CAFFEINATED ENERGY DRINKS IN EGYPT

A Risk Assessment Approach

National Food Safety Authority of Egypt (2024)

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Introduction

A monograph for Caffeinated Energy Drinks (CEDs) was developed by the National Food Safety Authority of the Arab Republic of Egypt (NFSA), as the basis of approval of formulations of CEDs destined to be marketed in Egypt.

This monograph includes set formulation and labelling provisions and will serve as the basis for rapid review and approval of such products.

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Introduction

This presentation offers the evidence-based justification of the decisions reached by NFSA regulators supporting the CED monograph.

It is based on the review and adaptation of previous assessments conducted by reputable international food regulatory organisations, such as the European Food Safety Authority (EFSA) and Health Canada.

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What is an ENERGY DRINK?

A **non-alcoholic** beverage, **carbonated or not**, that contains a higher level of **caffeine** than other known soft drinks, with the purpose to induce the effect of **alertness** associated with this ingredient.

These products can be flavored or not and may include other food ingredients commonly present in food and beverages allowed for sale in Egypt.

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Portion Size

250 mL portions

RISK

Safety assessments associated with CEDs have uncovered that some risks associated with possible *overexposure to active ingredients* in these products, such as Caffeine, are mainly attributed to consumption behaviors rather than the actual composition of the products.*

Mitigation

Although the effects noted are transient and would no longer be observed upon stopping the consumption of these products, measures were considered to avert such risks through ***Portion Size Control*** i.e., limiting the portion for each consumption.**

This measure was recognized as a suitable approach of risk mitigation, contributing to possible lower consumption of the food/beverage**

The adopted monograph established a standard **250 mL portion size** for the product which was identified as a common commercially available size for CEDs., with all composition requirements based on this size.

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** Rotstein J., et al., 2013*

*** Vanderbroele et al. 2019; Jayawardena et al. 2021, Cleghorn et al. 2019, Raghoebar et al. 2019*

Consumption

2 Servings/day

RISK

Safety assessments associated with CEDs have uncovered that some risks associated with possible *overexposure to active ingredients* in these products, such as Caffeine, are mainly attributed to consumption behaviors rather than the actual composition of the products.*

Mitigation

Most risk assessments carried out by food regulators internationally concluded that the consumption of *2 servings* of a «typical» Energy Drink product (i.e., modelled on a 250 mL) is considered *safe for the general population.* **

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** Rotstein J., et al., 2013*
*** Health Canada, (2015 and 2021)*

Composition Requirements (Caffeine)

- Acts as a stimulant.
- May produce mild side effects like anxiety, headaches, etc.
- Stronger effects when higher amounts are absorbed quickly.
- Effects are transient, ceasing when intake stops.
- Some individuals may be more sensitive to the caffeine.
- Not considered clinically addictive.
- It's possible to determine safe, non-adverse intake levels.

- EFSA Reports Indicated that Over (1/3) of Caffeine Intake for the **European Population** is Associated with the Consumption of **Coffee and Coffee Products.**
- The Contribution of **Coffee and Coffee Products** to Caffeine Intake was Found to be Higher in the **United States** and was Reported at about 64% of the Total Caffeine Intake.

** Beverage Caffeine Intake in the U.S. Food ; Mitchell, D.C., Knight, C.A., Hockenberry, J., Teplansky, R., Hartman, T.J., 2014. Chem. Toxicol. 63, 136–142*

Composition Requirements

Caffeine

Safe levels: *

- 400 mg / day for adults equivalent to 5.7 mg /kgbw/day (70 kg individuals)
- 2.5 mg/kg bw/day for Children
- Between 200 mg/ day (EFSA) and 300 mg/ day (HC) for Pregnant Women;

Conservative approach

The safe intake of caffeine for children and adolescents has been set at levels varying between **2.5 mg/kg body weight/day and 3 mg/kg body weight/day**. Adopting such low safety levels initially derived for children, to adolescents is considered a very ***conservative approach*** and therefore quite protective.

400 mg/L in energy drinks, with a minimum of 200 mg/L to differentiate them as "special foods."

For Volumes higher than 250 mL: A maximum caffeine limit of 180 mg per container is also set, corresponding to a moderate coffee cup leading to a recommendation for consumption by those 16 years and older.

Such level would ensure that a consumer would not exceed the ingestion of more than 180 mg of Caffeine in one consumption setting.

This would correspond to a level varying between 2.5 mg/kgbw and 3mg/kgbw for individuals, weighing 70 kg and 60 kg body weight respectively.

** Health Canada (Nawrot, 2003)*

Composition Requirements

Taurine	**1000 mg per 250 ml serving of CEDs**, based on guidance that occasional consumption of up to 2000 mg per day from multiple supplemented foods would not result in adverse effects.
Glucuronolactone	Not to exceed **600 mg of Glucuronolactone** for a volume of 250 mL, based on most common formulations of these products for these volumes.
Inositol	Not to exceed **200 mg of Inositol** for a volume of 250 mL, based on most common formulations of these products for these volumes.

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Composition Requirements Vitamins & Minerals (Maximum Limit)

- The methodology applied to calculate the maximum amounts of supplemental ingredients permitted in CEDs (>150 ppm) was adapted from the guidance developed Health Canada (2022a). For most vitamins and mineral nutrients, the maximum amount is determined with the following formula:

$$Maximum\ amount = \frac{Safe\ daily\ amount - Daily\ food\ and\ supplement\ intake}{5}$$

- **The Safe daily amount:** indicated the total daily amount that is likely to pose no adverse effects to most individuals and that should not be exceeded, **Tolerable Upper Intake Levels (UL).**
- **Daily food and supplement intake** would represent the **Recommended Dietary Allowance (RDA).**
- NFSA used a denominator of **5 servings per day** to account for the possibility that individuals might consume multiple supplemented foods containing the ingredient, mirroring an approach taken by Health Canada.
- NFSA considered **5 servings per day to be a suitable and conservative** estimate for Egyptian consumers as well.

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Composition Requirements

Vitamins & Minerals (Maximum Limit)

- $Vitamin\ B12 = \frac{(1000-2.4)}{5} = 199.52\ \mu g$
- $Vitamin\ B5 = \frac{(500-5)}{5} = 99\ mg$
- $Vitamin\ B1 = \frac{(100-1.2)}{5} = 19.76\ mg$
- $Vitamin\ B2 = \frac{(1000-1.3)}{5} = 19.74\ mg$
- $Vitamin\ B3 = \frac{(900-16)}{5} = 176.80\ mg$
- $Vitamin\ B6 = \frac{(80-1.3)}{5} = 15.74\ mg$
- $Vitamin\ C = \frac{(1800-75)}{5} = 345\ mg$
- $Vitamin\ E = \frac{(800-15)}{5} = 157\ mg$
- $Magnesium = \frac{350}{5} = 70\ mg$
- $Phosphorous = \frac{(4000-1250)}{5} = 550\ mg$
- $Calcium = \frac{(2500-1300)}{5} = 240\ mg$
- $Potassium = \frac{(200-4.7)}{5} = 39.06\ mg$

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Restrictions in CED formulations

CEDs must be formulated as functional foods, without **therapeutic or hormonal ingredients.**

CEDs must be non-alcoholic, with alcohol not exceeding 0.1% v/v.

Certain ingredients are prohibited in CEDs, including:

Vitamin A (retinol forms).	Folic acid and its salts.	Nicotine.	Other therapeutic herbs.

NFSA may consider evaluating and approving additional ingredients separately.

To ensure CEDs are targeted at adults and adolescents 16+, formulations known to appeal to children are restricted:

No milk or dairy ingredients.	Fruit/vegetable juices limited to <25% of composition.	The term "Juice" cannot be used in the product name.

Labelling

The proposed following statements are proposed to be made compulsory on the product label:

- Overconsumption of this product is to be avoided and it is recommended to consume this product up to 2 servings / products per day.
- This product is not recommended for children, individuals under 16 years of age, to pregnant women, lactating mothers and individuals with known sensitivity to Caffeine.

To further support the risk management measures enabling the safe consumption of these products as functional or Special foods, other labelling restrictions are to be observed, including:

- The prohibition to include the word juice in the name of the product, including the use of the wording Juice drinks or Energy Juice.
- The prohibition to have any health claim identifying the product as a hydrating product or as a source of electrolytes.
- The prohibition to identify the product as “water” part of the name of the product.
- The prohibition to use claims that promote the product as a sports drink or an enhancer of physical or sports performance.

Other Risk Management Measures

Risks and mitigation strategies for CEDs:

- Risks often linked to misuse or overconsumption, beyond regulatory measures
- Need for both regulatory and non-regulatory measures:

Regulatory measures:

- Restrict formulation requirements
- Set labelling obligations

Non-regulatory measures:

- Targeted consumer information and education campaigns
- Collaborate with health professionals, youth, and educational organizations
- Provide information on CED composition, conditions of use, and healthy consumption

Best practices in food risk management:

- Integrate food standard development, regulatory measures, and non-regulatory interventions
- Align with WTO recommendations:
  - Use risk-analysis based process to develop food standards
  - Regulatory measures justified by robust risk assessment and commensurate to potential health risks

This Approach is Under Consultation….

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Main Comments

- Objection on size restriction
- Broaden the list of ingredients in the monograph to include other vitamins and minerals
- Objection on not using milk or dairy products in CEDs and the term “juice”

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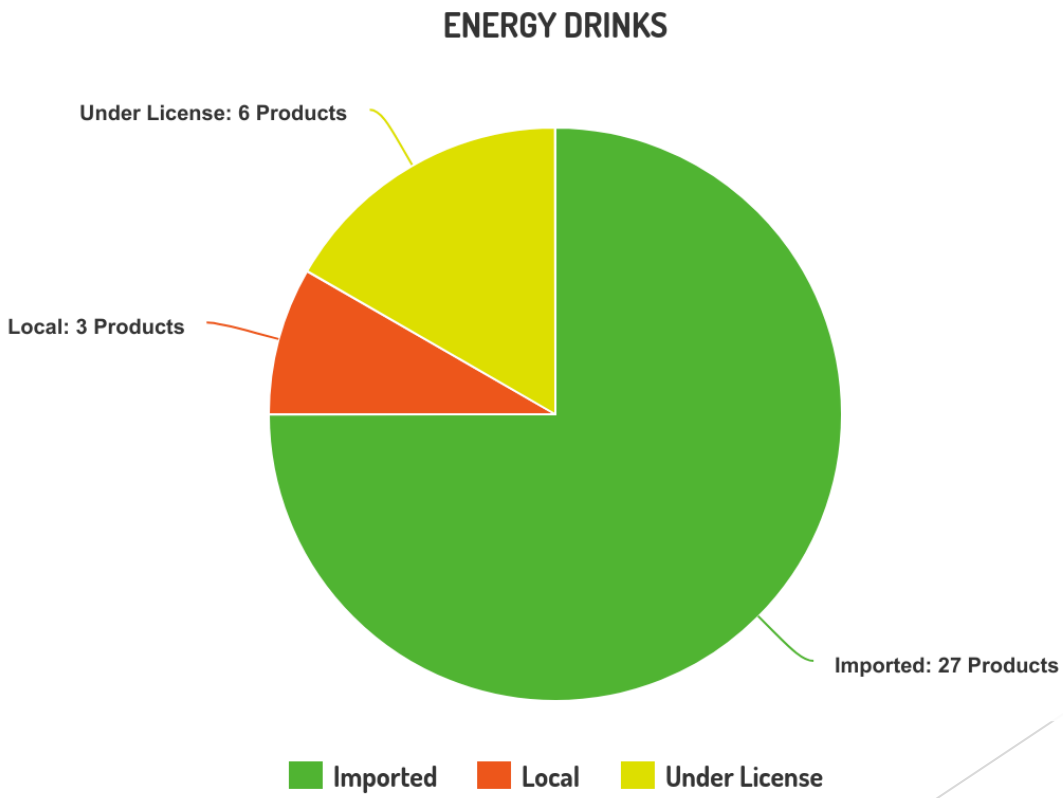
Registered products From 2018 till now FSDU-NFSA

- **All products registered in FSDU: 9516 products**
- **Energy Drinks: 36 products**
  - **Imported: 27 products**
  - **Under License: 6 products**
  - **Local: 3 products**



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- Website: https://www.nfsa.gov.eg/
- Mail: info@nfsa.gov.eg
- FSDU Mail: functional.food@nfsa.gov.eg

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