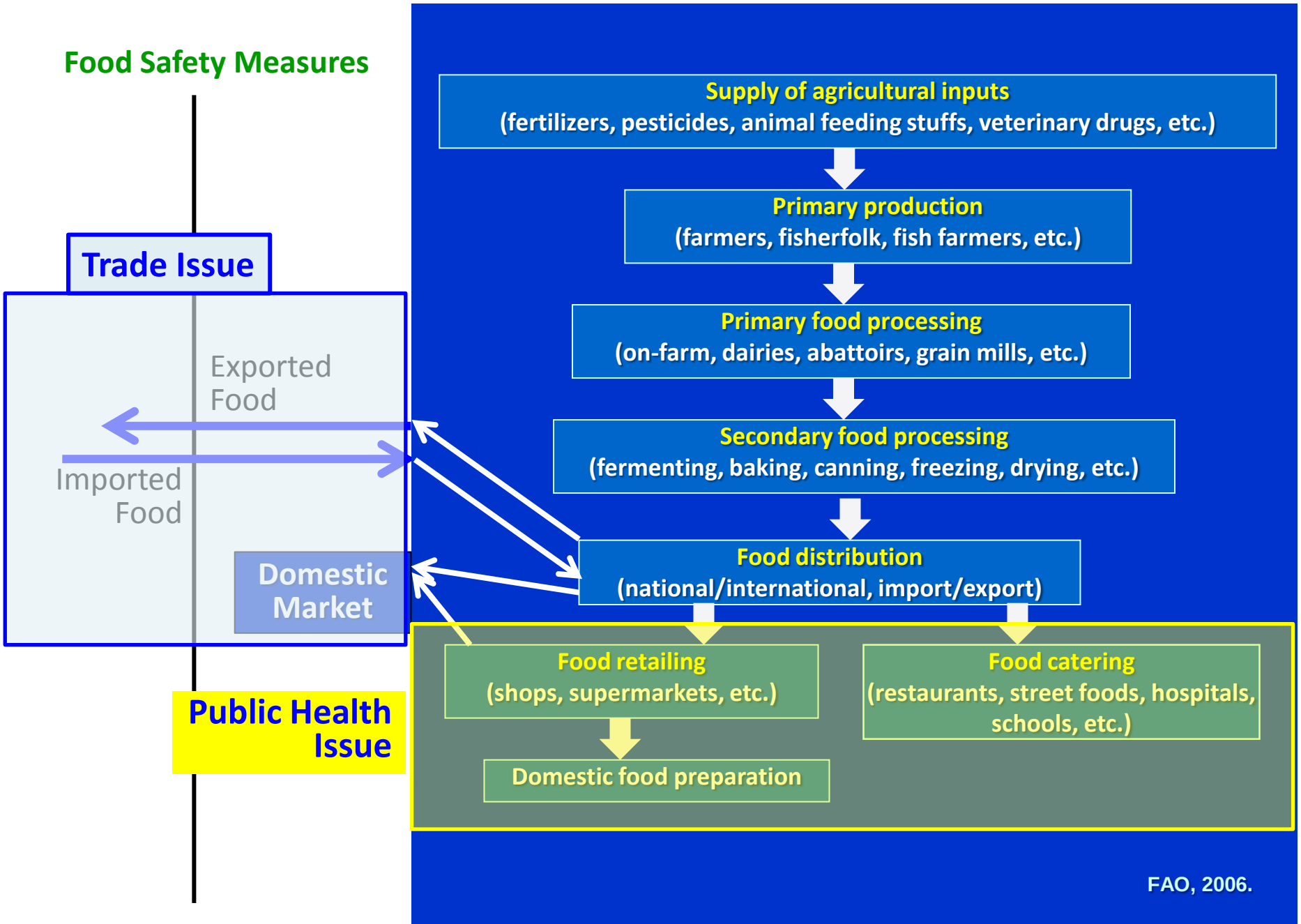
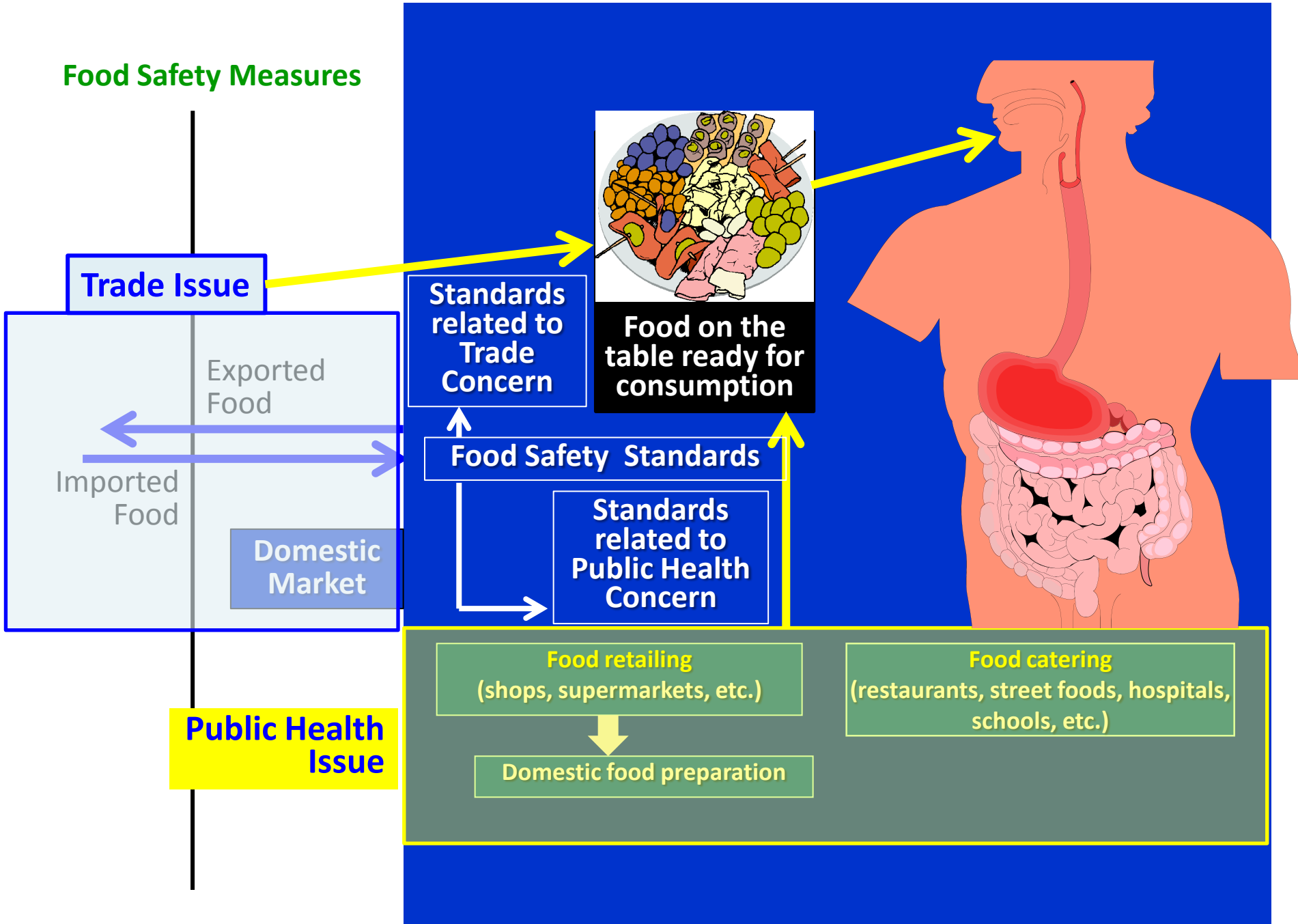
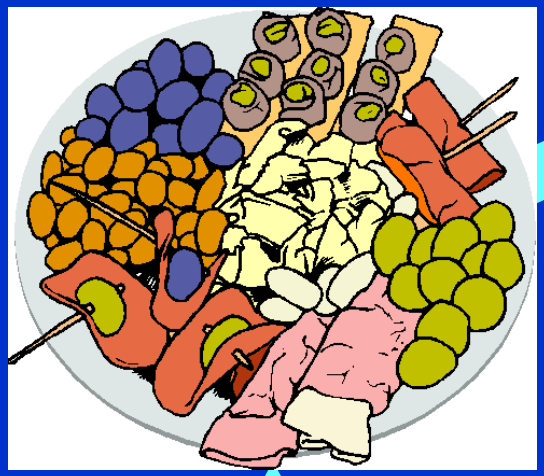
Risk Assessment Process - an Overview
(Principles, Concepts, Methodologies)

Dedi Fardiaz
Department of Food Science and Technology, Faculty of Agricultural Engineering
SEAFAST Center
BOGOR AGRICULTURAL UNIVERSITY
INDONESIA

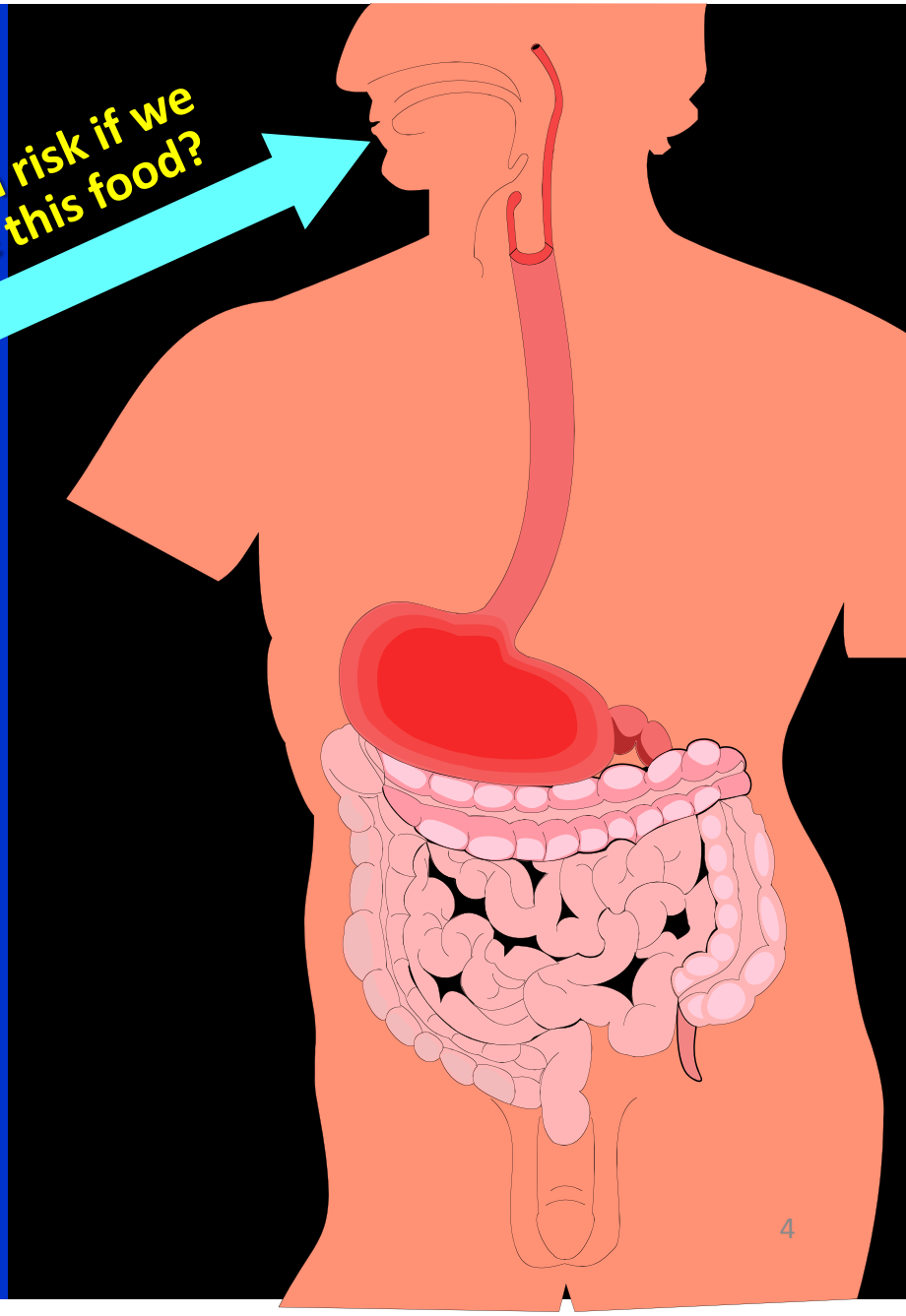

Food Safety Measures
Trade Issue
Exported Food
Imported Food
Domestic Market
Public Health Issue
Supply of agricultural inputs
(fertilizers, pesticides, animal feeding stuffs, veterinary drugs, etc.)
Primary production
(farmers, fisherfolk, fish farmers, etc.)
Primary food processing
(on-farm, dairies, abattoirs, grain mills, etc.)
Secondary food processing
(fermenting, baking, canning, freezing, drying, etc.)
Food distribution
(national/international, import/export)
Food retailing
(shops, supermarkets, etc.)
Food catering
(restaurants, street foods, hospitals, schools, etc.)
Domestic food preparation
FAO, 2006.

Food Safety Measures





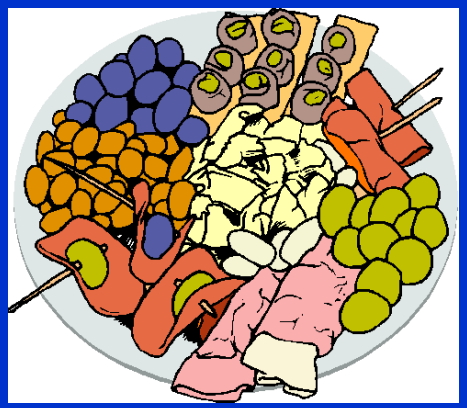
Any health risk if we consume this food?



- Any hazard associated with this food?
- What type?
- Chemical or Microbial Hazards?
- How do you know?

Could you identify risk factors associated with this food chain from farm to table?

- What type of food in this meal?
- Animal, plant, fishery origin?
- What is the risk factors associated with these foods in the whole food chain from farm to table?



Supply of agricultural inputs
(fertilizers, pesticides, animal feeding stuffs, veterinary drugs, etc.)

↓

Primary production
(farmers, fisherfolk, fish farmers, etc.)

↓

Primary food processing
(on-farm, dairies, abattoirs, grain mills, etc.)

↓

Secondary food processing
(fermenting, baking, canning, freezing, drying, etc.)

↓

Food distribution
(national/international, import/export)

↓

Food retailing
(shops, supermarkets, etc.)

↓

Domestic food preparation

Food catering
(restaurants, street foods, hospitals, schools, etc.)

FAO, 2006.

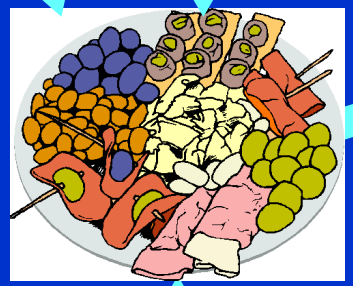
Chemicals Hazards
(contaminants or food additives)

Microbial Pathogens

Any significant level change?
Commonly, No

Any significant level change?
Yes, because of environmental difference (T and t), cross contaminations, processing practices, etc. (from Harvest, Post-Harvest, to Consumption)

Discuss examples!



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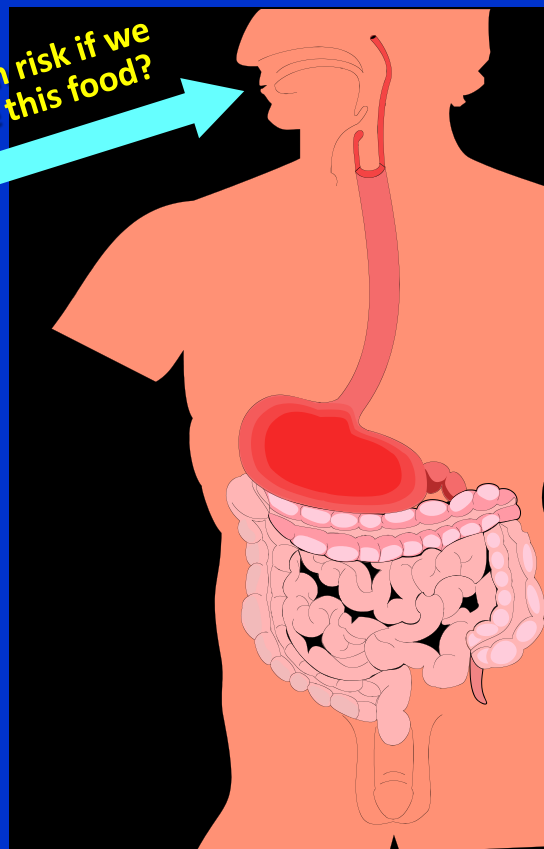
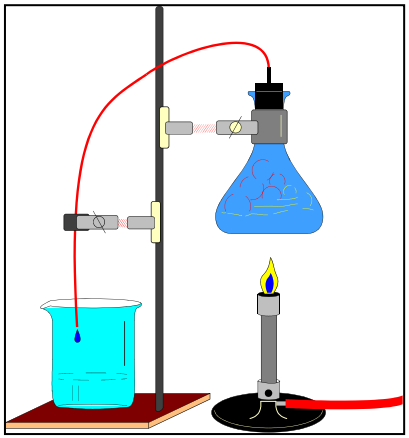


- Any hazard associated with this food?
- What type?
- How do you know?

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

Hazard



- Hazard is a fact
- Risk is a probability

Analysis of food is to detect and measure the hazard not the risk

Risk

How do we know the risk?

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

Maximum level (ML)
The Codex maximum level (ML) for a contaminant in a food or feed commodity is the maximum concentration of that substance recommended by the CAC to be legally permitted in that commodity.

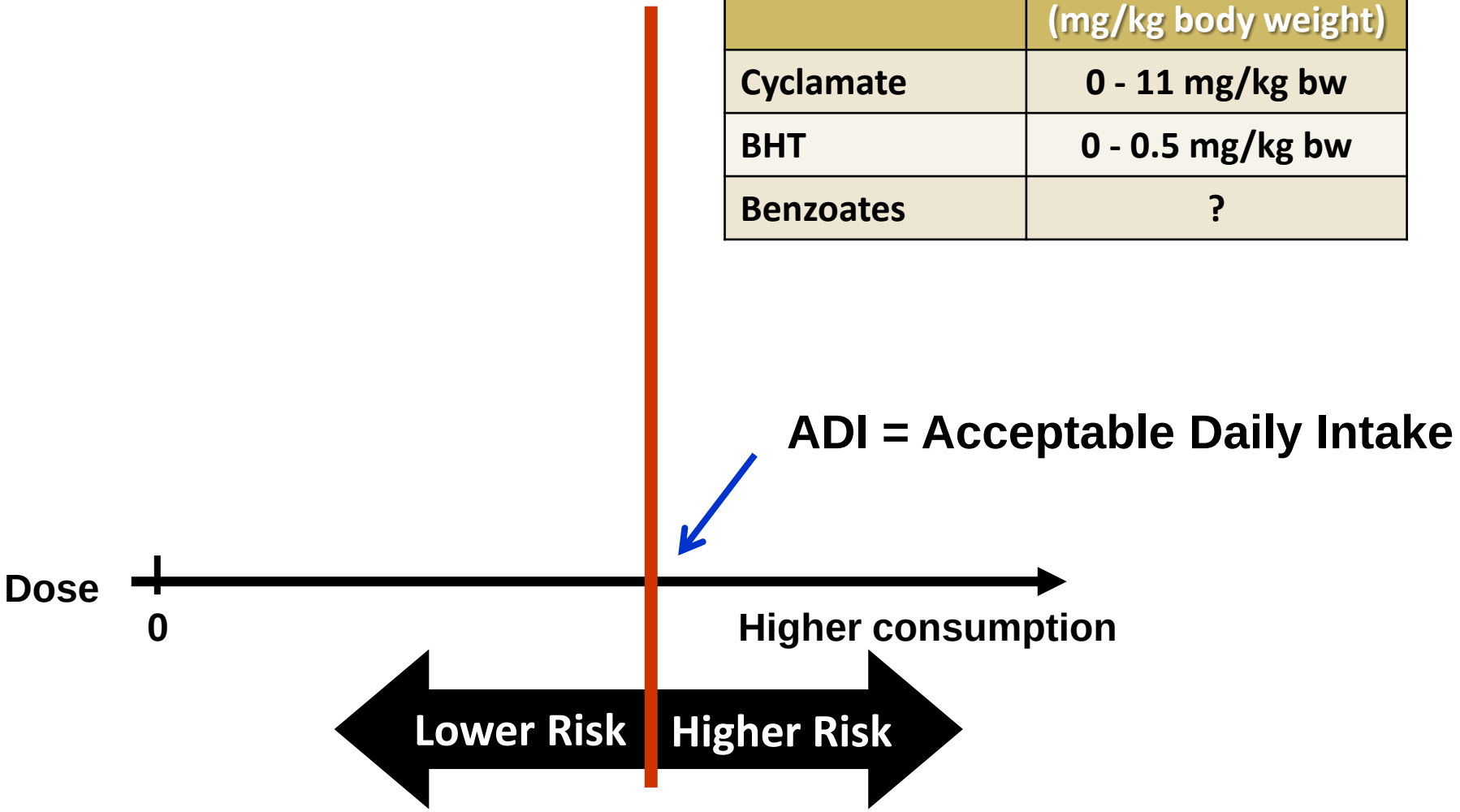
Maximum residue level (MRL)
The maximum concentration of residue in a food or animal feed resulting from use of a veterinary drug or a pesticide, (expressed in mg/kg or µg/kg on a fresh weight basis).

Acceptable daily intake (ADI)
An estimate of the amount of a substance in food or drinking water, expressed on a bodyweight basis, that can be ingested daily over a lifetime without appreciable risk (standard human = 60 kg). The ADI is listed in units of mg per kg of body weight.

Tolerable daily intake (TDI)
Analogous to Acceptable Daily Intake. The term Tolerable is used for agents which are not deliberately added such as contaminants in food.

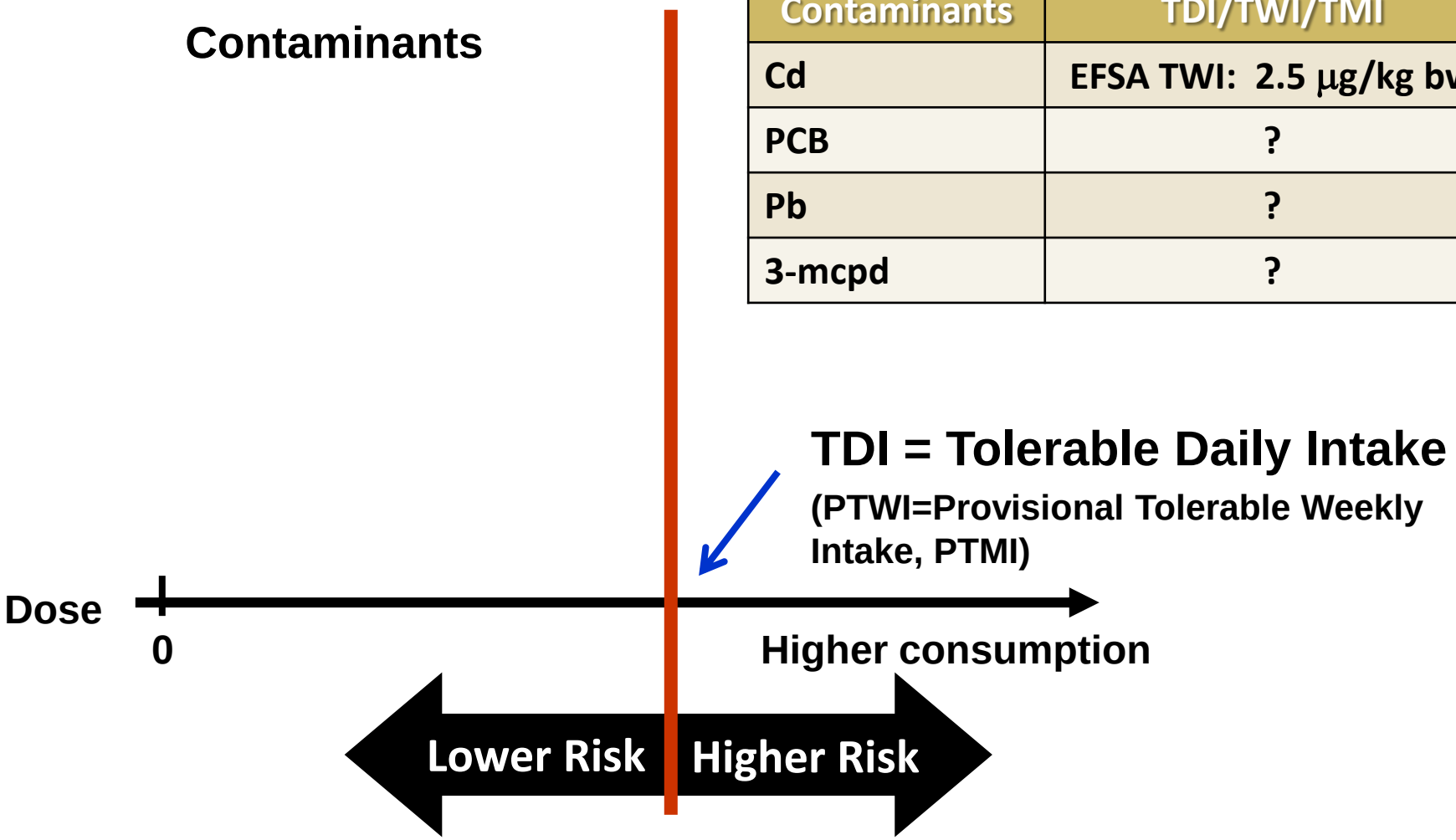
Food Additives

Food Additives	ADI (mg/kg body weight)
Cyclamate	0 - 11 mg/kg bw
BHT	0 - 0.5 mg/kg bw
Benzoates	?



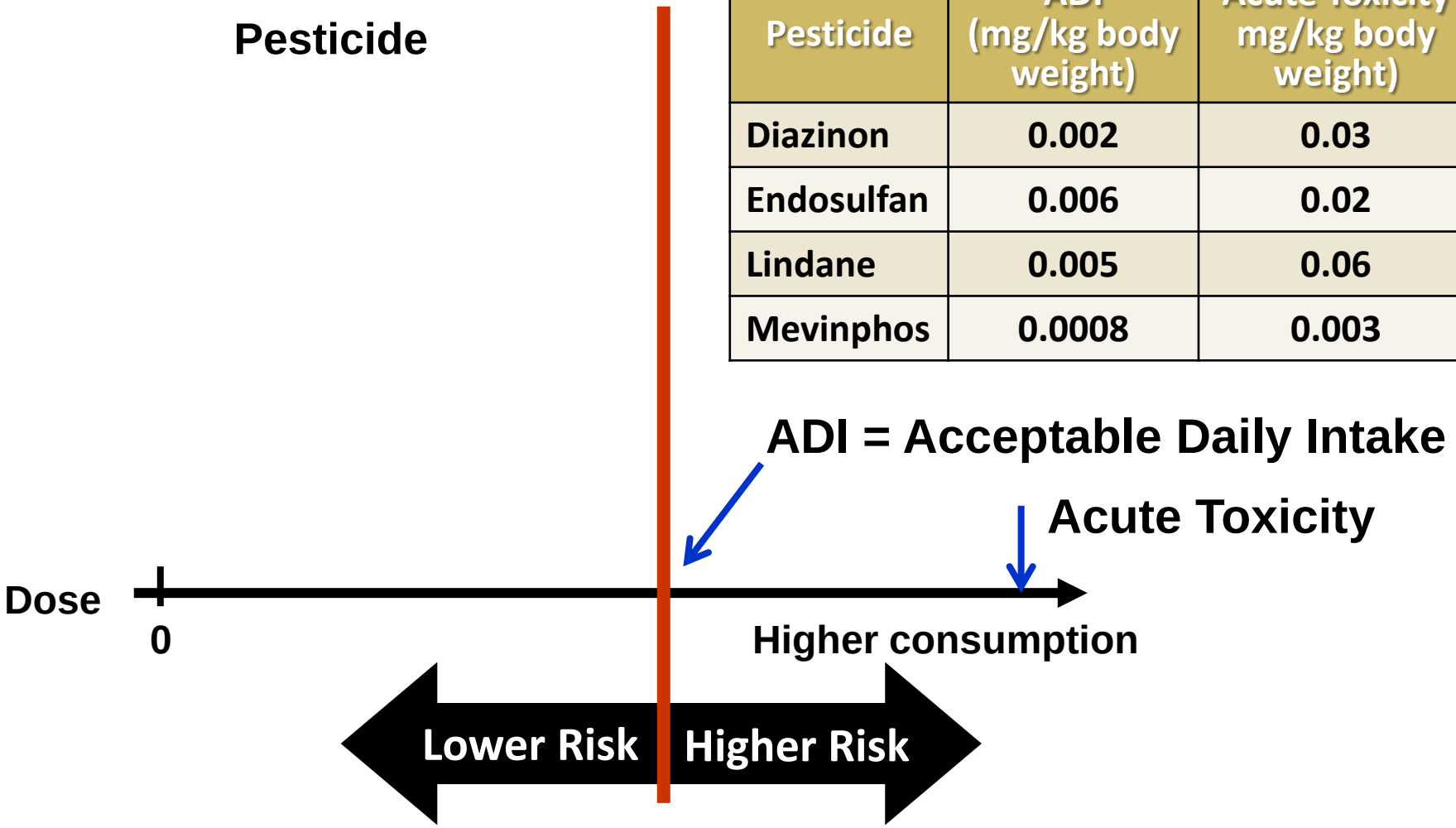
CHEMICAL HAZARD: Contaminants

Contaminants	TDI/TWI/TMI
Cd	EFSA TWI: 2.5 μg/kg bw
PCB	?
Pb	?
3-mcpd	?



CHEMICAL HAZARD:
Pesticide

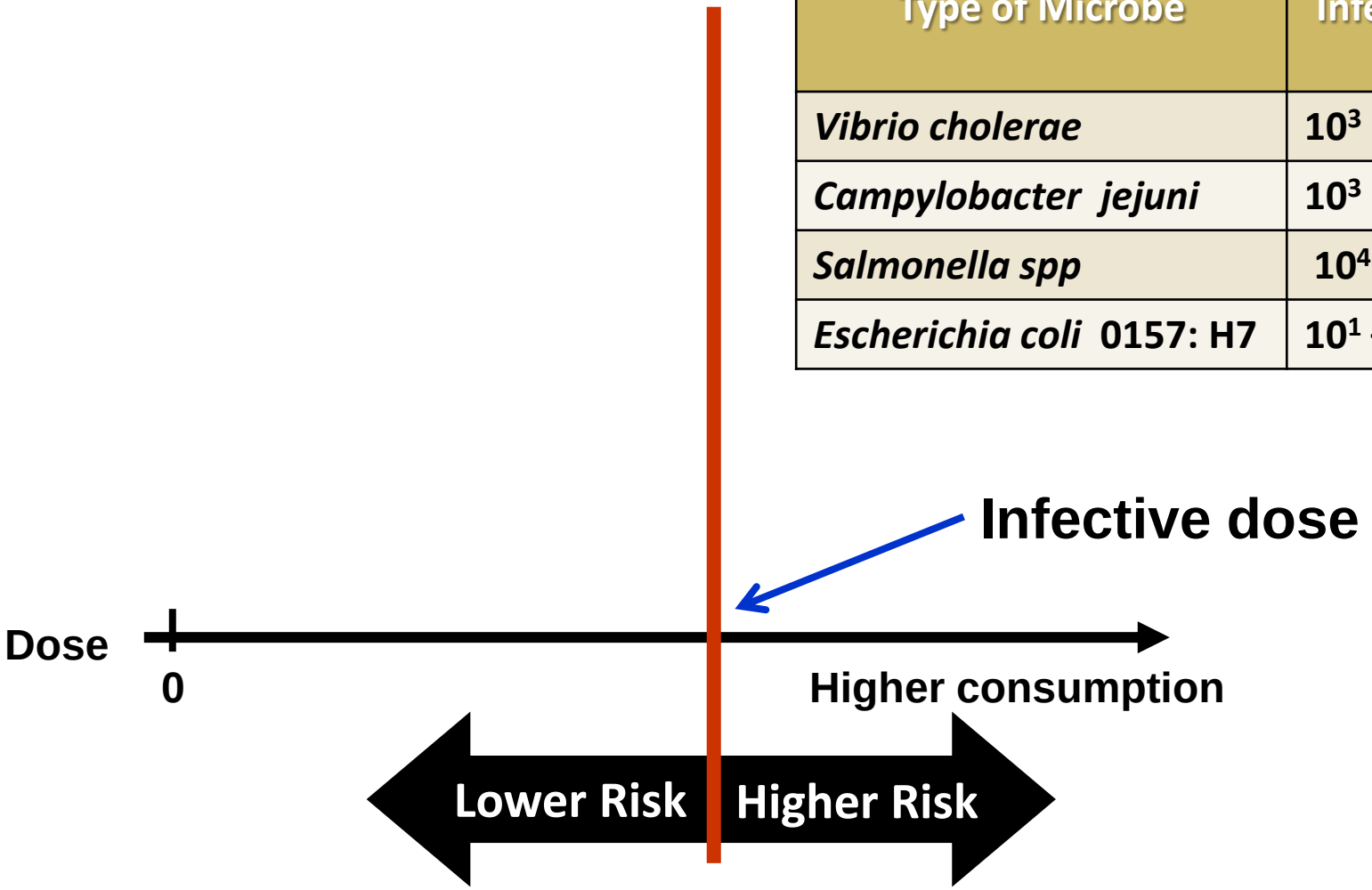
Pesticide	ADI (mg/kg body weight)	Acute Toxicity mg/kg body weight)
Diazinon	0.002	0.03
Endosulfan	0.006	0.02
Lindane	0.005	0.06
Mevinphos	0.0008	0.003



Example of Microbial Infective Dose

MICROBIOLOGICAL HAZARD

Type of Microbe	Infective Dose (cells)
Vibrio cholerae	10^3
Campylobacter jejuni	10^3
Salmonella spp	10^4-10^{10}
Escherichia coli 0157: H7	$10^1 – 10^2$



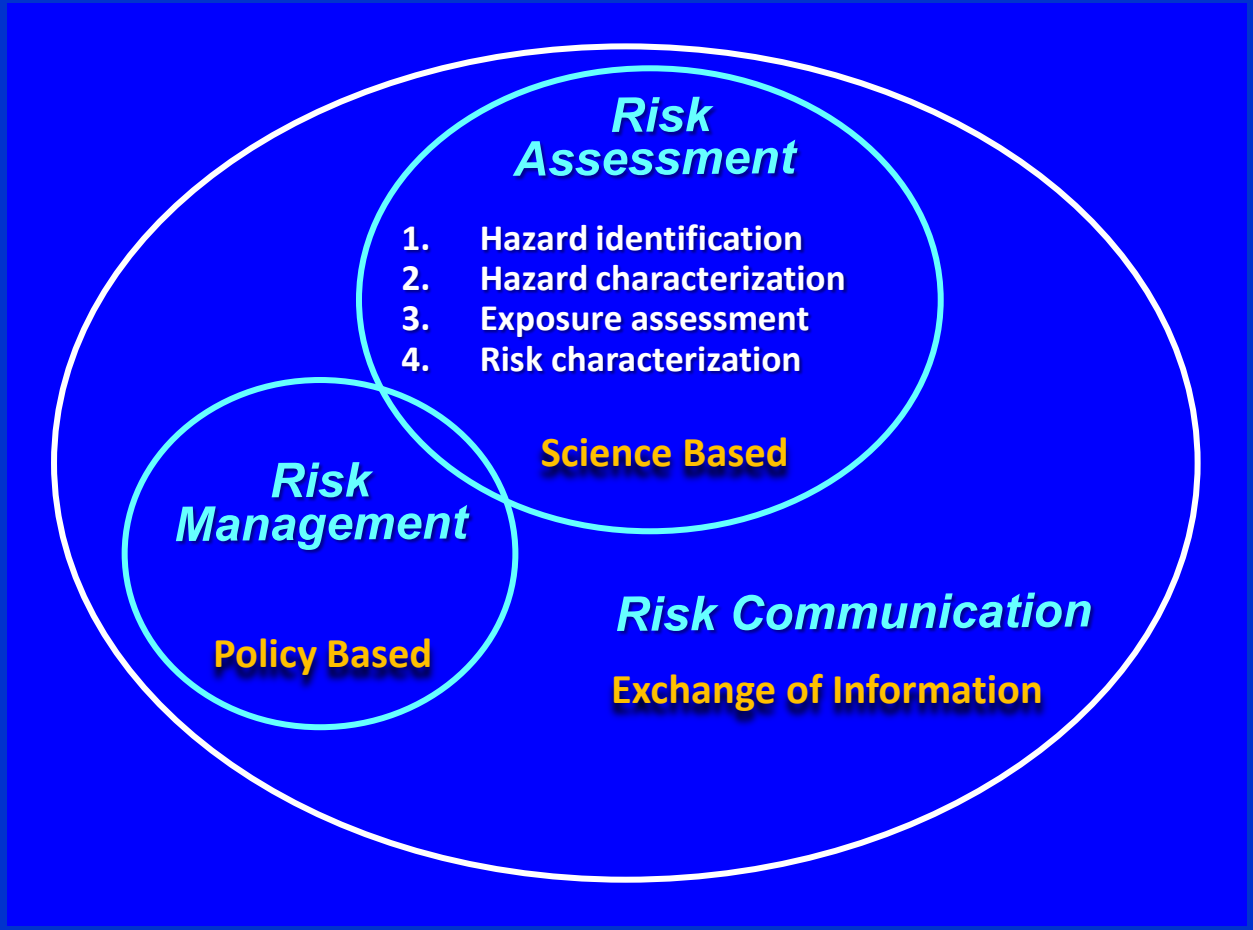
Some characteristics of microbial and chemical hazards that influence the choice of risk assessment methodology

Microbial Hazard	Chemical Hazard
Hazards can enter foods at many points from production to consumption.	Hazards usually enter foods in the raw food or ingredients, or through certain processing steps (e.g. acrylamide or packaging migrants).
The prevalence and concentration of hazard changes markedly at different points along the food production chain.	The level of hazard present in a food after the point of introduction often does not significantly change.
Health risks are usually acute and result from a single edible portion of food.	Health risks may be acute but are generally chronic.
Individuals show a wide variability in health response to different levels of hazard.	Types of toxic effects are generally similar from person to person, but individual sensitivity may differ.

Risk analysis is used:

- to develop an estimate of the risks to human health,
- to identify and implement appropriate measures to control the risks, and
- to communicate with stakeholders about the risks and measures applied.

Risk Analysis
(Codex Alimentarius Commission)



Risk analysis is a powerful tool for carrying out science-based analysis and for reaching sound, consistent solutions to food safety problems.

The use of risk analysis can promote ongoing improvements in **public health** and provide a basis for **expanding international trade in foods.**

Generic Codex description of the components of risk assessment

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.
For chemical agents, a dose-response assessment is performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.

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.

General characteristics of food safety risk assessments

- A risk assessment should be objective, transparent, fully documented and available for independent scrutiny.
- The functions of risk assessment and risk management should be carried out separately to the extent practicable.
- Risk assessors and risk managers should engage in an iterative and on-going dialogue throughout risk assessment.
- Risk assessment should follow a structured and systematic process.
- Risk assessment should be based on scientific data and should take into account the whole "production-to-consumption" food pathway.
- Uncertainties in risk estimates and their origins and impacts should be clearly documented, and explained to risk managers.
- A risk assessment should be subject to peer review if considered appropriate.
- A risk assessment should be reviewed and updated as new information permits or requires.

Definitions of Risk Analysis Terms Related to Food Safety

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.
Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.
Risk Analysis: A process consisting of three components : risk assessment, risk management and risk communication.
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.

Risk Assessment Policy: Documented guidelines on the choice of options and associated judgements for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained.
Risk Profile: The description of the food safety problem and its context.
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 Estimate: The quantitative estimation of risk resulting from risk characterization.
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. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.
Dose-Response Assessment: The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response).

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.

Food Safety Objective (FSO): The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP).

Performance Criterion (PC): The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO.

Performance Objective (PO): The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable.

Sources of scientific information for risk assessments

- Published scientific studies.
- Specific research studies carried out (by the government agency or external contractors) in order to fill data gaps.
- Unpublished studies and surveys carried out by industry, such as data on the identity and purity of a chemical under consideration as well as toxicity and residue studies carried out by the chemical's manufacturer*.
- National food monitoring data.
- National human health surveillance and laboratory diagnostic data.
- Disease outbreak investigations.
- National food consumption surveys, and regional diets e.g. those constructed by FAO/WHO.
- Use of panels to elicit expert opinion where specific data sets are not available.
- Risk assessments carried out by other governments.
- International food safety databases.
- International risk assessments carried out by JECFA, JMPR and JEMRA.

* Manufacturers often may agree to supply data only if it remains confidential. Risk managers must judge the need to trade off transparency so as to obtain relevant and sufficient data.

Let's do an exercise

egg, bean sprout, vegetables, peanut sauce, peanut butter, chilli sauce

Could you tell if any HAZARD maybe present in these various types of food?

RISK

- **Contaminant data?**
- **Who are the consumers?**
- **How large is the portion?**
- **How often is the consumption?**
- **How big is the chance to cause disease in a host?**

Need Exposure Assessment

Example Exposure Assessment of Food Additive (Benzoic Acid)

Type of Food Eaten	Daily Food Intake Consumption	Maximum Level (ML) Permitted Use mg/kg Food (ppm)	Daily Intake of Benzoic Acid (mg/person)
1. Meat Products			
1.1 Croquettes of meat, poultry, game	negligible	1500	-
2. Fish Products			
2.1 Caviar and other roe	17 mg	8000	negligible
2.2 Semi-preserved of fish and invertebrates	3.6 gr	1500	5.4
2.3 Shrimps	1.4 gr	8000	11.2
2.4 Smoked salmon	50 mg	1500	
2.5 Croquettes of fish, shrimps	negligible	1000	-
3. Liquid Fruit Syrup	included in total soft drinks intake	250	
4. Vegetables			
4.1 Gherkins	2.2 gr	600	1.3
5. Potato Croquettes	negligible	250	-
6. Drinks			
6.1 Soft Drinks	600 ml	100	60.0
6.2 Cider	0.9 ml	300	-
7. Condiments .			
7.1 Mustard	0.9 g	250	0.2
7.2 Emulsified sauces (from egg-yolk)	20.0 g	1000	20.0
TMDI (Theoretical Maximum Daily Intake)			98.1

Food Category System (GSFA, 2005)

Check GSFA or national standards for ML of food additives in food

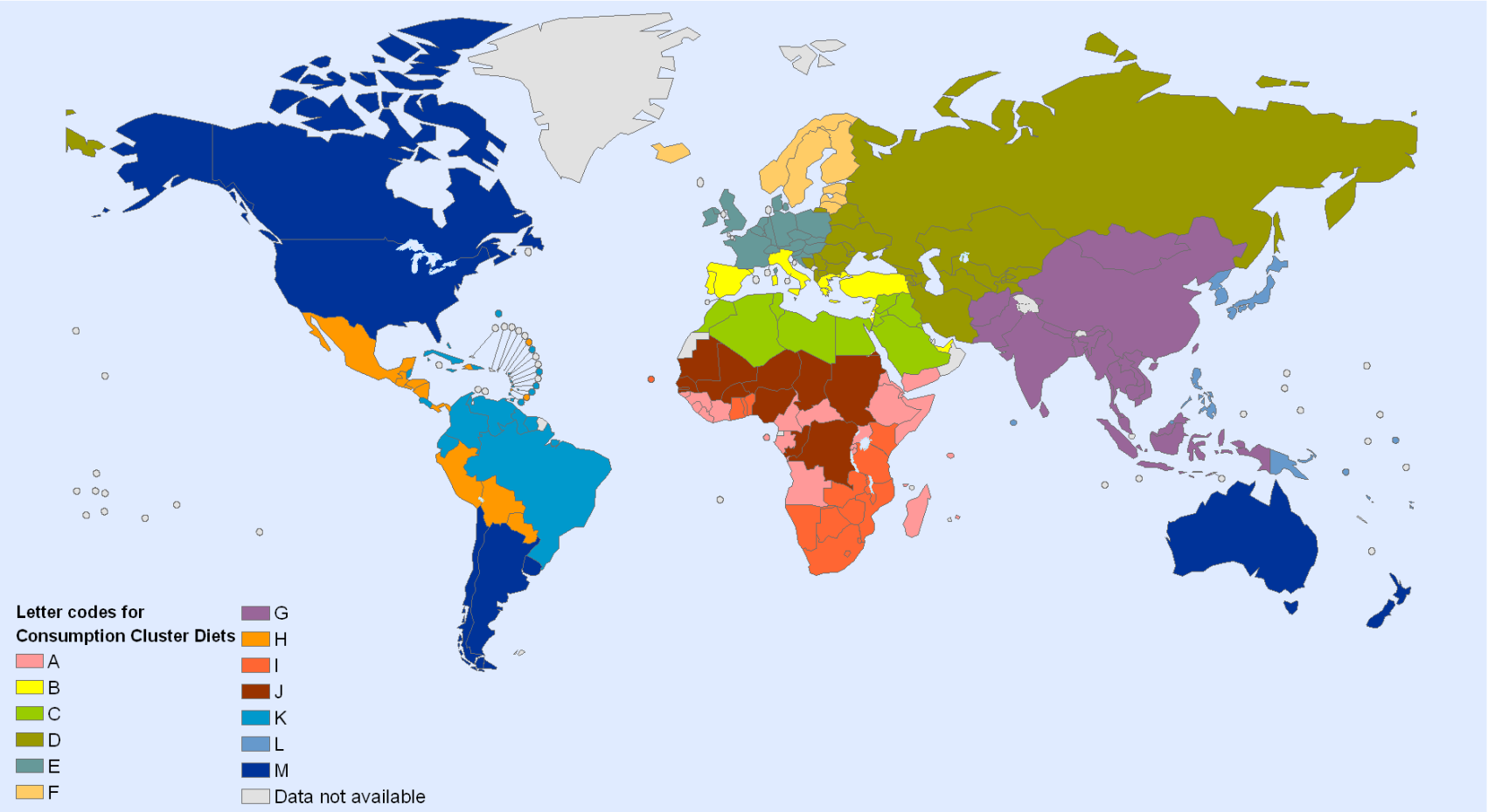
No.	Name of Food
01.0	Dairy products and analogues, excluding products of food category 02.0
02.0	Fats and oils, and fat emulsions
03.0	Edible ices, including sherbet and sorbet
04.0	Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds
05.0	Confectionary
06.0	Cereals and cereal products, derived from cereal grains, from roots and tubers, pulses and legumes, excluding bakery wares of food category 07.0
07.0	Bakery wares
08.0	Meat and meat products, including poultry and game
09.0	Fish and fish products, including mollusks, crustaceans, and echinoderms
10.0	Eggs and egg products
11.0	Sweeteners, including honey
12.0	Salts, spices, soups, sauces, salads, protein products (including soybean protein products) and fermented soybean products
13.0	Foodstuffs intended for particular nutritional uses
14.0	Beverages, excluding dairy products
15.0	Ready-to-eat savouries
16.0	Composite foods - foods that could not be placed in categories 01 - 15.

GEMS/Food Regional Diets

Cereals
Roots and Tubers
Pulses
Sugars and Honey
Nuts and Oilseeds
Vegetable Oils and Fats
Stimulants
Spices
Vegetables
Fish and Seafood
Eggs
Fruit
Milk and Milk Products
Meat and Offals
Animal Oils and Fats

For Contaminant Exposure Assessment

GEMS/Food Consumption Cluster Diets



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: World Health Organization
Map Production: Public Health Information and Geographic Information Systems (GIS)
World Health Organization

World Health Organization

GEMS/Food Regional Diets

Cereals
Roots and Tubers
Pulses
Sugars and Honey
Nuts and Oilseeds
Vegetable Oils and Fats
Stimulants
Spices
Vegetables
Fish and Seafood
Eggs
Fruit
Milk and Milk Products
Meat and Offals
Animal Oils and Fats

Mean Food Consumption (g /person/day)	Chemical Contaminant in Food (μg /g food)	Contaminant Consumed (μg/person/day)

Exanple of Microbial Exposure Assessment

Exposure Assessment

Frequency and likely level of exposure to a pathogenic microorganism.

In this risk assessment, the likelihood of exposure to pathogenic microorganism from consumption should be evaluated. The Exposure Assessment may divided into three modules: Harvest, Post-Harvest, and Consumption.

Exposure Assessment (Harvest, Post Harvest, Consumption)

Data:
- **Water temperature**
- **Total vs. Pathogenic microorganism in food**
- **Time-to-refrigeration**
- **Air temperature**
- **Growt rates**
- **Food consumed/serving**

Modeling:
- **Pathogenic microorganism levels in food at harvest**
- **Growth between harvest and refrigeration**
- **Pathogenic microorganism in food at consumption**

Risk Characterization

- Number of illnesses: per serving and per annum
- Severity of illness (gastroenteritis vs. septicemia)
- Uncertainty and variability analysis
- Model validation

'What-If' Scenario

- 4.5-log $_{10}$ reduction (heat; ultra high pressure)
- 2-log$_{10}$ reduction (freezing) approximately
- 1-log $_{10}$ reduction (immediate cooling)
- Impact of time-to-refrigeration after harvest
- Sample-based control plan

Risk Characterization

The integration of the Dose-Response relationship with the Exposure Assessment to predict the probability of potential adverse outcomes for individuals or populations.

One of the benefits of performing a quantitative product pathway risk assessment is that the model can be used to estimate the likely impact of intervention strategies on the predicted number of illnesses. The impact of different harvesting methods, season (i.e., water and air temperatures), time until refrigeration, and length of storage before consumption were included in the baseline model. By changing one or more of the input parameters and measuring the resulting change in the model outputs, the likely impact of new or different processing procedures or regulatory actions can be evaluated. These changes to the baseline model are commonly referred to as conducting "what-if" scenarios.

Thank You Very Much