Risk Assessment
Acrylamide – A Case Study

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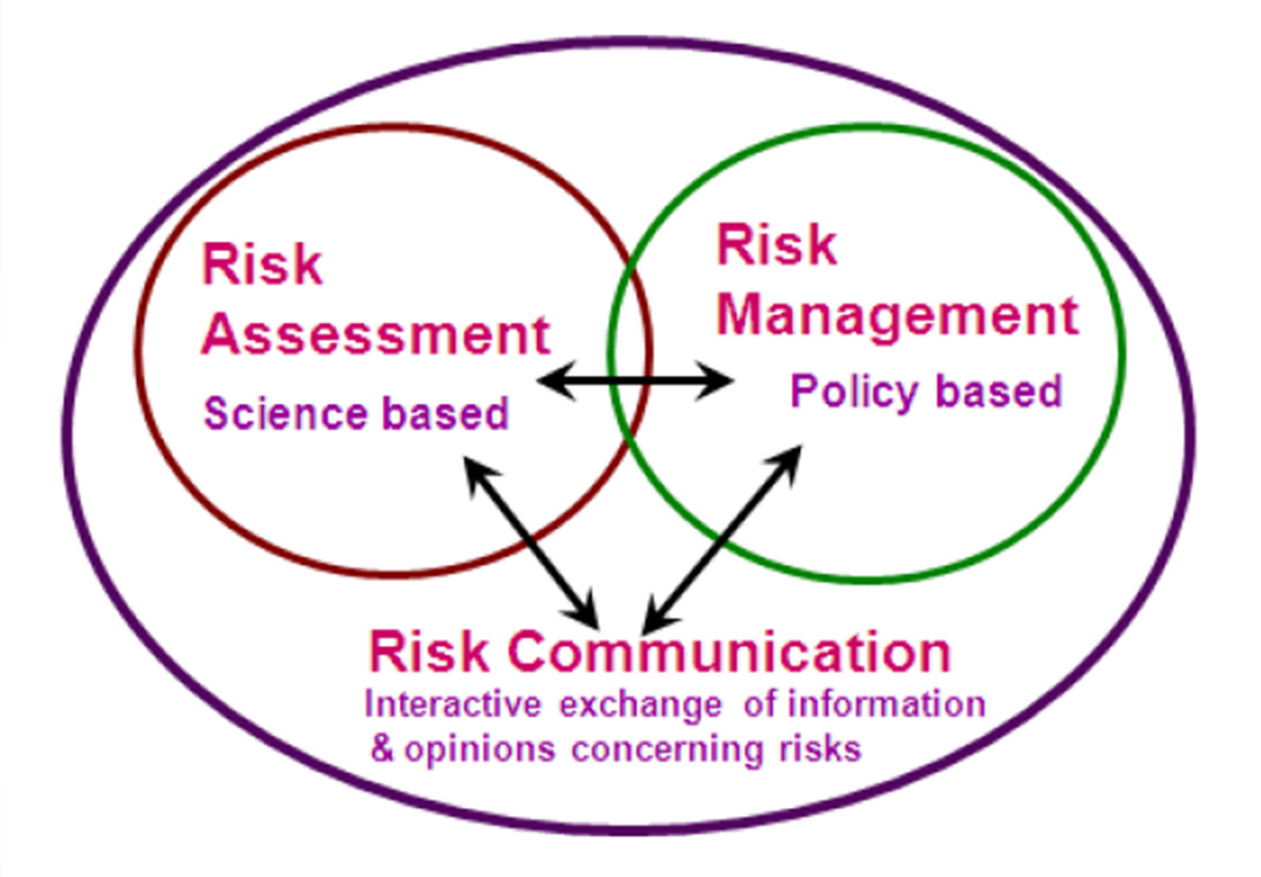
Contents

Safe Food for All

Food Safety and Standards Authority of India
भारतीय खाद्य संरक्षा एवं मानक प्राधिकरण

- **Public Health Protection**
- **Enshrined in the Food Safety and Standards Act 2006**
- **Application of risk analysis to be integral part of National Food Safety Systems**
- **Codex CAC/GL 62-2007 mandates Risk Analysis to be**
  - **applied consistently;**
  - **open, transparent and documented &**
  - **evaluated and reviewed as appropriate in the light of newly generated scientific data**

Risk Analysis Framework



- **Risk Assessment**
- **Risk Management**
- **Risk Communication**

Codex Definition of Few Terms

- **Hazard** - A biological, chemical or physical agent in, or condition of, food with the potential (or *possibility*) to cause an adverse health effect

- **Exposure Assessment** - The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant

- **Risk** - A function of the *probability* of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food

What is Risk

Risk is a function of hazard and exposure

Risk = Hazard x Exposure

Health Consequences
Severity
(degree of adverse consequences)
+
Potency
(amount to cause ill effects)

Routes
(how are we exposed)
+
Likelihood
(improbable to common)

Approaches

- **Hazard** – based safety assessment
- **Risk** – based safety assessment

Why Risk Based Approach – Two Main Reasons

- **Hazard** – based safety assessment – only a potential to cause an adverse health effect
- ignores impact and contributes to poor regulatory policy making
  - may lead to the banning of a wide array of substances
- **Risk** – based safety assessment – a probability of an adverse health effect and the severity of that effect
  - examine the weight of evidence as to whether a risk actually exists
  - often provide a quantitative indication of the probability of various outcomes

- **Food Safety and Standards Act** – Section 16(2)(i)
  - Underscores FSSAI's approach on evolving standards using risk analysis approach

A requisite - as make a shift from prevention of adulteration to a comprehensive Food Safety Management System

Principles of Risk Assessment

- **Risk Assessment** - A scientifically based process consisting of the following steps:
  - Hazard identification: *The identification of biological, chemical, and physical agents capable of causing adverse health effects*
  - Hazard characterization: *The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with the hazard*
  - Exposure assessment
  - Risk characterization: *The process of determining the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects*

Contaminant – Codex and FSSAI Definition

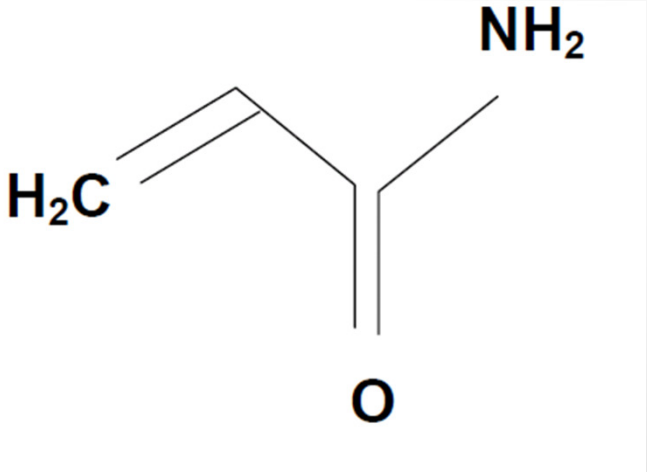
- Codex Standard 193-1995(2010) & FSS Act 2006 Section 3(g) defines 'contaminant' as follows:
- Any substance not intentionally added to food, which is present in such food as a result of the
  - **production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine),**
  - **manufacture,**
  - **processing,**
  - **preparation,**
  - **treatment,**
  - **packing, packaging,**
  - **transport or**
  - **holding of such food or as a result of environmental contamination.**
  - **The term does not include insect fragments, rodent hairs and other extraneous matter"**

Acrylamide – Codex / EFSA Approach

What is Acrylamide

- Acrylamide is a well-known and regulated substance used in various industries, including the manufacture of plastics.
  - known to induce cancer in animals, damage nerves and impair male fertility
  - Until recently, it was not known to occur in starchy food

- Acrylamide is a chemical intermediate (monomer) used in the synthesis of polyacrylamides
- Polyacrylamide is used as
  - Flocculent in the treatment of municipal water supply and in paper and pulp processing
  - Cosmetic additives,
  - Soil conditioning agents
  - In formulation of grouting agents



Acrylamide – Formation / Cause of Concern

- In April 2002, Swedish scientists found acrylamide in certain cooked foods
- Formed in carbohydrate-rich foods during high-temperature cooking, e.g. during frying, baking, roasting, toasting and grilling
- Acrylamide is mainly formed in food by the reaction of asparagine (an amino acid) with reducing sugars (particularly glucose and fructose) as part of the Maillard Reaction
- Formation primarily takes place under conditions of high temperature (usually in excess of 120 °C) and low moisture

Acrylamide – Approach Taken

- Major international efforts have been mounted to investigate the
  - principal sources of dietary exposure,
  - assess the associated health risks and
  - develop risk management strategies
- JECFA undertook a comprehensive analysis of acrylamide occurrence data from 24 countries
  - It was concluded that the major contributing food groups were French fries, potato crisps[3], coffee, biscuits/pastries, bread and rolls/toasted bread
- European Commission – Heatox Project (€ 4.2 Million)
  - Estimate health risks from compounds in heated foods
  - To study reaction pathways Testing raw materials, production / cooking processes – industrial and at home to reduce formation of such compounds
  - Impact on cooking and nutritional properties of food due to altered practices
  - Level of acrylamide in various food-stuffs

Acrylamide – EFSA Study Areas 1- 10

- Levels of acrylamide in Foods
- Acrylamide Dietary Exposure
- Ways to reduce
- Formation mechanism
- Bioavailability in Foods
- Toxicology-carcigenocity Studies
- Biomarkers of acrylamide
- Epidemiology
- Methods of Analysis
- International Activities

Acrylamide – Measures Taken vs MRLs

- Codex has issued Code of Practice intends to provide
  - National and local authorities,
  - Manufacturers and
  - Other relevant bodies with
- Guidance to prevent and reduce formation of acrylamide in potato products and cereal products.
- The guidance covers three strategies (where information is available) for reducing acrylamide formation in particular products:
  - Raw materials;
  - Control / addition of other ingredients; and
  - Food processing and heating

Acrylamide – Collaborative Approach

- European Commission enlists acrylamide under Chemicals for which investigations are ongoing
- EC has so far issued
  - Recommendation on the monitoring of acrylamide levels in food
  - Recommendation on investigations into the levels of acrylamide in food
- Member States advised to carry out investigations in cases where the levels of acrylamide in a foodstuff, tested in the monitoring exercise, exceeds acrylamide "signal levels" determined for specific foods which are not safety values, rather based on levels observed
- Commission will assess the situation again by December 2012 basis data submitted on exceeding the "signal levels"
- **The food industry** in close co-operation with the national authorities and the European Commission, has developed a "toolbox" to highlight ways to lower levels of acrylamide in food
- **No MRL or contaminant limit fixed yet by Codex or EFSA**

Thank You