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ALDICARB

SPECIAL REVIEW

TECHNICAL SUPPORT

DOCUMENT

- ACKNOWLEDGMENTS -

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- EXECUTIVE SUMMARY -

On July 11, 1984, the Environmental Protection Agency (the Agency) issued a Notice of Rebuttable Presumption Against Registration (RPAR or Special Review) and Continued Registration of Pesticide Products Containing Aldicarb (49 FR 28320). That action was based on a finding that registrations of pesticide products containing aldicarb met or exceeded risk criteria in 40 CFR 162.11(a)(6)(i) which provides that a Special Review be initiated if it appears that, "based on toxicological data, epidemiological studies, use history, accident data, monitoring data, or such other evidence as is available to the Administrator, the pesticide may pose a substantial question of safety to man or the environment..."

As part of the Special Review process, the Agency evaluates the risks and benefits associated with the use of a pesticide and then proposes any regulatory actions necessary to assure that use of that pesticide results in no unreasonable adverse effects.

Aldicarb is a soil incorporated carbamate pesticide that is absorbed by plant roots. It provides systemic control of insects, mites and nematodes. The Agency estimates that approximately 5.2-5.7 million pounds of active ingredient are used annually. Rhone-Poulenc AG Company is the sole registrant of aldicarb and its first registration in 1970 was for use on cotton. Aldicarb is now registered for use on: citrus, dry beans, grain sorghum, ornamentals, pecans, peanuts, potatoes, seed alfalfa, soybeans, sugar beets, sugarcane, sweet potatoes and tobacco.

Aldicarb is an acutely toxic pesticide, causing reversible cholinesterase inhibition. The oral LD50 in rats is 0.9 mg/kg. A wide range of clinical signs in humans are related to cholinesterase inhibition including: gastrointestinal disturbances, unconsciousness, blurred vision, excessive salivation, seizures, and disorientation. Extensive cholinesterase inhibition may result in death. A No Observed Effect Level for human clinical signs has been reported to be 0.05 mg/kg, with an estimated No Observed Effect Level of 0.01 mg/kg for human cholinesterase inhibition.

A number of reports of accidental exposures following misuse of aldicarb indicate that cholinergic signs, even severe cholinergic signs, may occur at doses below 0.1 mg/kg. Calculated doses of 0.01-0.0026 mg/kg have been associated with these reports. These data are anecdotal and it is difficult to determine precise consumption, but they may indicate a broad range of sensitivity to aldicarb's acute effects.

Potential risks are associated with consumption of raw agricultural commodities and drinking water contaminated with residues of aldicarb. Aldicarb has been detected in ground or drinking water wells in 16 states at levels ranging from under 10 ppb to over 500 ppb. Because aldicarb residues can persist in ground water for several years, ground water contamination by aldicarb may be a widespread, long-term problem.

Dietary Risk from Treated Commodities

The Agency has estimated maximal dietary exposure to aldicarb, resulting from a single exposure from legally treated potatoes and citrus by using the upper 5 percent residues. The Agency used data in support of tolerances submitted by the registrant and FDA market basket survey data. The exposure estimates were then compared against aldicarb's cholinesterase inhibition characteristics to determine the margins of safety for these two crops for different sectors of the population. Infants and children consuming the treated commodity are at the highest risk of acute aldicarb toxicity from the consumption of citrus and potato products with as many as 55 percent of consumers of the commodity with upper 5 percent residue levels in these sub-populations exposed to aldicarb at an amount providing less than a tenfold margin of safety for cholinesterase inhibition.

The Agency has encouraged pesticide registrants to conduct monitoring studies which, it believes, will give a more accurate representation of the level of pesticide residues to which the public is exposed. The registrant has recently conducted a National Food Survey for aldicarb which monitors for residues in the market place. Preliminary results from this survey suggest that most aldicarb residues in commodities in the market place are at or below the limit of detection (0.01 ppm). The final results have been submitted and, along with the tolerance data and the FDA market basket survey data, will be used in the final **dietary risk assessment. A regulatory proposal regarding dietary risks is being deferred pending analysis of these data.**

Dietary Risk from Contaminated Drinking Water

The Agency has also estimated the percent of affected populations receiving certain levels of exposure from consuming drinking water, assuming different levels of aldicarb residues in the water. The Agency has provided a margin of safety estimate for these exposure levels. The focus of the analysis was on the population at greatest risk, infants, because they consume most of their diet as formula and fruit juice, both of which are frequently prepared using tap water. The Agency has assumed that the daily intake of drinking water will be composed of two separate doses because it is reasonable to assume that an individual would not consume all of the water in his/her diet at one time. The assessment also reflects the fact that aldicarb can cause cholinesterase inhibition by a single acute exposure and that about six hours are required for recovery. The Agency calculated that when drinking water containing aldicarb at 10 ppb, as many as 13 percent of consuming infants could be exposed to a dose of 0.001 mg/kg or greater of aldicarb. The corresponding margin of safety for cholinesterase inhibition would then be 10 or less, based on the No Observed Effect Level estimated by the National Academy of Sciences.

Ground Water Risk Assessment

The Agency assessed the ground water vulnerability, or potential for aldicarb to reach ground water, using two different methods. The Agency looked at all ground water sources, not just current drinking water sources, since these potential sources could be used in the future. One method uses Heath Regions (11 hydrogeologic ground water regions of the U.S.) to identify states as the geographical unit for regulatory purposes, and the other method uses counties as the geographical unit.

Three major parameters were employed in the Heath Region assessment to evaluate the ground water vulnerability of these regions: hydrogeologic characteristics of counties, ground water monitoring data, and crop use practices. Hydrogeologic characteristics were evaluated by a close evaluation of 138 counties where aldicarb is used and through use of a hydrogeologic model called DRASTIC. DRASTIC is a screening system which estimates ground water vulnerability using seven characteristics: depth to ground water; recharge; aquifer media; soil media; topography; impact of the vadose zone and hydraulic conductivity of the aquifer. Crop use practices include cultivation methods, rate of application, and temperature for each of the five major crops grown in a particular region.

An integrated, qualitative weight-of-evidence approach was used with the greatest emphasis placed on actual monitoring data when reliable and representative data were available. Major aldicarb use crops were evaluated as to ground water vulnerability in regions where they are grown. The result of this analysis is a high, medium, and low "potential to leach" ranking for 32 crop/Heath region combinations.

The county assessment evaluated ground water vulnerability in three ways: 1) use of actual monitoring data, 2) evaluation of use/usage data, and 3) use of DRASTIC scores for each county. As in the Heath Region assessment, an integrated, qualitative weight-of-the-evidence approach was used with the greatest emphasis placed on positive monitoring data, when available. The result is a high, medium, or low "potential to leach" ranking for all counties of the country. The Agency has completed this assessment in four selected states: California, Florida, North Carolina, and Wisconsin.

Benefits Assessment

The benefits of aldicarb use were assessed in terms of the economic impact of cancellation on society as well as the impact on users and consumers. Assessments were based on changes in production costs, crop yield reductions and possible grower shifts to other enterprises. Impacts on users were considered on a per-unit and per-establishment basis as well as at the county (for some uses), state, regional, and national levels.

For cancellation in all areas of the country, significant impacts would be expected for citrus ($54.5 million for Florida oranges and Texas grapefruit) and peanuts ($17-33 million). Moderate economic impacts on a national level would be expected for cotton ($20-29 million), potatoes ($11-15 million), tobacco ($0.1-0.7 million), sweet potatoes ($1.3-2.7 million) and pecans ($0.48 million). For all uses, the impacts result primarily because alternatives are less effective than aldicarb.

Prohibition of use of aldicarb would have the greatest impact in the southeast (citrus: $49 million, peanuts: $22 million, pecans: $0.2 million, sweet potatoes: $0.9 million, and tobacco: $0.7 million), north central (potatoes: $1.6 million and sugarbeets: $0.6 million), and the northwest (potatoes: $4 million).

Ground Water Strategy

The Agency recently initiated a number of long-term strategies on significant environmental issues which require cross-media coordination. One strategy under development addresses agricultural chemicals in ground water. As part of the strategy development process, the Agency sponsored workshops at Coolfont, West Virginia on June 24-27, 1986 and July 23-24, 1987. The workshop participants discussed, among other issues, regulatory strategies to limit the amount of pesticides and fertilizers leaching into ground water. Representatives of state health, environmental, and agricultural offices; other Federal agencies; industry; user groups; researchers; Cooperative Extension Services; and environmental groups participated in those workshops. On February 25, 1988, the Agency issued a proposed strategy for addressing ground water contamination by agricultural chemicals (Agricultural Chemicals in Ground Water: Proposed Pesticide Strategy). This document is the Agency's proposed long-term strategic plan for protecting ground water from contamination by agricultural chemicals and the Agency is soliciting public comment on this plan.

Risk/Benefit Assessment and Regulatory Options

It is the Agency's preliminary determination that on a national basis, the risks posed by aldicarb contamination of ground water exceed the benefits derived from aldicarb's continued use. Consequently, regulatory action is necessary to prevent unreasonable adverse effects on the environment.

The Agency believes it is possible to reduce the risks significantly by imposing certain regulatory restrictions short of cancellation of all uses. Accordingly, the Agency evaluated three options to prevent the contamination of the nation's ground water by aldicarb above an unacceptable level. The Agency believes that vulnerable areas are likely to have leaching of aldicarb into ground water at levels greater than the Health Advisory. These options are: 1) Risk reduction measures/user determines applicability, 2) Labeling/monitoring/state management plans determined by Heath Regions, and 3) Labeling/ monitoring/state management plans determined by county.

In Option 1, the registrant would be required to place additional risk reduction measures on aldicarb labels (i.e., drinking water well setbacks, modifications to application rates and timing, and monitoring requirements). Restrictions imposed through labeling would be targeted at the users and the costs of monitoring ground water contamination and of corrective actions would be borne by the registrant. Preventive measures would be tailored to specific conditions of the application site in order to prevent contamination of drinking water wells above an unacceptable level.

Option 2 provides states the opportunity to play an active role in protecting ground water. This option includes three components: labeling, monitoring and State Pesticide Ground Water Management Plans. The labeling component consists of uniform, national actions which would prohibit the use of aldicarb within 300 feet from any drinking water well and classify aldicarb as a restricted use pesticide due to ground water concerns. These measures would serve as baseline requirements in all areas where aldicarb is used. In addition to these baseline efforts, monitoring would be required in representative areas which have been evaluated in the Agency's ground water assessment as having a medium potential to leach. The data resulting from this monitoring will be used to further characterize the medium areas and to determine whether additional regulatory action beyond the baseline requirements will be needed in these areas.

The most stringent measures the Agency is proposing are in those areas identified as having the greatest potential for aldicarb to reach ground water. The Agency believes that the states are in the best position to regulate the use of aldicarb to prevent/reduce unacceptable ground water contamination in the areas of greatest concern by implementing Management Plans. The Heath Region approach of assessing ground water vulnerability was used in identifying 10 states where Management Plans would be needed. These states include: Alabama, Florida, Georgia, Maine, Michigan, Minnesota, New York, North Dakota, Pennsylvania, and Wisconsin. Acceptable Management Plans will serve as the basis for the continued registration of aldicarb within these states.

Option 3 is identical to Option 2 in that it would have the same labeling and monitoring components. However, the states that would need to develop Management Plans would be identified using a county approach which identified counties where the Agency believes aldicarb has the highest tendency to leaching. Under this approach, states would need to develop and implement a Management Plan for those counties classified as such. The Agency has only evaluated the counties of four states using the county approach for assessing ground water vulnerability. As a result of this assessment, the following results were obtained: California has 3 out of 58 counties, Florida has 26 out of 67 counties, and Wisconsin has 8 out of 72 counties needing a Management Plan. North Carolina did not have any counties which were ranked high enough to need the establishment of a Management Plan. However, the vulnerability to ground water contamination was sufficiently high in all other counties in each of these four states to be classified as medium in vulnerability. The registrant will be required to undertake a monitoring study that will be representative of those moderately vulnerable areas. The Agency anticipates that 15 to 24 states would be required to submit plans for one or more counties if this option were chosen.

The Agency proposes Options 2 and 3 to impose label restrictions and monitoring requirements, and to allow the use of aldicarb in certain states/counties which have approved Management Plans and cancel the use of aldicarb in certain states/counties which choose not to implement Management Plans.

The Agency's proposed approach for aldicarb implements the recently proposed long-term strategy addressing the concern of pesticides in ground water. This aldicarb proposal uses graduated measures in order to prevent unacceptable ground water contamination. The extent of preventive measures required in a specific area would depend on the area's vulnerability to such contamination. The most stringent prevention measures would be required in those areas where there is the greatest potential for unacceptable levels of ground water contamination by aldicarb.

The Agency believes that Management Plans are the best way to prevent ground water contamination without subjecting areas where contamination is less likely to occur to unnecessarily stringent regulatory controls. The Agency believes that, in areas without Management Plans, certain restrictions on the use of aldicarb are necessary to reduce the risks of ground water contamination to acceptable levels. These restrictions would be incorporated through labeling on all aldicarb products. The Agency also believes that further monitoring data would improve its ability to predict the likelihood of the contamination of ground water in medium vulnerability areas and is imposing monitoring data requirements for these areas. The Agency is seeking public comment and preferences in selecting state or county level Management Plans.

Additionally, the Agency is seeking comments on other issues which are pertinent to the proposed regulatory action. These issues include: 1) content of national labels, 2) design of monitoring protocols, 3) conduct of local risk/benefit assessments, 4) involvement in refining ground water contamination assessments, 5) involvement of the registrant in developing the Management Plans, and 6) design of Management Plans.

A further unresolved issue concerns who should be responsible for remedial action (e.g. developing, approving, and implementing corrective action plans such as funding clean-up costs or providing an alternative water supply) when ground water is contaminated by a registered pesticide use. The document Agricultural Chemicals in Ground Water: Proposed Pesticide Strategy discusses this issue in more detail. Since this is a generic issue which pertains to all pesticides which leach rather than just to aldicarb, any comments regarding this issue should be made in response to the above document.

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CHAPTER I

INTRODUCTION

A. GENERAL BACKGROUND AND ORGANIZATION

On March 30, 1984, the Environmental Protection Agency (the Agency) issued its requirements for the interim registration of pesticide products containing aldicarb in the Aldicarb Registration Standard. On July 11, 1984 (49 FR 28320), the Agency initiated a Special Review of aldicarb because aldicarb appeared to meet or exceed the risk criteria in 40 CFR 162.11(a)(6). That section provides that a Notice of Intent to Cancel the registration of a pesticide may be issued if "... based on toxicological data, epidemiological studies, use history, accident data, monitoring data, or such other evidence as is available to the Administrator, the pesticide may pose a substantial question of safety to man or the environment...." The basis of the aldicarb Special Review is the potential for unreasonable adverse effects to humans from dietary exposure to drinking water from ground water wells contaminated with aldicarb. The use of aldicarb has led to ground water contamination in 50 counties of 16 states, with contamination ranging to 515 ppb.

This Aldicarb Technical Support Document (TSD) reiterates the basis for initiating the Special Review stated in Position Document 1 (PD 1) and describes the Agency's proposed regulatory actions to reduce the potential adverse effects from aldicarb.

Aldicarb is one of the most acutely toxic pesticides registered. It is a potent cholinesterase (ChE) inhibitor, causing reversible inhibition of erythrocyte acetylcholinesterase (red blood cell ChE) as well as plasma butyryl ChE. Acetylcholinesterase is an enzyme necessary for transmission of impulses at nerve synapses. Sufficient inhibition of these enzymes can result in serious toxic effects, including death. Data indicate that aldicarb does not cause chronic effects and that acute cholinesterase inhibition is the only toxicologically significant effect.

The Agency has reviewed crop residue data to evaluate potential exposure to residues of aldicarb and its metabolites in treated commodities. The Agency also reviewed environmental fate and monitoring data to determine the potential for and magnitude of exposure via consumption of ground water.

The TSD contains five chapters. Chapter I is this introduction and provides general background information on the pesticide. Chapter II describes estimates of human and environmental risk from use of aldicarb and its principle alternatives, including descriptions and evaluations of the risk information, responses to public comments to the PD 1, as well as the risk conclusions. Chapter III discusses the quantitative estimates of the benefits of use of registered aldicarb products on various crops, describes the major alternatives, and describes the assumptions/limitations of these estimates, as well as the benefits conclusions. All public comments associated with benefits information are incorporated into the benefit analysis chapter. Chapter IV describes the possible regulatory options to reduce the risk from use of aldicarb, evaluates the impacts on risks and benefits of aldicarb under these regulatory options, and recommends a specific combination of actions. Chapter V is the bibliography.

B. LEGAL BACKGROUND

1. THE STATUTE

A pesticide product may be sold or distributed in the United States only if it is registered or exempt from registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended (7 U.S.C. 136 et seq.). Before a product can be registered unconditionally, it must be shown that it can be used without "unreasonable adverse effects on the environment" (FIFRA §3(c)(5)), that is, without causing "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of the pesticide" (FIFRA §2(bb)). The burden of proving that a pesticide meets this standard for registration is at all times on the proponents of registration and continues as long as the registration remains in effect. If at any time the Agency determines that a pesticide no longer meets this standard for registration, then the Administrator may cancel the registration under FIFRA §6.

2. THE SPECIAL REVIEW PROCESS

The term "Special Review" is the name being used for the process previously called the Rebuttable Presumption Against Registration (RPAR) process (40 CFR 162.11, 1985). Modifications to the process are described in the final Special Review regulations (50 FR 49003, codified in 40 CFR part 154). These regulations, promulgated on November 19, 1985, became effective on May 14, 1986.

The Special Review process provides a mechanism to gather information about the risks and benefits of pesticides which appear to pose unreasonable risks to man and the environment. Through issuance of various notices and support documents, the Agency publicly states its position and invites pesticide registrants, other Federal and state agencies, user groups, environmental groups, and other interested persons to participate in the Agency's review of suspect pesticides. All comments on the Agency's position documents are filed in a public docket.

Information concerning risks is evaluated and considered in light of the information on the benefits of the pesticide. If the Agency determines that risks outweigh benefits, the Agency can initiate action under FIFRA to cancel, suspend, or require modification of the terms and conditions of registration.

C. CHEMICAL BACKGROUND

1. CHEMICAL AND PHYSICAL CHARACTERISTICS OF ALDICARB

Aldicarb is the common chemical name for [2-methyl-2-(methylthio)propionaldehyde-O-(methylcarbamoyl)oxime]. Trade names include: Temik 10G, Temik 15G and Temik TSX. Aldicarb sulfone, a related chemical, is also registered under the trade name Aldoxycarb. Aldicarb sulfone is approximately 20 times less toxic than aldicarb. Aldicarb sulfone is considered in this Special Review because aldicarb sulfone is a degradate of parent aldicarb in treated commodities and ground water.

Pure aldicarb is a white crystalline solid with a melting point of 98-100° C. Under normal conditions, aldicarb is a heat sensitive, inherently unstable chemical and must be stabilized to obtain an extended shelflife.

2. REGISTERED USES AND PRODUCTION

There are five FIFRA §3 Federal registrations and 11 intra-state registrations for aldicarb. Rhone-Poulenc AG Company is the sole producer and registrant of aldicarb products. Aldicarb was originally produced and registered by the Union Carbide Agricultural Products Company, Inc. which sold its interests in aldicarb to Rhone-Poulenc. (Hereafter Rhone-Poulenc and Union Carbide are referred to as "the registrant".)

Aldicarb is a restricted-use pesticide that may be purchased and used only by certified applicators or individuals under the direct supervision of certified applicators.

Technical aldicarb is formulated into and sold as 5 percent, 10 percent and 15 percent active ingredient (a.i.) granular end-use products. These end-use products are incorporated into soil either at planting, at emergence or, in the case of established trees, at first foliage flush and used for control of a variety of insects, mites, and nematodes. Major sites of aldicarb usage include: citrus, cotton, potatoes, peanuts, and soybeans. Aldicarb is also used on sugar beets, tobacco, ornamentals, sweet potatoes, dry beans, pecans, sugarcane, seed alfalfa (California only) and grain sorghum.

Approximately 5.2 to 5.7 million pounds a.i. of aldicarb are used annually in the U.S.

3. **TOLERANCES**

Tolerances have been established for aldicarb and its ChE inhibiting metabolites under 40 CFR 180.269. A list of these tolerances follows.

U.S. ALDICARB TOLERANCES

Crop	Maximum Residue Limit (ppm)	Crop	Maximum Residue Limit (ppm)
Bananas	0.3	Lemons	0.3
Beans (dried)	0.1	Limes	0.3
Beets, sugar	0.05	Milk	0.002
Beets, sugar, tops	1.0	Oranges	0.3
Cattle, fat	0.01	Peanuts	0.05
Cattle, meat by-products	0.01	Peanuts, hulls	0.5
Cattle, meat	0.01	Pecans	0.5
Coffee	0.1	Potatoes	1.0
Cottonseed	0.1	Sheep, fat	0.01
Goats, fat	0.01	Sheep, meat by-products	0.01
Goats, meat by-products	0.01	Sheep, meat	0.01
Goats, meat	0.01	Sorghum, fodder	0.5
Grapefruit	0.3	Sorghum, grain	0.2
Hogs, fat	0.01	Soybeans	0.02
Hogs, meat by-products	0.01	Sugarcane	0.02
Hogs, meat	0.01	Sugarcane, fodder	0.1
Horses, fat	0.01	Sugarcane, forage	0.1
Horses, meat by-products	0.01	Sweet Potatoes	0.1
Horses, meat	0.01		

CHAPTER II

RISK ASSESSMENT AND ANALYSIS OF PUBLIC COMMENTS

This chapter is composed of three parts. The first part describes the Agency's assessment of human health risk from the consumption of treated food commodities and contaminated drinking water containing residues of aldicarb and its metabolites. The second part describes the Agency's assessment of the ground water contamination data for aldicarb as well as the vulnerability of ground water to contamination. The last part of this chapter addresses all rebuttal comments submitted in response to the Position Document 1 (PD 1).

A. DIETARY RISK ASSESSMENT

This section describes the Agency's conclusions about dietary risk. The section is composed of four subsections: toxicology, exposure to treated food commodities, exposure to contaminated ground water, and a risk assessment. The Agency's assessment of the data base on oncogenicity, teratogenicity, reproductive effects, and mutagenicity have been discussed in the Registration Standard and PD 1 and therefore will not be presented again in this document.

1. TOXICOLOGY SUMMARY

The Agency examined the entire toxicology review file during both the preparation of the Registration Standard and this Technical Support Document. The Agency concluded from these data that aldicarb has not been shown to cause immunologic, oncogenic, teratogenic, reproductive or mutagenic effects in laboratory animals.

Additionally, the Agency has reviewed a study in which the Centers for Disease Control (CDC) and the Wisconsin Division of Health (Fiore, et al, 1986), examined the association between immune function and aldicarb contaminated ground water. This involved a cross sectional study of 50 women who were thought to be free from other primary risk factors for altered immune function. Although the Agency believes the results of this study are of some interest, it believes the clinical significance of the reported difference in T lymphocytes and Candida response is highly questionable. The T data fall within the normal range as indicated by Marti, et al (1985). The Candida response data are also within normal limits that have been routinely observed at the University of Wisconsin Medical Center. The results of this study present no evidence for a causal relationship between consumption of water contaminated with aldicarb and dysfunction of the immune system.

The Agency believes the only reliably demonstrated toxic effect of aldicarb is acute cholinesterase (ChE) inhibition. A discussion of the studies available which demonstrate this effect are presented below.

a. Laboratory Studies

1) Animal Studies

The Agency reviewed over 50 metabolism and acute toxicity studies during the preparation of the Registration Standard (EPA, 1984). These studies indicate that aldicarb is rapidly absorbed by mammals and metabolized to aldicarb sulfoxide, the major metabolite. Aldicarb sulfoxide is subsequently and more slowly degraded to aldicarb sulfone. All three compounds inhibit red blood cell (RBC) and plasma cholinesterase (ChE) with aldicarb sulfoxide the most potent ChE inhibitor. The rapid conversion in animals of aldicarb to aldicarb sulfoxide and subsequent rapid ChE drop is probably responsible for the acute toxic reaction associated with aldicarb. All metabolites are rapidly and completely eliminated from the body, with 80 to 90 percent excreted within 24 hours, leaving no detectable residues by the fifth day. Data demonstrate that aldicarb is not stored in body tissues. Both RBC and plasma ChE are restored to normal levels within six hours after exposure to a single dose.

Aldicarb is very highly toxic to mammals by oral exposure. The lower acute oral toxicity of the formulations reflects the reduced concentration of aldicarb as formulated on the granular material. The oral LD_{50}'s of aldicarb and its principal metabolite, aldicarb sulfoxide, are similar (0.9 mg/kg), while aldicarb sulfone (oral LD_{50} of 24 mg/kg) is less toxic than aldicarb. The other aldicarb metabolites are considerably less toxic, with LD_{50}'s ranging between 350 mg/kg (aldicarb sulfone nitrile) to greater than 15,000 mg/kg (amide derivative). The dose-effect curve for aldicarb can be extremely steep. For example, Maripot, et al. (1980) administered aldicarb in corn oil, p.o., to fasted rats and found that the lowest dose producing clinical signs, 0.1 mg/kg, also killed two of the 10 rats.

The registrant has submitted two monkey studies (Union Carbide, 1987a and 1987b). In these studies, 12 monkeys consumed either bananas or watermelons (six monkeys/fruit) containing aldicarb to obtain a dose of 0.005 mg/kg. No clinical signs of toxicity were observed. However, plasma ChE and, to a lesser extent, RBC ChE was inhibited at this low dose.

The toxicity of aldicarb when injected intraperitoneally or intravenously is almost the same as when it is given orally, suggesting rapid absorption into the body when aldicarb is ingested. The Agency's evaluation of the dermal LD_{50}'s indicates that aldicarb (5 mg/kg), aldicarb sulfoxide (greater than 20 mg/kg) and aldicarb sulfone (greater than 20 mg/kg) are less toxic dermally than by the oral route, but still highly toxic. The Agency's evaluation of the inhalation toxicity of aldicarb indicates that, while extremely toxic when inhaled, aldicarb does not vaporize at ambient temperatures and thus does not produce toxic vapors. There is no appreciable inhalation exposure from application (i.e., it is not sprayed) or from dietary consumption.

2) Human Studies

A wide range of clinical signs in humans are related to ChE inhibition including: gastrointestinal disturbances, unconsciousness, blurred vision, excessive salivation, seizures, and disorientation. Extensive ChE inhibition may result in death.

The Agency evaluated a human study performed by the registrant (Dernehl and Block, 1971). Four men per dose each consumed a single dose of 0.025, 0.05, and 0.1 mg/kg (body weight) aldicarb in 100 ml of water. The high dose produced clear, spontaneously reversible, clinical signs (i.e., blurred vision and nausea) and ChE inhibition (54-86 percent inhibition). The middle dose produced no clinical signs, but produced ChE inhibition (52-70 percent inhibition). The lowest dose produced no clinical signs, but also inhibited ChE (35-54 percent inhibition). These were measured in whole blood.

The Agency determined that the LOEL and NOEL for clinical signs in this study are 0.1 mg/kg and 0.05 mg/kg, respectively. The LOEL for ChE inhibition in this study is 0.025 mg/kg. The National Academy of Sciences (NAS) extrapolated a NOEL for whole blood ChE inhibition of 0.01 mg/kg from this study. The Agency is using the NAS calculation of the NOEL for whole blood ChE inhibition.

In another human study (Cope and Romine, 1973), two men were each given a single dose of 0.5 and 0.26 mg/kg aldicarb in water. The higher dose caused severe clinical signs, requiring the administration of atropine, indicating again the steepness of the dose-effect curve.

3) Conclusions

The Agency has concluded that aldicarb is an extremely potent ChE inhibitor. The precipitous drop in ChE levels resulting from exposure to aldicarb is the principle cause of the toxic effects. The dose-effect curve for aldicarb is very steep with little distance between the dose causing no clinical signs or mild clinical signs and those causing severe clinical signs.

b. Other Data

1) Human Incidents

There are a number of reports of accidental exposures following misuse of aldicarb products. In 1966, a woman ate approximately 0.5 to 1.0 gm of mint leaves from a plant growing near an aldicarb treated rosebush. She developed severe clinical signs, but recovered completely after administration of atropine. Analysis of unconsumed mint samples contained up to 318 ppm of aldicarb.

In 1977 and 1978, two separate incidents occurred in which 14 people exhibited clinical signs of ChE inhibition after ingestion of local, hydroponically grown cucumbers which were illegally treated with aldicarb. No patient received specific medical treatment and all recovered quickly and completely. Analysis indicated that the cucumbers contained 6.6 to 10.7 ppm of aldicarb.

In 1985, the Canadian Department of Health and Welfare reported 13 cases of people who showed clinical signs of ChE inhibition following the consumption of local, hydroponically grown cucumbers. Contamination of the cucumbers ranged from 0.156 to 8 ppm of aldicarb.

The largest documented episode of foodborne pesticide poisoning in North American history occurred in July 1985 from aldicarb contaminated California watermelons. More than a thousand probable cases were reported from California, Oregon, Washington, Alaska, Idaho, Nevada, Arizona and Canada. The spectrum of illness attributed to aldicarb ranged from mild to severe and included cases of grand mal seizures, cardiac arrhythmias, severe dehydration, bronchospasms, and at least two stillbirths occurring shortly after maternal illness. The prompt embargo of watermelons on July 4, 1985 abruptly terminated the major portion of the outbreak and reported illnesses occurring after the implementation of the watermelon certification program were far fewer and milder in comparison to earlier cases. Contamination of the watermelons ranged up to 3.3 ppm of aldicarb sulfoxide (ASO) (Goldman and Jackson, 1986).

2) Epidemiology Studies

The Agency reviewed a 1979 epidemiological study conducted in Suffolk County, New York (Whitlock et al, 1982). An initial association between diarrhea in children under 12 and consumption of aldicarb contaminated drinking water was not confirmed upon reexamination with an expanded population size. Interviews of emergency room personnel and local physicians revealed no evidence of symptomology associated with aldicarb residues in drinking water or food commodities.

A second epidemiology study in Long Island, New York (Varma et al, 198?) attempted to support an association between spontaneous abortions and exposure to aldicarb contaminated drinking water. The Agency, however, concluded that there were specific problems concerning the design and conduct of this study and therefore no valid conclusions could be made.

3) Conclusions

The doses estimated from the human incidents reported have been as low as 0.0026 mg/kg body weight. These estimates are based largely on anecdotal data on consumption, and rarely have analyses for aldicarb been done on the items consumed. Thus there is considerable uncertainty regarding these estimated doses. The human study reported above (Dernehl and Block, 1971), which found a LOEL and NOEL for clinical signs of 0.1 mg/kg and 0.05 mg/kg, respectively, was based on four subjects per dose. Thus, there is some uncertainty regarding these values as well. The frequency of dose estimates from incidents that are at least an order of magnitude lower than the 0.1 mg/kg LOEL reported indicates that the true LOEL for clinical signs is probably lower than this, and that the NOEL reported by Dernehl and Block could well be an effect level for some individuals. The NOEL for ChE inhibition extrapolated from this study, 0.01 mg/kg, may also be high, as monkeys fed 0.005 mg/kg aldicarb had slightly depressed ChE (Union Carbide, 1987a and 1987b); no clinical signs were reported at this dose under controlled laboratory conditions. Although there is uncertainty about the NOEL and LOEL for humans based on the available data, the Agency believes that the NOELs for ChE inhibition and clinical signs of such inhibition are close to 0.01 mg/kg; and that at 0.001 mg/kg, it is unlikely that many individuals will show clinical signs or have depressed ChE activity.

2. EXPOSURE ASSESSMENT FOR TREATED FOOD COMMODITIES

The Agency has reviewed the entire residue chemistry and environmental fate data base of aldicarb and concluded that the two principal routes of exposure are consumption of legal residues on treated commodities and drinking contaminated ground water. Considering the acute nature of potential intoxication by consumption of aldicarb residues, the Agency determined that a single dose exposure is the exposure of concern. Hence, all discussions of exposure will focus on the upper end estimate of a single dose exposure.

a. Description of the Tolerance Assessment System

The Agency estimated exposure to aldicarb treated commodities utilizing the Tolerance Assessment System (TAS). TAS estimates of dietary exposure to pesticide residues on a treated commodity are based on food consumption and residue data files. A brief description of each of these files is presented below.

1) Food Consumption Data Files

Food consumption estimates were derived from the 1977-78 Nationwide Survey of Food consumption, conducted by the U.S. Department of Agriculture. These consumption estimates were generated for specific food items, i.e., pizza, apple pie, etc. However, tolerances are established for Raw Agricultural Commodities (RACs) as they enter commerce, e.g., apples, milk and beef, but not for apple pie or pizza. Therefore, a USDA survey food item was broken down into its component parts (raw agricultural commodities or RACs) i.e., apple pie was translated into wheat, apples, sugar, etc. The composition of each food was determined as a percentage by weight of appropriate RACs. Wherever possible, the form of the food "as eaten" i.e., cooked, raw, fried, etc., was noted.

Each survey respondent's consumption of each food (or food form) was adjusted by their self-reported body weight, so that all consumption estimates are expressed as grams of food per kilogram body weight per day (g/kg/day). Each person's food record is also associated with demographic and socio-economic information about that person (age, sex, ethnic origin, region of the country, season surveyed, pregnant or nursing).

2) Residue Data Files

There are two principal types of residue data used by TAS: tolerances and anticipated residues. The tolerance is used by FDA to tell whether there are illegal residue levels. The tolerance represents a level of residue that is not expected to be exceeded if the pesticide is properly used, and in fact, is a level unlikely to be encountered on food as it is eaten. Although the tolerance is not intended to reflect expected levels of the pesticide in foods at the time of consumption, it is used to estimate an upper limit of potential dietary exposure to pesticides.

The value selected for the tolerance also does not consider the effects of processing on residue levels. Food is generally processed in some manner prior to consumption. Examples of processing include: discarding outer leaves, rinsing, cooking, freezing, canning, refining food oils, etc. These processing procedures generally lower the amount of pesticide residue in food, although the proportion of parent chemical or toxic metabolite may remain constant or increase with processing for some pesticides and some methods of processing.

b. Exposure Estimates

The Agency initially estimated exposure to treated food commodities in a screening process. These estimates assumed that all appropriate treated food commodities contained aldicarb residues at the tolerance level, and that 100 percent of the crop was treated with no correction for concentration/reduction of residues during processing. Only two treated commodities, citrus and potatoes, that required a further, more refined analysis were identified during this process. All other treated food commodities had a sufficiently low exposure to be of insignificant dietary concern. The Agency does not expect any concentration of residues by processing that would result in elevated residues.

The Agency then performed the more refined estimate of exposure by using the Detailed Acute Analysis function of the TAS. When the toxicological issue of concern is based on studies in which exposure is acute, food consumption estimates must be for "users only" (i.e., the number of people who would consume a particular commodity on a given day). The estimate must also be for the amount of food ingested on a given occasion and not the average consumption over a lifetime, as would be the case for an estimate of chronic consumption. It is possible to estimate the distribution of acute exposure within the population using TAS. TAS estimates the percentage of an entire population, as well as selected subpopulations, consuming treated commodities (citrus or potatoes).

1) Population Consuming Citrus and Potatoes

The Agency's estimates of the percentage of people (both in the general population and certain subpopulations) consuming citrus and potatoes on a typical day, based on FDA market basket data, are presented below.

	Percent Consuming:	
Population	Citrus	Potatoes
General Pop.	45.0	56.2
Infants	19.9	38.3
Children	42.6	60.0
Adult Males	47.0	52.4
Adult Females	44.0	59.5

As previously discussed, TAS can estimate the percentile of subpopulations that consume various quantities of treated commodities, in this case citrus and potatoes. Assuming that these commodities contain a defined amount of aldicarb residues, the Agency can estimate the size of subpopulations that consume various quantities of aldicarb residues. TAS estimates of subpopulation sizes are, however, stated as percentiles. Thus, the estimates of subpopulation size are stated as: "x percent of the infant subpopulation are exposed to greater than or equal to y mg/kg of aldicarb residue via consumption of treated citrus containing 95 percent confidence level, upper 5 percent residues".

2) Percent of Crop Treated

i. Citrus

Aldicarb is registered for use on four citrus commodities: oranges, grapefruit, lemons and limes. Oranges and grapefruit constitute the vast majority of annual citrus production. The Agency's analysis uses only orange and grapefruit data from Florida for the following reasons. The four citrus commodities are grown in Florida, Texas and California/Arizona with only Florida and Texas using aldicarb in citrus production. Only a minor amount of aldicarb (less than 1,000 lbs a.i./yr) is used in California/Arizona. Limes, grown only in Florida, and Texas-grown oranges and grapefruit each represent only 1 percent or less of the national annual citrus production.

Usage of aldicarb on Florida citrus is concentrated on fruit for the fresh market. About 25 percent of all Florida oranges for processing are treated with aldicarb and about 89 percent of all Florida fresh oranges are treated. Approximately seven percent of Texas grapefruit and 90 percent of Florida grapefruit are treated with aldicarb.

Florida oranges and grapefruit represent approximately 72 and 81 percent, respectively, of national orange and grapefruit production. Thus, the Agency's citrus analysis covers the majority of citrus.

ii. Potatoes

Eleven states produce approximately 97 percent of all U.S. grown potatoes. The Agency estimated the percent of crop treated for the nation and found that in 1986, 23 percent of the total U.S. potato acreage was treated with aldicarb.

3) Crop Residues

The Agency believes that "average" residue values are inappropriate to estimate aldicarb exposure because aldicarb causes acute effects from a single exposure of sufficient magnitude. Therefore, the Agency used 95 percent confidence limit values of the anticipated residues derived from field trial data and residue reduction (processing) data in the TAS analysis. These data, submitted by the registrant, were used to support tolerances. A 50 percent reduction factor was applied to potatoes and certain citrus commodities, based on the average loss of aldicarb residues during processing (cooking).

The registrant also submitted additional residue data on citrus and potatoes for the Special Review. These data essentially parallel data submitted in connection with the pesticide tolerance petitions.

The Agency used the following 95 percent confidence limit residue values to calculate the exposure used in the food commodity risk analysis:

* Citrus - 0.18 ppm
* Citrus (processed) - 0.09 ppm
* Potatoes - 0.82 ppm
* Potatoes (processed) - 0.41 ppm

The calculated residue level for potatoes reflects only those data used to establish the current tolerance of 1 ppm. The registrant submitted additional residue data from continuing field trials indicating average residue values which are lower than those determined from review of the tolerance petition data. These new data reflect pre-harvest intervals (the period between treatment and harvest, "PHI") longer than those approved on the label. Under optimal conditions, early varieties of potatoes can be harvested 90 days after planting. Aldicarb is applied either at planting or at emergence, resulting in either a 90 day or 50 day PHI, respectively. The registrant selected samples at PHI's ranging from 79 to 246 days, with many samples collected between 110 to 246 days after application. Collection of samples at these times skews the residues to lower values. For comparison, the 95 percent confidence level residue for the registrant's new data is 0.43 ppm for unprocessed potatoes.

Additionally, the Agency reviewed market basket survey data from the Food and Drug Administration (FDA). The data base included 491 raw agricultural commodity samples analyzed for aldicarb residues. Seventy-six samples were found to contain aldicarb residues (72 white potatoes, 2 sweet potatoes, 1 peach, 1 collard green, and 1 for an unspecified Hawaiian commodity). The 72 white potatoes with detectable levels represent 40 percent of the 180 white potatoes sampled in the survey. Two of the white potato samples had residue values exceeding the tolerance and were seized by FDA.

A review of the data reveals that detectable residues were high in 1983 and started to drop in 1984. This latter observation may be associated with the small sample size in 1984 and 1985. The majority of the FDA potato samples were taken in 1983 (142 samples). Thirty-three potato samples were taken in 1984, and five in 1985. The mean and 95 percent confidence level residues of positive samples in potatoes are 0.2 ppm and 0.72 ppm, respectively. This corresponds very well to the mean and 95 percent confidence level residues calculated from pesticide petitions, 0.22 ppm and 0.82 ppm, respectively. Thus, the market basket survey data support the conclusion that the registrant's recent data are unrepresentative of actual residue levels likely to occur.

The Agency has encouraged pesticide registrants to conduct monitoring studies to give a more accurate representation of the level of pesticide residues to which the public is exposed. The registrant has recently submitted the results of a National Food Survey which monitored for residues of aldicarb in the market place. These data are currently under review. These data, along with the tolerance data and the FDA market basket survey data, will be used in the final dietary risk assessment.

3. CONTAMINATED GROUND WATER

a. Background Information

The Agency estimated exposure to ground water contaminated with aldicarb using the TAS by considering water as if it were another treated commodity. Unlike exposure to treated commodities which are distributed throughout the nation in a reasonably uniform fashion, contaminated ground water is a highly localized phenomenon. Because it is impossible or impractical to sample all ground water, the Agency cannot, as it did with treated commodities, estimate the maximum proportion of the population who could be exposed to aldicarb residues in ground water. Exposure to aldicarb contaminated ground water would most likely occur in those areas where there is a high vulnerability to leaching.

b. Exposure Estimates

The Agency's estimate of exposure to contaminated ground water represents, as with treated commodities, a range of exposure levels dependent on consumption patterns. This range of estimated exposures occur because infants, children and adults (1) consume differing quantities of water in their foods (infants have essentially an entire liquid diet while adults have both a liquid and solid food diet), (2) the consumed water may be treated differently (cold water vs. warm formula vs. hot coffee) and (3) personal preferences (sipping all day vs. consuming the entire quantity at one time).

1) Water Residues

No comprehensive collation of all water samples analyzed for aldicarb residues has been compiled to-date. However, the Agency developed a distribution of aldicarb residues in 7,809 wells in Suffolk County, New York, in 1981 from data supplied by the Suffolk County Health Department (Baier and Moran, 1981). Approximately 25,000 of the over 35,000 water samples, taken nationally over the years, are from Long Island. All wells in this survey were within 2,500 feet of potato fields and thus, represent an area of intensive potato cultivation and aldicarb use. Additionally, these areas are highly vulnerable to ground water contamination by aldicarb.

Approximately 74 percent of all the Suffolk County wells sampled in 1981 contained no detectable aldicarb residues. Twenty-seven percent of the wells (2,054 samples) were positive. Fifty-six percent (1,158 samples) of the 2,054 positive samples ranged from 1 to 10 ppb, 40 percent (815 samples) ranged from 11 to 100 ppb and 4 percent (81 samples) greater than 100 ppb. Historic information on well contamination in general was also provided in a separate section of this survey. Five of 68 tested public wells contained aldicarb residues above 7 ppb. Sixty-seven of 274 school and commercial establishment wells contained aldicarb residues, with 22 wells exceeding 7 ppb. The vast majority of all wells tested to date contain levels of aldicarb residues of less than 10 ppb.

2) Processing Factors

Aldicarb degrades from heat, especially the high heat associated with cooking. The Agency believes that exposure to heated water contaminated with less than 10 ppb aldicarb will have levels no higher than 5 ppb; however, this was not factored into the Agency's estimates of exposure.

4. RISK ASSESSMENT

The Agency has estimated acute dietary risk from exposure to legal residues of aldicarb in treated commodities and aldicarb residues in ground water. This section describes the Agency's assessment of risk.

This risk assessment differs considerably from previous assessments because it uses TAS and actual residue estimates rather than the Theoretical Maximum Residue Concentration (TMRC) to estimate exposure and risk. Previously, the Agency utilized the TMRC to determine the maximum possible exposure to legal residues. That analysis was used primarily to determine whether additional tolerances should be established by the Agency. That analysis also assumed average consumption of treated commodities. The analysis in this document uses TAS and upper 5 percent residue values at the 95 percent confidence limit to determine the distribution of exposure, and hence risk, for various subpopulations.

There are two important assumptions inherent in the risk assessment. First, this assessment assumes that all food consumed on a single day is consumed at a single sitting. This is an important consideration because ChE inhibition by aldicarb, and other carbamates, is immediate, but rapidly reversible. Secondly, when risk estimates are presented for people exposed by eating several types of processed foods on a single day, the Agency assumes that all appropriate commodities contain residues.

a. Introduction

The Agency assumed that consumption of all treated food commodities, each containing the 95 percentile level of residue, either with or without contaminated water, on a single occasion, is highly improbable. Three major sources of dietary exposure were identified:

Citrus (oranges or grapefruit),
Potatoes, and
Water (contaminated with 10 ppb aldicarb).

These three sources of dietary aldicarb exposure are the focus of the Agency's risk analysis.

b. Toxicology Endpoints

As previously mentioned, ADIs have traditionally been used to account for chronic consumption, while the current analysis focusses on acute exposure to aldicarb. The endpoint judged most appropriate for establishing a Reference Dose (RfD) for this type of exposure was the extrapolated NOEL for human ChE inhibition, 0.01 mg/kg. A ten-fold uncertainty factor was applied to this dose to account for inter-subject variability, yielding an RfD of 0.001 mg/kg, or 1 ug/kg/day. This dose has been highlighted in all of the risk assessment tables.

The Agency, in describing the risks associated with consumption of aldicarb in the diet, has calculated margins-of-safety (MOS) for the various doses distributed among the populations. These MOSs are described with respect to both the NOEL for clinical signs, 0.05 mg/kg from Dernehl and Block, and the extrapolated NOEL for ChE inhibition, 0.01 mg/kg. Consumption of doses higher than the RfD represents an MOS less than 10 for ChE inhibition and less than 50 for clinical signs.

c. Risk from Food Residues

The Agency performed a detailed estimate of the percent of an affected population which may be exposed to various amounts of aldicarb via residues in or on citrus and potatoes. A distribution of exposure (risk) was calculated for various affected populations. These estimates assume exposure to 95th percentile residue values in citrus (oranges and grapefruit) and potatoes. The distribution reflects differences in amount consumed per unit body weight.

The most important conclusion from the risk analysis of treated commodities is that individuals with exposure to the 95th percent confidence level residue values have MOS levels that are low in most cases. The percent of affected populations and MOS for average residues are presented in Table II-1. The 95 percent confidence level residue values for oranges, grapefruit, and potatoes are presented in Table II-2.

1) Oranges

Thirty-four percent of children and 18 percent of infants are expected to consume oranges on any given day. Of this group, it is predicted that 10 percent of these children and 3 percent of infants consuming oranges with 95th percentile aldicarb residues would have dietary exposures of 1 ug/kg or greater, which would correspond to an MOS of less than or equal to 10 for ChE inhibition and an MOS less than or equal to 50 for clinical signs. (See Table II-2)

2) Grapefruit

Only a small percentage of any subgroup is predicted to be a consumer of grapefruit on any given day (from 0.5 percent in infants to 6.4 percent of females of 13+ years). However, large percentages of the infants (34 percent) and children (42 percent) consuming grapefruit with 95th percentile aldicarb residues would be predicted to have exposures of 1 ug/kg or greater, which corresponds to an MOS of less than or equal to 10 for ChE inhibition and less than or equal to 50 for clinical signs. (See Table II-2)

3) Potatoes

It is predicted that from 20 to 55 percent of the consumers of potatoes containing 95th percentile aldicarb residues in each of the subgroups studied would have dietary exposures of 1 ug/kg or greater, which corresponds to an MOS of less than or equal to 10 for ChE inhibition and less than or equal to 50 for clinical signs. (See Table II-2)

d. Risks from Contaminated Drinking Water

Table II-3 was compiled from the results of a TAS analysis to determine exposure to aldicarb from all dietary sources of water. The TAS analysis is based on the total dietary intake. The focus of this analysis was on the population at greatest risk: infants. Infants consume most of their diet as formula and fruit juice; both of these are frequently prepared using tap

TABLE II-1

PERCENT OF AND MOS FOR AFFECTED POPULATIONS CONSUMING AVERAGE RESIDUES

Population[1/]	Percent Users[2/]	Exposure ug/kg = 0.5	0.8	1.0	1.5	2.0	2.5	5.0
	MOS[3/] =	100	63	50	33	25	20	10
	MOS[4/] =	20	13	10	7	5	4	2
		Percent Population/Subpopulation Exceding Exposure		RfD				
CITRUS								
General Pop.	45.0	2	1	0	0	0	0	0
Infants	19.9	29	11	6	1	1	0	0
Children	42.6	18	6	3	1	0	0	0
Females	47.0	0	0	0	0	0	0	0
Males	44.0	0	0	0	0	0	0	0
POTATOES								
General Pop.	56.2	6	2	1	0	0	0	0
Infants	38.3	15	8	6	3	2	1	0
Children	60.0	22	7	6	2	1	0	0
Females	52.4	3	0	0	0	0	0	0
Males	59.5	3	1	0	0	0	0	0

1/ Infants (<1 year), children (1-6 years), females (13+ years), and males (13+ years).
2/ Percent population anticipated to be exposed to a commodity containing aldicarb residues.
3/ Compared to the NOEL for clinical signs in the registrant's human study.
4/ Compared to the extrapolated NOEL for ChE inhibition in the registrant's human study.

TABLE II-2

PERCENT OF AND MOS FOR AFFECTED POPULATIONS CONSUMING 95 PERCENT CONFIDENCE LEVEL RESIDUES

		Exposure							
	ug/kg =	0.2	0.5	0.8	1.0	1.5	2.0	2.5	5.0
	MOS[3/] =	250	100	63	50	33	25	20	10
	MOS[4/] =	50	20	13	10	7	5	4	2

Population[1/]	Percent Users[2/]	Percent Population/Subpopulation Exceeding Exposure							
					RfD				
ORANGES									
General Pop.	29.6	16	8	3	2	1	0	0	0
Infants	18.4	13	4	3	3	2	1	1	0
Children	34.5	20	14	12	10	6	3	2	0
Females	28.7	15	6	1	0	0	0	0	0
Males	28.2	15	4	1	1	0	0	0	0
GRAPEFRUIT									
General Pop.	4.7	65	22	5	3	1	0	0	0
Infants	0.5	100	61	44	34	26	17	9	0
Children	1.2	91	65	48	42	23	8	6	0
Females	6.4	66	22	4	2	0	0	0	0
Males	4.6	61	14	2	1	0	0	0	0
POTATOES									
General Pop.	56.2	79	59	37	28	14	8	6	1
Infants	38.3	89	56	33	28	22	17	14	5
Children	60.0	84	71	61	55	41	28	21	4
Females	52.4	77	55	29	20	8	3	2	0
Males	59.5	80	56	34	24	10	4	3	0

1/ Infants (<1 year), children (1-6 years), females (13+ years), and males (13+ years).
2/ Percent population anticipated to be exposed to a commodity containing aldicarb residues.
3/ Compared to the NOEL for clinical signs in the registrant's human study.
4/ Compared to the extrapolated NOEL for ChE inhibition in the registrant's human study.

TABLE II-3

PERCENT OF AND MOS FOR AFFECTED
POPULATIONS CONSUMING WATER FROM ALL DIETARY SOURCES[1]

Population[2]	Percent Users[3]	Exposure ug/kg =	0.5	1.0	1.5	2.0	2.5	5.0	10.0
		MOS[4] =	100	50	38	25	20	10	5
		MOS[5] =	20	10	8	5	4	2	1
		Percent Population/Subpopulation Exceeding Exposure		RfD					
60th Percentile Residues (10 ppb)[6]									
General Pop.	99.9		3	0	0	0	0	0	0
Infants	94.9		63	13	2	1	0	0	0
Children	100.0		15	1	0	0	0	0	0
Females	99.9		0	0	0	0	0	0	0
Males	100.0		0	0	0	0	0	0	0
70th Percentile Residues (20 ppb)[7]									
General Pop.	99.9		15	3	1	0	0	0	0
Infants	94.9		90	63	28	13	5	0	0
Children	100.0		69	15	3	1	0	0	0
Females	99.9		4	0	0	0	0	0	0
Males	100.0		5	0	0	0	0	0	0
80th Percentile Residues (30 ppb)[7]									
General Pop.	99.9		35	7	3	1	0	0	0
Infants	94.9		95	84	63	39	22	2	0
Children	100.0		90	46	15	5	2	0	0
Females	99.9		23	1	0	0	0	0	0
Males	100.0		23	1	0	0	0	0	0
90th Percentile Residues (70 ppb)[7]									
General Pop.	99.9		73	29	13	7	4	0	0
Infants	94.9		96	94	87	77	64	12	0
Children	100.0		98	88	68	46	28	2	0
Females	99.9		66	16	3	1	0	0	0
Males	100.0		67	17	4	1	0	0	0

TABLE II-3 (continued)

PERCENT OF AND MOS FOR AFFECTED
POPULATIONS CONSUMING WATER FROM ALL DIETARY SOURCES[1/]

Population[2/]	Percent Users[3/]	Exposure							
		ug/kg =	0.5	1.0	1.5	2.0	2.5	5.0	10.0
		MOS[4/] =	100	50	38	25	20	10	5
		MOS[5/] =	20	10	8	5	4	2	1
		Percent Population/Subpopulation Exceeding Exposure		RfD					
95th Percentile Residues (100 ppb)[7/]									
General Pop.	99.9		88	52	27	15	10	2	0
Infants	94.9		97	95	93	89	82	36	4
Children	100.0		99	95	86	72	56	9	0
Females	99.9		85	41	14	4	1	0	0
Males	100.0		85	42	15	5	2	0	0
99th Percentile Residues (230 ppb)[7/]									
General Pop.	99.9		99	92	78	62	47	13	2
Infants	94.5		99	98	96	96	95	87	50
Children	100.0		100	99	98	97	94	67	16
Females	99.9		97	90	73	53	35	3	0
Males	100.0		97	90	73	54	36	4	0

1/ Includes water in coffee, tea, soft drinks, infant formula, etc.
2/ Infants (<1 year), children (1-6 years), females (13+ years), and males (13+ years).
3/ Percent population anticipated to be exposed to a commodity containing aldicarb residues.
4/ Compared to the NOEL for clinical signs in the registrant's human study.
5/ Compared to the extrapolated NOEL for ChE inhibition in the registrant's human study.
6/ 10 ppb is the current Health Advisory Level (HAL).
7/ Obtained from the 1981 Sulfolk County Drinking Water Survey.

water. Infants are also awake about 12 hours a day; thus, the total daily intake was divided in two, with each half being the amount expected to be consumed within a six hour period, the duration of ChE inhibition from a single dose of aldicarb.

e. Conclusions

Infants and children are at highest risk of acute aldicarb toxicity. As many as 55 percent of these subpopulations consuming the 95th percentile residues are exposed to an amount greater than the RfD, based on analysis of citrus and potatoes. The Agency calculated that when drinking water containing aldicarb at 10 ppb, as many as 13 percent of consuming infants could be exposed to a dose of 0.001 mg/kg or greater of aldicarb. The corresponding Margin of Safety for cholinesterase inhibition would then be 10 or less, based on the NOEL estimated by the National Academy of Sciences.

B. GROUND WATER VULNERABILITY ANALYSIS

This analysis is divided into two sections. The first section summarizes current information on the environmental fate of aldicarb. The second section summarizes two assessments used by the Agency in predicting the likelihood of ground water contamination resulting from the use of aldicarb.

Due to the length and extensive technical scope of this Technical Support Document, the Ground Water Vulnerability Analyses have been summarized and only a portion of the scientific details and documentation have been included in this Support Document. The Ground Water Vulnerability Analyses and references can be viewed in the Public Docket, located in room 236, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, Virgina. Two additional references were used extensively in these analyses and are also part of the Public Docket:

"Ground Water Regions of the United States," United States Geological Survey, Water Supply Paper 2242, Ralph C. Heath, 1984.

"Ground Water Vulnerability Assessment in Support of the First Stage of the National Pesticide Survey," Alexander, Liddle, Mason, Yeager. Research Triangle Institute, February 14, 1986.

The first of these references provides explanatory material relating to the geographic areas of study in the first method of assessing ground water vulnerability, i.e. Heath Regions. The second reference provides documentation for one of the vulnerability assessment approaches used for each assessment method, i.e. DRASTIC.

1. ENVIRONMENTAL FATE

a. Leaching Potential

Aldicarb is mobile in most types of soil in which it is applied, with adsorption coefficient values (K_d) typically less than 1.0, often near 0.1 and occasionally lower (Cohen et al, 1984). K_d values less than the 1 - 5 range indicate that the pesticide has considerable mobility. Incidents of ground water contaminated by aldicarb have been primarily associated with sandy soils. This is because aldicarb binds poorly to sandy soils (sands, loamy sands, and sandy loams, primarily) and any water input to sandy soil (i.e., rain and irrigation) tends to recharge rapidly through the profile, carrying aldicarb with it (Cohen et al, 1984).

b. Metabolism and Degradation

Soil half-lives for degradation of aldicarb and its metabolites to nontoxic residues in the root zone vary from a week to greater than two months, but are typically between one and two months. The primary mode of degradation in the root zone is oxidative metabolism by microorganisms, although hydrolysis may also occur. Factors which affect the robustness of the microbial community also affect the microbial decay of aldicarb in the root zone. Warm soil temperatures, high soil moisture content, and high organic matter content all result in more rapid rates of aldicarb degradation. In a nondegradative pathway, aldicarb oxidizes to aldicarb sulfoxide in a matter of days, and a portion of the aldicarb sulfoxide oxidizes to aldicarb sulfone. Aldicarb sulfoxide and sulfone residues are found approximately in a one-to-one ratio (Cohen et al, 1984).

The primary mode of degradation below the root zone is chemical hydrolysis. Typically, the rate of hydrolysis degradation is slower than microbial degradation. Measured and extrapolated half-lives vary from several weeks to greater than 20 years under ambient conditions, depending on pH and temperature. An unexpected finding in two studies is that hydrolysis is significantly slower in Long Island (Lemley and Zhong, 1984) and Florida (Miles and Delvino, 1985) ground water microcosms than in conditions found in standard laboratory hydrolysis studies. Aldicarb sulfoxide (the first degradation product of aldicarb) is partially reduced to the parent aldicarb in Floridian aquifer microcosms, possibly explaining the enhanced half-life under these conditions (Ou et al, 1985a and b).

Other modes of pesticide dissipation include volatilization and photolysis. Aldicarb's high water solubility and low vapor pressure preclude volatilization as a loss mechanism. The method of application, soil incorporation, and stability to sunlight in water (93 percent of applied dose remaining after 14 days in one study (Union Carbide, 1983)) precludes photodegradation.

2. GROUND WATER ASSESSMENT

The Agency does not believe that methods presently exist to perform accurate quantitative assessments of the amount of a pesticide which may appear in ground water. Thus, the Agency's review provides a qualitative, rather than quantitative, assessment of the vulnerability of ground water to aldicarb contamination.

The objective of performing ground water assessments is to determine the potential for aldicarb to leach and contaminate ground water in the U.S. The Agency used two methods to accomplish this: one involving Heath Regions and one involving counties. A discussion of the two methods follows:

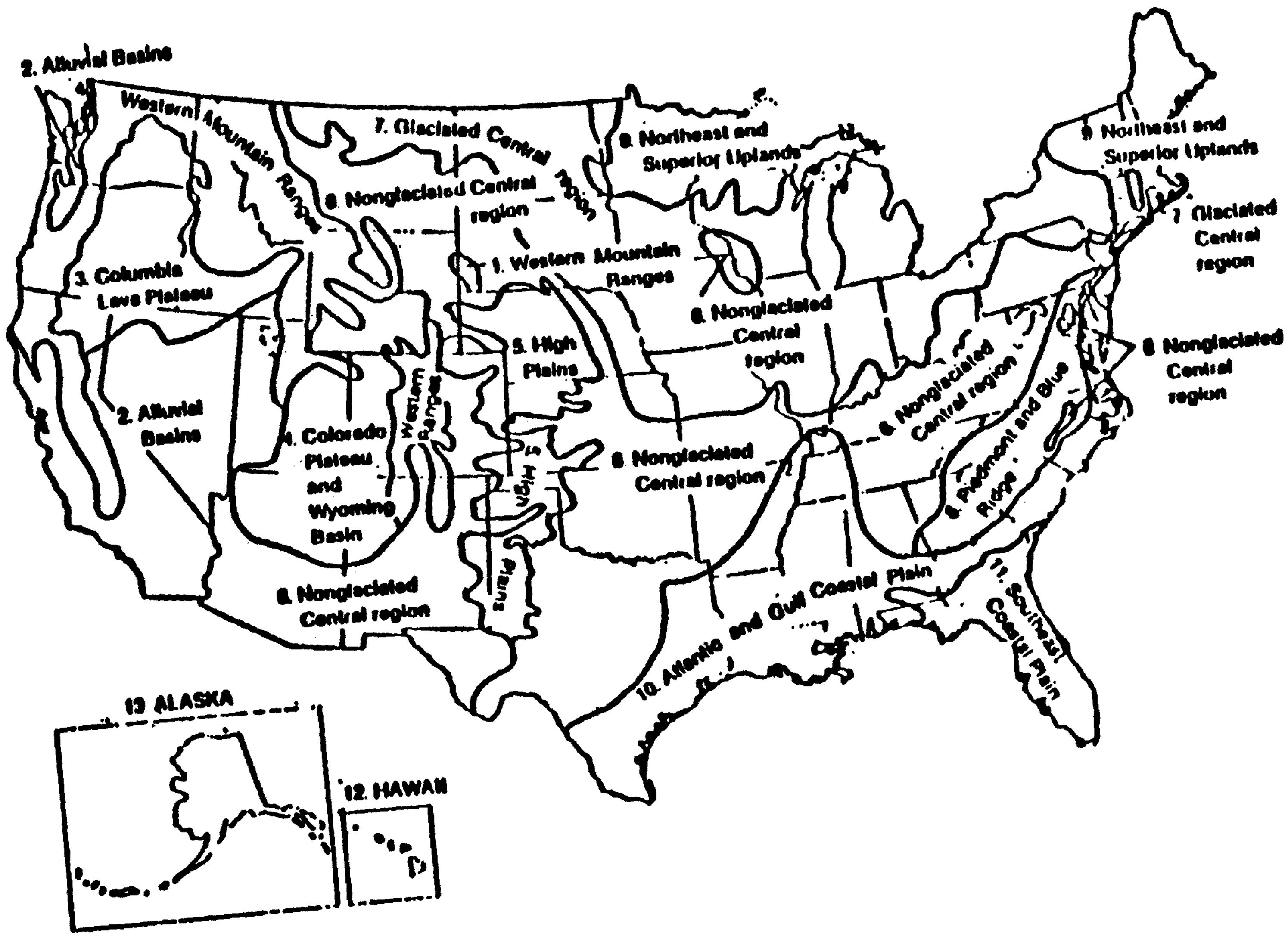
a. Ground Water Assessment by Heath Region

This assessment evaluates the potential for aldicarb to reach ground water as a result of its use on the major aldicarb crops - citrus, potatoes, cotton, soybeans, and peanuts. Those crops account for over 90 percent of its use. The methodology developed was aimed at key vulnerable situations, and provides the background for future evaluations of other aldicarb uses. This analysis focusses on the first encountered potable aquifer.

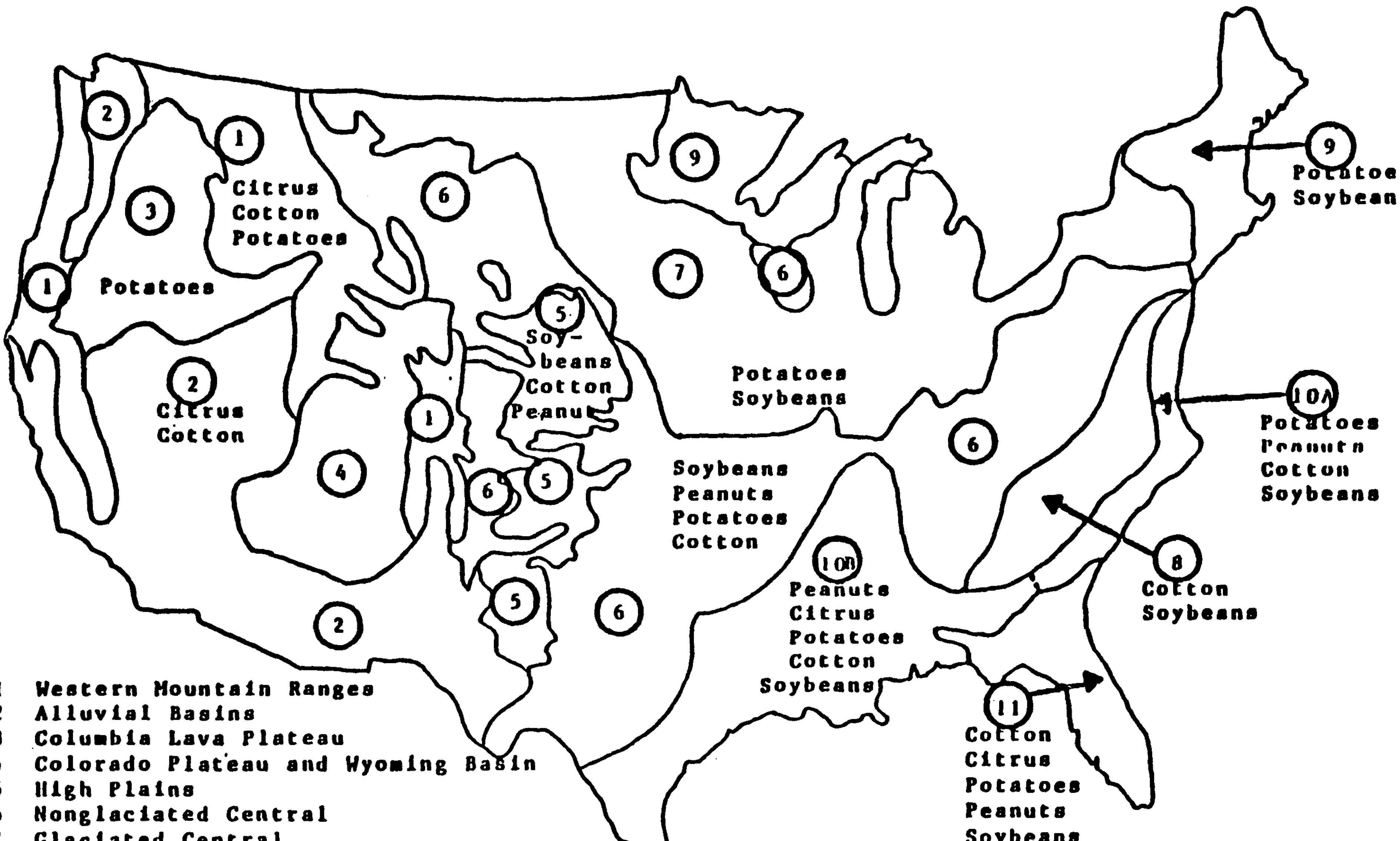
In order to structure the ground water contamination problem, ground water regions, as defined by Heath (Heath, 1985), were used. These regions were determined by distinct factors which affect the occurrence and availability of ground water (mineral composition of the rock matrix, recharge and discharge conditions, etc.). These regions are shown in Map II-1. Eleven of the regions were deemed appropriate for examination based on extent of crop acreage of the five chosen crops in the regions. This structuring resulted in 32 crop/region combinations which were evaluated for their potential for aldicarb contamination of ground water from aldicarb usage and shown in Map II-2.

For each crop/region combination, three major parameters were employed to evaluate the ground water vulnerability of these regions. An evaluation of hydrogeologic vulnerabilities of counties within the crop/region combination were examined using two methods. The first method was an evaluation of 138 counties where aldicarb is used, and the second method a measure of hydrogeologic vulnerability using a system called DRASTIC. The second parameter was an evaluation of monitoring results for aldicarb. The final parameter involved an evaluation of crop/site-specific parameters. Each of these parameters is discussed below.

MAP II-1
HEATH REGIONS



MAP II-2
ALDICARB CROP/REGION COMBINATIONS



Region 1 Western Mountain Ranges
2 Alluvial Basins
3 Columbia Lava Plateau
4 Colorado Plateau and Wyoming Basin
5 High Plains
6 Nonglaciated Central
7 Glaciated Central
8 Piedmont and Blue Ridge
9 Northeast and Superior Uplands
10 Atlantic (10A) and Gulf Coastal (10B) Plain
11 Southeast Coastal Plain

1) Hydrogeologic Vulnerability

i) 138 County Evaluation

The vulnerability of the top soil and the depth of the first encountered potable aquifer were examined in detail for 138 counties. These counties were chosen based on actual aldicarb usage data, amount of acreage devoted to crops on which aldicarb could be used (to factor in aldicarb's potential, rather than current use), and positive monitoring data. These 138 counties are a subset of the 300-400 counties in which aldicarb is currently used.

The Agency determined the average vulnerability rating of each of the 138 aldicarb usage counties by assessing two principle parameters which affect the ground water contamination potential of aldicarb: leachability of the topsoil and depth to ground water. A scale was constructed for each of these parameters, numbered from 1 (least) to 5 (most vulnerable). An average vulnerability rating score was then computed as a simple arithmetic mean of the topsoil and depth to ground water evaluations, leading to a final ranking of ground water vulnerability for the counties as either **high, medium, or low.** For purposes of this analysis, equal importance was assigned to topsoil and depth to ground water as they relate to overall ground water vulnerability.

Topsoil vulnerability ratings were derived in a three step process. First, topsoils were rated high, medium, or low as a function of soil properties including: permeability, organic matter, and hydrologic soil group. Then the percent of land area for each topsoil rating was estimated. Finally, a weighted average of these different land areas was calculated as the final topsoil vulnerability rating. The depth to ground water vulnerability rating was similarly calculated by first determining the percent of land area below which potable ground water was: 0-25 feet (**high vulnerability**), 25-50 feet (**medium vulnerability**), and greater than 50 feet (**low vulnerability**). Similar to the topsoil rating scheme, shallow depth to ground water (**highly vulnerable**) was assigned a rating of 5.0; medium depth to ground water was assigned a rating of 3.0; and great depth (**low vulnerability**) a rating of 1.0. A weighted average of the land area in each category determined the final county depth to ground water vulnerability rating.

Topsoil vulnerability ratings vary from a low of 1.5 to a high of 5.0 and do not fall within well defined groups. States containing highly vulnerable (topsoil) counties (of the 138 chosen for the assessment) include: Florida, Michigan, Georgia, Washington, South Carolina, Virginia, Massachusetts and Wisconsin.

Depth to ground water ratings for the Gulf, Atlantic and Southeastern coastal plains range from 4.1 through 4.9. Michigan and Wisconsin depth to ground water ratings are 4.2 and 3.5, respectively. Depth to ground water ratings for Western states range from 1.0 to 2.8, indicating deep aquifers.

Overall vulnerability ratings (the mean of topsoil and depth to ground water vulnerability rating) were examined for each crop/region combination (e.g., cotton in Region 1).

Groupings of counties specific to each crop in each region were averaged to represent the crop/region combination ranking. For purposes of this analysis, overall ground water vulnerability ratings between 1.00-2.30 were classified **low**, 2.30-3.65 **medium**, and 3.65-5.00 **high**.

In general, the counties in which large amounts of citrus are grown had the highest average vulnerability scores, followed by peanut, potato and cotton counties. However, the "medium" score of counties in which large amounts of potatoes are grown can be misleading. A separate analysis of Wisconsin counties evaluated for potatoes showed that the potato-growing regions were in areas of sandy, highly vulnerable soils. As explained later in the crop/site-specific analysis, potatoes are typically grown in sandy, well drained soils. Therefore, the high variability and average ratings for counties in Wisconsin mask the fact that potatoes are grown in vulnerable portions of a county that overall may be classified as having medium vulnerability. This phenomenon is likely to be true for counties in other potato growing states as well.

ii) DRASTIC Analysis

The second measure of hydrogeologic vulnerability used a rating system devised by the National Well Water Association (Aller et al, 1985) known as **DRASTIC**. DRASTIC is a screening system which estimates ground water vulnerability. DRASTIC uses seven characteristics: **D**epth to ground water; **R**echarge; **A**quifer media; **S**oil media; **T**opography; **I**mpact of the vadose zone and hydraulic **C**onductivity of the aquifer. Weights of the relative importance of each characteristic are assigned as well as weights within a characteristic.

Each county in the U.S. was first evaluated using the DRASTIC methodology. Using the results of this project, all counties with significant acreage of the five selected crops within each crop/region combination could be examined for hydrogeologic vulnerability. DRASTIC scores were then given qualitative ratings of **Low** (scores of less than 102), **Medium** (scores of 102 - 142) or **High** (scores greater than 142).

See Map II-3. The resulting scores are indicators of the overall vulnerability of a county.

Comparison and use of both hydrogeologic methodologies on the 138 counties the Agency evaluated allowed for assessment of the consistency of the two approaches. In general, all crop/ region combinations were rated medium to high. There was general agreement between the assessment using DRASTIC and the analysis rating each county on topsoil and depth to groundwater. Of the 138 counties of the county-level vulnerability assessment, only three of the 138 counties showed a clear discrepancy between the assessment using DRASTIC and the vulnerability analysis rating each county for topsoil and depth to ground water. The East Coast crop/region combinations were rated highly vulnerable.

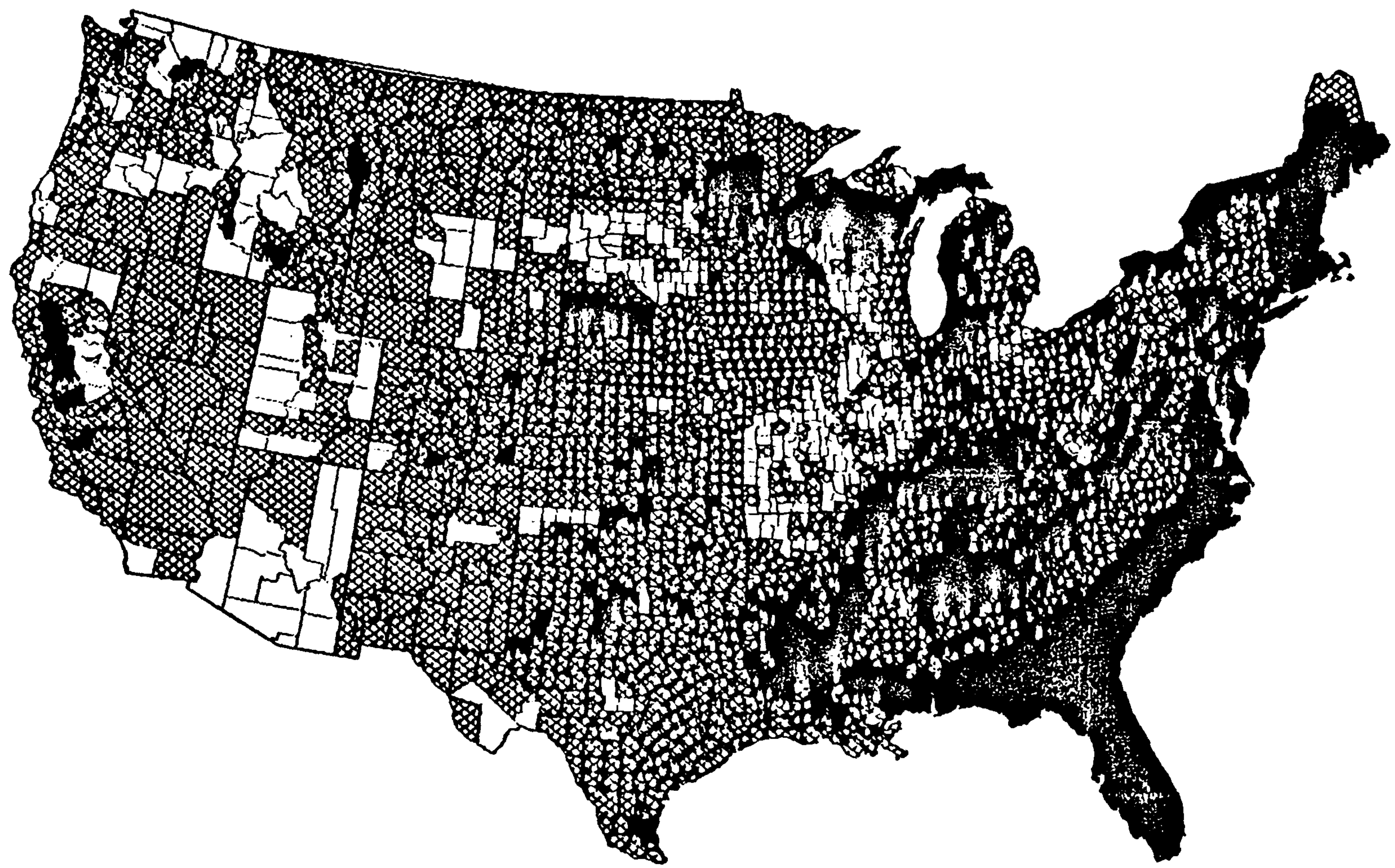
In general, the three Heath regions with the highest scores (in descending order of percentage of counties and average scores) are the Southeast Coastal Plain (Heath Region 11), the Atlantic and Gulf Coastal Plain (Heath Region 10), and the Glaciated Central Region (Heath Region 7). The Southeast Coastal Plain consists principally of Florida and southern Georgia. The potential contamination problem in the Atlantic Ocean side of the Atlantic and Gulf Coastal Plain seems greater than the Gulf of Mexico side. The Glaciated Central Region includes the Connecticut River Valley, the Central Sands area of Wisconsin and other areas of the northern plains.

2) Monitoring Data Evaluation

The second parameter was an evaluation of monitoring results for aldicarb. Although more ground water monitoring for aldicarb has occurred nationwide than for any other pesticide, monitoring data are still lacking for many areas. Overall monitoring results were summarized, and specific case studies were examined in detail for trend analysis. Monitoring data, where available, were given greater emphasis than the other means of analysis.

The Agency has evaluated sampling programs encompassing over 35,000 samples. The programs chosen for evaluation by the Agency were those specifically focussing on "impacted" ground water; that is, the first encountered potable aquifer in the vicinity of aldicarb treated fields. Included in the analysis were state monitoring programs which sampled wells in the vicinity of aldicarb treated fields, observations from non-drinking water wells placed in or near treated fields for research or related purposes, and water quality testing results from national agencies such as EPA or the U.S. Geologic Survey. Approximately 32 percent of all samples were positive. Over 25,000 of the 35,000-plus samples were taken in Suffolk county, New York, with

MAP II-3
DRASTIC EVALUATIONS



DRASTIC SCORES

- 50 - 101
- 143 AND ABOVE
- 102 - 142

17 percent containing aldicarb residue levels greater than 10 ppb. Residues of aldicarb have been found in 48 counties within 16 states. A summary of aldicarb monitoring by state is shown in Table II-4.

The highest residues have been associated with areas producing potatoes, tulip bulbs and citrus. Peanut and pecan producing areas have not been adequately monitored although they are in hydrogeologically vulnerable areas. Following are observations from monitoring data and summaries of significant state programs.

* "Moratorium" areas in Wisconsin (where aldicarb use is banned for a one mile radius around wells contaminated with aldicarb at greater than 10 ppb) coincide with areas where aldicarb is used on potatoes and where top-soil vulnerability is rated as high (Noren et al, 1985). In a comprehensive monitoring program by the registrant and the Wisconsin Department of Natural Resources (Union Carbide, 1986), approximately 53 percent of 2,474 samples taken were positive, with 20 percent of these positives higher than 10 ppb.

* The Florida (Lake Hamilton) site showed shallow ground water (5 - 30 feet below ground surface) aldicarb concentrations at 63 ppb, more than 400 feet from the boundary of the field plot, three years after application of 11.2 kg a.i./ha (Union Carbide, 1985b). There was a stream located over 400 feet from the field edge, which intercepted residues from traveling further. At another citrus field site located in Highlands County, aldicarb had been applied at the label rate of 5.6 kg a.i./ha in 1984, 1986, and 1987 (no application in 1985). Monitoring wells were established from 200 to approximately 1,000 feet from the field edge. On four sampling dates in 1987, 80 samples were taken from 25 wells equally spaced between 500 and 1,000 feet from the field edge (not all wells were sampled on all four dates). These wells tapped the shallow surficial aquifer at depths between five and 20 feet. Of these 80 samples, 52 were positive, with 39 samples above 10 ppb, and a mean positive of 57 ppb. High readings of 416 and 276 ppb were noted at 800 and 900 feet, respectively (Jones, 1987).

Both of these field sites were joint projects of the registrant and the Florida Department of Environmental Regulation. These participants have similar efforts at several other aldicarb use sites in Florida, including fernery and potato use sites. Thus far, the citrus and fernery sites have shown high residue levels in the ground water as well as residue movement off-site. However, possibly because of the agronomic practices associated with potato cultivation in Florida, no residues have been found in ground water at that site.

Table II-4

ALDICARB MONITORING RESULTS

SUMMARIES BY STATE

State	# of Counties Reporting Positive Results	Total Samples	Total Positives	Positive Results in ppb 0-10	11-30	>30
Arizona	1	2	1	1	0	0
Arkansas	1	8	2	0	1	1
California	1	522	381	232	81	68
Florida	5	4,743	994	367	175	451
Maine	2	690	384	322	43	19
Massachusetts	3	385	70	39	20	11
Minnesota	2	315	5	3	1	1
New Jersey	2	68	5	4	0	1
New York	6	25,399	8,076	3,705	4,319	52
North Carolina	3	95	10	8	2	0
Oregon	1	1	1	1	0	0
Rhode Island	2	720	109	75	25	9
Texas	1	3	3	3	0	0
Virginia	3	97	24	19	5	0
Washington	1	1	1	1	0	0
Wisconsin	14	2,543	1,312	802	378	132
Totals	48	35,592	11,378	5,582	5,051	745

The Florida Department of Agriculture and Consumer Services (DACS) has been monitoring drinking water wells in the vicinity of aldicarb treated fields (Inman, 1986). These wells were located through the DACS program which requires users of aldicarb to register their use of the pesticide. Thus far, of approximately 950 samples (encompassing roughly the same number of drinking water wells - some wells were retested), six wells in four counties contained residues, with the highest reading of 27 ppb.

The apparent discrepancy between the DACS studies and the DER studies is attributed to the differences in ground waters which were tested. The DER studies focussed on samples from water table aquifers drawn from research wells. The DACS studies involved samples from existing wells, which, in all likelihood, were drilled to deeper, more protected depths, and which were also probably further away, and in some cases, upgradient from the aldicarb use site.

Since aldicarb was banned in Suffolk County, NY in 1979, the Suffolk County Department of Health has been monitoring all drinking water wells in which contamination occurred (Andreoli, 1986). The county has located approximately 7,500 wells which are near potato fields formerly treated with aldicarb. A summary of sampling results for the six-year period, 1980-1985, is found in Table II-5. As can be seen, residues have shown little fluctuation. Residues above the New York health guidance level of 7 ppb ranged from 13 to 28 percent of the total positives with 23 percent of the positives above 7 ppb in 1985.

In a research study by Porter et al (1986), 150 wells were sampled in Suffolk County, N.Y., during 1983 and 1984 which had originally been sampled in 1980. He characterized subsets of these wells as shallow, medium, and deep and concluded the following:

- aldicarb contamination in shallow wells is declining;

- aldicarb contamination in moderately deep screened wells is relatively unchanged; and

- aldicarb contamination at greater depths is increasing.

* The Massachusetts Department of Food and Agriculture sampled 316 wells associated with potato use as of March 1985 (Sylva, et al, 1985). Approximately 18 percent of the total samples were positive, with eight percent of all samples greater than 10 ppb.

* In Maine, wells near potato fields have been sampled since 1980 in a program jointly administered by the University of Maine

Table II-5

SUFFOLK COUNTY DEPARTMENT OF HEALTH

MONITORING OF IMPACTED WELLS, 1980-1985

Year	# Samples	>8 ppb	1-7 ppb	Mean*	Median*
1980	8,595	1,193	1,167	24.7	8
1981	677	190	275	11.7	5
1982	2,905	380	265	20.0	10
1983	4,659	804	661	19.9	8
1984	3,974	670	546	17.2	8
1985	4,022	942	688	18.7	8
Total	24,832	4,187	3,602	20.2	8

* Mean and median of positive wells only

and the registrant (Union Carbide, 1985). Between 1980 and 1985, approximately 56 percent of the 690 samples taken have been positive, with nine percent of all samples above 10 ppb.

* The North Carolina Department of Agriculture collected 138 samples from 104 wells associated with tobacco and cotton fields in late 1982 (Graham, 1984). Twelve positive samples were found and two of the 12 well samples associated with cotton fields contained aldicarb residues of 27 and 28 ppb. Subsequent samples from the positive wells were found to be negative for aldicarb residues when retested in early 1983.

* The Rhode Island Department of Health has an extensive aldicarb monitoring program associated with testing private wells near potato fields (Rhode Island Department of Health, 1985 and Union Carbide, 1985a). Thus far, of a total of 720 samples (697 wells), 15 percent of all of the the samples have been positive, with four percent of all of the samples greater than 10 ppb. The maximum observation was 73 ppb aldicarb.

* In Del Norte County, California, wells near lily bulb fields were monitored, starting in 1983 (Union Carbide, 1985a). As of 1985, 522 samples from 60 wells showed 73 percent positive, with 28 percent of all of the samples greater than 10 ppb. As a result of sampling in 1983, the California Department of Food and Agriculture suspended the use of aldicarb in Del Norte County in June, 1983. A follow-up study performed by the registrant found 63 positives in 74 total samples.

* The Idaho Department of Health and Welfare conducted a sampling program in 1981 and monitored three areas adjacent to potato and sugar beet fields (Brokopp, 1987). There were no positives out of 251 samples.

* The Agency conducted a comprehensive field study in the Dougherty Plains of Georgia (Carsel, 1987). This area is associated with the production of peanuts. The results indicated that aldicarb has not moved beyond two to three feet below the soil surface and the field half-life was calculated to be two to three weeks.

The results of these various monitoring studies have indicated that most monitoring has been associated with potato and citrus production areas whereas there has been a lack of monitoring associated with peanuts, cotton, and soybeans. Relatively high percentages (5 to greater than 50 percent) of positive findings occurred in Wisconsin and Northeastern states (NY, MA, RI, CT, ME) associated with potato use. Also, there was substantial evidence of leaching to shallow ground water associated with citrus use in Florida. Monitoring in several citrus use sites, within 1000 feet of the field and beyond, showed several positive findings above 100 ppb and one finding above

1,000 ppb beneath a field site (Miller et al, 1984). There were some monitoring efforts associated with peanuts and cotton on the East Coast, and potatoes in Idaho, all showing few positives.

3) Crop/Site-Specific Correlation Approach

The 138 county and DRASTIC analyses measure and evaluate hydrogeologic vulnerability. However, they do not consider factors such as: agronomic practices (irrigation, crop preference for certain soil types), rate of aldicarb application, and temperature (which influences degradation). For that reason, an analysis which considers these factors for each crop/region combination was undertaken.

Specifically, for each crop/region combination, the following factors were used: 1) "recharge" (rainfall and irrigation practices were used as a surrogate for recharge), 2) air temperature, 3) rate of application, 4) root-crop consideration, and 5) regional soil order predominance.

Cotton and soybeans were evaluated as low in terms of rate of application (0.6-1.7 kg/a.i./ha), potatoes and peanuts medium (2.2-4.4 kg/a.i./ha), and citrus high (5.6-11.2 kg/a.i./ha). Root crops prosper in and prefer sandy, well- drained soil profiles. Since peanuts and potatoes are root crops, they were rated high. Conversely, cotton, soybeans, and citrus were rated low in terms of the root crop consideration. Finally, assessments of high, medium, and low were made for nine soil "orders" (as defined by the Soil Conservation Service taxonomic system) in which the crops are typically grown in each region.

The final crop/site-specific ratings were determined by a weight-of-evidence evaluation of the five factors described above.

Observations from the crop/site-specific analysis include:

a) Potatoes in Heath Region 11 (Florida) were rated as medium because agricultural practices in Florida are designed to avoid saturated soil conditions. There is immediate runoff and shallow drainage through the use of tiles draining into canals. These practices minimize leaching. Monitoring has shown no contamination of ground water. Personal communication with State Department of Environmental Regulation personnel indicate that aldicarb has been found in drainage canals associated with potato (and fern) cultivation.

b) Peanuts were rated medium to high, because it is a root crop and typically grown in sandy soils in the Southeast and because in this region, warm temperatures exist at aldicarb application time, and warm temperatures hasten aldicarb metabolism. Further justification for a medium to high rating is a medium rate of application.

c) Cotton is irrigated primarily in California, Arizona, and New Mexico and is rated low to medium. A significant percentage of Georgia cotton is also irrigated, where it is also rated as medium. Cotton is not irrigated to any great extent in other States. California is the only State where it is possible to generalize about soil types for cotton. California and Arizona soils, known as "Aridosols", are typically found in arid climates and require irrigation to be productive. Otherwise, cotton is grown in a variety of soils.

d) Citrus is rated as high and is grown in sandy soils in Florida, with approximately two-thirds of the crop irrigated at a maximum rate of about 20 inches/year.

e) Soybeans were rated low to medium in all growing regions. The application rates for soybeans are low. Factors which warranted a medium rating included temperature and high rate of rainfall in many of the soybean regions.

4) Results of Integrated Ground Water Assessment by Heath Region

Each of the four methodology factors was given a qualitative rating of "high", "medium", "low", or "insufficient data" (H, M, L, ID) for each crop/region combination. A "weight-of-evidence" approach was then used to evaluate each crop/region combination as high, medium, or low potential to contaminate ground water and can be defined as follows:

Low - Crop/region combinations which have a low potential for aldicarb to leach to ground water.

Medium - Crop/region combinations where there exists a moderate potential for aldicarb to reach ground water due to many possible factors such as moderate hydrogeologic vulnerability, agronomic practices, or geographic variability. Increased monitoring in these crop/regions could elevate some of them to the High category or conversely, could alleviate concern and place them in the Low category.

High - Crop/region combinations where the weight-of-evidence indicates that aldicarb has a high probability to leach to ground water. Additionally, a crop/region combination will be placed in the High category if there are positive aldicarb monitoring data associated with it.

A tabular summary of the results is provided in Table II-6. Separate columns for each of the previously discussed methods of analysis with individual ground water vulnerability ratings are also shown. Map II-4 illustrates the results of Table II-6, showing the high, medium, and low vulnerability areas by crop and depicts the Heath region.

The Agency believes that this weight-of-evidence approach and corresponding qualitative ground water vulnerability ratings provide a rational basis for depicting potential ground water contamination from aldicarb usage.

The overall ground water vulnerability ratings, based on the four independent approaches, show a high vulnerability for potatoes in Heath Regions 7 and 9 and citrus and peanuts in Heath Region 11. In the first three of these crop/regions, monitoring data has confirmed the vulnerability rating. In the case of peanuts in Heath Region 11, the county, DRASTIC, and site-specific analyses indicated a high vulnerability and if monitoring data were available, positive findings would be expected.

Cotton in Heath Regions 1 and 2 shows a low vulnerability due primarily to the low application rates and the deep ground water associated with these regions.

The remaining crop/region combinations were given medium vulnerability ratings based on the four approaches. It should be understood that a portion of these medium crop/regions could be placed in the high or the low vulnerability category if additional monitoring data were available.

b. Ground Water Assessment by County

Another method developed by the Agency to evaluate the likelihood of ground water contamination was to perform an assessment at the county level. The advantage to this method is that it focusses on a smaller geographic unit, the county, than the Heath Region which was used in the first method. This assessment uses three parameters.

1) DRASTIC Analysis

The first parameter in this assessment was the DRASTIC rating system, which was also part of the Heath Region assessment found on page II-23. The resulting scores, as in the Heath Region assessment, are then given qualitative ratings of **Low** (scores of less than 102), **Medium** (scores of 102 - 142) or **High** (scores greater than 142).

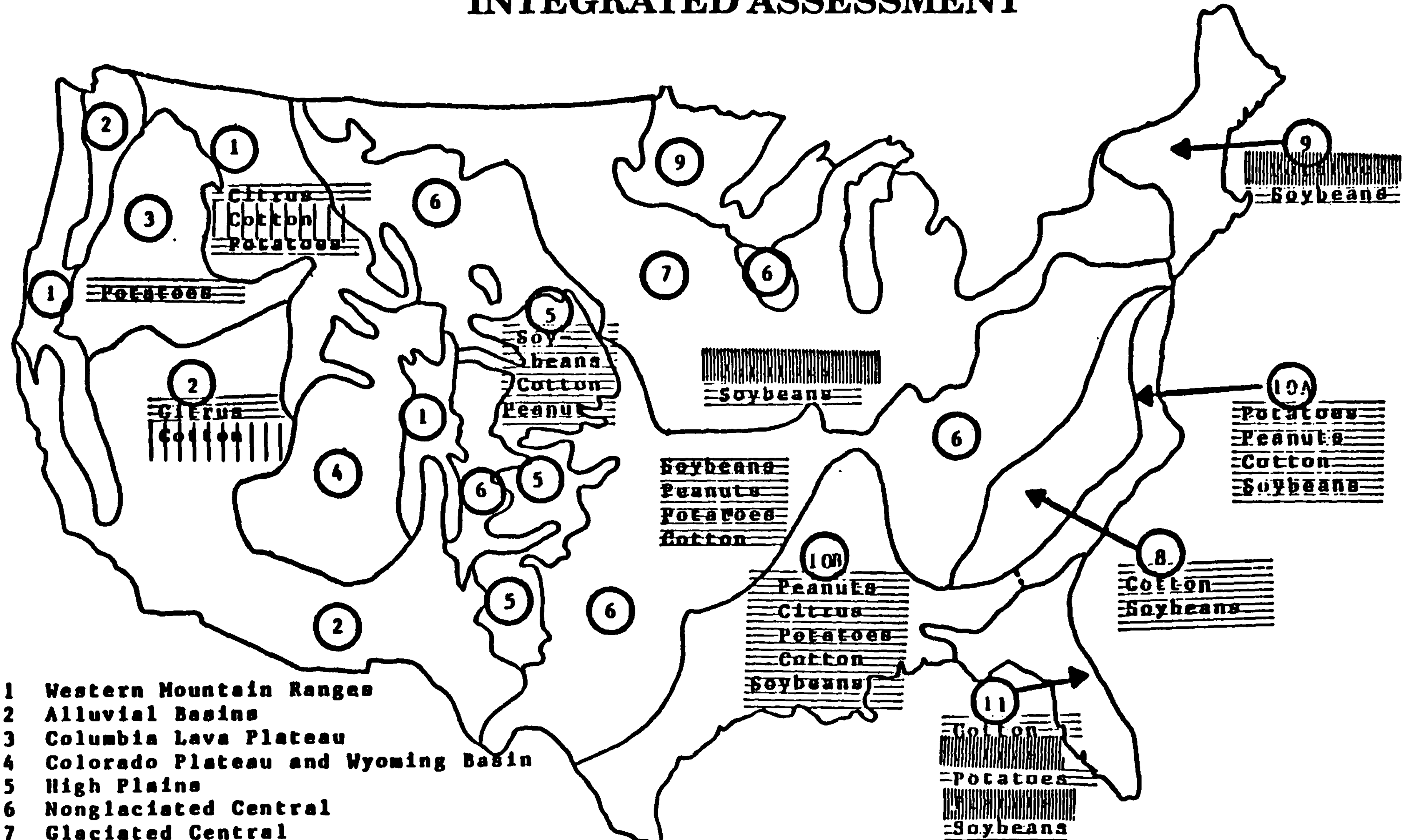
TABLE II-6

GROUND WATER VULNERABILITY

Heath Region	Crop	County-Level	DRASTIC	Crop/Site Specific	Monitoring	Final VR
1	Citrus	L	M	M-H	ID	M
	Cotton	L	M	M	ID	L
	Potatoes	L	M	M-H	ID	M
2	Cotton	L	L-H	L-M	ID	L
	Citrus	L	L-H	M	ID	M
3	Potatoes	L	M	M	L	M
5	Cotton	M	M	L-M	ID	M
	Peanuts	M	M	M	ID	M
	Soybeans	ID	M	L	ID	M
6	Potatoes	M	M-H	M	ID	M
	Cotton	H	M	L-M	ID	M
	Peanuts	L	M	M	ID	M
	Soybeans	H	M-L	L-M	ID	M
7	Potatoes	M	M-H	M-H	H	H
	Soybeans	ID	L-M-H	L-M	ID	M
8	Cotton	H	H	L-M	ID	M
	Soybeans	H	M-H	L-M	ID	M
9	Potatoes	H	M-H	M-H	H	H
	Soybeans	ID	M-H	L	ID	M
10A	Potatoes	H	H	M	M	M
	Peanuts	H	H	M-H	ID-L	M
	Cotton	H	H	M	ID-L	M
	Soybeans	H	H	M	ID	M
10B	Citrus	M	M	M	ID-L	M
	Potatoes	ID	H	M	ID	M
	Cotton	M	M-H	L-M	ID-L	M
	Soybeans	M	M-H	L-M	ID	M
	Peanuts	H	M-H	M	ID-L	M
11	Cotton	H	H	M	ID	M
	Citrus	H	H	H	H	H
	Potatoes	H	H	M-H	ID-L	M
	Peanuts	H	H	M-H	ID	H
	Soybeans	H	H	L-M	ID	M

H: high concern, M: medium concern, L: low concern, ID: insufficient data

MAP II-4
FINAL RESULTS OF ALDICARB INTEGRATED ASSESSMENT



Region 1 Western Mountain Ranges
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4 Colorado Plateau and Wyoming Basin
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7 Glaciated Central
8 Piedmont and Blue Ridge
9 Northeast and Superior Uplands
10 Atlantic (10A) and Gulf Coastal (10B) Plain
11 Southeast Coastal Plain

H M L

2) Use and Usage

The second parameter considered the use rates and/or total amount of aldicarb applied in a county. The Agency assumed that the greater the rate of application or amount of pesticide used, the greater the amount which is available to leach to ground water.

The Agency classified each county's **Use/Usage** ranking by first reviewing each county's top three crops, then selecting the crop with the highest application rate, and finally classifying each county based on the crop with the highest application rate. The Agency has obtained crop ranking data from the registrant which qualitatively describes the primary, secondary and tertiary aldicarb use crops in each county. The current application rate for aldicarb ranges from 1 to 10 lbs. a.i./A. The Agency ranked aldicarb application rates into three categories: **low** (<1 lb. a.i./A), **medium** (2-5 lbs. a.i./A) and **high** (>5 lbs. a.i./A).

The Agency recognizes the potential disadvantages of such a design (e.g., a county's top three crops may have low use rates, but an unidentified 4th top crop may have a high application rate.) The Agency believes, though, that by taking into account the usage rate (lbs. a.i./county/yr) the likelihood of missing a high use county is reduced. The current poundage data base, supplied by the registrant, compiles county level usage data from 1979 through 1983. The Agency classified aldicarb county usage rates into the following two categories: **low** (<25,000 lbs. a.i./county/yr.) and **high** (>25,000 lbs. a.i./county/yr.).

The Agency classified a county's final **Use/Usage** ranking by using the higher of the application rate ranking and total county usage data to classify a county as **Low**, **Medium** or **High**. For example, counties with low application rates and high annual usage and counties with high application rates and low annual usage would both be rated as high. The rating system's upward bias reflects the Agency's concern for exposures to contaminated ground water.

The Agency recognizes that this method of evaluating loadings may classify certain counties as High when there is, in fact, very little exposure (e.g., 200 pounds used annualy at an application rate of 10 lbs. a.i./A.). The Agency may, in these counties, modify its final assessment and would be reviewed on a case-by-case basis.

In order to avoid instances where a county's usage is rated lower than it should be because of gaps in the Agency's use data base, the Agency will also consider usage data in assigning a final aldicarb use rating for a county for the use/usage criteria. The current poundage data base, confidential information supplied by the registrant, compiles county level usage data from 1979 through 1983.

3) Monitoring Data Assessment

The ground water assessment by Heath Region section discusses in detail the many data which are available to the Agency regarding the absence or presence of aldicarb in ground water and/or drinking water. The county assessment utilizes these same data in much the same manner as they were used in that assessment.

Although there are more monitoring data for aldicarb than for any other pesticide, many areas still lack adequate data. This deficiency is even more evident in the county assessment than in the Heath Region assessment due to the difference in the geographic unit being evaluated.

Monitoring data for a particular county are evaluated and assigned a rating of pattern positive, limited positive, or none/negative. In general, a pattern positive rating will be assigned in those instances where there are a large number of samples and a significant percentage of positive detections. Detections of aldicarb in any county above the Health Advisory (HA) for aldicarb (10 ppb) will serve to flag that county for consideration of a pattern positive rating. However, while performing the monitoring data assessment, levels above or below the HA will not solely influence the designation assigned to a county.

Designation of a pattern positive for a county requires a "weight-of-evidence" assessment of available monitoring data. As with the Heath Region approach, these monitoring data were examined with a specific focus on: 1) whether the data are representative of the quality of the first encountered potable aquifer in the vicinity of the aldicarb use sites, and 2) how extensive the data are.

Ranging from most representative to least representative of the different monitoring data available to the Agency, the first criterion leads to the following general guidelines.: 1) research or similar field site monitoring near fields of aldicarb use, 2) U.S. Geologic Survey or similar area-wide water quality monitoring (within 500 feet of the treated field), 3) private drinking water well data (within 500 feet of treated fields), 4) private drinking water wells not near the treated field, 5) on site irrigation wells, and 5) community or public drinking water wells (greater than 100 feet deep and far from the treated fields).

The second criterion (extensiveness of sampling) refers to the total number of samples required in order for the data to definitively show a pattern of positive results. Clearly, the more sampling available, the better. Also, a fewer number of samples would be needed for a definitive conclusion if the samples originate from the most representative monitoring (field site testing) than samples from wells less representative of the impacted aquifer. As few as 20 samples from a carefully designed research field site could be sufficient for a county-wide judgement, if it can be shown that the field site is representative of aldicarb use sites in that county. If the monitoring data originates from within 500 feet of a use site, it is presumed that at least 50 samples are required in order to justify a pattern positive rating.

Assuming a sufficient data set exists in the county, a final judgement on pattern positive is dependent only on a percentage of positive hits. The monitoring data available indicated a rate from 5 to over 50 percent positives with the lower percentages for drinking water surveys and the higher rates for research or other aquifer characterization studies. On that basis, a general guideline followed for pattern positive is at least a 5 percent positive rate for sufficient drinking water data, and at least a 10 to 20 percent positive rate for research-oriented monitoring.A limited positive rating is assigned whenever there is a positive finding. This rating may be upgraded to pattern positive depending on the outcome of the assessment. In general, a limited positive rating would be assigned when there is only a small number of samples available, regardless of the concentration detected. Finally, a limited positive rating is assigned if a small percentage of samples are positive with the highest level of detection near and not significantly different from the HA.

The third rating which can be assigned is none/negative. Such rating would be assigned for a county in which no monitoring data are available or where monitoring has occurred but the study is considered inadequate. Additionally, the Agency has decided to assign this rating in those instances where monitoring has been conducted but aldicarb has not been detected. This decision is based on the difficulty in concluding that aldicarb will not leach in a particular county and to reduce resources necessary to conduct this evaluation.

4) Results of Integrated Ground Water Assessment by County

Given that the county ground water assessment involves three criteria, each of which involves three different ratings, there are 27 possible rating combinations. The Agency believes that it can use these various rating combinations in order to predict the likelihood of ground water contamination by aldicarb within a county.

Each of the above three parameters would be qualitatively rated for a particular county. This approach was used to evaluate each of the 27 rating combinations as either being classified as having a **high**, **medium** or **low** potential to contaminate ground water, and can be defined as follows:

Low - Counties which have a low potential for aldicarb to leach to ground water.

Medium - Counties where there exists a moderate potential for aldicarb to reach ground water due to many possible factors such as moderate hydrogeologic vulnerability, agronomic practices, or geographic variability. Additional monitoring data from these counties could elevate some of them to the High category or conversely, could alleviate concern and place them in the Low category.

High - Counties where the weight-of-evidence indicates that aldicarb has a high probability to leach to ground water. Additionally, a county will be placed in the High category if there is a pattern of positive aldicarb residues associated with the county.

The assignment of one of these three classes to each of the 27 combinations is presented in Table II-7. As in the Heath Region assessment, the Agency believes that the weight-of-evidence approach and corresponding qualitative leaching potential ratings provide a rational basis for depicting ground water vulnerability to aldicarb contamination.

The Agency has not performed a county ground water assessment for all counties. However, the assessment has been performed for counties in four states (California, Florida, North Carolina, and Wisconsin). The results of these assessments are summarized in the following Table II-8.

Table II-7

COUNTY ASSIGNMENTS

Vul.	Use/Usage	Monitoring	Potential To Leach
High	High	Pattern Positive	High
High	High	Limited Positive	High
High	High	None/Negative	High
High	Medium	Pattern Positive	High
High	Medium	Limited Positive	Medium
High	Medium	None/Negative	Medium
High	Low	Pattern Positive	High
High	Low	Limited Positive	Medium
High	Low	None/Negative	Medium
Medium	High	Pattern Positive	High
Medium	High	Limited Positive	Medium
Medium	High	None/Negative	Medium
Medium	Medium	Pattern Positive	High
Medium	Medium	Limited Positive	Medium
Medium	Medium	None/Negative	Medium
Medium	Low	Pattern Positive	High
Medium	Low	Limited Positive	Medium
Medium	Low	None/Negative	Medium
Low	High	Pattern Positive	High
Low	High	Limited Positive	Medium
Low	High	None/Negative	Medium
Low	Medium	Pattern Positive	High
Low	Medium	Limited Positive	Medium
Low	Medium	None/Negative	Low
Low	Low	Pattern Positive	High
Low	Low	Limited Positive	Medium
Low	Low	None/Negative	Low

TABLE II-8
FINAL RESULTS OF COUNTY ASSESSMENT

County	Vul.	Use/Usage	Monitoring	Leaching Potential H	M	L
CALIFORNIA						
Kings	H	H	none/neg	X		
Merced	H	H	none/neg	X		
Colusia	H	M	none/neg		X	
Glenn	H	M	none/neg		X	
Sacramento	H	M	none/neg		X	
San Joaquin	H	M	none/neg		X	
Solano	H	M	none/neg		X	
Yolo	H	M	none/neg		X	
Sutter	H	L	none/neg		X	
Fresno	M	H	none/neg		X	
Kern	M	H	none/neg		X	
Los Angeles	M	H	none/neg		X	
Madera	M	H	none/neg		X	
Orange	M	H	none/neg		X	
Riverside	M	H	none/neg		X	
Santa Barbara	M	H	none/neg		X	
Tulare	M	H	none/neg		X	
Ventura	M	H	none/neg		X	
Imperial	M	M	none/neg		X	
Monterey	M	M	none/neg		X	
Nevada	M	M	none/neg		X	
San Luis Obispo	M	M	none/neg		X	
Alameda	M	L	none/neg		X	
Butte	M	L	none/neg		X	
Contra Costa	M	L	none/neg		X	
Del Norte	M	L	pattern positive		X	
Humbolt	M	L	none/neg		X	
Inyo	M	L	none/neg		X	
Lake	M	L	none/neg		X	
Marrin	M	L	none/neg		X	
Mendocino	M	L	none/neg		X	
Modoc	M	L	none/neg		X	
Mono	M	L	none/neg		X	
Napa	M	L	none/neg		X	
Plumas	M	L	none/neg		X	
San Benito	M	L	none/neg		X	
San Bernardino	M	L	none/neg		X	
San Francisco	M	L	none/neg		X	
San Mateo	M	L	none/neg		X	

Table II-8 (cont'd).

County	Vul.	Use/Usage	Monitoring	Leaching Potential H	M	L
CALIFORNIA (cont'd)						
Santa Clara	M	H	none/neg		X	
Siskiyou	M	L	none/neg		X	
Sonoma	M	L	none/neg		X	
Stanislaus	M	L	none/neg		X	
Tehema	M	L	none/neg		X	
Yuba	M	L	none/neg		X	
Santa Cruz	L	H	none/neg		X	
San Diego	L	H	none/neg		X	
Alpine	L	L	none/neg			X
Amador	L	L	none/neg			X
Calaveras	L	L	none/neg			X
El Dorado	L	L	none/neg			X
Lassen	L	L	none/neg			X
Mariposa	L	L	none/neg			X
Placer	L	L	none/neg			X
Shasta	L	L	none/neg			X
Sierra	L	L	none/neg			X
Trinity	L	L	none/neg			X
Tuolumne	L	L	none/neg			X
WISCONSIN						
Adams	H	M	pattern positive		X	
Barron	H	M	pattern positive		X	
Florence	H	M	none/neg		X	
Langlade	H	M	pattern positive		X	
Lincoln	H	M	none/neg		X	
Marathon	H	M	pattern positive		X	
Marquette	H	M	none/neg		X	
Oneida	H	M	none/neg		X	
Portage	H	M	pattern positive		X	
Racine	H	M	none/neg		X	
Shawano	H	M	none/neg		X	
Waupaca	H	M	limited positive			X
Waushara	H	M	pattern positive		X	
Ashland	H	L	none/neg		X	
Bayfield	H	L	none/neg		X	
Burnett	H	L	none/neg		X	
Chippewa	H	L	none/neg		X	
Douglas	H	L	none/neg		X	
Forest	H	L	none/neg		X	
Iron	H	L	none/neg		X	

Table II-8 (cont'd).

County	Vul.	Use/Usage	Monitoring	Leaching Potential H	M	L
WISCONSIN (cont'd)						
Juneau	H	L	pattern positive	X		
Marinette	H	L	none/neg	X		
Menominee	H	L	none/neg	X		
Oconto	H	L	none/neg	X		
Polk	H	L	none/neg	X		
Price	H	L	none/neg	X		
Rusk	H	L	none/neg	X		
Sawyer	H	L	none/neg	X		
Taylor	H	L	none/neg	X		
Vilas	H	L	none/neg	X		
Washburn	H	L	none/neg	X		
Wood	H	L	limited positive		X	
Milwaukee	M	H	none/neg	X		
Columbia	M	M	none/neg	X		
Dodge	M	M	none/neg	X		
Jefferson	M	M	limited positive		X	
Kenosha	M	M	none/neg	X		
Walworth	M	M	limited positive		X	
Brown	M	L	none/neg	X		
Calumet	M	L	none/neg	X		
Clark	M	L	none/neg	X		
Dane	M	L	none/neg	X		
Door	M	L	none/neg	X		
Dunn	M	L	none/neg	X		
Eau Claire	M	L	none/neg	X		
Fond Du Lac	M	L	none/neg	X		
Green Lake	M	L	none/neg	X		
Kewaunee	M	L	none/neg	X		
Manitowoc	M	L	none/neg	X		
Monroe	M	L	none/neg	X		
Outgamie	M	L	none/neg	X		
Ozaukee	M	L	none/neg	X		
Pepin	M	L	none/neg	X		
Rock	M	L	none/neg	X		
St. Croix	M	L	none/neg	X		
Sheboygan	M	L	none/neg	X		
Washington	M	L	none/neg	X		
Waukesha	M	L	limited positive		X	
Winnebago	M	L	none/neg	X		
Sauk	L	M	limited positive		X	

Table II-8 (cont'd).

County	Vul.	Use/Usage	Monitoring	Leaching Potential H	M	L
WISCONSIN (cont'd)						
Buffalo	L	L	none/neg		X	
Crawford	L	L	none/neg		X	
Grant	L	L	pattern positive	X		
Green	L	L	none/neg		X	
Iowa	L	L	none/neg		X	
Jackson	L	L	none/neg		X	
La Crosse	L	L	none/neg		X	
Lafayette	L	L	none/neg		X	
Pierce	L	L	none/neg		X	
Richland	L	L	none/neg		X	
Trempealeau	L	L	none/neg		X	
Vernon	L	L	none/neg		X	
NORTH CAROLINA						
Beaufort	H	M	none/neg		X	
Bertie	H	M	none/neg		X	
Bladen	H	M	none/neg		X	
Camden	H	M	none/neg		X	
Carteret	H	M	none/neg		X	
Chowan	H	M	none/neg		X	
Columbus	H	M	none/neg		X	
Craven	H	M	none/neg		X	
Currituck	H	M	none/neg		X	
Duplin	H	M	none/neg		X	
Edgecombe	H	M	none/neg		X	
Gates	H	M	none/neg		X	
Greene	H	M	none/neg		X	
Halifax	H	M	limited positive		X	
Hertford	H	M	none/neg		X	
Johnston	H	M	none/neg		X	
Jones	H	M	none/neg		X	
Martin	H	M	none/neg		X	
Northampton	H	M	limited positive		X	
Pamlico	H	M	none/neg		X	
Pitt	H	M	none/neg		X	
Sampson	H	M	none/neg		X	
Tyrrell	H	M	none/neg		X	
Washington	H	M	none/neg		X	
Wayne	H	M	none/neg		X	
Wilson	H	M	none/neg		X	
Alleghany	H	L	none/neg		X	
Avery	H	L	none/neg		X	
Brunswick	H	L	none/neg		X	
Buncombe	H	L	none/neg		X	

Table II-8 (cont'd).

County	Vul.	Use/Usage	Monitoring	Leaching Potential H	M	L
NORTH CAROLINA (cont'd)						
Cherokee	H	L	none/neg		X	
Dare	H	L	none/neg		X	
Hawood	H	L	none/neg		X	
Henderson	H	L	none/neg		X	
Hyde	H	L	none/neg		X	
Jackson	H	L	none/neg		X	
Lee	H	L	none/neg		X	
Macon	H	L	none/neg		X	
Madison	H	L	none/neg		X	
Mitchell	H	L	none/neg		X	
Moore	H	L	none/neg		X	
New Hanover	H	L	none/neg		X	
Onslow	H	L	none/neg		X	
Pender	H	L	none/neg		X	
Perquimans	H	L	none/neg		X	
Richmond	H	L	none/neg		X	
Swain	H	L	none/neg		X	
Transylvania	H	L	none/neg		X	
Watauga	H	L	none/neg		X	
Wilkes	H	L	none/neg		X	
Yancey	H	L	none/neg		X	
Clay	H	M	none/neg		X	
Cumberland	H	M	none/neg		X	
Harnett	H	M	none/neg		X	
Hoke	H	M	none/neg		X	
Lenoir	H	M	none/neg		X	
Nash	H	M	none/neg		X	
Pasquotank	H	M	none/neg		X	
Robeson	H	M	none/neg		X	
Scotland	H	M	limited positive		X	
Almance	M	M	none/neg		X	
Forsyth	M	M	none/neg		X	
Franklin	M	M	none/neg		X	
Granville	M	M	none/neg		X	
Guilford	M	M	none/neg		X	
Person	M	M	none/neg		X	
Rockingham	M	M	none/neg		X	
Stokes	M	M	none/neg		X	
Surry	M	M	none/neg		X	
Vance	M	M	none/neg		X	
Wake	M	M	none/neg		X	
Warren	M	M	none/neg		X	
Yadkin	M	M	none/neg		X	
Alexander	M	L	none/neg		X	

Table II-8 (cont'd).

County	Vul.	Use/Usage	Monitoring	Leaching Potential H	M	L
NORTH CAROLINA (cont'd)						
Anson	M	L	none/neg		X	
Ashe	M	L	none/neg		X	
Burke	M	L	none/neg		X	
Cabarrus	M	L	none/neg		X	
Caldwell	M	L	none/neg		X	
Caswell	M	L	none/neg		X	
Carawba	M	L	none/neg		X	
Chatham	M	L	none/neg		X	
Cleveland	M	L	none/neg		X	
Davidson	M	L	none/neg		X	
Davie	M	L	none/neg		X	
Durham	M	L	none/neg		X	
Gaston	M	L	none/neg		X	
Graham	M	L	none/neg		X	
Iredell	M	L	none/neg		X	
Lincoln	M	L	none/neg		X	
Mcdowell	M	L	none/neg		X	
Mecklenburg	M	L	none/neg		X	
Montgomery	M	L	none/neg		X	
Orange	M	L	none/neg		X	
Polk	M	L	none/neg		X	
Randolph	M	L	none/neg		X	
Rowan	M	L	none/neg		X	
Rutherford	M	L	none/neg		X	
Stanley	M	L	none/neg		X	
Union	M	L	none/neg		X	
FLORIDA						
Brevard	H	H	none/neg	X		
Broward	H	H	none/neg	X		
Collier	H	H	none/neg	X		
Dade	H	H	none/neg	X		
De Soto	H	H	none/neg	X		
Glades	H	H	none/neg	X		
Hardee	H	H	none/neg	X		
Hendry	H	H	none/neg	X		
Highlands	H	H	pattern positive	X		
Hillsborough	H	H	pattern positive	X		
Indian River	H	H	none/neg	X		
Lake	H	H	none/neg	X		
Manatee	H	H	none/neg	X		
Marion	H	H	none/neg	X		
Martin	H	H	none/neg	X		
Okeechobee	H	H	none/neg	X		
Orange	H	H	limited positive	X		

Table II-8 (cont'd).

County	Vul.	Use/Usage	Monitoring	Leaching Potential H	M	L
FLORIDA (cont'd)						
Osceola	H	H	none/neg	X		
Palm Beach	H	H	none/neg	X		
Pasco	H	H	none/neg	X		
Polk	H	H	pattern positive	X		
Sarasota	H	H	none/neg	X		
Seminole	H	H	none/neg	X		
St. Johns	H	H	none/neg	X		
St. Lucie	H	H	none/neg	X		
Volusia	H	H	pattern positive	X		
Alachua	H	M	none/neg		X	
Flagler	H	M	none/neg		X	
Monroe	H	M	none/neg		X	
Putnam	H	M	none/neg		X	
Baker	H	L	none/neg		X	
Bay	H	L	none/neg		X	
Bradford	H	L	none/neg		X	
Calhoun	H	L	none/neg		X	
Charlotte	H	L	none/neg		X	
Citrus	H	L	none/neg		X	
Clay	H	L	none/neg		X	
Columbia	H	L	none/neg		X	
Dixie	H	L	none/neg		X	
Duval	H	L	none/neg		X	
Escambia	H	L	none/neg		X	
Franklin	H	L	none/neg		X	
Gadsden	H	L	none/neg		X	
Gilchrist	H	L	none/neg		X	
Gulf	H	L	none/neg		X	
Hamilton	H	L	none/neg		X	
Hernando	H	L	none/neg		X	
Holmes	H	L	none/neg		X	
Jackson	H	L	none/neg		X	
Jefferson	H	L	none/neg		X	
Lafayette	H	L	none/neg		X	
Lee	H	L	none/neg		X	
Leon	H	L	none/neg		X	
Levy	H	L	none/neg		X	
Liberty	H	L	none/neg		X	
Madison	H	L	none/neg		X	
Nassau	H	L	none/neg		X	
Okaloosa	H	L	none/neg		X	
Pinellas	H	L	none/neg		X	
Santa Rosa	H	L	none/neg		X	
Sumter	H	L	none/neg		X	

Table II-8 (cont'd).

County	Vul.	Use/Usage	Monitoring	Leaching Potential H	M	L
FLORIDA (cont'd)						
Suwannee	H	L	none/neg		X	
Taylor	H	L	none/neg		X	
Union	H	L	none/neg		X	
Wakulla	H	L	none/neg		X	
Walton	H	L	none/neg		X	
Washington	H	L	none/neg		X	

C. ANALYSIS OF PUBLIC COMMENTS

All public comments submitted in response to Position Document 1 (PD 1) published by the Agency in the Federal Register on July 11, 1984 (49 FR 28320) were reviewed. A listing of 245 respondents are contained in the public docket and appear in Appendix I of this document. Comments on risk are discussed below. Comments on benefits are reflected in Chapter III.

Respondent Number 7

Mr. Curtis Mason, Extension Pesticide Coordinator of the Arkansas Cooperative Extension Service, indicated that the potential for aldicarb to contaminate wells in his state is slight because "... Most of our wells in Arkansas are deep wells with impervious layers between the aquifer and the surface...".

Agency Response

The Agency has not performed any specific analysis of the conditions in Arkansas. The Agency is appreciative of Mr. Mason's comments, and will maintain them on file should a review of Arkansas' hydrogeologic conditions be necessary in the future.

Respondent Number 33

Mr. Louis Steflik, president of Steflik Farms in Bunnell, Florida, notes that a layer of hardpan clay lies three feet below the soil surface. He states that this clay layer limits downward movement of water into the water table. He further states that tests by both the registrant and the Florida Department of Agriculture have failed to detect aldicarb residues in shallow wells.

Agency Response

The Agency agrees that the presence of a clay lens limits downward movement of aldicarb into the water table. The Agency also notes that the conditions on Mr. Steflik's farm are not uncommon in Florida. However, the following is also true for Florida conditions.

1) The clay hardpan lens common to Florida is not strictly continuous in nature, that is, there are cracks and channels through which water and pesticide residues can leach to further depths (these channels are natural or man-made - drilling of wells creates channels).

2) The seemingly continuous clay lenses have distinct endpoints where recharge occurs.

3) Significant areas in Florida do not have this restrictive clay lens and recharge to major water-bearing aquifers is direct.

4) The hydrogeologic conditions of Florida (sandy soil and heavy rainfall) virtually guarantee that residues will leach to the top of the clay lens and travel horizontally off the field site.

The Florida Department of Agriculture and Consumer Services (DACS) has recently embarked on a rural well testing program. In this program, they are specifically targeting drinking water wells near aldicarb-treated fields (the current Florida law requires users to file a "notice of intent to use" aldicarb - which is how the Agriculture Department locates target wells). Testing has occurred since 1984, and as of May, 1987, approximately 950 samples in 11 high use counties have been analyzed for aldicarb and its metabolites (there is approximately a one-to-one correspondence between number of wells and number of samples - there are more samples than wells since some samples are second and third tests of the same wells). Thus far, six wells in four counties have shown positive results, with a high of 27 ppb aldicarb.

The Florida Department of Health and Rehabilitative Services has also been conducting monitoring of drinking water wells. They sampled approximately 50 private drinking water wells per county, and their program is scheduled to continue through 1990. Their objective is to get a representative sample from the aquifer most often tapped for drinking water. As such, they have not targeted agricultural field sites, and are not concentrating on any specific pesticides. As of May, 1987, 308 wells in seven counties have been sampled with no positive findings of aldicarb.

However, the Florida Department of Environmental Regulation (DER) has been conducting comprehensive testing of specific field sites, with assistance from the registrant. Most notable in these field sites is the Lake Hamilton site, discussed earlier in the ground water assessment. In this field site, a single 10 lb/A treatment in 1983 resulted in several residue readings above 500 ppb aldicarb in the ground water beneath the field (located approximately 15 feet deep), with one reading above 1,000 ppb. Several readings in the 50-60 ppb range were 400 feet from the edge of the field. Field site testing in another site showed positives in 65 percent of the 80 samples taken in 1987. The 80 samples were taken from 25 wells equally spaced between 500 and 1,000 feet from the field edge (not all wells sampled on all four dates). These wells tapped between five and 20 feet into the shallow surficial aquifer. Of these 80 samples, 52 were positive, with 39 samples above 10 ppb, and a mean positive of 57 ppb. High readings of 416 and 276 ppb were noted at 800 and 900 feet, respectively (Jones, 1987).

The difference between DER and DACS's testing is that DER's testing involves "research-oriented" wells, which are drilled to near the top of the water table, whereas DACS is testing existing drinking water wells, which are almost always in deeper, more protected portions of aquifers.

Respondent Number 66

Mr. Robert M. Rakich, president of the Arizona Agricultural Chemicals Association, states that the likelihood of well contamination by aldicarb (which is used primarily for cotton in Arizona) is slight for the following reasons: 1) drip irrigation is becoming more prevalent due to rising water costs and its greater efficiency compared to other methods of irrigation, 2) 90 to 95 percent of all well water used for irrigation is extracted from wells which are 100 to 450 feet deep, and, assuming properly set well casings and proper back flushing valves, these wells themselves stand little chance of contamination, and 3) the soil pH and temperature is high, environmental conditions conducive to aldicarb degradation.

Agency Response

The Agency agrees with Mr. Rakich, and has evaluated the use of aldicarb on cotton in Arizona to have a "low" probability of leaching into ground water. The Agency's evaluation was based on hydrogeologic conditions. Mr. Rakich is also correct in noting that drip irrigation significantly reduces the leaching of pesticides in comparison to other, less efficient, means of irrigation.

Respondent Number 67

Mr. R.S. Edsall, president of Edsall Grove Service, Inc., in Vero Beach, Florida, recommends that the Agency adopt Florida's regulation that aldicarb not be used within 1,000 feet of a drinking water well, plus continual close monitoring of wells.

Agency Response

The Agency agrees with Mr. Edsall that close monitoring of potentially impacted wells is critical to their continued safe use for drinking purposes.

Respondent Number 97

Dr. Roger Boron, president of Agricultural Chemical Testing in McAllen, Texas, has commented on the topsoil characteristics of Hidalgo, Willacy and Cameron counties in the Lower Rio Grande Valley of Texas. Dr. Boron states that, "Permeability of our cropland is classed as slow, moderately slow or moderate. This means that water moves in saturated soil at rates of 0.06 to 0.2, 0.2 to 0.6, or 0.6 to 2.0 inches per hour." He also states, "We have a few sandy areas in which permeability is classed as rapid, 6.0 to 20.0 inches per hour, but these spots are too droughty for cropping and are used only for rangeland."

Agency Response

The Agency is in general agreement with Dr. Boron's conclusions concerning topsoil and the probability that aldicarb will not leach to ground water in the Lower Rio Grande Valley. The Agency also notes that there are some areas with soils of high permeability, but disagrees with Dr. Boron that these soils would only support rangeland. Specifically, there is significant acreage of farmland in Brooks, Kennedy, and Jim Hogg counties in an area above the Rio Grande Valley known as the Rio Grande Plain which is dominated by soils which are prone to leaching. Examples of "soil series" (lowest classification of soils according to soil taxonomy) typical of this area and the crops for which these soils are suited include: Sariata (6.0-20.0 in/hr permeability) - watermelon, peanuts, and pasture, and Fulfurrias (6.0-20.0 in/hr) - pasture alone.

Respondent Number 98

The Natural Resources Defense Council (NRDC) presented a number of comments pertinent to the aldicarb Special Review. The following are the Agency's review of these comments.

Comment 1 (Pg 1)

The NRDC urges the Agency to carefully consider the precedent of the Agency's review of ground water contamination from aldicarb relative to contamination of ground water by other pesticides.

Agency Response

The Agency has considered the implications of the aldicarb Special Review relative to ground water contamination by alternative pesticides. The Agency's efforts in this area are discussed in Chapter IV. The reader is referred to that chapter for a thorough discussion of this subject.

Comment 2 (Pg 2)

The NRDC recommended that the Agency change aldicarb labeling to include restrictions on aldicarb use based on soil type and other environmental conditions which affect leaching and decay of aldicarb.

Agency Response

The Agency has considered a wide range of regulatory options, including the above recommended use restrictions. The reader is referred to Chapter IV for analysis of this option.

Comment 3 (Pg 3)

The NRDC comments that past analyses did not consider exposure via bathing in contaminated water and inhalation of tobacco treated with aldicarb.

Agency Response

The Agency has not included these exposures in its risk analysis because they represent a minute amount of exposure due to the small amount of aldicarb residues in water used for bathing, the percent absorption through the skin, the small percent of tobacco crop treated, the mixing/curing of tobacco, and the lack of a tolerance for this sec. 24(c) FIFRA use.

Comment 4 (Pg 3)

The NRDC comments that non-dietary sources of exposure should be considered in the Special Review as well as dietary sources of exposure.

Agency Response

The Agency considered applicator exposure initially in the Special Review but believes that the exposure to applicators and workers is expected to be minimal given the label statements requiring the use of boots in treated fields (e.g., during field irrigation) and the use of gloves in greenhouses while handling plants. These label statements are sufficient to reduce worker exposure and were required in the Registration Standard issued in 1984.

Comment 5 (Pg 3)

The NRDC stated that it was difficult to comment on the appropriateness of the ADI and requested that the Agency provide a fuller description of the different ADI's for aldicarb.

Agency Response

The Agency's Office of Drinking Water (ODW) has selected an ADI of 0.001 mg/kg/day for aldicarb. This ADI is derived from the NOEL of 0.12 mg/kg/day, in a six month rat feeding study with aldicarb sulfoxide and use of an Uncertainty Factor of 100. ODW determined that use of this Uncertainty Factor was appropriate for aldicarb because aldicarb's extremely steep dose-response curve, high acute toxicity and possibility of concurrent exposure to other acetylcholinesterase (ChE) inhibitors in the diet may lead to ChE inhibition. The Agency's Office of Pesticide Programs (OPP) has endorsed ODW's ADI for aldicarb.

However, as previously discussed, OPP believes that an acute dietary analysis is the most appropriate way to assess the dietary risks of aldicarb. Thus, OPP conducted its analysis for dietary exposure to aldicarb using a reference dose from the extrapolated NOEL for acute human ChE inhibition, and a ten-fold uncertainty factor. A reference dose of 0.001 mg/kg was used.

Comment 6 (Pg 4)

The NRDC is concerned that low level exposure to aldicarb residues may cause subtle neurologic disorders in humans. They cite findings from a 1982 Suffolk County, NY study suggesting an incidence of neurological disorders among residents consuming water contaminated with high concentrations of aldicarb. Additionally, the NRDC questions whether prenatal and/or perinatal exposure to aldicarb will impair neurological or behavioral development.

Agency Response

The Agency's review of epidemiologic studies has not identified an association between low level aldicarb exposure and neurologic disorders. Review and evaluation of the 1982 Suffolk County study by epidemiologists both within and outside the Agency failed to substantiate the claims in that report. Although monitoring data show that persons have been exposed to levels of aldicarb resulting in clinical signs of ChE inhibition, there is no indication from these data or from extensive studies in several laboratory animal species that aldicarb affects neurological or behavioral development at such low levels.

Comment 7 (Pg 4)

The NRDC stated that it is concerned about reaction of aldicarb with nitrates to form nitrosamines. In some areas, nitrates are a common contaminant in ground water. Nitrosamines are a class of chemical, many of which have shown oncogenicity in laboratory animals.

Agency Response

The Agency is unaware of any evidence which suggests that aldicarb and nitrates react to form nitrosamines under normal environmental conditions. The Agency would appreciate the opportunity to review any evidence that the NRDC might have to support such a concern.

Comment 8 (Pg 5)

The NRDC commented that most toxicology studies forming the data base for aldicarb were conducted prior to 1974. NRDC requested that the Agency consider whether the quality of these studies is consistent with the October 1982 Agency Guidelines.

Agency Response

The Agency reviewed all available toxicologic data during the Registration Standard process. The Agency cited all data that meet current Agency guideline requirements. Toxicologic data currently supporting the aldicarb data base, except as noted in the Registration Standard, are sufficient to conform with Agency guidelines. Several studies supporting the registration of aldicarb have been conducted in the late 1970's and as recent as 1987.

Comment 9 (Pg 5)

The NRDC encouraged the Agency to consider the inclusion of an ongoing study on the environmental fate and health impacts of aldicarb use on Florida citrus in the next Special Review document.

Agency Response

The Agency has received information on several joint studies on citrus, ferneries, and potatoes being conducted by the registrant in conjunction with the Florida Department of Environmental Regulation. Summaries of these studies are included earlier in this chapter.

Comment 10 (Pg 6)

The NRDC asked the Agency to take no action on the pending registration of aldoxycarb, an aldicarb metabolite. It also asked that the Agency grant no new uses of aldicarb.

Agency Response

The Agency granted a registration for aldoxycarb, but only for use in containerized plantings, because it believes that this use will probably not cause ground water contamination. Leaching studies for aldoxycarb are currently underway. The Agency has granted no registrations for new uses of aldicarb. However, NRDC should be aware of the significant difference between the toxicities of aldicarb and aldoxycarb, and furthermore, that aldicarb degrades naturally to the less toxic aldoxycarb, but not vice versa.

Respondent Number 125

Mr. John Bolduc, with the Conservation Law Foundation of New England, Inc., had three comments.

Comment 1 (Pg 1)

Mr. Bolduc requested that the Agency provide a brief summary of the fate and transport characteristics of pesticides which are alternatives to aldicarb, as well as a brief summary of toxicity characteristics of the alternatives.

Agency Response

The Agency has provided a brief summary of the environmental fate, toxicology and ecological effects of aldicarb and its major alternatives in this Technical Support Document, in Chapter IV.

Comment 2 (Pg 1)

Mr. Bolduc commented on the use of advisory warnings on labels directing users not to apply aldicarb in areas with well-drained soils. He notes that this type of label statement is difficult to enforce.

Agency Response

In Chapter IV of this document, the various regulatory options are discussed. The requirement for label statements is discussed in that chapter.

Comment 3 (Pg 1)

Lastly, Mr. Bolduc requested a summary of monitoring information for Rhode Island and citations and supporting documentation for monitoring in Connecticut.

Agency Response

A brief summary of this monitoring information can be found in Chapter II. Additional information on monitoring results for Rhode Island can be obtained from: Aldicarb Team Leader, Exposure Assessment Branch, Hazard Evaluation Division, Office of Pesticide Programs (TS-769), EPA, Washington, D.C. 20460. Citations and/or supporting documentation for the findings in Connecticut were not present in either the Federal Register or the Registration Standard. Messrs. Paul Marin (Dept. of Env. Protection, Water Compliance), Greg Piontek (EPA, Connecticut Pesticide Program) and Jim Murphy (Dept. of Env. Protection) were contacted by the Agency. These individuals were unaware of aldicarb findings in Connecticut, and the Agency believes it reasonable to conclude that aldicarb has not been found in Connecticut to date.

Respondent Number 134

Mr. L.O. Nelson (pesticide administrator, Indiana State Chemist and Seed Commissioner) stated that aldicarb infiltration and leaching depends heavily on local geology, climate and agricultural practices. Mr. Nelson states that leaching pesticides are best regulated at the local level.

Agency Response

The Agency agrees with Mr. Nelson's first comment. In reaching its proposed regulatory decision, the Agency took into account numerous ideas provided by state regulatory agencies on the role of local, state, and Federal regulators. In formulating the proposed regulatory decision on aldicarb, the Agency considered regulation at the local level. The reader is referred to Chapter IV for further discussion.

Respondent Number 141

Dr. Jeffrey Wyman, associate professor of entomology at the University of Wisconsin-Madison, submitted detailed comments on efficacy and a technical paper on leaching. The efficacy comments are considered in the benefit analysis. Specifically, the technical paper contained field studies of aldicarb applied to potato crops in Wisconsin and addressed issues concerning leaching potential of aldicarb in Wisconsin. There were two studied field sites and several scenarios examined within those sites including: permutations of application date, rate, and irrigation scheduling. A major conclusion was that aldicarb would not leach in one site with sandy loam soil. "...The mean concentration of aldicarb residues at the Cameron location ... demonstrated that residues did not leach below 1.2 m throughout the 208-day sampling period ..." Conclusions concerning the second site, which had a loamy sand soil, were not as definitive."... At Hancock, no aldicarb residues were detected below 2.4 m following the emergence application under either medium or heavy irrigation schedules ... Small traces of aldicarb residue were detected at the 2.4 to 3.0 m level under both irrigation regimes following the 3.36 kg ai/ha planting application ... Some leaching of aldicarb residues probably occurred below the 3.0 m level in the plots treated at planting and receiving heavy irrigation while leaching below 2.4 m did not occur in the emergence treatments receiving medium ET based irrigation. No conclusions could be drawn about whether leaching occurred below the 3.0 m level in the planting application with medium irrigation or the emergence application with heavy irrigation ...". Leaching was indicated for some of the scenarios tested for the loamy sand at Hancock.

Agency Response

One method to estimate the extent of leaching is to use computer simulation modeling programs. In fact, both these field sites and the leaching data were evaluated with PRZM, as part of a technical paper (Lorber and Offutt, "A Method for the Assessment of Ground Water Contamination Potential Utilizing PRZM - A Pesticide Root Zone Model for the Unsaturated Zone, 1986). In this study, PRZM was calibrated to the field data for the loamy sand and the sandy loam site. Then, the amount of leaching below the depth of sampling in these experimental field sites was estimated by PRZM. Only a minor amount (0.3 percent of applied rate) was estimated to leach below the depth of sampling for the sandy loam site. However, aldicarb was estimated to leach below 3 m for all scenarios at the loamy sand site. For the heavy irrigation scenarios, approximately 25 percent of the applied rate leached below 3 m. For other scenarios, between 3.6 and 8.9 percent of applied aldicarb was simulated to leach below 3 meters. The author concluded, with these and other simulations described in the publication, that aldicarb has the potential to leach in field sites with soil similar to the loamy sand at Hancock, but little potential to leach on soil types similar to the sandy loam soil at Cameron.

Dr. Wyman did not state whether his study supported a conclusion on the leaching potential of aldicarb in Wisconsin soils. Rather, he concluded that, "... The changes in application procedures for Temik, together with effective irrigation management, cultural management techniques and intelligent state regulation and use monitoring, thus significantly reduce the risk portion of any risk/benefit analysis and favor the continued use of this product." The modeling study (Lorber and Offutt, 1986) also supports a conclusion that changes in cultural practice (i.e. application of aldicarb later in the season) would reduce the amount of aldicarb. However, Lorber and Offutt (1986) also concluded that aldicarb has the potential to leach in loamy sand soils similar to the loamy sand of the field site reported in Dr. Wyman's publication, even when improved cultural practices are in effect. The Agency believes that the appropriate direction to take at this point is to determine the extent of loamy sand soils in Wisconsin, the use of aldicarb on these soils, and current monitoring, if any, in these areas.

Respondent Number 144

Dr. D.P. Weingartner, a plant pathologist at the University of Florida, summarized the importance of aldicarb to potato growers in northeast Florida (NEF) and provided detailed summaries and several publications on potato diseases, nematicide options and related aldicarb issues. He states that, "The reasons for regulating aldicarb use due to contamination of well water in some locations do not appear valid in NEF flatwoods area." He also reports on surficial runoff from NEF potato fields. Only these two issues (fate and transport) are considered in this response.

Dr. Weingartner presents an argument as to why it is unlikely that drinking water would become contaminated with aldicarb in NEF due to potato uses. He claims that, "Cultivated flatwood soils are sublayered by a zone of weakly cemented pan to cemented pan." This results in a situation of lateral, rather than vertical, drainage from potato fields. Furthermore, he claimed that artesian flow below the clay lenses do not easily allow intrusion by solutes into the ground water. "There is therefore a greater probability in such a system for contamination of surficial runoff water during heavy rains than ground water beneath the clay."

Agency Response

In general, the Agency agrees with Dr. Weingartner's conclusion that the potato agronomic practices in the potato growing region of Florida results in a moderate potential to leach into ground water and it is not likely to contaminate the drinking water wells located more than 100 feet deep, primarily because of the existence of the clay pan. The Agency notes, however, that the top soil in NEF is sandy, as Dr. Weingartner recognizes, and confirmed by Florida soil maps. Therefore, aldicarb has a high probability of leaching to the cemented clay layer located three to six feet below the soil surface. Dr. Weingartner does not provide information on the extent of this clay layer. His rebuttal states, "... presence of an impervious zone of clay sublayering most NEF fields ...". "Most" has not been defined by the author. Aldicarb contamination of ground water is likely to be a problem to the extent that there is any extraction of surficial water from above the clay lenses, for drinking water or otherwise. The only positive aldicarb sample came from a surficial aquifer beneath a potato field. Further, ground water contamination is also possible under treated fields if the clay layer described by Dr. Weingartner is not present.

In summary, Dr. Weingartner presents a strong argument against the possibility of ground water contamination in NEF from aldicarb use on potatoes. He acknowledges aldicarb's mobility with evidence of surface runoff into the Deep Creek system and concentrations of aldicarb (1.1 ppb) at the inlet to the St. John's River in Florida. Since aldicarb is mobile, it will move with water. Dr. Weingartner shows why it is more likely to move with surface runoff rather than ground water recharge.

Respondent Number 146

Dr. John M. Harkin, Associate Director of the Environmental Toxicology Center, University of Wisconsin, provided a study entitled, "Aldicarb in Groundwater." The submitted study summarizes results of field monitoring of aldicarb used on potatoes over the Central Sands Aquifer. Dr. Harkin acknowledges the inevitability of ground water contamination of the Central Sands Aquifer from aldicarb use, "the contamination of ground water by aldicarb residues has created some minor localized problems in Wisconsin, but these are neither unsurmountable nor permanent."

Dr. Harkin presents a case indicating that aldicarb will contaminate the Central Sands Aquifer when used on potatoes. However, the primary contamination will occur near the surface of the water table and degradation of aldicarb in the ground water will prevent it from contaminating deeper portions of the aquifer. He believes that aldicarb use should continue with the following precautions: 1) all wells in construction should be completed to deep portions of the aquifer, 2) selected wells should continually be monitored, 3) contaminated well water could possibly be handled by consumers of the water by baking soda - "A tiny pinch of baking soda can be added to water before boiling to prepare hot beverages ...The ease of hydrolysis of aldicarb provides a cheap, convenient method of removing it from drinking water ...", 4) careful irrigation practices should be practiced, and 5) studies of aldicarb movement should continue.

Agency Response

The Agency agrees with four of the five conclusions, but does not believe that baking soda is an adequate means to handle contaminated ground water. Dr. Harkin believes that use in Wisconsin should continue, but with proper precautions, assuming that ground water contamination is a price of progress. The Agency believes that there are many similarities between the Central Sands of Wisconsin and Long Island, New York, suggesting that the same regulatory strategy should be carried out in both places. Some of these similarities include:

1. Strong dependence on ground water for drinking water.

2. Shallow water table.

3. Sandy soils overlying the shallow water table.

4. Cool, wet climate which decreases pesticide degradation (cool climate) and the likelihood of transport (wet climate).

5. Dependence on aldicarb in an extensive potato growing region.

Respondent Number 157

Mr. James Graham (Commissioner, Department of Agriculture, North Carolina) supports continued use of aldicarb on tobacco and ornamentals in North Carolina. He summarized the registrant's data in North Carolina, which includes the results of monitoring of 23 wells in Northampton and Halifax counties in 1980 and 1981. Although the total number of samples was not given, only two samples were positive, one sample showing 1 ppb and another showing 2 ppb. In addition, he submitted data from the North Carolina Department of Agriculture (NCDA) which sampled wells in Cumberland, Edgecombe, Gates, Halifax, Martin, Northampton, Pitt and Scotland Counties in 1983. Seven samples from 104 wells were positive, with two samples from Scotland County containing 28.2 and 27.6 ppb aldicarb and three containing 2 ppb. Three samples from Halifax County contained trace levels of aldicarb, estimated at less than 1.5 ppb. All wells sampled by NCDA were verified to be less than 600 feet from fields using aldicarb.

Mr. Graham recommends that, "... future registration of aldicarb or any other water soluble mobile pesticides be conditioned upon the establishment of a structured monitoring program developed and supervised by the Agency. Further, we recommend that, at registration, it establish maximum allowable levels for any pesticide likely to impact ground water so that such monitoring could have a meaningful impact."

Agency Response

The data submitted by Mr. Graham were considered in the development of the ground water vulnerability assessment. Aldicarb has a Health Advisory Level (HA) of 10 ppb.

Respondent Number 180

Mr. Thomas J. Dawson, Public Intervenor with the Wisconsin Department of Justice, submitted extensive comments detailing his efforts on aldicarb dating back to 1981. His submission contains eight appendices and concludes that § Ag 29.17 Wis. Adm. Code, governing the present use of aldicarb, is a failure.

Section Ag 29.17 Wis. Adm. Code which was adopted in 1982, imposes restrictions on continuing aldicarb use, rather than a State-wide moratorium, to "prevent aldicarb residues in ground water from reaching a level exceeding 10 ppb" and to "afford an opportunity for groundwater quality recovery." Further, the rule is based on the requirement that "adequate monitoring and testing of groundwater supplies would be done, intensive research would be conducted to refine the regulatory scheme, and that the rule would not be the final word on the aldicarb contamination issue." Briefly, the regulatory components of § Ag. 17 are:

1. Aldicarb shall be used at a rate no higher than 2 lb/A and should be used only in alternate years on a site.

2. Aldicarb shall be applied only by certified applicators.

3. Aldicarb shall be applied between 28 and 42 days following planting, and fields treated by aldicarb shall be harvested no sooner than 50 days following application.

4. No person may apply aldicarb unless a report of intended application has been filed with the department at least 30 days before the pesticide is applied.

5. The State of Wisconsin has the right to prohibit the intended application of aldicarb with a "summary special order" if "the intended application site is located within a township quarter-quarter section lying wholly or in part within one mile of a sample point at which aldicarb residues have been detected at a level exceeding 10 ppb." Exemptions to a "summary special order" are listed in Ag 29.17.

6. Distributors and retail dealers of aldicarb shall keep records and report sales of aldicarb.

7. All findings of aldicarb in ground water at levels of 1 ppb or more shall be reported to the proper authorities.

Mr. Dawson believes that, "Ag 29.17 has failed to prevent aldicarb residues in ground water from reaching unacceptable levels, that ground water quality in Wisconsin is not recovering from its aldicarb contamination as hoped, and that there is no credible evidence showing that the label and use-restrictions are adequate to protect Wisconsin's ground water ... The Wisconsin "experiment" has been tried, and it has failed."

The major evidence on which Mr. Dawson bases his contention is the result of the sampling of 144 drinking water wells for aldicarb in June of 1984 by the Wisconsin Department of Natural Resources (DNR) and the Portage County Department of Health. The results of this survey are: 82 wells showed positive findings, 33 of which were above the 10 ppb level, with a high reported value of 69 ppb. In addition, "Of wells with previous residue histories, about 22 were seen to decrease, 11 increased and 36 remained near the same." Mr. Ron Becker of DNR states, "No distinct overall downward trends were apparent from the June data ... Aldicarb is moving with the groundwater and has been seen to contaminate new areas as it moves." Mr. Dawson also believes that other intentions of Ag 29.17 were not met as of September 1984: "... although groundwater monitoring has occurred, it has been far from adequate to obtain a fair and complete picture of the extent to which Wisconsin groundwater is contaminated by aldicarb residues. At best, the results of the latest monitoring provide an extremely conservative indication of contaminated areas."

Agency Response

It is impossible to judge from available data what impact the Wisconsin restrictions have had on the extent and level of aldicarb contamination of ground water. It is clear, however, that ground water contamination continues to be found in Wisconsin despite these restrictions. Thus, one cannot conclude that they are completely successful.

The Agency agrees with Mr. Dawson that "... questions about how aldicarb residues are acting in already contaminated groundwater, remain unanswered." A recent study by Dr. Miles (University of Florida) indicates that aldicarb sulfoxide reduces to aldicarb sulfide under Florida ground water conditions. This would support the contention that in some conditions aldicarb persists longer in ground water than previously thought.

Respondent Number 186

Mr. C.D. Besadny, Secretary of the Wisconsin Department of Natural Resources (DNR), submitted a computer printout summarizing the results of testing 840 wells in Wisconsin as of March 1984 for aldicarb residues. In addition, he submitted two communications between the DNR and Department of Health and Social Services (DHSS) to the Department of Agriculture, Trade, and Consumer Protection (DATCP).

Some concerns expressed by DNR and DHSS in their first letter to DATCP dated August 10, 1982 were not adequately met in the law governing aldicarb, Ag 29.17. Both agencies preferred to see a moratorium on aldicarb use when residues are found at some fraction of the Suggested No Adverse Response Level (SNARL; this level is not defined in the letter and it is assumed that SNARL is also 10 ppb), rather than above the SNARL. AG 29.17 reads:

> "Aldicarb applications are subject to prohibition ... if the intended application site is located within a township quarter-quarter section lying wholly or in part within one mile of a sample point at which aldicarb residues have been detected in ground water at a level exceeding 10 parts per billion ..."

The "purpose" language of Ag 29.17 regarding "2 to 10" ppb addresses this concern but does not allow for a moratorium.

This letter also addressed a concern that "... The proximity to irrigation wells should not be a basis for disregarding a sample. The only criterion should be whether the sample is indicative of ground water quality. A landowner's rights should be preserved to assure that he may construct a future well which will provide a safe water supply." Ag 29.17 reads:

> "... Samples shall not be drawn from a high capacity irrigation well, or any well located within 300 feet of a high capacity irrigation well."

Mr. Besadny suggested that the proposed rule "... require review after one or, at most, two years allowing for additional data from research and sampling and input the Legislative Council's Special Committee on Groundwater Management ..." This concern was handled in a general manner in the "purpose" section, which said that "The department shall evaluate the need for further actions ... when groundwater samples are found to contain aldicarb residues at a level from 2 to 10 parts per billion."

Agency Response

In the data submitted by Mr. Besadney, of the 840 tested wells, 180 have shown at least a detectable concentration of aldicarb, and 75 have produced at least one sample result with an aldicarb concentration over 10 ppb.

Respondent Number 188

Mr. J.E. Legates, Dean, School of Agriculture and Life Science, North Carolina State University, summarizes a survey by the North Carolina Department of Agriculture in 1982 and 1983 of drinking water wells in or adjacent to treated fields of cotton, peanuts, and tobacco. Aldicarb residues of 1 to 2 ppb in seven of 104 wells. He notes that the HA is 10 ppb.

Agency Response

While this evidence would seem to indicate that the population served by these drinking wells is in no immediate danger, it is difficult to extrapolate further without knowledge of: 1) depth of these wells, 2) soil type and geology where the samples were taken, 3) if these wells were "deep", are there also "shallow" wells used for drinking water, and so on.

Respondent Number 191

Ms. Lori Johnston, former Assistant Director, Pest Management, Environmental Protection and Worker Safety, Department of Food and Agriculture, California, comments that "we believe aldicarb is being used safely in California." She notes that aldicarb was banned in Del Norte county, due to a "combination of high rates of use, permeable soils, low pH, cool temperatures, and a shallow water table." She notes that other aquifers over which aldicarb is being used have been sampled with no findings. She states that, "If the mechanism of pesticide mobility through soil to ground water was understood, it might be possible to print restrictions on the label which would be simple but accurate enough to eliminate the possibility of residues in ground water."

Agency Response

The Agency agrees that the factors identified by Ms. Johnston as conducive to the leaching of aldicarb in Del Norte county are factors which increase the likelihood of aldicarb reaching into the ground water. In Chapter IV, in the proposed regulatory options section, there is a discussion of using label restrictions as a means for reducing ground water contamination.

Respondent Number 192

Dr. James P. McKeown, Cotton Entomologist, Jackson, Mississippi, briefly commented on the continued use of aldicarb, and does not think there will be a ground water contamination problem "since the ground water in my area is at least 150 feet below the surface."

Agency Response

The Agency believes that Dr. McKeown's statement is not correct as a generalization for the state of Mississippi, nor for counties in the state where aldicarb is used. As part of the exposure assessment for ground water described in this document, six counties in Mississippi were evaluated on an average basis for the depth to ground water. On a scale of 1 to 5, (where 5 = high vulnerability: 0-25 feet below the surface, 3 = medium: 25-50 feet below the surface, and 1 = low: greater than 50 feet below the surface), results for the Mississippi counties were as follows: Tallahatchie - 4.8; Bolivar - 4.5; Washington - 3.6; Yazoo - 2.5; Sunflower - 2.4; and Warren - 1.2. Of these six counties, Yazoo and Sunflower had significant land area rated either high or medium such that the average results were 2.5 and 2.4, respectively. Only Warren County, with an average rating of 1.2, can be considered to have low vulnerability as measured by depth to ground water. It might be noted that Jackson is in

Hinds County, which is adjacent to Warren County, so it is quite possible that ground water is, in fact, deep in Dr. McKeown's area.

Respondent Number 221

Mr. G. Talmadge Balch, Pesticide Education Specialist, Alabama Cooperative Extension, Auburn University, commented mainly on the benefits from the present use of aldicarb on peanuts, soybeans, pecans, sweet potatoes, Irish potatoes, and cotton. Additionally, Mr. Balch notes that there is little danger due to worker exposure, citing its safety record in Alabama. He also briefly describes a small monitoring program in order to address issues of potential ground water contamination.

Agency Response

Insufficient data were submitted to draw any conclusions about the potential for and/or existence of ground water contamination in Alabama. Useful information would include: depth of water extraction, depth to ground water, surface soil type in the neighboring cotton fields, etc. Soil type and hydrogeologic conditions in all areas of Alabama where aldicarb is used are necessary to determine the potential for ground water contamination in state.

Respondent Number 232

Mr. La Verne Ausman, Secretary of State of Wisconsin Department of Agriculture, Trade and Consumer Protection, notes that implementation and enforcement of State regulations restricting aldicarb use in Wisconsin have worked effectively. He states, though, that the effectiveness of these regulations will not be determined for several years. He believes that state, as opposed to Federal, regulation provides an adequate means to mitigate ground water contamination. Mr. Ausman provided a number of attachments, including monitoring and fate data.

Agency Response

The Agency has utilized the data supplied by Mr. Ausman in its risk analysis for aldicarb. The Agency has also contacted state regulatory agencies to determine the most appropriate regulatory strategy for aldicarb. The reader is referred to Chapter IV, Regulatory Options.

Respondent Number 236

Dr. John M. Harkin, Professor of Soil Sciences and Water Resources, Wisconsin Resource Center, provided monitoring data. He stated that up to 200 ppb of aldicarb residues have been observed to date, but that observations of aldicarb in ground water proved to be erratic. He provided numerous observations of environmental parameters associated with aldicarb contamination. He closed by stating that the regulatory and remedial actions taken by the states appear to be adequate.

Agency Response

The Agency has utilized the data supplied by Dr. Harkin in its risk analysis for aldicarb. The Agency has also contacted state regulatory agencies to determine the most appropriate regulatory strategy for aldicarb. The reader is referred to Chapter IV, Regulatory Options.

Respondent Number 242

The registrant submitted its rebuttal comments which consist of two appendices. Appendix I specifically addresses Agency statements presented in the PD 1. Appendix II specifically addresses risk, exposure and benefits associated with aldicarb in a narrative fashion, with six volumes of benefits data on selected crops.

<u>Appendix I</u>

<u>Comment 1</u>

The registrant agreed with the Agency that aldicarb has been detected in ground water in a large number of States. The registrant states that the vast majority of tested wells had no detectable aldicarb residues and that a small percentage of drinking water wells contained residues above the HA.

Agency Response

The Agency agrees that the majority of tested wells had no detectable residues of aldicarb. In a compilation of ground water samples (not wells), the Agency estimates that approximately one-third of the samples were positive. The Agency also agrees that aldicarb may be the most extensively studied pesticide, relative to ground water contamination. It must be noted, though, that approximately two-thirds of the over 35,000 well water samples are from one locality, Long Island. Additionally, most ground water testing for aldicarb has been from drinking water wells and primarily after ground water contamination has been detected. The Agency has concluded that, while ground water contamination by aldicarb may have been extensively studied, the current data base has not been derived in an organized and statistically valid fashion.

The Agency agrees with the registrant that the vast majority of well water samples contain aldicarb residues below the Health Advisory. The Agency disagrees with the registrant's statement that only eight states have detected aldicarb residues above the Health Advisory. The Agency's review indicates that ten states have detected aldicarb residues at greater than or equal to the Health Advisory. The important difference between the data bases examined by the registrant and the Agency is that the registrant examined drinking water wells only, whereas the Agency examined all ground water sampling results that were indicative of ground water quality in impacted aquifers; the first-encountered aquifer in the vacinity of the use site. These included results from drinking water wells, and also observations on other wells not used for drinking water purposes. The Agency, though, does not believe it necessary to concentrate on the amount of aldicarb residues in any particular well. The Agency believes that it is not necessarily possible to correlate a level of residue contamination with the vulnerability of a specific location at this time.

Comment 2

The registrant questioned the Agency's statement in the PD 1 that: "... Aldicarb sulfoxide and aldicarb sulfone ... persist longer under anaerobic conditions ... than under aerobic conditions." The registrant cites two studies which show the reverse trend, that persistence is longer in aerobic conditions than in anaerobic conditions.

Agency Response

The registrant statement regarding degradation is accurate. The Agency does not state that aldicarb sulfoxide and sulfone persist longer under anaerobic conditions than aerobic conditions. The Agency refers to laboratory experiments which show rapid degradation of aldicarb and aldicarb sulfone under anaerobic conditions. However, it also references studies performed in Florida with Floridian ground water. Ground water is considered an anaerobic environment. In these experiments, the persistence of aldicarb and the sulfoxide and sulfone degradation products were studied with and without limestone aquifers (the Floridan Aquifer is a limestone aquifer). Of six comparisons between half-lives (three products, two comparisons each), five demonstrated longer half-lives under anaerobic conditions by a significant amount.

The statement, as originally made by the Agency, was made in recognition that microbial decay, which predominates in the aerobic environment of the root zone of crops, is a more robust degradation process (in that it leads to shorter half-lives) than chemical hydrolysis which predominates in the anaerobic environment of the ground water. Exceptions to this rule occur (as noted in two cited references) when anaerobic microorganisms promote rapid degradation of aldicarb products.

Comment 3

The registrant contends that aldicarb residues exceeding the Health Advisory have not been identified in Missouri, but have been seen in Rhode Island. The registrant reiterates that "over 91 percent of all "worst case" wells analyzed show no detectable levels of aldicarb residues; approximately 1.4 percent exceed 10 ppb and less than 0.6 percent exceed 30 ppb." The registrant adds that the highest detected aldicarb residue outside of Long Island is one well at 75 ppb.

Agency Response

The Agency has completely rereviewed its entire monitoring data base for aldicarb. The registrant is correct that aldicarb residues have not been detected in Missouri, but have been detected in Rhode Island. The Agency cannot comment on the percent of "worst case" wells with no detectable residues because the registrant has not defined "worst case". The Agency notes that approximately 15 percent of all samples (not wells) outside of Long Island contained detectable aldicarb residues greater than the Health Advisory Level. According to the Agency compilation, two percent of samples outside Long Island exceed 30 ppb. The registrant's statement that "... the maximum aldicarb residue in drinking water wells outside Long Island is one well at 75 ppb." is correct. Much higher levels, however, have been found in other monitoring. The Agency has determined that aldicarb residues have been identified in one sample at greater than 1,000 ppb. That sample was obtained by the registrant from beneath a citrus field test site. That site was, though, experimental with an application rate twice that currently permitted on Florida citrus. Additionally, residues of several hundred ppb were found beneath and downstream from other citrus field sites that were jointly monitored by the registrant and the Florida Department of Environmental Regulation.

Comment 4

The registrant commented on the Agency's statement that levels of aldicarb up to 500 ppb have been found in New York. The registrant stated that residues were, in fact, 515 ppb and that residues had declined to 108 ppb as of September 1984. The registrant continued by stating that "Of the 445 wells sampled during the last year, the highest reading has been one well at 207 ppb." The registrant stated that 25 percent of "worst case" wells had detectable aldicarb residues, with 6 percent of these "worst case" wells containing 30 ppb. Other New York findings indicated that only three wells exceeded the Health Advisory Level.

Agency Response

The Agency agrees that 515 ppb, not 500 ppb, is the correct highest level of detected aldicarb residues in New York. The Agency agrees that the level of contamination has declined since the 515 ppb level was detected. It must be noted, though, that a decline in residues can be attributed either to degradation or to plume movement away from the well. Thus, the cause for a decline in residues is more important than just stating that the residues have declined over time. Generally, the Agency believes that aldicarb residues on Long Island have degraded over time. Data indicate that plumes of aldicarb residues in Long Island ground water have moved both laterally off-site and vertically down to deeper aquifers.

Comment 5

The registrant commented on the Agency's statement that 1 to 10 ppb of aldicarb had been detected in Arizona, Connecticut, Florida, Washington, South Carolina and possibly other States. The registrant stated that "States which at last analysis had (aldicarb residues within) drinking wells..." (emphasis added) were: Arkansas, Florida, Idaho, North Carolina, South Carolina, Texas and Washington.

Agency Response

Since the PD 1 was issued, additional monitoring for aldicarb has taken place, and hence, more information was available for analysis in this document. The Agency has specifically focussed on monitoring results which characterize "impacted" aquifers associated with aldicarb use. "Impacted" can be defined as the first encountered aquifer in the vicinity of treated fields. As such, the Agency's compilation has evaluated rural drinking water well surveys as well as research oriented monitoring. Currently, positive results have been found in 48 counties in 16 states.

Comment 6

The registrant disputed the Agency's generalization about typical degradation rates of aldicarb as being incorrect. The registrant supplied information to rebut the Agency's statement: "Because aldicarb residues have half-lives as long as several years, under conditions typically found in ground water, the time required for degradation of aldicarb ground water residues to nontoxic compounds will be long." The registrant then concludes that "Therefore, in most areas where aldicarb is used, residues do not persist from year to year."

Agency Response

The Agency agrees that the quoted statement is not an accurate conclusion about degradation under typical conditions. It is, however, true that in some places the half-lives can be as long as several years. The data from Long Island, for example, show that residues have persisted there through 1985 despite discontinuation of aldicarb use since 1979.

Comment 7

The registrant commented that the Theoretical Maximum Residue Contribution (TMRC) to the daily diet overestimates pesticide residue exposure and that exposure is considerably lower.

Agency Response

The Agency agrees that the TMRC for aldicarb overestimates dietary exposure. The Agency's assessment of dietary risk is presented in an earlier section of Chapter II of this document and utilizes the Tolerance Assessment System.

Comment 8

The registrant commented that the Agency should maintain the Allowable Daily Intake (ADI) at 0.003 mg/kg/day.

Agency Response

A description of the acceptable daily intake (ADI) for aldicarb is found earlier in the Agency's response to the NRDC (Respondent Number 98).

In a human study performed by the registrant, four men/dose each consumed 0.025, 0.05, and 0.1 mg/kg aldicarb in 100 ml of water. The high dose produced clear, spontaneously reversible signs of cholinesterase inhibition. The middle dose produced no clinical signs, although one man complained of a runny nose. This dose inhibited ChE activity. The lowest dose also inhibited ChE activity. The Agency determined that the LOEL and NOEL for clinical signs are 0.1 mg/kg and 0.05 mg/kg, respectively. The LOEL for ChE inhibition in this study is 0.025 mg/kg. The NAS extrapolated the NOEL for whole blood ChE inhibition to be 0.01 mg/kg, and the Agency uses this value in its calculations. A safety factor of 10 applied to the extrapolated NOEL for ChE inhibition yields an RfD of 0.001 mg/kg. Thus the RfD for acute and chronic ChE inhibition are comparable. This estimate is further supported by several studies in rats, dogs, monkeys, and rabbits; all of which show a uniform cholinergic response demonstrating a ChE NOEL at or near 0.01 mg/kg.

The doses estimated from the human incidents reported have been as low as 0.0026 mg/kg body weight. These estimates are based largely on anecdotal data on consumption, and rarely have analyses for aldicarb been done on the items consumed. Thus there is considerable uncertainty regarding these estimated doses.

The human study previously described (Dernehl and Block, 1971), which found a LOEL and NOEL for clinical signs of 0.1 mg/kg and 0.05 mg/kg, respectively, was based on four subjects per dose. Thus, there is some uncertainty regarding these values as well. The frequency of dose estimates from incidents that are at least an order of magnitude lower than the 0.1 mg/kg LOEL reported indicates that the true LOEL for clinical signs is probably lower than this, and that the NOEL reported by Dernehl and Block could well be an effect level for some individuals. The NOEL for ChE inhibition extrapolated from this study, 0,01 mg/kg, may also be high as monkeys fed 0.005 mg/kg aldicarb had slightly depressed ChE (Union Carbide, 1987a and 1987b); no clinical signs were reported at this dose under controlled laboratory conditions. The Agency believes that the NOELS for ChE inhibition and clinical signs of such inhibition are close to 0.01 mg/kg and that at 0.001 mg/kg, it is unlikely that an individual will show clinical signs or have depressed ChE activity.

Comment 9

The registrant commented that "... realistic exposure to aldicarb residues is negligible, as can be confirmed by examination of FDA market basket surveys. As shown in monitoring reports, actual exposure to aldicarb residues in drinking (emphasis added) water is also extremely low. Careful consideration of actual exposure to aldicarb residues should be given."

Agency Response

The Agency is concerned with making the best possible estimate of likely exposure in determining the potential risk from aldicarb usage. The Agency has reviewed FDA residue data. These data confirm that potato residues in the market place closely parallel residue data developed to establish the aldicarb tolerance on potatoes. The FDA data do not confirm the citrus residue data used to establish the citrus tolerance. The Agency believes, though, that the small sample size taken by FDA would make finding aldicarb treated commodities difficult. Relative to actual exposure, the Agency has concluded that several hundred parts per billion of aldicarb have been found in ground water.

Appendix II - Chapter One

Comment 1 (Pg 1)

The registrant stated that the Agency intends to "...determine an acceptable level of aldicarb residues in drinking water, commonly referred to as the Health Advisory Level (HA)."

Agency Response

The HA is established in accordance with established Agency guidelines. The Agency believes that these levels are consistent with the guidance in FIFRA for assessment of risk. Further, the Agency believes that situations will occur rarely where benefits exceed this level of risk.

Comment 2 (Pg 4)

The registrant stated that the appropriate HA for aldicarb is "...30 ppb based on EPA's ADI or 50 ppb based on the World Health Organization ADI for aldicarb."

Agency Response

The registrant has incorrectly calculated the HA for aldicarb by using the Agency's past ADI of 0.003 mg/kg/day and not the current ADI of 0.001 mg/kg/day.

Comment 3 (Pg 5)

The registrant stated that, based on human and test animal studies, the HA derived by the Agency is extraordinarily conservative.

Agency Response

The Agency believes that the HA for aldicarb is appropriately conservative because water represents a large portion of the diet, especially an infant's and child's diet.

Comment 4 (Pg 6)

The registrant states that aldicarb degrades, under appropriate environmental conditions, in the soil. A supplementary document describes the microbial degradation of aldicarb, including environmental factors enhancing and retarding this process. The registrant states that the half-lives of aldicarb and its metabolites range from four to eight weeks.

Agency Response

Because of aldicarb's environmental fate characteristics, it is highly mobile and leaches out of the root zone into other portions of the unsaturated zone and into the saturated zone. The registrant fails to address degradation in the saturated zone. Degradation in this zone is considerably slower than root zone degradation. While consistent with the discussion of aldicarb fate and transport, the registrant does not clarify that this half-life is associated only with microbial decay which occurs in the root zone of crops. The registrant states that microbial decay predominates near the soil surface, and that hydrolysis is the major mode of degradation several feet below the surface. The registrant does not mention the hydrolysis half-life, which is significantly longer than microbial half-lives. Hydrolysis half-lives range from months to years.

Comment 5 (Pg 6)

The registrant states that evaporation can be "an important factor in limiting downward movement (of aldicarb)." The registrant also supplied, in a separate document, four references supporting a conclusion concerning the importance of the upward movement of aldicarb. Specifically these documents stated that, "In most agricultural soils, these movements result in little or no net loss of aldicarb from surface soils due to leaching." These documents are unpublished studies by the registrant previously unavailable to the Agency.

Agency Response

To some extent, evaporating water near the soil surface will play a role in retarding leaching. In a recent modeling study, (Lorber and Offutt, 1986), evaporating water was listed as one of four reasons why aldicarb appeared to be staying near the soil surface longer than would be expected. However, the energy necessary to pull water upward against gravity is high and would negate the possibility of this process being significant, if at all present, lower than a foot below the surface. Since aldicarb is soil incorporated, residues easily move below a depth where upwardly moving evaporating water can affect its movement. Thus, evaporation does not play a significant role in leaching retardation.

Comment 6 (Pg 7)

The registrant stated that aldicarb "...residues typically remain in the upper portion of the affected aquifer immediately beneath or within a short distance down gradient from treated sites...Aldicarb residues continue to degrade in the saturated zone, with halflives ranging from a few days up to three years, depending on conditions."

Agency Response

The registrant's statement that residues remain in the upper portion of the aquifer, immediately below or a short distance down gradient from treated fields, while generally true, ignores conclusions of studies performed in Long Island and Florida. The Long Island study indicates that aldicarb residues are appearing in deep wells. Data from Florida indicate that aldicarb residues have moved several hundred feet off-site. In one field site, residue levels at 416 and 276 ppb were noted at 800 and 900 feet, respectively. The half-life in Long Island well water has been estimated at 5.8 years, with a range of 170 to 4,580 days. Conditions in individual aquifers will alter the half-life estimates.

<u>Comment 7 (Pg 7)</u>

The registrant states that "...exposure to birds and wildlife is even more limited since their drinking water is from surface water sources where aldicarb residues are unstable." The registrant generally discusses that granular aldicarb is soil incorporated to minimize potential surface runoff.

Agency Response

Several studies indicate only the amount of pesticide in the first few centimeters of soil are available for loss via runoff. However, aldicarb has been found in surface waters in Florida. In a Congressionally mandated study of drinking water wells in Florida, no aldicarb was found in wells, but aldicarb was detected in a river supplying drinking water in Lee County, Florida. These residues could have appeared in the river either from runoff or through ground water recharge of the river. The registrant submitted study indicated that runoff of aldicarb would not be a problem, although they stated that "total toxic residues in the runoff water did not exceed 1 ppm." Realizing that 1 ppm is two orders of magnitude higher than the HA, runoff from treated fields is a matter of concern. Still, as the registrant pointed out, these levels were the result of broadcast application followed by flooding and as such, were highly atypical of aldicarb use.

<u>Comment 8 (Pg 8)</u>

The registrant states that only shallow wells that are down gradient from a treated field and pulling water from the upper portion of the water table are likely to draw contaminated ground water.

Agency Response

The Agency's review of the entire monitoring data base for aldicarb clearly indicates that aldicarb contamination has occured in shallow aquifers and that aldicarb residues, under appropriate conditions (e.g. Long Island), can migrate to deeper aquifers.

Comment 9 (Pg 8)

The registrant states that aldicarb degrades to non-detectable levels "within a relatively short and predictable distance from the point of entry."

Agency Response

The registrant, while correct that aldicarb degrades to non-detectable levels, has failed to define "relatively short". Porter (1984) identified aldicarb residues 4,000 feet from an application site in Wisconsin. The Florida DER has, by contrast, established a 1,000 foot drinking water well setback. The Agency agrees that current technology can be utilized to establish a rough estimate of the travel distance from the point of application to and through a shallow, unconfined aquifer, given adequate knowledge of the appropriate parameters, and adequate data to verify projected travel distances.

Comment 10 (Pg 9)

The registrant states that "Properly constructed and located wells are not likely to draw water from the upper portions of a aquifer."

Agency Response

The Agency believes that the registrant's statement is relevant to new wells, assuming they are constructed to penetrate the aquifer at a deep point. The Agency cautions, though, that it is unlikely that a significant proportion of currently operated drinking water wells are either properly constructed or located to intercept a plume. The Agency also doubts that well owners have the appropriate information about their own wells.

Comment 11 (Pg 9)

The registrant states that the national population in general is not exposed to aldicarb residues in its drinking water.

Agency Response

While the Agency agrees that the majority of the population does not consume drinking water with detectable residues of aldicarb, the Agency is concerned about the potential for exposure to individuals in hydrogeologically vulnerable areas.

Comment 12 (Pg 10)

The registrant maintained that contamination of drinking water wells above the HA represent isolated incidents.

Agency Response

The Agency agrees with the registrant that wells contaminated with aldicarb above the HA are isolated, but also believes these contamination incidents might have significant health impacts. Also, monitoring to date has also been comparatively isolated.

Comment 13 (Pg 12)

The registrant states that aldicarb residues in shallow Long Island aquifers have decreased over time and that residues in deeper aquifers are "less apparent".

Agency Response

Porter, et al (1984) supports the registrant's contention that residues in shallow wells have decreased over time. However, the same study also indicates the residues have increased in deep wells. Hence, the Agency disagrees that residues in deeper aquifers are "less apparent".

Comment 14 (Pg 12)

The registrant states that "...label changes have been effective in reducing potential movement of aldicarb residues to ground water" in Wisconsin and Florida.

Agency Response

The Agency has reviewed data and comments from both states on the effectiveness of label restrictions to mitigate aldicarb contamination of ground water. The Agency is not convinced that these label restrictions are necessarily effective. While the label restrictions in these states have reduced the amount of aldicarb that enters ground water, the important point is whether these additional restrictions have reduced residues below a toxicologically significant level. The Florida Department of Agriculture has been monitoring wells near fields with registered known use of aldicarb, and, as of early 1987, have found only a few positives. However, the Florida DER, in cooperation with the registrant, have established monitoring wells in or near aldicarb use sites and have positive readings of up to 300 ppb in wells as much as 400 feet from the application site. Wisconsin, by contrast, established a program specifically to test the effectiveness of its new regulations. Data from Wisconsin indicate that label restriction may be insufficient to reduce contamination of shallow potable aquifers in highly vulnerable environments below a toxicologically significant level.

Comment 15 (Pg 14)

The registrant states no adverse effects and no unreasonable adverse effects have been observed from consumption of contaminated drinking water or ground water, respectively.

Agency Response

The premise of this statement is that no organized effort currently exists for identifying an association between clinical signs of aldicarb intoxication and exposure to low levels of aldicarb residues in ground water. The lack of observed effects does not preclude the existence of effects. Finally, and most importantly, it is not the Agency's policy to wait for observed effects before taking a regulatory action.

Comment 16 (Pg 26)

The registrant stated that "Land-values and potential land use are not adversely affected by concerns of build-up of residues or permanent land contamination from toxic residues..."

Agency Response

The registrant has presented no data to substantiate the above claim. Indeed, the Agency doubts such valid data exists. The registrant should present such data, if available.

CHAPTER III

BENEFITS SUMMARY

A. INTRODUCTION

Aldicarb is a systemic pesticide formulated as a granular and used for control of a variety of insects, mites, and nematodes. Major sites of aldicarb usage include: citrus, cotton, potatoes, peanuts, and soybeans. Together these sites utilize about 4.8-5.3 million pounds active ingredient (a.i.) or about 92 percent of annual aldicarb usage. The remaining eight percent of aldicarb is used on sugar beets, tobacco, ornamentals, sweet potatoes, dry beans, pecans, sugarcane, seed alfalfa and grain sorghum (see Table III-1). In total, about 5.2-5.7 million pounds a.i. of aldicarb are used on approximately 4.1-5.4 million acres annually.

The information used to evaluate the benefits of aldicarb was derived from several sources. These sources include: public comments in response to PD 1, the U.S. Department of Agriculture, the registrant, state extension personnel, published state pest control recommendations, scientific literature from the National Agricultural Library, analyses prepared by the Agency staff, Cooperative Agreements between the Agency and the University of Illinois and the University of Georgia, and an Agency contractor, Development Planning and Research Associates. Comments received in response to the PD 1 will not be addressed specifically, but will be incorporated as appropriate thoughout this chapter.

The general approach of this analysis was to evaluate the possible economic impacts assuming that the registration for aldicarb is cancelled, causing users to switch to alternative pest control technology. The most probable alternatives to aldicarb were chosen on the bases of cost, efficacy, market availability and the suggested uses by States. Chemical alternatives were determined from a listing of registered pesticides, without regard to their current Agency status. Future Agency action could change the availability and use of alternatives. This analysis does not anticipate or speculate on all combinations of possible effects due to specific regulatory actions on other chemicals.

Economic impacts on society as well as for users and consumers were based on projected changes in production costs, crop yield reductions and possible grower shifts to other enterprises. Impacts on users were considered on a per-unit and per-establishment basis as well as at the county (for some uses), state, regional, and national levels. Grower level impacts were utilized for projections at commodity market levels. Commodity market impacts were used to estimate the distribution of impacts among consumers, users, and non-users.

TABLE III-1

SUMMARY OF ALDICARB BENEFITS BY SITE

Site/State	Annual Usage: Lbs.A.I.	Annual Usage: Acres Treated	Annual Usage: % Crop Treated	Availability of Alternatives	Producer/Grower Impacts: Increased Production Costs	Producer/Grower Impacts: Change in Value of Production	Producer/Grower Impacts: Total Revenue Loss (Gain)	Consumer Impacts	Loss to Society
	- - - - x 1000 - - - - -				- - - - - - - - - - - - -$ million- - - - - - - - - - -				
Cotton	1,400	2,400-3,300	23-32	several	20-29	none	20-29	minor	minor
Potatoes	1,200-1,500	485-607	37-47	several	11-15	none	11-15	minor	minor
Citrus[a/]	1,200	229	18	several	4.5	-50	54.5	13.5	n.e.
Peanuts	800	650	42	several	17-33	none	17-33	none	minor
Soybeans	187-375	250-500	< 1	several	minor	minor	minor	minor	minor
Sugarbeets	180-200	60-85	6-8	several	minor	none	minor	n.a.i.	n.a.i.
Pecans	95	24	3	some	.48	none	.48	n.a.i.	negl.
Tobacco	58	25	7	several	.1-.6	none	.1-.6	none	none
Sweet Potatoes	43-60	10-14	25-35	several	1.3-2.7	possible decrease	1.3-2.7	n.a.i.	n.a.i.
Ornamental	30-50	unknown	unknown	several	higher	decrease decrease	moderate	b/	minor
Seed Alfalfa	9	3-4	< 1	several	slightly lower	possible decrease	yield loss likely to offset lower production costs	n.a.i.	n.a.i.
Grain Sorghum	< 7	< 5	< 1	several	minor	none	negligible	none	n.a.i.
Dry beans	3	3	< 1	several	slightly higher	none	none	none	none
Sugarcane	negligible usage	negligible	negl.	several	none	none	none	none	none
Total	5,212-5,757	4,144-5,446			54.38-85.28	<-50	104.38-135.28	13.5	

a/ First year impact following fully effective cancellation.
- Assumes Brazilian imports offset U.S. orange production losses (by 80%).

b/ Possible short supplies of some items.

n.e. = not estimated

n.a.i. = no appreciable impact

In preparing the benefit analysis, the Agency reviewed all rebuttal comments for information needed to perform an economic impact analysis of aldicarb on a site/pest basis. These data (e.g., quantity used, units treated, comparative efficacy, use of the next best alternative, etc.), were often not reported, were reported in an unusable manner, or were claimed as confidential. In an attempt to clarify rebuttal comments and to derive the fundamental data needed to quantify the benefits from aldicarb use, contacts were made with individuals in the pesticide industry, the USDA Cooperative Extension Services, state departments of agricultural, county agricultural commissioners, and other sources.

B. ANALYSIS OF INDIVIDUAL COMMODITIES AND ALTERNATIVES

1. COTTON

Aldicarb is used as an insecticide, acaricide and nematicide either at-planting or after emergence of cotton seedlings. Major target pests include thrips, aphids, nematodes, plant bugs, cotton leaf perforators, mites, flea hoppers, leafhoppers, whiteflies and boll weevils. In 1984, an estimated 2.4 to 3.3 million acres of cotton (about 23 to 32 percent of U.S. acreage) were treated with about 1.4 million pounds a.i. of aldicarb.

If the aldicarb registration is cancelled on cotton, current users would employ a variety of pesticides and pest management strategies to control insects, diseases, and nematodes. Depending on target pest, alternatives include disulfoton, phorate, carbofuran, dimethoate, carbaryl, oxamyl, dicrotophos, methamidophos, and chlorpyrifos. For insect and nematode control, use of alternatives could increase production costs by about $1.48/A (a reduction of 1.5-5.2 percent of net cash receipts). Cotton producers in the southeastern and southwestern states where aldicarb is used for insect and nematode control would be most severely affected. Because net cash receipts per acre are modest for cotton producers in these areas, the estimated $15.75 increase in production costs could reduce net cash receipts by about 50 percent (southeast) to 56 percent (southwest). The aggregate annual cost increase would approach $20 to $29 million, which is less than 1 percent of the value of cotton produced in the United States.

The impact on cotton producers would be widespread with large variation in regional impacts. Aldicarb is used extensively in the Southeast (Alabama, Georgia, North Carolina and South Carolina), Louisiana and Mississippi. Texas has the largest acreage treated and, because nematodes are the major pest, Texas cotton producers would incur the highest cost increases (about $19 per acre compared to $9 per acre for other areas) as well as nearly half of the economic impact of cancelling aldicarb usage on cotton.

The cancellation of aldicarb registrations would potentially have a significant impact on cotton growers in Texas and the southeastern States. Consumers are not expected to be significantly affected because overall supplies of cotton are not expected to decline due to regulatory action.

2. POTATOES

Aldicarb is used to control Colorado potato beetles, aphids, nematodes and leafhoppers either at-planting or after emergence of potato seedlings. An estimated 485,000-607,000 acres of potatoes (about 37-47 percent of the U.S. potato acreage) were treated with an estimated 1.2-1.5 million pounds a.i. of aldicarb in 1984.

If the aldicarb registration is cancelled on potatoes, aldicarb users will utilize alternative pest management strategies that are significantly more costly. Where insects are the target pest, potato growers will utilize combinations of disulfoton, fenvalerate, methomyl, permethrin, methamidophos, azinphos-methyl, and endosulfan. Usage of these alternatives could increase grower insect control costs from $1-$26/A (<4 percent increase in variable production costs).

Few alternatives are available for nematode control. Ethoprop and oxamyl are the only non-fumigant materials available but both are more expensive than aldicarb. Fumigants that could be used include 1,3-dichloropropene and metam-sodium, but both are more expensive. Cost impacts for use of alternatives range from $58 to $94 per acre where both insects and nematodes are problem pests. States most affected would be Idaho, Wisconsin, Michigan and Florida where control cost increases could exceed 20 percent of current variable expenses.

Based on 1984 crop data, some states have reported yield increases using metam-sodium instead of aldicarb. These increased yields will partially offset the higher costs where metam-sodium is used in lieu of aldicarb. While current users of aldicarb will be impacted if aldicarb is not available, effects to consumers are not expected to be serious. Potato supplies should remain adequate if aldicarb is not available.

3. CITRUS

Aldicarb is registered for use on citrus to control a variety of insects, mites and nematodes. The Agency's analysis focussed on Florida oranges and Texas grapefruit. An estimated 1.2 million pounds a.i. of aldicarb were used on a total of 228,500 acres in 1982. Approximately 25 percent of all Florida and about 15 percent of all Texas citrus acreage is treated with aldicarb in normal years. California and Arizona report negligible aldicarb usage on citrus.

If the aldicarb registration is cancelled on citrus, users will be forced to utilize available alternatives. In Florida for nematode control, fenamiphos is the most likely alternative while oxamyl is the most likely alternative in Texas. Several pesticides are available and recommended for control of insects and mites in both states. For insect control, major alternatives include dimethoate, ethion, oil and azinphos-methyl. For mite control, the most widely accepted and effective alternatives include dicofol, ethion, oil, propargite, fenbutatinoxide and sulfur.

If the aldicarb registration on citrus is cancelled, Florida and Texas producers could experience increased production costs averaging approximately $30.00/A. Aggregate annual production costs would increase by an average of $4.4 million in Florida and $70 thousand in Texas. Alternatives appear to be somewhat less effective than aldicarb. Florida growers currently using aldicarb could incur yield losses of approximately 15 percent without aldicarb, while Texas yields could decrease by about 7 percent. The average annual yield reduction statewide would range from 2.2-7.1 percent in Florida, depending upon efficacy and usage of aldicarb and alternatives. Texas could experience average annual statewide yield losses ranging from 0.7-2.3 percent.

Yield reductions to Florida processing oranges producers would normally result in increased prices because of the relatively inelastic demand for frozen concentrate orange juice (FCOJ) at the retail level. The final price at the grower level, however, depends to a large extent upon frozen concentrate imports, primarily from Brazil. Assuming Brazialian imports cover an estimated 80 percent of any reduced Florida production, on-tree price received per box of oranges for processing is estimated to increase by approximately 3.4 percent, without the availability of aldicarb. Corresponding yield reductions, however, will result in an estimated 12 percent overall reduction in gross revenue per acre. The 12 percent reduction in gross revenue per acre combined with an average four percent increase in production costs is estimated to result in average decreased net returns of $335/acre for the 1988/1989 season. This amounts to about a 20 percent decline in total net revenue per acre, for current aldicarb users. Aggregate net returns are projected to decline by about $54.6 million for the 1988/1989 season. This figure represents approximately six percent of the average annual value of all Florida citrus production over the last eight years and 13 percent of the 1985/1986 total on-tree value of all Florida oranges produced for processing.

Texas fresh grapefruit growers are also expected to be somewhat worse off without the availability of aldicarb. The on-tree price per box could decline by about 11 percent (due mainly to quality losses), with corresponding yield losses of 6.5 percent. These two factors, combined, result in an average annual gross revenue decrease of $206 per acre, or nearly 17 percent. Accumulated returns for the state show an average annual decrease of $583,000, without the availability of aldicarb. Fresh grapefruit imports are not expected to have any significant impact on returns to Texas growers.

The consumer can be expected to face higher prices for both orange and grapefruit products if aldicarb is cancelled. The retail price for fresh grapefruit is expected to increase by about 7.1 percent while the price for FCOJ would increase by approximately 1.4 percent. Such price changes at the retail level are expected to result in an estimated 0.4 percent increase in consumer orange expenditures and a 1.3 percent decrease in consumer grapefruit expenditures. This converts to an estimated increase of $23.7 million nationwide for orange products and a $10.2 million nationwide consumer expenditure decrease for grapefruit products. Total nationwide consumer expenditures are expected to increase, therefore, by approximately $13.5 million. This figure represents less than 1 percent of the total value of domestic citrus consumption in the United States each year.

4. **PEANUTS**

Aldicarb is used by peanut growers in all major producing regions for both insect and nematode control. Georgia, Alabama, North Carolina, Texas, Virginia, Florida and Oklahoma comprised over 98 percent of the 1984 peanut production. In 1984, an estimated 800,000 pounds a.i. of aldicarb were used to treat approximately 650,000 acres (42 percent of U.S. acres) of peanuts. The use of aldicarb rose in 1982 sharply due primarily to cancellation of ethylene dibromide, a major soil fumigant/ nematicide for peanuts.

If aldicarb is not available for use, peanut producers would most likely employ other chemicals for nematode and insect control. The most likely alternatives include fenamiphos, carbofuran, ethoprop, and 1,3-dichloropropene. These alternatives are generally more costly and somewhat less effective than aldicarb.

If the aldicarb registration on peanuts is cancelled, affected producers could experience lower income because of higher production costs and lower yields. At a minimum, affected producers could receive a $30 to $45 per acre reduction in income which is about 3.8 to 5.7 percent of the per acre value of peanuts. In the aggregate, impacts on U.S. peanut producers could range from $17 million to $33 million annually.

If the aldicarb registration is cancelled for peanuts, normal market adjustments in acreage and prices are not expected because the government sets production quotas and supports price and therefore adjustment in prices due to changes in production (quantity) do not fully occur. Affected growers will experience lower profitability unless government price supports are modified. If price supports are raised to account for lost revenue, unaffected producers would receive windfall profits and consumers of whole peanuts and peanut products would pay slightly higher prices. Overall, the impact will moderately affect aldicarb users but is not expected to have serious effects at either the industry or retail/consumer levels.

5. SOYBEANS

Aldicarb is registered for control of nematodes and Mexican bean beetles on soybeans. Approximately 250,000 - 500,000 acres of soybeans were treated with about 187,500 - 375,000 lbs. a.i. during 1985. Most usage occurs in the southeastern States where nematodes are a problem pest. North Carolina and South Carolina are believed to be important states for aldicarb usage on soybeans. The remaining usage is divided between Georgia, Louisiana, Tennessee, Arkansas, Missouri, Illinois, Virginia and Alabama. In total, less than 1 percent of the nearly 63 million acres of soybeans harvested were treated with aldicarb in 1985.

Several alternative pesticides are registered and readily available for control of Mexican bean beetle and nematodes on soybeans. Alternative nematicides include: fenamiphos, fensulfothion and 1,3-dichloropropene. Several insecticides are registered for control of Mexican been beetle on soybeans. These include: azinphos-methyl, carbaryl, dimethoate, malathion, methomyl and methyl parathion.

If the aldicarb registration for soybeans is cancelled, producers presently using aldicarb for nematode control would be more likely impacted than users of aldicarb for insect control. Usage of aldicarb on insect pests of soybeans is a very minor market. In most cases, current aldicarb users could substitute a granular material with nominal cost impacts (approximately $1.00/A) or more extensive use of resistant varieties and crop rotations. Fumigant alternatives for nematode control are prohibitively expensive. Some reduction in soybean yield is possible for aldicarb users with very heavy nematode infestations. Producers in North Carolina and South Carolina could be most affected if growers abandon nematode control or if alternatives prove less cost effective than aldicarb. In situations where aldicarb is used at high rates, the treatments may not be cost effective (i.e., treatment cost exceeds the value of additional yield). Some growth stimulation from aldicarb may occur but the amount appears to vary with test conditions. Additional yield does not always exceed the cost of treatment.

Since soybean yields could fall somewhat for those farms with more severe nematode infestations that currently use aldicarb, there could be a slight decrease (less than 1 percent) in total regional soybean production. This could lead to slightly higher soybean prices, gains for farmers (both users and non-users of aldicarb) and higher prices to consumers. Because a relatively small acreage of soybeans would be affected (less than 1 percent of U.S. acreage treated) and because per acre losses are severe only to a localized area, no significant impacts are expected at the national level.

6. SUGAR BEETS

Aldicarb is registered for insect control primarily of the sugar beet root maggot, along with aphids, leafhoppers and leafminers. Aldicarb also controls the sugar beet cyst and sugar beet root knot nematodes. There are numerous alternatives available for insect control, including carbofuran, chlorpyrifos, diazinon, fonofos, phorate and terbufos. Available alternatives for nematode control are more limited, including 1,3-dichloropropene, methyl isothiocyanate and sodium methyldithiocarbamate.

About 180,000-200,000 pounds a.i. of aldicarb are applied annually on about 60,000 to 85,000 acres of sugar beets throughout the north central and western regions of the U.S. This constitutes roughly 6 percent to 8 percent of total U.S. sugar beet acreage. About 80 percent of the aldicarb usage is for insect control, while the remaining 20 percent is used to control nematodes. Without the use of aldicarb, sugar beet producers experiencing insect problems will most likely use either chlorpyrifos or terbufos. Crops with nematode infestations will be treated with 1,3-dichloropropene, the primary alternative.

The use of alternative insecticides, particularly chlorpyrifos and terbufos, can potentially lower the treatment costs of producing sugar beets by approximately $12-$21/A (3 percent of production costs). Assuming no significant yield impacts from the use of alternative chemicals, a loss of aldicarb for insect control may reduce the total cost of sugar beet production by approximately $400,000-$1,200,000 which represents less than 1 percent change in net farm income. By contrast, the use of the primary alternative nematicide, 1,3-dichloropropene can potentially raise treatment costs by $41.58/A (9 percent/A increase in production costs). This may result in an increase in total production costs of $415,000-$580,000 for sugar beet producers with nematode infestations.

Since there were no data available to determine the relative efficacy of aldicarb and 1,3-dichlropropene, it was not possible to evaluate yield effects. However, data suggest that the use of 1,3-dichlorpropene could increase sugar beet yields over the average yield achieved when treated with aldicarb. If 1,3-dichloropropene use results in higher yields, then the increased treatment costs could be partially offset by higher production and revenues.

Overall, the cancellation of this aldicarb registration is not expected to produce any significant impacts on sugar beet producers. The change in production costs which may occur from the cancellation of the insecticidal use could offset potential increases in production costs if the nematicidal use is cancelled. Overall production of sugar beets is not expected to be impacted by a loss of aldicarb. Since the cancellation of this use is not expected to significantly change the supply of sugar beets, negligible impacts are expected for the sugar market and the consumer.

7. PECANS

Aldicarb is registered on pecans for control of aphids and mites as well as for suppression of phylloxeras. Alternatives registered to control aphids (the major pest) and mites on pecans include: phosalone, carbophenothion, fenvalerate, diazinon, methidathion, dimethoate, ethion, dicofol and fenbutatin-oxide. Approximately 24,100 acres, (3 percent of the 710,700 acres of managed pecans) were treated with approximately 95,000 pounds of aldicarb in 1984. Approximately 68 percent of the acreage treated is in the southeastern United States; Georgia pecan growers treated approximately 12,000 acres. Other leading aldicarb using states include Alabama, Texas, and New Mexico.

The aggregate user impact from a possible cancellation of the aldicarb registration on pecans could total approximately $481,000 annually. The impacts would be most severe in Georgia where aphid problems may lead to an abandonment of some acreage unless new methods of aphid control are developed. Losses in Georgia could total approximately $290,000 annually with nearly 50 percent of this loss concentrated in two counties.

The overall market impacts of cancelling the aldicarb registration on pecans are not expected to be significant. Because such a small proportion of the U.S. pecan acreage is treated, the annual loss in production would not significantly affect growers' prices.

Likewise, consumers would not be seriously effected since the possible increase in consumer prices will be very small.

8. TOBACCO

Aldicarb is currently registered under FIFRA section 24(c) in North Carolina and Virginia for field control of aphids, flea beetles and root knot nematodes on tobacco. Estimated annual usage is approximately 58,000 pounds a.i. on 25,000 acres (about 7 percent of flue-cured acreage). North Carolina alone accounts for nearly three-fourths of the total aldicarb usage on tobacco.

Although growers in recent years have apparently experienced diminished aphid control with disulfoton, there are a variety of alternatives available. Acephate, applied foliarly for simultaneous control of aphids and worms (hornworm, budworm) is by far the leading aphicide on flue-cured tobacco. Similarly, ethoprop used either singularly or in combination with insecticides is the leading nematicide. Several other nematicides considered equally efficacious are available and extensively used.

Under certain pest situations, especially a simultaneous infestation of root knot nematodes and aphids, aldicarb is less costly (from $8.03 to $41.13 per acre) than its alternatives. Under other situations, especially a simultaneous infestation of aphids and worms (hornworm and budworm), various alternatives are less costly than aldicarb. Use of these chemicals would cost from $5.32 to $26.74 less per acre than use of aldicarb.

In the event of cancellation of the aldicarb registration on tobacco, current users would sustain increased production costs (but no yield-related losses, since equally efficacious alternatives are available) ranging up to $41 per acre, depending on whether aldicarb is used as an aphicide or a nematicide. This increase would represent a change ranging up to 2.4 percent of variable costs. The average variable cost is about $1,700 per acre. On a typical farm of 35 acres, this would amount up to about $1,435. In the aggregate, tobacco users could sustain annual increases ranging from $0.1 - 0.7 million as a result of using alternative pesticides.

Given foreseeable supply-demand conditions for flue-cured tobacco, it is unlikely that the affected producers would be able to pass their increased costs on either to processors or consumers of finished tobacco products. Since, for most producers, tobacco is substantially more profitable than other crops commonly grown in North Carolina and Virginia, the impacted growers would absorb these added costs by realizing lower "quota profits," which are made possible by the existing tobacco price support program. Since affected producers earn more on tobacco than on other crops (as verified by existence of quota rents), they have no incentive to shift acreage. Hence short term and long term impacts are identical.

9. SWEET POTATOES

Aldicarb is used for nematode control on about 11,900 acres (0.3 percent of U.S. acres) of sweet potatoes annually. About 30,000-40,000 pounds a.i. aldicarb are used annually to treat sweet potatoes. North Carolina, being the biggest sweet potato producing state with 35 to 40 percent of U.S. sweet potato acreage and production, is the major user of aldicarb.

If the aldicarb registration on sweet potatoes is cancelled, producers will employ alternatives such as 1,3-dichloropropene, fensulfothion, ethoprop and oxamyl. Alternatives such as metam-sodium, methyl-isothiocyanate and 1,3-dichloropropene could also be used but significant usage is not expected due to their expense. While no yield impacts are expected from substituting 1,3-dichloropropene, lower yields are possible where fensulfothion, ethoprop and oxamyl replace aldicarb. While the extent of these impacts could not be estimated with available data, yield changes are not expected to be severe.

Sweet potato production costs could increase by about $1.3 to $2.7 million annually, or about 1-2 percent of the value of U.S. sweet potatoes, if the aldicarb registration is cancelled. Since 1,3-dichloropropene is as effective as aldicarb and is expected to be used on about 50-80 percent of the acreage currently treated with aldicarb, no serious production losses are anticipated. Supplies of sweet potatoes should be adequate to meet consumer demand and no significant retail impacts are expected.

10. ORNAMENTALS

Aldicarb is registered for use as an insecticide on several commercial greenhouse floriculture crops as well as field grown and nursery plantings. Use of aldicarb on field grown and nursery plantings has declined significantly in recent years and currently, very little aldicarb is applied to these crops. Commercial greenhouse usage has also declined to some extent but aldicarb remains an important pest control in the production of greenhouse floriculture crops. An estimated 30,000-50,000 pounds a.i. of aldicarb were applied to greenhouse floriculture crops in 1984. Growers primarily apply aldicarb to control aphids, thrips, whiteflies, leafminers and spider mites on several flowering plants, particularly chrysanthemums, poinsettias, lilies, carnations, snapdragons and gerbera. Foliage plants (e.g., ferns, ivy) are also frequently treated with aldicarb at rates ranging up to 10 lbs. a.i./A.

According to state recommendations, several pesticides are recommended for one or all of the pests previously listed. The most frequently recommended alternative pesticides are oxydemeton-methyl, diazinon, malathion, dimethoate, acephate and chlorpyrifos. Growers and state extension specialists indicate that in addition to these, other important controls include bendiocarb, dicofol, endosulfan, fluvalinate, oxamyl, and resmethrin. The alternatives are not completely interchangeable in terms of host plant tolerance or efficacy against various pests. Few of the alternatives are as effective as aldicarb on the same broad spectrum of plants and pests; several alternatives have become ineffective due to pest resistance.

Estimating the economic impacts of cancelling aldicarb for ornamental/floriculture crops is difficult because of the complexity of the floriculture industry. Floriculture is unlike other areas of agriculture in that the plants are priced according to the aesthetic value. While minor insect damage may not affect the yield or value of an agricultural crop, it significantly reduces the value of potted plants and often makes them unmarketable.

Cancellation of the aldicarb registration on ornamentals could potentially have a significant impact on growers of several commercially grown floricultural crops including chrysanthemums, poinsettias, foliage plants and lilies. In the event of cancellation, current users of aldicarb will use one or a combination of several available alternatives. The extent of the impact will mainly be determined by the severity of pest infestations without aldicarb and the effectiveness of the alternative chemicals. Generally the substitutions for aldicarb and its alternatives are not made on a one-for-one basis since few of the alternatives are as effective on the same broad spectrum of plants and pests.

In addition, aldicarb and the alternatives differ in their mode of activity as well as timing and mode of application. Aldicarb is a granular systemic insecticide incorporated into the soil of individual plants or as a broadcast treatment. Most of the alternative compounds are contact insecticides and are typically applied as foliar sprays, fogs or smoke. These types of applications generally require frequent reapplication.

Substituting the alternatives for aldicarb may have some effect on growers' production costs, i.e., additional treatment costs resulting from frequent applications of the alternatives. However, growers are likely to be less concerned with slight fluctuations in production costs and more concerned with how effectively they can control insect infestations and prevent further development of pesticide resistance.

If the alternatives used in the absence of aldicarb do not effectively control thrips, leafminers, whiteflies, etc., growers could incur significant economic losses in the form of decreased sales and revenues. Since commercially grown floricultural crops are highly valued, growers could incur significant revenue losses even if only a small portion of their crop is unmarketable.

A significant decline in the supply of clean, high quality plants may result in increased prices to retailers and consumers. How much prices will increase depends on current market situations and the perceived value of the product. Because of competition from imported flowers and the substitutability of other gift type items (e.g., silk flowers and candy), retail prices will likely be less responsive to a decrease in supply.

11. SEED ALFALFA

Aldicarb is registered for use on seed alfalfa only in California with an intrastate product for control of lygus bugs and aphids. The alternatives to aldicarb are oxydemeton-methyl, disulfoton and trichlorfon. While aldicarb and its alternatives provide similar insect control, aldicarb offers longer residuals, simultaneous control of nematodes and insects, and a lower toxicity to pollinating bees.

Aldicarb is used on less than 5 percent of the California seed alfalfa or about 1 percent of the total U.S. crop. Approximately 9,000 lbs a.i. of aldicarb are used annually on an average 3,000-4,000 acres of seed alfalfa, primarily in four central California counties: Fresno, Kings, Imperial and Kern.

If the aldicarb registration on seed alfalfa is cancelled, production costs could decline by $115,000-$200,000 annually (less than 1 percent of the value of California seed alfalfa production) since the alternatives are less expensive. The use of aldicarb provides other benefits that the alternatives do not and, as a result, yield effects may occur which more than offset the decrease in production costs from the use of the alternatives. Given the low magnitude of aldicarb usage as well as the possibility of benefits offsetting the lower treatment costs of the alternatives, no serious impacts on the producers, consumers, or the market are expected.

12. GRAIN SORGHUM

Aldicarb is used on grain sorghum primarily to control chinch bugs and sorghum greenbugs. Although very little data are available regarding the usage of aldicarb on grain sorghum, less than 5,000 acres of grain sorghum, representing less than 1 percent of the total U.S. acreage, are treated annually. At the recommended rates of 1.3 lbs a.i./A, a maximum of 6,500 lbs a.i. aldicarb would be used annually. If the aldicarb registration for use on grain sorghum is cancelled, growers will employ alternatives including carbofuran, parathion, mevinphos, methomyl, disulfoton and phorate. These alternatives are readily available, in current use, and for certain pests, more effective than aldicarb. In addition, alternatives are similarly priced and in some cases, less expensive based on chemical costs alone. Kansas is the only major sorghum producing state recommending aldicarb, and lists it only for suppression of chinch bug and sorghum greenbug.

Because effective alternatives are available at similar or lower costs per acre, and very small amounts of aldicarb are used, no appreciable impacts on users, consumers or society are anticipated if aldicarb use is cancelled on grain sorghum.

13. DRY BEANS

Less than 3,000 acres of dry beans (<1 percent of U.S. acres) are estimated to be treated with aldicarb. At standard treatment rates, about 3,000 lbs a.i. of aldicarb are used on dry beans. Aldicarb is registered for use to control insects on dry beans. However, only Michigan and California indicated any significant usage of aldicarb on dry beans. Alternatives such as disulfoton and phorate are available, equally effective, and less expensive than aldicarb.

Cancellation of the aldicarb registration for use on dry beans is not viewed as a serious problem for producers of this crop. Cancellation of the aldicarb registration would have no measurable economic impacts on users or consumers.

14. SUGARCANE

The aldicarb registration for use on sugarcane is under section 24(c) of FIFRA in Louisiana for nematode control. Currently, estimates suggest that negligible amounts of aldicarb or any other nematicide are used on Louisiana sugarcane. Nematode infestation usually occurs in light sandy soils. Louisiana sugarcane is grown in a heavier clay soil that is not a conducive environment for nematodes. Therefore, nematode infestations are not a severe problem in Louisiana.

Since negligible amounts of aldicarb are used on sugarcane, a cancellation of the aldicarb registration would not have a significant economic impact on users, consumers or the market.

C. CONCLUSIONS

After a thorough review of comments and subsequent attempts to obtain specific data, the Agency determined that data sufficiently detailed to prepare a highly quantitative analysis of aldicarb benefits on a site/pest basis were limited. Data on the minor use sites were generally incomplete or unavailable. As a result, the analyses presented herein often rely on the judgement and estimates provided by experts knowledgeable about various cropping practices and aldicarb use. Field tests comparing efficacy and performance of aldicarb and alternatives were unavailable for many site and pest combinations. Registrant and user data for comparative performance are solicited for all use sites.

If aldicarb registrations are cancelled, producer/grower control costs could increase by an estimated $54 to $85 million annually. For potato, cotton and peanut producers/growers, the increased costs could be significant. Significant user losses and consumer expenditure impacts are expected as a result of lower citrus production.

In addition to these tangible benefits, a number of existing benefits are difficult to quantify. Aldicarb simultaneously controls nematodes, mites and insects, especially if applied at the higher nematicidal application rates. Many alternatives cannot provide simultaneous control of these three pests without being used in combination with other pesticides. The systemic action of aldicarb provides residual pesticide effects. Many alternatives, by contrast, are applied as foliar sprays and provide a shorter duration of pest control. Alternatives must be applied two, three, or more times to provide equivalent pest control. Aldicarb is applied as a soil incorporated granule, while most of the probable alternatives are applied as sprays. Alternatives are, therefore, more subject to off-target drift and attendant mixer/loader/applicator exposure.

CHAPTER IV

REGULATORY OPTIONS AND RISK/BENEFIT ANALYSIS

A. INTRODUCTION

FIFRA requires the Agency to weigh the risks against the benefits for the pesticide use of concern to determine whether continued registration would cause unreasonable adverse effects on man and the environment. In Chapter II the Agency described the risks posed by exposure to aldicarb through ground water contamination and the diet. In Chapter III the Agency identified the major alternative pesticides for the uses for which aldicarb is registered and described the benefits from aldicarb use.

To determine whether continued registration of aldicarb is appropriate, this section reviews the Agency's conclusions concerning the risks and benefits of aldicarb and its alternatives. This section also identifies the regulatory options available to the Agency to reduce the risks from aldicarb use. Each option has been evaluated for its impact on the risks and benefits of the registered uses of aldicarb and the most appropriate regulatory options have been proposed. The human risks and potential for ground water contamination by alternative pesticides have also been summarized.

B. RISK SUMMARY

1. TOXICITY SUMMARY

Aldicarb has a high acute toxicity via the oral, inhalation and dermal routes of exposure and has been assigned to toxicity category I, based on all three routes of exposure. It is a potent cholinesterase inhibitor with an acute LD_{50} in rats of 0.9 mg/kg. In a study using human test subjects, the Lowest Observed Effect Level (LOEL) for clinical signs (e.g., gastrointestinal disturbances, unconsciousness, blurred vision, excessive salivation, seizures, and disorientation) is 0.1 mg/kg and the No Observed Effect Level (NOEL) for clinical signs is 0.05 mg/kg. There was no NOEL for cholinesterase inhibition in the registrant's human study; the lowest dose of aldicarb tested, 0.025 mg/kg, caused a 35 to 54 percent decrease in cholinesterase levels. The National Academy of Sciences used these data to extrapolate a NOEL of 0.01 mg/kg for cholinesterase inhibition.

No known reports of cholinesterase inhibition and/or clinical signs have been reported as a result of legal application of aldicarb. A number of reports of accidental exposures following misuse of aldicarb indicate that cholinergic signs, even severe cholinergic signs, may occur at doses considerably below 0.1 mg/kg, the LOEL for clinical signs in the human study described above. These effects are reported to occur at doses as low as 0.0026 mg/kg. These data are anecdotal, however, and it is difficult to precisely quantify exposures for these accident data. The data may indicate a broad range of sensitivity to aldicarb's acute effects. In light of all information, the Agency believes that the NOELs for cholinesterase inhibition and clinical signs associated with such inhibition are close to 0.01 mg/kg and at 0.001 mg/kg it is unlikely that many individuals will show clinical signs or have depressed cholinesterase activity.

The chronic toxicity data base for aldicarb is complete. Aldicarb is negative for delayed neurotoxicity, oncogenicity and reproductive effects. It is also negative for teratogenicity. The one effect of concern is acute cholinesterase inhibition. There is a 10 ppb Health Advisory level for aldicarb residues that contaminate drinking water, based on the cholinesterase inhibition seen during chronic exposure. The Health Advisory is set by the Agency's Office of Drinking Water, is based on consideration of risks, and reflects that Office's judgement that exposures to residues of aldicarb in drinking water above the Health Advisory would not protect human health adequately.

2. RISKS FROM TREATED COMMODITIES

The Agency has estimated dietary exposure to aldicarb, resulting from a single exposure, from legally treated potatoes and citrus using the upper 5 percent residues. The Agency used data submitted by the registrant in support of tolerances and FDA market basket survey data. The exposure estimates were then compared against aldicarb's cholinesterase inhibition characteristics to determine the margins of safety for these two crops for different sectors of the population. Infants and children consuming the treated commodity would be at the highest risk of acute aldicarb toxicity from the consumption of citrus and potato products. As many as 55 percent of those consuming the upper 5 percent residue levels of aldicarb in these food commodities would have less than a tenfold margin-of-safety for cholinesterase inhibition.

The Agency has encouraged pesticide registrants to conduct monitoring studies to give a more accurate representation of the level of pesticide residues to which the public is exposed. The registrant has recently submitted the results of a National Food Survey which monitored residues of aldicarb in the market place. These data are currently under review and, along with the tolerance data and the FDA market basket survey data, will be used in the final dietary risk assessment.

3. RISKS FROM CONTAMINATED DRINKING WATER

The Agency has estimated the percent of the population consuming various quantities of drinking water in their diet.

The Agency has also calculated a dose of aldicarb and provided a Margin of Safety estimate for these populations assuming various levels of contamination. The focus of the analysis was on the population of greatest risk, infants, because they consume most of their diet as formula and fruit juice which are both frequently prepared using tap water. The Agency calculated that when drinking water containing aldicarb at 10 ppb, as many as 13 percent of consuming infants could be exposed to a dose of 0.001 mg/kg or greater of aldicarb. The corresponding Margin of Safety for cholinesterase inhibition would then be 10 or less, based on the NOEL estimated by the National Academy of Sciences. Clearly not all ground water in the nation contains aldicarb, nor where contamination is found will it always be above 10 ppb.

Because aldicarb can cause cholinesterase inhibition by a single acute exposure, and because it is reasonable to assume that an individual would not consume all of the water in his diet at one sitting, the Agency has assumed that the daily intake of drinking water will be composed of two separate doses. The numbers represent the percentage of consumers who get the dose from an acute exposure (within a six hour period).

C. BENEFITS SUMMARY

The benefits were assessed in terms of economic impacts from use cancellation and subsequent switching to alternative pest management practices. If aldicarb is cancelled in all areas of the country, significant impacts are expected for Florida oranges and Texas grapefruit ($54.5 million) and peanuts ($17-33 million). Moderate economic impacts at the national level are expected for cotton ($20-29 million), potatoes ($11-15 million), tobacco ($0.1-0.7 million), sweet potatoes ($1.3-2.7 million) and pecans ($0.48 million). For all uses, the impacts result primarily because alternatives are less effective and more expensive than aldicarb.

If aldicarb is regulated on the basis of vulnerability to ground water contamination, cancelling use would mostly affect the southeast (citrus: $49 million, peanuts: $22 million, pecans: $0.2 million, sweet potatoes: $0.9 million and tobacco: $0.7 million), north central (potatoes: $1.6 million and sugar beets: $0.6 million), south central (Texas cotton: $14 million), and the northwest (potatoes: $4 million).

D. ANALYSIS OF ALTERNATIVE PESTICIDES

Alternative pesticides are available for almost all uses of aldicarb. This section discusses briefly the relative hazards of these alternative pesticides to humans and wildlife as compared to aldicarb. Table IV-1 summarizes the human toxicology hazards.

Aldicarb is at least twice as acutely lethal to humans as any of the listed alternatives. However, many of the alternatives also are acutely lethal and only differ by less than one order of magnitude from aldicarb. These include azinphos-methyl, disulfoton, fenamiphos, fensulfothion, phorate, oxamyl, and terbufos. Chlorpyrifos, dimethoate, and phosalone are two orders and acephate is three orders of magnitude less acutely toxic than aldicarb. See Table IV-1 for the LD_{50}s of these alternative pesticides.

Disulfoton and fenamiphos have also been found to be teratogenic and thus could pose other significant health risks. Fensulfothion, 1,3-D, and metam-sodium have not been tested for teratogenicity.

In terms of oncogenicity, acephate and dicofol have been categorized as class C oncogens (possible human oncogen), and 1,3-D is a class B_1 oncogen (probable human oncogen).

A number of the major alternatives have some potential to leach, although the leaching potential is variable. Carbofuran is probably less a ground water threat than aldicarb; however, it has been found in ground water in Wisconsin, New York and Maryland. Oxamyl also has been found in ground water. Ethoprop, fensulfothion, fenamiphos, and metam-sodium show a moderate potential to leach, based on limited data. Disulfoton has a low potential to leach. Although 1,3-D is not believed to be a significant threat to ground water, 1,2-D, a contaminant in its formulation, may be a ground water contaminant. A Special Review has been initiated on 1,3-D because of its potential oncogenicity as well as its potential to leach to ground water. Acephate, dimethoate, and methamidophos all show moderate to high potential to leach. Terbufos, phosalone, fenvalerate, chlorpyrifos, azinphos-methyl, ethion, and phorate show little, if any, potential to leach. In general, all the other alternatives can be considered to have less potential to leach as compared to aldicarb, except for carbofuran and oxamyl. Of these two, only oxamyl approaches aldicarb in acute toxicity potency.

The Agency has concluded that, within the limitations of the present analysis, some alternatives appear to be less acutely hazardous than aldicarb, at the given application rates, to both birds and aquatic organisms. Oxamyl (for potatoes and sweet potatoes), ethoprop (for peanuts), fenvalerate (for pecans and potatoes) and carbophenthion (for pecans) do not meet or exceed the more restrictive endangered species risk criteria for birds. It must be noted, though, that all major alternatives meet or exceed avian and/or aquatic risk criteria for non-endangered and endangered species. Carbofuran is currently under Special Review because of its acute toxicity to birds.

TABLE IV-1

TOXICOLOGY OF ALDICARB AND ITS ALTERNATIVES

	LD_{50} mg/kg	Onco.	Develop-mental	Muta.
Aldicarb	0.9	-	-	-
Acephate	900	+	-	ID
Azinphos-methyl	4.5	-	ID	ID
Carbofuran	11.0	-	-	ID
Chlorpyrifos	97-276	-	-	ID
Carbophenothion	6.8-36.9	-	ID	ID
1,3-dichloropropene (1,3-D)	250-500	+	ID	ID
Demeton	50	-	-	ID
Dicofol	640	+	ID	ID
Dicrotophos	15-22	ID	ID	ID
Dimethoate	215	-	-	ID
Disulfoton	2-12	-	+	ID
Endosulfan	30-110	ID	ID	ID
Ethion	96-208	-	ID	ID
Ethoprop	61.5	ID	-	ID
Fenamiphos	3.0	-	+	ID
Fensulfothion	2-10	ID	ID	ID
Fenvalerate	3,200	-	-	-
Metam-Sodium	1,700	ID	ID	ID
Methamidophos	18-21	-	-	ID
Methomyl	17	-	-	-
Monocrotophos	8-23	-	ID	ID
Oxamyl	3.0	-	-	-
Phorate	2-4	-	-	ID
Phosalone	120	-	-	-
Terbufos	4.5-9.2	ID	ID	ID

(+) = Positive
(-) = Negative
(ID)= Insufficient data

In conclusion, many of the alternatives have insufficient data regarding toxicological testing as Table IV-1 indicates. These data will or are currently being produced in response to the Agency's reregistration process; data will be required on the others in the future. Aldicarb is more acutely toxic to humans than any of the alternatives; however, the acute toxicity of some alternatives differ by less than one order of magnitude from aldicarb. Additionally, aldicarb has demonstrated a potential to leach, posing additional concern. Some of the alternatives to aldicarb have been found to be contaminants in ground water. On the other hand, other alternatives have been identified as oncogens, mutagens, or teratogens, while aldicarb has been found to be negative in these three categories.

E. PUBLIC COMMENT CONCLUSIONS

The Agency has addressed and incorporated all public comments in its analysis. Few comments were received by the Agency relative to dietary exposure to aldicarb residues in treated commodities. These comments focussed on the improbability of high residues. The Agency agrees with this premise and has used actual residue data to estimate dietary risk. Additionally, the registrant has conducted monitoring studies to determine the level of residues of aldicarb in the market place. The Agency is currently reviewing these data.

Few comments were received by the Agency relative to dietary exposure to contaminated drinking water. These comments, however, focussed primarily on the appropriateness of the Health Advisory and argued that no unreasonable adverse effects are probable. The Agency believes that use of the Health Advisory is appropriate for protection of the public's health and that regulatory measures to mitigate ground water contamination below this level are necessary to assure that the public's health is not jeopardized.

The vast majority of comments focussed on measures to mitigate ground water contamination. The Agency has considered these comments in identifying the regulatory options presented in this document.

The Agency has reviewed comments on the benefits of aldicarb use as well as the risks and benefits associated with alternatives. Again, where appropriate, these comments have been incorporated into the regulatory options of this document. A full listing of the respondents to the PD 1 can be found in **Appendix** I at the end of this document.

F. REGULATORY OPTIONS

This section discusses the regulatory options for mitigating risks from consumption of aldicarb-contaminated drinking water and presents three possible options for protecting ground water from contamination with aldicarb at levels that would cause unreasonable adverse effects on the environment.

Before proposing any regulatory action concerning dietary risks due to aldicarb residues on food, the Agency wishes to examine the data from the registrant's food survey. The final data have been submitted and are currently being evaluated. After the data are reviewed, the Agency will conduct a final dietary risk assessment.

1. PROTECTING GROUND WATER

The Agency recently introduced a number of long-term strategies on significant environmental issues which require cross-media coordination. One strategy under development addresses agricultural chemicals in ground water. As part of the strategy development process, the Agency sponsored a workshop at Coolfont, in West Virginia, on June 24-27, 1986 and another on July 23-24, 1987. The workshop participants discussed, among other issues, regulatory strategies to limit the amount of pesticides and fertilizers leaching into ground water. Representatives of State health, environmental, and agricultural offices; other Federal agencies; industry; user groups; researchers; Cooperative Extension Service; and environmental groups participated in those workshops. The options in this section evolved from that process.

On February 26, 1988, the Agency announced its proposed strategic plan for addressing ground water contamination by pesticides (Agricultural Chemicals in Ground Water - Proposed Pesticide Strategy, see also 53FR 5830). A copy of this document may be obtained from: Environmental Protection Agency, Public Information Center, PM-211B, 401 M Street, S.W., Washington, D.C. 20460. This document is the Agency's proposed long-term strategic plan for protecting ground water from contamination by pesticides.

The options of the proposed strategy are presented in this Aldicarb Technical Support Document because they are pertinent to the proposed regulatory decision for aldicarb. The Agency requests comment on each of these options relative to aldicarb. By requesting comment on all options, the Agency considers that all options have been proposed and that any option could be included in the Final Position Document without reproposal. Individuals commenting on these options in a generic sense (i.e., not relating to aldicarb per se) should submit comments in response to the proposed strategy rather than to this position document. These options reflect varying amounts of Federal and state involvement. The amount of Federal and state involvement reflects the level of concern in the Agency and state regulatory offices about the potential for and risk associated with ground water contamination.

The options for regulating the use of aldicarb for the protection of people exposed through drinking contaminated ground water are:

Option 1 - Risk Reduction Measures/User Determines Applicability

Option 2 - Labeling/Monitoring/State Management Plans Determined by Heath Regions

Option 3 - Labeling/Monitoring/State Management Plans Determined by County

OPTION 1 - RISK REDUCTION MEASURES/USER DETERMINES APPLICABILITY

This option reflects a registrant submitted application for amended registration which includes additional risk reduction measures on the aldicarb label. Adoption of this option would be appropriate if the Agency has concluded that the risks of consuming ground water contaminated by aldicarb above a specified level could be reduced to acceptable levels, provided various risk reduction measures were adopted and followed. These measures are:

a. Drinking Water Well Setbacks

There is a 300 foot well setback for all uses in Florida, except for citrus in very sandy soils, where the setback is 1,000 feet. The premise of the drinking water well setback is that the level of aldicarb residues, which leach into ground water, will degrade sufficiently so that by the time they reach the drinking water well, the concentration will not exceed 10 ppb. Parameters affecting the well setback are rate of degradation and ground water velocity.

The registrant has proposed the following additional setbacks for wells. For purposes of these instructions, shallow drinking water wells are defined as those wells which are cased less than 100 feet deep and are cased less than 30 feet below the water table. Additionally, for all other areas, there will be a restriction that aldicarb not be applied within 50 feet of any well used for drinking water, except where more restrictive state regulations apply.

USE PROHIBITIONS:

The following environmental conditions, when all are present in combination, reduce the rate of degradation of this product in soil and may allow movement of the product residues to ground water. Therefore, do not use this product when all these conditions exist:

1) Fields with average soil temperature in the root zone below 50° F at time of application;

2) Heavy anticipated rainfall within one month after use (rainfall at rates substantially exceeding evaporation, based on historical records);

3) Fields with soil averaging less than 15 percent (by volume) field moisture holding capacity (permeable surface and subsoils);

4) Fields with soil averaging less than one percent organic matter in the top foot; and

5) Acidic subsoil (average pH less than 6.0).

USE RESTRICTIONS:

For ME, NH, VT

Do not apply within 500 feet of shallow drinking wells (as defined above) if both of the following conditions are met:

* Soil type is sandy loam, loamy sand, or sand;
* The water table is less than 50 feet deep.

For NY, MA, RI, CT, NJ, PA, WI

Do not apply within 500 feet of shallow drinking wells if all four of the following conditions are met:

* Soil type is sandy loam, loamy sand, or sand;
* Subsoil type is loamy sand or sand (with field capacity less than 15 percent by volume);
* The average organic matter in the upper 12 inches is less than two percent by weight; and
* The water table is less than 25 feet deep.

<u>For DE, MD, VA</u>

Do not apply within 300 feet of shallow drinking wells if all four of the following conditions are met:

* Soil type is loamy sand or sand;
* Subsoil type is loamy sand or sand (with field capacity less than 15 percent by volume);
* The average organic matter in the upper 12 inches is less than two percent by weight; and
* The water table is less than 20 feet deep.

<u>For NC, SC, GA</u>

Do not apply within 300 feet of shallow drinking wells if all four of the following conditions are met:

* Soil type is loamy sand or sand;
* Subsoil type is loamy sand or sand (with field capacity less than 15 percent by volume);
* The average organic matter in the upper 12 inches is less than two percent by weight; and
* The water table is less than 10 feet deep.

b. Application Rate, Frequency, and Timing Modifications

The registrant proposes to reduce the maximum application rate for the insecticidal use of aldicarb in Florida on producing pecan trees from 10 to 5 lbs. a.i./A, and on newly transplanted pecan trees from 5 to 3 lbs. a.i./A. The registrant also proposes to limit application timing for the insecticidal uses of aldicarb on producing pecan trees and newly transplanted pecan trees to between January 1 and April 30 (i.e., after the rainy season) in Florida.

The registrant proposes to limit the number of applications for non-containerized ornamental plants (flower crops, trees, shrubs, bulb crops, foliage plants and small woody shrubs) to once per year. The application rates would not be changed.

The registrant proposes that aldicarb application to potato fields occur at post-emergence only in the following states: CT, DE, MA, MD, ME, NH, NJ, NY, PA, RI, VA, VT, and WI. These restrictions coincide with warmer temperatures, higher soil microorganism activity, higher rate of aldicarb degradation, and reduced amounts of aldicarb available for leaching.

Finally, the registrant proposes to restrict citrus application to once per year.

c. Monitoring

The registrant proposes to monitor statistically representative drinking water wells and to provide activated carbon filtration units to individuals with drinking water wells that contain water with aldicarb contamination greater than 10 ppb.

d. General Restrictions

The registrant proposes a six-month general crop rotation restriction. The company also proposes to provide a certified applicator training course on best management practices to protect ground water.

OPTION 2 - LABELING/MONITORING/STATE MANAGEMENT PLANS DETERMINED BY HEATH REGIONS

The Agency has developed a second option which would require a three-phase approach in protecting ground water and better defining those areas where the possibility of ground water contamination is the greatest. This option includes labeling modifications, monitoring of ground water, and establishment of State Pesticide Ground Water Management Plans (Management Plan) in certain states. In identifying which states would need to develop such plans, the Agency utilized the ground water assessment by Heath Region as described in Chapter II. The components of this option are described below.

1. LABELING COMPONENT

One means of reducing or eliminating the possibility of ground water contamination by aldicarb is by imposing certain label restrictions.

The previous option considered labeling as the sole risk reduction measure. Option 2 considers labeling as one of several risk reduction measures, with increasingly stringent measures being used in increasingly vulnerable areas. Under this option, labeling would be a minimum requirement applicable to any use of aldicarb in any area of the country, regardless of whether the state or county in which it is used has a Management Plan. The label would prohibit application or mixing/loading operations of aldicarb within 300 feet of any drinking water well. States could set more stringent well setback requirements (including more stringent ones for public wells vs. private wells) if they so choose. The Agency believes that this measure will serve to reduce contamination of drinking water because it reduces the likelihood that aldicarb will directly contaminate a drinking water supply.

The label would also designate aldicarb as a restricted use pesticide due to ground water concerns. Aldicarb is already classified as a restricted use pesticide due to its acute toxicity. The ground water restriction would serve to heighten a certified applicator's awareness of the concerns regarding the possibility of ground water contamination and target aldicarb users for training using the newly-developed ground water educational module (soon to be available to the states).

The Agency has considered additional site conditional measures that could be added to the label to deal with situations where leaching has been shown to occur. For example, the Agency has information which demonstrates that leaching occurs when aldicarb is used on soils classified by the USDA Soil Conservation Service as "sand" or "sandy loam" and when the field overlies shallow ground water suitable for drinking, where shallow is defined as an average water table depth of less than 30 feet. A site specific measure prohibiting use of aldicarb in areas where these two conditions are met could be instituted. However, the Agency has concerns whether this information is available to growers and whether these prohibitions are enforceable. Thus, the Agency is not specifically proposing site conditional measures at this time but requests comment on their feasibility.

2. MONITORING COMPONENT

The registrant would be required, under FIFRA section 3(c)(2)(B), to perform monitoring in representative areas rated as medium. The registrant would be required to design monitoring programs to evaluate the occurrence of aldicarb residues in ground water associated with specific areas in states/counties specified by the Agency.

The Agency would be deferring a proposal regarding the need for additional regulatory measures (i.e., requirement for implementing Management Plans) to manage the use of aldicarb in areas not subject to the requirement for a Management Plan until these additional monitoring data are submitted and assessed. This deferral is due to information available which suggests that medium areas are less susceptible to leaching than high vulnerability areas. Data generated would be evaluated in order to better characterize these areas. The Agency sees some potential for leaching in medium vulnerability areas in large part because of the variability of hydrogeological conditions. However, because of the limits of the Agency's understanding of this variability and how specific factors relate to leaching, the Agency does not have as much basis for concern as in high vulnerability areas. The Agency believes that additional monitoring would significantly help the Agency to understand the potential for aldicarb to leach in these medium vulnerability areas. Consequently, the Agency is not proposing to regulate the use of aldicarb by requiring additional regulatory measures in these areas at this time. In the interim period, the use of aldicarb in the medium vulnerability areas would be regulated through labeling restrictions/prohibitions described in the prior section.

The exact design of the monitoring program in the medium vulnerability areas would be developed at a later date. The registrant would conduct the monitoring under the provisions of section 3(c)(2)(B). Monitoring would not be required in all states/counties growing a particular crop but rather in representative areas. The monitoring program would account for key areas of vulnerability and use.

The protocols would contain at least the following key ingredients:

1) Delineation of cropping areas of concern based on aldicarb sales and/or crop acreage.

2) Further delineation of these identified areas on the basis of hydrogeologic vulnerability (i.e., the more vulnerable areas should be monitored.)

3) Sampling of existing wells within these delineated areas. Candidate wells include all well types, e.g., drinking water wells, irrigation wells, USGS observation wells, or other wells will need to be identified and described. There will be no statistical component to well selection; wells are deliberately selected and should only be those which could be impacted by aldicarb use; i.e., in the vicinity of known or strongly suspected aldicarb use-sites.

3. STATE PESTICIDE MANAGEMENT PLAN COMPONENT

The Agency believes that one of the best methods of preventing ground water contamination by any pesticide is through restrictions on use imposed under a Management Plan. There are a number of approaches the Agency could use in providing guidance to the states in developing Management Plans. These various approaches range from establishing a performance standard based on a goal of preventing unacceptable contamination (i.e., the Maximum Contaminant Level or Health Advisory level) and allowing the states to develop Management Plans to meet that standard, to providing a specific Management Plan which all states must adopt. The Agency favors a middle path of providing a framework for the plan but providing flexibility to recognize that different states may use different approaches in accomplishing the same goal of protecting ground water from unacceptable contamination. However, each state would need to meet the performance standard through implementation of its Management Plan. The description of the Management Plan can be found in **APPENDIX** II of this document. The Agency is seeking extensive comment on the design of Management Plans and will be sponsoring a series of regional workshops beginning in summer 1988 to further explore the concept.

As envisioned by the Agency, Management Plans would be a comprehensive description of a state's approach for managing the use of a pesticide(s) for the purpose of protecting the ground water resource with specific attention given to preventing unacceptable contamination of current and potential drinking water supplies. The plan should:

(1) Describe the state's overall philosophy and approach to protecting its ground waters from unacceptable pesticide contamination.

(2) List the specific risk reduction measures to be employed For example, the plan may include one or more of the following: cancellation of use or moratoriums; reduction in the rate of use; application method and timing limitations; more stringent well setback restrictions; wellhead protection of public drinking water; mixing and loading requirements; changes in agronomic practices; permit or advance notice programs; and user education training.

(3) Identify the state's enforcement authorities and capabilities which can be used to assure compliance with the provisions of the plan.

(4) Identify the location of ground water that is currently and could potentially be a source of drinking water in the future or that is of ecological importance.

(5) Contain a monitoring scheme designed to ensure that the efforts to avoid contamination through proper use are effective or to identify contamination resulting from misuse/accident.

(6) Establish contingency plans to deal with contaminated ground water.

(7) In cases where contamination is at an unacceptable level, describe the mechanisms to be used to reduce contamination, including the source of funding.

(8) Describe how the public is kept informed and can become involved.

The Agency requests comments on these and other possible components of a Management Plan and discussion on whether a middle path between the performance standard approach and the specified plan approach is preferred.

The Agency realizes that there could be much variation among state plans to account not only for differing state conditions but also varying state approaches. The Agency would be flexible in its review of the various state plans, recognizing that different approaches can be used to obtain the same goal (i.e., preventing contamination or reducing the likelihood of a pesticide in ground water reaching an Agency-designated level). States may elect to work collectively in developing various components of a plan; however, each state would be responsible for the development and implementation of its own plan.

The Management Plan should basically be a two-part strategy: a generic part to deal with pesticides which are regulated for ground water purposes and a chemical-specific (aldicarb) part. The generic part of the plan should set forth the basics for implementing a plan which could be used for any pesticide. The chemical-specific part should include only those portions of the plan that are specific to aldicarb, such as monitoring designs to ensure compliance with the Health Advisory and identifying areas of aldicarb use.

Management Plans would be needed for those areas designated as having the greatest potential for aldicarb to reach ground water. As described in Chapter II, the Agency used two methods of assessing the potential for ground water contamination: one which uses the Heath Region as the geographical unit and one which uses the county. The need to implement Management Plans will differ depending on which assessment is relied upon to identify those areas where there is the greatest possibility of aldicarb reaching ground water. The following discussion describes the Heath Region assessment in terms of how it relates to this option.

Although the Agency believes it would be advantageous for all states to implement Management Plans, it realizes that it would be onerous for both states and the Agency. Therefore, the Agency has developed this option, using the Heath Region approach of ground water assessment, to identify states that would need to implement a Management Plan.

To identify which states would need to develop Management Plans, the Agency first identified the areas where there is the greatest possibility of ground water contamination resulting from the use of aldicarb. The ground water assessment by Heath Region, as discussed previously, identified those areas potatoes are grown in Heath Regions 7 and 9 and those areas citrus and peanuts are grown in Heath Region 11, as having the greatest possibility of ground water contamination resulting from aldicarb use.

The Agency then looked at the states which account for a large percent of the areas where aldicarb could be expected to be used the most and that contained a significant percent of the acreage of the crop (of the crop/Heath Region combination rated as highly vulnerable) in the high vulnerability areas.

For example, potato growing areas in Heath Regions 7 and 9 were rated as having a high vulnerability. In order to determine which states had the greatest number of acres within these Heath Regions, county totals of potato acreage from the 1980 Ag Census were summed. (In those instances where a state is divided by a Heath Region, only the potato acreage within the Heath Region was considered.) Then, those states with the greatest potato acreage within the two Heath Regions were identified.

It was determined that seven states (ND, MN, MI, WI, NY, PA, and ME) account for 98 percent of the potato acreage in Regions 7 and 9. Further, three states in Heath Region 11 (AL, FL and GA) account for virtually 100 percent of the peanut and citrus acreage within that Region. Therefore, there are 10 states that would need to submit Management Plans (ND, MN, MI, WI, NY, PA, ME, AL, FL, and GA). There are 480 counties in these 10 states that are considered to be highly vulnerable and in 165 of these, aldicarb is used. Therefore, this option would cover 68 percent of the highly vulnerable counties in these three regions in which aldicarb is used. Other states in these regions with lower acreage would be covered by national labeling requirements and by monitoring requirements.

Additionally, as a condition for registration, the registrant would have to agree to monitor in high vulnerability areas where aldicarb is used which are not subject to a Management Plan. This would involve monitoring in the states of SC, CT, IA, IL, IN, KS, MA, MO, MT, NE, NH, OH, RI, SD, VT, and HI.

This monitoring effort would involve sampling in fields where aldicarb is used. The wells to be sampled could either be suitable existing wells or specially constructed monitoring wells. Monitoring would be performed over a specified period of time and the data would be evaluated in order to assess the effect of the imposed labelling restrictions in terms of eliminating or reducing ground water contamination.

OPTION 3 - LABELING/MONITORING/STATE MANAGEMENT PLANS DETERMINED BY COUNTY

This third option is identical to Option 2 in that it would have the same labeling and monitoring components. However, the states that would need to develop Management Plans would be identified using a county approach which identified counties where the Agency believes aldicarb has the highest tendency to leaching. Under this approach, states would need to develop and implement a Management Plan for those counties classified as such.

The criteria used to identify which counties would need a Management Plan are very similar to those used to select states in Option 2. The major difference is the size of the geographic area being analyzed. The criteria are hydrogeologic vulnerability, use/usage of aldicarb, and availability of positive monitoring data. These criteria are detailed in Chapter II.

In the four states that the Agency selected as examples for this assessment, California has 3 out of 58 counties, Florida has 26 out of 67 counties, and Wisconsin has 8 out of 72 counties needing a Management Plan. North Carolina did not have any counties which were ranked high enough to need the establishment of a Management Plan. However, the vulnerability to ground water contamination was sufficiently high in all other counties in each of these four states to be classified as medium in vulnerability. The registrant will be required to undertake a monitoring study that will be representative of those moderately vulnerable areas.

The Agency has not completed an assessment of all counties within the United States. However, the Agency estimates that between 15 and 24 states would need to generate a Management Plan under this option. If this option is adopted, the Agency would apply these criteria to all counties to identify those which need a Management Plan.

G. <u>RISK/BENEFIT ANALYSIS OF REGULATORY OPTIONS</u>

1. INTRODUCTION

In the previous two chapters of this document, the Agency evaluated the risks and benefits of the use of aldicarb and considered the regulatory means by which the risks might be reduced. The purpose of this section is to determine the most appropriate regulatory options and modifications for each use of aldicarb. To accomplish this, the risks of use are compared with the benefits of use. If this comparison shows that there are unreasonable adverse effects to man from the current use patterns, the regulatory options are evaluated to determine which produces the most favorable balance of the risks and benefits.

2. DIETARY EXPOSURE TO ALDICARB RESIDUES IN TREATED COMMODITIES

The Agency is deferring a decision regarding the potential risks due to dietary exposure to aldicarb from consumption of treated food commodities until the final results from the registrant's National Food Survey have been evaluated. At such time, the Agency will consider whether further regulatory action will be necessary.

3. DIETARY EXPOSURE TO CONTAMINATED GROUND WATER

a. Introduction

This section analyzes the options the Agency explored to mitigate the risks of ground water contamination due to the use of aldicarb.

Limitations on the scientific understanding of ground water contamination, as well as limitations in the available data base, make it difficult to perform a quantitative risk analysis for these various options. Traditionally, quantitative risk analyses have been conducted to assess the impact of various regulatory mechanisms designed to reduce dietary exposure from consumption of treated crops and/or applicator exposure. Data are available or can be generated which can provide fairly accurate estimates of the levels of such exposure likely to result from application of a pesticide. In contrast to dietary exposure, many factors influence how much aldicarb will leach into ground water and those factors vary greatly from location to location. Therefore, while available data allow the Agency to predict those conditions for which there exists the greatest potential for aldicarb to reach the ground water, the Agency has a limited ability to estimate levels of exposure or the size of the exposed population. For example, hydrogeologic variation is so great that it cannot be predicted with great certainty where contamination is likely to occur and the level of contamination in those instances. One of the key problems is the Agency's inability to make general statements, on a national or local basis, about the proximity of drinking water wells to fields where aldicarb is used. As a consequence, neither the number of individuals exposed to drinking water contaminated with aldicarb at levels of concern nor the length of time they will be exposed can be estimated accurately. However, given the low level at which there is a risk from drinking water contaminated with aldicarb and the numerous areas in which aldicarb has already been detected, the Agency is concerned in all instances where leaching would appear likely to occur.

Complicating the risk/benefit analysis in this case is the difficulty of placing a value on ground water. The Agency believes that ground water is a valuable resource and that its protection from unacceptable contamination is extremely important. Once contaminated, clean-up of an aquifer is exceptionally expensive or technically difficult, especially if the contamination is at a low level and widespread. If an alternate water source is to be provided, it can be both costly and inconvenient.

The Agency has analyzed the risks of aldicarb resulting from ground water contamination, as well as the associated benefits, and concludes that use of aldicarb generally causes unreasonable adverse effects on the environment. As explained below, in the Agency's judgement, the risks from all uses of aldicarb exceed the benefits of such use. Because the Agency concludes that the risks are predominantly associated with use in certain highly vulnerable areas of the country, and because the Agency has no reason to think that the corresponding benefits of such use are disproportionately associated with such use sites, the Agency is proposing to require Management Plans in highly vulnerable areas.

As explained in Chapter II, people are at risk from consuming water contaminated with aldicarb residues. Although it is not possible at this time to generate reliable quantitative estimates of either the number of people exposed to contaminated ground water or the levels of such exposure, some information exists which enables the Agency to put the risks associated with ground water contamination into perspective. The extent of aldicarb contamination of ground water is significant. Thousands of wells have been contaminated with detectable levels of aldicarb. The Agency evaluated studies which comprise over 35,000 samples of ground water from some vulnerable areas. As described in Table II-4, nearly one-third of all samples in these studies were positive, and over half of the positive samples exceeded the Health Advisory.

Many areas of the country where aldicarb is used are vulnerable to contamination (see Chapter II), and not all of these areas have been sampled. Therefore, it is reasonable to assume that there are other wells which have been contaminated by aldicarb but which have not yet been identified.

Available information also indicate that the eventual cost of preventing exposure to drinking water contaminated with unacceptable levels of aldicarb could be quite sizable. Ground water contamination in Suffolk County, New York, serves as an example of how significant these costs can be. Since 1980, granular activated carbon treatment units have been installed in 3104 households where the water supply had been contaminated by aldicarb above 7 ppb. (The New York State Health Department established 7 ppb as the allowable guideline level for aldicarb residues in drinking water.) The cost of each filter is approximately $600 and the costs of installation are about $100. On the average, each filter is effective for one year after which time it must be replaced. The costs for a replacement filter and for installing it are about $150. The total costs for filters and the initial installation for Suffolk County is approximately $2.2 million with annual replacement costs of $465,600.

The Agency believes that the total cost of cleaning up such wells could approach or even exceed the total benefits of aldicarb which have been estimated up to $135 million a year. Obviously, clean-up costs are not the only measure of risk, since some exposure would occur before filters are installed for a water supply. In light of all potential risks, therefore the Agency concludes that the risks posed from consuming water contaminated by aldicarb above the Health Advisory outweigh the benefits of use.

When the Agency concludes that the risks of use of a pesticide outweigh the benefits, it may propose to cancel the registration of all products containing that pesticide. In the case of aldicarb, however, the Agency believes that cancellation of all use is not necessary since less stringent regulatory restrictions are capable of reducing the risks to a point where the remaining benefits outweigh the risks. As indicated in Chapter II, the likelihood of ground water contamination varies throughout the country. The Agency believes that the greatest risks are associated with aldicarb use in areas where the ground water is highly vulnerable to contamination. By prohibiting or restricting the use of aldicarb in those vulnerable areas, the Agency concludes that the risks of aldicarb would be significantly reduced to a level where they would no longer outweigh the remaining benefits. This conclusion is justified because the Agency has no reason to believe that the benefits of aldicarb are significantly greater in highly vulnerable areas than in less vulnerable areas. Thus, while regulatory actions to reduce the risk in vulnerable areas may have some impact on benefits, the overall impact of such actions should be to improve the balance of risks and benefits. The Agency believes that the combination of measures recommended in this document would allow the continued use of aldicarb without unreasonable adverse effects on the environment.

In summary, the Agency believes that ground water is a natural resource which must be protected from contamination by pesticides. There are many instances in which aldicarb, an acutely toxic pesticide, has contaminated ground water above the Health Advisory. Data available to the Agency confirm that aldicarb has a great leaching potential. The Agency's assessment methods, using the Heath Region or county approach, can target areas where there is the greatest possibility of aldicarb leaching to ground water above the Health Advisory. It is in these areas that the Agency believes that the use of aldicarb must be regulated most stringently. The Agency believes that the states can accomplish this most effectively through Management Plans. Although the Agency considers that aldicarb is an important agricultural chemical which provides substantial benefits to growers and producers, it believes that the risks from unacceptable ground water contamination resulting from aldicarb use in the vulnerable areas outweigh the benefits. Consequently, regulatory action to prevent ground water contamination is necessary.

The following section discusses in detail the various regulatory options considered to mitigate the risks of ground water contamination.

b. Discussion of Ground Water Options

1) **Option 1** - Risk Reduction Measures/User Determines Applicability

This option reflects the registrant submitted proposal to place additional risk reduction measures on aldicarb labels. These measures would be targeted to the users and the costs of monitoring ground water contamination and corrective actions would be borne by the registrant. Preventive measures could be tailored to specific conditions of the application site in order to prevent contamination of drinking water wells above the Health Advisory in high or medium vulnerability areas.

The Agency believes that if implemented accurately by users, the registrant's proposal would reduce ground water contamination. The Agency believes, however, that this option would result in a label which is excessively difficult for users to interpret and states to enforce. Also, this approach emphasizes protection of existing drinking water sources rather than ground water in general. Since ground water can be a potential drinking water source, simply protecting existing drinking water wells is insufficient because aldicarb could still reach the ground water.

If this option were adopted, it would have to include a comprehensive monitoring program which is designed to test a statistically significant number of sites where aldicarb is being used.

The Agency concludes, in view of the benefits, that levels of aldicarb not exceeding the 10 ppb Health Advisory are sufficiently protective of human health. However, once levels are detected, even if they are detected at levels below 10 ppb, there is no assurance that they will stay at that level. Thus, this option would need to include the additional provision for a corrective action program whenever aldicarb levels are detected.

Different prevention measures would apply in different areas depending on the specific climatic and soil conditions associated with the application site. The risk reduction associated with this option may be considerable. Not only is there a substantial reduction in the likelihood that ground water will be contaminated, but there is also a provision for detecting any contamination which does occur.

The costs of this option could be considerable. The risk reduction measures themselves will result in increased costs in the use of aldicarb as well as a prohibition on its use on certain farms where it is now used or at certain times when it is now used without restrictions. There are additional costs associated with monitoring and implementing corrective action plans.

Additionally, the restrictions are very technical, requiring knowledge of soil type and temperature, and depth to ground water. It will be difficult in some instances for growers to obtain this information and for states to determine whether the use of aldicarb is appropriate.

As stated earlier, the Agency believes that the registrant's proposal has merits in reducing or eliminating ground water contamination. Therefore, the Agency is prepared to accept some of the proposals set forth by the registrant. Specifically, the Agency will be amending aldicarb registrations to incorporate modifications relating to reduction of the rate and frequency of application, and restricting the period of time aldicarb may be applied. The Agency believes these modifications are straightforward to interpret and, thus, generally easier to enforce. It should be noted, however, that these modifications alone are not considered to be adequate to mitigate the potential for contamination of ground water above the Health Advisory.

2) **Option 2** - Labeling/Monitoring/State Management Plans Determined by Heath Region

This option provides states the opportunity to play an active role in protecting ground water. This option requires labeling modifications for all aldicarb use which will provide a basic level of protection against ground water contamination and a monitoring requirement. It also identifies, using the Heath Region ground water assessment, those states which would need to implement Management Plans in areas where there is the highest likelihood of ground water contamination by aldicarb.

(i) Labeling

Under this option, specific labeling modifications would be required. Such labeling would apply to aldicarb use throughout the country. Specifically, the modifications required would be restricted use due to ground water concerns. Since aldicarb is already a restricted use pesticide due to its acute toxicity, it is not believed that this requirement will impact significantly on the costs associated with applying aldicarb.

Another labeling modification which will be required is a 300 foot drinking water well setback. The Agency believes that this measure will serve to reduce contamination of drinking water because it reduces the likelihood that aldicarb will directly contaminate a drinking water supply. It is difficult to estimate the costs incurred from not using aldicarb in these areas since the Agency has no basis to estimate the number of wells in areas treated with aldicarb. Some reduction in use is anticipated, but the impacts are not expected to be significant. The Agency requests comment on whether the 300 foot length is appropriate, or whether a greater or lesser length should be established.

Finally, the Agency is seeking comment on whether site conditional measures should be required for aldicarb labels. A specific measure has not been proposed. The Agency believes that unacceptable ground water contamination is likely to occur in certain situations, e.g., when applied to a certain soil type when the depth-to-ground water is less than a specified number of feet. Consequently, a label restriction prohibiting use of aldicarb in such instances would be useful in preventing unacceptable ground water contamination. However, given that a specific measure has yet to be identified, the Agency cannot comment on the level of risk protection afforded or the cost impacts resulting from implementing this measure.

(ii) Monitoring

Monitoring in areas representative of medium vulnerability is an integral part of this option. The data generated will be used in deciding whether further regulatory action (i.e., implementing Management Plans) will be needed in these areas. The costs associated with generating these data will not be considered part of the risk/benefit analysis as it is part of the expense involved in supporting the continued registration of this pesticide. However, states with areas classified as medium vulnerability, depending on the outcome of the review of monitoring data, may need to implement a Management Plan. Since this review and identification process will not occur until sometime in the future, the specific costs associated with the implementation of Management Plan in such instances cannot be discussed at this time.

(iii) Management Plans

Management Plans provide the greatest site-specific assurances of proper use without overly protecting areas where unacceptable contamination is unlikely. Management Plans put the primary responsibility on the state for regulating these specific areas and allows for evaluation of site-specific prevention measures based on the use, value and vulnerability of ground waters. The areas where use of aldicarb that will need to be addressed by Management Plan under this option are entire states.

Using the Heath Region ground water assessment, ten "high vulnerability" states would need to implement Management Plans. Additionally, monitoring would be required in "high vulnerability" states which do not need to implement Management Plans. It is the intent of the Agency to cancel the use of aldicarb in those states where a state would need to, but decided not to, implement a Management Plan.

The estimated cost resulting from cancellation in the ten states assuming that a Management Plan were not developed, could exceed $60 million.

The Agency has evaluated the possible costs for developing and implementing Management Plans in the ten states. Estimates of the possible costs were developed from available published data where possible. For some cost components (e.g., number of wells affected, severity of contamination, exposed population, duration of contamination,) precise data were not available to estimate the potential costs associated with these plans. Furthermore, environmental and geographic conditions vary widely among and between the states needed to submit Management Plans. Without knowing in advance the measures each state may wish to employ to manage the use of aldicarb, precise estimates could not be developed. The Agency is aware that further refinement of the estimated costs will be necessary as more data become available. Given the data limitations, the Agency believes that the cost estimates are sufficiently accurate to serve as input in assessing initial economic effects.

The costs associated with the development and implementation of the Management Plans must also be taken into account for this option. The following cost estimates have been developed for the Heath Region approach.

Through conversations with various state agencies that currently have management programs, it is estimated that the development and set up costs of Management Plan could range from about $150,000 to $710,000 per state for the 10 states needed to submit Management Plans. These costs would include the expenses associated with the actual development or structuring of the Management Plan ($10,000 to $25,000), construction of compliance monitoring wells including easements and land costs ($44,000 to $488,000), and mapping ($100,000 to $200,000). (Some of the development costs would roughly be the same for both approaches as the costs are not dependent on whether the entire state or only one county needed to be governed by a Management Plan.) Development and set up costs are a one-time expense. Should a state need to have Management Plan for another pesticide, part of the requirements for Management Plan would have been satisfied by the aldicarb Management Plan. Similarly, compliance monitoring wells could also be used in detecting ground water contamination from other pesticides applied to the same fields as aldicarb.

The Management Plans would also have annual costs associated with implementation. These costs are estimated to range from $275,000 to $434,000 on a per state basis. These costs would include the expenses of such activities as enforcement, sampling and analysis for aldicarb contamination. These costs would occur on a yearly basis but may decline if fewer samples are analyzed in later years or if voluntary compliance reduces enforcement costs.

In its Management Plan, a state will define those conditions under which the use of aldicarb may be allowed. These include, for example: banning the use in certain areas or under certain conditions, specifying how much aldicarb may be used on a per acre basis, or how many times aldicarb may be applied per year. The Agency expects that the Management Plan will result in reducing the probability of ground water contamination by aldicarb above the Health Advisory in the areas covered by the Management Plan and thus reduce the risk to an acceptable level.

In determining whether it is worthwhile to implement a Management Plan or allow use of aldicarb to be banned, one must also consider the long-term in addition to short-term costs. Even though it has been estimated that the first year costs for the development, set up, and implementation of Management Plans in the 10 states could be as high as $8.17 million; $4.7 million would be one-time costs. Additionally, if other pesticides which leach require similar regulation in the future, some of the costs would already have been borne from regulating aldicarb. For example, the costs to develop a Management Plan do not occur on a yearly basis. Once a Management Plan is in place, it would be fairly easy to apply it to another pesticide which leaches. Similarly, although construction of compliance monitoring wells is fairly expensive, this is also a one-time expense. These wells may be used to determine whether other pesticides being applied in the same field are reaching the ground water.

Finally, if it is determined that the Management Plan was successful in eliminating the leaching of aldicarb into ground water, requirements for sampling, one of the more expensive yearly costs associated with implementation of Management Plan, may be greatly reduced or eliminated. In addition, the potential costs of remedial actions which can range from several hundred dollars to more than $2,000 per household (annualized for five years), would also be eliminated if the Management Plan was successful in protecting ground water from unacceptable contamination. The estimated cost resulting from cancellation in the ten states, assuming than a Management Plan were not developed, could exceed $60 million.

3) **Option 3** - Labeling/Monitoring/State Management Plans Determined by County

This third option is identical to Option 2 in that it would have the same labeling and monitoring components. However, the states that would need to develop Management Plans would be identified using a county approach which identified counties where the Agency believes aldicarb has the highest tendency to leaching. Under this approach, states would need to develop and implement a Management Plan for those counties classified as such.

The Agency has not completed an assessment of all counties within the United States. If this option is adopted, the Agency would apply these criteria to all counties to identify those which need a Management Plan. Because the total number of counties needing a Management Plan is not yet identified, the costs resulting from a cancellation action under the county approach, assuming none of the states submit Management Plans for their county(ies), cannot be estimated at this time. However, the Agency believes this cost would lie in the range of the costs associated with the Heath Region approach and those resulting from cancellation of all aldicarb uses (i.e., between $60 million and $104 to $135 million).

H. <u>PROPOSED ACTIONS</u>

The Agency is deferring a decision regarding the potential risks due to dietary exposure to aldicarb from consumption of treated food commodities until the final results from the registrant's National Food Survey are evaluated. At such time, the Agency will consider whether further regulatory action will be necessary.

The Agency believes that ground water is a natural resource which must be protected from unacceptable contamination by pesticides. Data available to The Agency confirm that aldicarb has a great leaching potential and that contamination of ground water above the Health Advisory has occurred in many instances. The Agency's ground water assessment methods, using the Heath Region or county approach, have examined areas of the country where aldicarb is used and have identified areas which are highly vulnerable to contamination. The Agency believes that contamination above the Health Advisory is likely to occur at sites throughout these areas.

There are risks to people consuming drinking water contaminated by aldicarb above the Health Advisory. While the Agency cannot predict the level of exposure to contaminated drinking water or the number of people exposed to such contamination, it is known that many wells have been contaminated by aldicarb. Available information suggests that the costs of correcting such contamination would be considerable. The Agency concludes that on a national basis, the risks posed from contamination outweigh the benefits of use. Consequently, regulatory action to prevent ground water contamination is necessary to prevent unreasonable adverse effects on the environment.

The Agency believes that it is possible to reduce the risks significantly by imposing certain regulatory restrictions short of cancellation of all use. These restrictions would be a graduated response to an area's vulnerability in such a way that the most stringent measures would be required in areas where there is the highest likelihood of unacceptable ground water contamination. The Agency believes that such restrictions would reduce exposure to a point where the remaining benefits would outweigh the risks of use.

The Agency has evaluated three options to prevent the unacceptable contamination of the nation's ground water by aldicarb and believes that Management Plans afford the greatest assurance of protecting ground water contamination without overprotecting areas where contamination is unlikely or can reasonably be prevented. The Agency further believes that it is necessary to impose certain restrictions on the use of aldicarb as a basic level of protection nationwide in order to reduce the potential for ground water contamination. Additionally, The Agency does not believe that there are adequate data available to predict the likelihood of the contamination of ground water in medium vulnerability areas.

Options 2 and 3 both accomplish these goals. They classify aldicarb as a restricted use pesticide due to its ground water contamination potential, in addition to its acute toxicity. They also provide a 300-foot well set-back on aldicarb use and require monitoring in medium vulnerability areas and Management Plans in the areas where ground water contamination is most likely to occur. Option 2 uses the Heath Region approach in identifying the need for Management Plans on a state basis and Option 3 uses the county approach in identifying the need for Management Plans on a county basis. Because of the legal mechanisms established under FIFRA for accomplishing these goals, the alternative to establishing Management Plans in those states or counties where a Management Plan is needed but not implemented is cancellation of aldicarb use in those areas. The Agency is seeking public comment as to whether Option 2 (state approach) or Option 3 (county approach) is favored.

The major problem with the Options 2 and 3 is that some states may not have the legal authority, technical skills, or resources to establish or implement an effective Management Plan. Both approaches provide states a strong incentive to submit an acceptable Management Plan since, without it, use in the entire state or certain counties would be prohibited. In contrast to the county approach, the Heath Region approach may be more likely to have areas that are either overly protected or underprotected since the classification of vulnerability was based on large Heath Regions. The county evaluation was based on a more specific geographic unit, the county.

The Agency proposes Options 2 and 3 to impose label restrictions and monitoring requirements, and to allow the use of aldicarb in certain states/counties which have approved Management Plans and cancel the use of aldicarb in certain states/counties which choose not to implement Management Plans.

In comparing the two options proposed by the Agency, three basic differences are evident. Under Option 2, the state would need to implement a Management Plan which addresses all counties within the state rather than only specified counties as under Option 3. However, the Agency recognizes that in addressing each county in a statewide plan, the state may properly conclude that only certain counties need to implement risk reduction measures. Another difference is the number of states which would need to implement a Management Plan. The Agency estimated that the number of states which would need to implement a Management Plan under the approach in Option 3 will be between 15 and 24 compared to the ten states identified under Option 2.

Finally, under Option 3, states would need to implement a Management Plan in all counties with a high potential to leach. Under Option 2, there are a number of states containing areas rated as having a high potential to leach (but with low aldicarb use) which would not need to implement a Management Plan. In these states the registrant, as a condition of registration, would be required to monitor ground water in high vulnerability areas to assure that the national uniform measures are sufficient to prevent ground water contamination at levels that would cause unreasonable adverse effects on the environment.

The Agency is considering two different procedures for implementing the provisions of Options 2 and 3. Under one procedure, The Agency would implement the Management Plan approach using the cancellation procedures in FIFRA section 6. In general, after appropriate opportunities for public and state participation, the Agency would seek to cancel the use of aldicarb in areas where a Management Plan was considered necessary to prevent unreasonable adverse effects on the environment but for which areas no adequate Management Plan had been developed. As the first step of this process, once the Agency decided how it would select the areas for which Management Plans are needed, it would explain the selection procedure, identify the areas, and establish a deadline for states to submit a description of their plans. Following the Agency review and an opportunity for states to improve any plans which The Agency might consider inadequate, the Agency would issue a Notice of

Intent to Cancel, identifying those areas in which cancellation would occur. Registrants and other adversely affected persons would then have an opportunity to challenge the Agency's determinations in an adjudicatory hearing under FIFRA section 6.

Because the cancellation process can be so lengthy and consumes so many resources, the Agency is considering an alternative process. The alternative process would rely on the authority in FIFRA §3(d)(1)(C) to issue regulations classifying a pesticide for restricted use and imposing "other regulatory restrictions" on its use. Generally, the Agency would issue a proposed and final rule under FIFRA §3(d)(1)(C) which restricted the use of aldicarb in certain areas (e.g., the areas identified using Option 4) to use in conformity with Management Plan. The regulations would establish requirements for the content of Management Plans; procedures for comment and review of Management Plans by the Agency; and implementation by the states.

The Agency requests public comment on these alternative procedures for implementing the Management Plan approach. The Agency is particularly interested in comments addressing the time needed for full implementation under each alternative. In addition, if the rulemaking approach is chosen, the Agency is interested in the procedures that should be established for review and approval of Management Plans. Finally, the Agency would be interested in other proposals on the process that should be used to implement Management Plan approach.

The Agency is also soliciting public comment on the labeling requirement that aldicarb not be applied any closer than 300 feet of a drinking water well. Comment is specifically being requested on whether a 300-foot setback is appropriate, whether it should be a greater or lesser length, and whether there should be a different prohibition for public versus private wells. The Agency is also interested in the anticipated impacts resulting from the proposed well setback in terms of decreases expected to yields.

In addition, because the regulatory approach recommended by the Agency differs significantly from previous decisions under FIFRA, the Agency requests comment on the way in which it has explained and supported its position. In particular, the Agency invites public comment on the most appropriate analytical framework for weighing risks and benefits for a pesticide which has the potential to contaminate ground water. Should a more quantitative risk assessment be performed and if so, how should it be performed? What should be included in the assessment, (e.g., number of people exposed, cost of monitoring, treatment or clean-up, lost land values, value of potential drinking water)?

At what level of resolution should the benefits analysis be conducted, (e.g., national, state, county, or local)? In making risk/benefit decisions on the county level, the Agency could consider information such as the following:

1) The importance of aldicarb to the county, including the relative size of the contribution aldicarb-treated crops make to the local economy and additional local employment which depends on these crops (e.g., processing plants).

2) The importance of ground water to the county, including the extent to which the community depends on ground water as a drinking water source, the number of people who rely on private wells for drinking water, the degree to which this dependence is likely to change, and the importance of ground water in terms of projected land use (e.g., possible residential, commercial, or industrial development).

3) Management costs associated with mitigating the effects of the use of aldicarb in communities, including monitoring, point-of-use controls, importation of water, and clean-up costs.

4) The importance of conditions on efficacy of alternatives to aldicarb, including unique or special climatological or agronomic factors (e.g., age of citrus trees, amount and timing of rainfall).

5) Aldicarb's effectiveness, use (i.e., application rate by crop and county and usage), especially for high value (e.g., ornamentals), continuous cultivation crops (e.g., bananas), and crops with rapidly changing usage (e.g., soybeans).

The Agency is soliciting comments on the appropriateness of the above factors, on additional factors which should also be considered, and on who should be responsible for developing this information. The Agency proposes that outside parties (e.g., the registrant or user groups) interested in retaining the local use of aldicarb, will be responsible for gathering and providing local information needed to rebut the Agency's presumption that risks outweigh benefits when the Health Advisory is exceeded.

When looking at regulatory decisions affecting a particular geographical area (e.g., a state or county), how should the Agency evaluate risks and benefits? Who is responsible for gathering information to support such an analysis and who should conduct the analysis (i.e., the Agency or the states)? At what stage of the regulatory process should such an analysis be performed? Under what circumstances, if any, should a state perform the analysis?

The Agency also requests comment on the analytical approaches it has used to identify the areas in which aldicarb use is most likely to contaminate ground water. In particular, the Agency invites consideration of alternative criteria in applying the county-based analysis such as: setting the break points between high, medium, and low ratings for vulnerability at different DRASTIC scores, and giving a higher usage rating to counties in which root crops constitute a larger percentage of use. The Agency also invites comment on the break points which were used in determining where a state needs to implement Management Plan for all or some of the counties.

The Agency recognizes that the criteria used in assessing the potential for aldicarb to leach to the ground water and thus whether a county or state needs Management Plan, create inconsistencies. For example, under the Heath Region assessment, counties which have a high potential to leach would not be subject to Management Plan or monitoring by the registrant if the counties are not within a state which was part of a crop/Heath Region combination rated high in terms of potential to leach. Similarly, under the county assessment, various areas of a county may have a high potential to leach but the majority of the county has a medium potential to leach. Consequently, the state would not have to implement Management Plan for that county.

The Agency is also seeking comments in three other areas which are pertinent to the regulatory actions proposed. First, comments are being solicited on whether it is appropriate for the registrant to be involved in refining assessments regarding the likelihood of ground water contamination in an area and, if so, how such an assessment should be performed. The areas where such an assessment would occur should also be addressed. For example, instead of relying on a county's DRASTIC rating in a medium vulnerability area, the registrant could be required to assess vulnerability to leaching at the sub-county level, based on such factors as soil type, depth to ground water level, and location of crops which may be treated with aldicarb. This information would then be used as a basis to determine whether Management Plan would be needed.

The Agency is also interested in obtaining additional information on the costs associated with the development and implementation of Management Plans. Another related issue the Agency is concerned with is the level of involvement the registrant should have in developing Management Plans. Comments are being solicited both on the appropriateness of registrant involvement in developing Management Plans, and whether there should be a limit to their involvement.

Finally, the Agency is soliciting comment regarding the issue of ground water contamination and liability. One unresolved question regarding ground water contamination is who is responsible for remedial action (e.g. developing, approving, and implementing corrective action plans such as funding clean-up costs or providing an alternate water supply) when contamination results from a registered pesticide use. The Agency's proposed ground water strategy document, Agricultural Chemicals in Ground Water: Proposed Pesticide Strategy, discusses this issue in more detail. Ground water contamination and liability is a generic issue which pertains to all pesticides which leach rather than just to aldicarb; consequently, any comments regarding this issue should be made in response to the above document.

CHAPTER V

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APPENDIX I

LIST OF REBUTTORS TO PD 1

1 Murray, Murray Groves, Inc.
2 Weires, N.Y. Agri. Experiment Station
3 Corban, Miss Coop Extension Service
4 Reinking, Dennison's Mid Valley Chemical
5 McDaniel, A.R. Coop Extension Service
6 Floyd, U.D. Floyd Farms
7 Mason, A.R. Coop Extension Service
8 Jordan, Jordan & Jordan, Inc.
9 Worley, Univ. of Georgia
10 Phillips, Certifine Fruit Co.
11 Ghidiu, Rutgers Coop Extension Service
12 Stuckey, Univ of KY Coop Extension Service
13 Davis, Heart of GA Peanut & Gin Co.
14 Adkinson, Private Individual
15 Johnston, Rutgers Coop Extension Service
16 Smith, Texas Agri. Extension Serv.
17 Mitchener, Mitchener Farms
18 Chapin, Clemson Coop Extension Service
19 Enns, Private Individual
20 Phillips, J.L. Phillips Farms
21 Langlois, Rutgers Coop Extension Service
22 Nabors, Miss Coop Extension Service
23 Craven, Univ. Of GA Coop Extension Service
24 Boaman, Natural Resource Ecology Lab.
25 Averre, NC Agri. Extension Service
26 McKinley, Southern Agri. Insceticides, Inc.
27 Willingham, J.E.Willingham, Jr, esq.
28 Snapp, G&P Seed Co.
29 Striche, Striche Farms
30 Spilsbury, Wilbur-Ellis Co.
31 Bell, FL Fertilizer Co.
32 Annon.
33 Steflick, Steflik Farms, Inc.
34 Haskett, Asgrow Florida Co.
35 Pustejovsky, Private Individual
36 Eich, AL Coop. Extens. Service
37 Timmer, Univ. of FL
38 Albers, NY Coop. Extens. Service
39 Roe, Wm. G. Roe & Co., Inc.
40 Zipperer, GA Coop. Extens. Serv.
41 Dunaway, Dixie Bonded Warehouse & Grain Co.
42 Wilson, Southwestern Peanut Grower's Assn.
43 Lee, TX Agric. Extens. Serv.
44 Miner, Soilserv, Inc.
45 Icardo, I & I Farms, Inc.
46 Bagent, LA Coop. Extens. Service
47 Harper, Wilbur-Ellis Co.
48 Pavelski, Pavelski Farms, Inc.

49 Amalgamated Sugar Co.
50 Sump, Puregro Co.
51 O'Neal, NC Agric. Extens. Service
52 Chalfant, Univ. of GA
53 Rutkowski, NY Coop. Extens. Service
54 Reed, Univ. of AK Agric. Exper. Station
55 Deeter, J.R. Simplot Co.
56 Thomas, NM Univ. College of Agr. & Home Econ.
57 Aitken, Gorsuch & Alverson, Clemson Univ.
58 Bovee, Rio Farms, Inc.
59 Evans, Wilbur/Ellis Co.
60 Mahany, Steuben County Potato Growers Assn.
61 Hirrel, Univ. of AK Div. of Agric.
62 Dilbeck, St. Johns County Coop Exten. Serv.
63 Lloyd, Wilbur/Ellis Co.
64 Vanvranken, Rutgers Univ. Coop. Exten. Serv.
65 MacNeil, Cornell Univ. Coop. Exten. Serv.
66 Rakich, AZ Agric. Chem. Assn.
67 Edsall, R.S. Edsall Co.
68 Small, NC State Univ.
69 Sibbett, Univ. of CA Coop. Exten.
70 Semtner, VA Poly. Inst. & State Univ.
71 Samulis, Rutgers Univ.
72 Cheshire, Univ. of GA Coll. of Agric.
73 Tregaskes, AZ Agrochemical Co.
74 Baldwin, Commonwealth of VA
75 Schwartz, CO State Univ.
76 Diem, VA Coop. Exten. Serv.
77 Burns, Z.V. Pate, Inc.
78 Summers, Golden Kernal Pecan Co.
79 Homan, Univ. of Idaho Coop. Exten. Serv.
80 Burris & Rogers, LA State Univ. Agric. Cntr.
81 Johnson, Walt Johnson
82 Johansen, WA State Univer.
83 Herzog, Univ. of GA
84 Buford, Buford Plantations
85 Trett, F.M. Upton & Sons
86 Minton, USDA
87 Tucker, Univ. of GA Coop. Exten. Serv.
88 Hagenston, Brown & Bryant, Inc.
89 Burch, LA Coop. Exten. Serv.
90 Boykin, W.B. Boykin
91 Obreza, A. Duda & Sons, Inc.
92 James, LA Coop. Extens. Serv.
93 Anderson, The Dune Co. of Imper. Valley
94 Lowder, Lowder Bros. Gin Co.
95 Henninger, Rutgers Univ.
96 Wittmeyer, Ohio State Univ.
97 Boren, Roger Boren, Inc.
98 Mott, NRDC
99 Lane, McNair Farms
100 Bash, Ohio Farm Bureau Federation

101 Gonzales, The Fertilizer Place
102 Winstead, None
103 Marley, Bouldin A. Marley
104 King, King Farms
105 LeBlanc, Nutrite Corp.
106 McCleskey, McCleskey Gin
107 Stone, TX A&M Univ.
108 Sturdivant, Duck Land Planting Co.
109 Jackson, Triangle J. Farms
110 Hudson, Tri-State Chemicals,
111 Owens, Wilbur-Ellis
112 West, West Consulting
113 Overstreet, LA Coop. Exten. Serv.
114 Dutcher, Univ. of GA
115 Probasco, Rutgers Coop. Extens. Serv.
116 Spackman, Univ. of WY Agric. Exten. Serv.
117 Noetzel, Univ. of MN Agric. Exten. Serv.
118 Moore, OK Farm Bureau
119 Pitts, Helena Chemical Co.
120 Dunlap, Arizona Agrochemical Co.
121 Larson, Amalgamated Sugar Co.
122 Raski, Univ. of CA at Davis
123 Jones, R.W. Jones
124 Lamm, NC Agric. Exten. Serv.
125 Bolduc, Conserv. Law Found. of N.E.
126 Shenot, Agway
127 Dickson, Univ. of FL
128 Smilowitz, PA State Univ.
129 Updike, Alcoma Packing Co.
130 Barnes, Barnes FArm
131 Parker, TX Agric. Exten. Serv.
132 Tynes, LA Coop. Exten. Serv.
133 Roberts, Univ. of CA Coop. Exten. Serv.
134 Nelson, IN State Chemist and Seed Commissioner
135 Sims, R. Douglas Sims
136 Cleveland, OK Agric. Chem. Assn.
137 Heiden, H-Four Farms
138 Young, Sandyland Farms
139 Fulford, GA Coop. Exten. Serv.
140 Kantzes, Univ. of MD
141 Wyman, Univ. of Wisconson-Madison
142 Crawford, Univ. of GA
143 Hancock, Helena Chemical Co.
144 Weingartner, Univ. of FL
145 Wright, Univ. of Idaho Coop. Exten. Serv.
146 Harkin, Wisconson Water Resource Cntr.
147 Moore, USDA
148 Hafez, Univ. of Idaho
149 Barnes, Wayne Barnes
150 Pearson, Rainbow Plantation
151 Santo, WA State Univ.
152 Sallstrom, MN Plant Food and Chemicals Assn.

153 Leiby, PA State Univ. Coop. Exten. Serv.
154 Geiger, Lehigh Valley Potato Growers Assn.
155 Tillinghast, SUNY @ Cornell
156 Leep, Henry G. Leep
157 Graham, NC Dept of Agric.
158 Bailey, Dixie Ag. Supply
159 Musick, Crop-Gard Inc.
160 Bonner, AK Coop. Exten. Serv.
161 Cooper, Nat'l. Food Proc. Assn.
162 Turner, Brooks Turner
163 Johnson, Wes Johnson
164 Huelett, Buddy Huelett
165 Lunceford, Marvin L. Lunceford
166 Kelly, Ohio Potato Growers Assn.
167 Matthews, Matthews Farms
168 Sheffield, Helena Chemical Co.
169 Benedict, TX A&M Univ.
170 Mosley, Southern Farmers Assn.
171 Whitehead, Valley Chemical Co.
172 French, TX A&I Univ. Citrus Cntr.
173 Thomason, Univ. of CA
174 Raley, Rodney Raley
175 Walden, Enoy Walden
176 Schultz, Commonwealth of VA
177 Lonergan, George L. Lonergan
178 Morgan & McCarty, MS State Univ.
179 Baughman, Barbara Baughman
180 Dawson, Wisconson Dept. of Justice
181 O'Toole, Union Oil Co.
182 Curswell, Bill Curswell
183 Stuart et al., Red River Co-op.
184 Datt, Amer. Farm Bureau Fed.
185 Harte, Chandler Harte
186 Besadny, State of Wisconson
187 Shiels, Shiels Farms
188 Legates, NC State Univ.
189 Marley, Chritian T. Marley
190 Yandell, West End Planting Co.
191 Johnston, CA Dept. of Food & Agric.
192 McKeown, James P. McKeown
193 Lynn, Grower Service Corp.
194 Myrick, AL Farm Bureau Fed.
195 Hancock, Diamond R Fertilizer Co.
196 Graustein et al., Univ. of Deleware
197 Long, Michigan State Coop. Exten. Serv.
198 O'Tuel, E.M. O'Tuel Cotton Co.
199 Arnold, Professional Agricultural Serv.
200 Zimpel, T.H. Agri-Chemicals
201 Conrad, Estes Chemicals
202 Lambert, GA Coop. Exten. Serv.
203 Sawyer, NC Agric. Exten. Serv.
204 Williamson, Don Williamson

205 Reilly, VPI
206 Komm, VA Coop. Exten. Serv.
207 Tugwell, Univ. of Ark.
208 Moore, VA Farm Bureau Fed.
209 Houston, W.H. Houston & Son
210 Murphy, Indian Sun Groves
211 Myrick, Ala. Farm Bureau Fed.
212 Griffiths, Harry J. Griffths
213 Lawson, Lawson Farms
214 Youngker, Chas. Youngker & Son Farms Co.
215 Johnson, Melvin Johnson
216 Walther, L. Walther & Sons
217 Mohr, Rutgers Coop. Exten. Serv.
218 Hofmaster, Commonwealth of VA
219 Crawford, Crawford Farms
220 Orr, USDA
221 Balch, AL Coop. Exten. Serv.
222 Simpson, John Langford Inc.
223 Griffin, NC Agric. Exten. Serv.
224 James, Ruben Earl James
225 Bateman, NC Agric. Exten. Serv.
226 Paul, Carolina Eastern Inc.
227 Price, Bruce G. Price
228 Graugnard, LA Farm Bureau Fed.
229 Lee, Neil C. Lee
230 Child, Childstock Farms
231 Parker, Harris Farms
232 Ausman, State of Wisconsin
233 Flowers, Delta Council
234 Sayers, Asgrow Seed Company
235 Munter, Wm. Gehring Inc.
236 Harkin, WI Water Resource Center
237 Lentz, Univ. of Tenn
238 Williams, Western Growers Chem.
239 Quick, PureGro
240 Irwin, Agvise
241 Lanier, Growers Supply
242 Lovell, Union Carbide (6 vols.)
243 Sears, Nat. Cotton Council
244 Bourret, Wyoming Farm Bureau
245 Smith, NC Dept. of Agriculture

APPENDIX II

STATE PESTICIDE GROUND WATER MANAGEMENT PLAN FOR ALDICARB

A. BACKGROUND

The general concept of a State Pesticide Ground Water Management Plan (Management Plan) is presented in the Agency's proposed strategy to address the pesticides in ground water concern. The proposed strategy was released for public review and comment on February 26, 1988 and is available through the Agency's Public Information Center at (703) 382-2080.

In releasing its proposed strategy to address the pesticides in ground water concern, the Agency is particularly interested in receiving public comment on the general concept of a Management Plan. To facilitate such input, the Agency is planning a series of workshops beginning in the summer of 1988 to explore with state agencies and others the Management Plan concept including appropriate components and emphasis of such plans and the degree of oversight that the Agency should have in their development and implementation.

There is a range of approaches that the Agency could use as guidance to the states in developing their Management Plans. At one end of the range would be an approach whereby the Agency establishes an environmental performance standard (i.e., the Maximum Contaminant Level or Health Advisory level) for each pesticide, but allows each state the flexibility to decide which management measures it will utilize to meet that goal.

The other end of the range would be for the Agency to establish detailed specifications for state management plans including required adoption of certain.

There are a number of possible approaches between the above two extremes. The Agency could establish environmental performance standards and then provide a basic framework for state Management Plans which would allow a state some flexibility in deciding the specific pesticide management measures needed to meet the standard. Which aspects of a Management Plan would be flexible, and to what degree, provides the variety of approaches that the Agency can consider in developing guidance for the states.

At this time, the Agency is generally of the opinion that it should follow some middle path that establishes an environmental performance standard but allows some degree of flexibility for States to determine the specifics of their Management Plans. The Agency believes that there are likely to be several valid state Management Plan approaches and that flexibility will be needed for states to tailor management measures to specific local ground water protection needs. The Agency requests comments on this approach, and requests discussion on whether it is preferred over either the performance standard or specified plan approaches.

A state's Management Plan should be a comprehensive description of a state's strategy for managing the use of a pesticide(s) for the purpose of protecting the ground water resource. To be consistent with the goal of the Agency's proposed strategy, a state's Management Plan should pay specific attention to preventing contamination of current and potential drinking water supplies.

In general, a Management Plan should: 1) describe the state's overall philosophy and approach to protecting its ground waters from pesticide contamination, 2) identify a state's capabilities and authorities in implementing the plan, 3) identify the location of all ground water that is currently and could potentially be a source of drinking water in the future or that is of ecological importance, 4) contain a monitoring scheme designed to ensure the effectiveness of the Management Plan and flag contamination problems resulting from misuse/accident, 5) establish contingency plans to deal with contaminated ground water, 6) in cases where contamination occurs above the specified level, describe the mechanisms to be used to reduce contamination, including the source of funding and, 7) describe how the public is kept informed and can become involved. The plan should also set forth the state's enforcement authorities and capabilities which can be used to assure compliance with the provisions of the plan. The Agency requests comment on whether these are the appropriate components of a plan as well as the appropriateness of the description of information to be included in each of the components.

Many of the Management Plan components presented above were derived from discussions at a workshop held during the summer of 1987 to review an earlier draft of the Agency's proposed strategy to address the pesticides in ground water concern. The workshop had representatives from other federal agencies and state agencies as well as from agricultural and environmental interest groups. These participants provided the Agency with specific recommendations on possible Management Plan components.

The Agency realizes that there could be much variation among state plans to account not only for differing state conditions but also varying state approaches. The Agency will be flexible in its review of the various state plans, recognizing that different approaches can be used to obtain the same goal (i.e., preventing contamination or reducing the likelihood of a pesticide in ground water reaching an Agency-designated level). States may also elect to work collectively in developing various components of a plan; however, each state will be responsible for the development of its own plan.

A state's Management Plan may have to include a chemical-specific part, as well as a more generic part that deals with all pesticides which are of ground water concern. The generic part of the plan would set forth the basics for implementing a plan which could be used for any pesticide. The chemical-specific parts of such a plan would include those portions of the plan that are specific to a particular pesticide, such as monitoring designs to ensure compliance with an Agency-designated levels, identifying specific areas where a certain pesticide is used, etc.

B. RELATIONSHIP BETWEEN MANAGEMENT PLANS AND OTHER AGENCY/STATE WATER QUALITY EFFORTS

There are a number of Agency and state drinking water and water quality programs that can impinge upon or be used to address various aspects of the pesticides in ground water concern. Under the Safe Drinking Water Act (SDWA), the Agency is providing guidance to the states on wellhead protection programs which are aimed at managing potential sources of ground water contamination in identified areas around public water wells. The Agency is also examining possible future SDWA regulations that will involve the states in controlling Class V injection wells which could include agricultural drainage wells.

Under the Clean Water Act and more recently, the Water Quality Act of 1987, the Agency is developing guidance to the states for implementation of various sections of these acts. Each state is to develop a State Clean Water Strategy that will set the overall direction of a state's efforts to address water quality protection efforts. Specific guidance has been developed for a state's efforts to address nonpoint source problems with consideration given to ground water concerns. Under these acts, most states have also been given support by the Agency to develop overall ground water protection strategies.

It is the Agency's intent that a state's efforts to develop a Management Plan to address pesticides in ground water concerns be coordinated with the above water quality efforts. The Agency will be taking steps to ensure that consistent guidance is provided to the states through these various efforts. It is expected that a state's Management Plan will show how it is specifically being coordinated with these various strategies and programs.

C. COMPONENTS OF MANAGEMENT PLANS TO SUPPORT ALDICARB REGISTRATION

The following constitutes the components of a Management Plan that will likely be necessary to support the continued registration of aldicarb in a state or county designated by the Agency as requiring a Management Plan. Possible aldicarb-specific parts of the plan are identified as such; otherwise, the following guidance relates to the generic Management Plan. Again, the Agency is seeking comment and discussion on these components, the need for additional components and the emphasis that should be given to each in a Management Plan.

1. STATE LEAD AGENCY

The governor should designate a state lead agency to serve as the contact with the Agency for all matters regarding the Management Plan. The lead agency will also function as the coordinator of all agencies within the state involved in carrying out the functions of the plan. The Management Plan should identify the agencies involved, contain a discussion of their respective responsibilities and functions, and contain a discussion of the mechanisms for assuring coordination of functions among state agencies.

2. LEGAL AUTHORITY/TECHNICAL EXPERTISE

The plan will describe the general capability of the state to implement the plan successfully. Included in this description shall be the legal authorities available to the state with citation to and copies of the relevant state laws and regulations, a description of the technical expertise available, and a projection of the level of resources the state intends to commit to carry out the Management Plan. The plan must at a minimum demonstrate the state's authority to: 1) conduct or to require others to conduct monitoring, 2) supply or require others to supply alternate sources of water, 3) close wells, 4) impose civil and criminal penalties for misuse and 5) enforce other relevant authorities. The Agency is soliciting comments on whether a Management Plan should be approved without these authorities or whether additional authorities are necessary.

3. MAPS

The Management Plan will ultimately contain maps for all areas within the state. These maps will be used in assessing the vulnerability to contamination in an area (see below). A suggested set of maps include the following:

1) Soil maps which describe: soil type (e.g., sand, loam, silt clay loam, etc.), organic matter variations, Soil Conservation Service runoff classification (i.e., A, B, C, or D).

2) Identification of areas where ground water is a current or potential drinking water source and identification of high use and/or high value ground waters, including any wellhead protection areas or zones or waters of ecological importance. [States will provide definitions and criteria used to identify the various types of waters.]

3) Depth from soil surface to ground waters.

4) Identification of recharge areas.

5) Isopleth maps of recharge including artificial recharge (e.g., irrigation).

6) Identification of agricultural areas including specific crop identification or more general agricultural delineations (e.g., pasture, vegetable crops, grain, etc.).

Aldicarb-specific part of the Management Plan: The Management Plan will contain maps for all areas (counties or sub-counties) where aldicarb is normally used and on what crops, the vulnerability of those different locations, and the use and value of ground water that may be affected. The Agency is soliciting public comment on whether it is reasonable for states to develop aldicarb-specific maps within the time period (two years) that the Management Plan is developed and accepted and, if not, what a reasonable time would be for development of these maps.

The Agency has, in this document, classified various states or counties into three categories of likelihood for ground water contamination by aldicarb (i.e., high, medium and low). Under Option 4, proposing a means of regulating the use of aldicarb to prevent ground water contamination, states should initially adopt the Agency's ratings for vulnerability. These areas may be further delineated by applying the Agency criteria to more specific areas. (The Agency criteria are summarized in the Aldicarb Technical Support Document.) Refinement of vulnerability areas may be made using the suggested maps described in the generic part of the plan. If an area is placed into a lower category (from high to medium or medium to low), the state will be required to provide a justification for the change. The Agency will review the rating and justification and inform the state of its decision regarding the change. The Agency is soliciting public comment on the mechanism described above that a state must follow for changing an area's vulnerability rating.

4. GROUND WATER CONTAMINATION PREVENTION MEASURES

Aldicarb-specific part of the Management Plan: States will be required to define specific preventive measures which will, at a minimum, prevent or reduce any reasonable likelihood of unacceptable contamination of ground water that is a current or potential drinking water source. It will be incumbent on the state not to only identify these specific measures but also to justify why such measures are believed adequate. The state, in developing these measures, should consider the capability of the user in identifying the criteria (i.e., if use is limited to areas where ground water is at least a specified depth, the plan must contain an explanation as to why it is reasonable to assume that users will know that ground water is at least the specified depth, that users are likely to follow such a limitation, and an explanation as to why contamination is not expected to result to ground water at this depth). Specific measures which may be imposed, alone or in combination, include:

1) cancellation of use or moratoriums,

2) reduction in the rate of use,

3) more stringent well setback restrictions (a 300 foot set-back for drinking water wells is being proposed as a national preventive measure to reduce the potential for contamination),

4) application method limitations,

5) application time of year restriction,

6) wellhead protection of public drinking water,

7) rules on disposal of excess product/unused spray mix/ containers,

8) mixing/loading requirements,

9) changes in agronomic practices (e.g., tilling),

10) permit or advance notice program (if used, identify criteria for issuing permits or denying use),

11) user education/training, (One of the best defenses in the protection of ground water is to educate the pesticide applicator of the problem and provide training on measures to employ in avoiding contamination. User education/ training heightens the user's awareness to the problem and the extent of training applicators will be required to take.), and

12) use restrictions on a farm-specific basis, i.e., restrict use if farm conditions such as soil type, depth to ground water, or other hydrogeologic parameters exceed specified limits.

The measures for prevention of contamination should be most stringent in the most susceptible areas (i.e., those areas where vulnerability is the greatest) and those areas where the ground water is most important as a resource.

The plan should provide that the Management Plan's prevention measures could be modified if it is obvious, based on experience and/or monitoring results, that such measures are not providing adequate protection.

State measures must, at a minimum, provide reasonable confidence of preventing or reducing the likelihood of aldicarb contamination reaching the Health Advisory level of 10 ppb in ground water.

5. **RELAYING USE INFORMATION**

The Management Plan shall have a detailed discussion of how information regarding use restrictions/precautions will be relayed to users. Such discussion should include not only the form but also the distribution methods. The enforceability of imposing requirements under this approach should also be addressed.

6. **ENFORCEMENT**

The plan should describe the state's enforcement capabilities and authorities in terms of assuring compliance with the measures imposed to protect ground water from contamination and in terms of response actions where contamination has already occurred. Both civil and criminal enforcement authority should be available to the state under the Management Plan.

7. **MONITORING**

States must establish a comprehensive monitoring program which will be statistically designed to evaluate the impact of use of a pesticide, identified as posing a threat to ground water contamination. Many monitoring designs are possible and each Management Plan must provide justification for the design chosen. In general, acceptable designs would contain the following objectives and features:

1) The majority of monitoring will occur in areas of most concern based on hydrogeologic vulnerability and pesticide use patterns; some sampling should also occur in areas of less concern.

2) The design should be stratified on use and hydrogeologic vulnerability in the sense that smaller areas monitored will be statistically representative of larger areas similar in hydrogeology and use patterns.

3) Monitoring must be focussed on the quality of the ground waters that are a current as well as potential drinking water source. This important objective often will require the implementation of new monitoring wells, or use of existing high quality wells of known attributes, such as USGS monitoring wells.

4) Monitoring designs must contain a quality assurance program, including participation by the state. The state role could include, for example, participation in sample collection and shipment, analytical quality control including use of an independent state-appointed laboratory, additional monitoring, etc.

Aldicarb-specific part of the Management Plan: The following type of information should be included in the plan:

1) the number of wells to be sampled,
2) selection criteria for the wells,
3) statistical evaluation of the sensitivity of the monitoring plan,
4) identification of the analytical method(s) used to analyze samples, and
5) frequency of monitoring.

The Agency acknowledges that there two means to require monitoring for contamination of ground water by aldicarb. One is to impose the monitoring program, including the program design, implementation, and cost, on the registrant, as a condition of registration. The other is to impose this as a requirement of the state as part of the Management Plan. The Agency is soliciting comment on the merits of either approach.

8. ACTION IN RESPONSE TO GROUND WATER CONTAMINATION

The Management Plan will specify what measures will be implemented to ensure that the Agency-designated level (in most cases the Maximum Contaminant Level or Health Advisory) will not be reached once ground water contamination is detected in ground water that is a current or potential drinking water source and, if this level is reached or exceeded, how the state will prevent contaminated ground water from being used as a source of drinking water.

The plan shall specify whose responsibility it will be to identify how the contamination occurred, to rectify the contamination problem when a specific level is reached, and, when necessary, to provide (fund) an interim source of drinking water.

Specifically, the plan must describe the steps that will be taken to identify, if possible, the source of contamination and, if possible, to ascertain whether use was in accordance with label directions and other requirements and the contamination resulted from normal use, leaching and subsequent ground water contamination; or whether ground water contamination resulted from misuse or accident (e.g., spillage). The plan shall also specify the means which will be employed in reducing pesticide contamination of ground water to acceptable levels when the specified level (Maximum Contaminant Level or Health Advisory) is exceeded and for providing an interim drinking water source for contaminated wells.

It is the responsibility of a state under its Management Plan not only to protect ground water from contamination within its boundaries but also to mitigate contamination of a source of drinking water in another state. It may therefore be necessary for states to inform one another when applications are made in bordering counties where ground water moves across state boundaries. In those cases where it can be clearly demonstrated that ground water contamination above the specified level occurred as a result of application/accident from a neighboring state, it will be the responsibility of the state in which the pesticide use occurred to ensure that corrective action is taken.

Aldicarb-specific part of the Management Plan: In accordance with the generic part of the Management Plan, the plan will designate the Health Advisory level for aldicarb (10 ppb) as the maximum level of contamination which will be allowed in ground water that is a current or potential drinking water source. Because the level of detection (1 ppb) is so close to the level of protection, the problem identification and response program will be initiated when any level above 1 ppb is identified.

9. PUBLIC PARTICIPATION

The Management Plan should provide detail how the public will be informed of significant findings and important regulatory actions under the plan. The plan should also address the public role regarding decision making under a state plan.

10. RECORDS/RECORDKEEPING

The state plan shall include a provision to maintain Management Plan records on monitoring efforts, including sample analysis, issuance of permits, etc., and the types and number of enforcement actions, site-specific regulatory actions, administrative action, etc. Such records shall be maintained for a minimum of five years and be made available to the Agency upon request. An annual report shall be sent to the Agency Headquarters through the Agency Regional Office.

The plan will require that all findings through monitoring will be reported immediately to Agency. The plan will also include a provision that the Agency will be notified on a semi-annual basis of the results of all routine monitoring.

Aldicarb-specific part of the Management Plan: The Agency shall be notified immediately of all positive findings of aldicarb in ground water. Included in the notification will be the level of contamination, county of occurrence, and the measures implemented to curtail further contamination.

11. TIMEFRAME FOR IMPLEMENTATION

Those states desiring to maintain use of aldicarb within their state will be required to have an Agency-approved Management Plan within two years.

12. AGENCY OVERSIGHT

The Agency will approve a Management Plan (both generic and pesticide-specific parts) submitted by any state, or any modification thereof, if such plan 1) demonstrates a practical approach to managing the use of a pesticide for the purpose of protecting ground water from contamination, and specifically making reasonably sure that no one is exposed to aldicarb residues in ground water at levels greater than 10 ppb, 2) contains satisfactory assurances that the state lead agency has or will have the legal authority and qualified personnel necessary to carry out the Management Plan, 3) gives satisfactory assurances that the state will devote adequate funds to the administration of the plan, and 4) provides that the state will make reports available as required. Conversely, the Agency may reject a Management Plan if the Management Plan does not meet the standards described above.

The Agency's approval of the Management Plan may be withdrawn at any time that it is determined that the state is not properly administering the Management Plan in accordance with its provisions. The Agency will inform the state of its intention to withdraw its approval of the plan and provide the state the opportunity to institute corrective actions. If after a reasonable period, not to exceed 90 days, such action has not been instituted, the state will be notified that the Agency's approval of the plan has been withdrawn.

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