



Health  
Canada

Santé  
Canada

*Your health and  
safety... our priority.*

*Votre santé et votre  
sécurité... notre priorité.*

# Health Canada's Proposed Approach to Managing Caffeinated Energy Drinks

October 2011

Food Directorate  
Health Products and Food Branch



Canada 

## Table of Contents

<b>Background</b> .....	3
<b>Assessment of the Potential Health Risks</b> .....	3
<b>Health Canada’s Proposed Approach to Manage Caffeinated Energy Drinks</b> .....	4
<b>1. Setting Formulation and Labelling Requirements</b> .....	4
<i>1.1 Composition Requirements</i> .....	4
<i>1.2 Labelling Requirements</i> .....	5
<i>1.3 Prohibition of Premixed Alcoholic Beverages with Caffeinated Energy Drinks</i> .....	5
<i>1.4 Consumption Incident Reporting</i> .....	5
<b>2. Consumer Education</b> .....	5
<b>3. Research and Monitoring of Long-term Health Effects</b> .....	5
<b>4. Leverage Tools Developed by Stakeholders</b> .....	6
<b>Conclusion</b> .....	6
<b>Comments</b> .....	6

### Background

In recent years, an increasing number of caffeinated beverages have been introduced into the Canadian marketplace. Some of these products are known as “Energy Drinks”, which usually contain a range of unique ingredients and may feature health claims related to their capacity to restore energy and alertness. A common substance found in most Energy Drinks is caffeine at levels ranging from those found in a weak cup of coffee to much higher levels. These products also generally contain other ingredients such as vitamins and minerals, and may contain various herbals.

Health Canada has determined, based on consumption patterns, history of use, representation to consumers, and in accordance with its guidance document on “[Classification of Products at the Food-Natural Health Product Interface: Products in Food Formats](#)”, that products known as Energy Drinks fit the regulatory definition of a food and as such intends to classify these products as foods. As a result, the Department intends to assess, manage the potential risks associated with these products, and regulate their availability in the Canadian marketplace in the context of their use as a beverage.

This is consistent with the policy intent of the NHPR, as outlined in the [regulatory impact analysis statement](#) of these regulations published in 2004, as well as the outcomes of the NHPR regulatory review conducted in 2007, which reiterated that foods are excluded from the scope of the NHPR. This is also consistent with the approach followed by Canada's major trading partners, where Energy Drinks are consumed and regulated as foods.

### Assessment of the Potential Health Risks

There are indications that the overall dietary intake and consumption patterns of caffeine by Canadians, particularly by adolescents and young adults, is increasing. This is supported by the fact that Energy Drinks with high levels of caffeine are marketed to this subset of the population and are readily available in several locations such as convenience stores, gas stations and grocery stores. These caffeinated beverages are having an increasing impact on the dietary habits of Canadians.

Due to the high levels of caffeine found in most of these beverages, concerns were raised over the potential to exceed the maximum caffeine intake levels recommended by Health Canada for various groups, particularly for susceptible subgroups such as children and adolescents (< 18 years old).

Therefore, Health Canada conducted a scientific assessment of the potential hazards and exposure associated with the common ingredients found in these caffeinated beverages (including caffeine, vitamins, minerals, taurine etc.). The common amounts consumed of similar beverages, such as caffeinated soft drinks, were considered to help assess the risks to different populations based on different formulations. Children and adolescents were found to be the most at risk of exceeding Health Canada's Recommended Maximum Daily Intakes (RMDI) for caffeine because of the volumes potentially consumed and the lower RMDI established for these

## Health Canada's Proposed Approach to Managing Caffeinated Energy Drinks

populations, in comparison to adults. This assessment also identified that if children and adolescents who normally consume caffeinated carbonated soft drinks as their primary source of caffeine replaced them with Energy Drinks, a greater percentage of these individuals would exceed Health Canada's RMDI for their age group. Health Canada's assessment has concluded that a number of information gaps need to be addressed to support the Department in its efforts to regulate these products and enable their safe consumption. Similar concerns regarding overexposure of children and adolescents to caffeine were expressed by the Independent Expert Advisory Panel on Caffeinated Energy Drinks (the Panel) convened by Health Canada. The Panel also highlighted the need for additional data. Health Canada's scientific assessment will be peer reviewed prior to its publication in the international scientific literature.

### Health Canada's Proposed Approach to Manage Caffeinated Energy Drinks

Based on the outcomes of Health Canada's scientific assessment, and additional information such as the findings of the Panel on caffeinated Energy Drinks, the Department has identified a number of measures to mitigate the potential risks associated with the overconsumption of these beverages.

A multifaceted policy approach is being proposed and will include the following elements:

#### 1. Setting Formulation and Labelling Requirements on Energy Drinks Made Available as Beverages

As a result of the classification decision that caffeinated beverages known as Energy Drinks are foods, Health Canada is setting additional safety requirements to account for the way these products are perceived and consumed by Canadians. Health Canada will also collect additional information through data submitted by industry in order to assess the effectiveness of some of the management options. The proposed new requirements are:

##### *1.1 Composition Requirements*

Specific requirements will be established to better control the types and levels of ingredients added to Energy Drinks. These requirements include, for example, setting minimum and maximum limits for caffeine from all sources (natural and synthetic sources), vitamins and minerals as well as other ingredients e.g. herbal extracts.

Specific to caffeine, Health Canada's scientific assessment supports the establishment of an initial maximum limit for total caffeine of **400 mg per litre** with a maximum amount of caffeine **not to exceed 180 mg per container presented as a single-serve container**. Health Canada has determined that any Energy Drink container that cannot be resealed will be treated as a single-serve container. Health Canada has determined that re-sealable containers equal to or less than 591 mL will be treated as single-serve containers.

## Health Canada's Proposed Approach to Managing Caffeinated Energy Drinks

### *1.2 Labelling Requirements*

Caffeinated Energy Drinks will be subject to all food labelling provisions such as ingredient labelling, nutrition facts panel, allergen labelling etc. Health Canada proposes the following additional labelling information requirements:

- The amount of caffeine from all sources in mg per container or serving size.
- A statement on the label identifying the product as a “high source of caffeine” given that a Energy Drink will be required to contain a minimum amount of caffeine that is deemed to be sufficiently high.
- A statement indicating that the product is “Not recommended for children, pregnant or breastfeeding women, and individuals sensitive to caffeine”
- The statement “Do not mix with alcohol”

Depending on the formulation of the product, additional labelling requirements may be required.

### *1.3 Prohibition of Premixed Alcoholic Beverages with Caffeinated Energy Drinks*

Health Canada would prohibit the use of caffeinated Energy Drink beverages as an ingredient in pre-mixed alcoholic beverages.

### *1.4 Consumption Incident Reporting*

Health Canada would require that industry collect data on any consumption incident associated with their products that they receive through consumer complaints. These data would be reported to Health Canada every six months.

Products that meet these requirements will be issued a Temporary Marketing Authorization (TMA) and will be subjected to data collection related to the product consumption, market share and consumer complaints (incident reporting etc).

## **2. Consumer Education**

Health Canada proposes to work with its partners in the Provinces and Territories, health professional groups and other stakeholders to develop education tools and materials regarding the risks associated with caffeinated products, in particular Energy Drink beverages. In conjunction with labelling information, consumers will be better equipped to make informed decisions about the caffeinated products they choose.

## **3. Research and Monitoring of Long-term Health Effects**

Research and monitoring for long term health effects has been identified as an information gap in Health Canada's scientific assessment and by the Panel. Health Canada would collaborate with

## Health Canada's Proposed Approach to Managing Caffeinated Energy Drinks

Provincial, Territorial and international partners, in government and academia, to gather further data related to the long-term potential health effects associated with the consumption of caffeinated beverages such as Energy Drinks. Health Canada's initial focus will be on collecting up to date information on Canadians' consumption patterns for caffeinated beverages in order to better estimate exposure to caffeine and other ingredients, and the associated risks to support appropriate regulatory oversight.

### 4. Leverage Tools Developed by Stakeholders

Health Canada would work closely with all interested stakeholders to develop and implement other appropriate risk management approaches such as marketing and advertising Codes of Practice.

### Conclusion

The approach outlined above is intended to manage the availability of Energy Drinks in the Canadian market while collecting the proposed additional information necessary for the development of the final regulatory requirements for these products. Health Canada will continuously monitor and review the effectiveness of these measures. Should new information be made available on emerging health risks associated with the consumption of caffeinated Energy Drinks, Health Canada would take the appropriate action required to protect the health and safety of Canadians – actions ranging from updated information to Canadian consumers to the cancellation of the Temporary Marketing Authorizations for the targeted products.

### Comments

Comments on this propose approach may be submitted in writing, either electronically or by regular mail. If you are submitting your comments electronically, please use the term "Energy Drinks" in the subject box of your e-mail. **Comments must be received by 12:00 a.m. EDT, November 15, 2011.**

Mailing address:  
Bureau of Policy, Regulatory and Governmental Affairs  
251 Sir Frederick Banting Driveway  
Tunney's Pasture, PL: 2202E  
Ottawa, Ontario  
K1A 0L2

E-mail address:  
[energydrinks-boissonsenergisantes@hc-sc.gc.ca](mailto:energydrinks-boissonsenergisantes@hc-sc.gc.ca)