

United States Environmental Protection Agency Prevention, Pesticides and Toxic Substances (7508P) EPA September 2007

# Reregistration Eligibility Decision for Aldicarb

# **Reregistration Eligibility Decision (RED) Document** for Aldicarb

## List A

Case Number 0140

Approved by:

Date: \_\_\_\_\_

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### **Glossary of Terms and Abbreviations**

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formulation
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
EC	Emulsifiable Concentrate Formulation
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
GLN	Guideline Number
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 a 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
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	Milligram Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification Number. EPA's system for recording and
	tracking studies submitted.
MUP	Manufacturing-Use Product
NOAEL	No Observed Adverse Effect Level
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	Pre-harvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Pesticide Root Zone Mode/Exposure Analysis Modeling System, Tier II
	Surface Water Computer Model
Q*	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-GROW2	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

#### Abstract

This document presents the Environmental Protection Agency's (EPA's or the Agency's) decision regarding the reregistration eligibility of the registered uses of the active ingredient aldicarb. The Agency has conducted human health and environmental fate and effects risk assessments for aldicarb and has assessed whether the aldicarb tolerances are safe from an individual-chemical standpoint (considering all issues other than cumulative exposures to other n-methyl carbamate pesticides). The Agency has determined that, with label amendments and changes as specified in this document, aldicarb can be used without resulting in unreasonable adverse effects on the environment, and that there is a reasonable certainty that no harm will result to the general U.S. population, infants, children, or other major identifiable population subgroups, from the use of aldicarb (considering all issues other than cumulative exposures to other n-methyl carbamate pesticides). The Agency has therefore determined that products containing the active ingredient aldicarb are eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures.

EPA has identified potential human health risks of concern associated with the current registered uses of aldicarb from drinking water exposure, and potential environmental risks of concern to birds, mammals and fish. To reduce these potential exposures and to address current risks of concern, the Agency, in agreement with the technical registrant of aldicarb, will implement label restrictions (increase drinking water well set-backs when certain criteria are triggered) for application to peanuts in the southeastern coastal plains for ground water contamination concerns. Additionally, application rate reductions, state limitations, application restrictions, label amendments, and termination of certain uses will also be implemented to reduce environmental concerns. The Agency is also requiring appropriate data to confirm the decisions presented in this Reregistration Eligibility Decision.

#### 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 data submitted to the Environmental Protection Agency (hereafter 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 hazards arising from the currently registered uses of a 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" standard of FIFRA.

On August 3, 1996, the Food Quality Protection Act (FQPA) was signed into law. This Act amended FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA) to require reassessment of all existing tolerances for pesticides in food. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment would be accomplished through the reregistration process. Under FQPA, 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 among infants and children, and the cumulative effects of pesticides that have a common mechanism of toxicity. In determining whether aldicarb tolerances can be reassessed as safe, the Agency has concluded that the risks from aggregate exposure to aldicarb are acceptable, and that the tolerances can be reassessed as safe if they are acceptable when viewed in light of the cumulative assessment of n-methyl carbamate pesticides.

The intentional dosing human toxicity study (the Inveresk study) used in the human health risk assessment for aldicarb has been reviewed by EPA's Human Studies Review Board, as required by EPA's Human Subjects Protections rule. The Agency presented the Inveresk study to the HSRB at a meeting on April 2 - 4, 2006. The HSRB discussed the study extensively and concluded that the cholinesterase data from the aldicarb human study were reliable for use in the aldicarb single chemical, aggregate risk assessment from both a science and ethical standpoint. The final report of the HSRB is available at http://www.epa.gov/osa/hsrb/files/april2006mtgfinalreport62606.pdf

Risks summarized in this document are for aldicarb only. 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 exposure 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. Aldicarb is a member of the N-methyl carbamate class of pesticides. The Agency has classified the N-methyl carbamate pesticides and their common degradates as having a common mechanism of toxicity.

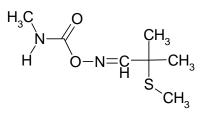
A cumulative risk assessment, which evaluates exposures based on a common mechanism of toxicity, was conducted to evaluate risk from food, drinking water, residential use, and other non-occupational exposures resulting from registered uses of N-methyl carbamate pesticides, including aldicarb. EPA has concluded that the cumulative risks associated with the N-methyl carbamate pesticides are below the Agency's level of concern. With this determination, the Agency has concluded the reassessment process for aldicarb tolerances mandated by section 408(q) of the FFDCA. For additional information, refer to the document, Revised N-methyl Carbamate Cumulative Risk Assessment, which is available in the EPA docket EPA-HQ-OPP-2007-0935 and on the website, http://www.epa.gov/pesticides/cumulative/.

This document presents EPA's revised human health and environmental fate and effects risk assessments, its progress toward tolerance reassessment, and the reregistration eligibility decision for aldicarb. The document consists of six sections. Section I contains the regulatory framework for reregistration and tolerance reassessment. Section II provides a description of the chemical and a profile of the use and usage of the chemical. Section III references the revised human health and environmental fate and effects risk assessments attached as Appendices to this document. Section IV presents the Agency's risk management, reregistration eligibility, and tolerance reassessment decisions. Section V summarizes the data requirements necessary to confirm the reregistration eligibility decision as well as specific label changes and language necessary to implement the risk mitigation measures outlined in Section IV. Section VI, the Appendices, provides related information and supporting documents. The preliminary and revised risk assessments for aldicarb are available in the public docket EPA-HQ-OPP-2005-0163 located on-line in the Federal Docket Management System (FDMS) at http://www.regulations.gov.

#### **II. Chemical Overview**

#### A. Chemical Identity

Chemical Structure:



Empirical Formula:	$C_7H_{14}N_2O_2S$
Common Name:	Aldicarb
CAS Name:	2-methyl-2-(methylthio)propionaldehyde O- (methylcarbamoyl)oxime
CAS Registry Number:	116-06-3
OPP Chemical Code:	098301
Case Number:	0140
Technical Registrant:	Bayer CropSciences
Degradates:	Aldicarb sulfoxide: 2-Methyl-2-(methylsulfinyl)propionaldehyde O- (methyl carbamoyl) oxime, and Aldicarb sulfone: 2-Methyl-2- (methylsulfonyl)propionaldehyde O-(methyl carbamoyl) oxime

The regulated residues are the combined residues of aldicarb and its two cholinesteraseinhibiting metabolites, aldicarb sulfoxide and aldicarb sulfone. Aldicarb sulfoxide is considered to have similar potency to the parent in terms of toxicity, while aldicarb sulfone is less potent. Aldicarb and the sulfoxide and sulfone metabolites are the residues of concern in both the tolerance expression and the reregistration decision.

Aldicarb is registered for use as a systemic insecticide and nematicide on agricultural crops. Aldicarb is absorbed by the root system, and is subsequently translocated throughout the plant. Aldicarb is a restricted use pesticide and there are no aldicarb products intended for sale to homeowners or for use in residential settings. Aldicarb is currently sold in the United States by Bayer CropScience, the basic producer, under the trade name of Temik<sup>®</sup>.

#### **B.** Regulatory History

Aldicarb was first registered in 1970. Marketing of aldicarb was stopped in Long Island in 1980 due to high levels of aldicarb degradates found in ground water there. In 1981, aldicarb was classified as a restricted use pesticide and in 1984 was placed under Special Review. Aldicarb is currently under Special Review because of concerns regarding ground water contamination. Position Documents (PD's) 1 and 2/3 were published on 7/11/84 (49 FR 28320) and 6/29/88 (53 FR 24630), respectively. A Special Review Data Call-In-Notice (DCI) was issued 6/3/89 requiring the registrant to submit additional ground water data. In addition, because a National Food Survey identified discrepancies between anticipated residues in foods and actual residues from food survey samples, the Special Review required a variety of studies related to use on potatoes and citrus crops. In 1990, the sale of aldicarb on potatoes was voluntarily suspended due to detection of tolerance-exceeding aldicarb residues on individual potatoes. The registrant agreed to dietary risk reduction actions involving voluntary cancellation of use on bananas and registration amendments for uses on potatoes, sweet potatoes, oranges and grapefruit. The registrant subsequently submitted extensive field residue and commercial storage and processing data showing that more controlled application techniques would ensure residues below the established tolerance and would not pose any increased dietary risk. The use on potatoes was re-instated in the states of FL, ID, WA and OR, after new application methods demonstrated significantly lower residues in potatoes. Although dietary risk concerns relating to use on potatoes have been resolved, aldicarb remains in EPA's Special Review process because of concerns about risks of ground water contamination. In 1998, the Agency issued a proposal as part of Special Review to manage risks due to ground water concerns through national measures consisting of the prohibition of aldicarb use within 300 feet of a drinking water well, and geographically specific measures consisting of the requirement for State Management Plans. The Agency will begin the process to close out the Special Review of aldicarb in the near future.

#### C. Use and Usage Profile

The following is information on the currently registered uses of aldicarb. Sections IV and V include information on those currently registered uses which are eligible for reregistration and Appendix A provides a detailed table of those uses which are eligible for reregistration.

Type of Pesticide: Aldicarb is a systemic insecticide, acaricide and nematicide used to control the following pests: a number of nematode species (suppression); leaf phylloxera; bud moth;; aphids; mites; white flies; thrips; fleahoppers, leafminers; leafhoppers; overwintering boll weevil; lygus; cotton leaf perforator; seedcorn maggot; Mexican bean beetle; flea beetles; Colorado potato beetle; greenbug; chinch bug; three cornered alfalfa hopper (suppression); and sugar beet root maggot.

Formulations:	Aldicarb is formulated and marketed solely as a granular pesticide under the trade name Temik®. The granulars (5, 10 and 15% a.i.) consist of aldicarb adhered to a corn cob grit or gypsum substrate, which are formulated to produce less dust than typical clay substrates used for granular pesticides. The gypsum granular is available in closed loading systems.		
Methods of Application:	End-use products containing aldicarb are restricted use and can only be applied by a certified applicator. Typically, aldicarb is applied early in the growing season, either pre-plant, at-planting, or early post-emergent, using ground application equipment. Positive displacement application equipment and immediate soil incorporati are required. Aldicarb is also applied as a split-season use to pean It is applied as a broadcast (at-pegging) to the canopy of the pean ut plant for nematode control.		
Use Sites:	No aldicarb products are intended for sale to homeowners or for use by professional applicators in residential environments. Aldicarb is currently registered for use on agricultural crops including citrus, cotton, dry beans, peanuts, pecans, potatoes, sorghum, soybeans, sugar beets, sugarcane, sweet potatoes, and seed alfalfa (CA). In addition, aldicarb may be applied to field grown ornamentals (CA), tobacco, and on coffee grown in Puerto Rico.		
Application Rates:	The maximum application rates range from 1.05 pounds (lbs) active ingredient (ai) per acre (A) for sorghum to 10.05 lbs ai/A for pecans.		
Estimated Usage:	Approximately 4.5 million pounds of aldicarb are used annually. Aldicarb is used mostly on cotton (approximately 64% of total aldicarb use). Other high use crops include peanuts, potatoes, sugar beets, and citrus.		

#### **D.** Tolerances

Tolerances for aldicarb are expressed in terms of the combined residues of aldicarb and its cholinesterase-inhibiting metabolites aldicarb sulfoxide and aldicarb sulfone in plant, livestock, and processed food and feed commodities [40 CFR §180.269, §185.150 (a), and §186.150]. Section IV includes a summary of the tolerance reassessment decision for aldicarb and lists those tolerances the Agency will propose to revoke, decrease, increase, maintain, reassign, and establish.

#### III. Aldicarb Human Health and Environmental Fate and Effects Risk Assessments

Human health effects and environmental fate and effects risk assessments have been performed for aldicarb. These assessments demonstrate potential human health risks of concern for ground water contamination in the southeastern coastal plains resulting from the use on peanuts, and environmental risks of concern to both terrestrial and aquatic organisms resulting from all uses of aldicarb. A summary of potential risk concerns are presented below. For additional information and the risk assessments in their entirety, please refer to the revised human health and environmental fate and effects risk assessments for aldicarb, dated February 26, 2007, and November 30, 2005, respectively. These documents are also available in the public docket EPA-HQ-OPP-2005-0163 located on-line at <a href="http://www.regulations.gov">http://www.regulations.gov</a>.

#### A. Human Health

As discussed in Section 5.2 of the human health risk assessment (found at <u>http://www.regulations.gov./</u>), there are risk estimates that exceed EPA's level of concern from aggregate dietary exposure to residents living in the U.S. southeastern coastal plain who consume water from rural ground water wells.

Four drinking water (from ground water sources) concentration scenarios were modeled for aldicarb: three ground water scenarios for use on peanuts/cotton in Georgia with an assumption of a 300 ft., 500 ft., and 1000 ft. setback, as well as an additional scenario in Florida for aldicarb use on citrus with a 1000 ft. setback. The estimated risks at the 99.9<sup>th</sup> percentile are below the Agency's level of concern for all four scenarios, and for all population subgroups except for infants under the Georgia 300ft. scenario (139% - 147% of the acute population adjusted dose (aPAD)). For all other scenarios, risk are not of concern to the Agency.

#### **B.** Environmental Fate and Effects

There are multiple lines of evidence, including studies in the open literature and registrant submitted data, clearly demonstrating that aldicarb is very highly toxic to both aquatic and terrestrial non-target organisms (e.g., a single granule of TEMIK® 15G can kill a small bird). However, the degree to which there is exposure to aldicarb or its degradates in the terrestrial and aquatic environments is much more uncertain. This is due in part to the physical properties (e.g., color, size, and solubility) of the aldicarb granule, the variety of application techniques, amounts applied, number of applications, application intervals, and timing of applications. Typically, the aldicarb granules are spread on the surface and incorporated into the soil by "shanking in", "working into the soil", "covering with soil", and/or "wetting in". Applications directly "infurrow" are also performed for some crops (e.g., sweet potato), but may be followed by later applications that are less effectively soil-incorporated. The ecological risk assessment was conducted assuming that the aldicarb granules are incorporated into the soil with efficiencies ranging from 85 to 99 percent, leaving just 1 to 15 percent of the applied granules on the soil surface available to terrestrial organisms or to runoff to surface water (resulting in exposure to aquatic organisms). Certain application techniques, specifically, in-furrow applications and banded applications that utilize state-of-the-art methods (such as positive displacement and immediate soil incorporation), may theoretically result in incorporation efficiencies of 99

percent. Other types of applications may result in incorporation efficiencies closer to 85 percent. Because of this uncertainty, both scenarios were addressed in the ecological risk assessment. In addition to this, risk quotients were calculated for both maximum labeled rates and typical application rates, showing the range of expected outcomes.

There are two aldicarb degradates of concern, aldicarb sulfoxide and aldicarb sulfone, that are also considered in the assessment. These degradates appear to form primarily in the shallow subsurface (although some may also form within plant tissue) and are potentially more mobile and persistent than the parent. As a conservative assumption, all three forms (parent aldicarb, sulfoxide, and sulfone) are considered as a single constituent for aquatic exposure estimates because of the longer degradate half-lives. Parent only is considered for terrestrial exposure because of its higher toxicity to animals, the likelihood that most exposure would be to whole granules, and because only small amounts of the degradates, relative to the parent, are expected to be present directly on the surface.

Given the methods of application of the aldicarb granule (i.e., ground application and incorporation into the soil), its high water solubility, low vapor pressure, and low bioaccumulation potential, terrestrial exposure to aldicarb is primarily confined to the treated field. Off-site terrestrial exposure to aldicarb would be limited to cases where, 1) a granule is redeposited to lower-lying areas affected by aldicarb runoff from nearby fields, or 2) a granule in the gut or on a prey item such as a small bird or mammal is consumed by a predator. The series of events that would need to transpire in order to result in off-site exposure are considered unlikely.

Summarizing the risk to terrestrial organisms, the acute risk level of concern for birds and mammals is exceeded for all target crops at both maximum allowed label rates and typical use rates. The levels of concern are consistently exceeded by a factor of greater than 100X and are frequently exceeded by more than 1000X. These results consider both 85 and 99 percent incorporation efficiencies. The granules left exposed on the surface appear to be the main source of exposure, but other sources such as residues taken up by plants and soil invertebrates (e.g., earthworms) may also serve as a means of exposure.

The following tables (Table 1 and Table 2) provide risk quotients that were calculated based on maximum labeled application rates and the average or typical application rates taken from the Biological and Economic Analysis Division's Quantitative Usage Analysis dated August 9, 2004, as well as label-indicated band widths and row spacing. Granule incorporation efficiency was set at 85 percent (Table 1) or 99 percent incorporation (Table 2). Based on this information, it is evident that risk levels of concern are exceeded even at rates that are less than the application rates allowed by the product labels and at granule incorporation efficiencies approaching 100 percent.

Crop (max. rate/typical rate in lbs ai/acre)	ypical rate in Avian RQs Avian RQs		Maximum Rate Mammalian RQs	Typical Rate Mammalian RQs
Citrus (4.95/3.7)	9 - 771	6 - 577	11 – 261	8 - 195
Cotton (4.05/0.6)	71 - 6396	11 - 948	93 - 2161	14 - 320
Dry Beans (2.1/1.0)	29 - 2620	13 - 1248	38 - 885	18 - 422
Peanuts (3.0/0.9)	31 - 2807	9 - 842	41 - 948	12 - 285
Pecans (10.05/3.1)	17 – 1566	5 - 483	23 - 529	7 - 163
Potatoes (3.0/2.7)	33 - 2963	30 - 2667	43 - 1001	39 - 901
Soybeans (3.0/0.7)	26 - 2339	6 - 546	34 - 790	8 - 184
Sugar beets (4.95/1.8)	32 - 2831	11 - 972	41 – 956	14 - 328
Alfalfa (3.0/NA)	5 - 451	not available	7 - 158	not available
Coffee (4.4/NA) <sup>1</sup>	246 - 22,110	not available	332 - 7738	not available
Sugarcane (3.0/NA)	50 - 4512	not available	68 – 1579	not available
Tobacco (3.0/NA)	20 - 1805	not available	27 - 632	not available
Ornamental (5.0/NA)	0.6 - 52	not available	0.8 - 18	not available

 Table 1. Ranges of acute risk quotients for small, medium, and large birds and mammals

 exposed to maximum label rate and typical application rates at 85% incorporation efficiency.

<sup>1</sup> No incorporation assumed based on product label directions.

Table 2. Ranges of acute risk quotients for small, medium, and large birds and mammals
exposed to maximum label rate and typical application rates at 99% incorporation efficiency.

Crop (max. rate/typical rate in lbs ai/acre)	Maximum Rate Avian RQs	Typical Rate Avian RQs	Maximum Rate Mammalian RQs	Typical Rate Mammalian RQs
Citrus (4.95/3.7)	0.6 - 52	0.4 - 39	0.8 - 17	0.6 - 13
Cotton (4.05/0.6)	5-428	0.7 - 63	6 - 145	0.9 - 21
Dry Beans (2.1/1.0)	2 – 175	0.9 - 84	3 - 59	1 - 28
Sorghum (1.05/0.4)	2 - 193	0.8 - 73	3 - 65	1 - 25
Peanuts (3.0/0.9)	2 - 188	0.6 - 56	2.7 - 64	0.8 - 19
Pecans (10.05/3.1)	1 - 105	0.4 - 32	2-35	0.5 - 11
Potatoes (3.0/2.7)	2 – 198	2 - 179	3 - 67	3 - 60
Soybeans (3.0/0.7)	2 - 157	0.4 - 37	2 - 53	0.5 - 12
Sugar beets (4.95/1.8)	2 - 190	0.7 - 65	3 - 64	0.9 - 22
Sweet potatoes (3.0/1.4)	1 – 125	0.7 - 58	2 - 42	0.8 - 20
Ornamental (5.0/NA)	0.6 - 52	not available	0.8 – 18	not available

The potential for mortality to birds has been an area of initial focus, given aldicarb's mode of action and very high acute toxicity. Chronic risk to birds has not yet been quantitatively assessed. However, based on inference from mammalian data, which involved comparing magnitudes of  $LD_{50}$ s between the mallard duck (1.0 mg/kg-bw) and rat (0.9 mg/kg-bw) and then using this information together with the chronic information available for the laboratory rat (reproductive NOAEL = 0.7 - 0.9 mg/kg-bw), the Agency expects that birds (as well as mammals) that survive acute exposure to aldicarb may suffer adverse reproductive (chronic) effects. The Agency is requesting additional data to confirm this hypothesis.

While there are some exceedences of acute levels of concern for aquatic species, risk from chronic exposure to aldicarb and its degradates appears to be more significant. The chronic level of concern is exceeded for several uses at maximum application rates and 99 percent incorporation efficiency for freshwater fish and invertebrates, as well as for estuarine/marine fish and invertebrates. However, under typical application rates, these risks for the most part are mitigated. In addition to risk based on exposure estimates from aquatic exposure modeling, there were also exceedences of the Agency levels of concern based on EECs derived from monitoring data.

There have been 29 incidents related to aldicarb reported in the Environmental Incident Information System database (reported to the Agency from 1988 to 2005). Of these 29 incidents, 16 were from misuse, 11 were of undetermined use, and 2 were registered agricultural uses. Approximately 17 of the 29 incidents reported included bird kills. Fourteen bird kill incidents were from intentional misuse, and 3 were of undetermined use. Eight of these incidents also resulted in mammal kills (all misuse or undetermined use).

When evaluating incident data, it is important to note that currently, no systematic or reliable mechanism exists for the accurate monitoring and reporting of wildlife kill incidents to the Agency. Moreover, before a pesticide incident can be reported or investigated, the dead animals must first be found. In the absence of monitoring following pesticide applications, kills are not likely to be noticed in agro-environments which are generally away form human activity. It is likely that poisoned birds may fly from the use sites, succumbing outside of the area or scavengers may remove carcasses before they can be observed, significantly reducing the chance of detection.

#### IV. Risk Management, Reregistration, and Tolerance Reassessment Decisions

#### 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 the generic (technical grade) data required to support reregistration of products containing aldicarb 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 aldicarb provided the registrations are amended in a manner consistent with this document.

The Agency has completed its review of submitted data and its assessment of the dietary (both food and drinking water), occupational, and ecological risks associated with the use of pesticide products containing the active ingredient aldicarb. Based on these data and public comments received on the Agency's assessments for the active ingredient aldicarb, the Agency has sufficient information on the human health and ecological effects of aldicarb to make a decision as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA.

Based on its evaluation of aldicarb, the Agency has determined that products containing the active ingredient aldicarb, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA and FFDCA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take appropriate regulatory action to address the risk concerns from the use of aldicarb. If all changes outlined in this document are incorporated into the product labels, then all current risks for aldicarb will be adequately addressed for the purposes of this determination under FIFRA. Once a comprehensive endangered species assessment is completed, further changes to these registrations may be necessary as explained in Section IV.D.4 of this document below.

#### **B.** Public Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach these regulatory decisions for aldicarb. The Phase 3 public comment period on the risk assessments, opened on May 17, 2006, and the Phase 5 public comment period on the risk assessments and solicitation for additional input to use/usage opened on November 14, 2006. The Agency received comments from several stakeholders (including stakeholders from public interest groups), and the technical registrant, Bayer CropScience. A complete listing of these comments can be found at <a href="http://www.regulations.gov./">http://www.regulations.gov./</a>

These comments were reviewed and taken into consideration in preparing the revised risk assessments and their supporting documents, including this aldicarb RED. The comments are available in their entirety in the public docket EPA-HQ-OPP-2005-0163 located on-line at <a href="http://www.regulations.gov./">http://www.regulations.gov./</a>. The Agency's responses to substantive comments are available in

memoranda in the public docket and the revised assessments available in the public docket reflect these responses.

#### **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 aldicarb. The Agency has concluded that, with the risk mitigation measures outlined in this document, the aggregate risk from food and drinking water exposures to aldicarb is within its own "risk cup." The Agency has determined that the human health risks from these combined exposures are within acceptable levels and that, considering every issue other than the cumulative impacts of exposure to other n-methyl carbamate pesticides, the established tolerances for aldicarb, with label amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to Section 408(b)(2)(C) and 408(b)(2)(D) of the FFDCA. In reaching these determinations, EPA has considered the available information on the special sensitivity of infants and children.

# **b.** Determination of Safety to U.S. Population (Including Infants and Children)

The Agency has determined that there is a reasonable certainty that no harm will result to the general U.S. population, infants, children, or other major identifiable subgroups of consumers, from the use of aldicarb. The safety determination considers factors such as the toxicity, use practices and exposure scenarios, and environmental behavior of aldicarb. In determining whether or not infants and children are particularly susceptible to toxic effects from exposure to residues of aldicarb, the Agency considered the completeness of the hazard database for developmental and reproductive effects, the nature of the effects observed, and other information.

The Agency determined it was necessary to retain a 2X FQPA database uncertainty factor for aldicarb residues in the dietary human health risk assessment because magnitude of the brain cholinesterase inhibition was approximately 2-fold greater in the young rat compared to the adult rat at similar acute doses. For specific information relating to the Agency's decision on the FQPA factor, refer to section 3.4 in the February 26, 2007 Human Health Revised Risk Assessment found at <u>http://www.regulations.gov./</u>

#### 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 such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory

Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disrupter Screening Program (EDSP) have been developed and vetted, aldicarb may be subjected to additional screening and/or testing to better characterize possible effects related to endocrine disruption.

#### d. Cumulative Risks

FFDCA Section 408(b)(2)(D)(v) requires that the Agency consider "available information" concerning cumulative effects of a particular pesticides residues and "other substances that have a common mechanism of toxicity" when considering whether to establish, modify, or revoke a tolerance for pesticide residues in food. EPA considers cumulative effects from pesticides and other substances because low-level exposures to multiple chemical substances causing a common effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to each individual substance.

Aldicarb is a member of the N-methyl carbamate class of pesticides, which share a common mechanism of toxicity by affecting the nervous system via cholinesterase inhibition. A cumulative risk assessment, which evaluates exposures based on a common mechanism of toxicity, was conducted to evaluate risk from food, drinking water, residential use, and other non-occupational exposures resulting from registered uses of N-methyl carbamate pesticides, including aldicarb. EPA has concluded that the cumulative risks associated with the N-methyl carbamate pesticides are below the Agency's level of concern. For additional information, refer to the document, Revised N-methyl Carbamate Cumulative Risk Assessment, which is available in the EPA docket EPA-HQ-OPP-2007-0935 and on the website, http://www.epa.gov/pesticides/cumulative/.

#### 2. Tolerance Summary

The tolerance summary and tolerance reassessment decision is presented for aldicarb in Table 3 below. Currently there are forty tolerances listed in 40 CFR §180.269, 40 CFR §185.150, and 40 CFR §186.150 for residues of aldicarb on raw and agricultural commodities and livestock commodities.

The available aldicarb residue chemistry data are considered adequate to reassess most tolerances. The Agency will propose establishing a citrus fruit crop group tolerance of 0.3 ppm.

Some commodities with established tolerances must be revised to reflect the correct commodity definition. Additional data are needed to determine appropriate tolerances for residues in/on cottonseed and cotton gin by-products.

The established tolerance for residues in peanut hulls should be revoked since this raw agricultural commodity is no longer considered to be significant livestock feed items (OPPTS Series 860.1000, Table 1, 8/96). The Agency recommends classification of residues in livestock

commodities under 40 CFR §180.6(a)(3); therefore, tolerances for residues in livestock commodities should be revoked.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ [Correct Commodity Definition]
		Listed Under 40 Cl	FR 180.269:
Barley, hay	-	3.0	
Barley, grain	-	0.02	Rotational crop tolerances recommended by
Barley, straw	-	0.1	HED.
Beans (dry)	0.1	0.1	[bean, dry, seed]
Beets, sugar	0.05	0.05	[beet, sugar, roots]
Beets, sugar, tops	1	1	[beet, sugar, tops]
Cattle, fat	0.01		
Cattle, mbyp	0.01	Revoke	There is no reasonable expectation of finite residues.
Cattle, meat	0.01		Testudes.
Coffee beans	0.1	0.1	[ <i>coffee, green bean</i> , import tolerance only]
Cottonseed	0.1	0.1	[cotton, undelinted seed]
Goats, fat	0.01		
Goats, mbyp	0.01	Revoke	There is no reasonable expectation of finite residues.
Goats, meat	0.01		residues.
Grapefruits	0.3	0.3	
Lemons	0.3	0.3	The registrant has proposed a crop group
Limes	0.3	0.3	tolerance of 0.3 ppm for <i>fruit, citrus, group</i> .
Oranges	0.3	0.3	
Hogs, fat	0.01		
Hogs, mbyp	0.01		
Hogs, meat	0.01		
Horses, fat	0.01	Revoke	There is no reasonable expectation of finite residues.
Horses, mbyp	0.01		Testutes.
Horses, meat	0.01		
Milk	0.002		
Peanut	0.05	0.05	
Peanut, hulls	0.5	Revoke	Peanut hulls are not considered to be a significant livestock feed item.
Pecan	0.5	Revoke	Revoke
Potato	1	0.2	The available data reflecting the supported use pattern indicate the established tolerance should be reduced.
Sheep, fat	0.01		
Sheep, mbyp	0.01	Revoke	There is no reasonable expectation of finite residues.
Sheep, meat	0.01		

 Table 3. Tolerance Reassessment Summary for Aldicarb and Aldicarb Sulfone and

 Aldicarb Sulfoxide.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ [Correct Commodity Definition]			
Sorghum, stover (fodder)	0.5	Revoke				
Sorghum, grain	0.2	Revoke				
Soybean	0.02	0.02	soybean, seed			
Sugarcane	0.02	Revoke	[import tolerance only]			
Sugarcane, fodder	0.1	Revoke	These commodities are not considered to be			
Sugarcane, forage	0.1	Revoke	significant livestock feed items.			
Sweet potatoes	0.1	0.1	sweet potato, root			
Wheat, forage	-	1.0				
Wheat, grain	-	0.02	Rotational crop tolerances recommended by			
Wheat, straw	-	0.1	HED.			
Wheat, hay	-	3.0				
Required Tolerances to be Listed Under 40 CFR §180.269						
Cotton, gin byproducts		TBD <sup>a</sup>				
	Tolerances Listed Under 40 CFR §186.150:					
Citrus pulp, dried	0.6	Revoke	Commodity covered by the raw agricultural commodity tolerance.			
Cottonseed, hulls	0.3	Revoke	Commodity covered by the raw agricultural commodity tolerance.			

<sup>a</sup> Data depicting the magnitude of aldicarb residues of concern in cotton gin byproducts are required in accordance with Table 1 of OPPTS Series 860 Residue Chemistry Test Guidelines, 8/96.

#### **D. Regulatory Rationale**

The Agency has determined that products containing the active ingredient aldicarb are eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures. The following is a summary of the risk mitigation measures and EPA's rationale for the decision for managing risks associated with the use of aldicarb. Where labeling revisions are warranted, label changes and language are specified in Section V.

#### 1. Human Health Risk Management and Mitigation

#### a. Dietary Risk Mitigation (Drinking Water)

As discussed in Section 5.2 of the human health risk assessment (found at <u>http://www.regulations.gov./</u>), there are risk estimates that exceed EPA's level of concern from aggregate dietary exposure to residents living in the U.S. southeastern coastal plain who consume water from rural ground water wells in specific vulnerable areas.

Four ground water scenarios were modeled for aldicarb. The estimated risks at the 99.9<sup>th</sup> percentile are below the Agency's level of concern for all four scenarios, and for all population

subgroups except for infants under the Georgia 300 feet peanut scenario. For all other scenarios, risk are not of concern to the Agency.

Therefore, in order to mitigate potential drinking water concerns in the peanut growing regions in the states of Georgia, Alabama, South Carolina, and Florida, an increased well setback from 300 to 500 feet is required for wells not encased to a depth of 100 feet in vulnerable soils, and a shallow depth to ground water (less than 25 feet).

The determination for this buffer was based upon both monitoring data and modeling. The Agency utilized the Natural Resource Conservation Service's (NRCS) criteria for high leaching potential soils for Florida and encourages the technical registrant, Bayer CropScience to use the same criteria when determining vulnerable soils for other states. The Agency's review of "A Retrospective Ground Water Monitoring Study for Aldicarb and Its Metabolites in the Southeastern United States; Mississippi Delta; Texas; California; and Pacific Northwest", dated July 24, 2007, and found at <u>http://www.regulations.gov./</u> contains the reference to the NRCS criteria.

#### b. Aggregate Risk Mitigation

As previously discussed, food and drinking water are below the Agency's level of concern with the mitigation for ground water in the Southeastern states of Alabama, Georgia, South Carolina, and Florida. There are no residential exposures, therefore, no additional mitigation is needed to address aggregate risk. Label changes and language necessary for reregistration are specified in Table 5 in Section V.

#### c. Occupational Risk Mitigation

As discussed in Section 10 of the human health risk assessment there are no risks of concern to workers performing tasks such as mixing, loading, and applying, based on current labeling. Moreover, since aldicarb is applied to soil when little foliage is present, there are no reentry risks, given the current Restricted-Entry Intervals (REIs). Therefore, no additional mitigation is necessary.

#### 2. Ecological Risk Management and Mitigation

As discussed in the environmental fate and effects risk assessment, ecological risks (direct adverse acute effects) to non-target aquatic and terrestrial organisms are of concern from the use of aldicarb. Additionally, there are chronic risks to aquatic invertebrates (freshwater and estuarine/marine) and freshwater fish. Aldicarb is also a potential ground water, and possibly surface water, contaminant. The ecological risk assessments exhibit RQ values which exceed the various target levels of concern. Risks are much higher, as evidenced by higher RQ values, for terrestrial organisms, especially to birds. In addition to the mitigation outlined below, the Agency intends to require additional confirmatory data which are listed in Table 4 of Section V.

#### a. Terrestrial and Aquatic Organisms

#### **Terrestrial**

The Agency's assessment suggests the potential for acute effects to terrestrial organisms for all application scenarios. Aldicarb is highly toxic to birds, mammals, honeybees, and earthworms; however, due to aldicarb's granular formulation and, in most cases, immediate incorporation into the soil, risks from exposure (undissolved granules left on the surface) to birds and mammals are lessened. In summary, the Agency is concerned with all use patterns for acute effects to birds and mammals. As appropriate under FIFRA, the Agency has weighed the potential risk with the expected benefits of continued use. These conclusions are presented below.

#### Aquatic

The Agency's assessment also suggests the potential for adverse effects to aquatic invertebrates and fish. Adverse effects include reduced survival and reduced reproduction when exposed to aldicarb and/or its metabolites (aldicarb sulfoxide, aldicarb sulfone) as a result of labeled use. Aquatic plants are also subject to adverse effects (reduced survival) when exposed to aldicarb and/or its metabolites (aldicarb sulfoxide, aldicarb sulfone) as a result of labeled use.

For potential risk to aquatic species, the chronic level of concern is exceeded for several uses at maximum application rates and 99 percent incorporation efficiency for freshwater fish and invertebrates, as well as for estuarine/marine fish and invertebrates. However, under typical application rates, these risks for the most part are mitigated. Direct application of aldicarb to streams, lakes, and ponds is forbidden by product labels; however, following a rain event, aldicarb may reach aquatic environments from areas of application in sheet and channel-flow runoff, because aldicarb is moderately persistent in terrestrial environments and soluble in water. It is unlikely that aquatic organisms will be directly exposed to granules, both because of the highly soluble nature of the compound (whole granules will dissolve rather than be transported intact) and because of the application methods (directly onto field). Aquatic organisms could also be exposed to aldicarb residues and degradates from ground water that is subsequently discharged into a surface water body.

#### 3. Mitigation Summary and Crop-Specific Analyses

The Agency has worked with the technical registrant, Bayer CropScience, to reduce potential exposure of aldicarb to wildlife and aquatic life. Subsequently, Bayer has agreed to voluntarily cancel all current registrations on the following crops:

- Coffee
- Ornamentals
- Pecans
- Sugarcane
- Sorghum
- Tobacco
- Alfalfa grown for seed

These proposals for cancellation will be announced in the Federal Register (FR). A subsequent FR Notice will finalize the cancellation absent significant comment to change the

Agency's position. As part of the Agency's mitigation plan, labels will be amended shortly to remove these uses.

To further reduce ecological concerns, the Agency has determined that the label changes (as specified in Table 5 in Section V), as agreed upon by the technical registrant Bayer CropScience, and discussed with stakeholders for specific scenarios and crops, are appropriate and required for reregistration eligibility. Listed below are the specific crop use sites/patterns for aldicarb along with corresponding RQs of concern for birds and mammals, stakeholder input on use, alternatives/benefits, mitigation, and EPA's decision regarding reregistration eligibility. As a general matter, the Agency has determined that although there is potential for harm to wildlife because of use of aldicarb, that harm will generally be limited in time and space. The Agency also determined that these risks are often outweighed by the benefits expected from use of aldicarb instead of existing alternatives. The Agency was also mindful in this analysis that aldicarb does not pose risks of concerns to pesticide applicators or to farm workers generally.

#### Citrus

#### Current Use Pattern

Aldicarb is used on citrus in Florida and Texas only. Application currently consists of a side-dress application and is usually applied along the side of the tree row in furrow and immediately covered with soil. The maximum application rate for use on citrus is currently 4.95 lbs ai/A. Due to the nature of how aldicarb is applied to citrus (2 inches in depth), the Agency has assumed that 85% of the aldicarb applied is covered with soil, and that 15% may remain on the surface for potential terrestrial organism exposure.

Because of acute toxicity and ground water contamination concerns, anyone who applies aldicarb in Florida is required to obtain a permit from the Florida Department of Agriculture and Consumer Services for each application to be made. This permitting process involves the collaborative efforts of the registrant, state officials and growers to ensure that every application of aldicarb is permitted and recorded. For additional information on the aldicarb permitting system in Florida's State Division of Agricultural Environmental Services, please see <a href="http://www.flaes.org/temik/">http://www.flaes.org/temik/</a>.

#### Risks of Concern Assuming 85% Soil Incorporation

RQs modeled for birds using maximum rates range from 9 to 771. RQs modeled for birds calculated using typical rates range from 6 to 577. RQs modeled for mammals using maximum rates range from 11 to 261. RQs modeled for mammals using typical rates range from 8 to 195. Additionally, although RQs are low, the Agency's assessment also suggests the potential for adverse effects to aquatic invertebrates and fish.

#### Stakeholder Involvement/Input on Citrus

During Phases 5 and 6 of the Public Participation Process, in addition to the written comments received from respondents as listed in section IV. B. above, the Agency met with and received comments from Bayer CropScience, the Florida Department of Agriculture and Consumer Services (FDACS), Florida Fruit and Vegetable Association (FFVA), USDA, and many other interested stakeholders with specific knowledge relating to aldicarb use on citrus.

These stakeholders have provided additional information regarding aldicarb usage (application methods and rates) and the use of aldicarb in citrus production. In particular, these stakeholders noted that aldicarb appears to effect plant growth, resulting in increased yields when used on citrus. Subsequent meetings, site visits and teleconference calls with Bayer, FDACS, and FFVA have led to the Agency's understanding of the aldicarb permitting process in Florida.

#### Alternatives and Benefits

Aldicarb is a recommended insecticide for mites, the Asian Citrus Psyllid (AsCP), and nematode control. Citrus greening is a severe vascular disease transmitted by the Asian citrus psyllid. The psyllid is a relatively new pest that now ranges throughout all the citrus producing areas in Florida and Texas. Greening is a disease that slowly weakens and kills all types of citrus trees, and causes fruit to become lopsided and taste bitter. No cure exists for a tree that contracts the disease. As of 2006, greening had been found in more than 440 different locations in at least 11 Florida counties. Although the AsCP has been found in the Rio Grande Valley of Texas, citrus greening has not been found there at this time.

There are several alternatives to aldicarb for control of mites, but there appears to be no feasible alternative to aldicarb for nematode control. Estimated yield losses in Florida without aldicarb are 5 to 10 percent, which corresponds to an annual loss of about \$4.6 to \$9.3 million for oranges and grapefruit combined. There are no alternatives for control of AsCP, the vector for citrus greening.

For nematode control specifically, aldicarb is used to control the citrus and burrowing nematodes although it does not effectively control the burrowing nematode as aldicarb only remains in the shallow part of the root zone. Other nematodes with limited economic importance in Florida are the sting nematode and lesion nematode.

EPA's analysis concludes that the absence of aldicarb for use on citrus acreage for controlling both nematodes and other insects can result in yield losses of 5 to 10 percent. Therefore, the cost to growers will be quite high. A 5 to 10 percent yield loss to the "average" grower in Florida corresponds to a \$97 to \$193 in lost revenue per acre. For the grapefruit grower, a 5 to 10 percent yield loss corresponds to a loss in revenue of \$109 to \$218 per acre. If the loss to nematodes increased over time, as nematode populations increase, these losses may get worse. The 2000/2001 – 2004/2005 value of orange production in Florida was about \$1.1 billion and the value of grapefruit production was approximately \$209 million. A 10 percent reduction on the 7 percent of acreage treated with aldicarb would result in a loss of approximately \$3.9 to \$7.8 million annually to Florida orange growers, and \$0.7 to \$1.5 million to Florida grapefruit growers.

For additional information, refer to the Agency's complete alternative/quantitative impact memo for citrus and the BEAD response to Phase 3 comments for citrus, cotton and pecans which are available in the public docket EPA-HQ-OPP-2005-0163 and located on-line at <u>http://www.regulations.gov/</u>.

#### Mitigation

To reduce potential ecological risks, the Agency, in agreement with the technical registrant of aldicarb, has developed several mitigation measures to help address the above mentioned concerns. They include:

- Label clarifications to specify application of granules in 3 to 6 furrows beside individual trees, that are 2 inches deep and spaced on approximately 12 inch centers, immediately covering with soil.
- Label modifications to help reduce the amount of aldicarb left on the surface of the soil making it less available for the wildlife potentially at risk. For specific label language, please refer to Table 5 in Section V.

#### EPA Decision

Aldicarb has the potential to cause adverse effects to birds, mammals and aquatic species. However, due to the physical properties of aldicarb's granules (e.g., color, size, and solubility) and how aldicarb is soil incorporated, actual exposure of potentially affected populations to aldicarb granules is uncertain and may be overestimated. Potential risks to birds and mammals would be limited primarily to the treated fields where wildlife, if present, could ingest granules that are not incorporated in the soil and that have not yet dissolved. Therefore, the extent of exposure, both spatially and temporally, is expected to be limited. The Agency recognizes, however, that actual exposure of wildlife to aldicarb is uncertain.

Additionally, the Agency also acknowledges that, although risks were calculated assuming 85% soil incorporation, actual aldicarb granules available on or just under the soil's surface for potential consumption by birds or mammals is unlikely, given the methods of application including positive displacement (mechanized placement of granules beneath the soil) and lock-and-load containers which minimize potential spillage of product.

The Agency has determined that there are benefits of aldicarb use on citrus and, as quantified above, losing its use would involve additional costs to growers. Aldicarb has advantages to citrus growers for which EPA cannot estimate dollar values, such as simplicity of management, confidence in the level of control in the face of unexpected infestation, and cost effectiveness when considering the full range of pests and duration of control.

Aldicarb provides control against insects, including nematodes, in portions of citrus production areas. Because of its long residual activity, in many cases growers can apply one treatment of aldicarb, rather than multiple treatments of other chemicals for equivalent insect control. Also, potential worker risks from multiple foliar applications of these alternative products are not insignificant. Therefore, the use on citrus is eligible for reregistration.

#### **Cotton**

#### Current Use Pattern

Aldicarb is used on cotton primarily for control of thrips, although it controls other insect pests. In addition, there is also evidence of aldicarb use to control nematodes on cotton. Aldicarb is applied at-plant or as a side-dress application. The at planting application is administered in the furrow with the cotton seed and immediately covered with soil. Greater than

97% of the use on cotton is this at-plant application. The side-dress application is usually administered after the cotton has emerged from the soil and is applied along the side of the plant row (8 inches from the plants, two or three inches deep) in furrow and immediately covered with soil. The maximum application rate for use on cotton is currently 4.05 lbs ai/A. Due to the nature of how aldicarb is applied to cotton (at a depth greater than 2 inches), the Agency has estimated that 99% of the aldicarb applied is covered with soil, and that only 1% remains on the surface for potential terrestrial organism exposure.

#### Risks of Concern Assuming 99% Soil Incorporation

RQs modeled for birds using maximum rates range from 5 to 428. RQs modeled for birds calculated using typical rates range from 0.7 to 63. RQs modeled for mammals using maximum rates range from 6 to 145. RQs modeled for mammals using typical rates range from 0.9 to 21. Additionally, although RQs are low, the Agency's assessment also suggests the potential for adverse effects to aquatic invertebrates and fish.

#### Stakeholder Involvement /Input on Cotton

During Phases 5 and 6 of the Public Participation Process, in addition to the written comments received from respondents as listed in section IV. B. above, the Agency met with and received comments from Bayer, the National Cotton Council of America, Cotton Growers Association, Georgia Cotton Commission, USDA, as well as many other interested stakeholders with specific knowledge relating to aldicarb use on cotton. In particular, these stakeholders noted that aldicarb appears to effect plant growth, resulting in increased yields when used on cotton.

#### Alternatives and Benefits

The Agency acknowledges that the use of aldicarb has benefits to cotton growers. Although thrips and other insects are targeted, aldicarb is applied to cotton in Texas and the Southeast to control nematodes as well. Based on EPA proprietary data, an annual average of about 1.4 million acre treatments (about 38% of total applications) of aldicarb have targeted nematodes between 2002 and 2006. The state with the most acre treatments against nematodes is Georgia, with an annual average of about 360,000 acres, followed by Texas (about 270,000 acres annually) and North Carolina (about 200,000 acres annually).

For thrip control, no one chemical could replace aldicarb, but a combination of chemicals could be used effectively. This combination for insect control was more expensive than aldicarb: the Agency estimates that chemical costs alone would be about \$2 per acre higher in Mississippi and \$22 per acre higher in California. These chemicals also do not share the advantages of aldicarb which are a longer period of effectiveness and control over multiple pests, including nematodes. If nematodes are considered a target pest, as they are in Texas and the Southeast, growers have fewer alternatives to aldicarb. The best control for nematodes would be 1,3-dichloropropene (1,3-D). The additional cost for replacing aldicarb with 1,3-D, along with the combination of chemicals to provide control of thrips is about \$38 per acre. Of that figure, \$36 per acre is based on the chemical costs are over \$50 million annually.

For additional information, refer to the Agency's complete alternative/quantitative impact memo for cotton which is available in the public docket EPA-HQ-OPP-2005-0163 and located on-line at <u>http://www.regulations.gov/</u>.

#### **Mitigation**

To reduce potential ecological risks, the Agency has directed, and the registrant has agreed, to develop several mitigation measures to help address the above mentioned concerns. They include:

- At-plant application rate will be reduced to a maximum of 1.5 lbs ai/A. This equates to a 63% reduction in rate as compared to the current label.
- Side-dress application rate will be reduced to 2.1 lbs ai/A. This equates to a 30% reduction as compared to the current label.
- Per-season application rate is limited to 3.6 lbs ai/A. This equates to a 63% reduction as compared to the current label.
- Label specifications to clarify the depth at which aldicarb is applied. Additionally, modifications in label language to help reduce the amount of aldicarb left on the surface of the soil, making it less available for wildlife potentially at risk. For specific label language, please refer to Table 5 in Section V.

#### EPA Decision

Aldicarb has the potential to cause adverse effects to birds, mammals and aquatic species. However, due to the physical properties of aldicarb's granules (e.g., color, size, and solubility) and how aldicarb is soil incorporated, actual exposure of potentially affected populations to aldicarb granules is uncertain and may be overestimated. Potential risks to birds and mammals would be limited primarily to the treated fields where wildlife, if present, could ingest granules that are not incorporated in the soil and that have not yet dissolved. Therefore, the extent of exposure, both spatially and temporally, is expected to be limited. The Agency recognizes, however, that actual exposure of wildlife to aldicarb is uncertain.

The Agency has determined that there are benefits of aldicarb use on cotton and, as specified above, losing its use would involve additional costs to growers, some of which can be quantified directly. Aldicarb has advantages to cotton growers for which EPA cannot estimate dollar values, such as simplicity of management, confidence in the level of control in the face of unexpected infestation, and cost effectiveness when considering the full range of pests and duration of control.

Aldicarb provides control of insects, including nematodes, in portions of cotton production areas. Alternative pesticides, which can be used to control insect pests (e.g., thrips), are not effective in controlling multiple pests. Aldicarb also provides protection for a longer period of time than any of the alternatives. As stated above, because of its long residual activity, in many cases growers can apply one treatment of aldicarb, rather than multiple treatments of other chemicals for equivalent insect control. Also, potential worker risks from multiple foliar applications of these alternative products are not insignificant. Therefore, the use on cotton is eligible for reregistration.

#### Dry Bean

#### Current Use Pattern

Aldicarb application to dry beans currently consist of an at-plant application. The atplanting application is administered in the furrow with the dry bean seed and immediately covered with soil at a depth greater than 2 inches. The maximum application rate for use on dry bean is currently 2.1 lbs ai/A. Due to the nature of how aldicarb is applied to dry bean, the Agency has estimated that 99% of the aldicarb applied is covered with soil and that only 1% remains on the surface for potential terrestrial organism exposure.

#### Risks of Concern Assuming 99% Soil Incorporation

RQs modeled for birds using maximum rates range from 2 to 175. RQs modeled for birds calculated using typical rates range from 0.9 to 84. RQs modeled for mammals using maximum rates range from 3 to 59. RQs modeled for mammals using typical rates range from 1 to 28. Additionally, although RQs are low, the Agency's assessment also suggests the potential for adverse effects to aquatic invertebrates and fish.

#### Stakeholder Involvement/Input for Dry Bean

During Phases 5 and 6 of the Public Participation Process, in addition to the written comments from respondents as listed in section IV. B. above, the Agency has met with and received comments from Bayer CropScience, USDA, as well as many other interested stakeholders with specific knowledge relating to aldicarb use on dry bean.

#### Alternatives and Benefits

The Agency understands that aldicarb use on dry bean is of benefit to dry bean growers in the states of Idaho, Michigan, Oregon and Washington. Aldicarb use in dry bean production is a valuable tool for controlling aphids, leafhoppers, the Mexican bean beetle, and several species of nematodes. There are both foliar and seed treatment alternatives, such as thiamethoxam, but only aldicarb provides season long control at planting, and growers do not have to spray multiple times. In Michigan, aldicarb is also used to control the root-lesion nematode, which can cause 10% yield reduction and is present in 50% of the dry bean acreage if left uncontrolled. On the acreage with nematodes that is not treated, growers expect lower yields.

As with other crops, the main value of aldicarb as an insecticide is that a single at-plant treatment will protect the seedling and young plant for several weeks from attack by nematodes and several insect pests, some of which are vectors of plant viruses. Although alternatives (such as esfenvalerate, dimethoate, propargite, and others) exist for use against all insect pests controlled by aldicarb, it would likely take at least two applications of foliar insecticides to provide the same level of protection afforded by an at-plant aldicarb treatment. Where nematodes are also a problem, it would also take a pre-plant application with a soil fumigant, such as 1,3-D. While aldicarb alternatives exist, the Agency believes that the economic impact on dry bean growers of shifting to such alternatives for nematode control are likely to be cost prohibitive, in which case the likely result of loss of aldicarb would be that growers would face a financial penalty from reduced yield because of nematodes.

#### Mitigation

To reduce potential ecological risks, the Agency has directed, and the registrant has agreed, to develop several mitigation measures to help address the above mentioned concerns. They include:

- Geographically restricting the use to Idaho, Michigan, Oregon, and Washington.
- Modifications in label language to help reduce the amount of aldicarb left on the surface of the soil, thereby making it less available for wildlife potentially at risk. For the label language modifications, please refer to Table 5 in Section V.

#### EPA Decision

Aldicarb has the potential to cause adverse effects to birds, mammals and aquatic species. However, due to the physical properties of aldicarb's granules (e.g., color, size, and solubility) and how aldicarb is soil incorporated, actual exposure of potentially affected populations to aldicarb granules is uncertain and may be overestimated. Potential risks to birds and mammals would be limited primarily to the treated fields where wildlife, if present, could ingest granules that are not incorporated in the soil and that have not yet dissolved. Therefore, the extent of exposure, both spatially and temporally, is expected to be limited. The Agency recognizes, however, that actual exposure of wildlife to aldicarb is uncertain.

The Agency has determined that there are benefits of aldicarb use on dry bean and that losing its use would involve additional costs to growers. Aldicarb has advantages to dry bean growers for which EPA cannot estimate dollar values, such as simplicity of management, confidence in the level of control in the face of unexpected infestation, and cost effectiveness when considering the full range of pests and duration of control. Therefore, the use on dry bean is eligible for reregistration.

#### Peanut

#### Current Use Pattern

Aldicarb is applied when peanuts are planted, or can be used as a split treatment, where aldicarb is applied at-plant and also applied later in the season when the plants are forming pegs, which develop into peanuts. This application is referred to as "at-pegging". Aldicarb is generally used to control nematodes and thrips on peanuts, primarily in the southern States, as well for the suppression of leafhoppers and spider mites. To better understand the potential risk and resulting mitigation, these two use patterns are discussed in more detail below.

#### **At Planting**

Aldicarb is applied to peanuts at planting for protection against thrips and several species of nematodes (e.g. root-knot, lesion, stubby root, sting). For thrips control the granules are applied in the seed furrow and then covered with soil. The peanut seed is then planted into the treated zone. When used for nematode control, aldicarb granules are applied in a 6 to 12 inch band over an open furrow and covered with soil to a depth of 2 to 4 inches. Due to the nature of

how aldicarb is applied to peanuts at planting (at a depth greater than 2 inches), the Agency has estimated that 99% of the aldicarb applied is covered with soil and that only 1% remains on the surface for potential terrestrial organism exposure.

Rest of Concern for the At-Plant Application Method Assuming 99% Soil Incorporation RQs modeled for birds using maximum rates range from 2 to 188. RQs modeled for birds calculated using typical rates range from 0.6 to 56. RQs modeled for mammals using maximum rates range from 2.7 to 64. RQs modeled for mammals using typical rates range from 0.8 to 19. Additionally, although RQs are low, the Agency's assessment also suggests the potential for adverse effects to aquatic invertebrates and fish.

#### At Pegging

Aldicarb can also be applied later in the season when the plants are forming pegs (atpegging), which develop into peanuts. In this case, aldicarb is typically applied at the initiation of pegging, in a 12 to 18 inch band over the peanut row. Unlike other aldicarb application practices, soil incorporation does not occur because the plant has already formed pegs (which develop into peanuts) just under the surface of the soil. Attempts to incorporate the granules would damage the roots of the plants and any pegs that have formed. Due to the nature of how aldicarb is applied to peanuts at pegging (without any mechanical means of soil incorporation), the Agency has assumed that 100% of the aldicarb applied remains on the surface for potential terrestrial organism exposure.

#### Risks of Concern for the At-Pegging Application Method

RQs modeled for birds using maximum rates range from 31 to 2,807. RQs modeled for birds calculated using typical rates range from 9 to 842. RQs modeled for mammals using maximum rates range from 41 to 948. RQs modeled for mammals using typical rates range from 12 to 285. Additionally, although RQs are low, the Agency's assessment also suggests the potential for adverse effects to aquatic invertebrates and fish.

#### Stakeholder Involvement/Input for Peanuts

During Phases 5 and 6 of the Public Participation Process, in addition to the written comments from respondents listed in section IV. B. above, the Agency has met with and received comments from Bayer, the National Peanut Board, Florida Fruit and Vegetable Association, Florida Department of Agriculture and Consumer Services, USDA, and other interested stakeholders with specific knowledge relating to aldicarb use on peanuts.

#### Alternatives and Benefits

For the at-plant use of aldicarb, early season control of nematodes may be achieved with a pre-plant soil fumigation with 1,3-D; however, it would require one or more other insecticides (primarily ethoprop) to address other pests. Therefore, for the at-plant use of aldicarb, there are no chemical or non-chemical alternatives that can provide both insect and nematode control on peanuts during the first month after plant emergence.

For the at-pegging use of aldicarb, multiple treatments of the alternatives may be required, and none of those alternatives also control nematodes. Because of aldicarb's ability to control both nematodes and insect pests, alternatives to aldicarb will consist of at least one insecticide application for thrips control and one nematicide application in areas where both pests exist.

Based upon data reviewed by the Agency, withholding the at-pegging aldicarb treatment caused a yield decrease of 56%. Applying this loss to dollars per acre, it is estimated that without the aldicarb at-pegging use, revenues would fall from \$290 to \$227 per acre.

Another important factor considered by the Agency was that nematode damage to peanut plants does not stop with yield damage, but also causes damage to the peanuts that are harvested. The Agency is aware that, potentially, this damage could correspond to a discount of about 10 cents per pound. Therefore, revenue loss from reduced quality could be as high as losses from reduced yields.

In conclusion, without aldicarb, costs to growers from the yield losses due to nematode damage alone are estimated to exceed \$15 million a year in Georgia, and up to \$22 million a year nationwide. It is clear to the Agency that without the use of aldicarb there would be substantial costs to growers who are currently using aldicarb approximately 30-45 days after plant (at-pegging); up to \$300 per acre based upon data from field trials performed in Georgia.

For additional information, refer to the Agency's complete alternative/quantitative impact memo for peanuts which is available in the public docket EPA-HQ-OPP-2005-0163 and located on-line at <u>http://www.regulations.gov/</u>.

#### **Mitigation**

To reduce potential ecological risks, the Agency has directed, and the registrant has agreed, to develop several mitigation measures to help address the above mentioned concerns. They include:

- For the split-season, at-pegging use of aldicarb, application must be made late in the afternoon or early evening and immediately followed by irrigation, and completed within 24 hours which will help dissolve granules thereby making them unavailable for wildlife.
- Label clarifications for post-emergent use: apply granules in a band 12 to 18 inches wide on the row and into the plant canopy. Ensure that plant foliage is dry prior to application. Dislodge granules from foliage by suitable means that will not damage the plant.
- Label clarifications to ensure that at-planting applications are done over an open furrow which is 4 to 6 inches in width, known as "T-band" applications.
- For the specific label language for the application modifications, please refer to Table 5 in Section V.

#### EPA Decision

Aldicarb has the potential to cause adverse effects to birds, mammals and aquatic species. However, due to the physical properties of aldicarb's granules (e.g., color, size, and solubility) and how aldicarb is soil incorporated, actual exposure of potentially affected populations to aldicarb granules is uncertain and may be overestimated. Potential risks to birds and mammals would be limited primarily to the treated fields where wildlife, if present, could ingest granules that are not incorporated in the soil and that have not yet dissolved. Therefore, the extent of exposure, both spatially and temporally, is expected to be limited. The Agency recognizes, however, that actual exposure of wildlife to aldicarb is uncertain.

The Agency has determined that there are benefits of aldicarb use on peanut (both the atplanting and at-pegging use) and that losing its use would involve additional costs to growers, as quantified above. Aldicarb also has advantages to peanut growers for which EPA cannot estimate dollar values, such as simplicity of management, confidence in the level of control in the face of unexpected infestation, and cost effectiveness when considering the full range of pests and duration of control. Therefore, the use on peanut is eligible for reregistration.

#### Potato

#### Current Use Pattern

Aldicarb is currently registered for use on potatoes only in Oregon, Idaho, Washington, Montana, northern Florida, and parts of Utah and Nevada. Aldicarb is used primarily to control green peach aphid, Colorado potato beetle, and also provides some protection against several species of nematodes. Other pests controlled include leafhoppers and flea beetles.

Aldicarb application to potatoes typically consists of an at-plant or pre-plant application using positive displacement equipment. Aldicarb granules are applied within the row furrow and buried along with the seed potato at planting to a depth of four to eight inches. The potato plant absorbs aldicarb through its roots, and once in the plant, the residual activity of aldicarb protects the treated plant against pest nematodes and insects for six to eight weeks. The maximum application rate for use on potato is currently 3.0 lbs ai/A. Due to the nature of how aldicarb is applied to potatoes (at a depth of 4 to 8 inches), the Agency has estimated that 99% of the aldicarb applied is covered with soil, and that only 1% remains on the surface for potential terrestrial organism exposure.

#### Risks of Concern Assuming 99% Soil Incorporation

RQs modeled for birds using maximum rates range from 2 to 198. RQs modeled for birds calculated using typical rates range from 2 to 179. RQs modeled for mammals using maximum rates range from 3 to 67. RQs modeled for mammals using typical rates range from 3 to 60. Additionally, although RQs are low, the Agency's assessment also suggests the potential for adverse effects to aquatic invertebrates and fish.

#### Stakeholder Involvement and Input for Potatoes

During Phases 5 and 6 of the Public Participation Process, in addition to the written comments received from respondents listed in section IV. B. above, the Agency has met with and received comments from Bayer, the National Potato Council, USDA and other interested stakeholders with specific knowledge relating to aldicarb use on potatoes. These stakeholders have provided additional information regarding aldicarb usage (application methods and rates) and the need for aldicarb use to remain in potato production. In particular, these stakeholders noted that aldicarb appears to effect plant growth, resulting in increased yields when used on potatoes.

#### Alternatives and Benefits

The Agency has determined that the benefits to growers of aldicarb use on potatoes are very high in certain states (Washington, Oregon, Idaho and Florida) and that losing its use would involve substantial costs to growers. There are also concerns with the potential for resistance if aldicarb were not available. Several nematodes, including the root-knot nematode, the root lesion nematode, and the stubby root nematode are major pests of potatoes and have wide host ranges, making management with crop rotation difficult and relatively ineffective, although they can be controlled by fumigants. Aldicarb may also be used to reduce root-knot nematode populations that remain high after soil fumigation.

There are several alternatives for the use of aldicarb on potatoes, but none of these will be an adequate substitute. Even if aldicarb is applied specifically to target nematodes, it is inappropriate to ignore the beneficial effect of controlling insect pests, as well. For this reason, an analysis of alternatives to aldicarb considered multiple chemicals so that both nematodes and insects can be targeted.

Because of aldicarb's ability to control both nematodes and insect pests, alternatives to aldicarb will consist of multiple chemicals used to target multiple pests. The estimates of additional costs for using alternatives to aldicarb range from \$77 - 257 per acre in the Pacific Northwest, and \$77 - 218 in Florida. It is clear that alternatives will involve significant costs to growers who are currently using aldicarb.

For nematode control, the Agency believes that the most likely alternative to aldicarb is the use of a fumigant, such as 1,3-D, although additional chemicals would be required to control insect pests. While synthetic insecticides remain the most effective means for its control, resistance by the Colorado potato beetle to all classes of insecticides has been documented in many U.S. potato-producing regions. Widespread and locally diverse esfenvalerate and phosmet resistance was detected in all counties in southern and eastern Idaho.

For additional information, refer to the Agency's complete alternative/quantitative impact memo for potatoes which is available in the public docket EPA-HQ-OPP-2005-0163 and located on-line at <u>http://www.regulations.gov/</u>.

#### **Mitigation**

To reduce potential ecological risks, the Agency has directed, and the registrant has agreed, to develop the mitigation below to help address the above mentioned concerns:

• Modifications in label language to clarify the manner in which aldicarb is applied to potatoes, and immediately covering with soil. For the label language modifications, please refer to Table 5 in Section V.

#### EPA Decision

Aldicarb has the potential to cause adverse effects to birds, mammals and aquatic species. However, due to the physical properties of aldicarb's granules (e.g., color, size, and solubility) and how aldicarb is soil incorporated, actual exposure of potentially affected populations to aldicarb granules is uncertain and may be overestimated. Potential risks to birds and mammals would be limited primarily to the treated fields where wildlife, if present, could ingest granules that are not incorporated in the soil and that have not yet dissolved. Therefore, the extent of exposure, both spatially and temporally, is expected to be limited. The Agency recognizes, however, that actual exposure of wildlife to aldicarb is uncertain.

As discussed above, the Agency has determined that there are benefits of aldicarb use on potatoes and that losing its use would involve substantial costs to growers. Aldicarb also has advantages to potato growers for which EPA cannot estimate dollar values, such as simplicity of management, confidence in the level of control in the face of unexpected infestation, and cost effectiveness when considering the full range of pests and duration of control. Therefore, the Agency finds the use on potatoes eligible for reregistration.

#### Soybean

#### Current Use Pattern

Aldicarb is applied to soybean at planting. Aldicarb granules are applied within the row furrow and buried along with the soybean seed at planting. The maximum application rate for use on soybean is currently 3.0 lbs ai/A. Due to the nature of how aldicarb is applied to soybean (at a depth greater than 2 inches), the Agency has estimated that 99% of the aldicarb applied is covered with soil, and that only 1% remains on the surface for potential terrestrial organism exposure.

#### Risks of Concern Assuming 99% Soil Incorporation

RQs modeled for birds using maximum rates range from 2 to 157. RQs modeled for birds calculated using typical rates range from 0.4 to 37. RQs modeled for mammals using maximum rates range from 2 to 53. RQs modeled for mammals using typical rates range from 0.5 to 12. Additionally, although RQs are low, the Agency's assessment also suggests the potential for adverse effects to aquatic invertebrates and fish.

#### Stakeholder Involvement/Input for Soybean

During Phases 5 and 6 of the Public Participation Process, in addition to the written comments from respondents listed in section IV. B. above, the Agency has met with and received comments from Bayer, USDA and soybean growers in Georgia, Minnesota and South Carolina with specific knowledge relating to aldicarb use on soybeans.

#### Alternatives and Benefits

Aldicarb is used as a nematicide in late maturity soybean varieties grown in Georgia, North Carolina, and South Carolina. Because there are few late maturity soybean varieties that are resistant to nematodes (root-knot, reniform, and Columbian lance), growers of such varieties depend more on aldicarb than growers of early maturity soybean varieties, for which nematode resistant varieties exist. In South Carolina, approximately 60% of the soybean acreage has nematode problems. The only available aldicarb alternative for nematode control, 1,3-D, is too expensive for soybean production. Without aldicarb, soybean growers in the affected states would stop growing soybeans or shift to very long rotations with other crops. Aldicarb, therefore, is a critical tool for soybean growers.

#### Mitigation

To reduce potential ecological risks, the Agency has directed, and the registrant has agreed, to develop several mitigation measures to help address the above mentioned concerns. They include:

- Limiting the use to the following states: Georgia, North Carolina, and South Carolina.
- Reducing the application rate from 3.0 lbs ai/A to 1.5 lbs ai/A. This equates to a 50% reduction when compared to the current label.
- Modifications in label language to help reduce the amount of aldicarb in use and left on the surface of the soil (i.e., clarifications in the use of positive displacement technology), making it less available for the wildlife potentially at risk. For the label language modifications, please refer to Table 5 in Section V.

## EPA Decision

Aldicarb has the potential to cause adverse effects to birds, mammals and aquatic species. However, due to the physical properties of aldicarb's granules (e.g., color, size, and solubility) and how aldicarb is soil incorporated, actual exposure of potentially affected populations to aldicarb granules is uncertain and may be overestimated. Potential risks to birds and mammals would be limited primarily to the treated fields where wildlife, if present, could ingest granules that are not incorporated in the soil and that have not yet dissolved. Therefore, the extent of exposure, both spatially and temporally, is expected to be limited. The Agency recognizes, however, that actual exposure of wildlife to aldicarb is uncertain.

The Agency has determined that there are benefits of aldicarb use on soybeans in Georgia, North Carolina and South Carolina, and that losing its use would involve additional costs to growers. Aldicarb also has advantages to soybean growers for which EPA cannot estimate dollar values, such as simplicity of management, confidence in the level of control in the face of unexpected infestation, and cost effectiveness when considering the full range of pests and duration of control. Therefore, the Agency finds the use on soybeans eligible for reregistration.

## Sugar Beet

Current Use Pattern

Aldicarb application to sugar beets currently consists of an at-plant and a side-dress application. The at planting application is administered with the sugar beet seed and immediately covered with soil. The side-dress application is usually administered after the sugar beet has emerged from the soil and is applied along the side of the plant row in furrow and immediately covered with soil.

Aldicarb is used to manage sugar beet root maggot, nematode, particularly sugar beet cyst nematode, beet leafminer, beet leafhopper, aphids, flea beetles, wireworms, and cutworms, primarily in Idaho.

The maximum application rate for use on sugar beet is currently 4.95 lbs ai/A. Due to the nature of how aldicarb is applied to sugar beet (at a depth greater than 2 inches), the Agency has

estimated that 99% of the aldicarb applied is covered with soil, and that only 1% remains on the surface for potential terrestrial organism exposure.

#### Risks of Concern Assuming 99% Soil Incorporation

RQs modeled for birds using maximum rates range from 2 to 190. RQs modeled for birds calculated using typical rates range from 0.7 to 65. RQs modeled for mammals using maximum rates range from 3 to 64. RQs modeled for mammals using typical rates range from 0.9 to 22. Additionally, although RQs are low, the Agency's assessment also suggests the potential for adverse effects to aquatic invertebrates and fish.

#### Stakeholder Involvement and Input for Sugar Beet

During Phases 5 and 6 of the Public Participation Process, in addition to the written comments from respondents listed in section IV. B. above, the Agency has met with and received comments from Bayer, American Sugarbeet Growers Association, Western Sugar Cooperative, NYSSA-NAMPA Beet Growers Association, USDA, and other interested stakeholders with specific knowledge relating to sugar beet production. These stakeholders have provided additional information regarding aldicarb usage (application techniques and application rates) and the need for aldicarb use to remain in sugar beet production. In particular, these stakeholders also noted that aldicarb appears to effect plant growth, resulting in increased yields when used on sugar beet.

#### Alternatives and Benefits

The Agency understands that aldicarb use on sugar beet is of great benefit to the sugar beet industry, particularly in Western states, and that losing its use would involve substantial costs to growers in those states. The available usage data indicate 75 percent of the sugar beet acreage in Idaho, Montana, Oregon and Washington was treated with aldicarb in 2005. Aldicarb is used primarily to manage sugar beet root maggot and nematodes on sugar beets, which are major pests of sugar beets. If left uncontrolled, yield losses from sugar beet root maggot can be as much as 80%. Yield losses from nematodes can be equally as devastating to a sugar beet crop.

For insect control, sugar beet root maggot is a major pest of sugar beets and aldicarb effectively controls both adults and larvae. If aldicarb were not available for the control of sugar beet maggot, growers would likely use terbufos which is not as effective on both the adult fly and larvae. Additionally, EPA has required, and the terbufos registrant has agreed, to a phased approach that will ultimately reduce sales of terbufos by 55% by 2008. Other pesticides available and used to a lesser extent than aldicarb and terbufos include phorate, chlorpyrifos, and carbofuran. Phorate controls larvae but is mostly used in areas with low pest pressure. Carbofuran was available in Idaho and Oregon under 24c labels to control larvae but does not have a long residual value. Further, the Agency expects to initiate action in the near future to cancel all uses of carbofuran. Esfenavalerate and zeta-cypermethrin control adult flies but another insecticide would need to be used to control larvae. For nematodes, only fumigants are available for control besides aldicarb but are significantly more expensive than aldicarb.

For nematode control specifically, only fumigants are available as alternatives, such as 1,3-D. A major disadvantage to using 1,3-D is the chemical cost relative to aldicarb (see below). Another disadvantage of using 1,3-D is that growers must wait for the soil to warm before fumigating, and then wait for the gas to dissipate before planting, shortening the growing season. Growers would also need to consider the added costs due to different application equipment using 1,3-D.

The estimates of costs for using aldicarb alternatives are more than \$20 per treatment per acre to control the sugar beet root maggot and approximately \$88 to control nematodes. For comparison, the cost of aldicarb is about \$40 per acre. This assumes that the alternatives are equally efficacious. Although the alternatives for control of the sugar beet root maggot appear to be less expensive, other considerations may preclude their use. If the alternatives are less effective than aldicarb, yield or quality impacts could also occur. In addition, if multiple pests targeted by aldicarb are present, multiple chemicals/applications may be needed to achieve a similar level of control.

For additional information, refer to the Agency's response to Phase 5 comments found EPA-HQ-OPP-2005-0163 and located on-line at <u>http://www.regulations.gov/</u>.

#### **Mitigation**

To reduce potential ecological risks, the Agency has directed, and the registrant has agreed, to develop several mitigation measures to help address the above mentioned concerns. They include:

- Limit use to the following states: California, Colorado, Idaho, Montana, Nebraska, Oregon, Washington and Wyoming.
- Modifications in label language to help reduce the amount of aldicarb left on the surface of the soil (i.e., clarifications in the use of positive displacement technology) and making it less available for the wildlife potentially at risk. For the label language modifications, please refer to Table 5 in Section V.

## EPA Decision

Aldicarb has the potential to cause adverse effects to birds, mammals and aquatic species. However, due to the physical properties of aldicarb's granules (e.g., color, size, and solubility) and how aldicarb is soil incorporated, actual exposure of potentially affected populations to aldicarb granules is uncertain and may be overestimated. Potential risks to birds and mammals would be limited primarily to the treated fields where wildlife, if present, could ingest granules that are not incorporated in the soil and that have not yet dissolved. Therefore, the extent of exposure, both spatially and temporally, is expected to be limited. The Agency recognizes, however, that actual exposure of wildlife to aldicarb is uncertain.

As discussed above, the Agency has determined that there are benefits of aldicarb use on sugar beets in certain states (California, Colorado, Idaho, Montana, Nebraska, Oregon, Washington and Wyoming) and that losing its use would involve substantial costs to growers. Aldicarb also has advantages to sugar beet growers for which EPA cannot estimate dollar values, such as simplicity of management, confidence in the level of control in the face of unexpected infestation, and cost effectiveness when considering the full range of pests and duration of control. Therefore, the Agency finds the use on sugar beet eligible for reregistration.

## Sweet Potato

## Current Use Pattern

Aldicarb application to sweet potato typically consists of an at-plant application using positive displacement equipment. Aldicarb granules are applied within the row furrow and buried along with the seed piece at planting to a depth of four to eight inches. The sweet potato plant absorbs aldicarb through its roots and once in the plant, the residual activity of aldicarb protects the treated plant against pest nematodes and insects for six to eight weeks. The maximum application rate for use on sweet potato is currently 3.0 lbs ai/A. Due to the nature of how aldicarb is applied to sweet potatoes (at a depth of 4 to 8 inches), the Agency has estimated that 99% of the aldicarb applied is covered with soil, and that only 1% remains on the surface for potential terrestrial organism exposure.

## Risks of Concern Assuming 99% Soil Incorporation

RQs modeled for birds using maximum rates range from 1 to 125. RQs modeled for birds calculated using typical rates range from 0.7 to 58. RQs modeled for mammals using maximum rates range from 2 to 42. RQs modeled for mammals using typical rates range from 0.8 to 20. Additionally, although RQs are low, the Agency's assessment also suggests the potential for adverse effects to aquatic invertebrates and fish.

## Stakeholder Involvement and Input for Sweet Potato

During Phases 5 and 6 of the Public Participation Process, in addition to receiving written comments from respondents listed in section IV. B. above, the Agency has met with and received comments from Bayer, USDA, and other interested stakeholders relating to aldicarb use on sweet potato. These stakeholders have provided additional information regarding aldicarb usage (application and application rates) and the need for aldicarb use to remain in sweet potato production.

## Alternatives and Benefits

The Agency understands that aldicarb use on sweet potatoes is of benefit in the states of Louisiana and Mississippi and that losing aldicarb's use would involve substantial cost to growers. It is a very important tool for sweet potato growers where nematode pressure is present. Alternatives include 1,3-D, oxamyl and ethoprop, but they do not, however, control a particular pest, the reniform nematode, as well as aldicarb. This nematode causes smaller, misshapen sweet potatoes that cannot be marketed and aldicarb is the only tool which completely controls this pest species. Not controlling nematodes may result in 100% yield loss, and partial control can yield poor quality sweet potatoes, which if sold on the processing market, will only bring 10% of the prices of marketable sweet potatoes.

#### **Mitigation**

To reduce potential ecological risks, the Agency has directed, and the registrant has agreed, to develop several mitigation measures to help address the above mentioned concerns. They include:

- Limit application of aldicarb to: Louisiana and Mississippi only.
- Addition of label language specifying granules be applied in a 12-inch band within an open furrow and covered immediately during bed forming by mechanically hilling 8 to 10 inches.
- Slight modifications in label language to help reduce the amount of aldicarb left on the surface of the soil (i.e., clarifications in the use of positive displacement technology) and making it less available for the wildlife potentially at risk. For the label language modifications, please refer to Table 5 in Section V.

## EPA Decision

Aldicarb has the potential to cause adverse effects to birds, mammals and aquatic species. However, due to the physical properties of aldicarb's granules (e.g., color, size, and solubility) and how aldicarb is soil incorporated, actual exposure of potentially affected populations to aldicarb granules is uncertain and may be overestimated. Potential risks to birds and mammals would be limited primarily to the treated fields where wildlife, if present, could ingest granules that are not incorporated in the soil and that have not yet dissolved. Therefore, the extent of exposure, both spatially and temporally, is expected to be limited. The Agency recognizes, however, that actual exposure of wildlife to aldicarb is uncertain.

As discussed above, the Agency has determined that there are benefits of aldicarb use on sweet potatoes in certain states (Louisiana and Mississippi) and that losing its use would involve substantial costs to growers. Aldicarb also has advantages to sweet potato growers for which EPA cannot estimate dollar values, such as simplicity of management, confidence in the level of control in the face of unexpected infestation, and cost effectiveness when considering the full range of pests and duration of control. Therefore, the Agency finds the use on sweet potatoes eligible for reregistration.

## 4. Other Labeling Requirements

In order to be eligible for reregistration, additional aldicarb information needs to be included in the labeling of all end-use products containing aldicarb. Uses and use patterns need to be clarified as indicated in Table 5 below to reflect and better describe actual use patterns for aldicarb. For the specific label statements and a list of additional data requirements necessary to confirm this decision, refer to Section V of this IRED document.

## 5. Threatened and Endangered Species Considerations

The Agency's screening level risk assessment for endangered and threatened species concluded that use of aldicarb has direct adverse effects on listed species in the following taxonomic groups: terrestrial invertebrates, birds, terrestrial phase amphibians, reptiles, mammals, freshwater fish, freshwater invertebrates, estuarine/marine invertebrates, and estuarine/marine fish. There is also the potential for indirect adverse effects for listed species in multiple taxonomic groups that are dependent upon species that do experience direct adverse effects. These findings are based solely on EPA's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act.

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on threatened and endangered species and to implement mitigation measures that address these impacts. The Endangered Species Act 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 REDs and considers it in relation to individual species by evaluating important 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 species-specific analysis will take into consideration any risk mitigation measures that are being implemented at the time as a result of this RED.

Following this future species-specific analysis, a determination that there is a likelihood of potential effects to a listed species or its critical habitat may result in further limitations on use of aldicarb, other measures to mitigate any potential effects, or consultations with the Fish and Wildlife Service and/or the National Marine Fisheries as appropriate. If the Agency determines use of aldicarb "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). Until a species-specific analysis is completed, the risk mitigation measures being implemented through this RED (e.g., rate reductions and geographic restrictions) will reduce the likelihood that endangered and threatened species may be exposed to aldicarb at levels of concern. EPA is not requiring specific aldicarb label language at the present time relative to threatened and endangered species. If, in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program.

EPA is currently engaging in informal consultations with the Fish and Wildlife Service and the National Marine Fisheries Service, which is a part of the National Oceanic and Atmospheric Administration. This means that the Agencies are working together to conduct a full endangered species assessment for aldicarb, which is separate from this RED. The likelihood of potential impacts to endangered species will need to be assessed for all counties in which: 1) crops registered for aldicarb use are grown; and 2) contain habitat for at least one listed species.

#### V. What Registrants Need to Do

The Agency has determined that products containing the active ingredient aldicarb are eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures. The Agency intends to issue DCIs for generic (technical grade) data and product-specific data. Generally, registrants will have 90 days from receipt of a generic DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. The DCIs will include specific requirements and instructions on how to respond. Table 4 below presents the additional generic data the Agency intends to require for aldicarb to confirm the decision that products containing the active ingredient aldicarb are eligible for reregistration. For product-specific DCIs, registrants will have eight months from receipt of the DCI to submit data and to submit amended labels. In order for products containing the active ingredient aldicarb to be eligible for reregistration, all product labels must be amended to incorporate the specific changes and language presented in Table 5 below. Table 5 also describes how the required language should be incorporated.

## A. Manufacturing-Use Products

## 1. Additional Generic Data Requirements

The generic database supporting the reregistration of aldicarb has been reviewed and determined to be substantially complete. However, EPA is requiring the following additional data to confirm the decisions presented in this RED. The Agency intends to issue a generic DCI for this data.

Data Requirement	New OPPTS Guideline Number (GLN)
Magnitude of the Residue in Plant Studies	
Data depicting the magnitude of aldicarb residues of concern in cotton gin byproducts are required in accordance with Table 1 of OPPTS Series 860 Residue Chemistry Test Guidelines, 8/96.	860.1500
Terrestrial Plant Toxicity – Tier 1 (seedling emergence)	850.4100
Terrestrial Plant Toxicity – Tier 1 (vegetative Vigor)	850.4150
Aquatic Plant toxicity Test – using Lemna spp. – Tiers I and II	850.4400
Avian Reproduction Study in Quail Avian Reproduction Study in Duck	850.2300
UV/Visible Aborption	830.7050
Comparative Cholinesterase Assay	Special Study

Table 4. Data rec	uirements for t	the reregistration	of aldicarb.
			01 0101001 000

## 2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, labeling for all manufacturing-use products (MUPs) should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the specific language presented in Table 5 below.

## **B. End-Use Products**

## 1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The registrant must review previous data submissions to ensure 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 can be cited according to the instructions in the Requirement Status and Registrations Response Form provided for each product. The Agency intends to issue a separate product-specific DCI outlining specific data requirements.

## 2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV above. The specific changes and language are presented in Table 5 below. 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.

Description	Amended Labeling Language for Manufacturing Use Products	Placement on Label
For all Manufacturing Use Products	"Only for formulation into an <i>insecticide/nematicide</i> for the following uses: citrus, cotton, dry bean, peanuts, potatoes, soybean, sugar beets, sweet potatoes."	Directions for Use
	"Only formulation into low dust granular products such as products that use a vinyl binder coating to adhere the aldicarb to either a corn cob grit or a gypsum substrate. Binding aldicarb to clay substrate is prohibited."	
Note to Registrant	This product may not be used to formulate products for use on alfalfa grown for seed, coffee, ornamentals, pecans, sorghum, sugarcane, and tobacco.	
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	<ul> <li>"This product may be used to formulate products for specific uses not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such uses."</li> <li>"This product may be used to formulate products for any additional uses not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such uses."</li> </ul>	Directions for Use
Environmental Hazards Statements	"This pesticide is extremely toxic to birds and mammals. This pesticide is toxic to fish and aquatic invertebrates. 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 Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements

Table 5. Summary of Required Labeling Changes for Aldicarb Products.

	End Use Products Intended for Occupational Use		
Restricted Use Pesticide	<ul> <li>"Restricted Use Pesticide"</li> <li>"Due to acute oral toxicity and to ground water contamination. For retail sale to and use only by Certified Applicators or persons under the direct supervision of a Certified Applicator, and only for those uses covered by the Certified Applicator's certification."</li> </ul>	This statement must appear at the very top of the label's front panel [see 40 CFR 156.10(j)(2)(i) for more information]. No other wording or symbols should appear above the RUP statement.	
PPE Requirements Established by the RED <sup>1</sup> for low- dust granular formulations that are packaged in closed loading and application systems (e.g., Lock 'n Load, Smartbox)	<ul> <li>"Personal Protective Equipment (PPE)"</li> <li>"Some materials that are chemical-resistant to this product are" (<i>registrant inserts correct chemical-resistant material</i>). "If you want more options, follow the instructions for category" [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] "on an EPA chemical-resistance category selection chart."</li> <li>"All loaders, applicators, and other handlers must wear;</li> <li>&gt; long-sleeved shirts and long pants,</li> <li>&gt; shoes plus socks.</li> <li>In addition, loaders and handlers cleaning equipment or spills must wear:</li> <li>&gt; chemical-resistant gloves made of any waterproof material, and</li> <li>&gt; chemical-resistant apron.</li> </ul>	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals.	
PPE Requirements Established by the RED <sup>1</sup> for granular	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (registrant inserts correct	Immediately following/below Precautionary	

low- dust formulations that are	chemical-resistant material). "If you want more options, follow the instructions for category" [registrant inserts A,B,C,D,E,F,G,or H] "on an EPA chemical-resistance	Statements: Hazards to Humans and Domestic
not packaged in a closed loading and	category selection chart."	Animals.
application system.	<ul> <li>"All loaders, applications and other handlers must wear at a minimum:</li> <li>&gt; coveralls over long-sleeved shirts and long pants,</li> <li>&gt; chemical-resistant gloves made of any waterproof material,</li> <li>&gt; chemical-resistant footwear plus socks, and</li> <li>&gt; protective eyewear.</li> </ul> In addition, loaders and handlers cleaning equipment or spills must wear:	
	<ul> <li>&gt; chemical-resistant apron, and</li> <li>&gt; 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."</li> <li>"See engineering controls for additional options."</li> </ul>	
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.
Engineering Controls for granular low- dust formulations that are packaged in closed loading and application systems (e.g., Lock 'n Load, Smartbox)	<ul> <li>"Engineering Controls"</li> <li>"This product is formulated into a (<i>registrant inserts the trade name of the closed system in which the product is marketed, such as Lock 'N Load or SmartBox</i>) system that meets the definition of a closed loading and application system in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Loaders and applicators using the closed-system packaging must:</li> <li> wear the personal protective equipment required in the PPE section of this labeling for</li> </ul>	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
, ,	loaders during loading, and wear the personal protective equipment required in the PPE section of this labeling for	

	applicators during applying, and be provided, have immediately available, and use in an emergency, such as a broken package, spill, or equipment breakdown: chemical-resistant gloves, chemical-resistant apron, chemical-resistant footwear, protective eyewear, 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."	
Engineering Controls: Enclosed Cabs for Ground Applicators	<ul> <li>"Engineering Control Options for Enclosed Cabs:</li> <li>Applicators using an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] may wear reduced personal protective equipment, provided they:</li> <li> wear a long-sleeve shirt, long pants, shoes, and socks</li> <li> are provided, have immediately available, and use in an emergency, such as a broken package, spill, or equipment breakdown: chemical-resistant gloves, chemical-resistant apron, chemical-resistant footwear, protective eyewear, 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.</li> <li> take off any PPE that was worn in the treated area before reentering the cab, and</li> <li> store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab."</li> </ul>	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
User Safety Recommendations	<ul> <li>"User Safety Recommendations"</li> <li>"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.</li> <li>Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.</li> <li>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."</li> </ul>	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental	"This pesticide is extremely toxic to birds and wildlife. Birds feeding on exposed granules	Precautionary Statements

Hazards	may be killed. Cover or immediately soil incorporate granules spilled during loading."	immediately following the User Safety
	"This pesticide is toxic to fish and aquatic invertebrates. Run-off from treated areas may be hazardous to fish in neighboring areas. Do not apply directly to water, to areas where surface water is present or to inter-tidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash waters."	Recommendations
	"This product is toxic to bees exposed to direct treatment. Do not apply this product while bees are actively visiting the treatment area."	
	"Aldicarb is known to leach through soil into ground water under certain conditions as a result of labeled use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination."	
	"See use directions for individual crops for additional ground water restrictions. See soil tables."	
Environmental Hazards Statements Required by the	"Under the Endangered Species Act, it is a Federal Offense to use any pesticide in a manner that results in the death of a member of an endangered species.	Precautionary Statements
RED and Agency Label Policies	This Act protects Attwater's Greater Prairie Chicken in the Texas counties of Aransas, Austin, Brazoria, Colorado, Galveston, Goliad, Harris, Refugio, and Victoria.	
	Prior to making applications in these counties, the user must determine that this species is not located in or immediately adjacent to the area to be treated. If the user is in doubt whether or not the above named endangered species may be affected, he should contact either the regional U.S. Fish & Wildlife Service office (Endangered Species Specialist) or personnel of the State Fish and Game office."	

Restricted-Entry Interval for products with directions for use within scope of the Worker Protection Standard for Agricultural Pesticides (WPS)	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours." "Exception: If the product is soil-incorporated or soil-injected, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated."	Agricultural Use Requirements Box
Early Entry Personal Protective Equipment for products with directions for use within the scope of the WPS	<ul> <li>"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 plants, soil, or water, is:</li> <li>* coveralls worn over long-sleeve shirt and long pants,</li> <li>* chemical-resistant gloves made of any waterproof material,</li> <li>* chemical-resistant footwear plus socks, and</li> <li>* protective eyewear."</li> </ul>	Direction for Use Agricultural Use Requirements box
Double notification requirement	"Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas."	Agricultural Use Requirements Box
General Application Restrictions	"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 Direction for Use directly above the Agricultural Use Box.
Other Application Restrictions for <b>all</b> products	"Application must be made using a motorized ground spreader. Application using aircraft, handheld, backpack spreaders, or push-type spreaders is prohibited."	Directions for Use Associated with the Specific Use Pattern
Other Application Restrictions for products with directions for use on <b>Citrus</b>	CITRUS The maximum single application rate is 4.95 lbs ai/A. Do not make more than one application per tree per use season. Do not allow livestock to graze in treated area. The Preharvest Interval is 30 days.	Directions for Use Associated with the Specific Use Pattern

(Note: The maximum allowable application rate and maximum allowable seasonal rate must be listed as pounds or gallons of formulated product per acre, not just as pounds active ingredient per acre.)	All application must be made with granular applicators which use Positive Displacement Metering Units. For all applications, immediately deep-disc any spills at row ends or elsewhere to ensure the granular is completely covered with a layer of soil. Granules must be place into bottom of the seed furrow and immediately covered with at least 2 inches of soil by mechanical means. <u>For Mature Citrus Trees:</u> "apply in a band along the drip line on both sides of tree row. Apply granules in 3 to 6 furrows that are 2 to 3 inches deep and spaced on approximately 12 inch centers. Immediately cover with soil by mechanical means. The width of each band should equal 1/4 the tree row spacing." <b>OR</b> For furrow irrigation applications to mature citrus, "apply granules 2 to 3 inches deep in the irrigation furrow using 2 shanks per furrow." <u>For Immature Citrus Trees (1-2 years old):</u> "0.3 oz ai/tree (do not exceed 4.95 lbs ai/acre). Apply granules in a furrow beside individual trees and cover with at least 2 inches of soil."	
Other Application Restrictions for products with directions for use on <b>Cotton</b>	<u>COTTON</u> The maximum single at-plant application rate is 1.5 lbs ai/A. The maximum single side-dress (post-emergence) application rate is 2.1 lbs ai/A. Do not exceed a total of 3.6 lbs ai/A per year. Do not make more than one at-plant application and one post-emergence application per	Directions for Use Associated with the Specific Use Pattern
(Note: The maximum allowable application rate and maximum allowable seasonal rate must be listed as pounds or gallons of formulated product per acre, not just as pounds active ingredient per acre.)	<ul> <li>crop.</li> <li>Do not apply within 90 days of harvest.</li> <li>Do not feed cotton forage to livestock or allow livestock to graze in treated area.</li> <li>If it is not known whether the water table is greater than 25 ft below ground surface, assume that the water table is less than 25 feet below ground surface.</li> <li>For all applications, immediately deep-disc any spills at row ends or elsewhere to ensure the granular is completely covered with a layer of soil.</li> <li><u>At Planting:</u> "Apply granules in the seed furrow and immediately cover with soil by mechanical means.</li> </ul>	

	OR         If rate exceeds 1.05 lbs ai/A on 40 inch rows, "apply granules in a 4 to 6 inch band (T-band) over open seed furrow and immediately cover by mechanical means."         At First Squaring:       "Apply side dress granules in a furrow that is 6 to10 inches to one or both sides of the plant row to a depth of 2 to 3 inches."	
Other Application Restrictions for products with directions for use on <b>Dry Bean</b> (Note: The maximum allowable application rate and maximum allowable seasonal rate must be listed as pounds or gallons of formulated product per acre, not just as pounds active ingredient per acre.)	<ul> <li>DRY BEANS (other than sovbeans)</li> <li>For use in Oregon, Washington, Idaho, and Michigan only.</li> <li>Do not exceed a total of 2.1 lbs ai/A/season.</li> <li>Do not make more than one application per crop.</li> <li>Do not apply within 90 days of harvest.</li> <li>Do not feed green forage, hay, or straw to livestock.</li> <li>Do not allow livestock to graze in treated areas before harvest.</li> <li>Do not use green pods as food for humans.</li> <li>If it is not known whether the water table is greater than 25 ft below ground surface, assume that the water table is less than 25 feet below ground surface.</li> <li>Immediately deep-disc any spills at row ends or elsewhere to ensure the granular is completely covered with a layer of soil.</li> <li>For all applications, except for where furrow irrigation is used: "Apply granules in seed furrow and immediately cover with soil by mechanical means.</li> <li>OR</li> <li>Apply in a furrow that is 2 to 3 inches to the side of seed row and 2 to 3 inches deep in seed furrow and immediately cover with soil by mechanical means.</li> <li>OR</li> <li>Apply granules on a 4 to 6 inch band over open furrow and immediately cover with soil by mechanical means.</li> <li>When furrow irrigation is used: "apply granules 3 to 4 inches deep and 3 inches from the seed row on the water furrow side and immediate cover with soil by mechanical means."</li> </ul>	Directions for Use Associated with the Specific Use Pattern
Other Application Restrictions for	<b><u>PEANUT</u></b> Do not exceed a total of 3.0 lbs ai/A/season	Directions for Use Associated with the

products with	Do not harvest within 90 days of application.	Specific Use Pattern
directions for use on	Do not hog-off treated fields.	_
Peanut	Do not allow livestock to graze in treated areas before harvest.	
	Do not feed hay or vines to livestock.	
(Note: The maximum	Post-emergence applications can only be used in fields where overhead irrigation is	
allowable application	available.	
rate and maximum	Do not make more than one application per crop in states other than Alabama, Florida,	
allowable seasonal	Georgia, North Carolina, Oklahoma, Texas, and Virginia.	
rate must be listed as	Do not make the split application to Spanish peanuts or other short season varieties (a	
pounds or gallons of	minimum of 90 days is required between pegging applications and harvest).	
formulated product	If aldicarb is applied to peanuts in AL, GA and SC and a vulnerable soil is present and the	
per acre, not just as	water table is less than 25 feet below ground surface, do not apply within 500 feet of a	
pounds active	drinking water well unless wells are either cased to 100 feet below ground level or a	
ingredient per acre.)	minimum of 30 feet below the water table. If it is not known whether the water table is	
	greater than 25 feet below ground surface, assume that the water table is less than 25 feet	
	below ground surface.	
	If aldicarb is applied to peanuts in Florida and a vulnerable soil is present (see soils listed	
	below), and the water table is less than 25 feet below ground surface, do not apply within	
	500 feet of a drinking water well unless wells are either cased to 100 feet below ground	
	level or a minimum of 30 feet below the water table. In Florida, it is the responsibility of	
	the applicator to document the construction of wells claimed not to be shallow. This must	
	consist of: (a) a copy of the well completion report issued by the appropriate water	
	management district; or (b) a statement certified as to accuracy by a licensed well	
	contractor. The U.S.D.A. Natural Resources Conservation Service which serves your	
	county can tell you if the soils on your farm fall within the following types of vulnerable	
	soils. If it is not known whether the water table is greater than 25 feet below ground	
	surface, assume that the water table is less than 25 feet below ground surface.	
	For all applications, immediately deep-disc any spills at row ends or elsewhere to ensure	
	the granular is completely covered with a layer of soil.	
	Thrips At Planting: "Apply granules in seed furrow and immediately cover with soil by	
	mechanical means to a depth of 2 to 4 inches."	
	Nematodes At Planting: "Apply granules in a 4-6 inch band over open seed furrow (T-	
	<u>remaindes At Francing.</u> Apply granules in a 4-0 men band over open seed fullow (1-	

	<ul> <li>band) and immediately cover with soil by mechanical means to a depth of 2 to 4 inches.</li> <li>OR</li> <li>Apply granules in a 6 to 12 inch band and immediately cover with soil by mechanical means to a depth of 2 to 4 inches. Plant seed into treated zone."</li> <li><u>At Pegging:</u> "Apply granules in a band 12 to 18 inches wide on the row and into the plant canopy. Ensure that plant foliage is dry prior to application. Dislodge granules from foliage by suitable means that will not damage the plant. Application must be made late in the afternoon or early evening, immediately followed by irrigation, and completed within 24 hours unless rainfall is received."</li> </ul>	
Other Application Restrictions for products with directions for use on <b>Potato</b> (Note: The maximum allowable application rate and maximum allowable seasonal rate must be listed as pounds or gallons of formulated product per acre, not just as pounds active ingredient per acre.)	<ul> <li>POTATOES</li> <li>For use only in the states of Florida, Idaho, Montana, Oregon, and Washington; in Utah in the counties of Beaver, Boxelder, Cache, Carbon, Davis, Duchesne, Iron, Millard, Plute, Salt Lake, Sanpete, Sevier, Ulntah, Utah, Wasatch, Washington, and Weber; and in Nevada in the counties of Humboldt and Pershing.</li> <li>Do not exceed 3.0 lbs ai/A/season.</li> <li>All applications must be made with Positive Displacement Applicators such as Horstine Microband® or Gandy PDM® or with other Positive Displacement Applicators approved under the Bayer CropScience Equipment Certification Program. The applicator must be certified through the Bayer CropScience Stewardship program.</li> <li>Do not harvest within 100 days of application for potatoes grown in Florida and within 150 days of application for potatoes grown in the Pacific Northwest (Idaho, Montana, Oregon, Washington, and certain counties in Nevada and Utah).</li> <li>Do not make more than one application per crop. If replanting is necessary, do not retreat the second crop with (registrant insert brand name).</li> <li>Do not allow livestock to graze in treated areas before harvest.</li> <li>In state other than Florida, do not use furrow irrigation on aldicarb-treated potatoes.</li> <li>Do not use this product on potatoes in any state other than those immediately listed above.</li> <li>If it is not known whether the water table is greater than 25 ft below ground surface, assume that the water table is less than 25 feet below ground surface.</li> <li>Immediately deep-disc any spills at row ends or elsewhere to ensure the granular is completely covered with a layer of soil.</li> </ul>	Directions for Use Associated with the Specific Use Pattern

	At Planting: "Apply granules in a 6 inch band and immediately cover with 4 to 8 inches of soil by mechanical means. Plant seed pieces into treated zone. OR Apply granules in furrow with seed piece. Immediately cover with 4 to 8 inches of soil by mechanical means."	
Other Application Restrictions for products with directions for use on <b>Soybean</b> (Note: The maximum allowable application rate and maximum allowable seasonal rate must be listed as pounds or gallons of formulated product per acre, not just as pounds active ingredient per acre.)	<ul> <li><u>SOYBEAN</u></li> <li>For use on soybeans grown only in Georgia, North Carolina, and South Carolina.</li> <li>Do not exceed a total of 1.5 lbs ai/A/season.</li> <li>Do not make more than one application per crop.</li> <li>Do not apply within 90 days of harvest.</li> <li>Do not allow livestock to graze in treated areas before harvest.</li> <li>Do not feed green forage, hay or straw to livestock.</li> <li>If it is not known whether the water table is greater than 25 ft below ground surface, assume that the water table is less than 25 feet below ground surface.</li> <li>Immediately deep-disc any spills at row ends or elsewhere to ensure the granular is completely covered with a layer of soil.</li> <li><u>At Planting:</u> "Apply granules in seed furrow and immediately cover with soil by mechanical means.</li> <li>OR</li> <li>If rate exceeds 0.9 lbs ai/A on 30 inch rows, "Apply a 4 to 6 inch band over open seed furrow and immediately cover with soil by mechanical means."</li> </ul>	Directions for Use Associated with the Specific Use Pattern
Other Application Restrictions for products with directions for use on <b>Sugar Beet</b> (Note: The maximum allowable application	SUGAR BEETSFor use only in California, Colorado, Idaho, Montana, Nebraska, Oregon, Washington, and Wyoming.The total maximum rate per crop cycle is 4.95 lbs ai/A. Do not make more than one at-planting application and two post-emergence applications per crop. Do not apply within 90 days of harvest.If tops are to be fed to livestock, do not apply within 120 days of harvest."	Directions for Use Associated with the Specific Use Pattern

rate and maximum allowable seasonal rate must be listed as pounds or gallons of formulated product per acre, not just as pounds active ingredient per acre.)	Do not use tops as food to humans. If it is not known whether the water table is greater than 25 ft below ground surface, assume that the water table is less than 25 feet below ground surface. For all applications, immediately deep-disc any spills at row ends or elsewhere to ensure the granular is completely covered with a layer of soil. <u>Nematodes At Planting:</u> "Apply granules in a 4 to 6 inch band and immediately cover with soil by mechanical means. Plant seed into or above treated zone. <b>OR</b> where furrow irrigation is employed for seed germination, drill granules 3 to 4 inches deep and 3 inches from seed row on water furrow side." <u>Aphids, Leafminers and Leafhoppers At Planting</u> : "Drill granules 1 to 3 inches below seedline." <u>Sugar Beet Root Maggot At Planting</u> : "Apply granules in a 2 to 3 inch band over seed row and immediately cover with soil by mechanical means. <b>OR</b> where furrow irrigation is employed for seed germination, drill granules 2 inches deep and 2 inches from seed row on water furrow side. For the 7 lb. rate, apply granules in a 1 to 2 inch band in front of the press wheel as the furrow is closing." <u>Post-emergence:</u> "Apply granules to both sides of plant row and immediately cover with soil by mechanical means. <b>OR</b> for furrow irrigation side-dress granules 4 to 8 inches to water furrow side of plant row at furrow depth. Irrigate soon after application. Apply within 60 days after planting."	Directions for Use
Other Application	<b>SWEET POTATOES</b>	Directions for Use
Restrictions for	For use in Louisiana and Mississippi only.	Associated with the
products with	Maximum application rate is 3 pounds ai/A/crop.	Specific Use Pattern

directions for use on	Do not make more than one application per crop.	
Sweet Potato	Do not harvest within 120 days of application.	
	Do not feed sweet potato vines to livestock.	
(Note: The maximum	Application must be made with granular applicators which use Positive Displacement	
allowable application	Metering Units. Apply granules in a 12-inch band open furrow. Immediately cover	
rate and maximum	granules by mechanical hilling soil at least 8 to 10 inches.	
allowable seasonal	If it is not known whether the water table is greater than 25 ft below ground	
rate must be listed as	surface, assume that the water table is less than 25 feet below ground surface.	
pounds or gallons of	Immediately deep-disc any spills at row ends or elsewhere to ensure the granular is	
formulated product	completely covered with a layer of soil.	
per acre, not just as		
pounds active	Pre-plant or At Planting: "Apply granules in a 12-inch band open furrow or soil surface	
ingredient per acre.)	and cover immediately during bed forming by mechanically hilling up 8 to 10 inches.	
	Place transplant in center of treated zone."	

<sup>1</sup> PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

SITE NAME	LIMITATI	ONS					
Application Equipment, Timing, and Type (for any Reg.# at any rate)	Max. Single Appl. Rate	Form Code(s)	Max. Seasonal Rate	Max. # Apps/ cc & yr	M R I	REI	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
CITRUS (Oranges, Grapefruit, Lemons, and Limes only)	<ul> <li>30 day(s) preharvest interval.</li> <li>All application must be made with granular applicators which use Positive Displacement Metering Units.</li> <li>Apply only while wearing prescribed protective gloves.</li> <li>Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.</li> <li>Do not apply this product to fields within 50 feet of wells used for drinking water. More restrictive setbacks may apply.</li> <li>Do not contaminate water by cleaning of equipment or disposal of equipment wash waters.</li> <li>Do not contaminate water, food or feed.</li> <li>Do not contaminate water, food, or feed by storage or disposal.</li> <li>Do not graze dairy animals in treated areas.</li> <li>Do not graze livestock in treated areas.</li> <li>Do not graze meat animals in treated areas.</li> <li>Do not store or use in or around the home or home garden.</li> <li>Endangered species restriction.</li> <li>For terrestrial uses, 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.</li> <li>Ground water restriction.</li> <li>Incorporate to a minimum depth of 2 inches.</li> <li>Proper ventilation required.</li> <li>Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas.</li> <li>This product is highly toxic to birds, fish, and other wildlife.</li> <li>For all applications, immediately deep-disc any spills at row ends or elsewhere to ensure the granular is completely covered with a layer of soil.</li> <li>10 months rotational/plant back crop restriction with the following exceptions: Do not plant wheat, barley, bulb crops, or brassica crops within 6 months after the last application.</li> <li>Geographic disallowable: CA, CT, MA, ME, NH, NJ, NY, PA, RI, VT, WI, or in Curry</li> </ul>						
Foliar Soil in-furrow treatment /Soil shanking treatment /Soil treatment. Granule applicator.	4.95 lb ai/A	G	4.95 lb ai/A 4.95 lb ai/cc	1/1 cc	NS	48 h	
COTTON (UNSPECIFIED)	90 day(s) preharvest interval. Apply only while wearing prescribed protective gloves. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply this product to fields within 50 feet of wells used for drinking water. More restrictive setbacks may apply.						

## Appendix A. Aldicarb Uses and Use-Patterns Eligible for Reregistration

SITE NAME	LIMITATI	ONS					
Application Equipment, Timing, and Type (for any Reg.# at any rate)	Max. Single Appl. Rate	Form Code(s)	Max. Seasonal Rate	Max. # Apps/ cc & yr	MRI	REI	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
	Do not apply when drift is likely to occur. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water by cleaning of equipment or disposal of waste. Do not contaminate water, food or feed. Do not contaminate water, food, or feed by storage or disposal. Do not feed forage to livestock or allow livestock to graze in treated areas. Do not graze dairy animals in treated areas. Do not graze meat animals in treated areas. Do not store or use in or around the home or home garden. Endangered species restriction. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Ground water restriction. Incorporate to a minimum depth of 2 inches. Proper ventilation required. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. This pesticide is toxic to aquatic invertebrates. This product is highly toxic to birds, fish, and other wildlife. For all applications, immediately deep-disc any spills at row ends or elsewhere to ensure the granular is completely covered with a layer of soil. 10 months rotational/plant back crop restriction with the following exceptions: Do not plant wheat, barley, bulb crops, or brassica crops within 6 months after the last application. Geographic disallowable: CT, MA, ME, NH, NJ, NY, PA, RI, VT, WI, or in Del Norte or Humbolt counties in CA or in Curry County, OR.						
At planting Band treatment /Soil band treatment /Soil drill treatment /Soil in-furrow treatment. Granule applicator.	1.5 lb ai/A	G	3.6 lb ai/A 3.6 lb ai/cc	2/cc	NS	48 h	
At first squaring Soil sidedress treatment.Granule applicator.	2.1 lb ai/A	G	3.7 lb ai/A 3.6 lb ai/cc	2/cc	NS	48 h	
Squaring through early bloom Soil in-furrow treatment /Soil sidedress treatment.	2.1 lb ai/A	G	3.8 lb ai/A 3.6 lb ai/cc	2/cc	NS	48 h	

SITE NAME	LIMITATI	ONS					
Application Equipment, Timing, and Type (for any Reg.# at any rate)	Max. Single Appl. Rate	Form Code(s)	Max. Seasonal Rate	Max. # Apps/ cc & yr	M R I	REI	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
Granule applicator.							
BEANS, DRIED- TYPE	Apply only Do not apply below the m Do not apply restrictive se Do not contr Do not contr Do not contr Do not contr Do not contr Do not grazz Do not store Do not store Do not store Do not store Do not store Do not use g Endangered For terrestri to intertidal Ground wat Incorporate Proper venti Runoff from This pesticie This produc For all app ensure the 10 months r wheat, barle plant corn, o	areas below ther restriction. to a minimum lation require the treated areas de is toxic to a the shighly tox lications, import granular is co otational/plan	g prescribed p vater, or to are er mark. to fields with pply. by cleaning of by cleaning of by cleaning of by cleaning of food or feed f, food, or feed hay, or straw is in treated are treated areas. s in treated are tround the hor food for huma- ction. t apply directl he mean high a depth of 2 in d. may be hazar quatic inverted ic to birds, fiss mediately de ompletely co t back crop re or brassica cu uiting vegeta D, MI, OR, W CT, MA, MI	eas where surf in 50 feet of v of equipment of equipment of d by storage of to livestock. reas. reas. reas. reas. y to water or water mark. thes. rdous to aquate brates. sh, and other v eep-disc any overed with a striction with rops within 6 bes within 8 r A only. E, NH, NJ, N	Tace water is p wells used for or disposal of or disposal of r disposal. arden. to areas where tic organisms wildlife. spills at row a layer of soi the following months after th	drinking wate equipment wa waste. e surface wate in neighboring ends or else l. exceptions: he last applica	er. More ash waters. or is present or g areas. where to Do not plant ation. Do not tion.
At planting Soil band treatment /Soil in- furrow treatment. Granule applicator.	2.1 lb ai/A	G	2.1 lb ai/A 2.1 lb ai/cc	1/1 cc	NS	48 h	
PEANUTS (UNSPECIFIED)	Do not mak TX, and VA	reharvest inter e more than or  e split applica	ne application				

SITE NAME	LIMITATI	ONS					
Application Equipment, Timing, and Type (for any Reg.# at any rate)	Max. Single Appl. Rate	Form Code(s)	Max. Seasonal Rate	Max. # Apps/ cc & yr	M R I	REI	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
	Do not allow Do not apply below the m Do not apply restrictive se Do not apply Do not conta Do not conta Do not conta Do not conta Do not conta Do not feed Do not feed Do not feed Do not graze Do not graze Do not graze Do not graze Do not graze Do not graze Do not store Drift and rut Endangered For terrestri- to intertidal Ground wate vulnerable s apply within ground leve water table i than 25 feet soil is preses surface, do n 100 feet below responsibility shallow. The appropriate well contract county can to If it is not kut that the wate Incorporate Keep out of Proper ventif Runoff from This pesticio This produc For all applig granular is c 10 months r	tean high wate y this product etbacks may a y when drift is aminate water aminate water aminate water aminate water aminate water hay or vines treated hay or e dairy animal e livestock in e meat animal down treated e or use in or a noff may be h species restri al uses, do no areas below t er restrictions oil is present <b>500 feet</b> of a l or a minimu is greater than below ground nt (see soils li not apply with ow ground leve ty of the appli is must consis water manage tor. The U.S.I cell you if the nown whether er table is less to a minimum lakes, stream lation require a treated areas de is toxic to a t is highly tox completely co- otational/plan	graze treated vater, or to are er mark. to fields with apply. s likely to occe by cleaning of by cleaning of by cleaning of by cleaning of the stock. r vines to live ls in treated are treated areas. s in treated areas. treated areas. s in treated areas. s in treates	areas before eas where sur in 50 feet of our. of equipment of equipment d by storage of stock. reas. reas. reas. me or home g quatic organi dy to water or water mark. s applied to p table is less to er well unles below the water of a drinking w num of 30 fee ment the conse y of the well or (b) a state Resources Co farm fall with ble is greater to below ground or (b) a state resources Co farm fall with ble is greater to below ground or ches.	harvest. face water is p wells used for or disposal of or disposal of or disposal of or disposal. arden. sms in neighbor to areas where beanuts in AL, than 25 feet be swells are eith er table. If it is face, assume the blied to peanut table is less the vater well unlee t below the was struction of we completion re- ment certified onservation Se in the following than 25 feet be sufface.	oring areas. e surface wate GA and SC a elow ground su her cased to 10 s not known w hat the water ta ts in Florida an han 25 feet bel ess wells are eff ater table. In F ells claimed no port issued by a s to accurace rivice which se ing types of vu	er. More ash waters. ash water

SITE NAME	LIMITATI	ONS								
Application Equipment, Timing, and Type (for any Reg.# at any rate)	Max. Single Appl. Rate	Form Code(s)	Max. Seasonal Rate	Max. # Apps/ cc & yr	MRI	REI	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)			
	Geographic	plant corn, cucurbits, or fruiting vegetabes within 8 months after the last application. Geographic disallowable: CT, MA, ME, NH, NJ, NY, PA, RI, VT, WI, or in Del Norte or Humbolt counties in CA or in Curry County, OR.								
At planting Soil band treatment /Soil in- furrow treatment. Granule applicator	3 lb ai/A	G	3 lb ai/A 3 lb ai/cc	2/cc	NS	48 h				
At pegging Soil band	1.5 lb ai/A	G	3 lb ai/A 3 lb ai/cc	2/cc	NS	48 h	Geographic allowable: AL, FL, GA, NC, OK, TX, and VA only. Do not make split application to Spanish peanuts or other short season varieties. Ensure that plant foliage is dry prior to application. Dislodge granules from foliage by suitable means that will not damage the plant. Irrigate immediately after application and complete within 24 hours unless rainfall is received			

SITE NAME	LIMITATI	ONS					
Application Equipment, Timing, and Type (for any Reg.# at any rate)	Max. Single Appl. Rate	Form Code(s)	Max. Seasonal Rate	Max. # Apps/ cc & yr	M R I	REI	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
ΡΟΤΑΤΟ	150 day(s) p NV (Humbo Iron, Millard Weber). All applicat Metering Un Apply only Do not allow Do not appl below the m Do not appl restrictive se Do not cont Do not cont Do not cont Do not cont Do not graz Do not store Endangered For terrestri to intertidal Ground wat Incorporate Proper venti Runoff from This pesticio This produc For all appli granular is c 10 months r wheat, barle plant corn, c Geographic	olt and Pershin d, Plute, Salt I ion must be m nits. while wearing v livestock to y directly to w ean high water aminate water aminate water aminate water aminate water aminate water aminate water aminate water aminate water aninate ani	erval for potat ng) and UT (E Lake, Sanpete hade with gran g prescribed p graze treated vater, or to are er mark. to fields with pply. by cleaning of c, food or feed at treated areas. s in treated ar treated areas. s in treated areas. s in treat	oes grown in Seaver, Boxeld, seaver, Boxeld, seaver, Boxeld, seaver, Boxeld, sular applicator rotective glow areas before heas where surf in 50 feet of w of equipment of the substorage of reas. The or home gate by to water or water mark. aches. rdous to aquate ebrates. sh, and other w disc any spills ayer of soil. striction with rops within 6 bes within 8 r C, WA, and ce Cache, Carbon h, Wasatch, W E, NH, NJ, N	ID, MT, OR, der, Cache, Ca ah, Utah, Was ors which use es. harvest. face water is p wells used for or disposal of r disposal of r disposal. arden. to areas where ic organisms wildlife. s at row ends of the following months after th ronths after th row and a contracts the following months after th roth solution, an	arbon, Davis, satch, Washin, Positive Displ present or to in drinking wate equipment was e surface wate in neighborin; or elsewhere t g exceptions: the last applica in NV (Hum lesne, Iron, M	gton, and acement Itertidal areas er. More ash waters. r is present or g areas. o ensure the Do not plant ation. Do not tion. polt and illard, Plute,
At planting Soil band treatment /Soil drill treatment /Soil in-furrow treatment. Granule applicator.	3 lb ai/A	G	3 lb ai/A 3 lb ai/cc	1/cc	NS	48 h	

SITE NAME	LIMITATI	ONS					
Application Equipment, Timing, and Type (for any Reg.# at any rate)	Max. Single Appl. Rate	Form Code(s)	Max. Seasonal Rate	Max. # Apps/ cc & yr	M R I	REI	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
SOYBEANS (UNSPECIFIED)	Apply only Do not allow Do not apply below the m Do not apply restrictive so Do not appl Do not appl Do not cont Do not graz Do not store Endangered For terrestri to intertidal Ground wat Incorporate Proper venti Runoff from This pesticio This produc For all appli granular is c 10 months r wheat, barle plant corn, c Geographic	lean high wate y this product etbacks may a y to any body y when drift is aminate water aminate water aminate water aminate water green forage, e dairy animal e livestock in e meat animal e or use in or a species restri- al uses, do no- areas below the er restriction. to a minimum lation require h treated areas de is toxic to a t is highly tox cations, imme- completely co- otational/plan cy, bulb crops, cucurbits, or fi- allowable: Ga	g prescribed p graze treated vater, or to are er mark. to fields with pply. of water. s likely to occe by cleaning of by cleaning of the straw ls in treated are treated areas. s in treated are treated areas. s in treated are tround the hor ction. t apply directl he mean high a depth of 2 in d. may be hazar aquatic inverted ic to birds, fis ediately deep- vered with a 1 t back crop re or brassica c ruiting vegeta A, NC, and SC CT, MA, MI	areas before I eas where surf in 50 feet of v ur. of equipment of equipment d by storage o to livestock. reas. reas. me or home g y to water or water mark. the s. rdous to aquate ebrates. sh, and other v disc any spill ayer of soil. estriction with rops within 6 bes within 8 r C only. E, NH, NJ, N	harvest. Face water is p wells used for or disposal of or disposal of or disposal. arden. to areas where tic organisms wildlife. s at row ends of the following months after th	e surface wate in neighboring or elsewhere t	er. More ash waters. r is present or g areas. o ensure the Do not plant ation. Do not tion.
At planting Soil band treatment /Soil drill treatment /Soil in-furrow treatment. Granule applicator /Not on label.	1.5 lb ai/A	G	1.5 lb ai/A 1.5 lb ai/cc	1/cc	NS	48 h	
SUGAR BEET		preharvest int reharvest inter		ps are to be fe	ed to livestock		

SITE NAME	LIMITATI	ONS						
Application Equipment, Timing, and Type (for any Reg.# at any rate)	Max. Single Appl. Rate	Form Code(s)	Max. Seasonal Rate	Max. # Apps/ cc & yr	M R I	REI	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)	
	Apply only while wearing prescribed protective gloves. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply this product to fields within 50 feet of wells used for drinking water. More restrictive setbacks may apply. Do not apply when drift is likely to occur. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water by cleaning of equipment or disposal of waste. Do not contaminate water, food or feed. Do not contaminate water, food or feed by storage or disposal. Do not graze dairy animals in treated areas. Do not graze dairy animals in treated areas. Do not graze meat animals in treated areas. Do not graze meat animals in treated areas. Do not store or use in or around the home or home garden. Do not use tops as food for humans. Endangered species restriction. Ground water restriction. Incorporate to a minimum depth of 2 inches. Proper ventilation required. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. This product is highly toxic to birds, fish, and other wildlife. For all applications, immediately deep-disc any spills at row ends or elsewhere to ensure the granular is completely covered with a layer of soil. 10 months rotational/plant back crop restriction with the following exceptions: Do not plant wheat, barley, bulb crops, or brassica crops within 6 months after the last application. Geographic disallowable: CA, CO, ID, MT, NE, OR, WA, and WY only. Geographic disallowable: CT, MA, ME, NH, NJ, NY, PA, RI, VT, WI, or in Del Norte or							
<b>Preplant</b> Soil band treatment /Soil drill treatment. Granule applicator.	4.95 lb ai/A	G	4.95 lb ai/A 4.95 lb ai/cc	3/cc	NS	48 h		
At planting Soil band treatment /Soil drill treatment /Soil in-furrow treatment /Soil incorporated treatment by irrigation /Soil sidedress	4.95 lb ai/A	G	4.95 lb ai/A 4.95 lb ai/cc	3/cc	NS	48 h		

SITE NAME	LIMITATI	ONS					
Application Equipment, Timing, and Type (for any Reg.# at any rate)	Max. Single Appl. Rate	Form Code(s)	Max. Seasonal Rate	Max. # Apps/ cc & yr	M R I	REI	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
treatment. Granule applicator.							
<b>Postemergence</b> Soil in-furrow treatment /Soil incorporated treatment by irrigation /Soil sidedress treatment /Soil treatment. Granule applicator.	4.05 lb ai/A	G	4.95 lb ai/A 4.95 lb ai/cc	3/cc	NS	48 h	
SWEET POTATO	All applicat Metering U: Apply only Do not allow Do not appl below the m Do not appl restrictive s Do not appl Do not cont Do not graz Do not graz Do not graz Do not graz Do not graz Do not graz Do not store Endangered For terrestri to intertidal Ground wat Incorporate Proper vent Runoff fron This pesticie This produc For all appli granular is o	nits. while wearing w the feeding y directly to we hean high wate y this product etbacks may a y when drift i aminate wate aminate wate aminate are as below t are as a as a below t are as as a below t are as	ade with gran g prescribed p of vines or gr vater, or to are er mark. to fields with apply. s likely to occor r by cleaning or r by cleaning or r, food or feed r, food, or feed to livestock. ls in treated are as in treated are as in treated are as in treated are around the hor ction. t apply direct he mean high a depth of 2 ir ed. s may be haza aquatic inverted ic to birds, fis ediately deep- vered with a l	rotective glov azing of folia eas where sur- tin 50 feet of cur. of equipment of equipment l. d by storage of reas. reas. me or home g ly to water or water mark. nches. rdous to aqua ebrates. sh, and other disc any spill ayer of soil.	ves. ge by livestoc face water is p wells used for or disposal of or disposal of or disposal. arden. to areas wher tic organisms wildlife. s at row ends a the following	oresent or to ir drinking wate equipment wa waste.	er. More ash waters. er is present or g areas. o ensure the Do not plant

SITE NAME	LIMITATIONS						
Application Equipment, Timing, and Type (for any Reg.# at any rate)	Max. Single Appl. Rate	Form Code(s)	Max. Seasonal Rate	Max. # Apps/ cc & yr	M R I	REI	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)
	plant corn, cucurbits, or fruiting vegetabes within 8 months after the last application. Geographic allowable: LA and MS only. Geographic disallowable: CT, MA, ME, NH, NJ, NY, PA, RI, VT, WI, or in Del Norte or Humbolt counties in CA or in Curry County, OR.						
At planting Soil band treatment. Granule applicator.	3 lb ai/A	G	3 lb ai/A 3 lb ai/cc	1/cc	NS	48 h	

# Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

## **Guide to Appendix B**

Appendix B contains listing of data requirements which support the reregistration for active ingredients within case #0140 (aldicarb) covered by this RED. It contains generic data requirements that apply to aldicarb in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

- 1. <u>Data Requirement</u> (Column 1). The data requirements are listed in the order in which they appear in 40 CFR part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.
- 2. <u>Use Pattern</u> (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.
  - A. Terrestrial food
  - B. Terrestrial feed
  - C. Terrestrial non-food
  - D. Aquatic food
  - E. Aquatic non-food outdoor
  - F. Aquatic non-food industrial
  - G. Aquatic non-food residential
  - H. Greenhouse food
  - I. Greenhouse non-food
  - J. Forestry
  - K. Residential
  - L. Indoor food
  - M. Indoor non-food
  - N. Indoor medical
  - O. Indoor residential
- 3. <u>Bibliographic Citation</u> (Column 3). If the Agency has acceptable data in its files, this column list the identify number of each study. This normally is the Master Record Identification (MIRD) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix (Appendix D) for a complete citation of the study.

New Guideline	Old Guideline	Requirement	Use Pattern	Bibliographic Citation(s)
Number	Number	Due	de et Cherrister	
830.1550	61-1	Product Identity and Composition	duct Chemistry A,B,C	00152095 letter dated 8/12/86
830.1530	61-2a	Start. Mat. & Mfg. Process	A,B,C A,B,C	00152095 letter dated 8/12/86
830.1600	61-2a 61-2b	Description of Production Process	, ,	00152095
			A,B,C	
830.1670	61-2b	Discussion of Impurities	A,B,C	00152095
830.1700	62-1	Preliminary Analysis	A,B,C	00152095
830.1750	62-2	Certification of limits	A,B,C	00152095 letter dated 8/12/86
830.1800	62-3	Analytical Method	A,B,C	00152095 letter dated 8/12/86
830.6302	63-2	Color	A,B,C	00152095
830.6303	63-3	Physical State	A,B,C	00152095
830.6304	63-4	Odor	A,B,C	00152095
830.6313	63-13	Stability temp and ions	A,B,C	00152095
830.6314	63-14	Oxidation and Reduction	A,B,C	00152095
830.6315	63-15	Flammability	A,B,C	00152095
830.6316	63-16	Explodability	A,B,C	00152095
830.6317	63.17	Storage stability	A,B,C	00152095
830.6319	63-19	Miscibility	A,B,C	00152095
830.6320	63-20	Corrosion Characteristics	A,B,C	00152095
830.7000	63-12	рН	A,B,C	00152095
830.7050	N/A	UV/Visible absorption	A,B,C	00152095 Data Gap
830.7100	63-18	Viscosity	A,B,C	00152095
830.7200	63-5	Melting point/melting range	A,B,C	00152095
830.7220	63-6	Boiling point/range	A,B,C	00152095
830.7300	63-7	Density	A,B,C	00152095
830.7370	63-10	Dissociation Constants in Water	A,B,C	00152095
830.7550	63-11	Partial Coefficient, shake flask method	A,B,C	00152095
830.7840	63-8	Water Solubility	A,B,C	00152095
830.7950	63-9	Valer Boldonity Vapor Pressure	A,B,C	00152095
030.7750	05-7		ironmental Fate	
835.2120	161-1	Hydrolysis	A,B,C	aldicarb: 00053377 00096547 00102011 00102048 00102057 00102072 00102065
835.2240	161-2	Photodegradation Water	A,B,C	sulfoxide: 00102066 aldicarb: 00102067 00102068 42498201

835.2410	161-3	Photodegradation Soil and Air	A,B,C	aldicarb: Waived sulfoxide: Waived sulfone: Waived
835.4100	162-1	Aerobic Soil Metabolism	A,B,C	aldicarb: 00029989 00093641 00096968 00102050 00101915 00102051 00102054 00035365 00101934 00102071 00053366 00080820 00093640 00093642 43805702 44005001 sulfone: 00053370
835.4400	162-3	Anaerobic Aquatic Metabolism	A,B,C	aldicarb: 43805701 sulfoxide: 45592110 sulfone: 45592111
835.4300	162-4	Aerobic Aquatic Metabolism	A,B,C	aldicarb: N/A sulfoxide: 45592108 sulfone: 45592109
835.1240	163-1	Leaching/Adsorption/Desorption	A,B,C	aldicarb: 00053380 00053381 00053385 00101915 00101939 00102079 42498202 sulfoxide: 43560301 sulfone: 43560302
835.6100	164-1	Terrestrial Field Dissipation	A,B,C	aldicarb: 00036313 00053364 00068252 00080815 00101910 00101923 00101935 00101937 00102064 00101936 00101968 00102061 00102078
835.6200	164-2	Aquatic Field Dissipation	A,B,C	aldicarb: 00094799 00101940
		Environmental Fate -	- Drinking Wat	er Monitoring Data
835.7100	166-1	Prospective Ground water Monitoring Study	A,B,C	46793702 46793703 46793704 46793705 46793706
		Ec	ological Effects	
850.2100	71-1a	Avian Oral LD50 Quail/Duck	A,B,C	BOWOAL02 107398 (Beavers/1979)
850.2200	71-2a	Avian Dietary LC50 Quail	A,B,C	00102132 1096727 (Beavers/1979)
850.2200	71-2b	Avian Dietary LC50 Quail	A,B,C	096397 0022923 (Hill/1975)
850.2300	71-4a	Avian Reproduction Quail	A,B,C	Data Gap
850.2300	71-4b	Avian Reproduction Duck	A,B,C	Data Gap
850.1075	72-1a	Freshwater Fish LC50 Bluegill (warm water)	A,B,C	40098001 3503 (Mayer and Ellersieck 1986)
850.1075	72-1c	Freshwater Fish LC50 Rainbow trout (cold water)	A,B,C	40098001 (Mayer and Ellersieck 1986)
850.1010	72-2a	Freshwater Invertebrate LC50 Daphnia magna	A,B,C	Acc # 096683 (Vilkas/1977) Foran et al. 1985

850.1045	72-3a	Estuarine/Marine Fish LC50	A,B,C	40228401 (USEPA/1986)
850.1025	72-3b	Estuarine/Marine Mollusk EC50	A,B,C	40228401 (USEPA/1986) 00066341 (USEPA/1981)
850.1035	72-3c	Estuarine/Marine Shrimp EC50	A,B,C	40228401 (USEPA/1986)
850.1400	72-4a	Fish Early Life-Stage (freshwater)	A,B,C	44598601 (Pickering and Gilliam 1982) 66341 (USEPA/1981)
850.1400	72-4a	Fish Early Life-Stage (estuarine/marine)	A,B,C	44598601 (Pickering and Gilliam 1982) 66341 (USEPA/1981)
850.1300	72-4b	Aquatic Invertebrate Life-Cycle (freshwater)	A,B,C	00066341 (USEPA/1981)
850.1350	72-4b	Aquatic Invertebrate Life-Cycle (estuarine/marine)	A,B,C	00066341 (USEPA/1981)
	123-2	Aquatic Plant Growth	A,B,C	40228401 (USEPA/1986)
850.4100	N/A	Terrestrial Plant Toxicity (seedling emergence)	A,B,C	Data Gap
850.4150	N/A	Terrestrial Plant Toxicity (vegetative vigor)	A,B,C	Data Gap
850.4400	122-2	Aquatic Plant Growth (Tier 2)	A,B,C	Data Gap
850.3020	141-1	Honey Bee Acute Contact LD50	A,B,C	00036935 (Atkins/1975)
N/A	N/A	OECD, Section 2 #207	A,B,C	Mosleh (2003)
		Earthworm Acute Toxicity Test		
			idue Chemistr	
860.1300	171-4a	Nature of Residue in Plants	A,B,C	00053358 00053364 00053366 00053368 00085455 00101929 00101930 00101931 00101977 00101996 00102009 00102178 42436602-42436606 43902401
860.1300	171-4b	Nature of Residue in Livestock	A,B,C	00053371 00053373 00080697 00080813 00101933 00101967 00159570 43084101
860.1340	171-4c	Residue Analytical Method plant	A,B,C	00025167         00036315         00069739         00069740         00101973         00101978           00101992         00101993         00101997         00101998         00101999         00102004           00102005         00102007         00104553         00135031         00140487         42436501
860.1340	171-4d	Residue Analytical Method livestock	A,B,C	00101924 00101990 00101991
860.1340	171-4d	Residue Analytical Method water/fish	A,B,C	N/A
860.1360	171-4m	Multiple Residue Methods	A,B,C	PAM Volume I Section 302 and 401

860.1380	171-4e	Storage Stability Data	A,B,C	PP#0F1008PP#9F0798PP#3F1414PP#7E1996PP#6F1953PP#7F1995PP#8F2107PP#8F0637PP#9F2201PP#6E1792PP#8F2096FAP#6H510800159571424673014246730243844701438424014329900543299006
860.1400	171-4h	Nature and Magnitude of the Residue in Water, Fish and Irrigated Crops	A,B,C	N/A
860.1460	171-4i	Magnitude of the Residue in Food Handling Establishments	A,B,C	N/A
860.1480	171-4j	Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	A,B,C	00053372 00101967 PP#3F1414
860.1480	171-4j	Eggs and the Fat, Meat, and Meat Byproducts of Poultry	A,B,C	00053373
860.1500	171-4k	Magnitude of Residue (potato)	A,B,C	00080815 00102012 00102014 00102172 00164424 42827802- 42827804 43299002 43385001
860.1500	171-4k	Magnitude of Residue (sugar beet, roots)	A,B,C	00035368 00035369 00101966
860.1500	171-4k	Magnitude of Residue (sweet potato)	A,B,C	PP#7F1995 42722301
860.1500	171-4k	Magnitude of Residue (sugar beet, tops)	A,B,C	00035368 00035369 00101966
860.1500	171-4k	Magnitude of Residue (beans, dry)	A,B,C	00135031
860.1500	171-4k	Magnitude of Residue (soybean, seed and aspirated grain fractions)	A,B,C	00135031
860.1500	171-4k	Magnitude of Residue (soybean, forage and soybean, hay)	A,B,C	N/A
860.1500	171-4k	Magnitude of Residue (grapefruit)	A,B,C	00102129 00148971
860.1500	171-4k	Magnitude of Residue (lemon)	A,B,C	00102129
860.1500	171-4k	Magnitude of Residue (lime)	A,B,C	00102129
860.1500	171-4k	Magnitude of Residue (orange)	A,B,C	00036313 00102075 00102115 00102174 42004401 42016901 43110601
860.1500	171-4k	Magnitude of Residue (pecan)	A,B,C	00140487

860.1500	171-4k	Magnitude of Residue (sorghum, grain and aspirated grain fractions)	A,B,C	PP#8F2107
860.1500	171-4k	Magnitude of Residue (sorghum, forage and sorghum, stover (fodder))	A,B,C	PP#8F2107
860.1500	171-4k	Magnitude of Residue (coffee, bean)	A,B,C	00102024 PP#7F1953
860.1500	171-4k	Magnitude of Residue (cotton, seed and cotton gin by-products)	A,B,C	00101977 00102061 PP#7F1995 PP#9F0798 Data Gap
860.1500	171-4k	Magnitude of Residue (peanut, nutmeat and peanut, hulls)	A,B,C	00102013 PP#3F1414
860.1500	171-4k	Magnitude of Residue (sugarcane)	A,B,C	00101923 PP#2F1188
860.1500	171-4k	Magnitude of Residue (tobacco)	A,B,C	00102179 00102180
860.1520	171-41	Processed Food/Feed (citrus)	A,B,C	00102114 00102130 00140001
860.1520	171-41	Processed Food/Feed (coffee, bean)	A,B,C	PP#7F1953 00162562
860.1520	171-41	Processed Food/Feed (cottonseed)	A,B,C	00101977 00102061
860.1520	171-41	Processed Food/Feed (peanut)	A,B,C	00102123 PP#3F1414
860.1520	171-41	Processed Food/Feed (potato)	A,B,C	00080815 00102012 00102014 00102172 00164424 00159572 42305801 42827801 43299004
860.1520	171-41	Processed Food/Feed (sorghum)	A,B,C	PP#8F2107
860.1520	171-41	Processed Food/Feed (soybean)	A,B,C	00135031 00159573 40884601
860.1520	171-41	Processed Food/Feed (sugar beet)	A,B,C	00035368 00035369 00101966
860.1520	171-41	Processed Food/Feed (sugarcane)	A,B,C	00101923 PP#2F1188
860.1850	165-1	Confined rotational crops	A,B,C	42226201
860.1900	165-2	Field rotational crops	A,B,C	42226201
			Toxicology	
870.1100	81-1	Acute Oral Toxicity Rat	A,B,C	00057333
870.1200	81-2	Acute Dermal Toxicity Rabbit/Rat	A,B,C	00091241 00069916
870.1300	81-3	Acute Inhalation Toxicity Rat	A,B,C	00069916 00057333
870.2400	81-4	Primary Eye Irritation Rabbit	A,B,C	00069916
870.2500	81-5	Primary Skin Irritation	A,B,C	00069916
870.2600	81-6	Dermal Sensitization	A,B,C	N/A
870.3150	82-1b	13-Day Dietary Dog	A,B,C	41919901

870.3700a	83-3a	Developmental Toxicity (Teratogenicity) Rat	A,B,C	41004501
870.3700b	83-3b	Developmental Toxicity (Teratogenicity) Rabbit	A,B,C	0132668
870.3800	83-4	2-Generation Reproduction Rat	A,B,C	42148401
870.4100a	83-1	Chronic Toxicity Rat	A,B,C	43045401
870.4100b	83-1	Chronic Toxicity Dog	A,B,C	40695401 42191501
870.4200	83-2	Carcinogenicity Rat	A,B,C	43045401
870.4300	83-5	Chronic Toxicity/Carcinogenicity Mouse and Rat	A,B,C	00044732 00044733 00044734
870-5300		Gene Mutation	A,B,C	00148168
870.5385	84-2	Mammalian Cytogenetics: Bone Marrow Chromosome Aberration	A,B,C	41661301 41663102
870.5550	84-2	Unscheduled DNA Synthesis in Mammalian Cells	A,B,C	00141673
870.6200a		Acute Neurotoxicity Screening Battery	A,B,C	43442301
870.6200b		Subchronic Neurotoxicity Screening Battery	A,B,C	43829602
870.6300		Developmental Neurotoxicity	A,B,C	43829601
870.7485		Metabolism and Pharmacokinetics	A,B,C	00102022 00102023
N/A	N/A	Rat Dominant Lethal Study	A,B,C	43575101
N/A	N/A	Special Neurotoxicity Studies: Moser VC	A,B,C	45068601 (1999) TAP 157 94-106
N/A	N/A	Acute Oral Study (Human) Inveresk	A,B,C	42373001 (1992) 46131001 (supplementary report)
Special Study	N/A	Comparative Cholinesterase Assay	A, B,C	Data Gap
			nal/Residue Ex	xposure
N/A	N/A	Aldicarb Specific Study	A,B,C	43852501
N/A	N/A	Terbufos Study	A,B,C	44793301

## **Appendix C. Technical Support Documents**

Additional documentation in support of this RED is maintained in the OPP docket EPA-HQ-OPP-2005-0253. This docket may be accessed in the OPP docket room located at Room S-4900, One Potomac Yard, 2777 S. Crystal Drive, Arlington, VA. It is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m. All documents may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: http://www.regulations.gov.

The docket initially contained preliminary risk assessments, supporting documents, and technical (or manufacturing-use) registrant error comments for aldicarb as of November 14, 2006. After a sixty-day public comment period, EPA considered the public comments that were submitted to the docket and revised the risk assessments as necessary. The revised risk assessments, any supporting documents that needed to be revised, impact assessments, and memos describing the the Biological and Economic Assessment Division (BEAD), Environmental Fate and Effects Division (EFED), and Health Effects Division (HED) response to public comments will be added to the docket on September 26, 2006.

The Agency documents in the docket include:

- 1. Federal Register Notice: Aldicarb Interim Reregistration Eligibility Decision; Notice of Availability.
- 2. Reader's Guide to the Aldicarb E-Docket # EPA-HQ-OPP-2005-0163.
- 3. Reregistration Eligibility Decision (RED) Document for Aldicarb.
- 4. BEAD Response to Comments Submitted to Docket EPA-HQ-OPP-2005-0163.
- 5. Quantitative Impact Analysis for At-peg Application of Aldicarb to Peanuts (DP 337549).
- 6. Significance of Aldicarb Use in the Production of Dry Beans, Soybeans, Pecans, Sweet Potatoes, Cotton and Citrus.
- 7. EFED Response to Public Comments for Aldicarb RED: Docket ID# Opp-2005-0163-0176.
- 8. Aldicarb Ecological risk results for alternative application rate and incorporation efficiencies.
- 9. Use of Aldicarb for Lygus Bug Suppression, Aphids, and Mites on Alfalfa Grown for Seed Production.
- 10. Use of Aldicarb for Leaf Minors on Coffee, for Nematodes on Coffee and Sugarcane, and for Aphids and Flea Beatles on Tobacco.

- Review of "A Retrospective Ground Water Monitoring Study for Aldicarb and Its Metabolites in the Southeastern United States (MRID 467937-06); Mississippi Delta (MRID 467937-05); Texas (MRID 467937-04); California (MRID 467937-03); and Pacific Northwest (MRID 467937-02).
- 12. ADDENDUM to: Aldicarb Ecological risk results for alternative application rate and incorporation efficiencies
- 13. Aldicarb (List A Case 0140, Chemical ID No. 098301). HED Response to Comments Received During the Public Comment Period.
- 14. HED Revised Human Health Risk Assessment for the Reregistration Eligibility Decision Document (RED).

## Appendix D. Citations Considered to be Part of the Database Supporting the Reregistration Decision (Bibliography)

## Guide to Appendix D

- 1. <u>Contents of Bibliography</u>. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
- 2. <u>Units of Entry</u>. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
- 3. <u>Identification of Entry</u>. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
- 4. <u>Form of Entry</u>. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
  - a. Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.
  - b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the

document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

- c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
  - (1) Submission date. The date of the earliest known submission appears immediately following the word "received."
  - (2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
  - (3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
  - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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# Appendix E. Generic Data Call-In (GDCI)

Note that a complete generic DCI, with all pertinent instructions, will be sent to registrants under separate cover.

# Appendix F. Product-Specific Data Call-In (PDCI)

Note that a complete product-specific DCI, with all pertinent instructions, will be sent to registrants under separate cover.

### **Appendix G. EPA's Batching of Aldicarb Products for Meeting Data Requirements for Reregistration**

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing ALDICARB as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwith-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Six products were found which contain Aldicarb as the active ingredient. These products have been placed into two batches in accordance with the active and inert ingredients and type of formulation.

## Batching Instructions:

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Batch 1	EPA Reg. No.	Percent Active Ingredient
	264-330	15.0
	264-417	15.0
	264-426	15.0
	264-523	15.0

Batch 2	EPA Reg. No.	Percent Active Ingredient
	264-322	10.0
	264-331	10.0

# **Appendix H. List of Available Related Documents and Electronically Available Forms**

**Pesticide Registration Forms are available at the following EPA internet site:** <u>http://www.epa.gov/opprd001/forms/.</u>

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

#### **Instructions:**

- 1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
- 2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.
- 3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the following address for the Document Processing Desk:

Document Processing Desk (distribution code)\* Office of Pesticide Programs (7504P) Environmental Protection Agency 1200 Pennsylvania Ave, NW Washington, DC 20460-0001

\* Distribution Codes are as follows: (APPL) Application for product registration (AMEND) Amendment to existing registration (CAN) Voluntary Cancellation (EUP) Experimental Use Permit (DIST) Supplemental Distributor Registration (SLN) Special Local Need (NEWCO) Request for new company number (NOTIF) Notification (PETN) Petition for Tolerance (XFER) Product Transfer

DO NOT fax or e-mail any form containing "Confidential Business Information" or "Sensitive Information."

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at *williams.nicole@epamail.epa.gov*. If you want these forms mailed or faxed to you, please contact Lois White, *white.lois@epa.gov* or Floyd Gayles, *gayles.floyd@epa.gov*.

If you have any questions concerning how to complete these forms, please contact OPP's ombudsperson for conventional pesticide products: Linda Arrington, (703) 305-5446

The following Agency Pesticide Registration Forms are currently available via the Internet at the following locations:

	t	1
8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98- 5.pdf
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98- 5.pdf
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98- 1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98- 1.pdf

#### **Pesticide Registration Kit** http://www.epa.gov/pesticides/registrationkit/

Dear Registrant:

For your convenience, we have assembled an on-line registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

- 1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FOPA) of 1996.
- 2. Pesticide Registration (PR) Notices
  - a. 83-3 Label Improvement Program-Storage and Disposal Statements
  - b. 84-1 Clarification of Label Improvement Program
  - c. 86-5 Standard Format for Data Submitted under FIFRA
  - d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
  - e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
  - f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
  - g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
  - h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR Notices.

- 3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)
  - a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendmentb. EPA Form No. 8570-4, Confidential Statement of Formula

  - c. EPA Form No. 8570-27, Formulator's Exemption Statement
  - d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
  - e. EPA Form No. 8570-35, Data Matrix
- 4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)
  - a. Registration Division Personnel Contact List
  - b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
  - c. Antimicrobials Division Organizational Structure/Contact List
  - d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
  - e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
  - 40 CFR Part 158, Data Requirements for Registration (PDF format) f.
  - g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

- 1. The Office of Pesticide Programs' Web Site
- 2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

National Technical Information Service (NTIS) 5285 Port Royal Road Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

- 3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their website.
- 4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their website: <a href="http://npic.orst.edu">http://npic.orst.edu</a>

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

- Date of receipt
- EPA identifying number
- Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.