# Supplemented Foods
# A Growing Trend in Canada

**Canadian Association of Professionals in Regulatory Affairs - Webinar**

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# Today's Agenda

1. About Supplemented Foods
2. Requirements for Supplemented Foods
3. Future of Supplemented Foods

# The Food-NHP interface

- The *Natural Health Products Regulations* (NHPR) came into force in January 2004.

- Because of the restrictions in the *Food and Drug Regulations* (FDR), and the compliance policy associated with the NHPR (enabling immediate market access), food products with added vitamins and minerals, bioactives or with certain health claims sought and were able to gain market access as Natural Health Products (NHPs):




# Food-NHP classification

- The Food-NHP Classification Committee was formed several years ago to oversee the classification of products at the Food-NHP interface.
- The committee consists of an equal number of members from the Food Directorate and the Natural and Non-Prescription Health Products Directorate.
- Classification decisions are based on 4 specific guiding principles (first outlined in the guidance document *Classification of Products at the Food-Natural Health Product Interface: Products in Food Formats*).




# The transition

- Health Canada determined, based on product format, public perception and history of use, product representation to consumers, and product composition that most of the products at the Food-NHP interface fit the definition of a food.

- Health Canada undertook a phased approach to the transition:
  1) Caffeinated Energy Drinks (CEDs) were transitioned first, following the Ministerial announcement in October 2011.
  2) Additional categories began to transition in April 2012.




# The transition (cont'd)

- Nature of products challenged traditional food regulatory approach:
  - Current model of food consumption generally without conditions (*ad libitum*), while these products often need conditions of use.
  - Generally contained nutrients at levels beyond public health need, as well other ingredients not usually found in foods and promoted for health benefits.
  - No regulatory provisions to accommodate most products under current FDR (non-compliant).

- Information gaps to develop final regulatory requirements for these products → decision to use Temporary Marketing Authorizations (TMAs) for transition




# Temporary marketing authorization letter (TMAL)

- Health Canada uses TMALs* (FDR B.01.054-055) to allow non-compliant foods to be sold temporarily while gathering the information needed for potential regulatory amendments that will modernize the food regulatory framework.

- TMAL issuance comes with certain requirements, e.g.:
  - Conduct research to address data gaps;
  - Submit sales and marketing data;
  - Include label caution statements needed for safe use, if required;
  - Submit annual report on consumption incidents, if required;
  - Withdraw food from sale upon request if Health Canada is of the opinion that it is in the public interest to do so; and
  - Abide by other terms or conditions deemed necessary (e.g. no caffeinated energy drink sampling to children).




# The transition (cont'd)

- End goal: Products that look like foods and are consumed as foods are regulated as foods.
  - Canadians are able to make informed choices due to consistent nutrition information and labelling.
- Health Canada continues to use classification criteria as needed to determine the appropriate regulatory framework for these food products.
- Continue to issue TMALs for supplemented food products.




# What is a supplemented food?

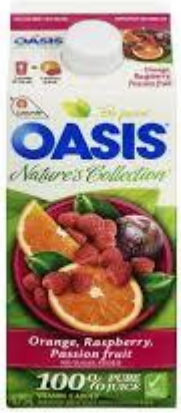
A supplemented food is broadly defined as "*a pre-packaged product that is manufactured, sold or represented as a food, which contains added vitamins, minerals, amino acids, herbal or bioactive ingredients. These ingredients may perform a physiological role beyond the provision of nutritive requirements*"

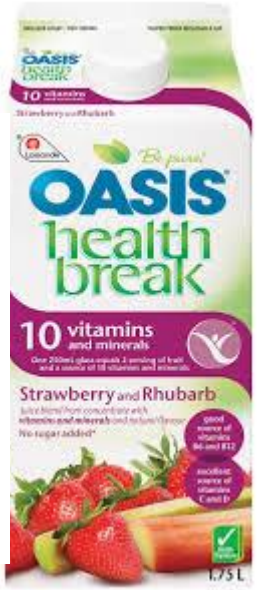



# Which Products are Supplemented Foods?





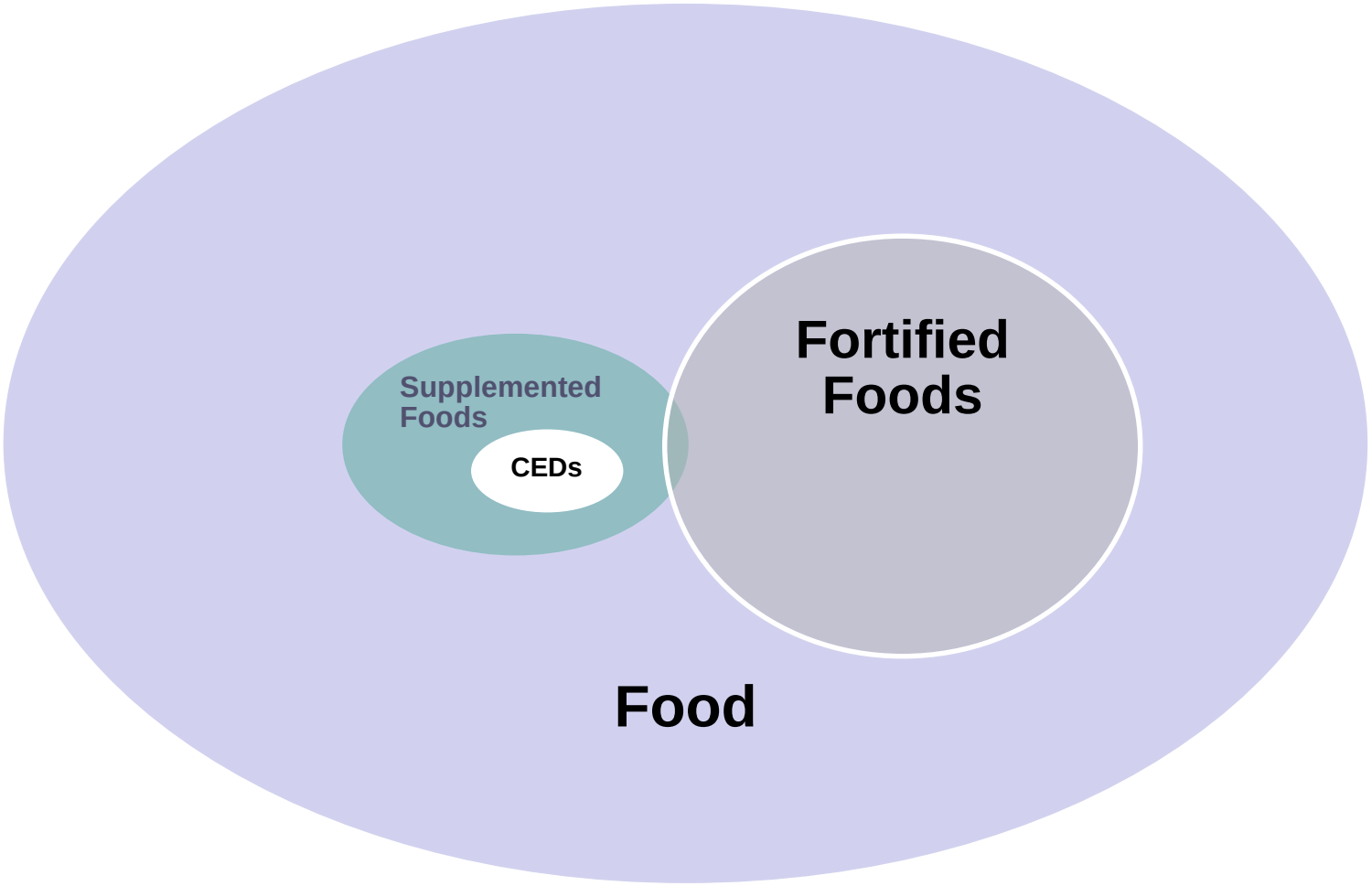






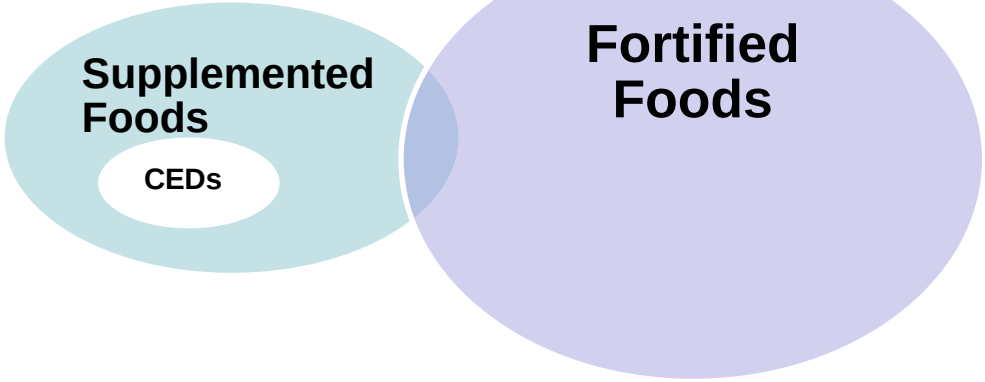

# Situating supplemented foods




# Situating supplemented foods








# Guidance

- Requirements for CEDs are outlined in *Category Specific Guidance for Temporary Marketing Authorization: Caffeinated Energy Drinks* (published March 2012, updated December 2013).

- Health Canada published the guidance, entitled *Category Specific Guidance for Temporary Marketing Authorization: Supplemented Food* February 2016.

- Both guidance documents set out  scope, compositional and labelling / advertising requirements.

- There are a number of categories of food that are scoped out of the definition of supplemented food.


Guidance document available*:*
***www.hc-sc.gc.ca/fn-an/legislation/guide-ld/sf-tma-amt-as-eng.php***

# Caffeinated energy drinks

- Compositional requirements: limits on caffeine, type/level of vitamins, milk/juice content
- Labelling requirements: standard FDR (e.g. Nutrition Facts table), declaration of amount of caffeine from all sources, caution statements
- Consumption incident reporting




# Supplemented food guidance

- Applies to a subset of supplemented foods with added vitamins, minerals, amino acids, herbals and/or bioactives that were issued TMALs, and similar new products in the formats that were seen during the transition.
  - i.e. beverages, beverage mixes and concentrates, powders, bars and some types of confectionaries.

- Sufficient pool of products from which to collect data.




# Maximum levels of vitamin and mineral addition

- Maximum levels have been established for vitamins and minerals to help ensure that their addition to foods does not contribute to excessive intakes.
  - Maximum levels will not be set for amino acids at this time.

- Health Canada has developed a 2 tier approach; each path corresponds to a set of maxima and, in the case of Path 2, labelling requirements.




# Maximum levels

## Two-path approach

### Path 1

- Captures products with a lower potential for adverse health effects
- Appropriate for use by the general population, ≥ 4 years

### Path 2

- Captures products with a higher potential for adverse health effects
- Not intended for children, < 14 years
- Cautionary labelling and directions for use (as needed)

*The 2-path approach will help consumers to more clearly distinguish between products with a lower vs. those with a higher potential for adverse health effects*




# Details of 2-path approach

| PATH | APPROACH | LABELLING |
|---|---|---|
| **PATH 1** (max per serving) | (SDM – 95$^{th}$% dietary intake– supplements) [1] ÷ 5 | • No additional labelling required |
| **PATH 2** (daily max) | (SDM – 95$^{th}$% food)$^{2}$ ÷ 2 | • Cautionary statements required<br>• As levels increase more cautionary statement are required |

1. Inputs determined by most vulnerable pop, ≥ 4 years
2. Inputs determined by most vulnerable pop, ≥ 14 years




# Novel ingredients

- Some supplemented foods contain ingredients that are included solely for their purported health benefits, with no known food purpose.
- The majority of these ingredients are likely to be considered novel based on the regulatory definition.
- Recognising that the approach taken during the transition challenges the current food regulatory structure, the Food Directorate has developed an option to risk manage this sub-set of ingredients while a broader review of the Novel Food regulations is underway.




# Labelling

- Health Canada is exploring the possibility of an identifier to be included on the principal display panel of the label for all supplemented foods to assist consumers in recognizing that these products are different from regular foods.
- In addition, accompanying label specifications such as standard formatting around caution statements and directions for use is also being investigated for these products.
- Different identifiers/labelling has been developed which will be tested.



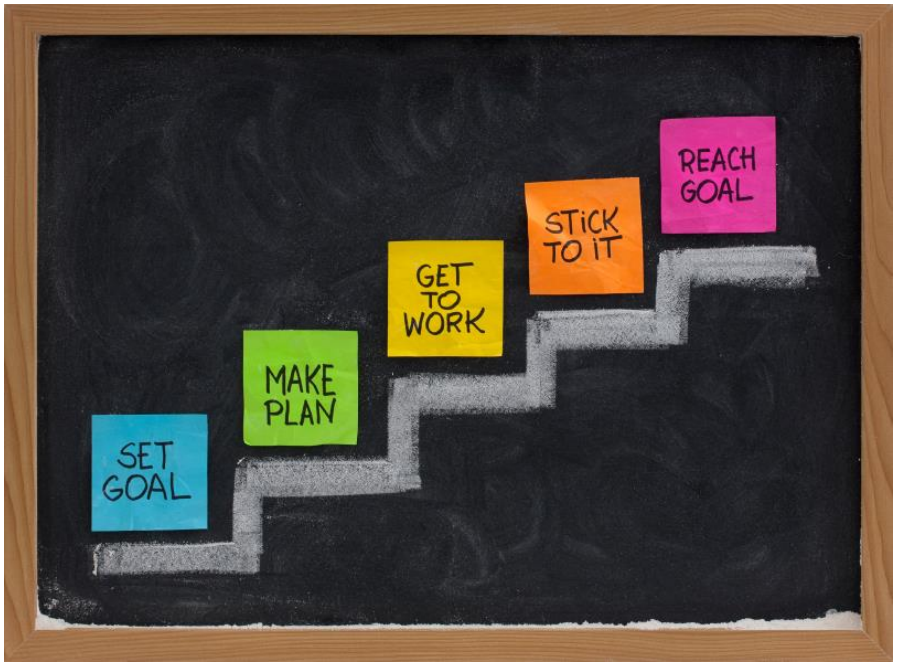

# Need for education

- There are many complexities around what is considered a supplemented food.
- Intermediaries and consumers may not be aware that these products are on the market and are different from regular foods.
- Intermediaries and consumers may not understand the information they see on the labels of these foods (e.g. high %DV, directions for use, caution statements).

**A Knowledge Translation & Education (KT&E) strategy is needed to help inform intermediaries and consumers about supplemented foods**

# Goal of the KT&E Strategy

To help Canadians make informed choices about supplemented foods







# Key Research Activities

**Prevalence and Trends In Canadian Market**

**Discussion Groups with Consumers (health literacy lens)**


**Discussion Groups with Health Intermediaries**

**2 On-line Surveys**

# On-Line Course

- Developing an online course about supplemented foods.
- Course to be divided into different modules.


A PHAC Collaboration
"Skills on Line"




# Path Forward

## KT&E

- Consumer and health intermediary research to be conducted on the ability to notice, understand, assess benefits and risks, and use supplemented food label information to make informed choices.

## Regulatory path

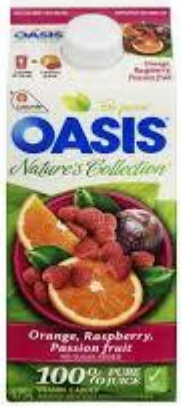
- Multi-Directorate working group formed to begin analysis and development of regulatory options for supplemented foods.




# Which Products are supplemented foods?













# Questions?




# Thank You!

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