Aldicarb
PC Code No. 098301

Review of the Preliminary Environmental Fate and Ecological Effects (EFED) Risk Assessment for the Aldicarb Reregistration Eligibility Decision

May 6, 2005

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STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA § 10(d)(1)(A), (B), or (C).

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The above statement supersedes all other statements of confidentiality that may occur elsewhere in this report.

GOOD LABORATORY PRACTICE STATEMENT

This study does not meet the requirements for 40 CFR Part 160 and differs in the following way:

1) This report is not subject to Good Laboratory Practices as promulgated in the Federal Register, 54, No. 158, 34067-34704.

Sponsor/Submitter: L. R. Hodges Date: May 6, 2005

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KEY ISSUES AND GENERAL COMMENTS

Bayer CropScience's General Comments on the Preliminary Environmental Fate and Ecological Effects Risk Assessment for Aldicarb May 6, 2005

The following comments summarize many of Bayer CropScience's major points and concerns with the preliminary Environmental Fate and Ecological Effects (EFED) risk assessment for aldicarb. Specific comments on portions of the preliminary risk assessment and more detailed discussion follow in our Line-By-Line and Discussion sections of this document, respectively.

General

The environmental fate and ecological effects document, as written, presents risk concerns in key areas that are totally inconsistent with incident and effect data from over 30 years of field use of TEMIK® Brand Aldicarb Pesticide. A clear example is that while the preliminary EFED risk assessment predicts 100% mortality of birds and mammals for nearly all application scenarios, there have been few documented incidents of field kills of wild birds or mammals in the U.S. associated with the use of TEMIK®. Recorded incidents have almost always been due to misuse or improper application. The Agency has not used the extensive database available to refine the low-tier analyses used to characterize the risks from aldicarb. Speculative reasoning is, however, introduced to imply that the lack of field mortality observations is due to affected animals leaving the treated area despite the fact that the effects of aldicarb exposure are rapid as is recovery (see the section on comparison with carbofuran). Although the current reregistration phase is intended for error correction, it is not appropriate for EPA to publicly release an unrefined risk assessment that experience has shown grossly overestimates actual risk as it will undermine public confidence in the risk assessment process. Prior to publication, a clear perspective on the risk assessments should be added to the document indicating that, even though the screening methodology indicates potentially high risks, practical experience does not bear this out and thus further refinements are warranted. In our comments below, Bayer CropScience provides EPA with specifics on studies and other information relevant to the environmental fate and ecological effects of aldicarb. Approaches for appropriately refining the risk assessments are provided.

It is disappointing that despite the long history of TEMIK® use (35 years), the extensive database available, the availability of extensive water monitoring data, the significant changes made over the years to the label and use practices, and the comprehensive and on-going product stewardship and education programs; the Agency has continued to rely on low-tier analyses for characterizing the risks from the active ingredient, aldicarb, and the formulated product, TEMIK®. Bayer CropScience pointed out these deficiencies in a response to an earlier draft EFED chapter (our submission of August 31, 2001, MRID No. 45529101). While the current EFED preliminary risk assessment is an improvement over the 2001 version, it still suffers from many of the same misrepresentations and misinterpretations of data.

Terrestrial Risk Assessment

<u>Selective Use of Available Data in Analysis</u>

The Agency has consistently selected toxicity values that result in the highest possible risk quotient calculations. This introduces a conservative bias into the assessment that is inappropriate in an objective scientific assessment and is not acknowledged in the discussion of uncertainties.

RQ Methodology/Concept

From scientific, practical and historic standpoints, Bayer CropScience disagrees with the approach and conclusions for estimating the risk to birds and mammals that are expressed in the preliminary EFED risk assessment for aldicarb:

- Bayer disagrees with the terrestrial risk calculations of both the EEC (mg of aldicarb available per square foot) and toxicity value (LD_{50} value should be for the TEMIK® granule rather than the ai, and no body-size scaling adjustment should be used in the calculation). The values presented in the preliminary EFED risk assessment are at least 1 to 2 orders of magnitude too high since the Agency's methodology produces artificially inflated hazard indices for narrow band applications.

- The quotient that is calculated to assess acute risk to birds and mammals (LD_{50s}/ft^2) is a hazard index and not a risk quotient. It is not a risk quotient because it lacks a biologically meaningful exposure component. The exposure component of the LD_{50s}/ft^2 index is the pesticide load available per an arbitrarily chosen unit area. It is not an estimate of pesticide intake for individual birds or mammals, and therefore can not be used in conjunction with the dose-response relationship of acute oral toxicity tests to make predictions about the probability of adverse effects. Because there is no way to relate pesticide load available per unit area to pesticide intake of individuals, there is no basis for concluding that 0.1, 1, 10, 100 or any other number of LD_{50s}/ft^2 represents a threshold between minimal risk and high risk.

- The proper use of the LD_{50s}/ft^2 index is as a screening tool. The purpose of a screening tool is to identify chemical use scenarios that clearly are not of concern as opposed to those that require further assessment. Bayer CropScience does not object to the use of this index for that purpose. However, no conclusions can or should be made about the magnitude of risk on the basis of LD_{50s} $/ft^2$. It is especially inappropriate for the Agency to calculate estimates of expected mortality levels predicted on the basis of LD_{50s}/ft^2 and the acute oral toxicity dose-response curve.

- The Agency's method of calculating the amount of TEMIK® granules per ft^2 only within the application band and ignoring the fact that only a small fraction of a crop field is treated does not make practical sense and is inappropriate for a granular product that is unattractive to birds, is applied to non-food source crops and is efficiently incorporated. Birds do not forage only in pesticide-treated bands. The Agency's methodology produces artificially inflated hazard indices for band-incorporated applications (including in-furrow treatments) in comparison to a broadcast application with the same soil incorporation efficiency. Intuitively, treatment of 100% of the field area represents a greater hazard than treatment of 10% of the field area, but the Agency's methodology predicts just the opposite. There is no scientific justification for performing the calculation the way the Agency has.

- The Agency referred to several bird field kill incidents from the use of TEMIK® in the U.S. as a supporting line of evidence for a conclusion that TEMIK® applications pose a high risk to birds. Fourteen incidents involving birds were listed in Appendix F. Of these, 10 were classified as the result of misuse, 2 from undetermined uses, and 2 the Agency apparently believes were from registered use. However, the 2 incidents from "registered use" were in fact the same incident from March 1991 in North Carolina and according to officials of the North Carolina Department of Agriculture and Consumer Services, this incident was NOT from a registered use but rather from a clear case of misuse. The granules were not incorporated per label directions, and TEMIK® was not registered for use on the crop that was treated. The 2 incidents classified as "undetermined" use also appear to be cases of misuse and are very similar to the other misuse cases which involve carrion eating species (vultures, corvids, raptors) that died after feeding on animal carcasses illegally laced with TEMIK® granules in an attempt to poison coyotes. A careful review of each case the Agency cites leads to the conclusion that there is not a single bird kill incident that can be attributable to registered use of the product in the U.S. While a lack of documented incidents can not prove that none have occurred, it most certainly does stand in stark contrast to what one would expect to be the case if TEMIK® really posed a high acute risk to birds. Simply put, the record of incidents does NOT support a conclusion that TEMIK® poses a high risk and the Agency's statements to the contrary are misleading.

- A notable flaw with the Agency's approach is that it assumes organisms will encounter aldicarb, the active ingredient, rather than TEMIK®, the formulated end use product. TEMIK® is a coated granule with the active ingredient, aldicarb, bound to the granule by a polyvinyl coating. The toxicity of the formulated product is significantly less than that of the active ingredient but more importantly, the characteristics of the granular formulation and methods of application and incorporation greatly reduce potential risk. Extensive research has proven the lack of attractiveness of TEMIK® to birds; therefore, birds have to accidentally encounter the product, which is generally unavailable since it is incorporated into the soil.

- The preliminary EFED risk assessment cites 1581 documents that were consulted (Appendices I, J and K), yet makes no mention of the many research articles published in the 1990's by Dr. Louis Best and colleagues at Iowa State University on the factors that influence the likelihood that birds will ingest granular pesticides. Citations of these papers were brought to the Agencies attention in previous correspondence with the Agency, and Dr. Best has served on SAP panels that have reviewed avian risk assessments. Dr. Best's research shows that factors other than granule availability are often the most important and help explain why TEMIK® poses a small risk to birds even though the aldicarb on the TEMIK® granule is inherently toxic to them. Citations of relevant papers and summaries of relevant information are included in our detailed line-by-line review and discussion sections.

Incorporation Efficiency

EPA's incorporation efficiency estimates for banded and in-furrow applications are overly conservative and disagree with EPA's previous policy and incorporation study data. Work conducted by Bayer CropScience (previously Rhone-Poulenc Ag Company) in the late 1980's demonstrated incorporation efficiency from 99.96 to 100% for in-furrow applications. All TEMIK® applications on the federal label require that granules be covered with soil. It is also important to take into account that incorporation occurs during the application. In the March 1992 "Comparative Analysis of Acute Avian Risk from Granular Pesticides" EPA used a 99% incorporation efficiency for "Banded, cover with specified amount of soil" and "In-furrow, drill, or shanked-in" applications. These conditions cover virtually all of the applications of TEMIK® that are in use today. Bayer believes that at least 99.96% to 100% should be used for in-furrow calculations and 89% to 100% should be used in calculations for banded applications since the TEMIK® label requires covering the product with soil. The Agency should also incorporate into its assessments data for typical use rates, patterns, and application methods. Bayer's survey of users of TEMIK® for all row crops clearly shows that the vast majority of applications are applied in furrow and at less than maximum labeled rates (e.g., 98% of cotton applications are made in-furrow and no broadcast citrus applications are used). Consideration of these data in the risk calculations and resulting assessments will have a significant impact in evaluating real world risk which is clearly shown to be low based on the historical environmental and ecotoxicological record.

In our line-by-line comments, we have offered suggestions for improving the screening level assessment by using available TEMIK® usage data along with the Agency's standard generic assumptions about granule incorporation efficiency. However, the option of using the TEMIK®-specific soil incorporation data rather than the generic estimates should be retained in higher tier assessments.

Aquatic Risk Assessment

Recalculated RQ Values

From scientific, practical and historic standpoints, Bayer CropScience disagrees with the approach and conclusions for estimating the risk to fish and aquatic invertebrates that are expressed in the preliminary EFED risk assessment for aldicarb. Bayer recalculated aquatic RQ values taking into account the various application methods and the Agency's generic assumptions about granule incorporation efficiency for each application type. This analysis indicated that aquatic and terrestrial risks were far more limited than indicated by the Agency's assessment.

The following conclusions can be drawn for risk to freshwater fish:

1. There are no acute LOC exceedences for potato, citrus or soybeans uses that actually occur in the real world (based on the usage survey information).

2. The acute LOC is exceeded for 0.3% of cotton applications; 99.7% of cotton use does NOT exceed the acute LOC.
3. The acute LOC is exceeded for 23% of pecan applications, 77% of pecan use does not exceed the acute LOC.
4. There are no chronic LOC exceedences.

The following conclusions can be drawn for risk to freshwater invertebrates:

1. There are no acute LOC exceedences for potato, citrus or soybeans uses that actually occur in the real world (based on the usage survey information).
2. Endangered species, restricted use and acute risk LOCs are exceeded for 0.3% of cotton applications; only the endangered species LOC is exceeded for 99.7% of cotton uses.
3. Endangered species, restricted use and acute risk LOCs are exceeded for 23% of pecan applications, 77% of pecan use does not exceed any freshwater invertebrate acute risk LOCs.
4. There are no chronic LOC exceedences.

The following conclusions can be drawn for risk to estuarine/marine fish:

1. There are no acute LOC exceedences for potato, citrus or soybeans uses that actually occur in the real world (based on the usage survey information).
2. The acute LOC is exceeded for 0.3% of cotton applications; 99.7% of cotton use does NOT exceed the acute LOC.
3. The acute LOC is exceeded for 23% of pecan applications, 77% of pecan use does not exceed the acute LOC.
4. There are no chronic LOC exceedences.

The following conclusions can be drawn for risk to estuarine/marine invertebrates:

1. Acute and chronic LOCs are exceeded for cotton.
2. There are no acute or chronic LOC exceedences for potato, citrus or soybeans uses that actually occur in the real world (based on the usage survey information), except for a very slight exceedence of the endangered species LOC in potato.
3. Acute and chronic LOCs are exceeded for 23% of pecan applications that are broadcast-incorporated; 77% of pecan use has a slight exceedence of the acute endangered species LOC only.

Use of Beaver Creek Watershed Data

The Agency has chosen to disproportionately use data from one site to base many of its characterizations of the risk of aldicarb in aquatic systems. Beaver Creek is not representative of “real world” environmental conditions, particularly for estimating residue concentrations downstream. The water samples of concern to the Agency were taken from the Beaver Creek sampling station at the field edge. At the point of sampling, Beaver Creek is a ditch running throughout a cotton field. It is considered intermittent and is listed as such on maps. Beaver Creek supports neither a resident fish population nor significant invertebrate aquatic life throughout the year. Following any runoff event, downstream dilution greatly reduces the residue concentrations. Furthermore, there is significant breakdown of residues before they reach a significant or permanent aquatic environment. The Agency should correct its analyses and base its assessments upon monitoring data from significant water systems (e.g., NAWQA monitoring data). The weight of evidence clearly demonstrates that surface water contamination from the use of TEMIK® is not a concern. If such losses occurred uniformly in a moderate size watershed, or even somewhat frequently over a larger area, certainly more instances of aldicarb carbamate residues would have been present in the NAWQA, California, and other monitoring programs.

Field Dissipation

Sufficient studies have been performed to fulfill the field dissipation study requirement. The studies reviewed as part of the EFED preliminary risk assessment are older studies and mostly not field dissipation studies. Many of the more recent studies on the EPA Guideline Status report (listed under 164-1 and 164-5) were apparently not considered. The degradation of aldicarb carbamate residues in the United States (summarized in Jones and Estes, 1995) is well understood, with half lives ranging from 0.5 to 3.5 months. Because risk assessments have been performed based on total carbamate resides, the results of these studies have also been presented in terms of total carbamate residues. For studies conducted since 1994, data on the three individual compounds (aldicarb, aldicarb sulfoxide, and aldicarb sulfone) are also available and could be provided to EPA.

LINE-BY-LINE REVIEW

Bayer Crop Science's Line-by-Line Review of the Preliminary Environmental Fate and Ecological Effects Risk Assessment for Aldicarb May 6, 2005

TRANSMITTAL MEMORANDUM

Paragraph: 3 Line: 4
EPA comment: data gap for “161-1 Hydrolysis (sulfone)"

Bayer response: A guideline study (MRID Nos. 00053377, 45592104) is available on the rates of hydrolysis and nature and magnitude of the degradation products of radiolabeled aldicarb sulfone (Andrawes, 1976). Aldicarb sulfone was stable at pH 5 but degraded at pH 7 and 9 with half-lives ($t_{1/2}$) of 81 days and 0.87 days, respectively. At low temperatures (5°C), the rate of hydrolysis at pH 9 was considerably slower than at 25°C with a $t_{1/2}$ of 31 days. This study satisfies the 161-1 guideline requirement for aldicarb sulfone. Refer to the discussion section for more details.

Paragraph: 3 Line: 5
EPA comment: data gap for “161-2 Photodegradation in Water (sulfoxide, sulfone)"

Bayer response: Field monitoring and laboratory studies under controlled conditions demonstrate that it is unlikely for any significant aldicarb sulfoxide and aldicarb sulfone residues to occur in open bodies of water, or to exist for sufficient duration to allow for photodegradation to play an important role in the environmental impact of aldicarb. Non guideline studies have shown that photodegradation in water is limited for both aldicarb sulfoxide and aldicarb sulfone. Therefore, further investigation of the photodegradation of the two carbamates is not warranted. Refer to the discussion section for more details.

Paragraph: 3 Line: 6
EPA comment: data gap for “162-1 Aerobic Soil Metabolism (sulfoxide, sulfone)"

Bayer response: Two new studies, one in which parent aldicarb was applied, and one in which aldicarb sulfone was applied have been submitted to EPA (Allan, 2002a; 2002b, MRID Nos. 45739801, 45739802). The design of these two studies was approved by EPA. These two studies meet the guideline requirement for the degradation of aldicarb, aldicarb sulfoxide (from formation and degradation in the aldicarb study), and aldicarb sulfone.

Paragraph: 3 Line: 7
EPA Comment: “164-1 Terrestrial Field Dissipation (parent aldicarb, sulfoxide, sulfone)”

Bayer response: The registrant has identified numerous field dissipation studies conducted for aldicarb and previously submitted to the Agency that have not been included in the preliminary EFED risk assessment. The degradation of aldicarb carbamate residues in the United States (summarized in Jones and Estes, 1995) is well understood, with half lives ranging from 0.5 to 3.5 months. The discussion section provides a complete response to this comment.

I. EXECUTIVE SUMMARY

Page: 4 Paragraph: 1 Line: 7
EPA comment: "... all federal-label listed uses: citrus, cotton, dry beans, grain sorghum, peanuts, pecans, potatoes, soybeans, sugar beets, sweet potatoes, and ornamentals."

Bayer response: Sugarcane was omitted from the list of registered uses here and elsewhere in the document. The terms grain sorghum and sorghum are used interchangeably throughout the chapter. It would be preferable to refer to the crop as sorghum.

Page: 4 Paragraph: 6 Lines: 2-3
EPA comment: "... for freshwater fish and invertebrates and estuarine/marine fish."

Bayer response: This phrase is repeated and out of place. Delete phrase.

Page: 4 Paragraph: 8 Lines: 1-2
EPA comment: "The chronic level of concern is also exceeded for freshwater fish ..."

Bayer response: Chronic levels of concern for fish are NOT exceeded if standard EPA risk assessment methods are used. The Agency's standard method is to use the lowest chronic NOAEC value observed in the chronic RQ calculation. The lowest fish chronic NOAEC is 78 ppb. If this value is used, the resulting RQs range from 0.02 to 0.36 and these are all below the Agency's LOC.

Rather than use the experimentally determined NOAEC of 78 ppb which was determined in a test with the fathead minnow, the agency instead has calculated an expected no-effect concentration (ENEC) for the bluegill sunfish of 0.46 ppb and used this in the RQ calculation. Bayer believes the ENEC was calculated inappropriately for reasons presented in detail later (see Bayer's comments on EFED's Ecological Effects Characterization on pages 27-29). Such calculations carry a high degree of uncertainty and it is preferable to use experimentally measured values when an appropriate test has been performed. In this case, an experimentally measured chronic NOAEC is available for a fish species that has been demonstrated to be approximately equal in sensitivity to aldicarb as the bluegill sunfish. This species is the sheepshead minnow. The reported LC_{50} in this species ranges from 41 to 170 ppb with a geometric mean of 83 ppb. The reported LC_{50} values for the bluegill sunfish range from 52 to 115 ppb with a geometric mean of 72 ppb. Based on this comparison, tests with the sheepshead minnow should be a reasonably good surrogate for tests with the bluegill sunfish. The chronic NOAEL value experimentally determined for the sheepshead minnow is 50 ppb. If this value is used in the fish chronic risk assessment, resulting RQ values range from 0.03 to 0.56, and these are all below the Agency's LOC. Based on this analysis, it can be concluded that aldicarb poses a minimal chronic risk to both freshwater and saltwater fish.

Page: 4 Paragraph: 10 Lines: 1-2
EPA comment: "In addition to risk based exposure estimates from modeling, there were also exceedances of the Agency levels of concern based on monitoring data."

Bayer response: This is true for one field monitoring data point (Beaver Creek), but is a misleading summary of the totality of field monitoring data which generally shows that for more than 99% of the time, the Agency levels of concern are not exceeded. The overwhelming weight of the evidence from monitoring studies points to the conclusion that aldicarb concentrations very rarely exceed the Agency's levels of concern for aquatic organisms.

<u>Page: 5 Paragraph: 11 Lines: 1-4</u>
EPA comment: "<u>Using Multiple Lines of Evidence</u> (such as use scenarios, average or "typical" application rates, registrant submitted toxicity studies, open literature data, and field monitoring data), lead to the same conclusion: **Aldicarb poses acute risks (mortality) to birds, mammals, and aquatic organisms**. In addition, there are chronic reproductive effects in fish and aquatic invertebrates."

Bayer response: The open literature and field incident reports do NOT support a conclusion of high risk to birds, fish or aquatic invertebrates. Surface water monitoring data indicate that aldicarb concentrations in real world rivers and streams are almost always far below toxic thresholds to aquatic species. There are no documented cases of chronic reproductive effects in fish and aquatic invertebrates, and none would be expected to occur based on the surface water monitoring data. There have been few documented incidents of field kills of wild birds or mammals in the U.S. associated with the use of aldicarb. Recorded incidents have almost always been due to misuse or improper application. Thus, the data from incident monitoring programs stands in stark contrast to the Agency's assessment which predicts 100% mortality of birds and mammals for nearly all application scenarios. Such a risk prediction is obviously erroneous when one considers the multiple lines of evidence.

The Agency has not used all available information. Conspicuously absent in the Agency's assessment is any mention of the numerous published studies by Dr. Louis Best and colleagues at Iowa State University on the factors that influence whether birds are likely to ingest pesticide granules. These studies indicate that availability of granules per unit area on the soil surface is a relatively unimportant factor in comparison to features such as size, shape, composition and color of granules. These studies demonstrate that birds rarely ingest TEMIK® granules even when they are readily available to them. More details including relevant citations are provided in the line-by-line comments which follow.

An objective use of multiple lines of evidence would consider whether real world observations confirm whether the magnitude of risk is as high as suggested by the calculated risk quotients. Bayer believes multiple lines of evidence clearly point to a conclusion that risks in the real world posed by aldicarb to birds, mammals and aquatic organisms are NOT as high as indicated by the screening assessment. The Agency's assessment should point this out.

II. PROBLEM FORMULATION

A. Introduction

<u>Page: 6 Paragraph 1: Line: 1</u>
EPA comment: "Aldicarb (propanal (2-methyl-2-(methylthio)-, O-[(methylamino) carbonyl]oxime)), . . ."

Bayer response: This chemical name does not agree with the IUPAC chemical name on page 7. Change to the IUPAC chemical name: 2-methyl-2-(methylthio)propionaldehyde O-(methylcarbamoyl)oxime.

<u>Page: 6 Paragraph: 1 Lines: 4-6</u>
EPA comment: "In the US., aldicarb is used on alfalfa (in CA only), citrus, cotton, dry beans, peanuts, pecans, potatoes, citrus, soybeans, sugar beets, sweet potatoes, tobacco (NC and VA only), and ornamentals."

Bayer response: Citrus is listed twice (on lines 4 and 5). Sorghum and sugarcane (LA only) should be included in the list of crops.

<u>Page: 6 Paragraph: 1 Line: 10</u>
EPA comment: "This document includes an assessment of risks to terrestrial animals resulting from the use of aldicarb on all federal-label listed (non-special local need, SLN, 24c) uses: . . ."

Bayer response: Sugarcane (LA only) should also be listed.

<u>Page: 6 Paragraph: 1 Line: 13</u>
EPA comment: "... sugar beets, sweet potatoes, ..."

Bayer response: Sugarcane (LA only) should be included in the list of crops.

<u>Page: 6 Paragraph: 1 Line: 9</u>
EPA comment: "This screening level risk assessment follows the Agency's Ecological Risk Assessment Guideline (USEPA, 2000)."

Bayer response: Bayer appreciates the efforts the EFED has made in trying to follow the EPA Risk Assessment Forum's Guidelines for Ecological Risk Assessment. Implementation of these guidelines should improve the quality of EFED assessments. However, Bayer has noted several instances where the aldicarb assessment appears to be inconsistent with the ERA guidelines and terminology. Specific instances are noted in the comments below.

B. Stressor Source and Distribution

<u>Page: 7 Chemical and Physical Properties Line: 10</u>
EPA comment: "The vapor pressure value is 1 x 10^{-6} @ 25°C"

Bayer response: The vapor pressure in MRID No. 00152095 (dated November, 1984) is 1 x 10^{-4} mm Hg @ 25^{0}C (Page A-18). However, the registrant had generated vapor pressure data in 1987 for aldicarb to fulfill the data reporting requirements for the California Department of Food and Agriculture (McDaniel and Weiler, 1987). The vapor pressure of aldicarb was determined to be **2.55 X10^{-5}mg Hg @ 25°C** by the vapor saturation method. This data supersedes the value reported from previous studies.

- McDaniel, R. L. and Weiler, D. W. (1987). Aldicarb Vapor Pressure. Rhone-Poulenc Ag Company Project Report, Project No.: 803P15, June 29, 1987. (MRID No. 42796001).

<u>Page: 8 Paragraph: 9 Line: 1</u>
EPA comment: "Aldicarb use on potatoes was reinstated in Florida, Idaho, Washington, ..."

Bayer response: Use was also reinstated in Montana and in some counties of Nevada and Utah.

<u>Page: 8 Paragraph: 11 Line: 1</u>
EPA comment: "Approximately 4.8 millions pounds of aldicarb active ingredient (ai) are used per year on 4.9 million acres (BEAD) Quantitative Usage Analysis, August 9, 2004)."

Bayer response: Doane and Bayer's internal tracking information indicate that during 2004 actual applications were 4.53 million pounds of aldicarb active ingredient on 5.45 million acres.

<u>Page: 8 Paragraph: 11 Lines: 3-5</u>
EPA comment: "The five crops to which the most pounds of aldicarb are applied within the United States are, in order, cotton, peanuts, potatoes, sugar beets, and oranges."

Bayer response: These five crops do not agree with the five major aldicarb use crops listed on Page 18, Paragraph 1, Lines 5-7 and Page 20, Paragraph 3, Line1: "... cotton, potato, citrus, pecan, and soybean ... "

<u>Page: 8 Paragraph: 11 Line: 5</u>
EPA comment: "Aldicarb is also used on a variety of other crops, such as . . ."

Bayer response: Sugarcane (LA only) should also be listed.

<u>Page: 9 Paragraph: 1 Lines: 7-8</u>
EPA Comment: "Additional use restrictions vary by state and by soil, and prohibit application within some distance (300 to 500 feet) of wells used for drinking water."

Bayer response: Application distance from wells used for drinking water range from 50 feet to 1000 feet. See the General Ground Water Limitations section and the State Specific Ground Water Limitation section of the TEMIK® Brand 15G label.

<u>Page: 9 Paragraph: 1 Line: 9</u>
EPA comment: ". . . formulated and sold as 10 percent or 15 percent ai pellets."

Bayer response: The correct terminology for the formulated product is "granules" not "pellets."

<u>Page: 9 Table: 1 Line: 4</u>
EPA comment: "264-426, Temik® Brand 15G Aldicarb Pesticide for Sale and Use in CA only."

Bayer response: The correct name is, "264-426, TEMIK® Brand 15G Aldicarb Pesticide for Sale and Use in California Only."

<u>Page: 9 Table: 1 Line: 5</u>
EPA comment: "264-523, Temik® Brand 15G NW Aldicarb Pesticide for Use on Potatoes."

Bayer response: The correct name is, "264-523, TEMIK® Brand 15G NW Aldicarb Pesticide."

<u>Page: 9 Table: 1</u>
EPA comment:

Bayer response: One TEMIK® registration was omitted from the table. Add, "264-417, TEMIK® Brand 15G CP Aldicarb Pesticide, 15."

<u>Page: 9 Paragraph: 2 Line: 9</u>
EPA comment: "Single application rates for aldicarb range from 0.4 lbs active ingredient per acre (lbs ai/A) for sorghum to a maximum of 10.05 lbs ai/A for pecans."

Bayer response: The lowest labeled use rate for TEMIK® Brand 15G Aldicarb Pesticide is 2.0 lbs product per acre for cotton (in Texas, Oklahoma and New Mexico only). This rate equals 0.3 lbs ai/A. The TEMIK® 15G label allows the further reduction of the cotton rate of 0.3 lbs ai/A by ½ (to 0.15 lbs ai/A) if seeds and TEMIK® are applied by the hill-drop method.

<u>Page: 10 Table: 2 Cotton</u>
EPA comment: Column 4. # of applications (interval). "Cotton. 2 (30 days)"

Bayer response: The TEMIK® label does not specify an application interval for cotton. Delete the reference "(30 days)."

<u>Page: 10   Table: 2   Dry Beans</u>
EPA comment: Column 5. Maximum label rate (lb ai/A). "Dry Beans. 1.05"

Bayer response: The maximum application rate for dry beans is 2.1 lbs ai/A.

<u>Page: 10   Table: 2   Potatoes</u>
EPA comment:

Bayer response: One registration was omitted for the crop potatoes. Add: TEMIK® 15G, 264-330, 1 application, 3.0 lb ai/A maximum rate, and add the following states FL and MT.

<u>Page: 10   Table: 2</u>
EPA comment:

Bayer response: One crop was omitted from Table 2. Add: Sugarcane, TEMIK® 15G, 264-330, 1 application, 3.0 lb ai/A maximum rate, LA only.

<u>Page: 11   Table: 3</u>
EPA Comment: "Aldicarb Typical State and Crop Use Information – food-use crops (BEAD) Quantitative Usage Analysis, August 9, 2004)."

Bayer response: EPA lists crops that are either not registered on the TEMIK® federal or supplemental labels or not registered in certain states. These states and crops are:

- **California:** cantaloupe, corn, tomatoes, and wheat –TEMIK® is not registered on these crops and has never been registered for use on these crops in any state.

- **Alabama, Arizona, Kansas, Minnesota, North Carolina and North Dakota**: potatoes. TEMIK® is not registered for use on potatoes in these states but in some of the states (Alabama and North Carolina) it may be used on sweet potatoes.

<u>Page: 13   Paragraphs: 1-2   Line:</u>
EPA comment: Entire section, "5. Measurement Endpoints"

Bayer response: This section does not present any useful information about the measurement endpoints that have been chosen for this assessment. It is confusing to discuss measurement endpoints without first defining what the assessment endpoints are. This section is also out of place in that is doesn't belong under the heading "Stressor Source and Distribution". Here and throughout the entire document, the authors appear to confuse toxicity measurements with measurement endpoints. The avian LD_{50} is a measurement endpoint. The LD_{50} of 1.0 mg/kg bw in mallards is a toxicity measurement. Measurement endpoints are properties of the test population such as the LC_{50} or the NOAEC. They are not specific numbers. For example, the title of Table 13 (EFED page 30) is "Acute Toxicity Endpoints for Freshwater Invertebrates", but this table lists toxicity measurements, not endpoints. There are numerous other tables throughout this document that summarize toxicity measurements that have been given the incorrect title of "toxicity endpoints".

C. Conceptual Model

<u>Page: 14   Paragraph: 3   Line: 1</u>
EPA comment: "Immediately following application of aldicarb and prior to soil incorporation, granules are expected to be available at the soil surface on agricultural sites. Wildlife exposure could result . . ."

Bayer response: Granule application and soil incorporation are essentially simultaneous events. Application equipment used in modern agriculture provides both deposition of the granules and soil incorporation without the need for separate operations. Therefore under normal use granules would not be expected to be available at the soil surface.

Page: 14   Paragraph: 3   Lines: 1-5
EPA comment: "Immediately following granular application of aldicarb and prior to soil incorporation, granules are expected to be available at the soil surface on agricultural sites." . . . "Later soil incorporation of the granules is expected to result in movement of aldicarb down into the soil column."

Bayer response: TEMIK® granules are incorporated into the soil at the same time they are applied. There is no time lag between application and incorporation during which a bird could be exposed. These sentences should be deleted.

Page: 14   Paragraph: 3   Line: 4
EPA comment: "Later soil incorporation of the granules is expected to result in the movement of aldicarb down into the soil column."

Bayer response: This sentence is incorrect and confusing. How does EFED define "later"?

Page: 14   Paragraph: 4   Lines: 1-2
EPA comment: "Terrestrial organisms will be exposed mostly to granules, except under conditions where there is surface saturation and dissolved aldicarb remains in pooled water at the surface."

Bayer response: The sentence should be changed to read, "Terrestrial organisms will be potentially exposed mostly to granules, except . . ." The word "potentially" should be added because the vast majority of terrestrial organisms will not be exposed at all. As already explained in our response to Page 14, Paragraph 3, Line 1, TEMIK® is applied to crops and covered or incorporated in a single and continuous process. There is no time between the granules hitting the soil and the granules either being completely covered by soil or incorporated into the soil, thus, there is no exposure. TEMIK® is not applied to saturated soil and if there is sufficient rainfall to saturate the soil after application all of the TEMIK® granules will have disintegrated and the aldicarb will have moved down into the soil. As EPA is aware, TEMIK® granules are composed of gypsum and disintegrate when they become wet. As mentioned elsewhere in the EFED chapter, aldicarb is soluble and moves down in soil and out of the area where birds and mammals would be exposed.

Page: 14   Paragraph: 5   Lines: 1-5
EPA comment: "Wildlife exposure could also result from a number of other exposure pathways and wildlife actions and behaviors including inhalation of dust particulates: dermal intake . . ."

Bayer response: This sentence is complete speculation without any evidence to support these claims.

D. Key Uncertainties and Information Gaps

Page: 17   Paragraph: 9   Line: 1
EPA comment: data gap for "161-1 Hydrolysis (sulfone)"

Bayer response: A guideline study (MRID Nos. 00053377, 45592104) is available on the rates of hydrolysis and nature and magnitude of the degradation products of radiolabeled aldicarb sulfone (Andrawes, 1976). Aldicarb sulfone was stable at pH 5 but degraded at pH 7 and 9 with half-lives ($t_{1/2}$) of 81 days and 0.87 days, respectively.

At low temperatures (5°C), the rate of hydrolysis at pH 9 was considerably slower than at 25°C with a $t_{1/2}$ of 31 days. This study satisfies the 161-1 guideline requirement for aldicarb sulfone. Refer to the discussion section for more details.

Page: 17 Paragraph: 9 Line: 2
EPA comment: data gap for "161-2 Photodegradation in Water (sulfoxide, sulfone)"

Bayer response: Field monitoring and laboratory studies under controlled conditions demonstrated that it is unlikely for any significant aldicarb sulfoxide and aldicarb sulfone residues to occur in open bodies of water, or to exist for sufficient duration to allow for photodegradation to play an important role in the environmental impact of aldicarb. Non guideline studies have shown that photodegradation in water is limited for both aldicarb sulfoxide and aldicarb sulfone. Therefore, further investigation of the photodegradation of the two carbamates is not warranted. Refer to the discussion section for more details.

Page: 17 Paragraph: 9 Line: 3
EPA comment: data gap for "162-1 Aerobic Soil Metabolism (sulfoxide, sulfone)"

Bayer response: Two new studies, one in which parent aldicarb was applied, and one in which aldicarb sulfone was applied have been submitted to EPA (Allan, 2002a 2002b, MRID Nos. 45739801, 45739802). The design of these two studies was approved by EPA. These two studies meet the guideline requirement for the degradation of aldicarb, aldicarb sulfoxide (from formation and degradation in the aldicarb study), and aldicarb sulfone.

Page: 17 Paragraph: 9 Line: 4
EPA Comment: "164-1 Terrestrial Field Dissipation (parent aldicarb, sulfoxide, sulfone)"

Bayer response: The registrant has identified numerous field dissipation studies conducted for aldicarb and previously submitted to the Agency that have not been included in the preliminary EFED risk assessment. The degradation of aldicarb carbamate residues in the United States (summarized in Jones and Estes, 1995) is well understood, with half lives ranging from 0.5 to 3.5 months. The discussion section provides a complete response to this comment.

E. Analysis Plan

Page: 18 Paragraph: 1 Line: 1
EPA comment: "This document includes an assessment of risks to terrestrial animals resulting from the use of aldicarb on all federal-label listed (non-special local need, SLN, 24c) uses: . . ."

Bayer response: Sugarcane (LA only) should also be listed.

Page: 18 Paragraph: 1 Lines: 5-7
EPA comment: "Risks to aquatic organisms are assessed based on modeled EECs for the cotton, potato, citrus, pecan, and soybean uses of the chemical. These five aquatic scenarios were chosen because they are the major aldicarb use crops . . . "

Bayer response: These five crops do not agree with the five major aldicarb use crops listed on Page 8, Paragraph 11, Lines 3-5: "The five crops to which the most pounds of aldicarb are applied within the United States are, in order, cotton, peanuts, potatoes, sugar beets, and oranges."

Page: 18 Paragraph: 3 Lines: 1-10
EPA comment: Entire paragraph, "Assessment endpoints are defined as . . . . . issues of concern."

Bayer response: This paragraph presents a good generic introduction of what assessment endpoints are, but then nothing specific is written about what the assessment endpoints are for the aldicarb assessment. Questions that EFED needs to answer are: What are the assessment endpoints? Why were they chosen? How do they relate to management (conservation) goals?

Page: 18 Paragraphs: 4-5
EPA comment: Entire section, "*a. Toxicity Endpoints*"

Bayer response: The section on Toxicity Endpoints has to do with measurement endpoints, not assessment endpoints. What's written here belongs in the measurement endpoints section.

Page: 19 Table: 4
EPA comment: Entire table, "Table 4. Summary of Assessment and Management Endpoints used in calculations."

Bayer response: Table 4 is supposed to present the assessment and measurement endpoints for the aldicarb assessment. For birds, the assessment endpoint that is listed is "survival, reproduction and growth". These appear to be the assessment endpoints generic to all pesticide assessments, and not the ones specifically used in the aldicarb assessment. The measurement endpoints listed are the acute oral LD_{50} of 1.0 mg/kg for the mallard and the subacute dietary LC_{50} of 71 mg/kg for the bobwhite quail. The specific toxicity measurements should not be listed (this is confusing toxicity measurements with measurement endpoints). This comment applied also to measurement endpoints listed in this table for mammals, freshwater animals, saltwater animals, terrestrial insects and aquatic plants. For birds, the only measurement endpoint that should be listed is the acute oral LD_{50}. The subacute dietary LC_{50} is not used in this risk assessment and therefore should not be listed. For mammals, a second measurement endpoint should be added, the chronic NOAEC. For freshwater animals, the chronic measurement endpoint for fish should be the Chronic NOAEC, rather than the Bluegill ENEC (for reasons explained in Bayer's comments on EFED's Ecological Effects Characterization on pages 27-29).

This table would be considerably enhanced if a third column was added that listed the Agency's management goal for each taxa. Ideally, the management goal is the first thing to be defined, then assessment endpoints should correspond to management goals and measurement endpoints should in turn correspond with assessment endpoints. For example, with respect to granular pesticides and birds, the Agency has previously stated that widespread and repeated avian mortality is unacceptable unless there are countervailing societal benefits. Therefore the management goal appears to be to not allow pesticide uses that cause widespread and repeated bird mortality and the assessment endpoint would be reductions in bird survival rates sufficient to cause "widespread and repeated" mortality. The avian LD_{50} is the measurement endpoint appropriate for this assessment since short-term bouts of exposure via ingestion of granules, rather than prolonged dietary feeding, is the relevant scenario by which granular pesticides may cause bird mortalities.

Page: 19 Paragraph: 1 Line: 2
EPA comment: "Ingestion of pellets . . ."

Bayer response: The correct terminology for the formulated product is "granules" not "pellets".

Page: 20 Table: 5 Line: 4
EPA comment: "Broadcast" is listed a method of application.

Bayer response: There are no broadcast methods of application on the TEMIK® labels.

<u>Page: 20 Paragraph: 3 Line: 1</u>
EPA comment: "The following five scenarios representing cotton, potatoes, citrus, soybeans, and pecans, were used . . ."

Bayer response: These five crops do not agree with the five major aldicarb use crops listed on Page 8, Paragraph 11, Lines 3-5: "The five crops to which the most pounds of aldicarb are applied within the United States are, in order, cotton, peanuts, potatoes, sugar beets, and oranges".

III. ANALYSIS

A. Exposure Characterization

<u>Page: 22 Table: 7 Line: 8</u>
EPA comment: "The vapor pressure value is 1 x 10^{-6} @ 25°C"

Bayer response: The vapor pressure in MRID No. 00152095 (dated November, 1984) is 1 x 10^{-4} mm Hg @ 25^{0}C (Page A-18). However, the registrant had generated vapor pressure data in 1987 for aldicarb to fulfill the data reporting requirements for the California Department of Food and Agriculture (McDaniel and Weiler, 1987). The vapor pressure of aldicarb was determined to be **2.55 X10^{-5}mg Hg @ 25°C** by the vapor saturation method. This data supersedes the value reported from previous studies.

- McDaniel, R. L. and Weiler, D. W. (1987). Aldicarb Vapor Pressure. Rhone-Poulenc Ag Company Project Report, Project No.: 803P15, June 29, 1987. (MRID No. 42796001).

<u>Page: 23 Paragraph: 2 Line: 1</u>
EPA Comment: "At this time EPA lacks valid guideline data on the aquatic metabolism of aldicarb . . ."

Bayer response: EFED should consider rewriting the entire paragraph, to better focus on degradation from the guideline studies, and include the data from MRID No. 45592107. Other specific issues in this paragraph are listed below. The study of Vink (1997) is not an appropriate study since sediment is not included and the work described by Lightfoot (1986) shows that the presence of sediment enhances degradation under aerobic and anaerobic conditions.

<u>Page: 23 Paragraph: 2 Lines: 1-9</u>
EPA Comment: "At this time EPA lacks valid guideline data on the aquatic metabolism of aldicarb. . . . In a Guideline laboratory anaerobic aquatic metabolism study (MRID 43805701) aldicarb degraded into acid, nitrile and alcohol forms, with a half life of 3 hours. No sulfone or sulfoxide were formed in this study, suggesting that anaerobic degradation can detoxify aldicarb residues very rapidly. The value of this study is in doubt, though; redox potential was inconsistent and variable throughout the study period (127 days), contrary to guideline requirements. In addition, no discernable pattern of formation and decline of degradates was observed (data were highly variable and inconsistent)."

Bayer response: The anaerobic aquatic study meets the requirements of guideline 162-4, and therefore the reported aldicarb half-life of 2 hours is scientifically valid, and should be used throughout the EFED risk assessment. Throughout the study, the test systems were maintained under a reducing environment as required by the current guidelines, with redox potentials (E_h) of -113 to -181 mV. According to the classification of Wolfe, et. al., a reducing environment exists at E_h of -50 to -200 mV. The reducing conditions are also consistent with the lack of the oxidative sulfoxide and sulfone degradates observed in aerobic studies. Also, the oxygen content showed anaerobic conditions (0.08-0.27 ppm) throughout the study.

With regard to formation and decline of degradates, a clear pattern is observed, with aldicarb aldehyde forming and completely degrading within one day, and aldicarb nitrile, aldicarb alcohol, aldicarb acid reaching maximum concentrations in the first week, and then declining only slightly during the remainder of the study. The “variable and inconsistent” data noted by the reviewer, is recognized, but the overall conclusions of the study remain acceptable. In consideration of the reviewer’s noted deficiencies, the determination of the aldicarb half-life must be recognized as scientifically valid, due to its complete degradation to non-carbamate moieties, within 1 day of application. The short half-life also agreed with work conducted by EPA with aldicarb sulfoxide and sulfone by Wolfe (1985).

A detailed response to the EFED data evaluation record for this study is provided in Holmsen (2000), and a full kinetic evaluation of the formation and decline of degradates is provided in Ramanarayanan (2000).

Page: 23 Paragraph: 2 Line: 9
EPA Comment: “However, the fate of the parent aldicarb under anaerobic aquatic conditions (particularly ground water) is of less concern that that of the degradates (aldicarb sulfoxide and aldicarb sulfone) which have been detected in groundwater long after application of the parent chemical had ceased (e.g., degradates detected in Long Island, NY groundwater decades after usage was stopped).”

Bayer response: The EPA is incorrect in citing the example of persistence in Long Island ground water as an example of slow anaerobic aquatic degradation rates. The main reason for the persistence of aldicarb residues in Long Island ground water is that the upper part of the aquifer is highly aerobic, not anaerobic. As EPA points out the degradation rate under anaerobic conditions is faster than under aerobic conditions. The decline of aldicarb sulfoxide and aldicarb sulfone residues in Long Island ground water has been consistent with a half-life of about five years. Wells currently with residues in excess of 7 ppb (NY guideline) comprise about 1.5 percent of the wells that have had been identified with residues greater than 7 ppb during the past 25 years. Degradation in surface water under aerobic and anaerobic conditions is more rapid than in ground water. One explanation is that microbial degradation appears to me a contributing process in (aerobic and anaerobic) surface water, while degradation in ground water is primarily chemical (hydrolysis catalyzed by the presence of ferrous ion on solid surfaces under anaerobic conditions).

Page: 23 Paragraph: 2 Line: 15
EPA Comment: “. . . potentially equally toxic metabolite of aldicarb sulfone, hydroxymethyl aldicarb sulfone . . .”

Bayer response: The speculation by EPA that hydroxymethyl sulfone could be as toxic as aldicarb sulfone is incorrect. The toxicity of hydroxymethyl aldicarb sulfone is about two orders of magnitude less than aldicarb sulfone. A LD_{50} value for rat of 2,460 mg/kg bw was reported by Weil, and Carpenter (1972), MRID No. 00054419.

Page: 23 Paragraph: 2 Line: 29
EPA Comment: “The metabolite hydroxymethyl aldicarb sulfone, which forms from aldicarb sulfone under both aerobic and anaerobic conditions, can persist for long periods in oxic, suboxic, and anoxic groundwater within aquifers, which may account for their detection long after above ground application of the parent aldicarb has been terminated.”

Bayer response: This statement is purely speculative in stating that the detection of aldicarb sulfoxide and aldicarb sulfone in ground water is due to formation from the hydroxymethyl aldicarb sulfone. The formation of aldicarb sulfoxide and aldicarb sulfone from the hydroxymethyl aldicarb sulfone will not occur under aerobic conditions (see discussion section for more details) and is unlikely to occur under anaerobic conditions (although the formation of aldicarb sulfone and aldicarb sulfoxide under anaerobic conditions is not of concern since they are not persistent under anaerobic conditions.) Therefore, the degradation rates obtained for aldicarb sulfoxide and aldicarb sulfone in the aquatic aerobic and anaerobic metabolism studies are suitable for use as input parameters in the surface water modeling simulations.

In addition, field data shows that the persistence of aldicarb sulfone (and aldicarb sulfoxide) can be explained by the aerobic conditions within the aquifer. For example, data from the Netherlands show that aerobic conditions can exist for 20-30 m and while aldicarb sulfoxide and aldicarb sulfone are traveling downward in this portion of the aquifer, residues degrade rather slowly. However, rapid degradation occurred as soon as anaerobic conditions were encountered in the aquifer. There is no reason to assume, as EPA suggests, that aerobic degradation in ground and surface water should be similar. In surface water, microbial degradation is more likely to be important.

The guideline aquatic studies with aldicarb sulfone (MRID Nos. 45592109 and 45592111) were conducted for a duration of only 30-37 days post-application, and thus, EFED's conclusion that hydroxymethyl aldicarb sulfone "can persist" is based on a very long-range extrapolation from a two-week duration where these residues appear stable.

Page: 23 Paragraph: 3 Line: 7
EPA Comment: "However, the monitoring data in areas with historical contamination confirm the high persistence of total aldicarb residues in ground water."

Bayer response: The monitoring data confirm that aldicarb carbamate residues are persistent under aerobic conditions in ground water. The persistence is related to temperature and the time required for movement to deeper anaerobic ground water. Changes to TEMIK® labels made in the late 1980's have essentially eliminated residues in drinking water wells resulting from applications made after this date. This has been accomplished by eliminating uses in highly vulnerable areas such as Long Island, the northeastern United States, Wisconsin, and northern coastal California and instituting well set-backs in some of the use areas.

Page: 24 Paragraph: 1 Line: 7
EPA Comment: "The quality of the lab studies was deemed questionable because the half-life values from the field dissipation studies were consistently (and substantially) longer than those from the lab studies . . ."

Bayer response: This statement is not correct and is probably due to confusion between total carbamate residues and parent residues. The half-lives of total carbamate residues in the laboratory studies conducted during the past 20 years are generally longer than measured in the field studies although degradation rates for parent in laboratory studies are faster than for total carbamate residues observed in field studies. Some of the degradation rates for total carbamate residues observed in the earlier laboratory studies conducted under more moist conditions than according to current guidelines show rates comparable to field studies.

Page: 24 Paragraph: 1 Line: 13
EPA Comment: "Therefore an intermediate value of 60 days, derived from the field studies, was used."

Bayer response: As shown by the results in Jones and Estes (1995), this is a reasonable value to use in the northern United States. For applications in the southern half of the United States, a half-life of 15-30 days would be more appropriate.

Page: 24 Paragraph: 4 Lines: 14-15
EPA Comment: "15% is the standard used whether the application is set at soil-incorporated (e.g., granular T-band application) or surface applied."

Bayer response: The TEMIK® labels do not recommend "T-band" application.

Page: 25 Table: 8 Line: 1
EPA Comment: "Input value of 60 days for aerobic soil"

Bayer response: As shown by the results in Jones and Estes (1995), this is a reasonable value to use in the northern United States. For applications in Mississippi, Georgia, and Florida, a half-life of 15-20 days would be more appropriate.

Page: 25 Table: 8 Line: 2
EPA Comment: "Input value of 120 days for aerobic aquatic"

Bayer response: An input value of 5 days for the aerobic aquatic half-life is appropriate based on the guideline aerobic aquatic water/sediment studies for aldicarb, aldicarb sulfoxide and aldicarb sulfone (MRID Nos. 45592107, 45592107, 45592107, respectively). The aldicarb aerobic aquatic half-life was 5.5 days – although the half-life is based on the total system, it represents the water half-life since aldicarb was only detected in the sediment in only one interval, at low concentrations. The aldicarb sulfoxide aerobic aquatic half-life was 5 days for both the total system and the water phase (from EFED Data Evaluation Record). The aldicarb sulfone aerobic aquatic half-life was 3.5 days for the whole system and water phase (from EFED Data Evaluation Record). Although the data evaluation records note some minor deficiencies in the sulfoxide and sulfone studies, these deficiencies do not affect the scientifically valid calculation of the half-lives, and thus, an aerobic aquatic half-life of 5 days is appropriate. The rapid aquatic degradation of aldicarb under aerobic conditions is also supported by the guideline study of Skinner (1995; MRID No. 43805702), which showed a half-life of 9 hours. Persistence in ground water is not an indication of persistence in surface water due to microbial activity in surface water.

Page: 25 Table: 9 Line: 1
EPA comment: Application Scenario: "MS Cotton, (4.05 lbs ai/A) (1 app) = max"

Bayer response: This table appears to indicate that 4.05 lbs ai/A of aldicarb could be made in a single application, however, for use in cotton in the state of Mississippi the TEMIK® 15G label restricts a single applications to at-plant 1.5 lbs ai/A (10 lbs product/A) or a post-emergent side-dress application of 3.0 lbs ai/A (20 lbs/A).

Page: 25 Table 9 Line: 2
EPA comment: Application Scenario: "MS Cotton, (4.95 lbs ai/A) total (2 apps) = max"

Bayer response: This table appears to indicate that 4.95 lbs ai/A of aldicarb could be made in a total of two applications, however, for use in cotton in the state of Mississippi the TEMIK® 15G label restricts usage to a maximum single at-plant application of 1.5 lbs ai/A (10 lbs product/A) and a post-emergent side-dress application of 3.0 lbs ai/A (20 lbs product/A) for a seasonal maximum of 4.50 lbs ai/A (30 lbs product/A).

Page: 25 Table 9.
EPA comment: Footnote at the bottom of the table reads "*Discrepancies between EECs in this document and the 2002 document are due to changes in the meteorological data set (particularly rainfall) used for the PRZM model runs in the interim."

Bayer response: The statement is false. The main reason for the discrepancies between EECs in this document and the 2002 document is the assumption of how much pesticide is available on the surface of the soil and susceptible to run-off. In this document, 15% is used. In the 2002 document, the chemical was assumed to be evenly mixed in the top few inches of the soil, and so less was assumed available for runoff. The assumption of 15% that is used in this modeling is a gross overestimate for real-world use of TEMIK®, most of which is applied in-furrow or as a band *below* the surface of the soil. The Agency's default assumption of 1% availability is more appropriate for the vast majority of TEMIK® applications. Under this assumption, the EECs obtained would be 15-fold lower than the values reported in Table 9. While it is acceptable for the Agency to calculate EECs for worst-case scenarios, it is important that EECs for typical scenarios also be presented. In this case, the Agency's typical values are not very typical at all because they do not reflect the application method (in-furrow) that is predominantly used in many of the crops considered. In these instances, the real "typical" EECs should be 15-fold lower.

Page: 26 Paragraph: 1 Lines: 4-6
EPA Comment: "In NAWQ monitoring sites, aldicarb and its sulfone and sulfoxide transformation products were detected infrequently (about 0.1 percent of all samples) at low concentrations (total residues <1.6 ppb)."

Bayer response: The registrant agrees with the characterization of the NAWQA data that residues were detected infrequently. However, an examination of the detections indicates that many of these infrequent detections are suspect. The discussion section provides a complete response to this comment including discussion of data from other monitoring programs.

Page: 26 Paragraph: 1 Lines: 6-8
EPA Comment: "However, targeted monitoring in smaller streams suggest that aldicarb may occasionally pose a contamination hazard. For example, Williams and Harris (1996) found substantially higher aldicarb concentrations in small southeastern streams after a rainfall . . ."

Bayer response: The concentrations in this intermittent stream are sufficient to result in residues in downstream rivers and reservoirs, which is inconsistent with the findings of surface water monitoring programs. Therefore, the residues observed at this site must be a rare occurrence. Intermittent streams are not an appropriate location to apply risk quotients.

Page: 26 Paragraph: 2 Lines: 3-5
EPA Comment: "In the case of aldicarb, which is applied only in a granular form, the method used in calculating terrestrial EECs took into account this granular formulation and its soil incorporation."
and
Page: 26 Table: 10
EPA comment: "Table 10. Terrestrial EECs for aldicarb, calculated based on application method, application rate (maximum and average), and % unincorporation of granules."

Bayer response: While it is appropriate to consider the formulation and soil incorporation during an aldicarb application when conducting exposure modeling, it is also appropriate to use values that reflect how the product is actually being applied in the field. A survey of TEMIK® usage and methods of application conducted in 2001 across the U.S. (Hall, 2003) showed for, instance, that greater than 99% of cotton applications are applied in-furrow or shanked. By following US EPA (1992), the assumed incorporation efficiency for in-furrow or shanked applications is 99%. Values listed below should be incorporated into Table 10 (EFED page 26) to reflect a more realistic assessment of application types by crop.

	Percentage of acreage treated by application type		
Crop	**In-furrow, drilled or shanked**	**Banded** and covered with a specific amount of soil	**Sidedress, banded** mixed or lightly incorporated
Cotton	99.7	0.3	0
Dry Beans	100	0	0
Sorghum	100	0	0
Peanuts	81	9	10
Potatoes	82	18	0
Soybeans	100	0	0
Sugar beets	83	11	6
Sweet Potatoes	0	100	0
Citrus	100	0	0
Pecans	77	23	0

<u>Page: 26   Paragraph: 2   Lines: 5-7</u>
EPA comment: "The model assumes that only 1% (in-furrow application) or 15% (banded application) of the applied granules remain on the surface and have the potential for terrestrial animal exposure."

Bayer response: Following US EPA (1992) and clarifying statements by Mr. Douglas Urban at the Agency's public meetings on the Comparative Analysis of Acute Risk from Granular Pesticides, the assumed incorporation efficiency for banded applications is 85% where there is light incorporation via drag chains or spring tines, 92% where there is coverage with a specified amount of soil such as with a T-band application and press wheel, and 99% for in-furrow or shanked-in applications. The first situation in which 15% of the granules are assumed to be left unincorporated would apply to the "Sidedress, banded mixed or lightly incorporated" applications that are sometimes made to peanuts (see summary table of TEMIK® usage survey results, immediately above). The second situation with 8% of granules assumed left unincorporated would apply to "Banded and covered with a specific amount of soil" applications made in cotton, peanuts, potatoes, sugar beets, sweet potatoes and pecans peanuts (see summary table of TEMIK® usage survey results, immediately above).   The in-furrow or shanked-in use, in which 1% of granules are assumed left unincorporated would apply to the "in-furrow, drilled or shanked-in" applications that are by far the most frequent use of the product. EFED's calculations in the preliminary risk assessment should incorporate the above usage information and the assumed amount of granules left on the soil surface should be modified accordingly.

<u>Page: 26   Paragraph: 2   Line: 11</u>
EPA comment: "EEC = [Application rate x 453,950 mg/lb] / [# of rows per acre x bandwidth x row length]"
<u>and</u>
<u>Page: 26   Table: 10</u>
EPA comment: "Table 10. Terrestrial EECs for aldicarb, calculated based on application method, application rate (maximum and average), and % unincorporation of granules."

Bayer response: The Agency's method of calculating the amount of TEMIK® granules per ft^2 only within the application band and ignoring the fact that only a small fraction of the crop field is actually treated does not make practical sense and is inappropriate for a granular product that is unattractive to birds, is applied to non-food source crops, and is efficiently incorporated. Birds do not forage only in pesticide-treated bands. The Agency's methodology produces artificially inflated hazard indices for band applications in comparison to a broadcast application with the same soil incorporation efficiency. Intuitively, treatment of 100% of the field area represents a greater hazard than treatment of 10% of the field area, but the Agency's methodology calculates 10-fold greater exposure for the band application that for the broadcast application. There is no scientific justification for performing the calculation this way.

Using cotton, as an example from Table 10, page 26, of the preliminary risk assessment, the EEC calculation is (4.05 lb ai/Acre X 15% unincorporated granules X 453,950 mg/lb) / (13 rows/acre X 0.33 ft bandwidth X 1005 ft) = 64 mg ai/row ft^2.   Note that this assessment is based on exposure to the product only within the 4-inch band. The balance of the area, 90% of the total area, which does not have any TEMIK® applied is ignored in these calculations. Correcting for the percentage of applied area per acre, 4,311.5 row ft^2 / 43,560 ft^2/acre, reduces this value to 6.33 mg ai/ Acre.

Table 10 Revised. Shows terrestrial EECs for aldicarb that have been recalculated after correcting for the percentage of each acre that is actually treated.

Crop	Application Method	Application Rate (lb ai/Acre)		% Unincorporated	EEC (mg ai/ Acre ft^2)	
		Max	Avg		Max	Avg
Cotton (single Application)	Banded (4" band width) (40" row spacing)	4.05	0.6	15 1	64.1* 6.33** 0.42***	9.5* 0.90** 0.06***
Dry Beans	Banded (6" band width) (48" row spacing)	2.1	1.0	15 1	26.3 3.15 0.21	12.5 1.50 0.10
Sorghum	In-furrow (2" band width) (36" row spacing)	1.05	0.4	1	1.9 1.58	0.001 0.60
Peanuts	Banded (6" band width) (36" row spacing)	3.0	0.9	15 1	28.1 4.50 0.30	8.4 1.35 0.09
Potatoes	Banded (6" band width) (38" row spacing)	3.0	2.7	15 1	29.7 4.50 0.30	26.7 4.05 0.27
Soybeans	Banded (6" band width) (30" row spacing)	3.0	0.7	15 1	23.5 4.5 0.30	5.5 1.05 0.07
Sugar Beets (single application)	Banded (6" band width) (22" row spacing)	4.95	1.8	15 1	28.4 7.43 0.50	9.7 2.70 0.18
Sweet Potatoes	Banded (12" band width) (48" row spacing)	3.0	1.4	1	1.3 0.30	0.6 0.14
Citrus	Broadcast Shanked	4.95	3.7	15 1	7.7 7.43 0.50	5.8 5.55 0.37
Pecans	Broadcast Shanked	10.05	3.1	15 1	15.7 15.09 1.01	4.8 4.65 0.31
Ornamentals	Broadcast	5.0	NA	15	7.8	NA

*EEC from EFED Table 10.
**EEC recalculated by Bayer correcting for percentage applied area per total acre (15% unincorporation).
***EEC recalculated by Bayer correcting for percentage applied area per total acre (1% unincorporation).

B. Ecological Effects Characterization

Page: 28 Paragraph: 1 Lines: 7-9

EPA comment: "A supplemental study from the open literature also concluded that aldicarb was moderately toxic to the fathead minnow *Pimephales promelas* with a reported 48-hour EC_{50} was 8860 ppb (Moore *et al*. 1998)."

Bayer response: In addition to the study cited, Pickering and Gilliam (1982) reported the LC_{50} of the fathead minnow to be 1370 ppb. This study has been accepted as a core study by the Agency and was used in EFED's 2001 assessment.

Page: 29 Paragraph: 1 Lines: 2-3
EPA comment: ". . . the MATC (median acute toxicity concentration . . ."

Bayer response: MATC does not stand for "median acute toxicity concentration". It stands for maximum acceptable toxicant concentration.

Page: 29 Paragraphs: 1-2
EPA comment: "A freshwater fish early life-stage test using aldicarb (99% ai) has been conducted with the fathead minnow. The NOAEC was 78 ppb, the LOAEC was 156 ppb and the MATC (median acute toxicity concentration = geometric mean of the NOAEC and LOAEC) was 100 ppb. . . . However, according to the acute freshwater fish data the bluegill sunfish was the most sensitive freshwater fish tested with an LC_{50} of 52 ppb. This LC_{50} of 52 ppb is lower than the NOAEC of 78 ppb for the fathead minnow, indicating that the bluegill is much more sensitive to aldicarb than the fathead minnow. Therefore, chronic risk to fish was also assessed using a predicted chronic ENEC for the bluegill sunfish estimated using the acute-to-chronic ratio for the fathead minnow."

Bayer response: The extrapolation procedure the Agency has used to calculate a predicted chronic ENEC for the bluegill has many sources of uncertainty and should be avoided if an acceptable straightforward procedure for deriving an appropriate chronic fish endpoint is available. For example, the acute-to-chronic ratio (ACR) calculation is highly susceptible to variability found in acute and chronic toxicity values. There are several fathead minnow acute and chronic values the Agency could have chosen to use in the ACR calculation. The combination of values that were used are the ones that result in the largest possible ACR (114), which in turn yields the lowest possible estimate of the ENEC for the bluegill. In the 2001 draft chapter, EFED calculated an ACR for the fathead minnow that was an order of magnitude lower. Based on the toxic mechanism of action of aldicarb, a high acute to chronic ratio is quite unexpected. It is well known that animals that do not die from exposure to carbamate pesticides usually recover fully and effects on reproduction and growth are generally not seen at concentrations far below those that are lethal. For example, the rat LD_{50} value is 0.9 mg/kg and the rat chronic NOAEL is 0.4 mg/kg/day. Thus, the ACR for the rat is 2.3.

A more straightforward approach to the problem is use the sheepshead minnow chronic NOAEC as a surrogate for the bluegill. The sheepshead minnow has been demonstrated to be approximately equal in sensitivity to aldicarb as the bluegill sunfish. The reported LC_{50} for the sheepshead minnow ranges from 41 to 170 ppb with a geometric mean of 83 ppb. The reported LC_{50} values for the bluegill sunfish range from 52 to 115 ppb with a geometric mean of 72 ppb. Based on this comparison, tests with the sheepshead minnow should be a reasonably good surrogate for tests with the bluegill sunfish. The chronic NOAEC value experimentally determined for the sheepshead minnow is 50 ppb. It is more reasonable to use this value to estimate the NOAEC for the bluegill than to extrapolate an ACR from the fathead minnow. Bayer believes this value should be used in the risk assessment. It also represents the lowest fish chronic NOAEC value available that has been experimentally measured for aldicarb. Therefore, use of this value in the risk assessment is consistent with the Agency's standard practice.

Page: 33 Paragraphs: 2-3
EPA comment: "The chronic risk to freshwater invertebrates is based on the estuarine/marine chronic study using *Mysidopsis bahia . . .*"

"A supplemental chronic toxicity study was submitted that evaluated the effect of aldicarb (99.9% ai) on *Daphnia magna*. An EC_{50} of 90 ppb, NOAEC of 20 ppb, and LOAEC of 60 ppb were reported for mortality and immobilization. An EC_{50} with a range of 190 to 570 ppb, NOAEC of 190 ppb and LOAEC greater than 190 ppb were reported for reproductive effects. The most sensitive endpoint was reproductive effects [MRID No. 45592112]. This study is classified as supplemental and is not upgradeable to core due to the study's deviations. **Therefore, the aquatic risk assessment will utilize the mysid shrimp data (NOAEC = 1.0 ppb).**"

Bayer response: The risk assessment for freshwater invertebrates should be carried out with *Daphnia magna* chronic data available from the supplemental study. Studies rated as supplemental by the Agency are considered to be scientifically sound and suitable for use in risk assessments. In this case, since the most sensitive endpoint was mortality/immobility, the MATC (geometric mean of NOAEC and LOAEC, = 35 ppb) should be used as the chronic toxicity endpoint. The Agency's statement, "The most sensitive endpoint was reproductive effects" is incorrect. Since a scientifically sound *Daphnia magna* chronic study is now available, it is no longer appropriate to use the Mysid chronic toxicity value in the freshwater invertebrate risk assessment.

Page: 33 Paragraph: 4

EPA comment: "Based on results from the preferred test species, sheepshead minnow, the LC_{50} falls in the range of 41 to 170 ppb." . . . . "The most sensitive estuarine/marine fish species tested was the sheepshead minnow with an LC_{50} of 41 ppb . . ."

Bayer response: When there are multiple scientifically sound studies on the same test species, the geometric mean of the individual study measurements should be used as the reference value for the species. In this case, there are two scientifically sound acute toxicity studies with the sheepshead minnow. One produced an LC_{50} estimate of 41 ppb, the other produced an LC_{50} estimate of 170 ppb. The geometric mean of these two values, 83 ppb, should be used as the toxicity reference value for the sheepshead minnow. It is poor scientific practice to ignore studies that produced higher toxicity estimates and use only the study that produced the lowest value.

Page: 35 Paragraph: 5 Lines: 1-2

EPA comment: "The LD_{50} is 1.0 mg/kg for aldicarb, and the LD_{50} for aldicarb sulfone is 33.5 mg/kg. The most sensitive species tested for both aldicarb and aldicarb sulfone is the mallard duck."

Bayer response: There are multiple scientifically sound studies available for the mallard. Three studies have been conducted with adult birds per EPA guidelines. These produced LD_{50} values of 1.0 mg/kg (Beavers and Fink, 1979), 3.4 mg/kg (Hudson, Tucker and Haegele, 1979) and 4.44 mg/kg (Hudson, Tucker and Haegele, 1972). When there are multiple scientifically sound studies on the same test species, the geometric mean of the individual test measurements should be used as the toxicity reference value for the species. In this case, the geometric mean is 2.5 mg/kg. Based on this value, the mallard may not be the most sensitive species to aldicarb.

The entry for mallard LD_{50} in Table 20 (EFED page 37) should be changed accordingly to 2.5 mg/kg.

Pages: 35 Paragraph: 5 Lines: 1-2

EPA comment: "The most sensitive species tested on a subacute basis for both aldicarb and aldicarb sulfone is the bobwhite quail."

Bayer response: This sentence should be changed to read, "The most vulnerable species tested . . ." Dietary LC_{50} studies tests are often a poor indicator of toxicological sensitivity, but instead reflect vulnerability to food stress created by the no-choice test conditions.

Pages: 36 Paragraph: 2

EPA comment: "No avian reproduction studies were submitted by the registrant. Avian reproduction studies on the mallard duck and bobwhite quail using the TGAI are required for aldicarb because the following conditions are met: (1) birds may be subject to repeated or continuous exposure to the pesticide, especially preceding or during the breeding season, and (2) the pesticide is stable in the environment to the extent that potentially toxic amounts may persist in animal feed."

Bayer response: Bayer believes avian reproduction studies would provide no useful information and therefore should not be required because (1) the Agency has no methods to use the toxicity data produced by these studies in a risk assessment, (2) TEMIK® granules do not persist (they dissolve with the first rainfall, or upon contact with moist soil) in the field, and so the important route of exposure for birds (ingesting granules) will not occur over a long period of time, and (3) studies in other animals (mammals, daphnids, etc.) all point to the conclusion that aldicarb is an acute toxicant only (due to rapid metabolism and reversibility of the cholinesterase inhibition, animals can withstand repeated exposure up to levels that are nearly lethal). Aldicarb is only formulated as a granular product (TEMIK® Brand Aldicarb Pesticide). The Agency's policy for assessing avian risks of granular products is to calculate LD_{50s} per square foot. The Agency has no methodology for calculating an EEC for avian diets for granular products. Thus, if avian reproduction NOAECs were available, they could not be used in a risk assessment. As confirmation of this, one only has to look at the way chronic mammalian test results were used in this preliminary risk assessment. They weren't! The Agency had high quality chronic toxicity studies of aldicarb with mammals yet the entry in Table 20 (EFED page 37) for the mammalian chronic toxicity endpoint used in the risk assessment is "N/A" presumably for "not applicable". There were chronic NOAELs from tests with mammalian species but they weren't used in any RQ calculations for the reasons indicated above. What is the point of requiring two very expensive (>$100,000 each) studies when the data generated will not affect the outcome of, or even be used in, a risk assessment? The requirement of these studies should be waived.

Pages: 38 Paragraph: 1 Lines: 2-3

EPA comment: "A field study by Hawkes et al. (1996) demonstrated reduced cover-seeking in mourning doves and bobwhite quail following exposure to a lethal aldicarb dose."

Bayer response: The statement is technically correct, but we suggest the following rewording to make the main finding clearer and more accurate. We suggest the statement be changed to read, "A field study by Hawkes et al. (1996) demonstrated that mourning doves and bobwhite quail administered a lethal dose became immobilized before they were able to seek cover." We suggest the rewording to make it clear that this study demonstrated that the knock-down effect of the compound is so rapid it is unlikely that birds leave aldicarb treated fields and die off-site where they are less likely to be found or noticed.

Page: 38 Paragraph: 4 Lines: 1-2

EPA Comment: "There have been 26 incidents related to aldicarb reported in the Environmental Incident Information system (EIIS) database (reported to the Agency from 1991 to 2002). Of these 26 incidents . . .

Bayer response: The fact that the EIIS reports 26 incidents is completely erroneous and not applicable to EFED's argument that aldicarb kills fish, birds and other wildlife. The number of incidents involving fish, birds and other wildlife, as listed in Appendix F, pages F-1 to F-5, that occurred between 1991 and 2002 is 18 not 26. The remaining incidents either involve plant response rather than fish, birds or other wildlife or the incident occurred before 1991 or there is no date associated with the incident.

Page: 38 Paragraph: 4 Lines: 2-4

EPA Comment: "Of these 26 incidents, 14 were from misuse (accidental or intentional), 4 were of undetermined use, and 8 were registered agricultural uses."

Bayer response: If you examine Appendix F, pages F-1 to F-5 you will find the incidents involving fish, birds and other wildlife should be broken down as follows: 15 incidents were from misuse (accidental or intentional), 1 was of undetermined use, and 2 were registered agricultural uses.

Page: 38 Paragraph: 4 Lines: 4-5

EPA Comment: "Approximately 14 of the 23 incidents reported included bird kills. Eleven were from intentional misuse, 2 were of undetermined use . . ."

Bayer response: If you examine Appendix F, pages F-1 to F-5 you will find that of the 18 incidents involving fish, birds and other wildlife, 13 incidents reported dead birds. Twelve were from intentional misuse and 1 was undetermined but probably associated with baiting since the dead bird was a vulture. There were no bird kill incidents associated with any registered agricultural use of TEMIK®.

<u>Page: 38 Paragraph: 4 Line: 5</u>
EPA Comment: "... and 1 bird kill incident involved registered use on potatoes in North Carolina."

Bayer response: The above statement that a North Carolina bird kill incident resulted from the registered use on potatoes is false and does not agree with the report from the N.C. Department of Agriculture, food and Drug Protection Division that is reported on page F-2 of Appendix F. TEMIK® has not been registered for use on potatoes in NC since April 1990 and the reported incident occurred in March 1991. If, in fact, TEMIK® was associated with this incident, it was a clear case of misuse.

<u>Page: 39 Paragraph: 1 Line: 1</u>
EPA Comment: "Two aquatic incidents in North Carolina involving fish kills were reported, one as a result of registered use and one of undetermined use."

Bayer response: Details of these two incidents, cited on pages F-4 and F-5 of Appendix F, indicate that aldicarb was one of several pesticides applied to corn and tobacco. There is no conclusive evidence that aldicarb was involved in the fish kill. In fact, aldicarb is unlikely to be involve in these incidents because: (1) TEMIK® is applied to tobacco from one week before transplanting to immediately before transplanting and tobacco in usually planted well before June 12 in North Carolina, and (2) TEMIK® is shanked 4 to 5 inches deep in the soil and not available for runoff. The involvement of TEMIK® in these fish kills is clearly inconsistent with label use directions.

IV. RISK CHARACTERIZATION

A. Risk Estimation – Integration of Exposure and Effects Data

<u>Page: 41 Table: 21</u>
EPA comment: "Table 21: Acute and chronic risk quotients for freshwater fish"

Bayer response: The LOC exceedences for acute and chronic risk indicated in Table 21 come from RQ calculations that assumed 15% of granules applied remain on the soil surface. This assumption about the proportion of granules left unincorporated is the Agency's standard assumption for band-incorporated, side-dress and broadcast-incorporated applications (US EPA, 1992). For in-furrow, drilled, or shanked-in applications, the standard assumption is 1% of granules available, and for banded applications covered with a specific amount of soil (such as T-banded applications), the standard assumption is 8% availability. In a survey of TEMIK® usage and methods of applications, Hall (2003) showed that the vast majority of TEMIK® applications are made via in-furrow, drilled or shanked-in applications. These data were discussed previously in comments on Table 10. Thus, for the vast majority of real-world TEMIK® applications, the RQs are 15-fold less than what is indicated in Table 21, and there would be no acute LOC exceedences.

The chronic RQs presented in Table 21 over predict chronic risk levels for 2 reasons (1) the EECs are too high because (a) the assumed number of granules remaining on the surface is overestimated (for reasons presented immediately above), and (b) the aquatic half-life assumed in the modeling is too long (60-120 days used vs. the 3-day half-life found in aquatic metabolism studies) and (2) an inappropriate chronic toxicity value is used (see our comments on the fish chronic NOAEC value, Page: 29, Paragraphs: 1-2).

The following table recalculates RQs and LOC exceedences by considering the TEMIK® usage information provided by Hall (2003) and using the appropriate fish chronic toxicity value. The table does not correct for the overestimated half-life values used in the modeling, so the RQ values presented are still somewhat biased on the high side. Data in **bold** type are new; data in regular type are exactly as presented in EFED Table 21.

Table 21. Recalculation of acute and chronic risk quotients for freshwater fish

Site/ Rate in lbs ai/A/year (no. appl.)/ % ai on soil surface	Appl. Method/ % of total usage in this crop	Acute toxicity value (ppb)	Chronic toxicity value (ppb)	EEC Initial/peak (ppb)	EEC 60-day average (ppb)	Acute RQ	Chronic RQ
Cotton 4.05 (1 app) 15%	Band-incorporated 0%	52	**50**	28.04	24.55	0.54***	**0.49**
Cotton 4.05 (1 app) 8%	**Banded and covered with soil 0.3%**	52	**50**	**14.95**	**13.09**	**0.29****	**0.26**
Cotton 4.05 (1 app) 1%	**In-furrow, drilled or shanked 99.7%**	52	**50**	**1.87**	**1.64**	**0.04**	**0.03**
Cotton 4.95 (2 apps) 15%	Band-incorporated 0%	52	**50**	18.40	15.90	0.35**	**0.32**
Cotton 4.95 (2 apps) 8%	**Banded and covered with soil 0.3%**	52	**50**	**9.81**	**8.48**	**0.19****	**0.17**
Cotton 4.95 (2 apps) 1%	**In-furrow, drilled or shanked 99.7%**	52	**50**	**1.23**	**1.06**	**0.02**	**0.02**
Potato 3.00 (1 app) 15%	Band-incorporated 0%	52	**50**	1.43	1.35	0.03	**0.03**
Potato 3.00 (1 app) 8%	**Banded and covered with soil 18%**	52	**50**	**0.76**	**0.72**	**0.01**	**0.01**
Potato 3.00 (1 app) 1%	**In-furrow, drilled or shanked 82%**	52	**50**	**0.095**	**0.090**	**0.002**	**0.002**
Citrus 4.95 (1 app) 15%	Band-incorporated 0%	52	**50**	2.96	2.50	0.06*	**0.05**
Citrus 4.95 (1 app) 1%	**In-furrow, drilled or shanked 100%**	52	**50**	**0.20**	**0.17**	**0.004**	**0.003**
Soybeans 3.00 (1 app) 15%	Band-incorporated 0%	52	**50**	7.12	6.05	0.14**	**0.12**
Soybeans 3.00 (1 app) 1%	**In-furrow, drilled or shanked 100%**	52	**50**	**0.47**	**0.40**	**0.009**	**0.008**
Pecans 10.05 (1 app) 15%	Broadcast-incorporated 23%	52	**50**	12.04	10.19	0.23**	**0.20**
Pecans 10.05 (1 app) 1%	**In-furrow, drilled or shanked 77%**	52	**50**	**0.80**	**0.68**	**0.015**	**0.014**

*exceeds endangered species LOC (LOC = 0.05)
**exceeds endangered species and acute restricted use LOC (LOC = 0.1)
***exceeds endangered species, restricted use and acute risk LOC (LOC = 0.5)
****exceeds chronic LOC (LOC = 1)

Based on the recalculated RQs, the following conclusions can be drawn for risk to freshwater fish:

1. There are no chronic LOC exceedences.
2. There are no acute LOC exceedences for potato, citrus or soybeans uses that actually occur in the real world (based on the usage survey information).
3. The acute LOC is exceeded for 0.3% of cotton applications; 99.7% of cotton use does NOT exceed the acute LOC.
4. The acute LOC is exceeded for 23% of pecan applications, 77% of pecan use does not exceed the acute LOC.

Incorporation of the usage survey information and use of corresponding granule incorporation estimates in the risk assessment leads to a very different impression about the potential for aldicarb to cause adverse effects in freshwater fish. Instead of a broad concern associated with nearly all crops, the potential risk is limited for the most part to one crop (pecans) where the LOCs are only slightly exceeded. This information should be incorporated into the Agency's risk assessment.

Page: 42 Table: 22

EPA comment: "Table 22: Acute risk quotients for freshwater invertebrates. Risk quotients for freshwater invertebrates based on an adult *Daphnia laevis* EC_{50} of 20 ppb using technical grade Aldicarb (Moore *et al.* 1998)."

Bayer response: The toxicity value used in these RQ calculations comes from a test with *Chironomus tetans*, not *Daphnia laevis*.

As discussed in comments immediately above regarding freshwater fish risk estimation, the EECs presented are based on unrealistic assumptions of proportion of granules left unincorporated. Incorporating the TEMIK® usage data from Hall (2003), the following more complete table of RQ values and LOC exceedences is obtained. Data in bold type are new; data in regular type are same as presented in EFED Table 22.

Table 22. Recalculation of acute risk quotients for freshwater invertebrates

Site/ Rate in lbs ai/A/year (no. appl.)/ % ai on soil surface	Appl. Method/ % of total usage in this crop	Acute toxicity value (ppb)	EEC Initial/peak (ppb)	Acute RQ
Cotton 4.05 (1 app) 15%	Band-incorporated 0%	20	28.04	1.40***
Cotton 4.05 (1 app) 8%	**Banded and covered with soil 0.3%**	20	**14.95**	**0.75*** **
Cotton 4.05 (1 app) 1%	**In-furrow, drilled or shanked 99.7%**	20	**1.87**	**0.09***
Cotton 4.95 (2 apps) 15%	Band-incorporated 0%	20	18.40	0.92***
Cotton 4.95 (2 apps) 8%	**Banded and covered with soil 0.3%**	20	**9.81**	**0.49****
Cotton 4.95 (2 apps) 1%	**In-furrow, drilled or shanked 99.7%**	20	**1.23**	**0.06***
Potato 3.00 (1 app) 15%	Band-incorporated 0%	20	1.43	0.07*
Potato 3.00 (1 app) 8%	**Banded and covered with soil 18%**	20	**0.76**	**0.04**
Potato 3.00 (1 app) 1%	**In-furrow, drilled or shanked 82%**	20	**0.095**	**0.005**
Citrus 4.95 (1 app) 15%	Band-incorporated 0%	20	2.96	0.15*
Citrus 4.95 (1 app) 1%	**In-furrow, drilled or shanked 100%**	20	**0.20**	**0.01**
Soybeans 3.00 (1 app) 15%	Band-incorporated 0%	20	7.12	0.36**
Soybeans 3.00 (1 app) 1%	**In-furrow, drilled or shanked 100%**	20	**0.47**	**0.02**
Pecans 10.05 (1 app) 15%	Broadcast-incorporated 23%	20	12.04	0.60***
Pecans 10.05 (1 app) 1%	**In-furrow, drilled or shanked 77%**	20	**0.80**	**0.04**

*exceeds endangered species LOC (LOC = 0.05)
**exceeds endangered species and acute restricted use LOC (LOC = 0.1)
***exceeds endangered species, restricted use and acute risk LOC (LOC = 0.5)

Based on the recalculated RQs for acute risk to freshwater invertebrates, the following conclusions can be drawn:

1. There are no acute LOC exceedences for potato, citrus or soybeans uses that actually occur in the real world (based on the usage survey information).
2. Endangered species, restricted use and acute risk LOCs are exceeded for 0.3% of cotton applications; only the endangered species LOC is exceeded for 99.7% of cotton uses.
3. Endangered species, restricted use and acute risk LOCs are exceeded for 23% of pecan applications, 77% of pecan use does not exceed any freshwater invertebrate acute risk LOCs.

Page: 43 Table: 23
EPA comment: "Table 23: Chronic risk quotients for freshwater invertebrates. Chronic RQ calculated using NOAEC for mysid shrimp (*Americamysis bahia*) (**1.0 ppb**)."

Bayer response: As mentioned in comments on the effects assessment, the chronic toxicity value that should be used in this assessment is the MATC from a chronic test with *Daphnia magna*. This chronic toxicity value is 35 ppb. This is the lowest chronic NOAEC available from tests with freshwater invertebrates. Daphnia magna is a freshwater species; *Americamysis bahia* is an estuarine/marine species.

As discussed in comments above regarding freshwater fish risk estimation, the EECs presented are based on unrealistic assumptions of proportion of granules left unincorporated. Incorporating the TEMIK® usage data from Hall (2003), the following more complete table of RQ values and LOC exceedences is obtained. Data in bold type are new; data in regular type are same as presented in EFED Table 23.

Table 23. Recalculation of chronic risk quotients for freshwater invertebrates

Site/ Rate in lbs ai/A/year (no. appl.)/ % ai on soil surface	Appl. Method/ % of total usage in this crop	Chronic toxicity value (ppb)	EEC 21-day average (ppb)	Chronic RQ
Cotton 4.05 (1 app) 15%	Band-incorporated 0%	35	26.56	0.76
Cotton 4.05 (1 app) 8%	**Banded and covered with soil 0.3%**	35	**14.17**	**0.40**
Cotton 4.05 (1 app) 1%	**In-furrow, drilled or shanked 99.7%**	35	**1.77**	**0.05**
Cotton 4.95 (2 apps) 15%	Band-incorporated 0%	35	17.53	0.50
Cotton 4.95 (2 apps) 8%	**Banded and covered with soil 0.3%**	35	**9.35**	**0.27**
Cotton 4.95 (2 apps) 1%	**In-furrow, drilled or shanked 99.7%**	35	**1.17**	**0.03**
Potato 3.00 (1 app) 15%	Band-incorporated 0%	35	1.40	0.04
Potato 3.00 (1 app) 8%	**Banded and covered with soil 18%**	35	**0.75**	**0.02**
Potato 3.00 (1 app) 1%	**In-furrow, drilled or shanked 82%**	35	**0.093**	**0.003**
Citrus 4.95 (1 app) 15%	Band-incorporated 0%	35	2.80	0.08
Citrus 4.95 (1 app) 1%	**In-furrow, drilled or shanked 100%**	35	**0.19**	**0.01**
Soybeans 3.00 (1 app) 15%	Band-incorporated 0%	35	6.76	0.19
Soybeans 3.00 (1 app) 1%	**In-furrow, drilled or shanked 100%**	35	**0.45**	**0.01**
Pecans 10.05 (1 app) 15%	Broadcast-incorporated 23%	35	11.4	0.32
Pecans 10.05 (1 app) 1%	**In-furrow, drilled or shanked 77%**	35	**0.76**	**0.02**

****exceeds chronic LOC (LOC = 1)

Based on the recalculated RQs for chronic risk to freshwater invertebrates, the LOC is not exceeded for any of the use patterns considered.

<u>Page: 44 Table: 24</u>

EPA comment: "Table 24: Acute and chronic risk quotients for estuarine/ marine fish. Risk quotients for estuarine/marine fish based on a sheepshead minnow (MRID No. 40228401) LC_{50} of **41 ppb** and sheepshead minnow (MRID No. 00066341) NOAEC of **50 ppb** using technical grade aldicarb."

Bayer response: The LOC exceedences for acute and chronic risk indicated in Table 24 come from RQ calculations that assumed 15% of granules applied remain on the soil surface. This assumption about the proportion of granules left unincorporated is the Agency's standard assumption for band-incorporated, side-dress and broadcast-incorporated applications (US EPA, 1992). For in-furrow, drilled, or shanked-in applications, the standard assumption is 1% of granules available, and for banded applications covered with a specific amount of soil (such as T-banded applications), the standard assumption is 8% availability. In a survey of TEMIK® usage and methods of applications, Hall (2003) showed that the vast majority of TEMIK® applications are made via in-furrow, drilled or shanked-in applications. These data were discussed previously in comments on Table 10. Thus, for the vast majority of real-world TEMIK® applications, the RQs are 15-fold less than what is indicated in Table 24, and there would be no acute LOC exceedences.

No chronic RQs were presented in Table 24, but since a valid chronic study with the sheepshead minnow is available, chronic RQs may be calculated. These are all below the Agency's LOC, so it can be concluded that chronic risks to estuarine and marine fish are minimal.

The following table recalculates RQs and LOC exceedences by considering the TEMIK® usage information provided by Hall (2003) and using the appropriate fish chronic toxicity value. The table does not correct for the overestimated half-life values used in the modeling, so the RQ values presented are still somewhat biased on the high side. Data in **bold** type are new; data in regular type are exactly as presented in Table 24.

Table 24. Recalculation of acute and chronic risk quotients for estuarine/ marine fish

Site/ Rate in lbs ai/A/year (no. appl.)/ % ai on soil surface	Appl. Method/ % of total usage in this crop	Acute toxicity value (ppb)	Chronic toxicity value (ppb)	EEC Initial/peak (ppb)	EEC 60-day average (ppb)	Acute RQ	Chronic RQ
Cotton 4.05 (1 app) 15%	Band-incorporated 0%	41	**50**	28.04	24.55	0.68***	**0.49**
Cotton 4.05 (1 app) 8%	**Banded and covered with soil 0.3%**	41	**50**	**14.95**	**13.09**	**0.36****	**0.26**
Cotton 4.05 (1 app) 1%	**In-furrow, drilled or shanked 99.7%**	41	**50**	**1.87**	**1.64**	**0.046**	**0.03**
Cotton 4.95 (2 apps) 15%	Band-incorporated 0%	41	**50**	18.40	15.90	0.45**	**0.32**
Cotton 4.95 (2 apps) 8%	**Banded and covered with soil 0.3%**	41	**50**	**9.81**	**8.48**	**0.24****	**0.17**
Cotton 4.95 (2 apps) 1%	**In-furrow, drilled or shanked 99.7%**	41	**50**	**1.23**	**1.06**	**0.03**	**0.02**
Potato 3.00 (1 app) 15%	Band-incorporated 0%	41	**50**	1.43	1.35	0.03	**0.03**
Potato 3.00 (1 app) 8%	**Banded and covered with soil 18%**	41	**50**	**0.76**	**0.72**	**0.02**	**0.01**
Potato 3.00 (1 app) 1%	**In-furrow, drilled or shanked 82%**	41	**50**	**0.095**	**0.090**	**0.002**	**0.002**
Citrus 4.95 (1 app) 15%	Band-incorporated 0%	41	**50**	2.96	2.50	0.07*	**0.05**
Citrus 4.95 (1 app) 1%	**In-furrow, drilled or shanked 100%**	41	**50**	**0.20**	**0.17**	**0.005**	**0.003**
Soybeans 3.00 (1 app) 15%	Band-incorporated 0%	41	**50**	7.12	6.05	0.17**	**0.12**
Soybeans 3.00 (1 app) 1%	**In-furrow, drilled or shanked 100%**	41	**50**	**0.47**	**0.40**	**0.01**	**0.008**
Pecans 10.05 (1 app) 15%	Broadcast-incorporated 23%	41	**50**	12.04	10.19	0.29**	**0.20**
Pecans 10.05 (1 app) 1%	**In-furrow, drilled or shanked 77%**	41	**50**	**0.80**	**0.68**	**0.019**	**0.014**

*exceeds endangered species LOC (LOC = 0.05)
**exceeds endangered species and acute restricted use LOC (LOC = 0.1)
***exceeds endangered species, restricted use and acute risk LOC (LOC = 0.5)
****exceeds chronic LOC (LOC = 1)

Based on the recalculated RQs, the following conclusions can be drawn for estuarine/marine fish:

1. There are no chronic LOC exceedences.
2. There are no acute LOC exceedences for potato, citrus or soybeans uses that actually occur in the real world (based on the usage survey information).
3. The acute LOC is exceeded for 0.3% of cotton applications; 99.7% of cotton use does NOT exceed the acute LOC.
4. The acute LOC is exceeded for 23% of pecan applications, 77% of pecan use does not exceed the acute LOC.

Incorporation of the usage survey information and use of corresponding granule incorporation estimates in the risk assessment leads to a very different impression about the potential for aldicarb to cause adverse effects in estuarine/marine fish. Instead of a broad concern associated with nearly all crops, the potential risk is limited for the most part to one crop (pecans) where the LOCs are only slightly exceeded. This information should be incorporated into the Agency's assessment.

Page: 44-45 Table: 25

EPA comment: "Table 25: Acute and chronic risk quotients for estuarine/ marine invertebrates. Risk quotients for estuarine/marine invertebrates based on a Pink Shrimp (*Penaeus duorarum* MRID No. 40228401) LC_{50} of **12 ppb** and Mysid Shrimp (*Americamysis bahia* MRID No. 00066341) NOAEC of **1 ppb** using technical grade aldicarb."

Bayer response: The LOC exceedences for acute and chronic risk indicated in Table 25 come from RQ calculations that assumed 15% of granules applied remain on the soil surface. This assumption about the proportion of granules left unincorporated is the Agency's standard assumption for band-incorporated, side-dress and broadcast-incorporated applications (US EPA, 1992). For in-furrow, drilled, or shanked-in applications, the standard assumption is 1% of granules available, and for banded applications covered with a specific amount of soil (such as T-banded applications), the standard assumption is 8% availability. In a survey of TEMIK® usage and methods of applications, Hall (2003) showed that the vast majority of TEMIK® applications are made via in-furrow, drilled or shanked-in applications. These data were discussed previously in comments on Table 10. Thus, for the vast majority of real-world TEMIK® applications, the RQs are 15-fold less than what is indicated in Table 25, and there would be no acute LOC exceedences.

The following table recalculates RQs and LOC exceedences by considering the TEMIK® usage information provided by Hall (2003). The table does not correct for the overestimated half-life values used in the modeling, so the RQ values presented are still somewhat biased on the high side. Data in **bold** type are new; data in regular type are exactly as presented in Table 25.

Table 25. Recalculation of acute and chronic risk quotients for estuarine/ marine invertebrates

Site/ Rate in lbs ai/A/year (no. appl.)/ % ai on soil surface	Appl. Method/ % of total usage in this crop	Acute toxicity value (ppb)	Chronic toxicity value (ppb)	EEC Initial/peak (ppb)	EEC 21-day average (ppb)	Acute RQ	Chronic RQ
Cotton 4.05 (1 app) 15%	Band-incorporated 0%	12	1	28.04	26.56	2.34***	**26.56***
Cotton 4.05 (1 app) 8%	**Banded and covered with soil 0.3%**	12	1	**14.95**	**14.17**	**0.80****	**14.17***
Cotton 4.05 (1 app) 1%	**In-furrow, drilled or shanked 99.7%**	12	1	**1.87**	**1.77**	**0.16****	**1.77***
Cotton 4.95 (2 apps) 15%	Band-incorporated 0%	12	1	18.40	17.53	1.53**	**17.53***
Cotton 4.95 (2 apps) 8%	**Banded and covered with soil 0.3%**	12	1	**9.81**	**9.35**	**0.82****	**9.35***
Cotton 4.95 (2 apps) 1%	**In-furrow, drilled or shanked 99.7%**	12	1	**1.23**	**1.17**	**0.10****	**1.17***
Potato 3.00 (1 app) 15%	Band-incorporated 0%	12	1	1.43	1.40	0.12**	**1.40***
Potato 3.00 (1 app) 8%	**Banded and covered with soil 18%**	12	1	**0.76**	**0.75**	**0.06***	**0.75**
Potato 3.00 (1 app) 1%	**In-furrow, drilled or shanked 82%**	12	1	**0.095**	**0.093**	**0.002**	**0.093**
Citrus 4.95 (1 app) 15%	Band-incorporated 0%	12	1	2.96	2.80	0.07*	**2.80***
Citrus 4.95 (1 app) 1%	**In-furrow, drilled or shanked 100%**	12	1	**0.20**	**0.19**	**0.008**	**0.19**
Soybeans 3.00 (1 app) 15%	Band-incorporated 0%	12	1	7.12	6.76	0.59***	**6.76***
Soybeans 3.00 (1 app) 1%	**In-furrow, drilled or shanked 100%**	12	1	**0.47**	**0.45**	**0.04**	**0.45**
Pecans 10.05 (1 app) 15%	Broadcast-incorporated 23%	12	1	12.04	11.4	1.0***	**11.4***
Pecans 10.05 (1 app) 1%	**In-furrow, drilled or shanked 77%**	12	1	**0.80**	**0.76**	**0.07***	**0.76**

*exceeds endangered species LOC (LOC = 0.05)
**exceeds endangered species and acute restricted use LOC (LOC = 0.1)
***exceeds endangered species, restricted use and acute risk LOC (LOC = 0.5)
****exceeds chronic LOC (LOC = 1)

Based on the recalculated RQs, the following conclusions can be drawn for estuarine/marine invertebrates:

1. Acute and chronic LOCs are exceeded for cotton
2. There are no acute or chronic LOC exceedences for potato, citrus or soybeans uses that actually occur in the real world (based on the usage survey information), except for a very slight exceedence of the endangered species LOC in potato.
3. Acute and chronic LOCs are exceeded for 23% of pecan applications that are broadcast-incorporated; for 77% of pecan use has a slight exceedence of the acute endangered species LOC only.

Page: 45 Table: 26
EPA Comment: "Table 26. Acute risk quotients for aquatic organisms based on actual field data."

Bayer response: The LC_{50} and EEC values are expressed in ppm whereas the values in all of the other tables are expressed in ppb. To be consistent, the values in Table 26 should also be expressed in ppb.

Page: 46 Paragraph: 2.
EPA Comment: "The LD_{50} values entered into T-REX are adjusted for animal class (20, 100 and 1000g birds and 15, 35 and 1000g mammals) using the following equations: . . . "
and
Page: 47 Paragraph: 1 Lines: 3-7
EPA Comment: "However, research by Mineau et al. (1996) suggests that the scaling factor for aldicarb should be 1.4, rather than 1.15. Substituting the aldicarb-specific scaling factor of 1.4 into the above avian equation results in RQ values as high as 22,000 (20g bird, maximum cotton application rate). It is therefore possible that the RQ calculations present in this risk assessment are underestimated."

Bayer response: The body-size extrapolation method should not be used unless it can be demonstrated that a significant statistical relationship generally holds between body size and toxicological sensitivity. In the case of birds, this was NOT shown by Mineau et al. in the cited paper (Mineau et al. 1996). These authors reported the slope (1.15) of their regression of LD_{50} and body mass was not significantly different from 1.0, the slope under the null hypothesis that sensitivity does not differ with body size. Therefore, there is not sufficient justification to reject the null hypothesis of no difference in toxicological sensitivity for birds of different body sizes.

In the case of aldicarb, Mineau et al. (1996) reported a slope of 1.40 and this slope was significantly greater than 1. However, in their analysis, they used an LD_{50} estimate for the mallard duck of 3.4 mg/kg, and not the 1.0 mg/kg, the estimate EPA has used in the current assessment. If one substitutes a value of 1.0 for the mallard and repeats the Mineau et al. regression analysis for aldicarb, the slope is no longer significantly different from 1.

Intuitively, it does not make sense to do this body size adjustment for birds in the current assessment. The purpose of this procedure is to take into account that smaller birds are more sensitive than larger birds. But for aldicarb, the largest bird tested (mallard) has been identified by the Agency as being the most sensitive species, so the underlying assumption doesn't hold. It is especially inappropriate to apply this extrapolation method, as the Agency has done, to the lowest of several LD_{50} values that have been generated for the mallard. In this case, the Agency's procedure of choosing the lowest available LD_{50} estimate from among 10+ species that have been tested already adequately accounts for interspecies variability in sensitivity. The mallard value of 1.0 mg/kg should be used in the RQ calculations without further adjustment.

Contrary to the statement on the bottom of page 47, the Agency's extrapolation procedure has likely resulted in an overestimate of the RQ values, not an underestimate.

Page: 46 Paragraph: 3 Line: 7
EPA Comment: "Chronic risk assessments are not currently performed for granular pesticides on terrestrial organisms."

Bayer response: Bayer fully concurs with this statement. Given this fact, the Agency should not require avian chronic tests with pesticides only formulated as granulars.

Page: 46 Paragraph: 3 Lines: 2-4
EPA Comment: "As previously stated, the method used in calculating terrestrial EECs took into account the granular formulation of the product and its soil incorporation."
and
Pages: 46-49 Tables: 27 and 28
EPA comment: "Table 27. Avian Acute Risk Quotients for Aldicarb (maximum and average use rates)" and "Table 28. Mammalian Acute Risk Quotients for Aldicarb (maximum and average use rates)."

Bayer response: While it is appropriate to consider the formulation and soil incorporation during an aldicarb application when conducting exposure modeling, it is also appropriate to use values that reflect how the product is actually being applied in the field. A survey of TEMIK® usage and methods of application conducted in 2001 across the U.S. (Hall, 2003) showed, for instance, that greater than 99% of cotton applications are applied in-furrow or shanked. By following US EPA (1992), the assumed incorporation efficiency for in-furrow or shanked applications is 99%. Values listed below should be incorporated into Tables 27 and 28 (Pages: 46-49) to reflect a more realistic assessment of application types by crop.

	Percentage of acreage treated by application type		
Crop	**In-furrow, drilled or shanked**	**Banded** and covered with a specific amount of soil	**Sidedress, banded** mixed or lightly incorporated
Cotton	99.7	0.3	0
Dry Beans	100	0	0
Sorghum	100	0	0
Peanuts	81	9	10
Potatoes	82	18	0
Soybeans	100	0	0
Sugar beets	83	11	6
Sweet Potatoes	0	100	0
Citrus	100	0	0
Pecans	77	23	0

Pages: 46-49 Tables 27, 28 and 29
EPA Comment: the acute avian and mammalian risk quotients presented in Tables 27, 28 and 29.

Bayer response: As indicated previously, Bayer disagrees with the calculations of both the EEC (mg of aldicarb available per square foot) and toxicity value (the LD_{50} value should be for the TEMIK® granule rather than aldicarb, and no body-size scaling adjustment should be used in the calculation). Bayer believes the values presented in these tables are at least 1 to 2 orders of magnitude too high since the Agency's methodology produces artificially inflated hazard indices for band applications in comparison to a broadcast application with the same soil incorporation efficiency.

Page: 50 Paragraph: 4 Lines: 1-2
EPA Comment: "Seven bird die-off incidents were reported in Great Britian from 1975 to 1976 involving from 3 to 100 bird species each."

Bayer response: Is this really bird "species" or birds?

Page: 51 Paragraph: 4 Lines: 1-2
EPA Comment: "This indicates that there is potential risk to honeybees as well as other beneficial insects."

Bayer response: A different conclusion is stated on Page 36, Paragraph 5, Lines 1-2, states that, ". . . aldicarb due to its granular formulation, its use is not expected to result in honey bee exposure."

Page: 52 Paragraph 2: Line: 3 and Aldicarb Soil Conceration
EPA comment: ". . . the following soil concentrations can be calculated for a depth of 15 cm." and "aldicarb soil concentration = 7.47 mg/kg"

Bayer response: The aldicarb soil concentration here does not agree with the "aldicarb soil concentration = 112 mg/kg" cited on Page 67, Paragraph 3. The reasoning behind using incorporation depths of 1 cm and 15 cm needs to be clearly and fully explained and documented so that we can understand the point that EFED is trying to make by using two very different calculations.

B. Risk Description – Interpretation of Direct Effects

Page: 53 Paragraph: 1 Lines: 4-6
EPA Comment: ". . . using the most sensitive endpoint of EC_{50} of 20 ppb for *Daphnia laevis*. A comparison of freshwater invertebrate toxicities indicates *Daphnia laevis* is more sensitive than other invertebrate species . . ."

Bayer response: The statement is incorrect for *Daphnia laevis*. The correct species to mention in this context is *Chironomus tetans.*

Pages: 52-53 Risks to Aquatic Animals: Summary of Major Conclusions
EPA Comment: The entire Acute Risk and Chronic Risk summaries

Bayer response: As presented in an earlier section, Bayer recalculated RQ values and reached the following conclusions that differ from the Agency.

The following conclusions can be drawn for risk to freshwater fish:

1. There are no acute LOC exceedences for potato, citrus or soybeans uses that actually occur in the real world (based on the usage survey information).
2. The acute LOC is exceeded for 0.3% of cotton applications; 99.7% of cotton use does NOT exceed the acute LOC.
3. The acute LOC is exceeded for 23% of pecan applications, 77% of pecan use does not exceed the acute LOC.
4. There are no chronic LOC exceedences.

The following conclusions can be drawn for risk to freshwater invertebrates:

1. There are no acute LOC exceedences for potato, citrus or soybeans uses that actually occur in the real world (based on the usage survey information).
2. Endangered species, restricted use and acute risk LOCs are exceeded for 0.3% of cotton applications; only the endangered species LOC is exceeded for 99.7% of cotton uses.
3. Endangered species, restricted use and acute risk LOCs are exceeded for 23% of pecan applications, 77% of pecan use does not exceed any freshwater invertebrate acute risk LOCs.
4. There are no chronic LOC exceedences.

The following conclusions can be drawn for risk to estuarine/marine fish:

1. There are no acute LOC exceedences for potato, citrus or soybeans uses that actually occur in the real world (based on the usage survey information).
2. The acute LOC is exceeded for 0.3% of cotton applications; 99.7% of cotton use does NOT exceed the acute LOC.
3. The acute LOC is exceeded for 23% of pecan applications, 77% of pecan use does not exceed the acute LOC.
4. There are no chronic LOC exceedences.

The following conclusions can be drawn for risk to estuarine/marine invertebrates:

1. Acute and chronic LOCs are exceeded for cotton.
2. There are no acute or chronic LOC exceedences for potato, citrus or soybeans uses that actually occur in the real world (based on the usage survey information), except for a very slight exceedence of the endangered species LOC in potato.
3. Acute and chronic LOCs are exceeded for 23% of pecan applications that are broadcast-incorporated; for 77% of pecan use has a slight exceedence of the acute endangered species LOC only.

C. Threatened and Endangered Species Concerns

Page: 54   1. Taxonomic Groups Potentially at Risk
EPA Comment: Comments refer to the entire section: "1. Taxonomic Groups Potentially at Risk"

Bayer response: The list of taxonomic groups potentially at risk must be considered a very preliminary starting point since it is based on a screening assessment in which unrealistic exposure estimates have been used. Even simple adjustments to the aquatic EECs, such as those provided in our recalculated RQ estimates, show that many of the triggered concerns are unfounded. A more refined assessment should be performed to determine which taxonomic groups are really at risk for the various crops and application scenarios.

Page: 58   3. Probit Slope Analysis-response analysis
EPA Comment: Entire section on "Birds" and entire section on "Mammals"

Bayer response: The entire section on "Birds" and entire section on "Mammals" should be deleted. The amount of toxicant per square foot is an arbitrarily defined number—it is not a valid estimate of pesticide intake for individual birds or mammals. It is scientifically indefensible to calculate percent mortality risk as is done here.

Page: 56   Paragraph: 4   Lines: 1-13
EPA Comment: "The Agency has developed . . . . . . Marine Fisheries Service as necessary."

Bayer response: This whole paragraph is a repeat of the paragraph immediately above. Delete paragraph.

Page: 60   Paragraph: 8   Lines: 1-4
EPA Comment: "The high acute toxicity of aldicarb to honeybees may lead to mortality to this and other insect-pollinators." . . . . "Additionally, the potential risk to bird species from aldicarb use could also affect bird pollinated plant species."

Bayer response: These statements are speculative, lack foundation and conflict with the statement on Page 36, Paragraph 5, Lines 1-2 which states, ". . . aldicarb due to its granular formulation, its use is not expected to result in honey bee exposure." Risks to pollinating species are minimal for insecticides applied in granular form to the soil. There is no evidence that systemic residues will pose a risk to any pollinating species.

D. Comparison of Aldicarb to Carbofuran

Page: 61 Paragraph: 5 Line: 4
EPA comment: "For instance, there have been 400 incidents reported for carbofuran versus 23 incidents reported for aldicarb."

Bayer response: The fact that the EIIS reports 26 incidents is completely erroneous and not applicable to EFED's argument that aldicarb kills fish, birds and other wildlife. The number of incidents involving fish, birds and other wildlife, as listed in Appendix F, pages F-1 to F-5, that occurred between 1991 and 2002 is 18 not 26. The remaining incidents either involve plant response rather than fish, birds or other wildlife or the incident occurred before 1991 or there is no date associated with the incident. The fact that there are only 18 reported incidents for aldicarb versus 400 for carbofuran is indicative of significant differences in product formulation and method of application.

Page: 61-62 1. Incidents
EPA Comment: In this section, EPA asserts that comparison of the history of reported wildlife kill incidents between aldicarb and carbofuran is not appropriate because of:

1. Differences in the crops that are treated
2. Differences in label use directions (application rates, number of applications, etc.)
3. Differences in state restrictions
4. Differences in toxicokinetics that affect whether animals die in visible locations
5. Differences in conspicuousness of species that use crops treated with each chemical

Bayer response: Bayer disagrees strongly. A comparison between the incident record associated with use of granular carbofuran and granular aldicarb is both appropriate and instructive. The Agency's 1992 Comparative Analysis of Acute Avian Risk from Granular Pesticides presented data on acres treated by crop (see EPA 1992, Appendix 3). Granular aldicarb was estimated to be used annually on 5.035 million acres, mainly row cropland where it is applied to bare soil at planting time. Granular carbofuran was estimated to be used annually on 5.025 million acres, mainly row cropland where it was applied to bare soil at planting time. Although the specific crops differ somewhat, both are applied to large bare ground fields and the species of wildlife that use such fields do not differ substantially. For example, there is no reason to think that more large, conspicuous species of wildlife used cropland treated with carbofuran than used cropland treated with aldicarb. The two compounds have similar toxicokinetic profiles in vivo. Both are fast acting, reversible cholinesterase inhibitors. Balcomb et al. (1984) reported average time to death for birds dosed near the LD_{50} level was 14 minutes with carbofuran, and 18 minutes for aldicarb. Kendall (1990) and (1992) reported that mourning doves and bobwhite quail dosed with aldicarb at levels near the LD_{50} died as quickly as within 5 to 15 minutes. Clearly there is little difference between these compounds in how rapidly birds become incapacitated if they ingest a lethal dose.

Page: 62 3. Acute Toxicity
EPA Comment: "In summary, although aldicarb and carbofuran are both quick "knock down" carbamate insecticides with similar toxicities . . . . and modes of action . . . , the pharmacokinetics of each chemical appears to be significantly different in regards to intoxication and recovery times of non-target organisms….Thus, the effects from exposure are likely to occur more quickly from carbofuran poisoning than aldicarb . . . . Thus, the recovery time for non-targets is much quicker for aldicarb than carbofuran. This is one possible explanation for why there have been many more incidents attributed to carbofuran than aldicarb."

Bayer response: Based on the time to death data cited immediately above, effects occur only slightly faster, if at all, in carbofuran poisoned birds in comparison to aldicarb. The difference is certainly not enough to explain why fewer incidents have occurred with aldicarb. Likewise, Bayer does not think differences in recovery time are large enough to be a likely explanation for why incidents are less likely to occur with aldicarb. However, if this second point is true, then this would support the concept of using incident records to compare the relative risk of the two compounds.

Page: 63 4. Cholinesterase Activity

EPA Comment: "The *in vitro* inhibition of cholinesterase activity by aldicarb is spontaneously reversible, having a half life of thirty minutes to forty minutes. Although aldicarb is a potent inhibitor of cholinesterases and has a high acute toxicity, recovery from its effects are spontaneous and complete within six hours, unless death intervenes (WHO 1991). Carbofuran is also highly toxic after acute oral exposure. In contrast, the toxic signs typical for cholinesterase inhibition (salivation, cramps, trembling and sedation) are observed within minutes and continue for up to three days . . . A bird exposed to carbofuran (unless death is the immediate outcome) will have difficulty flying or leaving the site of exposure due to cholinesterase inhibition and will be repeatedly exposed to the carbofuran for up to three days. This could lead to the high numbers of wildlife kills that are observed in fields and adjacent properties. Aldicarb, on the other hand, requires higher concentrations for cholinesterase inhibition and the effects are spontaneously reversible within 6 hours. Birds and mammals would experience the effects at the site of exposure but would return to normal behaviors within six hours and would be able to fly and move from the area."

Bayer response: This is highly speculative and probably should be deleted from the document. Although there may be some difference in *in vitro* measurements of inhibition of cholinesterase activity, the *in vivo* evidence in birds suggest both compounds have similar properties: rapid knock-down and rapid recovery.

E. Description of Assumptions, Uncertainties, Strengths, and Limitations

Page: 64 3.a. The LD_{50} /sq ft Index Line: 1

EPA comment: "The concept was based on field observations of DeWitt (1966) who suggested that ecological effects are expected to occur when exposure residues that equal or exceed the LD_{50} value for a pesticide, as determined in laboratory studies, are reached in the field."

Bayer response: DeWitt (1966) proposed a possible relationship between exposure levels in the field and the quantity that resulted in mortality in *sub-chronic feeding studies*, not acute oral toxicity studies.

Page: 65 b. Uncertainties Associated with LD_{50} /sq ft Index Lines: 1-6

EPA comment: "Risk quotients based on the LD_{50} /sq. ft. hazard index have been criticized as being too conservative and overestimating "real world" risk. It has been argued that the method greatly oversimplifies the exposure component to hazard assessment by not specifically addressing the temporal and spatial situations that non-target wildlife species experience under field conditions. Although this is somewhat correct there are still many other exposure related and toxicological factors that are not accounted for by the index which may actually underestimate risk from this method."

Bayer response: The problem of the LD_{50}/sq. ft method is not that it "oversimplifies the exposure component to hazard assessment by not specifically addressing the temporal and spatial situations that non-target wildlife species experience under field conditions". The problem is that it doesn't estimate exposure in a biologically meaningful way. Exposure is simply assumed to equal the amount of toxicant in an arbitrarily defined unit area. This is obviously not going to be a valid assumption. Although it might be possible to come up with reasons for why the LD_{50}/ft^2 index may "actually underestimate risk", there is no empirical evidence to support such a conclusion and a mountain of evidence to refute it. For example, Fischer and Best (1995) showed that under actual field conditions granule consumption was a tiny fraction of the number of granules available per square foot even when the most attractive granule type was applied. Stafford and Best (1998) showed that mortality rates were consistently low (10-15%) across exposure levels ranging from 50 to 2000 LD_{50s}/ft^2. In the preliminary risk assessment, the predicted risk level according to the LD_{50}/ft^2 method was 100% in all groups. It is difficult to understand how the Agency could envision this index as underestimating risk of granular products when for most registered products it predicts that 100% bird mortality is expected to occur most of the time!

<u>Page: 67 Paragraph 2: Line: 3 and Aldicarb Soil Concentration</u>
EPA comment: "... the following soil concentrations can be calculated for a depth of 1 cm." and "aldicarb soil concentration = 112 mg/kg"

Bayer response: The aldicarb soil concentration here does not agree with the "aldicarb soil concentration = 7.47 mg/kg" cited on Page 52, Paragraph 3. The reasoning behind using incorporation depths of 1 cm and 15 cm needs to be clearly and fully explained and documented so that we can understand the point that EFED is trying to make by using two very different calculations.

<u>Page: 69 6. Data Gaps and Limitations of the Risk Assessment, a: Ecotoxicity Data Gaps</u>
EPA comment: "71-4(a) Avian reproduction – Quail, 71-4(b) Avian Reproduction. – Duck"

Bayer response: The lack of these data have no bearing on the outcome of the risk assessment because, as is stated by EFED on Page 46, Paragraph 3, Lines 7-8, "Chronic risk assessments are not currently performed for granular pesticides on terrestrial organisms." The lack of this information is therefore not a data gap.

<u>Page: 69 Paragraph: 7 Line: 1</u>
EPA comment: data gap for "161-1 Hydrolysis (sulfone)"

Bayer response: A guideline study (MRID Nos. 00053377, 45592104) is available on the rates of hydrolysis and nature and magnitude of the degradation products of radiolabeled aldicarb sulfone (Andrawes, 1976). Aldicarb sulfone was stable at pH 5 but degraded at pH 7 and 9 with half-lives ($t_{1/2}$) of 81 days and 0.87 days, respectively. At low temperatures (5°C), the rate of hydrolysis at pH 9 was considerably slower than at 25°C with a $t_{1/2}$ of 31 days. This study satisfies the 161-1 guideline requirement for aldicarb sulfone. Refer to the discussion section for more details.

<u>Page: 69 Paragraph: 7: Line: 2</u>
EPA comment: data gap for "161-2 Photodegradation in Water (sulfoxide, sulfone)"

Bayer response: Field monitoring and laboratory studies under controlled conditions demonstrate that it is unlikely for any significant aldicarb sulfoxide and aldicarb sulfone residues to occur in open bodies of water, or to exist for sufficient duration to allow for photodegradation to play an important role in the environmental impact of aldicarb. Non guideline studies has shown that photodegradation in water is limited for both aldicarb sulfoxide and aldicarb sulfone. Therefore, further investigation of the photodegradation of the two carbamates is not warranted. Refer to discussion section for more details.

<u>Page: 69 Paragraph: 7 Line: 3</u>
EPA comment: data gap for "162-1 Aerobic Soil Metabolism (sulfoxide, sulfone)"

Bayer response: Two new studies, one in which parent aldicarb was applied, and one in which aldicarb sulfone was applied have been submitted to EPA (Allan, 2002a; 2002b, MRID Nos. 45739801, 45739802). The design of these two studies was approved by EPA. These two studies meet the guideline requirement for the degradation of aldicarb, aldicarb sulfoxide (from formation and degradation in the aldicarb study), and aldicarb sulfone.

<u>Page: 69 Paragraph: 7 Line: 4</u>
EPA Comment: "164-1 Terrestrial Field Dissipation (parent aldicarb, sulfoxide, sulfone)"

Bayer response: The registrant has identified numerous field dissipation studies conducted for aldicarb and previously submitted to the Agency that have not been included in the preliminary EFED risk assessment. The degradation of aldicarb carbamate residues in the United States (summarized in Jones and Estes, 1995) is well understood, with half lives ranging from 0.5 to 3.5 months. The discussion section provides a complete response to this comment.

Page: A-1 Table: A-1 Line: 4
EPA Comment: 264-426, Temik® Brand 15G Aldicarb Pesticide for Sale and Use in CA only."

Bayer response: The correct name is, "264-426, TEMIK® Brand 15G Aldicarb Pesticide for Sale and Use in California Only."

Page: A-1 Table: A-1 Line: 5
EPA comment: "264-523, Temik® Brand 15G NW Aldicarb Pesticide for Use on Potatoes."

Bayer response: The correct name is, "264-523, TEMIK® Brand 15G NW Aldicarb Pesticide."

Page: A-1 Table: A-1
EPA comment:

Bayer response: One TEMIK® registration was omitted from the table. Add, "264-417. TEMIK® Brand 15G CP Aldicarb Pesticide. Conditionally Registered 26-Dec1984. 15."

Page: A-2 Table: A-1 Line: 6
EPA comment: "FL800003"

Bayer response: The correct registration number is FL880003.

Page: A-3 Table: A-1 Line: 7
EPA comment: "PR960001"

Bayer response: This registration is not on our maintenance list.

Pages: A-2 - A-3 Table: A-1
EPA comment:

Bayer response: These SLN registrations for TEMIK® 15G Aldicarb Pesticide are not listed in table A-1: GA790016 soybeans; MT000003 potatoes; NC770012 peanuts; OK780009 peanuts; TX780013 peanuts; VA770003 peanuts.

Page: A-5 Table: A-2
EPA comment: "PR96000100, PR, yams"

Bayer response: This registration is not on our maintenance list.

Pages: A-4 - A-5 Table: A-2
EPA comment:

Bayer response: These SLN registrations are not listed in table A-2: GA790016 soybeans; MT000003 potatoes; NC770012 peanuts; OK780009 peanuts; TX780013 peanuts; VA770003 peanuts.

DISCUSSION

Bayer CropScience's Discussion of the Preliminary Environmental Fate and Ecological Effects Risk Assessment for Aldicarb May 6, 2005

I. DATA REQUIREMENTS – ENVIRONMENTAL FATE

161-1. Hydrolysis: The agency has requested that additional data using applied aldicarb sulfone be developed. The guideline study (MRID Nos. 00053377, 45592104) is sufficient to meet this requirement. Following is the summary of this study.

1. Andrawes, N. R. and G. C. Holsing (1976). Hydrolysis of UC-21865 Sulfocarb Pesticide in Aqueous Buffer Solutions. Union Carbide Corp. Project Report, File No. 22928. December 9, 1976. (MRID Nos. 00053377, 45592104)

Aldicarb sulfone was being developed in 1976 as a pesticide under the name Sulfocarb. S-methyl-^{14}C- and tert-^{14}C-labeled aldicarb sulfone was used. The rates of hydrolysis of S-methyl-^{14}C aldicarb sulfone and the nature and magnitude of the degradation products were studied in aqueous buffer solutions at pH 5, 7, and 9 at 25°C using a 10 ppm concentration.

Aldicarb sulfone was stable in pH 5 but degraded in pH 7 and 9 with half lives ($t_{1/2}$) of 81.34 days and 0.87 days, respectively. At low temperatures (5°C), the rate of hydrolysis in pH 9 was considerably slower than at 25°C with a $t_{1/2}$ of 31.36 days.

Aldicarb sulfone oxime, aldicarb sulfone nitrile, 2-hydroxy isobutyraldehyde oxime and methane sulfonic acid were identified as the major hydrolysis products. Minor amounts of aldicarb sulfone aldehyde, aldicarb sulfone amide, and aldicarb sulfone acid were also detected. At any given time point, each of these compounds was present at a concentration corresponding to less than 7 % of applied radioactivity. Aldicarb sulfone oxime degraded rapidly in pH 9 ($t_{1/2}$ 19.7 days) while aldicarb sulfone nitrile was relatively stable in all pH levels.

Additional supplementary studies to define the kinetics of hydrolysis and the mechanism for degradation of aldicarb sulfone are published and listed below. The study in Lightfoot is the most extensive and provides data to support equations providing hydrolysis rates as a function of pH and temperature.

2. Lemly, A.T. and W.Z. Zhong (1983) Kinetics of Aqueous Base and Acid hydrolysis of Aldicarb, Aldicarb Sulfoxide and Aldicarb Sulfone. J. Environ. Sci. Health, B18 (2):189-206 (1983). (MRID No. 45602901)

3. Hansen, J.L. and M.H. Spiegel (1983) Hydrolysis Studies of Aldicarb, Aldicarb Sulfoxide and Aldicarb Sulfone. Environmental Toxicology and Chemistry , (2): 147-153 (1983). (MRID No. 45602902)

4. Lemly, A.T. and W.Z. Zhong (1984) Hydrolysis of Aldicarb, Aldicarb Sulfoxide, and Aldicarb Sulfone at Parts per Billion Levels in Aqueous Medium. J. Agr. Food Chem., (32):714-719 (1984). (MRID No. 45602903)

5. Lightfoot, E.N., P.S. Thorne, R.L Jones, J.L. Hansen, and R.R. Romine (1987) Laboratory Studies on the Mechanisms for the Hydrolysis of Aldicarb, Aldicarb Sulfoxide, and Aldicarb Sulfone. Environmental Toxicology and Chemistry, (6):377-394 (1987). (MRID No. 45602904)

161-2. Photodegradation in Water: The agency has requested additional data for aldicarb sulfoxide and aldicarb sulfone. However, aerobic and anaerobic aquatic metabolism studies of aldicarb have shown that oxidation of aldicarb to aldicarb sulfoxide and aldicarb sulfone did not occur in biologically active pond water and sediment systems (studies listed below). Aldicarb sulfoxide and aldicarb sulfone are the major degradation products of aldicarb in soil. Since aldicarb is incorporated in the soil, the majority of the two carbamate residues are located below the soil and thus not exposed to sunlight. The same conclusion applies to any residues reaching ground water. Surface run-off and drainage may result in some carbamate residues reaching open bodies of water. In addition to the dilution, extensive and rapid aerobic and anaerobic degradation takes place, which minimize the exposure to sunlight.

Non-guideline studies (Andrawes and Holsing, 1976a and 1976b) showed that S-methyl ^{14}C-aldicarb sulfoxide and S-methyl ^{14}C-aldicarb sulfone were very stable to photolysis under UV irradiation (>290nm). Only 2% of aldicarb sulfoxide was degraded in 14 days of continuous illumination while aldicarb sulfone was degraded with a half-life of 37.8 and 35.5 days in the nonsensitized and sensitized reactions respectively. The major degradation product of aldicarb sulfone was aldicarb sulfone nitrile. Minor amounts of aldicarb sulfone oxime, aldicarb sulfone aldehyde, aldicarb sulfone amide, and water-soluble components were reported.

1. Andrawes, N. R. and Holsing, C. G. (1976a) Photostability of Aldicarb Sulfoxide. Union Carbide Project Report, File No. 22936, December 13, 1976. (MRID No. 00068246).

2. Andrawes, N. R. and Holsing, C. G. (1976b) Photochemical transformation of UC 21865 Sulfocarb Pesticide. Union Carbide Project Report, File No. 22936, December 13, 1976. (MRID Nos. 00053376, 45592105).

3. Skinner, W. (1995) Aerobic Aquatic Metabolism of(Carbon 14)-Aldicarb: Lab Project Number: 467W-1: 467W:EC-94-274. Unpublished study prepared by PTRL West, Inc. (MRID No. 43805702).

4. Skinner, W. and Jao, N. (1995) Anaerobic Aquatic Metabolism of (Carbon 14)-Aldicarb: Lab Project Number: 468W-1: 468W:EC-94-275. Unpublished study prepared by PTRL West, Inc. MRID No. 43805701

5. Jesudason, P.A. (2001a) Aerobic Aquatic metabolism of [S- Methyl-^{14}C] Aldicarb Under Laboratory Conditions at 25ºC (OPP. §162-4). Aventis Crop Science, Research Triangle Park, NC, Study Number 602YT, December 20, 2001, 127 pages. (MRID No. 45592107)

6. Lui, A.C. (2001) Aerobic Aquatic metabolism of [S- Methyl-^{14}C] Aldicarb Sulfoxide Under Laboratory Conditions at 25ºC (OPP. §162-4). Aventis Crop Science, Research Triangle Park, NC, Study Number 604YT, December 13, 2001, 135 pages. (MRID No. 45592108).

7. Jesudason, P.A. (2001b) Aerobic Aquatic metabolism of [S- Methyl-^{14}C] Aldicarb Sulfone Under Laboratory Conditions at 25ºC (OPP. §162-4). Aventis Crop Science, Research Triangle Park, NC, Study Number 603YT, December 20, 2001, 149 pages. (MRID No. 45592109).

8. Rupprecht, J.K. (2001) Anaerobic Aquatic metabolism of [S- Methyl-^{14}C] Aldicarb Sulfoxide Under Laboratory Conditions at 25ºC (OPP. §162-4). Aventis Crop Science, Research Triangle Park, NC, Study Number 606YT, December 13, 2001, 107 pages. (MRID No. 45592110).

9. Huang, M.N. (2001) Anaerobic Aquatic metabolism of [S- Methyl-^{14}C] Aldicarb Sulfone Under Laboratory Conditions at 25ºC (OPP. §162-4). Aventis Crop Science, Research Triangle Park, NC, Study Number 605YT, December 13, 2001, 109 pages. (MRID No. 45592111).

162-1. Aerobic Soil Metabolism: The agency has requested additional soil metabolism studies for aldicarb sulfoxide and aldicarb sulfone. However, two new studies, one in which parent aldicarb was applied, and one in which aldicarb sulfone was applied have been submitted to EPA.

1. Allan, J. D. (2002a). The Route and Rate of Degradation of [S- Methyl-^{14}C] Aldicarb Under laboratory Aerobic Conditions at 25ºC (OPP. §162-1). Aventis Crop Science, Research Triangle Park, NC, Study Number 601YT, August 15, 2002, 167 pages. (MRID No. 45739801).

2. Allan, J. D. (2002b). The Route and Rate of Degradation of [S- Methyl-^{14}C] Aldicarb Sulfone Under laboratory Aerobic Conditions at 25ºC (OPP. §162-1). Aventis Crop Science, Research Triangle Park, NC, Study Number 607YT, August 15, 2002, 101 pages. (MRID No. 45739802).

The design of these studies was based on communications between Bayer CropScience (at that time Aventis CropScience). In the May 24, 2000 letter from Monica Alvarez of SRRD to Aventis, the Agency pointed to the need of additional data required using applied aldicarb sulfoxide and sulfone. In the June 30, 2000 letter from Gail Powell of Aventis to Monica Alvarez of SRRD, Aventis proposed a study for up to one year using parent aldicarb to initiate the sequential degradation process to aldicarb sulfoxide and sulfone. Aventis proposed a time frame of three months in this new study to observe up to 50% of carbamate compound disappearance. If this does not occur, studies using applied sulfoxide and sulfone are proposed to be initiated. This proposal from Aventis was accepted in the October 4, 2000 memorandum from the Agency. An aerobic soil metabolism study using parent aldicarb (Allan, 2002a) is sufficient to address the disappearance of aldicarb and aldicarb sulfoxide. A separate study using applied aldicarb sulfone was conducted to meet the guideline requirement (Allan, 2002b).

164-1. Terrestrial Field Dissipation: EPA has requested data for parent aldicarb, aldicarb sulfoxide, and aldicarb sulfone.

On pages 17 and 69 of the preliminary risk assessment EPA states that the data requirement for 164-1, Terrestrial Field Dissipation, is not satisfied. Appendix B of the preliminary risk assessment for aldicarb lists the environmental fate data requirements for aldicarb for each of the various guidelines. Guideline 164-1, Terrestrial Field Dissipation (Page B-2), lists thirteen MRID numbers for studies that the Agency reviewed in coming to the above conclusion that this guideline is not satisfied. Five of the documents reviewed were considered supplemental while eight were considered invalid. The 13 studies included in the Agency review were the following:

1. Gunther, F.A.; Carman, G.E.; Baines, R.C.; et al. (1975) Aldicarb (Temik)) Residues in Oranges, Orange Leaves, and Soil after Soil Application in an Orange Grove. Unpublished study received Oct 10, 1975 under 6G1689; prepared in cooperation with Univ. of California--Riverside, Citrus Research Center and Agricultural Experiment Station, Dept. of Entomology and others, submitted by Union Carbide Corp., Washington, D.C.; CDL: 096440-H. (MRID No. 00036313).

2. Romine, R.R.; Meeker, R.L. (1972) Temik Aldicarb Pesticide: Leaching of Aldicarb into Sandy Soil with Irrigation of a Temik Treated Sugar Beet Field: UCC Project Report No. 17079. Unpublished study received Aug 4, 1977 under 1016-79; submitted by Union Carbide Corp., Arlington, Va.; CDL:231503-U. (MRID No. 00068252).

3. Union Carbide Corporation (1965) Residue Data: UC 21149 . Compilation; unpublished study received Jan 25, 1966 under 6G0473; CDL:090525-O. (MRID No. 00080815).

4. Union Carbide Corp. (1973) Residues: Temik 10G and Temik 15G . Unpublished study received Jun 21, 1974 under 1016-78; CDL: 026641-A. (MRID No. 00101910).

5. Union Carbide Corp. (1971) Magnitude of the Residues: Aldicarb . Compilation; unpublished study received May 3, 1972 under 2F1188; CDL:091000-I. (MRID No. 00101923).

6. Kearby, W.; Ercegovich, C.; Bliss, M. (1970) Residue studies on aldicarb in soil and Scotch pine. Journal of Economic Entomology 63(4):1317-1318. Also In unpublished submission received Dec 6, 1977 under 1016-69; submitted by Union Carbide Corp., Arlington, VA; CDL:096671-X. (MRID No. 00102078).

7. Bull, D.L. (1968) Metabolism of UC-21149 (2-Methyl-2-(methythio)propionaldehyde o -(methylcarbamoyl)oxime) in cotton plants and soil in the field. Journal of Economic Entomology 61(6):1598-1602. Also In unpublished submission received Jan 18, 1977 under 1016-Ex-37; submitted by Union Carbide Corp., Arlington, Va.; CDL:228979-D. (MRID No. 00053364).

8. Andrawes, N.; Bagley, W.; Herrett, R. (1968a) Temik Metabolism: Fate of C14-Temik in Cultivated Soil: File No. 9218. Unpublished study received Apr 18, 1969 under 9F0798; submitted by Union Carbide Corp., New York, NY; CDL:091372-K. (MRID No. 00101935).

9. Union Carbide Corp. (1969) Soil: Decline of Aldicarb . (Unpublished study received Aug 20, 1970 under 0F1008; CDL:091748-M). MRID No. 00101968.

10. Woodham, D.; Edwards, R.; Reeves, R.; et al. (1973) Total toxic aldicarb residues in soil, cottonseed, and cotton lint following a soil treatment with the insecticide on the Texas high plains. J. Agr. Food Chem. 21(2):303-307. Also In unpublished submission received Dec 9, 1977 under 1016-69; submitted by Union Carbide Corp., Arlington, VA; CDL:096670-V. (MRID No. 00102061).

11. Andrawes, N.; Bagley, W.; Herrett, R. (1971) Fate and carryover properties of Temik aldicarb pesticide 2-methyl-2-(methylthio)-propionaldehyde O-(methylcarbamoyl)oxime in soil. Agricultural and Food Chemistry 19(4):727-730. Also In unpublished submission received Dec 6, 1977 under 1016-69; submitted by Union Carbide Corp., Arlington, VA; CDL:096671-C. (MRID No. 00102064).

12. Clarkson, V.; Weiden, M. (1968) Temik Insecticide: The Persistence of Temik in an Agricultural Soil As Indicated by Field and Laboratory Bioassay: File No. 10490. Unpublished study received Apr 18, 1969 under 9F0798; Union Carbide Corp., New York, NY; CDL:091372-L. (MRID No. 00101936).

13. Andrawes, N.; Bagley, W.; Herrett, R. (1968b) Temik Metabolism: Degradation and Carry-over Properties of ... (Temik) in Soil: File No. 10494. Unpublished study received Apr 18, 1969 under 9F0798; submitted by Union Carbide Corp., New York, NY; CDL: 091372-M. (MRID No. 00101937).

The Pesticide Assessment Guidelines: Subdivision N, states that the purpose of the field soil dissipation study is ". . . to determine the extent of pesticide residue dissipation under actual field use conditions. . . " by evaluating the ". . . mobility, degradation, and dissipation of the residues." The above reports and publications that are dated between 1965 and 1975 and other studies conducted in the 1980's and 1990's do address the field dissipation of aldicarb and the sulfoxide and sulfone metabolites. The field studies referenced and summarized below (see Table 2, Jones and Estes, 1995) have evaluated the degradation and movement of aldicarb residues in 40 plots in 14 states, involved eight different crops, and have collected and analyzed approximately 19,000 soil samples. The following studies were not reviewed in the preliminary EFED risk assessment:

14. Hornsby, A. G., Rao, P. S. C., and Jones, R. L. (1990) Fate of Aldicarb in the Unsaturated Zone Beneath a Citrus Grove, Water Resour. Res., 26, 2287-2302.

15. Jones, R. L.; Kirkland, S. D.; Chancey, E. L.; Proter, K. S.; Walker, M.; Ferro, D. N. (1991) Measurement of Aldicarb Degradation and Movement in Upstate New York and Massachusetts Potato Fields: Rhône-Poulenc Ag Company, NY State Water Resources Institute and Department of Entomology, University of Massachusetts, August 19, 1991. J. Contam. Hydro., 10: 251-271 (1992). (MRID Nos. 40493302, 40493303).

    This study, conducted on plots in potato fields in Massachusetts and New York, was a cooperative effort of state agencies, universities and the manufacturer. In Massachusetts the soil was a very fine sandy loam while in New York the soil was a loamy fine sand. Aldicarb was applied to the plots at a rate of 2.24 kg/ha

and 3.45 kg/ha in the Massachusetts and New York plots, respectively. Soil samples were taken at each plot just prior to treatment, as well as one, two, four, and six months post-treatment. Post-treatment samples were collected from four subplots within the treated area. At each post-treatment sampling interval, 16 cores were collected down to a depth of 1.8 to 4.8 meters in Massachusetts and to a depth of 1.2 meters to 1.8 meters in New York. Samples were analyzed for residues of aldicarb, aldicarb sulfoxide and aldicarb sulfone as individual analytes. Results from both the Massachusetts and New York potato fields showed that total carbamate residues (aldicarb + aldicarb sulfoxide + aldicarb sulfone) degraded at a rate corresponding to a half-life of about 1.1 months.

16. Hegg, R. O.; Shelley, W. H.; Jones, R. J.; and Romine, R. R. (1988) Movement and Degradation of Aldicarb Residues n South Carolina Loamy Sand Soil, Agriculture, Ecosystems and Environment, 20 (1988) 303-315. (MRID No. 40493318).

    The movement and degradation of aldicarb residues was measured in a loamy sand soil in Barnwell County, South Carolina. Aldicarb was applied at a rate of 3.4 kg/ha (maximum label rate for soybeans) incorporated as a 0.15-meter band over the center of the seed row. Soil samples were collected prior to application as well as 35, 70, and 131 days after treatment. Samples were taken to a depth of 1.8 meters. Analysis of soil samples for residues of aldicarb, aldicarb sulfoxide and aldicarb sulfone as individual analytes indicated a half-life of total carbamate residues (aldicarb + aldicarb sulfoxide + aldicarb sulfone) of approximately 9 days.

17. Jones, R. L. (1987) Central California Studies on the Degradation and Movement of Aldicarb Residues., J. Contam. Hydrol., 1: 287-298.). (MRID No. 40493308).

    Studies were conducted to measure the degradation and movement of aldicarb residues (aldicarb, aldicarb sulfoxide and aldicarb sulfone) in soil at three central California locations. The test sites, which consisted of a tomato field near Manteca and vineyards near Livingston and Fresno are representative of conditions in central California under which aldicarb residues would be most likely to reach drinking water. Results indicate that total carbamate residues (aldicarb + aldicarb sulfoxide + aldicarb sulfone) degrade in soil with a half-life of 1.5-2.0 months.

18. Jones, R. L. (1991) Measurement of Aldicarb Degradation and Movement for Winter Applications to Grapes: Rhône-Poulenc Ag Company, May 8, 1991. (MRID No. 40493304).

    This study, which measured the degradation and movement of aldicarb residues following winter application to grapes, was conducted in flood-irrigated vineyards at two sites in California. One site contained fine sandy loam while the other site contained a loamy sand. Aldicarb was applied to each site at a rate of 4.48 kg/ha. Soil samples were taken at one, two, four and six months following application. At one site additional samples were taken at eight months following application. Soil samples were analyzed for individual carbamate residues (aldicarb, aldicarb sulfoxide and aldicarb sulfone). The results indicated the degradation rate of total carbamate residues (aldicarb + aldicarb sulfoxide + aldicarb sulfone) resulting from winter applications (3.5 months) was significantly longer than previously measured with spring applications (1.5-2.0 months). It should be noted that this is not a typical application scenario since aldicarb is not registered for winter application.

19. Norris, F. A. (1991) A Terrestrial Soil Dissipation Study with Aldicarb the Active Ingredient of Temik® Brand Insecticide, Applied to Cotton at Two Field Sites in California: Rhône-Poulenc Ag Company, July 24, 1991.

    The degradation and movement of aldicarb residues was measured following application of aldicarb to cotton in California. The soils in the two sites were a low organic loam soil and a sandy clay loam soil. The aldicarb was applied at a rate of 1.18 kg ai/ha in furrow at planting followed two months later by a sidedress application at a rate of 2.35 kg ai/ha. Analysis of soil samples for aldicarb, aldicarb sulfoxide and aldicarb sulfone (individually) showed that total carbamate residues had a half-life of 1.5 to 2.0 months.

20. Jones, R. L.; Hornsby, A. G.; and Rao, P. S. C.; Degradation and Movement of Aldicarb in Florida Citrus Soils, Pestic. Sci., 1988. 23, 307-325. (MRID No. 40493322).

    The movement and degradation of aldicarb residues was monitored in two Florida citrus groves. Soil core samples were collected at 0.3 or 0.6 meter depth increments six times over an eight month period and were analyzed for aldicarb, aldicarb sulfoxide and aldicarb sulfone as individual analytes. These analyses showed a relatively rapid degradation of aldicarb followed by an increase in aldicarb sulfoxide and aldicarb sulfone. The levels of the carbamate metabolites peaked after about 50 days and began to decline. The dissipation rate of aldicarb carbamate residues in surface soils corresponded to a half-life of 10 to 20 days at both field sites. The half-life in subsoils appeared to be greater than 60 days.

21. Wyman, J. A.; Jones, R. L.; Medina, J.; Curwen, D.; and Hansen, J. L. Environmental Fate Studies of Aldicarb and Aldoxycarb Applications to Wisconsin Potatoes, Journal of Contaminant Hydrology, 2 (1987) 61-72. (MRID No. 40493314).

    Aldicarb and aldoxycarb (aldicarb sulfone) were applied to potato fields in Central Wisconsin to study the degradation and movement of their carbamate residues within the soil profiles. Aldicarb was applied at planting at a rate of 3.36 kg/ha and at emergence at a rate of 2.24 kg/ha. Aldoxycarb (aldicarb sulfone) was applied at planting at a rate of 3.36 kg/ha. Soil samples were analyzed for total carbamate residues (aldicarb, aldicarb sulfoxide and aldicarb sulfone). Total carbamate residues following application of aldicarb and aldoxycarb residues degraded at similar rates with half-lives ranging from 0.9 to 1.3 months.

22. Wyman, J. A.; Jensen, J. O.; Curwen, D.; Jones, R. L. and Marquardt, T. E. (1985) Effects of Application Procedures and Irrigation on Degradation and Movement of Aldicarb Residues in Soil. Environ. Toxicol. Chem., 4: 641-651.

    This was an earlier study to Wyman, et.al., above where aldicarb was applied to potato fields in Wisconsin at the same rate as above. Sample analysis gave a half-life for total carbamate residues of 1.2 to 2.0 months, similar to the above results.

23. Jones, R. L., Hansen, J. L., Romine, R. R., and Marquardt, T. E. (1986) Unsaturated Zone Studies on Degradation and Movement of Aldicarb and Aldoxycarb Residues. Environ. Toxicol. Chem., 5: 361-372

    Studies were reported in which aldicarb was applied to cotton in Arizona (at planting and emergence), corn in Michigan and Indiana, tobacco in North Carolina and Virginia, and potatoes in Washington. Results of aldoxycarb (aldicarb sulfone) applications to tomatoes in Florida, cotton in Arizona and tobacco in North Carolina and Virginia were also reported. These studies showed the half-life of total carbamate residues (aldicarb, aldicarb sulfoxide and aldicarb sulfone) following application of aldicarb to be from 0.7 to 2.1 months. The half-life of total carbamate residues following application of aldoxycarb (aldicarb sulfone) was found to be from 0.6 to 1.3 months.

24. Jones, R. L., Rourke, R. V. and Hansen, J. L. (1986) Effects of Application Methods on Movement and Degradation of Aldicarb Residues in Maine Potato Fields. Environ. Toxicol. Chem., 5: 167-173

    The effects of application methods on the movement and degradation of aldicarb was studied in a Maine potato field by comparing movement and degradation of aldicarb applied in furrow at planting with aldicarb applied as a top dress at emergence. Movement was greater from the at-planting application with residues found in the top 0.6 meters of soil while the top-dress application at emergence showed residues down to 0.3 meters. The half-life of total carbamate residues in these cooler Maine soils was approximately 3 to 3.5 months.

As indicated in Jones and Estes (1995), the movement and degradation of aldicarb residues in soil is a complex process affected by soil properties, hydrogeological properties, climate conditions and agricultural practices. The environmental fate database for aldicarb is substantial, including field research, monitoring studies, laboratory experiments, potable well analyses and modeling simulations. The field dissipation studies, which were conducted in numerous locations (Arizona, California, Florida, Maine, Massachusetts, New York, North Carolina, South Carolina, Virginia, Washington, Wisconsin, etc.) representing varying climates, crops and soil conditions, show that total aldicarb carbamate residues (aldicarb, aldicarb sulfoxide and aldicarb sulfone) degrade in soil with a half-life of approximately one month (range of 0.5 to 3.5 months). This degradation rate is sufficient to prevent aldicarb residue movement to the water table under most use conditions. In the relatively few areas where aldicarb residues reach ground water, the primarily lateral movement of the ground water and continuing degradation usually limit the presence of aldicarb residues to shallow ground water near treated fields.

The above referenced studies conducted from 1983 to 1990 do, in fact, ". . . determine the extent of pesticide residue dissipation under actual field use conditions . . ." by evaluating the ". . . mobility, degradation, and dissipation of the residues . . ." and therefore, satisfy the requirements for the field soil dissipation study. This position is supported by the OPP Chemical Review Management System Guideline Status Report for Aldicarb (Run Date: 7/20/01), which lists the Guideline Status for Guideline 164-1, Terrestrial Field Soil Dissipation, as "Acceptable/Satisfied. Risk assessments for aldicarb residues are based upon dissipation of total carbamate residues (aldicarb, aldicarb sulfoxide and aldicarb sulfone) and, therefore, do not actually require individual analysis for the three carbamates. However, as indicated above, many of the studies do analyze separately for aldicarb, aldicarb sulfoxide and aldicarb sulfone. Therefore, these studies evaluate the dissipation of not only aldicarb, but the sulfoxide and sulfone metabolites as well. In addition, studies were conducted where aldoxycarb (aldicarb sulfone) was applied in the field and the degradation and movement of aldoxycarb measured with time.

These soil dissipation studies are supported by numerous other soil dissipation studies as well as ground water monitoring studies and modeling simulations. Data from all of these studies allow a good assessment of the mobility, degradation, and dissipation of aldicarb residues in the environment. Therefore, there is no need to conduct any additional aldicarb field soil dissipation studies.

II. SURFACE WATER CONCENTRATIONS FROM FIELD MONITORING

On Page 26, Paragraph 1, the preliminary EFED risk assessment states that aldicarb may occasionally pose a contamination hazard in low-order streams in high use areas. The monitoring data cited by the EPA in this and other sections in the preliminary risk assessment, other monitoring results cited by the registrant in this response, and the general experience of the registrant indicates that the only agricultural setting where residues can be present in significant concentrations outside treated fields in more than an infrequent occurrence is in bedded citrus grown on flatwoods soils in southern Florida, where irrigation/drainage ditches run between the rows of trees. In addition to samples collected from surface water bodies, samples of irrigation runoff water have also been sampled. For examples in California, state officials (D. A. Gonzalez and D. J. Weaver, Monitoring Concentrations of Aldicarb and its Breakdown Products in Irrigation Water Runoff and Soil from Agricultural Fields in Kern County, 1985, Environmental Hazards Assessment Program, State of California Department of Food and Agriculture, Environmental Monitoring and Pest Management, March 1986) collected 11 water samples from eight fields including water standing in furrows between the crop rows, water flowing in a drainage ditch, and water from a sump pit. Aldicarb carbamate residues were not found in any sample. This is similar to the experience of the registrant in a 1984 study near Livingston, California (Merced County), in which the irrigation water was sampled as it moved past an aldicarb treated section in a vineyard (data on file). No aldicarb residues were detected. Summaries of the aldicarb analyses from NAWQA program and the California Surface Water Monitoring Database are also included later in this discussion section.

All of the factors (other than the rainfall events on the day of application) contributing to the transient aldicarb carbamate residues of several hundred ppb in the ditch with intermittent flow upstream of the Beaver Creek sampling station 07030249 in 1991 and 1993 are not known to the registrant. Much less was found at another nearby sampling station 07030241 in which samples were collected at the same time during 1991 (analyses of samples from this site were not reported during the relevant time in 1993) but which drained a smaller watershed also composed principally of silt loam soils. An explanation of why the differences between the two sites would be quite helpful. Possible explanations include differences in incorporation, site characteristics, or even cleanup practices. It is known that the ditch is recorded on maps as "intermittent" and physical examination revealed that cotton is planted (and may have been treated) to the edge of the ditch, making it a part of the treated field and therefore, any residues should be considered in-field in nature. The ditch does not contain sufficient water to support a resident fish population.

The lack of significant findings of aldicarb carbamate residues in surface water outside of Florida bedded citrus helps demonstrate the losses in the ditch upstream of the Beaver Creek sampling station 07030249 are rare. As EPA points out, losses of this magnitude might result in concentrations of around 10 ppb in small reservoirs. If this were so, even higher concentrations would be found in small creeks and streams downstream of surface water bodies the size of intermittent creek that was sampled in the Beaver Creek watershed. If such losses occurred uniformly in a moderate size watershed, or even somewhat frequently over a larger area, certainly more instances of aldicarb carbamate residues would have been present in the NAWQA, California, and other smaller monitoring programs. The infrequent detection of residues in these programs and the total absence of residues at the levels expected based on the Beaver Creek data indicate that these specific data taken from an intermittent ditch located within (adjacent to) a cotton field should not be the sole basis of a higher tier aquatic exposure assessment. The weight of evidence indicates that exposure of aldicarb to aquatic organisms in surface water is extremely low and is achieved by the successful mitigation measures utilized during the application of the product.

Summary of Surface Water Data from the NAWQA Program

On Page 26, Paragraph 1, the preliminary EFED risk assessment summarized available surface water monitoring data from the NAWQA program as having only a few detections (0.1 percent of all sites) with a maximum concentration of 1.6 ppb. Table 1, Summary of Surface Water Data from the NAWQA Program, summarizes the aldicarb analyses available from this program. The source is the USGS database, which was downloaded by state from their web site during the fourth quarter of 2000.

Of the 5530 samples analyzed, aldicarb residues were detected in 12 samples (0.2 %). However, the analyses of 11 of these samples were suspect for several reasons (only one carbamate compound present or little or no aldicarb use in the county). The concentration of total aldicarb carbamate residues in the one sample (0.02 % of all samples) that is not suspect is 1.68 ppb. Table 2 provides information on surface water samples with detectable residues:

The small number of detections of aldicarb residues in the surface water samples from the NAWQA program supports EPA's conclusion that aldicarb residues have not been widely detected in surface waters.

Summary of Surface Water Data from the California Surface Water Monitoring Database

On Page 26, Paragraph 1, the preliminary EFED risk assessment summarized surface water monitoring data from various sources. One source not included in this discussion is the California Surface Water Monitoring Database. The number of analyses and the detections of aldicarb carbamate residues are summarized in the Table 3:

The California Surface Water Monitoring Database shows three samples with detectable aldicarb residues, all in Stanislaus County in 1991 to 1992. A sample taken on July 2, 1991 at the San Joaquin River Hills Ferry sampling station in Stanislaus county showed detectable concentrations of aldicarb (0.12 ppb) and aldicarb sulfoxide (0.28 ppb). Follow-up sampling at the same site was conducted with a high frequency of sampling (4 more samplings in July and 8 samplings in August). All the samples showed no detectable concentrations of aldicarb or its metabolites except for the sample collected on August 27, 1991 that showed 0.05 ppb of aldicarb sulfone, but no detectable aldicarb or aldicarb sulfoxide. Sampling on February 18, 1992 at the Turlock Irrigation District Drain #5 sampling site in Stanislaus county showed detectable concentrations of aldicarb sulfone (0.26 ppb), but aldicarb and aldicarb sulfoxide were not detectable in that sample. The absence of aldicarb sulfoxide in this sample makes this analysis suspect.

Table 1. Summary of Surface Water Data from the NAWQA Program.

State	Number of Analyses for the Indicated Compound				Number of Samples with Detectable Aldicarb Residues
	Total[a]	Aldicarb	Aldicarb Sulfoxide	Aldicarb Sulfone	
Alabama	8	8	8	8	0
Arizona	77	77	77	76	0
Arkansas	39	39	38	38	0
California	244	244	244	244	1
Colorado	232	232	232	232	2
Connecticut	107	107	107	107	0
Florida	232	232	231	231	0
Georgia	629	629	626	626	2
Idaho	103	103	103	103	0
Illinois	217	217	217	217	0
Indiana	362	362	358	358	0
Iowa	94	94	94	94	0
Louisiana	43	43	43	43	2
Manitoba, Canada	22	22	22	22	0
Maryland	39	39	39	39	0
Massachusetts	13	13	13	13	0
Michigan	30	30	30	30	0
Minnesota	261	261	260	260	0
Mississippi	111	111	110	110	0
Missouri	109	109	109	109	0
Nebraska	53	53	53	53	0
Nevada	117	117	117	117	1
New Hampshire	10	10	10	10	0
New Jersey	121	121	121	121	1
New Mexico	66	66	66	66	0
New York	113	113	113	113	0
North Carolina	112	112	112	112	1
North Dakota	93	93	91	92	1
Ohio	79	79	79	79	0
Oklahoma	3	3	3	3	0
Oregon	139	139	139	139	0
Pennsylvania	178	178	178	178	0
South Carolina	83	83	82	82	1
Tennessee	175	175	175	173	0
Texas	478	478	478	478	0
Vermont	9	9	9	9	0
Virginia	198	198	198	198	0
Washington	345	345	345	345	0
West Virginia	32	32	32	32	0
Wisconsin	150	150	150	150	0
Wyoming	4	4	4	4	0
Total	5530	5530	5516	5514	12

[a] Number of samples which included an analysis for aldicarb, aldicarb sulfoxide, or aldicarb sulfone.

Table 2. Information on Surface Water Samples with Detectable Residues.

State	County	Land Use	Sample Location	Sample Date and Time	Concentration (ppb)			Comments
					Aldicarb	Aldicarb Sulfoxide	Aldicarb Sulfone	
California	Merced	Mixed	Merced R A River Road Bridge nr Newman, CA	Apr 14, 1993 11:30 am	0.46*	<0.021	<0.016	Analysis suspect due to the absence of aldicarb sulfoxide. Aldicarb carbamate residues were not found in samples collected the previous and following weeks.
Colorado	Weld	Mixed	South Platte River nr Kersey, CO	July 28, 1994 12:10 pm	0.08	<0.021	<0.016	Analysis suspect due to the absence of aldicarb sulfoxide, especially given the timing of this sample relative to application. Aldicarb carbamate residues were not found in samples taken 2 weeks previously or 2 weeks afterwards.
Colorado	Weld	Agriculture	Lonetree Creek nr Greeley, CO	Aug 10, 1994 10:05 am	<0.016	0.98	<0.016	Analysis suspect due to the absence of aldicarb sulfone, especially given the timing of this sample. Aldicarb residues not found in samples taken 2 weeks previously or 3 weeks afterwards.
Georgia	Sumter	Agriculture	Lime Creek (County Road) nr Cobb, GA	Apr 13, 1994 9:30 am	<0.016	0.92	<0.016	Analysis suspect due to the absence of either parent aldicarb or aldicarb sulfone. Aldicarb carbamate residues were not found in samples taken 2 days previously or 3 hours afterwards.
Georgia	Pulaski	Agriculture	Tucsawhatchee C (GA HWY 27) nr Hawkinsville, GA	June 2, 1993 8:40 am	<0.016	0.29*	<0.016	Analysis suspect due to the absence of aldicarb sulfone. Aldicarb carbamate residues were not found in samples collected the previous and following weeks.
Louisiana	Madison	Agriculture	Tensas R at Tendal, LA	May 22, 1997 11:15 am	<0.016	1.91*	<0.016	Analysis suspect due to the absence of aldicarb sulfone. Although aldicarb residues were detected in samples on May 22 and May 28, aldicarb residues were not detected in samples collected on May 5 or June 11.
Louisiana	Madison	Agriculture	Tensas R at Tendal, LA	May 28, 1997 9:15 am	<0.016	0.5	<0.016	Analysis suspect due to the absence of aldicarb sulfone. Although aldicarb carbamate residues were detected in samples on May 22 and May 28, aldicarb carbamate residues were not detected in samples collected on May 5 or June 11.
Nevada	Washoe	Mixed	Steamboat C at Cleanwater Way nr Reno, NV	July 14, 1994 9:15 AM	<0.016	<0.021	0.07	Analysis suspect due to the absence of aldicarb sulfoxide and the absence of TEMIK® use in this area. Aldicarb carbamate residues were not found in samples taken a month previously or 3 hours afterwards.
New Jersey	Somerset	Urban	Bound Brook at Middlesex, NJ	July 7, 1997 10:00 am	0.13	<0.021	<0.016	Analysis suspect due to the absence of aldicarb sulfoxide and the absence of TEMIK® use in this area. Aldicarb carbamate residues were not detected in samples taken 2 weeks previously or 2 weeks afterwards.
North Carolina	Beaufort	Agriculture	Albemarle Canal nr Swindell, NC	Apr 27, 1993 12:15 pm	0.34	<0.021	<0.016	Analysis suspect due to the absence of aldicarb sulfoxide. Aldicarb carbamate residues were not found in samples collected the previous and following weeks.
North Dakota	Grand Forks	Agriculture	Turtle R at Turtle R State Park nr Arvilla, ND	Apr 15, 1993 10:20 am	0.51*	<0.021	<0.016	Analysis suspect due to the absence of aldicarb sulfoxide. Also the use of TEMIK® is currently quite limited in this area. Aldicarb carbamate residues were not detected in samples taken 2 weeks previously or 2 weeks afterwards.
South Carolina	Orangeburg	Agriculture	Cow Castle Creek nr Bowman, SC	May 29 1996 9:30 am	0.48	1.2	<0.016	Aldicarb carbamate residues were not found in samples collected the previous and following weeks.

*Estimated concentration due to concentrations below the limit of quantification or the presence of interfering peaks

Table 3. Summary of Surface Water Data from the California Surface Water Monitoring Database

County	Aldicarb			Aldicarb Sulfoxide			Aldicarb Sulfone			
	Total No. of Samples	Samples with Residues*	Sample Dates	Total No. of Samples	Samples with Residues*	Sample Dates	Total No. of Samples	Samples with Residues*	Date From	Date To
Colusa	3	0	2/10/92 to 2/24/92	0	0	-	0	0	-	
Contra Costa	1	0	2/10/92	0	0	-	0	0	-	
Imperial	113	0	3/15/93 to 2/14/94	65	0	3/15/93 to 1/24/94	65	0	3/15/93 to 1/24/94	
Merced	165	0	4/26/91 to 6/12/95	194	0	4/26/91 to 6/12/95	194	0	4/26/91 to 6/12/95	
Monterey	65	0	8/1/94 to 8/1/95	65	0	8/1/94 to 8/1/95	65	0	8/1/94 to 8/1/95	
Sacramento	63	0	1/20/96 to 8/13/98	53	0	11/26/96 to 8/13/98	53	0	11/26/96 to 8/13/98	
San Joaquin	44	0	4/18/91 to 2/10/93	24	0	4/18/91 to 2/10/93	24	0	4/18/91 to 2/10/93	
Solano	3	0	2/10/92 to 3/23/92	0	0	-	0	0	-	
Sonoma	51	0	8/16/94 to 8/8/95	51	0	8/16/94 to 8/8/95	51	0	8/16/94 to 8/8/95	
Stanislaus	409	1 (0.12)	2/25/91 to 10/24/98	438	1 (0.28)	2/25/91 to 12/29/93	438	2 (0.26)	2/25/91 to 12/29/93	
Sutter	58	0	1/27/92 to 11/7/94	52	0	11/15/93 to 11/7/94	52	0	11/15/93 to 11/7/94	
Yolo	22	0	11/7/96 to 4/15/98	22	0	11/7/96 to 4/15/98	22	0	11/7/96 to 4/15/98	

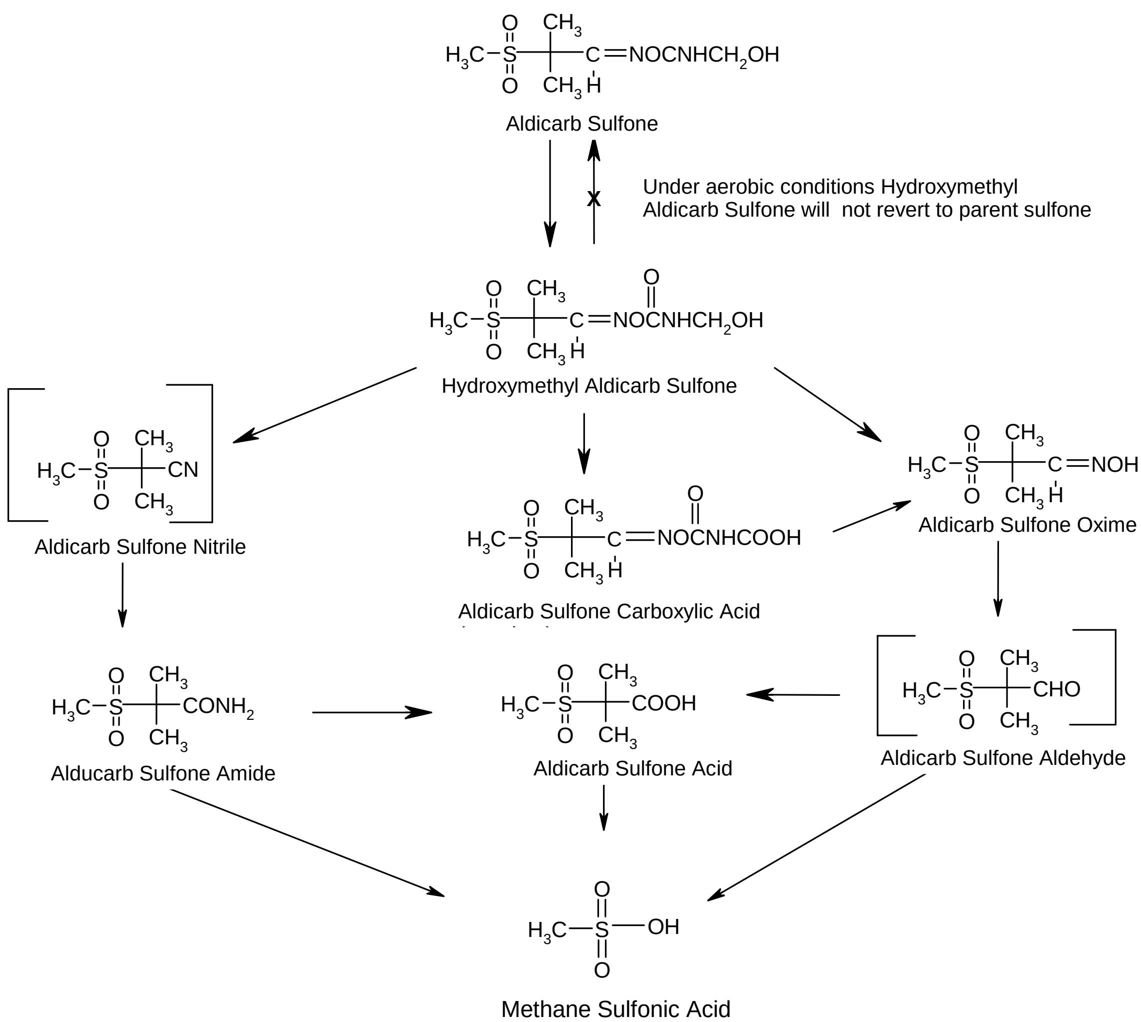
*Maximum concentration in ppb is given in parenthesis.

III. POTENTIAL FOR HYDROXYMETHYL ALDICARB SULFONE TO REVERT TO ALDICARB SULFONE

The hydroxymethyl aldicarb sulfone (metabolite formed) in the aerobic aquatic metabolism of aldicarb sulfone will not revert to the parent sulfone under aerobic conditions. The registrant agrees with the reviewer's comment on DER Report (Aerobic Biotransformation of Aldicarb Sulfone in Water Sediment System, EPA MRID No. 45592109) pages 3 and 17, that hydroxymethyl sulfone will undergo oxidation to corresponding carboxylic acid. These types of amino carboxylic acids are extremely unstable and will eliminate carbon dioxide instantaneously and upon hydrolysis yield sulfone oxime. In addition, as stated in the DER report hydroxymethyl aldicarb sulfone will undergo hydrolysis to form sulfone oxime, or elimination to form aldicarb sulfone nitrile. The nitrile upon hydrolysis will yield sulfone amide and further to aldicarb sulfone acid. Similarly aldicarb sulfone oxime will undergo hydrolytic/oxidative pathway to yield aldicarb sulfone acid. Aldicarb sulfone acid and aldicarb sulfone amide upon hydrolysis yield methane sulfonic acid which will be the ultimate transformation product.

Therefore under aerobic conditions the hydroxymethyl aldicarb sulfone will transform into a methane sulfonic acid and it will not revert to the parent aldicarb sulfone. The proposed transformation of hydroxymethyl aldicarb sulfone to methane sulfonic acid is depicted in Figure 1.

Figure 1. Proposed Metabolic Pathway of Aldicarb Sulfone Under Aerobic Aquatic Conditions



[ ] Proposed Intermediate not found in the study

IV. COMPARISON OF ALDICARB TO CARBOFURAN

Both aldicarb and carbofuran are highly toxic carbamate insecticides formulated as granules. Numerous bird kill incidents have been reported for granular carbofuran, but not for aldicarb. Bayer believes the reason for this difference has very little to do with the inherent toxicity of these two active ingredients to birds (they are both highly toxic) or the number of LD_{50s}/ft^2 that result when these products are applied. Instead, the reason granular aldicarb poses a low risk is because the TEMIK® granule is inherently unattractive to birds as either food or grit, and it doesn't stay intact long in the environment since it dissolves upon contact with moist soil or rain water. Granular carbofuran, on the other hand, posed a high risk because it was formulated on a sand carrier that was very attractive to birds as grit, and did not physically break down in the environment. So long as rainwater didn't wash the active ingredient off of the granule, carbofuran granules could remain intact for months and bird kills sometimes occurred a month or more post application.

The above synthesis is not mere speculation, but reflects the results of a decade of collaborative work between Bayer CropScience and Iowa State University. Significant research publications that should be considered by the Agency in assessing risk of TEMIK® and other granular pesticides to birds are listed in the following table along with the major findings of each paper.

Publication	Relevance to Aldicarb Risk Assessment
Best, L. B. and J. P. Gionfriddo. 1991. Characterization of grit use by cornfield birds. *Wilson Bull* 103:68-82.	Quantified number, size, shape and composition of natural grit particles consumed by birds associated with cropland where granular insecticides are applied. Allows comparison between characteristics of natural grit and the number of particles consumed with characteristics of granular insecticides.
Best, L. B. and J. P. Gionfriddo. 1994. House sparrow preferential consumption of carriers used for pesticide granules. *Environ Toxicol & Chem* 13:919-925.	Showed that birds do not select grit randomly, but have strong preferences for sand particles in comparison to most materials used to formulate pesticide granules. The carrier type LEAST likely to be selected as grit was gypsum granules that are used to formulate TEMIK®. The degree of preference for sand particles in comparison to TEMIK® carrier was extremely strong, 1000 to 1. This finding suggests that birds are very unlikely to select TEMIK® granules as grit.
Best, L. B. and J. P. Gionfriddo. 1991. Integrity of five granular insecticide carriers in house sparrow gizzards. *Environ Toxicol & Chem* 10:1487-1492.	Gypsum granules (the carrier used in TEMIK®) were shown to break down quick in the GI-tract of birds. These granules would therefore be useless to birds as grit.
J. P. Gionfriddo and L. B. Best. 1992. Grit color selection by house sparrows and northern bobwhites. *J. Wildl. Manage.* 60:836-842.	Both species showed a preference for grit particles that were colored yellow, white or green, and an avoidance of blue and black particles. To make granules least attractive to birds, they should be colored blue or black. The color of the TEMIK® carrier is black, one of the least attractive colors.

Best, L. B., T. R. Stafford and E. M. Mihaich. 1996. House sparrow preferential consumption of pesticide granules with different surface coatings. *Environ Toxicol & Chem* 15:1763-1768.	Birds avoid gypsum granules with graphite coating (as found in TEMIK® formulations), more readily accept uncoated gypsum granules.
Best, L.B. and D.L. Fischer. 1992. Granular insecticides and birds: factors to be considered in understanding exposure and reducing risk. *Environ Toxicol & Chem* 11:1495-1508	Many factors may influence avian risk besides quantity of pesticide per unit area in the bird's environment.
Fischer, D.L. and L.B.Best. 1995. Avian consumption of blank pesticide granules applied at planting to Iowa cornfields. *Environ Toxicol & Chem* 14:1543-1549.	Large numbers of birds ingest a few granules per day and a few birds ingest up to 20 granules per day. A probabilistic basis for estimating granule consumption rates is presented.
Stafford, T. R., L.B. Best and D.L. Fischer. 1996. Effects if different formulations of granular pesticides on birds. *Environ Toxicol & Chem* 1606-1611.	Granules with higher pesticide loads pose more risk than granules with lower pesticide loads. Silica and clay granules pose more risk than corn cob granules. Granule size and color were less important factors.
Stafford, T. R. and L. B. Best. 1997. Effects of granular pesticide formulations and soil moisture on avian exposure. *Environ Toxicol Chem* 16:1687-1693.	Pesticide exposure was higher in penned sparrows when granules were presented on wet soil, probably due to greater dermal absorption.
Stafford, T.R and L. B. Best. 1998. Effects of application rate on avian risk from granular pesticides. *Environ Toxicol & Chem* 526-529.	Mortality was relatively low (10-20%) and increased only slightly as exposure conditions ranged from 50 to 2000 LD_{50s}/ft^2. The relationship between avian risk and granule availability was asymptotic, not linear.

V. REFERENCES

Allan, J. D. (2002a). The Route and Rate of Degradation of [S- Methyl-^{14}C] Aldicarb Under laboratory Aerobic Conditions at 25ºC (OPP. §162-1). Aventis Crop Science, Research Triangle Park, NC, Study Number 601YT, August 15, 2002, 167 pages. (MRID No. 45739801).

Allan, J. D. (2002b). The Route and Rate of Degradation of [S- Methyl-^{14}C] Aldicarb Sulfone Under laboratory Aerobic Conditions at 25ºC (OPP. §162-1). Aventis Crop Science, Research Triangle Park, NC, Study Number 607YT, August 15, 2002, 101 pages. (MRID No. 45739802).

Andrawes, N. R. (1976). Hydrolysis of UC-21865 Sulfocarb Pesticide in Aqueous Buffer Solutions. Union Carbide Corp. Project Report, File No. 22928. December 9, 1976. (MRID Nos. 00053377, 45592104).

Andrawes, N.; Bagley, W.; Herrett, R. (1968a) Temik Metabolism: Fate of C14-Temik in Cultivated Soil: File No. 9218. Unpublished study received Apr 18, 1969 under 9F0798; submitted by Union Carbide Corp., New York, NY; CDL:091372-K. (MRID No. 00101935).

Andrawes, N.; Bagley, W.; Herrett, R. (1968b) Temik Metabolism: Degradation and Carry-over Properties of ... (Temik) in Soil: File No. 10494. Unpublished study received Apr 18, 1969 under 9F0798; submitted by Union Carbide Corp., New York, NY; CDL: 091372-M. (MRID No. 00101937).

Andrawes, N.; Bagley, W.; Herrett, R. (1971) Fate and Carryover Properties of Temik Aldicarb Pesticide 2-methyl-2-(methylthio)-propionaldehyde O-(methylcarbamoyl)oxime in Soil. Agricultural and Food Chemistry 19(4):727-730. Also In unpublished submission received Dec 6, 1977 under 1016-69; submitted by Union Carbide Corp., Arlington, VA; CDL:096671-C. (MRID No. 00102064).

Andrawes, N. R. and Holsing, C. G. (1976a) Photostability of Aldicarb Sulfoxide. Union Carbide Project Report, File No. 22936, December 13, 1976. (MRID No. 00068246).

Andrawes, N. R. and Holsing, C. G. (1976b) Photochemical Transformation of UC 21865 Sulfocarb Pesticide. Union Carbide Project Report, File No. 22936, December 13, 1976. (MRID Nos. 00053376, 45592105).

Aventis CropScience. 2001. Aldicarb, PC Code No. 098310. Review of the Reregistration Eligibility Decision Draft Chapter on Environmental Fate and Ecological Effects. Aventis CropScience. August 31, 2001. 94 pages. (MRID No. 45529101).

Balcomb, R., R. Stevens and C. Bowen II. 1984. Toxicity of 16 Granular Insecticides to Wild-Caught Songbirds. Bull. Environ Contam Toxicol 33:302-307.

Beavers, J. and R. Fink. (1979). Acute Oral LD_{50} – Mallard Duck: Technical Grade Aldicarb. Project No. 142-119. (MRID No. 00107398).

Best, L. B. and J. P. Gionfriddo. 1991. Characterization of Grit Use by Cornfield Birds. Wilson Bull 103:68-82.

Best, L. B. and J. P. Gionfriddo. 1994. House Sparrow Preferential Consumption of Carriers Used for Pesticide Granules. Environ Toxicol & Chem 13:919-925.

Best, L. B. and J. P. Gionfriddo. 1991. Integrity of Five Granular Insecticide Carriers in House Sparrow Gizzards. Environ Toxicol & Chem 10:1487-1492.

Best, L. B., T. R. Stafford and E. M. Mihaich. 1996. House Sparrow Preferential Consumption of Pesticide Granules with Different Surface Coatings. Environ Toxicol & Chem 15:1763-1768.

Best, L.B. and D.L. Fischer. 1992. Granular Insecticides and Birds: Factors to be Considered in Understanding Exposure and Reducing Risk. Environ Toxicol & Chem 11:1495-1508.

Bull, D.L. (1968) Metabolism of UC-21149 (2-Methyl-2-(methythio)propionaldehyde o -(methylcarbamoyl)oxime) in cotton plants and soil in the field. Journal of Economic Entomology 61(6):1598-1602. Also In unpublished submission received Jan 18, 1977 under 1016-Ex-37; submitted by Union Carbide Corp., Arlington, Va.; CDL:228979-D. (MRID No. 00053364).

Clarkson, V.; Weiden, M. (1968) Temik Insecticide: The Persistence of Temik in an Agricultural Soil As Indicated by Field and Laboratory Bioassay: File No. 10490. Unpublished study received Apr 18, 1969 under 9F0798; submitted by Union Carbide Corp., New York, NY; CDL:091372-L. (MRID No. 00101936).

Fischer, D.L. and L.B.Best. 1995. Avian Consumption of Blank Pesticide Granules Applied at Planting to Iowa Cornfields. Environ Toxicol & Chem 14:1543-1549.

Gionfriddo, J. P. and L. B. Best. 1992. Grit Color Selection by House Sparrows and Northern Bobwhites. J. Wildl. Manage. 60:836-842.

Gonzalez, D. A.; D. J. Weaver (1986) Monitoring Concentrations of Aldicarb and its Breakdown Products in Irrigation Water Runoff and Soil from Agricultural Fields in Kern County, 1985, Environmental Hazards Assessment Program, State of California Department of Food and Agriculture, Environmental Monitoring and Pest Management, March 1986.

Gunther, F.A.; Carman, G.E.; Baines, R.C.; et al. (1975) Aldicarb (Temik)) Residues in Oranges, Orange Leaves, and Soil after Soil Application in an Orange Grove. (Unpublished study received Oct 10, 1975 under 6G1689; prepared in cooperation with Univ. of California--Riverside, Citrus Research Center and Agricultural Experiment Station, Dept. of Entomology and others, submitted by Union Carbide Corp., Washington, D.C.; CDL: 096440-H) (MRID No. 00036313).

Hall, L. S. (2003) Temik® 15G Brand Aldicarb Product Usage and Methods of Application. Bayer CropScience. Unpublished Report. August 15, 2003. 23 pages.

Handley, J.W., I.G. Sewell and A.J. Bartlett (1991). An assessment of the effect of aldicarb on the reproduction of *Daphnia magna*. Safepharm Project No. 282/112. October 14, 1991. (MRID No. 45592112).

Hansen, J.L. and M.H. Spiegel (1983) Hydrolysis Studies of Aldicarb, Aldicarb Sulfoxide and Aldicarb Sulfone. Environmental Toxicology and Chemistry , (2): 147-153 (1983). (MRID No. 45602902).

Hawkes, A.W., L.W. Brewer, J.F. Hobson, M.J. Hooper and R.J. Kendall. 1996. Survival and Cover-Seeking Response of Northern Bobwhites and Mourning Doves Dosed with Aldicarb. Environ Toxicol Chem 15:1538-1543.

Hegg, R. O.; Shelley, W. H.; Jones, R. J.; and Romine, R. R.; Movement and Degradation of Aldicarb Residues in a South Carolina Loamy Sand Soil, Agriculture, Ecosystems and Environment, 20 (1988) 303-315. (MRID No. 40493318).

Holmsen, J.D. (2000) Response to EPA Aldicarb Data Evaluation Record 2, Anaerobic Aquatic Metabolism of [14C]aldicarb (Agency/EFED Review dated May 18, 2000) Aventis Document No: B002980, 21 pp. (MRID No. 45178002).

Hornsby, A. G., Rao, P. S. C., and Jones, R. L. (1990) Fate of Aldicarb in the Unsaturated Zone Beneath a Citrus Grove, Water Resour. Res., 26, 2287-2302.

Huang, M.N. (2001) Anaerobic Aquatic metabolism of [S- Methyl-^{14}C] Aldicarb Sulfone Under Laboratory Conditions at 25ºC (OPP. §162-4). Aventis Crop Science, Research Triangle Park, NC, Study Number 605YT, December 13, 2001, 109 pages. (MRID No. 45592111).

Hudson, R.H., R.K. Tucker and M.A. Haegele . 1972. Effect of Age on Sensitivity: Acute Oral Toxicity of 14 Pesticides to Mallard Ducks of Several Ages. Toxiocol. Appl. Pharmacol. 22:556-561.

Hudson, R.H., R.K. Tucker and M.A. Haegele . 1984. Handbock of Toxicity of Pesticides to Wildlife. US Fish and Wildlife Service Resource Publication 153.

Jesudason, P.A. (2001a) Aerobic Aquatic metabolism of [S- Methyl-^{14}C] Aldicarb Under Laboratory Conditions at 25ºC (OPP. §162-4). Aventis Crop Science, Research Triangle Park, NC, Study Number 602YT, December 20, 2001, 127 pages. (MRID No. 45592107).

Jesudason, P.A. (2001b) Aerobic Aquatic metabolism of [S- Methyl-^{14}C] Aldicarb Sulfone Under Laboratory Conditions at 25ºC (OPP. §162-4). Aventis Crop Science, Research Triangle Park, NC, Study Number 603YT, December 20, 2001, 149 pages. (MRID No. 45592109).

Jones, R. L. (1987) Central California Studies on the Degradation and Movement of Aldicarb Residues., J. Contam. Hydrol., 1: 287-298. (MRID No. 40493308).

Jones, R. L. (1991) Measurement of Aldicarb Degradation and Movement for Winter Applications to Grapes: Rhône-Poulenc Ag Company, May 8, 1991. (MRID No. 40493304).

Jones, R. L., and T. L. Estes (1995) Summary of Aldicarb Monitoring and Research Programs in the U.S.A. Journal of Contaminant Hydrology 1:107-140.

Jones, R. L., Hansen, J. L., Romine, R. R., and Marquardt, T. E. (1986) Unsaturated Zone Studies on Degradation and Movement of Aldicarb and Aldoxycarb Residues. Environ. Toxicol. Chem., 5: 361-372.

Jones, R. L.; Hornsby, A. G.; and Rao, P. S. C. Degradation and Movement of Aldicarb in Florida Citrus Soils, Pestic. Sci., 1988. 23, 307-325. (MRID No. 40493322).

Jones, R. L.; Kirkland, S. D.; Chancey, E. L.; Proter, K. S.; Walker, M.; Ferro, D. N. (1991) Measurement of Aldicarb Degradation and Movement in Upstate New York and Massachusetts Potato Fields: Rhône-Poulenc Ag Company, NY State Water Resources Institute and Department of Entomology, University of Massachusetts, August 19, 1991. J. Contam. Hydro., 10: 251-271 (1992). (MRID No. 40493302, 40493303).

Jones, R. L., Rourke, R. V. and Hansen, J. L. (1986) Effects of Application Methods on Movement and Degradation of Aldicarb Residues in Maine Potato Fields. Environ. Toxicol. Chem., 5: 167-173.

Kearby, W.; Ercegovich, C.; Bliss, M. (1970) Residue Studies on Aldicarb in Soil and Scotch pine. Journal of Economic Entomology 63(4):1317-1318. Also In unpublished submission received Dec 6, 1977 under 1016-69; submitted by Union Carbide Corp., Arlington, VA; CDL:096671-X. (MRID No. 00102078).

Kendall, R. .J. 1990. Behavior, Survivability and Biochemical Response of Wild Mourning Doves (*Zenaida macroura*) Dosed with Aldicarb. Performed by The Institute of Wildlife and Environmental Toxicology, Clemson University. (MRID No. 417086-04).

Kendall, R. J. 1990. Behavior Survivability and Biochemical Response of Wild northern Bobwhites (*Colinus virginianus*) Doseed with Temik®. Performed by The Institute of Wildlife and Environmental Toxicology, Clemson University. Report 08035. 29 pages. (MRID No. 41708604).

Lemly, A.T. and W.Z. Zhong (1983) Kinetics of Aqueous Base and Acid hydrolysis of Aldicarb, Aldicarb Sulfoxide and Aldicarb Sulfone. J. Environ. Sci. Health, B18 (2):189-206 (1983). (MRID No. 45602901).

Lemly, A.T. and W.Z. Zhong (1984) Hydrolysis of Aldicarb, Aldicarb Sulfoxide, and Aldicarb Sulfone at Parts per Billion Levels in Aqueous Medium. J. Agr. Food Chem., (32):714-719 (1984). (MRID No. 45602903).

Lightfoot, E.N., P.S. Thorne, R.L Jones, J.L. Hansen, and R.R. Romine (1987) Laboratory Studies on the Mechanisms for the Hydrolysis of Aldicarb, Aldicarb Sulfoxide, and Aldicarb Sulfone. Environmental Toxicology and Chemistry, (6):377-394 (1987). (MRID No. 45602904).

Lui, A.C. (2001) Aerobic Aquatic metabolism of [S- Methyl-^{14}C] Aldicarb Sulfoxide Under Laboratory Conditions at 25ºC (OPP. §162-4). Aventis Crop Science, Research Triangle Park, NC, Study Number 604YT, December 13, 2001, 135 pages. (MRID No. 45592108).

McDaniel, R. L. and Weiler, D. W. (1987). Aldicarb Vapor Pressure. Rhone-Poulenc Ag Company Project Report, Project No.: 803P15, June 29, 1987. (MRID No. 42796001).

Mineau, P., B.T. Collins, and A. Baril. 1996. On the Use of Scaling Factors to Improve Interspecies Extrapolation of Acute Toxicity in Birds. Regulatory Toxicology and Pharmacology 24:24-29.

Moore, M.T., D. B. Huggett, W.B. Gillespie, J.H. Rogers and C.M. Cooper. 1998. Comparative toxicity of Chlordane, Chlorpyrifos and Aldicarb to Four Aquatic Testing Organisms. Arch. Environ. Contam. Toxicol. 34:152-157.

Norris, F. A. (1991) A Terrestrial Soil Dissipation Study with Aldicarb the Active Ingredient of Temik® Brand Insecticide, Applied to Cotton at Two Field Sites in California: Rhône-Poulenc Ag Company, July 24, 1991.

Pickering, Q. H. and W. T. Gilliam. 1982. Toxicity of Aldicarb and Fonofos to the Early-Life-Stage of the fathead Minnow. Arch. Environ. Contam. Toxicol. 11:699-702.

Ramanarayanan, T. S. (2000) Kinetics Modeling of Degradation of Aldicarb and its Metabolites in Anaerobic Aquatic Condition, Aventis Report B002970, 30pp. (MRID No. 45178001).

Romine, R.R.; Meeker, R.L. (1972) Temik Aldicarb Pesticide: Leaching of Aldicarb into Sandy Soil with Irrigation of a Temik Treated Sugar Beet Field: UCC Project Report No. 17079. Unpublished study received Aug 4, 1977 under 1016-79; submitted by Union Carbide Corp., Arlington, Va.; CDL:231503-U. (MRID No. 00068252).

Rupprecht, J.K. (2001) Anaerobic Aquatic metabolism of [S- Methyl-^{14}C] Aldicarb Sulfoxide Under Laboratory Conditions at 25ºC (OPP. §162-4). Aventis Crop Science, Research Triangle Park, NC, Study Number 606YT, December 13, 2001, 107 pages. (MRID No. 45592110).

Skinner, W. (1995) Aerobic Aquatic Metabolism of(Carbon 14)-Aldicarb: Lab Project Number: 467W-1: 467W:EC-94-274. Unpublished study prepared by PTRL West, Inc. (MRID No. 43805702).

Skinner, W. and Jao, N. (1995) Anaerobic Aquatic Metabolism of (Carbon 14)-Aldicarb: Lab Project Number: 468W-1: 468W:EC-94-275. Unpublished study prepared by PTRL West, Inc. (MRID No. 43805701).

Stafford, T. R., L.B. Best and D.L. Fischer. 1996. Effects of Different Formulations of Granular Pesticides on Birds. Environ Toxicol & Chem 1606-1611.

Stafford, T. R. and L. B. Best. 1997. Effects of Granular Pesticide Formulations and Soil Moisture on Avian Exposure. Environ Toxicol Chem 16:1687-1693.

Stafford, T.R and L. B. Best. 1998. Effects of Application Rate on Avian Risk from Granular Pesticides. Environ Toxicol & Chem 526-529.

Union Carbide Corporation (1965) Residue Data: UC 21149 . Compilation; unpublished study received Jan 25, 1966 under 6G0473; CDL:090525-O. (MRID No. 00080815).

Union Carbide Corp. (1973) Residues: Temik 10G and Temik 15G. Unpublished study received Jun 21, 1974 under 1016-78; CDL: 026641-A. (MRID No. 00101910).

Union Carbide Corp. (1971) Magnitude of the Residues: Aldicarb. Compilation; unpublished study received May 3, 1972 under 2F1188; CDL:091000-I. (MRID No. 00101923).

Union Carbide Corp. (1969) Soil: Decline of Aldicarb . (Unpublished study received Aug 20, 1970 under 0F1008; CDL:091748-M). (MRID No. 00101968).

US EPA (1992). Comparative Analysis of Acute Avian Risk from Granular Pesticides. Office of Pesticide Programs. U.S. Environmental Protection Agency. Washington, D.C., March, 1992.

Weil, C.S. and C.P. Carpenter (1972) Miscellaneous Toxicity Studies, Mellon Institute Report No. 35-41. Submitted to EPA on Aug. 4, 1977. (MRID No. 00054419).

Wolfe, N.L. (1985). Transformation of Reactions of Aldicarb Sulfoxide and Aldicarb Sulfone in Reducing Sediment Samples. U.S. Environmental Protection Agency, Athens, GA.

Woodham, D.; Edwards, R.; Reeves, R.; et al. (1973) Total Toxic Aldicarb Residues in Soil, Cottonseed, and Cotton Lint Following a Soil Treatment with the Insecticide on the Texas High Plains. J. Agr. Food Chem. 21(2):303-307. Also In unpublished submission received Dec 9, 1977 under 1016-69; submitted by Union Carbide Corp., Arlington, VA; CDL:096670-V. (MRID No. 00102061).

Wyman, J. A.; Jones, R. L.; Medina, J.; Curwen, D.; and Hansen, J. L. Environmental Fate Studies of Aldicarb and Aldoxycarb Applications to Wisconsin Potatoes, Journal of Contaminant Hydrology, 2 (1987) 61-72. (MRID No. 40493314).

Wyman, J. A.; Jensen, J. O.; Curwen, D.; Jones, R. L. and Marquardt, T. E. (1985) Effects of Application Procedures and Irrigation on Degradation and Movement of Aldicarb Residues in Soil. Environ. Toxicol. Chem., 4: 641-651.