

**COMMENTS BY THE CENTER FOR REGULATORY EFFECTIVENESS ON EPA'S
INTERIM REGISTRATION ELIGIBILITY DECISION FOR ATRAZINE
(Docket No. OPP-2003-0072)**

The Center for Regulatory Effectiveness ("CRE") submits the following comments on the Interim Registration Eligibility Decision for atrazine. 68 FR 9652 (Feb. 28, 2003).

DATA QUALITY ACT PETITION ON ENVIRONMENTAL RISK ASSESSMENT

CRE, the Triazine Network, and the Kansas Corn Growers Association ("Petitioners") filed a Request for Correction of EPA's Environmental Risk Assessment for atrazine under the Data Quality Act (Attachment A). EPA sent the Petitioners a letter stating that the Agency would respond to their Request for Correction in its response to comments on the draft atrazine IRED (available online at <http://www.epa.gov/oei/qualityguidelines/afreqcorrectionsub/2807Ack.pdf>). CRE asks EPA to confirm that EPA does not intend any other response to the Petitioners' Request for Correction under the Data Quality Act.

With regard to EPA's response to the Data Quality Act Petition, CRE understands that:

- EPA does not believe that endocrine effects can be a regulatory endpoint for atrazine at this time; and
- EPA has revised the atrazine Environmental Risk Assessment to "clearly state that based on the existing data uncertainties [about endocrine effects], the chemical should be subject to more definitive testing once the appropriate testing protocols have been established."¹

CRE asks EPA to confirm that this is EPA's response to the Petition.

INDIRECT EFFECTS

EPA's IRED reiterates the concern stated in EPA's Environmental Risk Assessment that atrazine may cause indirect effects on aquatic communities. In other words, EPA is concerned that atrazine may cause short-term decreases in the quantity of aquatic vegetation at the bottom of the food chain, which in turn may reduce the higher-level organisms that depend on this aquatic vegetation. *E.g.*, IRED, pp. 2, 61; Environmental Risk Assessment, pp. 1-2, 16.

CRE's prior comments in the atrazine re-registration review questioned EPA's statements regarding indirect effects (Attachment B). These comments will not be reiterated here, but are summarized as follows:

¹ EPA Response to Comments on the Atrazine Environmental Risk Assessment, pp. 18-20; EPA Atrazine IRED, pp. 68, 72.

- EPA's Risk Quotient Method, used in the atrazine risk assessment, cannot assess indirect effects and is of limited utility except as a screening tool.

- By its own admission, EPA does not have a method able to assess atrazine's indirect effects, nor does the Agency have the data necessary to assess atrazine's indirect effects.

- EPA acknowledges that there are substantial uncertainties regarding the field and laboratory standards used to support the Environmental Risk Assessment's conclusion of indirect effects: *e.g.*, lack of reproducibility and lack of transparency.

EPA's response to CRE's comments admitted the limitations of its models and data base. EPA further responded as follows:

“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 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 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 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 quantitative risk assessment. The extensive databases as well as the refined assessment increase the certainties 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, page 65, dated April 22, 2002).”

EPA Response to comments From Syngenta etc..., p. 18, Frankenberry *et al.* (January 28, 2003)(emphasis added)

CRE understands EPA's position to be that indirect effects from atrazine have not been shown with any certainty, but are uncertain and “potential” only.

This uncertainty is inevitable because EPA does not now have a proven, reliable method for assessing the indirect effects of atrazine or any other pesticide. Over a decade ago, EPA acknowledged:

“Although the Agency believes that long-term, indirect effects of pesticide use on

ecosystems may be important, the Agency does not have a testing scheme in place to accurately measure such effects within the time specified for Reregistration.”²

Nothing has changed since. ECOFRAM’s Terrestrial Work Group recently concluded that:

“Indirect effects are considerably more complex to understand and to quantify experimentally. As a result the pesticide registration process historically has not addressed indirect effects, and as currently constituted, may be incapable of addressing this issue.”³

The atrazine re-registration provides EPA with an opportunity to develop a method of addressing the indirect effects issue. Until and unless EPA develops such a method here or elsewhere, indirect effects cannot be used as a regulatory endpoint. In particular, EPA needs to develop accurate, reliable and reproducible models and microcosm/mesocosm test protocols.

Need for Validated Models

The inability of EPA’s Risk Quotient Method to reliably and accurately assess indirect effects was discussed in CRE’s Previous comments and will not be reiterated here (see Attachment B, at pp. 2-3). CRE does, however, note that ECOFRAM’s Aquatic Work Group stated that this method “cannot be used for estimating indirect effects of toxicants.”⁴

In addition, EPA relies heavily on the PRIZM/EXAMS Model in its analysis of indirect effects of atrazine.⁵ This model has never been fully validated.⁶ EPA has explained, “In some instances, the [PRIZM/EXAMS] screening model estimates are more than an order of magnitude greater than the highest concentrations reported in available monitoring data; in other instances, the model estimates are less than the monitoring concentrations.”⁷ Moreover, this model is

² Decisions on the Ecological Fate and Effects Task Force, Linda J. Fisher, EPA Assistant Administrator, Attachment: Program Guidance on Ecological Risk Management, p. 1 (Oct. 29, 1992).

³ ECOFRAM Terrestrial Draft Report, pp 4-23 to 4-24 (May 10, 1999).

⁴ ECOFRAM Aquatic Draft Report, Chapter 4-16 (May 4, 1999).

⁵ *E.g.*, Environmental Risk Assessment, at pp. 35-37.

⁶ Proposed Methods for Determining Watershed-Derived Percent Crop Areas etc..., EPA presentation to FIFRA Science Advisory Panel, pp. 5, 41, Effland *et al.* (May 27, 1999).

⁷ *Id.* at p. 3.

inherently biased. It is intended only as a screen that over predicts pesticide concentrations.⁸

EPA's use of the PRIZM/EXAMS model violates current EPA policy and guidance because the model has never been validated; and "validation" is "essential for regulatory environmental model development and application...in risk assessment."⁹ EPA's use of the PRIZM/EXAMS for atrazine also violates the Data Quality Act because, without validation, the model cannot be considered accurate, reliable and reproducible.

Need for Validated Micocosm/Mesocosm Test Protocols

EPA relies heavily on simulated field studies (microcosm or mesocosm) to support the Agency's conclusion that atrazine may cause indirect effects. There are no EPA-promulgated Ecological Effects Test Guidelines for assessing indirect aquatic effects in microcosms or mesocosms. CRE is not aware of any other standardized, properly validated guidelines or protocols for assessing such indirect effects. Consequently, one cannot know with reasonable certainty that the microcosm/mesocosm studies on which EPA relies are accurate, reliable, reproducible and useful. In fact, one cannot know how to conduct such studies in a reliable, accurate, reproducible and useful way.

The different results in the atrazine studies demonstrate the need for a validated, standardized test protocol. Depending on the study, atrazine may or may not cause indirect effects. The studies indicating sub-lethal indirect effects vary considerably at the level at which such effects occur and do not seem to be reproducible. There are also no standardized studies to determine the significance of indirect effects on populations in ecosystems. Depending on the study, recovery occurs, or does not occur, at levels and exposure durations that vary from study to study.¹⁰ Until and unless EPA develops a reliable, reproducible, standardized protocol for conducting microcosm and mesocosm studies, no one can know with any reasonable degree of certainty:

- Whether atrazine causes indirect effects;
- If so, then at what level atrazine causes indirect effects;
- At what level and duration of exposure time recovery occurs; and
- The impact of confounders.

⁸ *Id.* at pp. 2, 41.

⁹ Memorandum, Strengthening Science at the Environmental Protection Agency, Christine Todd Whitman ((May 30, 2002); see Guidance for Quality Assurance Project Plans for Modeling, p. 24, EPA QA/G-5M (December 2002)(models must be validated before they can be used).

¹⁰ *E.g.*, Environmental Risk Assessment, pp. 26-322.

The Data Quality Act standards, sound science, and regulatory policy preclude regulation based on this level of uncertainty.

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