### AGENDA Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel Meeting June 12-14, 2012

### Scientific Issues Associated with Problem Formulation for the Reassessment of Ecological Risks from the Use of Atrazine

Docket number: EPA-HQ-OPP-2012-0230

**OPP Docket Tel: 703-305-5805** 

# Please note that all times are approximate (See note at the end of the Agenda)

### Tuesday, June 12, 2012

- **9:00 A.M. Opening of Meeting and Administrative Procedures** Sharlene Matten, Ph.D., Designated Federal Official, Office of Science Coordination and Policy, EPA
- **9:05 A.M.** Introduction and Identification of Panel Members Daniel Schlenk, Ph.D., Chair, FIFRA Scientific Advisory Panel
- 9:15 A.M. Opening Remarks Steven Bradbury, Ph.D., Director, Office of Pesticide Programs, EPA
- **9:20 A.M.** Framework for Assessing the Potential Ecological Risks Posed by Atrazine Dana Spatz, M.S., Chief, Environmental Risk Branch III, Environmental Fate and Effects Division, Office of Pesticide Programs, EPA
- **9:45 A.M.** Evaluation of Amphibian Toxicity Data for Atrazine Amy Blankinship, M.S., Chemist, Environmental Fate and Effects Division, Office of Pesticide Programs, EPA
- 10:30 A.M. Break
- **10:45 A.M.** An Overview of the Methodology for Determining the Level of Concern for Atrazine Based on Aquatic Plant Communities – Frank Farruggia, Ph.D., Biologist, Environmental Fate and Effects Division, Office of Pesticide Programs, EPA and Russell Erickson, Ph.D., Research Chemist, Mid-Continent Ecology Division, Office of Research and Development, EPA
- 12:15 P.M. Lunch
- 1:15 P.M. Method for Comparing Monitoring Data to the Aquatic Plant Community CE-LOC for Atrazine James Hetrick, Ph.D., Senior Science Advisor, Environmental Fate and Effects Division, Office of Pesticide Programs, EPA
- **2:15 P.M.** Public Comments

- 3:15 P.M. Break
- 3:30 P.M. Public Comments, continued
- 5:45 P.M. Adjournment

#### Wednesday, June 13, 2012

- **9:00 A.M. Opening of Meeting and Administrative Procedures** Sharlene Matten, Ph.D., Designated Federal Official, Office of Science Coordination and Policy, EPA
- **9:05 A.M.** Introduction and Identification of Panel Members Daniel Schlenk, Ph.D., Chair, FIFRA Scientific Advisory Panel
- **9:10 A.M.** Follow-up from Previous Day's Discussion Donald Brady, Ph.D., Director, Environmental Fate and Effects Division, Office of Pesticide Programs, EPA
- 9:20 A.M. Public Comments, cont'd
- 10:45 A.M. Break
- **11:00 A.M. Introduction to the Charge Questions:** Donald Brady, Ph.D., Director, Environmental Fate and Effects Division, Office of Pesticide Programs, EPA

#### 11:10 A.M. Panel Discussion of Charge Questions

#### **Topic A: Evaluation of the Data on Amphibians**

There are an increasing number of literature studies examining whether there is a causal relationship between atrazine exposure and abnormal sexual development, metamorphosis and growth, and/or immune response in amphibians (Chapter II of the White Paper). In order to determine the degree to which these studies are appropriate for incorporation into risk assessment, EPA evaluated the data within the context of considering the nature and degree of the uncertainties in each study.

- 1. Is the SAP aware of any other laboratory-based or field-based studies not included in this White Paper that should be considered?
- 2. EPA identified test design elements that could potentially confound the ability of a study to discern a causal relationship between exposure to atrazine and an effect on amphibians (Section 7.2). Based on consideration of those test design elements, EPA then evaluated the available amphibian data and assigned a classification (*e.g.*, Quantitative, Qualitative (high, medium, and low level of confidence), and Invalid) to each study indicating EPA's confidence in the study's conclusions (Section 7.3 and Appendix C). The confidence in each study was based on an evaluation of the identified test design elements and resulting level of uncertainty in determining a direct causal relationship between atrazine and potential effects to amphibians.
  - a. Please comment on the completeness of EPA's list of pertinent test design elements. Also, please comment on the degree to which these test design elements, singularly or in combination, would be expected to contribute towards confounding the test results.

b. Please comment on EPA's conclusions about the level of confidence placed on each study's results.

### 12:30 P.M. Lunch

#### 1:30P.M. Topic A: Evaluation of the Data on Amphibians, cont'd

3. After evaluating all the available amphibian studies, one study was found to have accounted for all the identified test design elements (Question #2) and determined to be suitable for quantitative use in risk assessment for the endpoints of survival, growth and development (Section 7.3 and Appendix C). This study was required by an EPA Data Call-In (DCI) Notice following the recommendations from the 2003 SAP on atrazine and amphibians. The resulting study examined the effects of atrazine on *Xenopus laevis* at concentrations of 0.01 to 100 μg/L at two different laboratories. Based on the 2007 SAP, the conclusion was, and there was agreement by the Panel, that the data from this study were robust and sufficient to conclude that exposure to atrazine at concentrations ranging from 0.01 to 100 μg/L had no effect on *X. laevis* development (which included survival, growth, metamorphosis and sexual)

100 µg/L had no effect on X. *laevis* development (which included survival, growth, metamorphosis and sexual development).

- a. Please comment on whether any new information has become available that leads to a different conclusion from the one which EPA reached in that the results of the DCI study were adequate to evaluate potential effects of atrazine exposure to amphibians.
- b. If such information is now available, please comment on how a threshold determination (a concentration that is expected to cause no effect) may be accomplished using the identified studies.
- 4. After evaluation of the available amphibian toxicity data, EPA concluded that the DCI study mentioned in Question #3 was appropriate for quantitative use in a risk assessment for survival, growth and development. While the 2007 SAP Panel agreed that atrazine appeared to have no effect on *X. laevis* development at atrazine concentrations ranging from 0.01 to 100 µg/L, they expressed concerns about the suitability of *X. laevis* as a surrogate for native species. Review of the available toxicity data utilizing indigenous species suggests that suitable protocols, including adequate husbandry methods in particular, that would enable EPA to quantify a toxicity endpoint representative of a clear and consistent response from atrazine for native species, may not exist. *Please comment on whether there are suitable methods for testing native amphibians with particular regard to husbandry and laboratory culturing conditions, consistent with the design elements recommended by the 2003 SAP.*

### 3:15 P.M. Break

#### 3:30 P.M. Topic A: Evaluation of the Data on Amphibians, cont'd

- 5. A number of studies report the potential for atrazine to modify immune function and infection susceptibility in amphibians (Appendix C). EPA believes the research on these different hypotheses does not provide sufficient data to establish causal linkages among different levels of biological organization to result in adverse effects. Therefore, EPA concluded that a mode of action or adverse outcome pathway leading to effects on amphibian survival, growth or development cannot be established at this time.
  - a. Please comment on whether the data in the existing database reasonably supports the hypotheses, or demonstrates that atrazine affects immune function and/or infection susceptibility leading to adverse effects on survival, growth or development; i.e., are there sufficient data to establish an adverse outcome pathway for atrazine effects on immune function? Please provide a rationale for the Panel's position and discuss the associated strengths and weakness with the data supporting the rationale.

b. If the Panel concludes that the existing data are sufficient to formulate hypotheses that atrazine adversely affects immune function and infection susceptibility, but are not sufficient to test the hypotheses (refute or confirm), then please comment on specific study protocols that can be used to test these hypotheses with sufficient rigor to identify effects that can be directly and quantitatively attributed to adverse impacts on amphibian reproduction, growth and/or survival.

# 4:15 P.M. Topic B: The Method for Determining the Atrazine Level of Concern for Aquatic Plant Communities

Chapter I, Section 6.14 and Appendix D discuss the mesocosm and microcosm (cosm) study selection criteria for determining acceptability in evaluating the impact of atrazine exposure on the structure, function and productivity of aquatic plant communities. Chapter I, Section 6.14, and Appendix G(f) also provide summaries of the source of the natural communities used to populate the acceptable cosm studies, as well as details on species composition of the cosms. The acceptable cosm studies were used in the establishment of an Aquatic Plant Community Concentration Equivalent Level of Concern (CE-LOC) for atrazine. EPA has refined its method for determining an CE-LOC for atrazine based on the recommendations provided by SAPs in 2003, 2007, and 2009 (Chapter IV, Sections 13 & 14; for a summary of changes since 2003 please refer to Table 21). This methodology will be used for a national-scale assessment of atrazine concentrations in freshwater and estuarine/marine ecosystems in the upcoming registration review. The following questions concern the composition and biological relevance of the cosm studies, and the method, assumptions and uncertainties in determining a CE-LOC for atrazine.

- 6. The cosms were comprised of natural communities of periphyton/phytoplankton; in some cases, vascular plants, invertebrates and vertebrates present in those communities were included in the study (Chapter I, Section 6.1.4). These sources were generally described as streams, lakes, reservoirs, and springs, and are considered to be representative of the structure and function of aquatic plant communities in such water bodies. *Given the diversity of sources and the described communities, please comment on the extent to which these cosm studies taken together provide useful and reasonable physical models of the natural aquatic plant communities exposed to atrazine in the U.S.*
- 7. The Aquatic Plant Community CE-LOC methodology for atrazine is a four stage process that uses singlespecies plant toxicity data and cosm studies to discern atrazine concentrations and exposure durations that may cause adverse effects on aquatic plant communities. As a result, a CE-LOC for atrazine is developed which, together with monitoring data, can be used to identify watersheds where concentrations may result in adverse effects to aquatic plant community structure, function, and/or productivity. *Please comment on the methodology EPA has used to derive the atrazine CE-LOC for aquatic plant communities, and in particular on EPA's characterization of the uncertainties and assumptions in this methodology (Chapter IV, Sections 13 & 14).*

#### 5:30 P.M. Adjournment

#### Thursday, June 14, 2012

- **9:00 A.M. Opening of Meeting and Administrative Procedures** Sharlene Matten, Ph.D., Designated Federal Official, Office of Science Coordination and Policy, EPA
- **9:05 A.M.** Introduction and Identification of Panel Members Daniel Schlenk, Ph.D., Chair, FIFRA Scientific Advisory Panel
- **9:10 A.M.** Follow-up from Previous Day's Discussion Donald Brady, Ph.D., Environmental Fate and Effects Division, Office of Pesticide Programs, EPA

# 9:20 A.M. Topic B: The Method for Determining the Atrazine Level of Concern for Aquatic Plant Communities, cont'd

- 8. The 2009 SAP recommended using an effects index or concentration metric, rather than categorical LOC thresholds in order to take advantage of data from Syngenta's Atrazine Ecological Exposure Monitoring Program (AEEMP). At that time the LOC threshold for atrazine effects to plant communities was established at 10 μg/L for a 60-day rolling average. The current analysis using the Plant Assemblage Toxicity Index (PATI) indicates the CE-LOC can range from 4 to 7 μg/L (Chapter IV, Section 14.3 & 14.4). *Please comment on this CE-LOC and whether it reasonably represents a range below which permanent or irreversible change in aquatic plant community structure, function, and/or productivity due to atrazine exposure would not be expected.*
- 9. Based on previous analyses of the available ecotoxicity data, EPA concluded for atrazine that the level of concern for effects on aquatic plant communities (CE-LOC) was lower than the atrazine concentrations observed to produce significant direct or indirect effects on invertebrates, fish and amphibians. Given the current analysis of the ecotoxicity data (Chapter I, Section 6) and the Aquatic Plant Community LOC methodology, EPA continues to believe the original conclusion still holds true. *Please comment on how well the available database supports EPA's conclusion that the CE-LOC is lower than exposures that result in significant effects on the growth, survival and reproduction of aquatic animals.*

#### 10:30 A.M. Break

# 10:45 A.M. Topic C: Method for Comparing Monitoring Data to the Aquatic Plant Community LOC for Atrazine

Chapter V and Section 16 address the issue of identifying surface water bodies with potential levels of atrazine that exceed the aquatic plant community levels of concern (CE-LOC). EPA evaluated several statistical methods (kriging, stochastic simulation, covariate analysis, and bias factors) to address uncertainties associated with sampling frequency as it impacts the ability to quantify atrazine concentrations from monitoring data (USEPA, 2011). The FIFRA SAP in 2011 advised that use of bias factors was a viable approach for addressing uncertainty in monitoring data. The following questions are related to the use of bias factors in identification of surface water bodies exceeding the atrazine CE-LOC.

10. Please comment on the strengths and limitations of EPA's development and use of bias factors (Chapter V, Section 16.1) for addressing uncertainties in monitoring data.

#### 12:30 P.M. Lunch

## 1:30 P.M. Topic C: Method for Comparing Monitoring Data to the Aquatic Plant Community LOC for Atrazine, cont'd

- 11. Prediction of bias factors is dependent on the selection of an appropriate model. EPA illustrated (Chapter V, Section 16.1) both categorical and regression methods for prediction of bias factors based solely on the number of samples taken in the 2<sup>nd</sup> and 3<sup>rd</sup> quarters of the year (April 1<sup>st</sup> to September 30<sup>th</sup>).
  - a. Please comment on EPA's prediction of bias factors from monitoring data using categorical or regression method approaches.
  - b. Please comment on any additional methods for estimating bias factors that would be useful in this situation.

12. EPA illustrated (Chapter V, Section 16.1) both categorical and regression methods for estimation of bias factors as a function of the sampling frequency of monitoring data. Step-wise regression analysis indicates that watershed size and average flow rate in the 2<sup>nd</sup> and 3<sup>rd</sup> quarters of the year are not significant variables for prediction of bias factors. However, the number of samples in the 2<sup>nd</sup> and 3<sup>rd</sup> quarters of the year was found to be a significant variable, accounting for 46% of the variation in the bias factor. *What other variables, if any, should be considered in the prediction of bias factors?* 

#### 3:15 P.M. Break

# **3:30 P.M.** Topic C: Method for Comparing Monitoring Data to the Aquatic Plant Community LOC for Atrazine, cont'd

- 13. EPA examined (Chapter V, Section 16.1) the performance of various regression equations to assess the failure percentage for identification of monitoring site-years with true maximum 60-day average concentrations exceeding the CE-LOC for atrazine. This analysis showed that application of a bias factor, based on sample number during the 2<sup>nd</sup> and 3<sup>rd</sup> quarter of the year, substantially reduced the number of sites with underestimation of true maximum 60-day means. *Given the EPA analysis, what other tests, if any, should be conducted to assess the performance of regression models for prediction of bias factors?*
- 14. An important consideration for bias factor prediction is the ability to identify monitoring sites that potentially exceed the CE-LOC for atrazine. EPA provided an example (Chapter V, Section 16.2 and 16.3) of the use of a log-linear regression equation to estimate bias factors from the USGS National Water Quality Assessment Program NAWQA data and identification of monitoring site-years exceeding the CE-LOC for atrazine. This analysis identified sites in both the Midwestern United States as well as outside the major corn growing areas with atrazine concentrations potentially above the CE-LOC. *What are the strengths and limitations of using a single regression model for prediction of spatially and temporally explicit bias factors for a nationally-distributed monitoring data set*?

#### 5:30 P.M. Adjournment

Please be advised that agenda times are approximate; when the discussion for one topic is completed, discussions for the next topic will begin. For further information, please contact the Designated Federal Official for this meeting, Dr. Sharlene Matten, telephone: (202)-564-0130, fax: (202) 564-8382, or email: matten.sharlene@epa.gov.