What Regulators and Other Government Authorities Are Saying

On the Science Underpinning Approvals of Glyphosate-Based Herbicides

Multiple leading regulators around the world 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."

U.S. Environmental Protection Agency (EPA) Interim Registration Review Decision for Glyphosate, January 2020

In January 2020, the U.S. EPA reaffirmed the safety of glyphosate in its Interim Registration Review Decision based on the agency's expert review over a 10-year period. The Decision concludes that the extensive body of science continues to support the safety of herbicides containing glyphosate and that this active ingredient is not carcinogenic.

- EPA stated that it *"did not identify any human health risks from exposure to glyphosate."*
- The EPA also said that *"it used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of glyphosate. The EPA thoroughly assessed risks to humans from exposure to glyphosate from all registered uses and all routes of exposure and did not identify any risks of concern."*
- EPA also reiterated its conclusion that *"glyphosate is not likely to be carcinogenic to humans."*

The New Zealand Environmental Protection Authority (EPA) on the use of glyphosate in New Zealand, October 2019

In response to concerns about reports linking glyphosate to health impacts, the EPA of New Zealand released a statement affirming the safety of products containing glyphosate.

- *"As a regulator of hazardous substances in New Zealand, the EPA gathers information from multiple credible sources when deciding whether substances are safe to use. Products containing glyphosate are considered safe, provided that all of the rules around their use are followed."*
- *"We are in alignment with the vast majority of regulatory bodies around the world – including in the European Union, United States, Australia and Canada - which agree that glyphosate is unlikely to cause cancer."*

- *"IARC's role is to identify potential hazards. Our role as regulator is to ensure those hazards are adequately managed by appropriate controls (rules for use)."*

- *"We continue to monitor research into health effects from glyphosate. Since 2016 there have not been any further significant studies to support the IARC finding, despite further research that continues to be conducted internationally."*

U.S. Food and Drug Administration (FDA) Pesticide Residue Monitoring Program Report for FY 2017, September 2019

In September 2019, the U.S. FDA issued its annual Pesticide Residue Monitoring Program report for FY 2017, in which the agency tested for 761 pesticides and industrial chemicals across 6,504 total samples. The findings, which are consistent with previous years' findings, show that the majority of samples were below the tolerance levels set by the U.S. Environmental Protection Agency (EPA).

- *The second assignment, the herbicides assignment, is a continuation of a two-year sampling effort that began in FY 2016. In FY 2017, the agency analyzed 119 corn, soybean, milk, and egg samples for glyphosate and glufosinate. No glyphosate or glufosinate residues were detected in any of the milk and egg samples, or 82.1 % of the corn and 60.0 % of the soybean samples. In the samples where residues were detected, all were below the tolerance levels set by the EPA.*

- *In summary, in FY 2017, the FDA concluded the herbicides assignment that began in FY 2016, with a total of 879 samples of corn, soy, milk and eggs analyzed for glyphosate and glufosinate. No violative residues of glyphosate or glufosinate were detected over the two-year assignment. Testing for glyphosate and glufosinate is now part of the routine pesticide monitoring program.*

The German Federal Institute for Risk Assessment (BfR) response to new meta-analysis, April 2019

In response to a meta-analysis authored by Luoping Zhang of University of California, Berkeley that concluded that people who had the greatest exposure to plant protection products containing glyphosate contracted NHL more often than persons with lower or no exposure, the BfR issued an updated review of glyphosate reiterating its conclusion that glyphosate is not carcinogenic.

- *"If used properly and for its intended purpose, glyphosate is not carcinogenic. This was the conclusion arrived at by the German Federal Institute for Risk Assessment (BfR) and numerous other national and international authorities. A new meta-analysis in which already published studies are evaluated collectively does not alter the assessment of the BfR."*

- *"Although the meta-analysis with its reference to glyphosate-based plant protection products is interesting from a scientific point of view, it involves great uncertainty: It could not be determined with sufficient accuracy in the studies how much glyphosate the study participants were actually exposed to."*

- *"Several of the case-control studies used by Zhang and colleagues found an increase in the NHL risk. These studies should only be given very limited consideration, however, when assessing the active substance glyphosate, as no distinction can be made between glyphosate and the various co-formulants contained in the products that were spread. Furthermore, it was not taken sufficiently into account in several studies that the farmers were possibly exposed to other plant protection products too."*

- *"When all of the findings are viewed together, therefore, a causal connection between exposure to (contact with) the active substance glyphosate and the occurrence of NHL has still not been substantiated, in the view of the BfR."*

Brazil's National Health Surveillance Agency (ANVISA), "Public consultation on glyphosate approved," February 2019

Following ANVISA's February 2019 routine re-assessment of glyphosate, the agency presented a Preliminary Technical Note on the conclusions of its safety evaluation of glyphosate.

- *"...the product has not been classified as mutagenic, carcinogenic, toxic for reproduction, teratogenic (causing fetal malformation), among others*."

- *"The conclusion is similar to that obtained in other countries that have recently reviewed the use of glyphosate in the field, such as the United States and Canada, in addition to the European Union."*

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."*

Health Canada Statement, January 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."*

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."*

German Federal Institute for Risk Assessment (BfR) response to plagiarism allegations, January 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."*

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 U.S. 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 U.S. 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)."