# foodregsci

### STARTING THE RISK ASSESSMENT APPROACH

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### Review of a Risk Assessment Approach...

#### Reviewing the notions of Hazard and Risk

Reviewing the various approaches to achieve hazard characterization for chemicals in food





### Food Safety and Standards

#### Food Safety is a Prerequisite to Food Availability

#### Food Safety is therefore a Pillar of Food Security

#### If Food is Not Safe it is Wasted





### Robust Food Safety Decisions Based on Risk Analysis

#### **Key Pillars of a Robust Food Control System**





### The Scientific Basis of Codex





# Food is a Complex Mixture / Sources of Contaminants

#### **Nutrients**

- Carbohydrates, proteins, lipids, minerals, vitamins....
- **Non-nutrients**
- □Naturally occurring plant substances:
  - E.g. plant hormones, natural plant pesticides, plant anti-nutrients (e.g. chymotripsin inhibitors), plant toxins (as part of the composition of the plant)
- □Substances from other origin:
  - From the environment or related to human activity (microorganisms and chemicals)
    - Environmental / Natural sources: chemicals produced during plant growth, storage or processing (fungal and algal toxins), heavy metals from the environment (Cd, Hg)
    - $\circ~$  Human activity related chemicals:
      - Deliberate addition /use : Food additives, flavoring agents and Residues: e.g. pesticides, veterinary drugs
      - Contaminants that accumulate in the environment and enter food chain e.g. PCBs, heavy metals (e.g. Cd, Hg)
      - Chemicals that are due to food processing: e.g. nitrosamine, acrylamide, PAHs



#### Scientific Assessment / JECFA areas of Work Covers all Aspects

#### □Safety evaluation / Risk Assessment of :

- Food Additives
- Processing aids (considered as food additives)
- Flavouring agents (by groups of related compounds)
- Contaminants
- Natural toxins
- Residues of Veterinary Drugs in animal products



- Specifications and analytical methods, Residue definition, MRL proposals (veterinary drugs)
- Development and improvement of general principles
  - FAO/WHO Update on the Principles and Methods for the Risk Assessment of Chemicals in Food, EHC 240 2010; http://www.who.int/foodsafety/publications/chemical-food/en/



### Key Concept: Hazard vs Risk?

### Hazard







# The difference is the EXPOSURE



### Key Concept: Hazard vs Risk? (2)

# Hazard







# The difference is the EXPOSURE



### Risk = Hazard x Probability of Exposure

#### Hazard constant and probability of exposure is increasing



Excerpt Prof. Lemmens Slides – BOKU - Austria



#### Starting the Risk Assessment Process





#### Moving to Scientific Assessment





### Risk Assessment Procedure: A Scientific Process





# Data Needed for Assessment / Needed by JECFA

#### Toxicological data:

- □ Metabolism and pharmacokinetic studies
- □ Short-term toxicity, long-term toxicity / carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies

#### Epidemiological studies

Special studies designed to investigate specific effects, such as the mechanism of toxicity (including interactions among related contaminants), immune responses, or macromolecular binding

#### **Occurrence data:**

- Levels and patterns of occurrence (and co-occurrence) of the contaminant in raw commodities and finished food products
- Levels of the contaminant in animal feed
- □ Information on carry-over from feed to animals for human consumption
- Effects of processing on contaminant in food as consumed and in feed
- Analytical techniques used by investigators or authorities for identifying and quantifying the contaminant in foodstuffs and/or human and animal tissues;

□ Sampling protocols

Methods available for the prevention and control



## Assessment of Chemicals in Food

#### **Data sources:**

- Regulatory data submission by manufacturer/industry
  - For compounds intentionally added to foods
- Data from governments
  - Monitoring data; epidemiological data; research data
- Open scientific literature
  - Experimental research, human data





#### Assessment of Hazards and Exposure in Food: Data Characteristics

#### Data for hazard assessment:

- Experimental (toxicological) studies performed according to (inter)national guidelines (e.g. OECD text guidelines)
  - Independent of country or region!
- Human data: epidemiological data; occupational data; volunteer studies
  - May reflect susceptibility (e.g. genetic predisposition, life-style factors)
- Data for dietary intakes/dietary exposure assessment:
- □National occurrence and consumption data
- International and national dietary intakes/exposure estimates





