What Regulators and Other Government Authorities Are Saying

On the Science Underpinning Approvals of Glyphosate-Based Herbicides

Multiple regulators from large countries have reaffirmed their positive conclusions about glyphosate, rejected criticisms that their own scientific reviews were unduly influenced by Monsanto and/or outlined the significant limitations in IARC's classification of glyphosate as a "probable carcinogen."

Critics of glyphosate have been pressuring regulators across the globe to reconsider their approvals of glyphosate-based herbicides. These efforts have typically rested on claims that Monsanto improperly influenced regulators' scientific reviews and that IARC's categorization of glyphosate warrants reconsideration.

But as the below shows, regulators investigating those claims have not found any cause to alter their original assessments that glyphosate-based herbicides, which have been on the market around the world for more than 40 years and are among the most thoroughly studied products of their kind, are safe when used as directed. Notably, the reaffirmations by regulators take into account allegations heavily promoted by plaintiffs' lawyers and their advocates through the promotion of the so-called "Monsanto Papers."

Health Canada Statement, Jan. 11, 2019

Health Canada tapped a group of 20 of its own scientists who were not involved in its 2017 re-evaluation and approval of glyphosate to investigate allegations that the industry improperly influenced that re-evaluation. On January 11, 2019, the results of that investigation were announced, and Health Canada stated the following:

- *"After a thorough scientific review, we have concluded that the concerns raised by the objectors could not be scientifically supported when considering the entire body of relevant data. The objections raised did not create doubt or concern regarding the scientific basis for the 2017 re-evaluation decision for glyphosate. Therefore, the Department's final decision will stand."*

- *"Our scientists left no stone unturned in conducting this review. They had access to all relevant data and information from federal and provincial governments, international regulatory agencies, published scientific reports and multiple pesticide manufacturers. This includes the reviews referred to in the Monsanto Papers. Health Canada also had access to numerous individual studies and raw scientific data during its assessment of glyphosate, including additional cancer and genotoxicity studies."*

- *"No pesticide regulatory authority in the world currently considers glyphosate to be a cancer risk to humans at the levels at which humans are currently exposed."*

In subsequent letters to objectors explaining its decision, Health Canada gave further details on why it rejected the notion that its glyphosate re-evaluation process was influenced by studies "implicated in alleged misconduct or had authors implicated in alleged misconduct:"

- *"In excess of 1,300 relevant scientific studies were considered for the glyphosate re-evaluation and were detailed in the Reference List section of both the proposed and final re-evaluation decision documents issued by Health Canada."*

- *"Most of the review articles, which are referenced as problematic in the letter from Ecojustice, dated October 29, 2018, were published after Health Canada published the Proposed Re-evaluation Decision (PRVD2015-01) in 2015. In addition, the review articles themselves, are not actual studies, but a summary of several individual studies."*

- *"Of main importance is that Health Canada scientists had access to the individual studies, including the raw data underpinning those studies, during the re-evaluation of glyphosate. Within each individual study, Health Canada scientists were able to review and conduct their own analyses of the raw data. The actual review of the individual studies was completed by Health Canada scientists prior to the release of most review articles noted in the letter."*

Report of the Australian Senate Rural and Regional Affairs and Transport References Committee on "Independence of regulatory decisions made by the Australian Pesticides and Veterinary Medicines Authority (APVMA)", February 2019

In response to critics of glyphosate who cited, in part, the so-called Monsanto Papers as cause for concern, the Australian Senate Rural and Regional Affairs and Transport References Committee investigated the scientific independence of the Australian Pesticides and Veterinary Medicines Authority (APVMA). In particular, the committee looked at the APVMA's response and review of glyphosate following IARC's 2015 classification of glyphosate as a "probable carcinogen." The committee report, which was released in February 2019, reaffirmed the APVMA's independence, and stated:

- *"The Committee acknowledges the range of strongly-held views about the APVMA's decision on glyphosate. However, it considers the APVMA's scientific processes to be robust, noting that all 264 of the studies referenced in the IARC report were independently evaluated by the OCS [Office of Chemical Safety], in addition to other studies and data."*

- *"Further, the Committee was informed that the regulator did not receive any new scientific evidence during the consultation period relating to the possible carcinogenicity of glyphosate that it had not already considered."*

- *"The Committee points out that many of the concerns raised about the APVMA assessment are addressed in the APVMA's Final Regulatory Position report on glyphosate and in other APVMA material about the decision."*

U.S. Environmental Protection Agency (EPA) letter to Australian Senate's Rural and Regional Affairs and Transport References Committee, December 2018

In 2018, Australia's Senate came under pressure from critics of glyphosate to investigate the scientific independence of the Australian Pesticides and Veterinary Medicines Authority. In a letter to the Australian Senate's Rural and Regional Affairs and Transport References Committee, the EPA wrote that its own 2017 post-IARC cancer risk assessment, which concluded that glyphosate is "not likely to be carcinogenic to humans," included a "more comprehensive systematic review" because of "the high

level of public interest in glyphosate's reevaluation and the IARC's conclusion regarding glyphosate's cancer potential." The EPA described its review thusly:

- *"EPA's risk assessment for glyphosate was conducted independently of any other organization and the IARC decision did not influence EPA's conclusions."*

- *"EPA's cancer classification for glyphosate is based on a weight-of-evidence evaluation in accordance with the agency's 2005 Guideline for Carcinogen Risk Assessment. The dataset considered by EPA included studies submitted for registration of glyphosate, as well as studies identified in the open literature as part of a systematic review. EPA also incorporated data that were not previously available into its evaluation."*

- *"IARC only considers data that have been published or accepted for publication in the openly available scientific literature."*

- *"As a result, IARC only considered a subset of the studies included in EPA's evaluation."*

- *"EPA also did not use some studies that IARC incorporated into their evaluation process because EPA did not believe the studies were appropriate for determining the human carcinogenic potential of glyphosate. For example, genotoxicity studies conducted in non-mammalian species (i.e. worms, fish, reptiles, plants) were excluded from the EPA's evaluation because they were not considered relevant for informing the genotoxic risk in humans."*

- *"EPA's conclusion is consistent with other countries and regulatory authorities including the Canadian Pest Management Regulatory Agency, Australian Pesticide and Veterinary Medicines Authority, European Food Safety Authority, the European Chemicals Agency, German Federal Institute for Occupational Safety and Health, The Joint FAO/WHO Meeting on Pesticide Residues, the New Zealand Environmental Protection Authority, and Food Safety Commission of Japan."*

European Food Safety Authority, May 2017

The European Union was the first to conduct an inquiry into allegations that the so-called "Monsanto Papers" showed improper industry influence over the approval of glyphosate for use in European Union countries. Following that investigation, the European Food Safety Authority (EFSA) asserted the following in May of 2017:

- *"Following this investigation, EFSA can confirm: that there are no grounds to suggest that industry improperly influenced the EU assessment of glyphosate; and that the role of industry and of other actors in the process was carried out according to standard procedures."*

- *"There is no information contained within the 'Monsanto papers' or that EFSA is otherwise aware of that indicates that industry attempted to falsify or manipulate the findings and raw data of the mandatory guideline studies used in the glyphosate assessment."*

- *"In the case of glyphosate, EFSA is satisfied that the evidence EU experts had access to was sufficient to allow for a thorough, independent evaluation of the toxicity of the substance and of the possible risks regarding intended uses."*

- *"Furthermore, the process was comprehensive (lasting three years and covering hundreds of scientific references), consistent (applied in the same way as for previous assessments), and transparent (with detailed information published on EFSA's website about how every study was appraised)."*

German Federal Institute for Risk Assessment (BfR) Response to Allegations of Plagiarism, Jan. 15, 2019

In response to allegations that it had copied portions of a 2015 report assessing the health impact of glyphosate from industry submissions, the German Federal Institute for Risk Assessment (BfR) reiterated that its assessment was conducted in an independent manner, saying the following:

- *"The BfR did not in any way adopt the applicant's conclusions without first assessing their validity. In accordance with its statutory mandate, the BfR reviews the originals of all reported studies. Critical remarks from the BfR are contained within the RAR [Renewal Assessment Report]. The sole criterion for the consideration of study results is the scientific quality and evidence of the studies themselves. Possible interests of the applicants, politics or other interest groups cannot and must not play any role in a scientific assessment. The BfR rejects all accusations of deliberate deception."*