

October 23, 2009

# Comments from the Natural Resources Defense Council to the EPA meeting of the FIFRA SAP to present the approach to re-evaluate atrazine

EPA-HQ-OPP-2009-0759 November 3, 2009

We are very encouraged by EPA's announcement on October 7, 2009 to engage its Scientific Advisory Panel to review the following approach and timeline as outlined by EPA in a federal register notice:<sup>1</sup>

- February 2010 EPA will present and seek scientific peer review of its proposed plan for incorporating data from human epidemiology and incident data into the atrazine risk assessment. It will also review epidemiology that uses an ecological design that have been published since the last atrazine assessment.
- April 2010 EPA will present and seek peer review of its evaluation of atrazine non-cancer effects based on animal laboratory toxicology studies, selection of safety factors in the risk assessment, and the sampling design currently used to monitor drinking water in community water systems. Studies used in past assessments, as well as those that have been published since then will be included. Alternative modes of action not considered since the 2003 assessment will also be considered.
- September 2010 EPA will present and seek peer review of its evaluation of atrazine cancer and non-cancer effects based on animal toxicology studies and epidemiology studies. This review is intended to include the most recent results from the National Cancer Institute's Agricultural Health Study, anticipated for publication in 2010, as well as studies used in past assessments. Any new science related to setting the FQPA safety factor will also be considered.

In all of the above cases the SAP will be asked to comment on the soundness of the scientific approach, considering all available data. The FR notice states that "At the end

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<sup>&</sup>lt;sup>1</sup> 74 Fed. Reg. 51593 (Oct. 7, 2009).

of this year-long effort, the Agency will determine if the current risk assessment for atrazine should be revised and whether or not the Agency's current regulatory position and community water system monitoring requirements should be changed."

## NRDC history with atrazine regulation

NRDC has a long history with the regulation of atrazine. In 2001, NRDC and EPA settled a lawsuit with a Consent Decree ("2001 Consent Decree") establishing a schedule by which EPA would complete certain steps in the reassessment and reregistration process for numerous pesticides, including atrazine. This order required EPA to issue an IRED for atrazine in January 2003, and a revised IRED by October 31, 2003. For the revised IRED, EPA was required to consider the effects of atrazine on amphibian species, and the association between atrazine and cancer in humans.

In May 2003, NRDC submitted a Freedom of Information Act (FOIA) request to EPA and other agencies concerning the involvement of industry in the atrazine special review and re-registration processes. When after six months EPA failed to respond, NRDC filed suit in November 2003. The documents that NRDC received from this suit revealed that during the IRED process, rather than canceling, suspending, or imposing any significant restrictions on the use of atrazine as NRDC and many others concerned about the health and environmental effects of the chemical had urged, EPA entered into a detailed Memorandum of Agreement (MOA) with Syngenta and other companies which required Syngenta to undertake a water monitoring program to determine the extent of atrazine pollution in the environment.

NRDC again sued EPA in October 2003, seeking another scientific review of the possible links between all cancers and atrazine, which EPA had been required to do under a court order issued two years earlier. In response, EPA convened a Scientific Advisory Panel in 2003, but charged the panel with only reviewing prostate cancer data, thereby ignoring available data on other cancer sites and relevant data on atrazine as an endocrine disruptor. On August 29, 2003 the Atrazine Cancer Scientific Advisory Panel issued a report criticizing EPA for ignoring atrazine's links to other cancers, stating that it might be "misleading" to review only prostate cancer data.

# NRDC analysis of EPA water monitoring data shows elevated peaks exceed levels of concern

EPA regulates the use of atrazine as well as the presence of atrazine in drinking water. Under the Safe Drinking Water Act (SDWA), EPA has determined that no more than 3 parts per billion (ppb) of atrazine (as a running annual average) may be present in drinking water. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),

<sup>3</sup> NRDC v. Office of Management and Budget, No. 03-2345 (PLF) (D.D.C. filed Nov. 13, 2003)

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<sup>&</sup>lt;sup>2</sup> NRDC v. Whitman, No. 99-3701 WHA, 2001 WL 1221774 (N.D. Cal. Sept. 24, 2001).

EPA allows atrazine to be used on, among other things, corn, sorghum, sugarcane, and lawns. Despite the fact that atrazine used in fields eventually ends up in surface water and treated drinking water, the regulation of atrazine under these two statutes is poorly coordinated.

NRDC issued a report this summer titled *Atrazine: Poisoning the Well* that analyzed the results of surface water and drinking water monitoring required by EPA to create a more comprehensive analysis of atrazine pollution across the Midwestern and Southern United States (NRDC report incorporated by reference). We found that EPA's inadequate monitoring systems and weak regulations have compounded the problem, allowing levels of atrazine in watersheds and drinking water to peak at high concentrations.

Our analysis of the Ecological Watershed Monitoring Program data confirms that the surface waters of the Midwestern and Southern United States suffer from pervasive contamination with atrazine.<sup>5</sup>

- All 40 watersheds tested showed detectable levels of atrazine, and 25 had average concentrations above 1 ppb, which is the concentration at which the primary production of aquatic non-vascular plants (such as algae) is reduced.
- The watersheds with the 10 highest peak concentrations of atrazine are in Indiana, Missouri, and Nebraska.
- Nine of the monitored watersheds (22 percent) had at least one sample showing atrazine levels above 50 ppb, and four watersheds (10 percent) had peak maximum concentrations of atrazine exceeding 100 ppb. At Little Pigeon Creek in Indiana, the annual average atrazine concentration was 7.5 ppb, but the maximum concentration was a staggering 237.5 ppb, detected in May 2005.

Our analysis of the EPA's Atrazine Monitoring Program data also reveals disturbingly high levels of atrazine contamination in the drinking water in some public water systems. <sup>6</sup>

- More than 90 percent of the samples taken in 139 water systems had measurable levels of atrazine in both 2003 and 2004.
- Three water systems had running annual averages for atrazine in finished (tap) water that exceeded the 3 ppb drinking water standard: Versailles Water Works in Indiana (4.60 ppb), Mount Olive Water Works in Illinois (3.79 ppb), and Evansville in Illinois (3.20 ppb).
- Fifty-four water systems (39 percent) had a one-time peak atrazine concentration above 3 ppb. The highest peak concentration of atrazine in finished water among

<sup>&</sup>lt;sup>4</sup> NRDC report. <u>Atrazine</u>: Poisoning the Well. How the EPA is ignoring atrazine contamination in the <u>Central United States</u>. August, 2009. http://www.nrdc.org/health/atrazine/default.asp

<sup>&</sup>lt;sup>5</sup> NRDC report. <u>Atrazine: Poisoning the Well. How the EPA is ignoring atrazine contamination in the Central United States</u>. August, 2009. http://www.nrdc.org/health/atrazine/default.asp

<sup>&</sup>lt;sup>6</sup> NRDC report. <u>Atrazine: Poisoning the Well. How the EPA is ignoring atrazine contamination in the Central United States</u>. August, 2009. http://www.nrdc.org/health/atrazine/default.asp

all tested public water systems was 39.69 ppb in the Evansville water system in Randolph County, Illinois.

Because of the potential adverse effects to aquatic wildlife and possibly to humans associated with even short exposures to atrazine, the spikes detected in the watersheds and the public drinking water systems are particularly alarming. Yet, because EPA focuses on *average* concentrations of atrazine, it has effectively ignored these peaks.

### New 2009 science confirms hazards of atrazine exposure

Drs. Rohr and McCoy recently conducted a review and meta-analysis of published, peer-reviewed scientific studies, (Rohr and McCoy, 2009. Env Health Perspect). This rigorous and comprehensive review found consistent, sub-lethal adverse effects of atrazine on freshwater aquatic wildlife across multiple species, across multiple systems including endocrine and immune, in studies from multiple independent laboratories, and from multiple study designs. This kind of scientific consistency in results provides extremely strong evidence that atrazine disrupts endocrine and immune system function in exposed aquatic wildlife. Some of the detailed findings of their meta-analysis are:

- Atrazine reduced size at or near metamorphosis in 19 of 19 studies (responses were non-monotonic, meaning metamorphosis was sometimes delayed and sometimes accelerated in atrazine-exposed test animals)
- Atrazine reduced anti-predator behavior in 6 of 7 studies
- Atrazine was associated with impaired immune function in 35 of 42 endpoints and with an increased infection in 13 of 16 endpoints
- Atrazine altered gonad development in 8 of 10 studies, and impaired gonad function by altering spermatogenesis in 2 of 2 studies, and altered sex hormone concentrations in 6 of 7 studies

Although the authors point out that it remains uncertain how these atrazine-associated effects in individuals would manifest themselves at the population level; some damaging effects can reasonably be anticipated. At the very least, it is no longer scientifically-defensible to hold that atrazine is not an endocrine disruptor, nor that atrazine is safe for aquatic populations.

Other significant scientific studies published in 2009 provide laboratory evidence that atrazine interferes with normal hormone function:

• Even a single dose of atrazine (200 mg/kg) given to male Wistar rats caused a measurable increase in steroid hormone release within 15 minutes after dosing. (Laws et al, 2009. Tox Sci)

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<sup>&</sup>lt;sup>7</sup> Rohr JR, K McCoy. 2009. A qualitative meta-analysis reveals consistent effects of atrazine on freshwater fish and amphibians. *Environ Health Perspect* doi:10.1289/ehp.0901164 available via <a href="http://dx.doi.org/">http://dx.doi.org/</a> [Online 23 September 2009]. http://www.ehponline.org/docs/2009/0901164/abstract.html

- Rats fed atrazine-contaminated feed for 1 or 2 weeks (120 mg/kg, 200 mg/kg) had a dose-dependent reduction in sperm number and impaired daily sperm production. (Abarikwu et al, 2009. Arch Environ Contam Toxicol)
- Rats fed atrazine-contaminated feed (50 mg/kg, 200 mg/kg) for 25 days had a significant dose-dependent reduction in steroid production in the Leydig cells of the testes (Pogrmic et al, 2009. Toxicol Sci)
- Rats treated for 5 months with atrazine-laced drinking water (30 or 300 μg/kg [ppb]) had associated insulin-resistance leading to obesity (Lim et al, 2009. PLoS One)

In an interesting study of the effects of atrazine and other pesticides in mixtures, one laboratory reported that when tiger salamander larvae were raised for 2 weeks in water containing atrazine (20 or 200 ppb) or chlorpyrifos (2, 20, or 200 ppb) no increase in deaths was observed. When the larvae were exposed to the combination of atrazine and chlorpyrifos together, however, there was a significant increase in larval deaths from increased viral infection and disease, suggesting that the treatment critically impaired immune function (Kerby and Storfer, 2009. Ecohealth)

Despite the growing body of scientific evidence that atrazine is a potent endocrine disrupting chemical and widespread water contaminant, Syngenta-supported scientists continue to tout its safety:

"Based on a weight of evidence analysis of all the data" the hypothesis that atrazine is associated with reproductive abnormalities "is not supported by the vast majority of observations". The same conclusion is reached for other reported effects such as impaired immune function, stress, or population-level effects (Solomon et al, 2008. Crit Rev Toxicol)

## Previous SAPs were limited in scope and scientific content

The EPA convened two scientific advisory panels of outside experts in the summer of 2003; the first panel was to review atrazine endocrine effects, <sup>8</sup> and the second to review potential cancer risks. <sup>9</sup> In each case EPA requested only a limited data review, preventing its SAP experts from providing advice based on a comprehensive data review. The SAP on endocrine effects was limited to a review of developmental frog studies, including a dozen conducted by Syngenta within the year preceding the review, only one of which had been published at the time. <sup>10</sup> Relevant rodent or other data were not included in the review.

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<sup>&</sup>lt;sup>8</sup> U.S.EPA. FIFRA Scientific Advisory Panel Meeting on Potential Developmental Effects of Atrazine on Amphibians; June 17-20, 2003; Arlington, VA.

<sup>&</sup>lt;sup>9</sup> U.S.EPA. FIFRA Scientific Advisory Panel meeting: Characterization of Epidemiology Data Relating to Prostate Cancer and Exposure to Atrazine (EPA Dockets - OPP-2003-0186). Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting Held July 17, 2003. August 29 2003

<sup>&</sup>lt;sup>10</sup> U.S.EPA. White paper on potential developmental effects of atrazine on amphibians: in support of an interim reregistration eligibility decision on atrazine. Washington D.C: Office of Prevention, Pesticides,

The 2003 cancer SAP was limited to consideration of prostate cancer risks only. The panel expressed its frustration with EPA's unduly narrow charge, stating that it was "misleading" to review prostate cancer data but not data pertaining to other cancer risks. The panel also disagreed with EPA for asserting that there is no link between prostate cancer and atrazine, reminding EPA that in an advisory report several years earlier, the panel had expressed concern that several studies on Non-hodgkin's lymphoma (NHL) were discounted by EPA. The 2003 advisory panel had also encouraged EPA to consider "whether hormonal effects in childhood or adolescence may have an impact on cancer occurrence in later years", something EPA has thus far continued to avoid considering in its assessment. Following pressure from NRDC, EPA agreed to review cancer risks more comprehensively at a later date.

In 2007 the EPA again solicited advice from its SAP on atrazine and amphibian gonadal development. This time EPA provided the SAP with 19 studies, but noted that only the studies conducted or sponsored by Syngenta complied with the design elements and laboratory practices required by the Agency. EPA at that time was seeking confirmation that atrazine did not adversely affect amphibian gonadal development at environmentally-relevant exposures. The SAP rejected this conclusion, specifically noting that the registrant-supplied studies on the African frog could not be reliably extrapolated to North American frog species in the wild. The SAP repeated its 2003 request for data on North American frog species and field study data.

#### Recommendations

We recommend that SAP get assurances that EPA will provide all published, peer-reviewed studies of relevant data, including but not limited to animal bioassays, in vitro data, human epidemiology, incident data, and ecological epidemiology.

and Toxic Substances, Office of Pesticide Programs, Environmental Fate and Effects Division; May 29 2003.

<sup>&</sup>lt;sup>11</sup> U.S.EPA. FIFRA Scientific Advisory Panel meeting: Characterization of Epidemiology Data Relating to Prostate Cancer and Exposure to Atrazine (EPA Dockets - OPP-2003-0186). Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting Held July 17, 2003. August 29 2003.

<sup>&</sup>lt;sup>12</sup> U.S.EPA. FIFRA Scientific Advisory Panel Report. Atrazine: Hazard and Dose-Response Assessment and Characterization. SAP Report No. 2000-05. http://www.epa.gov/scipoly/sap/2000/index.htm. Washington, D.C. June 27 2000.

<sup>&</sup>lt;sup>13</sup> U.S.EPA. FIFRA Scientific Advisory Panel Report. Atrazine: Hazard and Dose-Response Assessment and Characterization. SAP Report No. 2000-05. http://www.epa.gov/scipoly/sap/2000/index.htm. Washington, D.C. June 27 2000.

<sup>&</sup>lt;sup>14</sup> NRDC. Natural Resources Defense Council v. Whitman, No. C-99-3701 (WHA), Declaration of James J. Jones. Northern District of California (filed Nov. 13) 2003.

<sup>&</sup>lt;sup>15</sup> Transmittal of meeting minutes of the FIFRA Scientific Advisor Panel meeting held October 9-11, 2007 on the Potential for Atrazine to Affect Amphibian Gonadal Development. January 3, 2008.

We recommend that SAP get assurances that its review will not be limited only to studies published since the last SAP review, given that previous SAP reviews did not consider all data available at the time, and given that any proper scientific review must consider all relevant data available without artificial non-scientific constraints. There is no statute of limitations on the truth.

We recommend that SAP get assurances that the cancer and non-cancer review will include both human and animal data from published, peer-reviewed studies, including but not limited to animal bioassays, in vitro studies, occupational epidemiology, and ecological epidemiology. The SAP should consider data on all endpoints relevant to cancer, including endocrine endpoints.

#### Conclusion

Many farms, including many surrounded by heavy atrazine use like in Illinois, are ahead of the regulatory curve with effective and affordable agricultural practices that avoid using atrazine and other toxic chemicals (www.thelandconnection.org). These farms are successfully applying new science and new technology to create a sustainable and healthy farming future starting today. Given the pesticide's limited usefulness and the ease with which safer agricultural methods can be substituted to achieve similar results, NRDC recommends phasing out the use of atrazine, more effective atrazine water monitoring, the encouragement of farming techniques to minimize the use of atrazine and prevent it from running into waterways.

Respectfully submitted,

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