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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrants:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its revised Atrazine Interim Reregistration Eligibility Decision (IRED), consistent with the Consent Decree, as amended, entered in Natural Resources Defense Council v. Whitman, Case Number C -99-3701 CAL, N. D. California (2002)). It does not alter the conclusions of the January 31, 2003 IRED document except as described below. There will be a 90-day public comment period for this document. At a later date, the Agency will publish a comprehensive atrazine IRED incorporating changes, if any, resulting from public comment and combining the January and October documents into one document.

In August 2002, the court supervising the implementation of the Consent Decree granted a request from EPA and Natural Resources Defense Council (NRDC) that the Decree's deadline for the atrazine IRED be extended. The new schedule included the completion of an IRED by January 31, 2003, and a revised IRED by October 31, 2003. The amended Consent Decree states that the revised Interim RED for atrazine must address the following: (1) data received by EPA prior to February 28, 2003, relating to the potential effects of atrazine on amphibian species; and (2) to the extent not addressed in the January 31, 2003 Interim RED, data, received prior to February 28, 2003, relating to the association between atrazine exposure and the incidence of prostate or other cancer in humans. The amended Consent Decree also specifies that EPA is to hold FIFRA Science Advisory Panel (SAP) meetings on these two issues.

Ecological monitoring of watersheds was required in the January IRED due to the potential for community-level and population-level risk to aquatic ecosystems from atrazine. The January IRED states that to mitigate these ecological risks to aquatic communities, the Agency is requiring that atrazine registrants, in consultation with EPA, develop a program under which the registrants monitor for atrazine concentrations and mitigate environmental exposures if EPA determines that mitigation is necessary. The program will focus on watershed impacts of atrazine use.

This revision to the January 31, 2003 IRED consists of three sections: 1) potential

association between atrazine exposure and the incidence of prostate cancer and other cancers in humans; 2) potential effects of atrazine on amphibian endocrinology and development; and 3) ecological monitoring and mitigation of atrazine in watersheds. In each section, this document summarizes the conclusions in the January IRED pertaining to the section, developments since the IRED, and next steps, as appropriate. The technical documents supporting these revisions are listed below and appended to this IRED.

A. Review of Atrazine Cancer Epidemiology,
B. Potential Effects of Atrazine on Amphibian Gonadal Development,
C. Final Reports of the Atrazine Ecological and Monitoring Subgroups,
D. Atrazine Ecological Subgroup Final Report: Recommendations for aquatic community Level of Concern (LOC) and method to apply LOC(s) to monitoring data,
E. Microcosm and Mesocosm Data,
F. Atrazine Toxicity Data for CASM Simulations,
G. CASM Results: Steinhaus Similarity Toxicity Scenario,
H. Comparison of Annual Average CASM Steinhaus Similarity for a Series of Chemographs Calculated with the Logistic Regression vs. Actual CASM Simulations,
I. Comparison of Simulated Change in Annual Production for Phytoplankton, Periphyton, Macrophytes, Zooplankton, Benthic Invertebrates, and Fish for CASM Parameterizations,
J. Decrease in Annual Total Production,
K. Atrazine Ecological Monitoring Program Subgroup: Recommendations for Monitoring Design, and
L. Assessment of Potential Mitigation Measures for Atrazine, February 13, 2003.

Potential Association Between Atrazine Exposure and Prostate Cancer and Other Cancers in Humans

January 31, 2003 IRED

The Agency's human health risk assessment for the January 31, 2003, IRED did not include a quantitative risk assessment for cancer due to a determination by the EPA, consistent with conclusions reached by the SAP (June 2000), that it is unlikely that atrazine's cancer mode of action in the Sprague-Dawley rat is operative in humans. EPA's Cancer Assessment Review Committee (CARC), in accordance with the 1999 Draft Guidelines for Carcinogen Risk Assessment, classified atrazine as "not likely to be carcinogenic to humans."

The review of the cancer epidemiology study for the January 31, 2003, IRED did, however, include epidemiological data on workers at the Syngenta St. Gabriel Louisiana plant where atrazine is manufactured. The study reported a statistically significant increase in the incidence of prostate cancer among plant workers. The Agency, upon review of this study, requested additional information on the exposure profile of the employees diagnosed with

prostate cancer and this information was provided and reviewed. Based on this review, it appeared that most of the increase in prostate cancer incidence at the St. Gabriel plant was likely due to intensive prostate specific antigen (PSA) screening of employees. The study was insufficiently large and had limitations that prevent ruling out atrazine as a potential contributor to the increase observed. On balance, however, a role for atrazine seemed unlikely because prostate cancer was found primarily in current employees who received intensive PSA screening; there was no increase in advanced tumors or mortality; and proximity to atrazine manufacturing did not appear to be correlated with risk.

Other cancers besides prostate were found to have an elevated, though not statistically significant, increase in risk at the St. Gabriel plant. Other studies have suggested an increased risk for ovarian, breast, and other cancers, including non-Hodgkin's lymphoma (NHL). However, EPA had previously concluded that these studies were at best preliminary and should not serve as a basis for implicating atrazine as a human carcinogen due to their methodological limitations.

July 17, 2003 SAP

To further analyze the question of exposure to atrazine and prostate cancer, an SAP meeting was held on July 17, 2003 (http://www.epa.gov/scipoly/sap/index.htm). Given the limited nature of the new cancer data that stimulated the request for a second SAP meeting, EPA's submission to the SAP focused primarily on the new prostate cancer data rather than the epidemiological data that the SAP in 2000 had judged inconclusive or later studies received since 2000 that EPA found to be inconclusive. EPA asked the Panel to comment on the Agency's conclusion regarding prostate cancer and particularly the preliminary results from a nested case-control study of the St. Gabriel manufacturing plant in Louisiana. In addition to this study, the SAP was provided with other epidemiological studies on atrazine exposure and prostate cancer, a review by the Agency discussing the St. Gabriel data and epidemiological data bearing on prostate cancers, comments from four external peer reviewers, a Syngenta-sponsored expert panel review, and comments by the Natural Resources Defense Council. As stated in the January IRED, EPA's view of the study was that the increase in PSA screening for the St. Gabriel workers could explain the increase in prostate cancer observed in these workers and therefore a role for atrazine seemed unlikely. EPA acknowledged, however, that due to limitations in the St. Gabriel study, atrazine could not be ruled out as a potential causal factor.

The SAP's analysis of the St. Gabriel study differed to a degree from the Agency's conclusion. The SAP did conclude that "the increase in Prostate Specific Antigen (PSA) screening at the St. Gabriel plant likely led to an increase in the detection of cases of prostate cancer." Further, the Panel noted that "[s]ubstantive and persuasive arguments have been made to support the EPA's conclusion that PSA screening could explain the observed increase in prostate cancer incidence in the workers." Nonetheless, the Panel did not believe there was sufficient evidence to conclude that it was "unlikely" that atrazine had a role in the increased prostate cancer cases seen in the St. Gabriel study "given the severe limitations of the St. Gabriel study, particularly those pertaining to small sample size, questionable exposure assessment and

lack of an appropriate comparison group." According to the SAP, PSA screening may be only a "partial explanation" for the increase in prostate cancer seen in the St. Gabriel study and that "atrazine cannot be ruled out as a potential cause."

The Agency agrees with the SAP's analysis and has rewritten its conclusion as follows:

> The increase in prostate cancer incidence at the St. Gabriel plant in Louisiana is consistent with the intensive PSA screening. This is because prostate cancer was found primarily in active employees who received intensive PSA screening, there was no increase in advanced tumors or mortality, and proximity to atrazine manufacturing did not appear to be correlated with risk. No evidence was identified, such as dose-response evidence, that permit a determination that some of the increase was likely due to exposure to atrazine although atrazine exposure cannot be ruled out at this time as a cause. However, the study was insufficiently large and suffered from other limitations that prevent a determination that all of the increase in prostate cancer was probably due to the intensive screening program. Therefore, EPA concludes that the St. Gabriel study does not contribute any evidence supporting atrazine as a likely human carcinogen. (see Appendix A)

The SAP suggested that the Agency consider additional analysis of the St. Gabriel cohort. However, the resulting sample size would still limit the opportunity to draw further conclusions. The Agency questions whether additional analysis is warranted for other potential risk factors (such as smoking, diet and previous work history, and non-occupational or pre-employment exposure to triazine herbicides). Because of the way the study was designed, this information is not available to investigators and it may not be feasible to obtain such information for the St. Gabriel workers.

The other epidemiologic studies investigating the relationship between atrazine exposure and prostate cancer did not alter the Panel's opinion that the evidence presented is inadequate to support the Agency's conclusion of atrazine as an "unlikely" cause of prostate cancer seen in the St. Gabriel study. One study by Mills (1998) found a borderline statistically significant positive association between atrazine use by county with prostate cancer incidence rates in African American males. A second study by Alavanja et al. (2003) showed no association of self-reported atrazine exposure with prostate cancer in cohort analysis of pesticide applicators.

Epidemiological Data on Other Cancers

EPA has re-reviewed the epidemiological data regarding atrazine and cancer that were examined for the SAP meetings on atrazine in 2000 and 2003. EPA has also reviewed data that have become available since the latest meeting of the SAP in 2003. The results of those reviews are also summarized in Appendix A to this document. In brief, the Agency does not find any results among the available studies that would lead us to conclude that a potential cancer risk is likely from exposure to atrazine.

Even though the epidemiological evidence and animal data, when viewed separately, do not support a positive cancer finding for atrazine, EPA examined the totality of animal and human data to determine if that approach showed that atrazine was likely to cause a carcinogenic response in humans. Specifically, EPA reviewed the available animal data to determine if a mechanism could be identified which supports the biological plausibility of atrazine as a human carcinogen taking into account the tumors that were identified in the epidemiological data. This review showed that (1) lymphomas, including NHL, were generally not seen in atrazine animal bioassays; (2) a mechanistic role for atrazine contributing to NHL has not been identified in laboratory studies; (3) tumors at any endocrine site other than mammary gland tumors in female SD rats (e.g., prostate, ovarian tumors) have not been identified in atrazine bioassays; (4) the SAP concluded in 2000 that the mammary gland tumors in rats caused by atrazine are produced via a mechanism not relevant to humans; and (5) the endocrine tumors that have been raised in epidemiological studies (other than mammary gland tumors) can not be biologically tied to atrazine's mode of action (i.e., decrease prolactin, decrease luteinizing hormone (LH) and suppression of ovulation). Thus, at this time, joint consideration of the available animal cancer and mode of action data and epidemiological studies, does not indicate that atrazine is likely to cause cancer in humans.

Conclusion

In the January 31, 2003 IRED, EPA concluded that, considering the animal data and the human epidemiological data, atrazine is "not likely to be carcinogenic in humans". That conclusion allowed EPA to find that there is a reasonable certainty of no harm from exposure to atrazine so far as cancer risk is concerned. Results in the St. Gabriel study and other recent epidemiological studies regarding atrazine's potential link to cancer do not alter that conclusion. Further, any weight attributable to these data is weakened by the data in animals that fail to reveal any mechanism of action for atrazine consistent with the cancers observed in the studies. Accordingly, EPA concludes that atrazine is not likely to be a human carcinogen."

Next Steps

Since the July 2003 SAP meeting, EPA has received two new pieces of information: (1) a report from the National Cancer Institute (NCI) re-analyzing previous epidemiologic studies of atrazine and non-Hodgkin's lymphoma using hierarchical techniques to adjust for the effects of multiple exposures; and (2) a nested case-control study conducted for Syngenta of workers at the St. Gabriel plant using more detailed job histories to evaluate exposure indices. The Agency plans to conduct a comprehensive review of both studies. EPA's preliminary view of these studies is discussed in Appendix A. EPA is also expecting to receive additional epidemiological studies and analyses concerning atrazine and cancer from the NCI's Agricultural Health Study in the next one to two years. These studies and analyses include the following: an update of the Agricultural Health Study on prostate cancer capturing additional prostate cancer cases; an analysis of all the non-Hodgkin's lymphoma cases reported in the Agricultural Health Study; and a special analysis of all cancers related to atrazine exposure in the same Agricultural Health Study cohort. The latest projection is that the NCI will complete these studies and analyses in

mid-2005.

After all of the information has been submitted and reviewed, the Agency plans to convene another SAP meeting concerning atrazine and its possible association with carcinogenic effects. At that meeting, EPA intends to present the SAP with all of the data bearing on atrazine and cancer, including the old and new epidemiology studies. In the meantime, EPA will continue its review of all new data submissions. If at any time, results from any of the new data submissions raise significant questions that would benefit substantially from SAP review prior to submission of all of the data, the Agency will hold a SAP meeting before all aspects of the Agricultural Health Study are completed.

EPA intends to thoroughly review any SAP report from any future meeting, once issued, and to revise its determinations regarding the cancer potential of atrazine, as necessary. Any revisions will be included in either a revision to the October 31, 2003 IRED or the final reregistration decision for atrazine depending on the timing of the future SAP meeting relative to issuance of the final atrazine reregistration decision.

Potential Effects of Atrazine on Amphibian Endocrinology and Development

January 31, 2003 IRED

In the ecological risk assessment for the January 31, 2003 IRED, the Agency did not suggest that endocrine disruption, or potential effects on endocrine-mediated pathways, was regarded as a regulatory endpoint for ecological effects. Nor did the Agency have reliable evidence at that time to state that atrazine caused endocrine effects in the environment. The IRED stated that based on the existing uncertainties in the available database, atrazine should be subject to more definitive testing once the appropriate testing protocols have been established. The Agency was aware that several pertinent studies were being performed by researchers that may reduce some of the uncertainties in understanding potential atrazine effects on amphibian endocrinology and reproductive and developmental responses.

June 17-20, 2003 SAP

Since the January IRED, the Agency has conducted a comprehensive evaluation of the available data regarding the potential effects of atrazine on amphibian gonadal development and presented its assessment for external peer review to a SAP in June 2003. In a May 29, 2003 white paper, the Agency summarized seventeen studies consisting of both open literature and registrant-submitted laboratory and field studies involving both native and non-native species of frogs (see Appendix B). In its white paper the Agency concluded that none of the studies fully accounted for environmental and animal husbandry factors capable of influencing endpoints that the studies were attempting to measure. The Agency also concluded that the current lines-of-evidence did not show that atrazine produced consistent effects across a range of exposure concentrations and amphibian species tested.

Based upon this assessment, the Agency concluded and the SAP agreed that there is sufficient evidence to formulate a hypothesis that atrazine exposure may impact gonadal development in amphibians, but there are currently insufficient data to confirm or refute the hypothesis (http://www.epa.gov/oscpmont/sap/2003/June/junemeetingreport.pdf). Because of the inconsistency and lack of reproducibility across studies and an absence of a dose-response relationship in the currently available data, the Agency has determined that it does not change the conclusions reached in the January 31, 2003 IRED regarding atrazine's effects on amphibians.

Next Steps

Based on the conclusions from the Agency's white paper and recommendations of the SAP, the Agency will seek additional data to reduce uncertainty regarding the potential risk to amphibians (http://www.epa.gov/oscpmont/sap/2003/june/dataevaluationreports.htm). This data collection will follow the multi-tiered process outlined in the Agency's white paper. This approach to collecting additional information through further studies, which was endorsed by the SAP, can be used to address uncertainties associated with the potential causal relationships between atrazine exposure and gonadal development and characterize the nature of any concentration-response relationship.

Ecological Monitoring and Mitigation of Atrazine in Watersheds

January 31, 2003 IRED

The ecological risk assessment for the January IRED stated that the Agency has ecological risk concerns from the use of atrazine and identified the potential for community-level and population-level risk to aquatic ecosystems at prolonged concentrations of atrazine from 10 to 20 ppb. To mitigate these ecological risks to aquatic communities and to determine that atrazine is eligible for reregistration, the Agency required that atrazine registrants, in consultation with EPA, develop a program under which the registrants monitor for atrazine concentrations and mitigate environmental exposures if EPA determined that mitigation is necessary. This program would focus on watershed impacts of atrazine use.

The January IRED further stated that the program will include an appropriate ecological level of concern (LOC), identified by EPA; development of a protocol for a monitoring program that specifies the frequency, location, and timing of sampling, as well as an appropriate coordination with Total Maximum Daily Load (TMDL) programs; triggers for mitigation measures; and description of mitigation measures that will be taken if triggers are exceeded. This monitoring and mitigation program would be designed, conducted and implemented on a tiered watershed level and must be consistent with existing state and federal water quality programs.

Follow-up to January 31, 2003 IRED

The following description highlights how EPA developed the specifics of the ecological monitoring and mitigation program consistent with the January 2003 IRED. The Office of Pesticide Programs, the Office of Research and Development, and the Office of Water collaborated to integrate and develop this program.

Level of Concern (LOC)

The sensitive endpoint in the ecological assessment for atrazine is a change in the structure and function of primary producers in the aquatic community. Concentrations of atrazine that affect plant productivity and community structure typically occur at levels lower than those that directly intoxicate fish and aquatic invertebrates. By focusing on aquatic plant community structural changes, the most sensitive endpoint, the Agency intends to protect fish and invertebrates from the direct effects of atrazine as well as the effects that atrazine could have on the habitat and food sources of aquatic animals (see Appendices C- K).

The Level of Concern (LOC) was derived to ensure that the atrazine concentrations in watersheds will not cause significant changes in aquatic plant community structure. The LOC is based on an analysis of 25 microcosm and mesocosm studies cited in the Final Report of a report provided in Appendix D. To establish the LOC, it was necessary to quantify the results of the mesocosm and microcosm studies by rating their reported results based on the significance of the effects on aquatic plant productivity and community structure. Each study was analyzed to establish the reported effect(s) and the atrazine exposure profile, which reflects the magnitude, frequency and duration of atrazine concentrations in the study. This analysis revealed a wide range of study designs and quality and also indicated that a wide range of atrazine exposure profiles could result in significant change in aquatic community productivity and structure. A method was developed to separate the reported results on plant community productivity and structure observed in these studies into those that were significant versus those with slight to no-effects.

Since atrazine exposure profiles in natural systems, in this case streams, will typically be complex, it was necessary to develop a method to analyze monitoring data to determine when monitored exposure profiles are functionally-equivalent to those profiles observed in mesocosm and microcosm studies showing significant changes when the monitored profiles are functionally-equivalent to those studies that showed no significant effects.

Using a range of atrazine exposure profiles representative of those that caused significant effects in the microcosm and mesocosm studies, as well as those that did not result in significant effects, an ecological food chain model that predicts changes in aquatic communities in streams (in this case, Comprehensive Aquatic Systems Model, CASM), was used to develop the means of interpreting whether or not any atrazine exposure profile observed in the monitoring study would likely be associated with a significant effect on aquatic communities. These analyses determined that a community similarity index (CSI) that quantifies the average changes in biomass for plant species of the modeled aquatic community, is the most useful model parameter to segregate those mesocosm and microcosm studies that exhibited significant effects from those

that did not. Conceptually, this index is consistent with the observed effects of atrazine on primary producers in aquatic ecosystems. More specifically, through this analysis it was determined that an average CSI change of 5% or greater over the course of a study reasonably discriminated micro- and mesocosm exposure profiles associated with significant effects (i.e., irreparable changes to ecosystems) from those that did not show significant effects.

Consequently, these analyses establish the LOC as any measured atrazine exposure profile obtained through a monitoring study that would result in a predicted 5% or greater average change in the CSI through the use of CASM. Additional analyses over the duration of the three year monitoring study will evaluate the use of additional aquatic community models (e.g., Aquatox), and comparable modeled indices, to provide additional model options for States, Tribes or other parties to evaluate data that may be collected in other monitoring programs.

Monitoring Program Protocol

The monitoring protocol is initially focused on flowing water bodies (i.e., streams) associated with corn and sorghum production (see Appendix K). Future efforts (see below) will address the need to monitor estuaries and water bodies associated with sugarcane production. In addition, results of raw water monitoring from the on-going atrazine monitoring program for drinking water, as described in the January 31, 2003 IRED, will be analyzed to determine its potential utility in evaluating potential ecological effects in static water bodies.

The purpose of the monitoring program in flowing waters is to estimate the magnitude and extent to which water bodies with the greatest potential vulnerability to atrazine exposure (primarily based on atrazine use and runoff potential) are exceeding the level of concern consistent with the atrazine ecological risk assessment, which was described above. The initial analyses identified three tiers of watersheds relevant to atrazine use in corn and sorghum. The first tier of approximately 10,000 watersheds had some level of atrazine use on corn and sorghum. The watersheds identified in this assessment were primarily at the 5th, or Hydrologic Unit Code (HUC)-10/11, level of a hierarchal system of mapping watersheds established by the United States Geological Survey (USGS). At this level, watersheds are typically 40,000 to 250,000 acres in size. From this first tier, a second tier of 5,860 HUC-10/11 watersheds was identified based on use intensities of 0.25 lb active ingredient (ai)/county acre or higher. From this second tier of watersheds, a third tier of 1,172 watersheds was identified based on their predicted potential to be among the most vulnerable to atrazine surface water loading from use on corn and sorghum. Through the development of a statistically-based survey design, EPA then selected 40 HUC-10/11 watersheds which will give a statistical representation of the third tier of 1,172 such watersheds predicted to be most potentially vulnerable. These 40 monitored watersheds are located in 10 states: Ohio, Indiana, Kentucky, Illinois, Iowa, Missouri, Nebraska, Minnesota, Tennessee, and Louisiana. The selected watersheds averaged 129 square miles in size, with a median size of 121 square miles. Monitoring sites (index sites) will be located in flowing water bodies within the 40 watersheds. Two years of monitoring results from these sites will be compared to the LOC values. The registrant shall collect monitoring samples every 4 days prior to, during, and following the growing season. In addition, the registrant is required to

monitor 10 watershed sites daily following flow events to better estimate temporal variability for the data collected in the remaining 30 watersheds. Based on the results from the two-year monitoring study in each watershed, as interpreted by the LOC, the Agency will evaluate the need for more monitoring and/or mitigation actions in the 40 HUC-10/11 watersheds and the implications, if any, for the larger set of 1,172 most potentially vulnerable watersheds.

Future Monitoring Decisions for Other Water Bodies

Estuaries will not be monitored in 2004. Discussions will be conducted with the Oceans and Coastal Protection Division in the Office of Wetlands, Oceans, and Watersheds (OWOW) to review all relevant data to determine whether and to what extent monitoring for levels of atrazine should be undertaken for estuaries. The role of dilution and transport in estuaries must be determined. It may be possible to gather some information on these parameters by looking at nitrate concentrations or other chemical as a marker to ascertain how to approach an estuary monitoring program. This analysis will be completed by March 2004. If it is determined a monitoring study is required, it is recognized additional efforts will be necessary to develop a monitoring program.

To evaluate the potential for ecological concerns in static water bodies (i.e., lakes and reservoirs), raw water data on atrazine concentrations collected from the approximately 140 Community Water Systems that are being monitored for human health concerns will initially be used. In addition, the registrant will provide historical data from the Voluntary Monitoring Program (VMP) sites. The methods used to determine the LOC for flowing water bodies are amenable for use in static water bodies. The EPA must determine on a statistical and ecosystem basis to what extent the monitoring data from the drinking water monitoring program should be interpreted for a given water body and how statistical inferences from the results of this set of static water bodies can be made to a larger population of potentially vulnerable static water bodies. This information will provide the basis for developing a monitoring strategy for static water bodies.

A strategy will be developed to select the most appropriate locations and number of sites for monitoring atrazine in sugarcane growing areas. The sugarcane use area is a unique situation which has clear freshwater and estuarine issues. As a pilot, the registrant has offered to monitor four additional sites distributed between Louisiana and Florida with one being the Iberville Community Water System already designated for increased monitoring in the drinking water program. The selection of these pilot sites for evaluating potential ecological effects and the protocol for monitoring will be completed by March 2004.

Triggers for Mitigation Measures in Flowing Water Bodies

For the 40 watersheds, the registrant shall monitor an index site within the watershed for two years, regardless if a decision to initiate remediation occurs in the first year. If monitoring within a watershed indicates exceedences of the 5% average CSI threshold, based on CASM model results, in each of the two years, the registrant will initiate and conduct a TMDL or

comparable watershed management program within the particular watershed where the exceedence occurred, consistent with the state's ongoing TMDL or watershed program. If a TMDL or comparable watershed management program is already in place by USDA, state, or other entity in a given watershed, the registrant will then work with these existing programs to address the atrazine exceedence. If an exceedence occurred in the first year of sampling within a watershed, the registrant will, at a minimum initiate stewardship outreach, preferably through an existing USDA or state-sponsored watershed management program if one exists.

If an index site in a watershed has exceeded the similarity threshold over a two year period, the registrant shall initiate and conduct a TMDL (or similar) program to reduce atrazine concentrations associated with the stream reach at the index site by additional monitoring and managing atrazine uses in those portions of the watershed that feed into the index site and result in the exceedences. At the same time, the registrant shall conduct additional monitoring at other sites in the watershed suspected to be similar to the index site in order to determine if other water bodies in the watershed also exceed the 5% similarity threshold. If these areas are determined to exceed the similarity threshold, then the registrant shall initiate and conduct TMDL (or similar) mitigation in those areas.

The registrant must also initiate and conduct remediation immediately in any watershed which shows an exceedence of $ 15% of the CSI rather than wait for a second year of data. However, monitoring will still continue at the original index site in the second year.

If monitoring results indicate an exceedence in one of the two years for a given index site within a watershed, a decision regarding additional monitoring or other watershed management activities will be based on the specific data for the location and the results of the overall study. The data derived from all of the 40 watersheds will provide information needed to better quantify and interpret sampling variability in the context of the exceedence threshold. These future analyses will inform decision criteria for those cases where variability in monitoring data overlaps uncertainties in the LOC derivation.

For an index site within a watershed, if monitoring results indicate no exceedences of the 5% average similarity threshold index based on CASM model results in each of the two years, then no further action will be required in the watershed.

For all of the data collected in the 40 watersheds, interpretation of monitoring data after two years would include an assessment as to whether or not unusual meterological conditions (e.g., high or low rainfall) existed during the monitoring period. This could require a third year of sampling to make an informed decision on a watershed's condition.

In addition, if States or Tribes use the same or comparable LOC and monitoring protocols (e.g., comparable sampling frequencies and analytical techniques) at a selected stream reach outside of the 40 watersheds, as described in the ecological and atrazine monitoring subgroup reports (Appendix C-J), as well as, employ decision criteria comparable to those described above, the registrant will initiate and conduct a TMDL or comparable watershed management

program within that watershed if the State or Tribal data shows an exceedence of the LOC for two years, consistent with the state's ongoing TMDL or watershed program.

After the Agency receives the data from the 40 watersheds, it will be analyzed to interpret the status of the 1,172 Tier 2 watersheds. Due to the nature of this monitoring design it will be possible to make statistical inferences with the data collected from the 40 watersheds as to the magnitude and extent to which LOC exceedences could be occurring in the remaining tier of 1,172 watersheds considered to be the most potentially vulnerable. After these statistical inferences are completed, a decision about monitoring in the remaining 1,172 vulnerable watersheds will be made, with the understanding it is possible that further monitoring and/or mitigation may be required of the registrant in these other watersheds.

Description of Mitigation Measures

The specific techniques to be employed by the registrant to reduce atrazine loads in a watershed that has atrazine concentrations that exceed the LOC will be watershed specific and undertaken in partnership with any existing watershed management programs. The registrant will follow steps that are typically employed in the Clean Water Act TMDL program or similar management programs as follows:

1. Problem Identification -
   Identify pollutant causing impairment and impaired water body and determine the pollutant reductions needed to achieve water quality standards (note that in this specific situation exceedence of the atrazine LOC will have already established an impairment and a cause, with the understanding that for a given water body additional pollutants could also be contributing to biological impairment).

2. Current Situation and Desired Objective -
   Indicate desired outcome of TMDL process.

3. Source Assessment -
   Identify pollution source and contribution to impairment.

4. Allocation of loads -
   Allocate the pollutant loadings among the various pollutant sources.

5. Implementation -
   Describe actions to mitigate the sources of pollution (e.g., best management practices).

6. Follow-up Monitoring -
   Determine effectiveness of implemented mitigation measures.

7. Feedback Mechanism -

Review of mitigation measures during implementation period to determine if adjustments are needed.

The Clean Water Act requires that States identify waters that fail to attain water quality standards and establish TMDLs at levels that attain or maintain their water quality standards. EPA is required to review and approve or disapprove the list of impaired waters and TMDLs. If EPA disapproves the State's list or the TMDL, EPA is required to identify the impaired waters or establish TMDLs. The States and EPA establish TMDLs in a particular watershed by determining pollutant loads that will allow the attainment of water quality standards, analyzing existing pollutant loads and sources, and specifying the pollutant load reductions necessary to attain water quality standards. TMDLs are implemented through existing Federal, State or local requirements and programs. EPA encourages TMDLs that are established and implemented as part of an overall watershed strategy for improving water quality.

The Agency expects that the TMDL process (or similar watershed management program) will result in mitigation measures that, when implemented, will effectively lower the level of atrazine to below the level of concern. These mitigation measures could include: buffer zones, different application or incorporation methods, restrictions on the timing of application due to rain, and lower application rates. Implementation of these controls also will include confirmatory follow up monitoring to insure that the atrazine levels are below the LOC. Given the rapid progress the States have made by incorporating TMDL approaches in watershed management programs, EPA is confident that management activities undertaken by the registrant consistent with meeting the loading reductions identified in a TMDL are expected to be successful in reducing loadings of atrazine. Since 1996, more than 9000 TMDLs have been established and approved, leading to activities that have improved water quality. Pollutant loadings have been reduced and water quality improved as reported by the Office of Water's Office of Wetlands, Oceans and Watersheds (see http://www.epa.gov/owow/tmdl/). In the unlikely event that implementation of loading reductions identified in TMDLs is not effective, the Agency reserves the right to take further action under FIFRA to mitigate this risk from atrazine and will consider, as appropriate, the benefits of atrazine use in the particular watershed.

Benefits of Atrazine Use

The total or national economic impact resulting from the loss of atrazine to control grass and broadleafed weeds in corn, sorghum and sugarcane would be in excess of 2.0 billion dollars per year if atrazine were unavailable to growers (Appendix L, "Assessment of Potential Mitigation Measures for Atrazine", February 13, 2003).

A watershed-specific analysis has not been factored into this assessment because of the uncertainty surrounding potentially impacted watersheds and any required mitigation. However, economic impacts could be expected to parallel those for drinking water as described below.

Specifically, EPA analyzed what would be the impact to the corn industry in areas in

watersheds contributing to Community Water Systems which find atrazine concentrations exceeding the Agency's level of concern, and found that growers would incur an average loss of 9 bushels per acre (nationwide corn yield averaged 138 bushels per acre in 2001), as well as an increased cost for a replacement herbicide. This yield loss plus increased herbicide cost may result in an average estimated loss of $28 per acre. This translates to a yearly loss of 1.6 billion dollars of lost revenue annually nationwide.

Likewise, the impact to the sugarcane industry would also be substantial. If growers in the watersheds contributing to the Community Water Systems which find atrazine concentrations exceeding the Agency's level of concern, no longer had atrazine available to them, a 10 to 40 percent crop loss would be incurred along with an increase in alternative herbicide cost. This translates to a yearly loss of $89.5 million but could be as much as $343.6 million if a 40 percent loss were realized.

Finally, if atrazine were eliminated from the market, the most likely chemical broadleaf weed control options would be post-emergence applied herbicides (dicamba, 2,4-D, bromoxynil, and prosulfuron). Post-emergence application of herbicides carries certain risks. These include: 1) greater competition of the weeds with the crop early in the season as weed control is delayed into the growing season; 2) crop injury from herbicides applied directly to the emerged crop and weeds; and 3) if the opportunity to apply the herbicide is missed due to weather or some other factor, there are fewer or no emergency remedies for weed control. Thus, there are non-monetary costs that would be associated with the loss of atrazine as well as the substantial financial impacts.

Determination of Interim Reregistration Eligibility

The Agency has determined that atrazine products are eligible for reregistration provided that: (i) the circumstances described in this document (including implementation of any ecological risk mitigation measures identified through the monitoring program) are realized; (ii) any current data gaps and additional data needs are addressed; and, (iii) the consideration of the cumulative risk for the triazines supports a final reregistration eligibility decision. Further we have concluded that during the period of data collection and risk mitigation measures called for in this document, the benefits of continued use of atrazine will outweigh any potential ecological risk.

Although the Agency has not considered the cumulative risk for all the triazines, the Agency is issuing this amendment to the interim reregistration eligibility decision now in order to identify risk reduction measures that are necessary to support the continued use of atrazine. Based on the current evaluation of atrazine, the Agency has determined that atrazine products, unless used in accordance with the conditions of this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take further regulatory action to address the risk concerns from the use of atrazine products.

Because the Agency has not yet considered cumulative risk for all of the triazines, this reregistration eligibility decision does not fully satisfy the reassessment of the existing atrazine food residue tolerances as called for by the Food Quality Protection Act (FQPA). When the Agency has completed the cumulative assessment, atrazine tolerances will be reassessed in that light. At that time, the Agency will reassess atrazine along with the other triazine pesticides to complete the FQPA requirements and make a final reregistration eligibility determination. By publishing this interim decision on reregistration eligibility and requesting mitigation measures now for the individual chemical atrazine, the Agency is not deferring or postponing FQPA requirements; rather, EPA is taking steps to assure that uses which exceed FIFRA's unreasonable risk standard do not remain on the label indefinitely, pending completion of assessment required under the FQPA. This decision does not preclude the Agency from making further FQPA determinations or tolerance-related rulemakings that may be required on this pesticide or any other in the future.

What Registrants Need to Do

In order to be eligible for reregistration, registrants need to implement the risk mitigation measures outlined above, which include, among other things, development and submission of the following:

Potential Effects of Atrazine on Amphibian Endocrinology and Development

Phase I:	Response of larval *Xenopus laevis* to estradiol: assessment of development and gonadal morphology. Response of larval *Xenopus laevis* to atrazine: assessment of development and gonadal morphology.
Phase II:*	Response of larval *Xenopus laevis* to atrazine: assessment of gonadal and plasma sex steroid concentrations.
Phase III:*	Response of larval *Xenopus laevis* to atrazine: assessment of gonadal aromatase activity.
Phase IV:*	Response of larval *Xenopus laevis* to atrazine and an aromatase inhibitor: assessment of development, gonadal morphology, sex steroid concentrations and aromatase activity.
Phase V:*	Response of *Rana pipiens* to atrazine: assessment of reproductive fitness.

* Conducting the studies in phases II through V are conditional on the results from the previous phase indicating an effect. For example, if morphological abnormalities are observed in the gonads of larval *Xenopus laevis* after exposure to atrazine (Phase I) then the Phase II studies on gonadal and plasma sex steroid concentrations would be conducted. However, if the Phase I studies show negative results then the registrant does not need to proceed with the subsequent

study. EPA requests to review all of the protocols before the studies are initiated.

Ecological Monitoring and Mitigation of Atrazine in Watersheds

Atrazine Monitoring For Potential Ecological Effects on Aquatic Communities: Part 1. Flowing Water Bodies in Corn and Sorghum Use Areas.

Atrazine Monitoring For Potential Ecological Effects on Aquatic Communities: Part 2. Water Bodies in Sugarcane Use Areas.

Atrazine Monitoring For Potential Ecological Effects on Aquatic Communities: Part 3. Static Water Bodies.

Atrazine Monitoring For Potential Ecological Effects on Aquatic Communities: Part 4. Estuarine Water Bodies.

Data Call-In data for the ecological monitoring of watersheds will be sent to Office of Pesticide Programs (OPP) and Office of Water (OW), as well as the State or Tribe where the data are collected. Once the monitoring data has been quality controlled it will be posted in OW's publically available STORET database.

If you have questions on this document, please contact the Chemical Review Manager, Eric R. Olson at (703) 308-8067.

Sincerely,

Betty Shackleford, Acting Director
Special Review and Reregistration Division

12 Attachments