Examples of overestimation of risk by EPA models and assessments:
EPA Atrazine Ecological Risk Assessment for Atrazine

- Atrazine is currently undergoing Registration Review by EPA, the normal 15-year re-registration process required for all pesticides.
- A draft ecological risk assessment was posted by EPA for public comment in June of 2016 (note that this document was initially posted and removed by EPA in April 2016 without explanation or public comment).

- The preliminary assessment contains a number of determinations based on unsound science that, if uncorrected, could have a significant impact on the ultimate registration review decision and atrazine's use and availability for growers. Moreover, if the same approach were adopted for ecological risk assessments for other herbicides, this would impact the availability of all or virtually all major herbicides.

- This assessment proposes an aquatic level of concern (LOC) that uses poor quality studies that drives the number far below biological impacts. This preliminary assessment disregarded recommendations made by multiple Science Advisory Panels (SAPs; 2007, 2009 and 2012) concerning the setting of an aquatic level of concern. The aquatic level of concern (LOC) proposed in the preliminary assessment is based on a dataset containing numerous fundamentally flawed, inconsistent and misinterpreted micro/mesocosm (cosm) studies, contrary to the recommendations of multiple SAPs to correct these errors.
    - The assessment acknowledges the methodology utilized to derived the LOC is highly sensitive to scoring effects in the cosm dataset
    - The assessment disregarded consistent recommendations of multiple SAPs and retained data points from studies with obvious errors and weaknesses
    - Retaining these data points results in a LOC that is artificially low and not biologically relevant
    - If the recommendations of the 2012 SAP are followed, the LOC is >20 ppb as a 60-day rolling average, at least 6-fold higher than the value referenced in EFED's document

- The 2012 SAP overwhelmingly and strongly recommended that additional focused cosm studies are needed to specifically address the durations of exposure expected at environmentally relevant concentrations. A definitive state-of-the art cosm study based on the Panel's design suggestions (including natural conditions, size, design reflecting water body type , duration, spectrum of plant diversity, source of algal re-colonization and replicated treatments) was conducted at the Baylor University aquatic stream facility by a team led by Professor Ryan King. This cosm study indicated no significant effects on primary producer community structure and only slight transient (recoverable) effects on most other functional endpoints. The preliminary assessment mischaracterized, misinterpreted and inappropriately dismissed this benchmark study. This is the same research facility and a similar protocol that was used by Dr. King to resolve a long standing dispute between Arkansas and Oklahoma over defining a phosphorus standard through a high quality study commissioned by Oklahoma Attorney General Scott Pruitt, current Administrator of the U.S. EPA.

- The preliminary assessment uses models that overestimate the estimated environmental concentrations of atrazine in water. Robust and comprehensive monitoring data are available, for example from the Atrazine Ecological Monitoring Program (AEMP; 2004-2015) which has generated 239 site-years of daily or near-daily monitored data from 70 watersheds, representing the upper 20th centile most vulnerable agricultural watersheds in the Midwestern and Southern U.S. in terms of susceptibility to potential runoff and agrichemical losses. This dataset represents the high-end scenarios for potential exposure to atrazine and is therefore highly protective with minimal uncertainty and negates the need for conventional regulatory modelling that relies on theoretical conservative assumptions.
    - The AEMP provided a 90th centile 60-day rolling average is ~14 ppb.
        - Considering all available monitoring data from multiple state, university and government programs, the 90th centile 60-day rolling average is ~8 ppb.
    - Instead of relying on these real world monitoring data, EPA relied on modeling to estimate atrazine the 90th centile 60-day rolling exposures of up to 111 ppb for corn use.
    - Previous comprehensive EPA assessment from 2003 reregistration modeled an estimated environmental concentration range from 26 – 36 ppb for the 90th centile 60-day rolling average.
    - Even as recent as this month, the principle EPA modelers showed modeled individual values of greater than 7000 ppb, as shown in attachment 1.
    - Average atrazine use rates over this time have remained flat or decreased, as shown in attachment 2. The changes in values result from over-estimation of EPA models.

- This assessment inappropriately lowers the endpoints for assessment of fish toxicity. The chronic fish No Effect Concentration (NOEC) identified in the assessment (5.0 µg/L) was derived from a non-Good Laboratory Practices (non-GLP) published Japanese medaka study that is clearly an outlier when all fish studies, including EPA-conducted fish studies, are considered; a quantitative weight of evidence approach should be used to evaluate the quality and relevance of all chronic fish studies.
    - This non-GLP study followed a non-validated design predating standardization of EPA and OECD guidelines and exhibited numerous weakness and significant deviations from the standard guideline, including a non-recommended male/female ratio which has been shown to reduce egg production.
    - A more recent guideline compliant, GLP study found no effects on medaka egg production, and no statistically significant or dose-response related effects on reproduction at treatment levels up to 10X higher than the NOEC identified in the preliminary assessment.

- The preliminary assessment's stated position on potential effects on amphibians represents a reversal of its positions of the last 10+ years and overall conclusions of SAPs held in 2003, 2007 and 2012. The preliminary assessment relies on studies previously deemed by the EPA to be of low quality, studies that deviate from the EPA requirements for standardized protocols and under GLP, and published literature for which study methods and data transparency are

insufficient. In some cases the EPA is relying on studies which they previously stated could not be evaluated due to uncertainties and lack of data transparency.

- The preliminary assessment inexplicably lowered the chronic avian (mallard reproduction) No Observed Adverse Effects Concentration (NOAEC) (from 225 to 75 mg/kg-diet). The 225 mg/kg NOAEC was historically supported by the Agency in previous risk assessments and identified in the study Data Evaluation Record (DER); this change in conjunction with highly conservative and unrealistic assumptions used to parameterize higher-tier models such as TIM and MCnest resulted in uncorroborated and severely exaggerated effect predictions for bird species.

- The preliminary document incorrectly characterizes potential impacts on mammals: The assessment utilized unrealistic, unrefined and hyper-conservative screening-level exposure estimates (including continuous consumption of a singular food item containing maximum residues) to reach a conclusion of risk for mammalian species chronically exposed to atrazine even though the assumptions are implausible and completely improbable.

- The preliminary assessment misinterpreted and mischaracterized guideline-specific terrestrial plant studies (vegetative vigor and seedling emergence). These studies were recently conducted with the current formulation to evaluate recovery and update studies conducted over a decade earlier. These updated studies clearly demonstrated reduced seedling emergence effects and recovery for most species affected for vegetative vigor.

Attachment 1 –

REREGISTRATION ELIGIBILITY SCIENCE CHAPTER FOR ATRAZINE ENVIRONMENTAL FATE AND EFFECTS CHAPTER, January 28, 2003, page 35

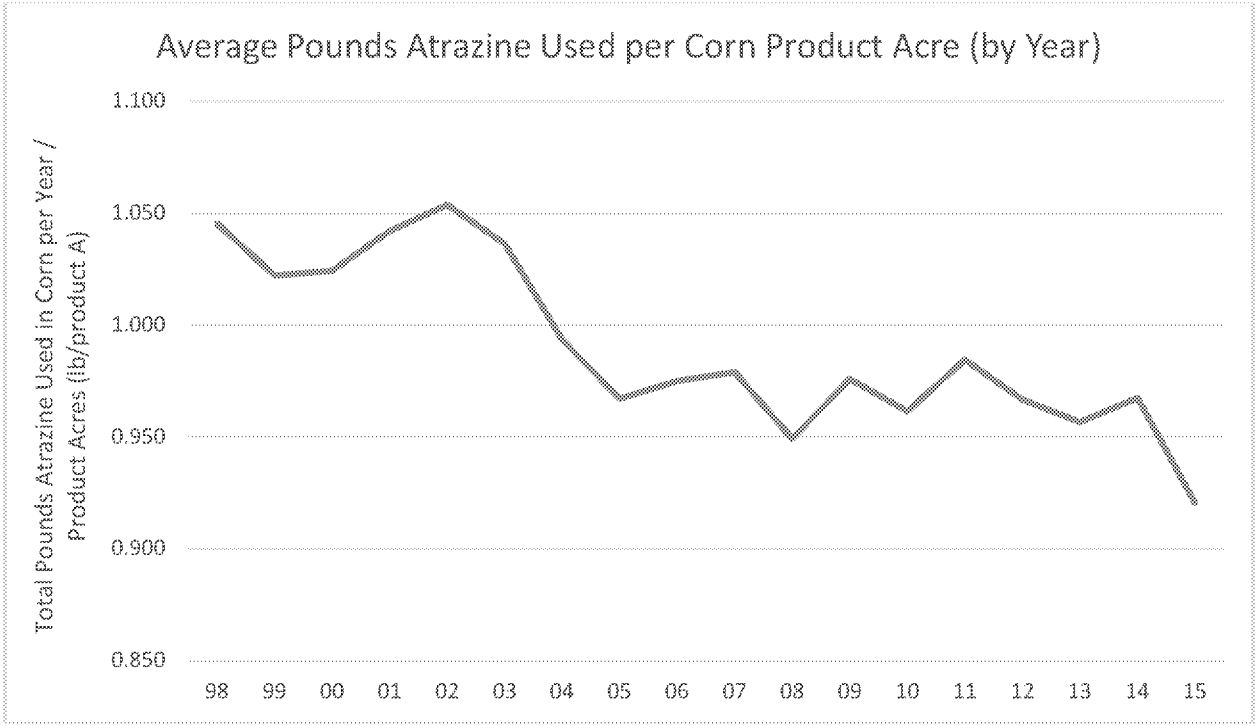
Treated Crop	Scenario	Atrazine EEC Values ppb (µg/L)				
		Peak Conc.	96-hour Average	21-day Average	60-day Average	90-day Average
Sugarcane (4.0 lb ai/a)	1[1]	205	204	202	198	194
	2[2]	167.6	166.7	163.8	157.8	152.9
	3[3]	207	206	203	195	189
	4[4]	200.6	199.6	196.7	189.8	183.8
Corn (2.0 lb ai/a)	1	38.2	38.0	37.2	35.5	34.2
	2	29.7	29.4	28.4	26.6	25.1
	3	35.3	35.0	33.8	31.6	30.0
Sorghum (2.0 lb ai/a)	1	72.7	72.3	70.6	67.7	65.9
	2	47.9	47.4	46.0	42.7	40.4
	3	58.4	57.8	56.0	52.0	49.2

[1] Orignial environmental fate inputs found in Agency's Science Chapter;
[2] Based on Syngenta's suggested environmental fate inputs;
[3] Based on Syngenta's suggested environmental fate inputs;
[4] Ground application of 99% efficiency and 1% off-target spray drift for sugarcane use with Syngenta's suggested input values.

Jim Hetrick slides, April 2017:

Monitoring Program	Monitoring Program Design	Site Percentile				
		50th	75th	90th	95th	99th
		µg/L				
NWIS	Non-Targeted Low Sample Frequency	3.4	30.8	227	750.3	7059.7
STORET		12.0	51.1	188.7	412.4	1787.7
AEEMP	Targeted High Sample Frequency	52.7	105.1	195.46	283.4	568.8
PWC Model	Corn Split App 2.5 lbs/A	67.5	91.5	120.3	141.7	192.7

Attachment 2 –



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