

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 99.9th 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 99.8th 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 99.9th 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 95th 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.