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# Health Canada's Proposed Management Approach in Response to the Expert Panel on Caffeinated Energy Drinks

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Food Directorate  
Health Products and Food Branch



Canada 

# Health Canada's Proposed Management Approach in Response to the Expert Panel on Caffeinated Energy Drinks

## Background

In 2010, Health Canada convened an Expert Panel on Caffeinated Energy Drinks (the Panel) to provide an external perspective on the most appropriate way to mitigate safety concerns related to caffeinated Energy Drinks currently being marketed in Canada. The Panel's recommendations were [outlined in its report](#) submitted to Health Canada in the fall of 2010.

Subsequent to the receipt of the Report, Health Canada has analysed the recommendations, completed a health risk assessment, and continued its information gathering and exchange with major food safety regulators in Canada (Provincial / Territorial governments) and internationally. The Panel recommendations, supplemented with additional information gathered from Canadian and international sources, helped shape the Department's [proposed management approach](#) for products known as "Energy Drinks". This document summarizes the key topics discussed by the Expert Panel and Health Canada's response to three key themes identified through the Panel's recommendation. Health Canada's response is encompassed in the Department's [proposed management approach for Energy Drinks](#).

## Summary of the Expert Panel's Recommendations

The Panel expressed concerns regarding the potential health risks of caffeinated Energy Drinks and recommended limiting the amount of caffeine per dosage unit, more explicit labelling, public education, and enhanced post-market monitoring to mitigate these potential health risks. The Panel also recommended limiting the retail availability of these products, as well as advertising of these products to children and adolescents.

## Health Canada's Response to the Expert Panel Recommendations through its Proposed Management Approach

In addition to reviewing the recommendations from the Panel's report, Health Canada conducted a scientific assessment of the potential hazards and exposure associated with the common ingredients found in caffeinated Energy Drinks (including caffeine, vitamins and minerals, taurine etc). This assessment is being peer reviewed prior to publication in the scientific literature.

Subsequently, Health Canada developed a proposed multi-faceted management approach taking into consideration these recommendations amongst a number of sources of information collected nationally and internationally. Health Canada's [proposed management approach](#) aligns with the risk mitigation strategies stemming from the Panel's recommendations, as well as that adopted by major food safety regulators internationally.

**Theme 1: Address Health Risks through Limitations Imposed on Product  
Formulation and Labelling**

**What we heard:**

The Panel reiterated that excessive consumption of caffeinated energy drinks has been associated with adverse health effects, particularly with vulnerable subsets of the population targeted by these caffeinated products (i.e., children and adolescents < 18 years old). The Panel indicated that there was a lack of key information regarding the content of Energy Drinks on their packaging (for example: amount of total caffeine). Of particular concern to the Panel was the use of caffeinated Energy Drinks in combination with alcohol, which they indicated may cause significant behavioral changes, although published evidence on this interaction is very limited as of yet.

**In response to these concerns and in accordance with the findings of its risk assessment Health Canada will:**

- Establish minimum and maximum limits for caffeine content from all sources
- Set limits on other ingredients such as vitamins and minerals and develop a list of accepted and unaccepted ingredients
- Prohibit use of Energy Drinks as an ingredient in pre-mixed alcoholic beverages
- Require statements on the label indicating that the product is “not recommended for children, pregnant/breastfeeding women, individuals sensitive to caffeine”, and “do not mix with alcohol”
- Require a statement on the label identifying the product as a “High source of caffeine”
- Require the labelling of the amount of caffeine from all sources in mg per container or per serving size
- Ensure that all general food labelling provisions apply (e.g., nutrition facts table, ingredient labelling, allergen labelling etc)
  - ❖ Depending on the formulation of the product, additional labelling requirements may be imposed.

In addition, Health Canada will ensure that only products meeting the formulation and labelling requirements described above be eligible to be sold in Canada as beverages.

Health Canada will also direct industry to develop and implement a Code of Practice (addressing packaging, advertising and sampling).

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### **Theme 2: Address Potential Health Risks through Enhanced Education and Communication**

#### **What we heard:**

The Panel recommended an education strategy intended to help consumers identify caffeine content in these products and inform consumers about the potential health risks. Such an education strategy should be pursued in conjunction with provincial governments, public health, school boards and professional groups.

#### **In response to this set of recommendations, and as part its proposed management approach for Energy Drinks, Health Canada will:**

- Continue to improve its outreach to parents and teens, using both these new social media tools (e.g., twitter, facebook, and youtube videos) and more traditional approaches, to communicate about the risks of highly caffeinated products.
- 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.

### **Theme 3: Address Uncertainties and Data Gaps through Monitoring and Research on Potential Long-Term Health Effects**

#### **What we heard:**

The Panel emphasized that there is a lack of data and research relating to the impact of caffeinated Energy Drinks on the Canadian population and regarding the frequency of use of these products both by the targeted groups such as adolescents and the general population. The Panel recommended that information be collected on “who is consuming caffeinated Energy Drinks, when, where, and how much”. The Panel also recommended that an extensive literature review regarding caffeine interactions with other medications be conducted.

#### **In response to this set of recommendations, and as part of its proposed management approach for Energy Drinks, Health Canada will:**

- In collaboration with Provincial, Territorial and international partners, in governments and academia, gather further data related to the long-term potential health effects associated with the consumption of caffeinated beverages such as Energy Drinks. Health

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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.

- Use the TMA process to gather data (e.g. market data, consumer pattern of use, effectiveness of labelling) and to fill some of the data gaps identified in its assessment. This updated information will support the determination of an up to date intake estimation for caffeine and other substances (e.g., vitamins and minerals) from Energy Drinks. This data will help Health Canada in adjusting its [proposed management approach](#) for these products.
- ❖ In the context of this data collection initiative and should new information be made available on emerging health risks associated with the consumption of caffeinated Energy Drinks, Health Canada will take the appropriate action required to protect the health and safety of Canadians – actions could range from updated information to Canadian consumers to the cancellation of the Temporary Marketing Authorizations for the targeted products.

## Annex 1 - Health Canada's Response to the Expert Panel on Caffeinated Energy Drinks Report Recommendations

Panel Recommendation	Response
<p><b>1</b> “Health Canada desists from using the term “energy drinks”. A more accurate designation to consider might be “stimulant drug containing drinks”. This term should be clearly indicated on the front panel of the product.”</p>	<p>Health Canada will provide guidance to industry to ensure that all claims made on products known as “Energy Drinks” are consistent with the food labelling requirements such that products would not be mis-represented to consumers in a deceiving manner or in a way that may have negative consequences on consumers’ health.</p>
<p><b>2</b> “Health Canada must act to mitigate the growing confusion for the general public between electrolyte replacement beverages and these stimulant drug containing drinks as more of these stimulant drug containing drinks now contain electrolytes and are marketed as sports drinks.”</p>	<p>Proposed actions to be taken under “<b>Themes 1 and 2</b>” and related to restrictions in product formulation as well as to education and information dissemination will address this recommendation.</p> <p>Health Canada will also direct industry to develop a code of practice on labelling, advertising and sampling of these products so that advertising to children is limited.</p>
<p><b>3</b> “Health Canada recognizes that, given the large number of these products sold on a monthly basis, there is evidently a large number of Canadians “exposed” to the drug. Even if the risk (probability of occurrence) of serious adverse events is expected to be very low, cases of serious adverse events have occurred. Therefore, due to the high volume of use, the risk of adverse events is considered to be a public health issue as these stimulant drug containing drinks are not being medically prescribed for a health indication. In the absence of real therapeutic and medically indicated benefits, the Panel considers that the risks associated with the use of these drugs outweigh the benefits. Public health at the federal/provincial/territorial levels need to be apprised of the risks and efforts made to co-ordinate steps to mitigate risk.”</p>	<p>Health Canada conducted a health risk assessment, considering the patterns of use of these products, and hence offering the ability to better estimate the exposure to caffeine included in these products in a manner that aligns with their consumption patterns.</p> <p>Health Canada’s risk assessment is being peer reviewed before being made available in the international scientific literature.</p> <p>As a result of this assessment, Health Canada has proposed measures to mitigate over exposure through limits imposed on product formulation (for caffeine and for other active ingredients such as vitamins and minerals), as well as labelling requirements that aim to enhance consumers’ awareness about product composition, particularly vis a vis caffeine content.</p>

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<p><b>4</b></p>	<p>“Health Canada at a minimum maintains stimulant drug containing drinks in the category of natural health product and NOT move them to foods due to the significant drug effects of the caffeine added to these products. This is recommended regardless of how other countries have chosen to deal with these products.</p> <p>N.B.: Some members of the panel noted that these products should be formally handled as drugs (i.e., even more stringent than under NHP).”</p>	<p>Health Canada has determined that Energy Drinks should be classified as foods given their consumption patterns, history of use, and representation. This determination is consistent with Health Canada’s guidance on the <a href="#">“Classification of Products at the Food-Natural Health Product Interface: Products in Food Formats”</a>. This classification will enable Health Canada to assess these products and their potential health risks in the context that they are perceived and consumed by Canadians.</p> <p>This approach allows Health Canada to set limitations related to product formulation and labelling requirements that are aligned with the way these products are perceived and consumed by Canadians.</p> <p>This approach is also consistent with the way these products are assessed and regulated internationally.</p>
<p><b>5</b></p>	<p>“Concern was expressed at the number of stimulant drug containing products on the Canadian market that do not have a NHP licence nor an exemption number. Some of these products do not meet NHP labeling guidelines. Many contain high levels of caffeine and could pose a hazard to consumers. Strategies need to be implemented to rapidly deal with these products as soon as possible (i.e., meet NHP requirements or be removed from the market)”.</p>	<p>The outcomes of Health Canada’s health risk assessment have determined concerns that are consistent with this finding. As a result, and in order to mitigate potential over exposure to caffeine from these products, Health Canada has proposed to set limits on caffeine content for products known as Energy Drinks. These limits, as well as the updated labelling requirements, will help mitigate the potential risks of overexposure to caffeine from Energy Drink products.</p>
<p><b>6</b></p>	<p>“The Panel notes that this is a safety concern and recommends that Health Canada ensure that all products meet strict labelling requirements, fully disclose the exact caffeine concentration (mg) prior to receiving an exemption number. Without caffeine amounts consumers are unable to abide by Health Canada’s recommendation on caffeine consumption.”</p>	<p>Health Canada’s <a href="#">proposed management approach</a> addressed this recommendation, by requiring enhanced labelling requirements of caffeine from all sources as well as requiring the use of the statement “high sources of caffeine” on product labels.</p>

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7	<p>“Since serious adverse event signals (cardiac events, and to a lesser extent seizures) have been detected, Health Canada should, in collaboration with the provinces and territories, consider steps to investigate further and mitigate these risks:</p> <ol style="list-style-type: none"> <li>a) Contact the Provincial Chief Coroners across the country to determine if there is paediatric death review data where stimulant drug containing drinks have been consumed that Health Canada has not had access to.</li> <li>b) Alert the Provincial Chief Coroners and their review committees that Health Canada has detected a signal. Propose the inclusion of a question regarding the ingestion of stimulant drug containing drinks when data is being collected systematically on cases.</li> <li>c) Alert practitioners that a signal has been detected. Although practitioners may not be prescribing stimulant drug containing drinks, they may see adverse events and need to report them.</li> <li>d) Consider setting up an active surveillance system, possibly in collaboration with PHAC, in sentinel emergency rooms across the country to actively search for serious ADRs following the consumption of stimulant drug containing drinks with and/or without alcohol and other products. The system could be modeled on the long running <b>IMPACT</b> system which actively carries out surveillance for serious adverse events following immunization (<a href="http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/00vol26/dr2615ea.html">http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/00vol26/dr2615ea.html</a>, <a href="http://www.cps.ca/English/surveillance/impact/impact.htm">http://www.cps.ca/English/surveillance/impact/impact.htm</a>).</li> <li>e) Examine the data on fatal car crashes and the relationship with the consumption of stimulant</li> </ol>	<p>Health Canada will continue to collect information on potential hazards associated with caffeine in food. Health Canada will leverage all sources of information available on potential adverse reactions or incidents reported as a result of consuming products known as Energy Drinks. In the context of its <b>proposed management approach</b> for Energy Drinks, Health Canada will be requiring from manufacturers and importers of products eligible to be made available on the Canadian market as beverages, to collect information and report consistently to the Department any consumption incident information communicated by consumers.</p> <p>Health Canada will also partner with Provincial, Territorial and international partners to collect and assess information on the potential acute and longer term health effects related to the consumption of these products by the various subsets of population.</p> <p>Should new information collected as result of these data gathering mechanisms indicate the need to update Health Canada's management approach of these products, Health Canada will adjust its regulatory requirements and limitations on these products in a manner that ensures the optimum protection of Canadian consumers.</p>
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	<p>drug containing drinks taken concurrently with alcohol. In addition, consider the examination of blood samples from these cases for both alcohol and caffeine concentration. This work might be done in collaboration with the Provincial Chief Coroners.</p> <p>f) Conduct a utilization study of stimulant drug containing drinks in both adults and underage youth, and co-consumption rates with alcohol.</p> <p>g) Health Canada considers contracting with Health Evidence Canada at McMaster University to do a systematic review of the published and gray literature on adverse events of caffeine, caffeine-alcohol interactions, and outcome and caffeine interactions with other biologicals and pharmaceuticals in stimulant drug containing drinks.</p>	
<p><b>8</b></p>	<p>“Health Canada should maintain stimulant drug containing drinks for use only in adults age <math>\geq</math> 18 years. No expansion of age groups.”</p>	<p>Health Canada will continue to assess the safety of these products within the context of their use by Canadian consumers (i.e. as beverages). Given that the effects of Caffeine can be greater for individuals of a lighter weight, Health Canada will continue to advise consumers and parents not to seek these products for children and adolescents and to limit their consumption.</p> <p>Health Canada will also enhance the dissemination of information related to caffeine and maximum recommended intakes of this substance from food sources.</p>
<p><b>9</b></p>	<p>“For adults, Health Canada needs to specify</p> <ul style="list-style-type: none"> <li>• maximum dose per single dose container of 80 mg of caffeine.</li> <li>• maximum of 0.32 mg caffeine /ml if in a beverage format</li> </ul>	<p>The <a href="#">proposed management approach</a> for Energy Drinks sets clear compositional requirements regarding the allowable total amount of caffeine in a product. These limits aim to mitigate potential consumption of high amounts of caffeine from Energy Drinks.</p>

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	<ul style="list-style-type: none"> <li>• total maximum caffeine per day of no more than 400 mg/day <i>from all caffeine sources</i></li> <li>• the frequency of caffeine stimulant drug containing drink use of only every 3 to 4 hours”</li> </ul>	<p>A limit of 400 mg per Litre of Caffeine from all sources is proposed to ensure that small volumes of energy drinks do not represent very high sources of intake of caffeine. With this limit, a 250 mL can of an Energy Drink product would not exceed 100 mg of caffeine per container. This level is less than the amount of caffeine contained in a small cup of moderately strong coffee.</p> <p>Similarly and in order to ensure that one “single consumption episode” of higher volumes of Energy Drinks does not result in exceeding Health Canada’s maximum recommended intake of caffeine for adolescents that would be consuming these beverages, a limit of 180 mg of caffeine per container (for a single serve volume) will be imposed. The consumption of larger volumes of “single serve” Energy Drink products would therefore not lead to over exposure to caffeine, in particular for adolescents.</p>
<p><b>10</b></p>	<p>“Health Canada, in collaboration with the provinces and territories, needs to support the development of education programs that will allow the public to easily identify the amount of caffeine in different foods and stimulant drug containing drinks, the maximum caffeine per day, and the interval. Collaboration with school boards across the country was suggested as a means to access the youth population. Social networking strategies such as “YouTube” and other techniques need to also be considered.”</p>	<p>As part of the <a href="#">proposed management approach</a> for Energy Drinks, Health Canada will develop new information and tools to further inform consumers of food caffeine sources, as well as the levels not to be exceeded, to mitigate potential health effects related to over consumption of caffeine.</p> <p>Health Canada has also identified new communication tools targeted to younger demographics to disseminate these messages.</p> <p>Health Canada will partner with Provincial and Territorial governments, health professional organisations and NGOs to develop and disseminate education materials on this topic.</p> <p>Health Canada aims to share its risk assessment of Energy Drink products consumed as a beverage with its Provincial and Territorial partners so that it could be used as needed to further guide their actions and management approaches under their oversight (e.g.</p>

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		intervention on availability of products in school settings etc.).
11	<p>Health Canada require that the labels on stimulant drug containing drinks include</p> <ul style="list-style-type: none"> <li>• that the product is not recommended for children or adolescents under the age of 18 years</li> <li>• clearly indicate the concentration of caffeine from all sources in mg. As this is a drug of known concentration, the variability of drug should not exceed 10% (in contrast to the 120% currently allowable as a natural health product).</li> <li>• maximum daily caffeine dose from all sources and the interval for dosing</li> <li>• that caffeine is addictive even with moderate dosing</li> <li>• the known adverse reactions to caffeine including: insomnia, anxiety, palpitations, arrhythmias, allergic reaction and symptoms with withdrawal</li> <li>• a caution that if sustained palpitations or fainting occur, to discontinue use and consult a health practitioner.</li> <li>• that these products should <i>Not be used with alcohol</i></li> </ul> <p>N.B.: This point demands much education and should be highlighted in all education sessions for the general public.</p> <ul style="list-style-type: none"> <li>• that serious adverse events, including death, have been seen with these products, possible due to cardiac events</li> </ul>	<p>Health Canada's <a href="#">proposed management approach</a>, guided by the outcomes of its risk assessment as well as the recommendations of the Panel, aims to enhance labelling requirements for Energy Drinks.</p> <p>Health Canada will impose the labelling of the amount of caffeine from all sources on Energy Drink products, as well as the identification of these products as a "High source of Caffeine".</p> <p>Labelling requirements related to the unsuitability of these products for children, pregnant/breastfeeding women as well as individuals sensitive to caffeine will be maintained. Similarly the labelling requirement to recommend these products NOT be mixed with alcohol will also be maintained.</p> <p>Health Canada will subject Energy Drink products eligible to be sold as beverages to collect data aiming to assess consumer response and reaction to these labelling requirements. This information will support the development of the evidence needed to assess the effectiveness of the labelling provisions and enhance them as required.</p> <p>Health Canada will also require that Energy Drink products be subject to all ingredient, nutrition and allergen labelling requirements for foods and beverages to ensure consumers have the information they need to make informed choices.</p>

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	<ul style="list-style-type: none"> <li>• all information on the container be in a font size that is easily readable by an adult</li> <li>• all information to be presented in appropriate language for the general public”</li> </ul>	
<p><b>12</b></p>	<p>Education programs be developed that:</p> <ul style="list-style-type: none"> <li>• Enhance the public’s ability to discern that stimulant drug containing drinks are drugs, not foods, and that these products differ from electrolyte replacement beverages.</li> <li>• These products are not for children or adolescents under the age of 18 years.</li> <li>• Describe common side effects of caffeine, including withdrawal symptoms, even after short intervals with only moderate doses.</li> <li>• Clearly describe the risk of imbibing on stimulant drug containing drinks concurrently with alcohol.</li> <li>• Enhance knowledge of what foods contain caffeine, maximum dosing of caffeine per day, and per interval.</li> <li>• Is tailored to meet the needs of different populations and risk groups including underage users and marginalized populations.</li> <li>• Focus not only on enhanced public knowledge about risks of stimulant drug containing drinks but also on mitigation of behaviours that can further increase risk for adverse events or adverse behavioural problems.</li> </ul>	<p>Same response as for recommendation 10.</p>

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	<ul style="list-style-type: none"> <li>• These education programs need to be developed and carried out in collaboration with public health in the provinces and territories and/or school boards.</li> </ul>	
<b>13</b>	<p>“Health Canada require post-marketing surveillance for the detection of rare serious adverse events for stimulant drug containing drinks, which is currently required for other drugs. Detection of such events, if causally assessed to be due to the contents of the stimulant drug containing drinks, could lead to withdrawal of licensure, a change in the label, as well as further education programs.”</p>	<p>Health Canada will continue to collect data from domestic and international sources on the potential health effects of Energy Drinks.</p> <p>As part of its <a href="#">proposed management approach</a>, Health Canada will impose data collection requirements for products eligible to be sold in Canada, including consumption incident reporting by manufacturers and importers. This information added to various other sources provided by partners and stakeholders will support further evaluation of the effectiveness of the various measures proposed by Health Canada for Energy Drinks.</p>
<b>14</b>	<p>“Health Canada review to ensure that stimulant drug containing drinks are not being advertised to children and youth given that these are only licensed for those 18 years and over. The penalty for improper advertising must be stiff given the high volume of these products currently being sold.”</p>	<p>Health Canada will direct industry to develop and apply a code of practice to refrain from advertising and sampling to children.</p> <p>Health Canada will also partner with Provincial and Territorial partners to support their actions limiting the advertising and sampling of these products to children, as required.</p>
<b>15</b>	<p>“Given that these are drugs, Health Canada must ensure that companies do not give out free samples as this is precluded for drugs. The penalty for giving out free samples must be stiff given the high volume of these products currently being sold. The distinction between ‘sampling’ and ‘free distribution’ needs to be very clear. Both practices need to be prohibited.”</p>	<p>Same as response to recommendation 14.</p>
<b>16</b>	<p>Health Canada, in collaboration with the provinces and territories, develop a</p>	<p>Health Canada's response to this recommendation is considered in the Department's <a href="#">proposed</a></p>

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	<p>communication strategy for dissemination of risk information on stimulant drug containing drinks to a wide audience. In order to optimize the reach to work not only with public health in the provinces and territories, but also with professional groups such as:</p> <ul style="list-style-type: none"> <li>• Canadian Paediatric Society</li> <li>• Canadian Nurses Association</li> <li>• Canadian Medical Association</li> <li>• Canadian College of Family Physicians</li> <li>• Mothers Against Drunk Drivers</li> <li>• Canadian Association of Emergency Physicians</li> <li>• Canadian Nurse Practitioners Association</li> <li>• Canadian School Boards Association</li> <li>• Canadian Home and School Association</li> <li>• Youth sport coaching associations</li> </ul>	<p><a href="#">management approach</a> for Energy Drinks and is detailed in the response offered for recommendation 10.</p>
<p><b>17</b></p>	<p>Given that stimulant drug containing drinks contain active drugs and are not prescribed for health indications, they need to be treated like a drug and a change in allowable point of sale to NAPRA schedule III needs to be considered. This would more formally signal to the general public that these are drug products, not foods. Label information alone is unlikely to rectify this confusion.</p>	<p>Health Canada's <a href="#">proposed management approach</a>, guided by the outcomes of its risk assessment as well as the Panel recommendations, has determined that Energy Drinks should be classified as foods given their consumption patterns, history of use, and representation. This determination is consistent with Health Canada's guidance on the "<a href="#">Classification of Products at the Food-Natural Health Product Interface: Products in Food Formats</a>".</p> <p>This classification will enable Health Canada to assess these products and their potential health risks in the context that they are perceived and consumed by Canadians.</p> <p>This approach allows Health Canada to set limitations related to product formulation and labelling requirements that are aligned with the way these products are perceived and consumed by Canadians.</p> <p>This approach is also consistent with the way these products are assessed and regulated internationally.</p>

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<b>18</b>	<p>The Panel also expressed concern to Health Canada on the large number of stimulant drug containing drink products on the market without a licence due to backlog. Given the huge volume of sales, and the potential health risks, this situation needs to be addressed quickly in order to mitigate risk.</p>	<p>In implementing its <a href="#">proposed management approach</a> for Energy Drink products, Health Canada will only issue Temporary Marketing Authorizations for products that meet the new limitations imposed by Health Canada as a result of its health risk assessment. This will ensure that products that may have higher amounts of caffeine, or other ingredients and that do not meet the enhanced requirements to be removed from the market. Health Canada will offer industry a transition period of a maximum of 18 months to ensure that products meet the new requirements.</p>
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