OPP-34144

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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

RECEIVED

SEP - 2 1999

PUBLIC DOCKET

MEMORANDUM

SUBJECT: Response to Public Comments on the Preliminary Risk Assessments for the Organophosphate Ethoprop

FROM: Kathryn Boyle, Chemical Review Manager
Special Review and Reregistration Division
Office of Pesticide Programs

Kathryn Boyle

TO: OPP Public Docket for Ethoprop
Docket # 34144 and 34144A

Introduction

This document addresses public comments that were received in response to EPA's Notice of Availability (63 FR 48213, September 9, 1998) of preliminary risk assessment[s] for the seven organophosphate chemicals: cadusafos, dimethoate, ethoprop, fenthion, sulfotepp, temephos and tribuphos. This document addresses comments specific to ethoprop. There were also comments that were submitted to the OPP Public Dockets for each of the seven chemicals or for a significant sub-set of the seven. The Agency's responses to non-specific comments were released to the public in the Cadusafos Response to Comments Document, which is now available on the Agency website and in the OPP Public Docket for Cadusafos.

Ethoprop-Specific Comments and Responses

A. Response to Comments on the Preliminary Human Health Risk Assessment

Comment: The registrant, Rhone-Poulenc, commented that the Agency used 100% crop treated (CT) for bananas as an assumption in estimating dietary risk, while only 3% of the imported banana crop is treated with ethoprop.

EPA Response: The Agency's preliminary dietary risk assessments were performed using 100% CT, which was the best information available to the Agency at the time. Since then, the Agency has estimated a percent CT for bananas. In estimating this percent CT, the Agency

considered that most of the bananas consumed in the United States are imported. Percent crop treated data from six Central and South American countries, representing 94% of the country's imported bananas, were used to estimate the percent of US banana imports that have been treated with ethoprop. This estimate is an average of the percent crop treated in these countries, weighted according to quantities exported to the US. The maximum (high-end) estimate of 16% will be used in the Agency's acute dietary assessment, and the likely weighted average of 6.4% will be used in the Agency's chronic (non-cancer) and carcinogenic dietary assessments.

Comment: The registrant commented that the ratios for the chronic (non-carcinogenic) and acute dietary assessments should not include the O-ethyl-S-propylphosphorothioate metabolite (M1). The M1 metabolite is not of toxicological concern for these two dietary risk assessments, but is of toxicological concern for dietary cancer risk assessment. Likewise, M1 should not be included in the expression of the total toxic residue from field studies. Including M1 over-estimates potential ethoprop residues in foods.

EPA Response: The Agency agrees with Rhone-Poulenc that M1 is not a residue of concern for the acute and chronic (non-cancer) dietary assessments. Rhone-Poulenc and the Agency have discussed the residue chemistry data requirements for reregistration. At this time the Agency is not requiring new crop field trials and processing studies in which determination of all residues of concern would be required. However, for the purposes of reregistration the Agency needs to estimate residues levels for the metabolites of concern (SME, OME, and M1). The available residue field trial data is for ethoprop and the M1 metabolite. The Agency made conservative assumptions regarding the levels of the other ethoprop metabolites using information from the ethoprop metabolism studies. Thus, a ratio, or adjustment factor, was used to convert the data on parent and M1 from residue field trials to residues reflecting the total residues of concern. For the various crops the adjustment factors ranged from 0.3 to 5.3 with the average being 2.8.

Upon reconsideration, the Agency agrees that the ratio can be performed without the M1 metabolite. The adjustment factors determined without using data for the M1 metabolite now range from 1.1 to 6.0 with the average being 2.8.

Comment: The registrant commented that the Agency did not address the situation where no detectable residue of either parent or metabolites were observed in the metabolism studies. Results of these studies suggest that no metabolites will be present if parent residues are not observed. The majority of the samples analyzed in field studies did not contain measurable residues of either parent or of M1 - even at exaggerated application rates. By assuming a value of half the limit of detection (½LOD) for both the parent and the M1 metabolite, the Agency has grossly over-estimated residue levels in foods. A more realistic estimate would be to simply assume ½LOD for the parent - with no further adjustments.

Comment: The registrant also commented that EPA's policy regarding use of the limit of detection/quantitation (LOD/LOQ) value has changed since the ethoprop acute Monte Carlo analysis was submitted. Many of the field trial studies reported samples as less than the LOQ

2912

value or as non-detects (ND); however, the LOQ value only was identified in the studies. As a conservative estimate for those samples reported as ND, it was assumed that the LOD value would be half the LOQ value. In reality, the LOD value is lower than half the LOQ.

EPA Response: In the past year, the Agency has re-examined its science policy regarding the numerical value that should be assigned to each sample reported as being less than LOD or less than LOQ for use in a quantitative exposure assessment. (Assigning Values to Nondetected/Nonquantified Pesticide Residues in Human Health Dietary Exposure Assessments, draft 11/30/98). Overall, the Agency's goals are to assure a scientifically supportable basis for assigning residue values and to avoid underestimating exposure to potentially sensitive or highly exposed groups. In the case of anticipated residue calculations for acute, chronic, and carcinogenic risk assessments, the LOD is preferred over the LOQ to represent "nondetects", provided that the LOD has been properly determined. In most cases in which residues are detectable yet not quantifiable, i.e., between the LOD and the LOQ, ½ LOQ can be used to numerically represent such samples.

After much discussion the Agency, at a meeting on December 16, 1998, has concluded that where no detectable residues of parent or M1 were observed in field trials, using half the LOD or LOQ and multiplying by the appropriate adjustment factor accounts for all metabolites of concern.

For the ethoprop risk assessment the Agency used the LOQ to derive the LOD. The Agency's acute dietary risk assessment was performed using ½ LOQ, ½ LOD, or zero to represent the "non-detects". This sensitivity analysis was performed to determine if the outcome of the risk assessment was significantly impacted by the value chosen to represent the "non-detects." The results of these analyses are documented in the Piper memorandum, dated July 12, 1999.

Comment: The registrant disagrees with the Agency's requirement, specified in the June 19, 1998 Piper memorandum, to use an adjustment factor (ratio) of 6 for all commodities for the acute dietary assessment.

EPA Response: Upon reconsideration the Agency agrees that the average adjustment factor of 2.8 can be used for blended commodities in the acute dietary assessment, and for all commodities in the chronic (non-cancer) dietary assessment. For cabbage, the adjustment factor for the acute dietary assessment is 4.0 based upon a cabbage metabolism study. For potatoes and sweet potatoes, the adjustment factor is 1.1 based upon a radish metabolism study. The highest adjustment factor of 6.0 will be used for all other single serving (unblended) commodities in the acute dietary assessment.

Comment: The registrant commented that comparison of the oral and dermal NOELs provide convincing evidence that the dermal absorption for ethoprop is not 100%. Rhone Poulenc further noted that accepted methods exist for estimating a dermal exposure value, when both dermal and oral NOELs are available, which could provide a more realistic dermal exposure in oral

3812

equivalents.

EPA Response: On December 3, 1998, ethoprop's toxicology database was evaluated to determine if a dermal absorption factor could be estimated for use in the carcinogenic occupational assessment. In the absence of a guideline dermal penetration study, dermal absorption can be estimated by comparing the doses at which effects occur, providing that the Agency has acceptable oral and dermal toxicity studies of similar durations and in the same species. The estimated dermal absorption is equal to the LOAEL from the oral study divided by the LOAEL from the dermal study times 100. For ethoprop, a 21-day dermal toxicity study in rabbits and an oral developmental toxicity study in rabbits were available. In the 21-day dermal toxicity study the LOAEL is 1 mg/kg/day based on decreased body weights. There were no signs of maternal toxicity in the oral developmental toxicity study at the highest dose tested, 2.5 mg/kg/day. Using the 2.5 mg/kg/day and the 1.0 mg/kg/day to estimate a dermal absorption factor, mathematically, the calculation would be 2.5 (even though this is a NOAEL, it is the highest dose tested) divided by 1.0 times 100 for a dermal absorption factor of 250%. The available information indicates that ethoprop is well absorbed in rabbits. Thus, in the absence of a study to specifically determine a dermal absorption factor for ethoprop, the Agency will continue to implicitly assume that ethoprop is absorbed through the dermal pathway to the same degree as oral ingestion; i.e., this standard assumption indicates that absorption by the dermal and oral routes are considered to be equivalent. There is not enough available information to more accurately estimate or characterize a dermal absorption factor.

Comment: The registrant strongly disagrees with EPA's classifying ethoprop as a "likely" human carcinogen to be regulated by linear low dose extrapolation.

EPA Response: In response to this classification, the registrant submitted new historical control data and arguments for re-classifying ethoprop as "not likely". The registrant's arguments and the new data were considered by the Agency at a meeting on April 1, 1998. The Agency's concerns regarding a specific type of tumor in the adrenal gland were mitigated somewhat by the new historical control data. However, it was determined to retain the current classification, of "likely", as well as the use of a linear low dose (Q_1^*) approach for cancer risk assessment. To consider reclassification of ethoprop's carcinogenic potential, the Agency requested that Rhone-Poulenc examine all adrenals in the low- and mid-dose groups of the 1992 chronic rat study. Until all these adrenals are examined, there would be insufficient evidence to change the carcinogenicity classification of ethoprop. However, Rhone-Poulenc has just informed the Agency that they have decided to not perform the re-evaluation of the adrenals; therefore, the classification will remain as "likely".

Comment: The registrant commented that the statistical approach taken in the EPA review of the cancer classification is not considered to be optimal.

EPA Response: The Agency acknowledges that the selection of the "optimal" statistical approach is a judgement call. EPA uses the Peto prevalence test which also accounts for

4912

differential survival among groups and is more sensitive than logic regression analysis.

Comment: The registrant commented that an April 18, 1998, letter to the Agency proposed plant-back restrictions in lieu of additional field trial data, and that as of August 19, 1998, they had not received any information on their proposal.

EPA Response: Correspondence addressing this issue was sent to Rhone-Poulenc on December 14, 1998.

Comment: Rhone-Poulenc's ethoprop field trial data for peanuts were generated considering three application patterns: at-plant only, at-pegging only, and at-plant/at-pegging. Because the studies were conducted as side-by-side field trials, Rhone-Poulenc considers it appropriate to use these data to determine the impact on residue levels resulting from the different use patterns. Applying a bridging factor to the at-plant/at-pegging studies results in a more robust data set for which to evaluate potential dietary exposure from residues in peanuts.

EPA Response: Two sets of peanut field trial studies were submitted to the Agency to support the use of ethoprop on peanuts for an at-plant application, followed by a second application at-pegging. After examining the two sets of data, the Agency considers it inappropriate to use a bridging set consisting of five samples, three of which showed no difference in total residue when at plant was compared to at plant/at pegging. Therefore, the at plant field trial data was the only data set used in the Agency's dietary assessments.

Comment: The Northwest Potato Crop Protection Coalition (Coalition) commented that the data generated by USDA's Pesticide Data Program (PDP) from 1993 to 1996 showed no detectable residues of ethoprop in all potatoes sampled.

EPA Response: In the timeframe 1993 to 1996 ethoprop was not a PDP required pesticide, i.e. it was not part of the routine analytical screen required by USDA for PDP laboratories. Potatoes were analyzed by PDP laboratories from May 1991 to December 1995. In 1994, PDP laboratories analyzed 694 potato samples, but reported only a total of 36 potato samples with analytical results of "non-detect"for ethoprop. Thus, the 658 potato samples analyzed in PDP laboratories which were not including ethoprop as part of their routine screen, cannot be considered to be a non-detect as ethoprop was not looked for. Even though these 36 samples were not required to be analyzed for ethoprop, by reporting these as "non-detects" a PDP laboratory was certifying that these 36 samples generally met the quality assurance/quality control protocols required by PDP for required pesticides. However, given the small number of samples, these 36 samples cannot be considered to have the national representation that is statistically built into the 694 potato samples analyzed in 1994. It is Agency policy that at least 100 samples are necessary for using monitoring data, such as PDP, in dietary risk assessments.

Comment: The Coalition commented that a significant proportion of potatoes are kept in storage for several months after harvest which provides additional time for any potential residues

5812

to degrade. Additionally, a majority of the potatoes in the Pacific Northwest are processed, which results in further breakdown of any potential residues on potatoes. Thus, these post-harvest storage intervals and processing will result in additional degradation of residues in potatoes, from the time of harvest. The Coalition believes that post-harvest storage intervals and processing should be taken into consideration when estimating potato residues for dietary assessment.

EPA response: Data from the potato processing study are adequate to show that ethoprop residues do not concentrate in processed potatoes. However, the available processing study does not show if residues are reduced upon processing. The Agency has no data to show if, or how much, residues decline during storage prior to consumption. This type of information is not routinely required by the Agency; however, if available, this type of study could be used to refine the risk assessment.

Comment: The Coalition commented that ethoprop is no longer applied by air in the Pacific Northwest on potatoes.

EPA Response: Currently, there are three granular ethoprop labels that contain directions for aerial application. Rhone-Poulenc has voluntarily offered to cancel aerial application on potatoes. Since aerial application is still on the ethoprop labels, aerial application must be considered in the Agency's risk assessment.

Comment: The Coalition commented that ethoprop is critical for at-plant applications to control wireworms on potatoes in the Pacific Northwest. With the loss of fonofos on potatoes, ethoprop is now the only chemical that growers can rely upon for control of serious wireworm infestations.

Comment: Another commentor, a farmer, stated that the use of ethoprop on potatoes at-plant is critical since carbofuran will no longer be available.

EPA Response: The Agency will consider these factors when making risk management decisions.

Comment: The commentor, a private citizen, stated that the Agency should promptly revoke the ethoprop tolerances for mushrooms, okra, and soybean commodities, since these uses were not supported for reregistration.

EPA Response: The tolerance revocation process begins when the registrant voluntarily decides to cancel certain products or product uses and informs the Agency in writing. The Agency then publishes a Notice in the Federal Register indicating that the registrant is voluntarily agreeing to amend their registration. The Notice requests public comment from affected individuals, usually providing a 30-day period for public comment. If no adverse comments are received, the Agency issues a final Federal Register Notice canceling the affected registrations. The Agency can propose the tolerance for revocation 180 days after the publication

6912

of the Notice. This proposed rule is published in the Federal Register and provides a 60-day period for public comment. At the end of the 60-day period, comments are considered, and a final rule (the tolerance revocation) can be published in the Federal Register. However, a major consideration in establishing the date for final tolerance revocation is the amount of product - the existing stocks - that bear the old labeling which legally allows the use on affected commodities. The Agency must allow reasonable time for the formulated pesticide product and a treated commodity to move through the channels of commerce before revoking the tolerance. Without the tolerance, the treated commodity would be considered adulterated and thus subject to seizure.

There are no longer any active labels which allow the use of ethoprop on soybeans, mushrooms, or okra. Notices amending the registrations to delete the use on soybeans were published in the Federal Register - on March 4, 1992, and July 19, 1995. Tolerances for soybeans; soybeans, forage; and soybeans, hay were proposed for revocation on February 5, 1998, and then revoked in a Federal Register Notice on October 26, 1998. A Notice, published in the Federal Register on April 7, 1999, proposed to remove the ethoprop tolerances for mushrooms. The comment period for this Notice closed on June 7, 1999. A Notice of Revocation for the mushroom tolerance was published in the Federal Register on July 21, 1999. Additionally, six ethoprop tolerances were proposed for revocation in the Federal Register on May 24, 1999. These tolerances (bean, snap, forage; pineapples, fodder; pineapples, forage; sugarcane, fodder; and sugarcane, forage) were proposed for revocation because they are no longer regulated feed items. The okra tolerance will be revoked.

B. Response to Comments on the Preliminary Ecological Effects Risk Assessment

Comment: The registrant commented that the Table found on page 35 of the preliminary environmental assessment appears to contain errors (exposed mg/ft2 values) for the tobacco and cucumber scenarios.

EPA Response: These errors were corrected in the Errata Sheet dated November 18, 1998. Correction of these values does not change the conclusions of the risk assessment.

Comment: The registrant commented that in the PRZM/EXAMS calculations, the EECs were the highest for cucumbers when the application rate on cucumbers is the lowest on the label.

EPA Response: EECs for cucumbers were recalculated to correct an error in the original input file. The corrected EECs are in Table 1, in the Errata Sheet dated February 18, 1999.

Comment: The registrant commented that the small number of incident reports do not support the risk quotients that have been developed for birds, mammals, or fish.

EPA Response: The Agency does not believe that the lack of incident reports involving birds or mammals proves unequivocally that animals are not at risk and succumb from exposure to ethoprop. Finding dead animals in the field is difficult, even when experienced field biologists

7912

are searching treated fields. Only carefully designed field studies can give any indication of the likelihood of field kill incidents occurring. The Agency no longer requires field studies for pesticides. Incident data are an adjunct to the risk assessment; they are not the sole basis for a risk assessment. If an assessment indicates risk, and there are many highly probable incidents, it would increase the confidence in the assessment. However, if an assessment indicates risk and there are few incidents, it does not negate the concerns.

Comment: The registrant commented that ethoprop is not a persistent compound in the environment. With the parameters used in the model, the calculated 300 day half-life for soil and 600 day half-life for water are gross overestimations. There are other studies (confined rotational crop studies and a field soil dissipation study) that suggest much lower half lives (30 days or less) that should be used by the Agency.

EPA Response: The fate parameters used for PRZM/EXAMS (Pesticide Root Zone Model/ Exposure Analysis Modeling System) are listed on page 16 of the Environmental Fate and Effects Risk Assessment (RED Chapter). Ethoprop is stable to hydrolysis and does not undergo photodegradation in water or on soil. Microbially-mediated rates of metabolism in soil for a particular chemical can be influenced by a number of factors, so the degradation rate can vary considerably. To account for this variability and consider sensitive populations, the Agency prefers that soil metabolism studies are conducted on several different types of soil. When only a single study on one soil type is performed, there is no empirically-based information to account for the inter-site variability in these fate parameters. To account for these uncertainties, the Agency employs a factor of 3 to approximate an upper bound (90% UCL; upper confidence limit) of the possible distribution of metabolic degradation half-lives. For ethoprop a single aerobic soil metabolism study established a half-life of 100 days which was then multiplied by 3 to achieve a half-life of 300 days. There is also a single anaerobic soil metabolism study which demonstrated a half-life of 100 days. This was also multiplied by 3 to achieve a half-life of 300 days.

When no aerobic aquatic metabolism data are available, the Agency's standard operating procedure calls for multiplying the aerobic soil input value by a factor of 2. Therefore, the 600-day half-life representing aerobic aquatic metabolism was calculated by multiplying using the half-life of 300 by an additional uncertainty factor of 2. It should be noted that this data gap was discussed in the Summary section of the environmental risk assessment. It was explained that submission of an acceptable aerobic aquatic metabolism study could reduce the amount of uncertainty associated with this potential route of dissipation and hence, possibly lower the aquatic EECs (estimated environmental concentrations).

A field dissipation rate is the result of a combination of numerous degradation and dissipation pathways in an actual field environment. In the laboratory each mechanism of dissipation is studied individually. The differences between the half lives in the laboratory studies versus the field studies may be due in part to leaching/run-off as well as increased soil moisture and temperature. The current tools for modeling the fate of a chemical post-field application consider

8812

the contribution of a number of individual degradation and dissipation pathways, rather than the combined pathways as reported in a field study. Field dissipation data are used to characterize risk and predict chemical dissipation rates and degradation products. To substitute a field dissipation half-life or a confined rotational crop half-life for soil metabolism as an input parameter would essentially "double count" many of the other dissipation and degradation pathways.

Comment: The registrant commented that GENEEC (Generic Expected Environmental Concentrations) and PRZM/EXAMS models have limitations. The models were designed to estimate exposure for ecological risk assessments and can substantially overestimate pesticide residues in drinking water.

EPA Response: Both GENEEC and PRZM/EXAMS estimate runoff from a ten hectare agricultural field into a one hectare by two meter deep pond. The Agency recognizes the concerns/limitations regarding the use of the farm pond scenario to estimate concentrations of pesticide residues in drinking water. However, in the absence of more sophisticated modeling techniques the Agency uses the models as a screening tool that is sufficiently conservative to ensure protection of human health and the environment.

The Agency is currently moving towards a probabilistic approach for modeling that could allow increased consideration of a parameter's distribution in the calculation of EECs. Until the Agency adopts a probabilistic drinking water assessment, the Agency will continue to employ the current approach.

Comment: EPA requested fish full life-cycle studies in freshwater and marine species. The registrant offered to conduct a fish full life-cycle study in sheepshead minnow as the marine surrogate, but requested a waiver for the freshwater species, stating that marine species are more sensitive than freshwater species without exception.

EPA Response: The Agency agrees with the registrant that the available data indicate estuarine/marine fish are more sensitive to ethoprop than are freshwater fish. However, the Agency does not agree that testing in a marine species should be used to waive freshwater testing. The Agency already uses each of these species as a surrogate for all such organisms in a specific environment and believes that further extrapolation of these data would lead to unacceptable levels of uncertainty in the risk assessment.

Comment: EPA requested that the two avian reproduction studies in quail and mallard be repeated due to the absence of a NOEC. The registrant commented that careful review of the quail reproduction study indicates that the effects, although statistically significant, are not biologically relevant. Rhone-Poulenc does acknowledge, however, that a NOEC was not reached in the mallard reproduction study and is willing to repeat it to reach a NOEC.

EPA Response: The Agency's review indicated that neither the quail or the mallard study

9913

produced a NOEC (the regulatory endpoint needed to assess chronic risk to wildlife). To fulfill guideline requirements both studies must be repeated. However, based on the information that was discernable in the studies, the Agency believes that no added information would result from repeating the mallard duck study. The mallard LOEC of 40 ppm was greater than the quail LOEC of 7.5 ppm, and thus, the results of the quail study, as representative of the more sensitive species, were used in the Agency's environmental risk assessment. The registrant has suggested repeating the mallard study. The Agency believes that the quail reproduction study should be repeated since it is likely to yield the lower NOEC.

Comment: The registrant commented that they are preparing to submit 5 field studies which demonstrated no statistical difference in avian or mammalian mortality between control fields and potato fields, tobacco fields or golf courses treated with ethoprop.

EPA Response: These studies have not yet been submitted to the Agency. Once submitted, the studies will be reviewed and evaluated.

Comment: The registrant, Rhone-Poulenc, disagrees with the statement that marine organisms are exposed to higher concentrations in surface water than freshwater organisms. The PRZM/EXAMS estimates for coastal areas are for coastal freshwater areas and are not reflective of concentrations in marine environments. PRZM/EXAMS is inadequate to model pesticide concentrations in marine environments, and the probability is high that the concentrations in estuaries are much lower than that predicted by PRZM/EXAMS in freshwater due to large water volume inputs and tidal overwash in marine ecosystems.

EPA Response: The Agency agrees that PRZM/EXAMS is not the ideal tool to estimate pesticide concentrations in marine environments, particularly in areas of high flushing. Currently, it is the only model available to the Agency. Until a model is developed for marine environments the Agency must continue to use conservative, protective assumptions.

Comment: The Northwest Potato Crop Protection Coalition commented that the use of ethoprop poses a low risk to the environment, as evidenced by the fact that USGS Survey reports from the Pacific Northwest do not show any detections of ethoprop in surface or groundwater.

Comment: The registrant commented that USGS National Water Quality Assessment (NAWQA) Pesticide National Synthesis Project database should be used. These data are from a first cycle of water assessments taken during 1991-1995 and include the analyses of 85 pesticides (including ethoprop) in approximately 5000 samples of ground and surface water in 20 of the nation's major watersheds.

EPA Response: NAWQA is designed to assess the status of and trends in the quality of the Nation's ground and surface water resources, with an emphasis on understanding the natural and human factors that affect the water quality. A NAWQA Study Unit (SU) is a major hydrologic system which is defined by a combination of ground and surface water features. The 60 study

units cover approximately 40 percent of the United States, encompass 60 to70 percent of the national water use as well as the populations served by public water supplies, and include diverse hydrologic systems. The data is intended to characterize geographic and seasonal distributions of water-quality conditions and trends. NAWQA data was not intended for quantitative drinking water risk assessment, but does provide extremely useful information for understanding and characterizing possible risk from consumption of drinking water containing residues of ethoprop. Use of NAWQA data is highly dependent on whether a NAWQA study area overlaps the pesticide's use areas, whether sample sites are in close proximity to use sites, whether the sampling dates correspond to the times that the pesticide is likely to be applied, and whether an adequate number of samples were taken at the appropriate locations.

To conserve resources, the Agency conducts its review of NAWQA data in an iterative fashion. During the preliminary review, Agency scientists compare the NAWQA Study Units to the pesticide's use areas to find overlap areas. The data is screened for any detections above the method's detection limit or level of quantitation, and any detections that approach or exceed the Agency's modeling results. If the estimation of DWLOCs indicate a possible concern, then a more detailed, secondary review is performed.

For ethoprop, a preliminary review of the NAWQA surface water monitoring data was conducted after acquisition of the raw monitoring data from the USGS. This review included: (1) the total number of samples, (2) a comparison of the location of the NAWQA Study Units and sampling sites within the SU in relationship to potential ethoprop use areas, and (3) the analytical results of the study. The preliminary review concluded that:

- water samples were taken from surface source waters that were not the most vulnerable sources for either human or aquatic exposures
- sample collection was not performed in association with confirmed ethoprop use at the field level
- most sampling did not occur during anticipated application periods for many of the SUs, therefore, potentially missed periods of higher ethoprop concentration

These sampling limitations make definitive statements of exposure impossible. Thus, based on this review, the Agency determined that it was not possible to make conclusive statements on the value of the surface water monitoring data for use in either human or aquatic exposure assessments.

Based on the estimation of DWLOCs and possible concerns from consumption of drinking water containing residues of ethoprop, the Agency has now performed a secondary review of the data to ascertain whether any of the monitoring data could be used in a regional assessment of ethoprop.

A gross comparison of the NAWQA Study Units (SU) against ethoprop use areas was performed. Of the 20 SUs where ethoprop data were collected, six potentially overlapped the

11813

highest use areas reported by the registrant. These six areas did not include the major use area in Florida; the sugarcane growing region of Southern Florida which represents 43% of ethoprop use, but did include some peanuts, beans, vegetable truck crop and corn areas which total less than 20 percent of ethoprop use nationwide. There is some monitoring in the Pacific Northwest, a major potato growing region. Potatoes represent approximately 24 percent of ethoprop use nationwide in which the Pacific Northwest appears to be the dominant use area. There is also some data within the corn growing region of the US.

Within each of these areas, a review of the monitoring data based on sample timing was conducted. Of the six SUs with possible overlap, only two were monitored during potential ethoprop application times. None of the sampling locations were determined to be from vulnerable surface water sources, e.g., lakes and reservoirs. A number of the sampling locations were in urban and suburban areas. Ethoprop is not registered for home use.

To conduct further analysis of the data, will require field level use data during the sampling events in the key NAWQA SUs to determine the usefulness of the data for a regional assessment. Without this data, a cause and effect relationship cannot be established.

12912