NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** CANADA**If applicable, name of local government involved (Article 3.2 and 7.2):**  |
| **2.** | **Agency responsible:** Department of Health**Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** Canada's Notification Authority and Enquiry PointTechnical Barriers and Regulations DivisionGlobal Affairs Canada111 Sussex DriveOttawa, Ontario, K1A 0G2CanadaTelephone: (343)203-4273Fax: (613)943-0346Email: enquirypoint@international.gc.ca |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****],** **5.7.1 [****], 3.2 [****], 7.2 [****],** **other****:**  |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Sterilization and disinfection (ICS: 11.080), Chemicals for industrial and domestic disinfection purposes (ICS: 71.100.35) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Biocides Regulations; (100 page(s), in English and French) |
| **6.** | **Description of content:** Products that sanitize or disinfect hard or soft non-living surfaces to prevent disease in humans or animals (collectively referred to as biocides) are currently subject to different requirements, despite having similar risks, benefits, uses and ingredients. Health Canada is proposing a new set of regulations under the *Food and Drugs Act* (FDA) specific to biocides, that would see:* the transfer of disinfectants that are currently regulated under the *Food and Drug Regulations* (FDR) and surface sanitizers regulated under the *Pest Control Products Act* (PCPA) that meet the definition of a drug, to the proposed *Biocides Regulations*;
* the creation of a modern authorization and regulatory framework with safety, efficacy and quality regulatory requirements better suited to biocides;
* the maintenance of a life-cycle approach to the regulation of biocides while supporting requirements and authorities for the continuous post-market monitoring of a biocide's risks and benefits; and
* the creation of a pathway for authorization based on decisions from foreign regulatory authorities.
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| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The objective of this proposal is to introduce a new, modern regulatory framework under the FDA that is specific to the authorization and lifecycle management of biocides. Tailored application and regulatory requirements for these products would facilitate greater international harmonization, reduce administrative burden, provide stronger post-market oversight, and provide Canadians with more timely access to biocides. |
| **8.** | **Relevant documents:** *Canada Gazette*, Part I, 7 May 2022, pages 2081-2180 <https://www.gazette.gc.ca/rp-pr/p1/2022/2022-05-07/pdf/g1-15619.pdf> (available in English and French)Proposed Guidance Document:<https://www.canada.ca/en/health-canada/programs/consultation-proposed-biocides-regulations.html> (English)<https://www.canada.ca/fr/sante-canada/programmes/consultation-projet-reglement-biocides.html> (French) |
| **9.** | **Proposed date of adoption:** To be determined**Proposed date of entry into force:** The proposed Biocide Regulations would come into force one year after they are registered. At this point, all new products entering the market would have to meet the proposed requirements. Those who hold a registration for a surface sanitizer under the PCPA or an authorization for a disinfectant under the FDR would have a transition period of four years from the coming into force date to obtain an authorization under the proposed Biocides Regulations by using an abbreviated application. As registrations for surface sanitizers under the PCPA are renewed every five years, registrants would be able to file an abbreviated application under the proposed Biocides Regulations as their product registrations are set to expire. |
| **10.** | **Final date for comments:** 16 July 2022 |
| **11.** | **Texts available from: National enquiry point [****X]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:** The electronic version of the regulatory text can be found at:<https://gazette.gc.ca/rp-pr/p1/2022/2022-05-07/html/reg2-eng.html> (English) <https://gazette.gc.ca/rp-pr/p1/2022/2022-05-07/html/reg2-fra.html> (French) |