Canadian Consumer Specialty Products Association (CCSPA)

Submission to the Parliamentary Standing Committee on International Trade (CIIT)

October 31, 2023

CIIT Study: Effects of the proposed Canadian *Biocides Regulations* on competition from foreign products within Canada

Who is CCSPA?

The Canadian Consumer Specialty Products Association (CCSPA) is a national trade association that includes 40 member companies in 84 facilities across Canada. We are a $20 billion industry directly employing over 12,000 people and our annual exports are in excess of $1 billion. Our companies manufacture, process, package and distribute consumer, industrial and institutional specialty products such as soaps and detergents, pest control products, aerosols, hard surface disinfectants, deodorizers and automotive chemicals.

Within our purview, we represent leading businesses in the surface disinfectant and sanitizer (biocide) industry, representing a significant portion of the Canadian market. Our members' products can be found in households, hospitals, long-term care facilities, commercial businesses and food establishments across Canada, providing solutions for everyday needs, making our lives safer, and healthier.

What are biocides and how are they currently regulated in Canada?

Biocides include products that sanitize or disinfect both hard and soft surfaces to prevent disease in humans and animals. Under the current framework, disinfectants are regulated as drugs under the *Food and Drug Act* and its Regulations. Disinfectants, when supported by data, can make specific claims (i.e., 99.99% effective) against a range of pathogens, including common bacteria and viruses found in homes, businesses, hospitals and long-term care facilities. Disinfectant claims can include direct efficacy against influenza, respiratory syncytial virus (RSV), salmonella, E. coli, and SARS-Cov-2, the virus that causes COVID-19 and other emerging viral pathogens.

Surface sanitizers are currently regulated as pest control products under the *Pest Control Product Act* and its Regulations. Sanitizers can still inactivate some of the same pathogens as disinfectants, but to a lesser degree of certainty (i.e., 99.9% effective). While both disinfectants and sanitizers share similar risks, benefits, uses and ingredients, their regulation under separate frameworks poses challenges for manufacturers and importers of these products.

Why do we support this draft regulation for disinfectants and sanitizers?

This framework would create one regulation and review within Health Canada, support international alignment, facilitate trade, reduce unnecessary regulatory burden, and encourage new infection prevention and control innovations to be brought to the Canadian marketplace.

To date, our association has actively participated as a key stakeholder in Health Canada's pre-consultation and *Biocides Regulations Canada Gazette*, Part I, regulatory consultation.

CCSPA appreciates the opportunity to appear before Parliamentary Standing Committee on International Affairs as it explores the proposed *Biocides Regulations* and the potential impact of the implementation of a foreign biocide authorization pathway on Canadian manufacturing.

CCSPA believes that the Study and its recommendations will support and further strengthen the proposed Biocides Regulations as it will remove current barriers to biocide market entry and promote greater access to these important products for Canadians in the future.

What are the rationales to support this regulation?

Over the past twenty years, CCSPA has been committed to working with Health Canada and Innovation, Science and Economic Development Canada to advance one risk-based framework for disinfectants and sanitizers under the *Food and Drugs Act*.

In 2020, Canadians faced a new hurdle as a result of the COVID-19 pandemic and the need for a modernized framework was highlighted, as severe shortage of disinfectants and sanitizers were reported in homes, businesses and in health-care settings. As an interim solution, Health Canada implemented temporary policy measures and regulatory flexibilities to successfully allow for the exceptional importation of products approved by comparable foreign regulators. This was to the benefit all Canadians.

Health Canada's new Biocides Framework responds directly to lasting economic challenges and Canadians' increased focus on infection prevention and control in a post COVID-19 environment. It will:

- Create a single regulatory framework that captures all surface disinfectants and sanitizers, including food-contact sanitizers;
- Provide for a rigorous and science-based review system to support a range of pathways for biocide product registration;
- Formalize flexibilities developed during the COVID-19 pandemic through an additional defined Use of Foreign Decision (UFD) pathway;
- Support a competitive business environment;
- Support efficient Health Canada review processes and cost-effective provisions for industry; and
- Diversify and increase the availability of infection prevention and control products in Canada.

This last point is more important than ever as institutional settings, including hospitals and long-term care facilities have reported the significant increase of health care associated infections in the past 5 years, impacting one in every nine hospital patients[1].

How does the Use of Foreign Decision provision within the *Biocides Regulations* support the Government's overall policy objectives post COVID-19 pandemic?

What is the Use of Foreign Decision Pathway?

The Use of Foreign Decision (UFD) pathway is one type of a Health Canada submission approval pathway available to manufacturers and importers of biocides. It allows a company to leverage the approved product decision of a trusted foreign regulatory authority when applying for a new market authorization for the same biocide in Canada.

[1] Provincial Infection Control Network of British Columbia, Healthcare-Associated Infections Surveillance

By doing so, this pathway helps to reduce: 1) authorization time since the safety, efficacy and quality review was conducted previously through the trusted regulatory authority and 2) associated fees to align with the level of effort[2]. To meet the requirements under the UFD pathway, a company must meet several criteria outlined in the Regulations, including identical formulation, same conditions of use, same manufacturing process and specifications, and confirmation that the company possesses or has immediate access to all information submitted to the foreign regulator to support approval. At this time, Health Canada has proposed to limit the use of this pathway to products authorized by the U.S Environmental Protection Agency (EPA), although inclusion of other comparable jurisdictions is being considered as a longer-term objective.

This pathway does not replace current disinfectant registration pathways. Several other authorization pathways exist under the proposed *Biocides Regulations*, including a full biocide review, a novel biocide review, and more condensed registration review options, including a monograph pathway, administrative pathway and labelling-only pathway.

How does the UFD pathway benefit and enhance the Biocides Framework?

Facilitates Increased Supply of Disinfectants and Sanitizers via a Risk-based Framework

As noted above, the proposed Use of Foreign Decision (UFD) registration pathway would rely on the comprehensive and scientifically rigorous review process of trusted foreign regulators to streamline biocide approval in Canada. Through this pathway, manufacturers with products registered in Health Canada approved foreign jurisdictions could leverage already generated and reviewed data, through a streamlined Canadian review process. This is expected to encourage new biocide manufacturers and importers to pursue Health Canada registrations, that may otherwise overlook the Canadian market due to size and return on investment. This pathway is anticipated to result in faster market entry, increased innovation and greater product access for Canadians.

It is also expected to address sustained increases in biocide applications received by Health Canada in the past 2 years, which has accounted for a 201% increase in disinfectant submission volume, as compared to the pre-pandemic period[3].

Supports International Trade and Advances Regulatory Cooperation While Maintaining Canadian Health and Safety Standards

The future *Biocides Regulations* would promote international trade and regulatory cooperation with other jurisdictions, including our largest trading partner, the United States. For the past several years, Health Canada has used information and data to support applications in other jurisdictions, to better inform the review of biocides for market authorization in Canada. Health Canada is proposing to build upon of this practice by formally acknowledging alignment in end-use product biocide scientific review standards between Canada and recognized foreign jurisdictions. This is anticipated to strengthen trade between Canada and other jurisdictions, beginning with the U.S., as more companies enter both markets as a result of this pathway.

[2] Health Canada Draft Biocides Guidance, May 7, 2022

[3] Natural and None-Prescription Health Products Directorate Drug Submission Performance Annual Report, 2021-2022

The UFD review pathway does not diminish Canadian health and safety standards. Manufacturers and importers who submit applications through this authorization pathway will need to meet all Canadian regulatory requirements, including bilingual product labelling, standardized safety statements, robust incident reporting, and post market surveillance obligations. Additionally, any safety signals or foreign regulator issued product changes related to the biocide must be directly reported to Health Canada. The Minister will also be able to request the original data package that the market authorization holder submitted to the foreign regulator as well as any additional information to decide on the benefits and risks of the product.

Supports Competitive Business Environment and Red Tape Reduction

The UFD pathway supports a competitive environment for Canadian businesses and removes barriers to register new technologies on the Canadian market. Recent global events, including geo-political instability and the continued inflationary environment, have increased commodity chemical prices and strained global supply chains. Alignment and use of UFD drives efficiencies throughout the supply chain, reducing complexities for global manufacturers and mitigating potential business and supply disruption. The UFD pathway will also encourage investment in the Canadian market, increasing competition and access to new and diverse infection control and prevention technology at a time when our GDP growth is declining. This authorization pathway is expected to save the biocide industry approximately $26,473,259 million dollars over 15 years ($2,906,622 annualized) and Health Canada approximately $898,230 over the same period[4].

Aligns with Emergency Preparedness Objectives

As noted above, to address significant shortages during the COVID-19 pandemic, Health Canada enabled the importation of disinfectant products authorized in foreign jurisdictions. Throughout this time, Canada imported 289 disinfectants authorized in other jurisdictions, with approximately 93%[5] of product approved by the United States Environmental Protection Agency (US EPA). As we work to strengthen future emergency preparedness and build more resilient supply chains, it is critical that Canada's regulatory system be agile and responsive to potential global disruptions. An authorization pathway that leverages foreign regulator decisions and North American trade channels meets these objectives by not only increasing supply of biocides on the Canadian market, but encouraging new technologies to be registered that may otherwise be cost prohibitive in a smaller market.

Compliments Health Canada's Small and Medium Sized Canadian Business Strategy

The pathway to bringing novel infection prevention and control innovation to the market can be cost prohibitive for small and medium sized businesses. Many companies' business models support "generic" brand or store brand products and smaller niche markets where major market players may be less likely to enter. The UFD pathway offers an important option for these businesses and their customer profile to have more novel and specialized technologies, by enabling companies to sub-license off of biocide innovation supported by global companies. This supports Canadian owned and operated businesses to achieve biocide registration with a lowered barrier to entry, through reduced submission requirements, timelines and registration fees.

[4] Canada Gazette, Part 1, Volume 156, Number 19: Biocides Regulations, May 7, 2022
[5] Health Canada List of biocides for exceptional importation and sale, March 02, 2022

In addition to the UFD pathway, Canadian businesses are supported through a suite of complimentary policy measures that work to ensure Canadian manufacturers can be successful in the biocide market.

- Data generation can be one of the most cost-prohibitive elements of a disinfectant submission, with efficacy testing and quality and safety studies costing well over $100,000 dollars. This is why in 2022, in an effort to strengthen Canada's domestic disinfectant production capacity, the National Research Council and Health Canada, developed, tested and pre-registered disinfectant formulations free of charge to qualified Canadian producers. The three separate registered formulations are intended for use in domestic and commercial settings, have broad-spectrum efficacy and align with both the US EPA and Health Canada approach for claims against Emerging Viral Pathogens.

- Health Canada offers a unique registration pathway for disinfectants that meet pre-defined criteria, known as the Labelling Standard (Monograph) pathway. This pathway, unavailable in comparable jurisdictions, allows for an abbreviated review process for disinfectants that have a well characterized safety and efficacy profile under specific conditions of use and labelling requirements[6]. This pathway is commonly used by small and medium size businesses to support new disinfectant registrations on the Canadian market.

- Canadian small businesses are also supported through fee reduction measures. The 2020 fee update for drugs, including disinfectants, introduced small business fee reduction measures that would be maintained for biocides in the accompanying fee proposal. These small business fee reduction measures would help to protect the interests of small businesses.

Next Steps

The future *Biocides Regulation* provides Canadian regulators and biocide manufacturers and importers the opportunity to embrace a modern, science-based, agile tool which will encourage infection prevention and control innovation and increased consumer choice, at a time when Canadians need it most. The future regulation will also create a more competitive business environment, that facilitates trade, and removes barriers to market entry.

As the Committee undertakes its study of the *Biocides Regulations*, we are respectfully requesting that the Committee fully consider the benefits realized by the implementation of this regulation, including the UFD pathway. As such, we are requesting publication and resources for implementation of this regulation, without delay, which advances our collective objectives of regulatory modernization and agility. This regulation compliments Government of Canada's broader strategies, including addressing ongoing drug shortage challenges, supply chain disruption, and applying lessons learned from the COVID-19 pandemic for future emergency preparedness.

The health and safety of Canadians is our priority, and we are committed to ensuring they have access to these important products, now and in the future.

[6] Guidance Document Management of Disinfectant Drug Applications, April 04, 2020