Message

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Subject: News Update: NTP Preparing To Assess Glyphosate's Carcinogenicity In Toxicology Study

NTP Preparing To Assess Glyphosate's Carcinogenicity In Toxicology Study

By Maria Hegstad
Inside EPA
June 20, 2016
http://insideepa.com/risk-policy-report/ntp-preparing-assess-glyphosates-carcinogenicity-toxicology-study

The National Toxicology Program (NTP) is preparing to assess the carcinogenicity of glyphosate, the most commonly used herbicide worldwide, amid ongoing debate about EPA's process for re-registration of the chemical and following an international body's finding last year that glyphosate is probably carcinogenic.

NTP scientist Stephanie Smith-Roe said at a June 15 meeting of NTP's Board of Scientific Counselors (BSC) that she and colleagues are preparing to undertake short-term cancer related toxicology tests of glyphosate, including both the active ingredient and a formulation or multiple formulations of the finished product, with an eye to providing information quickly to unnamed decision makers.

Smith-Roe described the plan as containing "rapid screening of glyphosate and at least one formulation . . . then short-term *in vivo* testing. We propose a very focused approach . . . in order to provide decision makers with information very quickly, hopefully within a year."

EPA is planning to issue for public comment draft risk assessments supporting its registration review of glyphosate by the end of the year, and the agency is facing much external pressure as advocacy groups press the agency to ban the chemical's use. The groups complain that EPA relies solely -- and too heavily -- on information supplied by the manufacturers, biasing the agency's decision-making process.

Meanwhile, EPA's ongoing efforts to re-register glyphosate are under congressional scrutiny, following the agency's release in April and then subsequent withdrawal from its public electronic docket of a review finding glyphosate is unlikely to cause cancer. The move prompted House Science, Space and Technology Committee Chairman Lamar Smith (R-TX)

to begin an inquiry into the agency's handling of the cancer review, seeking documents and interviews with agency scientists (*Risk Policy Report*, June 14).

In addition to concerns that EPA relies too heavily on industry-sponsored research, advocates have questioned EPA's approach of evaluating only pesticide products' active ingredients, rather than product formulations, and failing to capture real-word exposures. As a result, EPA failed to adhere to the Federal Insecticide, Fungicide and Rodenticide Act standard precluding unreasonable risks to human health and the environment in evaluating pesticides' human health and ecological risks, the groups claim.

NTP's evaluation follows that program's 13-week study of glyphosate fed to rats, published in 1992, which found that lab animals "exposed to fairly high doses, presented no gross lesions. [Results were] negative in micronucleus assays and also in mutagenicity tests, Smith-Roe said.

But last year the International Agency for Research on Cancer (IARC) concluded that glyphosate probably causes cancer in people, leading NTP to reconsider whether to conduct further testing. The IARC conclusion has been widely cited by advocacy groups in their efforts to ban glyphosate's use.

Industry counters by pointing to recent evaluations by the World Health Organization (WHO) and the European Food Safety Authority, which concluded that glyphosate does not pose a public health risk. Industry groups argue that advocates' claims that glyphosate causes cancer are based on a study that has been widely criticized for using incomplete data sets.

Smith-Roe acknowledged these conflicting findings in her remarks to the BSC. "Whether glyphosate causes cancer has become a high profile issue," she told BSC members, noting the IARC determination and EPA's ongoing re-registration process. She said that the differences between conclusions by IARC and the other agencies could be due to their different processes and purposes -- IARC's purpose is hazard identification, while the regulatory agencies are conducting risk analyses with dose-response calculations.

Other differences could be the regulatory agencies' "greater access to confidential data -- these groups are looking at different data sets to make their conclusions. Risk assessments are limited to active ingredients, whereas IARC looked at glyphosate formulation," Smith-Roe added.

She continued, "We have worked to put together a work group to formulate how we might put together a problem formulation on glyphosate. There are very few studies where [the active ingredient] and formulation are compared. Turns out formulations seem to be more toxic."

"Two of the key factors used to inform the IARC classification were studies suggesting that glyphosate and various formulations were genotoxic and induced oxidative stress," according to NTP background documents. "Furthermore, where glyphosate was compared directly to glyphosate-based formulations, the formulations were generally more toxic than glyphosate alone." *Relevant documents are available on InsideEPA.com. (Doc. ID: 192394)*

Though early in the planning stages of the study, Smith-Roe said that the work group has already concluded that "while we see information related to cancer endpoints, there is very little information about other endpoints that we might be concerned about."

One of the BSC members, charged with reviewing the project, noted his interest based on the widespread use of the chemical, and the potential for resides on produce eaten by the general public. "While I have some enthusiasm for the project, it is significantly dampened by the [fact that] agencies that have more experience with the chemical and more data" reached other conclusions than IARC's, said George Corcoran, chairman of pharmaceutical sciences at Wayne State University.

John Bucher, associate director of NTP, sought to assure Corcoran that "We do bring all of our thoughts to our agency partners. This isn't being done in isolation."

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