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OFFICE OF
PREVENTION, PESTICIDES
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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SUBJECT: EPA Response to Comments from Syngenta and its Contractors, the Triazine Network, the Center for Regulatory Effectiveness, the American Water Works Association, the State of New York Office of Attorney General, the U.S. Department of Interior Fish and Wildlife Service, the California Regional Water Control Board, the American Farm Bureau Federation, and the Louisiana Farm Bureau Federation, about the EPA Reregistration Eligibility Science Chapter for Atrazine, Environmental Fate and Effects Chapter, dated April 22, 2002.

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FROM: Mary Frankenberry, Statistician
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The U. S. Environmental Protection Agency (EPA) has reviewed the comment documents from Syngenta Crop Protection, Inc. and its contractors, the Triazine Network, the Center for Regulatory Effectiveness, the American Water Works Association, the State of New York Office of Attorney General, the U.S. Department of Interior Fish and Wildlife Service, the California Regional Water Control Board, the American Farm Bureau Federation, and the Louisiana Farm Bureau Federation. Many of Syngenta's comments referred to the assessment performed by the

Atrazine Ecological Risk Assessment Panel, “Aquatic Ecological Risk Assessment of Atrazine-- A Tiered Probabilistic Approach” (Giddings *et al.* 2000), as well as Syngenta’s “Supplement to ‘Aquatic Ecological Risk Assessment of Atrazine - A Tiered Probabilistic Approach’ Including Responses to EPA’s Comments,” dated February 26, 2002 (Giddings *et al.* 2002). EPA has previously responded to the former in Urban *et al.* 2002, and is responding to the latter in Frankenberry *et al.* 2002. EPA has thoroughly reviewed the comments and made extensive responses on specific areas, such as the choice of technical studies included for the assessment, the validation/status of the exposure models employed, problem formulation and scope of the study, and the level or “tier” of assessment actually performed, especially in light of refined risk assessment guidelines under development by the Environmental Fate and Effects Division (EFED) in EPA’s Office of Pesticide Programs (OPP). EPA has met with Syngenta and its panel of scientists to discuss these comments. Therefore, this response to comments will address both general and specific statements from all the commenters, and will also refer to EPA’s review of the Syngenta risk assessment and supplement where appropriate.

General Response to Comments Concerning Potential Endocrine Effects

EPA is in the process of evaluating data on the potential endocrine disrupting effects of atrazine on a range of non-target animals. These data focus primarily on the effects of atrazine on endocrine-mediated gonadal development in amphibians, fish and aquatic organisms. Some of the studies under evaluation have been submitted by pesticide registrants while the remainder have been taken from open literature; thus, the studies include both published and unpublished literature. Effect concentrations vary widely, with effects on gonadal development reported at exposures from 0.1 part per billion (ppb) to 25 ppb. EFED is in the process of reviewing the studies and writing data evaluation records (DERs). Where possible, raw data from these studies are being analyzed and study methodologies are being documented to determine whether procedural errors may have confounded the study’s ability to detect treatment effects. Based on this review, EFED will evaluate whether the data support the conclusions reached by the study’s author.

Pertinent studies are being performed both by the pesticide registrants and by independent researchers, which could shed additional light on this sub-lethal endpoint for atrazine. In accord with the agreement reached with the Natural Resource Defense Counsel, OPP is planning to summarize all these studies in preparation for a Federal Insecticide Fungicide and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) meeting scheduled for June 2003. To facilitate the preparation of this summary document, OPP will continue to accept studies on this endpoint up to February 28, 2003. These studies can only be accepted in final form and must represent “publication quality”; no preliminary data can be accepted for this summary document. Data submitted prior to the February cutoff date will be included in the summary document and discussed in the June 2003 SAP meeting. While EPA does not intend to exclude any pertinent studies from consideration, the February 28th deadline is necessary for the Agency to have sufficient time to review, evaluate and summarize the available studies and present them for timely science review by the FIFRA SAP. In addition, the results from this SAP meeting are

considered crucial input for the amended interim reregistration eligibility decision on atrazine scheduled for October 2003.

Syngenta Comments in Response to Reregistration Eligibility Science Chapter for Atrazine Environmental Fate and Effects Chapter, April 22, 2002 [OPP 02-0026-_____]

P. 11 Terrestrial Birds and Mammals - Syngenta states that the current risk assessment inaccurately depicts the chronic risk of atrazine to birds and mammals. While Syngenta agrees with the EPA that the risk quotients are overestimates due to the preliminary screening methods used, they disagree with the use of two specific inputs. First, they disagree with the use of a No Observed Adverse Effect Level (NOAEL) for small mammals of 10 parts per million (ppm) and points to the Atrazine: Toxicology Chapter for the Reregistration Eligibility Decision, SECOND REVISION, dated April 11, 2002 which reports on page 67 that the offspring NOAEL is 3.78 mg/kg/day, which is equivalent to 50 ppm. Second, they disagree with the 17-day short-grass foliar dissipation half-life value used by EFED in the FATE model, and maintains that the value should be 4-days. Finally, Syngenta maintains that when realistic exposure information is used, the data show that there are no unacceptable risks to terrestrial vertebrates.

While there are data in the Health Effects Division (HED) TOX ONELINER database (dated 11, August 1999) that reports a NOAEL of 10 ppm based on body weight reduction, EFED agrees to use the 50 ppm value as reported by the HED in their second revision of the HED toxicology chapter. The change will result in a reduction in the LOC exceedences for small mammals, but not in the elimination of the potential risk. The available foliar residue data show that estimates of atrazine half-lives vary considerably (from 3.2 to 17-days). Since EFED was limited by the available data for performing a screening level assessment for risks to birds and mammals, the choice of a conservative estimate of 17-days for the foliar half-life value is appropriate. EFED will verify the FATE model calculations including the number of days exceeding the LOCs.

P. 12 Terrestrial Plants - Syngenta questions EPA's statements that widespread atrazine exposure results in direct acute effects in many terrestrial plant species causing indirect effects on wildlife claiming the conclusion is not based on field investigations and/or refined risk assessments.

EFED agrees that there are no field studies showing the linkage between direct effects of atrazine and indirect effects on wildlife. Also, EFED recognizes that the incident reports of direct effects of atrazine on terrestrial plants is limited. However, the screening level assessments shows a great potential for direct effects on terrestrial plants. Therefore, EFED will change the statements to clearly indicate that there is a potential risk for direct effects on terrestrial plants, and that potential indirect effects on wildlife exist for atrazine as well as other herbicides via habitat degradation and possible disruption of the food chain.

P. 12 Toxicity of Degradates Compared to Parent Atrazine - Syngenta disagrees with EPA's description of the atrazine metabolites as "long lived". They point to previously submitted metabolite residue information from HED's Product and Residue Chemistry Chapters (DP Barcode D272006). In summary, they point to the maximum reported residue after 30-days of

3.21 ppm for the chloro-metabolites. They state that this residue level is far below any effect level for terrestrial vertebrates indicating that metabolites are not “long-lived.”

EFED believes the environmental fate profile of atrazine and monitoring data support the existence of “long-lived” atrazine metabolites. The 3.21 ppm level for the chloro-metabolites in a residue monitoring study merely shows that these metabolites were transformed from the parent atrazine. The study does not provide sufficient data to establish the kinetics of the formation and decline of the chloro-metabolites. Further, the 3.2 ppm residue level does not refute EFED’s conclusion that the atrazine metabolites are “long-lived.”

P. 13 Incident Reports - Syngenta continues to disagree with EPA’s summary of incident data reported in the reregistration eligibility decision chapter (RED).

As stated in the previous response to comments (April 9, 2002, EFED Review of Comments from Syngenta and its Contractors about the EPA Revised Environmental Risk Assessment for Atrazine, page 15), EFED minimally agrees with the 14 incidents that Syngenta attributed to atrazine. These incidents in addition to the screening level risk assessment for terrestrial plants results in a revised EPA conclusion that there is a potential for direct effects on terrestrial plants, and that the potential for indirect effects (habitat degradation and disruption of food chain) on wildlife exists for atrazine as well as for other herbicides.

P. 14 Uncertainty of Atrazine Co-Occurrence With Other Chemicals - Syngenta provides arguments questioning EPA’s suggestion that synergistic effects could have caused some of the non-plant related incidents.

EFED agrees that references to synergistic effects as causing the non-plant related incidents are speculative and therefore will remove them from the document.

P. 15 Indirect Effects - Syngenta states that there no data to support aquatic and terrestrial indirect effects caused by atrazine given the reversible nature of its phytotoxic effect on plants.

EFED’s response concerning indirect effects has been presented in the preceding responses on terrestrial effects. However, concerning indirect effects on aquatic systems, EFED disagrees with Syngenta. As stated in a previous response (April 9, 2002, EFED Review of Comments from Syngenta and its Contractors about the EPA Revised Environmental Risk Assessment for Atrazine, page 20), although aquatic plants initially showed rapid recovery of photosynthetic capacity, mean photosynthesis rates for atrazine-treated plants were less than controls 77 hours following exposure. Additionally, Jones *et al.* did not report the results for biomass for controls and treatments to confirm full recovery compared to controls.

Syngenta's reference to recovery may only hold under short-term exposures to atrazine in lotic (flowing) aquatic environmental. Following a 2-day exposure to 10 µg/L atrazine, Johnson (1986) reported recovery by Day 7. Although the rate of photosynthesis may recover to pre-

exposure levels, plant biomass in atrazine-treated plants do not recover if the exposure duration was sufficient to kill some plant species, as reported by Kettle *et al.* (1987).

P. 16 to 18 Indirect Aquatic Effects - Syngenta questions EPA's use of three field studies as primary support for the conclusion that atrazine may have caused indirect effects on aquatic communities, including reductions in populations in aquatic macrophytes, invertebrates and fish at from 10 to 20 µg/L, i.e., Kettle *et al.* 1987, Lampert *et al.* 1989, and Davies *et al.* 1994. Syngenta contends that these field studies are questionable due to design weaknesses such as lack of replication, lack of controls, and lack of consideration of possible confounding effects. In addition, Syngenta states that the conclusion is inconsistent with the weight of evidence provided in numerous, higher quality field studies and the conclusions of Giddings *et al.*, 2000 and 2002, i.e., that indirect effects on aquatic animals are unlikely to occur at or below the inferred no-adverse effect level for plants of 50µg/L.

EFED has responded to these questions previously in Urban *et al.* 2001, in its responses to Syngenta's earlier comments (EFED Review of Comments from Syngenta and its Contractors about the EPA Revised Environmental Risk Assessment for Atrazine, April 9, 2002), and most recently in Frankenberry *et al.* 2002. All three provide detailed responses to Syngenta's questions. EFED acknowledges that there are reasons to question each of the studies that Syngenta considers unreliable or questionable; however, EFED continues to maintain that these studies and others identified in the EPA Revised Risk Assessment for Atrazine are useful in the risk assessment. They raise reasonable concerns that low atrazine levels (10 to 20 µg/L) may indirectly impact fish and aquatic invertebrate populations as well as macrophyte communities, and thus support the EFED's concerns for indirect effects on aquatic communities.

Giddings *et al.* 2002 also identifies Bester *et al.* 1995, used by EFED to support potential reduction in primary production in estuarine/marine aquatic environments as questionable and unreliable. Upon further review, EFED agrees that there are major problems with this study and will remove it from the assessment endpoints of concern for estuarine/marine environments.

As noted in the EPA Revised Risk Assessment for Atrazine (page 12), the Giddings *et al.* 2002 conclusion is consistent with EPA's position when they states that in certain *high-exposure situations, atrazine may reach concentrations that could cause ecologically significant effects on plant productivity and community structure. In cases where the effects are severe (and there are, to our knowledge, no confirmed effects on plant communities in nature), indirect effects on fish and invertebrates are possible.*"

P. 19 Direct and Indirect Terrestrial Effects - Syngenta questions EPA's conclusion that in areas of high atrazine use, there is widespread environmental exposure that has resulted in direct acute effects on many terrestrial plant species at both maximum and typical use rates, as well as indirect terrestrial wildlife effects. Syngenta questions the basis for these conclusions, i.e., tier 1 risk quotients, incident reports, and a review paper by Freemark and Boutin, 1994.

As noted in responses to previous comments, EFED recognizes that risk quotients in screening level risk assessments provide a basis for potential adverse effects as well as indicating a need for additional data for a refinement in the risk assessment. EFED acknowledges that there are no field studies showing the linkage between direct effects and indirect effects of atrazine on wildlife. However, the screening level assessment shows a great potential for direct effects on terrestrial plants.

In a previous response to Syngenta's comments by Syngenta (EFED Review of Comments from Syngenta and its Contractors about the EPA Revised Environmental Risk Assessment for Atrazine, April 9, 2002, page 7), EFED referenced Freemark and Boutin (1994) to propose that herbicide use has had an adverse indirect effect on terrestrial wildlife via habitat alteration. Syngenta contends that that is not the whole picture, since atrazine has a role in conservation practices which decrease detrimental effects on wildlife. EFED acknowledges that arguments can be made to support both contentions, but definitive data remain to be collected. Therefore, EFED will change the statements to clearly indicate that there is a potential risk for indirect effects on wildlife due to atrazine as well as other herbicides.

P. 21 - 25 Sublethal Effects - Syngenta claims that a detailed review and assessment of its own research and the published literature on the potential endocrine effects of atrazine in fish, amphibians and reptiles, do not indicate widespread effects or serious consequences to wildlife from potential exposure to atrazine. Syngenta then provides a review of available atrazine studies on largemouth bass, amphibians, and atrazine olfactory effects on salmon attempting to explore endocrine-mediated effects. Syngenta concludes that it is premature to consider any of these results in the atrazine risk assessment until the studies are validated and the significance of their results is established.

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Additional pertinent studies are being performed both by the pesticide registrants and by independent researchers, which could shed additional light on this sub-lethal endpoint for atrazine. In accord with the agreement reached with the Natural Resource Defense Counsel, OPP is planning to summarize all these studies in preparation for a FIFRA Science Advisory Panel (SAP) meeting scheduled for June 2003. To facilitate the preparation of this summary document, OPP will continue to accept studies on this endpoint up to February 28, 2003. These studies can

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Concerning the Syngenta sponsored Wieser and Gross (2002) study on largemouth bass (LMB) which EPA has reviewed and evaluated, Syngenta questions EPA’s contention that the presence of quantitative levels of vitellogenin (egg yolk precursor protein) in male bass indicates exposure to an estrogenic compound, and EPA’s conclusion that high variability confounds the study. Syngenta noted that male fish can express variable amounts of this protein, and that the interpretations and differences presented in the report are both conservative and within normal physiological expectations.

EPA believes that vitellogenin is a sex-specific protein and can only be detected in males exposed to estrogenic substances. While Syngenta is correct that male fish can express variable amounts of this protein, LMB can only do so in response to variable levels of estrogen. The current test results indicate that this particular vitellogenin assay provided inconsistent results. Given that mean vitellogenin levels in male LMB exposed to 100 ug/L atrazine was 7 times control values, the test was unable to detect a treatment effect. EFED is concerned that atrazine's ability to impact vitellogenesis may be a subtle effect that the present study was unable to differentiate conclusively. Furthermore, recent evidence has suggested that atrazine affects on reproduction may include a suite of endpoints not typically captured by current guideline studies. It is clear from the largemouth bass study that endogenous hormones are affected. However, the ability of atrazine to induce vitellogenesis in males remains uncertain.

P. 25 Endangered Species - Syngenta notes that they have previously identified inconsistencies in EPA’s risk assessment as it pertains to endangered species. In addition, Syngenta states that EPA inaccurately indicates that terrestrial plant endangered species are likely to be affected and wildlife species may be indirectly affected by atrazine use.

EPA bases its risk concerns for endangered terrestrial plants on risk exceedences, and these risk exceedences are based on spray drift and runoff into the habitats for terrestrial and semi-aquatic plants. The revised EPA risk assessment clarifies this point. In addition, EPA has revised the section under Endangered Species Concerns to eliminate statements indicating that wildlife species may be indirectly affected by atrazine use. EPA determined that such statements for atrazine alone were speculative. Rather, the use of any herbicide could have adverse chronic effects on terrestrial and aquatic plants in areas adjacent to treated fields that may have indirect effects on these animals from the loss of food sources and the loss of vegetative habitat for cover, reproduction and the survival of offspring (Freemark and Boutin, 1994).

P. 26 Environmental fate

Syngenta questions that EFED has not used the best available environmental fate data for atrazine. Specifically, Syngenta has suggested that EFED consider the submissions by Burnett et al, 2000 and 2002.

In reviewing the two submissions by Burnett, et al., EPA found that only summaries were presented. EFED needs to review complete study reports in order to determine a study's acceptability. In the atrazine technical briefings in April, 2002, EFED used Syngenta's 'suggested' fate parameters as input for the modeling runs to demonstrate that the resultant exposure values still pose potential aquatic risk concerns. With regard to the results of the new soil photolysis study, EFED will upgrade the DER's classification to acceptable. However, regarding the use of this parameter in the Pesticide Root Zone Model (PRZM) runs, currently, EFED's guidance does not support the use of this input parameter. EFED believes that the suggested changes to PRZM would have a minimal impact on the model's output and therefore would be unlikely to alter the current risk assessment.

P. 27 Clarification of Estuarine Analysis

Syngenta states that "This conclusion [of estuary] is in error since the atrazine concentration data used in the EPA comparisons are not representative of concentrations monitored in the Chesapeake Bay proper and near-shore embayments. These higher concentrations are representative of freshwater sites on streams and rivers within the Chesapeake watershed and not sites within the open waters of the Bay or near-shore Bay waters." Syngenta also questions the use of data from the Louisiana Department of Agriculture and Forestry (LDAF).

EFED questions how the registrant arrives at this conclusion, especially the claim that the higher concentrations are representative of freshwater sites. In the book entitled "Life in the Chesapeake Bay: An Illustrated Guide to Fishes, Invertebrates, and Plants of Bays and Inlets from Cape Cod to Cape Hatteras," the authors (Alice and Robert Lippson) describe the Chesapeake Bay, which, "like all estuaries, contains waters that range from fresh to nearly as salty as ocean waters. An estuary is defined as a somewhat restricted embayment in which the flow of freshwater mixes with high salinity ocean water. At the head of the Bay and at the head of each tributary stream (the geographical fall line), tidal influence is apparent, but little or no ocean-derived salt is present." First, the registrant did not provide any salinity data to show that the monitoring results are for fresh water, and secondly, freshwater can also be part of an estuary.

The same statement can be applied to the Louisiana estuary. If the registrant can provide more monitoring data at the locations which they view as "estuarine" sites, then the results can be used for refinement purposes. No monitoring data were presented to verify the assumption of no detections.

The registrant claims that, based upon the available toxicity data, there is no indication that estuarine organisms are more sensitive to atrazine than freshwater organisms and refers to

Giddings *et al.* 2000. However, a closer review of page 168 and 169 of that report, Table 5.3 (Summary of atrazine acute toxicity distributions) and Table 5.4 (Summary of atrazine chronic toxicity distributions) show that while the sensitivities of freshwater and saltwater organisms to atrazine are similar, the 10th percentiles for chronic effects for all saltwater species are almost three times lower than those for freshwater species (4.9 to 16 µg/L) . The number of chronic studies upon which this comparison is based is limited (n = 8 for saltwater species; 23 for freshwater species); however, increased concern for potential adverse effects in estuarine systems appears to be warranted at this time.

Syngenta's Supplement to "Aquatic Ecological Risk Assessment of Atrazine - A Tiered Probabilistic Approach" Including Responses to EPA's Comments, February 26, 2002 (Giddings *et al.* 2002) [OPP 02-0026-_____]

Syngenta's Atrazine Ecological Risk Assessment Panel , EcoRisk, Inc. provided EPA with a supplemental document (Giddings *et al.* 2002) to their original tiered probabalistic risk assessment for atrazine (Giddings *et al.* 2000). The former is a formal response to Urban *et al.* 2002 which in turn was EPA's response to Giddings *et al.* 2000.

EPA has prepared its review and response to the supplemental report on atrazine (Frankenberry *et al.* 2002). Following the pattern of these reports from Syngenta's Atrazine Ecological Risk Assessment Panel, this response (like the previous one) is organized by tiers. With the technical assistance of it's contractors, EPA provides responses to the issues raised as well as a critique of the supplemental information. In summary, the EPA concludes that the supplemental information is not sufficiently compelling to warrant a significant change in EPA's conclusions presented in the Revised Environmental Risk Assessment for Atrazine dated April 22, 2002, *i.e.*, "Based on the results of this refined assessment, the Agency finds that in areas of high atrazine use, there is widespread environmental exposure that (1) may have resulted in and may continue to result in direct acute effects on many terrestrial plant species at both maximum and typical use rates, (2) may have caused and may continue to cause direct effects on aquatic non-vascular plants which in turn could have caused reductions in primary productivity, (3) may have caused and may continue to cause reductions in populations of aquatic macrophytes, invertebrates and fish, (4) may have caused and may continue to cause indirect effects on aquatic communities due to loss of species sensitive to atrazine and resulting in changes in structure and functional characteristics of the affected communities. Potential adverse effects on sensitive aquatic plants and other nontarget aquatic organisms as well as their populations and their communities, are likely to be greatest where atrazine concentrations in water equal or exceed approximately 10 to 20 µg/L on a recurrent basis or over a prolonged time period. Based on monitoring data, maximum concentrations at up to 35% of the sites exceeded the atrazine concentration (>10 µg/L) at which these adverse effects are found in simulated field studies. Up to 20% of the sites exceeded the atrazine concentration (>20 µg/L) at which adverse effects are found in simulated field studies as well as many of the 10th [per]centile values for acute and chronic effects from analyses of laboratory data. The frequency of occurrence and extent of the potential impacts will vary depending upon the type of water bodies and their proximity in time and space to atrazine

applications. Recovery from the effects of atrazine and the development of resistance to the effects of atrazine in some vascular and non-vascular aquatic plants is reported and adds uncertainty to these findings. Further research is needed to quantify the impact that these effects would have on these risk conclusions.”

Triazine Network - written comments (OPP-34237C) [OPP 02-0026-0218]

P.10 Analysis Failed To Consider Trend of Atrazine Usage and Application--The Triazine Network believes that the EFED’s evaluations are not representative of current conditions and therefore overstate atrazine exposure.

Table 1 presented by the Triazine Network shows the patterns of decreasing usage and decreasing rates of application per unit area. EFED would like to see the rate reduction reflected in the labels. If the lower rate applications are feasible and accurate as the data suggest, then there is no need to maintain the higher maximum application rates as listed on the current label, and label reduction would be a best mitigation measure. Except for the farm pond exposure assessment which is based on modeling, EFED has based its assessment on available monitoring data for other types of water bodies. The monitoring data should be reflective of the recent/current conditions; therefore EFED is not overstating atrazine exposure.

P.11 Trends in Surface and Groundwater Water Concentration--The Triazine Network claims that in its review of the median atrazine concentration, observed in the high-use areas, the atrazine levels have consistently decreased over time.

Figure 3 presented by the Triazine Network shows the median concentrations from 1989 to 1996. Upon closer examination, EFED does not observe a clear, decreasing trend in this figure. Also, since the Triazine Network has not provided any monitoring data at smaller scale sites such as farm ponds, which are widely distributed in agricultural ecosystems, EFED can not determine whether or not atrazine concentrations in the surface water of such ecosystems have truly decreased.

Use of data from community water systems to demonstrate trends can be misleading, since the results are for finished water. It would be expected that due to better detection and treatment technologies, the atrazine in finished water would be lower, as the data suggest. For the purpose of demonstrating decreasing atrazine levels, the Triazine Network should analyze raw water samples and not finished water samples. EFED has reviewed the trend analysis reports and found that for nearly 63% (or 39/62) of the CWSs, the data indicate either no change in the concentration or an increase in the concentration. Reevaluating the data with $\alpha = 0.05$ or 0.01 would likely result in even fewer indications of a negative trend.

P.13 Occurrence of Atrazine in Surface and Groundwaters Focused on High Use Areas and Characterized Worst-Case Impacts--The Triazine Network criticizes EFED for focusing on high use areas based on limited sampling data and only considering the maximum concentrations.

They point out that the EFED report focused on sampling data from receiving waters within 21 major atrazine use states.

In the original RED, EFED considered primarily the PLEX monitoring data, which were available only for 21 states at that time. With subsequent submissions by Syngenta, EFED has also reviewed and considered an additional 11 states. EFED is considering all the submitted data from a total of 32 states from 1993 to 2000.

P.13 Limited Sampling--The Triazine Network questions that in every case, EPA based its evaluation on a consideration of limited data sets.

EFED agrees with the limitations of sampling as identified by the Triazine Network, and is puzzled by its comments that EFED did not consider all the available data. EFED has pointed out that the available monitoring programs, including the U.S. Geological Survey (USGS) 76 mid-western reservoirs, National Water Quality Assessment (NAWQA) and others, were not designed to capture possible peak atrazine concentrations which usually occur in association with high rainfall events closely following atrazine applications. Since the monitoring results did not likely capture the possible peaks, EFED can not derive the true 90th, 95th, or 99th percentile values with confidence. For this reason, EFED decided to present the results as shown in the RED.

P.14, 15 Maximum Concentrations (Lakes, Streams, Estuaries)--EFED methods overestimate the nature of potential effects by comparing peak exposure values to chronic toxicity test endpoints. The Triazine Network expressed concerns that the use of "maximum values" from the abundance of monitoring data was inappropriate and that time-weighted averages should be calculated and used in the risk assessment.

EFED has noted that most of the sampling programs were not designed to allow calculation of appropriate time-weighted averages. In the absence of such data, available exposure data must be used. Since these values likely under represent peak values, they are more likely closer to longer term averages. As such their use in the risk assessment more likely approximates a time-weighted average exposure rather than a peak exposure.

EFED has constructed the exceedence curves using Weibull plots by ranking the available maximum concentrations for each of the water bodies and assigning a probability associated with the rank divided by the sum of the number of samples plus 1. The use of this methodology may be subject to discussion, but with the limitations of available monitoring data, EFED felt that it is the most reasonable way to characterize potential exposure conditions.

The Triazine Network claimed that the USGS study of 9 mid-western streams was specifically conducted to compare the peak atrazine concentration following runoff events and this study obtained samples collected at close intervals readily amenable to time series analysis. If the Triazine Network's contention is correct, they are encouraged to perform the analyses and present the results to EFED.

P. 16 Detailed Evaluation of Magnitude and Duration of Atrazine Exposure Demonstrates Exposure Evaluation Flawed--The Triazine Network states that without accurately defining the duration of exposure, it is impossible to associate an assessment endpoint with a concentration.

EFED agrees with the assessment that “without accurately defining the duration of exposure, it is impossible to associate an assessment endpoint with a concentration.” EFED has explained previously that due to the limited availability of time series data, the exposure duration can not be accurately defined, and EFED has decided to use the available maximum observations for each available sampling site to construct the exposure exceedence probability curve. The Triazine Network claimed that there are peak atrazine concentrations being captured in some streams and lakes, and EFED should base its assessment on these to characterize long-term average atrazine concentration. It is not clear to EFED what sets of monitoring data are being referred to. The Triazine Network is encouraged to present their findings. Even if the quality and quantity of monitoring data were good enough for these streams and lakes, they could only be used for those specific monitoring sites; due to the limited number of monitoring sites available, the monitoring data could not be considered representative of all areas in which atrazine is used.

P. 16 USGS Data on Small Streams--The Triazine Network presents its approach in analyzing this dataset.

The Triazine Network presented the time series plots of Maple Creek, Nebraska, Robert’s Creek, Iowa and Silver Creek, Illinois. Figure 5 represents the results of Maple Creek. There are no monitoring results for 1994, 1995, and 1996. The monitoring results in this figure clearly demonstrate that sampling frequency is insufficient to accurately characterize long-term exposure. Figures 6 and 7 are time series plots for Robert’s Creek, and Silver Creek, respectively. EFED’s plots are based on the monitoring results in USGS Open-File Report 94-396 for the period from 1990 to 1992. Since the Triazine Network has the most recent results from April 2002 to July/August 2002, EFED would like to request a copy of these data. As for Table 3, which presents the summary results of nine streams, the Triazine Network calculated the 30-day and 60-day averages based on observations within 30 or 60 calendar days. The use of available observations in calculating the average may miss the true average value since samples were not collected daily. Even in this case, the results of the last sampling site, West Fork Big Blue River, Nebraska, clearly show exceedence of the draft chronic criterion of 12.0 ug/L atrazine.

P. 20 USGS Data on Lakes/Reservoirs--The Triazine Network presents its approach in analyzing this data-set.

EFED has cited the observed peak concentrations of 12.4 ug/L in 1992 and 11.0 ug/L in 1993. These were based on the USGS Open-Report 96-393, which consisted of 3 to 5 grab samples collected in each water body in 1992 and 1993. Three to five samples are insufficient to characterize long term exposure, especially since it is quite possible the sampling scheme of only 3 to 5 samples per site will likely miss the “true” peak concentrations. More rigid and frequent sampling is needed to truly quantify the proper exposure duration results.

P.22 Reassessment of Estuarine Exposure to Atrazine--The EFED assessment did not address atrazine in the open waters of an estuary.

The Triazine Network claimed that EFED did not address atrazine in the open waters of an estuary. EFED used available data such as that from the Upper Terrebonne Watershed and the Chesapeake Bay. Although the sampling data may not have been taken in the open waters, they are in close proximity to the open water; and in the absence of more appropriate data, EFED believes that these data are reasonable surrogates. EFED can not refine it's analysis without additional data.

All available monitoring data within the Chesapeake Bay should be representative of an estuary. EFED based its assessment on the monitoring data, even though they are limited in their scope of sampling sites and frequencies. The Triazine Network summarized the data as shown in Table 4. They classified the data according to receiving water type and presented the maximum, Spring mean and overall average values. The Triazine Network suggested that if these are then compared with EFED's assessment endpoint, there are no expected environmental impacts. Before these inferences can be made, EFED needs to closely examine the data. Due to the limited data, Table 4 did not show any Spring means for non-tidal creeks, nor were some of the overall averages available. The limited monitoring data can be used as a potential indicator of atrazine residues. For the purpose of a more precise risk assessment, however, sampling frequencies and locations would have to be markedly increased.

P.24 Surface Water Exposure Summary--The Triazine Network claims that EFED has not properly evaluated the available data to calculate the long-term exposure of atrazine.

The Triazine Network discussed various water bodies: small streams, large streams and rivers, lakes and reservoirs, and estuaries. The potential exposure in small streams can be representative of possible worst-case exposure. There are many small streams in the atrazine use area, in which the impact can be great. Also, the Triazine Network did not discuss the exposure of the "farm" pond environment. Without specific monitoring data for farm pond environments, EFED has had to rely on the PRZM coupled with the Exposure Analysis Model System (EXAMS) modeling results indicating that the aquatic exposure is likely to be highest for this type of environment. (On page 35) The Network claims that EFED did not provide any data to support the model results. It questions EFED's model results, which suggest that elevated concentrations persist for an extended period of time. Furthermore, it claims that if a farm pond responds in this manner, it should be relatively easy to find high atrazine concentrations in farm ponds long after the spring application period. The lack of any supporting data compromises the credibility of the Triazine Network's assertions. EFED disagrees with the Network's assessment and welcomes the Network to provide monitoring data from farm ponds in order to substantiate their claims and refute EFED's assessment. However, based on available monitoring data for other types of water bodies, EFED expects atrazine exposure to be higher due to less dilution and to the close proximity of the treated agricultural field to the farm pond.

P30--All studies indicating effects at low levels (<20ppb) were reversible effects, or were ecologically insignificant (i.e. would not reduce populations significantly).

The Triazine Network believes that the majority of effects which occur at <20ppb, are reversible or ecologically insignificant, *i.e.*, would not significantly reduce populations, and should not be used in the risk assessment. Recovery is defined as a return of a measured parameter to the normal range of the controls. Whether or not recovery occurs for effects observed at atrazine concentrations <20ppb depends on the selected parameters and a careful assessment of pre-exposure status.

EFED has selected direct effects on terrestrial and aquatic plants and indirect effects on aquatic communities as assessment endpoints. There is little argument that these effects can result from atrazine exposure. However, EFED contends that the issue of recovery is highly speculative and subjective. Without complete characterization of pre-exposure conditions, post-exposure conditions can not adequately be addressed, and certainly can not be classified as recovery. This issue is also discussed in Frankenberry *et al* 2002, pages 15, and 21 to 24. While EFED agrees that the extent of ecological effects resulting the loss of sensitive species is uncertain, in the absence of data, it would be speculative and inconsistent with EPA's mandate to be protective to conclude that no adverse effects on aquatic populations or communities are likely.

P32--Other factors could affect plant growth.

EFED acknowledges the role other factors can play in organism response. Atrazine effects are dependent on available light since it affects photosynthesis. In the absence of light, atrazine has little effect. If light penetration is diminished, so should the effect be diminished. However, EFED can not confidently state whether or not any remaining effect upon plants is significant, nor the relative importance of agrochemical and non-chemical effects.

P32--Algal endpoints should not be applied to small streams.

The Triazine Network does not believe that algal endpoints should be applied to streams where algal communities will not be prevalent. EFED responds that retention times in small temporary and permanent streams are irrelevant for other photosynthetic plants species such as periphytic algal communities upon which numerous macroinvertebrate organisms depend for survival.

P35--Impact evaluation in ponds should be deferred until confirmation of 1) atrazine persistence in ponds, 2) ecological relevance of ponds, and 3) extension of federal regulations to farm ponds.

The Triazine Network does not accept the atrazine concentration profile modeled for farm ponds given the pattern of atrazine attenuation observed in stream and reservoir monitoring data. EFED recognizes the limitation of current models to take overflow into consideration. However, many farm ponds in fact do not overflow with each rain event, doing so only when major rainfalls take place. Evaporation does occur but, as stated in the Triazine Network document, would not result in complete drying of the water body unless there is a severe drought. Complete drying would

also occur if the water body was quite shallow, less so than the standard water body scenario modeled by EFED.

PRZM/EXAMS models are a Tier 2 aquatic exposure models that EFED and the regulated community use to estimate pesticide concentrations in surface waters following applications of pesticides to agricultural crops. Typically, these concentrations are compared to ecotoxicological values derived from laboratory or field/semi-field tests, in order to arrive at a ratio of estimated exposure to observed effects, i.e., a risk quotient. These risk quotients are compared to established levels of concern so that EFED can conclude that there either is or is not a potential risk to aquatic organisms from exposure to the pesticide in surface water, **not farm ponds**. We acknowledge that because the modeled system is a farm pond, applying these risk estimates to other types of water bodies increases the uncertainty of our risk estimates. This uncertainty can be reduced by refining the risk assessment, i.e., by gathering additional data, either ecotoxicological or exposure data. Concerning the exposure data, additional exposure data, such as monitoring data for other water bodies, such as chemical monitoring data, can reduce the uncertainty in the PRZM/EXAMS models due to modeled system being a farm pond.

The Triazine Network does not believe that farm ponds are ecologically relevant. Many natural water bodies have been eliminated over the past century through developmental and agricultural activities. These water bodies range from small ephemeral pools that last a few weeks to larger, more permanent water bodies. Many organisms have depended on these water bodies either throughout the year (most obligatory aquatic organisms) as their only site of existence or for brief periods of time as a layover point during migration (waterfowl), as feeding sites (mammals, birds, reptiles) or as breeding sites (amphibians, birds, reptiles). In the absence of natural water bodies, these organisms must find suitable replacements. Farm ponds serve act as replacements for these natural water bodies, and are therefore ecologically relevant and essential for the organisms that depend on small water bodies for their existence.

Comments on EFED RED Chapter for Atrazine, April 22, 2002 - by Atrazine Ecological Risk Assessment Panel (June 27, 2002), submitted by Syngenta [OPP 02-0026-_____]

P. 4 Exposure Modeling--The panel questions EFED's exposure modeling approach and the use of selective parameters for model inputs.

The panel discussed the issues of scenario, application methods, and physicochemical properties. Relating to the scenario issues, neither the dynamic pond volume issue nor the approach used have not yet been officially reviewed by EFED. The buffer zone issue and its relationship to runoff can not be properly quantified by the model. With regard to application methods, if aerial application is very rare for corn and sugarcane, then it is desirable to remove this method of application from the label. As for the physicochemical properties, EFED follows the model input parameter guidance document to perform PRZM/EXAMS modeling simulations. Based on the results presented by the panel with variable pond volume consideration, the exposure estimate using the model PONDWQ for the upper 10th percentile value is about 25 ug/l (ppb), which is in

the range of aquatic risk concern. In addition, the farm pond environment is assumed, as a minimum, to have 10 hectares of drainage area around the pond to maintain water in the pond during droughts. This is based on the requirement of drainage area according to the USDA Ponds Handbook (No. 590) for the Mississippi, Alabama, and Georgia Region. Given the smaller annual rainfall amount in Ohio area, the minimum drainage area should be higher; however, this factor is not reflected in the current modeling simulations.

Since there are several aspects up for discussion regarding the proper use of model simulations, it would be helpful for the registrant to provide monitoring results from this type of water body for discussion of EFED's modeling results.

P. 4 Exposure Model Sensitivity Analysis--The panel brings up the issue of using model parameters for soil photolysis and plant uptake.

The panel raised the input parameter issue about soil photolysis and plant uptake. The use of this information is not yet approved according to EFED's model input parameter guidance document. Even if they were to be considered, EFED believes that the change would not be large enough to impact the modeling results. Again, as mentioned previously, it will be helpful to examine monitoring results for this type of water environment for comparison with the modeling results.

P. 5 Influence of Mixing on Exposure--The panel questions the accuracy in the modeling of farm pond scenarios regarding the influence of mixing for larger water bodies.

EFED only uses PRZM/EXAMS to assess the farm pond environment. For large water bodies, EFED uses available monitoring data for the exposure assessment.

P.5 Use of Monitoring Data in Probabilistic Ecological Risk Assessment--The panel questions EFED's descriptive statement (pp. 4, 53) concerning the NAWQA monitoring data.

The panel questions EFED's statement (pp. 4, 53) concerning the study design and use of NAWQA monitoring data. The statements on pages 4 and 53 are based on descriptions and consultation from USGS scientists who have been involved in the NAWQA study. EFED is puzzled by the panel's claim that the distribution of concentrations, including upper centiles, can be estimated from proper analysis of such data, given the Panel's awareness that maximum concentrations are likely missed due to the infrequent sampling design of the NAWQA study.

The panel also questions whether the pesticide was used as directed or not. Since monitoring data were used, EFED would assume that the results should be reflective of directed use, rather than misuse, unless the panel has evidence otherwise.

As for the claim about the unreliability of two high detections in Robert's Creek, EFED relies on the quality assurance/quality control (QA/QC) performed by USGS on all of the data it collects.

P. 6 Concentrations in Estuaries--The panel questions EFED's use of monitoring data for estuarine environments.

As a common practice, "salinity" is used to determine whether a water body is brackish or fresh water. Even if the samples are fresh water samples, they were taken from the Chesapeake Bay and constitute that part of its makeup, as noted above, where "little [or no] ocean-derived salt is present."

With regard to the Upper Terrabonne Watershed in Louisiana, EFED based its analysis on the available data. Although the sampling data may not have been taken in the open waters, they are in close proximity.

P. 6 Persistence in Lake Michigan and in Streams--The panel questions EFED's reference with regard to estimated half life.

The panel questions the reference EFED has provided by Rygwelski, estimating a half life in Lake Michigan of 31 years. It presents results by Schottler and Eisenreich (1997), which show the degradation half-life of atrazine in Lake Michigan as 14 years. The work by Rygwelski has been published in J. Great Lakes Res. 25(1): 94-106, Inetrnat. Assoc. Great Lakes Res., 1999, entitled "A Screening-Level Model Evaluation of Atrazine in the Lake Michigan Basin." In this article, the author also discusses the discrepancy between his results and the work of Schottler and Eisenreich. Even with a half-life of 14 years, atrazine shows considerable persistence in Lake Michigan.

P. 6 Deposition Inputs--The panel questions the importance of atrazine deposition inputs and questions EFED's estimates.

Whether it is 25% or 30% of the total load, the numbers show the relative importance of the deposition inputs to Lake Michigan. Even when all surface runoffs of atrazine would have been eliminated from Lake Michigan, about 25% or more of the current atrazine total load is still calculated to have been input to Lake Michigan through deposition.

Response to Comments [OPP 02-0026-0198] by the Center for Regulatory Effectiveness (CRE) on the Atrazine Environmental Fate and Effects Risk Assessment (Docket Control Number OPP-34237C), November 4, 2002, and the Request for Correction of Information Contained in the Atrazine Environmental Risk Assessment by the CRE, Kansas Corn Growers Association, and the Triazine Network, November 25, 2002 [OPP 02-0026-____].

CRE Comment

The CRE commented that the science chapter should be revised to delete any conclusion that atrazine causes indirect effects on wildlife. They based this on excerpts from the EFED Review of Public Comments in Response to the EFED Revised Environmental Risk Assessment for Atrazine, page 3, dated April 10, 2002, and from the Registration Eligibility Science Chapter for

Atrazine, Environmental Fate and Effects Chapter, pages 63 and 64, dated April 22, 2002. In these documents EPA admitted that there were no methods or models available which can be used to statistically analyze indirect field effects data. Additionally, EPA had identified uncertainties in the data used in the assessment, especially in the field effects data and the monitoring data.

EPA Response

The sections extracted from the risk assessment chapter and the responses to comments were written to establish that the major, but by no means the only, endpoint of concern for the current use of atrazine, was the potential indirect adverse effects on aquatic populations and communities. Further, they intended to explain that field data showing these potential effects, as well as the monitoring data that established widespread potential exposure, could not be used in a probabilistic analysis in a manner similar to the existing aquatic laboratory toxicity data and the exposure modeling data. Risk assessments are typically performed with data limitations and under uncertainty. Neither prevent risk managers from arriving at risk conclusions; rather, by clearly identifying the data limitations and the uncertainties, and describing the risk conclusions as potential, EPA is being objective and transparent in its assessment. Finally, in spite of the data limitations and uncertainties, EPA contends that “the robust body of surface water monitoring data, combined with extensive effects data for aquatic organisms, enabled EFED to provide quantitative conclusions on the frequency and extent of adverse effects of atrazine in a refined aquatic risk assessment. The extensive databases as well as the refined assessment increase the certainty of the conclusions beyond preliminary risk assessments that are typical for all other herbicides.” (Registration Eligibility Science Chapter for Atrazine, Environmental Fate and Effects Chapter, pages 65, dated April 22, 2002)

CRE Comment

The CRE maintained that since there are no validated test methods for assessing endocrine effects, the atrazine environmental risk assessment should state that there is no reliable evidence that atrazine causes endocrine effects in the environment. According to the CRE:

“EPA’s final Reregistration Eligibility Science Chapter for Atrazine: Environmental Fate and Effects Chapter (April 22, 2002) (“Environmental Risk Assessment”) pages 11, 90 - 94, states that atrazine causes endocrine effects in various organisms including frogs. In that there are no validated test methods for assessing any such effects, these pages of the Environmental Risk Assessment should be corrected to state that there is no reliable evidence that atrazine causes endocrine effects in the environment.

EPA Response

Contrary to what the CRE maintains, the risk assessment does not state that atrazine “causes endocrine effects.” Rather, the assessment identifies potential effects of atrazine on endocrine-mediated systems as an endpoint that warrants additional study. To assure that there is no ambiguity about the Agency’s position, minor editorial changes have been incorporated into the revised assessment. The revised assessment does not suggest that endocrine disruption, or potential effects on endocrine-mediated pathways, be regarded as

a legitimate regulatory endpoint at this time. Nor does the Agency have evidence to state that there is no reliable evidence that atrazine causes endocrine effects in the environment. In response to the CRE, we revised the chapter which clearly states that based on the existing data uncertainties, the chemical should be subject to more definitive testing once the appropriate testing protocols have been established.

To reduce some of the uncertainties in understanding potential atrazine effects on amphibian endocrinology and reproductive and developmental responses, pertinent studies are being performed by external parties. In accordance with the agreement reached with the Natural Resources Defense Council, these studies in progress along with the studies in question will be summarized and analyzed for an external scientific review by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Science Advisory Panel (SAP) at a public meeting which is scheduled for June, 2003. The Agency anticipates that the results from this SAP meeting will provide significant input for us to amend the analysis of the potential effects of atrazine on amphibian endocrinology and development in the interim reregistration eligibility decision which is scheduled for October 2003.

CRE Comment

The CRE also states that the “Data Quality Act” requires proper test validation before it is used to generate information to support regulatory decisions.

...for Influential Scientific Information, such as the Environmental Risk Assessment, EPA’s Data Quality Guidelines require that EPA “ensure reproducibility for disseminated original and supporting data according to commonly accepted scientific, financial, or statistical methods.” EPA cannot ensure reproducibility of original and supporting data from atrazine endocrine-effects tests until and unless that data is generated by reliable tests, and validation is necessary to ensure reliable tests.

EPA’s Environmental Risk Assessment statements regarding atrazine’s endocrine effects also violate the Data Quality Act’s Utility Standard. This Standard requires that information disseminated by EPA be useful to its intended users, including the public. Information from new or revised tests is not useful when it is generated from unvalidated, unreliable, unreproducible tests.”

EPA Response:

EPA’s use of data, including the use of studies that have not been formally validated, is consistent with EPA and OMB Information Quality Guidelines and applicable statutory and regulatory requirements. Rather than being requirements, EPA’s Information Quality Guidelines contain EPA’s policy regarding information the Agency disseminates to the public. EPA implements these Guidelines in order to achieve the purposes of the information quality law, section 515, P.L. 106-554. EPA’s use of data for pesticide registration is governed by 40 CFR Part 158, which references EPA’s Pesticide Assessment Guidelines containing suggested protocols for developing data (§158.70). It is important to note that the availability of a final guideline does not in any way affect the Agency’s

authority to collect the data. The use of non-guideline studies is consistent with the process outlined in the 40 CFR Part 158. Part 158 states that “data routinely required by Part 158 may not be sufficient to permit EPA to evaluate every pesticide product. If the information required under this part is not sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment, additional data requirements will be imposed” (§158.75). In cases where a final guideline is not available, the Agency or a registrant may search for available scientific literature.

In determining whether data are acceptable, the Agency considers a number of factors, (e.g., study design including sample size, replication, use of appropriate controls, etc.) including the use of GLPs, to determine whether scientifically sound methods were employed. “If data are submitted prior to the development of appropriate protocols, the Agency will consider the data provided they permit sound scientific judgements to be made.” The 40 CFR specifically states that such “data will not be rejected merely because they were not developed in accordance with suggested protocols” (§158.80). Additionally the CFR states that the Agency can implement changes in the data requirements on a case-by-case basis (§ 158.85). Whether a test has been validated may be taken into account when the Agency considers what weight the test should be given in a weight of the evidence approach. For atrazine, EPA considered what weight should be given to studies that have not been formally validated, and revised the assessment to clarify the discussion of the existing data uncertainties, as indicated in the response to the previous comment. Thus, the analysis is consistent with the weight of the evidence approach and applicable regulations.

The use of open literature in the atrazine assessment to identify significant knowledge gaps is consistent with EPA policy to establish data quality objectives that must be addressed to help reduce uncertainties regarding the potential effects of any chemical under review. While the CRE is correct in pointing out that specific guideline tests for studying the endocrine disrupting potential of chemicals have not been formally adopted by the Agency, the absence of such tests does not preclude EPA from using information available from peer-reviewed open literature to identify uncertainties and areas for additional research.

The information generated from unvalidated tests is useful to intended users, including EPA and the public. When a review of the peer-reviewed literature chemicals demonstrates the potential of a chemical to cause a broad range of effects, not detected in current guideline studies, it is widely accepted in the scientific community and the Agency’s Ecological Risk Assessment Guidelines (EPA, 1998) to use this literature as a means to identify uncertainties. Consistent with the process defined in the 40 CFR, the Agency can direct that additional testing be conducted to examine non-guideline endpoints and uncertainties in greater detail. Consequently, EPA used the open literature to identify uncertainties and additional research that may need to be conducted to examine the endocrine disrupting potential of atrazine. This approach is consistent with FIFRA and with EPA guidance on data quality objectives. In identifying an uncertainty, OPP can then work with risk managers to better define data quality objectives that will have to be addressed through more detailed research.

CRE also raised the issue of reproducibility of the studies in question. This is one of several science issues that the Agency has identified and is asking the SAP to address. EPA has not determined that the studies are influential information. Until we receive input from an independent scientific panel at the SAP meeting, we are not prepared to address CRE's concerns regarding reproducibility of the studies. The Agency will address issues regarding the transparency of information in the amended registration eligibility document scheduled to be completed after the SAP meeting (October, 2003).

CRE Comment

The CRE commented that the quotient method EPA used in the Registration Eligibility Science Chapter for Atrazine, Environmental Fate and Effects Chapter is arbitrary and lacks utility, and EPA should defer any conclusions about the environmental effects of atrazine until EPA has developed a reliable probabilistic risk assessment method for adverse environmental effects. Further, CRE states that the quotient method is not accurate, reliable or useful in assessing the indirect or other environmental effects of atrazine.

EPA Response

According to the EPA Guidelines for Ecological Risk Assessment (1998; pages 92, 95-97), the first step in characterizing ecological risk is estimating the risk. This is the process of integrating exposure and effects data and evaluating any associated uncertainties. Risk estimates can be developed using a number of different techniques including comparisons of single-point exposure and effects estimates. The simplest approach for comparing the estimates is a ratio (or quotient) where an exposure concentration is divided by an effects concentration. The guidelines state that *“the principal advantages of the quotient method are that it is simple and quick to use and risk assessors and managers are familiar with its application. It provides an efficient, inexpensive means of identifying high- or low-risk situations that can allow risk management decisions to be made without the need for further information.”* The guidelines also recognize that *“a number of limitations restrict application of the quotient method....While a quotient can be useful in answering whether risks are high or low, it may not be helpful to a risk manager who needs to make a decision requiring an incremental quantification of risks... In addition, the quotient method may not be the most appropriate method for predicting secondary effects (although such effects may be inferred)...Finally, in most cases, the quotient method does not explicitly consider uncertainty....Some uncertainties, however, can be incorporated into single-point estimates to provide a statement of likelihood that the effects point estimate exceeds the exposure point estimate.”* Thus, from the standpoint of published and peer reviewed EPA guidance for ecological risk assessments, the use of the quotient method in the EFED science chapter for atrazine is neither arbitrary nor does it lack utility. Consistent with this guidance, EPA used the risk quotient method to characterize atrazine as being problematic and then proceeded to utilize probabilistic methods to further characterize the risks. EPA compared the estimates of effects to distributions of monitoring data, a probabilistic approach which addresses some of the uncertainties inherent in the data.

American Water Works Association (July 3, 2002) [OPP 02-0026-217]

Estimate of Water Systems “At Risk”

AWWA commented that EPA has likely underestimated the number of water systems “at risk”. EFED agrees with this comment and would encourage more frequent monitoring be conducted at more systems.

Significant data gaps still remain for analytical methodologies, treatment data and occurrence data

Specifically AWWA has concerns with respect to metabolites related to the above issues. Among these issues, EFED is most interested in the limitation due to lack of occurrence data. AWWA’s analysis shows that the sampling frequency can strongly affect the bias in 90-day average concentrations, based on a comparison of two log-normal distributions using daily, weekly and biweekly sampling frequencies. AWWA also questioned OPP’s exposure assessment which was based on weekly or biweekly monitoring data. AWWA is considering conducting an occurrence study of both the metabolites and parent compounds in calendar year 2002 and invites EPA’s input into the design of this study. EFED applauds AWWA for this effort and is willing to provide technical assistance in the design of this study

AWWA suggested a number of mitigation options

OPP appreciates the suggested mitigation options presented by AWWA. The seven items suggested will be considered for the overall mitigation measures: further label restrictions (application rate and residential use); further restriction on use; the implementation of additional best management practices (buffer strips, containment ponds, etc.); a memorandum of understanding with the registrant to pay for the additional testing necessary to characterize the intermediate exposure; the enactment of a "water quality tax" (in the range \$0.01-\$0.25 per ton) to pay for additional testing and treatment; a partial ban for impacted watersheds; and, a complete ban on the use of the chemical.

**New York State Office of Attorney General (Docket Control Number OPP-34237C)
July 5, 2002 [OPP-02-0026-160]**

The NYOAG commented to the Agency that EPA must initiate consultations with the FWS because EPA’s issuance of a reregistration decision for atrazine triggers the ESA consultation requirement and stated that the ESA requires that the Agency consider any existing FWS biological opinion.

Atrazine has been reviewed on several occasions by the FWS as described in Section III above under the discussion on endangered species. Currently, the the Agency is developing a proposal to implement its Endangered Species Protection Plan (ESPP). The Agency is

soliciting public opinion on this proposal through issuance of a Federal Register Notice, Endangered Species Protection Program Field Implementation, December 2, 2002. The Agency obtained input on several key aspects of the program in a workshop held in September 2002 that included the pesticide industry, pesticide user groups, and environmental advocacy organizations. An Advance Notice of Proposal Rulemaking (ANPR), Endangered Species and Pesticide Regulation, was issued jointly by the Agency, the Department of Interior and the Department of Commerce on January 24, 2003. The ANPR is soliciting comments regarding methods to make the consultation process more efficient..

Contamination of New York Lakes, Streams and Groundwater Wells

The State AG's Office submitted four reports of studies conducted by the U.S. Geological Survey containing monitoring data on many compounds for New York rivers, streams, lakes, and groundwater wells. The documents included monitoring data from areas in the Hudson River Basin, in Hemlock and Canadice Lakes and tributaries in Western New York, pesticides and their metabolites in well water in Suffolk County, and samples from three small public water systems in Western New York.

The reports show the prevalence of the compound at levels generally found in the various types of water sources considered the EFED assessment. Although the State is correct in contending that OPP did not assess the potential health effects afforded by exposure to multiple sources of contaminated drinking water, the EPA reports did attempt to assess exposure to and potential health effects of the total chlorotriazines.

Atmospheric Deposition—The State contends that the risk assessment “fails to consider the additional exposure pathway of atrazine in air and its deposition in surface water and drinking water supplies.”

Although EFED qualitatively considered the additional contribution to exposure of atrazine deposition to drinking water sources, it did not possess the substantial amount of data necessary to properly assess exposure from this source in a quantitative manner. We agree that it may be significant in some areas, and presented information on Lake Michigan in the chapter.

State of Connecticut, Office of Attorney General RE: Docket Control Number OPP-34237C Atrazine (July 3, 2002) [OPP 02-0026-0186]

The State's Office of Attorney General stated that atrazine is ubiquitous and warrants careful and thorough study. It reported that, according to the US Geological Study between 1992 and 1995, atrazine was the most commonly detected pesticide in the Connecticut, Housatonic and Thames River Basins. In addition, it was detected in 50% of the samples taken from the Norwalk River at Winnipauk, Connecticut. The office also stated that the revised risk assessment does not adequately consider the endocrine effects of atrazine, it's

widespread presence in ground water, drinking water and the atmosphere, and endangered species concerns. The office concludes that atrazine should be immediately cancelled.

EFED appreciates the comments and information that indicate that even outside the Mid-West, atrazine can be commonly detected in water bodies. This shows that there is widespread environmental exposure due to the use of atrazine, even in water bodies in Connecticut. EFED also notes that the frequency of occurrence and extent of the potential impacts will vary depending upon the type of water bodies and their proximity in time and space to atrazine applications. Thus, additional information would be needed to address the potential risk to aquatic organisms from this exposure.

U.S. Department of Interior, Fish & Wildlife Service (EPA Docket Control Number OPP-34237C) [OPP 02-0026-_____]

EFED has reviewed comments (Document: FWS/AFHC/DEQ) submitted by the U. S. Fish and Wildlife Service (FWS) regarding the recently completed environmental risk assessment conducted to support the reregistration review for atrazine. In their letter, FWS expressed concern that because atrazine is located in all environmental compartments, *e.g.*, soil, water, fog, rain, it is likely to affect a broad range of organisms. FWS believes that EFED's ecological risk assessment does not adequately characterize either direct or indirect impacts to endangered species since it relies on toxicity data collected from a limited number of surrogate species, none of which are listed. Additionally, the FWS believes the risk assessment failed to account for sublethal effects and the aggregate effects of atrazine plus each of the chemicals (inerts) co-formulated with the active ingredient. FWS is particularly concerned about the potential impacts of atrazine on amphibians given recent studies showing atrazine effects on African clawed frogs (*Xenopus laevis*) and Northern leopard frogs (*Rana pipiens*). Based on their concerns, FWS provided several recommendations for mitigating risks associated with the use of atrazine.

EFED appreciates FWS' comments regarding the environmental fate and ecological effects assessment in support of the reregistration eligibility decision on atrazine. EFED acknowledges that there are uncertainties associated with any risk assessment which limit the comprehensiveness of the assessments. In writing its assessment of potential ecological effects of a pesticide, EFED has to rely on surrogate species toxicity test data. Generally these data are restricted to a relatively select group of animals that survive well under laboratory conditions and may not be representative of the most sensitive organisms. Invariably, these data do not include toxicity tests run on threatened and/or endangered species. FWS is encouraged to provide any data it may have to support its concerns that EFED's assessment is not likely representative of risks posed to threatened and/or endangered species.

Risk assessments are typically performed with data limitations and under uncertainty. Neither prevents risk assessors from arriving at risk conclusions; rather, by clearly

identifying these data limitations and uncertainties, and describing the risk conclusions as potential, EPA is being objective and transparent in its assessment. Finally, in spite of the data limitations and uncertainties, EPA contends that “the robust body of surface water monitoring data, combined with extensive effects data for aquatic organisms, enabled EFED to provide quantitative conclusions on the frequency and extent of adverse effects of atrazine in a refined aquatic risk assessment. The extensive databases as well as the refined assessment increase the certainty of the conclusions beyond preliminary risk assessments that are typical for all other herbicides.” (Registration Eligibility Science Chapter for Atrazine, Environmental Fate and Effects Chapter, pages 65, dated April 22, 2002)

At present, EFED does not conduct aggregate risk assessments of active ingredients and all of the potential “inert” chemicals associated with the formulated products. In many cases, formulated product testing is required if EFED has reason to believe that the formulated product will represent a substantially increased risk to nontarget organisms. Similar to risk assessments conducted on technical grade pesticides, the Agency is in the process of evaluating risks associated with individual inert ingredients. Again, if the FWS has data to support its concern that specific inert ingredients in combination with atrazine represent an increased risk to nontarget organisms, it is encouraged to submit these data for review.

EFED is in the process of evaluating data on the potential endocrine disrupting effects of atrazine on a range of non-target animals. These data focus primarily on the effects of atrazine on endocrine-mediated gonadal development in amphibians, fish and aquatic organisms. The studies under evaluation have been submitted by pesticide registrants and taken from open literature. They include both published and unpublished studies. The reported results vary widely, with effects on gonadal development reported at exposures from 0.1 ppb) to 25 ppb. Where possible, raw data from these studies are being analyzed and study methodologies are being documented to evaluate whether the data support the conclusions reached by the study’s author.

Additional pertinent studies are being performed both by the pesticide registrants and by independent researchers, which could shed additional light on this sub-lethal endpoint for atrazine. In accord with the agreement reached with the Natural Resources Defense Council, EPA is planning to summarize all these studies in preparation for a FIFRA SAP meeting scheduled for June 2003. To facilitate the preparation of this summary document, OPP will continue to accept studies on this endpoint up to February 28, 2003. These studies can only be accepted in final form and must represent “publication quality”; no preliminary data can be accepted for this summary document. Data submitted prior to the February cutoff date will be included in the summary document and discussed in the June 2003 SAP meeting. While EPA does not intend to exclude any pertinent studies from consideration, this deadline is necessary for the Agency to have sufficient time to review, evaluate and summarize the available studies and present them for timely science review by the FIFRA SAP. In addition, the results from this SAP meeting are considered crucial input for the amended reregistration eligibility decision on atrazine scheduled for October 2003. Therefore, FWS is encouraged to provide data on atrazine’s effects on amphibians for review by February 28, 2003.

EFED is encouraged by FWS' willingness to participate in the process of developing a comprehensive and meaningful risk assessment for pesticides under review by the Agency and appreciates the Service's willingness to provide constructive comments and propose mitigation options. While it is clear that the Agency will likely be engaged in a consultation on atrazine under Section 7 of the Endangered Species Act, informal discussions between the two agencies can only serve to improve EFED's understanding of FWS' concerns and perhaps provide a conduit for exchanging relevant data on chemicals under review.

California Regional Water Quality Control Board (June 19, 2002) [OPP 02-0026-0223]

The Board has concerns about the discrepancies between OPP and OW regarding the effect levels and exposure methodologies.

While OPP found effects at a range of 10-20 ug/L, Office of Water's (OW) has proposed an effect criterion at essentially the same level, 11-12ug/L. However, EPA does not regulate pesticides under the Clean Water Act but rather under the FIFRA. Although methodologies to derive aquatic life criteria in OW differ from the methods used by OPP to derive risk quotients and compare them against established levels of concern, both offices reviewed all of the available data with the result being that the proposed OW standard for atrazine approximates the level proposed by OW. OPP and OW are currently exploring methods to better reconcile each office's approach.

Endangered Species Concerns (esp. Salmonids and sublethal effects on amphibians)

EPA has responded earlier in this document to comments regarding endangered species and sublethal effects. The reader is encouraged to review the relevant preceding sections in this document.

Urban uses

The Board pointed out that OPP only addressed agricultural uses and not urban use. Since most of the atrazine load has been associated with agricultural uses, EFED focused on this aspect. The NAWQA monitoring data EFED considered, however, also included samples taken at some urban indicator sites. The detections of atrazine at these sites were not as high as some of the detections in agricultural indicator sites. If the Board has any additional atrazine monitoring data emphasizing the contribution of atrazine from urban uses, EFED would like to review them.

American Farm Bureau Federation (AFBF) (July 3, 2002) [OPP 02-0026-____]

Exposure through Drift—While the AFBF claims that atrazine is not subject to volatile drift, EFED's concern is the off-target spray drift during the application. The Spray Drift Task Force's Agdrift model output shows the likely occurrences of off-target spray drift for both ground and aerial spray applications.

Persistence—AFBF contends that atrazine “breaks down in the soil in a matter of weeks or a few months.” More detailed environmental fate properties of atrazine have been presented in the RED and in the technical briefing. Atrazine half-lives range from 20 to 146 days in the aerobic soil metabolism studies. In aquatic environments, however, depending on conditions in aquatic bodies (lakes, mesocosm, and experimental pond), the half-lives from six studies vary from 41 to 237 days. In addition, a large Agency project, the “Lake Michigan Lake-Wide Management Plan” estimated a half-life of 31 years, due to the cold temperature, low productivity, high pH, low nitrate and low dissolved organic carbon of the lake.

Effect level—AFBF cites effect levels of 20 and 50 ppb for long and short term exposure, respectively, from a study performed by Solomon and Giddings (Ecological Risk Assessment Panel). OPP’s assessment found effects in the field at environmental levels from 10-20 ppb. OPP’s response to the above study cited by AFBF is included in this document and in detailed responses in Urban *et al* 2002 and Frankenberry *et al* 2002.

Louisiana Farm Bureau Federation (July 3, 2002) [OPP 02-0026-0156]

EFED has based its assessment on the PRZM/EXAMS modeling results and on the Louisiana Department of Environmental Quality’s monitoring data of 1998 for the risk assessment report. Since there are new data from Louisiana Department of Agriculture and Forestry, the Farm Bureau Federation is welcome to submit these new data for EFED to consider.