مجلة الهيئة القومية لسلامة الغذاء
Journal of the National Food Safety Authority

Pre-Publication for Consultation: JNFSA.2024-1

To Submit Comments Click Here

Consultation Deadline: 31 August 2024

Evidence-Based Requirements for Authorizing Caffeinated Energy Drinks in the Arab Republic of Egypt

Mohamed Mamdouh, Mohamed Said and Rasha Galal [a,*]

[a] *Special Foods Division, National Food Safety Authority of Egypt, (NFSA), Cairo, Arab Republic of Egypt*

* *Corresponding Authors; rasha.galal@nfsa.gov.eg.*

1. Abstract

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 recommended requirements of formulation and labelling and will serve as the basis for rapid review and approval of such products. CED Products seeking to access the Egyptian market and **fulfilling these requirements** will be considered in compliance with the obligations of safety and quality needed for these products and will then follow a swift registration procedure by the National Food Safety Authority of Egypt (NFSA).

This report offers the evidence-based justification of the decisions reached by NFSA scientists and 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. This report does not represent a typical risk assessment as some data such as those related to consumption information of the Egyptian population of these products are lacking.

Making this report available, to support NFSA's food regulatory decision on CEDs fulfills the commitments of transparency pursued by NFSA as part of the implementation of the Authority's Strategic Plan for 2023-2026.

The first version of this paper, published in the Journal of the National Food Safety Authority of Egypt (JNFSA) is intended for public consultation and input from peer scientists, regulators and NFSA's stakeholders, domestically and internationally.

It is also meant to accompany NFSA's notification to the World Trade Organization (WTO), fulfilling the obligations of the Sanitary and Phytosanitary (SPS) Agreement.

Contents

2. Background

Decision 1 issued by the National Food Safety Authority of Egypt (NFSA) on 15 August 2018 related to the registration of "Special Foods" and the associated executive decision issued on 18 February 2019, grants NFSA the authority to register products identified as "special foods", which are considered to be foods used by consumers for special dietary purposes.

NFSA developed a policy to support the smooth transition of the registration procedures related to Special Foods, which aims to reduce trade restrictions, while achieving the highest levels of protection to Egyptian consumers, ensuring the safety and quality of the targeted products.

The adoption of the **monograph approach** by NFSA supports swift registration and access to the Egyptian market of products that are deemed to fulfil the requirements of safety and quality.

A **monograph** is a set of formulation and labelling provisions, that are evidence-based and are reached on the basis of a scientific assessment that includes the review of the most up-to-date scientific information, data provided by the industry sector representing the targeted category of special food products, as well as assessments and decisions reached by other reputable food regulatory organizations internationally, while ascertaining that these decisions are adapted to the Egyptian food consumption, production and food regulatory environment.

The provisions set in a monograph do not represent the only conditions of acceptability of a given "Special Food" category, rather, other conditions may be considered, based on submissions by industry and supported by evidence. A monograph may therefore be amended based on these requirements.

This report offers the evidence-based justification of the decisions related to product formulation and labelling, reached by NFSA scientists and regulators supporting the CED monograph. Previous assessments conducted by reputable international food regulatory organisations, such as the European Food Safety Authority (EFSA) and Health Canada were reviewed and adapted for this purpose. This report does not represent a typical risk assessment as some data such as those related to consumption information of the Egyptian population of these products are lacking. It includes both scientific and food regulatory policy considerations aligned with the Egyptian environment and with international best food regulatory practices.

3. Proposed Definition of Energy Drinks

The proposed **definition of a Caffeinated Energy Drink (CED)** is set as "*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 caffeine*". These products can be flavored or not and may include other food ingredients commonly present in food and beverages allowed for sale in Egypt.

All provisions applicable to beverages such as allowable food additives at set levels of use, natural flavors or maximum levels of contaminants, also apply to CEDs as a category of beverages.

It is possible to have other active ingredients be added to the composition of the product. The ingredients mentioned and cleared in the monograph are covered by safety assessments and are therefore allowed in the formulation of the CEDs at the levels set. Should there be interest to add other ingredients, it is possible to do so, after clearing the new composition with NFSA.

4. Proposed Serving Size for the Monograph – Portion Control Based Requirements

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 behaviours rather than the actual composition of the products (**Rotstein J., et al., 2013**). 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 (**Vanderbroele et al. 2019; Jayawardena et al. 2021).**

As a result, the adopted monograph included **a set portion at 250 mL,** identified as one of the most common commercially available sizes for CEDs, differentiating them from other soft drinks.

All composition requirements that follow are set on the basis of **a 250 mL** portion size.

250 mL is therefore set as a **Maximum Volume** established for this monograph.

It will be possible however for manufacturers to suggest other portion sizes.

This document will discuss deviations from the set Maximum Volume established by this Monograph, based on the survey of products available on the Egyptian market.

Composition and labelling requirements **will be adjusted** for the volumes different than 250 mL. The adjusted formulation and labelling conditions will be considered **acceptable for sale in Egypt**. This approach fulfills the principles followed by NFSA in promulgating the "Special Foods Regulations", aiming to ensure the protection of Egyptian consumers and to cause minimum disruption to the stream of commerce.

5. Recommended Level of Consumption

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 behaviours rather than the actual composition of the products (Rotstein J., et al., 2013), although the effects noted are transient and would no longer be observed upon stopping the consumption of these products.

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 of a product formulated as the brand "Red Bull") **is considered safe for the general population** (Rotstein et al. 2013).

Some potential risks related to Energy Drink consumption were found to be associated with excessive and possibly risky consumption behaviour for some subsets of the population and not specifically due to hazards present in the food product itself.

For higher volumes than 250 mL, such as 400 mL or 500 mL, as surveyed on the Egyptian market, the advice would be to not exceed a volume of 500 mL of these products per day. Labeling provisions related to this measure may be adapted to read as "**it is advised not to consume more than 500 mL of this product**", or any equivalent iteration of this advice, conveying the same meaning.

6. Proposed CED Composition Requirements and their Justification

6.1 Caffeine and Other Active Ingredients

6.1.1 Caffeine

Various food regulatory authorities published or updated their health risk assessments related to caffeine in food and energy drink consumption, including the European Food Safety Authority (EFSA, 2015), Health Canada (La Vieille et al., 2021), the Norwegian Scientific Committee for Food and Environment (VKM) (VKM 2019 and 2021).

One of the most authoritative reviews on caffeine effects on human health remains the study carried out by Nawrot et al (2003), which established reference doses for caffeine intake.

In summary, it is possible to consume up to **400 mg of caffeine per day** (or 5.7 mg/kg body weight per day, for an adult weighing 70 kg) with no adverse health effects. Such safe level is reduced for pregnant women and lactating mothers to daily caffeine amounts varying from **300 mg** according to Health Canada's recommendations (Nawrot, 2003), to **200 mg** according to EFSA's recent evaluation (EFSA, 2015).

The safe intake level 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, for adolescents is considered a very conservative approach and therefore quite protective. The maximum recommended levels that are not associated with adverse effects are considered to be cumulative amounts of caffeine consumed from various food sources during a single day. Most of the possible adverse effects associated with the ingestion of amounts of caffeine close to the maximum recommended safe levels are considered to be mild and transient health effects, when such consumption is made in a short period of time such as 1-2 hours. Symptoms observed included headaches, insomnia and stomach aches, which would dissipate when consumption of caffeine is stopped. Consumers' reaction to caffeine is considered to vary and it is possible to observe some individuals that are more sensitive than others to caffeine, with some physiological reactions observed at lower intake levels.

As to sources of exposure to caffeine, recent reviews indicated that over one third (1/3) of caffeine intake for the European population is associated with the consumption of coffee and coffee products (Mitchell et al., 2014). 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 (Rotstein et al. 2013). The distribution of caffeine intake from different food sources, would gain to be collected for Egypt to support any projected update of this assessment. The likelihood of possible interaction of caffeine with other constituents of energy drinks or with physical exercise was found to be low (Rotstein et al. 2013).

As a result of this review, NFSA has adopted **a Maximum Allowable Concentration of Caffeine** in Energy drinks **set 400 mg/L**. A **minimum concentration of 200mg/L** was also adopted before products may be considered as CEDs and therefore as fulfilling the requirements of a "Special Food", according to the Egyptian food regulatory requirements, helping to differentiate these drinks from other soft drinks and to ensure that the claimed effects on "*Alertness"*, related to the inclusion of caffeine as an active ingredient are indeed fulfilled.

There is no need to establish **a maximum amount of caffeine per container** for the set volume of 250 mL, considering that the level of caffeine is already capped at the level of 100 mg per container, through the adoption of the maximum concentration set at 400 mg/mL. This would mean that a serving of CEDs or one setting of consumption of a 250 mL container of CEDs would equate to the intake of a maximum amount of caffeine (100 mg) lower than what would be provided by a moderate cup of coffee. This would also mean that the intake of caffeine in one consumption setting of these Energy drinks by an adolescent weighing between 50 and 70 kg is lower than the Health Based Guidance Value of 2.5 mg/kgbw/day, which was adopted as the conservative upper limit of caffeine intake for adolescents.

However, and should NFSA receive a request to register products at a higher volume e.g., 400 mL and 500 mL, there would be a need to adopt an additional measure beyond setting a maximum concentration level of caffeine in these products.

Setting a maximum amount of Caffeine per container at 180 mg /container 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 daily level varying between 2.5 mg/kg bw and 3mg/kg bw for individuals, weighing 70 kg and 60 kg body weight respectively. The 180 mg maximum cut-off per container, corresponds to the amount of caffeine expected to be contained in a moderately strong cup of coffee. Such limitation would allow to take into account the uncertainty related to maximum allowable level of caffeine for adolescents, due to limited data (Rotstein, et al, 2013, Nawrot et al., 2003).

This determination is also supporting a recommendation of consumption of these products to be limited to individuals **at 16 years old and higher**.

For products that deviate from the set Maximum Volume of 250 mL, the additional measure of 180 mg Caffeine per container for volumes higher than 250 mL and up to 500 mL would apply.

6.1.2 Taurine

The assessment of health risks associated with Taurine as an ingredient of CEDs did not identify a concern of possible adverse effects at the levels added in the CED products available in most international markets. Setting a Maximum Amount was not considered indispensable for this supplemental ingredient when added to CEDs. However, a maximum amount of 2000 mg per serving is being recommended for use in supplemented foods in general. According to Health Canada's guidance (2022a), occasional consumption of multiple servings of different supplemented foods (e.g., up to 5 servings), each containing taurine up to the maximum amount of 2000 mg/day, would not result in adverse health effects.

As a result, NFSA's recommended maximum amount for Taurine **is set at 1000 mg** for the set maximum volume of 250 mL of CEDs.

For products with volumes that deviate from the set Maximum Volume of 250 mL, the maximum amount may be adjusted proportionately.

6.1.3 Glucuronolactone and inositol

These ingredients are considered acceptable food ingredients – not supplemental ingredients – and their addition to foods, including CEDs and other supplemented foods, is subject to the technical requirements for the formulation of the product. NFSA has however established a

guidance for these ingredients not to exceed **600 mg of Glucuronolactone** and **200 mg of Inositol** for a volume of 250 mL, based on most common formulations of these products, for these volumes.

For products with volumes that deviate from the set Maximum Volume of 250 mL, the maximum amount may to be adjusted proportionately.

6.2 Maximum amounts of other supplemental ingredients in caffeinated energy drinks (CED)

6.2.1 Methodology

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

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

Where:

- The Safe daily amount: unless indicated otherwise is the **total daily amount** that is likely to pose no adverse effects to most individuals and that should not be exceeded. Such Values were extracted as **Tolerable Upper Intake Levels (UL)** from the Institute of Medicine (2006), from Health Canada's Multi-Vitamin / Mineral Monograph (2022b) or from data published by the European Food Safety Authority (EFSA).
- Daily food and supplement intake would represent the Recommended Dietary Allowance (RDA) or the Adequate Intake (AI) values established by the Institute of Medicine (2006). When a national nutrition survey is available (as is the case in Canada and other countries) the 95th percentile of the usual intake distribution, including nutrient intake data from both food and supplements, may be used.
- The denominator of 5 was used to account for the possibility that individuals might consume multiple servings of supplemented foods, providing intake of the supplemental ingredient in one day. Such method mirrored the Canadian approach, where a survey conducted during the period where Energy Drinks and other supplemented foods were granted a Temporary Marketing Authorization showed that a very small proportion of respondents consumed 5 or more CEDs and/or other supplemented foods per day (Health Canada, 2022a). Therefore, **5 servings were considered a suitable and conservative estimate** of the number of supplemented foods consumed per day by Egyptian consumers.

All inputs are based on the most vulnerable age-gender group (for individuals over 14 years of age and older), established as the smallest difference after subtracting background intakes from the safe daily amount.

Although lacking confirmation of some assumptions to be further validated for the Egyptian context, the proposed approach to set Maximum levels of other supplemental ingredients is considered to be conservative and protective of the Egyptian population.

It is recommended however that such assumptions be further validated after a set period of availability of CEDs, fitting these formulations on the Egyptian market.

The approach followed aimed to set **proposed maximum amounts of the targeted supplemental ingredients, likely to be included in CEDs,** that can be safely consumed by the Egyptian population, without exceeding the safe daily amount, while also enabling a minimum disruption to trade of these products, i.e., considering the formulations made available in international markets and submitted by product manufacturers.

6.2.2 Proposed Values for Other Supplemental Ingredients

Supplemental ingredients suitable to the establishment of maximum amounts were identified through international and Egyptian reports. The major ingredients found in CEDs sold in other jurisdictions such as Canada or Europe, and their average amounts, measured analytically, are shown in Table 1.

Table 1. Average amounts of major ingredients per serving of CED (analytical measures, Canada)

Ingredients	Range in CEDs† (per serving)	Typical CED in 2013 (per 250 mL serving)	Typical CED in 2019 (per 250 mL serving)	Typical CED in 2019 (per 473 mL serving‡,§)
Caffeine (mg)	40–180	80	80	160
Taurine (mg)	3–3000	1000	1000	2000
Glucuronolactone (mg)	5–1200	600	0	0
Inositol (mg)	5–200	50	0	0
Niacinamide (vitamin B3, mg)	3–100	18	20	36
Vitamin B6 (mg)	0.26–14	2	5	6
Vitamin B12 (μg)	0.48–25	1	5	12
Pantothenic acid (vitamin|B5, mg)	1.13–100	6	5	13
Thiamine (vitamin B1, mg)	2.25	2	0	0
Riboflavin (vitamin B2, mg)	0.6–10.2	1.65	0	1.7
Sugar (g)	0 (sugar free)–93	0–93	0–27	0–55

*Some other ingredients such as Guarana seed extract, Panax ginseng etc. . . may be present in some CEDs. Further research needed to identify other potentially major ingredients.
†Serving size ranges from 250 to 710 mL.
‡Based on average amount of ingredient across the 3 dominant brands of a 473 mL CED.
§The maximum number of servings per day indicated on the product label is adjusted in accordance with the daily maximum levels established for ingredients.

Extracted from La Vieille, et al. (2021)

CEDs sold in Egypt report similar values for vitamins on their labels (Table 2).

Table 2. Average amounts of major vitamins per 250 ml serving of CED (label declarations, Egypt)

Supplemental ingredient	Concentration (per 100 ml)			Average (per 250 ml)
	Red Bull	Power Horse	Monster	
Vitamin B5	2 mg	2 mg	4.2 mg	5 mg
Vitamin B6	2 mg	2 mg	0.8 mg	5 mg
Vitamin B12	2 µg	2 µg	2 µg	5 µg
Vitamin B3	8 mg	8 mg	8.5 mg	20 mg

A summary of the recommended maximum amounts of supplemental ingredients in a volume of **250 mL of CEDs**, as determined by the methodology described above, is presented in Table 3, followed by in-text detailed descriptions of data sources and calculations applied.

Table 3. Recommended maximum amounts of supplemental ingredients (SI) in CEDs marketed in Egypt

SI	Units	UL[1]	Age group	Source	Daily intake[2]	Population group	Source	Max. amount[3]
Vit. B12	µg	1000	All	Health Canada (2022b)	2.4	> 14, all	Institute of Medicine (2006)	200
Vit. B5	mg	500	All		5.0	> 14, all		100
Vit. B1	mg	100	All		1.2	> 14, M		20
Vit. B2	mg	100	14-18		1.3	> 14, M		20
Vit. B3	mg	900	All	EFSA (2014)	16.0	14-18		180
Vit. B6	mg	80	14-18	Institute of Medicine (2006)	1.3	14-18, M		15
Vit. C	mg	1800	14-18		75	14-18, M		350
Vit. E	mg	800	14-18		15	14-18, all		160
Magnesium[4]	mg	350	>14		--	> 14, all		70
Phosphorous	mg	4000	>14		1240	14-18, all		550
Calcium	mg	2500	>14		1500	> 14, all		240
Potassium	mg	200	>19	Health Canada (2022b)	4.7	> 14, all		40

1. Upper level.
2. Recommended daily allowance (RDA), except for calcium and magnesium, where adequate intake (AI) was used.
3. Rounded. Considering 5 servings of CEDs and/or other supplemented foods per day.
4. The upper level represents the highest level of magnesium taken acutely without food. Therefore, no daily intake was considered to establish maximum amount in CEDs.

6.2.3 Vitamin B12

Based on the difference between the UL and the RDA, the most vulnerable population was identified as all 14 year or older groups, by considering the smallest UL and the largest value of RDA among this age/gender group. The UL was extracted from Health Canada's monograph (2022b) and the RDA, from the publication by the Institute of Medicine (2006).

$$Maximum\ Vit\ B12\ amount = \frac{(1000 - 2.4)}{5} = 199.52\ \mu g$$

This value was rounded to 200 μg

6.2.4 Vitamin B5 (pantothenic acid)

Based on the difference between the UL and the RDA, the most vulnerable population was identified as all 14 year or older groups, by considering the smallest UL and the largest value of

RDA among this age/gender group. The UL was extracted from Health Canada's monograph (2022b) and the RDA, from the publication by the Institute of Medicine (2006).

$$Maximum\ Vit\ B5\ amount = \frac{(500 - 5)}{5} = 99\ mg$$

This value was rounded to 100 mg

6.2.5 Vitamin B1 (thiamin)

Based on the difference between UL and RDA, the most vulnerable population was identified as males, 14 years-old or older, by considering the smallest UL and the largest value of RDA among this age/gender group. The UL was extracted from Health Canada's monograph (2022b) and the RDA, from the publication by the Institute of Medicine (2006).

$$Maximum\ Vit\ B1\ amount = \frac{(100 - 1.2)}{5} = 19.76\ mg$$

This value was rounded to 20 mg

6.2.6 Vitamin B2 (riboflavin)

Based on the difference between the UL and the RDA, the most vulnerable population was identified as males, 14 years-old or older, by considering the smallest UL and the largest value of RDA among this age/gender group. The UL was extracted from Health Canada's monograph (2022b) and the RDA, from the publication by the Institute of Medicine (2006).

$$Maximum\ Vit\ B2\ amount = \frac{(1000 - 1.3)}{5} = 19.74\ mg$$

This value was rounded to 20 mg.

6.2.7 Vitamin B3 (niacin / niacinamide / nicotinamide)

Based on the difference between the UL and the RDA, the most vulnerable population was identified as males, 14 or older, by considering the group with the smallest UL and the largest value of RDA among this age/gender group. The UL was extracted from EFSA's Scientific Opinion (2014) and the RDA, from the publication by the Institute of Medicine (2006). This maximum amount is not applicable during pregnancy or lactation because of insufficient data on the upper levels (EFSA, 2014). Therefore, a cautionary statement **"Not recommended for pregnant or breastfeeding women"** may be required for products containing niacin above 30 mg per serving, based on the lowest UL established by the Institute of Medicine for pregnant and breastfeeding women (Health Canada, 2022a).

$$Maximum\ Vit\ B3\ amount = \frac{(900 - 16)}{5} = 176.80\ mg$$

This value was rounded to 180 mg.

6.1.4 Vitamin B6

Based on the difference between the UL and the RDA, the most vulnerable population was identified as 14-18 year-old males, by considering the group with the smallest UL and the largest value of RDA among this age/gender group. Both the UL and the RDA were extracted from the publication by the Institute of Medicine (2006).

$$Maximum\ Vit\ B6\ amount = \frac{(80 - 1.3)}{5} = 15.74\ mg$$

This value was rounded to 15 mg

6.2.8 Vitamin C

Based on the difference between the UL and the RDA, the most vulnerable population was identified as 14-18 year-old males, by considering the group with the smallest UL and the largest value of RDA among this age/gender group. Both the UL and the RDA were extracted from the publication by the Institute of Medicine (2006).

$$Maximum\ Vit\ C\ amount = \frac{(1800 - 75)}{5} = 345\ mg$$

This value was rounded to 350 mg

6.2.9 Vitamin E

Based on the difference between the UL and the RDA, the most vulnerable population was identified as 14-18 year-olds, by considering the group with the smallest UL and the largest value of RDA. Both the UL and the RDA were extracted from the publication by the Institute of Medicine (2006).

$$Maximum\ Vit\ E\ amount = \frac{(800 - 15)}{5} = 157\ mg$$

This value was rounded to 160 mg

6.2.10 Magnesium

The upper level, extracted from the Institute of Medicine (2006) and applicable to the population higher than 14 years of age, represents the highest level of magnesium taken acutely without food that is likely to pose no risk or adverse effects for most people. Therefore, a different approach was adopted for Magnesium. Setting the maximum magnesium level in CEDs was established based **on a possible acute dose**, and no daily intake was considered.

$$Maximum\ magnesium\ amount = \frac{350}{5} = 70\ mg$$

6.2.11 Phosphorous

Based on the difference between the UL and the RDA, the most vulnerable population was identified as 14-18 year-olds, by considering the group with the smallest UL and the largest value of RDA. Both the UL and the RDA were extracted from the publication by the Institute of Medicine (2006).

$$Maximum\ phosphorous\ amount = \frac{(4000 - 1250)}{5} = 550\ mg$$

6.2.12 Calcium

Based on the difference between the UL and the daily intake, the most vulnerable population was identified as 14–18-year-olds, by considering the group with the smallest UL and the largest value of daily intake. The UL was extracted from the publication by the Institute of Medicine (2006). An RDA for calcium has not been established by the Institute of Medicine (2006) due to inadequacy of the available data. Instead, an **adequate intake** was reported in the publication by the Institute of Medicine (2006) and is used here as surrogate for daily intake.

$$Maximum\ calcium\ amount = \frac{(2500 - 1300)}{5} = 240\ mg$$

6.2.13 Potassium

Based on the difference between the UL and the daily intake, the most vulnerable population was identified as all individuals higher than 14 years of age, by considering the group with the smallest UL and the largest value of daily intake. The Institute of Medicine (2006) **has not established a UL** for potassium, since, in healthy people, *excess potassium above the adequate intake is readily excreted in the urine*. Thus, the UL was extracted from Health Canada's monograph (2022b). An RDA for potassium has not been established by the Institute of Medicine (2006) either due to inadequacy of the available data. Instead, an **adequate intake** was reported by the publication by the Institute of Medicine (2006) and is used here as daily intake.

$$Maximum\ potassium\ amount = \frac{(200 - 4.7)}{5} = 39.06\ mg$$

This value was rounded to 40 mg.

However, and given the absence of UL for Potassium and although a set level of 40 mg was identified, possible higher amounts of Potassium could be allowed in CED formulations.

6.2.14 Amounts of Supplementing Ingredients in Other Volumes Deviating from the Maximum Volume of 250 mL

Considering the review of the formulation of products available on the Egyptian market and others being considered for introduction, it was deemed that the Maximum Values of

Supplementing Ingredients for the set Maximum Volume of 250 mL and shown in Table 3 would be considered applicable to other higher volumes of CED products. This measure supports a more conservative approach aiming to keep enough room for the possible introduction of these supplementing ingredients through other means in the diet and consumption habits e.g., use of supplements of vitamins and minerals.

7. Other Restrictions in CED formulations

Other risk management measures were considered as part of the formulation requirements of CEDs. In particular, the need to ensure that these products, while being functional foods, i.e., part of the regulatory definition of "Special Foods", would not contain therapeutic or other ingredients known to affect hormonal functions.

Similarly, these products are meant to be non-alcoholic beverages and would therefore be restricted to a level of alcohol not exceeding 0.1 % v/v.

Other functional ingredients known to induce possible adverse effects are explicitly prohibited to be included in CED formulations. These functional ingredients include:

- Vitamin A in its Retinol form, including Retinyl acetate and Retinyl palmitate,
- Folic Acid and its salts,
- Nicotin,
- Other therapeutic herbs.

Substances that have not been included in the monograph and assessed as part of this report, may be considered by NFSA, as part of separate evaluations, leading to specific formulations to be approved or leading to the amendment of this monograph.

Based on the risk management considerations to ensure this product remains destined to adults or adolescents from 16 years and older, some formulations known to be of interest to children as part of the beverage consumption of this subset of the population will be restricted:

- Milk and dairy ingredients are excluded from the formulation of CEDs.
- Fruit and Vegetable Juices are also restricted to be part of the formulation, such that they do not represent a proportion of 25% or higher of the composition of the product. Such measure will ensure that these products are not confused with the "Juice" or Juice product" categories, known to be sought after by children or other subsets of the population. The name "Juice" can not be included in the name of the product for the same reason.

8. Proposed Labelling Requirements and their Justification

CEDs as special foods remain subject to all labelling requirements of prepackaged foods, available for sale in Egypt. In addition, other specific requirements have been considered to support enhanced management of the risks associated with the possible mis-identification of the product and/or possible over consumption.

It is therefore recommended that the product be clearly identified as an **Energy Drink in the Principal Display Panel**. The Term **Energy Drink** has become a **common terminology** for products, known to consumers and in international trade, which identifies these products as

beverages promoting alertness because of caffeine and other possible ingredients in the formulation of the product(s).

All active ingredients described in this report, and included in the product formulation ought to be clearly labelled, **with the amounts included in the volume adopted by the producer**. This measure would allow consumers wishing to monitor their intake of specific active ingredients to do so, based on the simple declaration of amounts.

Additional labelling requirements are recommended to support the management of the consumption of these products, mitigating possible overconsumption scenarios, but also to clearly identify the target population for these products.

As a result, the following statements are proposed to be made compulsory on the product label:

- **Overconsumption of this product is to be avoided. It is recommended to consume this product up to 2 servings (or cans) 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**.

The first statement would be adjusted for higher volumes than the Maximum Set Volume of 250 mL, and up to 500 mL. This statement could read:

- **Overconsumption of this product is to be avoided. It is recommended to not exceed one Serving (or one can) of this product per day.**

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 performance.

Other claims in relation with the function of the active ingredients included in the formulation should be allowed for use, to help consumers identify the sought after function of such ingredients. Claims related to the alertness effect of caffeine and other ingredients are allowed, as well as the claims related to non-sugar sweeteners when these are concluded in the product formulation (low to zero calorie/sugar intake related claims).

9. Other Risk Management measures:

As is the case with several functional foods, possible risks related to the product tend to be linked to mis-use or over consumption of the product. That is why, beyond the measures taken through the regulatory instrument which restrict formulation requirements and set labelling obligations, there is a need to associate these measures with non-regulatory interventions

meant to maximize the effectiveness of the regulatory obligations. Such interventions should include targeted consumer information and education to support the identification of these products as functional products and to ensure that the possible risks associated with mis-use or over consumption are being understood and mitigated.

Education campaigns, collaboration with health professionals, youth and educational organizations to disseminate information related to the composition of the CEDs, their conditions of use and the need to observe healthy consumption behaviour should be pursed by NFSA and its partners, including industry partners.

Creating synergies between food standard development and regulatory measures and other non-regulatory interventions is considered a cornerstone of food risk management to support consumer protection. Such practices are deemed to be in line with recommendations of the World Trade Organization (WTO), which advocate the reliance upon risk-analysis to develop food standards and that food regulatory measures be justified by a robust and documented risk assessment, and be commensurate to potential health risks characterized.

10. Conclusion

This report offers a risk-analysis driven approach to support the development of evidence-based regulatory measures to authorize products, known as Caffeinated Energy Drinks or Energy Drinks in line with the Special Food Regulatory requirements in the Arab Republic of Egypt, under the authority of NFSA.

Several of the recommendations were based on the best available scientific information, while attempting to adapt such information to the Egyptian context. While the set requirements resulting from this analysis are in line with international best practices and are convergent with decisions issued by other regulators in Australia, New-Zealand, North America and Europe, it is recommended that this assessment be reviewed after 5-7 years from the issuance of the decision of the monograph that sets the conditions of formulation and labelling of CEDs to be made available for sale in Egypt.

Such review is also consistent with best practices enabling to ascertain the effectiveness of the risk management measures adopted supporting optimum protection of Egyptian consumers and NFSA’s role as a leading food regulatory authority in the Arab and African context.

11. References

European Food Safety Authority Panel on Dietetic Products, Nutrition and Allergies. 2014. Scientific Opinion on Dietary Reference Values for niacin. *EFSA Journal*, 12(7):3759

European Food Safety Authority, 2015, Scientific Opinion on the Safety of Caffeine – EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), EFSA Journal – 2015, 13(5), 4102.

Rotstein, J., Barber, J., Strowbridge, C., Hayward, S., Huang, R. and Godefroy, S.B., Energy Drinks: An assessment of the Potential Health Risks in the Canadian Context, Int. Food Risk Anal., 2013 (3) 1-29. DOI: 10.5772/56723

La Vieille, S., Gillespie, Z., Bonvalot, Y., Benkhedda, K., Grinberg, N., Rotstein, J., Barber, J. and Krahn, A.D. 2021. Caffeinated energy drinks in the Canadian context: health risk assessment with a focus on cardiovascular effects. *Appl. Physiol. Nutr. Metab.,* 46: 1019–1028. dx.doi.org/10.1139/apnm-2021-0245

Vandenbroele J, Vermeir I, Geuens M, Slabbinck H, Van Kerckhove A. Nudging to get our food choices on a sustainable track. *Proceedings of the Nutrition Society*. 2020;79(1):133-146. doi:10.1017/S0029665119000971

Jayawardena R, Swarnamali H, Ranasinghe P, Hills AP Impact of portion-control plates (PCP) on weight reduction: A systematic review and meta-analysis of intervention studies. *Obesity Research & Clinical Practice,* 2021; 15 (1) 106-113, https://doi.org/10.1016/j.orcp.2021.01.008.

Health Canada. 2022a. Guidance document: Supplemented Foods Regulations.

Health Canada. 2022b. Multi-Vitamin/Mineral Supplements Monograph.

Nawrot P., Jordan S., Eastwood J., Rotsetein J., Hugenholtz A. and Feeley M., 2003, Effects of Caffeine on Human Health, Food Additives and Contaminants, 2003 (1): 1-30.

Institute of Medicine. 2006. Dietary Reference Intakes: The Essential Guide to Nutrient Requirements. Washington, DC: The National Academies Press. https://doi.org/10.17226/11537.

VKM, 2019, Report from the Norwegian Scientific Committee for Food and Environment (VKM) 2019: 01 Risk assessment of energy drinks and caffeine.

VKM, 2021, Report from the Norwegian Scientific Committee for Food and Environment (VKM), 2021:05, Risk assessment of caffeine exposure from diet and personal care products.

Mitchell et al., 2014 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.