Hon. Judy A. Sgro, M.P.
Chair, Standing Committee on International Trade
House of Commons
Ottawa, Ontario
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Dear Ms. Sgro,

On behalf of the Government of Canada, I am pleased to present you with the Government response to the Standing Committee on International Trade's comprehensive report entitled: "Canada's Proposed Biocides Regulations: Potential Trade-Related Impacts." The Government acknowledges the Committee's interests and insights into this issue, which holds important implications for our trade relationships and economic landscape.

As the Committee heard during its study, biocides are used to sanitize or disinfect surfaces to prevent disease in humans or animals and are products that consistently play an important role in the lives of people in Canada. For example, the use of biocides on surfaces in food processing facilities help reduce the likelihood of food-borne illnesses, and the use of biocides in hospital settings to reduce the likelihood of infection. As you can imagine, the demand for biocides increased greatly as a result of the COVID-19 pandemic as they were essential in a coordinated approach to help prevent the spread of the virus.

To respond to this increased demand, the biocides industry was able to use temporary mitigation measures put in place by Health Canada to bring hundreds of disinfectants authorized in other jurisdictions into Canada. By ensuring a steady supply of disinfectants, sanitizers, and other essential products, we recognize the important role that the biocides sector played in preventing the spread of the SARS-CoV-2 virus. Industry's rapid response to increased demand, its commitment to maintaining high standards of product efficacy, and its innovation in developing effective solutions were instrumental in supporting global efforts to combat COVID-19. Even after the peak of the crisis, biocides continue to be important in helping people in Canada protect their health.

The Government has now adapted the exceptional measures to improve and maintain access to biocides through the new *Biocides Regulations* which were published in the *Canada Gazette*, Part II on June 19, 2024. To help increase the supply of biocides in Canada and avoid the need to rely on emergency measures to address future shortages, a 'use of foreign decisions' (UFD) pathway is part of the new modern regulatory approach to biocides under the *Biocides Regulations*.

This pathway formalizes Health Canada's existing practice of using data from applications submitted in other jurisdictions, when applicable, to better inform the review of biocides for sale in Canada and would be a tool to facilitate new and innovative products being brought to the Canadian market in an expedited manner. The pathway provides a number of benefits, by reducing authorization costs and times for stakeholders, reducing the time it takes for Health Canada to make a decision, and providing an incentive for companies to bring their products to the Canadian market. More generally, the *Biocides Regulations* will allow for the authorization and regulation of biocides under a single framework (instead of three separate ones) and separately from other health products, which is consistent with the approach taken internationally (e.g., in the United States (U.S.), the United Kingdom and the European Union). In totality, the *Regulations* are expected to reduce barriers and create efficiencies for most businesses wanting to bring biocides to the Canadian market, thereby creating opportunities for growth and continued viability. Most importantly, the Regulations will support public health by ensuring a safe, effective, and high-quality supply of biocides is maintained, and potentially providing Canadians access to a larger variety of biocides, including innovative biocides.

We recognize that the Committee heard testimony with respect to potential impacts of the pathway on the domestic competitiveness of the Canadian biocides sector, which have led to the recommendations outlined in the Committee's report. Health Canada, as the federal regulator for biocides products, will provide support to companies in transitioning to the new regulatory

framework and continue to engage with stakeholders and regulatory partners, including international regulators and other federal departments, to identify and explore opportunities to improve access to meet the health and safety needs of people in Canada. The Department will also continue work to pursue greater international harmonization, which in turn can lead to opportunities for Canadian firms to improve their market access.

Beyond regulatory access, Health Canada will continue to engage with federal departments to monitor the domestic biocides sector. If competitive challenges for domestic producers arise, Health Canada will work with other federal entities such as Innovation, Science, and Economic Development Canada (ISED) and Global Affairs Canada (GAC) to explore potential measures. Furthermore, the GR notes that the *Biocides Regulations* form a part of broader work on modern regulations related to the Government of Canada's overall Health and Biosciences Sector Regulatory Review Roadmap. Continuing engagement of stakeholders will remain an important part of Health Canada's approach to modernization going forward.

On that note, I am pleased to provide a response to the Committee's four recommendations which is enclosed to this letter. Once again, I would like to thank you, Ms. Sgro, and all members of the Standing Committee on International Trade for undertaking this study. I also acknowledge the time and effort of the various organizations who appeared and submitted written submissions in support of the study.

The Honourable Mark Holland, P.C., M.P.
Minister of Health

**GOVERNMENT RESPONSE TO THE 16TH REPORT OF THE STANDING COMMITTEE ON INTERNATIONAL TRADE, ENTITLED: "CANADA'S PROPOSED BIOCIDES REGULATIONS: TRADE IMPACTS FOR CERTAIN CANADIAN SECTORS"**

**Recommendation 1: That the Government of Canada, when implementing the proposed use of foreign decisions pathway, take actions designed to enhance the domestic competitiveness of Canadian biocides manufacturers. In this regard, the Government should identify and address existing challenges that negatively affect Canada's biocides sector.**

The Government of Canada acknowledges this recommendation put forward by the Committee. Health Canada has closely collaborated with industry stakeholders and has maintained an open dialogue on issues related to shortages during the COVID-19 pandemic, as well as challenges surrounding application processes and requirements. Consultations on the UFD pathway have identified challenges that were raised by Canada's biocides sector, and which have been outlined in your report. In response to these challenges, the Government of Canada has ensured that regulatory requirements are in place to support the continued competitiveness of Canadian biocides products.

For example, when implementing the UFD pathway, the Regulations ensure that:

- A biocide will only be authorized through the UFD pathway if the Minister determines its benefits outweigh its risks, as with all application pathways, to help ensure all biocides are held to this same standard for authorization.

- Requirements across application pathways reflect risk and serve to maintain consistent health and safety protections. For example, companies using the UFD pathway will not need to include the results of tests and studies conducted. This is because they were already reviewed by the foreign regulatory authority. Instead, companies will need to provide a list of those tests and studies and if requested, provide the results.

- Once authorized, biocides authorized through the UFD pathway will have the same post-market obligations as all other biocides, which include safety monitoring and serious incident reporting, including some additional obligations. For example, companies with biocides authorized under the UFD pathway will need to notify Health Canada if the foreign biocide has been recalled or the authorization to sell the foreign biocide has been suspended or revoked, as well as an obligation to provide information about a change to the foreign biocide, without delay. Combined, these requirements will allow Health Canada to identify and address safety risks for biocides authorized through the UFD pathway.

Furthermore, the implementation of new regulations for biocides will more generally address current challenges and benefit certain companies in Canada's biocides sector, such as by reducing duplication, formalizing Health Canada's existing practice of using international data during biocide review and expanding opportunities for regulatory cooperation and develop regulatory alignment wherever possible and bring biocides to the Canadian market sooner. The *Biocides Regulations* will allow for the authorization and regulation of biocides under a single framework (instead of three separate ones) and separately from other health products, which is consistent with the approach taken internationally (e.g., in the United States (U.S.), the United Kingdom and the European Union). This is expected to reduce barriers and create efficiencies for businesses, including Canadian businesses, wanting to bring biocides to the Canadian market, opening up opportunities to improve their growth, viability, and competitiveness.

The Government of Canada acknowledges that the UFD pathway may impact Canada's biocide sector differently depending on a company's business model. During the development of the Biocides Regulations, and as indicated in the published Regulatory Analysis and Impact Statement, some of the anticipated impacts of the regulations on the biocides industry (both potential benefits and negative consequences) were not quantified as the activities conducted by Canadian companies are dependent on each entity's business model. This pathway may have an

impact on the competitiveness of domestic biocide companies that have products solely marketed in Canada. However, it is not possible to quantify the depth of this impact, given that this requires access to confidential business information that the Government does not possess
.

Nevertheless, as heard throughout the development of the *Biocides Regulations* and in testimony from industry witnesses at committee meetings, there is mixed feedback with respect to the introduction of a UFD pathway and its impact on Canadian companies. For example, testimony from an association representing Canadian companies of all sizes and a small business in Ontario stated that the UFD pathway will enable companies to leverage authorizations from foreign jurisdictions to bring biocides to the Canadian market sooner and increase consumer choice without compromising health and safety. On the other hand, concerns were also raised around competitiveness of Canadian companies. While it is anticipated that this pathway may lead to a reduction in sales for some domestic manufacturers, the Regulations will reduce regulatory burden and provide long-term benefits and savings to Canada's biocide sector, including Canadian small businesses. The testimony of a small business located in Ontario that shared that up to 80-90% of small businesses rely on licensing agreements with other companies to bring biocides to market in Canada, as product development and testing can be cost-prohibitive, was noted. Allowing companies to use the UFD pathway would bring a greater variety of products to the Canadian market sooner. Industry also indicated their opinion that there is sufficient Canadian manufacturing capacity to meet the demand for biocides in Canada.

Health Canada maintains that the UFD pathway's inclusion in the *Biocides Regulations* supports the viability and competitiveness of the sector through these anticipated benefits. To take further action in the future, Health Canada could consider extending the benefits of the pathway to a wider range of companies who do business in other jurisdictions. This could be done by proposing to expand the list of trusted foreign regulatory authorities as appropriate and consulting on the proposed changes. Furthermore, in addition to the UFD pathway, all companies, including Canadian companies, will continue to have access to other less burdensome pathways such as ones that allows companies to seek authorization based on a comparison to a product that is already authorized for sale in Canada. Finally, Health Canada is working on a monograph that would allow eligible companies to reduce their costs for market authorization, which further supports their ongoing competitiveness.

**Recommendation 2: That the Government of Canada ensure that Health Canada has sufficient resources to assess, in a timely manner, applications for a market authorization to import biocides into Canada or to sell biocides domestically.**

**In addition, to ensure that Canadian firms have sufficient time to meet all requirements after the proposed Regulations are implemented, the Government should take two actions: Provide Canadian firms with a one-year period within which to submit an application for market authorization to import or sell biocides while continuing to rely on their existing authorization; and, establish a moratorium regarding the proposed Regulations, such that implementation would occur only after Health Canada has processed all of the applications submitted during that one-year period.**

The Government of Canada supports the recommendation that Health Canada have sufficient resources to assess applications for a biocide market authorization in a timely manner. Health Canada will charge fees for the examination of applications for market authorizations and changes to authorized biocides, as well as post-market monitoring of products on the Canadian market. The revenues from these fees along with internal reallocation of existing Departmental resources will support the ongoing implementation of the *Biocides Regulations*.

Operational measures, including updated improved IT systems to reduce manual functions and aid in the review process and developing Health Canada guidelines such as monographs to expedite review, are also being considered to alleviate the anticipated pressures associated with the volume of products following from the transition to the *Biocides Regulations*. Testimony before the Committee from a small business in Ontario indicated that testing could cost over half

a million dollars per product. The monograph pathway (mentioned earlier in Recommendation 1) is an abbreviated review pathway that enables companies to meet a portion of the application requirements by referencing a Health Canada monograph, which would reduce associated testing costs. The Government of Canada understands the importance of establishing appropriate transition times under the *Biocides Regulations* and has consulted with stakeholders to understand the factors that will affect the transition of their products and be able to mitigate any unnecessary disruptions to Canadian businesses and the market.

All stakeholder feedback was considered throughout the development of the *Biocides Regulations*, including the recommendation from associations representing biocides companies based in Quebec to include a moratorium to ensure Canadian industry has the time to become familiar with the Biocides Regulations and comply with its requirements. Feedback from other associations representing companies of all sizes across Canada, including small businesses, some Quebec manufacturers and global companies with Canadian operations, supported the introduction of the UFD pathway and indicated a desire to expand the UFD pathway to allow decisions from additional foreign regulatory authorities. Accounting for all feedback received from industry stakeholders, to ensure that Canadian firms have sufficient time to meet all requirements after the proposed Regulations are implemented, the *Biocides Regulations* have a one-year delayed coming into force for all companies, followed by a 4-year transition period for existing surface sanitizers currently registered under the *Pest Control Products Act* and disinfectants authorized under the *Food and Drugs Regulations*. There will also be a 6-year transition period for surface sanitizers for use in food premises to obtain a market authorization under the *Biocides Regulations*. This delayed coming into force period will provide time for industry to prepare and update internal processes to comply with the new requirements within their normal business cycle.

The longer transition periods are expected to decrease environmental impacts by allowing companies to transition at a time that allows them to clear current stock and update labels (if required) within their normal business cycle, decrease compliance costs for companies, afford companies with more options to decide when and how to transition their biocides, decrease the likelihood of a bottleneck in the application review process and, improve Health Canada's ability to manage the anticipated influx of applications.

**Recommendation 3: That the Government of Canada identify the most significant barriers to exports of Canadian biocides, including to the United States. The Government should then develop and implement a strategy to eliminate or reduce those barriers and to increase the value of these exports.**

The Government of Canada will use existing channels to identify, address and reduce significant barriers to export for Canadian businesses through the appropriate mechanism, and where necessary. These include the negotiation of comprehensive free trade agreements (FTA), providing support to exporters through the Trade Commissioner Service (TCS), and raising concerns about export barriers with Canada's trading partners both bilaterally as well as multilaterally through the World Trade Organization (WTO).

To provide commercially meaningful market access for Canadian exporters, the Government of Canada pursues robust obligations in its FTA negotiations that can support the elimination of non-tariff barriers (NTBs) that are protectionist, arbitrary, discriminatory, unnecessarily trade restrictive or unjustifiable (hereafter "unjustified"). Building on and complementing the WTO Agreements, Canadian trade negotiators seek the inclusion of strong and enforceable disciplines as well as consultative and dispute resolution mechanisms to prevent and address unjustified NTBs.

These provisions are especially important for small- and medium-sized enterprises (SMEs) with less capacity to manage regulatory burdens. The Government also supports SMEs by ensuring they have access to the right resources, information and tools required to participate in trade, access global opportunities and supply chains, benefit from international trade and investment opportunities, and succeed in global markets. The SME chapters included in Canada's most recent

FTAs seek to promote cooperation and the sharing of best practices between governments to encourage all parties to take constructive measures to facilitate the inclusion of SMEs in international trade. The current mandate of Global Affairs Canada's TCS includes advancing trade diversification by supporting Canadian companies, especially SMEs, through the promotion of Canada's FTAs. The TCS proactively promotes FTAs to Canadian businesses and stakeholders through awareness-building activities such as events, webinars, tools and online educational content, prioritizing Canada's FTAs with its largest trading partners, including the Canada-United States-Mexico Agreement (CUSMA), the Canada-European Union Comprehensive Economic and Trade Agreement (CETA), the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), and the Canada-Korea Free Trade Agreement (CKFTA). The TCS, with Global Affairs Canada colleagues and partner departments, will continue to support clients in exporting their products abroad and resolving market access issues.

The Government of Canada works with stakeholders and foreign governments to align regulatory requirements with trading partners, as appropriate, to reduce regulatory barriers to trade and increase transparency and coordination. In Canada, the Cabinet Directive on Regulation requires regulators to examine the regulatory systems of relevant jurisdictions as well as the work of international standard development organizations to identify potential areas for alignment or cooperation. Through bilateral and multilateral regulatory cooperation, the development and use of international standards and the use of conformity assessment arrangements, the Government is committed to strengthening Canada's trading relations with key partners with a view to eliminate, reduce, resolve and prevent unjustified NTBs. It is important to recall that regulations must respond to a country's unique domestic regulatory environment. It is possible that while two countries may regulate in different ways, the outcome of a regulatory process may be similar enough to give confidence that an imported product meets the same objective, such as safety and efficacy, as a product produced in Canada.

To the extent possible, Health Canada has taken steps to ensure that Canadian biocides for export are not subject to undue barriers. Biocides that are manufactured in Canada for export only (not to be sold in Canada) can be exempted from the *Food and Drugs Act* and *Biocides Regulations* if they meet certain conditions. For example, the product must not contravene any known legal requirement of the country to which it is being exported.

**Recommendation 4: That the Government of Canada, on an expeditious basis, establish a working group that would identify regulatory gaps and propose solutions to those gaps with the goal of eliminating obstacles to achieving reciprocity with the country's trading partners – particularly the United States – concerning the recognition of Health Canada's decisions regarding the market authorization for the domestic sale of biocides. This working group should include representatives from Canada's biocides sectors, as well as other relevant stakeholders.**

The Government of Canada recognizes the key role stakeholders play in identifying irritants and bottlenecks that affect innovation and economic growth in the health and biosciences sector. Building on work that is already in progress, the Government will use existing fora to explore these issues further, rather than creating a separate working group. For example, the *Biocides Regulations* form a part of broader work on modern regulations related to the Government of Canada's overall Health and Biosciences Sector Regulatory Review Roadmap. Engagement of stakeholders to identify regulatory barriers and solutions will continue to be an important component of this, and future sectoral reviews. In addition, increased harmonization is a continued topic of discussion with trusted counterparts (for example, the U.S. Environmental Protection Agency (U.S. EPA) and others through international scientific working groups). Health Canada participates in international scientific working groups such as the Organisation for Economic Co-operation and Development Working Party on Biocides with the goal of achieving improved international harmonization of standards for biocides. The Department also has bi-monthly working-level meetings with the U.S. EPA to ensure a consistent approach to reviewing biocides and the types of evidence required to support industry's biocide applications.

Health Canada will continue to prioritize this work and build on the harmonization initiatives through engagement with international regulators on the possibility of recognition of our

authorization of biocides. However, Health Canada will also continue to engage with representatives from the biocides sector to identify regulatory gaps and propose solutions to those gaps with the goal of eliminating obstacles to achieving reciprocity with foreign regulators.

In addition, when the *Biocides Regulations* come into force, the authorization and regulation of biocides will be under a single framework, which aligns with how they are regulated internationally (for example, in the U.S., the United Kingdom and the European Union). The Government of Canada actively works to expand opportunities for regulatory cooperation and the development of aligned regulations wherever possible, including with the *Biocides Regulations*.

There are several challenges with respect to reciprocity for biocide authorizations to note. For example, many international regulators have a review that is broader than the Canadian review (for example, environmental impacts, review/registration of active ingredients separately from an end use product); regulate biocides as pesticides, not drugs, given differences in legislative frameworks; and rely on different test methods for efficacy studies.

As international work to harmonize requirements for biocides progresses, reciprocity may be more likely in the future.