FIFRA science panel divided on EPA glyphosate cancer study

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WASHINGTON, March 16, 2017 - EPA's conclusion that glyphosate is "not likely" to cause cancer in humans has received a mixed review from a scientific review panel.

The Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) "was split," according to the report issued today. Some panelists agreed with the EPA issue paper, prepared by the Office of Pesticide Programs (OPP) and released last year. Other members felt the "not likely" characterization should be replaced by "suggestive evidence of carcinogenic potential." And still other members were not comfortable with either description, preferring instead "no credible evidence of carcinogenicity" or "equivocal."

The report, technically called the "minutes" of the Dec. 13-16 SAP meeting, follows by a day a report from the European Chemicals Agency that concluded glyphosate is not a human carcinogen.

Monsanto, which patented glyphosate in the early 1970s before using it as the active ingredient in Roundup, the world's most widely used herbicide, issued a statement that emphasized findings by "regulatory agencies globally" that the substance is not carcinogenic.

"This conclusion has been reached by the U.S. EPA (including two separate reports since 2015), the European Food Safety Authority (EFSA), regulators in Canada, Japan and other countries, and scientific bodies such as the Joint FAO/WHO Meeting on Pesticide Residues," the company said in response to the SAP report.

"The opinions of the members of EPA's Scientific Advisory Panel will be considered by EPA in the context of its ongoing registration review of glyphosate," Monsanto said. "We are confident the EPA will stand by its conclusion that glyphosate is not carcinogenic. Our scientists are currently reviewing the SAP minutes as well."

Jennifer Sass, a toxicologist with the Natural Resources Defense Council who criticized the issue paper in comments submitted to the agency, emphasized the panel's discussion of how EPA used its own 2005 cancer assessment guidelines. The report made it "very clear" that the OPP paper did not comply with those guidelines, she said.

"The panel concluded that the EPA evaluation does not appear to follow the EPA (2005) Cancer Guidelines in several ways, notably for use of historical control data and statistical testing requirements," the report said.

“Some panel members felt that the agency’s weight-of-evidence evaluation gave excessive weight to several factors, including lack of monotonic dose-response relationships, historical tumor rates, lack of statistical significance in pair-wise comparisons when there is a significant positive trend, and discounting results at exposures greater than the ‘limit dose’ of 1,000 mg/kg/day,” the report said.

The panel noted that a monotonic, or linear, dose-response relationship “is not a criterion for a positive rodent response” in the cancer guidelines, according to the report.

The EPA paper “represents a comprehensive review of the available epidemiologic data, laboratory animal bioassay data, and genotoxicity data, but also noted some limitations,” the report said.

For example, the epidemiological data “are limited to users of glyphosate-based herbicides (such as farmers and other herbicide-applicators), but, as EPA estimates, exposures are fairly low.” The agency would have benefited from studies of “potentially more highly exposed workers, such as those who manufacture, formulate or are involved in the wholesale handling or selling of glyphosate.”

Some of the panel members felt that “because the central epidemiologic question with regard to glyphosate is whether its use is associated with risk of developing non-Hodgkin lymphoma (NHL),” EPA’s evaluation would have benefited “from a broader review of NHL risk-factors that have long been associated with farming.”

Finally, “the issue paper does not present potentially relevant data on isopropylamine, despite the fact that most glyphosate in use is as the isopropylamine salt,” the report said.

There was also disagreement over the agency’s evaluation of the mouse and rat studies.

Some panel members said data are sufficient to conclude that glyphosate is a rodent carcinogen using the 2005 cancer guidelines, but other panelists “strongly disagreed with this conclusion, finding no reliable and consistent evidence that glyphosate induces or promotes tumors in laboratory rodents.”

The panel members who agreed with EPA’s conclusion “pointed out that true carcinogenic responses should be reproducible, and that the estimated positive results in some of the rodent bioassays of glyphosate were likely to be false positives,” the report said.

But other panel members “argued that there is sufficient evidence to conclude that glyphosate is a weak rodent carcinogen and/or tumor promoter. The panel noted that holistically interpreting results from 15 rodent cancer bioassays posed a unique challenge.”