Comments by the Center for Regulatory Effectiveness ("CRE") on Petition to Ban Atrazine, http://www.gpo.gov/fdsys/pkg/FR-2011-09-14/html/2011-23516.htm , Filed on November 14, 2011, at http://www.regulations.gov. , Docket ID # EPA-HQ-OPP-2011-0586

I. Executive Summary

The petition to ban atrazine is based on cited studies of the alleged ecological effects of atrazine, including studies by Dr. Jason Rohr and frog studies by Dr. Tyrone Hayes. Many of these alleged ecological effects are endocrine effects. For example, the petition includes the following statement: "We (40 scientists representing 10 countries, and six continents) have evaluated the existing studies examining atrazine as an endocrine disruptor along with emerging data on this topic." [1]

EPA should deny the petition to ban atrazine for the following reasons.

CRE filed a Data Quality Act ("DQA") Request for Correction ("RFC") of EPA's use of Dr. Hayes' frog studies and other alleged atrazine ecological effects studies. In response to CRE's RFC, EPA said it would not use any such studies to assess and regulate any alleged atrazine ecological effects on endocrine disruption until and unless the studies are based on properly validated tests. [2]

A this time, the only possibly validated atrazine ecological endocrine effects tests are

●The atrazine frog tests which were conducted in accordance with EPA/Science Advisory Panel ("SAP") instructions, supervision and review, and which could not replicate Dr.Hayes' different and unvalidated frog test results;[3]

●EPA's FIFRA Guideline tests to the extent that they are properly validated to detect ecological environmental effects; [4]

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[1] The petition does not identify these "40 scientists."

[2] See http://www.thecre.com/pdf/20030224-epa.pdf (EPA Risk Assessment, pages 68-69, 72-73).

[3] These SAP tests are peer reviewed online at http://www.epa.gov/scipoly/sap/meetings/2007/october/finalminutes.pdf (SAP minutes)

●Perhaps submitted OSRI tests; [5]

To the best of our knowledge, the Petitioners' cited studies do not use any of ***these possibly validated*** tests. EPA should not even consider using the Petitioners' cited studies to regulate alleged ecological endocrine effects until and unless those studies have been demonstrated to use tests which are properly validated. Validation should include compliance with the requirements of EPA's Quality System, including EPA's DQA Guidelines. [6] The Petitioners have not carried their burden of demonstrating that their cited studies use tests that meet these requirements.

Most of the Petitioners' cited studies allege endocrine effects, but the validation requirement should apply to tests for all endpoints in order to comply with EPA's Quality System, including EPA's DQA Guidelines. [7]

EPA representatives stated at the October 17th SFIREG meeting that EPA will soon ask a SAP to review EPA's quality requirements for using ecological effects studies.[8] If and when EPA does this, then the Agency should inform that SAP of:

●EPA's response to CRE's DQA RFC on Dr. Hayes' frog tests;

● EPA's Quality System requirements, including EPA's DQA Guidelines; and

● CRE's comments on these issues.

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[4] Available online at http://www.epa.gov/ocspp/pubs/frs/home/guidelin.htm . EPA's EDSP Tier 1 tests, which are among EPA's FIFRA Guideline tests (Series 890), include animal tests, but are designed to detect human endocrine effects. *Id.*

[5] See http://www.epa.gov/endo/pubs/EDSP_OSRI_Response_Table.pdf (EPA's OSRI response table for OSRI tests). OSRI is the acronym for Other Scientifically Relevant Information.

[6] EPA's DQA Guidelines are available online at http://www.epa.gov/quality/informationguidelines/ . EPA's Quality System website is at http://www.epa.gov/quality/

[7] See *id.*

[8] See http://aapco.ceris.purdue.edu/doc/announce/agen101711eqi.pdf (agenda for October 17th SFIREG meeting). SFIREG is the acronym for State-FIFRA Issues Research and Evaluation Group, whose website is available at http://aapco.ceris.purdue.edu/htm/committees_sfireg.htm

II. EPA Should Only Use Studies that are Demonstrated to Comply with EPA's Quality System Requirements, including Proper Validation

CRE's RFC on Dr. Hayes' Frog Tests is available online at http://www.epa.gov/quality/informationguidelines/documents/2807.pdf . The contents of this RFC are incorporated by reference into these CRE comments on the petition to ban atrazine. EPA's response to CRE's RFC stated in part:

> "Atrazine has been associated with sub-lethal effects in aquatic organisms and amphibians in research presented in the open, peer-reviewed literature. These include potential effects on endocrine-mediated processes in frogs at ~ 0.1 µg/L and in largemouth bass at ~ 50 µg/L, as well as olfactory effects in salmon at ~ 0.5 µg/L. In addition, some studies have been conducted to address this issue and found that these effects were not demonstrated.
>
> The Agency's ecological risk assessment does not suggest that endocrine disruption, or potential effects on endocrine-mediated pathways, be regarded as a 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. Based on the existing uncertainties in the available database, atrazine should be subject to more definitive testing once the appropriate testing protocols have been established. The Agency is aware that several pertinent studies are being performed at this time by researchers that may to reduce some of the uncertainties in understanding potential atrazine effects on amphibian endocrinology and reproductive and developmental responses. The Agency has committed to provide these studies along with other available studies, a summary of the available data and methodologies and various data analyses 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 to enable it publish an amendment to this IRED in October 2003 which will address the issue of the potential effects of atrazine on amphibian endocrinology and development." [9]

EPA's response also stated:

> "After reviewing the questions raised in the [CRE RFC], the Agency has decided that some minor clarifications of the April 2002 Environmental Risk Assessment for Atrazine may help to avoid any future misunderstanding of the Agency's position on the environmental effects of atrazine. Any such clarifications will be included in a revised Environmental Risk Assessment for Atrazine." [10]

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[9] http://www.thecre.com/pdf/20030224-epa.pdf (EPA Risk Assessment, pages 68-69).

[10] *Id*., pages 72-73.

The "minor clarifications" include the above-quoted EPA statement that properly validated tests are necessary to assess and regulate any alleged atrazine endocrine effects.

The June, 2003 SAP referenced in EPA's statement found significant problems in all of the then-available tests for "the potential effects of atrazine on amphibian endocrinology and development."[11] This SAP recommended that new frog tests be conducted in accordance with different test procedures established by the SAP, EPA and Syngenta. In 2007, a subsequent SAP peer reviewed the results of these new tests, approved them, and determined that Dr. Hayes' frog test results cannot be replicated. [12]

The CRE considers the new frog tests developed by the 2003 SAP and reviewed by the 2007 SAP to be validated. By contrast, peer review demonstrates that Dr. Hayes' different frog tests are unreliable. The petition to ban atrazine cites and relies on Dr. Hayes' frog tests. The petition should be denied for that and the other reasons discussed in CRE's comments.

The Executive Summary of CRE's comments on the petition identifies other tests that might be construed to be validated for purposes of assessing and regulating alleged atrazine ecological endocrine effects. None of these tests are used in the studies relied on by the petition to ban atrazine. Consequently, the petition should be denied for that and the other reasons discussed in CRE's comments.

Proper validation is necessary to comply with the requirements of EPA's Quality system, including EPA's DQA Guidelines. Consequently, the Petitioners should have to clearly demonstrate compliance with the validation and other Quality System requirements before EPA even considers using their cited studies to assess and regulate **ANY** alleged atrazine ecological effects.

The Petitioners have the burden of clearly demonstrating compliance with these requirements. They have not carried this burden; therefore, their petition should be denied.

[11] See http://www.epa.gov/scipoly/sap/meetings/2003/june/junemeetingreport.pdf for the meeting minutes for this SAP.

[12] The minutes for this subsequent SAP are available online at http://www.epa.gov/scipoly/sap/meetings/2007/october/finalminutes.pdf

III. EPA Should Inform Future SAPs of EPA's Response to CRE's RFC, EPA's Other Quality System Requirements, and CRE's Comments on these Issues

EPA representatives stated at the October 17, 2011, SFIREG meeting that EPA will soon ask a SAP to review EPA's quality requirements for accepting ecological effects studies.[13] If and when EPA does this, then the Agency should inform that SAP of:

- EPA's response to CRE's DQA RFC on Dr. Hayes' frog tests; and
- EPA's Quality System requirements, including EPA's DQA Guidelines;[14] and

On previous occasions, EPA has on commented on the application of EPA's DQA Guidelines and other Quality System requirements to the assessment and review of atrazine. These previous comments are incorporated herein by reference. [15]

We request that EPA assess and regulate atrazine in a manner consistent with these comments. The petition to ban atrazine does not meet these requirements; consequently, EPA should deny it.

We request that EPA inform any future SAPs of these comments.

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[13] See http://aapco.ceris.purdue.edu/doc/announce/agen101711eqi.pdf (agenda for October 17th SFIREG meeting).

[14] EPA's DQA Guidelines are available online at http://www.epa.gov/quality/informationguidelines/ . EPA's Quality System website is at http://www.epa.gov/quality/

[15] These CRE comments are available online at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2010-0481-0047 (CRE comments and attachment for September 2010 SAP); http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2010-0125-0048 (CRE comments and attachment for April 2010 SAP); and http://www.epa.gov/quality/informationguidelines/documents/2807.pdf (CRE's DQA RFC for Hayes frog tests).

IV. Conclusion

EPA should deny the petition to ban atrazine for the reasons stated in CRE's comments.

We thank EPA for the opportunity to submit these comments, and we look forward to the Agency's response.