

## Aldicarb - EPA Request for Benefits Information

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Date: May 25, 2006

To: [Rick Melnicoe](#), et al.

Cc: [Linda Herbst](#), et al.

From: Teung.F.Chin@aphis.usda.gov [mailto:Teung.F.Chin@aphis.usda.gov]

Subject: Aldicarb - EPA Request for Benefits Information

[Attachment 1](#)

[Attachment 2](#)

Dear Colleagues:

On May 17, EPA released its health effects risk assessment for aldicarb and related documents for a 60-day public comment period. Public comments on the risk assessment must be received by the EPA Public Docket by July 17, 2006 as part of its Reregistration Eligibility Decision (RED) for the pesticide.

All the EPA risk assessment documents may be reviewed in the EPA docket under Docket Identification Number "EPA-HQ-OPP-2005-0163" at <http://www.regulations.gov>. Enter the Docket identification Number into the appropriate space in the "Advanced Search" tab and in the "Docket ID" space.

EPA considered the use or proposed use of aldicarb on the following crops: Bananas (proposed imported tolerance) Citrus, Other (includes kumquats, limes, tangelos and tangerines), Grapefruit, Lemons, Oranges, Pecans, Potatoes, Sweet Potatoes, Yams, Beans/Peas, Dry, Beans/Peas, Green, Sorghum, Alfalfa, Peanuts, Soybeans, Sunflower, Cotton, Sugar Beets, Sugarcane, Coffee (imported), and Tobacco.

The following benefits information is needed:

In what regions (state/county, etc.) of the U.S. is aldicarb use occurring? What is the percent crop treated in the states where aldicarb is used? (this is especially important information for potatoes)

What are the pests that aldicarb is critical for controlling?

What are the details of typical usage patterns (e.g., number of applications per season, use rate per application, acres treated, and time of application in the season?)

What worker activities typically occur when aldicarb is applied?

What alternatives, if any, are available to replace aldicarb?

Please provide as much detail and documentation in your comments as possible so that the Agency is fully informed in its decision-making.

The EPA May 17 Federal Register provides additional information including how to submit your comments to the docket: <http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/E6-7496.htm>

Besides submitting your comments directly to the EPA public docket, please also send a copy to [teung.f.chin@usda.gov](mailto:teung.f.chin@usda.gov) and [sherrie.kinard@epa.gov](mailto:sherrie.kinard@epa.gov) so USDA and EPA may better coordinate.

For your information, EPA is also requesting interested parties:

1. To provide comments and input on the Agency's risk assessments for aldicarb. Such comments and input could address, for example, the availability of additional data to further refine the risk assessments, such as, additional toxicological data, worker exposure data, and usage information, or could address the Agency's risk assessment methodologies and assumptions as applied to this specific pesticide.
2. To provide risk management proposals for aldicarb. Risks of concern associated with the use of aldicarb are: acute dietary risk estimates for the general U.S. population and all population subgroups at the 99.9th percentile of exposure; acute aggregate food and water risk estimates for adults and children; and worker risk estimates for most mixers, loaders and applicators.
3. To submit risk management proposals for ecological risks of concern including those to birds, mammals, fresh water and marine fish and invertebrates. In targeting these risks of concern, the Agency solicits information on effective and practical risk reduction measures."

(See attached file: Aldicarb- EPA-HQ-OPP-2005-0163-EPA Request for Benefits Information.doc) ] (See attached file: Aldicarb Quantitative Usage Analysis (QUA) 1999 and 2000.doc)

Please do not hesitate to contact me if you have any questions or comments.

Best regards,

Teung

[Teung F. Chin, Ph.D.](#)

Biological Scientist

Office of Pest Management Policy

Agricultural Research Service

United States Department of Agriculture

LOCATED AT:

USDA Animal & Plant Health Inspection Service

4700 River Road, Unit 149 (Room 3D-06.8)

Riverdale, MD 20737-1237

Phone (301) 734-8943 Fax (301) 734-5992

5/17/06

## **Request for Additional Information and Suggestions for the Reregistration of Aldicarb Public Comment Period:**

Dear Reader:

The purpose of this document is to summarize the current human health risk picture for aldicarb and solicit mitigation options. The preliminary human health risk assessments will be released for 60-day public comment period May 17, 2006, and will end July 17, 2006.

### **Human Studies Review Board**

A human toxicity intentional dosing study was used in the aldicarb risk assessment. EPA's use of a human toxicity study in the aldicarb risk assessment is in accordance with the Agency's Final Rule promulgated on January 26, 2006. For additional information relating to the Human Studies Review Board determination for the adicarb-specific study used in the risk assessment, refer to EPA's website at <http://www.epa.gov/osa/hsrb/>.

### **Dietary Risks**

Under the Food Quality Protection Act (FQPA), all food and drinking water risks for a given pesticide must fit within the pesticide's "risk cup". The risk cup can be simply defined as the "acceptable level of exposure" to an individual from a pesticide, on an acute or chronic basis. When dietary risks are of concern, EPA is required to mitigate the risks down to acceptable levels.

The current dietary (food only) risk assessment utilizes PDP and the Carbamate Task Force (CTF) market-basket data for potatoes and citrus, respectively. Field trial data were used for all other commodities (except sorghum, sugar beet and sugar cane); however, residues were either very low or non-detectable. Percent crop treated information and processing/cooking data were also utilized where appropriate. It's important to note that since aldicarb is systemic, typical food preparation practices such as washing and peeling are not expected to significantly reduce residues.

Sugar beet and sugarcane were excluded from the assessment since aldicarb residues are not expected in the processed commodities as consumed. A low tolerance level was used for sorghum as well as percent crop treated but resulting estimates did not contribute to risk.

Estimated acute dietary exposure and risk from food alone exceed EPA's level of concern (i.e., >100 % of the aPAD) for children 1-2 years and children 3-5 years old when compared to the rat red blood cell (RBC) cholinesterase inhibition (ChEI) endpoint. The estimated dietary risks for these two population subgroups at the 99.9<sup>th</sup> percentile of exposure were 159% and 129%, of the acute population adjusted dose (aPAD), respectively. For the general U.S. population, the dietary risk was 72% of the aPAD. Estimated risks were below EPA's level of concern (i.e., <100 % of the aPAD) at the 99.8<sup>th</sup> percentile for both children 1- 2 years old and children 3-5 years old. Because dietary exposure estimates were above EPA's level of concern at the 99.9<sup>th</sup> percentile of exposure, an analysis was conducted to determine which food or food forms made the greatest contribution to dietary risk. For all population subgroups, aldicarb residues in potatoes were the most significant source of dietary exposure. When potatoes are removed from the dietary exposure assessment, all remaining risk estimates are below EPA's level of concern.

### **Drinking Water Risks**

Since acute dietary risks from food alone were above EPA's level of concern (i.e., >100 % of the

aPAD), a drinking water only assessment was conducted. If all of the allowable exposure occurred through drinking water, EPA would not have concerns for acute exposure to aldicarb residues in surface water. Acute surface water risk estimates for infants, the most highly exposed population subgroup, range from 1% of the aPAD [potatoes] to 15% of the aPAD [cotton] at the 95<sup>th</sup> percentile of exposure. Acute surface water risk estimates for the general U.S. population and all other population subgroups ranged from <1% of the aPAD to 7% of the aPAD.

Seven regional ground water monitoring residue levels were used to derive an acute dietary exposure estimate for ground water alone. The data indicate that acute exposure from ground water sources of drinking water is of concern, with acute risk estimates ranging from 20% of the aPAD to 945% of the aPAD.

Drinking water risks based on ground water monitoring data overestimate the risks for all but those who obtain their drinking water from wells in vulnerable aldicarb use areas. However, since acute food only exposures exceed the aPAD, EPA is concerned about any additional exposure (to all subpopulations) through drinking water, regardless of the source.

### **Occupational Risks**

The occupational risk assessment for aldicarb is based on potential exposure to agricultural workers during loading and application of granular products. Aldicarb is applied early in the growing season, and labels require immediate soil incorporation of granules; postapplication exposures are not expected for workers, so a quantitative postapplication risk assessment has not been conducted.

Unlike some pesticides, aldicarb has worker exposure data that has been conducted with aldicarb and mirrors how aldicarb is packaged, handled, and used in agriculture. This study was used to conduct the occupational risk assessment for aldicarb. Pesticide Handler's Exposure Data (PHED) were also used in conducting the risk assessment since the aldicarb-specific study did not quantify potential risks from closed loading and closed cab scenarios. Therefore, for the portion of the occupational assessment which used the aldicarb-specific worker exposure data, risks were not of concern for most loader and applicator exposure scenarios. However, risks for loaders were identified for two scenarios (MOEs for loaders range from 14 to 130 and MOEs for applicators range from 34 to 324).

When using the PHED data for the closed loading and closed cab scenarios, similar results to those found with the aldicarb-specific study were noted for loaders. However, when using PHED data for applicators, all scenarios exceeded EPA's level of concern (MOEs for loaders range from 14 to 139; MOEs for applicators range from 1 to 13).

### **Environmental Risks**

The environmental risk assessment is based on maximum rates and average usage rates of aldicarb. The environmental risk assessment includes risks to terrestrial and aquatic organisms. Using multiple lines of evidence (such as use scenarios, average or "typical" application rates, registrant submitted toxicity studies, open literature data, and field monitoring data), aldicarb poses acute risks (mortality) to birds, mammals, and aquatic organisms. In addition, there is the potential for chronic reproductive effects in fish and invertebrates.

#### *Terrestrial Organisms*

For terrestrial organisms, acute levels of concern are consistently exceeded by a factor of greater than 100x and are frequently exceeded by more than 1000x. Granules left exposed on the surface appear to be the main source of exposure, but other sources such as residues taken up by plants and contaminated earthworms may also serve as a means of exposure.

### *Aquatic Organisms*

For aquatic organisms, there are acute risks for freshwater fish and invertebrates and estuarine/marine fish and invertebrates for all of the registered uses with the exception of potatoes for freshwater fish and invertebrates and estuarine/marine fish.

The chronic level of concern is exceeded for freshwater invertebrates (reproductive effects) and estuarine/marine invertebrates (average number of offspring endpoint) for all of the registered uses. Chronic concerns (larval and juvenile survival) also exist for freshwater fish for soybean, cotton, and pecan use patterns.

Aldicarb residues are most likely to exceed levels of concern for fish and aquatic invertebrates in low-order streams because these streams are dominated by base flow conditions (where 100% of stream flow consists of discharged groundwater), and most of the toxic residues are believed to form within the subsurface (especially within the saturated zone). In addition, much larger contributing land areas sustain higher-order streams, so there is a greater dilution effect. In addition to risk based exposure estimates from modeling, there were also exceedances of the Agency levels of concern based on monitoring data.

### **Solicitation for Benefits Information and Risk Management Suggestions**

At this time the dietary and occupational risks from aldicarb are of concern for some registered uses. In addition, the Agency has performed preliminary alternatives analyses, to identify available alternatives for the uses of aldicarb that pose the highest risks (see “Preliminary Impact Analysis for Aldicarb on Potatoes”, “Preliminary Impact Analysis for Aldicarb on Major Citrus Crops”, and “Impact Analysis for Aldicarb on Cotton”). It is important to note that FQPA does not allow for the consideration of benefits analyses for risks associated with dietary exposure assessments; therefore, benefits analyses play an important role in only non-dietary considerations, such as ecological and worker risks. Alternative analyses for potatoes, citrus and cotton are available in the docket, and show that although there are alternatives available for aldicarb, they tend to be more costly and less effective. At this time, the Agency has not been able to identify many viable options for effectively mitigating the dietary risks from aldicarb. Thus, EPA is soliciting input from interested stakeholders on benefits information (i.e. critical uses of aldicarb, and impacts to growers from the loss of aldicarb), as well as risk management suggestions. If you would like to provide this type of input, please submit your comments directly to the docket.

Here is a list of sample questions that may help you in preparing comments:

- (1) In what regions (state/county, etc.) of the U.S. is aldicarb use occurring?
- (2) What are the pests that you feel aldicarb is critical for controlling?
- (3) What are the details of typical usage patterns (e.g., number of applications per season, use rate per application, acres treated, and time of application in the season?)
- (4) What worker activities typically occur when aldicarb is applied?
- (5) What alternatives, if any, do you believe are available to replace aldicarb?

Please provide as much detail and documentation in your comments as possible so that the Agency is fully informed in its decision-making.

Attachment 1: Percent Crop Treated Estimates for the Aldicarb Dietary Exposure and Risk Assessment.

**ALDICARB** Case #: 140 AI #: 98301 Analyst: John Faulkner Data years: 1988-98 QUA date: December 23, 1999  
aldicar9.wpd

**EPA's QUANTITATIVE USAGE ANALYSIS**

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb ai/ acre/yr	#appl /yr	lb ai/ A/appl	(% of total lb ai used on this site)
Citrus, Other *	55	2	4	4%	7%	7	12	3.5	1.1	3.3	FL 100%
Grapefruit	167	20	33	12%	20%	77	113	3.8	1.3	3.0	FL TX 100%
Lemons	62	0	2	1%	3%	2	5	3.8	-	-	CA 86%
Oranges	888	40	90	5%	10%	150	299	3.8	1.2	3.0	FL 90%
Pecans	469	18	39	4%	8%	55	134	3.1	1.2	2.5	GA MS TX AL 87%
Potatoes	1,433	150	289	10%	20%	400	703	2.7	1.0	2.7	WA FL MI OR 85%
Sweet Potatoes, Yams	82	13	30	15%	37%	17	41	1.4	1.0	1.4	NC TX AL 87%
Beans/Peas, Dry	2,190	25	39	1%	2%	24	67	1.0	1.1	0.9	WA ID MI 84%
Beans/Peas, Green	709	2	5	0%	1%	2	6	1.3	1.0	1.3	WA ID 90%
Sorghum	11,140	10	34	0%	0%	5	18	0.5	1.0	0.4	TX MO AR 82%
Alfalfa	23,701	1	12	0%	0%	1	12	1.3	1.0	1.3	CA MT 90%
Peanuts	1,582	480	749	30%	47%	540	931	1.1	1.1	1.0	GA AL NC VA 87%
Soybeans	63,141	76	136	0%	0%	52	93	0.7	1.0	0.7	SC IL VA AL WA TN 82%

Attachment 1: Percent Crop Treated Estimates for the Aldicarb Dietary Exposure and Risk Assessment.

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb ai/ acre/yr	#appl /yr	lb ai/ A/appl	(% of total lb ai used on this site)
Sunflower	2,789	1	2	0%	0%	-	-	-	-	-	
Cotton	12,967	3,500	4,330	27%	33%	2,600	3,271	0.6	1.0	0.6	GA TX CA NC MS AR 68%
Sugar Beets	1,425	130	160	9%	11%	238	387	1.8	1.1	1.7	ID NE WY CO MT 81%
Sugarcane	926	0*	0*	0*	0*	0*	0*	-	-	-	
Coffee		400	-	-	-	550	-	1.4	-	-	Brazil 94%
Tobacco	716	50	81	7%	11%	80	157	1.6	1.0	1.6	NC VA 92%
<b>Total</b>		<b>4,918</b>	<b>5,477</b>			<b>4,800</b>	<b>5,525</b>				

**COLUMN HEADINGS**

Wtd Avg = Weighted average--the most recent years and more reliable data are weighted more heavily.

Est Max = Estimated maximum, which is estimated from available data.

Average application rates are calculated from the weighted averages.

**NOTES ON TABLE DATA**

Calculations of the above numbers may not appear to agree because they are displayed as rounded to the nearest

1000 for acres treated or lb. a.i.

(Therefore 0 = < 500)

to the nearest whole percentage point for % of crop treated. (Therefore 0% = < 0.5%)

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

A dash (-) indicates that information on this site is NOT available in EPA sources or is insufficient.

\* Citrus, Other includes kumquats, limes, tangelos, and tangerines.

SOURCES: EPA data (1988-98), USDA (1990-97), and National Center for Food and Agricultural Policy (1992 data)





Attachment 1: Percent Crop Treated Estimates for the Aldicarb Dietary Exposure and Risk Assessment.

Site	Acres (000) Grown	Acres (000) Treated		% of Crop Treated		Lb ai (000) Applied		Average Application Rates			States/Regions	
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb ai/A/yr	# appl/year	lb ai/A/appl		
<b>Grapefruit</b>												
Fresh	165	26	41	16%	25%	122	191	4.7	1.3	3.5	34	FL
Processed	38	6	13	17%	33%	20	38	3.0	1.1	2.7	7	FL TX
Total	203	33	54	16%	26%	142	229	4.3	1.3	3.4	42	FL TX
<b>Oranges</b>												
Fresh	408	27	51	7%	13%	97	182	3.6	1.2	3.0	32	FL
Processed	518	59	120	11%	23%	185	377	3.1	1.1	2.9	64	FL TX
Total	926	86	171	9%	18%	283	559	3.3	1.1	3.0	96	FL TX
<b>COLUMN HEADINGS</b>												
*Acres grown applies to the entire US unless indicated with an asterisk (*) where it applies only to the region specified.												
Wtd Avg = Weighted average--the most recent years and more reliable data are weighted more heavily.												
Est Max = Estimated maximum, which is estimated from available data.												
Average application rates are calculated from the weighted averages.												
<b>NOTES ON TABLE DATA</b>												
Calculations of the above numbers may not appear to agree because they are displayed as rounded												
to the nearest 1000 for acres treated or lb. a.i. (Therefore 0 = < 500)												
to the nearest whole percentage point for % of crop treated. (Therefore 0% = < 0.5%)												
proj = projected. Numbers in italics and indicated with "proj" are projected or include projected amounts.												
SOURCES: EPA data (1988-98), USDA (1990-98), and National Center for Food and Agricultural Policy (1992 data)												
WEFA Group forecasts (1997 data)												