

Health Canada's re-evaluation of glyphosate and the Monsanto Papers

Context

The Monsanto Papers are discovery documents released in the course of U.S. federal and state litigation, particularly [Dewayne Johnson v Monsanto Company](#) in California State Court, the first cancer lawsuit against Monsanto's Roundup and other glyphosate-based herbicide products to proceed to trial.

The backgrounder describes the key events that led to the release of the Monsanto Papers and what these papers reveal regarding potentially inappropriate conduct by Monsanto to cover up the risks of their products and influence regulatory decisions.

Johnson v Monsanto

The lawsuit alleged that exposure to Monsanto's Roundup weed killer and its active ingredient, glyphosate contributed to Dewayne (Lee) Johnson's non-Hodgkin lymphoma - a form of blood cancer. Mr. Johnson worked as a school groundskeeper in the San Francisco Bay Area between 2012 and 2015 and regularly applied Roundup to school properties.

On August 10, 2018, after a 20-day trial, a jury issued a \$289 million [verdict](#), comprised of \$39 million in compensatory damages and \$250 million in punitive damages. The punitive damages were reduced to [\\$39.25 million by a California judge](#) on October 22, 2018, for a total of \$78 million in damages. According to [media reports](#), Mr. Johnson accepted the reduced award and will not seek a new trial.

Roundup Litigation

According to the organization [U.S. Right to Know \(USRTK\)](#) there are 580 federal court lawsuits pending against Monsanto in U.S. District Court in San Francisco, and there are an estimated 8000 plaintiffs making similar claims in US State courts. The US federal lawsuits allege that exposure to Roundup caused non-Hodgkin lymphoma to "them or their loved ones," and that Monsanto covered up the risks.

Glyphosate designated as "probably carcinogenic to humans" by IARC

In June 2015 the International Agency on Research on Cancer (IARC) of the World Health Organization determined that Glyphosate is [probably carcinogenic to humans](#). This designation, also known as Group 2A carcinogen, is the [second highest carcinogenic rating just below designating a substance as a known human carcinogen](#) or Group 1.

IARC's evaluation noted, "[a] positive association has been observed for non-Hodgkin lymphoma" and further noted that "[t]here is strong evidence that exposure to glyphosate or glyphosate-based formulation is genotoxic based on studies in humans in vitro and studies in experimental animals."

Canada re-evaluates and authorizes the use of glyphosate

In 2017, Canada's Pest Management Regulatory Agency (PMRA) completed its re-evaluation of glyphosate (re-evaluation decision RVD2017-01) concluding that glyphosate does not pose an unacceptable risk and authorizing its continued registration in pest control products for another 15 years. Several environmental and health groups submitted a Notice of Objection outlining serious scientific gaps in the re-evaluation of the adverse impacts on human health, monarch butterflies and the environment.

Re-evaluation of potentially inappropriate conduct in Monsanto Papers

Monsanto efforts to invalidate IARC designation of glyphosate as "probably carcinogenic to humans"

Internal Monsanto documents reveal that the company engaged in efforts to invalidate the IARC classification of glyphosate as a probable human carcinogen. For example,

- Monsanto reaching out to a scientist Henry Miller to ask if he "want to write more on the topic of IARC panel, its process and controversial decision?" In response, the scientist asked for a "high-quality draft" which Monsanto provides. See [here](#).
- A Monsanto strategy document included using the scientist to "inoculate/establish a public perspective on IARC" in its pre- IARC deliverable. See [here](#).
- Dr. Miller published a piece in Forbes Magazine in March 2015 critical of IARC, but that piece has since been [taken down off of Forbes web site](#) although still available through an [archive site](#). IARC [responded](#) to the criticism from Forbes and other media. The Monsanto strategy document includes other deliverables such as "Inform/Engage industry associations" to "Lead voice in 'who is IARC' plus 2B outrage". See [here](#).
- Monsanto Internal strategizing in response to IARC report includes suggestion: 'Publication on Animal Carcinogenicity Data' could be completed with a "Majority of writing done by Monsanto, keeping OS\$ down." See [here](#).
- Internal Monsanto email identifies one of the goals regarding post-IARC activities as "Publication on Animal Data Cited by IARC...Manuscript to be initiated by Mon as ghost writers." See [here](#).

The Canadian Connections

Emails between Monsanto employees in April and July 2016, including from Monsanto Canada, discuss collaboration with industry associations including CropLife Canada, "to capture the attention of the federal government and encourage an approach to motivate IARC to make adjustments to their current inappropriate practices" and "pulling together for action in Canada and ensure they are aligned with similar plans in the US and possibly elsewhere." See [here](#).

According to a July 2016 email Monsanto Canada "reached out to Keith Solomon and Len Ritter, both retired Professor Emeritus faculty from the University of Guelph. Len did confirm

that he has been contracted by the province of New Brunswick and the Ontario Public Health Agency, among others, to assist with their review of the IARC findings on glyphosate.” Later that month New Brunswick Public Health released a [report on glyphosate](#) downplaying the IARC classification calling it a “hazard assessment” and stating that the scientific consensus regarding the risks posed by glyphosate is still “elusive” pointing to the ongoing assessments in Canada, US, and Europe. See [here](#), the same document as above.

Mississauga based Intertek Scientific & Regulatory Consultancy, previously known as Cantox, was commissioned by Monsanto to assemble panels of scientific experts in the four areas considered by IARC: exposure; epidemiology; cancer in experimental animals; mechanistic and other relevant data (focused on genotoxicity and oxidative stress). The panel report was initially a manuscript that was heavily edited by Monsanto then divided into a multi-chapter supplement for publication in a special supplement of *Critical Reviews in Toxicology*. See [here](#), [here](#), [here](#) and [here](#).

At least one scientist was [contracted](#) by Monsanto to sit on the expert panel. The journal editor upon reviewing the Manuscript sent by Intertek stated, “These reports are essentially a rebuttal of IARC’s process and conclusions. There appears to be a reluctance to be absolutely clear in presenting exactly what IARC concluded, the Panels conclusions and how they differ.” The editor also requested clear declarations of interest including “how individuals were engaged, ie by Intertek. If you can say without consultation with Monsanto that would be great.” See [here](#).

The journal *Critical Reviews in Toxicology* issued an [Expression of Concern](#) in September over the completeness of acknowledged contributions to the supplement, “Critical Reviews in Toxicology, 46(S1): An Independent Review of the Carcinogenic Potential of Glyphosate” in the declarations of interest provided by the named contributors, for five articles. All five articles listed in the Expression of Concern were referenced by the PMRA in the re-evaluation decision. Corrections have been published for three of the articles.

Connections to Health Canada’s glyphosate re-evaluation

Ecojustice legal counsel and scientist conducted a review of the materials contained in the Monsanto Papers. This review reveals that the PMRA in its re-evaluation of glyphosate relied on some studies and papers in which Monsanto’s role is uncredited or unclear. For instance:

- The manuscript for the genotoxicity review study by Kier and Kirkland, 2013 was co-written by Monsanto scientist Dr. Saltmiras, although his name was not included on the study. See [here](#) on pages MONGLY02145925 and MONGLY02145918. The PMRA refers to this study on footnote 12 on page 20 of the re-evaluation decision in addressing comments about the IARC assessment.
- Dr. Saltmiras of Monsanto indicates he ghostwrote the cancer review paper Greim et al. 2015 that the PMRA relied on for assessing carcinogenicity studies in animals on footnote 13 on page 21 of the re-evaluation decision. Dr. Saltmiras is shown as the second author. See [here](#).
- Internal Monsanto email suggests ghost writing sections of a paper and having experts edit and sign, and recalls that that was how Monsanto handled Williams Kroes and Munro, 2000. See [here](#) MONGLY00977267. The Williams Kroes and Munro, 2000 study is listed in the reference list of the glyphosate re-evaluation decision.
- The manuscript for the report that led to the Williams GM et al. 2016 study titled, “A review of the carcinogenic potential of glyphosate by four independent expert panels and comparison to the IARC assessment” was reviewed and edited by a

Monsanto scientist even though it was presented as “independent.” See [here](#), [here](#), [here](#), and [here](#). The PMRA relied on this study in their decision regarding the re-evaluation.

- The Williams AL et al. 2012 study titled, “Developmental and Reproductive Outcomes in Humans and Animals after Glyphosate Exposure: A Critical Analysis” was edited and redrafted by a Monsanto scientist, but the Monsanto scientist’s name was removed from the manuscript before publication. See [here](#).
- There is evidence that we believe suggests close coordination that Mr. Johnson’s lawyers describe as “collusion” between Monsanto and the US EPA officials involved in the review of glyphosate. See [here](#), [here](#), and [here](#). According to the re-evaluation decision, the PMRA and the US EPA collaborated on the PMRA’s re-evaluation of glyphosate.
- Monsanto retained Dr. Parry, a professor at the University of Wales, to conduct an internal evaluation of the potential genotoxicity of glyphosate and the formulated products for Monsanto. Dr. Parry’s evaluation noted deficiencies in the data set and made recommendations for further studies. Email correspondence between several Monsanto colleagues about Dr. Parry’s evaluation discuss strategies to “dig” themselves out of this “genotox hole” and whether Dr. Parry can become a strong advocate without doing the additional studies. Emails also discuss dropping Dr. Parry and getting someone else. See [here](#), [here](#) and referred to in deposition [here](#).

In light of these findings, Ecojustice on behalf of the Canadian Association of Physicians for the Environment (CAPE), the David Suzuki Foundation, Environmental Defence Canada, Equiterre and Prevent Cancer Now, submitted a letter to the Health Minister reiterating their request made in the Notice of Objection to establish an independent review panel to investigate the re-evaluation conducted by the PMRA on glyphosate.

Timeline and glyphosate designations

March 20, 2015 - [IARC](#) designates glyphosate a probable human carcinogen

April 13, 2015 – Health Canada’s PMRA published a proposed [re-evaluation decision](#) for glyphosate proposing continued registration of glyphosate with new risk reduction requirements

June 12, 2015 - Ecojustice with other organizations submitted [comments](#) on the proposed decision

October 15, 2015 - The European Food Safety Commission concluded glyphosate is unlikely to pose a carcinogenic hazard to humans

March 3, 2016 - Christopher Poitier lead [commentary](#) on the difference between EFSA and IARC evaluations.

March 15, 2017 – The European Chemical Agency Committee for Risk Assessment [concluded](#) that available scientific evidence did not meet the criteria to classify glyphosate as a carcinogen, as a mutagen or as toxic for reproduction.

April 28, 2017 – Health Canada’s PMRA published a [final decision](#) continuing the registration of glyphosate in Canada with new risk reduction measures. The PMRA concluded that glyphosate is unlikely to be genotoxic or carcinogenic.

June/July 2017 – [12 objections](#) to the glyphosate decision were filed with the PMRA including those referred to in the Ecojustice letter. At least five mentioned the Monsanto papers.

December 18, 2017 – The US EPA published a [draft risk assessment](#) for glyphosate that concluded that glyphosate is not likely to be carcinogenic to humans. According to [media reports](#), the US Inspector General is investigating whether EPA staff colluded with Monsanto.

May 01, 2018 – NRDC Senior Scientist [commentary](#) of US EPA draft risk assessment.

June 7, 2018 – Bayer completes [acquisition](#) of Monsanto.

October 29, 2018 – Ecojustice letter on Monsanto papers and the glyphosate re-evaluation decision sent to the Minister of Health.

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for the Environment
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