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Report Name: Consultations Launched on A Regulatory Framework for Supplemented Foods

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Post: Ottawa

Report Category: Policy and Program Announcements

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Report Highlights:

Health Canada launched public consultations on a proposed regulatory framework for supplemented foods, closing on August 25, 2021. The draft regulations stipulate which foods can be supplemented and the supplemental ingredients that can be used. The draft regulations also include labeling requirements for a caution identifier and supplemented food facts table. Currently, supplemented foods are regulated on a case-by-case, temporary basis through marketing authorization letters.

Health Canada published proposed Regulations Amending the Food and Drug Regulations (Supplemented Foods) in Canada Gazette, Part I, and invited stakeholders to submit comments as part of a public consultation process **closing on August 25, 2021** at the following **email address:** hc.lrm.consultations-mlr.sc@canada.ca, adding " Proposed regulations for supplemented foods" in the subject line.

Supplemented foods are prepackaged foods containing supplemental ingredients, such as vitamins, mineral nutrients, amino acids, or other ingredients (like caffeine and herbal extracts). Typical examples include beverages with added minerals, caffeinated energy drinks, and snack bars with added vitamins. According to Health Canada, the presence of these supplemental ingredients sets these foods apart from regular foods, as they may pose a health risk if they are consumed in excess by the general population or if consumed by vulnerable populations such as children and pregnant women.

The proposed regulatory framework includes the following elements specific to supplemented foods:

- A "**List of Permitted Supplemented Food Categories**" capturing the specific categories of food to which supplemental ingredients may be added;
- A "**List of Permitted Supplemental Ingredients**" capturing all substances that may be added to a specified food as a supplemental ingredient, grouped by vitamins, mineral nutrients, amino acids, and other supplemental ingredients; additionally, this list would also set out specific requirements for each supplemental ingredient, such as the food categories in which the supplemental ingredient is permitted, the maximum level of use of the supplemental ingredient in the product, cautionary statements on the product label (if applicable), and other applicable ingredient-specific conditions;
- A "**Supplemented food facts table**" to be included on the product label, replacing the otherwise required Nutrition Facts Table; and
- Labeling requirements in terms of "**cautionary statements**" (in cases where the added supplemental ingredient would trigger such a statement) and a "**supplemented food caution identifier**" (for those foods where added supplemental ingredients triggered cautionary statements).

Currently, supplemented foods can be marketed in Canada based on a Temporary Marketing Authorization granted by Health Canada on a case-by-case basis. The department issued specific guidance for supplemented foods, and publishes a list of foods that have received Temporary Marketing Authorization (TMA) letters.

According to the proposed regulations, existing supplemented foods on the market (having TMAs issued by Health Canada) would be provided a transition period of three years to come into compliance once final regulations come into force.

Additionally, Health Canada indicated it would continue to accept TMA applications up until the coming into force date of the new regulations and would continue to process these applications following the coming into force date. Approved products would be allowed on the market based on conditions set out in the transitional provisions and on existing requirements under the TMA framework.

Such products would benefit from the remainder of the three-year transition period for complying with the new regulations.

However, new supplemented foods coming to market following the coming into force of the new regulations would be required to comply immediately with the new regulations.

To facilitate stakeholder engagement in the consultation process, Health Canada made available the following documents (all of which are attached to this report):

- List of Permitted Supplemented Food Categories
- List of Permitted Supplemental Ingredients
- Directory of Supplemented Food Facts Table Formats
- Directory of Supplemented Food Caution Identifier Specifications
- Threshold Levels for Cautionary Statements and Other Conditions of Use
- Guidance Document to facilitate an understanding of the proposed regulatory requirements for supplemented foods

Attachments:

EN Directory of Supplemented Food Caution Identifier Specifications.pdf

EN Directory of Supplemented Food Facts Table Formats.pdf

EN Guidance Document- Supplemented Food Regulations- June 2021.pdf

EN List of Permitted Supplemental Ingredients.pdf

EN List of Permitted Supplemented Food Categories.pdf

EN Threshold Levels for Cautionary Statements and Other Conditions of Use.pdf