



Health
Canada

Santé
Canada

Your health and
safety... our priority.

Votre santé et votre
sécurité... notre priorité.

Caffeinated Energy Drinks

Health Risk Assessment and Current Risk Management Approach

*Food Directorate, Health Canada
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Overview

- ❑ Introduction of the Food Regulatory System under the Food and Drugs Act
 - ❑ Main players in Food Safety and Nutrition
 - ❑ Principles / approach in regulating foods under the FDA

- ❑ Managing Energy Drinks :
 - ❑ Review of historical background
 - ❑ Outcomes of Health Canada's Risk Assessment
 - ❑ Current risk management approach in place

- ❑ Conclusion and next steps



Canada's Food Safety System: A Shared Responsibility

Industry

- farmers, food manufacturers, food distributors, food service establishments and retailers



Consumers



Government

- federal, provincial and territorial (P/T), municipal



Canadian Food Safety: The Role of Government

□ Canada's Constitution allows all levels of government (federal, provincial/territorial and municipal) to:

- Enact food safety and quality legislation;
- Establish and enforce policies, standards and laws;
- Provide information, guidance; and,
- Provide effective and efficient program delivery.



Key Federal Organizations



**Food Safety
Roles**



Health Canada
www.hc-sc.gc.ca



Canadian Food Inspection Agency
www.inspection.gc.ca



PUBLIC HEALTH AGENCY of CANADA
www.publichealth.gc.ca



Agriculture and Agri-Food Canada
www.agr.gc.ca



Canadian Food Safety: Key Federal Accountabilities

On-farm Food Safety

Policy &
Standards

Surveillance &
Early Warning

Education &
Outreach

Inspection &
Enforcement

Public Health Surveillance

Health Canada
www.hc-sc.gc.ca

Agriculture and Agri-Food Canada
www.agr.gc.ca

Canadian Food Inspection Agency
www.inspection.gc.ca

PUBLIC HEALTH AGENCY of CANADA
www.publichealth.gc.ca

AAFC

HC

CFIA

PHAC

- Contributes to research and development of on farm food safety programs

- Establishes food safety policy and standards
- Assesses the effectiveness of CFIA's food safety activities
- Conducts health risk assessments in support of food safety investigations
- Informs Canadians about potential risks to their Health

- Designs and delivers federal food inspection programs
- Monitors industry's compliance with the Acts and Regulations
- Undertakes enforcement action as necessary
- Conducts food safety investigations & food recalls

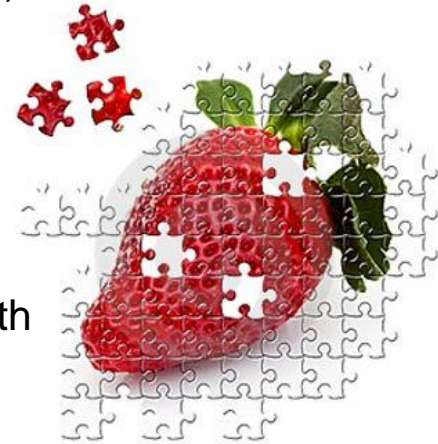
- Public health surveillance
- Leads foodborne illness outbreak investigations with P/T public health officials



Key Federal Food Safety Legislation

❑ ***Food and Drugs Act (1953) amended/updated in 2012***

- Core food safety statute and nutrition requirements
 - Applies to all food sold in Canada
- Consumer protection statute that deals with health and safety and marketplace deception with respect to food:
 - Prohibits sale of certain foods (e.g. food injurious to health)
 - Provides an inspection regime for food
 - Enables several regulations that pertain to food safety



❑ ***Canadian Food Inspection Agency Act (1997)***

- Enables the recall of food products that pose a risk to public health

❑ ***Safe Food for Canadians Act (2012)***

- All commodity legislations were consolidated and modernised



Regulatory Instruments are Commensurate to Risk

Principle

Food are inherently safe products

Regulatory requirements set rules related to safety and quality

Post-Market Rules (Examples)

- General provisions against adulteration and other mandatory practices
- Limits for selected contaminants in food
- Nutrition and other labelling provisions

Pre-Market Oversight (Examples)

- Pre-approval of added substances (e.g., additives)
- Pre-approval of novel processes / foods (e.g., GMOs)
- Pre-approval for foods destined to specific subsets of the population (e.g., infant formula)

RISK





- ❑ **Robust food regulatory regime:**
 - ✓ **Evidence-based** : Standard setting and compliance and enforcement
 - ✓ Focus on **Prevention** while enabling effective reaction
 - ✓ Relies on a mix of tools : regulatory and non regulatory
 - ✓ Commitment to continued **Evolution** to accompany innovation and anticipate / respond to emerging issues



We follow Codex's Risk Analysis framework

FAO/WHO Risk Analysis Paradigm



Background

- ❑ Energy Drinks were regulated under the Natural Health Products Framework until October 2011.
- ❑ Health Canada's proposed management approach on Caffeinated energy drinks stemmed from the consideration that these products are represented, perceived and consumed as beverages i.e. foods.
- ❑ Health Canada conducted a **risk assessment** to support the development of an **evidence/science-based** management approach for Caffeinated Energy Drinks as foods, when available for sale in Canada.



Defining Caffeinated Energy Drinks

- ❑ Health Canada does not currently have a definition or standard of identity for caffeinated energy drinks.

- ❑ For the purpose of this health risk opinion, a **typical caffeinated energy drink** is defined by its ingredients and serving size.
 - The ingredients include :
 - **caffeine,**
 - **taurine,**
 - **glucuronolactone,**
 - Inositol and a **variety of B vitamins,**
 - The serving size is 250 ml.



Risk Analysis Process

HAZARD IDENTIFICATION

HAZARD CHARACTERISATION

EXPOSURE ASSESSMENT

RISK CHARACTERISATION

RISK MANAGEMENT



Hazard Identification and Characterization

- ❑ It was not possible to conduct health hazard characterization on the basis of the product as a whole, rather to consider key ingredients with possible health end-points
- ❑ Caffeine was identified as the ingredient with the most significant potential health effects
- ❑ There are no expected health hazards associated with the consumption of high concentration of the other ingredients
- ❑ The addition of caffeine from these products to the diet would not **generally** result in consumers exceeding the recommended maximum daily intake of caffeine **for the majority of healthy adults.**
- ❑ **There are some uncertainties related to the combined effects of ingredients (e.g. caffeine and taurine)**



CONCLUSION

2 servings per day of a typical caffeinated energy drink would not be considered to pose a health hazard for a healthy adult.



Risk Analysis Process

HAZARD IDENTIFICATION

HAZARD CHARACTERISATION

EXPOSURE ASSESSMENT

RISK CHARACTERISATION

RISK MANAGEMENT



Health Risk – Exposure Modeling

- ❑ **Intake data** specific for energy drinks in Canada are **too limited** to determine the consumption of this product by **specific age groups**
- ❑ Needed to rely on exposure modeling scenarios (including worse case scenarios) :
 - Scenario : energy drinks substitute caffeinated carbonated soft drinks on a volume basis in Canadians' diet
- ❑ Health risk estimation was based on total dietary caffeine intake.



Toxicological Reference Values

- ❑ **2.5 mg/kgbw/day for Children**
- ❑ **400 mg / day for adults equivalent to 6.6 mg /kgbw/day**
- ❑ **300 mg/ day for pregnant women**
- ❑ **2.5 mg/kgbw/day was adopted for adolescents on a precautionary basis (due to lack of data).**



Health Risk – Exposure Modeling

Consumers of caffeinated carbonated soft drinks Caffeine intakes from all dietary sources (mg/kg bw/day)									
Age in years (sex)	Current market use			Substituted by volume			Substituted by serving		
	median	P75	P90	median	P75	P90	median	P75	P90
2-3	0.98	1.32	1.65	2.62	3.47	4.21	1.87	2.56	2.97
4-5	1.18	1.83	2.42	3.19	4.26	6.27	2.27	3.05	4.46
6-8	1.35	1.88	3.00	3.41	5.26	6.53	2.45	3.86	5.24
9-11 (male)	1.19	1.72	2.67	2.94	4.14	5.80	2.17	3.09	4.43
9-11 (female)	0.97	1.54	2.20	2.46	4.28	5.73	1.88	3.09	4.20
12-14 (male)	1.05	1.64	2.29	2.81	4.39	6.29	2.05	3.28	4.60
12-14 (female)	0.86	1.34	2.19	2.65	3.24	5.26	1.86	2.35	3.85
15-16 (male)	1.00	1.88	2.88	2.57	4.96	7.02	1.88	3.63	5.00
15-16 (female)	1.08	1.94	3.68	2.89	4.29	7.84	2.13	3.26	6.00
17-19 (male)	1.17	1.99	3.28	2.55	4.58	7.89	2.27	3.57	5.69
17-19 (female)	0.98	2.09	4.16	2.75	4.62	6.96	1.93	3.64	5.11
20+ (male)	2.67	4.66	7.55	4.19	6.39	9.61	3.60	5.68	8.84
20+ (female)	2.70	4.87	7.60	4.07	6.42	9.54	3.47	5.63	8.44
Pregnant	1.19	1.88	3.38	2.18	3.30	8.42	1.92	2.56	7.61

Bold indicates caffeine intake exceeds the Recommended Maximum Daily Intake.



Health Risk – Exposure Modeling

Consumers of caffeinated carbonated soft drinks with caffeine intakes exceeding the Recommended Maximum Daily Intake (%)			
Age in years (sex)	Current market use	Substituted by volume	Substituted by serving
2-3	3.3	56.8	30.8
4-5	8.3	68.9	45.0
6-8	13.5	62.9	49.8
9-11 (male)	14.0	61.3	40.1
9-11 (female)	7.3	46.7	32.8
12-14 (male)	8.2	59.3	37.0
12-14 (female)	6.7	55.7	22.9
15-16 (male)	12.6	52.0	39.2
15-16 (female)	20.4	60.6	41.1
17-19 (male)	19.6	59.0	37.8
17-19 (female)	17.3	54.1	39.3
20+ (male)	16.2	29.4	21.8
20+ (female)	15.5	28.1	22.5
pregnant	9.7	14.9	12.9



CONCLUSION

In a **worst case scenario**, replacing all caffeinated carbonated soft drinks with energy drinks on a volume basis **would result in a substantial percentage of the adults and nearly half of adolescent and children populations, exceeding Health Canada's RMDIs for caffeine.**



Putting the Results into Perspective

- ❑ These results stemming from Modelling using worse case scenarios
- ❑ Potential health effects of over exposure **are transient** and non-life threatening : e.g. Insomnia, agitation, headaches etc...
- ❑ Children would not/ should not have access to these products without parental control
- ❑ Adults are expected to access and follow dietary advice
- ❑ **Adolescents may have consumption behaviour leading to potential overexposure scenarios**



Managing Health Risk

- Managing potential risks stemming from these products should include multiple levers of action : **Regulatory and Non-Regulatory measures**
- The risk management approach should also be considered in the context of a holistic approach to help Canadians manage their caffeine intakes from food better.

Tool box of risk management measures



Risk Management Approach

Regulatory Elements

- Use of premarket oversight on a temporary basis : Temporary Marketing Authorisations
- Impose Composition Requirements for caffeinated energy drinks:
 - Maximum caffeine content from all sources (natural and synthetic) must be **less than 400 mg per litre.**
 - Maximum amount of caffeine in a single-serve* or non re-sealable container must **not exceed 180 mg** (* 750 ml re-sealable containers are considered a single serving).
 - Type and level of vitamins and minerals will be limited (“Formulation Guidelines”).
 - A list of unacceptable ingredients was developed (e.g., Herbal Extracts).
 - Several exclusion criteria (e.g., energy drinks should not contain 25% or more of juice).



Managing Health Risk : Regulatory measures

❑ Labelling Requirements:

- ❑ General food labelling provisions will apply (e.g., ingredient labelling).
- ❑ Amount of caffeine from all sources to be indicated on label in mg per container or per serving size.
- ❑ A statement on the principal display panel indentifying the product as a “**High source of caffeine**”, and statements on the label indicating that the product is “**Not recommended for children, pregnant women, or individuals sensitive to caffeine**”, and “**Do not mix with alcohol**”.

❑ Prohibition of Premixed Alcoholic Beverages:

- ❑ Prohibit energy drinks as an ingredient of an alcoholic beverage (i.e., pre-mixed with alcohol).

❑ Consumption Incident Reporting:

- ❑ Health Canada will require that industry collect data on any consumption incidents associated with their products and participate in yearly reporting to the Department.



Managing Health Risk

❑ Non-Regulatory Elements

❑ Education and Communication Strategy:

- ❑ Effective education tools and materials, particularly targeted at vulnerable populations, in collaboration with partners and stakeholders.
- ❑ Communication products to inform Canadians of the risks associated with combining energy drinks with alcohol.

❑ Long-Term Health Effects and Monitoring:

- ❑ Collaborate domestically and internationally on research and monitoring activities to gather further consumption and exposure data and to determine the potential long-term health impacts of energy drinks and their common ingredients.

❑ Codes of Practice:

- ❑ Industry to develop and apply codes of practices (e.g. on responsible marketing and advertising to limiting access of product to children).



Conclusion and Next Steps

- ❑ Current risk management approach will be evaluated based on data submitted by industry and research information collected by Health Canada
- ❑ Final regulatory framework for managing Energy Drinks will consider :
 - Any new findings from domestic and internationally available information
 - Overall Caffeine management approach
- ❑ Importance of non-regulatory measures or measures beyond federal oversight to manage risks associated with potentially inadequate “consumption behaviour”.



A collaborative approach is needed between all stakeholders : Government, Industry, health professionals and consumer groups to ensure effectiveness of the various risk mitigation measures





고맙습니다 谢谢 תודה!
mahalo *děkuji*

Thank You

شكرا *köszönöm* *gracias*
Ευχαριστώ *merci*
どうもありがとう *danke*

