Regulation and Potential Impact of Food &
Natural Health Products Advertising:
A Canadian Perspective

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Acknowledgement

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Outline

- **Definitions and Regulatory Framework**
  - Applicable legislation
  - Requirements, Policies, Guidelines
  - Advertising preclearance
  - Advertising vs. other activities
  - Health Canada and stakeholders’ roles

- **Advertising Issues and Potential Impact**
  - Food
  - Natural health products (NHPs)
Food

- Includes any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever (Section 2, Food and Drugs Act – F&DA)

- Food and Drug Regulations (FDR, Parts A, B & D)
Natural Health Products  
(Section 2, F&DA and Section 1, Natural Health Products Regulations - NHPR)

- **Subcategory of drug**: product license required before marketing
- **Non-prescription** (Section 2(2), NHPR)
- Means a **substance set out in Schedule 1** or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is **manufactured, sold or represented for use in**

  (a) the **diagnosis, treatment, mitigation or prevention of a disease**, disorder or abnormal physical statement or its symptoms in humans;
  
  (b) **restoring or correcting organic functions** in humans; or
  
  (c) **modifying organic functions** in humans, such as modifying those functions **in a manner that maintains or promotes health**.

Vitamin C

“A factor in the maintenance of good health”

90 capsules

NPN 12345678
Natural Health Products (cont’d)

- Schedule 1 substances

1. A plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material
2. An extract or isolate of a substance described in item 1, the primary molecular structure of which is identical to that which it had prior to its extraction or isolation
3. Any of the following vitamins: biotin, folate, ... vitamin K₁ & K₂
4. An amino acid
5. An essential fatty acid
6. A synthetic duplicate of a substance described in any of items 2 to 5
7. A mineral
8. A probiotic
Advertising – Applicable Legislation

- **Food and Drugs Act** (Health Canada)
  - Advertisement: Any representation, by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device

- **Consumer Packaging and Labelling Act** (Canadian Food Inspection Agency)
  - Applicable to food
  - Advertise: Make any representation to the public by any means, other than a label, for the purpose of promoting directly or indirectly the sale of a product …
Advertising – Applicable Legislation (2)

- **Competition Act** (Industry Canada)
  - Governs misleading advertising and deceptive marketing practices with general application to all Canadian media advertising
  - F&DA specifically applies to food and drugs; takes precedence over the Competition Act

- **Broadcasting Act** (Canadian Radio-television and Telecommunications Commission)
  - Broadcaster may be required to follow industry code as a condition of its licence
  - Self-regulatory codes and guidelines developed by the Canadian Association of Broadcasters
Prohibition: applicable to both food and NHPs

- “No person shall label, package, treat, process, sell or advertise any food / drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety” (5 & 9, F&DA)
  - Advertising information must be consistent with the terms of market authorization
  - Unauthorized products/claims cannot be promoted

- “No person shall advertise any food, drug … to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A” (3, F&DA)
  - Exemption (prevention claims only) for NHPs (103.2 & 103.3, NHPR)
  - Exemption does not apply to food (B.01.601, FDR)

- No reference, direct or indirect, to the Act, the FDR, or NHPR on any label or in any advertisement unless the reference is provided for, or specifically required by law (B.01.013, FDR; 92, NHPR)
Advertising – Policies & Guidelines

- **Food**
  - Guide to Food Labelling and Advertising (Canadian Food Inspection Agency)

- **NHPs, e.g.**
  - Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products)
  - Principles for Claims relating to Comparison of Non-therapeutic Aspects of Non-prescription Drug Products
  - Therapeutic Comparative Advertising – Directive and Guidance Document
  - The Distinction between Advertising and Other Activities
  - Health Canada’s Position Statement on the Preclearance and Complaint Adjudication of Exempted Natural Health Product Advertising Materials
Advertising vs. Other Activities

Considerations – Food

- Educational
  - Informing
  - Generic content – no mention of product brand names
  - Food groups or classes in diet context
  - Sponsorship identified without undue prominence

- Advertising
  - Promoting
  - Placement of educational material in close proximity to food referred to in the material
  - Emphasizing the benefit of a particular brand
Considerations – Drugs

- Context
- Audiences – primary and secondary
- Provider of the message
- Sponsor of the message
- Influence of the product manufacturer on the message
- Message content
- Frequency of the message
Advertising – Preclearance

- Advertising in all media directed to consumers
  - Preclearance not mandatory
  - Required by Code of Ethics of Canadian Association of Broadcasters
  - Strongly recommended by Health Canada and industry associations (drugs)
  - Must also meet broadcaster’s standards and be pre-approved by the broadcasters
  - Preclearance not required for food that does not make a claim
Advertising - Roles

- **Policies, guidance for interpretation**
  - Health Canada
    - Food Directorate: food
    - Marketed Health Products Directorate: drugs

- **Compliance & enforcement**
  - Canadian Food Inspection Agency: food
  - Health Canada - Inspectorate of the Health Products and Food Branch: drugs
Advertising – Roles (2)

- Advertising preclearance and complaint adjudication

  - Advertising Preclearance Agencies (APAs)
    - Independent of Health Canada
    - Recognized or qualified through attestation based on Health Canada’s criteria for review of drug advertising

  - Advertising to consumers
    - Food and Non-Rx drugs: Advertising Standards Canada & MIJO

  - Advertising to healthcare professionals
    - All health products (Rx and Non-Rx drugs): Pharmaceutical Advertising Advisory Board

- High proportion of children-directed marketing of foods high in fat, sugar or sodium
- Food marketing influences children’s food preferences, consumption patterns and body weight
Canada

- Self-regulated, except in French-speaking media in Quebec
  
  - Quebec
    - Prohibits advertising targeted to children under 13 yrs under provincial Consumer Protection Act
  
  - Other provinces
    - Canadian Code for Advertising to Children
    - Canadian Children’s Food and Beverage Advertising Initiative (CAI)
      - Voluntary for participating companies
      - Promote only company-defined “better-for you” products
      - Criteria for “healthy” foods?
Food Advertising to Children – Response

Federal Task Groups (Health Canada and Public Health Agency)

- Analysis of policy options
- Review of national and international definitions and applications of ‘healthy’ foods
- Development of core nutritional criteria for defining healthy foods in Canada
NHP Advertising - Issues

- Advertising aimed at inappropriate target group(s)
  - e.g. Energy drinks

- Advertising exceeding the terms of market authorization
  - e.g. Fibre supplement marketed for weight management

- Advertising of unauthorized products
## NHP Advertising - Issues (2)

- **Comparative claims across product categories: emerging issue**

<table>
<thead>
<tr>
<th>Point of Comparison</th>
<th>NHP (advertised)</th>
<th>Food (compared)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2X the fibre</td>
<td>Laxative bar</td>
<td>Cereal bar</td>
</tr>
<tr>
<td>↑vitamins - better for you</td>
<td>Enhanced water</td>
<td>Bottled water</td>
</tr>
<tr>
<td>Orange juice goodness with 50%↓calories &amp; sugar</td>
<td>Diluted juice sweetened with stevia + added vitamins &amp; minerals</td>
<td>Regular juice</td>
</tr>
<tr>
<td>Tasty treat</td>
<td>Supplement chew</td>
<td>Chocolate</td>
</tr>
</tbody>
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<th>Point of Comparison</th>
<th>Products (compared)</th>
<th>Food (advertised)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not a drug</td>
<td>NHP &amp; Rx drugs</td>
<td>Juice w/ phytosterol</td>
</tr>
</tbody>
</table>
NHP Use - Prevalence

- **NHP** (Baseline Survey 2005)
  - 71% Canadian adults had used a NHP
  - Among NHP users, 38% reported daily use
  - Most commonly used NHP: vitamins (57%), Echinacea (15%) … supplements (5%)

- **Vitamin-mineral supplements** (CCHS 2.2, 2004)
  - 40% Canadian adults reported use in the past month
Figure 1
Prevalence of vitamin/mineral supplement use, by household income group, age group and sex, household population aged 19 or older, Canada excluding territories, 2004

* significantly lower than highest income group (p<0.05)
Source: 2004 Canadian Community Health Survey—Nutrition.

Vatanparast et al. 2010
Figure 2
Prevalence of vitamin/mineral supplement use, by education, age group and sex, household population aged 19 or older, Canada excluding territories, 2004

Vatanparast et al. 2010
Why do people take NHPs? (Baseline Survey, Focus Group)

- **Vitamin-mineral supplements**
  - ‘Insurance’ to ensure adequate intakes?
  - Higher needs (e.g. pregnancy): recommended by healthcare professionals

- **Herbal preparations**
  - **Personal health concerns**: less side effects; perceived safety, even if less effective
  - Desire to maintain and promote personal health
  - On recommendation of others

- **Ergonomic aids**
  - Athletic performance
Methodological challenges in estimating usual intakes

Varies with the nutrient, e.g.

- **Calcium**
  - ↑ % meeting Adequate Intake (AI), esp. among older women
  - Some exceeding Upper Level (UL)

Sources: CCHS, 2004; Food Habits of Canadians Survey, 1997-98
Figure 3
Percentage meeting Adequate Intake for calcium from food and from food plus supplements, by age group and sex, household population aged 19 or older, Canada excluding territories, 2004

Source: 2004 Canadian Community Health Survey—Nutrition.

Vatanparast et al. 2010
Varies with the nutrient, e.g.

- **Folic acid**
  - % not meeting AI not affected, except for women >70 yr
  - Only 18% reproductive-aged women had recommended amount (400 µg) from diet & supplement
  - No observable benefit for supplements designed for children <14 yr; only children supplemented with folic acid had intake >UL

- **Vitamin C**
  - Supplement provided 43% intake
  - ↓Inadequate Intake by ~5% in most age-sex groups; ~10% among smokers

- **Niacin**
  - No Inadequate Intake
  - Nutrient most commonly exceeding UL (health impact?)

Sources: CCHS, 2004; Food Habits of Canadians Survey, 1997-98; Shakur et al., 2010
Vitamin-mineral supplement use

- Minimal population impact
- Inverse supplement hypothesis: used by people who don’t need to take supplements
- May benefit some individuals
  - Inadequate intakes
  - Restricted diet (e.g. <1200 kcal)

Supplements in food form

- Special labelling + education efforts sufficient in informing consumers about their safe use?
Impact of Food/NHP Advertising?

- Impact on product choices
  - Food advertising
    - Affects food choices
  - NHP/supplement advertising
    - Does NHP/supplement advertising promote use among non-users?

- Impact on diet quality: regulatory perspectives
  - Foods: nutritional criteria for foods advertised to vulnerable groups
  - NHP/supplements: rational basis for product composition