The Real Trouble with Risk Assessment

In their article, "Pesticide regulation amid the influence of industry," Boone and colleagues (2014) contend that a major weakness of the US Environmental Protection Agency's pesticide risk assessment is the use of industry-supplied data, which has inherent conflicts of interest. Therefore, studies performed by industry scientists or funded by industry sources are considered by the authors to be inherently biased and therefore not to be trusted, the implication being that publications by academic scientists or those funded by nonindustry sources are bias free and, therefore, by definition, suitable for use in risk assessment. However, the funding source is only one indicator of study quality, and there is no guarantee that studies funded by nonindustry sources are free of bias. The use of internationally accepted test guidelines and stringent standards of documentation and performance should go a long way toward avoiding the potential conflicts of interest with which the authors are concerned. Likewise, the use of consistent rubrics to rate the quality of potentially relevant studies for use in risk assessment seems a sensible course of action, particularly when the rubrics are based on widely recognized elements of good experimental design, such as replication, randomization of treatments, the use of proper controls, and other experimental details that increase confidence in test results. The authors seem to be missing the real problems with risk assessment, which are that most of the standard tests required for effects assessments are not measuring things that we care about and that the outputs of risk assessments are too far removed from what we want to protect (Forbes and Calow 2013). I agree with the authors that there is a need for more ecological relevance in our approaches to risk assessment, and I have advocated for the use of ecological models to help bridge the gap between standard test endpoints and environmental protection goals. I have learned that, in addition to sound science, it is essential to get buy-in from all of the key stakeholder groups on criteria for model acceptance and the role of such models in the overall assessment process. Significant progress on this front has been made in Europe (EFSA 2014), and the recent National Research Council Report (NRC 2013) provides an important opportunity for the United States to substantially improve the ecological relevance of risk assessment approaches.

Risk assessment of pesticides in the United States is at a critical juncture, particularly with regard to assessments of risks to threatened and endangered species. There is no question that there are many challenges ahead and that there is significant room for improvement in our risk assessment methodology. We all share the benefits and costs of using pesticides and the vast number of other chemicals on which society depends. Scientists from academia, government, and industry all have an important role to play in this process. We need to acknowledge that we come to the table with different perspectives and that only by working together across sectors and with sound science as our foundation are we going to improve the process of risk assessment.

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The Trouble with Risk Assessment Lies at the Foundation

Forbes indicates that we have missed the "real" problem of risk assessment in Boone and colleagues (2014)—the failure of standard tests to reveal the actual environmental risks. We agree that there are many issues to be addressed with risk assessment (e.g., Forbes and Calow 2013) and that risk assessments will fall short if we fail to incorporate or account for ecological complexity. Although Forbes indicates that we considered industry-funded work to be "inherently biased and therefore not [to] be trusted" as a result of its conflicts of interest (COIs), this is not the case, and it misrepresents a COI. Having a COI does not depend on underlying motives; rather, it is amoral, neither moral nor immoral—an objective state occurring when personal interests could benefit from professional decisions or judgments. A COI is, consequently, inherent in research directly conducted or funded by industry for assessments or regulatory purposes. Therefore, COIs should be managed. We acknowledge that there are other COIs (e.g., the desire for prestige) that can influence scientists, but financial COIs are the most insidious and have been documented to influence the outcome of results (e.g., Bekelman et al. 2003). Although financial COIs are most commonly managed through disclosure in the acknowledgement section of manuscripts, they could be further managed through a third-party funding agency that separates an industry from study analysis and interpretation, and eliminates restrictions on publication, regardless of outcome. For the public to have confidence in the scientific process, they need assurance that scientific outcomes are not influenced by personal financial gains. For this reason, failure to address and manage issues of financial COIs is a structural flaw in risk assessment. Addressing COIs still allows for "all of the key stakeholder[s]" to come together, but we need to explicitly acknowledge that some have a greater vested interest in the outcome and manage that risk.

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Whereas issues related to COIs are of great concern, the potential for exclusion of most of the available data in US Environmental Protection Agency (USEPA) risk assessments was our central criticism of the process. On the basis of a single industry-funded study, USEPA concluded that "exposure to atrazine at concentrations ranging from 0.01 to 100 [milligrams per liter] had no effect on *Xenopus laevis* development (which included survival, growth, metamorphosis, and sexual development)" (p. 60) and that the "level of concern for effects on aquatic plant communities… was lower than the atrazine concentration observed to produce significant direct or indirect effects on invertebrates, fish, and amphibians" (USEPA 2012, p. 97), which would eliminate further assessments of atrazine's impacts on amphibians despite significant effects at these concentrations in other studies. Fixing other issues of risk assessment, like incorporation of ecological data, will not improve the process if most of the independent research is omitted, whereas studies with inadequately managed COIs are included. If we do not repair the foundation of regulatory risk assessment, the best standard tests, ecological studies, and ecological models may currently not even be used to inform policy and regulatory decisions—the antithesis of evidence-based decisionmaking.

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