

# RISK ASSESSMENT FOUNDATIONS Introduction



#### Risk Assessment

□RA is the qualitative or quantitative characterization or estimation of potential adverse health effects associated with exposure of individuals or populations to hazards

Not used in isolation, but as a part of Risk Analysis



physical, chemical, or microbial agents



### Purpose of Risk Assessment

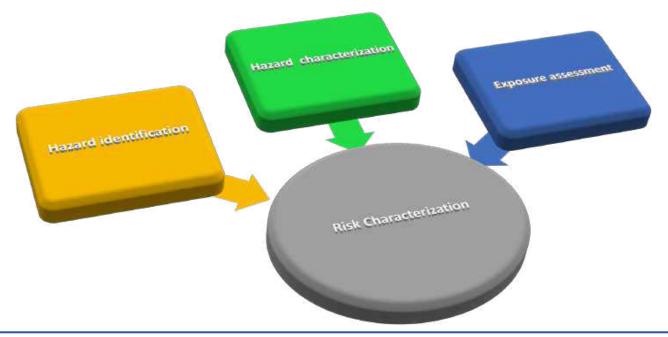
□A scientifically based process consisting of the following steps:

(i) hazard identification, (ii) hazard characterization,

(iii) exposure assessment, and (iv) risk characterization

**□**A systematic examination of an issue to help make better risk

management decisions





#### Risk vs HAZARD

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

□ Hazard - A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.



Health Issues



#### ISO 31000 Definition

- □ **Risk** is the "effect of uncertainty on objectives" and an effect is a positive or negative deviation from what is expected.
- ☐A change in the traditional understanding of risk, forcing organizations to tailor risk management to their needs and objectives a key benefit of the standard.

# def-i-ni-tion

/ defə|niSH(ə)n /

noun: a statement of the exact meaning of a word.



## Risk Assessment Components – Definitions

#### Codex Alimentarius Codex Alimentarius



- □ Hazard identification The identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods
- □ Hazard characterization The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical, and physical agents which may be present in food
  - A dose-response assessment should be performed if the data are available
- □ 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 characterization The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment

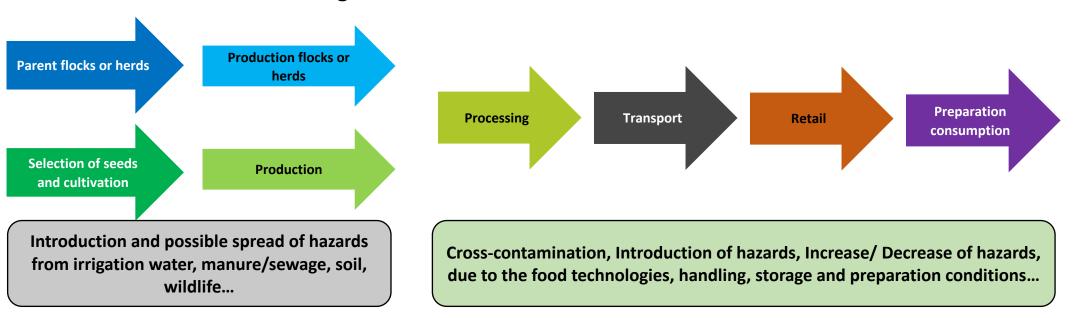


# Risk Assessment – Integrated Food Safety Approach

#### Integrate different types of data

- Foodborne illness surveillance
- Food contamination monitoring
- Environment monitoring
- Animal health surveillance
- Processing data

- Pathogen growth/survival data
- WGS data
- Pathogen virulence
- Toxicological data
- Diet and food handling data

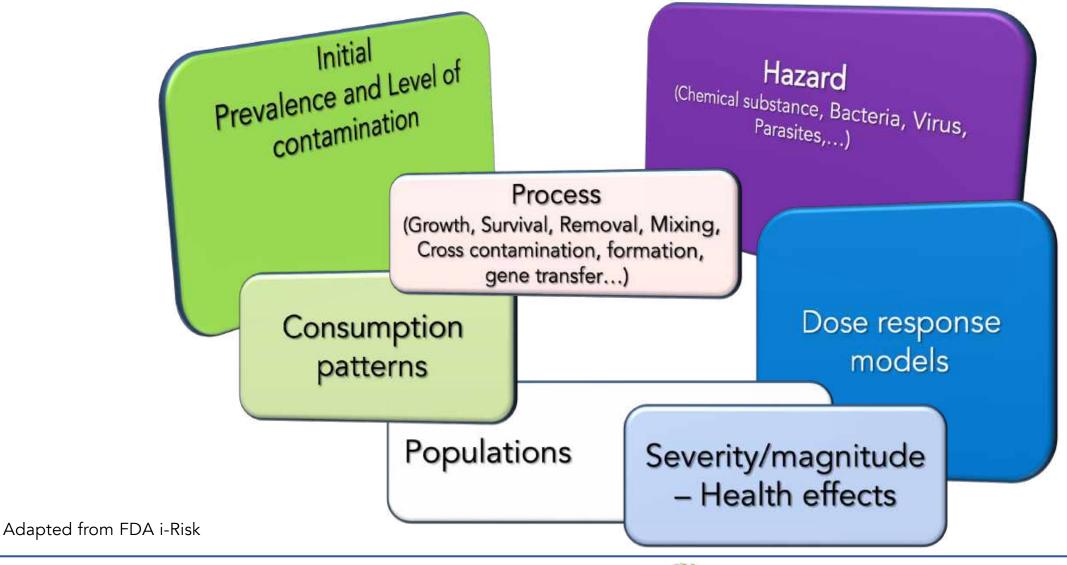


Exposure Human cases

Host – Hazard – Environment Interaction



#### Risk Determinants





# Safety or Risk Assessment

- □Safety assessment: provides a verdict of what is a 'safe' level based on the conventions of the analysis
- □ Risk assessment: quantifies the level of risk associated with specific exposures and degree of uncertainty inherent in the risk estimate. Used to compare options.
  - Quantitative assessment: the risk is expressed as a mathematical statement of the chance of illness or death after exposure to a specific hazard, and it represents the cumulative probabilities of certain events happening and the uncertainty associated with those events.
  - Qualitative risk assessments: use verbal descriptors of risk and severity (e.g., higher, lower), and often involve the aggregation of expert opinions.



Adapted from "Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food" FDA Threshold Working Group, March 2006



