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COMMENTS BY THE CENTER FOR REGULATORY EFFECTIVENESS ON DOCKET OPP-2003-0024

The Center for Regulatory Effectiveness ("CRE") agrees with EPA that amphibian effects cannot be a regulatory endpoint for atrazine at this time. If EPA believes that additional study of the amphibian effects issue is necessary to comply with the NRDC consent decree, then that additional study should not delay issuance of the October atrazine IRED. Any further tests relating to the amphibian effects issue should conform to the requirements of the Data Quality Act. Any further review of the amphibian effects issue should not extend past the period specified in the NRDC consent decree.

CRE'S DATA QUALITY ACT PETITION

CRE, the Triazine Network and the Kansas Corn Growers Association filed a Request for Correction of EPA's Environmental Risk Assessment for atrazine under the Data Quality Act, and under EPA's Information Quality Guidelines. [1] This Petition requested that EPA correct statements in its Environmental Risk Assessment that atrazine causes endocrine effects in wildlife, including but not limited to reproductive and developmental effects in amphibians. This Petition explained that the Data Quality Act precludes such statements because there are not yet accurate, reliable and reproducible tests for determining whether atrazine causes endocrine effects in wildlife.

EPA stated that the Agency would treat this Data Quality Act Petition as a comment on EPA's Interim Registration Eligibility Decision ("IRED") for atrazine, and that EPA would respond to the Petition in its Response to Comments on the IRED. [2]

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[1] 44 U.S.C. § 3516 historical and statutory notes (Data Quality Act); http://www.epa.gov/oei/qualityguidelines/EPA_OEI_IQG_FINAL_10-2002.pdf.)(Information Quality Guidelines). CRE's Data Quality Act petition is available at http://www.epa.gov/oei/qualityguidelines/afreqcorrectionsub/2807.pdf.

[2] http://www.epa.gov/oei/qualityguidelines/afreqcorrectionsub/2807Ack.pdf (EPA acknowledgment of Petition).

EPA in large part agreed with CRE's Data Quality Act Petition in the Agency's subsequent Response to Comments on the IRED. For example, EPA explained that

> The revised [atrazine Environmental Risk Assessment] does not suggest that endocrine disruption, or potential effects on endocrine-mediated pathway, 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 uncertainties, the chemical should be subject to more definitive testing once the appropriate testing protocols have been established.
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> 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. [3]

EPA has now published its review of the available data base for purposes of the amphibian effects SAP. EPA's review further confirms the points made in CRE's Petition.

EPA'S WHITE PAPER CORRECTLY CONCLUDES THAT EPA CANNOT NOW REGULATE ATRAZINE ON AMPHIBIAN EFFECTS

EPA developed a White Paper for the SAP "that critically evaluates currently available data, discusses the nature of remaining uncertainties in evaluating the potential effects of atrazine on amphibian development, and outlines the nature of future studies that will address these uncertainties." [4] EPA's White Paper correctly demolishes the current data base, and it is worth quoting at length:

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[3] EPA IRED Response to Comments, pp. 18-19 (available at http://www.epa.gov/oei/qualityguidelines/af_req_correction_sub.htm).

[4] White Paper on Potential Developmental Effects of Atrazine on Amphibians, p. 12 (EPA May 29, 2003) (available at http://cascade.epa.gov/RightSite/dk_public_collection_item_detail.htm?ObjectType=dk_docket_item&cid=OPP-2003-0024-0013&ShowList=xreferences&Action=view)

The Agency's evaluation of the relevant studies in the open literature and registrant-submitted laboratory investigations concludes that none of the laboratory studies fully accounted for environmental and animal husbandry factors capable of influencing endpoints which the studies were attempting to measure.

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After reviewing the entire body of information available from the laboratory investigations, EPA has concluded that the scientific evidence does not support many of the conclusions reached by the various study authors.

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The Agency also concluded that the currently available field studies are of limited value due to the high variability of environmental conditions (e.g., photoperiod, temperature, water quality) under which field-collected organisms lived, uncertainty as to amphibian developmental status and condition at the initiation of the studies, and an inability to relate the co-occurrence of atrazine with key developmental windows for the organisms under investigation. Consequently, EPA cannot determine whether the failure of several studies to show any relationship between measured or predicted aqueous atrazine concentrations and developmental effects reflects the absence of a causal relationship or the limitations of the study methodologies. In addition, the actual or possible co-occurrence of additional chemical and/or non-chemical stressors confound attempts to attribute any observed responses to atrazine exposure.

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Overall, the weight-of-evidence based on currently available studies does not show that atrazine produces consistent, reproducible effects across the range of exposure concentrations and amphibian species tested. The current body of knowledge has deficiencies and uncertainties that limit its usefulness in interpreting potential atrazine effects. Specifically, the demasculizing (decreased laryngeal dilator muscle area) effects were not replicated in multiple laboratories. Additionally, the feminizing effects (intersex/hermaphroditism/ovotestes) of atrazine were observed in three laboratory studies whose experimental designs could not be easily reconciled and that reported significant effects at different concentrations: one at 25 µ/L atrazine and the other two at 0.1 µg/L. While the feminizing effects observed in these different studies were consistent qualitatively, there was no consistency across the studies in the reported dose-response relationships. That inconsistency, together with the limitations in methodology in each study, does not allow a reliable determination of causality or the nature of any dose-response relationship. Although the Florida cane toads monitored in the field exhibited both demasculizing effects (genetic males with female colorization) and feminizing effects (oogenesis in male Bidder's organ), there were insufficient data to conclusively link atrazine exposure to the phenomena. Thus the available data do not establish a concordance of information to indicate

that atrazine will or will not cause adverse developmental effects in amphibians. [5]

The Data Quality Act, the Administrative Procedure Act, fundamental principles of sound science and good government preclude any regulation of atrazine at this time given EPA's correct assessment of the current data base. The only question legitimately before EPA now is whether to pursue this issue through development of more data, after first developing accurate, reliable and reproducible tests.

ANY FURTHER REVIEW OF THE AMPHIBIAN EFFECTS ISSUE IN ORDER TO COMPLY WITH THE NRDC CONSENT DECREE SHOULD NOT DELAY THE OCTOBER ATRAZINE IRED

Few, if any, substances have been subject to more prolonged, intensive and extensive regulatory scrutiny than atrazine. With regard to amphibian effects, EPA has concluded, "Overall, the weight-of-evidence based on currently available studies does not show that atrazine produces consistent, reproducible effects across the range of exposure concentrations and amphibian species tested." [6] In a rational world, EPA would be justified in concluding that 'enough is enough'; that the amphibian effects issue has been thoroughly reviewed; that additional study is unnecessary and inappropriate; and that the Agency should refocus its limited resources on other pressing matters. This, however, is not be a rational world.

Instead, EPA's review of this issue is driven by the consent decree between the Agency and the Natural Resources Defense Council. As modified, the NRDC consent decree apparently requires EPA to study the amphibian effects issue further even if EPA determines "that there are insufficient data to warrant regulatory action based on amphibian risk":

> If EPA concludes following review of the SAP report on the amphibian risk issue that additional data are needed before making a registration/reassessment determination pertaining to this issue, EPA may exclude the amphibian risk issue from the October 31, 2003 Interim RED so long as (1) EPA takes steps to insure that such additional data will be sought; and (2) EPA issues a memorandum signed by the Office of Pesticide programs, no later than October 31, 2003, determining that there are insufficient data to warrant regulatory action based on amphibian risk and explaining that decision. EPA shall have one year from which such data are submitted to address whether these data indicate it is appropriate to maintain registrations and,

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[5] White Paper, pp. 6-9 .

[6] White Paper, p. 9.

if applicable, tolerances for atrazine. [7]

If, after SAP review, EPA believes additional study is necessary in order to comply with the NRDC consent decree, then that additional study should not delay issuance of the October IRED. The NRDC consent agree permits EPA to issue the October IRED even if there are ongoing amphibian effect studies, and there is no justification for or reason to delay its issuance. Moreover, absent unexpected and exigent circumstances, any further EPA review of the amphibian effects issue should not extend beyond the period specified in the modified NRDC consent decree. NRDC should not be allowed to prolong this process any more.

EPA proposes a fairly detailed "conceptual model" for future tests in its White Paper. A prerequisite for any additional field or laboratory tests should be a demonstration that those tests are reliable, accurate and reproducible. Any information disseminated by EPA resulting from such tests should be subject to rigorous pre-dissemination review by EPA. [8]

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[7] Consent Decree, Paragraph 8, NRDC v. Whitman, Case No. C-99-3701 CAL (N.D. Cal.)

[8] See EPA Information Quality Guidelines at p. 29 (EPA administrative mechanism for pre-dissemination review).