Food Safety and Standards Authority of India
Proposes Regulation of Energy Drinks, and Caffeine (Revised)

Introduction

1. Energy drinks are non-alcoholic beverages containing caffeine, guarana, glucuronolactone, taurine, ginseng, inositol, carnitine, B-vitamins etc. as main ingredients that act as stimulants. In recent years, a number of different energy drinks have been introduced in the Indian market to provide an energy boost or as dietary supplements. These drinks contain high levels of caffeine which stimulates the nervous system.

2. Energy drinks are heavily marketed to young adults and others and manufacturers compare the effects of the drinks to the use of drugs like cocaine. Many of these drinks are heavily promoted in bars or for use in combination with alcohol, which could further increase the health risk to consumers. There are a number of scientific reports on the adverse consequences of excessive consumption of caffeine. The main sources of caffeine are tea, coffee and soft drinks. In energy drinks, caffeine is added at levels of up to 80 mg per serve. The drinks usually have a number of added water soluble vitamins such as, niacin, pathothenic acid, vitamin B_6 and vitamin B_{12} and other substances, such as amino acids.

3. There are, at present, no Codex Standards for soft drinks or non-alcoholic carbonated beverages. Several countries have approved energy drinks as dietary supplements. The health implications of caffeine have also been enquired into by several countries.

4. Caffeine is added to energy drinks ostensibly to increase mental performance. The detrimental effects of caffeine have been identified by several studies. Moreover, caffeine used in conjunction with alcoholic or other substances of dependence can have additional impact on health. The scientific community has been concerned at the potential access to caffeinated beverages by children and the carry over fortification from caffeine fortified foods to other products. Therefore, products which have caffeine as ingredient are usually prohibited from being used as ingredient in other beverages commonly consumed by children. Pregnant and lactating women are vulnerable groups for whom high consumption of caffeine is not advised. The supply of caffeine from all sources of a normal diet should also be considered while determining the maximum permissible limit.

Brief Review of Scientific Literature

5. The following is a brief summary of reports relating to energy drinks and caffeine. These are not necessarily based on peer reviewed scientific research nor do they purport to represent the views of the Food Authority.

6. In August 2008, a study conducted by the Cardiovascular Research Centre at the Royal Adelaide Hospital in Australia found that energy drinks could increase the risk of strokes and heart attacks. According to the research, even consuming one can of the caffeinated energy drink Red Bull could cause the blood to become sticky, increasing the risk of clotting.

7. A group of 100 scientists and physicians, led by a neuroscientist at Johns Hopkins School of Medicine, has sent a petition to FDA urging the agency to increase energy drink regulations, as the high caffeine drinks could increase the risk of caffeine intoxication and alcohol-related injuries. The group of scientists and experts believe that warnings and limits are necessary because there is a wide disparity in caffeine and alcohol content in the various brands of energy drinks. In some non-alcoholic energy drinks, caffeine content varies between 75mg and 150mg per can. In some other energy drinks, caffeine content drastically varies between 300mg and 500mg per can. Caffeine intoxication can result from drinking too much caffeine, with symptoms like rapid heart rate, anxiety, insomnia, nausea and vomiting, restlessness, tremors and even death, in rare cases. In many cases, multiple energy drinks may be consumed in a short period of time, which may increase the risk of injury. Non-alcoholic energy drinks also often mixed with alcohol, which can make it harder to gauge the level of intoxication, leading to a higher risk of auto accidents and other alcohol related injuries.

8. In humans, caffeine is a central nervous system stimulant, having the effect of temporarily warding off drowsiness and restoring alertness. Caffeine is the world's most widely consumed psychoactive substance, but unlike many other psychoactive substances it is legal and unregulated in many countries. The U.S. FDA lists caffeine as a "multiple purpose, generally recognized as a safe food substance".

9. Caffeine has diuretic properties, when administered in sufficient doses in subjects who do not have tolerance. Guarana, a prime ingredient of energy drinks, contains large

amounts of caffeine with small amounts of theobromine and theophylline in a naturally occurring slow-release excipient.

10. Caffeine readily crosses the blood–brain barrier that separates the bloodstream from the interior of the brain. Once in the brain, the principal mode of action is as a non-selective antagonist of adenosine receptors. Caffeine acts as a competitive inhibitor. By counteracting adenosine, caffeine reduces resting cerebral blood flow to between 22% and 30%. Caffeine also has a generally disinhibitory effect on neural activity.

11. Metabolites of caffeine also contribute to caffeine's effects. Paraxanthine is responsible for an increase in the lipolysis process, which releases glycerol and fatty acids into the blood to be used as a source of fuel by the muscles. Theobromine is a vasodilator that increases the amount of oxygen and nutrient flow to the brain and muscles. Theophylline acts as a smooth muscle relaxant that chiefly affects bronchioles and acts as a chronotrope and inotrope that increases heart rate and efficiency. Consumption of caffeine does not eliminate the need for sleep. It only temporarily reduces the sensation of being tired throughout the day.

12. In large amounts, especially over extended periods of time, caffeine can lead to a condition known as caffeinism, which usually combines caffeine dependency with a wide range of unpleasant physical and mental conditions including nervousness, irritability, anxiety, tremulousness, muscle twitching, insomnia, headaches, respiratory alkalosis, and heart palpitations. Four caffeine-induced psychiatric disorders recognized by the Diagnostic and Statistical Manual of Mental Disorders (Fourth Edition) are caffeine intoxication, caffeine-induced anxiety disorder, caffeine-induced sleep disorder, and caffeine-related disorder not otherwise specified.

13. The Food Standards Agency, UK has recently issued an advisory against excessive consumption of caffeine by pregnant women. The European Commission has established new rules governing labelling caffeine and quinine in drinks and food in a bid to protect consumers who may be prone to adverse reactions. According to the new rules, drinks containing more than 150 mg per litre of caffeine will be required to label the quantity of caffeine such as “High Caffeine Content” and the amount of caffeine used in the same field as the name of the product. This however, does not apply for drinks based on tea and coffee as long as the name of the drinks makes it clear that it has been made from tea or coffee.

Risk Assessment by National Institute of Nutrition, Hyderabad

14. At the request of FSSAI, a preliminary risk assessment was carried out by National Institute of Nutrition after review of the literature regarding safety aspect of caffeine, taurine, D-glucurono-y-lactone which are the ingredients present in energy drinks, the estimated exposure to these ingredients based on surveys done as well as the daily intake of caffeine from all sources both natural and added. The following paras summarise the findings :-

(a) Caffeine whose chemical name is 1, 3, 7 – trimethylxanthine is a naturally occurring alkaloid substance found in leaves, seeds and fruits of more than 63 plant species worldwide. Some of the common sources of caffeine are the kola nut (Cola acuminate), cacao bean (Theobroma cacao), yerba mate (llex paraguariensis) and guarana berries (Paullinia cupana), however, roasted coffee beans (Coffea Arabica and Coffea robusta) and tea leaves (Camellia sinensis) are the world's primary sources of dietary caffeine.

(b) Taurine and D-glucurono-y-lactone do not contribute to the daily intake in the Indian diet from other sources in any significant amount.

(c) Approximately 80% of the world population consumes a caffeinated product every day. Caffeine is consumed most frequently through beverages such as, coffee (71%), soft drinks (16%) and tea (12%). There is no chemical difference between synthetic caffeine and naturally sourced caffeine.

(d) The safety of caffeine intake has been assessed by several national regulatory scientific committees for use at the levels of consumption estimated by their respective populations. Daily intakes of caffeine vary enormously world-wide from 210 – 238 mg per day in the US and Canada and greater than 400mg per day in Nordic countries. Coffee consumption as a source of caffeine is estimated to be 0.1 kg per capita in India. In the case of caffeine intake in coffee, the ratio between India and USA is 42 : 100. While India and UK are traditionally tea drinking populations, per capita tea consumption is not expected to significantly impact caffeine intake. While in India, tea consumption is considerably higher than coffee, the latter is more popular in southern states. Tea consumption is estimated to be 52%, milk consumption 14% and coffee 13%. Tea contains more caffeine than coffee, weight for weight, but less amount of tea is used to brew a cup of tea. A cup of 250ml coffee contains 80-150 mg of caffeine compared to 60 mg from tea.

(e) The figure of 80mg per cup of coffee is based on a 250ml serving which is a large serving under Indian coffee drinking behaviour where serving sizes are much smaller varying from 100 – 150 ml per serve. The correct way of estimating the caffeine intake should be on the basis of the weight of coffee powder used per cup rather than the volume as consumed. According to the USDA one rounded teaspoon of instant coffee (1.8g) contains 57 mg of caffeine, which makes it more reasonable to expect approximately 60 mg caffeine per cup of coffee. Servings dispensed in cafe bars and up market retail outlets may be larger at around 250ml. However, these are patronized by a very small section of the population and is more an occasion-led than daily practice.

(f) The other source of caffeine is from caffeine containing beverages where caffeine content varies from 12 – 20 mg per 250 ml serving. However, the consumption of caffeine from cola beverages does not significantly contribute to the overall daily intake of caffeine. The major contributor is tea or coffee. In respect of carbonated drinks, it has been estimated that Indian consumption is about 28 times lower than UK and 59 times lower than the US. Carbonated beverages do not form a significant source of daily intake of caffeine. The risk assessment concludes that at current consumption level of caffeine, intake is likely to be less than or at the lower end of the low range (80 – 250 mg per day), and there is no cause for concern at current level of intake and unlikely to raise issues of safety concerns in the next few years.

(g) As pointed out earlier, the consumption of coffee in India is around 0.1-0.2 kg per capita and the expected caffeine intake would be 10-20 mg per day for coffee and 71 mg of caffeine per day for 3 servings of tea bags. These levels are much lower than caffeine intakes around the world.

(h) Energy drinks are described as any non-alcoholic, preferably carbonated drinks which claim the ability to provide heightened energy drinks and alertness by the use of caffeine or taurine and also other ingredients that claim to boost energy levels. To perform these functions, there is need to provide ingredients that fulfil the role for which their inclusions are made and at the level at which they are capable of doing so. Where a product lends itself to being defined by characterized ingredients that clearly determines its purpose or attributes, such as, performance, enhancement and alertness as in the case of energy drinks, compositional standards may be an

option towards developing a safety standard for energy drinks. This is the approach adopted by the Australia New Zealand Food Authority also.

(i) The European Union does not set an upper limit for caffeine but requires only labelling of caffeine content greater than 150mg per kg with "High Caffeine Content" (Xmg/100 ml). Coffee and tea are exempted. In Canada, caffeine is allowed at the level of up to 200mg/per litre in cola type beverages. Beverages containing 320 mg of caffeine per litre have been approved by the Canadian Health Authority as a natural health product requiring listing contents and nutritional facts. US FDA regulates caffeine content in soft drinks but does not regulate caffeine contained in energy drinks. Caffeine is considered 'generally regarded as safe' under US Code of Federal Regulations.

Expert Group on Energy Drinks

15. In India, there are no standards for energy drinks under PFA Act, 1954. The standards of carbonated water under PFA Rules, 1955 specify the maximum limits of caffeine of 200ppm which subsequently on recommendations by Central Committee on Food Standards were reduced to maximum level of 145ppm and notified vide notification GSR 431(E) dated 19.06.2009.

16. Food Safety and Standards Authority constituted an expert group with following Terms of Reference:-

(a) To examine the scientific literature and global position on use of caffeine and non-carbonated beverages and their labelling.

(b) To recommend the limit of caffeine in energy drinks and non-carbonated beverages under Food Regulations.

The Group was also asked to suggest whether any standards need to be laid down for energy drinks keeping in view the assessment of risk.

17. Expert Group made the following observations :-

(a) Caffeine is not an additive but a chemical with addictive property. Caffeine up to 200 ppm is added as a flavouring agent but above 200 ppm it is a functional

ingredient. The functionality of caffeine at 320 ppm need to be ascertained along with justification for fixing a cut-off limit at 320ppm.

(b) Energy drink is a beverage which is fortified with vitamins and there is no case for encouraging its consumption. The name 'energy drinks' is a misnomer as it gives the impression that this should be taken to get energy.

(c) The vegetarian and non-vegetarian symbol should also be given on the label of energy drinks as per the source of ingredients added.

(d) Standards for energy drinks, both carbonated and non-carbonated need to be laid down to enable better regulation of the product. These may be termed as 'caffeinated drinks'.

(e) There is a need to limit consumption of energy drinks by a person per day taking into account total caffeine content from all ingredients and items in the diet.

(f) Alternatively, instead of laying down separate standards for carbonated energy drinks, standards for carbonated beverages per se can be amended to include other ingredients like taurine, glucuronolactone, etc. which are found in energy drinks.

(g) There is also a need to get the market data of availability of energy drinks in India and analyse samples as a basis for fixation of standards according to Indian requirements.

18. The Expert Group on Energy Drinks concluded that various issues involved in drawing up a new standard for energy drinks need to be systematically identified through risk assessment. Thereafter, Food Safety and Standards Authority may initiate a process of consultation with stakeholders regarding the need for such standards, the components of the standard and the labelling requirements. The risk assessment of each ingredient also needs to be considered. It is also necessary to undertake a review of the impact on industry as well the WTO requirements.

19. FSSAI believes that the following issues would need to be considered while starting a process of developing standards for energy drinks:-

(a) Energy drinks are a part of newly defined category of foods which differ from general purpose and special dietary purpose foods. The combinations and levels of added substances in energy drinks should be based on evidence of safety rather than efficacy. Claims on energy drinks, therefore, should be subject to the same current prohibitions and conditions of substantiation such as health claims.

(b) Keeping in view the potential impact on dietary habits of vulnerable population, Food Safety and Standards Authority believes that it should develop an appropriate safety standard for energy drinks in the country. This will enable fixation of the ingredient levels, caffeine content and address other risk factors and appropriate regulation of the product. FSSAI is also aware that a number of brands of energy drinks are available within the country and presently they are not regulated.

(c) The new Standard will be applicable to caffeinated beverages as distinguished from caffeinated soft drinks. There is need to have a minimum caffeine level to ensure this differentiation.

(d) It is also proposed that appropriate provisions should be made for labelling of the product to discourage its use by the young population and pregnant and lactating women.

(e) Another issue of concern is the name of 'energy drink' which tends to create an impression that taking an energy drink is required to boost energy. A suggested alternative which has been adopted by Australian New Zealand Food Authority is to call it 'caffeinated beverage'.

20. Keeping in view the potential impact on consumption by young people and adverse effects on health, FSSAI proposes to seek public comments on the need to lay down standards for energy drinks in the country. The present brief indicates the scientific position regarding energy drinks, the regulatory experience of various countries and the results of the initial risk analysis undertaken by NIN in this regard. Stakeholders interested in sending in their comments may do so at the following address :-

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