

EPA revisits dioxin risks



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The Environmental Protection Agency recently examined its methodology for assessing cancer risks. Unfortunately, the agency did not take this opportunity to make a substantial move toward a more scientific basis for risk assessment.

The reexamination was part of a review of 2,3,7,8-TCDD (dioxin) risk. It was initiated, in part, in response to disagreement by outside scientists, including the Science Advisory Board on the accuracy of EPA's method of assessing dioxin risk. A review draft of a new Cancer Risk Specific Dose Estimate for dioxin was circulated late last year.

Dioxin is unquestionably one of the most potent animal carcinogens tested. But the risk of dioxin to humans is unclear. According to EPA, studies of dioxin on people have produced inconsistent results—from a high risk to none. Accordingly, EPA decided to use predictive models to estimate human risk at environmental exposure levels.

In the dioxin draft document, EPA considered three models for predicting the risks.

First, the linearized multistage model (LMS) is designed to predict a "plausible upper limit" and is based on an assumption that no threshold for cancer exists and that the low-dose relationship is linear. As EPA has stated, this model "does not necessarily give a realistic prediction of risk. The true value of the risk is unknown and may even be

zero." Thus the LMS risk estimate is by design, not testable against human data, even at high doses. EPA routinely uses the LMS to predict cancer risk to humans. It generally is the most conservative of the models available.

Second, the "traditional" toxicological approach is designed to predict not a risk, but a safe level. It is based on the assumption that a threshold for cancer does exist. This approach uses "no effect levels" from animal experiments divided by an uncertainty factor. Some European countries and Canada use this approach to estimate dioxin risk. This approach is most often the least conservative of the models considered, depending on the uncertainty factor chosen.

Third, the "best estimate" models are designed to predict a best or realistic estimate of the risk to humans. One of the most advanced is a two-stage biologically based model sponsored by EPA. These models incorporate more biological information, such as the time to tumor or whether the chemical is a promoter or an initiator. Thus these models are, by design, more testable. They are reported in the scientific literature but have not been formally adopted by regulatory agencies. The risk estimates from these models fall between those of the other two.

Predicting risks from models

The predicted risks for dioxin from these models differ greatly. Based on the LMS model, EPA previously found the risk dose (the dose responsible for a risk of one in a million) to be 0.006 pg/kg/day. This is by far the largest risk calculated by the U.S. agencies that use LMS. The best estimate approaches find the risk dose should be between 0.6 and 1.0. The traditional approach concludes that between 1.0 and 10.0 is a safe level.

EPA is proposing in this draft document that the risk dose should be raised from 0.006 to 0.1. In determining this

new risk estimate, EPA states that the LMS model should continue to be used for cancer risk assessment. EPA also states that the LMS model is not testable against human data. The LMS model is not testable from any of the models considered.

Second, a scientific basis for these decisions have led EPA to a decision to use the LMS model. The LMS model the agency proposes has not been justified on scientific grounds. At the same time, the agency's adherence to the concept of the plausible upper limit estimates a procedure that is not testable on its face. Failure to formally recognize the importance of incorporating biological information in risk models and only to recognize the need for conservatism will perpetuate the agency's dilemma.

EPA must begin to assess the cancer prediction models with the same rigor that it uses in its other areas. No less than for air pollution models, risk assessment models should purport to represent reality in some sense and must be testable. Without good scientific testing, a model (air or risk) is nothing more than a set of formulas that may bear no relation to the process it attempts to represent.

Policy choices, such as the need to be protective in the face of danger or conservative in the face of uncertainty, are justifiable. But there never is justification for foreclosing the possibility of allowing truth to test decision making. EPA's inflexibility in continuing to adhere to the upper plausible limit—even though an available model takes biological information into account and can be tested—is such a foreclosure.

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