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Pest
Management
Regulatory
Agency

Agence de
réglementation
de la lutte
antiparasitaire

JAN 11 2019

Reference No.2017-3045

Kathleen Ruff
RightOnCanada.ca
e-mail: kruff@bulkley.net

Dear Ms. Ruff,

Re: Notice of Objection to Re-evaluation Decision RVD2017-01, Glyphosate

Your notice of objection, filed under subsection 35(1) of the *Pest Control Products Act* (PCPA), regarding the re-evaluation decision for Glyphosate has now been reviewed and assessed in accordance with the PCPA and *Review Panel Regulations*.

The purpose of a notice of objection is to identify the area of science supporting the re-evaluation decision to which objection is taken, to provide the scientific basis of the objection and to request that the area of science in question be referred to a review panel for reconsideration and recommendation.

The PMRA has taken all reasonable measures to ensure impartiality in determining if a panel should be established. The notice of objection, including the scientific rationale, was assessed by a team of PMRA evaluators who were not involved in the original re-evaluation decision. This team provided recommendations as to the requirement for a review panel based on the validity and the scientific plausibility of the issues raised in the notice. The factors to be considered in determining whether to establish a review panel include:

- whether the information in the notice raises scientifically founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pesticide; and
- whether the advice of a review panel of expert scientists would assist in addressing the subject matter of the objection.

The following information was received and reviewed in support of your notice of objection:

- June 25, 2017 letter to PMRA

Canada

2720 promenade Riverside Drive, Ottawa, Ontario K1A 0K9

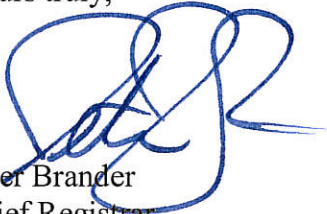
Ms. Ruff

The information which you submitted in support of your objection does not meet either of those factors and, accordingly, does not provide a basis for the establishing of a review panel. As a consequence, a review panel will not be established to reconsider the regulatory decision in response to your request.

The issues raised in the notice of objection are attached to this letter are **in bold text**, followed by PMRA responses which are not (see Attachment 1).

Should you have any questions regarding this letter, please contact Charles Smith at 613-736-3625 or charles.smith@canada.ca. Please quote Reference Number 2017-3045 in any correspondence regarding the Notice of Objection to re-evaluation of glyphosate.

Yours truly,

A handwritten signature in blue ink, appearing to read 'Peter Brander', is written over the printed name.

Peter Brander
Chief Registrar

PEST MANAGEMENT REGULATORY AGENCY

Attachment 1

Comment 1: A comment was received that referred to the article, "Differences in the carcinogenic evaluation of glyphosate between the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA)", which dealt with the differences between IARC and EFSA's assessment, was signed by 94 scientists and was primarily authored by the head of the IARC committee. This article critiqued EFSA's Renewal Assessment Report on glyphosate. The objector requests that the PMRA review the scientific flaws as documented in this article.

PMRA Response:

By way of background, other Notices of Objection contained the most recent open letter (May 2017) from Dr. Christopher Portier, Chair of the IARC Committee, to Jean-Claude Juncker, President of the European Commission, concerning the European Food Safety Authority's (EFSA's) re-evaluation of glyphosate. The open letter states that, following an evaluation of the raw tumour data from the EFSA re-evaluation, Dr. Portier believes that the evaluations applied to the glyphosate data are scientifically flawed (specifically as it pertained to statistical analysis), and any decisions derived from these evaluations will fail to protect public health.

In June 2017^a, EFSA and the European Chemicals Agency (ECHA) with the support of the Federal Institute for Risk Assessment (Germany; BfR), the lead country performing the re-evaluation, responded to Dr. Portier's open letter (May 2017). As stated in the EFSA/ECHA joint response, statistical analysis provides an important tool in a risk assessment. The response further notes, however, that "the results of any statistical analysis and its related uncertainties have to be weighted for their biological relevance to arrive at a comprehensive toxicological evaluation of the substances at hand."^b

The signing authorities on the joint response concluded that "Overall EFSA and ECHA are of the opinion that all the findings on the chronic rodent carcinogenicity studies referred to in your letter have been adequately considered and therefore we see no need for our evaluations to be revisited."^c

The PMRA is in agreement with the EFSA and ECHA conclusion that the statistical elements of the study have been adequately considered. Furthermore, the PMRA conducted an independent assessment of the data during the re-evaluation. Accordingly, the PMRA has determined that the statistical analysis and the PMRA evaluation do not need to be re-assessed.

^a EFSA (European Food Safety Authority) and ECHA (European Chemicals Agency). 2017. Re.: Your letter Review of the Carcinogenicity of Glyphosate by ECHA, EFSA and BfR. 06 July 2017. Available online from <https://www.efsa.europa.eu/sites/default/files/170706-glyphosate-letter.pdf> [Last accessed August 30, 2018]

^b Ibid

^c Ibid

The issues raised in the article referred to in this Notice of Objection, "Differences in the carcinogenic evaluation of glyphosate between the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA)", were previously sent to EFSA in Dr. Portier's November 2015 letter to Commissioner Andriukaitis^d. The issues and the EFSA response^e were considered by the PMRA and the conclusions are found within the RVD2017-01 document.

Following EFSA's 2016 response and the EFSA release of raw data from the studies forming the basis of the risk assessment, Dr. Portier sent an open letter to the President of the European Commission, Jean-Claude Juncker, questioning EFSA's statistical analysis^f. The signing authorities on the joint response (EFSA and ECHA) concluded that "Overall EFSA and ECHA are of the opinion that all the findings on the chronic rodent carcinogenicity studies referred to in your letter have been adequately considered and therefore we see no need for our evaluations to be revisited."

The PMRA considered the second critique (Portier, 2017) and found no substantive information beyond that already identified in the first critique (Portier, 2015). Accordingly, the PMRA considers that the issues have been adequately considered and there is no need for the PMRA to revisit its conclusions.

Comment 2: A comment was received that made the assertion that the US EPA ongoing review of glyphosate is compromised due to alleged interactions between Monsanto and EPA. Subsequently, that Health Canada's review of glyphosate is also compromised due to collaboration between Health Canada and EPA in the review of glyphosate.

PMRA Response:

The Glyphosate Re-evaluation Decision Document (RVD2017-01) published by Health Canada on April 28, 2017, is unrelated to alleged interactions between Monsanto and EPA. Although PMRA and EPA scientists did collaborate on the assessment of publically available literature for glyphosate, PMRA conducted its own independent assessment of any registrant-submitted information without EPA involvement, and overall assessments were conducted separately. PMRA also conducted its own independent risk assessment for glyphosate and determined the appropriate risk management options based on the outcome of its scientific review. Regulatory decisions were also taken separately in each country.

^d Portier 2015. Letter from Professor Portier to Commissioner Andriukaitis. Available online at https://www.efsa.europa.eu/sites/default/files/Prof_Portier_letter.pdf [Last accessed September 6, 2018]

^e EFSA (European Food Safety Authority). 2016. Glyphosate: EFSA responds to critics. Available online from <http://www.efsa.europa.eu/en/press/news/160113> [last accessed June, 2016]

^f Portier 2017. Open letter: Review of the Carcinogenicity of Glyphosate by EChA, EFSA and BfR. Available online at <https://www.nrdc.org/sites/default/files/open-letter-from-dr-christopher-portier.pdf> [Last accessed September 10, 2018]

Comment 3: The assertion that studies cited in Health Canada's published reference list for the final re-evaluation of glyphosate, are implicated in alleged misconduct, or have authors implicated in other alleged misconduct. The assertion questions the independence of some of the scientific review articles for glyphosate.

PMRA Response:

Health Canada's evidence-based re-evaluation decision considered relevant data and information from multiple registrants, published scientific reports, federal and provincial governments, and other regulatory agencies. 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.

With regard to the endpoints of concern highlighted within the NoO, it is important to note that there were many additional studies examined by Health Canada scientists that were relevant to the subject areas of interest, but were not considered in the review articles cited. For example, the review article on cancer studies included 14 studies, while Health Canada had access to approximately 20 studies, including the 14 cited in the review article. The review article on genotoxicity was based on approximately 25 studies for glyphosate (technical) while Health Canada had access to over 100 studies on glyphosate (technical), including the 25 cited in the review article. (Additional examples are shown in the attached table)

During the consultation period following publication of the PRVD for glyphosate, extensive comments and information were received from various stakeholders including registrants, growers, non-governmental organizations and the public. The review articles cited within the Ecojustice letter were considered during the response to comment period, however, these review articles in no way affected the final outcome of the re-evaluation published in RVD2017-01 or PMRA's risk assessment regarding the continued registration of glyphosate. When summary review documents are provided, as a matter of practice, Health Canada ensures that underlying studies upon which these reviews are based, along with the raw data, have also been examined. The references in the final Re-evaluation Decision document subsequently list all the additional information that were assessed.

Although the assertion with regard to improper or misleading citations is disconcerting, and is being examined by Health Canada officials, the review articles themselves did not alter the final decision.

While considered during the response to comment period, these review articles did not impact the final decision regarding continued registration of glyphosate.

Aspect of Review	Data - Review papers relied on	Data - PMRA relied on
Animal Carcinogenicity	Greim et al. (2015) examined 14 studies	Approximately 20 carcinogenicity study – including the ones examined by Greim et al. (2015)
Genotoxicity	Brusick et al (2016) examined about 25 studies for the glyphosate technical	Over 100 studies for the glyphosate technical – including the ones examined by Brusick et al. (2016)
Epidemiology studies examining cancer outcomes	Acquavella et al. (2016) conducted systematic review of the epidemiology data related to NHL and multiple myeloma	Over 50 cancer epidemiology data – including those reviewed by Acquavella et al. (2016)
Systematic toxicology and epidemiology review	Williams Kroes and Munor, (2000) examined over 50 studies of toxicology and epidemiology conducted up to the year 2000	Over 200 toxicology and epidemiology studies up to the year 2017 – including those reviewed by Williams Kroes and Munor (2000)
Developmental and Reproductive studies in animals Epidemiology studies examining reproductive and developmental outcomes	Williams et al. (2012) examined about 40 studies	Over 200 developmental, and reproductive toxicity studies in animals as well as all epidemiology data – including those examined by Williams et al. (2012)
Epidemiology studies on applicators	Solomon et al. (2016) about 10 studies in applicators	Over 50 epidemiology studies including those examined by Solomon et al. (2016)