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CANADA'S PROPOSED BIOCIDES REGULATIONS: POTENTIAL TRADE-RELATED IMPACTS

Report of the Standing Committee on International Trade

Honourable Judy A. Sgro, Chair

APRIL 2024
44th PARLIAMENT, 1st SESSION

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NOTICE TO READER

Reports from committees presented to the House of Commons

Presenting a report to the House is the way a committee makes public its findings and recommendations on a particular topic. Substantive reports on a subject-matter study usually contain a synopsis of the testimony heard, the recommendations made by the committee, as well as the reasons for those recommendations.

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THE STANDING COMMITTEE ON INTERNATIONAL TRADE

has the honour to present its

SIXTEENTH REPORT

Pursuant to its mandate under Standing Order 108(2), the committee has studied Canada's proposed biocides regulations: trade impacts for certain Canadian sectors and has agreed to report the following:

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LIST OF RECOMMENDATIONS

As a result of their deliberations committees may make recommendations which they include in their reports for the consideration of the House of Commons or the Government. Recommendations related to this study are listed below.

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. 10

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. 10

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. 10

CANADA'S PROPOSED BIOCIDES REGULATIONS: POTENTIAL TRADE-RELATED IMPACTS

INTRODUCTION

On 7 May 2022, following consultations with business trade associations, Health Canada pre-published proposed biocides regulations (hereafter, proposed regulations) in the Canada Gazette, Part I. The proposed regulations indicate that biocides are products that "sanitize or disinfect hard or soft non-living and non-liquid surfaces to prevent disease in humans or animals." They include disinfectants and surface sanitizers.

Disinfectants and surface sanitizers are regulated under the *Food and Drugs Act* (FDA) and the *Pest Control Products Act* (PCPA), respectively. Their ingredients, risks, benefits, safety and efficiency are similar, but they are subject to different market authorization requirements, approval fees and timelines.

According to Health Canada, the proposed regulations would: establish a single regulatory framework for biocides; enable a risk-based regulatory approach to biocides; and create a "use of foreign decisions pathway" (hereafter, UFD pathway or pathway) to allow firms making an application for a market authorization to import biocides or to sell identical biocides domestically to rely on a "trusted" foreign regulatory authority's decision when making their application to Health Canada. Biocides covered by the proposed regulations are disinfectants currently regulated under the Food and Drug Regulations and surface sanitizers that meet the FDA's definition of "drug."

Under the proposed regulations, provided that certain requirements are met, Health Canada would issue a market authorization to a firm wishing to "import, sell or advertise" a biocide. In its application for a market authorization, the firm would have to include a list of the biocide's active ingredients, information regarding the benefits and risks associated with the biocide, and the names and contact information for: the firm importing the biocide; the firm manufacturing the biocide; and the firm packaging or labelling the biocide. As well, if the biocide is a pest control product currently registered under the PCPA or a drug for which Health Canada has assigned a drug identification number, the firm's application would have to indicate the pest control product registration number or the drug identification number, respectively.

Health Canada plans to conduct additional consultations with business trade associations, and to consider the information gained during those consultations and

resulting from pre-publication of the proposed regulations, before publishing biocides regulations in the Canada Gazette, Part II.

On 17 October 2023, the House of Commons Standing Committee on International Trade (the Committee) adopted a motion to study the impacts of the proposed regulations, including its UFD pathway and the creation of a new category of regulated biocides, on the extent to which domestic and foreign biocides manufacturers compete with each other in Canada.

During two meetings held on 31 October and 2 November 2023, the Committee heard from Government of Canada officials, four trade associations and one Canadian firm. As well, the Committee received two written briefs.

This report summarizes comments made by witnesses and contained in the briefs submitted to the Committee about the proposed regulations. In particular, the first three sections provide observations about the proposed regulations' potential direct and indirect trade-related impacts on Canadian importers and consumers of biocides and related products, domestic manufacturers of biocides and related products, and Canada's trade relations. The final section contains the Committee's thoughts and recommendations.

The report does not summarize comments that are not focused on trade. For instance, Flexo Products Limited discussed the labelling provisions of the proposed regulations and the Government of Canada's decision to exclude air sanitizers from those regulations.

IMPACTS ON CANADIAN IMPORTERS AND CONSUMERS OF BIOCIDES AND RELATED PRODUCTS

Health Canada officials indicated that the proposed regulations are designed to "build on the lessons" that Canada "learned" during the COVID-19 pandemic when there was an "influx" of applications for a market authorization to sell biocides. They also said that, during the pandemic, interim measures were adopted to allow certain biocides to be imported into Canada. The Canadian Consumer Specialty Products Association contended that the proposed regulations would improve Canada's "preparedness" for a future pandemic. Flexo Products Limited, which manufactures biocides, noted the challenges that the firm experienced when importing raw materials—biocidal active ingredients—from the United States during the pandemic, and emphasized a need for Canada to have guaranteed access to these production inputs.

According to Health Canada officials, the proposed UFD pathway would streamline—and enhance the efficiency of—Health Canada's process for approving applications for a market authorization relating to the domestic sale of biocides that a designated foreign regulatory agency has already approved for sale. In claiming that Canada's current regulations regarding biocides are "cumbersome and inefficient," Food, Health and Consumer Products of Canada described the proposed regulations as "a step forward, … especially for [Canadian] consumers and taxpayers."

Health Canada officials also stated that the proposed UFD pathway would potentially increase the number of biocides for sale in Canada, especially innovative U.S. products. The Canadian Consumer Specialty Products Association argued that the proposed pathway would increase Canada's supply of disinfectants and sanitizers, with CropLife Canada asserting that the result could be the sale of innovative "infection prevention" products in Canada. Food, Health and Consumer Products of Canada predicted that the proposed pathway would increase competition and innovation in the Canadian biocides market, as well as the number of biocides that firms sell to Canadian consumers. In Food, Health and Consumer Products of Canada's opinion, implementation of the proposed regulations could enhance the affordability of biocides for consumers.

As well, Health Canada officials underscored that the proposed UFD pathway would reduce the cost that firms incur when applying to Health Canada for a market authorization to sell biocides domestically. Likewise, the Canadian Consumer Specialty Products Association's brief contended that the proposed pathway would help to reduce market authorization-related fees.

Moreover, Health Canada officials pointed out that the proposed UFD pathway would create opportunities for small Canadian firms to negotiate licensing agreements that would allow them to sell a foreign firm's biocides in Canada after obtaining a market authorization from Health Canada. Similarly, the Canadian Consumer Specialty Products Association's brief suggested that the proposed pathway would enable Canadian firms to negotiate such agreements, reduce the licensee's cost of registering a foreign firm's biocides with Health Canada, and expedite Health Canada's process for issuing a market authorization regarding the licensee's sale of a foreign firm's biocides.

Finally, Health Canada officials highlighted that, because Canada would apply international safety standards to biocides receiving a market authorization pursuant to the proposed UFD pathway, the safety of biocides available for sale in Canada would not be reduced. Likewise, Food, Health and Consumer Products of Canada asserted that the proposed pathway would not "compromise … consumer safety." However, the Association pour le développement et l'innovation en chimie au Québec claimed that

Health Canada has not yet indicated the approach that will be taken to ensure the safety of a foreign firm's biocides that are sold in Canada.

IMPACTS ON CANADIAN MANUFACTURERS OF BIOCIDES AND RELATED PRODUCTS

In describing Canada's biocides sector, Health Canada officials explained that about 69% of the firms that have received a market authorization from Health Canada to import biocides into Canada or to sell them in the country are domestic; the remaining 31% are foreign firms, of which more than 90% are U.S. firms. They added that about 25% of these Canadian firms are small in size, and that 75% of these small firms sell biocides domestically under the framework of licensing agreements with foreign firms.

Flexo Products Limited said that the firm imports, from U.S. suppliers, the active ingredients needed to manufacture biocides. According to Flexo Products Limited, because the cost to certify the safety and efficacy of disinfectants with a new active ingredient exceeds $500,000, most Canadian biocides manufacturers do not have the human and financial resources to prove the "biocidal claims" for disinfectants and surface sanitizers, instead relying on U.S. firms' biocides-related research and development.

As well, the Association pour le développement et l'innovation en chimie au Québec contended that the proposed regulations would establish a process with the following three phases for a Canadian firm wishing to manufacture biocides: conduct efficacy tests that cost "thousands of dollars," and then wait between 3 and 12 months for the test results; submit an application to Health Canada for a market authorization, which has a cost of between $10,000 and $12,000; and wait between 9 and 12 months for Health Canada to process the application. The Canadian Federation of Independent Business' brief stated that, according to its Quebec members in Canada's biocides sector, the proposed regulations would affect their ability to compete with their U.S. counterparts, which—when compared to domestic firms—could obtain a market authorization from Health Canada to sell biocides in Canada both more quickly and at a lower cost.

In asserting that Health Canada's market authorization process is different for U.S. firms than for Canadian firms, the Association pour le développement et l'innovation en chimie au Québec said that a U.S. firm making an application to Health Canada for a market authorization to sell a U.S. Environmental Protection Agency-approved biocide in Canada would be able to "file an expedited administrative application, pay [US]$3,500 and receive approval for its product within three months." In its opinion, the proposed regulations would "favour" U.S. firms over Canadian firms, most of which are small or

medium in size. The Association pour le développement et l'innovation en chimie au Québec called on the Government of Canada to impose a moratorium on implementation of the proposed regulations to give Canadian stakeholders time to determine the impacts on Canada's biocides sector.

Flexo Products Limited characterized the potential impacts of the proposed UFD pathway on Canada's biocides sector as a "dual-edged sword." The firm underlined that it depends on U.S. products and technologies, but suggested that the proposed pathway would likely increase the number of U.S. manufacturers selling biocides in Canada, and could reduce domestic manufacturers' sales of biocides.

The Association pour le développement et l'innovation en chimie au Québec argued that the proposed UFD pathway would allow food-contact surface sanitizers that have been approved for sale in the United States to "enter the Canadian market immediately," to the "detriment" of Canadian manufacturers of such sanitizers. As well, the Association pour le développement et l'innovation en chimie au Québec claimed that, after implementation of the proposed regulations, Health Canada would have to assess between 700 and 800 applications for a market authorization for these surface sanitizers, a category of products regarding which Health Canada does not currently require such an authorization. In its view, Health Canada would need "two to five years … to complete the entire [market authorization] process" for about 800 food-contact surface sanitizers. Food, Health and Consumer Products of Canada urged the Government of Canada to ensure that "the appropriate resources" are in place to avoid backlogs during Health Canada's market authorization process for biocides.

A reference document that the Canadian Consumer Specialty Products Association submitted to the Committee asserted that, following implementation of the proposed regulations, Health Canada would provide a six-year transition period to allow sufficient time for domestic manufacturers and importers of food-contact surface sanitizers to meet all regulatory requirements, during which time firms could sell these products in Canada without a "biocide authorization number." As well, the reference document mentioned four-year transition periods for other sanitizers and disinfectants, with firms being able to sell these products with a market authorization that Health Canada issued prior to the proposed regulations' entry into force.

In addition, the Canadian Consumer Specialty Products Association contended that the proposed UFD pathway would not "compromise" the domestic competitiveness of Canadian biocides manufacturers because these firms can use other "pathways" to obtain a market authorization from Health Canada for their innovative products. However, the Association pour le développement et l'innovation en chimie au Québec

asserted that allowing foreign approvals of biocides to be recognized in Canada for purposes of a market authorization by Health Canada, as would occur with the proposed regulations, would "harm" Canadian biocides manufacturers.

IMPACTS OF THE PROPOSED REGULATIONS ON CANADA'S TRADE RELATIONS

Global Affairs Canada officials indicated that Canada's trade partners have not raised concerns about the proposed regulations. In their opinion, the proposed regulations might help Canada to increase the value of its international trade relating to biocides.

Health Canada officials said that the proposed regulations would increase the extent to which Canada's regulations concerning biocides are aligned with those of other countries and regions. They also stated that the extent of alignment between Canadian and European Union rules for biocides that wash beef carcasses would be monitored. As well, they mentioned the possibility of discussing these monitoring efforts with their European Union counterparts.

CropLife Canada claimed that the proposed regulations would contribute to regulatory alignment among jurisdictions, and—similarly—the Canadian Consumer Specialty Products Association's brief asserted that regulatory cooperation would be enhanced. The brief also predicted that increased regulatory cooperation would "strengthen" Canada's trade with its partners.

The Association pour le développement et l'innovation en chimie au Québec maintained that the proposed regulations are "modelled on and aligned with" U.S. regulations regarding biocides. However, the Association pour le développement et l'innovation en chimie au Québec also contended that Canada's proposed regulations "don't align with what's happening in Europe and the United States."

In pointing out that Health Canada has identified the U.S. Environmental Protection Agency as the first designated foreign regulator for purposes of the proposed UFD pathway, Health Canada officials noted that other foreign regulators would also be designated, including—potentially—European Union regulators. Food, Health and Consumer Products of Canada stressed that Health Canada would designate only foreign regulators that have criteria for approving the sale of biocides that are aligned with its criteria. According to Food, Health and Consumer Products of Canada, a decision to designate regulators in the "eurozone" would create opportunities for Canadian firms to import biocides from that region.

Food, Health and Consumer Products of Canada also stated that it would be desirable for the U.S. Food and Drug Administration to recognize, through a process similar to Canada's proposed UFD pathway, Health Canada's decisions to provide a market authorization for the domestic sale of a biocide. Similarly, Flexo Products Limited suggested that the U.S. Environmental Protection Agency should adopt an approach similar to Canada's proposed pathway.

However, Flexo Products Limited asserted that, regardless of whether the U.S. Environmental Protection Agency adopts an approach that is similar to Canada's proposed regulations, various logistical and legal reasons would lead Canadian biocides manufacturers to have difficulty exporting to the United States. In providing an example, the firm claimed that such a Canadian manufacturer would have to register its biocide with the U.S. states. Similarly, Food, Health and Consumer Products of Canada argued that U.S. state–level regulatory requirements "complicate" Canadian manufacturers' ability to sell sanitizers that are used in U.S. factories.

The Association pour le développement et l'innovation en chimie au Québec underscored that, because of a lack of regulatory alignment between Canada and the United States both now and following implementation of the proposed regulations, U.S. regulators could not adopt a process for approving the sale of Canadian-manufactured biocides that is similar to Canada's proposed UFD pathway.

THE COMMITTEE'S THOUGHTS AND RECOMMENDATIONS

Biocides are essential to the health of Canadians: they help to prevent disease in humans and animals, and—under the proposed regulations—Canadians would continue to have access to safe and effective biocides. However, because the proposed UFD pathway could increase the number of foreign-manufactured biocides that are available for sale in Canada, the Committee is mindful that implementation of the proposed regulations could have negative impacts on some Canadian biocides manufacturers and their domestic sales. Ideally, the Government would implement the proposed regulations in a manner that would meet policy objectives without undue adverse effects on Canadian biocides manufacturers.

Resources that are appropriate in both type and amount improve the ability of federal departments to provide timely services. The Committee is aware that implementation of the proposed regulations could lead to an increase in the number of applications for a market authorization relating to biocides. To ensure timely authorizations, by the date on which the proposed regulations enter into force, Health Canada should have received resources that are adequate to ensure timely assessment of applications.

Finally, according to the Government of Canada's *2023 Fall Economic Statement*, Canada's trade partners should provide the country's firms with the same market access that Canada provides to foreign firms. The Committee acknowledges that the proposed UFD pathway would increase U.S. firms' access to the Canadian biocides market. A strategy designed to eliminate or reduce any barriers to the sale of Canadian-manufactured biocides in the United States, and to increase the value of Canadian biocides exports, would help to enhance the competitiveness of domestic biocides manufacturers in foreign jurisdictions.

In light of the foregoing, the Committee recommends:

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.

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.

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.

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 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.

APPENDIX A:
LIST OF WITNESSES

The following table lists the witnesses who appeared before the committee at its meetings related to this report. Transcripts of all public meetings related to this report are available on the committee's webpage for this study.

Organizations and Individuals	Date	Meeting
Association pour le développement et l'innovation en chimie au Québec	2023/10/31	78
André Côté, Member, Board of Directors		
Stéphane Lévesque, General Manager, Groupement provincial de l'industrie du médicament (GPIM)		
Canadian Consumer Specialty Products Association	2023/10/31	78
Shannon Coombs, President		
Department of Foreign Affairs, Trade and Development	2023/10/31	78
Callie Stewart, Executive Director, Technical Barriers and Regulations		
Department of Health	2023/10/31	78
Lisa Duncan, Acting Director General and Chief Registrar Officer, Registration Directorate		
David K. Lee, Chief Regulatory Officer, Health Products and Food Branch		
Celia Lourenco, Associate Assistant Deputy Minister, Health Products and Food Branch		
Association pour le développement et l'innovation en chimie au Québec	2023/11/02	79
André Côté, Member, Board of Directors		

Organizations and Individuals	Date	Meeting
CropLife Canada	2023/11/02	79
Émilie Bergeron, Vice-President, Chemistry		
Gregory Kolz, Vice-President, Government Affairs		
Flexo Products Limited	2023/11/02	79
Stephen Parker, President and Chief Executive Officer		
Food, Health & Consumer Products of Canada	2023/11/02	79
Gerry Harrington, Senior Vice-President, Consumer Health		

APPENDIX B:
LIST OF BRIEFS

The following is an alphabetical list of organizations and individuals who submitted briefs to the committee related to this report. For more information, please consult the committee's webpage for this study.

Canadian Consumer Specialty Products Association

Canadian Federation of Independent Business

REQUEST FOR GOVERNMENT RESPONSE

Pursuant to Standing Order 109, the committee requests that the government table a comprehensive response to this report.

A copy of the relevant *Minutes of Proceedings* (Meetings Nos. 78, 79, 92 and 100) is tabled.

Respectfully submitted,

Hon. Judy A. Sgro
Chair