CONFERENCE ON "FOOD ADDITIVES: SAFETY AND BENEFITS"

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Conference Report

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International Life Sciences Institute – INDIA
(ILSI-India)

About ILSI-India

ILSI-India is a branch of International Life Sciences Institute (ILSI) with Head Quarters in Washington D.C. It works on issues relating to food safety, nutrition, toxicology, risk assessment, biotechnology and environment. It works very closely with industry, R&D organizations, and government departments, Ministry of Health, Department of Biotechnology, Ministry of Science and Technology, Ministry of Agriculture and Ministry of Food Processing Industries.

ILSI-India carries out its mission through sponsoring workshops, conferences, seminars, training programs and research. It also brings out publications and organizes educational programs. ILSI-India activities cover India and South Asian Region.

ILSI is a non-profit, worldwide organization whose mission is to provide science that improves human health and well-being and safeguards the environment. It achieves this mission by fostering collaboration among experts from public and private sectors of society on conducting, gathering, summarizing, and disseminating science.

ILSI strategy encourages global action on identifying 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 security

ILSI branches include Argentina, Brazil, Europe, India, Japan, Korea, Mesoamerica, Mexico, Middle East, North America, North Andean, South Africa, South Andean, Southeast Asia Region, Taiwan, the Focal point in China, and the ILSI Health and Environmental science Institute. ILSI also accomplishes its work through the ILSI Research Foundation (composed of Center for Environmental Risk Assessment of Genetically Modified Crops (CERA), Center for Risk Science Innovation and Application (RSIA), Center for Nutrition and Health Promotion and Center for Integrated Modeling of Sustainable Agriculture & Nutrition Security (CIMSANS)

ILSI has a special consultative status with Food and Agriculture Organization of the United Nation.

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MAJOR FINDINGS

What are Food Additives

- Food Additives are natural, synthetic (manmade versions of natural additives) and artificial substances which can be used as emulsifiers / stabilizers, preservatives, acidulants, non-caloric sweeteners and colorants.

Why Food Additives

- Use of food additives has facilitated production of processed foods and beverages and has made it possible to preserve them for a longer duration. This has freed consumers from making all foods themselves, enjoy a variety of foods which would be impossible otherwise and access foods from anywhere in the country or from other countries.

- Use of food additives is a technological necessity in processed foods and beverages. In addition to preserving nutritional quality, they are used to provide necessary ingredients / constituents for consumers having special dietary needs, to enhance keeping quality and stability of food, to improve organoleptic properties , to facilitate processing, preparation, storage, distribution of food and finally to reduce wastage of food.

Safety of Food Additives

- Food additives have been studied by international experts and organizations like Codex and the levels for their use in the manufacture, processing, preparation, treatment, etc. laid down.

- Independent experts who are members of the JECFA (Joint Expert Committee of FAO and WHO on Food Additives) recommend ADIs and standards specifications of food additives. This may involve several rounds of discussions and deliberations over a number of years. The national authorities use these documents for guidance while deciding specifications for food additives under their regulations.

- The national food control authorities assess the safety of food additives before permitting their use under the country regulations. While assessing the safety, the regulatory authorities take into account toxicity, acceptable daily intake, synergy effect, food basket, international standards, and analytical limitations. The important pillars of national food control systems are: Regulations/ Standards; Surveillance/Inspection; Analytical Capabilities and Certification/Compliance.

- The Food Safety and Standards Authority of India lays down specifications for their use in the country. It looks at their usage from scientific angle and uses its task forces, scientific panels, product approval committees for this purpose.

- The Indian regulations for food additives should follow international norms like those recommended by Codex.

INTRODUCTION

ILSI-India organized a "Conference on Foods Additives: Safety and Benefits" on April 24, 2015 in Hotel Cladriges, New Delhi on the occasion of its Annual Meeting.

It was attended by more than 100 participants representing Government, industry, academia, regulatory authorities and international organizations like WHO and WFP. The Conference discussed the role of food additives in processed foods and beverages as also role of ingredients and nutrients for innovative and safe food products. The welcome address at the Conference was delivered by Mr. D.H. Pai Panandiker, Chairman, ILSI-India and the Conference was inaugurated by Dr. Rhona S. Applebaum, President, ILSI,Washington, DC. The Conference was addressed by 14 speakers. Highlights of the presentations made by the speakers are given below:

OPENING SESSION

Welcome Address

Mr. D.H. Pai Panandiker welcomed the participants to the Conference and observed that the benefits of food additives are obvious but safety has to be proved. Food additives have been used for production, processing, treatment, packaging, transportation and storage of foods. The object is to maintain safety and freshness of foods,maintain or improve their nutrition value and improve taste, texture and appearance. Without food additives achieving food security wouldbe extremely difficult.

Mr. Panandiker mentioned that public apprehension about food additives is mainly due to exposure to chemicals used in food.Use of food additives is regulated by national food regulatory authorities as also international organizations to ensure safety.Food additives have been studied for quite some time and are now better understood though absolute safety of any substance can never be proven.

There are additives which are generally regarded as safe or GRAS for short. JECFA evaluates safety of food additives based on long term exposure and there are a number of additives which have been studied and considered safe under Codex General Standard for Food Additives or GSFA. National food regulatory authorities should therefore permit use of substances which have been internationally considered as safe and if they conform to accepted daily intake and good manufacturing practices. Industry is continuously innovating food products with new additives. Mr. Panandiker underlined that it is necessary to encourage innovation which will enable industry to produce a variety of foods and for different categories of consumers like children, senior citizens, diabetics, obese, and so on. It is, therefore, important for industry to produce evidence about safety of the final product and for the authorities to take decisions without delay.

Inaugural Address

Dr. Rhona S. Applebaum, President, ILSI, Washington, DC inaugurated the Conference and informed the participants about One ILSI project with focus on tripartite collaboration. She said that the One ILSI approach reinforces the idea that scientists from multiple sectors of society and from around the world work together to improve health and safety. Further, at ILSI, prominent scientists work together toidentify emerging health challenges,deliver science to improve health/safety, deliver science to help harmonize policies and procedures, and encourage scientific dialogue among experts across all sectors of society.

The One ILSI approach recognizes that by working together each ILSI entity – the branches and the Research Foundation – can have greater impact than it might otherwise have.

She enumerated the following benefits of One ILSI approach:

- One ILSI allows for the organization to make a difference on human and environmental health and safety.
- The branch benefits because it is positioned as a scientific leader beyond borders. This in turn can be used to attract new members, new partners, and other sources of funding.
- ILSI members are investing in science when they give their time, energy, and financial support to ILSI. One ILSI maximizes this investment in science that makes the world a better place.

Vote Of Thanks

Ms. Rekha Sinha, Executive Director, ILSI-India thanked the speakers and participants and underlined ILSI and ILSI-India'scommitment to improving food safety and public health.

SESSION 1

Processed Foods: Role Of Food Additives

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

Observations By Chair

In his opening remarks in this Session **Dr Bawa** mentioned that food additives are used by the manufacturers to improve quality, shelf life as well as process ability of food products. At times their use is technologically necessary. A large number of food additives are used by the manufacturers and hardly any processed food, except ethnic products, is produced without food additives.

Why Food Additives: Need And Perception: Processed Foods

Dr. Shaminder Pal Singh, Vice President – SRA, Pepsico India Holdingsmade a presentation on"Why Food Additives: Need and Perception: Processed Foods". While talking about what is meant by food additives Dr. Shaminder Pal Singh said that food additives are substances not normally consumed as food by itself and are used as a typical ingredient of the food, whether or not they have nutritive value Their addition is intentional for a technological purpose (including organoleptic) in the manufacture,

processing, preparation, treatment, packaging, transportation or holding .Such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of / or otherwise affecting the characteristics of such food but does not include "contaminants" or substances added to food for maintaining or improving nutritional qualities.The regulatory definitions do not include "contaminants" whereas the generic definition also includes the "nutrients".

Dr. Shaminder informed about the different functional classes and uses of food additives (Table 1) and said that they are recognized with unique identification number.

Table 1
Functional Classes of Food Additives

Acidity Regulator	Flour Treatment Agent
Anticaking Agent	Foaming Agent
Antifoaming Agent	Gelling Agent
Antioxidant	Glazing Agent
Bleaching Agent	Humectant
Bulking Agent	Preservative
Carbonating Agent	Propellant
Colour	Raising Agent
Colour Retention Agent	Sequestrant
Emulsifier	Stabilizer
Emulsifying Salt	Sweetener
Firming Agent	Thickener\
lavour Enhancer	

Dr. Singh said that food additives are used for following purposes:

- To preserve nutritional quality
- To provide necessary ingredients / constituents for consumers having special dietary needs
- To enhance keeping quality and stability of food
- To improve organoleptic properties
- To improves processing, preparation, storage, distribution of food
- To reduce wastage of food

He emphasized that food additives should not change the nature, substance or quality of food so as to deceive or mislead the consumer or disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices.

Dr. Singh pointed out that food additives are used in small quantities and offer convenience and enjoyment of food in wide variety of appetizing, nutritious and palatable products with technological benefits and do not mislead consumers. Food additives are ingredients and they have to be labeled under ingredient list of labels.

Some food additives require special labeling. He said that following aspects are important for determining the safe use limits for food additives:

- Acceptable Daily Intake "Not Specified" (NS): ADI is a term applicable to a food substance of **very low toxicity** for which, on the basis of the available data (chemical, biochemical, toxicological, and other), the total dietary intake of the substance, arising from its use at the levels necessary to achieve the desired effect and from its acceptable background levels in food, does not, in the opinion of Joint FAO/WHO Expert Committee on Food Additives (JECFA), represent a hazard to health.
- Maximum Use Level: Maximum use level (UL) of an additive is the **highest concentration of the additive determined to be functionally effective in a food or food category and agreed to be safe**. It is generally expressed as mg additive/kg of food. The maximum use level will not usually correspond to the optimum, recommended, or typical level of use.

Dr. Singh also clarified some of the misconceptions about food additives as follows:

- **Processed foods uses lots of food additives** Only those food additives which are permitted for use in a food/category under food regulations can be used and they have to be within permissible limits. Further, some food products do not use additives such as UHT milk which is a processed food but without additives.
- **Food additives are harmful chemicals**. It should be noted that food additives are permitted for use by regulatory authorities based on:
  - Strong scientific risk analysis from safety, health and toxicological perspective.
  - Continuous re-evaluation of additives by independent scientific experts.

Talking about the **new food additive approval process** Dr. Singh felt that:

- The process is very lengthy robust and scientific.
- Sound scientific principles of risk assessment are conducted by independent expert organizations like JECFA, Scientific Panels / Scientific Committee in FSSAI.
- Rigorous process is adopted to review that ADI of food additive which is fixed on the basis of the additive being safe when consumed from all foods on a daily basis throughout life!

Why Food Additives: Need And Perception: Beverages

Mr. Sunil Adsule, Director - Scientific and Regulatory Affairs, Coca-Cola India Pvt. Ltd.made a presentation on"Why Food Additives: Need and Perception: Beverages". He said that beverages are part of food. It is any drink, usually other than water. A processed food is primarily a packaged food.

For decades food additives have attracted public attention. Their use has been debated. In some social media like twitter, blogs it has been alleged that foods additives may be obesity contributor, they are evil and are harmful.Mr. Adsule summarized some of the areas of common concerns about food additives in public domains. These are:

- Long, unfamiliar names similar to complex chemical compounds (low level of science literacy, complex labelling).
- Motive of economic adulteration.
- Advertising that have at times taken advantage of food additive or ingredient controversies;
- Improving the perceived quality – thickeners in juice or milk based beverages; and
- Use of unapproved additives, colorants; or using approved additives beyond permitted limits.

Uninformed-unaddressed concerns about the food industry's motives in manufacturing processed foods have led to increase in negative perceptions among the general public. Mr. Adsule underlined that food processing is primarily undertaken to transform perishable – at times unpalatable or hardly edible raw material into safe, flavourful, nutritious, stable and enjoyable foods. Processing activities may include any deliberate change in a food occurring between the point of origin and availability for consumption. The change could be as simple as rinsing and packaging by a food manufacturer to ensure that the food is not damaged before consumer accessibility, or as complex as formulating the product with specific additives for controlling microorganisms, maintaining desired quality attributes, or providing a specific health benefit, followed by packaging that may itself play a role in microbial control or quality preservation.

Mr. Adsule underlined that contemporary food science and technology have contributed greatly by integrating many other disciplines to enhance food safety - biology, chemistry, physics, engineering, materials science, microbiology, nutrition, toxicology, biotechnology, genomics, and computer science.Today, the food system chain of production-to-consumption is complex, and the food is largely safe, tasty, nutritious, diverse, convenient, and less costly and more readily accessible than ever before.Food processing, food additives and advances in technology help make that possible.

Food Additives perform a variety of useful functions in foods that consumers often take for granted. Some additives could be eliminated if people were willing to grow their own food, harvest and grind it, spend many hours cooking and canning, or accept increased risks of food spoilage. Mr. Adsule apprised that food additives are natural and manmade and are added to food:

- **To Maintain or Improve Safety and Freshness:**
- **Preservatives** slow product spoilage caused by mold, air, bacteria, fungi or yeast. In addition to maintaining the quality of the food,
- **To maintain product consistency – improve mouth-feel:**
- **Emulsifiers** give products a consistent texture and prevent them from separating. Stabilizers and thickeners give smooth uniform texture to deliver on consumer expectation
- **To improve or maintain nutritional value:**
- **Vitamins and minerals** are added to beverages which is vehicle to deliver targeted nutritional benefits. Such fortification and enrichment has helped address lack nutrients in diet
- **To maintain palatability and wholesomeness:**
- **Acidulants and Buffering Agents** help control the **acidity and alkalinity of foods**
- **Antioxidants** prevent flavour oils, oleoresins in beverage emulsions from becoming rancid or developing an off-flavor.
- **To enhance flavor or impart desired color:**
- Flavouring agents are integral part of beverages. These may be **natural, nature identical or artificial flavors** which besides enhancing taste of beverages also deliver feeling of refreshment & enjoyment.
- **Colors**, to maintain the appeal of beverages throughout its desired best before period.

Mr. Adsule said that beverages contain typically water; sweetness-nutritive/caloric sweetener ,non-nutritive/ non-caloric sweetener; sourness- acidulants , acidity regulators; colourants; flavouring agents; stabilizer / emulsifier and preservative.

Mr. Adsule informed about the Gen Next-Beverages in the offing. These include:

- Dairy Based and Fruit Juice Based Beverages fortified with Plant Stanols and Omega 3, DHA.
- Sports Drinks (to be consumed before or during exercise to prevent dehydration). They supply carbohydrates, provide electrolytes (such as sodium, potassium, calcium, magnesium) and vitamins or other nutrients
- Whey plus fruit juice combination. They use stabilizers to prevent separation and adding mouth-feel.
- Energy Drinks (Caffeinated Beverages).

New Developments In Food Additives

Dr. S. K. Saxena, Director, Export Inspection Council, Ministry of Commerce and Industry, GOI, made a presentation on "New Developments in Food Additives".Dr. Saxena underlined the necessity of adding food additives and categorized them as follows:

1. **Natural** – found naturally, such as extracts from beetroot juice (E162), used as a colouring agent;
2. **Manmade versions** – synthetic identical copies of substances found naturally, such as benzoic acid (E210), used as a preservative;
3. **Artificial** – produced synthetically and not found naturally, such as nisin (E234), used as a preservative in some dairy products and in semolina and tapioca puddings.

Dr. Saxena mentioned that natural additive is considered safe but their safety is not assessed. As against this safety of synthetic or artificial additives is assessed by detailed scientific process by National Food Control System (NFCS) which shoulders the prime responsibility for consumer safety.While undertaking safety evaluation regulators look at toxicity; acceptable daily intake; synergy effect; food basket; international standard; and analytical limitations.The important pillars of NFCSC are: Regulations/Standards; Surveillance/Inspection; Analytical Capabilities and Certification/Compliance. Similar kinds of objectives guide the work atWTO, SPS, TBT, CODEX, OIE, IPPC and many more international non-government organizations like ILSI, IDF, IFU and so many.

Industry undertakes R&D in developing food additives and their use in food product. While developing new products, industry looks at consumer acceptability; market access; competition; economic considerations and product durability and stability.

Dr Saxena shared some concerns on food additives from his perspective as a regulator. He said that at times export trade faces problem due to usage of food additives. If a food additive is not allowed in the country, but it is allowed in another country where food is being exported, traders would like to import that food additives and make the value addition into the food product and would like to re-export that product only for export not meant for domestic product. However, exporters are facing problem as they are not allowed to import the additives not permitted under the food regulations.

Dr. Saxena explained the standards making process at Codex. He said that the decisions on at Codex are based on science. The Food Standards, Guidelines and other Recommendations are based on the principle of sound scientific analysis.Codex Standards are framed to withstand the most rigorous scientific scrutiny. The principles of developing scientific advice at Codex incorporate the following:

- **Excellence:** international expertise, global scientific discussion and best practices.
- **Independence:** experts work in individual capacity; declare conflict of interest.
- **Transparency:** access to the reports, evaluation and basic information.
- **Universality:** broad base of scientific data, institutions and all interested through the world are invited to make data available.

At JECFA (Joint Expert Committee on Food Additives) standard food additives specifications are formulated by three groups of independent experts. These are chemists; toxicologists and nutritionists. So far it has evaluated 1500 additives. The outcome of JECFA meetings comes out as ADIs and specifications.

Dr. Saxena explained that FSSAI also looks at food additives in a scientific manner. It has:

- Scientific Committee
- Scientific Panels
- Task Forces
- Product Approval Committee
- NCCP and Codex Shadow Committees
- CAC for Implementation/Enforcement

As regards "way forward" Dr. Saxena recommended that capacity building be undertaken at FSSAI and practical approach be adopted on food additives. Further, FBO's should follow self-compliance; harmonization be undertaken with international standards; international practices be accepted; standards of other standard setting bodies be recognized and provisional standards fixed.

SESSION 2

Processed Foods: Role Of Ingredients& Nutrients For Innovative and Safe Food Products

Chair: Dr. V Prakash, FRSC, Distinguished Scientist of CSIR INDIA, Director, Innovation Research and Dev. At JSS MVP, Mysore

Observations By Chair

In his observations in this Session, Dr. Prakash underlined the importance of food additives and ingredients for processed foods. He said that there is great deal of R & D leading to emergence of new additives and ingredients. Additives are necessary for large scale production as compared to processing foods at household level. Additives should, however, be safe. He apprised about the safety assessment process at national and international levels. Safety limits are generally 10 times higher than what is permitted for addition under the food regulations. Therefore, consumers should not be concerned about the use of food additives permitted under the law. He also made the following observations:

- Wrong information circulated on use of food additives or ingredients should be countered by publication of scientific articles as also circulation of scientific facts through media including social media. Scientists should take proactive steps.
- There are a number of ingredients/additives used in India but they are not included under Codex. FSSAI should suggest their adoption under Codex.
- Specific issues relating to food additives should be addressed by concerned committees of FSSAI.
- There should be severe punishment for sale of unsafe foods and use of unsafe additives which cause harm to consumers' health.
- Indian experts/delegation participates in Codex meetings and JECFA meetings and are a party to adoption of standards at international level. Therefore, there should be no hesitation in their adoption at national level.
- Industry should give comments on draft FSSAI notifications in a timely manner. Comments should be based on science.

Dr. Prakash mentioned that a high level Committee was formed in December 2014 under His Chairmanship on "product approval system". Report of the Committee was submitted on April 22, 2015. He also mentioned that it should be the endeavor of FSSAI to have more horizontal and vertical standards so that there is no need for going through the system of product approvals.

Role Of Food Ingredients And Nutrients In Promoting Health

Dr. B Sesikeran, Chairman, RCGM and, Former Director, National Institute of Nutrition (NIN) made a presentation on "Role of Food Ingredients and Nutrients in Promoting Health". In his introductory remarks he said that ingredients have served useful functions in a variety of foods. Our ancestors used salt to preserve meats and fish, added herbs and spices to improve the flavor of foods, preserved fruit with sugar, and pickled cucumbers in a vinegar solution. Today, consumers demand and enjoy a food that is flavorful, nutritious, safe, convenient, colorful and affordable. Food additives and advances in technology help make that possible. Dr. Sesikeran informed that the Food and Drug Administration (FDA) maintains a list of over 3000 ingredients in its data base "Everything Added to Food in the United States", many of which are used at home every day (e.g., sugar, baking soda, salt, vanilla, yeast, spices and colors).

USFDA says that there are three main reasons for adding ingredients: to keep the food fresh and safe; to improve the nutritive value and give health benefits; and improves taste, texture and appearance. There are about 20 different categories of ingredients.

Dr. Sesikeran mentioned that consumption of diverse foods are the best way to include nutrient requirements. However, more than three quarters of the population of this country and other countries also never ever eat that kind of food and therefore it is unlikely that nutrient goals would ever be achieved. Even in food secure situations like in the affluent countries this does not seem to be possible and quite often they reach their micronutrient requirement through food fortifications. Nutrient supplements are also required for targeted population like in India because of the prevalence of iron deficiency. Supplements are given to pregnant women, adolescent and young children. He underlined that the best strategy to provide the required nutrients is through fortified food.

Dr. Sesikeran informed that data shows inadequate nutrient intakes and then their inadequacy creates several major health problems like Anemia, Goiter, Vitamin A and D deficiencies etc.

According to the Indian Brand Equity Foundation which is an initiative of the Ministry of Commerce and Industry, GOI, the share of processed food in Indian Market is 32% and almost every individual in this country is consuming some processed food.Therefore, processed foods are good way of delivering nutrients. Further, there is a need for higher intakes during various physiological phases like pregnancy, lactation, infancy, early childhood, adolescence, elderly; and during illness and convalescence, or permanent health problem.

Nutrients can be added to variety of foods and beverages such as - salt; flour; bread; rice; cereals; oils and fats; milk; fruit juices and other beverages and energy bars. He pointed out that the need for a nutrient is unrecognized by consumers and benefits of fortified foods are subtle and not felt.

The commonly added nutrients are:

- Thiamine, Riboflavine, Niacin, Folate, beta Carotene, KI, iron salts, Vitamin E, Vitamin C, Vitamin D, Calcium salts

- Amino acids- Lysine, Leucine, Tryptophan, Methionine, glycine
- Zn,Mg, Mn and other trace minerals

As regards the quantity of nutrient to be added, Dr. Sesikeran suggested that the quantity of a nutrient to be added could range from a fraction of the RDA to even multiples of RDA provided that it does not go beyond the safe upper limit (SUL). While RDA is the minimum required by a healthy individual to stay healthy, SUL is the maximum amount of a nutrient that an individual could take on a daily basis for an entire life time without medical supervision and yet not face any negative health effect

Dr. Sesikeran informed about different types of functional ingredients. These include:

- For calorie reduction - Non Nutritive sweeteners
- To reduce cholesterol absorption- Phytosterols
- Lower GI- Complex CHO - Resistant Starch, Dietary Fiber
- Promote Gut health – Pre and Probiotics
- Whey protein / Leucine to prevent muscle loss
- Calcium, Vitamin D, Vitamin K, Cu, Zn, F, Phyto estrogens- for bone health

There are ingredients for F100 formula to manage severe malnutrition: Skimmed milk powder, Cereal flour, Sugar, Vegetable oil, and Mineral mix.

Dr. Sesikeran chalked out the principles for addition of dietary active compounds to foods. These include:

- Presence of active compounds at a level which will not result in either excess or insignificant intake.
- Should be sufficient to exercise its beneficial effect.
- Should not result in an adverse effect on the metabolism of any other nutrient.
- Should be stable in food under customary conditions of packaging, storage, distribution and use.
- Should be biologically available from the food.
- Methods of measuring should be available.

Ingredients of concern for public health related to chronic degenerative diseases include high energy or high calorie intakes due to high refined carbohydrates or high fat content; sugars, salt – or higher sodium; saturated fat – Myristic and Palmitic acids and PHVO and Trans Fats.

In his concluding remarks Dr. Sesikeran underlined that food ingredients have been used for many years to preserve, flavor, blend, thicken and color foods, and have played an important role in reducing serious nutritional deficiencies among consumers. These ingredients also help ensure the availability of flavorful, nutritious, safe, convenient, colorful and affordable foods that meet consumer expectations year-round.

Food and color additives are strictly studied, regulated and monitored. Federal regulations require evidence that each substance is safe at its intended level of use before permitting its addition to food. Further, all additives are subject to ongoing safety review as scientific understanding and methods of testing continue to improve. Consumers should feel safe about the foods they eat.

Regulatory Requirements For Safety Assessment Of Food Ingredients

Dr. Brinda Mahadevan, Manager, Regulatory Affairs, Abbott Nutrition, USA made a presentation on "Regulatory Requirements for Safety Assessment of Food Ingredients". She outlined the US regulatory process for food ingredients supporting safety through manufacturing control and knowledge. She said that it is a practical approachfor demonstrating safety of a novel ingredient. "Dose makes the poison": this statement still holds true for food additives and novel ingredients. All chemicals can cause toxic effects in

large amounts however the perception that all chemicals are "bad" irrespective of the amount is incorrect. When used appropriately based on the technological need, the effects of chemicals as ingredients can be beneficial. Dose is very important, so the goal and responsibility of toxicology studies is mainly to ensure the safety of the ingredient for human use. The use and use level are important when it comes to determining the safety of an ingredient. The food industry views food safety as its highest priority and the objectives of many food safety programs are to manufacture products with safe ingredients.

Many countries, including the United States, European Union and Canada have comprehensive processes in place for the review of novel food ingredients to ensure the safety in the food supply. US regulatory classification considers the need for a novel ingredient or any food ingredient that is intended to become a component of/or affect the characteristics of food to be Generally Recognized As Safe (GRAS).

There are different regulatory paths for approval of food additives, GRAS and dietary supplements. Outlined below are some comparisons between the different petition processes for approval of a Food Additive, GRAS and New Dietary Ingredient. The safety standard for all the three regulatory processes is the same "Reasonable certainty of no harm".

Table 2

Petition Processes

FOOD ADDITIVE	GRAS	DIETARY SUPPLEMENT
Federal Food, Drug, and Cosmetic Act 1938	**Exemption to Food Additives. Food additives Amendment 1958 Notification Process Promulgated 1997**	**DSHEA 1994 Draft Guidance For Industry 2011**
Food Additive Petition	**General Recognition of Safety by Expert Panel: GRAS Dossier (self-GRAS or Notification)**	**Pre-1994: No FDA Notification Post-1994: New Dietary Ingredient (NDI) Notification to FDA**
Information and data may be unpublished	**Pivotal information and data must be published**	**Information and data may be unpublished**
Assumes lifetime exposure	**Assumes lifetime exposure**	**Duration and frequency of exposure dictated on label**
Cannot exclude sub-populations	**Cannot exclude sub-populations**	**Can target and exclude sub-populations on the label**

Generally Recognized as Safe – GRAS:

Dr. Mahadevan explained the scientific rigor and process involved in building a GRAS dossier for consideration of a novel ingredient to obtain GRAS status. The GRAS dossier may or may not be limited to the information listed below, and may include the following sections:

1. Description of GRAS substance
2. Historical Use and Consumer Exposure
3. Intended Effect
4. Analytical Methodology
5. Safety Data

1. Description of GRAS substance:

- Physical and chemical characteristics
  - Chemical Name, CAS registry number, chemical structure.
- Detailed description of the manufacturing process
  - Stepwise process which details all of the equipment and processing aid used in production of the ingredient.
- Established food grade specifications
  - Use of the ingredient and the specification is determined and documentation provided.
- Batch analysis results
  - Data on 3-5 non-consecutive lots which demonstrate the supplier ability to meet the specifications.
- Contaminants identified
  - Any potential contaminant, residual, impurity etc. must be disclosed
- Documented stability data for the supplied ingredient

2. Historical Use and Consumer Exposure

History of use of the ingredient in the food supply and or natural occurrence of the ingredient in the standard variable diet.

3. Intended Use

Details of the intended uses and use levels of ingredients is providedon following basis:

- Product category to be identified (food type and class adult, pediatric, infant, etc.) to determine exposure potential
- The level in which each product category is mentioned to determine potential dose.

The above information is reviewed and the estimated daily intake is then calculated for the mean exposure as well as the 90th percentile.

4. Analytical Methodology

- Validated analytical methods are needed for each of the different specifications.
- Method used is either publically available and standardized, and used as published or confirmed as validated for the intended ingredient.
- Unpublished or non-standard methods are provided for review.
- Data using these methods is also provided for 3-5 nonconsecutive lots which demonstrate the validity of the method for confirming each specification.

Dr Mahadevan emphasized that Product Stewardship is key to safetyand that the entire supply chain from purchasing, production and distribution must be in control. She pointed out that GRAS evaluates the ingredient – not the product that the ingredient will be present in (clinical studies are with product). In preclinical animal testing the ingredient is fed in a relevant diet for the animal to evaluate safety compared to control. Further, pivotal published and unpublished data including: *In vitro* and *in vivo* toxicology studies; ADME data and Clinical studies.

The studies are testing not only the safety of the ingredient but also any potential residuals or impurities from the manufacturing of the ingredient. Safety studies may address the following end points:

- Justification/data to be provided to address the topics below or a rationale to conduct or not conduct studies
- ADME/Pharmacokinetics
- Acute Toxicity
- SubChronic and Chronic Toxicity
- Carcinogenicity
- Reproductive Toxicity/ Teratology
- Neurotoxicity
- Immunotoxicity/ Allergenicity

The "Red Book" offers guidance on preclinical toxicology testing that may include the following:

- Genotoxicity Battery
  - Ames assay, *in vitro* cytogenetics, *in vivo* mammalian test
- ADME
- Repeat dose toxicity
  - 14-day range finding study
  - 90-day subchronic study
- Chronic Carcinogenicity
- Reproductive
  - One generation
  - Multi-generation
- Developmental / Teratology
- Decision to conduct studies is based on gaps, intended population, dose, frequency etc.

Toxicology studies are required when it is not possible to bridge the safety of ingredients for its intended use to documentation of historical use or because of changes in:

- *Chemical composition*
- *Indication for use*
- *Target population*
- *Delivery matrix or formulation change*
- *Dose or amount ingested*
- *Duration of administration*
- *Frequency of administration*

Dr. Mahadevan said that while interpreting the data it has to be kept in view that nutritional studies are not the same as pharmaceutical studies. Studies are designed to evaluate oral dietary exposure of a specific ingredient with likely chronic exposure – daily use over lifetime exposure. Similar to pharma – the appropriate model is chosen based on physiological similarities between the model and the relevant human population. Doses are limited based on physiological relevance and limitations. Results are interpreted based on the ingredient, its intended effect and the type of outcome.The study data is then used to support GRAS or other safety dossiers.

Ultimately, there is no clear path forward for food ingredients or additives – the burden to demonstrate safety and "reasonable certainty of no harm" is on the organization which intends to market the ingredient.

SESSION 3

Panel Discussion: Way Forward

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

The Panel of Experts included **Dr. Meenakshi Singh**, Food Safety and Standards Authority of India, **Dr. Santosh JainPassi**, Institute of Home Economics, **Dr. Ravindra Kumar**, DuPont India Pvt. Ltd., and **Mr. Rajesh Kumar Gupta**, Bikanerwala Foods Pvt. Ltd. Following points were made during Panel Discussion by panelists and participants:

1. Infrastructure

Food testing laboratories should be strengthened and modernized.

2. Regulations

- Food additives should be harmonized with Codex.
- Vertical standards should be harmonized and as regards horizontal standards a beginning should be made with additives falling under GRAS (Generally Recognized as Safe) standards.
- Time taken for product approval should be reduced.
- Most of the food products in developed countries are fortified with micronutrients however, in India fortification has been a difficult exercise due to lack of clarity in the regulations. The reason could be due to existence of two schools of thoughts of scientists, one group mentioning the need for fortification and another group underlining that food should not be fortified as fortificants having chemicals can harm. This confuses and delays policy making. However, the latter impression is incorrect and a scientific approach is followed all over the world. Food regulations should permit fortifications of foods keeping in view the level of malnutrition in the country.
- Nutrition labeling should be consumer friendly and should provide information in a way that the consumer could understands. e.g. if the level of nutrients in packaged food is given on the basis of per serving then the serving quantity/ size should be indicated to enable comparisons with labels where the nutrient composition is given on the basis of per 100 grams. However, such information which is not there on the label can be accessed through the company's website . At times there is a constraint of space to enable the industry to put very detailed information on the label.
- Better date marking should be used and storage conditions should be specified on packages to ensure proper storage of products. Side effects of some of the food additives should be clearly labeled.
- Food industry should provide comments on draft notifications of FSSAI in a scientific manner.
- Banned food additives should not be allowed to be used and the ban should be strongly implemented.

3. Consumer Education

- Consumer education programs should be undertaken to remove the misconceptions about food additives and create awareness about their benefitse.g. fortification of foods helps in reducing the problem of malnutrition andaddition of dietary fibers make the food more healthy and helps in addressing the issue of NCD.
- Consumer awareness programs should be not only through print media and television but social media should also be used.
- At times the wrong information is obtained by consumers through internet. This creates wrong impression about food additives. In such cases scientist should immediately address the issues.
- The prime responsibility for consumer education should be shouldered by FSSAI.

Summing up with discussions **Dr. Sesikeran** said that both the regulatory authority and industry have to keep consumer safety uppermost in the mind. Further, industry should focus on innovation and bring out new products as also upgrade the existing products.

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