatoes

When used alone mancozeb and maneb are labeled to control anthracnose, early blight, gray leaf spot, late blight, leaf mold, and Septoria leaf spot fungal diseases. When tank-mixed with copper fungicides, these chemicals also control bacterial spot and bacterial speck diseases. The principal alternatives for fungal disease control are chlorothalonil, strobilurins (azoxystrobin, trifloxystrobin), and Tanos (famoxadone + cymoxanil). The sole bacterial disease control alternative is Tanos, which only claims to suppress these diseases.

The alternatives Tanos and the strobilurins and are both considered high risks for pest resistance development and as such are labeled for a very limited number of applications and only in tank-mixtures and alternations with the available broad spectrum protectant fungicides (i.e., chlorothalonil and EBDCs). Chlorothalonil is not labeled for control of bacterial diseases and has a seasonal maximum rate that will sometimes preclude its use as a full-season EBDC fungicide replacement for control of fungal diseases.

The use of EBDCs in combination with copper are claimed to be very important in the

principal tomato production states of California and Florida, where it is considered the only reliable control measure for bacterial spot and bacterial speck diseases. Additionally, the EBDC treatment costs are about one-half that of the above-mentioned alternatives.

4. Summary of Risk Mitigation Measures

The following is a bulleted list that summarizes all mitigation measures necessary for the reregistration of maneb:

Maneb-All Formulations

- Sweet Corn - Cancel Use
- Grapes - Cancel Use
- Apples - Cancel Use
- Kadota Figs - Cancel Use
- Seed Treatment to Rice and Peanuts - Cancel Use
- Oats Seed Treatment - Reduce maximum application rate from 0.0031lb ai/lb seed to 0.0021 lb ai/lb seed
- Almonds- Reduce maximum seasonal rate from 25.6 to 19.2 lbs ai/acre/season and retain maximum application rate of 6.4 lbs ai/acre.
- Sod Farm Turf - Reduce maximum application rate from 17.4 lbs ai/acre to 8.7 lbs ai/acre, limit maximum seasonal rate to 34.8 lbs ai/acre/season and add a 3 day pre-harvest interval. Handlers mixing/loading of dry flowables and liquids for aerial or chemigation application, add a PF5 Respirator.
- Cut Flowers - Limit number of applications per year to 20
- Commercial Potato Seed-Piece Treatment (dust) - require engineering controls (e.g. dust collector equipment)

Maneb- Wettable Powder Formulation Only

- Sod Farm Turf - Cancel Use
- Chemigation/Aerial Applications - Delete Application Method
- For mixing/loading all remaining uses add PF 5 Respirator.

E. Other Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing maneb. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

1. Endangered Species Considerations

Based on available screening-level information there is a potential concern for maneb's acute effects on listed freshwater and estuarine/marine animals and chronic effects on listed birds and mammals should exposure actually occur. The Agency expects maneb poses a low acute risk to nontarget insects because maneb is practically nontoxic to honeybees (acute contact LD50 > 12 μg/bee). However, the Agency does not assess risk to bees using RQs because a screening- level RQ

assessment method for estimating the risk to bees is not available. The Agency does not currently have enough data to quantify risks for maneb at the screening-level and cannot preclude potential direct effects to the following taxonomic groups: listed nontarget terrestrial plants and vascular aquatic plants, freshwater invertebrates, and estuarine/marine fish (acute basis), and listed mammals and birds (chronic basis). These findings are based solely on EPA's screening-level assessment and do not constitute "may affect" findings under the Endangered Species Act (ESA) for any listed species.

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on federally listed endangered and threatened species, and to implement mitigation measures that address these impacts. The ESA requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs and considers ecological parameters, pesticide use information, the geographic relationship between specific pesticide uses and species locations and biological requirements and behavioral aspects of the particular species. When conducted, this analysis will consider regulatory changes recommended in this RED that are being implemented at that time. A determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, or consultations with the Fish and Wildlife Service or National Marine Fisheries Service as appropriate. If the Agency determines use of maneb "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). Until that species specific analysis is completed, the risk mitigation measures being implemented through this RED will reduce the likelihood that endangered and threatened species may be exposed to maneb at levels of concern.

2. Spray Drift Management

The Agency has been working closely with stakeholders to develop improved approaches for mitigating risks to human health and the environment from pesticide spray and dust drift. As part of the reregistration process, we will continue to work with all interested parties on this important issue.

From its assessment of maneb, as summarized in this document, the Agency concludes that no drift management measures are needed for maneb. In the future, maneb product labels may need to be revised to include additional or different drift label statements. Current, drift label statements are listed in the "spray drift management" section of the label table (Table 43) in Section V of this RED document.

V. WHAT REGISTRANTS NEED TO DO

The Agency has determined that maneb is eligible for reregistration provided that: (i) additional data are submitted to confirm this decision; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants will be required to amend their product labeling to incorporate the label statements set forth in the Label Summary Table (Table 43). In the near future,

the Agency intends to issue Data Call-In Notices (DCIs) requiring product-specific data and additional generic (technical grade) data at which time required label amendments will be submitted. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product-specific data, the registrant will have eight months to submit data and amended labels. For generic data, due dates can vary depending on the specific studies being required. Below are additional generic data and label amendments that the Agency intends to require for maneb to be eligible for reregistration.

A. Manufacturing-Use Products

Generic Data Requirements

The generic data base supporting the reregistration of maneb for the above eligible uses has been reviewed and determined to be substantially complete. However, the data listed below in Table 42 are necessary to confirm this RED.

Table 42. Outstanding and Confirmatory Generic Data Requirements for Maneb and ETU

Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
Human Health		
Directions for use	860.1200	171-3
Storage Stability - Plants	860.1380	171-4e
Crop field trials [potato, turnip tops, green onions, endive, head and leaf lettuce, loose-head Chinese cabbage, collards, kale, mustard greens, nonbell pepper, cranberry, almond hull, popcorn grain and stover, banana, papaya, and seed treatment (barley, field corn, cotton, flax, oats, rye, safflower, sorghum, wheat)]	860.1500	171-4k
Processing studies [potato]	860.1520	171-4l
Confined Accumulation in Rotational Crops	860.1850	165-1
Subchronic Inhalation Toxicity - Rat	870.3465	82-4
Developmental Toxicity - Rabbit**	870.3700	83-3
Developmental Neurotoxicity - Rat**	870.6300	83-6
Comparative Thyroid Assay **	Special Study	-----
UV/Visible Absorption	830.7050	None
Ecological		
Acute Fish Toxicity- Rainbow Trout (TGAI)	850.1075	72-1C
Acute Fish Toxicity- Rainbow Trout (TEP)	850.1075	72-1D
Whole Sediment Acute Toxicity - Freshwater Invertebrates	850.1735	None

Table 42. Outstanding and Confirmatory Generic Data Requirements for Maneb and ETU		
Guideline Study Name	**New OPPTS Guideline No.**	**Old Guideline No.**
Acute Estuarine/Marine Toxicity - Shrimp (TGAI)	850.1025	72-3C
Whole Sediment Acute Toxicity - Estuarine/Marine Invertebrates	850.1740	None
Acute Estuarine/Marine Toxicity - Shrimp (TEP)	850.1025	72-3F
Early Life Stage Fish - Estuarine	850.1350	72-4A
Life Cycle Aquatic Invertebrate - Freshwater	850.1350	72-4B
Life Cycle Aquatic Invertebrate - Estuarine	850.1350	72-4B
Life Cycle Fish - Estuarine	850.1500	72-5
Aquatic Plant Growth - Tier I	850.5400	122-2
Aquatic Plant Growth - Tier II	850.4400	123-2
TGAI= Technical Grade Active Ingredient TEP=Typical End-use Product * The study must be conducted under the current protocol. ** ETU data requirement		

Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing-use product (MUP) labeling must be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling must bear the labeling contained in Table 43.

B. End-Use Products

Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements.

Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 43. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific existing stocks time frames will

be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

C. Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table (Table 43) describes how language on the labels should be amended.

Table 43. Summary of Labeling Changes for Maneb		
Description	**Amended Labeling Language**	**Placement on Label**
Manufacturing Use Products		
For all Manufacturing Use Products	"Only for formulation into a fungicide for the following uses: [registrant fills in blank with only those uses being supported by MP registrants]." Technical and end-use product labels must be revised to delete all references to and use-directions for the following cancelled use patterns: apples, kadota figs, grapes, sweet corn, rice (seed treatment), and peanuts (seed treatment). Manufacturers of products formulated as wettable powders must prohibit application of wettable powder products by aerial and/or chemigation methods and use of wettable powder products on turf/sod farms. Manufacturers of products formulated as dusts must require closed systems for commercial seed and seed-piece treatment.	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the manufacturing use product label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the manufacturing use product label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use."	Directions for Use

Table 43. Summary of Labeling Changes for Maneb		
Description	**Amended Labeling Language**	**Placement on Label**
Environmental Hazards Statements Required by the RED and Agency Label Policies	"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 Eliminations 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 Environmental Protection Agency."	Precautionary Statements
End-Use Products Intended for Occupational Use (WPS and non-WPS)		
PPE Requirements Established by the RED for Liquid (EC) Formulations	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are [registrant inserts correct material(s)]. If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on an EPA chemical-resistance category selection chart." "Mixers, loaders, applicators, and other handlers must wear: - long-sleeve shirt, - long pants, - shoes and socks, and - chemical-resistant gloves." In addition, handlers mixing and loading for aerial or chemigation application to sod farms must wear a NIOSH-approved respirator with: - a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or - any N*, R, P, or HE filter." *Instruction to Registrant: Drop the "N" type filter from the respirator statement if the pesticide product contains, or is used with, oil.	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Table 43. Summary of Labeling Changes for Maneb		
Description	**Amended Labeling Language**	**Placement on Label**
	"See engineering controls for additional options and requirements."	
PPE Requirements Established by the RED for Wettable Powder (WP) Formulation	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are [registrant inserts correct material(s)]. If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on an EPA chemical-resistance category selection chart." "Mixer, loaders, applicators, and other handlers must wear: - long-sleeve shirt, - long pants, - shoes and socks, and - chemical-resistant gloves, and - a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with any N*, R, P, or HE filter when mixing, loading, cleaning up spills, or otherwise exposed to the concentrate." *Instruction to Registrant: Drop the "N" type filter from the respirator statement if the pesticide product contains, or is used with, oil. "See Engineering Controls for additional options and requirements."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Table 43. Summary of Labeling Changes for Maneb		
Description	**Amended Labeling Language**	**Placement on Label**
PPE Requirements Established by the RED for Dry Flowable (DF) Formulation	"Personal Protective Equipment (PPE) "Some materials that are chemical-resistant to this product are [registrant inserts correct material(s)]. If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on an EPA chemical-resistance category selection chart." "Mixer, loaders, applicators, and other handlers must wear: - long-sleeve shirt, - long pants, - shoes and socks, and - chemical-resistant gloves. In addition, handlers mixing and loading for aerial or chemigation application to sod farms must wear a NIOSH-approved respirator with: - a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or - any N*, R, P, or HE filter." *Instruction to Registrant: Drop the "N" type filter from the respirator statement if the pesticide product contains, or is used with, oil. "See engineering controls for additional options and requirements."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Table 43. Summary of Labeling Changes for Maneb		
Description	**Amended Labeling Language**	**Placement on Label**
PPE Requirements Established by the RED for Dust Formulation.	"Personal Protective Equipment (PPE) "Some materials that are chemical-resistant to this product are [registrant inserts correct material(s)]. If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on an EPA chemical-resistance category selection chart." "Loaders, applicators, and other handlers must wear: - long-sleeve shirt, - long pants, - shoes and socks, and - chemical-resistant gloves (except when bagging treated seeds). " "See engineering controls for additional options and requirements"	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
Engineering Controls: Optional Use by Handlers Liquid, Dry Flowable, and Wettable Powder Formulations	Engineering Control Statement for Optional Use (WPS Only) "Engineering Controls: When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4) to (5)], the handler PPE requirements may be reduced or modified as specified in the WPS."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Table 43. Summary of Labeling Changes for Maneb		
Description	**Amended Labeling Language**	**Placement on Label**
Engineering Controls: Closed System for Commercial Seed and Seed Piece Treatment. Dust Formulations	"Loaders must use a closed system designed by the manufacturer to enclose the pesticide to prevent it from contacting handlers or other people while it is being handled. The system must have a properly functioning dust control system and must be used and maintained in accordance with the manufacturer's written operating instructions. Handlers using the closed mixing/loading system must: -- wear the personal protective equipment required in the PPE section of this labeling for loaders, and -- be provided and must have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown: a NIOSH-approved respirator with a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C *or* any N, R, P, or HE filter."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE 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/ PPE 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 Statements under: Hazards to Humans and Domestic Animals (Must be placed in a box.)

Table 43. Summary of Labeling Changes for Maneb		
Description	**Amended Labeling Language**	**Placement on Label**
Restricted-Entry Interval	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours."	Directions for Use, in Agricultural Use Requirements box
Early Reentry Personal Protective Equipment for Products subject to WPS as required by Supplement Three of PR Notice of 93-7	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as soil or water, is: - Coveralls, - Shoes and socks, and - Chemical-resistant gloves made of any waterproof material.	Directions for Use, in Agricultural Use Requirements Box
General Application Restrictions All Formulations	"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."	Place in the Directions for Use directly above the Agricultural Use Box
Application Restrictions for Wettable Powder (WP) Formulation only	"Aerial application is prohibited" "Applying this product by chemigation is prohibited." Technical and end-use product labels must be revised to delete all references to and use directions for the following cancelled use pattern: Sod farm turf.	Directions for Use

Table 43. Summary of Labeling Changes for Maneb		
Description	**Amended Labeling Language**	**Placement on Label**
Application Restrictions All Formulations	Almonds: Reduce the maximum yearly application rate to 19.2 lb ai/A Cut Flowers: Limit to 20 applications per year. Oat Seed Treatment: Reduce application rate to 0.0021 lb ai/lb seed. Sod Farm Turf: Reduce one-time application rate to 8.7 lb ai/Acre and seasonal maximum application rate to 34.8 lb ai/A. Require a 3-day pre-harvest interval (PHI). All turf labels must state: "For Use on Sod Farms Only" The labels also must list the maximum application rates in pounds or gallons of formulation. Technical and end-use products must be revised to delete all references to and use directions for the following cancelled use patterns: apples, kadota figs, grapes, sweet corn, rice (seed treatment), and peanuts (seed treatment).	Directions for Use
Application Restrictions for seed or seed-pieces that have been treated with this product and that are then packaged or bagged for future use	"Seed/Seed-pieces that have been treated with this product and that are then packaged or bagged for future use must contain the following labeling on the outside of the seed/seed-piece package or bag:" "When opening this bag or loading/pouring the treated seed/seed-pieces, wear long-sleeved shirt, long pants, shoes, socks, chemical resistant gloves, and a NIOSH-approved respirator with: - a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or - any N*, R, P, or HE filter." *Instructions: Drop the "N" type filter from the respirator statement if the pesticide product contains, or is used with, oil. "Treated Seed/Seed-Pieces - Do Not Use for Food, Feed, or Oil Purposes." "After the seeds/seed-pieces have been planted, do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 24 hours. Exception: Once the seeds are planted in soil or other planting media, the Worker Protection Standard allows workers to enter the treated area without restriction if there will	Directions for Use

Table 43. Summary of Labeling Changes for Maneb		
Description	**Amended Labeling Language**	**Placement on Label**
	be no worker contact with the soil/media subsurface."	
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This pesticide is toxic to aquatic organisms. Do not apply directly to water, or to areas where surface water is present, or to inter-tidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwater or rinsate."	Precautionary Statements: Hazards to Humans and Domestic Animals
Spray Drift Label Language for Products Applied as a Spray	**"SPRAY DRIFT MANAGEMENT"** "A variety of factors including weather conditions (e.g., wind direction, wind speed, temperature, relative humidity) and method of application (e.g., ground, aerial, airblast, chemigation) can influence pesticide drift. The applicator must evaluate all factors and make appropriate adjustments when applying this product." **Wind Speed** "Do not apply at wind speeds greater than 15 mph. **Temperature Inversions** "If applying at wind speeds less than 3 mph, the applicator must determine if a) conditions of temperature inversion exist, or b) stable atmospheric conditions exist at or below nozzle height. Do not make applications into areas of temperature inversions or stable atmospheric conditions." **Other State and Local Requirements** "Applicators must follow all state and local pesticide drift requirements regarding application of maneb. Where states have more stringent regulations, they must be observed." **Equipment** "All aerial and ground application equipment must be properly maintained and calibrated using appropriate carriers or surrogates."	Spray Drift Label Language for Products Applied as a Spray

Table 43. Summary of Labeling Changes for Maneb		
Description	**Amended Labeling Language**	**Placement on Label**
	Additional requirements for aerial applications: 1. "The boom length must not exceed 75% of the wingspan or 90% of the rotor blade diameter." 2. "Release spray at the lowest height consistent with efficacy and flight safety. Do not release spray at a height greater than 10 feet above the crop canopy unless a greater height is required for aircraft safety." 3. "When applications are made with a crosswind, the swath must be displaced downwind. The applicator must compensate for this displacement at the up and downwind edge of the application area by adjusting the path of the aircraft upwind." *Additional requirements for ground boom application:* 1. "Do not apply with a nozzle height greater than 4 feet above the crop canopy."	

Note to Reader

The Appendices to the Maneb RED are undergoing final editing and will be made available in January 2006.