# Scientific Conference on Low Calorie / Non Nutritive Sweeteners: Uses & Safety

Tuesday, 15 September, 2015

New Delhi, India

*Conference Report*

Sponsored By

ILSI India

International Life Sciences Institute-India

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# MAJOR FINDINGS

## What are Low Calorie / Non Nutritive Sweeteners?

Nonnutritive sweeteners (also known as zero- or low-calorie sweeteners) are promising alternative to nutritive sweetener, such as table sugar (sucrose). Artificial sweeteners are synthetic sugar substitutes, but may also be derived from naturally occurring substances, including herbs or sugar itself. These sweeteners can be added to both hot and cold beverages and some can be used for baking. These sweeteners are also known as 'intense sweeteners' because they are many times sweeter than regular table sugar.

Artificial sweeteners provide no calorie / fewer calories per gram than sugar and they are not completely absorbed by the digestive system. Joint Expert Committee on Food Additives (JECFA), The Food and Drug Administration (FDA), Food Safety and Standards Authority of India (FSSAI), India has approved the use of the following nonnutritive sweeteners: acesulfame-K, aspartame, neotame, saccharin, sucralose and stevia on an Acceptable Daily Intake (ADI) basis.

## Health Benefits of Low Calorie / Non Nutritive Sweeteners

Low-calorie sweeteners provide consumers with many benefits, both psychological and physiological. Health professionals and consumers believe low-calorie sweeteners are effective for the following purposes: weight maintenance, weight reduction, management of diabetes, reduction of dental caries, and reduction in the risks associated with obesity.

## Low-Calorie Sweeteners can be Safely Consumed by the General Population, including People with Diabetes, Pregnant or Lactating Women and Children.

Joint Expert Committee on Food Additives (JECFA) approved low-calorie sweeteners can be safely consumed by the general population, including people with diabetes, pregnant women and children. One exception is people who have a rare hereditary condition called phenylketonuria (PKU), which means they cannot metabolize phenylalanine, a component of aspartame. For people with diabetes, low-calorie sweeteners can offer a sweet alternative that does not affect blood glucose levels.

Pregnant or lactating women and children can safely consume foods and beverages sweetened with low-calorie sweeteners. Current low-calorie sweetener consumption in children is well below the Acceptable Daily Intake (ADI) for all approved low-calorie sweeteners.

## Low-Calorie Sweeteners Do Not Cause or Increase the Risk to Other Health Conditions

Low-calorie sweeteners are often inaccurately linked to adverse health effects, such as seizures, infertility, stomach ailments, and possible effects on kidney and liver function. However, the existing body of research does not support such effects. Health authorities around the world have verified that low-calorie sweeteners are safe.

Low-calorie sweeteners provide an alternative to caloric sweeteners and may facilitate weight loss or maintenance by limiting calorie intake. In addition, randomized control trials suggest that the use of low-calorie sweeteners may increase adherence to low-calorie diets and improve body weight and weight loss maintenance over time. Because they are not deprived of sweets, individuals consuming low-calorie sweeteners may feel more satisfied with their eating plans, helping them to lose weight and keep it off.

# INTRODUCTION

ILSI-INDIA organized a Scientific Conference on "Low Calorie / Non Nutritive Sweeteners: Uses & Safety" on 15th September, 2015 at Hotel Le Meridien, New Delhi. The conference was attended by more than 100 delegates representing government, academia, industry, regulatory authorities and members of national and international societies. The conference discussed about the importance of artificial sweeteners which can be used to replace sugar. They are also called sugar substitutes, non-nutritive sweeteners (NNS), and non-caloric sweeteners. Low and no-calorie sweeteners are allowed for use in foods and beverages and have been extensively studied and found safe for use by all populations, including children, people with diabetes, and women who are pregnant or lactating. The welcome address at the conference was delivered by Mr. D. H. Pai Panandiker, Chairman, ILSI-India and the Keynote address was delivered by Major Gen. Dr. Raman K. Marwaha, Former Additional Director, Senior Consultant & Head, Dept. of Endocrinology and Thyroid Research Centre, INMAS, DRDO, Ministry of Defence, GOI. The conference was addressed by three eminent scientists who discussed about the uses and importance of low calorie sweeteners and their safety assessments and global regulatory approvals. Highlights of the presentations made by the speakers are given in this report.

# OPENING SESSION

**Welcome Address**

**Mr. D. H. Pai Panandiker** welcomed the participants and all the eminent speakers to the conference. **Mr. Panandiker** addressed the importance and necessity of low calorie sweeteners. He informed that sweeteners are a practical way of achieving energy balance. ***'Energy In must be Energy Out'*** for a good and healthy life. Energy can be taken up in the form of food sources like carbohydrates, sugars, fat, proteins and energy out is from the functioning of the body. If energy balance is not maintained it leads to obesity, fatigue, diabetes which further lead to complications like heart disease, kidney diseases, cancer etc. Mr. Panandiker mentioned that World Health organization (WHO) has issued the guideline that only 5-10% of energy should come from sugar. This can be achieved only with combination of reduction in sugar consumption and use of sugar substitute. Non Nutritive Sweeteners (NNS) is a very feasible safe alternative. The low/ zero calorie sweeteners play a very important role in leveling the energy balance.

**Keynote Address**

**Major Gen. Dr. Raman K Marwaha**, Former Additional Director, Senior Consultant & Head, Dept. of Endocrinology and Thyroid Research Centre, Institute of Nuclear Medicine & Allied Sciences, DRDO, Ministry of Defense, GOI in his keynote lecture emphasized that India has gone through drastic changes in last 2-3 decades because of industrialization, urbanization and economic betterment. Due to these demographic and epidemiologic transition our country moves from high fertility and mortality rates to low fertility and mortality rates and transition from infectious disease to non-communicable diseases (NCD) such as Obesity, Diabetes, Chronic heart disease (CHD), decreased fitness and activity, PCOS/MS, hypertension, stroke, many cancers, chronic lung disease, motor vehicle collisions and injuries etc. as the primary causes of mortality. He mentioned that the risk factors responsible for NCDs are diet, sedentary lifestyle, smoking, pollution, automobiles, aging population and urban migration.

Dr. Marwaha emphasized that at present India is in the midst of rapid socioeconomic, demographic nutrition and health transition. While India has still to overcome poverty, under nutrition and communicable diseases, yet, it is increasingly facing problems related to affluence such as obesity, metabolic syndrome, hypertension, diabetes mellitus and cardiovascular disorders. He mentioned that studies have been carried out which clearly showed the secular trends in height, weight and BMI in Indian children with significant increase in the prevalence of overweight (B-16.7% and G-19%) and obesity (B-5.6% and G-5.03%, $p<0.05\%$) from upper socio-economic strata as compared to overweight in ( B-2.6% and G-2.14%) and obesity in (B-0.42% Vs G-0.28%, $p<0.05\%$) from lower socio-economic strata. Children as young as 5 years of age started showing an increase in BMI, with

9% overweight and 8% obese in this age group.

Further, he informed the audience that both Indian children and adults have higher levels of serum triglycerides and low levels of high density lipoprotein (HDL) and higher % of body fat than the European subjects with comparable BMI values which has led to revision of WHO recommendations for appropriate BMI cut offs in Asian population. Cardiovascular disease risk factors, including abnormal lipid parameters, elevated body mass index and evidence of atherosclerotic changes have been reported in childhood and adolescence. Atherosclerotic cardiovascular disease is the leading cause of morbidity and mortality in the adult population globally, including India and other developing countries. South Asians have been shown to have earlier and more severe CHD as compared to white Caucasians.

Dr. Marwaha spelled out some facts that India has the highest prevalence of premature coronary heart disease and cardiovascular related deaths. Atherosclerotic disease accounts for most of the excess mortality especially in patients with diabetes as diabetics have higher values of intimal medial thickness than non-diabetics at any age for which aggressive anti-atherosclerotic intervention is warranted in diabetics. Therefore, from the life style point of view, urbanization and economic growth has resulted in children from upper socio-economic strata being significantly taller and heavier as compared to children from poor socio-economic background because of increased intake of energy dense foods, decrease in physical activity and a heightened level of psychological stress, all of which promote the risk of developing obesity, metabolic syndrome, diabetes and cardiovascular diseases.

The above observations indicate an urgent need to tackle NCDs and micronutrient deficiencies with concentrated national effort especially in children as the seeds for non-communicable diseases are sown during growing years through life style measures such as nutrition and physical activity. The diets consumed by Indians are predominantly cereal based vegetarian diets. The proteins though not adequate, generally come from pulses and milk products. The Indian diets are rich in carbohydrates and fats with fats contributing to >32% of energy intake. Current per capita consumption of sugar in India at 20.2 kgs is low compared to global per capita consumption of 24.8 kgs. However, its consumption is increasing at a fast pace and in last 50 years India's share in global consumption has gone up from 5% to 13%.

Public health attention has therefore, turned to reversing the obesity epidemic in individuals of all ages by choosing to use products containing artificial sweeteners which provide sweet taste to foods without associated high energy content of caloric sugars. Hence, the use of low calories sugar free products tripled world over in the last two decades of the 20th century. Comparatively in India the use of NNS in foods and beverages may be only slightly more than a decade old. A number of low

calorie / non-nutritive sweeteners are being used worldwide in more than 100 countries including US, Europe, Australia, New Zealand, Japan, China, India and Singapore. These are well known and chemical names are: Aspartame, Cyclamate Acesulfame –K, Neotame, Saccharin, Sucralose and Stevia. They are 30 to 13000 times sweeter than sugar and are added in small quantities to food and beverages as per regulations specific to countries but based on JECFA Acceptable Daily Intake. There is a question of how much is too much? An adult individual with 150 pound weight has to consume 97 sachets of Aspartame and 17 bottles of 12 oz diet sodas to reach the ADI level. As regards Acesulfame –K it will be 20.4 packets and 25.6 bottles.

Dr. Marwaha further informed about the awareness among people about non-nutritive sweeteners (NSS). What is the public perception of NNS? Why people consume them? In a 2012 survey of American adults by the International Food Information Council Foundation, when subjects were asked to select one or more choices from a list of reasons for using NNS, 41% chose "an option for people with diabetes mellitus", 41% chose "can reduce calorie content of foods", 40% chose "weight reduction" as the reason for use and 30% chose "they can be a part of overall healthful diet" and 30% did not know enough about the non-nutritive sweeteners to provide an answer. A small survey was carried out by Institute of Home Economics in Delhi college girls and working women in the age group of 18-30 years in 2015. The survey showed that 86% of the participants had knowledge of NNS and 50% of them were consuming NNS. The consumption was more in working girls and those from affluent families because of affordability.

He summed up his talk with a note that, there are benefits and concerns associated with NNS. Benefits are: weight management, prevention of dental carries, glycemic control and improved sense of well-being. A number of articles have appeared in reputed journals, these are single researchers covering specific aspects of impact of NNS on health as well as meta-analysis. Issues discussed are impact on appetite, hunger, energy intake, body weight, diabetes, glycemic response, CVD, kidney disease function of microbiota etc. Articles are both in favor and against. These need to be properly analyzed from scientific angel for conveying balanced messages to the public.

# SCIENTIFIC SESSION

## Uses Of Low Calorie / Non Nutritive Sweeteners

*Chair: Dr. A S Bawa, Director, Amity Institute of Food Technology*
*Vice President, Amity Food & Agriculture Foundation*

### Observations By The Chair

In the opening remark **Dr. Bawa** referred to observations made by Mr. Panandiker and Dr. Marwaha and mentioned that both of them had dealt with the subject in great details bringing out the significance, importance and necessity of artificial sweeteners. Further in his remark he also talked about issues relating to weight management and diabetes management and the importance and necessity of low calorie or zero calorie sweeteners. He mentioned that worldwide 6-7 sweeteners are permitted as table top sweeteners and for addition to food, confectionery, bakery items and beverages. They have to be used as per the limits laid down on Acceptable Daily Intake (ADI). The latest addition in sweeteners is Stevia from plant. It has been cleared by FSSAI and had harmonized with the CODEX for approval. He further elaborated that the toxicological and adverse effects of these artificial sweeteners are continuously studied by the scientists. However, consumers should avoid the excess use of these artificial sweeteners andthey should be used within limits.

### Uses Of Low Calorie / Non Nutritive Sweeteners: Global Perspective

**Dr. Tee E Siong**, President of Nutrition Society of Malaysia presented the global perspective on uses of low calorie / non-nutritive sweeteners. Dr. Siong pointed out that foods and beverages that are sweet offer pleasurable addition to daily meals or snacks. People do not realize just how much hidden sugar they are consuming daily. Sugar contributes additional calories and no nutrients to the diet. Increase in incidence of obesity worldwide has been attributed to excessive sugar intake, especially from sugar-sweetened beverages. The rising trend of obesity also leads to an increase in diet-related health problems such as diabetes, coronary heart disease and cancers. Over consumption of sugar also causes dental caries.

Dr. Siong informed that many dietary guidelines in Asia incorporate key messages recommending the consumers to reduce intake of sugar from the diet. The World Health Organization has recommended that in both adults and children, free sugars intake should be less than 10% of total energy intake. In order to maintain a palatable sweet taste, minus the calories, food manufacturers have developed a range of foods and beverages with sugar substitutes, to produce a variety of "sugar-

free" or "diet" products. The more health conscious individuals are opting for such foods and beverages as they contain less or no total sugars and therefore lower calorie.

His presentation provides an introduction to terminologies, various types and classification of sugar substitutes, their uses in a range of foods and beverages; and the overall benefits of using low calorie or non-nutritive sweeteners. The discussion also addressed consumer concerns regarding safety of these sugar substitutes.

Dr. Siong mentioned that currently many types of sugar substitutes are used and are known by various names such as "low calorie" or "non-nutritive sweeteners", or "artificial sweeteners". Some of these common sweeteners approved by many country regulators include acesulfame potassium, aspartame, neotame, saccharin and stevia. Low calorie or non-nutritive sweeteners are also known as intense sweeteners because they are many times sweeter than regular sugar. For example, acesulfamepotassium and aspartame are 200 times sweeter than sugar. Hence only small amounts are required to bring about the desired sweetness. These sugar substitutes, therefore, contribute very little or almost no calories to the diet.

Non-nutritive or low calorie sweeteners give consumers a choice to satisfy their innate desire for sweet taste without adding calories. Studies have shown that replacement of sugar with low calorie or non-nutritive sweeteners may help to reduce calorie intake in weight management. Hence, recommending the use of a sugar substitutes in beverages versus just a dietary restriction of all sweet beverages is more likely to increase dietary compliance in patients, as they can continue to enjoy sweet taste minus the sugars and calories. Because they are not deprived of "sweet foods", individuals consuming low-calorie sweeteners may feel more satisfied with their eating plans, thereby helping them to lose weight and keep it off. Substituting for sugars, these sweeteners may help in blood sugar control. The American Diabetes Association advises that these sweeteners may help people with diabetes in their diet management by cutting down their calorie intake. Individuals with Type 2 Diabetes will have greater flexibility with meeting dietary goals with low calorie sweeteners.

Dr. Siong informed that the challenge is that many people do not understand what low and no-calorie sweeteners really are and their purposes. It is important to educate consumers about the different types of sugar substitutes, in what foods or beverages they can they be found, how to identify these sweeteners, role of sugar substitutes in the diet, and how sugar substitutes can be used in cooking. Consumers should be informed that low or no calorie sweeteners are not only for diabetic patients or obese people. They can indeed be used for anyone who wishes to reduce sugar intake from their foods and beverages.

Consumers are also concerned whether these sugar substitutes are safe to consume in long term. It should be emphasized to the consumers that low or no-calorie sweeteners have a long history of safe use in a variety of foods and beverages. They are some of the most studied and reviewed food ingredients in the world today and have passed rigorous safety assessments. Several of these sweeteners have been approved for use for all age groups by many regulatory agencies around the world.

Dr Siong concluded that low calorie or non-nutritive sweeteners may help in weight management, blood sugar control and other conditions, but they are not magic bullets. They should only be used in moderation and with a healthy balanced diet and a regular exercise programme. It should be explained to the consumer that simply using these sugar substitutes alone without reducing intake of carbohydrate from sugary, starchy foods or fat will probably not help control their blood sugar level or energy intake. To help consumers have access to products with low or no calorie sugar substitutes, education on understanding food and nutrition labels should be carried out. He emphasized that such NNS products should be made available at a cheaper prices to consumers.

**Q & A**

After the presentation of Dr. Tee E Siong, an interactive question and answer session took place between the speaker and the participants. These are given below:

**Q:** Since we are talking a lot about the importance of artificial low calorie sweeteners especially for diabetic and obese people, is the government nationally or internationally making any policies for lowering down the price of artificial sweeteners?

**Response by Dr. Siong:** Bringing down the cost of non-nutritive sweeteners will be challenging. However, if the demand of these sweeteners increases then the prices of artificial sweeteners will definitely come down. It is important to bring awareness among consumers about the importance and safety of these low calorie/ non-nutritive sweeteners. Once consumer's confidence in artificial sweeteners develops, demand NNS will increase and that will subsequently bring down the cost of these sweeteners.

**Q:** Whether allergic symptoms, rashes or any other kind of complaints have been made by consumers using NNS? For this,

**Response by Dr Siong:** Till date he has not came across any medical complaint from the consumer's except that some of themhave informed about the different taste which is not very palatable.

**Q:** Why generally combination of Ace K and Aspartame is used? Ace K is also used with many other sweeteners, what is the reason?

**Response by participant:** Ace K is generally used with all the sweeteners to round off the taste as Aspartame is slightly metallic in taste. Generally they are used in the ration of 1:2.

**Q:** Has any research been carried out on the long term usage of these sweeteners? This is the one of the prime concern of the consumers.

**Response by Dr. Siong:** Long term history of safe usage of these sweeteners has already been proven. The issue has been scrutinized by many expert groups including JECFA, FDA, WHO and many regulatory agencies. Awareness among consumers is required that long term usage of these NSS is safe. To this,

**Q:** If sweeteners based on sugar alcohols are allowed to be mixed with indigenous dairy products in Malaysia?

**Response by Dr. Siong:** Yes, such sweeteners and polyols are permitted in Malaysia for use in a variety of dairy products eg. yogurt with the maximum levels/ limits.

## Uses Of Low Calorie / Non Nutritive Sweeteners: Indian Perspective

**Dr. B. Sesikeran**, former Director, National Institute of Nutrition, ICMR, Hyderabad in his presentation showed concern about the increasing incidence of non-communicable diseases which are the leading cause of death all over the world and in India. He underlined that there has been a rapid increase in the prevalence of obesity, overweight both in urban and rural India. A poor quality high energy diet with low levels of physical activity have contributed to this malady. A high intake of free sugars is associated with this problem. Energy density of foods is related to the quantity of free sugars as well as fat. WHO has strongly recommended that the free sugar intake should be reduced to less than 10% of the total daily energy intakes and if possible lower it further to 5%. This amounts to a maximum intake of six and quarter teaspoons of free sugars from all sources in a day.

Dr. Sesikeran informed that free sugars include mono and disaccharides added to foods and beverages by the manufacturer, cooks or consumers as well as sugars naturally present in honey, syrups, fruit juices and fruit juice concentrates. These are evidence-based recommendations. There is evidence to show that increase or decrease in consumption of free sugars is associated with a parallel change in body weights. Even in individuals with inadequate energy intakes, increasing the free sugar content of their food is not recommended (**Guideline: Sugars intake for adults and children. Geneva. World Health Organization, 2015**). This excludes therapeutic diets for Severe Acute Malnutrition (SAM) and Moderate Acute Malnutrition (MAM).

He mentioned that reducing free sugars in foods will greatly impact taste and we do know that lack of taste is the biggest impediment to compliance for reducing energy intakes. If free sugar intakes have to be brought down there is a need for artificial sweeteners if not in all foods at least in a few critical ones, which are consumed at a high frequency. Sugar substitutes will come into foods which hitherto had free sugars as ingredients e.g. beverages, traditional sweets, chocolates, candies, ice creams, bakery products and the home use of sugar. Artificial sweeteners are one type of sugar substitutes.

Dr. Sesikeran said that by definition, sugar substitutes are anything that are used in place of sugar and talked about the sweeteners which are already in market:

1. **Artificial sweeteners**- Acesulfame, Aspartame, Neotame, Saccharin, Sucralose.
2. **Sugar Alcohols-**Erythritol, Isomalt, Maltitol, Xylitol, Sorbitol.
3. **Novel sweeteners-** Stevia, Tagatose, Trehalose.
4. **Natural Sweeteners (caloric sweeteners) -** Agave nectar, Date sugar, Fruit juice concentrate, Honey, Maple syrup, Molasses.

**Saccharin:** This is the oldest artificial sweetener (discovered in 1878) and has been used for over 100 yrs. Initial rat experiments showed a tendency for urinary bladder tumors but this was not found to happen in any other species nor were there any human reports. It is about 300 times sweeter than sugar but has sometimes given a bitter after taste. Saccharin has been declared as safe by

American Cancer Society, AMA and academy of nutrition dietetics. It is not affected by heat and hence an advantage in baked foods. As per JECFA, ADI is 5 mg/kg of body weight [1].It is approved in more than 100 countries. Allowed by FSSAI in Carbonated water: 100 ppm, chocolates & Indian traditional sweets: 500 ppm, sugar based/sugar-free confectionery & chewing gum/bubble gum; 3000 ppm[9].

**Cyclamates:** Discovered in 1937, it refers to three different compounds-cyclamic acid, calcium cyclamate and sodium cyclamate. It is a low calorie sweetener. ADI set by JECFA is 11mg / Kg B wt. It is 30 times sweeter than sucrose. It is used in over 100 countries. Not approved under the FSSAI.

**Aspartame:** Discovered in 1965 it is 200 times as sweet as sugar. More than 500 studies were reviewed and it was found to be safe except in phenylketonurics. Allowed by FSSAI in Carbonated water: 700 ppm, non-carbonated water based beverages: 600 ppm, biscuit, bread, cakes: 2200 ppm, Indian sweets: 200 ppm, jams jellies: 1000 ppm, sugar based/free confectionery: 10000, chocolates: 2000 ppm, ice cream: 1000 ppm, flavored milk: 600 ppm, RTE cereal: 1000 ppm, still beverages: 600 ppm [2].

There is a labeling requirement that it is not recommended for children and in phenylketonurics. It has two amino acids phenylalanine and aspartic acid. It gets hydrolyzed into the two amino acids and a small amount of methanol, which is metabolized and is much less than the amount of methanol generated from other sources. More than 500 studies have been carried out on Aspartame and has been declared safe by all regulations. EFSA permits its use even in pre-pgnant women and children – ADI is 40mg/ Kg B wt.

**Neotame:** It is similar to aspartame about 7000- 13000 times sweeter than sugar. There are more than 100 studies establishing its safety. FSSAI has permitted its use in soft drinks at a maximum limit of 33 ppm. ADI according to JECFA is 2 mg/ Kg B wt.

**Acesulfame Potassium:** (ACE-K) It was discovered in 1967. 600 times sweeter than sugar. Used in a large variety of foods in over 90 countries. ADI is 15mg/Kg. FSSAI approves for use is allowed by FSSAI in carbonated water and non-carbonated water based beverages: 300 ppm, biscuits, cakes etc.:1000 ppm, Indian sweets: 500 ppm, sugar based/free confectionery: 3500 ppm, still beverages 300 ppm, ready to serve tea and coffee based beverages: 600 ppm.

**Sucralose:** It was discovered in 1976. It is derived from sucrose and 600 times sweeter. It is used in a wide variety of foods. In over 80 countries. It does not elevate blood glucose levels. ADI is 15 mg/ Kg. There are no reported safety concerns. It is allowed by FSSAI in carbonated water and non-carbonated water based beverages: 300 ppm, biscuits, cakes; 750 ppm, Indian sweets: 750 ppm, still beverages: 300 ppm, jams jellies: 450 ppm, ready to serve tea and coffee based beverages: 600 ppm, ice lollies/candies: 800 ppm, confectionery: 800 ppm-1500 ppm[2].

**Steviol Glycosides:** It has been approved by FSSAI in June 2015. It was approved by JECFA in 2009. They are natural constituents of the leaves of stevia rebaudiana. They are 200 to 400 times sweeter than sugar. Stevia glycosides- rebaudiside A, Stevioside-Rebaudioside D, Steviol glycoside. Mixtures

with rebaaudiside A and / or stevioside are all sweeteners.

Stevia sweeteners are approved as table top sweetener and for addition to food and beverages in approximately 49 countries including U.S., Japan, Brazil, Paraguay and EU. The use of stevia leaf and crude extract are not approved by USFDA. JECFA has approved an ADI value for steviol glycosides expressed as 4 mg of steviol equivalents per kg body weight per day. Approximately 12 mg of high purity stevia extracts per kg body weight per day.

**Sugar Alcohols:** They are calorific but do not get completely absorbed. Many of them are less sweet than sugar and need to be used in larger quantities. Due to inadequate absorption they have a laxative effect. They are naturally present in fruits and vegetables but can be synthesized. Consumption of greater than 50 gm of sorbitol and 20 gm of mannitol per day may cause diarrhea. Erythritol is absorbed fully and excreted. Oral bacteria do not grow on them hence they cannot contribute to caries. Sugar alcohols or polyols include Sorbitol, Mannitol, Xylitol, Isomalt, Lactitol and Maltitol.

Dr. Sesikeran underlined that artificial sweeteners now have a major role in reducing the burden of non-communicable diseases. They are very extensively studied for their safety and only then approved for long term consumption. They help in compliance by consumers who are advised not to take sugar in their diets and thus assists in long term survival despite obesity and type 2 DM.

**Q & A**

**Q:** Why it is generally labeled on the package of artificial sweeteners containing Aspartame that it is not recommended for phenylketonurics ? How does a common layman know that they are phenylketonurics or not?

**Response by Dr. Sesikeran:** Pphenylketonurics is a rare genetic disorder and a person with this disease knows it from the day he/ she is born. This disease has nothing to do with the artificial sweeteners except that people suffering from phenylketonurics should not use Aaspartame.

**Q:** Any study has been carried out on the combined usage of artificial sweetener ? Does it cause any issues?

**Response by Dr. Sesikeran:** Combinations are always studied and entire toxicological data is generated after combining the sweeteners, as in the case of Ace K and Aspartame and they are only used once approved by the regulatory bodies.

**Q:** Whether NNS increases the glucose level in the blood and if there is any possibility of insulin resistance in the body after long term usage of artificial sweeteners ?

**Response by Dr. Sesikeran:** Glucose level will never increase if artificial sweeteners are consumed because there is no sugar that will absorbed in the blood. However, when sugar alcohols are consumed there might be slight increase in sugar levels, as they have a very low amount of sugar. The possibility of insulin resistance in the body after long term usage of artificial sweeteners, is still a question for discussion. Some researches has been published on this which talks about the effect of NNS on insulin resistance. However, till now nothing concrete has been found.

**Q:** Salt and sugar are acquired tastes, so if children are given less amount of sugar from

childood then is there any possibility that the taste of sugar will not develop in the child ?

**Response by Dr. Sesikeran:** If less amount of sugar is given to a child, it does not mean that child will not develop taste for sugar. It might be true for salt but not for sugar. In any case child will develop taste for sugar from so many other sources like fruits, vegetables, milk etc.

**Q:** Stevia glycosides is approved for human consumption by FSSAI but has this been kept under the category of artificial sweetener or natural sweetener ? Are stevia glycosides safe for children ?

**Response by Dr. Sesikeran:** Stevia glycosides are natural sugar substitute and is a non-nutritive sweetener. Presently regulatory bodies do not recommend any sweeteners for children.

**Q:** Stevia leaves are banned in Indian market or not ? For this,

**Response by Dr. Sesikeran:** Stevia leaves extract are banned and are not approved in India as well as in the US. However, Stevia glycosides are only approved for human consumption by FSSAI & US, FDA.

## Low Calorie Sweeteners: Safety Assessment And Global Regulatory Approvals

**Dr. Berna Magnuson**, Fellow, Academy of Toxicological Sciences, Health Science onsultants, Inc., Canada focused on the safety assessments of low calorie sweeteners and their regulatory approvals. She said that NSS offer sweet satisfaction with few calories and with no impact on blood sugar, which makes them suitable for diabetics and popular among health conscious consumers.

Dr. Magnuson informed that low calorie sweeteners are categorized as food additives, and therefore must undergo an extensive safety evaluation prior to approval for use in foods and beverages. At the international level, this evaluation is conducted by JECFA (the Joint Food Additives Organization / WHO Expert Committee). Dr. Berna discussed the 4 steps in the risk assessment process for these sweeteners and other food additives. This assessment is based on the results of extensive toxicological testing which are utilized to establish the ADI or acceptable daily intake level. Toxicology studies are conducted to assess the absorption, metabolism, distribution and excretion pathways of the compound when it is consumed in laboratory animals and in humans Animal studies are also conducted to determine the potential for interaction with genetic material and potential for causing development of cancer or other adverse effects following long term consumption. In addition, potential effects on reproduction and development must be considered. As diabetics are a potential susceptible subgroup of consumers of low calorie sweeteners, lack of effects on blood sugar or insulin levels are critical criteria for approval of these food additives. In many cases, human clinical trials have been conducted following animals studies to confirm safety.

Dr Magnuson said that the conservative assumptions used to establish the ADI is to ensure its applicability for all different subgroups of the population, including pregnant women and children. Exposure estimates are based on proposed use levels and food categories, combined with estimates of food consumption levels by various members of the population. The comparison of the exposure estimates with the ADI is the basis of the risk assessment process.

There is a wide variety of low calorie sugar substitutes available for use globally, including advantame, acesulfame potassium, aspartame, cyclamate, monk fruit extract, neotame, saccharin, stevia extracts, and sucralose. Based on reported intake assessments in the peer-reviewed literature, even highest users of low calorie sweeteners are highly unlikely to exceed the ADI. Although there has been considerable controversy raised in recent years, all international regulatory experts agree that current use levels of low calorie sweeteners are safe for all members of the population. Moreover, the use of new sweeteners, such as steviol glycosides and use of sweetener mixtures lowers consumption of each sweetener, decreasing the probability of exceeding the ADI or experiencing any adverse effects from consumption of foods and beverages containing low calorie sweeteners.

**Q & A**

**Q:** A survey conducted by Christian Medical College has shown that 10-15% children are suffering from tooth caries, significant reason can be the high level of sugar and sweet consumption by children. what would be the public health measure for reduction of caries among children since artificial sweeteners are not suitable / recommended for children.

**Response by Dr Berna Magnuson:** ADI for NSS is not exclusively based on overweight obesity it is also based on worldwide studies on dental caries. So the ADI calculations are therefore based with the intent of reducing overweight and reduction in dental caries. Among the various kind of sweeteners sugar alcohols like xylitol, erythritol, sorbitol are specially preferred for cakes, candies, pastries etc because these sugar alcohols are not metabolized by the oral bacteria and thereby lower risk of dental caries.

**Q:** It is a general perception that anything natural is safe in this context Stevia being a natural sugar substitute is considered to be very safe by the people. However, research shows Stevia has a lowest ADI,

**Response by Dr Berna Magnuson:** The statement that 'anything natural is safe' is incorrect. Most of the toxic compounds, very harmful for human are natural. So study on the no adverse effect observed levels of certain artificial sweeteners at different concentration is also very important and this concentration may vary person to person, so acceptable daily intake (ADI) in not necessarily always a good parameter for safety of artificial sweeteners. Stevia glycosides cannot be considered safer than other artificial sweeteners because they are natural. The naturality means nothing from a scientific point of view.

**Q:** Stevia being an agricultural product is there any issue of pesticide residues.

**Response by Dr Berna Magnuson:** Stevia glycoside are extracted from plants and undergo high level of purification many times and therefore is no possibility of any pesticide residues.

# PANEL DISCUSSION

## Consumer Perceptions & Concerns About Sweeteners

**Chair: Dr. B Sesikeran, Former Director,**
**National Institute of Nutrition, ICMR, Hyderabad**

The panel of experts included **Dr. Tee E Siong**, President, Nutrition Society of Malaysia, Malaysia and **Dr. Berna Magnuson**, Fellow, Academy of Toxicological Sciences, Health Science Consultants, Inc., Canada. A lively interaction took place between the panelists and the participants. Following points were made during the Panel Discussion:

- The World Health Organization has recommended that in both adults and children, free sugars intake should be less than 10% of total energy intake.
- Artificial Sweeteners are safe for human consumptions. Low-calorie sweeteners can be safely consumed by the general population, including people with diabetes, pregnant and lactating women and children. FSSAI has released the list of artificial sweeteners which are safe for human consumption along with their ADI.
- Benefits of non-calorie/ non-nutritive sweeteners includes: weight management, prevention of dental carries, glycemic control i.e diabetes and improved sense of well-being.
- Food Safety and Standards Authority of India (FSSAI), has approved the use of the following nonnutritive sweeteners: acesulfame-K, aspartame, neotame, saccharin, sucralose and stevia on an Acceptable Daily Intake (ADI) basis.
- Stevia is a non – nutritive, natural sugar sweetener however, Stevia glycosides is only approved for human consumption by FSSAI. Stevia leave extracts are banned and are not approved by the USA as well as in India.
- Non calorie /Non- nutritive sweeteners specially sugar alcohols like Xylitol, Erythritol are safe for children's and can be used in various candies, chewing gums, cake, pastries, etc. this helps in prevention of dental caries among children and adults who have a sweet tooth. Sugar alcohols like erythritol and xylitol are not utilized by the oral bacteria and due to absence of fermentation and acid production there is reduced risk of dental caries.
- There is no credible proof or research which says that gut flora of human body is changed due to the use of artificial sweeteners and it has any adverse effect on digestion.
- It is very important to educate consumers and make them aware about the different types of sugar substitutes present in the market, in what foods or beverages can they be found, how to identify these sweeteners, role of sugar

substitutes in the diet, and how sugar substitutes can be used in cooking. Consumers should be informed that low or no calorie sweeteners are not only for diabetic patients or obese people. They can indeed be used for anyone who wishes to reduce sugar intake from their foods and beverages.

- Artificial sweeteners now have a major role in reducing the burden of non-communicable diseases. They are very extensively studied for their safety and only then approved for long term consumption.

## Vote Of Thanks

**Ms. Rekha Sinha**, Executive Director, ILSI-India thanked all the distinguished speakers and participants for joining the conference. She acknowledges and thanked Mr. Panandikar, Chairman, ILSI India for being the continuous source of encouragement and support. Ms. Sinha highlighted that awareness among consumers with relation to the importance and safety of these low calorie/ non-nutritive sweeteners is a must and a prime need of our country. She was happy to announced that ILSI India will be coming out shortly with a brief Monograph on artificial/ non calorie sugar sweetener.

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# About ILSI India

ILSI-India is a branch of International Life Sciences Institute (ILSI) with headquarters in Washington DC. ILSI-India provides scientific inputs and secretariat assistance to the South Asian Region, which includes Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan and Sri Lanka.

ILSI-India activities primarily focus on local and regional issues and involve leading national and international experts in the deliberations. ILSI-India has taken the lead in the region in focusing attention and devoting resources on critical areas in food and water safety, nutrition, risk assessment, harmonization of food regulations, improvement in the health profile of malnourished children and women and agriculture sustainability including biotechnology. Special attention has been given to the importance of complementary foods and food fortification.

ILSI-India carries out its mission through sponsoring workshops, symposia, conferences, seminars training programs, research projects and publications. ILSI-India works closely with government, industry, research institutions, academia and international organizations.

ILSI is a nonprofit, worldwide foundation whose mission is to provide science to improve the human health and well-being and safeguards the environment. Prominent researchers from industry and academia jointly lead the organization, guiding its work to conduct research, harmonize the use of science and encourage scientific dialogue and then resolving outstanding scientific questions in four thematic areas that capture the core of ILSI's work:

- Food And Water Safety
- Toxicology And Risk Science
- Nutrition, Health And Well-Being
- Sustainable Agriculture And Nutrition Securityp

These focus areas provide structure for responding to and raising awareness of the pressing issues society faces. They also help elucidate new opportunities for driving scientific progress. ILSI's work is guided by its Code of Ethics and Organizational Standards of Conduct.

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