

**Minutes of the 1<sup>ST</sup> Meeting of the Technical Group to examine the issue regarding the limit of caffeine in Energy Drinks held on 28.12.2010 at New Delhi.**

The 1<sup>st</sup> meeting of the Technical Group to examine the limit of caffeine in Energy Drinks was held on 28.12.2010 in FDA Bhawan, New Delhi. The list of participants is at Annexure- I

The Chairperson FSSAI welcomed the members of the Technical Group ADG (PFA) informed the members that as a need was felt to regulate energy drinks available in the market, Food Safety and Standards Authority constituted an Expert Group to examine the issue of limits of caffeine in energy drinks and suggest suitable standards.

The Expert Group deliberated in detail and reached the following conclusions .-

- The product should be named 'caffeinated beverage' because terming it as an 'energy drink' may create the impression that energy drinks are required to be taken to boost energy
- Caffeinated soft drinks in which caffeine is used as a flavouring agent may have limits of caffeine up to 145 mg per litre, while for heavily caffeinated beverages, the limit of caffeine should be more than 145 and up to 320 mg per litre
- Keeping in view the potential impact on consumption by young people and adverse effects on health, FSSAI sought public comments on the need to lay down standards for energy drinks in the country

The Expert Group reviewed the feedback received from stakeholders on the consultation document which was uploaded on the portal of FSSAI and widely circulated

The comments received from the stake holders were considered by the Expert Group in its third meeting which recommended that the product should be named 'caffeinated beverage' because terming it as an 'energy drink' may create the impression that energy drinks are required to be taken to boost energy

Caffeinated soft drinks in which caffeine is used as a flavouring agent may have limits of caffeine up to 145 mg per litre, while for heavily caffeinated beverages, the limit

of caffeine should be 320 mg per litre. The Group noted that on the basis of current scientific data and literature as well as the risk assessment carried out by various agencies, this range of caffeine content can be determined as a safe range beyond which toxic effects can be expected

Based on the above, the draft standards for 'caffeinated beverages' were suggested which were considered by the Food Authority and Scientific Committee wherein it was pointed out that a limit of 145ppm for caffeine was fixed for carbonated beverages after scientific deliberations and that a scientific evaluation of health risks from caffeine, keeping in view the consumption pattern within the country should be undertaken. This may be carried out by a Technical Group and that based on the report of this Technical Group, FSSAI may develop the required standards.

The Chairman of the Group sought the views of the Members on whether there is need to have standards for energy drinks and to suggest suitable safety limits of caffeine in the product.

The Members deliberated in detail on the limit of caffeine in carbonated beverages brought down to 145ppm from 200ppm by Central Committee for Food Standards and also took into account the limits of caffeine fixed for such drinks by other Food Authorities of other countries like Canada, ED, Korea, China and Ecuador. The following were the conclusions :-

1 There is a need to have a separate category for 'caffeinated beverages'

(a) The standards for carbonated beverages have already been prescribed wherein caffeine is used as a flavouring agent with an upper limit of 145ppm. Heavily caffeinated beverages need to be distinguished from the category of 'carbonated beverages' for enabling better regulation of such beverages and consumer awareness.

(b) Beverages wherein caffeine is added as a functional ingredient more than 145ppm and upto 320 ppm and containing ingredients like taurine, glucurodolactone, inositol, etc. which are not permitted in carbonated water may be termed as "caffeinated beverages". However, there should be no bar on the product being described as energy drinks or similar names provided it is also

indicated on the label that they are caffeinated beverages. Caffeine intake through these sources for the purposes of comparative intakes has been based on the amount contained in a 250ml serving. Accordingly the intake of caffeine from coffee is between 80-120mg depending on method of preparation. Energy drinks on a 250ml serve contains caffeine (80mg), equivalent to a serving of coffee. It has further been pointed out that coffee servings in regular consumption in India are in the range of 100-150ml and hence the serving size of 250 ml considered provides abundant caution in providing a limit.

(c) The above two products would be different from sports/electrolyte drinks which replaces lost electrolytes when consumed by sports persons. Standards for such products need to be developed separately

2. It was noted that already heavily caffeinated drinks are available in the market for more than 8 years and currently they are being categorized as 'proprietary foods' in view of the absence of an appropriate standard. Categorizing such drinks as 'proprietary foods' does not enable appropriate regulation of the caffeine content and other ingredients of this food item. From the point of view of effective regulation, it would be more appropriate to categorise products more scientifically and minimise recourse to the 'proprietary foods' category which are defined as food with no standards. Banning such products from the market is also not a feasible option since they are being used in more than 30 countries with appropriate restrictions and there is obviously a consumer demand for this product.

3. The Group agreed that a conservative approach should be adopted for allowing added substances to the heavily caffeinated beverages. Any additional item or ingredient proposed to be added, including herbal ingredients, should be subject to a safety assessment and substantiating scientific evidence before approval is given.

4. The Group also concluded that no health claims or enhanced functional claims may be made on caffeinated beverages unless specific approval has been granted

5. Caffeinated beverages should also be prohibited from bearing a nutrition information panel. Accordingly vitamin and nutritive claims should also be not permitted on such products.

6 The Group concluded that Caffeine in caffeinated beverages is present for a claimed functional effect and these beverages are not considered suitable for children. They also contain other added substances not permitted general purpose foods such as soft drinks. It is, therefore, necessary that such functional beverages should be differentiated from general purpose foods and the caffeine content used would be the most appropriate factor to provide this differentiation. It was concluded that as per scientific literature, it is the caffeine content that provided the feeling of energy while the effectiveness and purpose of other ingredients are not clearly established.

7 The Group also considered the issue of prescribing the minimum caffeine level of 145 ppm. It was concluded that such minimum level would be required to differentiate this product from carbonated beverages with lower caffeine content and which are available as a general purpose food. It will also convey the required information to the consumer on the content of caffeine along with appropriate cautionary advice on the upper limits of use.

8. The Group also concluded that there should be a restriction of packaging of this product to only 250 ml containers. This is required to provide an appropriate caution on the consumption of such beverages. The ingredients suggested in the standards would be optional ingredients subject to the limits mentioned. Any new ingredient or additive will be allowed only after an appropriate safety assessment and approval by the Authority.

9 The standards should also specify the caffeine content per serve of the product.

10 As regard issues raised in the Scientific Committee as to why 320ppm has been laid down as the upper limit, it was clarified that regarding caffeine intake levels it is generally agreed that low intake range is 80 - 250mg/day, moderate 300 - 400mg per day and high >500mg per day. The current exposure of Indians to caffeine from all sources is in the range of 80 - 250 mg which is considered to be at the low level range of intake and unlikely to raise issues of safety concerns in the next few years. Considering that a maximum level of caffeine is required to be recommended, the Expert Group relied on the actual caffeine content present in marketed products as well as regulatory actions internationally. Many countries including EU and USA have not placed a limit on the caffeine in energy drinks, except Australia, New Zealand which has placed a limit of 320mg/L. This is equivalent to taking about 4 cups of coffee per day (250ml). The amount of caffeine that can be consumed safely has been identified as 400mg/day or 6.5mg/kgbw. Considering the reference man of 60 kg, it works out to be 390mg/day. If it

is assumed that 50% of caffeine is contributed by energy drinks it would be 160mg (50% of proposed upper limit i.e. 320mg) and this amount is less than the safe intake of 195mg (50% of 390mg/day) Considering these regulatory practices and the need to restrict the intake of caffeine from energy drinks, the Expert Group recommended that a limit be placed on caffeine (320mg/L)

After detailed discussions, the Technical Group approved the draft regulations given at Annexure-II

The meeting ended with vote of thanks to the Members.

**Annexure I****The list of Expert Group members who attended the meeting on  
28.12.2010**

- 1 Dr B. Sesikeran, Director, National Institutes Nutrition, Hyderabad
- 2 Dr K. C Gupta, Director, Indian Institute of Toxicology Research,  
Lucknow

**The list of participants from FSSAI who attended the meeting on  
28.12.2010**

- 1 Chairperson, FSSAI
- 2 Director (M)
- 3 ADG (PFA)
- 4 TO (SG)
- 5 RA (V)

Annexure IIREGULATION 5.10.6: CAFFEINATED BEVERAGES

- 1 **Description :** Water-based non alcoholic flavoured drinks
- 2 **Essential Composition .** It shall contain not less than 145mg/l and not more than 320mg/l total caffeine from whatever sources it may be derived in the formulation of the product.

- 3 **Optional ingredients:** It may contain the following

Any of the substances listed in column 1 of the table given below provided that the amount of that substance is not more than the amount specified in relation to that substance in column 2 of the table subject to the following conditions:

- i Where any of the substances as mentioned in column 1 is used in the product, a declaration of the one day consumption shall be made namely: "Use not more than 2 cans"

- ii Number of cans that will cumulatively bring each substance mentioned in Column 1 to the level mentioned in column 2 will be calculated and the advised quantity will be the smallest of these number of cans that can be consumed per day For example if taurine is used at 1000mg per serve (250ml), and D-glucurono-Y-lactone 300 mg, the respective ceilings will be reached by consuming 2 cans and 4 cans respectively However, the one day advised quantity shall be the lower of the two numbers i e. not more than 2 cans where the package is 250ml

Column 1	Column 2
Substance	Maximum amount per day consumption
Taurine	2000mg
D-glucurono-Y-lactone	1200mg
Inisitol	100mg
Thiamin	} B vitamins may be added at 1 RDA level (100% RDA) with overages
Riboflavin	
Niacin	
Vitamin B6	
Vitamin B12	
Pantothenic Acid	10mg

4 In respect of sweeteners, food additives, contaminants and microbiological requirements the product shall conform to the standards for carbonated water

5 **Labelling :** The product shall comply with all provisions of General Labelling rules for pre-packaged foods, with the following additional provisions.

(a) High Caffeine "X mg/serving size" (where X is the amount of caffeine in milligrams per stated serving size (per can or per volume e.g 250ml)

(b) Prominent display of caution "Not recommended for children, pregnant or lactating women, persons sensitive to caffeine and sportspersons"

(c) The declaration "Use not more than 2 cans a day"

(d) Advice to the consumers that "The ingredients of this product consumed through other sources may also be kept in view"

6 **Packaging** 250ml containers.