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Caffeinated Energy Drinks: Similarities & Differences between the Marketing Authorization Procedures for Indian and Canadian Market

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Abstract

Although the intake of caffeine dates back to the time when various civilisations were just beginning, energy drinks (EDs) were only launched about 40 years ago. Since then, both India and Canada have seen an upsurge in the consumption of caffeinated energy drinks (CEDs). It has been contrasted between the regulatory standards in India and Canada for CED marketing permission. This covers the warnings for caffeinated beverages as well as the Recommended Daily Allowance (RDA) amounts for its ingredients. In order to comprehend the licencing process for caffeinated beverages in terms of manufacturing, distribution and sale, new start-ups and manufacturers will benefit from the comparison. The CED FSSAI guidelines are subject to individual interpretation. While the CEDs regulations in Canada are quite simple. Hence, the present review gives the exact information related to registration process of caffeinated beverages in Canada and India. Also, the standards set by Canada and India for energy drinks are mentioned in this review which helps new organisation and start-ups to explore the regulatory requirements for caffeinated energy drinks.

Keywords: Caffeinated energy drink • Recommended daily allowances • Health canada • FSSAI • Temporary marketed authorisation • Caffeine • ICBA • FDA • BIS certification • Dietary supplement • Food business operator

Introduction

Canada

One of the most popular energy drinks in Canada, caffeinated energy drinks (CEDs) contain caffeine as a key ingredient, which acts as a stimulant to the central nervous system. The basic purpose of energy drinks (EDs) and sports beverages is to increase physical energy during sports, exercises and other athletic activities. Caffeine-containing drinks (CEDs) are those that also contain other nutrients like taurine, glucuronolactone, B vitamins, minerals and herbal components. In Canada in 2017, there were no established guidelines for identifying these beverages [1]. Health Canada (the Department) stated in October 2011 that "CEDs were shifted from the food regulatory system to the natural health products regulatory framework." Health Canada has determined that in order to explain and finish the regulatory criteria for these products, a few remaining gaps must be filled. These include CED consumption trends in the context of food consumption and the effectiveness of labelling for mitigating the risks. A temporary marketing authorisation was determined to be the best regulatory mechanism for enabling certain items to be temporarily marketed under specific conditions (TMA). This data is currently being collected and examined. Among the specific marketing requirements are caps on the amount of caffeine, restrictions on the amount of vitamins and minerals, explicit caffeine content labelling, warning labelling and bans on promoting CEDs to children. Data on CED consumption among young people may have an impact on future restrictions for these items. According to scientific literature [2] and Health Canada, healthy persons in the general population are not at risk for caffeine's potential side effects at doses up to 400 mg per day. Health Canada conducted a rigorous assessment of the exposure to and potential dangers associated with the common compounds included in CEDs, such as caffeine and vitamins. Based on the maximum levels of caffeine, vitamins and minerals listed in the Health Canada advice paper for caffeinated beverages, CEDs currently offered for sale on the Canadian market provide no immediate safety risks when consumed as advised [3]. To support its efforts to control CEDs as a food and to properly manage any potential health hazards connected to these, Health Canada has decided that the data gaps must be filled [4]. Health Canada is concentrating on two areas to bridge these gaps: consumer comprehension and application of label information as a risk management tool and Canadian CED consumption habits to enhance evaluations of caffeine and other components exposure [5].

India

"Food Safety and Standard Authority of India (FSSAI)" is the regulatory body for CED. According to FSSAI, fruit juices, carbonated drinks and other EDs have become more and more popular among Indian children during the past two decades. The primary reasons for this product's high consumption are its straightforward convenience, simplicity and mouthfeel; busy families; appealing layout; engaging advertisements; low price; and vigorous marketing techniques [6]. EDs are non-alcoholic beverages that contain stimulants like caffeine, guarana, glucuronolactone, taurine, ginseng, inositol, carnitine and B vitamins [7]. In the Indian market, many Eds have been introduced as dietary supplements or to provide users an energy boost. Soft drinks, tea and coffee all contain significant amounts of caffeine, which stimulates the neurological system. EDs can contain up to 80 mg of caffeine each serve. The drinks also contain additives like amino acids and water-soluble vitamins like niacin, pathothenic acid, vitamin B6 and vitamin B12. Caffeine is an ingredient in EDs to enhance brain abilities. With millennials being open to testing new drinks, the 14 billion Indian rupee ($2 billion) EDs sector is optimistic about its future growth. There aren't enough studies on ED awareness, consumption habits, causes, beneficial and detrimental effects and a wide range of other topics in the Indian context. Manufacturers have recently shifted their focus away from athletes and onto young consumers. In areas where teenagers and young people gather, EDs are heavily advertised. Adenosine receptor inhibition is how caffeine predominantly operates. The hippocampus, cerebellum and cerebral cortex have the highest concentrations of adenosine receptors in the human brain, which has many of them. Caffeine inhibits adenosine receptors, causing changes in the levels of acetylcholine, glutamate, GABA, dopamine and serotonin. Because more people

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are aware of the health benefits of caffeine, more people are drinking caffeinated beverages. Caffeine reduces weariness and improves alertness. Caffeine has been found to enhance information processing in the brain as well as sensory and motor abilities.

There are two different ED types on the Indian market. One is offered in containers the same size as those used for typical soft drinks, such as a 16-oz bottle. The other variety is known as "energy shots" and it comes in small bottles with 2 to 21 ounces of concentrated drink. Energy shots are condensed versions of EDs because they might include the same total quantity of caffeine, vitamins, or other useful elements as their bigger cousins. Non-alcoholic carbonated beverages and soft drinks are not yet covered by any Codex Standards. According to FSSAI, EDs are currently accepted as dietary supplements in numerous countries.

International

Globally speaking, the non-alcoholic beverage industry is conscious of the need to positively influence discussions about caffeinated beverages. Customers all throughout the world have long enjoyed and safely consumed EDs. Even though EDs are recognised to be secure, ICBA notes that there are several intricate health and nutrition-related problems plaguing the world's population. To develop comprehensive and long-term solutions based on reliable science, it is essential that all societal stakeholders, including the non-alcoholic beverage industry, engage in cross-sector dialogue. The non-alcoholic beverage industry has been collaborating with the public sector, private sector, healthcare industry and consumers to help find a solution. For instance, on March 26, 2019, the ICBA (International Council of Beverages Association) amended the voluntary "Guidelines for the Composition, Labelling and Responsible Marketing of Energy Drinks" adopted by ICBA in 2013.

Materials and Methods

A comprehensive and detailed review of the literature was conducted by using the keywords “caffeine" and “CEDs" or “EDs" up to the first of October 2023 to find relevant literature in the PubMed, Google Scholar, ScienceDirect, carrot2, Scienec.gov, Bio line international and Worldcat databases. We considered information gathered between 2016 and 2023. The current analysis only included studies that claimed to be internationally representative and took into consideration information from official government regulatory websites like Health Canada and the Food Safety and Standards Authority of India (FSSAI). Studies that ignored data on caffeine intake from all (beverage) sources were excluded. We looked at studies describing CED and ED. Full text articles from potentially pertinent papers were found. Cross references for more publications were looked up. Supplemented foods that were permitted were found on the List of Temporary Marketing Authorization Letters webpage are included in this review. Regulation of nutrients as per Food Directorate Medical Canada. We compared the micronutrient levels of beverages and beverage mixes/concentrates to permitted levels of addition for both paths because the information online prevented accurately identifying the applicable regulatory path for products tracked in this way. The RDAs for essential nutrients from Health Canada and the FSSAI were also mentioned. Additionally, we compared the micronutrient content of various products to the Estimated Average Requirements (EARs) for the main nutrients present in CEDs, such as Vitamins B6, C and E, Calcium, Phosphorus, Niacinamide, Riboflavin, Thiamine, Vitamin B12, Magnesium, Potassium, Taurine and Amino Acids.

Marketing authorization process of caffeinated energy drinks

Canada: Manufacturers or distributors are advised to follow the guidelines in the General Guidance Document for Temporary Marketing Authorization for Foods when applying for marketing authorization in Canada. The Food and Drug Regulations' TMA (sections B.01.054, B.01.055), which mentions the requirements for CEDs specified in the segments below, is the ideal regulatory framework for acquiring the necessary data while allowing these products to be temporarily marketed. This document provides guidelines on how to produce a complete submission that complies with TMA requirements and when Health Canada may grant a TMA for a product. Foods sold in Canada must essentially adhere to the Food and Drugs Act (FDA) and the Food and Drug Regulations (FDR). To authorise the sale of a food that does not follow the FDR, regulatory changes are required. When proposing an amendment to the FDR, the maker or distributor must provide the supporting paperwork, including evidence of the food's safety as well as the rationale for the appropriateness of the proposed labelling if those imply a departure from the FDR's requirements. Sections B.01.054 and B.01.055 of the FDR permit the issuance of a TMA Letter in order to collect information in support of an FDR revision. During pre-submission discussions with industry or during the evaluation of a submission for changing the FDR, the potential need for a TMA could come up. Before the proposed regulatory changes to permit the sale of a food or a food category can be finalized, the department may decide that there are information gaps that must be filled. If a thorough risk analysis revealed that the meal lacks any food or food category, it may be temporarily approved for sale under certain conditions if there is a threat to the consumer's health and the missing data cannot be gathered without engaging in food marketing to carry out a TMA. The information would then be used to advise a regulatory modification to the Governor in Council using the present procedures for creating regulations. Health Canada conducted a scientific assessment of the hazards associated with and exposure to the typical ingredients included in CEDs, such as caffeine and vitamins. Based on the maximum doses of caffeine, vitamins and minerals mentioned in this guideline document, CEDs currently available on the Canadian market provide no immediate health or safety risks when taken as directed. However, in order to support its efforts to control CEDs as a food and to effectively manage any potential health concerns connected with these products, Health Canada has concluded that a number of data gaps must be filled. To obtain a TMA, a producer or distributor must sign a Letter of Agreement and offer the required data. According to B.01.054(2) of the FDR, a TMA Letter is given to a manufacturer or distributor for a specific food formulation and outlines the restrictions and conditions of the TMA. This Letter of Agreement, which is incorporated within the TMA Letter, attests to the manufacturer's or distributor's acceptance of the TMA Package's terms and conditions, which include withholding the food upon request from Health Canada. If a petitioner wants to change the provisions of a TMA Letter after it has been granted, Health Canada must authorise the change and the TMA Letter must be updated. A test-marketing tool is not what the TMA Letter is. For additional information about test marketing, see the website of the Canadian Food Inspection Agency (CFIA) or contact them *via* phone at Director, Consumer Protection Canadian Food Inspection Agency 1400 Merivale Road Ottawa, Ontario, K1A 0Y9.

Food makers or distributors must submit their requests using the food additive submission method described in section B.16.002 of the FDR if a new additive or a new use of an approved additive is desired. When reviewing the food additive submission, Health Canada may find that more non-safety information is required, but it can only be acquired by testing the additive in real-world market scenarios. Health Canada might in this case approve the limited sale of the food containing the additive *via* a TMA in order to gather the information. During pre-submission discussions with industry or during the evaluation of a submission for changing the FDR, it may become necessary to conduct a TMA. This section outlines the process for obtaining a TMA when the department determines one is required.

All information required by section B.01.054 of the FDR and requested by the department must be submitted by the petitioner in order to prepare a TMA filing. The submission must be succinct and should only include the information required to support the TMA request. After receiving the application, Health Canada will conduct an initial screening to make sure it is complete. If any information is lacking, the review procedure will be suspended and the petitioner will be notified. It won't be restarted until Health Canada has received all required data.

Submission delivery to health Canada: Health Canada's Food Directorate, Health Products and Food Branch, must receive the necessary TMA submission. Once Health Canada has examined a TMA submission and is satisfied with all TMA standards, including that the food won't jeopardise consumers' health, a Letter of Agreement is generated and given to the petitioner for signature. The petitioner acknowledges that the following conditions of clause B.01.054(1)(b) of the FDR apply to it:

1. Verify that the information about the food on the label or in a commercial is accurate and not false or deceptive.
2. On the label or in any marketing, use the symbols or phrases that Health Canada may require.
3. Upon request, send Health Canada the information gathered during the temporary marketing campaign.
4. When requested and deemed necessary by Health Canada, the food will be taken off the market.

After Health Canada has obtained the duly-signed Letter of Agreement, a

TMA Letter will be provided to the petitioner. The TMA Letter and the Letter of Agreement will include the information below.

1. Common terminology and a succinct description of the food.
2. The name of the food's distributor or producer and its location.
3. The distributor or manufacturer of the food's name and address.
4. The purpose of the TMA for the food
5. the maximum permitted sales volume of food
6. The type of food packaging, labelling, or advertising that is permissible when the letter is meant to allow a deviation from any packaging, labelling, or advertising requirement
7. The duration during which the food may be sold.
8. The authorised location where food sales are allowed.

The petitioner will receive a TMA package containing a duplicate of the Letter of Agreement and the TMA Letter, both of which have been signed by Health Canada. The TMA's objective is to allow the marketing of a food product so that Health Canada can gather the data required to finish an FDR amendment. Only a real market can provide access to this information. Depending on the particular amendment, data may be gathered, for example, on the effectiveness of a proposed label or advertisement in ensuring that the food reaches the targeted target group (s). Data on food consumption or use habits may also be gathered in order to more reliably estimate intake of certain substances, such as the added vitamins and minerals that are the TMA's main focus. In accordance with subparagraph B.01.054(1)(b)(iii) of the FDR, the petitioner is required to submit to Health Canada the information gathered during the time period specified in the TMA Letter.

The Department will examine the information acquired during the study phase before working to complete its regulatory determinations for the food or category of food. It is important to keep in mind that the details in the final proposed regulation (or regulations) may differ from those in the TMA Letter. Upon the implementation of the final regulation(s), manufacturers or distributors are required to abide by them.

The checklist includes the following to help with a quick and accurate assessment of the application and to ensure that a TMA submission is complete.

Segment 1 – Manufacturer Details

Segment 2 -Merchandise Specification

Segment 3 - Composition of the Good

Segment 4 - Detailed Product Information

Segment 5- Testimonial

Requirements under B.01.054 FDR (Part B of TMA Form):

1. The Purpose for which the TMA is Requested [B.01.054(1)(a)(i) FDR]
2. The Food's Description with a Sample and Proposed Label [B.01.054(1)(a)(ii) FDR]
3. 3. A summary of any proposed deviations from the FDR's requirements [B.01.054(1)(a)(iii) FDR].
4. Sufficient Data to Demonstrate That Use of the Food Won't Harm Buyer's or User's Health [B.01.054(1)(a)(iv) FDR]
5. The Amount of Food to Be Sold in the Proposed Amount [B.01.054(1)(a)(v) FDR]
6. The Proposed Period of Time Required for Such Sale [B.01.054(1)(a)(vi) FDR]
7. The Potentially Designated Area for Such Sale [B.01.054(1)(a)(vii) FDR]

Temporary marketing authorization

The TMA submission must include information about the research that will be carried out during the temporary marketing period, such as protocols for the studies that are being proposed, a precise statement of the goal and desired result and specifics about the methodology that will be employed to carry out the study and analyse the data. It is suggested that petitioners contact Health Canada's Food Directorate for a pre-submission consultation to discuss the proposed research and ensure that the type of research is appropriate for their food and will provide the necessary information so that a regulatory amendment can be implemented. Since this information can only come from the sales and marketing of the product, the information gathered should be pertinent to how the food is actually used in the market. The intended region designated for the sale of the foods mentioned in the TMA proposal should be taken into account when collecting data.

Labelling, Advertising and Claims

- In the case of CEDs, labelling, advertising and claims are crucial because they reveal the amount of caffeine content and any associated health benefits. The fundamental requirements for labelling and advertising are: -
- Common name;
- Net quantity;
- Company name and principal place of business;
- Ingredient list, in descending order by weight;
- Allergen labelling requirement;
- Nutrition Facts table; and
- Any additional information that must be displayed on the label, such as the disclosure of the presence of a non-nutritive sweetener like aspartame.

The claims are

- Quantitative statements
- Nutrient content claims

Eligibility for a TMA - caffeinated beverages: A single-serving container should not contain more than 180 mg of caffeine. A multi-serving container may contain no more than 180 mg of caffeine per serving (500 mL). It shouldn't have any alcohol in it [9]. 25% or more of the recommended daily amount of fruit and/or vegetable juice, puree, or pulp is not allowed, either individually or in combination. The words "juice", "puree" or "pulp" shall not appear on the label unless specifically stated in the list of ingredients. It should not be marketed as flavour or flavour-sweetened water. It should not be used for electrolyte replenishment or hydration before, during, or after physical activity. Beverages made from soy, rice, almonds, or other plant products with a dairy base are prohibited. Besides caffeine, no non-compliant food additives shall be included.

The minimum and maximum constituent levels for CED should be determined. Vitamins and minerals shall be included in CEDs at a minimum of 5% of the Daily Value per serving of the specified size. Daily maximum levels have been defined for each of these nutrients to help prevent excessive intakes when specific vitamins, minerals and amino acids are added to CEDs (Table 1).

India

Caffeine is an ingredient in EDs to enhance cognitive function. Numerous

Table 1. Daily maximum levels.

Vitamin/ Mineral nutrient	Daily maximum levels for CEDs
Niacinamide	126 mg
Riboflavin	27 mg
Thiamine	5 mg
Vitamin B_6	14 mg
Vitamin B_{12}	25 mcg
Vitamin C	276 mg
Vitamin E	141 mg
Calcium	225 mg

Table 2. Maximum limit allowed/day.

Ingredient	Maximum limit allowed/day
Taurine	2000 mg
D-glucurono-Y-lactone	1200 mg
Inositol	100 mg
Pantothenic Acid	10 mg

researches have shown that caffeine has drawbacks. Caffeine combined with alcohol or other addictive substances may be harmful to one's health. The scientific community is concerned about the likelihood of children having access to caffeinated beverages and the spread of food-based caffeine fortification to other products. Therefore, it is illegal to add caffeine-containing products to other beverages that children consume. Caffeine should be avoided by sensitive populations like expectant or breastfeeding women. The amount of caffeine present in a typical diet from all sources should be estimated when determining the upper limit.

The Food Safety and Standards Authority of India (FSSAI), which is a division of the Ministry of Health and Family Welfare in the Government of India, is in charge of regulating and overseeing food safety in the country in accordance with the Food Safety and Standards Act of 2006, the Food Safety and Standards Rules of 2011 and various food regulations that have been announced (and amended) since 2011. As of March 2017, the FSSAI has created regulations that cover numerous procedures, standards and practises relating to caffeinated beverages. The Ministry claimed that although the FSSAI was not required to create regulations in every circumstance, it had done so when it was most necessary. In India, the Bureau of Indian Standards (BIS) under the Ministry of Consumer Affairs, Food and Public Distribution and the Directorate of Marketing and Inspection (DMI) under the Department of Agriculture and Co-operation, respectively, certify both agricultural and non-agricultural products. AGMARK and BIS certifications are optional. According to FSS legislation, the designated food category requires both AGMARK and BIS certifications. The FSS regulations now include all necessary certification categories and the Prevention of Food Adulteration (PFA) Act of 1954 has been repealed. FSSAI did not evaluate the list of AGMARK and BIS certifications required by the PFA Act while establishing the FSS rules in 2011 to take into account additions or deletions. This would apply to circumstances in which the BIS/AGMARK certifications offered currently are insufficient or missing. In terms of components, additives, process, manufacturing, storage, transportation and sale, FSSAI-formulated standards have shortcomings.

The ministry claims that issues for the Scientific Panels/Committee to investigate and standards are identified using scientific data. The ministry forwarded a statement outlining the steps involved in formulating regulations, but an audit found that the first step (regarding the identification of food products on which guidelines are to be established) lacks clarity because there is no information available regarding the process by which such identification occurs. Regulatory and administrative framework is covered in Chapter II.

CEDs in category Dietary supplement under [Food Safety and Standards Regulations, 2023.] [Food Safety and Standards Authority of India Proposes Regulation of EDs and Caffeine (Revised)].

- Dietary supplements are not intended to treat or cure any deficiencies; rather, they are meant to complement a person's natural diet.
- Schedules I, II and IV (apart from Schedule III), which are routinely updated by the Food Authority, list the proteins, vitamins, minerals, amino acids and other additives with nutritional or physiological benefits that may be added to caffeinated beverages. A food company operator may add more nutrients than the daily suggested quantity, but not more than the maximum amounts of the vitamins and minerals stated in Schedule III.
- Nutrient utilisation levels must not go above those established by the Food Authority. Nutrient content must meet or exceed the recommended daily allowance (RDA) when there is a claim of increased nutrient content, but it cannot fall below 30% of the RDA. If the food authority does not specify consumption levels, they must be at least 15% of the Indian Council of Medical Research's recommended daily allowance (RDA) (ICMR). In the absence of such standards, it is recommended to use the Codex Alimentarius Commission, an international organisation that establishes food standards.
- Ingredients: The schedule's mentioned limitations. If daily minimum and maximum consumption levels have not been established, the Food Business Operator (FBO) should adopt the use level based on appropriate scientific evidence and maintain the recorded record of such data. As required, FBO will give the Food Authority this data.
- The delivery format must follow general specifications, in accordance with periodic Food Authority specifications outlining the purity standards for the ingredients used in each category of food product covered by these regulations.
- The items covered by these regulations may be in the form of liquids that are intended to be consumed orally in specific amounts and for a specific period of time, unless otherwise prohibited for categories under these regulations. The Food Authority may from time to time define any additional forms.

In addition to the fundamental labelling requirements established in the FSS (Labelling and Display) Regulations, 2020 [FSS (L&D)], categories identified by these regulations must furthermore carry the following information on the label.

Labelling and display

Front side of label contains:

The phrases “HEALTH SUPPLEMENT/ NUTRACEUTICAL/ FOOD FOR SPECIAL DIETARY USE/ FOOD FOR SPECIAL MEDICAL PURPOSE/ PREBIOTIC FOOD / PROBIOTIC FOOD" in capital and strong characters next to the product's name or brand name, as appropriate to the relevant category.

- A visible statement indicating the age group and/or target customer group, if the product has been designed for a specific age group.

Back side of label contains:

- The words “NOT FOR MEDICINAL USE" clearly displayed on the label, unless excluded for certain categories under these standards
- "Recommended consumption level"
- "Duration of usage" as appropriate
- Prominently displayed warning: “Not to exceed the recommended daily usage"
- A word of caution when drinking too much could be dangerous
- Any additional safety measures that should be taken before consuming the material, as well as any known side effects, prohibitions and known product or medicine interactions, where applicable
- A statement or warning stating that the product "is not to be used as a substitute for a varied diet," with the exception of those in the Food for Special Dietary Uses (FSDU) and Food for Medical Purposes (FSMP) categories.

Front or back side of label contain:

- A description of the number of nutrients or chemicals present in the product that have a nutritional or physiological effect.
- The label, accompanying leaflet, or other labelling and advertisement for each type of food product covered by these regulations must include information about the product's nature, purpose and specific usage instructions as well as safety precautions. Additionally, the information's presentation style needs to be appropriate for the consumer's intended usage.

The term "health supplements" on the label may also be used interchangeably with the phrases "dietary supplements" or "food supplements" by the Food Authority. [Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Prebiotic and Probiotic Food) Regulations, 2023].

Norms for caffeinated beverages

- The Food Safety and Criteria (Food Products Standards and Food Additives) Regulations, 2011, rule 2.10.8, requires that water used to make caffeinated beverages adhere to the same standards as packaged drinking water.
- There are no needs for EDs in India under the PFA Act of 1954. In accordance with the Food Safety and Standards Authority of India's proposal to regulate EDs and caffeine, the PFA Rules, 1955's requirements for carbonated water initially set a maximum limit of caffeine at 200 ppm, which was later reduced to a maximum level of 14,5 ppm and announced in notice GSR 431(E) dated 19.06.2009.
- Regardless of where it comes from, caffeine must be included in the product's composition in proportions totalling no less than 145 mg per litre and no more than 300 mg per litre.

- Ingredients may contain the following substances listed table given below (Table 2).
- For the vitamins thiamine, riboflavin, niacin, vitamin B6 and vitamin B12, the recommended daily allowance (RDA) is one level (100% RDA).
- Every additional item or ingredient that is intended to be added, aside from those chemicals listed in the aforementioned table, requires approval from the Food Authority after a safety review and the submission of supporting scientific documentation.
- "Drink not more than 500 ml per day" must be written on the label that shows the daily quantity.
- In terms of ingredients, flavours, sweeteners, food additives, pollutants and microbiological requirements, the product must meet the standards for carbonated water.

Labelling norms

- High Caffeine: “X mg/serving size" (where X is the number of milligrams of caffeine per pack or serve)
- Clearly displayed disclaimer: "Not recommended for children, pregnant or nursing mothers, or anybody who is caffeine sensitive."
- The term "non-carbonated water-based beverages" (non-alcohol) refers to liquids made with water that abide by the standards for packaged drinking water outlined in these regulations.
- The total amount of caffeine allowed in the product's composition cannot exceed 145 ppm, regardless of its source.

The products must comply with the microbiological requirements detailed in Appendix B under [FOOD SAFETY AND STANDARDS (FOOD PRODUCTS STANDARDS AND FOOD ADDITIVES) REGULATIONS, 2011].

Risk assessment

On the advice of FSSAI, the National Institute of Nutrition undertook a provisional risk analysis after reviewing the scientific literature regarding the safety of caffeine, taurine and D-glucurono-yl-lactone, the ingredients present in EDs, as well as the projected attention to these ingredients based on questionnaires completed and the daily intake of caffeine from all inputs, both natural and added. The results are outlined below: -

- Caffeine, a naturally occurring alkaloid substance with the chemical name 1, 3, 7-trimethylxanthine, is produced by more than 63 plant species worldwide in the form of leaves, seeds and fruits. Caffeine can be found in the theobroma cacao plant, kola nuts (Cola acuminate), yerba mate (llex paraguariensis) and guarana berries (Paullinia cupana). The world's top sources of dietary caffeine are tea leaves (Camellia sinensis) and roasted coffee beans (Coffee Arabica and Coffea robusta).
- Other sources of taurine and D-glucurono-yl-lactone do not contribute significantly to Indians' daily dietary needs.
- Around 80% of people use caffeine-containing foods on a daily basis. Caffeine is commonly found in coffee (71%), soft drinks (16%) and tea (12%).
- The safety of caffeine use at the levels of consumption expected by their different territorial populations has been assessed by a number of regulatory scientific agencies. The world's population consumes a wide range of amounts of caffeine, from 210 to 238 mg daily in the US and Canada to more than 400 mg daily in the Nordic countries. According to estimates, each person in India consumes 0.1 kg of coffee year. Coffee consumption in India and the United States is divided 42:100. Despite the fact that India and the UK have traditionally had tea drinkers, the per capita tea consumption has no impact on the amount of caffeine consumed. While coffee is more popular in southern states, tea is consumed more frequently overall in India. Tea, milk and coffee consumption are projected to be 52%, 13% and 14%, respectively. Tea contains more caffeine per gram than coffee does, despite the fact that less tea is used per cup of coffee. Compared to coffee, which has 80–150 mg of caffeine per cup, tea has 60 mg.
- The 80 mg per cup of coffee data is based on a serving size of 250 ml, however coffee serving sizes in India range from 100 to 150 ml. Therefore, based on the weight of coffee powder used per cup, the correct method for calculating caffeine consumption should be applied. Because the USDA calculates that one rounded teaspoon of instant coffee (1.8g) contains 57 mg of caffeine, there are approximately 60 mg of caffeine per cup of coffee. If served in cafe bars and high-end retail settings, the serving size may be 250 ml.
- Drinks that have a caffeine content of 12 to 20 mg per 250 ml serving are the second source of caffeine. However, the amount of caffeine taken in drinking cola drinks does not significantly increase the daily average. The main input is either tea or coffee. According to estimates, Indians consume carbonated beverages 59 times less frequently than Americans and 28 times less frequently than Britons. Given the current caffeine consumption, which is anticipated to be less than or at the lower end of the range of 80 to 250 mg per day, the risk assessment implies that there is no cause for concern.
- Each person in India consumes between 0.1 and 0.2 kg of coffee annually, with daily caffeine intakes ranging between 10 and 20 mg for coffee and 71 mg for three doses of tea bags. These quantities are much less than the average caffeine intake worldwide.
- Although there is no maximum caffeine limit in the European Union, items containing more than 150 mg of caffeine per kilogramme must be labelled as having a high caffeine content "(X mg/100 ml). Coffee and tea are not included. Coke-like beverages in Canada are permitted to have up to 200 milligrams of caffeine per litre. Beverages with 320 mg of caffeine per litre have been approved by the Canadian Health Authority as natural health products that demand an ingredient list and nutritional details. The US FDA limits the quantity of caffeine in soft drinks but does not regulate the caffeine in energy drinks. The US Code of Federal Regulations states that caffeine is "generally recognised as safe "[India's Food Safety and Standards Authority Proposes Caffeine and EDs Regulation].

Fssai registation process for bevrage licences

The Food Safety and Standards Authority of India (FSSAI) sets the hygiene and safety standards that ensure that healthy food is available in every eating place.

There are 3 types of registration which are

1. Basic Licence Registration
2. State Licence Registration
3. Central Licence Registration

Basic licence registration

The Food Standards and Safety Authority of India is in charge of regulating and overseeing food safety (FSSAI). As a result, it is necessary by law to complete the FSSAI Basic Registration. Small businesses or start-ups with an annual turnover of less than Rs. 12 lakhs may apply for a basic FSSAI Food safety registration. When operations grow and revenue reaches Rs. 12 lakhs, the basic registration must be upgraded to a state licence. Corporate businesses cannot use it because it is only a basic registration.

State license registration

Businesses that generate between Rs. 12 lakh and Rs. 20 crores in annual revenue must register for an FSSAI state license. Small- to medium-sized producers, storage facilities, transporters, retailers, restaurants, marketers and distributors are among the businesses that must obtain the FSSAI State License Registration

Central licence registration

Companies that earn more than 20 crores in annual revenue must register for a central licence. Operators in the food industry, including importers, manufacturers, operators for the central government, railroads, airports and seaports, must get a Central FSSAI licence, according to the FSSAI.

Discussion

Official guidelines show that Canada and India take distinct approaches to CEDs and their market. Below is a summary of the similarities and differences.

Similarities

- There are few similarities between Canada and India in terms of caffeinated beverages.
- Both regulatory bodies Health Canada and FSSAI set standards for the caffeinated beverages.
- They set up the minimum level and maximum level limits for caffeine and other ingredients.
- Target population is athletes and adults.
- The caffeinated beverages must comply with the disclaimer on product "not recommend for children and pregnant or lactating women" in both the markets.
- Both Health Canada and FSSAI require risk assessment of caffeinated beverages.
- There are diversities in marketing authorization of caffeinated beverages in Canada and India.
- Caffeine content level is high in Canada (NMT 180 mg per 500 ml) as compared to India (NMT 300 mg per 1000 ml)
- The licensing procedure for beverages in Canada is simple and contains one license.
- Despite having one food one law in India, there are 3 different licence procedures for different conditions.
- In India caffeinated beverages are regulated by FSSAI
- In Canada Health Canada regulate the CEDs
- In Canada they have the special class for CEDs, while in India there is no special class
- In Canada there is TMA for beverages, there is no such provision in India for beverages containing caffeine.
- The standards of caffeinated beverages in Canada is easily available as compared to India.
- The caffeinated beverages market in Canada is matured as compared to India.

To prevent any malpractice, the FSSAI requirements need to be stronger and more specific and the public should have easy access to information about standards. Although the FSSAI assesses the safety of caffeinated beverages, more research on the consumption of caffeine and caffeinated beverages is required.

Conclusion

The terms "CED," "ED," "Caffeinated Beverages," and "Energy shots" all refer to the same substance that acts as a central nerve stimulant and contains caffeine. These beverages are popular among young people and athletes. The rising intake of caffeinated beverages is contributing to an increase in the demand for EDs. Due to the need to standardise it for the welfare of a healthy people. Caffeinated beverages are subject to standards set by FSSAI and Health Canada. Caffeinated beverage standards are clear and dependable according to Health Canada. The FSSAI, on the other hand, has a different viewpoint on the rules for caffeinated energy, which leaves no set codex for energy drinks. The risk analyses of caffeinated beverages that were revealed by an audit from the ministry of health were ignored by FSSAI. For purposes of production, distribution and sale, entrepreneurs, manufacturers and new start-ups will find the differences in marketing authorization of caffeinated beverages useful.

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Conflict of Interest

The authors have no conflicts of interest to declare that are relevant to the content of this article.

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