Risk Assessment
Acrylamide – A Case Study

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ILSI India
Technical Workshop on Risk based Approaches
For Food Safety Management
New Delhi - September 2012
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Safe Food for All

• 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
  o applied consistently;
  o open, transparent and documented &
  o 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:
  
  o **Hazard identification**: *The identification of biological, chemical, and physical agents capable of causing adverse health effects*
  
  o **Hazard characterization**: *The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with the hazard*
  
  o **Exposure assessment**
  
  o **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
  o production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine),
  o manufacture,
  o processing,
  o preparation,
  o treatment,
  o packing, packaging,
  o transport or
  o holding of such food or as a result of environmental contamination.
  o 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
  o principal sources of dietary exposure,
  o assess the associated health risks and
  o develop risk management strategies

• JECFA undertook a comprehensive analysis of acrylamide occurrence data from 24 countries
  o It was concluded that the major contributing food groups were French fries, potato crisps, coffee, biscuits/pastries, bread and rolls/toasted bread

• European Commission – Heatox Project (€4.2 Million)
  o Estimate health risks from compounds in heated foods
  o To study reaction pathways Testing raw materials, production / cooking processes – industrial and at home to reduce formation of such compounds
  o Impact on cooking and nutritional properties of food due to altered practices
  o 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
  o National and local authorities,
  o Manufacturers and
  o 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:
  o Raw materials;
  o Control / addition of other ingredients; and
  o Food processing and heating
Acrylamide – Collaborative Approach

• European Commission enlists acrylamide under Chemicals for which investigations are ongoing
• EC has so far issued
  o Recommendation on the monitoring of acrylamide levels in food
  o 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