



# **Amendment to Reregistration Eligibility Decision (RED) for Propanil (March 2006) and the Propanil RED (September 2003)**

**This document contains both the  
amended RED and the initial RED**

Docket ID: EPA-HQ-OPP-2003-0348

Amendment to the Propanil RED (March 7, 2006):  
EPA-HQ-OPP-2003-0348-0024

Propanil RED (September 30, 2003):  
EPA-HQ-2003-0348-0002



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**CERTIFIED MAIL**

March 7, 2006

Dear Registrant:

**SUBJECT: AMENDMENT TO PROPANIL RED**

The Reregistration Eligibility Decision (RED) document for propanil was signed on 9/30/2003. A public comment period for the Propanil RED (and the supporting assessment) was conducted from 2/25/2004 to 4/26/2004. The risk assessments, benefit assessment, and public comments can be found on the federal docket system, available at [www.Regulations.gov](http://www.Regulations.gov) (docket # EPA-HQ-OPP-2003-0348). The Agency has reviewed the public comments submitted and has responded to those that relate specifically to the propanil RED. The Agency's responses are available for viewing under the same docket number on the Regulations.gov system. As a result of its review of the public comments and review of additional data submitted by the Propanil Task Force, the Agency is amending the Propanil RED, where appropriate. These revisions include label changes and an updated "Appendix B: Data Supporting Guideline Requirements for the Reregistration of Propanil". The label changes related to dry flowable closed systems are contingent on the outcome of exposure data that are due in December 2006.

In addition, the Agency has received a request from the California Rice Commission to reexamine the tolerance that was proposed in the 2003 RED on rice of 10 ppm. In order to facilitate trade in the Pacific region, the California Rice Commission would like to maintain the existing tolerance of 2 ppm. At this time, the Agency is moving forward with this Propanil Amendment decision, but will look into this request further as more information or supporting data are submitted.

**Risk Mitigation Measures Dependent on Worker Monitoring Studies**

In the 9/30/2003 Propanil RED, two handler exposure mitigation measures depended upon the outcome of worker monitoring (exposure) studies that, at the time the RED was signed, were under review by the Agency. The first proposed measure would have reduced the seasonal application rate of propanil from 8 lbs a.i. per acre to 6 lbs a.i. per acre. The second measure would have limited the maximum number of acres treated per day to 500. These measures were

to be implemented unless the data from exposure monitoring studies indicate that lesser or no further mitigation was warranted. As explained below, the results of the worker monitoring study were of only limited utility and comments from stakeholders raised concerns about the feasibility of the proposed measures. Thus EPA has modified the mitigation measures.

The Propanil Task Force II (PTF II) submitted both a bio-monitoring study in August 2003 and a passive dosimetry study in December 2003, to refine the exposure estimates for workers handling propanil. Upon completion of the review of the data in May 2004, the Agency accepted comments from the PTF II and has responded to the concerns raised by the PTF II in the November 23, 2004 memo from Alan Nielsen. The Agency has determined that, due to an insufficient number of acceptable replicates and other shortcomings, data from these two worker exposure studies could not be relied on exclusively to quantify the risk to workers using propanil. However, the results do help to characterize exposure under actual field conditions to aerial applicators and the mixer/loaders supporting aerial applications of propanil. For example, calculations based on passive dosimetry measurements from the study indicate that margins of exposure (MOEs) for aerial applicators could be up to 20-fold greater than those calculated based on the Pesticide Handler Exposure Database (PHED) that was used in the initial risk assessment; mixer/loader MOEs would be about three-fold greater. While the Agency believes that the passive dosimetry data represent only low-end exposures, they are useful in concluding that the existing assessment does not underestimate risk and, in-fact likely represents worst-case exposures. PHED is a database containing voluntarily submitted empirical exposure data for workers involved in the handling or application of pesticides in the field; it currently contains data for over 2000 monitored exposure events.

The following is an update on the two pending mitigation measures that were proposed in the 2003 RED to address risk to handlers of propanil. These proposed mitigation measures were specifically targeting risk to workers participating in mixing and loading liquid and dry flowable propanil for aerial application, and applying sprays for aerial application.

1. *Mitigation measure in the 2003 Propanil RED:*

The Agency proposed reducing the maximum seasonal application rate from 8 lbs a.i. /acre to 6 lbs a.i./acre.

*Comments and issues:*

The proposed rate reduction from 8 lbs a.i./acre per season to 6 lbs a.i./acre per season was intended to reduce the over all amount of propanil workers would be handling in a year and thus reduce worker exposure. Comments were received from growers concerned with limiting the maximum seasonal application rate of propanil to 6 lbs a.i./acre.

While this 6 lb a.i./acre per season rate is the typical seasonal rate, it is sometimes necessary to apply up to 8 lbs a.i./acre per season. In some areas of the U.S. it is more effective to control weeds with two 4 lbs a.i./acre applications of propanil in a season, while in other areas it is more effective to apply one application of propanil at 6 lbs a.i./acre. Despite the varying application rates, the Agency's use data (see page 6 of the BEAD memo from V. Werling, 9/30/2003) indicates that less than 5% of all applications of propanil are made at rates greater than 4 lbs a.i./acre on a national basis.

Given the benefits of propanil use and the information from the Agency's use data, the Agency is retaining the original 8 lbs a.i./acre seasonal application rate and establishing a maximum for a single application rate at 6 lbs a.i./acre which will continue to allow flexibility for growers in all regions of the United States to effectively control weeds in rice. Previously there was no maximum single application rate restriction on all propanil product labels. MOE are not calculated on yearly maximum rates, only single application rates, assuming that rate is used consistently over 30-90 days. Mixer/loader MOEs at 6 lbs ai/acre range from 50 to 1000 using only the PHED data (with a target of 300) depending on the formulation, equipment and number of acres treated. Based on usage information, it is unlikely that any single applicator uses the 6 lb rate consistently for 30 days. The most likely application scenario is 3-4 lbs/ai/acre, yielding MOEs in the 100-2000 range. The lowest MOE represents 3 lbs ai/acre, 1,200 acres treated daily for 30 days.

*Amended mitigation measure and data requirement:*

The maximum single application rate for rice is 6 lbs a.i./acre, with a maximum seasonal application rate of 8 lbs a.i./acre.

A new Data Call In requirement for confirmatory usage and application data spanning a period of 2 years is also being required by the Agency.

2. *Mitigation measure in the 2003 Propanil RED:*

The Agency proposed to restrict the number of acres treated per day for aerial applications to 500 acres.

*Comments and issues:*

The Agency received comments concerned with the difficulties a 500 acre daily application restriction would create for rice growers and state enforcement agencies. Rice growers and aerial applicators are concerned with being able to effectively treat the rice crop with an acreage restriction in place. The propanil application season is short and aerial applicators sometimes need to apply propanil to a large number of acres in a day in order to effectively control weeds in the rice crop due to early season wet weather

conditions which are conducive to weed germination. Comments received by the Agency ranged from suggesting the restriction be eliminated all together, to establishing a flexible weekly limit, a moving 7 day average, or a 30 day acreage average.

According to the May 2004 "Pesticide Use Survey Report for Agricultural Aviation" from the National Agricultural Aviation Association, the average acres of rice treated with any type of pesticide per day was 725 acres, while the maximum number of acres treated per day was 1,344 acres in 2003. EPA's assessment calculated MOEs assuming up to 3,200 acres treated per day. While growers have reported treating as much as 3,200 acres in a single day, there is no evidence to support the assumption that this high number of acres is treated for sustained periods of time by the same aerial applicator. Thus, the Agency is requiring the registrant to verify the use of propanil from 3 high propanil use areas outside of California, the results of which will be submitted to the Agency in two annual reports. Data are not required for California because an acreage limit of 720 acres per day is already in effect. This requirement is intended to confirm **average** number of acres treated over a month and thus determine a realistic average exposure for aerial applicators and mixers/loaders specifically to propanil. Acute or single day exposures are not a concern for propanil since no adverse effects attributed to a single exposure were identified in the toxicity data. The toxic effect of concern for propanil exposure (methemoglobin anemia) was observed in toxicity studies of short-term (30 day) duration.

Exposure/risk estimates for aerial applicators using PHED only vary from MOEs of 560 at 350 acres/day to 160 at 1,200 acres per day. At an average of 600 acres/day, the Agency estimates MOEs of approximately 320, above the target MOE of 300. Mixer/loader MOEs range from 100 to 2000 using typical application rates and the PHED data, depending on the formulation, equipment and number of acres treated.

The use data should be collected over a 2 year period and include the specific information that is listed in the "Additional Data Needs" section of this document. If the confirmatory data do not support the Agency's use assumptions on the average number of acres pilots treat with propanil, further mitigation measures may be taken. The Agency is not imposing any aerial acreage limitations at this time but is requiring all aerial applications occur in an enclosed cab (see #3 below) which will reduce pilot exposure to propanil. Mixer/loader exposure will be addressed with PPE and closed systems as discussed below.

*Amended requirement:*

A new Data Call In requirement for confirmatory usage and application data spanning a period of 2 years is being required by the Agency.

## Additional Amended Risk Mitigation Measures

Additional comments were received on other risk mitigation measures required in the 2003 Propanil RED. Based on public comments the following changes are being made:

3. *Mitigation measure in the 2003 Propanil RED:*

Closed cabs would be required for all applications of propanil (ground and aerial).

*Comments and issues:*

### Ground

At typical application rates (3 lbs ai/acre) and acreage (80 and 200 acres per day) for ground applications, the MOEs for propanil ranged from 300 to 740, are above the target MOE of 300, and are not of concern to the Agency. Only one scenario, at the maximum application rate (6 lbs. ai/acre) and area treated (200 acres/day), did not meet the target MOE at baseline attire. MOEs for the one outlier ranged from 150 at baseline to 500 with closed cabs. The Agency initially required closed cabs for ground applications due to this maximum application scenario calculation and to be consistent with the aerial enclosed cab requirements. After receiving comments expressing difficulty in modifying ground equipment used in rice fields with closed cabs and after further consideration, the Agency has decided that requiring closed cabs for ground applications would add a greater burden than necessary for all ground applicators. Therefore, applicators will be required to wear baseline attire when making ground applications of propanil.

### Aerial

Due to the large acreage that aerial applicators are able to treat and the potential for high exposure, combined with data from the PTF II indicating that closed cockpits are the current cultural practice used in the field, the Agency is requiring a closed cab for all aerial applications of propanil. With closed cabs, exposure/risk estimates for aerial applicators using PHED data only, vary from MOEs of 560 at 350 acres/day to 160 at 1,200 acres per day. At an average of 600 acres/day, the Agency estimates MOEs of approximately 320, above the target MOE of 300. Because of the benefits of propanil and existing information that high acreage and high rate applications do not co-occur frequently or repeatedly, the Agency is allowing this use.

*Amended mitigation measure:*

Baseline attire is required for **groundboom** applicators: long pants, long sleeved shirt, shoes and socks.

A closed cab is required for all **aerial** applications of propanil.

4. *Liquid and dry flowable mitigation measure in the 2003 Propanil RED:*

The Agency proposed to require a closed mixing and loading system for all formulations of propanil (liquid and dry flowables applied both aerially and with groundboom).

**Liquid Formulations**

*Comments and issues on liquid formulations:*

Comments were received from propanil user groups explaining the lack of current technology for a “completely” closed mixing and loading systems for liquid propanil formulations. The California Rice Commission, USA Rice Federation, and the Arkansas State Plant Board expressed concerns and raised potential problems associated with conforming to this requirement. They felt that closed mixing and loading systems would slow their loading speed and hinder their ability to mix propanil with other products and not provide additional protection for workers, which would make the requirement of closed mixing and loading system unworkable under field conditions. These additional comments can be viewed under this docket, OPP-2003-0348.

The Agency understands these concerns regarding the closed mixing and loading requirement for liquid formulations. Nonetheless, the Agency continues to have concerns for pesticide handlers exposed to the liquid formulations of propanil when mixing and loading large quantities of concentrated product. Closed mixing and loading systems are important to ensure workers are not exposed to excessive levels of propanil through dermal exposure when making both ground and aerial applications. Applications of propanil to rice are often made over a very short time frame (usually about 30 days) due to early season wet weather conditions which are conducive to weed germination. When these conditions exist, there is pressure to apply propanil to large acreage over a short time frame. These conditions could lead to handlers being exposed to quantities of liquid propanil that exceed the Agency’s level of concern for dermal exposure. The implementation of closed mixing and loading systems will help reduce handler dermal exposure.

In order to be eligible for reregistration all liquid formulations of propanil, including emulsifiable concentrates, flowable concentrates, ready to use solutions, soluble concentrates, and other liquid formulations, must be mixed and loaded in a closed system that will: (1) remove the pesticide from the container and transfer it into a mix tank, and (2) transfer it from the mix tank into the application equipment in a closed system that prevents dermal contact of handlers. EPA has published Pesticide Registration (PR) Notice 2000-9 about closed mixing and loading systems that describes a closed system as “a system designed by the manufacturer to enclose the pesticide to prevent it from

contacting individuals while it is being handled.” This PR Notice may be viewed at [http://www.epa.gov/PR\\_Notices/pr2000-9.pdf](http://www.epa.gov/PR_Notices/pr2000-9.pdf).

In addition to this PR Notice, the Propanil Task Force II, along with the California Rice Commission, presented to the Agency one of the current methods of liquid propanil transfer in some rice growing areas (see Letter from McDermott Will and Emory dated July 29<sup>th</sup>, 2005). This method utilizes a probe that is inserted into the drum and pumps the liquid propanil out and into a mixing tank. There is potential for dermal exposure to the liquid propanil concentrate if an un-rinsed probe is removed from a partially used container. It is necessary to remove probes from partially empty propanil containers when all of the propanil product cannot be utilized in one application. In these cases, the use of an anti-drip flange and additional PPE when an un-rinsed probe is removed could help reduce the potential for dermal exposure to liquid concentrate. While this specific probe system does not match all of the criteria of a closed mixing and loading system as defined in the Worker Protection Standard (WPS) and in PR Notice 2000-9, the Agency believes this probe system will allow mixers and loaders to be adequately protected from dermal exposure to propanil. A description of specific directions for mixing and loading liquid propanil are listed in the attached label table.

*Amended mitigation measure for liquid formulations:*

Mixers and loaders must use a closed system that meets the requirements listed in the Worker Protection Standard (WPS) for dermal protection of agricultural pesticides [40 CFR 170.240(d)(4)] or the probe system described in the attached label table. A dry disconnect or dry couple shut-off device must be used at every disconnect point for both ground and aerial mixing/loading operations.

### **Dry Flowable Formulations**

*Comments and issues on dry flowable formulations:*

The Agency is encouraging the registrant to work with growers and equipment manufacturers in order to address their specific concerns about closed mixing and loading systems for propanil dry flowable formulations. Currently the only engineering control the Agency is aware of for mixing and loading dry flowable formulations is through the use of water soluble packages. While the Agency acknowledges different chemicals have different physical properties that can make formulating into water soluble packages more challenging than others, there are currently no alternative engineering controls for this formulation. Therefore, the Agency is requiring all wettable powder formulations to be formulated in closed systems. In order to allow sufficient time to repackage the dry flowable formulation, registrants will have until December 1, 2007 to implement this requirement.



In addition, because of concerns from the propanil registrants and rice growers about repackaging the dry flowable formulation, the Agency is requiring, within the same time frame, registrants individually or in collaboration with existing task forces, develop exposure data for the dry flowable formulation. If reliable data indicate that exposures are less than currently estimated, the Agency will consider changing the mitigation measures for dry flowable formulations.

*Amended dry flowable mitigation measure:*

All dry flowable products must be formulated into water soluble packages or other closed systems by December 1, 2007 unless exposure data on the dry flowable indicate they are not needed to achieve adequate margins of exposure.

**Response to Comments on Mitigation Measures or Data Requirements  
That Are Not Being Modified**

Additionally, there are some clarifications to the 2003 Propanil RED that include:

5. *Mitigation measure:*

Apply only when the wind speed is less than or equal to 10 mph at the application site. This applies to both ground and aerial applications.

*Comments and issues:*

Comments were received requesting the label language change to allow more flexibility in making applications when the wind speed is above the 10 mph limit.

The Agency is not changing the wind speed requirement at this time. Spraying at the edge of the application area while wind speeds exceed 10 mph could lead to adverse effects for non-target plants and organisms from spray drift. Therefore, to ensure spray drift exposures and risks are adequately controlled, applications will only be allowed when the wind speed is 10 mph or less.

6. *Mitigation measure:*

60-day plant back interval for all rotational crops.

*Comments and issues:*

Many rice growers commented that a 60 day plant back interval is not practical

due to the short window of opportunity growers have to replant fields when the rice crop fails. In order to shorten the 60 day plant back interval the Agency would need data demonstrating no detectable residues at a shorter plant back interval were found in crops planted after propanil applications. Growers are encouraged to work with the registrant to develop data that would support the rotational crops the growers are interested in planting. Until the Agency has data on rotated crops following propanil applications, the Agency can not shorten the 60 day plant back interval.

Therefore, the 60-day plant back interval for all rotational crops will be required until data are submitted to support a different time interval.

7. *Required data:*

Development of toxicity and fate data on the major metabolic degradate of propanil, 3,4-DCA.

*Comments and issues:*

The Propanil Task Force II submitted comments on the lack of a need for a number of the data requirements for 3,4-DCA due to the availability of existing published literature on propanil. The Agency will issue the Data Call In (DCI) with all data requirements as listed in the Propanil RED. If the registrant believes a study is not warranted they may submit a waiver request and supporting information along with their 90-day response to the DCI that will be issued concurrent with the Propanil Amendment document. The Agency will review all data waiver requests when they are received.

Therefore, the data requirement to develop toxicity and fate data on 3,4-DCA will remain in the DCI.

8. *Mitigation measure:*

Establish a 7-day water holding (discharge) interval for all propanil application sites with two exceptions listed below:

- 1) a 10-day discharge interval in South Texas, south of I-10 from the Texas/Louisiana border to Houston and east of State Highway 35 from Houston to Port Lavaca; and
- 2) a 15-day discharge interval in Southern Louisiana, south of highway 14, to address Agency risk concerns for aquatic species, including those for endangered species.

Flood water must be held for the time specified unless excessive rainfall completely submerges the rice crop and forces premature release.

*Comments and issues:*

Various comments and suggestions were received about the water holding interval, specifically regarding the release provision. Many grower groups suggested defining the release provision with broader language allowing more exceptions for water to be released such as in cases of potential crop failure or delayed phytotoxicity syndrome. Water holds are required in order to reduce the potential exposure of propanil to aquatic species including endangered species. The Agency feels the effectiveness of the water hold would be reduced if too many exceptions are allowed.

Therefore, the water hold specifications will remain as listed above with the only exception for releasing water prematurely when excessive rainfall completely submerges the rice crop and forces premature release.

**Risk Mitigation Measures or Data Requirements That Received No Comments  
And Are Still Required by this Amendment**

9. *Mitigation measure:*

All labels with use directions on rice must be amended to specify restrictions against application to fields where catfish farming is practiced and draining water from treated fields into areas where catfish farming is practiced.

An updated label table attached to this document includes the following restriction for catfish farming:

“Application to fields where catfish farming is practiced and draining water from fields into areas where catfish farming is practiced is prohibited. Water drained from treated rice fields must not be used to irrigate other crops or released within ½ mile upstream of a potable water intake in flowing water (e.g., river, stream, etc.) or within ½ mile of a potable water intake in a standing body of water, such as a lake, pond, or reservoir.”

10. *Mitigation measure:*

There is a restricted entry interval (REI) of 24 hours for rice.

## **Required Mitigation Measures From the 2003 Propanil Red That Have Been Satisfied**

11. *Mitigation measure:*

Voluntary cancellation of use on small grains (spring (hard red) wheat, oats, spring barley and durum wheat).

All small grain use sites have been cancelled as indicated in 68 FR 68901 on December 10, 2003, and can be viewed on the federal docket system, available at [www.Regulations.gov](http://www.Regulations.gov), under docket number EPA-HQ-OPP-2003-0200.

12. *Mitigation measure:*

For turf, the registrant had agreed to reduce the maximum application rate on turf to 5 lbs a.i./acre and eliminate aerial applications of propanil to turf.

Subsequent to the RED, the only propanil turf product has been cancelled due to non-payment of maintenance fees as indicated in 70 FR 44637 and published on August 3, 2005.

13. *Required data:*

Development and submission of worker exposure (bio-monitoring) data for the liquid formulation were required in the 2003 RED.

Biomonitoring and passive dosimetry data was submitted by the registrant and reviewed by the Agency (See May 20, 2004 memo from Shanna Recore). The review and other related documents can be found on the federal docket system, available at [www.regulations.gov](http://www.regulations.gov) under docket number EPA-HQ-OPP-2003-0348.

### **Additional Data Needs**

In addition to the "Additional Data Requirements" listed in the 2003 Propanil RED, the Agency is requiring the following data:

(1) GLN 810.1000: Usage and application data from the registrants. Data are needed to confirm the Agency's assumptions for handler and applicator exposure to propanil. Data from 3 high propanil use areas outside of California will be collected and include :

- (a) how many pounds of propanil are handled/applied per day by individual mixers, loaders, and applicators,
- (b) how many hours per day a handler mixes and loads propanil,

- (c) the application rate of the active ingredient (pounds of propanil per acre per application),
- (d) the formulation of propanil used,
- (e) how many hours individual aerial applicators apply propanil per day, and
- (f) how many acres individual aerial applicators treat per day.

The use data should be collected over a 2 year period the results of which will be submitted to the Agency in two annual reports, the first of which is due one year after the Data Call In is issued. The second report should summarize the findings of the entire 2 year period, and is due 2 years after the Data Call In is issued.

(2) GLN 875.1100: Data on worker exposure to dry flowables. Registrants are required to submit data on exposure to dry flowable formulations either individually or in collaboration with existing task forces.

If you have questions on the propanil RED, the amendments listed in this document, or questions about the Generic DCI, please contact the Chemical Review Manager, Cathryn O'Connell at (703) 308-0136. For questions about product reregistration and/or the Product Specific DCI that accompanies this document, please contact Moana Appleyard at (703) 308-8175.

Sincerely,

Debra Edwards, Ph.D.  
Director  
Special Review and Reregistration Division

Attachments:

- Revised Propanil Label Table
- Updated Appendix B: Data Supporting Guideline Requirements for the Reregistration of Propanil
- GDCI
- PDCI
- 2003 Propanil RED

Documents Cited:

Evaluation of the Potential Exposure of Workers to Propanil during Mixing./Loading and Aerial Application to Rice Fields Using Simultaneous Dermal Dosimetry and Biological Monitoring Techniques. Alan Nielsen. November 23, 2004.

Fong, Harvard, "An Overview of Closed System Use in California 2001-2002." HS-1849, June 2003. (<http://www.cdpr.ca.gov/docs/whs/pdf/hs1849.pdf>)

Letter from McDermott Will and Emory dated July 29<sup>th</sup>, 2005

"Pesticide Use Survey Report for Agricultural Aviation." National Agriculture Aviation Association. May 2004.

Response of Propanil Task Force II to the Review of the U.S. Environmental Protection Agency.

Response to "Evaluation of the Potential Exposure of Workers to Propanil During Mixing/Loading and Aerial Application to Rice Fields Using Simultaneous Dermal Dosimetry and Biological Monitoring Techniques". Shanna Recore. May 20, 2004.



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**WASHINGTON, D.C. 20460-0001**

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**CERTIFIED MAIL**

Dear Registrant:

This is to inform you that the U.S. Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the risk assessments for the acetanilide herbicide propanil. Based on its review, EPA has identified risk mitigation measures that the Agency believes are necessary to address the human health and environmental risks associated with the current use of propanil. EPA is now publishing its reregistration eligibility and risk management decisions for the current uses of propanil, and its associated human health and environmental risks. The tolerance reassessment decision for propanil was completed in June 2002 [OPP-2002-0033; FRL-7179-4]. The Agency's complete reregistration decision including updated information on the tolerance reassessment for the individual chemical propanil can be found in the attached document entitled, "Reregistration Eligibility Decision for Propanil" which was approved on September 30, 2003.

A Notice of Availability for the Reregistration Eligibility Decision (RED) for propanil is being published in the *Federal Register*. To obtain a copy of the RED document, please contact the OPP Public Regulatory Docket (7502C), US EPA, Ariel Rios Building, 1200 Pennsylvania Avenue, NW, Washington, DC 20460-0001, telephone: (703) 305-5805. Electronic copies of the RED and all supporting documents are available on the Internet at the following address: <http://www.epa.gov/pesticides/reregistration/status.htm>.

As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), the Agency is undertaking a special effort to maintain open public dockets and to engage the public in the reregistration and tolerance reassessment processes. The human health and environmental risk assessments were placed in the public docket and an invitation for public comment was published in the *Federal Register* on June 5, 2002 [OPP-2002-0033; FRL-7179-4]. In cooperation with the U.S. Department of Agriculture, the Agency conducted a close-out conference call on September 29, 2003 with the registrants and various stakeholders, during which the Agency presented a summary of the risk assessment, the results of the risk management decisions and the resultant changes to the propanil labels.

Please note that the risks summarized in the attached RED are those that result only from the use of propanil. The FQPA requires that the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.” The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the other substances individually. The Agency does not have sufficient reliable information at this time to determine whether the acetanilide pesticides, such as propanil, share a common mechanism of toxicity. Further, the Agency is in the process of developing criteria for characterizing and testing endocrine disrupting chemicals and plans to implement an Endocrine Disruptor Screening Program in the near future. Propanil will be reevaluated at that time and additional testing may be required.

This RED contains a generic and a product-specific Data Call-In (DCI) that outline further data requirements for this chemical. Note that a complete DCI, with all pertinent instructions, will be sent to registrants under separate cover. Additionally, the first set of required responses to both DCIs are due within 90 days from the receipt of the DCI letter. The second set of required responses to the product-specific DCI are due eight months from the date of this letter.

Product labels should be revised by the manufacturer to adopt the changes set forth in Section IV of this document. Instructions for registrants on submitting revised labeling and the time frame established to do so can also be found in Section V of this document.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by the acetanilide herbicide propanil. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency’s action.

There will be a 60-day public comment period for this document commencing on the day the Notice of Availability publishes in the *Federal Register*.

If you have questions on this document or the proposed label changes, please contact the Chemical Review Manager for propanil, Carmen Rodia, at (703) 306-0327. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Karen Jones at (703) 308-8047.

Betty Shackleford, Acting Director  
Special Review and Reregistration Division

Attachment



**Reregistration Eligibility Decision**  
**for**  
**Propanil**  
**(N-(3,4-dichlorophenyl)propanamide)**

**List A**  
**Case 0226**

U.S. ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF PESTICIDE PROGRAMS  
SPECIAL REVIEW AND REREGISTRATION DIVISION

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## Glossary of Terms and Abbreviations

|                                      |   |
|--------------------------------------|---|
| AGDCI                                | Agricultural Data Call-In   |
| a.i.                                 | Active Ingredient   |
| aPAD                                 | Acute Population Adjusted Dose  |
| AR                                   | Anticipated Residue   |
| BCF                                  | Bioconcentration Factor   |
| CAS                                  | Chemical Abstract Service   |
| CFR                                  | Code of Federal Regulations   |
| cPAD                                 | Chronic Population Adjusted Dose  |
| CSF                                  | Confidential Statement of Formula   |
| CSFII                                | USDA Continuing Surveys for Food Intake by Individuals  |
| DCI                                  | Data Call-In  |
| DEEM                                 | Dietary Exposure Evaluation Model   |
| DFR                                  | Dislodgeable Foliar Residue   |
| DWLOC                                | Drinking Water Level of Comparison  |
| EC                                   | Emulsifiable Concentrate Formulation  |
| EC <sub>25</sub> or EC <sub>50</sub> | Effective Concentration (EC <sub>25</sub> for terrestrial plants and EC <sub>50</sub> for aquatic plants and invertebrates).<br>The concentration of a chemical in water at which an effect is observed that is 25% or 50% of the maximum effect.                               |
| EEC                                  | Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.  |
| EP                                   | End-Use Product   |
| EPA                                  | United States Environmental Protection Agency   |
| FAO                                  | Food and Agriculture Organization   |
| FDA                                  | Food and Drug Administration  |
| FIFRA                                | Federal Insecticide, Fungicide and Rodenticide Act  |
| FFDCA                                | Federal Food, Drug and Cosmetic Act   |
| FQPA                                 | Food Quality Protection Act   |
| FOB                                  | Functional Observation Battery  |
| GENEEC                               | Tier I Surface Water Computer Model   |
| GLC                                  | Gas Liquid Chromatography   |
| GLN                                  | Guideline Number  |
| HDT                                  | Highest Dose Tested   |
| IR                                   | Index Reservoir   |
| LC <sub>50</sub>                     | Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.          |
| LD <sub>50</sub>                     | Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of an animal, e.g., mg/kg. |
| LEL                                  | Lowest Effect Level   |
| LOAEC                                | Lowest Observed Adverse Effects Concentration The lowest concentration in an experiment at which an “adverse” health effect is seen (kg body weight/day).   |
| LOAEL                                | Lowest Observed Adverse Effects Level   |
| LOC                                  | Level of Concern  |
| LOD                                  | Limit of Detection  |
| MATC                                 | Maximum Acceptable Toxicant Concentration   |
| µg/g                                 | Micrograms Per Gram   |
| µg/L                                 | Micrograms Per Liter  |
| mg/kg/day                            | Milligram Per Kilogram Per Day  |
| mg/L                                 | Milligrams Per Liter  |
| MOE                                  | Margin of Exposure  |

|                  |  |
|------------------|--|
| MRID             | Master Record Identification (number). The EPA's system of recording and tracking studies submitted.   |
| MUP              | Manufacturing-Use Product  |
| NA               | Not Applicable   |
| NAWQA            | USGS National Water Quality Assessment   |
| NOAEC            | No Observed Adverse Effect Concentration   |
| NR               | Not Required   |
| NOAEC            | No Observed Adverse Effects Concentration. The highest concentration of a substance a group of experimental animals is exposed to that demonstrates the absence of adverse effects observed or measured at higher concentration levels (kg body weight/day). |
| NOAEL            | No Observed Adverse Effects Level  |
| OPP              | EPA Office of Pesticide Programs   |
| OPPTS            | EPA Office of Prevention, Pesticides and Toxic Substances  |
| Pa               | Pascal. The pressure exerted by a force of one newton acting on an area of one square meter.   |
| PAD              | Population Adjusted Dose   |
| PCA              | Percent Crop Area  |
| PDP              | USDA Pesticide Data Program  |
| PHED             | Pesticide Handler's Exposure Data  |
| PHI              | Preharvest Interval  |
| ppb              | Parts Per Billion  |
| ppm              | Parts Per Million  |
| PPE              | Personal Protective Equipment  |
| PRN              | Pesticide Registration Notice  |
| PRZM/EXAMS       | Pesticide Root Zone Model and Exposure Analysis Modeling System, which is a Tier II surface water computer model.  |
| Q <sub>1</sub> * | The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model  |
| RAC              | Raw Agriculture Commodity  |
| RBC              | Red Blood Cell   |
| RED              | Reregistration Eligibility Decision  |
| REI              | Restricted Entry Interval  |
| RfD              | Reference Dose   |
| RQ               | Risk Quotient  |
| SCI-GROW         | Screening Concentration in Ground Water modeling system, which is a Tier I ground water computer model.  |
| SAP              | Science Advisory Panel   |
| SF               | Safety Factor  |
| SLC              | Single Layer Clothing  |
| SLN              | Special Local Need (Registrations under section 24(c) of FIFRA)  |
| TC               | Toxic Concentration. The concentration at which a substance produces a toxic effect.   |
| TD               | Toxic Dose. The dose at which a substance produces a toxic effect.   |
| TEP              | Typical End-Use Product  |
| TGAI             | Technical Grade Active Ingredient  |
| TLC              | Thin Layer Chromatography  |
| torr             | A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.  |
| TRR              | Total Radioactive Residue  |
| UF               | Uncertainty Factor   |
| USDA             | United States Department of Agriculture  |
| USEPA            | United States Environmental Protection Agency  |
| USGS             | United States Geological Survey  |
| WPS              | Worker Protection Standard   |

## **Executive Summary**

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of propanil. This document also presents the Agency's tolerance reassessment decision for propanil, which includes the consideration of risk to infants and children for any potential dietary, drinking water, dermal, inhalation or oral exposures. The tolerance reassessment decision on propanil was published in the *Federal Register* on June 5, 2002 [OPP-2002-0033; FRL-7179-4]. The Agency made its tolerance reassessment decision based on the data required for reregistration, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that the current uses of propanil on rice and turf are eligible for reregistration, provided the changes specified in this document are made to the labels. The small grain use (spring (hard red) wheat, oats, spring barley and durum wheat) has been voluntarily cancelled by the registrants.

## **Use Summary**

Propanil is a selective post-emergent general use herbicide registered to control broadleaf and grass weeds on rice. It is also registered (but not currently marketed) for turf use at commercial sod farms. The small grain use was voluntarily cancelled by the registrants. There are no existing or proposed residential uses of propanil. EPA estimates that approximately seven million pounds of active ingredient are used annually on rice.

## **Carcinogenicity Classification**

Propanil has been classified into the “suggestive” category for carcinogenic potential. As a result, a quantified carcinogenic assessment ( $Q_1^*$  approach) is not appropriate for propanil.

## **Dietary Risks**

EPA's 2002 tolerance reassessment concluded that acute and chronic dietary risk for food and drinking water did not exceed the Agency's level of concern for all population subgroups; therefore, no mitigation was warranted for dietary exposure to propanil.

## **Worker Risks**

The risk to occupational handlers of propanil is potentially of concern for several of the aerial exposure scenarios, even with maximum personal protective equipment (PPE) and engineering controls. Additional use restrictions are needed. Propanil-specific worker exposure (bio-monitoring) data were developed by the Propanil Task Force II. These data were submitted to the Agency on September 15, 2003 and will be reviewed before final labels are approved.



Long-term handler exposure is not expected for propanil. All post-application worker risks associated with the rice use of propanil met or exceeded the target MOE of 300, and thus, are not of concern as long as the current restricted entry interval (REI) of 24 hours is retained. A REI of 18 days for the potential turf use is necessary to adequately address occupational post-application reentry risks.

### **Residential and Other Nonoccupational Risks**

There are no residential or other nonoccupational risk concerns because propanil does not have any residential uses.

### **Ecological Risks**

Propanil use on rice may cause adverse ecological effects at the current maximum seasonal application rate of 8 lbs. a.i./acre/yr (from two 4 lbs. a.i./acre applications) in areas where rice is produced. Acute risks are estimated for birds, small mammals, freshwater invertebrates and nontarget aquatic plants although RQs are relatively low. Chronic risks are potentially a concern for small mammals and freshwater fish and invertebrates.

The potential use of propanil on turf at the current maximum application rate of 10 lbs. a.i./acre may pose a risk to aquatic vascular/nonvascular plants and terrestrial plants in semi-aquatic areas, and acute risk to birds, small mammals, freshwater fish and invertebrates and estuarine/marine fish and invertebrates. Chronic risks are a concern for small mammals at the current label rate.

Currently, the Agency does not have data to determine the risk from propanil use on rice to terrestrial nontarget plants. In addition, no acceptable chronic avian data were available, so chronic risks for avian species could not be assessed. Data are required to address these gaps in the ecological assessment.

### **Cumulative Risk**

FQPA requires that the Agency consider the “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.” The Agency does not have sufficient information at this time concerning common mechanism issues to determine whether or not propanil shares a common mechanism of toxicity with other substances, including other acetanilides. Therefore, for the purposes of this risk assessment, the Agency has assumed that propanil does not share a common mechanism of toxicity with any other chemicals.

More detailed information can be found in the technical supporting documents for propanil referenced in this RED document. The revised risk assessments and related addenda are not included in this document, but are available in the Public Docket or on the Agency's web page at <http://www.epa.gov/pesticides/reregistration/status.htm>.

## Summary of Mitigation

Pesticide mixer, loader and applicator risks will be mitigated by a combination of reduced application rates, increased personal protective equipment, use of engineering controls, cancellation of the propanil small grain use, revised label language and development and the submission and review of worker exposure (bio-monitoring) data by the Propanil Task Force II. Specifically, the following mitigation measures will reduce risks to agricultural workers and wildlife:

- Establish a 7-day water holding (discharge) interval in the Mississippi Delta (Arkansas, Mississippi, Missouri and Northern Louisiana) & California; a 10-day discharge interval in Texas; and a 15-day discharge interval in Southern Louisiana to eliminate Agency risk concerns for aquatic species, including those for endangered species;
- Spray drift management practices consistent with best management practices for rice;
- Require engineering controls including closed cabs and closed mixing/loading systems;
- All labels with use directions on rice must be amended to specify restrictions against application to fields where catfish farming is practiced and draining water from treated fields into areas where catfish farming is practiced;
- All registered propanil labels must be revised to specify a 60-day plant-back interval for all rotational crops;
- Voluntary cancellation of use on the small grains (spring (hard red) wheat, oats, spring barley and durum wheat);
- Development of toxicity and fate data on the major metabolic degradate of propanil, 3,4-DCA;
- Maintain a reentry interval of 24 hours for rice;
- For turf, the registrant has agreed to reduce the maximum application rate on turf to 5 lbs. a.i./acre and eliminate aerial applications of propanil to turf; and
- Development and submission of worker exposure (bio-monitoring) data for the liquid formulation.

In addition, the following mitigation is needed unless EPA determines, based on the bio-monitoring data currently under review, that lesser or no mitigation is warranted:

- Reduce maximum seasonal application rate to 6 lbs. a.i./acre; and
- Reduce maximum number of acres treated to 500 per day.



## I. Introduction

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (hereafter referred to as EPA or “the Agency”). Reregistration involves a thorough review of the scientific database underlying a pesticide’s registration. The purpose of the Agency’s review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether or not the pesticide meets the “no unreasonable adverse effects” criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. FQPA amends FIFRA to require tolerance reassessment of all tolerances in existence at the time of enactment by 2006. The Agency has decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through the reregistration process.

FQPA also amends FFDCFA to require a safety finding in tolerance reassessment based on factors including an assessment of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.” The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect as would a high level of exposure to any one of the other substances individually. The Agency does not have sufficient information at this time to determine whether the acetanilide pesticides, such as propanil, share a common mechanism of toxicity. Further, the Agency is in the process of developing criteria for screening and testing chemicals for endocrine disruption potential and plans to implement an Endocrine Disruptor Screening Program in the near future. Propanil will be reevaluated at that time and additional testing may be required.

This document presents the Agency’s decision regarding the reregistration eligibility of the registered uses of propanil, including the consideration of risk to infants and children for any potential food, drinking water, dermal, inhalation or oral exposures. The tolerance reassessment decision on propanil was published in the *Federal Register* on June 5, 2002 [OPP-2002-0033; FRL-7179-4]. In an effort to simplify the Reregistration Eligibility Decision (RED), the information presented herein is summarized. More detailed information can be found in the technical supporting documents (risk assessments) for propanil referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available on the Agency’s website at <http://www.epa.gov/pesticides/reregistration/status.htm>, and in the OPP Public Docket.

This document consists of six sections. Section I is the introduction. Section II provides a profile of the use and usage of propanil and its regulatory history. Section III gives an overview

of the human health and environmental effects risk assessments, based on the data available to the Agency. Section IV presents the reregistration eligibility and risk management decisions for propanil. Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Finally, in Section VI, the Appendices list all related documents and how to access them, and the Data Call-In (DCI) information.

## II. Chemical Overview

### A. Regulatory History

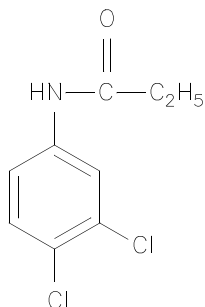
Propanil was the subject of a Reregistration Standard Guidance Document that was issued on December 23, 1987 and the Residue Chemistry Science Chapter of the Guidance Document was issued on August 26, 1987. These documents summarized the regulatory conclusions based on available residue chemistry data and specified the updated generic and product-specific chemistry data required by the Agency to support the continued use of propanil.

In addition to the data requirements imposed in the 1987 Guidance Document, a Data Call-In (DCI) notice dated June 9, 1989, required the registrant to analyze their propanil products for halogenated dibenzo-p-dioxin and dibenzofuran contaminants. Based on the submitted data, the Agency does not expect any potential for the formation of halogenated dibenzo-p-dioxin and dibenzofuran contaminants in measurable quantities during the manufacture of propanil. The Agency issued subsequent DCIs for propanil on July 1, 1994 and October 13, 1995. These data received in response to the DCIs were used to reach the reregistration eligibility conclusions for propanil that are presented in this RED.

In June of 2002, EPA issued a tolerance reassessment decision for propanil and released the human health and ecological risk assessments for public comment [OPP-2002-0033; FRL-7179-4]. Comments were received from the Propanil Task Force II and the California Department of Pesticide Regulation.

Subsequent to the tolerance reassessment, the use of propanil on the small grains (spring (hard red) wheat, oats, spring barley and durum wheat) was voluntarily cancelled by the technical registrants (Dow AgroSciences, LLC and RiceCo, LLC). The Agency announced receipt of written requests from the registrants to amend or voluntary cancel certain pesticide registrations and published the proposed cancellation for 30-day public comment in the *Federal Register* on June 27, 2003 [OPP-2003-0069; FRL-7310-6]. The Agency did not receive any comments. The Agency intends to allow the sale and distribution of existing stocks of the affected propanil products by the registrants for 12 months after publication of this Notice, until July 28, 2004. In a subsequent *Federal Register* notice, the Agency plans to issue a Cancellation Order granting the requested cancellation. As a follow-up to the voluntary cancellation of the small grain use, the Agency will propose revocation of the established tolerances for the unsupported uses of Barley, grain; Barley, straw; Oat, grain; Oat, straw; Wheat, grain; and Wheat, straw.

## B. Chemical Identification



Propanil is a medium to dark grey crystalline solid with a melting point of 87° to 89° C, density of 1.25 g/ml, vapor pressure of  $2.6 \times 10^{-7}$  mm Hg at 30 ° C and an octanol/water partition coefficient ( $P_{ow}$ ) of 193. Propanil is slightly soluble in water (0.13 g/L at 20° C) and is completely soluble in ketones, alcohols, ethers and chlorinated hydrocarbons.

- **Common Name:** Propanil [BSI, ISO & WSSA]
- **CAS NT-1 Systematic Chemical Name:** N-(3,4-dichlorophenyl)propanamide
- **Other Name:** 3',4'-dichloropropionanilide [IUPAC]
- **Chemical Family:** Acetanilide
- **Case Number:** 0226
- **CAS Registry Number:** 709-98-8
- **OPP Chemical Code:** 028201
- **Empirical Formula:** C<sub>9</sub>H<sub>9</sub>Cl<sub>2</sub>NO
- **Molecular Weight:** 218.1 g/mole
- **Trade Name:** Stam<sup>®</sup> and SuperWham<sup>®</sup>
- **Basic Manufacturer(s):** Dow AgroSciences, LLC and RiceCo, LLC

### C. Use Profile

The following is information on the currently registered uses of propanil products with an overview of use sites and application methods. A detailed table of the uses of propanil eligible for reregistration is contained in Appendix A.

|  |   |
|--|---|
| <b>Type of Pesticide:</b>                | Herbicide   |
| <b>Summary of Use:</b>                   | Propanil is a selective post-emergent general use herbicide registered to control broadleaf and grass weeds in commercial settings. Propanil is used alone and in combination with bensulfuron, carfentrazone, molinate, pendimethalin, quinclorac, thiobencarb and triclopyr.  |
| <u>Food:</u>                             | Propanil is used on rice, primarily in California and the mid-southern states (Arkansas, Louisiana, Mississippi, Missouri and Texas). Use on the small grains (spring (hard red) wheat, oats, spring barley and durum wheat) was voluntarily cancelled by the registrants.  |
| <u>Non-Food:</u>                         | Propanil is also registered (but not currently marketed) for turf use at commercial sod farms.  |
| <u>Residential:</u>                      | There are no existing or proposed residential uses of propanil products.  |
| <b>Target Pests:</b>                     | Barnyardgrass (watergrass), brachiaria, coffeeweed, crabgrass, croton, curly indigo, duckweed, foxtail, goose grass, gulf cockspur, mexicanweed, miller, morning glory, northern jointvetch, paragrass, pigweed, redstem, sesbania, small flower umbrella plant, smartweed, sourdock, spearhead, sprangletop and wiregrass. |
| <b>Formulation Types:</b>                | Formulated as an emulsifiable concentrate liquid (16.6-58% active ingredient (a.i.)), a water dispersible granule (or dry flowable) (59.6-81% a.i.), a soluble concentrate liquid (41.2-80.2% a.i.) and a flowable concentrate liquid (41.2% a.i.).   |
| <b>Methods and Rates of Application:</b> |   |
| <u>Equipment:</u>                        | Propanil is typically applied as a broadcast treatment with groundboom sprayers and aerial equipment.   |

Application Rates: The crops with their corresponding maximum application rates are as follows:

- **Rice:** the maximum seasonal application rate is 8 lbs. a.i./acre per season (from two 4 lbs. a.i./acre applications) or a single 6 lbs. a.i./acre emergency treatment; and
- **Sod Farms:** the maximum application rate is 10 lbs. a.i./acre.

Timing: Applied during the post-emergent phase (March through May) and requires an average temperature of 70° F to be effective.

**Use Classification:** General use.

#### **D. Estimated Usage of Pesticide**

Table 1 summarizes the best estimates available for the uses of propanil. The estimate for total domestic use (annual average) is approximately seven million pounds of active ingredient on approximately two million acres treated. Fifty to seventy percent (50% to 70%) of the U.S. rice crop is treated with propanil. The use of propanil on the small grains (spring (hard red) wheat, oats, spring barley and durum wheat) was voluntarily cancelled by the registrants.

**Table 1. Propanil Usage Summary.**

| Site   | Lbs. Active Ingredient Applied (Wtd. Avg.) <sup>1</sup> | Percent Crop Treated (Estimated Maximum) | Percent Crop Treated (Wtd. Avg.) <sup>1</sup> |
|--------|---|--|---|
| Barley | 1,000   | 0%                                       | 0%  |
| Oats   | 39,000  |  |   |
| Rice   | 7,030,000   | 67%                                      | 53%   |

<sup>1</sup> Wtd Avg (weighted average) = the most recent years and more reliable data are weighted more heavily.

Estimated Maximum = the maximum percentage amount applied as estimated from available data.

Average application rates are calculated from the weighted averages.

Usage data primarily covers 1990 through 2000.

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

- to the nearest 1,000 for acres treated or lbs. a.i. (Therefore 0 = < 500)
- to the nearest whole percentage point for % of crop treated. (Therefore 0% = < 0.5%)

Sources: EPA proprietary data, USDA/NASS, CAL EPA and National Center for Food and Agricultural Policy. EPA's June 11, 2001 estimates of propanil usage have been updated to include newly available data (EPA proprietary usage data covering the 2000 growing season) and usage information submitted to the Agency by the Propanil Task Force II at the SMART meeting on April 17, 2001.



### **III. Summary of Propanil Risk Assessments**

The following is a summary of EPA's human health and ecological effects risk findings and conclusions for the post-emergent acetanilide pesticide propanil, as presented fully in the documents: "Propanil. Human Health Risk Assessment (Revised)," dated February 28, 2002; "Review of Propanil Incident Reports," dated October 11, 2001; "Propanil: Report of the Hazard Identification Assessment Review Committee," dated August 15, 2001; "Review of Environmental Fate and Ecological Effects for the Reregistration Eligibility Decision (RED) for Propanil," dated October 4, 2001; and subsequent addenda which are cited within the RED.

The purpose of this section is to summarize the key features and findings of the risk assessments in order to help the reader better understand the conclusions reached in the assessments. Risks summarized in this RED document are those that result only from the use of propanil. While the risk assessments and related addenda are not included in this RED, they are available from the OPP Public Docket and may also be accessed on the Agency's website at <http://www.epa.gov/pesticides/reregistration/status.htm>.

#### **A. Human Health Risk Assessment**

##### **1. Dietary Risk from Food**

A brief overview of the toxicity studies used for endpoints in the dietary risk assessment is outlined below in Table 2. Further details on the toxicity of propanil can be found in the "Human Health Risk Assessment (Revised)," dated February 28, 2002 (including addendum, dated May 14, 2003) and the "Propanil Toxicology Disciplinary Chapter of the Reregistration Eligibility Decision Document," dated November 9, 2001.

##### **a. Toxicity of Propanil**

The Agency has reviewed all toxicity studies submitted for propanil and has determined that the toxicological database is minimally adequate for hazard characterization. The toxicity studies submitted to support guideline requirements are supplemented by relevant open literature publications.

In general, propanil has low acute toxicity although primary eye irritation is observed in rabbits (see Table 6). The principal toxic effect of propanil is methemoglobinemia and hemolytic anemia, which is seen in different species, in studies of varying lengths of time. Methemoglobinemia results in the development of hemolytic anemia which is associated with decreases in hemoglobin, red blood cell (RBC) count and packed cell volume.

Other than slightly decreased fetal body weights (with or without accompanying delays in skeletal ossification), there was no evidence of quantitative susceptibility following *in vivo* exposures to rats and rabbits (MRIDs 00058588-89 and 45518801, respectively) or following pre- or post-natal exposure to rats for two-generations (MRID 44604301). However, there was

evidence consistent with endocrine disruption (delayed vaginal opening and balanopreputial separation in adolescent females (signs of sexual development) and decreased mean sperm count in adult males) in the 2-generation reproduction rat study which indicated a qualitative susceptibility to the offspring. It should be noted that these possibly endocrine-related effects were seen at levels 6x higher than the methemoglobin endpoints used throughout the propanil risk assessments. Also, there is evidence in the peer-reviewed literature that propanil has immunotoxic potential.

No appropriate endpoints (effects) attributable to a single exposure (dose) were identified in any study including the rat or rabbit developmental toxicity study and a special nonguideline 30-day single- and repeated-dose methemoglobin study (MRID 45829301); therefore, an acute RfD was not established and EPA has not assessed acute dietary risk for propanil.

A common toxicological endpoint (methemoglobinemia) was selected for assessment of short- and intermediate-term exposure by oral, dermal (oral equivalent) and inhalation (oral equivalent) routes and are all based on the LOAEL (9.0 mg/kg/day) in the chronic toxicity/carcinogenicity study in rats. Exposures via these routes can be aggregated for each scenario. A common toxicological endpoint for propanil (increased methemoglobinemia, increased spleen weight in females and observations of small seminal vesicles and prostates in males) was selected for long-term exposure by oral, dermal (oral equivalent) and inhalation (oral equivalent) routes. Exposure via these routes can also be aggregated for this scenario.

The Agency has concluded that methemoglobin levels in the nonguideline 30-day methemoglobin study were adversely affected in male and female rats following 5 or more repeated doses of propanil at doses of 25 and 28 mg/kg/day (the lowest dose tested in males and females). Therefore, the special methemoglobin study did not provide doses that could be used in repeated-dose dietary/oral risk assessments for propanil, since the LOAEL from the chronic study was previously established at 9 mg/kg/day.

Risk assessment for chronic dietary, short- and intermediate-term dermal and inhalation exposures are all based on the LOAEL of the combined chronic toxicity/carcinogenicity study in rats. The methemoglobin findings in this study, coupled with the nonguideline 30-day study, show an extremely sensitive toxic response to propanil exposure. Other studies, such as the 28-day dermal toxicity study, more typically used for short- and intermediate-term worker exposures, did not assess this key effect. Based on a comparison of oral and dermal toxicity studies in rabbits, an (upper-bound) estimate of 20% has been calculated for dermal absorption. A 100% absorption rate was applied to inhalation exposure.

For chronic (cancer) dietary risk assessment, the Agency has classified propanil into the category *“Suggestive evidence of carcinogenic potential by all routes of exposure, but not sufficient to assess human carcinogenic potential.”* However, considering the nonmutagenicity of propanil, the available evidence for carcinogenicity did not reach the Agency’s criteria for classification as *“Likely to be carcinogenic in humans.”* Therefore, a quantified carcinogenic

assessment is not indicated for propanil and no mitigation measures are necessary to address chronic (cancer) dietary risk for propanil.

Propanil has been reported to be contaminated (at a low level) with the cytochrome P450 enzyme inducers 3,3',4,4'-tetrachloroazobenzene (TCAB) and 3,3',4,4'-tetrachloroazoxybenzene (TCAOB), which are structural analogs of 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD), and produce typical dioxin-like effects, although with 2 to 6 times less potency than dioxin. Combined chronic toxicity/carcinogenicity studies are not available for TCAB or for TCAOB. The *specific* endpoint(s) and related dose levels that may be observed in chronic toxicity studies, or the *specific* carcinogenic potential of these compounds is not known. However, since TCAB and TCAOB have been present in all toxicological test materials used to evaluate propanil risk, including test material for the combined chronic toxicity/carcinogenicity studies cited above, the Agency believes that propanil risk (*including carcinogenic potential*) has not been underestimated.

#### **b. FQPA Safety Factor**

Since EPA's 2002 tolerance reassessment of propanil, the Propanil Task Force II has submitted new data, a nonguideline 30-day repeat dose, dietary toxicity study in rats. These new data have enabled the Agency to better understand the toxic mode of action of propanil and precipitated a reconsideration of previous uncertainties related to pre- and post-natal toxicity. For a full discussion of changes to the propanil risk assessment see, "Propanil: Addendum to the Revised Human Health Risk assessment," dated May 14, 2003. In summary, the Agency's HIARC determined that the weight-of-evidence supports a receptor-mediated rather than a neurologically-mediated endocrine mode of action. On that basis, it was concluded that a developmental neurotoxicity study was not needed for propanil. However, in order to confirm the receptor-mediated endocrine mode of action, an *in vitro* androgen receptor binding assay is required. Further, the HIARC concluded that a 3x factor is sufficient to account for the lack of the androgen receptor assay. This factor is now referred to as a database uncertainty factor (UF<sub>DB</sub>). The HIARC felt that a 3x factor was sufficient in this case because the methemoglobin findings, an extremely sensitive toxic response to propanil exposure, utilized universally for endpoint and dose selection in the risk assessments for propanil, were observed at doses approximately 6 times lower than the dose where possible endocrine related effects were observed.

The net effect of the HIARC's reevaluation of propanil was a reduction of the FQPA safety factor from 10x to a 1x.

#### **c. Population Adjusted Dose**

Dietary risk is characterized in terms of the Population Adjusted Dose (PAD), which reflects the RfD, either acute or chronic, that has been adjusted to account for the FQPA SF.

## 1) Acute PAD

As discussed in Section III.A.1.a, EPA has not assessed acute dietary risk for propanil because no appropriate endpoint attributable to a single exposure (dose) could be identified. As a result, an acute dietary RfD was not established.

## 2) Chronic PAD

The total uncertainty factor (UF) for the propanil cPAD is 1,000 (10x for inter-species extrapolation, 10x for intra-species variability and 10x for data base uncertainty plus uncertainty associated with the lack of a NOAEL. Consequently, the cRfD and the cPAD are both 0.009 mg/kg/day. The Agency has determined that a 3-fold factor would be sufficient to address the NOAEL to LOAEL uncertainty, based upon the rationale noted in the chronic/carcinogenicity study in rats, that increases in methemoglobin at the low dose of 9 mg/kg/day were not significant for males at any time point evaluated. For low-dose females (11.5 mg/kg/day), the increases were significant at weeks 13, 26 and 52, but not at 78 or 104/105. These data demonstrate a NOAEL for increased methemoglobin at 9 mg/kg/day in males and suggest that the low-dose findings in females are very likely near the threshold of response. This indicates that a 3-fold uncertainty factor should be adequate for the extrapolation of LOAEL to NOAEL for this endpoint. A  $UF_{DB}$  of 3x is applied for the absence of an assessment of anti-androgenic potential.

**Table 2. Summary of Propanil Dietary Toxicity Endpoints.**

| Exposure Scenario   | Dose (mg/kg/day)   | Endpoint   | Study (MRID No.)  |
|---|--|--|---|
| Acute Dietary   | No appropriate endpoint attributed to a single dose was identified; therefore, an acute RfD was not established. |  |   |
| Chronic (Noncancer) Dietary   | LOAEL = 9.0<br>UF = 100<br>$UF_{DB} + UF_L = 10$<br>Total UF = 1,000   | Increased methemoglobin; increased spleen weight in females; and enlarged seminal vesicles/prostates in males. | Chronic toxicity/carcinogenicity study in rats (43303201) |
| <b>Chronic RfD = 0.009 mg/kg/day    Chronic PAD = 0.009 mg/kg/day</b> |  |  |   |

### d. Exposure Assumptions

Chronic dietary exposure was estimated using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), Version 1.3, which incorporates consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. The CSFII data are based on the reported food consumption by more than 20,000 individuals over two nonconsecutive survey days. For the chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups. Exposure estimates are reported in mg/kg body weight/day, and risk is expressed as a percent of the cPAD.

For the propanil chronic dietary risk assessment, the Agency used DEEM-FCID™ along with average residue estimated from field trial data, and estimated 70 to 88% of the rice crop was treated with propanil. Field trial data are generally considered to be an upper-bound estimate of actual residues. The registrant reports that total propanil usage is declining based on an observed decline in the overall use rate (lbs. a.i./acre) and the number of applications per season. Thus, actual dietary risk is likely to be less than indicated by the Agency's assessment.

Food and Drug Administration (FDA) monitoring data are available, but not sufficient for use in the chronic dietary exposure assessment, due to lack of analysis for 3,4-DCA. The Agency's Metabolism Assessment Review Committee (MARC) has reviewed the propanil toxicology and metabolism data (meeting dates of January 16, 1996 and August 7, 2001) and concluded that human health risk assessment should be based on estimates of exposure to propanil (parent), 3,4-DCA and related residues convertible to 3,4-DCA. 3,4-DCA is assumed to be of equal toxicity to the parent.

3,4-DCA is also a metabolite of two other pesticides, linuron and diuron. However, the MARC does not recommend aggregating residues of 3,4-DCA for the propanil, linuron and diuron risk assessments. 3,4-DCA is a degradate of these three pesticides; however, it is only a significant residue of concern for propanil. 3,4-DCA is not a residue of concern *per se* for linuron or diuron (<1%). The analytical method for quantifying residues of concern from linuron and diuron converts all residues to 3,4-DCA as a *convenience*, but 3,4-DCA was not a significant residue in any metabolism or hydrolysis study. Therefore, the MARC recommended that all residues convertible to 3,4-DCA would be included in the tolerance expression for linuron and diuron because no validated enforcement method was available for the quantification of individual components of the residues of concern.

#### **e. Dietary (Food) Risk Assessment**

##### **1) Acute Dietary Risk**

Acute dietary risk is not assessed for propanil since no appropriate endpoint attributable to a single dose has been identified.

##### **2) Chronic (Noncancer) Dietary Risk**

Chronic dietary risk is calculated by using the average consumption value for food and average residue values on those foods. The chronic dietary (food only) risk estimates associated with exposures to propanil do not exceed the Agency's level of concern (i.e., they are less than 100% of the cPAD) for any population subgroup. The chronic dietary risk estimate is 4% of the cPAD, for the most highly exposed population subgroups, all infants (<1 year) and children 1-5 years. Exposure and risk estimates are summarized in Table 3.

**Table 3. Chronic Noncancer Risk (Food Only).**

| Population Subgroups  | Exposure (mg/kg/day) | % Chronic PAD |
|-----------------------|----------------------|---------------|
| U.S. Population       | 0.000175             | 2%            |
| All Infants (<1 year) | 0.000314             | 4%            |
| Children 1-2 years    | 0.000394             |               |
| Children 3-5 years    | 0.000347             |               |
| Children 6-12 years   | 0.000236             | 3%            |
| Youth 13-19 years     | 0.000165             | 2%            |
| Adults 20-49 years    | 0.000161             |               |
| Females 13-49 years   | 0.000134             |               |
| Seniors 50+ years     | 0.000112             | 1%            |

For more information on chronic dietary risk assessment, please refer to the Dietary Exposure and Risk Analysis sections of the “Human Health Risk Assessment (Revised),” dated February 28, 2002 (including addendum, dated May 14, 2003).

## 2. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through ground and surface water contamination. In modeling for threshold drinking water risks, EPA considers acute (one day), chronic (long-term) and cancer (overall mean) exposure, and uses either modeling or actual monitoring data if available, to estimate those risks. To determine the maximum contribution from water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food and then determines a “drinking water level of comparison” (DWLOC) to determine whether modeled or monitoring exposure estimates exceed this level. Estimated environmental concentrations (EECs) that are above the corresponding DWLOC exceed the Agency’s level of concern.

In the case of propanil, an acute drinking water assessment was not conducted because an acute endpoint was not identified. The calculated chronic DWLOCs for propanil are 86 parts per billion (ppb) for children, 266 ppb for adult females and 308 ppb for adult males (see Table 5). Propanil and its principal metabolic degradate, 3,4-DCA, and residues convertible to 3,4-DCA are the residues of concern for the drinking water risk assessment. Monitoring data for propanil residues in ground and surface water are available but not adequate to develop EECs for the aggregate dietary (food and water) risk assessment. Although not targeted to specific propanil use areas, USGS monitoring data do provide some information on the magnitude and frequency of propanil and 3,4-DCA detections.

### a. Surface Water

*Modeling:* Estimated surface water (drinking water) concentrations are based on the Agency’s Exposure Analysis Modeling System (EXAMS) model, which is a Tier II assessment

that provides more refined, less upper-bound assumptions. A range of EECs representing rice paddy water was generated to represent different rice growing areas and normal vs. overflow release of paddy flood water.

*Monitoring:* At the present time, the Agency has limited monitoring data on the concentrations of propanil and 3,4-DCA in surface water. The U.S. Geological Survey (USGS) National Water Quality Assessment Program (NAWQA) reported in its pesticide occurrence and concentrations (database) for 62 agricultural streams (1992-1996) a detection rate for propanil of 2.6% of the 1,560 surface water samples analyzed, with a maximum concentration of 2 ppb. 3,4-DCA is a common degradate for propanil, linuron and diuron. A USGS study analyzed 346 water samples collected in Arkansas, Mississippi, Missouri and Northern Louisiana (mostly creeks, bayous and rivers) from February 1996 to February 2001 (sampling every 2 weeks to monthly) and showed that 3,4-DCA did not exceed 26 ppb in surface water (96.2% detection rate, 333 detections, 13 nondetections). Overall, concentrations ranged from below the detection limit of 0.05 ppb to 26 ppb, with the majority of the sample detections being <1 ppb. 3,4-DCA was detected in these regions year-round; higher concentrations were generally associated with the use period. In south Louisiana, there were only three samples analyzed for 3,4-DCA, with concentrations ranging from 0.01 to 0.06 ppb. 3,4-DCA detections in Arkansas, Mississippi, Missouri Northern Louisiana are likely the result of propanil applied to rice, since rice is the predominant crop in the area and the only one that receives propanil applications. All detections are well below the DWLOCs.

The Agency does not have a generally accepted model for predicting concentrations (EECs) in surface water from use of pesticides in rice paddies, therefore, a *provisional* screening calculation methodology was developed for rice. This method models drinking water concentrations for the primary rice growing regions in the U.S. (California, the Gulf Coast and the Mississippi Valley). The approach taken for the drinking water assessment was based on a hypothetical rice paddy, 1 hectare in size, flooded to a depth of 10 cm, with a sediment interaction zone of 1 cm. Estimated drinking water concentrations are based on the *Index Reservoir* in Shipman, Illinois, a 144,000 m<sup>3</sup> reservoir in a 172-hectare watershed. Based on the default Percent Cropped Area (PCA) factor of 0.87, the Agency assumed that there would be a maximum of 150 hectares of rice paddies in the watershed.

The primary way that rice culture causes contamination of surface water with pesticides is through release of the flood water from the paddy, occurring when precipitation causes overflow of the levee or through the intentional release of the paddy water as part of the agricultural management of the rice paddy. The peak drinking water concentration is the concentration in the paddy on the day of release of all 150,000 m<sup>3</sup> of paddy water into the reservoir on day 78 in California (i.e., normal release 90 days after planting), day 28 for the Gulf Coast (simulating a large storm 40 days after planting) and on day 43 in the Mississippi Valley (simulating a normal draining of the paddies). Please see Table 4 below for more detail. A chronic concentration was obtained by assuming decay of the peak concentration for a year at the aerobic aquatic rate and taking the average of that year. The modeling for drinking water was calculated based on anticipated large storms or intentional release causing runoff at specific times.

**Table 4. Sequence of Events for Rice Culture in Each Major Rice Growing Region.**

| Day   | Rice Growing Region   |   |  |
|-------|---|---|--|
|       | Mississippi Delta<br>(AR, MO, MS, Northern LA)<br>[dry-seeded rice]                           | Gulf Coast<br>(Southern LA, TX)<br>[delayed flood rice]                       | California<br>[permanent flood rice]                             |
| -40   |   | Flood to 4 inches of depth  |  |
| -10   | Seeding   | Seeding   |  |
| -9    | Flush as necessary to keep soil moist   | Drain field immediately for pegging   |  |
| -4    |   |   | Flood to 3 to 4 inches of depth                                  |
| 0     | Emergence   | Emergence   | Seeding  |
| 3-5   | Flush as necessary to keep soil moist   | Keep field moist  | Hold flood of 4 to 6 inches                                      |
| 7     |   |   |  |
| 10    |   |   |  |
| 15    | Keep soil moist<br>Application (not-typical)  | Keep soil moist until permanent flood. Partially drain or let water evaporate | Drain field or allow to evaporate                                |
| 21    | Keep soil moist   |   | Application  |
| 25    | Application (typical)   |   | Re-flood and hold flood  |
| 27    | Permanent flood to 4 inches of depth  |   |  |
| 28    |   |   |  |
| 31    |   |   |  |
| 33    | Permanent Flood<br>(3 <sup>rd</sup> Application, if needed, for rescue (not typical anymore)) | Permanent Flood   | 2 <sup>nd</sup> Application, if needed<br>(leave water standing) |
| 43    | Permanent Flood   |   |  |
| 45    |   |   |  |
| 46-59 |   |   |  |



| Day     | Rice Growing Region   |   |   |
|---------|---|---|---|
|         | Mississippi Delta<br>(AR, MO, MS, Northern LA)<br>[dry-seeded rice] | Gulf Coast<br>(Southern LA, TX)<br>[delayed flood rice] | California<br>[permanent flood rice]        |
| 60      | Permanent Flood   | Permanent Flood   | Raise water depth to at least 6 to 8 inches |
| 105     | Release Flood   | Release Flood   |   |
| 118-120 |   |   | Release Flood                               |
| 126     | Harvest   | Harvest   |   |
| 140     |   |   | Harvest                                     |

**b. Ground Water**

*Modeling:* Estimated ground water concentrations are based on the Screening Concentration in Ground Water (SCI-GROW) model, which is a Tier I assessment that provides a high-end estimate. This model is based on a regression approach which relates the concentrations found in ground water in Prospective Ground Water studies to the aerobic soil metabolism rate and soil-water partitioning properties of the chemical. The modeled drinking water EEC for ground water (0.4 ppb) is below the DWLOC for all population subgroups (see Table 5). The SCI-GROW EECs were  $\leq 0.001$  ppb, indicating that propanil and 3,4-DCA will not be found in high concentrations in ground water as compared to targeted monitoring data. However, both the modeling and the monitoring show results that are below the DWLOC.

*Monitoring:* The Agency has limited monitoring data on the concentrations of propanil in ground water. Validated monitoring data for propanil for the states of California, Arkansas, Missouri, and Mississippi shows that propanil was detected in 2 wells out of a total of 124 wells sampled in Missouri. The range of concentration was 0.06 to 0.07 ppb. The USGS NAWQA program analyzed pesticide occurrence and concentrations for major aquifers and shallow ground water in agricultural areas. Maximum propanil concentration in 933 samples, collected from major aquifers was 0.015 ppb (detection limit of 0.01 ppb). The maximum propanil concentration in 301 samples from shallow ground water sites was 0.015 ppb, which is higher than the predicted concentrations using the SCI-GROW model. The NAWQA data was “not targeted” to propanil use areas. Estimates from the modeling are higher than the limited existing surface water monitoring data for propanil targeted to the pesticide use area.

**Table 5. Comparison of Calculated Chronic DWLOCs and EECs for Propanil and 3,4-DCA.**

| Population Subgroup | cPAD (mg/kg/day) | Chronic Food Exposure (mg/kg/day) | Maximum Chronic Water Exposure (mg/kg/day) | Groundwater EEC (Rice) (ppb) | Surface Water EEC <sup>a</sup> (Rice) (ppb)<br>Based on Propanil and 3,4-DCA | Chronic DWLOC (ppb) |
|---------------------|------------------|-----------------------------------|--|------------------------------|--|---------------------|
| Children            | 0.009            | 0.000394                          | 0.008606                                   | 0.4                          | Range of 6 to 72   | 86                  |
| Females             |                  | 0.000134                          | 0.008866                                   |                              |  | 266                 |
| Males               |                  | 0.000196                          | 0.008804                                   |                              |  | 308                 |

<sup>a</sup> For surface water, this range of EECs reflect different geographic areas and climactic conditions for the propanil growing regions.

For more information on drinking water risks and the calculations of the DWLOCs, see the Water Exposure section of the “Human Health Risk Assessment (Revised),” dated February 28, 2002 (including addendum, dated May 14, 2003); the Water Resource section of the “Review of Environmental Fate and Ecological Effects for the Reregistration Eligibility Decision (RED) for Propanil,” dated October 4, 2001, Appendix E, for model assumptions and inputs; and the “Tier I Drinking Water Estimated Environmental Concentrations for Propanil and its Major Degradate, 3,4-dichloroaniline (3,4-DCA) from Use on Rice,” dated September 14, 2001.

### 3. Residential and Other Nonoccupational Risk

Propanil is not registered for residential (home) use, nor is it used in or around public buildings, schools or recreational areas where children might be exposed. Thus, there is no residential exposure to aggregate with the dietary exposure.

The turf use will be restricted to commercial sod farms only. Although propanil-treated sod may eventually be used in residential settings (i.e., residential lawns), residues are not expected to exceed the level of concern for residential post-application risk since the use on turf is post-emergent (applied at sod farms early in the growing season, when the turf is immature, well before harvest). The Agency concludes that the amount of time between treatment and transplant is adequate to allow residue dissipation to a level that would not pose any significant exposure to residents.

### 4. Aggregate Risk

The aggregate risk assessment for propanil examines the combined risk from exposure through food and drinking water *only*. There are no residential exposure scenarios since there are no residential uses for propanil. As detailed above for propanil, the only interval of exposure to be assessed is chronic (one year or more) and the only route of exposure to be assessed is oral

(food and water). Generally, combined risks from these exposures that are less than 100% of the cPAD, are not considered to be a risk concern.

The surface water EECs (ranging up to 72 ppb) are below the DWLOCs for all population subgroups. This range was derived from different modeling runs representing propanil use practices in different rice growing areas.

EPA has also considered the potential for aggregate exposure to 3,4-DCA from multiple pesticides. Available data indicates that 3,4-DCA is a major metabolic degradate of propanil. 3,4-DCA is also a metabolite of linuron and diuron, but to a much lesser extent. The Agency's MARC recommended not aggregating residues of 3,4-DCA for the propanil, linuron and diuron risk assessments because only propanil use results in significant residues of 3,4-DCA. Submitted data indicate that the maximum amount of 3,4-DCA formed from propanil is approximately 50% of propanil initially applied, based on results from the aerobic soil metabolism study (MRID 41538701). Neither linuron nor diuron metabolize to 3,4-DCA in appreciable amounts, less than 1% of the parent compound in animal, plant and water metabolism studies.

## **5. Occupational Risk**

People can be exposed to a pesticide while working through mixing, loading and application activities, when guiding aerial applications (flaggers) and when reentering a treated site. Worker risks are estimated by Margins of Exposures (MOEs) which determine how close the occupational exposure comes to a NOAEL. Generally, MOEs greater than 100 are not of concern. The level of concern MOE value for propanil is 300 due to uncertainty related to the lack of a NOAEL for the effect of concern, methemoglobinemia. Therefore, any MOE less than 300 is potentially a risk concern. For workers entering a treated site, MOEs are calculated for each day after application to determine the minimum length of time required before workers can safely reenter.

Occupational risk is assessed for exposure of mixers, loaders, applicators and flaggers (termed "handler" exposure) and for exposure following application (termed "post-application" exposure). Handler risk is based on combining both dermal and inhalation exposures. Post-application risk is assessed for activities such as scouting, irrigating, hand pruning, mechanical weeding and hand harvesting and is based primarily on dermal exposure. For rice, scouting was assessed for post-application exposure. For the turf use on sod farms, activities such as scouting, hand pruning, mechanical weeding, mechanical harvesting, hand harvesting and transplanting were assessed for post-application exposure.

For more information on the assumptions and calculations of potential risks to workers, see the "Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision (RED) Document for Propanil (1<sup>st</sup> Revision)," dated February 8, 2002 and the "Occupational Exposure section of the Human Health Risk Assessment (Revised)," dated February 28, 2001.

### a. Occupational Toxicity

For both short- and intermediate-term dermal and inhalation exposures, propanil MOEs are determined by a comparison of specific exposure scenario estimates to the LOAEL of 9.0 mg/kg/day observed at week 13 in the rat combined chronic toxicity/carcinogenicity study. In the absence of inhalation data, an inhalation absorption factor of 100% was assumed. A dermal absorption factor of 20% was calculated by comparing the LOAEL of oral and dermal rabbit studies. Long-term worker exposure is not expected for propanil because applications are targeted to the early growing season from March through May.

Propanil has low acute toxicity, with toxicity categories of III (oral) and IV (dermal, inhalation and primary skin irritation); no dermal sensitization was observed; however, primary eye irritation was observed in rabbits (toxicity category II). The acute toxicity profile for propanil technical is summarized in Table 6. Table 7 summarizes the toxicity endpoints used in the occupational risk assessment.

**Table 6. Acute Toxicity Profile for Occupational Exposure to Propanil.**

| Guideline No. | Route of Exposure               | MRID No. | Results   | Toxicity Category |
|---------------|---------------------------------|----------|---|-------------------|
| 81-1          | Oral (Rat)                      | 41360801 | * LD <sub>50</sub> = 1,080 mg/kg  | III               |
| 81-2          | Dermal (Rabbit/Rat)             | 41360901 | LD <sub>50</sub> > 2,000 mg/kg  | IV                |
| 81-3          | Inhalation (Rat)                | 41415501 | * LC <sub>50</sub> > 6.1 mg/L   | IV                |
| 81-4          | Primary Eye Irritation (Rabbit) | 41360501 | Iritis, conjunctivitis present in all rabbits, cleared by day 14; corneal opacity cleared by day 4. | II                |
| 81-5          | Primary Skin Irritation         | 41360601 | Slight dermal irritant  | IV                |
| 81-6          | Dermal Sensitization            | 41360401 | Not a dermal sensitizer   | Not Applicable    |

\* LD<sub>50</sub> or LC<sub>50</sub> = Median Lethal Dose or Median Lethal Concentration. A statistically driven dose or concentration of a substance that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation).

**Table 7. Summary of Propanil Occupational Toxicity Endpoints.**

| Exposure Scenario   | Dose (mg/kg/day) | Absorption Factor <sup>a</sup>    | Endpoint  | Study (MRID No.)  |
|---|------------------|-----------------------------------|---|---|
| Short- and Intermediate-Term (Dermal and Inhalation)<br>Target MOE 300 <sup>b</sup> | LOAEL = 9.0      | Dermal = 20%<br>Inhalation = 100% | Increased methemoglobin; increased spleen weight in females; and enlarged seminal vesicles and prostate in males. | Chronic toxicity/carcinogenicity study in rats (43303201) |

<sup>a</sup> Short-/intermediate-term dermal and inhalation exposure is based on a comparison of oral and dermal toxicity studies in rabbits, an (upper-bound) estimate of 20% has been calculated for dermal absorption. A 100% absorption rate was applied to calculate inhalation exposure.

<sup>b</sup> The “target” MOE of 300 includes the standard uncertainty factors of 10x (inter-species extrapolation); 10x (intra-species variability) and an additional 3x for the use of a LOAEL instead of a NOAEL, in the combined chronic toxicity/carcinogenicity study in rats (MRID 43303201), resulting in an uncertainty factor of 300.

For more occupational toxicity information, see the Hazard Profile section of the “Human Health Risk Assessment (Revised),” dated February 28, 2002 and the “Propanil. Toxicology Disciplinary Chapter of the Reregistration Eligibility Decision Document,” dated November 9, 2001.

### **b. Occupational Exposure**

Chemical-specific occupational exposure data were not available prior to the completion of the occupational and residential exposure assessment. Instead, risks to pesticide handlers were assessed using data from the Pesticide Handlers Exposure Database (PHED) Version 1.1, and standard assumptions about average body weight, work day, daily areas treated, volume of pesticide used, etc. The exposure factors (e.g., body weight, amount treated per day, protection factors, etc.) are all standard values used by the Agency, and the PHED unit exposure values are the best available estimates of exposure. EPA is currently reviewing a propanil-specific worker exposure (bio-monitoring) study that was recently completed by the Propanil Task Force II and received by the Agency on September 15, 2003..

Anticipated use patterns, application methods and range of application rates were derived from current labeling. The daily amount treated is based on usage information submitted by the Propanil Task Force II at the SMART meeting on April 17, 2001. Propanil can be applied by groundboom sprayers and aerial equipment. The maximum seasonal application rate is 8 lbs. a.i./acre per season (from two 4 lbs. a.i./acre applications) or a single 6 lbs. a.i./acre emergency treatment. The combined total of all propanil treatments must not exceed 8 pounds of applied product per acre per year. The typical (average) application rate for propanil on rice is 3.1 lbs. a.i./acre per application. For treating turf, the maximum application rate is 10 lbs. a.i./acre per application. There is no information available regarding a typical (average) application rate for turf, since there are no currently marketed turf products. Chemigation is prohibited on all propanil labels.

Occupational handler exposure assessments are conducted using different levels of protection. The Agency typically evaluates all exposures with minimal protection and then considers additional protective measures using a tiered approach (going from minimal to maximum levels of protection) in an attempt to obtain an adequate MOE. The lowest tier is represented by the baseline exposure scenario (i.e., single layer clothing, socks, and shoes), followed by, if MOEs are still of concern, increasing levels of risk mitigation such as personal protective equipment (PPE) and engineering controls (EC). End-use product labels currently specify a wide range of personal protective equipment. Most current propanil labels have the following PPE requirements for handlers: long sleeve shirt, long pants, waterproof gloves, shoes plus socks and protective eye wear. Some labels have additional PPE requirements of chemical-resistant headgear for overhead exposure. The levels of protection that formed the basis for calculations of exposure from propanil activities include:

|                       |  |
|-----------------------|--|
| Baseline:             | Long-sleeved shirt and long pants, shoes and socks.  |
| Minimum PPE:          | Baseline + chemical-resistant gloves and dust/mist respirator.   |
| Maximum PPE:          | Baseline + chemical-resistant gloves, double layer of clothing and a NIOSH-approved respirator with an organic-vapor removing cartridge.   |
| Engineering controls: | Engineering controls such as a package-based system (e.g., water-soluble packaging for wettable powders) or other closed mixing/loading systems and enclosed cockpit, cab or truck. Some engineering controls are not applicable for certain scenarios (e.g., for handheld application methods, there are no known devices that can be used to routinely lower the exposures). |

### **c. Occupational Handler Risk Summary**

The Agency has determined that there are potential exposures to mixer, loader, applicator and other handlers during the usual use patterns associated with propanil. Based on the use patterns, 5 major occupational handler exposure scenarios were identified as follows:

- Scenario (1a) mixing/loading liquids for aerial application to rice and turf;
- Scenario (1b) mixing/loading liquids for groundboom application to rice and turf;
- Scenario (2a) mixing/loading dry flowable for aerial application to rice;
- Scenario (2b) mixing/loading dry flowable for groundboom application to rice;
- Scenario (3) applying sprays for aerial application to rice and turf;
- Scenario (4) applying sprays for groundboom application to rice and turf; and
- Scenario (5) flagging for sprays application to rice and turf.

The dermal and inhalation MOE estimates for propanil were combined based on their having the same endpoint (methemoglobinemia) and dose. MOE estimates were calculated for all scenarios at baseline, minimum PPE, maximum PPE and engineering control level exposures if necessary. A 98% protection factor was applied to the baseline unit exposure values to determine the unit exposure for the engineering control level of protection for the dry flowable scenarios. Results of exposure and risk estimates for each occupational handler exposure scenario are presented in Table 8. For more information on the occupational risks, see the Risk Calculations, Occupational Exposure section of the “Human Health Risk Assessment (Revised),” dated February 28, 2002.

**Table 8. Summary of Occupational Exposure Scenarios/Risk Estimates for Propanil Handlers.**

| Scenario No.   | Crop   | Application Rate <sup>a</sup><br>(lbs. a.i./acre) | Area Treated<br>(Daily)      | Total Short- and Intermediate-term MOE <sup>f</sup> |                            |                            |                                     |            |
|--|--|---|------------------------------|---|----------------------------|----------------------------|-------------------------------------|------------|
|  |  |   |                              | Baseline PPE <sup>b,f</sup>                         | Minimum PPE <sup>c,f</sup> | Maximum PPE <sup>d,f</sup> | Engineering Controls <sup>e,f</sup> |            |
| <i>Mixer/Loader</i>  |  |   |                              |   |                            |                            |                                     |            |
| Mixing/Loading Liquids for Aerial Application (1a)           | Rice   | 6 (maximum application rate)                      | 350                          | 0.5   | 62                         | 85                         | <b>170</b>                          |            |
|  |  |   | 1,200                        | 0.15  | 18                         | 25                         | <b>49</b>                           |            |
|  |  |   | 3,200                        | 0.06  | 7                          | 9                          | <b>18</b>                           |            |
|  |  | 3 (typical application rate)                      | 350                          | 1   | 120                        | 170                        | 330                                 |            |
|  |  |   | 1,200                        | 0.3   | 36                         | 50                         | <b>97</b>                           |            |
|  |  |   | 3,200                        | 0.11  | 14                         | 19                         | <b>36</b>                           |            |
|  | Turf   | 10  | 350                          | 0.31  | 37                         | 51                         | <b>100</b>                          |            |
|  | Mixing/Loading Liquids for Groundboom Application (1b) | Rice  | 6 (maximum application rate) | 80  | 2.3                        | 270                        | 370                                 | --         |
|  |  |   |                              | 200   | 0.9                        | 110                        | 150                                 | <b>290</b> |
| 3 (typical application rate)                                 |  |   | 80                           | 4.5   | 540                        | --                         | --                                  |            |
|  |  |   | 200                          | 1.8   | 220                        | 300                        | --                                  |            |
| Turf   |  | 10  | 80                           | 1.14  | 160                        | 220                        | 440                                 |            |
| Mixing/Loading Dry Flowables for Aerial Application (2a)     | Rice   | 6 (maximum application rate)                      | 350                          | 21  | 22                         | 32                         | 1,100                               |            |
|  |  |   | 1,200                        | 6.3   | 6.6                        | 9.2                        | 320                                 |            |
|  |  |   | 3,200                        | 2.3   | 2.5                        | 3.5                        | <b>120</b>                          |            |
|  |  | 3 (typical application rate)                      | 350                          | 43.0  | 45                         | 63                         | 2,200                               |            |
|  |  |   | 1,200                        | 13.0  | 13                         | 18                         | 640                                 |            |
|  |  |   | 3,200                        | 4.7   | 4.9                        | 6.9                        | <b>240</b>                          |            |
| Mixing/Loading Dry Flowables for Groundboom Application (2b) | Rice   | 6 (maximum application rate)                      | 80                           | 94  | 98                         | 140                        | 4,800                               |            |
|  |  |   | 200                          | 38  | 39                         | 55                         | 1,900                               |            |
|  |  | 3 (typical application rate)                      | 80                           | 190   | 200                        | 280                        | 9,500                               |            |
|  |  |   | 200                          | 75  | 79                         | 110                        | 3,800                               |            |
| <i>Applicator</i>  |  |   |                              |   |                            |                            |                                     |            |
| Applying Sprays for Aerial Application (3)                   | Rice   | 6 (maximum application rate)                      | 350                          | See engineering controls                            |                            |                            | <b>280</b>                          |            |
|  |  |   | 1,200                        |   |                            |                            | <b>82</b>                           |            |
|  |  |   | 3,200                        |   |                            |                            | <b>31</b>                           |            |



| Scenario No.  | Crop | Application Rate <sup>a</sup><br>(lbs. a.i./acre) | Area Treated<br>(Daily) | Total Short- and Intermediate-term MOE <sup>f</sup> |                            |                            |                                     |
|---|------|---|-------------------------|---|----------------------------|----------------------------|-------------------------------------|
|   |      |   |                         | Baseline PPE <sup>b,f</sup>                         | Minimum PPE <sup>c,f</sup> | Maximum PPE <sup>d,f</sup> | Engineering Controls <sup>e,f</sup> |
| Applying Sprays for Aerial Application (3), continued | Rice | 3 (typical application rate)                      | 350                     | See engineering controls                            |                            |                            | 560                                 |
|   |      |   | 1,200                   |   |                            |                            | 160                                 |
|   |      |   | 3,200                   |   |                            |                            | 61                                  |
|   | Turf | 10  | 350                     |   |                            |                            | 170                                 |
| Applying Sprays for Groundboom Application (4)        | Rice | 6 (maximum application rate)                      | 80                      | 370   | --                         | --                         | --                                  |
|   |      |   | 200                     | 150   | 180                        | 230                        | 500                                 |
|   |      | 3 (typical application rate)                      | 80                      | 740   | --                         | --                         | --                                  |
|   |      |   | 200                     | 300   | --                         | --                         | --                                  |
|   | Turf | 10  | 80                      | 220   | 270                        | 350                        | --                                  |
| <i>Flagger</i>  |      |   |                         |   |                            |                            |                                     |
| Flagging for Sprays Application (5)                   | Rice | 6 (maximum application rate)                      | 350                     | 120   | 140                        | 150                        | 5,900                               |
|   |      | 3 (typical application rate)                      |                         | 240   | 290                        | 290                        | 12,000                              |
|   | Turf | 10  | 350                     | 71  | 87                         | 88                         | 3,500                               |

- a Application Rates are based on the maximum application rates listed on current Propanil labels.
- b Baseline dermal unit exposure represents long pants, long sleeved shirt, no gloves, open mixing/loading, open cab tractor and baseline inhalation unit exposure represents no respirator.
- c Minimum PPE for all dermal scenarios include chemical-resistant gloves (90% Protection Factor) and minimum PPE for all inhalation scenarios include a dust/mist respirator (5-fold Protection Factor).
- d Maximum PPE for all dermal scenarios include double layer of clothing (50% Protection Factor for clothing) and chemical-resistant gloves (90% Protection Factor) and maximum PPE for all inhalation scenarios include an organic vapor respirator (90% Protection Factor).
- e Engineering Controls for mixer/loader include closed mixing/loading, single layer clothing and scenario 1a and 1b also include chemical-resistant gloves. Engineering Controls for applicators and flaggers include enclosed cockpit, cab or truck, single layer clothing, no gloves.
- f Total MOE (combined dermal and inhalation) =  $1 / ((1/\text{dermal MOE}) + (1/\text{inhalation MOE}))$  where: Short-and Intermediate term dermal MOE = Short- and Intermediate-term NOAEL (9 mg/kg/day)/ Daily Dermal Dose (mg/kg/day) and Short- and Intermediate-term inhalation MOE = Short- and Intermediate-term NOAEL (9 mg/kg/day)/ Daily Inhalation Dose (mg/kg/day).

The level of concern MOE value is 300.

Scenarios calculated MOE exceeds the target MOE at the previous level of mitigation (MOE>300)

**Bolded MOEs** have a risk concern at the highest possible level of mitigation for corresponding scenarios

The target MOE of 300 was **met** or **exceeded** at either the *baseline, minimum PPE, maximum PPE* or *engineering control* levels for many of the short- and intermediate-term occupational exposure scenarios for mixing, loading, applying and flagging during application of propanil to rice and turf.

The combined dermal and inhalation MOEs were **less than** the target MOE of 300 with *maximum risk reduction measures* for the following occupational exposure scenarios:

- Scenario (1a) mixing/loading liquids for aerial application to rice at 350, 1,200 and 3,200 acres at 6 lbs a.i./acre; mixing/loading liquids for aerial application to rice at 1,200 and 3,200 acres at 3 lbs. a.i./acre; and mixing/loading liquids for aerial application to turf at 350 acres at 10 lbs. a.i./acre;
- Scenario (1b) mixing/loading liquids for groundboom application to rice at 200 acres at 6 lbs. a.i./acre;
- Scenario (2a) mixing/loading dry flowable for aerial application to rice at 3,200 acres at 6 lbs. a.i./acre and mixing/loading dry flowable for aerial application to rice at 3,200 acres at 3 lbs. ai/acre; and
- Scenario (3) applying sprays, using aerial application to rice at 350, 1,200, and 3,200 acres at 6 lbs. a.i./acre and applying sprays, using aerial application, to turf at 350 acres at 10 lbs. a.i./acre.

## 1) Post-Application Occupational Risk

Workers can be exposed to propanil residues, at varying levels, by entering previously treated areas to perform certain agricultural activities. Exposure also varies with the level of propanil residue in the environment and the duration of the activity. The Agency is concerned about post-application exposure to crop advisors (scouts) and all other workers (hoers, irrigators, etc.). Most of the current propanil labels show an REI requirement of 24 hours and specify the following early entry PPE: long sleeve shirts, long pants, waterproof gloves, shoes, socks and protective eye wear. A few labels also specify chemical-resistant footwear and chemical-resistant headgear for overhead exposure.

Although the Worker Protection Standard (WPS) provides a basic level of protection for agricultural (pesticide) workers, the reregistration process reexamines the REIs and entry restrictions necessary to protect reentry workers. The WPS prohibits routine entry to perform hand labor tasks during the REI and requires PPE to be worn for other early-entry tasks that require contact with treated surfaces. Lacking propanil-specific data relating to post-application exposure, a reentry exposure assessment has been performed by estimating the amount of residue available (dislodgeable foliar residue (DFR) and/or turf transferrable residue (TTR)) for uptake and by estimating the rate of uptake for specific activities by using “transfer coefficients.”

No propanil-specific DFR or TTR data exist. Instead, the DFR value is based on an estimate of 20% of the rate applied as initial DFR for rice and 5% of the rate applied as initial TTR for turf. A dissipation rate of 10% per day is estimated for rice and turf. Transfer coefficients used in the risk assessment for rice are from the Agricultural Reentry Task Force (ARTF) database. An interim transfer coefficient policy was developed by the Agency’s Science Advisory Council for Exposure using the ARTF database. It is the Agency’s intention that this policy will be periodically updated to incorporate additional information about agricultural practices in crops and new data on transfer coefficients. Much of this information will originate from exposure studies currently being conducted by the ARTF, from the further analysis of studies already submitted to the Agency and from the studies in the published scientific literature.

The rice surrogate assessment uses the lower transfer coefficient of 100 cm<sup>2</sup>/hr associated with minimal foliage development based on propanil’s early season use (application to rice approximately 14 and 35-40 days after planting with harvest at 120-140 days). The sod/turf farm surrogate assessment used a low transfer coefficient of 500 cm<sup>2</sup>/hr for the activities of aerating, fertilizing, mowing and scouting and a high transfer coefficient of 16,500 cm<sup>2</sup>/hr for the activities of transplanting and weeding. Table 9 shows the MOEs for various crops and post-application activities.

**Table 9. Agricultural Post-Application MOEs.**

| Crop | Application Rate (lbs. a.i./A) | Activity <sup>a</sup>   | Days after Treatment | MOE <sup>b</sup> |
|------|--------------------------------|---|----------------------|------------------|
| Rice | 6 (maximum application rate)   | Scouting, minimum foliage development.  | 0 (12 hours)         | <b>293</b>       |
|      |                                |   | 1                    | 325              |
|      | 3 (typical application rate)   |   | 0 (12 hours)         | 585              |
| Turf | 10 (maximum application rate)  | Transplanting.  | 0 (12 hours)         | <b>4</b>         |
|      |                                |   | 41                   | 320              |
|      |                                | Aerating, fertilizing, scouting, mechanically weeding and hand/mechanically harvesting. | 0 (12 hours)         | <b>141</b>       |
|      |                                |   | 8                    | 326              |

<sup>a</sup> Activities from Science Advisory Council on Exposure Policy 3.1. Every activity listed may not occur for every crop in the group.

<sup>b</sup> MOE = NOAEL (mg/kg/day)/dermal dose (mg/kg/day). Target MOE = 300.

MOEs in **bold print** do not meet the target MOE of 300.

The estimated MOE for rice (325) at the maximum application rate (6 lbs. a.i./acre) exceeds the target MOE one day after application (> 24 hours) for scouting (minimal foliage development based on early season use). In addition, the estimated MOE for rice (585) at a typical application rate (3 lbs. a.i./acre) is greater than the target MOE on the day of application (12 hours after application) for scouting (minimal foliage development). All of the post-application exposure scenarios for rice met or exceeded the target MOE of 300, and thus, are not of concern to the Agency.

The estimated MOE for sod farms (4) at the maximum application rate (10 lbs. a.i./acre) **does not meet or exceed** the target MOE of 300 on the day of application for a work activity such as transplanting. In addition, the estimated MOE for sod farms (141) at the maximum application rate (10 lbs. a.i./acre) **does not meet or exceed** the target MOE of 300 on the day of application for activities such as aerating, fertilizing, irrigating, scouting and mechanical harvesting and weeding. Therefore, all of the post-application exposure scenarios for turf **do not meet or exceed** the target MOE of 300, and thus, are of concern to the Agency. A REI of 41 days would result in an MOE greater than the target of 300.

## 2) Human Health Incident Data

In evaluating incidents to humans, the Agency reviewed reports from the National Poison Control Centers (PCC), CA Department of Pesticide Regulation, the National Pesticide Information Center (NPIC) and the Agency's Office of Pesticide Program's Incident Data System (IDS).

In the PCC database, there were a total of 8 cases of propanil exposure reported to Poison Control Centers for the years 1993 to 1998. Of these, 1 case was reported among children under 6 years of age, 2 cases among older children and adults exposed at their workplace and there were 5 nonoccupationally exposed cases. None of these cases reported a major adverse outcome.

Detailed descriptions of 2 cases submitted to the California Pesticide Illness Surveillance Program between 1982 and 1999 were reviewed for workers applying propanil by hand. In the first case, the worker reported a skin rash. In the second case, a worker reported chest pain and heart burn and was later diagnosed with gastritis. In both of these cases, the relationship between exposure and health effects was considered possible.

Since 1992, the Agency has received 2 reports of incidents from various sources including registrants, other federal/state health and environmental agencies and individual consumers. Reports submitted to the Office of Pesticide Program's IDS represent anecdotal reports or allegations only, unless otherwise stated. Typically no conclusions can be drawn

implicating the pesticide as a cause of any of the reported health effects. Nevertheless, sometimes with enough cases and/or enough documentation, risk mitigation measures may be suggested.

In 1997, a 21 year old female reported nausea, muscle weakness, respiratory problems and a skin rash less than 24 hours after spraying a mixture of propanil and MCPA. A review of the exposure circumstances led the registrant's toxicologist to conclude that the reported symptoms were not related to the exposure. A separate incident occurred in 1997, when a 16 year old child was exposed to propanil and reported eye irritation, pain and respiratory irritation. No further information on the disposition of either case was reported.

Morse *et al.* (1979) reported on a health effects evaluation conducted in August 1976 at a plant in rural Arkansas that manufactured methomyl and propanil. Of the 111 workers at the plant, 102 participated in the study. Production workers (28) exposed to dichloroaniline and propanil had symptoms of chloracne, blueness (cyanosis) and skin rash. An acetylcholinesterase test was conducted that showed no significant depression in the workers surveyed and concluded that the occurrence of chloracne in production workers was caused by dichloroaniline and propanil exposure. It should be noted that at the time of the report (1979), technical propanil was reported to be contaminated at a level much higher (up to 14%) than the trace level of contamination currently being reported.

Propanil was not reported to be involved in any human incidents on the list of the top 200 chemicals for which the National Pesticide Information Center (NPIC) received calls from 1984 through 1991, inclusively.

## **B. Environmental Risk Assessment**

A summary of the Agency's environmental risk assessment is presented below. Propanil has two registered use sites: rice and turf. Propanil is currently used on rice crops only. There is no evidence of any application to turf. The small grain use (spring (hard red) wheat, oats, spring barley and durum wheat) has been voluntarily cancelled by the registrants. Although the small grain use was assessed in the HED and EFED assessments for propanil, it will not be presented here since it is no longer registered. The following risk characterization is intended to describe the magnitude of the estimated environmental risks for the rice and turf use sites and any associated uncertainties.

More detailed information associated with the environmental risk from the use of propanil may be found in the "Review of Environmental Fate and Ecological Effects for the Reregistration Eligibility Decision (RED) for Propanil," dated October 4, 2001 (including addenda for risk to mammals and fish, dated September 11, 2002, EFED Response to Registrant Request for a Seven (7) Day Holding Period for Propanil Use in Rice Paddies, dated September

11, 2003 and the memo addressing the change in risk to aquatic plants based upon refined Tier I Rice Model, dated September 24, 2002. The complete environmental risk assessment and its addendum is not included in this RED, but may be accessed in the OPP Public Docket and on the Agency's website at <http://www.epa.gov/pesticides/reregistration/status.htm>.

### Risk Characterization of Rice Use

The uses of propanil on rice may cause adverse ecological effects at the maximum seasonal application rate of 8 lbs. a.i./A/yr (from two 4 lbs. a.i./A applications) in areas where rice is produced, specifically California, Arkansas, Louisiana, Missouri, Mississippi and Texas. The expected risks are: (1) acute risk to birds (including endangered species); (2) acute and chronic risk to mammals (including endangered species); (3) risk to nontarget aquatic nonvascular plants; and (4) potential risk to nontarget terrestrial plants. Any potential risks to freshwater and estuarine/marine fish and invertebrates (including endangered species) is expected to be prevented if the rice paddy water holding periods are fully implemented. Currently, the Agency does not have valid data to determine the risks from propanil use on rice to terrestrial nontarget plants; however, there is one reported incident in Arkansas of moderate-to-severe leaf damage to shade trees planted adjacent to a rice field shortly after application of propanil. In addition, the California Department of Pesticide Regulation has provided comments indicating phytotoxicity problems on prune and related stone fruits associated with the use of propanil on rice. See Section III.B.3 of this RED for more detail.

### Risk Characterization of Potential Turf Use

Although turf is a registered use, there is no current evidence of any applications to turf in the U.S. The potential use of propanil on turf at the current maximum application rate (10 lbs. a.i./acre) may pose: (1) acute risk to birds; (2) acute and chronic risk to small mammals; (3) a risk to aquatic vascular and nonvascular plants and terrestrial plants in semi-aquatic areas; (4) acute risk to freshwater and estuarine/marine fish and invertebrates; and (5) chronic risk to estuarine/marine fish and invertebrates.

#### **1. Fate and Transport**

The environmental fate database is sufficient to identify the exposure associated with propanil use. However, EPA intends to issue a DCI as part of this RED to require additional data for the parent and the major metabolic degradate, 3,4-DCA, to address areas of uncertainty. These data are expected to confirm the conclusions of this environmental risk assessment.

Available data indicates that propanil is of low soil persistence. Based on acceptable studies, propanil is rapidly metabolized under aerobic or anaerobic conditions in a water/soil matrix (laboratory half-life of 2 to 3 days). Propanil is metabolized rapidly in aerobic soil with a

half-life of 0.5 days; however, it is stable to hydrolysis at pHs 5, 7 and 9 in the laboratory and is also stable to unsensitized aqueous photolysis. A supplemental soil photolysis study also suggests that propanil is stable to photodegradation, and the observed transformation was due mainly to metabolic activity. Propanil is susceptible to biodegradation, yet stable to chemical degradation processes.

Propanil has medium mobility in sand, sandy loam and clay loam soils, and has low mobility in silty clay loam and silt loam soils, according to available mobility studies ( $K_{oc}$  values). The partition coefficient ( $K_d$ ) for propanil ranges from 0.538 (sand) to 11 (clay loam), and  $K_{oc}$  values ranged from 306 (sand) to 800 (silt loam), respectively. Acceptable aquatic field dissipation studies observed in rice paddies at two sites indicate short half-lives for propanil in the water (undetectable after no more than one day) and in the soil (sediment detections were near the quantitative limit (0.01 ppm) in 2-7 days). Detectable residues for propanil and 3,4-DCA are confined largely to the top 2 inches of the sediment. 3,4-DCA reached a peak value (2.7 ppm) in soil (sediment) at 1-5 days after the second of two applications, remained high for 1 to 2 weeks and was near detection limits (0.01 ppm) for 4-6 months.

Based on its mobility characteristics (highly soluble, medium  $K_d$  and  $K_{oc}$  values), propanil has the potential to reach ground water, but it is not likely to persist for a sufficient time to leach in amounts that would be above the DWLOC. The possible exception are sites of extreme vulnerability and low metabolic capacity which would most likely occur only for terrestrial uses. However, if propanil does reach ground water in these vulnerable areas, it is expected to be stable.

Due to limited environmental fate data on 3,4-DCA, the Agency is unable to sufficiently assess its environmental fate and transport. EPA has received surface water monitoring data that demonstrate the tendency for 3,4-DCA to leave propanil treated fields during flood release. Overall concentrations ranged from below the detection limit of 0.05 ppb to 26 ppb, with the majority of the sample detections being <1 ppb. 3,4-DCA was detected in these rice growing regions year-round; higher concentrations were generally associated with the use period. The Agency suspects that the primary source of the 3,4-DCA detections was from propanil use, because 3,4-DCA is the primary degradation product of propanil. Although the monitoring data indicates that 3,4-DCA concentrations in surface water may occur from propanil use, EPA requires guideline environmental fate and transport data in order to assess the potential risk of 3,4-DCA to nontarget organisms associated risks.

## **2. Ecological Risks**

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations (EECs) based on environmental fate characteristics and pesticide use data. To evaluate the potential risk to nontarget organisms from the use of propanil products, the Agency calculates a Risk Quotient (RQ), which is the ratio of

the EEC to the most sensitive toxicity endpoint values, such as the median lethal dose (LD<sub>50</sub>) or the median lethal concentration (LC<sub>50</sub>). These RQ values are then compared to the Agency's levels of concern (LOCs) which indicate whether a chemical, when used as directed, has the potential to cause adverse effects on nontarget organisms. When the RQ exceeds the LOC for a particular category (e.g., endangered species), the Agency presumes a risk of concern to that category. The LOCs and the corresponding risk presumptions are presented in Table 10.

**Table 10. LOCs and Associated Risk Presumptions.**

| IF...                                 | THEN the Agency presumes...   |
|---------------------------------------|---|
| <i>Mammals and Birds</i>              |   |
| The acute RQ > LOC of 0.5             | Acute risk  |
| The acute RQ > LOC of 0.2             | Risk that may be mitigated through restricted use                       |
| The acute RQ > LOC of 0.1             | Acute effects may occur in Endangered Species                           |
| The chronic RQ > LOC of 1             | Chronic risk <i>and</i> Chronic effects may occur in Endangered Species |
| <i>Fish and Aquatic Invertebrates</i> |   |
| The acute RQ > LOC of 0.5             | Acute risk  |
| The acute RQ > LOC of 0.1             | Risk that may be mitigated through restricted use                       |
| The acute RQ > LOC of 0.05            | Acute effects may occur in Endangered Species                           |
| The chronic RQ > LOC of 1             | Chronic risk <i>and</i> Chronic effects may occur in Endangered Species |

EPA suspects that 3,4-DCA may also pose risk to nontarget organisms. However, the Agency's risk concerns from exposure to 3,4-DCA are based on limited data (nonguideline supplementary information); therefore, guideline toxicity studies are needed to adequately assess the ecological effects of 3,4-DCA on nontarget organisms.

For a more detailed explanation of the ecological risks posed by the use of propanil, please refer to the Ecological Effects Hazard Assessment and Ecological Risk Assessment sections of the "Review of Environmental Fate and Ecological Effects for the Reregistration Eligibility Decision (RED) for Propanil," dated October 4, 2001 (including mammalian and fish risk addendum, dated September 11, 2002 and EFED Response to Registrant Request for a Seven (7) Day Holding Period for Propanil Use in Rice Paddies, dated September 11, 2003.

**a. Risk to Birds**

**1) Toxicity (Hazard) Assessment**

Propanil is classified as moderately toxic to birds on an acute oral basis since the LD<sub>50</sub> value is between 51 and 500 mg/kg (see Table 11). Additionally, since the LC<sub>50</sub> values fall within the range of 2,861 and >5,000 ppm, propanil is classified as slightly-to-practically nontoxic to birds on a subacute dietary basis. An LC<sub>50</sub> is a statistically estimated measure



(concentration) expected to be lethal to 50% of the test population. Table 11 summarizes the data that support the acute toxicity endpoints used in assessing the risks to birds.

**Table 11. Acute Toxicity Endpoints for Birds.**

| Toxicity Study                               | Test Species <sup>a</sup>                                 | % a.i. | Endpoint                     | Toxicity Category | MRID or Accession No. |
|--|---|--------|------------------------------|-------------------|-----------------------|
| <b>Acute (Single dose by gavage)</b>         |   |        |                              |                   |                       |
| Avian Oral                                   | Northern Bobwhite Quail<br>( <i>Colinus virginianus</i> ) | 97.6   | LD <sub>50</sub> = 201 mg/kg | Moderately Toxic  | 41361001              |
| <b>Subacute (Eight days of treated feed)</b> |   |        |                              |                   |                       |
| Avian Dietary                                | Northern Bobwhite Quail<br>( <i>Colinus virginianus</i> ) | 88.0   | LC <sub>50</sub> = 2,311 ppm | Slightly Toxic    | Acc. 246413           |

<sup>a</sup> Test species observed an additional three days while on untreated feed.

Currently, avian chronic toxicity tests have not been submitted to the Agency, therefore, it is not possible to determine the chronic effects to birds from propanil use. The Agency suspects that propanil may cause adverse chronic effects to birds because historical data suggest parallels to mammalian toxicity.

## 2) Exposure and Risk

The Agency believes that risk to birds is likely because rice paddies provide habitat and abundant food resources for various avian species, particularly migrant waterfowl. The rice growing regions in the U.S. are crucial over-wintering areas for millions of waterfowl and shorebirds of the Central, Mississippi and Pacific flyways. Each year, migratory ducks, geese and shorebirds visit rice fields to build strength for their return flight to northern nesting grounds. In addition, rice paddies in the U.S. are managed as artificial wetlands in order to provide habitat for various avian species. Rice paddies managed as artificial wetland habitats help to replace natural wetland habitats which have been depleted by a rising sea level, subsidence, salt water intrusion through navigation channels, and reduction in the volume of river born sediment. The RQ is 0.39.

The RQs are presented below in Table 12 for the avian risk due to propanil residues on various food items. The labeled use of propanil on rice is expected to result in an exceedence of the LOC for acute risks to birds, including endangered species. For the potential use on turf, an exceedence of the LOC is expected for acute risk to birds, including endangered species.

**Table 12. Avian Acute RQs for Birds from Propanil Application.**

| Use Site  | Application Rate<br>(lbs. a.i./acre) | Food Items               | Maximum EEC<br>(ppm) | Acute RQ<br>(EEC/LC <sub>50</sub> ) |
|---|--------------------------------------|--------------------------|----------------------|-------------------------------------|
| <b>Avian Acute LC<sub>50</sub> = 2,311 ppm (Northern Bobwhite Quail; Most sensitive acute toxicity value)</b> |                                      |                          |                      |                                     |
| Rice  | 4                                    | Short grass              | 1,593                | <b>0.69</b>                         |
|   |                                      | Tall grass               | 730                  | <b>0.32</b>                         |
|   |                                      | Broadleaf plants/insects | 896                  | <b>0.39</b>                         |
|   |                                      | Seeds                    | 100                  | <0.1                                |
| Turf  | 10                                   | Short grass              | 2,400                | <b>1.00</b>                         |
|   |                                      | Tall grass               | 1,100                | <b>0.50</b>                         |
|   |                                      | Broadleaf plants/insects | 1,350                | <b>0.60</b>                         |
|   |                                      | Seeds                    | 150                  | <0.1                                |

RQs in **bold print** signify an exceedence of the LOC for risk to birds including endangered species.

**b. Risk to Mammals**

**1) Toxicity (Hazard) Assessment**

Propanil is classified as slightly toxic to small mammals on an acute oral basis with an LD<sub>50</sub> value of 1,080 mg/kg (see Table 13). Mammalian toxicity data indicate that the use of propanil on rice exceeds the LOC for chronic risk to mammals. Chronic toxicity data for mammals from the 2-generation rat reproduction study indicate decreased body weight, decreased weight gain, decreased food consumption and pigmentation in macrophages (a special class of immune cells that are usually responsible for the initial attack against an invasion by microorganisms). Table 13 discusses the data that support the acute toxicity and chronic endpoints used in assessing the risks to mammals.

**Table 13. Mammalian Toxicity Endpoints for Rats Exposed to Propanil.**

| Test Species                                   | Test Type                 | Study Type | % a.i. | Toxicity Value<br>(mg/kg) | Affected Endpoints | MRID     |
|--|---------------------------|------------|--------|---------------------------|--------------------|----------|
| Laboratory Rat<br>( <i>Rattus norvegicus</i> ) | Mammalian Oral            | Acute      | 100.0  | LD <sub>50</sub> = 1,080  | Mortality          | 41360801 |
|  | 2-Generation Reproduction | Chronic    |        | NOAEL = 150               | Reproduction       | 00036091 |

**2) Exposure and Risk**

The Agency expects exposure to mammals from residues of propanil on food items. Exposure is probable because rice fields provide a habitat rich in food sources attractive to

various mammalian species. See Table 14 for expected environmental residues of propanil on various food items. The labeled use of propanil on rice is expected to exceed the LOC for acute and chronic risks to mammals (including endangered species). The potential use of propanil on turf is expected to exceed the LOC for acute risk to mammals (including endangered species).

**Table 14. Propanil Uses on Rice and Turf: Acute & Chronic RQs for Mammals.**

| Use Site   | Application Rate (lbs. a.i./acre)  | Food Items       | Max. EEC <sup>a</sup> (ppm) | Acute RQ for 15 gm. mammal (EEC/LD <sub>50</sub> ) | Acute RQ for 35 gm. mammal (EEC/LD <sub>50</sub> ) | Acute RQ for 1,000 gm. mammal (EEC/LD <sub>50</sub> ) | Chronic RQ for 15 gm. mammal (EEC/NOAEL) |
|--|------------------------------------|------------------|-----------------------------|--|--|---|--|
| <b>Mammalian Acute Oral LD<sub>50</sub> of 1,080 mg/kg, Mammalian Chronic NOAEL of 150 mg/kg (Rat)</b> |                                    |                  |                             |  |  |   |  |
| Rice   | 4 (two applications/21 days apart) | Short grass      | 1,593                       | <b>1.40</b>  | <b>0.97</b>  | <b>0.22</b>   | <b>10.62</b>                             |
|  |                                    | Broadleaf plants | 730                         | <b>0.64</b>  | <b>0.45</b>  | <b>0.10</b>   | <b>4.86</b>                              |
|  |                                    | Insects          | 896                         | <b>0.79</b>  | <b>0.55</b>  | <b>0.12</b>   | <b>5.98</b>                              |
|  |                                    | Seeds            | 100                         | <0.1   | <0.1   | <0.1  | <1                                       |
| Turf   | 10                                 | Short grass      | 2,400                       | <b>2.00</b>  | <b>1.50</b>  | <b>0.33</b>   | <b>8.00</b>                              |
|  |                                    | Broadleaf plants | 1,100                       | <b>0.97</b>  | <b>0.67</b>  | <b>0.15</b>   | <b>4.00</b>                              |
|  |                                    | Insects          | 1,350                       | <b>1.00</b>  | <b>0.83</b>  | <b>0.19</b>   | <b>5.00</b>                              |
|  |                                    | Seeds            | 150                         | <0.1   | <0.1   | <0.1  | 0.50                                     |

<sup>a</sup> The default half-life of 35 days was used to calculate EEC values since data indicating half-lives on plant residues was not available. The application rate is 4 lbs. a.i./acre at 2 applications and 21-day interval.

Note: Acute RQ = EEC (ppm)/LD<sub>50</sub> (mg/kg) x % Body Weight Consumed  
 Chronic RQ = EEC (ppm)/NOAEL (ppm)

RQs in **bold print** signify an exceedence of the LOC for risk to mammals including endangered species.

### c. Risk to Fish and Aquatic Invertebrates

Based on suggested rice paddy water holding periods, the Agency does not expect the risk to exceed the levels of concern for freshwater and estuarine/marine fish and invertebrates, including endangered species. The Agency used Tier I modeling to determine when the levels of newly applied propanil in paddy water are expected to decline below a toxic level of concern. The paddy water may then be released to adjacent streams that are inhabited by freshwater and estuarine/marine fish and invertebrates. Risks to aquatic organisms are calculated by using RQs (Tables 17, 18 & 19). The detailed procedures, documentation and results of the modeling may be found in the memorandum EFED Response to Registrant Request for a Seven (7) Day Holding Period for Propanil Use in Rice Paddies, dated September 11, 2003.

The Agency initially recommended that rice paddy water that contains newly applied propanil should be held for a minimum of 30 days before being released into adjacent streams. The intent of water holding periods in rice is to allow time for propanil (or any pesticide applied to rice fields) to degrade in the rice paddy to concentrations that minimize the risk to aquatic fish and invertebrates that inhabit the adjacent streams. In response to EPA's initial recommendation, on May 21, 2003, the Propanil Task Force II submitted a Tier II modeling effort using the RICEWQ model to estimate surface water concentrations of propanil and the primary degradate, 3,4-DCA, after application. The modeling output recommended a 7-day water holding period for all rice production areas. Although the Agency has not yet fully evaluated the RICEWQ model for use in risk assessment, the submitted modeling appears to be thorough, transparent and well-documented. In order to determine if the registrant's requested 7-day holding period would result in RQs below levels of concern, EPA conducted a refined Tier I assessment. Assuming the labeled rates of one or two applications of 4 lbs. a.i./acre of propanil, the Agency can concur with the registrant's request for a seven (7) day water holding period for dry-seeded rice in the Mississippi Delta and permanent flood rice in California. However, the Agency recommends a water holding period of 10 days for dry-seeded rice along the Gulf Coast (e.g. Texas) and for delayed flood rice (Louisiana), EPA recommends a water holding period of fifteen (15) days. These mitigation measures are expected to reduce the off-field concentrations of propanil to levels such that predicted RQs are below levels of concern for endangered and nonendangered aquatic organisms.

Freshwater Species

**1) Toxicity (Hazard) Assessment**

The available acute toxicity data on propanil, outlined in Table 15, indicate that it is slightly-to-moderately toxic to freshwater fish, based on LC<sub>50</sub> values ranging from 12.8 ppm to 16.0 ppm. A freshwater invertebrate toxicity test on propanil indicates that it is moderately to slightly toxic to freshwater invertebrates. Table 15 below displays the acute toxicity endpoints for freshwater fish and invertebrates.

**Table 15. Acute Toxicity Endpoints for Freshwater Fish/Invertebrates.**

| Test Species                                       | Test Type     | % a.i. | Toxicity Value (ppm of a.i.)     | Toxicity Category | MRID or Accession No. |
|--|---------------|--------|----------------------------------|-------------------|-----------------------|
| Rainbow Trout<br>( <i>Oncorhynchus mykiss</i> )    | Fish Toxicity | 44.0   | (96-hour LC <sub>50</sub> ) 12.8 | Slightly Toxic    | 41360201              |
|  |               | 88.0   | (96-hour LC <sub>50</sub> ) 2.3  | Moderately Toxic  | Acc. 246087           |
| Bluegill Sunfish<br>( <i>Lepomis macrochirus</i> ) | Fish Toxicity | 44.0   | (96-hour LC <sub>50</sub> ) 14.0 | Slightly Toxic    | 41359801              |
|  |               | 86.2   | (96-hour LC <sub>50</sub> ) 5.40 | Moderately Toxic  | Acc. 249347           |

| Test Species                           | Test Type             | % a.i. | Toxicity Value (ppm of a.i.)        | Toxicity Category | MRID or Accession No. |
|--|-----------------------|--------|-------------------------------------|-------------------|-----------------------|
|  |                       | 45.0   | (48-hour LC <sub>50</sub> ) 16.0    | Slightly Toxic    | Supplemental          |
| Water Flea<br>( <i>Daphnia magna</i> ) | Invertebrate Toxicity | 44.0   | (48-hour EC <sub>50</sub> ) 1.2 ppm | Moderately Toxic  | 41776801              |
|  |                       | 36.5   | (LC <sub>50</sub> ) 11.4 ppm        | Slightly Toxic    | Acc. 095187           |

Chronic data for freshwater fish and invertebrates show that growth and development was the most sensitive endpoint for propanil. Test results indicate that propanil may affect fish length and survival at concentrations greater than 9.1 ppb. Results also indicate that freshwater invertebrate reproduction impairment may occur at levels greater than 8.1 ppb. The reproductive toxicity endpoints for freshwater fish and invertebrates are outlined in Table 16.

**Table 16. Reproductive Toxicity Endpoints for Freshwater Fish/Invertebrates.**

| Test Species                                     | Test Type                          | % a.i. | NOAEC <sup>a</sup> (ppb) | LOAEC <sup>b</sup> (ppb) | Affected Endpoints | MRID                  |
|--|------------------------------------|--------|--------------------------|--------------------------|--------------------|-----------------------|
| Fathead Minnow<br>( <i>Pimephales promelas</i> ) | Fish - Early Life Stage            | 98.0   | 9.3                      | 19.0                     | Survival           | 41776501,<br>42259601 |
|  |                                    |        | 9.1                      | 21.0                     | Length             | 42475301              |
|  |                                    | 85.4   | Not reported.            | <24.0                    | Unknown            | Not reported.         |
| Water Flea<br>( <i>Daphnia magna</i> )           | Freshwater Invertebrate Life-Cycle | 98.0   | 86.0                     | 160.0                    | Reproduction       | 41776001              |

<sup>a</sup> NOAEC = No Observed Adverse Effects Concentration. The highest concentration of a substance a group of experimental animals is exposed to that demonstrates the absence of adverse effects observed or measured at higher concentration levels (kg body weight/day).

<sup>b</sup> LOAEC = Lowest Observed Adverse Effects Concentration. The lowest concentration in an experiment at which an “adverse” health effect is seen (kg body weight/day).

## Estuarine/Marine Species

### 1) Toxicity (Hazard) Assessment

Available acute toxicity data on technical propanil indicate that it is moderately toxic to estuarine/marine fish, with a LC<sub>50</sub> value of 4.6 ppm (Table 17). The EC<sub>50</sub> value (4.96 ppm) for technical propanil indicates that propanil is moderately toxic to the eastern oyster on an acute basis. The LC<sub>50</sub> value of 0.4 ppm for technical propanil indicates that propanil is highly toxic on an acute basis to the mysid shrimp. Nonguideline supplementary information suggest that 3,4-DCA may cause adverse effects in aquatic species; therefore, EPA will require acute

estuarine/marine fish and invertebrate toxicity tests on 3,4-DCA (Guidelines 850.1075 and 850.1010).

**Table 17. Acute Toxicity Endpoints for Estuarine Fish.**

| Test Species   | Test Type             | % a.i. | Toxicity Value (ppm of a.i.)     | Toxicity Category | MRID                  |
|--|-----------------------|--------|----------------------------------|-------------------|-----------------------|
| Sheepshead Minnow/Flow-Through<br>( <i>Cyprinodon variegatus</i> )                                     | Fish Toxicity         | 98.0   | (96-hour LC <sub>50</sub> ) 4.6  | Moderately Toxic  | 41776001              |
| Eastern Oyster/Flow-Through<br>(Shell deposition or embryo-larvae)<br>( <i>Crassostrea virginica</i> ) | Mollusk Toxicity      |        | (96-hour EC <sub>50</sub> ) 4.96 |                   | 41777101,<br>42253100 |
| Mysid Shrimp/Flow-Through<br>( <i>Americamysis bahia</i> )   | Invertebrate Toxicity |        | (96-hour LC <sub>50</sub> ) 0.4  | Highly Toxic      | 41776901              |

## 2) Exposure and Risk

### Propanil Rice Use Exposure and Risk

EPA conducted modeling to determine water-holding periods that would allow time for propanil concentrations in paddy water to degrade below levels of concern for organisms living outside the paddies. The paddy water that may contain propanil is eventually released to adjacent aquatic organism habitats. To reduce the exposure to propanil, the Agency has determined the concentrations of concern to endangered and nonendangered species of fish and aquatic invertebrates (Table 18) based on the most sensitive toxicity endpoints (Table 19), and the minimum water-holding periods in rice fields that would reduce predicted exposure to these organisms (Table 20). Exposure concentrations of concern for aquatic organisms were calculated by multiplying the most sensitive toxicity endpoints by the risk quotient level of concern. These levels of concern were 0.05 for acute endangered freshwater organisms, 0.1 for acute nonendangered estuarine/marine organisms and 1 for chronic toxicity to aquatic organisms. The exposure concentrations of concern were compared to the model outputs to determine the minimum water holding times in rice paddies.

**Table 18. Environmental Concentrations of Concern for Aquatic Species.**

| Test Species            | Acute Exposure Concentrations of Concern <sup>a</sup> (ppb) | Chronic Exposure Concentrations of Concern <sup>b</sup> (ppb) |
|-------------------------|---|---|
| Freshwater Fish         | 115   | 9.1   |
| Freshwater Invertebrate | 60  | 86  |

| Test Species                  | Acute Exposure Concentrations of Concern <sup>a</sup> (ppb) | Chronic Exposure Concentrations of Concern <sup>b</sup> (ppb) |
|-------------------------------|---|---|
| Estuarine/Marine Fish         | 230   | No data available   |
| Estuarine/Marine Invertebrate | 40  |   |

<sup>a</sup> Acute Concentration of Concern = Risk Quotient Level of Concern \* Most Sensitive LC50

<sup>b</sup> Chronic Concentration of Concern = Risk Quotient Level of Concern \* Most Sensitive NOAEL (No Observed Adverse Effect Level).

**Table 19. Toxicity Values Used to Calculate Target Environmental Concentrations.**

| Test Species                  | Exposure Type | Most Sensitive Species (Surrogate) | Toxicity                     |
|-------------------------------|---------------|------------------------------------|------------------------------|
| Freshwater Fish               | Acute         | Rainbow Trout                      | LC <sub>50</sub> = 2,300 ppb |
| Freshwater Invertebrate       |               | Daphnia magna                      | EC <sub>50</sub> = 1,200 ppb |
| Freshwater Fish               | Chronic       | Fathead minnow                     | NOAEC = 9.1 ppb              |
| Freshwater Invertebrate       |               | Daphnia magna                      | NOAEC = 86 ppb               |
| Estuarine/Marine Fish         | Acute         | Sheepshead minnow                  | LC <sub>50</sub> = 4,600 ppb |
| Estuarine/Marine Invertebrate |               | Mysid shrimp                       | LC <sub>50</sub> = 400 ppb   |

**Table 20. Required Water Holding Periods (days) to Reduce Acute Risk for Aquatic Organisms Based on Modeling.**

| Rice Production Method (location) | Freshwater Invertebrate (2/1 apps) <sup>a</sup> | Freshwater Fish (2/1 apps) <sup>a</sup> | Estuarine/Marine Invertebrate (2/1 apps) <sup>b</sup> | Estuarine/Marine Fish (2/1 apps) <sup>b</sup> |
|-----------------------------------|---|---|---|---|
| Dry-seeded (Mississippi Delta)    | 7/7   | 1/1                                     | Not Applicable  | Not Applicable                                |
| Dry-seeded (Texas)                | 7/7   | 1/1                                     | 10/10   | 0/0   |
| Water seeded (California)         | 7/7   | 1/1                                     | Not Applicable  | Not Applicable                                |
| Delayed flood (So. Louisiana)     | 12/12   | 6/6                                     | 15/15   | 0/0   |

<sup>a</sup> Based on Level of Concern = 0.05 for risk to endangered species because there are known endangered freshwater fish and invertebrates.

<sup>b</sup> Based on Level of Concern = 0.1 for acute restricted use for nonendangered species because there are no federally listed endangered estuarine/marine invertebrates.

## Propanil Turf Use Exposure and Risk

To assess the potential exposure of fish and invertebrates to propanil used on turf, the Agency calculated EECs using the Generic Expected Environmental Concentration Program (GENEEC), Version 2.0. The EECs are used for assessing acute and chronic risks to aquatic organisms (Table 18). Acute risk assessments are performed using peak EEC values for single and multiple applications. Chronic risk assessments are performed using the 21-day EECs for invertebrates and 60-day EECs for fish. Table 21 below shows the RQs for acute risk to freshwater and estuarine/marine fish and invertebrates and chronic risk to freshwater fish and invertebrates.

**Table 21. Propanil Use on Turf: Acute & Chronic RQs for Freshwater and Marine Estuarine Fish/Invertebrates.**

| Test Species                       | Exposure Type | Most Sensitive Species (Surrogate)                    | Toxicity (ppb of a.i.)   | Acute EEC (ppb) | Chronic EEC <sup>a</sup> (ppb) | Risk Quotient (EEC/Toxicity) |
|------------------------------------|---------------|---|--------------------------|-----------------|--------------------------------|------------------------------|
| Freshwater Fish                    | Acute         | Rainbow Trout<br>( <i>Oncorhynchus mykiss</i> )       | LC <sub>50</sub> = 2,300 | 217             | --                             | 0.09                         |
|                                    | Chronic       | Fathead Minnow<br>( <i>Pimephales promelas</i> )      | NOAEC = 9.1              | --              | 57.8                           | <b>6.3</b>                   |
| Freshwater Invertebrates           | Acute         | Water Flea<br>( <i>Daphnia magna</i> )                | EC <sub>50</sub> = 1,200 | 217             | --                             | <b>0.2</b>                   |
|                                    | Chronic       |   | NOAEC = 86               | --              | 125                            | <b>1.4</b>                   |
| Estuarine/<br>Marine Fish          | Acute         | Sheepshead Minnow<br>( <i>Cyprinodon variegatus</i> ) | LC <sub>50</sub> = 4,600 | 217             | --                             | 0.05                         |
| Estuarine/<br>Marine Invertebrates | Chronic       | Mysid Shrimp<br>( <i>Americamysis bahia</i> )         | LC <sub>50</sub> = 400   | 217             | --                             | <b>0.5</b>                   |

<sup>a</sup> The chronic EEC used for fish is the 60-day average and for invertebrates, it is the 21-day average.

RQs in **bold print** signify an exceedence of the LOC for risk to freshwater fish and invertebrates including endangered species.

### d. Risk to Nontarget Insects

Available data from a honey bee acute contact toxicity study indicated that technical propanil is practically nontoxic to the honeybee (with an LD<sub>50</sub> of >24.17 µg/bee) and its uses on rice and turf are predicted to pose minimal risk to nontarget insects.

### e. Risk to Nontarget Terrestrial Plants

#### 1) Toxicity (Hazard) Assessment



Tier 2 phytotoxicity tests (MRID 43069901) were used to measure the response of plants to propanil, relative to a control, and five or more test concentrations. However, the previously submitted vegetative vigor portion of this study is invalid because the method of application was inadequate. The technical treatment solutions were more dilute than what is used under actual field conditions. Since the guideline requirement for vegetative vigor has not yet been fulfilled for propanil, the vegetative vigor RQ could not be determined. The Agency therefore assumes risk to nontarget plants (risk includes endangered species) from propanil use on rice based on its herbicidal mode of action and the amount of spray drift that occurs from aerial applications of propanil. This conclusion is also supported by one reported incident of nontarget plant damage due to spray drift following a propanil aerial application to rice in Arkansas. In addition, the California Department of Pesticide Regulation has provided comments indicating phytotoxicity to prune and related stone fruit crops associated with the use of propanil on rice. See Section III.B.3 for more detail.

The EC<sub>25</sub> value of the five most sensitive species in the vegetative vigor study is compared to the drift exposure to determine the acute RQ due to drift. The guideline requirement for Tier 2 vegetative vigor (850.4250) has not yet been completely fulfilled for propanil. Acceptable vegetative vigor data are still required so that EPA can conduct a complete risk assessment for propanil exposure to nontarget terrestrial plants.

**Table 22. Terrestrial Nontarget Plant Toxicity Data (Tier 2) for Propanil.**

| Test Type          | % a.i. | Most Sensitive Species | EC <sub>25</sub><br>(lbs. a.i./acre) | NOEL<br>(lbs. a.i./acre) | MRID     | Study Classification |
|--------------------|--------|------------------------|--------------------------------------|--------------------------|----------|----------------------|
| Seed Germination   | 97.6   | Onion                  | 3.5                                  | 0.3                      | 43069901 | Acceptable           |
| Seedling Emergence |        |                        | 1.4                                  | 0.61                     |          |                      |

## 2) Exposure and Risk

To determine propanil risk to nontarget terrestrial plants from propanil use on turf, the EC<sub>25</sub> value for the five most sensitive species in the seedling emergence study (850.4200) is compared to runoff and drift exposure to determine the risk quotient (EEC/Toxicity Value). The EECs and acute RQs for terrestrial and semi-aquatic plants were based on the maximum label for the potential use on turf (single application of 10 lbs. a.i./A). Based on a single application at the maximum application rate, the plant acute LOCs are exceeded (RQ >1) for plants inhabiting semi-aquatic areas and terrestrial areas (Table 23). Currently, EPA does not perform chronic risk assessments for terrestrial and semi-aquatic plants.

**Table 23. Acute RQs for Plants Inhabiting Terrestrial and Semi-Aquatic Areas.**

| Site, Application Method & Rate (lbs. a.i./acre) | Seedling Emergence EC <sub>25</sub> (lbs. a.i./acre) | Total Loading to Adjacent Area (Sheet Runoff + Drift) (lbs. a.i./acre) | Total Loading to Semi-aquatic Area (Channelized Runoff + Drift) (lbs. a.i./acre) | Emergence RQ Terrestrial Plants (sheet) <sup>a</sup> | Emergence RQ Semi-Aquatic Plants (channel) <sup>b</sup> |
|--|--|--|--|--|---|
| Turf, Unincorporated Ground 10                   | 1.4  | 0.6  | 5.1  | <1   | 3.6   |
| Turf, Aerial 10                                  |  | 0.8  | 3.5  |  | 2.5   |

<sup>a</sup> Emergence RQ for Terrestrial Plants = Total Loading to adjacent area ÷ Seedling Emergence EC<sub>25</sub>

<sup>b</sup> Emergence RQ for Semi-Aquatic Plants = Total Loading to Semi-Aquatic Area ÷ Seedling Emergence EC<sub>25</sub>

**f. Risk to Nontarget Aquatic Plants**

**1) Toxicity (Hazard) Assessment**

Nontarget aquatic plant testing was required by EPA for propanil because aerial application and outdoor nonresidential aquatic use may result in exposure to aquatic plants. The test results (Table 24) indicate that exposure levels of propanil at 0.11 ppm or greater may cause detrimental effects to the growth and reproduction of vascular aquatic plant species (including endangered species). Also, algae and diatoms may be affected from propanil exposure levels of 0.016 ppm or greater.

**Table 24. Nontarget Aquatic Plant Toxicity (Tier 2) for Propanil.**

| Test Species                                      | % a.i. | EC <sub>50</sub> (ppm) | MRID                  |
|---|--------|------------------------|-----------------------|
| <i>Vascular Plants</i>                            |        |                        |                       |
| Duckweed ( <i>Lemna gibba</i> )                   | 98.0   | 0.11                   | 41777201              |
| <i>Nonvascular Plants</i>                         |        |                        |                       |
| Marine Diatom ( <i>Skeletonema costatum</i> )     | 98.0   | 0.030                  | 41777301 and 41777401 |
| Freshwater Diatom ( <i>Navicula pelliculosa</i> ) |        | 0.016                  | 41777501              |
| Blue-green Algae ( <i>Anabaena flos-aquae</i> )   | 98.0   | 0.11                   | 41777601              |

## 2) Exposure and Risk

Propanil is intended to control broadleaf weed activity within rice paddies. Therefore, the Agency only calculated the risks to nontarget aquatic plants inhabiting areas adjacent to the propanil-treated rice paddies. Thus, the RQ calculations are based on the EEC of propanil at the time of paddy water release (See Table 24). The RQs indicate that the LOC is not exceeded for risk to vascular aquatic plants inhabiting areas adjacent to rice paddies treated with propanil (Table 25). However, the LOC is exceeded for risk to nonvascular aquatic plants inhabiting areas adjacent to rice paddies treated with propanil. RQs calculated for the potential use of propanil on turf indicate that the LOC is exceeded for aquatic vascular plants (including endangered species) and nonvascular plants.

**Table 25. Propanil Uses on Rice and Turf: Acute RQs for Aquatic Plants.**

| Aquatic Plant Type | Most Sensitive Species                               | EC <sub>50</sub> (ppb) | EC <sub>05</sub> (ppm) | EEC (ppb)             | Acute RQ <sup>a</sup> | Endangered RQ <sup>b</sup> |
|--------------------|--|------------------------|------------------------|-----------------------|-----------------------|----------------------------|
| Vascular           | Duckweed<br>( <i>Lemna gibba</i> )                   | 110                    | 0.02                   | Turf: 217             | <b>2</b>              | <b>11</b>                  |
|                    |  |                        |                        | Rice, CA: 56          | <1                    | <1                         |
|                    |  |                        |                        | Rice, TX: 39          |                       |                            |
|                    |  |                        |                        | Rice, MS Delta: 55    |                       |                            |
|                    |  |                        |                        | Rice, Southern LA: 40 |                       |                            |
| Nonvascular        | Freshwater Diatom<br>( <i>Navicula pelliculosa</i> ) | 16                     | 0.0063                 | Turf: 217             | <b>14</b>             | Not Applicable             |
|                    |  |                        |                        | Rice, CA: 56          | <b>3.5</b>            |                            |
|                    |  |                        |                        | Rice, TX: 39          | <b>2.4</b>            |                            |
|                    |  |                        |                        | Rice, MS Delta: 55    | <b>3.4</b>            |                            |
|                    |  |                        |                        | Rice, Southern LA: 40 | <b>2.5</b>            |                            |

<sup>a</sup> The acute RQ is calculated as EEC/EC<sub>50</sub>.

<sup>b</sup> The Endangered Species RQ is calculated as EEC/EC<sub>05</sub> or EEC/NOAEC value.

RQs in **bold print** signify an exceedence of the LOC for risk to aquatic plants including endangered species.

### g. Risk to Endangered Species

The Agency's review of propanil resulted in a determination that propanil will have "no effect" on threatened and endangered aquatic species from the use on rice, with the implementation of the water holding periods (discharge intervals) in rice paddies. Using the data available, propanil exceeds a level of concern for: (1) birds (acute risk for rice and turf); (2) small mammals (acute and chronic risks for rice and turf); (3) freshwater fish (acute risk for turf); (4) freshwater invertebrates (acute and chronic risks for turf); (5) estuarine/marine fish and invertebrates (acute risk for turf); (6) nontarget terrestrial plants (acute risk for rice and turf); and (7) vascular aquatic plants (acute risk for turf). Although propanil is only slightly toxic to birds and small mammals, the LOC exceedences for these endangered animals are based on multiple applications or high application rates and a 35-day half-life default value in the exposure

analysis. Although the risks for estuarine/marine invertebrates and aquatic nonvascular plants are exceeded, there are no federally listed species in this taxa.

This assessment will be refined using data that will be submitted as a result of this RED, in order to determine whether a species-specific assessment needs to be conducted for aquatic species from the turf use and avian and mammalian species from both uses. As an herbicide, propanil has the potential to affect federally listed threatened and endangered vascular plants. Until additional data are submitted and a determination made whether a species specific assessment needs to be conducted for listed plants, the mitigation strategy articulated in this document will serve as interim protection to reduce the likelihood that listed species will be exposed to propanil.

### **3. Ecological Incident Reports**

There is one incident report associated with adverse effects (damage) to nontarget terrestrial plants as a result of spray drift of propanil applied to rice. Shortly after the application of propanil to 150 acres of rice in Craighead, Arkansas, shade trees planted adjacent to the treated area showed moderate-to-severe leaf injury. Symptoms included burnt and shedding leaves accompanied by a lack of new growth on older trees. A thorough analysis was not conducted, but due to the proximity of the aerial propanil application to the trees, the official report ruled that propanil spray drift was likely the cause of the tree injury. The state of California has initiated special regulations for the use of propanil on rice in that state because of numerous documented cases of phytotoxicity damage to prune and related stone fruit trees.

Although incident information suggests that spray drift may be a significant route of exposure to nontarget plants, the spray drift of propanil may depend on formulation type. Sanderson (1997) demonstrated that the propanil formulations containing a nonionic surfactant decreased the droplet size of propanil during application. This reduction in droplet size may consequently increase the spray drift potential.

## **IV. Risk Management, Reregistration and Tolerance Reassessment Decision**

### **A. Determination of Reregistration Eligibility**

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing propanil as an active ingredient. The Agency has completed its review of

these generic data, and has determined that the data are sufficient to support reregistration of all products containing propanil.

Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of propanil. These data were sufficient to allow the Agency to determine that propanil can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency, therefore, finds that all products containing propanil as the active ingredient are eligible for reregistration provided specified changes are made to the label and additional data identified in Section V of this RED confirm this conclusion. Actions needed to reregister particular products are addressed in Section V of this document.

The Agency may take appropriate regulatory action if new information comes to the Agency's attention regarding the reregistration of propanil. The Agency may also require the submission of additional data (1) to support the registration of products containing propanil; (2) if the data requirements for registration change; or (3) if the guidelines for generating such data change.

## **B. Regulatory Position**

### **1. Food Quality Protection Act Findings**

#### **a. Determination of Safety for U.S. Population**

The Agency has determined that the established tolerances for propanil, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCFA, that there is a reasonable certainty of no harm for the general population. EPA tolerance reassessment decision for propanil was completed in June, 2002. In reaching this determination, EPA considered all available information on the toxicity, use practices and scenarios and the environmental behavior of propanil. Propanil is not registered for residential (home) use, nor is it used in or around public buildings, schools or recreational areas where children might be exposed. Thus, there is no expected residential or other nonoccupational exposure. Therefore, EPA considered only dietary (food and drinking water) exposure sources in its aggregate risk assessment.

#### **b. Aggregate Dietary Risks**

The Agency has concluded that an acute dietary risk assessment for propanil is not warranted because no appropriate endpoints (effects) attributable to a single exposure (dose) were identified in any study.

EPA conducted a refined (Tier 3) analysis for chronic (noncancer) dietary (food) exposure to propanil, considering the level of propanil residue in/on food commodities and their potential consumption by multiple population subgroups. Based on the results of this analysis, the chronic (noncancer) dietary risk estimates associated with the use of propanil do not exceed the Agency's level of concern because they are less than 100% of the propanil cPAD (0.009 mg/kg/day) for all population subgroups. The most highly exposed population subgroups are "all infants < 1 year of age" and "children 1-5 years," with an estimated chronic dietary exposure corresponding to 4% of the cPAD.

Models have been used to estimate ground and surface water concentrations of propanil and 3,4-DCA expected from normal agricultural use. The DWLOC calculated to assess the surface water contribution to chronic (noncancer) dietary exposure is a range of 6 to 72 ppb for the U.S. general population (all population subgroups). The surface water EECs (ranging up to 72 ppb) are below the DWLOC for all population subgroups (see Table 5). The Agency's limited monitoring data indicates that the maximum propanil concentration in ground water was 0.015 ppb, which is higher than the predicted concentrations using the SCI-GROW model (with EECs that were  $\leq 0.001$  ppb). The NAWQA data was "not targeted" to propanil use areas and estimates from the modeling are higher than the limited existing surface water monitoring data targeted to the pesticide use area. Both the modeling and the monitoring show detections for propanil *per se* and 3,4-DCA (combined) that are well below the estimated DWLOC; therefore, EPA concludes (based on the cPAD approach) that no adverse toxicological effect will occur due to aggregate chronic exposure.

For chronic (cancer) dietary risk assessment, the Agency has classified propanil into the category "*Suggestive evidence of carcinogenic potential by all routes if exposure, but not sufficient to assess human carcinogenic potential.*" However, considering the nonmutagenicity of propanil, the available evidence for carcinogenicity did not reach the Agency's criteria for classification as "*Likely to be carcinogenic in humans.*" Therefore, a quantified carcinogenic assessment is not indicated for propanil and no mitigation measures are necessary to address chronic (cancer) dietary risk for propanil.

### **c. Determination of Safety for Infants and Children**

EPA determined in its 2002 tolerance reassessment decision that the established tolerances for propanil meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCFA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers the factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of propanil residues in this population subgroup.

As required by the Food Quality Protection Act (1996), the hazard database for propanil was examined to determine the potential for increased susceptibility to infants and children from exposure to propanil. On March 27, 2003, the HIARC revisited the toxicological database and concluded that it is sufficient to ensure that there are no residual uncertainties for pre- or post-natal toxicity. As a result, the FQPA SF was reduced from 10x to 1x. For dietary risk assessment, a 3x data base uncertainty factor ( $UF_{DB}$ ) is sufficient to account for the uncertainties associated with the absence of an *in vitro* androgen receptor binding assay. Thus, estimated dietary risk is lower than what was calculated at the time of the 2002 tolerance reassessment.

## **2. Endocrine Disruptor Effects**

EPA is required under the FFDCFA, as amended by FQPA on August 3, 1996, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) “*may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.*” Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), the Agency determined that there was scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC’s recommendation that the Agency include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCFA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, propanil may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

## **3. Cumulative Risks**

The FQPA also requires a safety finding in tolerance reassessment based on factors including an assessment of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.” The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect as would a high level of exposure to any one of the other substances individually. The Agency does not have sufficient information at this time to determine whether the acetanilide pesticides, such as propanil, share a common mechanism of toxicity. A careful evaluation of all the available data is still needed. A peer review by the FIFRA Science Advisory Panel is also necessary before a formal decision is made. Therefore, for the purposes of this risk assessment, the Agency has assumed that propanil does not share a common mechanism of toxicity with other pesticides.

After a decision is made regarding common mechanism of toxicity, and if the Agency determines that a cumulative assessment is necessary, the Agency will address any outstanding risk concerns at that time.

### **C. Canceled Uses/Amended Registrations (Small Grain Use)**

The registrants and the Propanil Task Force II are no longer supporting the use of propanil on the small grains (spring (hard red) wheat, oats, spring barley and durum wheat) and have collectively chosen to voluntarily cancel this use. Therefore, in written requests submitted to the Agency dated March 2002, March 2003, April 2003 and May 2003, the registrants requested that their propanil registrations be amended to terminate (cancel) all small grain uses.

### **D. Benefits Summary: Use Practices, Propanil Use in Rice Cultivation**

EPA has done a preliminary analysis of the benefits of propanil use and the use of other herbicides in rice production. The entire document: "Reregistration Support: Use of Propanil and Other Herbicides in Rice," dated September 30, 2003 can be found in the Public Docket and on the Agency's web page at <http://www.epa.gov/pesticides/reregistration/status.htm>. The document is summarized here.

Propanil is the most widely used herbicide for weed control in U.S. rice production. Propanil is considered a backbone herbicide for weed control in U.S. rice because it is economical, growers are familiar with its use and it reliably controls a broad spectrum of weeds with little risk of injury to the rice crop. Alternatives to propanil exist for certain weed control situations, but no direct substitute is currently available based on propanil's ability to control a broad-spectrum of weeds with little risk of injury to the rice crop. Current total U.S. propanil usage is as follows: 32% of U.S. rice acres are treated with propanil in the 2.5 to 3.0 lbs. a.i./acre rate range and 35% of U.S. rice acres are treated with propanil in the 3.5 to 4.0 lbs. a.i./acre rate range. According to EPA proprietary data, approximately 60% of the total acres of U.S. rice were treated with propanil from 1998 to 2001.

Although 3 lbs. a.i./acre of propanil provides effective weed control in some situations, a significant portion of propanil applications are made at the 4 lbs. a.i./acre rate. On a national basis, less than 2% of applications are between 4.0 to 6.0 lbs. a.i./acre rate range. However, the higher rates appear to be important regionally. California, for example, shows 18% of propanil applications at greater than 4.0 lbs. a.i./acre.

### **E. Tolerance Reassessment Summary**

The existing tolerances for residues of propanil in/on plant, animal and processed commodities are established under 40 CFR §180.274(a)(1) and (a)(2). These tolerances are



currently expressed as the combined residues of propanil (3',4'-dichloropropionanilide) and its metabolites (calculated as propanil). The Agency is now recommending that the propanil tolerance expression for plant and animal commodities be revised to specify that the residues of concern are propanil and its related compounds convertible to 3,4-dichloroaniline (3,4-DCA). To eliminate redundancy, the propanil tolerances separately listed under 40 CFR §180.274(a)(2) should be removed and 40 CFR §180.274(a)(1) should be redesignated as 40 CFR §180.274(a).

The Agency has updated the list of raw agricultural and processed commodities and feedstuffs derived from crops (Table 1 of OPPTS GLN 860.1000). As a result of these changes, propanil tolerances for certain raw agricultural commodities that have been removed from the livestock feed table need to be revoked. A number of tolerances are being revised (increased or decreased) to reflect updates to the propanil database based on the submission of new livestock feeding studies, analytical methods, processing data, recovery methods and/or field trial residue data. Additionally, some commodity definitions must be updated and/or corrected. A summary of propanil tolerance reassessments is presented below in Table 26.

### **1. Tolerances Currently Listed Under 40 CFR §180.274(a)(1)**

Adequate residue data have been submitted to support the established tolerances for Cattle, fat; Goat, fat; Hog, fat; Horse, fat; Milk; Poultry, meat; Rice, straw; and Sheep, fat. For these commodities, the established tolerances were found to be appropriate and will not change as part of this tolerance reassessment.

The established tolerance levels for Cattle, meat byproducts; Egg; Goat, meat byproducts; Hog, meat byproducts; Horse, meat byproducts; Poultry, meat byproducts and Sheep, meat byproducts have been increased based on the results of livestock feeding studies and revised dietary burden (exposure) to propanil. For Rice, grain; Rice, bran and Rice, hull, the existing tolerance levels were increased since data demonstrate that residues concentrate in bran and hulls when rice is processed, based on a reevaluation of crop field trial data.

As a follow-up to the voluntary cancellation of the small grain use, the Agency will propose revocation of the established tolerances for the unsupported uses of Barley, grain; Barley, straw; Oat, grain; Oat, straw; Wheat, grain; and Wheat, straw.

The available data indicate that the tolerance levels can be decreased for Cattle, meat; Goat, meat; Hog, meat; Horse, meat; Poultry, fat and Sheep, meat based on the results of a ruminant feeding study and a revised dietary burden.

The group commodity definition "Cattle, mbyp" should be revised to "Cattle, meat byproducts." The group commodity definition "Eggs" should be revised to "Egg." The group commodity definitions "Goats, fat," "Goats, mbyp" and "Goats, meat" should be revised to "Goat, fat," "Goat, meat byproducts" and "Goat, meat," respectively. The group commodity

definitions “Hogs, fat,” “Hogs, mby” and “Hogs, meat” should be revised to “Hog, fat,” “Hog, meat byproducts” and “Hog, meat,” respectively. The group commodity definitions “Horses, fat,” “Horses, mby” and “Horses, meat” should be revised to “Horse, fat,” “Horse, meat byproducts” and “Horse, meat,” respectively. The group commodity definition “Poultry, mby” should be revised to “Poultry, meat byproducts.” The group commodity definitions “Rice,” “Rice bran” and “Rice hulls” should be revised to “Rice, grain,” “Rice, bran” and “Rice, hull,” respectively. The group commodity definition “Sheep, mby” should be revised to “Sheep, meat byproducts.”

The established tolerances for “Rice mill fractions” and “Rice polishings” should be revoked according to Table 1 of OPPTS GLN 860.1000, since these commodities are no longer considered to be significant livestock feed items. As a result, the tolerances are no longer needed.

## 2. Tolerance to Be Proposed Under 40 CFR §180.274(a)

Adequate residue data has been submitted for the establishment of a propanil tolerance for Crayfish based on the crayfish metabolism study.

## 3. Tolerances Currently Listed under 40 CFR §180.274(a)(2)

The tolerances currently listed in 40 CFR §180.274(a)(2) are inadvertent duplicates of the tolerances established for the same commodities listed in 40 CFR §180.274(a)(1). The tolerances listed in 40 CFR §180.274(a)(2) should be removed because the duplicate tolerances found there are not needed.

**Table 26. Tolerance Reassessment Summary for Propanil.**

| Commodity  | Current Tolerance (ppm) | Reassessed Tolerance (ppm) | Comment<br>[Corrected Commodity Definition]  |
|--|-------------------------|----------------------------|--|
| <i>Tolerances Currently Listed Under 40 CFR §180.247(a)(1)</i> |                         |                            |  |
| Barley, grain  | .2                      | Revoke                     | Use deleted.   |
| Barley, straw  | .75                     | Revoke                     | Use deleted.   |
| Cattle, fat  | 0.1(N) <sup>1</sup>     | 0.10                       |  |
| Cattle, mby  | 0.1(N)                  | 1.0                        | [Cattle, meat byproducts] Increased residues based on ruminant feeding studies and a revised dietary burden from residues in rice. |

<sup>1</sup> (N) = negligible residues; however, the Agency is removing the “(N)” designation from all entries to conform to current Agency administrative practice.

| <b>Commodity</b> | <b>Current Tolerance (ppm)</b> | <b>Reassessed Tolerance (ppm)</b> | <b>Comment<br/>[Corrected Commodity Definition]</b>   |
|------------------|--------------------------------|-----------------------------------|---|
| Cattle, meat     | 0.1(N)                         | 0.05                              | Decreased residues based on ruminant feeding studies and a revised dietary burden from residues in rice.                            |
| Eggs             | 0.05(N)                        | 0.30                              | [Egg] Increased residues based on ruminant feeding studies and a revised dietary burden from residues in rice.                      |
| Goats, fat       | 0.1(N)                         | 0.10                              | [Goat, fat]   |
| Goats, mbyop     | 0.1(N)                         | 0.80                              | [Goat, meat byproducts] Increased residues based on ruminant feeding studies and a revised dietary burden from residues in rice.    |
| Goats, meat      | 0.1(N)                         | 0.05                              | [Goat, meat] Decreased residues based on ruminant feeding studies and a revised dietary burden from residues in rice.               |
| Hogs, fat        | 0.1(N)                         | 0.10                              | [Hog, fat]  |
| Hogs, mbyop      | 0.1(N)                         | 0.80                              | [Hog, meat byproducts] Increased residues based on ruminant feeding studies and a revised dietary burden from residues in rice.     |
| Hogs, meat       | 0.1(N)                         | 0.05                              | [Hog, meat] Decreased residues based on ruminant feeding studies and a revised dietary burden from residues in rice.                |
| Horses, fat      | 0.1(N)                         | 0.10                              | [Horse, fat]  |
| Horses, mbyop    | 0.1(N)                         | 0.80                              | [Horse, meat byproducts] Increased residues based on ruminant feeding studies and a revised dietary burden from residues in rice.   |
| Horses, meat     | 0.1(N)                         | 0.05                              | [Horse, meat] Decreased residues based on ruminant feeding studies and a revised dietary burden from residues in rice.              |
| Milk             | 0.05(N)                        | 0.05                              |   |
| Oat, grain       | .2                             | Revoke                            | Use deleted.  |
| Oat, straw       | .75                            | Revoke                            | Use deleted.  |
| Poultry, fat     | 0.1(N)                         | 0.05                              | Decreased residues based on ruminant feeding studies and a revised dietary burden from residues in rice.                            |
| Poultry, mbyop   | 0.1(N)                         | 0.50                              | [Poultry, meat byproducts] Increased residues based on ruminant feeding studies and a revised dietary burden from residues in rice. |
| Poultry, meat    | 0.1(N)                         | 0.10                              |   |
| Rice             | 2                              | 10                                | [Rice, grain] Tolerances were increased since residues were found to concentrate when rice is processed.                            |

| <b>Commodity</b>  | <b>Current Tolerance (ppm)</b> | <b>Reassessed Tolerance (ppm)</b> | <b>Comment<br/>[Corrected Commodity Definition]</b>   |
|---|--------------------------------|-----------------------------------|---|
| Rice bran   | 10                             | 40                                | [ <i>Rice, bran</i> ] Tolerances were increased since residues were found to concentrate when rice is processed.                                    |
| Rice hulls  | 10                             | 30                                | [ <i>Rice, hull</i> ] Tolerances were increased since residues were found to concentrate when rice is processed.                                    |
| Rice mill fractions   | 10                             | Revoke                            | These items have been deleted from Table 1 of OPPTS GLN 860.1000.   |
| Rice polishings   | 10                             | Revoke                            |   |
| Rice, straw   | 75(N)                          | 75                                |   |
| Sheep, fat  | 0.1(N)                         | 0.10                              |   |
| Sheep, mbyop  | 0.1(N)                         | 0.80                              | [ <i>Sheep, meat byproducts</i> ] Increased residues based on ruminant feeding studies and a revised dietary burden from residues in rice.          |
| Sheep, meat   | 0.1(N)                         | 0.05                              | Decreased residues based on ruminant feeding studies and a revised dietary burden from residues in rice.  |
| Wheat, grain  | 0.2                            | Revoke                            | Use deleted.  |
| Wheat, straw  | 0.75                           | Revoke                            | Use deleted.  |
| <b><i>Tolerance To Be Proposed Under 40 CFR §180.274(a)</i></b>       |                                |                                   |   |
| Crayfish  | None                           | 0.05                              |   |
| <b><i>Tolerances Currently Listed Under 40 CFR §180.274(a)(2)</i></b> |                                |                                   |   |
| Rice bran   | 10                             | Remove                            | These tolerances are not needed because they are inadvertent duplicate tolerances for rice commodities that already exist in 40 CFR §180.274(a)(1). |
| Rice hulls  | 10                             | Remove                            |   |
| Rice mill fractions   | 10                             | Remove                            |   |
| Rice polishings   | 10                             | Remove                            |   |

#### 4. Codex Harmonization

No Codex maximum residue levels (MRLs) have been established for propanil; therefore, issues of compatibility between Codex MRLs and U.S. tolerances do not exist.

#### 5. Residue Analytical Methods

Adequate residue analytical methods are available for tolerance enforcement and data collection. No additional data pertaining to this guideline topic are required for reregistration. The available methods for determining propanil residues of concern in/on plant and animal commodities are described below.

## Plants:

A GC/NPD method (designated as EN-CAS Method No. ENC-9/90; earlier referred to as Method TR 34-93-99) was submitted to EPA by the registrant. The method has been previously described and deemed adequate for data collection on rice and wheat matrices. It has been subjected to a successful independent laboratory validation (ILV) trial as required by PR Notice 96-1 and was adequately radiovalidated using <sup>14</sup>C-labeled samples from the confined rotational crop study (MRID 42963001).

The qualitative nature of the residue in plants is adequately understood based on acceptable metabolism studies conducted on rice and wheat. In plants, a majority of the radioactive residue is bound, either as 3,4-dichloroaniline (3,4-DCA) conjugates or incorporated into natural constituents. A maximum of 26% of the residue in rice is quantitated using the enforcement method [e.g., as free- and base-releasable 3,4-DCA]. Total radioactive residues were 0.234 ppm in the milled rice, 1.551 ppm in bran, 0.703 ppm in hulls and 1.218 ppm in straw. In wheat, 34% (0.68ppm) of the straw residue and none of the grain residue was quantitated by the enforcement method.

The salient features of the plant metabolism studies along with the results of the ruminant, poultry and crayfish metabolism studies were presented to the Agency's MARC for review on January 16, 1996. Water metabolism was subsequently submitted to the MARC on August 7, 2001. The MARC concluded that the residue to be regulated in plants and livestock is propanil and residues convertible to 3,4-DCA; there is no need for individual quantitation of propanil metabolites.

## Animals:

The current preferred enforcement method is the GC/ECD method listed in PAM Volume II as Method I. The August 26, 1987 Residue Chemistry Chapter of the Reregistration Standard Guidance Document (dated December 23, 1987) reported that the hydrolysis procedure used in this method (16 hours reflux distillation in 25% NaOH) has been shown to release approximately 55% to 65% of the total <sup>14</sup>C-residues as 3,4-DCA in milk and eggs collected from poultry and cows fed with ring-labeled [<sup>14</sup>C] propanil. The reported LOQ of Method I is 0.05 ppm. An adequate GC/NPD method was used to analyze samples of eggs, milk, and animal tissues collected from the poultry and ruminant feeding studies. The method is based on EN-CAS Method No. ENC-9/90, described above for crop matrices, with some modifications.

The qualitative nature of the residue in livestock is adequately understood based on acceptable ruminant and poultry metabolism studies. In livestock, significant metabolites such as 3',4'-dichloro-6'-O-sulfonic acid-acetanilide in the ruminant milk and liver, and 3,4-dichloroaniline-N-sulfamic acid in poultry liver, kidney, meat, skin and egg are not convertible to 3,4-DCA.

A major portion of the residue in livestock, and certain bound residues in plants, would not be included or quantitated using the enforcement method; therefore, the MARC was asked to confirm that propanil residues convertible to 3,4-DCA should be regulated in plants and livestock. Since the metabolites are in the detoxification pathway, it is likely that the metabolites will be excreted from the body more quickly than propanil or 3,4-DCA, the MARC concluded that the residue to be regulated in plants and livestock is propanil and residues convertible to 3,4-DCA; there is no need for individual quantitation of propanil metabolites.

## **F. Regulatory Rationale**

The regulatory rationale for each of the mitigation measures outlined below is discussed immediately after this list of mitigation measures. These mitigation measures will reduce, to acceptable levels, risks to agricultural workers and wildlife:

- Establish a 7-day water holding (discharge) interval in the Mississippi Delta (Arkansas, Mississippi, Missouri and Northern Louisiana) & California; a 10-day discharge interval in Texas; and a 15-day discharge interval in Southern Louisiana. The Agency believes that the establishment of these discharge intervals will address Agency concerns for both endangered and nonendangered aquatic species;
- Spray drift management practices consistent with best management practices for rice;
- Require engineering controls including closed cabs and closed mixing/loading systems;
- All labels with use directions on rice must be amended to specify restrictions against application to fields where catfish farming is practiced and draining water from treated fields into areas where catfish farming is practiced;
- All registered propanil labels must be revised to specify a 60-day plant-back interval for all rotational crops;
- Voluntary cancellation of use on the small grains (spring (hard red) wheat, oats, spring barley and durum wheat);
- Development of toxicity and fate data on the major metabolic degradate of propanil, 3,4-DCA;
- Maintain a reentry interval of 24 hours for rice;
- For turf, the registrant has agreed to reduce the maximum application rate on turf to 5 lbs. a.i./acre and eliminate aerial applications of propanil to turf; and
- Development and submission of worker exposure (bio-monitoring) data for the liquid formulation. (Note: Propanil-specific worker exposure (bio-monitoring) data were developed by the Propanil Task Force II. These data were submitted to the Agency on September 15, 2003)

In addition, the following mitigation is needed unless EPA determines, based on the bio-monitoring data currently under review, that lesser or no mitigation is warranted:

- Reduce maximum seasonal application rate to 6 lbs. a.i./acre on rice; and
- Reduce maximum number of acres treated to 500 per day for aerial applications of propanil on rice.

The following is a summary of the rationale for the measures specified above which are necessary for reregistration eligibility and for managing risks associated with the use of propanil. Where labeling revisions are warranted, specific language is set forth in the summary table of Section V (Table 27) of this RED document.

## **1. Human Health Risk Mitigation**

### **a. Dietary Mitigation**

#### **(1) Acute Dietary (Food)**

Acute dietary (food) risk was not assessed for propanil because no appropriate endpoints (effects) attributable to a single exposure (dose) were identified. An acute dietary reference dose (RfD) was not established. No mitigation measures are necessary at this time to address acute dietary (food) risk.

#### **(2) Chronic Dietary (Food)**

The chronic dietary risk for propanil does not exceed the Agency's level of concern (i.e., less than 100% of the cPAD) for all population subgroups. The most highly exposed subgroups are all infants (<1 year of age) and children (1-5 years), with 4% of the cPAD (0.009 mg/kg/day). No mitigation is necessary for chronic dietary (food) exposure.

#### **(3) Drinking Water**

Estimated environmental concentrations of propanil and its degradates for both groundwater and surface water sources of drinking water are below the Agency's DWLOCs. No mitigation is needed for drinking water.

#### **(4) Residential**

The Agency is not considering residential mitigation options for propanil since there are no existing or proposed residential or other nonoccupational sources of exposure and propanil is

not used in or around public buildings, schools or recreational areas where children might be exposed.

### **(5) Aggregate**

Since there are no residential uses for propanil, the aggregate risk assessment considered the combined risk from exposure through food and drinking water *only*. Chronic dietary risks from food and drinking water do not exceed the Agency's level of concern. In general, combined risks from these exposures are less than 100% of the cPAD and are not considered to be a risk concern. No mitigation is necessary for aggregate exposure.

## **b. Occupational Risk Mitigation**

### **(1) Handler Exposure**

There are potential risks to pesticide handlers mixing, loading and applying propanil to rice and turf. For the rice use, potential risks for the following scenarios can be addressed with engineering controls:

- Scenario (2b) mixing/loading dry flowable for groundboom application to rice
- Scenario (4) applying sprays for groundboom application to rice
- Scenario (5) flagging for sprays application to rice

For the turf use, potential risk for Scenario (4) applying sprays for groundboom application can be addressed with Baseline PPE.

For the turf use, potential risk for Scenario (1b) mixing/loading liquids for groundboom application can be addressed with Minimum PPE.

Even taking into account maximum PPE and engineering controls, three scenarios do not achieve MOEs of 300. In these instances, EPA first characterizes the worker risk estimates (high acreage/aerial applications) by examining the assumptions used in the risk assessment, the strengths and weaknesses of existing data, and the potential for additional data to further refine the risk assessments. The Agency then considers the benefits of a pesticide's use, in making its risk management decision.

In the toxicity assessment, EPA has selected an endpoint from an oral chronic rat study based on the observation of methemoglobinemia at week 13. This is a conservative regulatory endpoint that yields an upper-bound risk assessment. An acceptable 21-day dermal toxicity



study is available for propanil. Because of similarities in route and duration of exposure this study is more typically used to evaluate worker risk, but was not selected in this instance because it did not assess methemoglobinemia, which is thought to be the most sensitive indicator of the effect of concern for propanil.

Regarding acreage assumptions and applications, reliable data indicate that less than 2% of all applications are made at rates greater than 4 lbs/ai/acre on a national basis. Further, while it is technically possible to treat over 3,000 acres per day, it is unlikely that a specific applicator would treat over 3,000 acres with propanil every day for a week or longer.

EPA has used the Pesticide Handlers Exposure Database (PHED) to estimate unit exposure to mixer/loaders and applicators of propanil. PHED represents the best data currently available. Notwithstanding, propanil/rice-specific bio-monitoring data could allow EPA to further refine the propanil worker assessment. Such data have been developed by the Propanil Task Force II and are currently under review.

The following are detailed considerations for each scenario where current estimates show MOEs of less than 300:

#### Scenario (1a) mixing/loading liquids for aerial application to rice

Current MOE estimates range from 18, assuming maximum acreage at maximum application rate, to 330, assuming a typical application rate and minimal acreage. Limiting the number of acres that can be treated per day to 500 and decreasing the maximum seasonal application rate to 6 lbs. ai/acre/year will also decrease the amount of propanil handled. Implementation of these use restrictions will increase MOEs to approximately 120. These mitigation measures will be needed unless EPA determines, based on the bio-monitoring data that have been recently submitted, that lesser or no additional mitigation is appropriate for liquid formulations of propanil. The aerial application of propanil to turf has been canceled.

#### Scenario (2a) mixing/loading dry flowable for aerial application to rice

Current MOE estimates range from 120, assuming maximum acreage at maximum application rate, to 2,200, assuming a typical application rate and minimal acreage. Limiting the number of acres that can be treated per day to 500 and decreasing the maximum seasonal application rate to 6 lbs. ai/acre/year will also decrease the amount of propanil handled. Implementation of these use restrictions will increase MOEs to approximately 750 provided that closed mixing/loading systems are used.

#### Scenario (3) applying sprays for aerial application to rice

Current MOE estimates range from 31, assuming maximum acreage at maximum application rate, to 560, assuming a typical application rate and minimal acreage. Limiting the number of acres that can be treated per day to 500 and decreasing the maximum seasonal

application rate of the liquid formulations to 6 lbs. a.i./acre/year will result in MOEs of approximately 200. These mitigation measures will be needed unless EPA determines, based on the bio-monitoring data that have been recently submitted, that lesser or no additional mitigation is appropriate. The aerial application of propanil to turf has been canceled.

Given the benefits of propanil use and assuming that the mitigation specified above is implemented, EPA finds that the risks to workers from the use of propanil are not unreasonable. Propanil is considered to be an economical, reliable product since it controls a broad spectrum of weeds with little risk of injury to the rice crop. Alternatives to propanil exist for certain weed control situations, but no direct substitute is currently available based on propanil's ability to control a broad-spectrum of weeds with little risk of injury to the rice crop.

## (2) Post-Application Exposure

All post-application worker risks associated with the rice use of propanil met or exceeded the target MOE of 300, and thus, are not of concern as long as the current REI of 24 hours is retained. Therefore, no further mitigation measures beyond the 24 hour REI to protect the post-application worker is necessary.

For sod farm workers, all of the post-application exposure scenarios at the current maximum application rate (10 lbs. a.i./acre) for turf **do not meet or exceed** the target MOE of 300, and thus, are of concern to the Agency. To address sod farm worker risk, the registrant has agreed to **reduce the maximum application rate to 5 lbs. a.i./acre**. In order to further mitigate the Agency's remaining concerns, a REI of 34 days at the reduced maximum application rate of 5 lbs. a.i./acre would result in an MOE of 306 for transplanting sod. Further, a REI of 1 day following application at the reduced maximum application rate would result in an MOE of 312 for activities such as aerating, fertilizing, irrigating, scouting and mechanical harvesting and weeding.

## 2. Environmental Risk Mitigation

### a. Birds

For avian species, the acute LOCs are slightly exceeded for all uses of propanil based on current application rates and methods. That is, the estimated acute RQs are higher than the LOCs for avian species. The labeled use of propanil on rice (RQs ranging from 0.32 to 0.69) and the potential use on turf (RQs ranging from 0.50 to 1.00) are expected to result in an exceedence of the LOC for acute risk to birds, including endangered species.

To address avian concerns, the registrants have agreed to **reduce the application rate for propanil use on turf**.

An assessment of chronic risks to birds could not be conducted due to lack of appropriate toxicity data. Chronic avian toxicity data that will enable the Agency to conduct this assessment are being required, as discussed in Section V.A.1 of this document.

#### **b. Mammals**

The Agency predicts exposure to mammals from residues of propanil on food items from the use of propanil on rice. The labeled use of propanil on rice is expected to exceed the LOC for acute and chronic risks (RQs ranging from 0.10 to 1.40 and from 4.86 to 10.62, respectively) to mammals, including endangered species. The potential use of propanil on turf is expected to exceed the LOC for acute and chronic risks (RQs ranging from 0.15 to 2.00 and from 5.00 to 8.00, respectively) to mammals, including endangered species.

To address mammalian concerns, the registrants have agreed to **reduce the application rate for propanil on turf.**

#### **c. Fish and Aquatic Invertebrates**

Propanil is moderately toxic to both freshwater and marine fish and invertebrates. Available data indicate that propanil produced chronic growth effects in freshwater fish.

To address aquatic species concerns, including those for endangered species, the registrants have agreed to **establish a 7-day water holding (discharge) interval in the Mississippi Delta (Arkansas, Mississippi, Missouri & Northern Louisiana) and California; a 10-day discharge interval along the Gulf Coast (Texas); and a 15-day discharge interval in Southern Louisiana.** The Agency believes that the establishment of the above discharge intervals will address Agency concerns for both endangered and nonendangered aquatic species.

#### **d. Nontarget Insects**

Available data indicate that technical propanil is practically nontoxic to the honeybee. The labeled uses on rice and turf are predicted to not exceed any LOC for risk to nontarget insects. No mitigation is necessary for nontarget insects.

#### **e. Nontarget Terrestrial & Semi-Aquatic Plants**

Propanil risk to nontarget terrestrial and semi-aquatic plants were based on the maximum application rate for the potential use on turf. Based on this maximum application rate, the acute LOCs are exceeded for plants inhabiting terrestrial and semi-aquatic areas.

To address concerns for nontarget terrestrial and semi-aquatic plants, including those for endangered species, the registrants have agreed to **reduce the proposed maximum application rate on turf from 10 lbs. a.i./acre to 5 lbs. a.i./acre; eliminate aerial applications to turf; establish water holding (discharge) intervals for the rice use; and label language specifying best management practices for spray drift.**

#### **f. Nontarget Aquatic Plants**

Propanil is intended to control broadleaf and grass weed activity within rice paddies. Therefore, the Agency only calculated the risks to nontarget aquatic plants inhabiting areas adjacent to the propanil-treated rice paddies at the time of normal paddy water release. The RQs indicate that the LOC is not exceeded for risk to vascular aquatic plants inhabiting areas adjacent to rice paddies treated with propanil. RQs for nonvascular plants range from 2.4 to 14. The RQs calculated for the potential use of propanil on turf indicate that the LOC is exceeded (RQs ranging from 2 to 34).

To address nontarget aquatic plant concerns, the registrants have agreed to **reduce the proposed maximum application rate on turf from 10 lbs. a.i./acre to 5 lbs. a.i./acre and eliminate aerial applications to turf.**

#### **g. Summary of Environmental Risk Mitigation**

The registrants have agreed to reduce the application rate for propanil on turf, eliminate aerial applications of propanil to turf, establish a 7-day water holding (discharge) interval in the Mississippi Delta (Arkansas, Mississippi, Missouri & Northern Louisiana) and California; a 10-day discharge interval along the Gulf Coast (Texas); and a 15-day discharge interval in Southern Louisiana and has voluntarily cancelled the small grain use of propanil. The registrant has also agreed to submit data on the major degradate, 3,4-DCA, that will allow the Agency to adequately assess the ecological effects of 3,4-DCA exposure, thus refining these risk estimates. In addition, the following label statements are needed to address ecological concerns for propanil:

##### Ecological Hazard Label Advisory

“This pesticide is toxic to shrimp.”

##### Ground Water Label Advisory

“This chemical has properties and characteristics associated with chemicals detected in ground water. The use of this chemical prior to flooding may result in some shallow ground water contamination due to cracks in subsoil of the rice paddy.”

### Surface Water Label Advisory

“This product may contaminate water through runoff following rainfall events and by seepage through levees. This product has a high potential for runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours. Levees should be constructed with adequate time prior to chemical application so that they are compacted to reduce seepage and to hold a 3-6 inch flood.”

Other guidance is located at <http://www.agronomy.ucdavis.edu/ucce/ice/water/seep.htm> and from the document “Closed Rice Water Management Systems,” from the National Resource Conservation Service of USDA. Another publication, “The University of Arkansas Rice Production Book,” can be found at [http://www.uaex.edu/other\\_areas/publications/html](http://www.uaex.edu/other_areas/publications/html). This document provides information concerning levee production.

## **G. Other Labeling Requirements**

Other use and safety information needed for labeling of all end-use products containing propanil are indicated in Table 27.

### **1. Endangered Species Statement**

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that address these impacts. EPA is not requiring specific label language at the present time relative to threatened and endangered species. The general risk mitigation required through this RED will serve to protect listed species of potential concern until such time as the Agency refines its risk assessment for plants and for acute and chronic effects to avian and mammalian species and for aquatic organisms from exposure by the use of propanil on turf. If in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program.

The Endangered Species Protection Program as described in a *Federal Register* notice (54 FR 27984-28008, July 3, 1989) is currently being implemented on an interim basis. As part of the interim program, the Agency has developed County Specific Pamphlets that articulate many of the specific measures outlined in the Biological Opinions issued to date. The Pamphlets are available for voluntary use by pesticide applicators on EPA’s website at <http://www.epa.gov/espp>. A final Endangered Species Protection Program, which may be altered from the interim program, was proposed for public comment in the *Federal Register* December 2, 2002.

## 2. Spray Drift Management

“The Agency has been working closely with stakeholders to develop improved approaches for mitigating risks to human health and the environment from pesticide spray and dust drift. As part of the reregistration process, we will continue to work with all interested parties on this important issue.

From its assessment of propanil, as summarized in this document, the Agency concludes that certain drift mitigation measures are needed to address the risks from off-target drift for propanil products. Label statements implementing these measures are listed in the “spray drift management” section of the label table (Table 27) in Chapter V of this RED document. In the future, propanil product labels may need to be revised to include additional or different drift label statements.”

## 3. For Commercial Use Only

There are no existing or proposed uses of propanil for residential (home) use, nor is it used in or around public buildings, schools or other recreational areas where children might be exposed. Propanil is currently registered for use in commercial settings only as a post-emergent weed control on rice and commercial sod farms. Noncommercial use is prohibited. All product labels will be amended to state that propanil is “For commercial use only.”

## V. Actions Required of Registrants

### A. Manufacturing-Use Products

#### 1. Additional Generic Data Requirements

The generic database supporting the reregistration of propanil for the eligible uses has been reviewed and determined to be substantially complete. The following confirmatory data requirements have been identified by the Agency to further characterize the toxicity of propanil and 3,4-DCA:

| Guideline Test Name                                | New OPPTS Guideline No. | Old Guideline No. |
|--|-------------------------|-------------------|
| Sediment and Soil Adsorption/Desorption on 3,4-DCA | 835.1240                | 163-1             |
| Hydrolysis on 3,4-DCA                              | 835.2120                | 161-1             |

| Guideline Test Name  | New OPPTS Guideline No. | Old Guideline No. |
|--|-------------------------|-------------------|
| Photodegradation (Water) on 3,4-DCA                                    | 835.2240                | 161-2             |
| Freshwater Invertebrate Acute Toxicity on 3,4-DCA                      | 850.1010                | 72-2A             |
| Mysid Acute Toxicity on 3,4-DCA  | 850.1035                | 72-3C             |
| Freshwater and Estuarine/Marine Fish Acute Toxicity on 3,4-DCA         | 850.1075                | 72-1A/1C          |
| Early-Life Stage in Freshwater and Estuarine/Marine Fish on 3,4-DCA    | 850.1300                | 72-4A             |
| Life Cycle in Freshwater and Estuarine/Marine Invertebrates on 3,4-DCA | 850.1350                | 72-4B             |
| Avian Subacute Dietary Toxicity - Bobwhite Quail on 3,4-DCA            | 850.2200                | 71-2A             |
| Avian Reproduction - Bobwhite Quail for Parent Propanil and 3,4-DCA    | 850.2300                | 71-4A             |
| Avian Reproduction - Mallard Duck for Parent Propanil and 3,4-DCA      |                         | 71-4B             |
| Seedling Emergence (Tier 1) on 3,4-DCA                                 | 850.4100                | 122-1A            |
| Vegetative Vigor (Tier 1) on 3,4-DCA                                   | 850.4150                | 122-1B            |
| Vegetative Vigor (Tier 2) on Propanil - TEP                            | 850.4250                | 123-1B            |
| 90-Day Inhalation - Rat  | 870.3465                | 82-4              |
| Acute Neurotoxicity Screening Battery - Rat                            | 870.6200                | 81-8              |
| Immunotoxicity Study - Rat   | 870.7800                | 85-7              |
| Estimation of Dermal Exposure at Outdoor Sites                         | 875.1100                | 231               |

**a. Environmental Fate Data**

Hydrolysis half-life is needed to determine the estimated environmental concentration of the major degradate, 3,4-DCA. The estimated environmental concentration will be used to determine the exposure to aquatic organisms and humans.

Photodegradation rate in water is needed to determine the estimated environmental concentration of the major degradate, 3,4-DCA. The estimated environmental concentration will be used to determine the exposure to aquatic organisms and humans.

Soil-water partition coefficient,  $K_d$ , is needed to determine the estimated environmental concentration of the major degradate, 3,4-DCA. The estimated environmental concentration will be used to determine the exposure to aquatic organisms and humans.

## **b. Ecological Effects Data**

Available data indicates that 3,4-DCA is a major degradate of propanil. Nonguideline supplementary information and guideline studies suggest that 3,4-DCA may cause adverse effects to fish, mammals and aquatic invertebrates. Because the Agency's concerns of risk to nontarget organisms from exposure to 3,4-DCA are based on nonguideline supplementary information, guideline toxicity studies (850.1010, 850.1035, 850.1075, 850.1300, 850.1350 and 850.2200) are needed to adequately assess the ecological effects of 3,4-DCA exposure.

The Agency predicts that propanil's use on rice may cause chronic effects to birds because the level of concern is exceeded for chronic risks to mammals which is thought to be an indicator of avian risk. Therefore, data are needed to assess the potential for chronic risk to birds. In addition, nonguideline supplementary information and guideline studies suggest that the major degradate, 3,4-DCA, may cause chronic adverse reproductive effects to fish and invertebrates. This may indicate reproductive effects may occur in other organisms such as avian species. Therefore, guideline studies (850.2300) are needed to adequately assess the potential effects of parent propanil and 3,4-DCA exposure to avian species.

Tier 1 seedling emergence and vegetative vigor studies (850.4100 and 850.4150) should be conducted using the 5 most sensitive species identified in the respective studies using the parent compound. These studies are required for 3,4-DCA because it is longer-lived than the parent and the mode of action of the parent is herbicidal.

The previously submitted vegetative vigor study (MRID 43069901) is invalid because the method of application was inadequate. The chemical treatment solutions were more dilute than what is used under actual field use conditions. An acceptable Tier 2 vegetative vigor study (850.4250) is still required on propanil TEP.

## **c. Toxicological Data**

A 90-day inhalation study is not a guideline requirement for propanil; however, a 28-day inhalation study is required by the Agency to address the concern for inhalation exposure potential based on the use pattern. The registrant can follow the 90-day inhalation study protocol, but cease exposure at 28 days.

An acute neurotoxicity screening battery in rats (870.6200) needs to be submitted for propanil. Additionally, there is evidence in the published literature suggesting that propanil is a potential immunotoxic compound. Therefore, the registrant needs to conduct a guideline immunotoxic study (870.7800) or a literature study to better characterize the immunotoxic potential of propanil.



#### **d. Occupational/Residential Exposure Data**

Propanil/rice-specific worker exposure (bio-monitoring) data are needed to allow EPA to further refine the propanil worker assessment.

#### **2. Labeling for Manufacturing-Use Products**

To remain in compliance with FIFRA, manufacturing-use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MUP labeling should bear the labeling contained in the table at the end of this section. The MUP label will explicitly prohibit use of products that do not conform to Section V.B.2 of this document.

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

#### **1. Additional Product-Specific Data Requirements**

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

#### **2. Labeling for End-Use Products**

Labeling changes are necessary to implement measures outlined in Section V above. Specific language to implement these changes is specified in Table 27 at the end of this section.

### **C. Labeling Changes Summary Table**

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table (Table 27) describes how language on the labels should be amended.



**Table 27. Summary of Required Labeling Changes for Propanil (DRAFT)**

| Description  | Required Labeling Language   | Placement on Label   |
|--|--|--|
| <i>Manufacturing-Use Products</i>  |  |  |
| Required on all MUPs   | “Only for formulation into an herbicide for the following use(s) [fill blank only with those uses that are being supported by MP registrants].”  | Directions for Use   |
| One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group. | <p>“This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p> <p>“This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p>  | Directions for Use   |
| Environmental Hazards Statements Required by the RED and Agency Label Policies   | “This pesticide is toxic to fish and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Eliminations System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.”  | Directions for Use   |
| <i>End-Use Products Intended for Occupational Use (WPS and non-WPS)</i>  |  |  |
| Handler PPE Requirements for all formulations <sup>1</sup>   | <p>For <b>sole-active-ingredient</b> end-use products that contain propanil, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.</p> <p>For <b>multiple-active-ingredient</b> end-use products that contain propanil, the handler personal protective equipment/engineering control requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.</p> | Handler PPE  |
| Handler PPE Requirements for Dry Flowable (DF) Formulations <sup>1</sup>   | <p>“Personal Protective Equipment (PPE)</p> <p>Some materials that are chemical-resistant to this product are [registrant inserts correct material]. For more information, follow instructions in Supplement Three of PR Notice 93-7. If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on an EPA chemical-resistance category selection chart.”</p>  | Precautionary Statements: Hazards to Humans and Domestic Animals |

| Description   | Required Labeling Language  | Placement on Label  |
|---|---|---|
| <p>Handler PPE Requirements for Dry Flowable (DF) Formulations<sup>1</sup>, continued</p> | <p>“Mixers, loaders, and applicators must wear:</p> <ul style="list-style-type: none"> <li>– Coveralls over long-sleeved shirt and long pants,</li> <li>– Chemical-resistant gloves,</li> <li>– Chemical-resistant footwear plus socks,</li> <li>– Chemical-resistant headgear for overhead applications,</li> <li>– NIOSH approved respirator with: <ul style="list-style-type: none"> <li>– An organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or</li> <li>– A canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G),</li> <li>– Or a NIOSH approved respirator with an OV cartridge or canister with any N<sup>2</sup>, R, P or HE prefilter”</li> </ul> </li> <li>– Chemical-resistant apron when mixing, loading, or cleaning equipment.”</li> </ul> <p>“All other mixer, loaders, applicators and other handlers must wear:</p> <ul style="list-style-type: none"> <li>– Long-sleeved shirt and long pants,</li> <li>– Chemical-resistant gloves,</li> <li>– NIOSH approved respirator (except for applicators applying in-furrow to cotton) with: <ul style="list-style-type: none"> <li>– An organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or</li> <li>– A canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or</li> <li>– A NIOSH approved respirator with an OV cartridge or canister with any N<sup>2</sup>, R, P or HE prefilter”</li> </ul> </li> </ul> | <p>Precautionary Statements: Hazards to Humans and Domestic Animals</p> |
| <p>Handler PPE Requirements for Liquid (EC) Formulations<sup>1</sup></p>                  | <p>“Personal Protective Equipment (PPE)</p> <p>Some materials that are chemical-resistant to this product are [registrant inserts correct material]. For more information, follow instructions in Supplement Three of PR Notice 93-7. If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G OR H] on an EPA chemical-resistance category selection chart.”</p>   | <p>Precautionary Statements: Hazards to Humans and Domestic Animals</p> |

| Description   | Required Labeling Language  | Placement on Label   |
|---|---|--|
| <p>Handler PPE Requirements for Liquid (EC) Formulations<sup>1</sup>, continued</p> | <p>“Mixers, loaders, and applicators must wear:</p> <ul style="list-style-type: none"> <li>– Coveralls over long-sleeved shirt and long pants,</li> <li>– Chemical-resistant gloves,</li> <li>– Chemical-resistant footwear plus socks,</li> <li>– Chemical-resistant headgear for overhead applications,</li> <li>– NIOSH approved respirator with: <ul style="list-style-type: none"> <li>– An organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or</li> <li>– A canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G),</li> <li>– Or a NIOSH approved respirator with an OV cartridge or canister with any N<sup>2</sup>, R, P or HE prefilter”</li> </ul> </li> <li>– Chemical-resistant apron when mixing, loading, or cleaning equipment.</li> </ul> <p>“All other mixer, loaders, applicators and other handlers must wear:</p> <ul style="list-style-type: none"> <li>– Long-sleeved shirt and long pants,</li> <li>– Chemical-resistant gloves,</li> <li>– NIOSH approved respirator (except for applicators applying in-furrow to cotton) with: <ul style="list-style-type: none"> <li>– An organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or</li> <li>– A canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or</li> <li>– A NIOSH approved respirator with an OV cartridge or canister with any N<sup>2</sup>, R, P or HE prefilter</li> </ul> </li> </ul> | <p>Precautionary Statements: Hazards to Humans and Domestic Animals</p>  |
| <p>User Safety Requirements</p>   | <p>“Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product’s concentrate. Do not reuse them.”</p> <p>“Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.”</p>   | <p>Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements</p> |

| Description                 | Required Labeling Language  | Placement on Label   |
|-----------------------------|---|--|
| Engineering Controls        | <p><b>“ENGINEERING CONTROLS”</b></p> <p>“Mixers/loaders must use an enclosed mixing/loading system, single layer clothing and scenarios 1a and 1b must also include chemical-resistant gloves.”</p> <p>“Applicators and flaggers must be in an enclosed cockpit, cab or truck, single layer clothing, no gloves.”</p>   | <p>Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)</p>                          |
| User Safety Recommendations | <p><b>“USER SAFETY RECOMMENDATIONS”</b></p> <p>“Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.”</p> <p>“Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.”</p> <p>“Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”</p>   | <p>Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls</p> <p>(Must be placed in a box.)</p> |
| Environmental Hazards       | <p><b>“ENVIRONMENTAL HAZARDS”</b></p> <p><i>Ecological Hazard Advisory</i></p> <p>“This pesticide is toxic to shrimp.”</p> <p><i>Ground Water Advisory</i></p> <p>“This chemical has properties and characteristics associated with chemicals detected in ground water. The use of this chemical prior to flooding may result in some shallow ground water contamination due to cracks in subsoil of the rice paddy.”</p> <p><i>Surface Water Advisory</i></p> <p>“This product may contaminate water through runoff following rainfall events and by seepage through levees. This product has a high potential for runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours. Levees should be constructed with adequate time prior to chemical application so that they are compacted to reduce seepage and to hold a 3-6 inch flood.”</p> | <p>Precautionary Statements under Environmental Hazards</p>  |

| Description  | Required Labeling Language  | Placement on Label  |
|--|---|---|
| Restricted-Entry Interval for WPS products as required by Supplement Three of PR Notice 93-7                               | <p>“Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours.”</p> <p>“Do not enter or allow others to enter the treated area (except those persons involved in the incorporation) until the incorporation is complete following application.”</p>  | Directions for Use, Agricultural Use Requirements Box         |
| Early Reentry Personal Protective Equipment for Products subject to WPS as required by Supplement Three of PR Notice 93-7. | <p>“PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as soil or water, is:”</p> <p>For all end-use products:</p> <ul style="list-style-type: none"> <li>– Coveralls</li> <li>– Chemical-resistant gloves such as or made out of any waterproof material</li> <li>– Shoes plus socks</li> </ul>  | Directions for Use, Agricultural Use Requirements Box         |
| Spray Drift Label Language for Products Applied Outdoors as a Liquid   | <p><b>“SPRAY DRIFT MANAGEMENT”</b></p> <p>“Avoiding spray drift at the application site is the responsibility of the applicator and the grower. The interactions of many equipment and weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions.”</p> <p>“Apply only when the wind speed is less than or equal to 10 mph at the application site.”</p> <p>“Apply as a medium or coarser spray (ASAE standard 572).”</p> <p><u>“Additional requirements for ground applications:”</u></p> <p>“Apply using a nozzle height of no more than 4 feet above the ground or crop canopy.”</p> | Directions for Use under General Precautions and Restrictions |

| Description   | Required Labeling Language  | Placement on Label  |
|---|---|---|
| Spray Drift Label Language for Products Applied Outdoors as a Liquid, continued | <p>“<u>Additional requirements for aerial applications:</u>”</p> <p>“Do not apply by air if drift can occur to sensitive nontarget crops or plants that are within 100 feet of the application site.”<sup>3</sup></p> <p>“Do not release spray at a height greater than 14 feet above the ground or crop canopy.”</p> <p>“The boom length must not exceed 70% of the wingspan or 85% of the rotor blade diameter.”</p> <p>“Do not make aerial applications into temperature inversions.”</p> <p>“When applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind.”</p> | Directions for Use under General Precautions and Restrictions |

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

<sup>2</sup> If the product contains oil or bears instructions that will allow application with an oil-containing material, the “N” designation must be dropped. Instructions in the Required Labeling section appearing in quotations represent the exact language that must appear on the label.

<sup>3</sup> This statement was derived from existing label language and initial comments received from the Propanil Task Force II and grower groups.



#### **D. Existing Stocks**

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED) for propanil. Persons other than the registrants may generally distribute or sell such products for 50 months from the date of issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes and other factors. Refer to “Existing Stocks of Pesticide Products; Statement of Policy,” as prescribed in the *Federal Register* of June 26, 1991 (56 FR 29362) (FRL-3846-4).

The Agency has determined that registrants may distribute and sell propanil products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrants may generally distribute or sell such products for 50 months from the date of issuance of this RED. Registrants and persons other than the registrants remain obligated to meet pre-existing label requirements and existing stocks requirements applicable to products they sell or distribute.

## **VI. APPENDICES**



**Appendix A. PROPANIL (Case No. 0226): Table of Use Patterns Eligible for Reregistration**

| Site<br>Application Timing<br>Application Type<br>Application Equipment | Formulation<br>[EPA Reg. No.]                                | Maximum Single<br>Application Rate<br>(lbs. a.i./Acre) | Maximum No.<br>of Applications<br>Per Season | Maximum<br>Seasonal Rate<br>(lbs. a.i./Acre) | Preharvest<br>Interval (Days) | Use Directions and Limitations <sup>1,2</sup>  |
|---|--|--|--|--|-------------------------------|--|
| <b>Rice</b>   |  |  |  |  |                               |  |
| Postemergence<br>Broadcast<br>Ground or aerial                          | 3 lb/gal EC<br>[62719-386]<br><br>4 lb/gal EC<br>[62719-393] | 6  | Not Specified<br>(NS)                        | 8  | Not Specified<br>(NS)         | Use limited to rice grown in southern U.S. only. Application should be made using a minimum of 15 (ground; 3 lb/gal EC), 20 (ground; 4 lb/gal EC), or 10 (aerial) gal of water/A. Applications are not permitted 45, 55, or 60 days after planting depending on the variety of rice. When double cropping is practiced, application to the second rice crop is prohibited. Applications are to be made when fields have been drained of most of the standing water and fields should be flooded within 12 to 24 hours of spraying. Water drained from treated rice fields must not be used to irrigate other crops or released within ½ mile upstream of a potable water intake in flowing water (e.g., river, stream, etc.) or within ½ mile of a potable water intake in a standing body of water, such as a lake, pond, or reservoir. |
| Postemergence<br>Broadcast<br>Ground or aerial                          | 3 lb/gal EC<br>[62719-389]                                   | 5  | NS   | 6  | NS                            | Use limited to rice grown in southern U.S. only. Application should be made using a minimum of 15 (ground) or 5 (aerial) gal of water/A. Applications are not permitted 28, 35, or 42 days after planting depending on the variety of rice. When double cropping is practiced, application to the second rice crop is prohibited. Applications are to be made when fields have been drained of most of the standing water and fields should be flooded within 12 to 24 hours of spraying. Water drained from treated rice fields must not be used to irrigate other crops or released within ½ mile upstream of a potable water intake in flowing water (e.g., river, stream, etc.) or within ½ mile of a potable water intake in a standing body of water, such as a lake, pond, or reservoir.  |

| Site<br>Application Timing<br>Application Type<br>Application Equipment | Formulation<br>[EPA Reg. No.]     | Maximum Single<br>Application Rate<br>(lbs. a.i./Acre) | Maximum No.<br>of Applications<br>Per Season | Maximum<br>Seasonal Rate<br>(lbs. a.i./Acre) | Preharvest<br>Interval (Days) | Use Directions and Limitations <sup>1,2</sup>  |
|---|-----------------------------------|--|--|--|-------------------------------|--|
| <b>Rice (continued)</b>   |                                   |  |  |  |                               |  |
| Postemergence<br>Broadcast<br>Ground or aerial                          | <b>4 lb/gal EC</b><br>[62719-392] | 6  | NS   | 8  | NS                            | Use limited to rice grown in southern U.S. only. Application should be made using a minimum of 15 (ground) or 10 (aerial) gal of water/A. Applications are not permitted after the end of tillering depending on the variety of rice. Applications may be made alone or as a tank mix with other pesticides. Applications are to be made when fields have been drained of flood water and fields should be flooded within 24 hours of spraying. Application to fields where catfish farming is practiced and draining water from fields into areas where catfish farming is practiced is prohibited. Water drained from treated rice fields must not be used to irrigate other crops or released within ½ mile upstream of a potable water intake in flowing water (e.g., river, stream, etc.) or within ½ mile of a potable water intake in a standing body of water, such as a lake, pond, or reservoir. |
| Postemergence<br>Broadcast<br>Ground or aerial                          | <b>81% DF</b><br>[62719-413]      | 6  | NS   | 8  | NS                            | Application should be made using a minimum of 15 (ground) or 10 (aerial) gal of water/A. Applications are not permitted after the end of tillering depending on the variety of rice. Applications may be made alone or as a tank mix with other pesticides. Applications are to be made when fields have been drained of flood water and fields should be flooded within 24 hours of spraying. Application to fields where catfish farming is practiced and draining water from fields into areas where catfish farming is practiced is prohibited. Water drained from treated rice fields must not be used to irrigate other crops or released within ½ mile upstream of a potable water intake in flowing water (e.g., river, stream, etc.) or within ½ mile of a potable water intake in a standing body of water, such as a lake, pond, or reservoir.  |

| Site<br>Application Timing<br>Application Type<br>Application Equipment | Formulation<br>[EPA Reg. No.]  | Maximum Single<br>Application Rate<br>(lbs. a.i./Acre) | Maximum No.<br>of Applications<br>Per Season | Maximum<br>Seasonal Rate<br>(lbs. a.i./Acre) | Preharvest<br>Interval (Days) | Use Directions and Limitations <sup>1,2</sup>   |
|---|--------------------------------|--|--|--|-------------------------------|---|
| <b>Rice (continued)</b>   |                                |  |  |  |                               |   |
| Postemergence<br>Broadcast<br>Ground or aerial                          | <b>80.2% DF</b><br>[62719-436] | 4.03   | NS   | 8.0625                                       | NS                            | Use limited to rice grown in AR, LA, MO, MS, and TX. Application should be made using a minimum of 15 (ground) or 10 (aerial) gal of water/A. Applications may be made alone or as a tank mix with other pesticides. <b>Do not graze treated fields or feed treated forage within 80 days of the last application.</b> * Use on wild rice ( <i>Zizania</i> spp.) is prohibited. Applications are to be made when fields have been drained of flood water and fields should be flooded within 24 hours of spraying. Application to fields where catfish farming is practiced and draining water from fields into areas where catfish farming is practiced is prohibited. Water drained from treated rice fields must not be used to irrigate other crops or released within ½ mile upstream of a potable water intake in flowing water (e.g., river, stream, etc.) or within ½ mile of a potable water intake in a standing body of water, such as a lake, pond, or reservoir. |

DF = Dry Flowable

EC = Emulsifiable Concentrate

<sup>1</sup> The restricted entry interval (REI) for the 3 and 4 lbs./gallon EC (EPA Reg. Nos. 62719-392 and 62719-404) and 80.2% and 81% DF (EPA Reg. Nos. 62719-413 and 62719-436) is 24 hours.

<sup>2</sup> The following rotational crop restriction is established for the 80.2% DF (EPA Reg. No. 62719-436) formulation: “Do not rotate to crops other than rice for 120 days following application.”



## **Appendix B. Data Supporting Guideline Requirements for the Reregistration of Propanil**

### **GUIDE TO APPENDIX B**

Appendix B contains a listing of data requirements which support the reregistration for active ingredients within the chemical case covered by this RED. It contains generic data requirements that apply in all products, including data requirements for which a “typical formulation” is the test substance.

The data table is organized in the following formats:

1. Data Requirement (Columns 1, 2 & 3). The data requirements are listed in the order of New Guideline Number and appear in 40 CFR §158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161-0002, (703) 487-4650.
2. Use Pattern (Column 4). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.
  - A. Terrestrial food
  - B. Terrestrial feed
  - C. Terrestrial nonfood
  - D. Aquatic food
  - E. Aquatic nonfood outdoor
  - F. Aquatic nonfood industrial
  - G. Aquatic nonfood residential
  - H. Greenhouse food
  - I. Greenhouse nonfood
  - J. Forestry
  - K. Residential
  - L. Indoor food
  - M. Indoor nonfood
  - N. Indoor medical
  - O. Indoor residential
3. Bibliographical Citation (Column 5). If the Agency has acceptable data in its files, this column lists the identification number of each study. Normally, this is the Master Record Identification (MRID) Number, but may be a “GS” number if no MRID number has been assigned. Refer to the Bibliography (Appendix D) for a complete citation of the study.



## Appendix B. Data Supporting Guideline Requirements for the Reregistration of Propanil

| New Guideline Number         | Old Guideline Number | Requirement   | Use Pattern | Bibliographical Citation(s)    |
|------------------------------|----------------------|---|-------------|--------------------------------|
| <b>PRODUCT USE CHEMISTRY</b> |                      |   |             |                                |
| 830.1550                     | 61-1                 | Product Identity and Composition                                  | All         | 40477301, 44681701             |
| 830.1600                     | 61-2A                | Starting Materials and Manufacturing Process                      | All         |                                |
| 830.1620                     | 61-2B                | Description of Production Process                                 | All         |                                |
| 830.1670                     |                      | Discussion of Formation of Impurities                             | All         |                                |
| 830.1700                     | 62-1                 | Preliminary Analysis  | All         | 40477301, 43969201, 44681702   |
| 830.1750                     | 62-2                 | Certification of Limits   | All         |                                |
| 830.1800                     | 62-3                 | Enforcement Analytical Method                                     | All         | 40477301, 43969201, 44681703-4 |
| 830.6302                     | 63-2                 | Color   | B, D, H     | 40477302, 44751501             |
| 830.6303                     | 63-3                 | Physical State  | B, D, H     |                                |
| 830.6304                     | 63-4                 | Odor  | B, D, H     |                                |
| 830.7200                     | 63-5                 | Melting Point/Melting Range                                       | B, D, H     |                                |
| 830.7220                     | 63-6                 | Boiling Point/Boiling Range                                       | B, D, H     | 40900201                       |
| 830.7300                     | 63-7                 | Density, Relative Density, Bulk Density                           | All         | 40477302, 44751501             |
| 830.7840<br>830.7860         | 63-8                 | Solubility  | All         | 40477302                       |
| 830.7950                     | 63-9                 | Vapor Pressure  | All         | 40477302, 40900201, 40923201   |
| 830.7550                     | 63-11                | Octanol/Water Partition Coefficient                               | All         | 00150488                       |
| 830.7000                     | 63-12                | pH of Water Solutions or Suspensions                              | All         | 44751501                       |
| 830.6313                     | 63-13                | Stability   | All         | 40477302, 44751501             |
| 830.6314                     | 63-14                | Oxidizing/Reducing Action   | All         | 44751501                       |
| 830.6316                     | 63-16                | Explosibility   | All         |                                |
| 830.6317                     | 63-17                | Storage Stability   | All         |                                |
| 830.6320                     | 63-20                | Corrosion Characteristics   | All         |                                |
| <b>ECOLOGICAL EFFECTS</b>    |                      |   |             |                                |
| 850.2100                     | 71-1A                | Avian Acute Oral Toxicity, Bobwhite Quail                         | B, D, H     | 41361001                       |
|                              | 71-1B                | Avian Acute Oral Toxicity, Mallard Duck                           | B, D, H     | 41360701, Acc. No. 246087      |
| 850.2200                     | 71-2A                | Avian Subacute Dietary Toxicity, Bobwhite Quail                   | B, D, H     | 41361101, Acc. No. 246413      |
|                              |                      | Avian Subacute Dietary Toxicity, Bobwhite Quail on 3,4-DCA        | B, D, H     | Data Gap                       |
|                              | 71-2B                | Avian Subacute Dietary Toxicity, Mallard Duck                     | B, D, H     | 41360701, Acc. No. 246087      |
| 850.2300                     | 71-4A                | Avian Reproduction, Bobwhite Quail on Parent Propanil and 3,4-DCA | B, D, H     | Data Gap                       |

| New Guideline Number | Old Guideline Number | Requirement   | Use Pattern | Bibliographical Citation(s)                                    |
|----------------------|----------------------|---|-------------|--|
| 850.2300             | 71-4B                | Avian Reproduction, Mallard Duck on Parent Propanil and 3,4-DCA | B, D, H     | Data Gap   |
| 850.2500             | 71-5A                | Simulated Field Study   | B, D, H     | Reserved   |
|                      | 71-5B                | Actual Field Study  | B, D, H     | Reserved   |
| 850.1075             | 72-1A                | Fish Toxicity, Bluegill Sunfish                                 | B, D, H     | 40098001, 41359801, 41360201, Acc. No. 246087, Acc. No. 249347 |
|                      |                      | Fish Toxicity, Bluegill Sunfish on 3,4-DCA                      | B, D, H     | Data Gap   |
|                      | 72-1C                | Fish Toxicity, Rainbow Trout                                    | B, D, H     | 40098001, 41359801, 41360201, Acc. No. 246087, Acc. No. 249347 |
|                      |                      | Fish Toxicity, Rainbow Trout on 3,4-DCA                         | B, D, H     | Data Gap   |
| 850.1010             | 72-2A                | Invertebrate Toxicity   | B, D, H     | 41776801, Acc. No. 249347                                      |
|                      |                      | Invertebrate Toxicity on 3,4-DCA                                | B, D, H     | Data Gap   |
| None                 | 72-3A                | Estuarine/Marine Fish Acute Toxicity                            | B, D, H     | 41776001   |
| 850.1025             | 72-3B                | Estuarine/Marine Mollusk Acute Toxicity                         | B, D, H     | 41777101, 42253100   |
| 850.1035             | 72-3C                | Estuarine/Marine Invertebrate Acute Toxicity                    | B, D, H     | 41776901, 42253101   |
| 850.1300             | 72-4A                | Fish - Early Life Stage   | B, D, H     | 41776501, 42259601, 42479601, Acc. No. 095187                  |
|                      |                      | Fish - Early Life Stage on 3,4-DCA                              | B, D, H     | Data Gap   |
| 850.1350             | 72-4B                | Estuarine/Marine Invertebrate Life Cycle                        | B, D, H     | 41776001, 42145601   |
|                      |                      | Estuarine/Marine Invertebrate Life Cycle on 3,4-DCA             | B, D, H     | Data Gap   |
| 850.1400             | 72-4C                | Early Life Stage, Freshwater Fish (Daphnia)                     | B, D, H     | 41776001, 42145601   |
| 850.1500             | 72-5                 | Life Cycle Fish   | B, D, H     | 41776001, 42145601, 42475301                                   |
| 850.1710             | 72-6                 | Aquatic Organism Accumulation Study                             | B, D, H     | Reserved   |
| 850.1950             | 72-7A                | Simulated Field Testing for Aquatic Organisms                   | B, D, H     | Reserved   |
|                      | 72-7B                | Actual Field Testing for Aquatic Organisms                      | B, D, H     | Reserved   |
| 850.4100             | 122-1A               | Seedling Emergence, Tier 1 on 3,4-DCA                           | B, D, H     | Data Gap   |
| 850.4150             | 122-1B               | Vegetative Vigor, Tier 1 on 3,4-DCA                             | B, D, H     | Data Gap   |
| 850.4225             | 123-1A               | Seedling Germination and Seedling Emergence, Tier 2 on TEP      | B, D, H     | 43069901   |
| 850.4250             | 123-1B               | Vegetative Vigor, Tier 2 on TEP                                 | B, D, H     | Data Gap   |
| 850.4400             | 132-2B               | Aquatic Plant Toxicity Test Using <i>Lemma spp.</i> , Tier 2    | B, D, H     | 41777201, 41777301, 41777401, 41777501, 41777601               |
| 850.3020             | 141-1                | Honey Bee Acute Contact Toxicity                                | B, D, H     | 00018842   |
| <b>TOXICOLOGY</b>    |                      |   |             |  |
| 870.1100             | 81-1                 | Acute Oral Toxicity, Rat  | B, D, H     | 00008722, 40070201, 41360801                                   |
| 870.1200             | 81-2                 | Acute Dermal Toxicity, Rabbit/Rat                               | B, D, H     | 00008722, 40070202, 41360901                                   |

| New Guideline Number                     | Old Guideline Number | Requirement  | Use Pattern | Bibliographical Citation(s)  |
|--|----------------------|--|-------------|--|
| 870.1300                                 | 81-3                 | Acute Inhalation Toxicity, Rat                                     | B, D, H     | 00008423, 40070203, 41265901, 41415501                               |
| 870.2400                                 | 81-4                 | Primary Eye Irritation, Rabbit                                     | B, D, H     | 00008430, 41360501   |
| 870.2500                                 | 81-5                 | Primary Skin Irritation  | B, D, H     | 00008430, 40070202, 41360601   |
| 870.2600                                 | 81-6                 | Dermal Sensitization   | B, D, H     | 00008430, 40070204, 40871906, 40914506, 41319701, 41319801, 41360401 |
| 870.6200                                 | 81-8                 | Acute Neurotoxicity Screening Battery, Rat                         | B, D, H     | Data Gap   |
| 870.3100                                 | 82-1A                | 90-Day Subchronic Feeding, Rodent                                  | B, D, H     | 00015459, 00046259, 40402901   |
| 870.3150                                 | 82-1B                | 90-Day Subchronic Feeding, Nonrodent (Dog)                         | B, D, H     | 42962901, 43303201   |
| 870.3200                                 | 82-2                 | 21-Day Dermal, Rabbit/Rat  | B, D, H     | 41777001, 41961800-01  |
| 870.3465                                 | 82-4                 | 90-Day Inhalation, Rat   | B, D, H     | Data Gap   |
| 870.4100                                 | 83-1A                | Chronic Feeding Toxicity, Rodent                                   | B, D, H     | 43303201, 43677801   |
|  | 83-1B                | Chronic Feeding Toxicity, Nonrodent (Dog)                          | B, D, H     | 42962901   |
| 870.4200                                 | 83-2A                | Chronic Carcinogenicity (Feeding), Rat                             | B, D, H     | 00015419, 00155215, 43303201, 43391701, 43677801                     |
|  | 83-2B                | Chronic Carcinogenicity (Feeding), Mouse                           | B, D, H     | 00155215, 43391701   |
| 870.3700                                 | 83-3A                | Prenatal Developmental Toxicity, Rat                               | B, D, H     | 00058588   |
|  | 83-3B                | Prenatal Developmental Toxicity, Rabbit                            | B, D, H     | 00058589, 45518801   |
| 870.3800                                 | 83-4                 | 2-Generation Reproduction, Rat                                     | B, D, H     | 00036091, 44604301   |
| 870.4300                                 | 83-5                 | Combined Chronic Toxicity/Carcinogenicity Study, Rat               | B, D, H     | 43303201   |
| 870.5140                                 | 84-2A                | Gene Mutation (Ames Test)  | B, D, H     | 00028625, 00155084-5   |
| 870.5375                                 | 84-2B                | Structural Chromosomal Aberration                                  | B, D, H     | 00155083   |
| 870.5100                                 | 84-2                 | Bacterial Reverse Gene Mutation Assay Test                         | B, D, H     | 00155085   |
| 870.5300                                 |                      | Detection of Gene Mutations in Somatic Cells in Culture, Mammalian | B, D, H     | 00155084   |
| 870.5500                                 | 84-4                 | Other Genotoxic Effects  | B, D, H     | 00028625   |
| 870.7485                                 | 85-1                 | General Metabolism, Rat  | B, D, H     | 41796400-2   |
| 870.7800                                 | 85-7                 | Immunotoxicity Study, Rat  | B, D, H     | Data Gap   |
| <b>OCCUPATIONAL/RESIDENTIAL EXPOSURE</b> |                      |  |             |  |
| 875.2100                                 | 132-1A               | Foliar Residue Dissipation   | B, D, H     | Reserved   |
| 875.2400                                 | 133-3                | Dermal Passive Dosimetry Exposure                                  | B, D, H     | Reserved   |
| 875.2500                                 | 133-4                | Inhalation Passive Dosimetry Exposure                              | B, D, H     | 00143618, Reserved   |
| 875.1100                                 | 231                  | Estimation of Dermal Exposure at Outdoor Sites                     | B, D, H     | Data Gap   |
| <b>ENVIRONMENTAL FATE</b>                |                      |  |             |  |
| None                                     | 160-5                | Chemical Identity  | B, D, H     | 41066601   |

| New Guideline Number     | Old Guideline Number | Requirement                                    | Use Pattern | Bibliographical Citation(s)   |
|--------------------------|----------------------|--|-------------|---|
| 835.2120                 | 161-1                | Hydrolysis                                     | B, D, H     | 41066601  |
|                          |                      | Hydrolysis on 3,4-DCA                          | B, D, H     | Data Gap  |
| 835.2240                 | 161-2                | Photodegradation, Water                        | B, D, H     | 41074701  |
|                          |                      | Photodegradation, Water on 3,4-DCA             | B, D, H     | Data Gap  |
| 835.2410                 | 161-3                | Photodegradation, Soil                         | B, D, H     | 42820401  |
| 835.2370                 | 161-4                | Photodegradation, Air                          | B, D, H     | 41537801  |
| 835.4100                 | 162-1                | Aerobic Soil Metabolism Study                  | B, D, H     | 41537801, 42057801  |
| 835.4200                 | 162-2                | Anaerobic Soil Metabolism Study                | B, D, H     | 41848701, 41872601  |
| 835.4400                 | 162-3                | Anaerobic Aquatic Metabolism Study             | B, D, H     |   |
| 835.4300                 | 162-4                | Aerobic Aquatic Metabolism Study               | B, D, H     | 41848701, 41872601  |
| 835.1240                 | 163-1                | Leaching/Adsorption/Desorption                 | B, D, H     | 42780401, 43217201  |
|                          |                      | Leaching/Adsorption/Desorption on 3,4-DCA      | B, D, H     | Data Gap  |
| 835.1410                 | 163-2                | Laboratory Volatilization from Soil            | B, D, H     | Waived  |
| 835.6200                 | 164-2                | Aquatic Field Dissipation                      | B, D, H     | 42200401, 42200501  |
| 835.6500                 | 164-5                | Long-Term Terrestrial Field Dissipation        | B, D, H     | Reserved  |
| 835.7100                 | 166-1                | Small Scale Prospective Ground Water           | B, D, H     | Reserved  |
| <b>RESIDUE CHEMISTRY</b> |                      |  |             |   |
| 860.1850                 | 165-1                | Confined Accumulation in Rotational Crops      | B, D, H     | 42963001  |
| 860.1900                 | 165-2                | Field Accumulation in Rotational Crops         | B, D, H     | Reserved  |
| None                     | 165-5                | Bioaccumulation in Aquatic Nontarget Organisms | B, D, H     | Reserved  |
| 860.1300                 | 171-4A               | Nature of the Residue, Plants                  | B, D, H     | 00035588-9, 00035684, 00036100, 00052347-50, 42209201, 42382901-2, 43285401, 43372201 |
|                          | 171-4B               | Nature of the Residue, Livestock               | B, D, H     | 00035697-9, 00035905, 00067394, 41754401, 41755301, 41848801, 41983901                |
|                          | None                 | Nature of the Residue, Crayfish                | B, D, H     | 41848901, 41849101  |
| 860.1340                 | 171-4C               | Residue Analytical Method, Plants              | B, D, H     | 00035587, 00055547, 00067394, 00076113, 00111367, 00111388, 43196001, 44748202        |
|                          | 171-4D               | Residue Analytical Method, Animals             | B, D, H     | 00055547, 00111367, Reserved  |
| 860.1380                 | 171-4E               | Storage Stability                              | B, D, H     | 00035683, 42200401, 42200501, 44748201, 43157001-2                                    |
| 860.1400                 | 171-4F               | Magnitude of Residues in Potable Water         | B, D, H     | 00035688, 42200401, 42200501, 43406501  |
|                          | 171-4G               | Magnitude of Residues in Fish (Crayfish)       | B, D, H     | 00035692, 00111394, 43748101  |
|                          | 171-4H               | Magnitude of Residues in Irrigated Crops       | B, D, H     | 00035688  |

| <b>New Guideline Number</b> | <b>Old Guideline Number</b> | <b>Requirement</b>                                       | <b>Use Pattern</b> | <b>Bibliographical Citation(s)</b>                           |
|-----------------------------|-----------------------------|--|--------------------|--|
| 860.1480                    | 171-4J                      | Magnitude of Residues in Meat, Milk, Poultry and Eggs    | B, D, H            | 00035694-5, 44748201   |
| 860.1500                    | 171-4K                      | Crop Field Trials (Cereal Grains Group)                  | B, D, H            | 00035687-8, 00055546, 00078930, 00111370, 00111373, 43282801 |
|                             |                             | Crop Field Trials (Grass Forage, Fodder and Straw Group) | B, D, H            |  |
|                             |                             | Crop Field Trials (Rice)                                 | B, D, H            | 43157001, 43282801   |
| 860.1520                    | 171-4L                      | Processed Food (Barley, Oats and Wheat)                  | B, D, H            | 00035576, 00035687-8, 00052347, 42417401, Waived             |
|                             |                             | Processed Food (Rice)                                    | B, D, H            |  |
| 860.1360                    | 171-4M                      | Multiresidue Methods                                     | B, D, H            | 41755001   |
| <b>OTHER</b>                |                             |  |                    |  |
| None                        | None                        | 30-Day Repeated Dose Oral (Dietary) Toxicity, Rat        | B, D, H            | 45829301   |

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

Additional documentation in support of this RED is maintained in the OPP Public Regulatory Docket, located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202-4501. It is open Monday through Friday, excluding legal holidays, from 8:30 AM to 4 PM.

The propanil docket initially contained preliminary risk assessments and related documents as of June 5, 2002. Sixty days later, the comment period closed. The Agency then considered comments and added the formal "Response to Comments" documents to the docket. All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Agency's website at <http://www.epa.gov/pesticides/reregistration/status.htm>. These documents include:

BEAD Document:

1. Reregistration Support: Use of Propanil and Other Herbicides in Rice, (V. Werling and D. Donaldson, 09/30/2003).

HED Documents:

1. Propanil: Report of the Hazard Identification Assessment Review Committee, (S.L. Makris, 05/14/2003);
2. Propanil. Addendum to the Revised Human Health Risk Assessment, (R.F. Griffin, 05/14/2003);
3. Propanil (028201) - Review of Repeated Dose (30-Day) Dietary Toxicity Study in Rats, (S.L. Makris, 05/21/2003);
4. Review of Protocol: "Evaluation of the Potential Exposure of Workers to Propanil During Mixing/Loading and Aerial Application to Rice Fields Using Simultaneous Dermal Dosimetry and Biological Monitoring Techniques," (S.M. Recore, 08/13/2003).

EFED Documents:

1. EFED Response to Registrant Request for a Seven (7) Day Holding Period for Propanil Use in Rice Paddies, (J. Breithaupt, 09/11/2003); and
2. Change in Risk to Aquatic Plants based upon Refined Tier 1 Rice Model, (F. Jenkins, 09/24/2003).



## **Appendix D. Citations Considered to Be Part of the Data Base Supporting the Reregistration Eligibility Decision (Bibliography)**

### **GUIDE TO APPENDIX D**

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



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

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## **Appendix E. EPA's Batching of Propanil Products for Meeting Acute Toxicity Data Requirements for Reregistration**

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

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

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

In deciding how to meet the product-specific data requirements, registrants must follow the directions given in the Data Call-In notice (DCI) and its attachments appended to the propanil RED document. The DCI notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response" lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers

to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Forty products were found which contain propanil as the active ingredient. These products have been placed into nine batches and a “No Batch” category in accordance with the active and inert ingredients and type of formulation. The following bridging strategies may be employed:

- No Batch: Each product in this Batch should generate their own data.

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

| Batch 1 | EPA Reg. No. | % Active Ingredient |
|---------|--------------|---------------------|
|         | 62719-403    | 96.0                |
|         | 71085-1      | 95.0                |
|         | 71085-21     | 98.0                |

| Batch 2 | EPA Reg. No. | % Active Ingredient |
|---------|--------------|---------------------|
|         | 9779-338     | 80.0                |
|         | 62719-413    | 81.0                |
|         | 65656-2      | 80.0                |
|         | 71085-6      | 80.0                |

| Batch 3 | EPA Reg. No. | % Active Ingredient                        |
|---------|--------------|--|
|         | 9779-343     | Propanil: 79.2<br>Bensulfuron methyl: 0.6  |
|         | 62719-436    | Propanil: 80.2<br>Bensulfuron methyl: 0.6  |
|         | 71085-16     | Propanil: 80.0<br>Bensulfuron methyl: 0.62 |

| <b>Batch 4</b> | <b>EPA Reg. No.</b> | <b>% Active Ingredient</b> |
|----------------|---------------------|----------------------------|
|                | 5905-523            | 60.0                       |
|                | 9779-306            | 60.0                       |
|                | 71085-13            | 60.0                       |
|                | 71085-22            | 60.0                       |

| <b>Batch 5</b> | <b>EPA Reg. No.</b> | <b>% Active Ingredient</b> |
|----------------|---------------------|----------------------------|
|                | 9779-272            | 45.0                       |
|                | 19713-31            | 45.0                       |

| <b>Batch 6</b> | <b>EPA Reg. No.</b> | <b>% Active Ingredient</b> |
|----------------|---------------------|----------------------------|
|                | 19713-285           | 43.5                       |
|                | 71085-2             | 43.5                       |

| <b>Batch 7</b> | <b>EPA Reg. No.</b> | <b>% Active Ingredient</b> |
|----------------|---------------------|----------------------------|
|                | 5905-77             | 42.8                       |
|                | 5905-182            | 42.8                       |

| <b>Batch 8</b> | <b>EPA Reg. No.</b> | <b>% Active Ingredient</b> |
|----------------|---------------------|----------------------------|
|                | 56077-43            | 41.2                       |
|                | 71085-5             | 41.2                       |

| <b>Batch 9</b> | <b>EPA Reg. No.</b> | <b>% Active Ingredient</b> |
|----------------|---------------------|----------------------------|
|                | 19713-30            | 35.9                       |
|                | 35935-2             | 35.0                       |
|                | 71085-3             | 35.0                       |

| No Batch | EPA Reg. No. | % Active Ingredient                         |
|----------|--------------|---|
|          | 100-982      | Propanil: 33.10<br>Molinate: 33.10          |
|          | 100-1036     | Propanil: 33.10<br>Molinate: 33.10          |
|          | 5905-68      | 35.00                                       |
|          | 5905-495     | Propanil: 33.70<br>Pendimethalin: 11.25     |
|          | 9779-340     | Propanil: 59.60<br>Bensulfuron methyl: 0.40 |
|          | 34704-461    | 35.00                                       |
|          | 51036-233    | 45.50                                       |
|          | 62719-386    | 33.80                                       |
|          | 62719-389    | 35.00                                       |
|          | 62719-392    | 43.50                                       |
|          | 62719-393    | 44.50                                       |
|          | 62719-404    | Propanil: 33.00<br>MCPA: 15.00              |
|          | 71085-4      | 50.00                                       |
|          | 71085-9      | Propanil: 41.20<br>Bensulfuron methyl: 0.32 |
|          | 71085-20     | 43.50                                       |

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

Pesticide Registration Forms are available via the Agency's website at <http://www.epa.gov/opprd001/forms/>.

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

### **Instructions**

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

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

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at [williams.nicole@epa.gov](mailto:williams.nicole@epa.gov).

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

|         |  |   |
|---------|--|---|
| 8570-1  | Application for Pesticide Registration/Amendment   | <a href="http://www.epa.gov/opprd001/forms/8570-1.pdf">http://www.epa.gov/opprd001/forms/8570-1.pdf</a>         |
| 8570-4  | Confidential Statement of Formula  | <a href="http://www.epa.gov/opprd001/forms/8570-4.pdf">http://www.epa.gov/opprd001/forms/8570-4.pdf</a>         |
| 8570-5  | Notice of Supplemental Registration of Distribution of a Registered Pesticide Product              | <a href="http://www.epa.gov/opprd001/forms/8570-5.pdf">http://www.epa.gov/opprd001/forms/8570-5.pdf</a>         |
| 8570-17 | Application for an Experimental Use Permit   | <a href="http://www.epa.gov/opprd001/forms/8570-17.pdf">http://www.epa.gov/opprd001/forms/8570-17.pdf</a>       |
| 8570-25 | Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need     | <a href="http://www.epa.gov/opprd001/forms/8570-25.pdf">http://www.epa.gov/opprd001/forms/8570-25.pdf</a>       |
| 8570-27 | Formulator's Exemption Statement   | <a href="http://www.epa.gov/opprd001/forms/8570-27.pdf">http://www.epa.gov/opprd001/forms/8570-27.pdf</a>       |
| 8570-28 | Certification of Compliance with Data Gap Procedures   | <a href="http://www.epa.gov/opprd001/forms/8570-28.pdf">http://www.epa.gov/opprd001/forms/8570-28.pdf</a>       |
| 8570-30 | Pesticide Registration Maintenance Fee Filing  | <a href="http://www.epa.gov/opprd001/forms/8570-30.pdf">http://www.epa.gov/opprd001/forms/8570-30.pdf</a>       |
| 8570-32 | Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data | <a href="http://www.epa.gov/opprd001/forms/8570-32.pdf">http://www.epa.gov/opprd001/forms/8570-32.pdf</a>       |
| 8570-34 | Certification with Respect to Citations of Data (PR Notice 98-5)                                   | <a href="http://www.epa.gov/oppmsd1/PR_Notices/pr98-5.pdf">http://www.epa.gov/oppmsd1/PR_Notices/pr98-5.pdf</a> |
| 8570-35 | Data Matrix (PR Notice 98-5)   | <a href="http://www.epa.gov/oppmsd1/PR_Notices/pr98-5.pdf">http://www.epa.gov/oppmsd1/PR_Notices/pr98-5.pdf</a> |



|         |  |   |
|---------|--|---|
| 8570-36 | Summary of the Physical/Chemical Properties (PR Notice 98-1)                       | <a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf</a> |
| 8570-37 | Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1) | <a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf</a> |

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

Dear Registrant:

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

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

Other PR Notices can be found at [http://www.epa.gov/opppmsd1/PR\\_Notices](http://www.epa.gov/opppmsd1/PR_Notices)

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).
  - a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
  - b. EPA Form No. 8570-4, Confidential Statement of Formula
  - c. EPA Form No. 8570-27, Formulator's Exemption Statement
  - d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
  - e. EPA Form No. 8570-35, Data Matrix
4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader).
  - a. Registration Division Personnel Contact List
  - b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
  - c. Antimicrobials Division Organizational Structure/Contact List
  - d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)

- e. 40 CFR §156, Labeling Requirements for Pesticides and Devices (PDF format)
- f. 40 CFR §158, Data Requirements for Registration (PDF format)
- g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

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

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

National Technical Information Service (NTIS)  
5285 Port Royal Road  
Springfield, VA 22161-0002

The telephone number for NTIS is (703) 605-6000.

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

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

- Date of receipt;
- EPA identifying number; and
- Product Manager assignment.

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

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



## **Appendix G. Generic Data Call-In**

See the following table for a list of generic data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions, is being sent to registrants under separate cover.



## **Appendix H. Product Specific Data Call-In**

See attached table for a list of product-specific data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions, is being sent to registrants under separate cover.



**Appendix I. List of Registrants Sent this Data Call-In**



