

REPORT OF THE EXPERT GROUP ON AMAZE – BRAIN FOOD

Director, CFTRI had addressed a communication to Secretary (Health), Government of India and DGHS on 12th June, 2008 informing that Companies such as Kisan and Hindustan Unilever are marketing a proprietary food “Amaze Brain Food” claiming that it gives 33% of the key nutrients children need daily. He had pointed out that this proprietary food has not been cleared under the PFA Rules, 1955 and it is not correct to claim that such food gives 33% of the key brain nutrients children need daily.

Director, National Institute of Nutrition, Hyderabad had also expressed the view that based on the facts given on the label, Amaze Brain Food does not contain any unique nutrient required for brain functioning.

Based on these evaluations, the Ministry of Health & Family Welfare wrote to the company M/s Hindustan Unilever on 2nd September, 2008 suggesting deletion of words ‘brain food’ from the label as it contravened the provisions of Rule 37 of the PFA Rules 1955 and amounted to misrepresentation of facts and misbranding which is likely to delude the public. In response, the company made a detailed presentation to the Ministry and the PFA Authorities, justifying their claims and quoting scientific evidence in support of their stand.

After the constitution of Food Safety and Standards Authority this particular case was transferred to the Authority. The Food Safety and Standards Authority constituted an Expert Committee under the Chairmanship of Dr. Vasantha Muthuswamy, Senior Dy Director General (Retd) ICMR, New Delhi and having the following Members to consider the issue :-

- (a) Prof. B.N. Dhawan, Ex-Director
Central Drug Research Institute, Lucknow
- (b) Prof. Panna Choudhary, Professor of Paediatrics (Retd)
Maulana Azad Medical Collge, New Delhi
- (c) Dr. Anupa Siddhu, Director, Lady Irwin Collge
New Delhi
- (d) Dr. Kalpagam Polassa, Deputy Director, NIN, Hyderabad

The following were the Terms of Reference of the Committee:-

- (a) To examine whether the claims made by the company relating to brain development of children are supported by scientific evidence.

- (b) To examine whether the claims made by the company are likely to have an adverse impact on/or discourage healthy eating habits of children.
- (c) To examine what scientific evidence is required for entertaining claims of this nature and to identify the specific documents/reports to accompany a claim.
- (d) To identify the claims which can be allowed without a pre-market review and what should be the guidelines for such cases.

The Committee met on 26th October, 2009 in the Committee Room of FSSAI. The Committee also had a detailed interaction with the representatives of the Company who made a presentation before the Committee. Additional information was also provided to the Committee by the company on various issues. The Committee met again on 27th of January, 2010 to consider the view points of various Members and reviewed the scientific literature as well as the clarifications provided by the Company. On the basis of detailed deliberations, review of scientific literature and presentations made by the Company, the Committee has reached the following conclusions.

The following claims have been made by M/s Hindustan Unilever Ltd in respect of their product 'Amaze – Brain Food':-

1. The product claims that it gives 33% of key brain nutrients children need daily and contains the right type of nutrition in the right combination. The product is making nutritional claims and not health claims and are consistent with the Codex guidelines on the subject.
2. The Company claims that word "Brain Food" is used to convey to consumers what the product is in a consumer friendly language. It describes the product to indicate that ingredients used would help both the mental and physical development of children. It has been argued that it also helps the consumer in making an informed choice.
3. According to the company, the product is based on clear consumer insight identified after detailed consumer research that even in urban India, mothers find it difficult to ensure that the child consumes a balanced diet, as there is a nutrition transition taking place in India where children are attracted by other options including snacks and therefore, not receiving a holistic nutrition resulting in various issues of obesity etc. Consumer research also brings out a growing need expressed by mothers to address micronutrient deficiency of the brain.

4. The Company's R&D teams have developed the product specifically designed to provide 33% of recommended daily allowance (RDA) of all the key brain nutrients identified by FAO and WHO and have also tested the product across the world to address the need.
5. The Company claims that the product is in a format that is liked by children and which will fit into the daily diet of the children with ease, giving the mother an opportunity to meet the need expressed by her. Scientific studies show that Omega-3 intake is insufficient in the Indian population. The Company claims that 'Amaze' products can contribute positively to increase the intake of Omega-3.
6. According to the Company, the name 'brain food' is not misleading as the product meets nutritional requirements of the growing brain and the nutrients added in Amaze are required for brain structure and development.
7. The Company claims that in vitro bio-availability and internal in vitro bioavailability data have established that the iron in 'Amaze' powders is more bio available than iron in other key competitors. 'Amaze' products, according to the Company, are also designed to be low in saturated fats and trans fats as WHO recommends that amount of these items should be limited because they can be detrimental to health if taken in excess. 'Amaze' products are also nutrient dense and easily fit into a normal meal movement of a child and can replace the unhealthy snacks which children tend to get attracted to. They provide a nutritious option to mothers who find it difficult to feed their children nutrient rich foods like milk, pulses, green leafy vegetables, fish and meat etc. every day.
8. The Company also points out that there are several other similar products in the market which claim to benefit specific organs or bodily functions.

The group examined the above justification to support the claims made on the product and made the following observations and conclusions after detailed discussions:-

- (i) No evidence/ justification has been provided for the statement that the product meets the nutrient requirements of a growing brain. There is no convincing scientifically valid reason why they are focusing on 33% of nutrient requirement. It is also not clear that 33% nutrients claimed to be provided by this product are bio available, since no study has been given showing interactions between different minerals and their bio availability. In the literature on nutrition, there is nothing called "brain nutrients" or "key nutrients" of the brain. In WHO recommendations or ICMR Indian recommendations, there is no category of nutrient targeted for brain development or for special cognitive development.

Development is an inclusive word with physical, mental, social and emotional aspects. Accepting the argument of the company would amount to allowing claims related to muscle growth, heart growth, sexual growth or organ specific claims in respect of special nutrient mixes which is not supported by the current level of scientific development.

- (ii) No scientifically validated data has been provided by the company that will help an informed choice. Providing irrelevant and confusing data does not help the consumers in making an informed choice.
- (iii) Concluding which nutrients/micronutrients are needed by children based on the views expressed by mothers is not a scientific way for developing a product as mothers could be a motivated and ill informed group. The claim of the company to replace unhealthy snacks, in respect of the population who find it difficult to feed their children with nutrient rich foods like milk, pulses etc., is not substantiated with validated data. It is also not clear whether the product is supposed to replace normal meals which can lead to unhealthy developments in the diet of the population. The efficacy of the product to meet the perceived needs of nutrition transition occurring in India and micronutrient gap in urban well to do children need to be established.
- (iv) The information provided by the company is not specific for 'Amaze Brain food'. The evidence of similar studies can always be used as facts to support any other similar beverage. The present beverage powder has not been subjected to any clinical trial for substantial evidence. No data or any evidence has been provided by the company to support their claim that they have tested the product across the world to address the need.
- (v) No data on child population to support the claim with regard to Omega-3 has been provided. Further there is no evidence available for their product 'Amaze Brain Food' having positive contribution in increasing the intake of Omega- 3. The benefit of mental development in Amaze is linked to a cocktail of nutrients and not only to Omega-3 but also iron and iodine. Iron, zinc, vitamin B and C are also required for physiological function and these cannot be excluded while recommending nutrients for mental development.
- (vi) Brain growth and functional development are essentially complete in pre-school age. Some key micronutrients have a role in the cognitive development in early childhood. Except for iron, the role of other micronutrients in cognitive development is not proved in school age children. The impact of nutrients is limited to a population that is receiving a diet inadequate in micronutrients like, energy, fat and protein. The impact of key nutrients

in brain function is felt only when subjects are deficient in the said nutrients to start with. Indiscriminate consumption of the product can cause side effects which have not been identified or warned against.

There are critical periods of brain growth and development from gestation until the first two years of life. During this time brain development may be particularly sensitive to deficiencies in the diet. Thus most research has investigated the impact of nutrition on cognitive development under the age of two years. The target consumer group for this product is not likely to be the section of the society which is suffering from malnutrition. The micronutrients which are supposedly being added to 'Amaze Brain Food' may increase the overall wellness and concentration in children where there is inadequacy of some or all of them in their regular diet. But for others, it may only help in some overall growth and possibly has adverse health consequences. There is no evidence that the micronutrients incorporated in this specific formulation will pass the blood brain barrier and there is no evidence presented that the product has been appropriately field tested.

The research done by Unilever also mentions that further research is required to investigate the combined effects of various vitamins and micronutrients in various types of combined deficiencies. It also adds that research has not specifically investigated the effect of nutrition on functions of the frontal lobe.

- (vii) In the studies cited by the company, the descriptions of Fe availability, low Ca, low Zn and some vitamins C and B3, PUFA etc. in this combination do not establish any impact on iron availability or brain function. Only some comparative data on in vitro iron absorption of powdered drinks are presented without specifying the conditions of the experiment. The absorption in vitro is different from the specific bioavailability based on functional availability of nutrients in the presence of all natural dietary factors. In-vivo data has not been provided by the company to support its claim.

There is an established relationship between under nutrition and cognitive performance. However, factors such as, age, sex and years of education, socio-economic variables such as, parental income, education, health status, incidence of infection, social variables such as parental support, behavioural or motivational factors such as emotional state, lethargy and apathy all contribute to proper mental and physical development. The cause and effect relationship has not been established between consumption of the food and assumed benefits on the basis of any scientifically accepted, validated studies.

The National Institute of Nutrition have evaluated the effect of a micronutrient fortified beverage on mental function in school children and found that the mean intelligence quotient scores of the micronutrient fortified beverage group and the placebo group at baseline and final follow up were not significantly different. Mean verbal and performance scores and increments were also not different. Mean and incremental scores of the supplemented group on the memory scale were not significantly different from those of placebo group.

- (viii) If other companies are making similar claims, it does not justify making such claims, which are un-substantiated and misleading.
- (ix) Other comments on the label:-
 - i. The nutritive value given on the label is given along with the milk which is to be mixed with the product to form the beverage. Hence the claims on the product are not justified as it includes the nutrients provided by milk.
 - ii. Company has stated that they are giving this product to their own children but have not provided any data to support the claim.
 - iii. How the consumption of this beverage will provide nutrients which will make the child smart is not proved with any substantial documented evidence.
 - iv. Through the contents of their website and the claims of the product the company can be said to be misleading the parents as well as children.
- (x) The group also suggested that:-

There is need to generate data on other categories of food like health foods/nutritional supplements/foods which are meant to improve physiological and nutritional performance.

Conclusions:-

Query No. A

The group concluded that claims made by the company relating to brain development of children are not supported by adequate scientific evidence.

Query No. B

The group concluded that the claims made by the company are misleading giving a false sense of security.

If the product is brought in the market as “Brain Food”, the immediate perception of mothers would be that it would help to increase brain power like higher IQ, retention, concentration, sharpness etc. However, scientific reports show that the product may

deliver only a few and not all benefits and that too mainly if the child is particularly deficient in any particular nutrient.

Keeping in view the vagueness of the claim, the likely misuse of the product on the basis of assumed benefits and scientific support claimed, it can have an adverse impact on healthy eating habits. It also creates a wrong impression that consuming a cocktail of micronutrients provided by the product can take care of mental development of children, even if there is a total neglect of consumption of normal healthy diet.

Regarding **queries C and D** the group formulated the guidelines on Nutrition and Health Claims which are at **Annexure I** for consideration of the Food Safety and Standards Authority.

The list of participants in the Expert Group meetings held on 26.10.09 and 27.01.10 are at **Annexure-A**.

Annexure-A

List of participants in the Expert Group Meeting held on 26.10.2009

1. Dr. Vasantha Muthuswamy
Senior DDG, ICMR(Retd.) Chennai
2. Prof. Panna Choudhury
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Maulana Azad Medical College
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3. Dr. Anupa Siddhu
Director
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4. Dr. Kalpagam Polassa
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List of participants in the Expert Group Meeting held on 27.01.2010

1. Dr. Vasantha Muthuswamy
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2. Prof. Panna Choudhury
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