EU Committee of Parliament Calls for Stiffer Pesticide Restrictions

Members want overhaul and more precaution to protect health

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fter eight months of deliberation and discussion, the European Parliament's Special Committee (the PEST Committee) overwhelmingly approved its draft report in early December 2018 with recommendations to strengthen pesticide restrictions. PEST was established in January 2018 to assess the European Union's authorization procedure for pesticides. The group's charge was to review the European Union's (EU) pesticide authorization process, identify its failures in evaluating and approving pesticides and their use (including any conflicts of interest impacting the process), and make recommendations to improve the protection of human, animal, and environmental health from pesticides. The 30-member committee concluded: improvement of the system will require changes in the entirety of the pesticide approval processfrom the point of industry application for authorization of a pesticide, to the sale and use of any products containing the compound in EU Member States, to evaluation of impacts of its use once on the market.

A CALL TO TIGHTEN REGULATION

The approval, sale, use, and regulation of what the EU calls "Plant Protection Products" [PPP]—active substances used to "1) to protect plants or plant products against pests/diseases, 2) to influence the life processes of plants (such as substances influencing their growth, excluding nutrients) and 3) to preserve plant products"—are controlled by the "PPP" Regulation. The regulatory process uses a two-step approach: active substances (the base chemical compounds) are approved at the EU level, and plant pesticides, or formulations, are authorized at the national, or Member State, level. The convening and charge of this committee by the European Parliament (EP) was a response, in large part, to widespread pressure and considerable clamor from more than a million European citizens, and a number of NGO (non-governmental organization) advocacy and anti-toxics groups. Complaints sparked many months of controversy related to the compound glyphosate, the active ingredient in multiple herbicide formulations—most notably, Monsanto's (now Bayer's) Roundup and, pointedly, related to Monsanto's undue and inappropriate influence on scientific studies that comprised the basis of much of the review process. The European Food Safety Authority (EFSA) reportedly copied dozens of pages from a Monsanto study in providing evidence for its conclusion that glyphosate is "unlikely to pose a carcinogenic hazard to humans." (EFSA's recommendation was supposed to provide an independent analysis for EU Member States when deciding to renew approval of the compound.)

The coalition Citizens for Science in Pesticide Regulation, comprising 120+ groups and institutions, sent an open letter to EU regulators in Member States, calling for reform of the pesticide authorization process and increased levels of protection. The letter charged that the current model of pesticide risk assessment is failing to protect people and the environment from the harm caused by these chemicals, and must be reformed.

In May of 2017, the European Union proposed a 10-year extension on the approved use of glyphosate-based compounds. Member States of the European Commission (EC) came up short in the EC's bids to approve 10- and 15-year extensions on the continued use of the compound, and in November issued a limited (five-year) extension for use. The EC was holding out for further information on carcinogenicity, which was assessed by the European Chemicals Agency (ECHA), whose report was issued in March 2017; that assessment found that glyphosate is "unlikely to be carcinogenic." There is a stark disparity between the conclusions on glyphosate's potential carcinogenicity by the International Agency for Research on Cancer (IARC) of the World Health Organization and the EC and U.S. Environmental Protection Agency (EPA) official decision to the contrary.

DEFICIENICES IN EU PESTICIDE REGULATION

Among the many shortcomings of the EU's current pesticide approval system identified in the PEST Committee draft report are: involvement of the pesticide industry in the toxicity assessments of pesticides, misuse of the academic scientific literature, a lack of sensitive testing for neurological and other serious diseases, the lack of post-market monitoring data to assess the real impact of pesticides, and poor transparency of, and access to, the process for the public. The report calls out a multitude of specific failures of the existing process, such as: "the decision-making process has been found to be lacking in transparency throughout the procedure, from lack of public access to the full studies and raw data through to the risk management stage"; "national competent authorities involved in the approval and authorisation process are in some cases understaffed and underfunded"; and "there is currently no legal obligation to test active substances for their developmental neurotoxicity."

Recommendations by the PEST Committee are legion—72 of them, in fact—and constellate around those shortcomings and other issues. Importantly, the committee's product is a set of recommendations that *are not binding*. That said, they include calls for:

- heightened transparency across the entire pesticide assessment and approval process
- increased and "friendlier" public access to studies and data used in assessments
- equal weighting of scientific, peer-reviewed literature and lab-based studies
- use of data on final product formulations as part of assessment
- inclusion of key tests in risk assessment (e.g., current ecotoxicological tests for soil organisms, evaluation of environmental concentrations and residues in dust, wind, air, and water)
- a post-marketing monitoring system to enable assessment of the long-term effects on human and animal health, and the environment
- establishment of maximum residue levels for soils, using data collected through such post-market environmental monitoring

- completion and rapid implementation of cumulative risk assessments as part of the pesticide review process
- adoption of clear criteria for "unacceptable effects on the environment"
- inclusion of legally binding risk mitigation measures in approval of pesticides
- promotion of low-risk pesticides to help reduce adverse impacts of pest management
- use by risk managers of the Precautionary Principle in decision making on approvals of "active substances/plant protection products" (to include requisite conditions, and systematic communication about how this principle has been taken into account)

REGRETS FOR LONG DELAYS ON ACTIONS

Embedded in one recommendation is this retrospective comment: The European Parliament "regrets that the derogation by confirmatory data procedure has led to certain plant protection products that would have otherwise been banned to remain on the market for an extended period of time." This critique could readily be applied to the poor regulation of glyphosate—and any number of other pesticides—in the U.S., given long delays and phase-outs with the sell-off of existing stocks.

U.S. LAGS BEHIND EU IN ASSESSMENT AND APPROACH

Europe has generally been more proactive, precautionary, and protective of human and environmental health than has the U.S. Regulators, particularly at EPA, have faced similar concerns expressed by advocates, who see the need for a U.S. effort similar to the European Parliament's; there is certainly overlap in concerns between the EP's findings and critiques in the U.S. of the pesticide regulatory process. Advocates for human and environmental health have long pointed to a number of similar failings in U.S. regulatory processes, including transparency issues; "fox and henhouse" concerns (e.g., conflicts of interest in regulating bodies and processes), ecological and non-target harms, failure to evaluate impacts of final pesticide formulations, and inadequate environmental monitoring of pesticide use, not to mention repeated failures to follow the law.

In addition, EPA's general failure to use more-precautionary approaches in its evaluation of pesticides stands in contrast to the PEST Committee's recommendations. It likewise compares unfavorably with the recent decision of a French court to institute an immediate ban on the use of glyphosate, in which the court said that the French Agency for Food, Environmental and Occupational Health and Safety (ANSES) had not respected the precautionary principle in its consideration of the compound's potential health risks.

Sources: European Parliament, Draft Report, Special Committee on the Union's authorization, 9-17-18, favorable vote, 9-6=2018.