

18 December 2025

Original: English/French

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Committee on Sanitary and Phytosanitary Measures

NOTIFICATION

Addendum

The following communication, received on 17 December 2025, is being circulated at the request of the Delegation of <u>Canada</u>.

Exemption Order in Respect of Foods for a Special Dietary Purpose

The proposed measure notified in G/SPS/N/CAN/1576/Add.1 (dated 3 July 2025) was adopted and published on 17 December, 2025, as the *Exemption Order in Respect of Foods for a Special Dietary Purpose* (the Order).

This Order contains two parts:

- Part 1 enables the exceptional importation and/or sale of infant formula (IF), human milk fortifiers
 (HMF) and formulated liquid diets (FLD) in the case of a shortage or risk of shortage, by exempting
 foods that meet the class criteria from specified provisions of the Food and Drugs Act (FDA) and
 Food and Drug Regulations (FDR); and
- Part 2 permits the continued exceptional importation and sale of IFs and HMFs that are part of Health Canada's Transition Strategy (https://www.canada.ca/en/health-canada/services/food-nutrition/public-involvement-partnerships/notice-stakeholders-transition-strategy-prepare-expiration-interim-policy-mitigate-infant-formula-shortages.html) while the pre-market review for these foods is underway, by exempting them from specified provisions of the FDA and FDR.

To ensure that the Order's exemptions do not introduce unacceptable health and safety risks, specific conditions relating to the food's label, notifications to the Minister of Health and restrictions on the sale of HMFs are imposed.

The Order came into force on 17 December 2025, the day on which it was published in *Canada Gazette*, Part II.

This addendum concerns a:

| Modification of final date for comments |
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| Notification of adoption, publication or entry into force of regulation |
| Modification of content and/or scope of previously notified draft regulation |
| Withdrawal of proposed regulation |
| Change in proposed date of adoption, publication or date of entry into force |
| Other: |
| |

Comment period: (If the addendum extends the scope of the previously notified measure in terms of products and/or potentially affected Members, a new deadline for receipt of comments should be provided, normally of at least 60 calendar days. Under other circumstances, such as extension of originally announced final date for comments, the comment period provided in the addendum may vary.)

| [] | Sixty days from | the date o | f circulation | of the | addendum | to the | notification | and/or |
|----|-----------------|--------------|---------------|--------|----------|--------|--------------|--------|
| | (dd/mm/yy): No | t applicable | ! | | | | | |

Agency or authority designated to handle comments: [] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

Text(s) available from: [] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

The electronic versions are available at:

https://gazette.gc.ca/rp-pr/p2/2025/2025-12-17/html/sor-dors248-eng.html (English) https://gazette.gc.ca/rp-pr/p2/2025/2025-12-17/html/sor-dors248-fra.html (French)

or requested from: Canada's Notification Authority and Enquiry Point Technical Barriers and Regulations Division Global Affairs Canada 111 Sussex Drive Ottawa, Ontario K1A 0G2

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