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File No: 823

October 29, 2018

(edited and resent November 9, 2018)

VIA ELECTRONIC MAIL

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The Honourable Ginette Petitpas Taylor, Minister of Health
House of Commons
Ottawa, Ontario
Canada
K1A 0A6

Dear Minister Petitpas Taylor,

Re: Final Notice of Objection to Re-evaluation Decision RVD2017-01, Glyphosate, April 28, 2017

Based on information that has come to light as part of litigation against Monsanto in California, the undersigned organizations, represented by Ecojustice, reiterate their request that you establish an independent review panel under section 35(3) of the *Pest Control Products Act* (PCPA) in response to their Notices of Objection filed in response to the Glyphosate Re-evaluation Decision (RVD2017-01).

The litigation in California led to a \$289 million judgment in August 2018, comprised of \$39 million in compensatory damages and \$250 million in punitive damages.¹ According to very recent reporting, on a post-trial motion, the awarding of punitive damages was upheld, but the amount of punitive damages was reduced to 39.35 million, a still significant award.²

The punitive damage award was based on a jury finding that Monsanto acted with “malice or oppression.” Plaintiff’s attorneys in that litigation credited the verdict to newly-revealed, confidential company documents, stating “[w]e were finally able to show the jury the secret, internal Monsanto documents

¹ Official jury verdict form, found a <https://www.baumhedlundlaw.com/toxic-tort-law/monsanto-roundup-lawsuit/monsanto-secret-documents/> (accessed October 19, 2018).

² See: “California Judge Cuts Award To \$78.5 Million In Monsanto Weedkiller Case”, October 23, 2018: <https://www.npr.org/2018/10/23/659848853/california-judge-cuts-award-to-78-5-million-in-monsanto-weedkiller-case>

proving that Monsanto has known for decades that glyphosate and specifically Roundup could cause cancer.”³

The troubling conduct by Monsanto exposed in the California litigation appears to have influenced Canada’s Glyphosate Re-evaluation process. Studies cited by the Pest Management Regulatory Agency (PMRA) in the Reference List for the Re-evaluation have been implicated in alleged misconduct, or have authors implicated in other alleged misconduct.

We believe that the shocking nature of the allegations, further described below, rob the public of any confidence in the determination of the PMRA that glyphosate “...is not genotoxic and is unlikely to pose a human cancer risk” and “[d]ietary (food and drinking water) exposure associated with the use of glyphosate is not expected to pose a risk of concern to human health.” A transparent, independent review panel, with robust public participation, is absolutely necessary to both investigate whether the Re-evaluation decision is sound and to rehabilitate public confidence in the overall regulatory regime under the PCPA.

Johnson v. Monsanto Company (California Superior Court)

A California jury returned a verdict in the case of a former groundskeeper with terminal cancer against Monsanto Company, ordering the Monsanto Company to pay \$39.2 million in compensatory damages because the glyphosate-based pesticides were a substantial factor in causing harm to Mr. Johnson and punitive damages for failing to warn consumers that exposure to Roundup weed killer causes cancer.

Dewayne “Lee” Johnson filed the lawsuit against Monsanto alleging exposure to the Roundup herbicide he sprayed while working as a groundskeeper for a school district caused him to develop non-Hodgkin lymphoma. Mr. Johnson’s attorneys described Monsanto’s conduct in the following manner:

For years Monsanto has claimed that there is no evidence that Roundup causes cancer, yet a mountain of testimony and documents was admitted during the trial. Johnson’s attorneys proved through testimony from Monsanto’s witnesses that company employees “ghostwrote” scientific articles and paid outside scientists to publish the articles in their name.

Internal documents revealed that a scientific advisor hired by Monsanto told the company that past testing for Roundup was insufficient because glyphosate, the active ingredient in Roundup, was tested in isolation without the other chemical ingredients that make up the Roundup formulation.

“Many of these confidential Monsanto documents were unsealed for the first time,” said co-lead counsel David Dickens. “They show that Monsanto knew that its testing was insufficient and that there was a synergistic effect when glyphosate is combined with surfactants which help the glyphosate penetrate both plant and animal cell walls.” (emphasis added)⁴

³“Monsanto to Pay \$289.2 Million in Landmark Roundup Lawsuit Verdict”, Baum Hedland press release of August 10, 2018, found at: <https://www.baumhedlundlaw.com/289-million-first-roundup-lawsuit-verdict/> (accessed October 19, 2018)

⁴ Ibid.

The Monsanto Papers

Many of the internal documents that the Plaintiff's attorneys relied upon have been made publicly available online and are referred to as the "Monsanto Papers." These documents were obtained through pre-trial discovery and consist of internal Monsanto emails, text messages, company reports, studies, and other memoranda.⁵

The Monsanto Papers and Re-evaluation Decision RVD2017-01, Glyphosate

Legal counsel and scientists at Ecojustice have conducted a preliminary review of the materials contained in the Monsanto Papers⁶ and the materials relied upon by the PMRA. The results of that review give us grave concern. For example, Monsanto's documents seem to indicate that:

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. The PMRA refers to this study at footnote 12 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 at footnote 13 of the re-evaluation decision. Dr. Saltmiras is shown as the second author.

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. 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." 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.

There is evidence that we believe suggests close coordination and Mr. Johnson's lawyers describe as "collusion" between Monsanto and the US EPA officials involved in the review of glyphosate. According to the re-evaluation decision, the PMRA and the US EPA collaborated on the PMRA's re-evaluation of glyphosate.

⁵ "Monsanto Papers, Secret Documents", found at: <https://www.baumhedlundlaw.com/toxic-tort-law/monsanto-roundup-lawsuit/monsanto-secret-documents/> (accessed October 19, 2018).

⁶ Although not all of Monsanto Papers were publicly released prior to the expiration of the period to file a Notice of Objection, their existence and some concerns were identified in the submission of John Balantinecz that we understand is now being overseen by Mary Lou McDonald

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.

The journal titled *Critical Reviews in Toxicology* issued an Expression of Concern⁷ 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. As of September 26, 2018, the editor's report receiving corrigenda for three articles disclosing contributions, contractual status and potential competing interests of all authors and non-author contributors that were not fully disclosed when the articles were initially published. All five articles listed in the Expression of Concern were referenced by the PMRA in the re-evaluation decision. The five articles are:

Williams, G. M., Aardema, M., Acquavella, J., Berry, C., Brusick, D., Burns, M. M., de Camargo, J. L. V., Garabrant, D., Greim, H. A., Kier, L. D., Kirkland, D. J., Marsh, G., Solomon, K. R., Sorahan, T., Roberts, A., & Weed, D. L. (2016). A review of the carcinogenic potential of glyphosate by four independent expert panels and comparison to the IARC assessment. *Critical Reviews in Toxicology*, 46(S1), pp. 3–20. (Already mentioned above in the section on the Monsanto papers)

Solomon, K. R. (2016). Glyphosate in the general population and in applicators: a critical review of studies on exposures. *Critical Reviews in Toxicology*, 46(S1), pp. 21–27.

Acquavella, J., Garabrant, D., Marsh, G., Solomon, K. R., Sorahan, T., & Weed, D. L. (2016). Glyphosate epidemiology expert panel review: a weight of evidence systematic review of the relationship between glyphosate exposure and non-Hodgkin's lymphoma or multiple myeloma. *Critical Reviews in Toxicology*, 46(S1), pp. 28–43.

Williams, G. M., Berry, C., Burns, M. M., de Camargo, J. L. V., & Greim, H. A. (2016). Glyphosate rodent carcinogenicity bioassay expert panel review. *Critical Reviews in Toxicology*, 46(S1), pp. 44–55.

Brusick, D., Aardema, M., Kier, L. D., Kirkland, D. J., & Williams, G. (2016). Genotoxicity Expert Panel review: weight of evidence evaluation of the genotoxicity of glyphosate, glyphosate-based formulations, and aminomethylphosphonic acid. *Critical Reviews in Toxicology*, 46(S1), pp. 56–74.

Corrigenda have been received by the editors for Acquavella J. et al. 2016⁸, Brusick, D. et al, 2016⁹, Solomon K.R. et al. 2016¹⁰. These corrigenda occurred after the PMRA's re-evaluation decision on glyphosate and have not been addressed by the PMRA to our knowledge.

⁷ <https://www.tandfonline.com/doi/full/10.1080/10408444.2018.1522786?scroll=top&needAccess=true>

⁸ <https://www.tandfonline.com/doi/full/10.1080/10408444.2018.1522142?src=recsys>

⁹ <https://www.tandfonline.com/doi/full/10.1080/10408444.2018.1522133?src=recsys>

¹⁰ <https://www.tandfonline.com/doi/full/10.1080/10408444.2018.1522751?src=recsys>

Although the concerns with the conduct described above should be self-evident, we note that transparency and disclosure of all authors and their conflicts of interest are central tenants of scientific ethics and science-based decision making.

The Appropriate Next Steps

Even before the California verdict raising questions about the accuracy and reliability of much of the publicly available scientific information concerning Glyphosate, there were serious concerns about deficiencies in the PMRA's Re-evaluation. In our Notices of Objection, we identified the:

- failure to consider critical evidence about glyphosate's impact on milkweed and monarch decline;
- failure to consider critical evidence associated with glyphosate's impact on microbiomes - both human and in the soil;
- failure to consider critical evidence associated with glyphosate's health impacts, including cancer; and
- failure to evaluate roles of glyphosate as a chelator, in both soil depletion, and in the mobilization of the neurotoxic carcinogen cadmium in grains.

The undersigned groups also identify that, the PMRA has failed to consider evidence and has failed to acknowledge critical knowledge gaps in the following risk management strategies included in the Decision, such as the:

- failure to consider evidence that demonstrates that riparian buffer strips and buffer zones are inefficient as risk management strategies, particularly concerning efficacy, environmental persistence, and risks to groundwater and surface water contamination; and
- failure to consider some evidence that shows that labelling may not be an effective strategy to manage risk, and failure to acknowledge large knowledge gaps in the evidence on the efficacy of labelling to manage risks.

These deficiencies and the concerns raised by the Monsanto Papers rise to such a level that it is imperative for you to strike a review panel under s. 35(3) of the PCPA.



Randy Christensen
Legal Counsel for the undersigned groups

cc. Richard Aucoin, Executive Director, Pest Management Regulatory Agency.



**Kim Perrotta, Executive Director,
Canadian Association of Physicians for the Environment**



**Muhannad Malas, Toxics Program Manager,
Environmental Defence**



**Annie Bérubé, Director of Government Relations,
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Louise Hénault-Ethier

Louise Hénault-Ethier, Chef des projets scientifiques,
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M. E. Sears

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