

Attachments 2.

Environmental Health Perspectives, Vol. 113, No. 10 October 2005:

Toxicity Tests: "Inert" and Active Ingredients

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The findings of Richard et al. (2005) are an important addition to our understanding that the health and environmental effects of formulated pesticide products are not fully reflected in tests conducted on the active ingredient(s) alone. It has been long known that the adjuvants (commonly and misleadingly called "inert" ingredients) may be toxic and may enhance or supplement the toxic effects of the active pesticidal ingredient.

In the case of glyphosate-containing products, this phenomenon was well demonstrated in the data submitted to the (EPA) by the registrant (Monsanto), and summarized by the U.S. EPA in the Reregistration Eligibility Document (RED) for glyphosate (U.S. EPA 1993). For example, based on the registrant's own tests of acute toxicity to freshwater fish, the U.S. EPA classified technical grade glyphosate as "slightly toxic" to "practically non-toxic" and formulated products ranged from "moderately toxic" to "practically non-toxic." Tested alone, the surfactant adjuvant (identified as "inert") was "highly toxic" to "slightly toxic." Similar differences were reported in tests of acute toxicity to freshwater invertebrates.

Based in part on the data in the glyphosate RED (U.S. EPA 1993), the New York State Attorney General's office successfully pursued an action against Monsanto in 1996 (Attorney General of the State of New York 1996). At that time, Monsanto was making advertising claims about the toxicity of the Roundup products based on data from tests on the active ingredient alone. Such claims are scientifically unfounded and inherently deceptive. The Attorney General's action was facilitated by the availability of at least some limited information about the inert ingredients and their toxicity. That same sort of information enabled Richard et al. (2005) to conduct their study.

Unfortunately, that is not always the case, and for many pesticide products, little or no information about the identity of inert ingredients is publicly available. Registrants are generally required to conduct acute toxicity tests on formulated products, but they traditionally conduct chronic toxicity tests on the active ingredient alone. Even when formulated products are tested, the identity of inert ingredients is rarely revealed in the open literature, publicly available regulatory documents, or product labels. Therefore, independent research is stymied, and the public is ill-informed in the marketplace.

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Richard S, Moslemi S, Sipahutar H, Benachour N, Seralini G-E, 2005. Differential effects of glyphosate and Roundup on human placental cells. Environ Health Perspect 113:716-720.

U.S. EPA. 1993. Reregistration Eligibility Decision (RED). Glyphosate. EPA-738-R-93-014. Washington, DC: U.S. Environmental Protection Agency. Available: <http://cfpub.epa.gov/oppref/rereg/status.cfm?show=rereg> [accessed 1 September 2005].

"Inert" and Active Ingredients: Seralini Responds

Surgan raises interesting points in his analysis. This interest has been confirmed by reactions of agriculture authorities all over the world after publication of the article by Richard et al. (2005).

Indeed, scientific problems do exist in the registration of pesticides today, when chronic toxicity tests are conducted with the active ingredient alone--which is generally the case. First of all, chemists from companies may work hard for several years to find the right formulation that best amplifies the effects of the active ingredient. his formulation will allow penetration and stability and/or bioaccumulation of the active ingredient within plant, fungi, or insect cells, for instance, to reach the best toxicity. If there are any side effects in other animal or human cells, these will be also amplified by adjuvants, and thus not measured in chronic toxicity tests with the active ingredient alone. The active compound absorption by skin is generally calculated in the presence of formulated adjuvants, but this is clearly a short-term study and not sufficient to detect, for example, endocrine disruption or carcinogenesis, possibly promoted *in vivo* by the described synergy. This should even necessitate further care in case of the use of formulated products such as glyphosate-based herbicides on tolerant, edible plants.

As a matter of fact, most genetically modified crops have been modified and selected only to tolerate high-formulated herbicide absorption, but the plants are not submitted for registration requiring chronic toxicity studies involving long-term feeding of animals. Moreover, in the case of environmental pollution, active pesticide ingredients may encounter detergents or other lipophilic xenobiotics with comparable effects other than those of their own adjuvants, for instance, forming microvesicles to penetrate the cells. These combined effects should also be taken into account in authorized thresholds of pollution in order to avoid effects on wildlife or humans.

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Richard S, Moslemi S, Sipahutar H, Benachour N, Seralini G-E, 2005. Differential effects of glyphosate and Roundup on human placental cells. *Environ Health Perspect* 113:716-720.