Marc-André Gagnon (PhD) School of Public Policy and Administration, Carleton University, Ottawa, ON, Canada.

Marie-Hélène Bacon (PhD) Ecohealth Research Collective on Pesticides, Policies and Alternatives (CREPPA), Institute of Environmental Sciences, Université du Québec à Montréal (UQAM), Montréal, QC, Canada.

Louise Vandelac (PhD) Ecohealth Research Collective on Pesticides, Policies and Alternatives (CREPPA), Department of Sociology and Institute of Environmental Sciences, Université du Québec à Montréal (UQAM), Montréal, QC, Canada.

REINFORCING REGULATION AND TRANSPARENCY AT HEALTH CANADA'S PMRA

SOME NECESSARY CONSIDERATIONS

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About the authors

Marc-André Gagnon (PhD)

Marc-André Gagnon is Associate Professor at the School of Public Policy and Administration at Carleton University (Ottawa, Canada). He is a Research Fellow with the WHO Collaborating Center on Governance, Accountability and Transparency in the Pharmaceutical Sector. He holds a PhD in political science from York University, a Diplôme d'études approfondies in economics from Paris-I Sorbonne and École Normale Supérieure de Fontenay/Saint-Cloud. His did his postdoctoral studies in Law with the Centre for Intellectual Property Policy at McGill University and in Ethics with the Edmond J. Safra Centre for Ethics à l'Université Harvard. Marc-André Gagnon published extensively in academic journals and in Canadian media about Canadian pharmaceutical policy and environmental health policy. His research focuses on pharmaceutical policy and on the political economy of the drug industry. More specifically, his on-going research focuses commercial influence on medical research, on innovation policy and intellectual property in the knowledge-based economy, as well as institutional corruption in in the pharmaceutical and agro-chemical industries. Except for acting as an expert witness for Justice Canada for a case about drug prices in Canada, he has no conflict of interest to declare.

Louise Vandelac (PhD)

Louise Vandelac is full professor in the Department of sociology and in the Institute of Environmental Sciences at the University of Quebec in Montreal (UQAM). She directed several institutes, centres, and research groups. After a master's degree in political economy at the University of Paris VIII, she obtained her Ph.D. in sociology at the University of Paris VII, focusing on technoscience and health issues. Since then, she has led more than 60 subsidized research projects and published extensively in academic journals and in media about public policy on health, environment, and food systems. She is the founder and director of CREPPA, an eco-health research group on pesticides, policies and alternatives which gather 40 national and international academics, collaborators, and NGO's which is supported by the Quebec research fund FQRSC. Researcher with the strategic clusters RQRAD/agriculture, RRSPQ/health, CIRODD/sustainable development, CENTREAU/water, bringing together several hundred researchers, she is also member of diverse research groups: RISUQ, CINBIOSE, CIAPE and CEREV (Univ. Caen-Normandie). Co-director of the first francophone web and open access academic journal in environmental sciences, VertigO, the interdisciplinary expertise of Dr Vandelac on the socio-economic analysis of socio-technical transformations of the living (human, animal, and plant), focus on the public

scientific assessment and regulation, and their ecological, sanitary and democratic impacts. Dr. Vandelac work has earned her numerous awards and honors (Prix Multidisciplinarité de l'ACFAS; Honorary PhD Royal College of Kingston; Cercle des Phénix de l'environnement du Québec; Honorary Member of the Association des biologistes du Québec, etc.). She was appointed to a dozen public bodies, including the National Bioethics Council on human subjects, the Executive of the Canadian Commission for UNESCO and the International Scientific Council of the Réseau national des Maisons des sciences de l'Homme (CNRS and 23 French universities). She has no conflict of interest to declare.

Marie-Hélène Bacon (PhD)

Marie-Hélène Bacon holds a PhD in sociology and is a researcher at Université du Québec à Montréal (Montréal, Canada) and coordinator of the Ecohealth Research Collective on Pesticides, Policies and Alternatives (CREPPA), a transdisciplinary research group of 28 researchers, 11 collaborators and 13 civil society groups, working on innovative research projects with global and integrated perspectives on pesticides, agricultural transformation, and public policies in Quebec and Canada. She is an associate researcher at the Quebec Sustainable Agriculture Research Network (RQRAD), CentrEAU-Quebec Water Research Center, and the Health and Society Institute. Her interdisciplinary expertise focuses on scientific assessment, regulatory and policy frameworks of chemical substances, emerging technologies (biopharmaceuticals, genetic engineering, GMOs, etc.), and agrifood systems, as well as their related health, environmental and socio-economic issues. She has no conflict of interest to declare.

This document comments on Health Canada's Notice of Intent NOI2023-01, *Strengthening the regulation of pest control products in Canada* (1). While we are very happy to observe there are some ongoing efforts to reinforce regulation and transparency at Health Canada, we are appalled by the ongoing and obviously significant culture of secrecy at Health Canada's Pest Management Regulatory Agency (PMRA), which is apparent in this most recent current notice of intent. This culture of secrecy is a remnant of a past era and undermines any effort to improve regulation. After discussing the current opacity of pesticide regulation in Canada, this commentary highlights some required changes in terms of data transparency, without which, this notice of intent and this whole exercise of consultation will remain futile. Our comments and suggestions focus on the proposed amendment to facilitate access to confidential test data, including for research and re-analysis purposes (section 3.1 of the Notice of Intent).

Opacity of the PMRA: Some Recent Context

In 2021, Health Canada's PMRA proposed to double or almost quadruple in some cases the residue limits for glyphosate in basic food products such as oats and beans (2). This proposal, made at Bayer-Monsanto's request, came as a surprise to many researchers and physicians considering the serious concerns that exist regarding the health impact of glyphosate-based herbicides (GBH) in Canadians' food. In 2015, the World Health Organization's (WHO) International Agency for Research on Cancer (IARC) concluded after reviewing independent scientific literature, that both glyphosate and GBH are genotoxic and probable carcinogens to humans and that exposure to glyphosate has a positive association to non-Hodgkin lymphoma (3). Canada seems to be going against the grain in GBH regulation by now increasing thresholds above the ones found even in the United States and China, with the PMRA stating that residues of glyphosate "will not pose an unacceptable risk to any segment of the population"(2). When the civil society group Vigilance OGM submitted an access to Information request to obtain the studies supporting this claim, the PMRA took an entire year to comply with the request, and eventually, when they did respond, sent 229 completely blank pages (4). When pushed for more transparency, Health Canada announced that they would create a new "Science Advisory

Committee on Pest Control Products" made of independent scientific advisors. It was later learned in July 2023 that the co-president of the committee, Bruce Lanphear, resigned due to the committee's incapacity to access product safety data, and because of the chemical industry's significant influence over pesticide regulation (5).

Regulating Pesticides for Human Safety or Business Interests?

Many are becoming skeptical about the way the PMRA regulates pesticides in Canada. Although GBH commercial formulations contain so-called co-formulants (POEAs, PFAS, arsenic, petroleum, etc.) that increase toxicity up to 1000-fold compared with glyphosate alone, the PMRA only assesses and regulates glyphosate as the "active" ingredient, which is highly problematic (4). Moreover, the agency systematically evaluates product safety using manufacturers' data and literature, which are kept secret, labelled as "confidential business information" (CBI) and which therefore cannot be verified. For example, the evaluation of its toxicological hazards in the re-authorization of glyphosate in 2017 was initially based on 118 references to classified studies provided by industry and not subject to independent scientific peer review, as well as 7 "published" references with no authors or places of publication identified (6).

The PMRA considers as CBI pesticides risk evaluation and even the precise sales data of chemical companies in Canada, which means they are not publicly disclosed even through the *Access to Information Act,* and cannot be consulted by independent academic researchers. Such secrecy is mind-boggling considering the important efforts by Health Canada to improve transparency when it comes to therapeutic products.

Health Canada and CBI

The culture of data secrecy and CBI is not new for Health Canada. For decades, Health Canada was considered excessive in restraining access to safety data for pharmaceutical products, such as adverse drug reactions (ADRs) (7). Health Canada was even declared "the most secretive of government departments" by the Canadian Association of Journalists, and was given the "code

of silence award" in 2004 for its "remarkable zeal in suppressing information" and "concealing vital data about dangerous drugs''(8). Only after a media campaign by CBC about the risks of therapeutic products did Health Canada finally take steps toward greater transparency on drug information, and a database about existing ADRs was finally made publicly available online in 2005.

Health Canada has also faced serious criticism for its lack of transparency regarding clinical trial data that was considered CBI: while drug companies submitted all their clinical data for drug approval, they cherry-picked which data they made publicly available through medical publications, creating significant bias in drug information provided to prescribing physicians (9). Fortunately, these harmful practices were significantly reduced after the passage of Bill C-17, – an *Act to amend the Food and Drugs Act - Protecting Canadians from Dangerous Drugs Act*, also known as Vanessa's Law – in 2014. (10). Under the transparency provisions of Vanessa's Law, drug companies must make relevant information about the clinical trials and other safety studies they sponsor publicly available. The law also gave the Minister of Health new discretionary powers to share CBI without notice or consent from the party that claims ownership over that CBI, in particular if the Minister believes there is a serious risk to human health that could be mitigated or avoided by doing so (Canada Food and Drug Act, Art. 21.1 (1-2)). Even when no such risk appears to exist, the Minister still has the discretion to share CBI with anyone who "protects or promotes human health" or public safety, as long as the person does not use the CBI for commercial purposes (Canada Food and Drug Act, Art. 21.1 (3)). While Health Canada had previously refused to share unpublished safety and efficacy data related to therapeutic products on the grounds that it was CBI (11), these new discretionary powers allow the health minister to disclose safety data, and Health Canada even implemented a web portal in which the public can directly access all clinical data for the approval of new medicines. When it comes to transparency of data for pharmaceutical products, Health Canada went from global laggard to global leader (10).

Proposed Amendment 3.1 Will Not Solve Anything

We would like to thank the authors of the Notice of Intent for the entertainment they provided us as we reviewed section 3.1, dealing with manufacturer considerations with regard to data transparency: “Several pesticide manufacturer organizations noted that while Canada's pesticide regulatory system is already very transparent, a lack of timely access to data and information, and a lack of understanding about the PMRA's decisions reduces Canadians' overall confidence in the federal pesticide regulatory system” (1).

It seems that we clearly do not live in the same world as pesticide manufacturers with regard to our understanding of the situation. The lack of trust of Canadians have in terms of pesticide regulation is not due to their inability to understand PMRA decision-making, but because of a lack of trust in the agency itself. Gaining trust requires trustworthiness, which is clearly lacking at the PMRA, often considered as a classic case of “regulatory capture” of a public agency by commercial interests (4). Trustworthiness requires transparency and accountability. However, amendment 3.1 is far from enough to build trustworthiness.

To allow greater access to confidential test data (CTD), including for research and re-analysis purposes, Section 3.1 proposes to amend the Pest Control Products Regulations to enable inspection of CTD for research and re-analysis purposes. This amendment is absolutely necessary, but is unfortunately significantly insufficient by itself, as it does not cover CBI, which would continue to remain protected under this proposal. This is not useful, as pesticide manufacturers could continue to designate any information they want, including CDT, as CBI.

The Minister of Health has the authority to share pharmaceutical CBI with anyone who “protects or promotes human health”. The same ability should exist for agrochemical CBI in order to properly protect and promote human health. Amendment 3.1 necessitates the inclusion of such powers in the hands of the Health Minister when it comes to pesticides. Indeed, the role, purpose and ethics of the PMRA is to protect and promote human health when it comes to pesticide regulation. To refuse to share any data that could help protect and promote human health in order to protect business interests instead, goes against the mandate of the PMRA.

To be explicitly clear: *it is unethical to consider any information that could help protect or promote human health CBI.*

Health Canada has finally arrived at this conclusion in its regulation of therapeutic products (including veterinary products), but it still refuses to do the same for agrochemical products.

Time to Lift the Veil

While Vanessa's Law disturbed Health Canada's longstanding practices and non-transparency, these efforts stopped short: they only apply to therapeutic products. It is somewhat disconcerting that these powers are used only for improving the safety of some products while the opacity remains when it comes to other potentially harmful substances, such as agrochemical products. While abundant scientific literature demonstrates the serious human health impacts of pesticides (12), this culture of secrecy at Health Canada's PMRA is baffling.

A Federal agency mandated to protect the health of Canadians has no justification for hiding away data to serve commercial interests instead of human health (13). The health minister should use these necessary, discretionary powers to make sure that safety data is no longer concealed as CBI, as is done for therapeutic products.

Some say that democracies die in darkness. By restraining access to evidence and by imposing secrecy, Health Canada stands in the way of constructive public debates over important scientific and health issues, and concurrently nurtures the idea that governmental institutions are simply captured by business elites.

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