Chlorpyrifos: A Hostage of the Secret Science Rule?

By Michael Dourson — March 27, 2020

In short, the public is often worried about chemical exposure, as they should be when such exposure exceeds a safe dose. The public’s interest is best served by trusting experts dedicated to public health protection and not by withholding scientific data from independent analysis.

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Many groups have weighed-in on EPA’s recent secret science rule. Generally missing from nearly all these opinions is the perspective(s) of risk scientists charged with protecting public health.

As scientists know well, results of any one study, especially one with significant societal impact, should be replicated because positive findings occur, on average, in one out of every 20 studies due to chance. If a study cannot be replicated, then it (at least) needs to be consistent with the pattern of available data. Studies that are not replicated or that do not “make sense” in an overall pattern are still considered by EPA (and other authoritative agencies). Scientists within these agencies will often contact the authors(s) to obtain additional information in order to conduct their own analysis.

A case in point is the publication of a series of studies on a single human group from exposure to
chlorpyrifos that shows an unexpected effect at extremely low exposures [4]. This finding has not been replicated in other human studies and is in contrast to extensive animal and limited human studies that all point to changes in a blood enzyme (cholinesterase) as sentinel, at higher exposures. In this case, EPA scientists asked authors of studies from this single human group for the underlying data in order to confirm this lower effect. The authors demurred citing confidentiality concerns despite the fact that EPA has rigorous procedures in place to handle confidential information. Thus, EPA was not able to conduct its own analysis, and since EPA had neither confirmatory studies, nor information consistent with other studies, it chose not to use the information from this single human group.

A recent publication [5] confirms the EPA decision. In brief, Rauh et al. (2011) reported evidence of neurological deficits in children at 7 years old as a function of prenatal chlorpyrifos exposures that were much lower than levels causing cholinesterase inhibition. Since the raw data had not been made available, Dourson et al. (2020) extracted data from published figures of Rauh et al. (2011), and plotted these extracted data as response versus log dose, a common risk assessment approach. Surprisingly, a significant portion of the data was not found in these published figures. Moreover, the reported associations of chlorpyrifos levels were also not replicated in our analysis. Like EPA, Dourson et al. (2020) sent multiple requests to Rauh et al. (2011) for access to the data so that confirmation could be attempted. No response was forthcoming. This general lack of data, inconsistency with cholinergic responses in other research studies, and refusal by the authors to share data and to write an editor-invited letter to the editor, raises concerns about the lack of data transparency.

From our perspective as toxicologists and risk scientists, EPA’s decision not to use such studies where information is not provided, suitably redacted to protect confidential information, is correct. The public’s interest is best served when science is replicable and consistent. When studies cannot be replicated or are not consistent with other information, using such studies then depends on having access to the underlying data for independent analysis. If the underlying data are not provided, it is difficult to use such studies to make a credible scientific risk judgment, much less national rulemaking.

In short, the public is often worried about chemical exposure, as they should be when such exposure exceeds a safe dose [6]. The public’s interest is best served by trusting experts dedicated to public health protection and not by withholding scientific data from independent analysis. Others [7] have also had thoughts on this topic.

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