

Risk Analysis of Food Additives

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Consumers today demand a food that is tasty, safe, nutritious, convenient, and affordable. Advances in technology and food additives make that possible. However there are certain consumer concerns regarding food additives. There is a strong perception among consumers that processed foods are bad as they are produced by adding chemicals (food additives). The mechanism of evaluating the safety of the food additives, setting limits for their use in various foods and assessing risk, if any to consumers is carried by a science based method called risk analysis.

Risk analysis is a systematic and disciplined approach for making food safety decisions and its important component of modern food safety system (Table 1). The hall mark of risk analysis is that it follows a structured approach based on all available scientific data and that be applied consistently. It is open, transparent and documented, evaluated and reviewed as appropriate on the basis of new scientific data and it takes into account uncertainty and variability. The components of risk analysis are risk management, risk assessment and risk communication.

Table 1 Traditional food safety vs Modern food safety system

Traditional Food Safety System	Modern Food Safety System
Reactive approach	Preventive Approach
Main responsibility with Government	Shared responsibility
	Addresses farm-to-table continuum
No structured risk analysis	Science-based use of structured risk analysis
	Establishes priorities – Integrated food control
Relies on End product inspection & testing	Relies on process control
Level of Risk Reduction: Not always satisfactory	Level of Risk Reduction: Improved

The definitions of these components of risk analysis as provided by Codex are as follows:

Risk assessment: A scientifically based process consisting of the following steps: i) hazard identification; ii) hazard characterization; iii) exposure assessment; and iv) risk characterization.

Risk management: The process, distinct from risk assessment, of weighing policy alternatives in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

Risk communication: The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

What is food additive?

Food Additive is defined as any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging and transport. The term does not include contaminants, or substances added to food for maintaining or improving nutritional qualities.

There are two basic things that are required to be considered for any chemical to be a food additive.

1. It must have a technological function to perform in the food as defined.
 2. It should be safe at the levels of its use in foods. The food additives have to be used as per Good Manufacturing Practice i.e.
- a) It should be used at the lowest possible level necessary to accomplish its desired effect & b) The additive is prepared and handled in the same way as food ingredient.

Food Additive Safety: Joint (FAO/WHO) Expert Committee on Food Additives (JECFA) is an international expert scientific committee administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). JECFA serves as an independent scientific committee which performs risk assessments and provides advice to FAO, WHO and the member countries of both organizations. The evaluations carried out by this agency are used as guidance for permitting any food additive. The inclusion of a food additive in the standard will take into account any Acceptable Daily Intake (ADI) or ADI "Not Specified", or equivalent safety assessment established for the additive by JECFA and its probable daily intake from all food sources. Where the food additive is to be used in foods eaten by special groups of consumers (e.g. diabetics, those on special medical diets, sick individuals on formulated liquid diets), account will also be taken of the probable daily intake of the food additive by those consumers.

Risk assessment of Additives: Risk assessment has four components. 1. Hazard identification, 2. Hazard characterization, 3. Exposure assessment, and 4. Risk Characterization. In case of food additives, the hazard is the food additive and hazard characterization is the health hazards associated with it. In this context it is pertinent to understand the dictum of Paracelsus, the famous 16th Century alchemist who said "All things are poisons; nothing is without poison; only the dose makes a thing not a poison". Therefore mere addition of a food additive in food does not itself make food unsafe, but the quantity used in food, quantity of that food consumed and bodyweight will decide the safety.

Even before the additive is permitted to be used in foods safety evaluation is available and safe level of intake of any food additive is supposed to be ADI which is expressed as milligram per kilogram of body weight (mg/kg body wt) of an individual. Therefore, the critical part of risk assessment for food additives would be exposure assessment i.e. how much of an additive is ingested by an individual from all the foods in one day where the additive is present. The amount of additive ingested is expressed on per kg body weight basis and is compared with Acceptable Daily Intake of an additive. For the purpose of calculating the ADI, JECFA uses the body of 60kg (Standard reference man).

Risk characterization: Chemicals which are proved to be carcinogens in animal experiments are not permitted to be used as food additives as they will not have any ADI. Hence the question of risk characterization is limited to cases where the exposure to a particular additive should reach

the quantity to match Low Observed Adverse Effect Level (LOAEL) in experimental animals. To reach this level of exposure, quantity of food additive has to cross ADI and then No Observed Adverse Effect Level (NOAEL) (Table1). For example ADI of a synthetic food colour Tartrazine is 7.5 mg/kg bw/day. If we take reference man in India weighs only 50kg, then the ADI for 50kg Indian would be 375mg/day of tartazine. As per our regulations, it is permitted at 100mg/kg for confectionery, then one has to consume 3.75 kg of confectionery per day to reach ADI and ADI itself is safe intake. Even if we assume that a person takes all foods where the tartrazine is added it can never be 3.75kg of food per day. NOEAL is 100times more quantity than ADI. Practically no person can ingest that high amount of additive which can cause health hazard.

Risk management: As a precautionary measure for the purpose of risk management of food additives, while permitting the use of food additives, the quantity of additives permitted in various foods and total likely consumption is considered and made sure that the total intake of an additive is well below the ADI of that particular additive. Food additive intakes are regularly monitored and, if the intakes are likely to reach ADI, their limits in various foods are reviewed and appropriate risk management is done.ie either to reduce the permitted list or to reduce the number of foods where is it permitted etc.

Risk communication: It is a open and interactive exchange of information, facts and opinions about food safety risks. Risk communication is most important tool overlooked to improve public health as

"The risks that kill people and the risks that alarm people are completely different". Risk means something inherently different to lay public than what it means to scientist and regulators. There are different levels of risk communication that is to be done while carrying out risk analysis. There is an internal risk communication within the risk analysis team and once it is firmed up, risk analysis team interacts with external stake holders. The emotion defines the risk perception of consumers, so the risk communication to the consumers should take in to account the emotions and science. There is strong perception among the consumers that processed foods are bad, because they contain many chemicals (Food additives). There is a need to understand the factors shaping the risk perception of consumers with reference to food additives in general. The risk perception also varies from additive to additive.

To ensure food safety and consumer confidence in food supplies, there is a need to use science based ie structured risk analysis approach, but to perform successful risk analysis be it for additives or contaminants, there are three prerequisites. 1. A well functioning food safety system, 2. Support and participation of key stake holders ie government, industry, academia and consumers, 3. Basic knowledge of three main components of risk analysis.

Acceptable Daily Intake

The Acceptable Daily Intake (ADI) is an estimate by JECFA of the amount of a food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk (standard man - 60 Kg) (WHO 1987). The ADI is expressed in milligrams of the additive per

kilogram of body weight. For this purpose, "without appreciable risk" is taken to mean the practical certainty that injury will not result even after a life-time's exposure (Report of the 1975 JMPR, TRS 592, WHO, 1976).

Acceptable Daily Intake "Not Specified"

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 JECFA, represent a hazard to health.

LOAEL

The lowest tested dose of a substance that has been reported to cause adverse health effects on people or animals.

NOAEL

The highest tested dose of a substance that has been reported to have no adverse health effects on people or animals.

Table2 Relation between ADI, NOAEL & LOAEL

Name of Additive	Class of additive	ADI (mg/kgbw)	NOAEL (mg/kgbw)	LOAEL
Sodium Benzoate	Preservative	0-5	500 (Animal experiment data)	5-6 grams/ day Human volunteer data
Erythrosine	Food colour	0-0.1	1.0 (Human volunteer data)	200mg/day(Human volunteer data)

As you can see from the table that if an additive (Erythrosine) has an ADI of 0.1mg/kg bw, then the NOAEL is 1.0mg/kg bw and this is based on human volunteer data. And the minimum dose at which adverse health effects were observed in human volunteers was at 200mg. Regulations ensure the intake of Erythrosine to be less than ADI (0.1mg/kg bw) and for any health effects to be seen one has to consume at least 2000 times of ADI.

Role of Third Party Accreditation and Certification in Food Industry

Mr. Niraj Raje

Senior Assessor and food specialist, LRQA India

Challenges faced by food sector

We are all aware that food chain is highly complex and is wide spread from farm to fork. In India the situation is much more complex and challenging due to the size, climatic and regional diversity of our country.

Food processing industries are major part of this complex food chain and are facing various challenges in India. The key challenges are

- Meeting the local and global standards, statutory and regulatory requirements
 - Growing customer and consumer expectations
 - Poor infrastructure and hygienic conditions
 - Availability of trained, competent man power
 - Growing pressure from stakeholders for demonstrating self-governance, self-compliance
- In such a scenario; food industry will derive benefits from a third party accredited certification process.

Accredited certification process

- Accreditation and certification are proven concepts in many industries, including food industry.
- It provides a framework for assessing the competence and compliance of FSMS.
- These have been widely practiced and accepted for years in many parts of the world due to the checks and balances employed at each stage in the process.
- For those of us who believe in the value of HACCP, the model is entrenched strong verification and results based processes
- The model is also a continuum with defined timelines for improvements and demonstration that the improvements are sustained over time.

What Makes Accreditation & Certification Different

Accreditation

- *Validation* of a certification body about its infrastructure, resources and controls to assess conformity
- *Verification* of a CB's compliance to its processes

This process is achieved by conducting audit of certification body by the accreditation board.

This audit has multiple components - office audit and field audit of auditors commonly called a shadow or witness audit.

Certification

Objective of certification is assurance and verification that the facility maintains its food safety system as per applicable requirements. Certification Body verifies execution and compliance during the assessment/audit. Ongoing surveillance/ recertification process to check compliance

periodically. Certification body assess competence of auditors and auditors only audit to designated food sectors based on their competence. Non-conformances are classified as per standard definitions and corrective actions are verified and checked for effectiveness. Based on satisfactory audit the CB issues certificate to the site and “owns” certificate.

Stakeholders in the accredited certification process

There are three major stakeholders in this process.

International Accreditation Forum (IAF)

The IAF is a global association of Accreditation Bodies, Certification Body associations, industry associations and others involved with these types of assessments that deal with international standards. This is the apex body which governs this accredited certification process.

Accreditation Bodies (AB)

An Accreditation Body accredits a Certification Body. Typically each country has an accreditation body, e.g. UKAS (UK), ANSI (USA), NABC (INDIA), CNAS (CHINA). The ABs work together through the International Accreditation Forum.

There are recognition agreements among the ABs and a vigorous peer assessment process. The ABs are guided by international standards to assure conformity in their assessments. The concept behind accreditation is to provide confidence and integrity that specific requirements are being met by CBs during the third party assessments.

There is a multilateral recognition arrangement (MLA) amongst ABs. This means ABs will recognize certificates issued by CBs that have been accredited by other MLA members. In other words, accredited certificates are recognized and accepted throughout the world. The result is removal of technical barriers to international trade that otherwise might require a facility to have multiple certifications of the same kind.

The Accreditation Body framework is shown in figure 1

Accreditation Body Framework

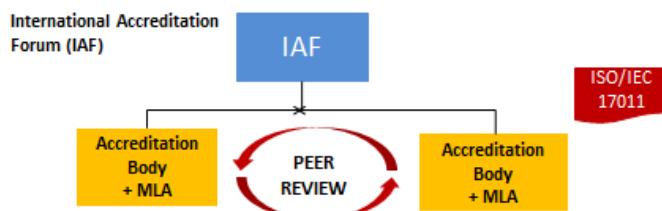


FIGURE 1

ABs assesses CB's competence of its entire operation from personnel to the validity of its methodology to the validity of its results. Assessment covers following checks

- CB's overall operating platforms

- Actual processes and procedures followed by CB related to certification:
 - Assurance of clear, measurable assessments
 - Processes for managing nonconformance issues and corrective action resolutions
 - How CBs insure impartiality and avoid conflicts of interest in the auditors we use.
- Auditor's competence and qualification.
- Ensure independent decision making and technical reviews of the audit report. It is important to understand that in the accreditation and certification model, decision to certify or not certify or to withdraw or suspend an existing certification is independent from the auditor.

Certification Bodies

Thus the Certification Bodies are 3rd party auditing companies

They formally demonstrate their competence to carry out specific certification/conformity assessments. CBs must meet specific requirements for the procedures and practices used.

Certification Bodies audit food facilities within the supply chain and certify them for compliance against a specific scheme e.g. FSSC 22000, BRC- Food, HACCP-Codex etc.

A certification body has to ensure following requirements

- To have proper operational Infrastructure (Back office)
- Meets International Certification Management Standards
- Licensed by the Scheme Owner (e.g. FSSC, BRC)
- Sustainable, compliant certification process procedures & practices, especially impartiality
- Competent auditors approved by Scheme owner
- Independent decision-making on issuing certification(technical review)
- Defined regular competence reviews of auditors and support staff

Accredited certification process is shown in Figure 2

Food Safety Certification Framework

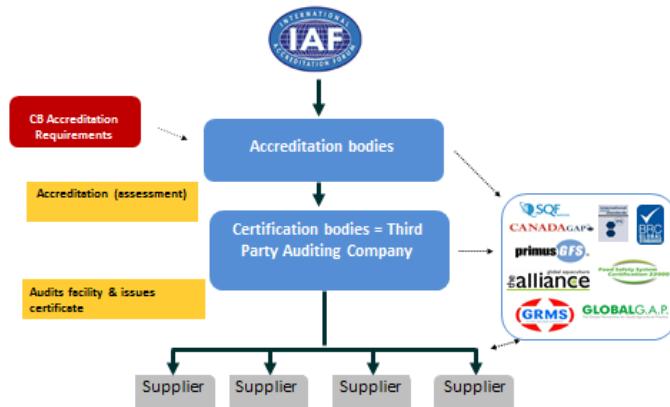


FIGURE 2

Third party certification system

The food industry/plant/supplier has to apply the standard in its own operations before the audit. Once the facility has internally developed, validated its FSMS and verified internally that it complies with its chosen scheme, and then it is ready for its certification audit. Choosing a proper certification body is very critical for a food business operator. This will ensure an effective assessment leading to value addition and continual improvement within the organization.

In this certification model there is a defined, standardized infrastructure above the auditing company to ensure the auditing company has the systems to perform correctly and consistently and can apply this level of standardization to the food plants it audits and certifies. This model has an ongoing loop of checks and balances. This model is routinely verified – the CBs are audited at least annually with surveillance audits. The ongoing audits check CBs compliance, performance and records as well as check auditor performance and competence.

Benefits of third party accredited certification

- Certification accepted globally (e.g. FSSC, BRC certified company names appear on their websites)
- Overcomes the trade barrier issues
- Enhances confidence of the buyers, customers and consumers
- Ensures compliance to stakeholders requirements e.g. regulatory, statutory requirements, sector specific requirements, customer requirements
- Enhances the food safety culture in the organisation
- Assurance from a reputed, independent third party about compliance with global food safety standards
- Drives an effective regime of self-governance

In conclusion, the food industry will have valuable benefits by adopting the process of third party certification to global food standards. It would enable adherence to stringent food safety and hygiene norms and thereby protect consumer health, prepare the industry to face global competition, enhance product acceptance by overseas buyers and keep the industry technologically abreast of international best practices.

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SEMINAR ON SAFETY OF PROCESSED FOOD PRODUCTS

By Ms. Siddhita Kadam, Food Scientist, PFNDI

Food and people are travelling thousands of miles to different countries more than ever before as well as newer ingredients including ones that have benefits well beyond conventional nutrient roles and ones having been genetically manipulated are appearing in markets with many advantages including taste, flavour, appearance, colour, nutrient content and ability to reduce the risk of many diseases.

Safety evaluation of food is not an easy task. As food products are now prepared using a large number of ingredients and additives as well as processing aids, using complex machinery and processes, many ingredients coming from distant places and also in complex forms, and as recently some botanicals and herbs have been permitted to be used for their health benefits. Under such conditions ensuring safety becomes complex. Some of the ingredients may be novel and used for the first time, some may use novel process. There are also ingredients from GM foods and botanicals whose safety we need to evaluate.

So many processed food products available in Indian market, from manufacturing to the finished products every industry should be taking care that these food products do not cause any health problems and absolutely safe for consumption.

To create more awareness on safety of processed food and to discuss the problem existing as well as innovative solutions related to processed foods that we produce and consume, a one day conference was organized on 11th September 2015, about "**Safety of Processed Food Products**" at Hotel Orchid, Mumbai.

On this occasion the delegates were welcomed by Mr. Bhupinder Singh, Chairman, PFNDI & CEO Vista Processed Foods. He talked about the changing commercial as well as regulatory scenario in food industry and how professionals must be aware of them in order to survive in today's competition. He said PFNDI always organised these events wherein various aspects could be discussed thoroughly by experts to evolve a consensus.

Seminar inaugural address was delivered by Dr. P. I. Suvrathan, ex-Chairperson, FSSAI, wherein he stated that 'No regulation can ensure the food safety in one hand. It depends upon regulators, producers and government and also the consumers'. While talking about safety standards and regulations, he emphasized on 'Pesticides level increases in transporting foods e.g. eggs, fruits, vegetables, fish etc. 90% of sale of such foods occurs on street and that 75 -80% food samples are contaminated with E. coli. To developed safety standards good agricultural practice is used in agriculture for appropriate us of pesticides along with active consumer awareness is also required'.

Dr. Vilas Sinkar, ex-VP R&D, Unilever briefly introduced about 'How to Provide Safe Processed Foods'. He stated that provide safe process food Recognized as a National priority. Food Safety & Standards Authority of India (FSSAI) created science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption. He also emphasized on Safety of processed foods provided by Better Farm Extension Programmes, Better organized Supply Chain, Greater investment in Agri and Foods R and D, Higher Consumer awareness of Quality and Safety,

Simplified and Transparent Regulatory Environment, Availability of Skilled Manpower, process is *transparent* and accessible to the public.

Mr. Ganesh Kamath, Director, Vital Nutraceuticals talked on “Safety & Regulation of Functional Foods, Supplements etc.” while discussing on functional foods he stated that dietary supplements, nutraceuticals are identified under section 22, regulation passed by parliament. Only the Central government has power to make regulations in production of nutraceuticals. Product approval is not a legal system. Scientific committee and panel should work on limit of additives while manufacturing the supplements, which will be helpful in food safety. Manufacturing conditions are also important. Manufacturers should visit their plants regularly and observed procedure daily. This will be helpful in producing safe product.

Dr. Madhavan Nair, Head, Micronutrient Res., NIN gave a presentation on Nutrients: Concept of RDA, UTL & NOAEL. He stated that Nutrients needs are variable and become population specific due to variations in genetic environment and socio-demographic characteristics of the population and within a population it varies among different physiological groups. He defined the Recommended Dietary Allowances (RDA) as the daily dietary intake level of a nutrient considered sufficient to meet the requirements of 97.5% of healthy individuals in each life-stage and gender group. RDA intake is based on Physical activity, Reference body weights, Habitual diet, Bioavailability and health status for all age groups and during pregnancy and lactation.

Approaches use to derived RDA for adult man average weight of 60 kg is iron (Fe) – 17 mg/d, Folic acid – 200 μ g/d, vitamin B₁₂ - 1 μ g/day and vitamin C – 60 mg/d. he also stated that the safety of exceeding fat-soluble vitamins are notoriously dangerous in excess (Vitamin A), while excesses of most water-soluble vitamins are excreted with no apparent harmful effects, exception -- Vitamin B₆ (pyridoxine) in excess causes irreversible neurological damage but excesses or imbalances of minerals are best avoided.

He highlighted on NOAEL (No observed adverse effect level) nutrients means highest continuing intake of a nutrient at which no adverse effects have been observed in the individuals or groups studied. He also explained the relation between NOAEL and UTL with definition such as upper tolerable limit (UTL) is meant to inform the public of risk of excess nutrient intake is built upon no observed adverse effect level (NOAEL), Lowest-observed-adverse-effect level (LOAEL) and uncertainty factor (UF). UTL is not a recommended intake level.

On the topic of Safety Assessment of Botanicals and Botanical Preparations, Mr. K. Bala Subramanian, Head, Technical, Chennai Mettexlab had given the presentation. He stated World Health Organization (WHO) assists national regulatory authorities; Guidelines for assessing the quality of botanical materials mainly emphasize the need to ensure the quality of medicinal plant products by using modern techniques and applying suitable standards.

He also discussed uses of botanical ingredients in food products including food supplements, the maximum permissible level of Chemical, Biological contaminants (e.g. pesticides, mycotoxins, heavy metals), Technical Exposure and Toxicological nature required in proposed data for safety assessment. He also presented on qualified presumption safety which is based on four principles such as taxonomy, body of knowledge, toxicity and end use. He also mentioned that in India over 70% of the population relies on some form of traditional medicine, mainly Ayurveda, Unani, and Siddha for that safety of botanical products analyzed on Toxicokinetics including

metabolism, Genotoxicity testing, Sub-chronic toxicity testing or further studies relevant to the products required.

Dr. JI Lewis, Advisor, FSSAI presented food safety issues. He presented on food safety issues which is cause by adulterants and that is mostly present in unsafe, sub standards and misbranded foods. These adulterants responsible for intrinsic risk (through pesticides residues, food additives, toxins, contaminants, high risk foods such as fish, eggs, meat, infant's food etc.) where as control risk occurred due to unsafe production. Food safety management system is required for managing both the control risk factors and intrinsic risk factors through HACCP, GHP-GMP-GLP, traceability, recall plan, self audit, performance and measurement. He also mentioned that food safety is a preventive system. It is neither an 'inspected attribute' and nor a 'single point control'.

Dr. Nimish Shah, Director, Safety & Environ. Assurance Centre, HUL presented on Science behind Food Safety. He highlighted on food analysis carry out by speed and sensitivity. PCR/Antibody based tests allow detection of single/ very few numbers of pathogens in matter of minutes-hours. He floated an idea about allow technical talent (professionals from different fields) come together in preparation of food safety models. He also suggested that used Multi Criteria Decision Analysis (MCDA). He lastly mentioned that "Establishment of FSSAI is a key milestone for the country".

Mr. Sujit Nair, Sr. Food Assessor, LRQA gave brief presentation on Role of Accreditation and Certification in Ensuring Safety of Food Products. He explained difference between accreditation and certification. While talking about this, he defined accreditation is validation of a certification body about its infrastructure, resources and controls to assess conformity and verification of a CB's compliance to its processes whereas Certification is assurance and verification the facility maintains its control measures(Facility identifies risks, validates FSMS and processes, controls these risks). To remember this he simplified as Accreditation Bodies "accredit" certification bodies and Certification Bodies are 3rd party auditing companies. He also highlighted on the benefits of accreditation certification. If company has this certificate then that would be globally accepted (FSSC, BRC certified),overcomes the trade barrier issues, enhances confidence of the buyers, customers and consumers, ensures compliance to stakeholders requirements e.g. regulatory, statutory requirements, sector specific requirements, customer requirements, enhances the food safety culture in the organisation, assurance from a reputed, independent third party about compliance with global food safety standards and drives an effective regime of self governance.

Risk Analysis of Food Additives on this topic Dr. Sudershan Rao, Deputy Director, NIN, Hyderabad, he discussed that risk analysis of food additives can be carry out by identify food additives, perform toxicity test, determine NOVEL, select safety factor, calculate ADI, calculate exposure and last Compare the exposure and the ADI when exposure exceeds ADI, Risk mitigation is required. He also stated that Good Manufacturing Practices (GMP) is required for food additives by using lowest possible level necessary to accomplish its desired effect and the additive is prepared and handled in the same way as a food ingredient. To reduced risk about food additives a well functioning food safety system, support and participation of key stakeholders, i.e. Government, industry, academia, consumers are needed.

Dr. Jasvir Singh, Asso. VP & Head: Sci. & Regul. Affairs, Mondelez presented on Codex scientific perspective on Food Additives Safety on behalf of Mr. Shaminder Pal Singh of Pepsico. He stated that Codex has developed global food standard for protect the health of consumers and Facilitate fair trade practices in the food trade and it's a global reference for consumers, Food Producers and Processors, National Food Control Agencies and International Food Trade. He also mentioned that codex is a voluntary standards but it gives significant benefits to enrich national legislations (esp. for developing world). He threw light on JECFA (joint expert committee of food additives) estimated the amount of a food additive, expressed on a body weight basis that can be ingested daily over a lifetime without appreciable health risk. JECFA performs a vital function in providing a reliable source of expert advice for countries that do not have the resources to perform their own risk assessments. Codex decision making process based on four principles such as Excellence, Independence, Transparency and Universality depends upon scientific basis of risk analysis.

Mr. SaileshVenkatesan, Vice chairperson chaired the panel discussion and spoke of effectiveness of product approval system. He mentioned that Approval required for products specified under Section 22 (Novel, GM, FSDU, Food supplement, Proprietary food etc.) to ensure product safety / safety of the consumer. It is done by prescribing Standards; or by an approval mechanism. He highlighted on for product approval detailed information such as ingredients list, additives list, recipe, source of origin, labels, agreement with the supplier/ vendor/ test certificates/ shelf life etc... were required to be furnished to FSSAI. If any changes in its composition or % thereof in the product needed fresh approval – “combinatorial effect” vs. bio availability and country specific. Except the product itself companies were made to submit everything including manufacturing process etc. Rejection can be made on even label claim related issues.

Panellists: Dr. Vaibhav Kulkarni, Director, Regulatory Affairs, Abbott; Dr. Jasvir Singh, Asso. VP & Head: Sci. & Regul. Affairs, Mondelez; Dr. Shatadru Sengupta, Sr. Director: Legal & Company Secretary, Hardcastle Restaurants; Dr. Ramasubramanian, Director, VR Food Tech; Dr. Nilesh Amritkar, MD, Envirocare Labs, and Mr. Kiran Desai, Manager, Mead Johnson. Each panellist gave a critical appraisal of the regulatory scenario stating that concepts of food product safety are not yet fully agreed upon so how to evaluate it will be discussed for some more time. Dr. Shatadru Sengupta threw light on the gazette of India extraordinary, in that form VII A report of food analysis included opinions, interpretations and conclusions. The public analyst does not have right to do this. He has just right to perform the tests. Mr. Sailesh Venkatesan then gave concluding remarks and the seminar was concluded with the vote of thanks.