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 Point Global Affairs Canada Technical Barriers and Regulations Division  111 Sussex Drive Ottawa (Ontario) K1A 0G2 Canada Telephone: (343)203-4273 Fax: (613)943-0346 Email: [enquirypoint@international.gc.ca](mailto:enquirypoint@international.gc.ca) |
| **3.** | **Notified under Article 2.9.2 [****],** **2.10.1 [****X],** **5.6.2 [****],** **5.7.1 [****],** **other****:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Human milk fortifiers; Prepackaged and prepared foods (ICS 67.230) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Regulations Amending the Food and Drug Regulations (Human Milk Fortifiers) (12 pages, available in English and in French) |
| **6.** | **Description of content:** The proposed regulations would amend the *Food and Drug Regulations* (FDR) to establish a regulatory framework for the sale of human milk fortifiers (HMFs) in Canada. HMFs are foods which are intended to be added to human milk to increase its nutritional value in order to meet the particular requirements of an infant in whom a physiological condition exists as a result of a disease, disorder or abnormal physical state. There are currently no provisions in the FDR specific to these products, meaning the general food framework applies. Amendments to the FDR are needed to permit HMFs to have added vitamins, mineral nutrients, and amino acids, and to include provisions to safeguard the health and safety of the vulnerable population using HMFs.  The proposed amendments would establish a premarket submission requirement for HMFs new to the market and HMFs that have undergone a major change; permit the addition of vitamins, mineral nutrients, and amino acids to HMFs; set out labelling requirements; and set out conditions of sale. The establishment of clear regulatory requirements would help to ensure continued access to safe and nutritionally adequate HMFs for certain vulnerable infant populations in Canada, enable their use outside of hospitals under medical supervision, and provide greater clarity to manufacturers and importers wishing to sell or advertise for sale these products in Canada. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The objectives of the proposed amendments to the FDR are to help ensure the health and safety of the infant population that rely on HMFs by establishing a regulatory pathway for the sale of these products in Canada. Due to the vulnerability of the infant population that requires these products and given that the proposed regulations are trade facilitating measures, this notification is issued under Article 2.10.1 to expedite the coming into force of these regulations.; Protection of human health or safety |
| **8.** | **Relevant documents:**   * Draft Regulations Amending the Food and Drug Regulations (Human Milk Fortifiers): Policy Paper – Fall 2020 (11 and 12 pages, available in English and French) |
| **9.** | **Proposed date of adoption:** On the day of their publication in the Canada Gazette, Part II.  **Proposed date of entry into force:** These Regulations come into force on the day of their publication in the Canada Gazette, Part II. HMFs which are currently marketed in Canada would have a period of 1 year after this date to come into compliance with the new regulations. |
| **10.** | **Final date for comments:** 15 November 2020 |
| **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 regulations can be downloaded at:  Canada's Notification Authority and Enquiry Point Global Affairs Canada Technical Barriers and Regulations Division  111 Sussex Drive Ottawa (Ontario) K1A 0G2 Canada Telephone: (343)203-4273 Fax: (613)943-0346 Email: [enquirypoint@international.gc.ca](mailto:enquirypoint@international.gc.ca)  <https://members.wto.org/crnattachments/2020/TBT/CAN/20_6165_00_e.pdf>  <https://members.wto.org/crnattachments/2020/TBT/CAN/20_6165_00_f.pdf>  <https://members.wto.org/crnattachments/2020/TBT/CAN/20_6165_01_e.pdf> |