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Human test data: Essential and safe

In "EPA To Okay Human Tests Of Pesticides," Bette Hileman discusses potential Environmental Protection Agency guidance on using human volunteers in the testing of chemicals used as pesticides ([C&EN, July 4, page 9](#)). The value of human data is underestimated.

Human studies are invaluable for responsible regulation of chemical technologies, including pesticides. Ethical human tests of pesticide products remove the uncertainty introduced by models that have not been validated and extrapolations from laboratory animal tests, much as the pharmaceutical industry relies upon similar tests for their products in healthy human volunteers with no intention of benefiting those volunteers.

Chemicals used as pesticides and disinfectants and many substances intended for residential use are vital for public safety. Those who provide these products are required by EPA to submit studies conducted with human subjects exposed to chemicals at label rates that are well below levels of concern, in order to support regulatory decisions for registration and reregistration. There is no avoiding the reality of unintended or inescapable human exposure as a result of use of these products, and responsible risk assessment requires scientific studies to ensure safe use. The protocols for these studies have been established during the past 50 years, and the results continue to document that adherence to labels results in exposures that are less than "no observed adverse effect levels."

The Food Quality Protection Act (FQPA) of 1996 (not 1986, as reported in the article) requires comprehensive assessment of pesticide exposure, dose, and effects. In particular, FQPA directs EPA to consider exposure to potentially sensitive subgroups in the population, coincident dietary and nondietary (that is, aggregate) exposure, and concurrent multichemical (that is, cumulative) exposure for pesticide risk assessment. To implement FQPA, EPA has been developing new methods and models to assess aggregate pesticide exposure that could occur in community settings. Human biomonitoring that is intended to establish biologically sums available environmental chemical levels (food, water, air, and so on), which would inevitably lead to inflated and misleading estimates of human exposure.

The pictured mosquito control truck is an inappropriate illustration. Human studies are not about "dosing," with pesticide "spewing" from the back of a truck. They are about low pesticide exposures relative to harmful amounts--below "no observed adverse effect levels"--to which we are all intermittently exposed. Knowledge of these levels of human exposure are essential for responsible pesticide regulation.

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