INTRODUCTION TO RISK ANALYSIS ctd.

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YOUR TURN

ON THE WAY BACK FROM XZ/TOWN
SUDDENLY
1. What is the hazard in this case?
2. What is the risk?
3. Who are the stakeholders?
FACTORS INVOLVED

MANY DIFFERENT FACTORS TO CONSIDER

- -- Speed
- -- State of mind

- -- Size of deer
- -- Concentration of deer

- -- Type of car
- -- Season
- -- Time of day

HOST factors

AGENT factors

ENVIRONMENTAL factors
HISTORY RISK ANALYSIS (RA)

1. the traditional view: zero-risk
   • not very useful and disease risk must be balanced against trade benefits

2. the acceptable risk concept
   - based on the acceptance of some risk
     - level and acceptance of the risk requires primary agreement by all involved in the negotiations on the magnitude of that risk
     - assessment of risk by means of methodology which is agreed upon by all parties
DIFFERENCIATE 'RISK'

in **MEDICINAL EPIDEMIOLOGY:**

*Risk* is the likelihood of occurrence of a disease in a population

in **RISK ASSESSMENT:**

*Risk* is the expected 'damage' in relation to a defined risk scenario
EVERYONE FACES SOME LEVEL OF RISK ON A DAILY BASIS:

Risks include injury, illness, financial stress or general decrease in quality-of-life to themselves, their loved-ones, colleagues, employees or their environment.

Several of these risks have certain probabilities of occurring and certain direct or indirect negative impacts.

Many aspects of these risks are uncertain.

THERE IS NO SUCH THING AS „ZERO-RISK“:

but one can attempt to control risks to tolerable levels by reducing either the probability or the impact component of risk, or both.
INTRODUCTORY EXAMPLES

Do assess qualitatively the probability* and consequences** of the following 'dangers':
- Car accident (no person injury)
- Technical failure in a nuclear plant
- Illness of malignant tumor due to high consumption of acrylamide-contaminated foods

What is your own risk perceptions of these 'dangers'?

Describe the circumstance(s) which in your view lead to the 'danger(s)' and state what information you would need to make your assessment (more) objective

* use terms like highly likely, likely, unlikely, highly unlikely
** use terms like negligible, low, moderate, high, very high
### EXAMPLES: PROBABILITIES AND CONSEQUENCES

<table>
<thead>
<tr>
<th>Event</th>
<th>Probability</th>
<th>Consequence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CAR ACCIDENT</strong></td>
<td>(relatively) likely</td>
<td>negligible ... moderate (for person concerned)</td>
</tr>
<tr>
<td><strong>FAILURE NUCLEAR PLANT</strong></td>
<td>highly unlikely</td>
<td>moderate ... very high (for popln.)</td>
</tr>
<tr>
<td><strong>ACRYLAMIDE-CONTAMINATED FOODS</strong></td>
<td>(relatively) unlikely</td>
<td>very high (for person concerned)</td>
</tr>
</tbody>
</table>
### EXAMPLES: SUBJECTIVE RISK ASSESSMENT

<table>
<thead>
<tr>
<th>Car Accident</th>
<th>Low Importance:</th>
<th>“I can avoid accidents by careful driving“</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High Importance:</td>
<td>“I just bought a new car“</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Failure Nuclear Plant</th>
<th>Low Importance:</th>
<th>“I think nuclear energy is clean energy“</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High Importance:</td>
<td>“I feel personally threatened“</td>
</tr>
</tbody>
</table>

| Acronymide-Contaminated Foods | Low Importance: | “Never have heard of such a risk“ |

What distinguishes laymen and experts and what role do experts play in risk assessment?
# EXAMPLES: NEEDED INFORMATION!

<table>
<thead>
<tr>
<th>Category</th>
<th>Needed Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CAR ACCIDENT</strong></td>
<td>- Total risk of property damages from car accidents within a year in country</td>
</tr>
<tr>
<td></td>
<td>- Number and sizes of property damages in area of interest and number of car owners</td>
</tr>
<tr>
<td><strong>FAILURE NUCLEAR PLANT</strong></td>
<td>- Risk for population of country during a prospective period of use of plant xy of 20 years</td>
</tr>
<tr>
<td></td>
<td>- Kind, frequency of technical disturbances, release of radiation, exposition of population, disease risk under exposition</td>
</tr>
<tr>
<td><strong>ACRYLAMIDE-CONTAMINATED FOODS</strong></td>
<td>- Likely number of tumor cases in the cohort of today 10-20 year olds of population in country from consumption of contaminated foods</td>
</tr>
<tr>
<td></td>
<td>- Measurements of acrylamide in foods, toxicological threshold values, consumption patterns, demographic data, dose-response-relationships</td>
</tr>
</tbody>
</table>
ROLE OF EXPERTS IN RISK ASSESSMENTS

Experts are needed to:

- specify the specific risk questions
- compile and evaluate the scenario models
- formulate and evaluate the validity of model assumptions
- provide and evaluate the suitability of data and information
- mathematically implement models and test their validity
- interpret and communicate the results

Models can (partly) be based on expert opinion

- when empirical (observational) data are missing
- when the danger concerned is new, so far unknown (ex-ante prediction)
- when a highly complex risk scenario is concerned
- when prediction of risk could have effect on reality (endogeneity)
EMPIRICAL DATA vs 'EXPERT OPINION'

Expert opinions are subjective. Some examples of mistakes of a single expert:

- **Motivation bias**: expert is bound by conflict of interest
- **Cognitive bias**: expert uses known information incorrectly

- **Availability bias**: the probability of exceptional events is over-estimated
- **Anchoring and adjustment**: assessment too much oriented on default values and initially discussed values
- **Unbounded probability problem**: events excluding themselves are estimated with probabilities with total >100%
- **Base-rate neglect**: a known probability of an event is ignored with supply/assessment of additional information
- **Gambler's fallacy**: the probability of an event is over-estimated when event has not occurred for some time, although it is an independent process
**EMPIRICAL DATA vs 'EXPERT OPINION'**

Expert opinions are susceptible to distortions from group-dynamic processes:

- **Path dependency and persistence:** results of group work are dependent on misleading ‘initial ideas’
- **Anchoring effect:** experts orient themselves too much on opinions of group members
- **Herding effect:** dependencies due to opinion leadership, group formation based on different ‘schools of thought’

**METHODOLOGY:**

Use of recognised inquiry techniques (e.g. ‘Delphi-Method’:
First individual (expert) opinions, then iterative change of single inquiries, feedback, group discussions)
METHODS OF RISK MODELLING

- SCENARIO TREE ANALYSIS
  - qualitative method, semi-quantitative
  - illustrates possible routes of infection - scenarios
  - calculates the probability of each possible scenario
  - results in a chain of conditional probabilities

- MONTE CARLO SIMULATION
  - uses random sampling from probability distributions to quantify problems
  - let each possible scenario be generated as a natural consequence of random simulation
  - Software often used is @RISK - a spreadsheet add in to Excel
SCENARIO TREE MODEL

The scenario model is the backbone of risk assessment

➢ **WORD MODEL**
  - describes the connection of start conditions and end points (consequences) for a risk question, considering all relevant frame conditions

➢ **FLOW DIAGRAM**
  - is a visualisation of a word model
EVENT and FAULT TREES in Microbiological Risk Analysis (MRA)

EVENT TREE:
- describes a scenario from the initiating event to a defined endpoint
- describes the (high-)risk pathways that lead to contamination and subsequent disease
- may identify risk variables for further data collection and/or modelling

FAULT TREE
- begins with occurrence of hazard
- moves backward to identify the events that could or must have occurred for the hazard to be present
EVENT TREE

How many units of a food are imported per year?

Are they contaminated with Salmonella? What is the probability that a unit contains Salmonella ($p_1$)?

Are contaminated units detected at port of entry? What is probability that Salmonella are detected and removed ($1-p_2$)?

Are Salmonella killed during preparation of food? What is the probability that the product receives a sufficient heat treatment to kill the pathogen ($1-p_3$)?

Units consumed each year that contain Salmonella
FAULT TREE

Encephalitis in immunocompromised patient

- Toxoplasma
- Listeria monocytogenes
- Other agents

OR

Other routes of transmission

Foodborne

- Poultry
- Dairy/cheese
- Fish
- Luncheon meat
- Others

OR

- Cold-smoked
- Hot-smoked
- Others

Bacterial growth

OR

- Shelf-life
- Temperature abuse
- Others

Contaminated smoked fish

OR

Insufficient heat treatment (smoking process)

Re-contamination of heat-treated product
RISK

Risk is a function of BOTH the **probability** of something undesirable happening AND the **magnitude** of the impact of that hazard.

Risk cannot be assessed by considering **probability** alone; one cannot choose between a probability of 1 in 10 vs 1 in 5000 until one knows the **magnitude** of the negative impact associated with each probability.

For example: Which risk do you accept more readily? a 1 in 10 probability of loosing € 5 or a 1 in 5000 probability of loosing your house?

**BUT:** we are often **UNCERTAIN** as to the - actual probability (1 in 10 or 1 in 5000?) and/or - the impact (€ 5 or house?)
Risk assessment uses scientific evidence to estimate the level of risk based on a combination of the likelihood and consequences of potential harm.
## ALL DAY RISKS

### ALL DAY RISKS OF HUMAN FATALITY:

<table>
<thead>
<tr>
<th>Risk</th>
<th>Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>motor vehicle accident (all)</td>
<td>$2.4 \times 10^{-4}$</td>
</tr>
<tr>
<td>motor vehicle accident (pedestrian)</td>
<td>$4.2 \times 10^{-5}$</td>
</tr>
<tr>
<td>home accidents</td>
<td>$1.1 \times 10^{-4}$</td>
</tr>
<tr>
<td>cigarette smoking</td>
<td>$3.6 \times 10^{-3}$</td>
</tr>
<tr>
<td>alcohol (moderate)</td>
<td>$2.0 \times 10^{-5}$</td>
</tr>
</tbody>
</table>
RANKING NUTRITIONAL RISKS IN EYES OF:

<table>
<thead>
<tr>
<th>Consumers</th>
<th>Scientists</th>
</tr>
</thead>
<tbody>
<tr>
<td>- chemical residues and contaminants</td>
<td>- nutritional behaviour</td>
</tr>
<tr>
<td>- additives</td>
<td>- pathogenic microorganisms</td>
</tr>
<tr>
<td>- nutritional behaviour</td>
<td>- biotoxins</td>
</tr>
<tr>
<td>- pathogenic microorganisms</td>
<td>- chemical residues and contaminants</td>
</tr>
<tr>
<td></td>
<td>- additives</td>
</tr>
</tbody>
</table>
RISK: DEFINITION

**WHO:**

*Risk:* The probability that a negative event or condition have to affect an individual in a given time and space ...

**OIE:**

*Risk:* The likelihood of the occurrence and the likely magnitude of the consequences of an adverse event to animal or human health *in the importing country* during a specified time period
RISK vs SAFETY

Consider:

- Nutritious –vs- tasty
- #1 rated car –vs- a good car
- A contract –vs- agreement
- The weather –vs- a bad day

_Risk is measurable, objective, and based on fixed criteria_
Risk: The **likelihood of the occurrence** and the **likely magnitude of the consequences** of an adverse event to animal or human health in the **importing country** during a specified time period

\[
p = \text{probability} \\
\text{m} = \text{magnitude} \\
c = \text{consequences}
\]

\[
\text{RISK} = p \times m \times c
\]
Section 1.3

IMPORT RISK ANALYSIS

Chapter 1.3.1. General considerations
Chapter 1.3.2. Guidelines for risk analysis
Chapter 1.3.3. Evaluation of Veterinary Services
Chapter 1.3.4. Guidelines for the evaluation of Veterinary Services
Chapter 1.3.5. Zoning and regionalisation
Chapter 1.3.6. Surveillance and monitoring of animal health
Chapter 1.3.7. Guidelines for reaching a judgement of equivalence of sanitary measures
HAZARD

Recall: **Risk** is a **probability**: it can be calculated

**Hazard** is a **potential**: it can be assessed but not 'calculated'

A Hazard is a Threat

Hazards are events (e.g. storm)  
**biological entities** (e.g. bacteria)  
or **physical agents** (e.g. heat)

**Codex**: Hazard = a biological, chemical or physical agent in or a condition of food with the potential to cause an adverse health effect
SO, WHAT IS RISK ANALYSIS?

A systematic way of gathering, evaluating, and recording information leading to recommendations for a position or action in response to an identified hazard.
Application of Risk Assessment

In veterinary medicine, risk assessment applicable in three main areas:

- INTERNATIONAL TRADE OF ANIMALS AND OF ANIMAL PRODUCTS
- FOOD HYGIENE
- VETERINARY BIOLOGICALS
Constraints to choice of approach for a risk assessment:

Available data

Quality of assumptions

Ranked decision questions

Timeframe

Guidelines?

Risk assessment design
  Qualitative to quantitative

Answer questions
Completion times of some farm-to-fork QRAs

- Harvard BSE: Final report
- CVM Campy: Final report
- FSIS E. Coli: Draft report
- FDA Listeria: Being revised
- USDA Vibrio: Draft report
- US FSIS SE: Final report
FINALLY

RISK ANALYSIS
4 COMPONENTS OF RISK ANALYSIS

- Hazard identification
- Risk assessment
- Risk management

Risk communication
RISK ASSESSMENT AS PART OF RA

Scientific Process

- Hazard Identification
- Risk assessment
- Risk Communication

Decision Process

- Risk management

Consideration of interests:
- economic
- society
- political
COMPONENTS OF RISK ANALYSIS

(OIE Scientific and Technical Review Vol 1, 1993)
THE "RISK CYCLE"

RISK ASSESSMENT
- Hazard identification
- Hazard characterisation
- Exposure assessment
- Risk characterisation
- Consolidated risk conclusions

RISK MANAGEMENT
- Option selection
- Regulatory/other control
- Other information e.g. technical factors; costs/benefits
- Socio-political factors e.g. risk perception

RISK COMMUNICATION
- Human health and/or environment
- Risk assessment
- Regulatory/other control
- Socio-political factors e.g. risk perception

Identification of concerns
Formulation of risk management questions
Review
Monitoring/surveillance
Implementation
Option selection
Regulatory/other control
Other information e.g. technical factors; costs/benefits
Socio-political factors e.g. risk perception
RISK MANAGEMENT

process where (usually) a regulatory agency decides what to do about the results of risk assessment, and implements this decision.

However, as economic, social and political considerations will influence the setting of the priorities, the design of the regulations could well be suboptimal in scientific and technical terms.
**Risk Management (generic framework, FAO)**

### Preliminary Risk Management Activities
- Identify food safety issues
- Develop risk profile
- Establish goals of risk management
- Decide on need for risk assessment
- Establish risk assessment policy
- Commission risk assessment, if necessary
- Consider results of risk assessment
- Rank risks, if necessary

### Identification and Selection of Risk Management Options
- Identify possible options
- Evaluate options
- Select preferred option(s)

### Implementation of Risk Management Decision
- Validate control(s) where necessary
- Implement selected control(s)
- Verify implementation

### Monitoring and Review
- Monitor outcomes of control(s)
- Review control(s) where indicated
Communicating the results to interested parties and decision makers is the final step to complete a risk assessment.

This certainly includes proposing effective controls to monitor the selected actions.
## Sources of conflict

<table>
<thead>
<tr>
<th><strong>Values</strong></th>
<th>The parties have different underlying values, beliefs and views of the world</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Interests</strong></td>
<td>The parties have different interests: commercial, environmental, social, ..</td>
</tr>
<tr>
<td><strong>Language</strong></td>
<td>The language used by scientists or experts may not be accessible to stakeholders</td>
</tr>
<tr>
<td><strong>Knowledge</strong></td>
<td>There are differing views on what is known and not known</td>
</tr>
<tr>
<td><strong>Lack of transparency or openness</strong></td>
<td>Stakeholders are not provided with relevant or sufficient information or not included in the decision making process</td>
</tr>
</tbody>
</table>
RISK COMMUNICATION

To consider: Factors in perception of risks by people as either tolerable or threatening

<table>
<thead>
<tr>
<th>Risks may be seen tolerate if they are:</th>
<th>Risks may be seen as threatening if they are:</th>
</tr>
</thead>
<tbody>
<tr>
<td>voluntary</td>
<td>involuntary</td>
</tr>
<tr>
<td>controlled</td>
<td>uncontrolled</td>
</tr>
<tr>
<td>familiar</td>
<td>unfamiliar</td>
</tr>
<tr>
<td>immediate</td>
<td>some time in the future</td>
</tr>
<tr>
<td>short term</td>
<td>long term</td>
</tr>
<tr>
<td>minor consequences</td>
<td>severe consequences</td>
</tr>
<tr>
<td>reversible</td>
<td>irreversible</td>
</tr>
<tr>
<td>personal involvement</td>
<td>no involvement</td>
</tr>
<tr>
<td>benefits</td>
<td>costs</td>
</tr>
<tr>
<td>probable</td>
<td>improbable</td>
</tr>
</tbody>
</table>

Source: Risk Analysis Framework, Commonwealth of Australia 2005
<table>
<thead>
<tr>
<th>EXPERT ASSESSMENT</th>
<th>PUBLIC ASSESSMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific</td>
<td>Intuitive</td>
</tr>
<tr>
<td>Probabilistic</td>
<td>Yes/no</td>
</tr>
<tr>
<td>Comparative risk</td>
<td>Personal</td>
</tr>
<tr>
<td>Population averages</td>
<td>consequences</td>
</tr>
<tr>
<td>Death is a death</td>
<td>Type of death</td>
</tr>
<tr>
<td></td>
<td>matters</td>
</tr>
<tr>
<td></td>
<td>Who is affected</td>
</tr>
</tbody>
</table>
RISK ASSESSMENT: a iterative process

**RISK ASSESSMENT LOOP**

- **What might happen?**
  Hazard identification and potential problem formulation, stressor/receptor

- **How likely is it to happen?**
  Likelihood, probability, frequency

- **How could it happen?**
  Exposure analysis, cause and effect pathways

- **What is the risk?**
  Risk identification, risk estimate, risk characteristics, risk scenarios

- **Can the risk be managed?**
  Risk evaluation, risk treatment, mitigation, management

- **How serious is it if it happens?**
  Consequences, magnitude, effects, impact analysis, dose-response

**EVIDENCE**

**UNCERTAINTY**

Source: Risk Analysis Framework, Commonwealth of Australia 2005

**UNCERTAINTY**

**EVIDENCE**
**Actors in RA**

**Risk assessors**
- Scientist carrying out risk assessments

**Risk managers**
- Food safety officials working for national governments
- Responsibility for
  - Ensuring that RA is carried out
  - Choosing and implementing food safety control measures

**Risk communicators**
APPROACHES TO RISK ANALYSIS

Risk assessment
- hazard identification
- hazard characterisation
- exposure assessment
- risk characterisation

Risk management
- risk evaluation
- option assessment
- monitoring and review

Risk communication

Risk assessment
- release assessment
- exposure assessment
- consequence assessment
- risk estimation

Risk management
- risk evaluation
- option evaluation
- implementation
- monitoring and review

Risk communication
3 COMPONENTS OF (OIE) RISK ASSESSMENT

Risk Estimation

Release assessment → Exposure assessment → Consequence assessment
4 COMPONENTS OF RISK-ASSESSMENT (CAC):

HAZARD IDENTIFICATION

HAZARD CHARACTERIZATION

HAZARD

Human

Contamination

Consume

RISK CHARACTERIZATION
SZENARIO OF A IMPORT RISK ANALYSIS

Export country

Trade
live animals
anim. products

Import country
HAZARD IDENTIFICATION

Factors:
- what agent?
- different infection prevalences (risk potential)?
- susceptible population present (animals, vectors, reservoirs)?
- exporting country: effective surveillance?
RELEASE ASSESSMENT

Factors:
- Epidemiological situation in export country, control of animal diseases (quarantine)?
- Export volume, agent multiplication?
- Efficiency of testing (pre-boarding)?
EXPOSURE ASSESSMENT

Factors:

• Properties of agent, vectors, host competency?
• Exposition pathways and disposition (live animals, products, offals)?
• Exposition risk of population?
CONSEQUENCE ASSESSMENT

Export country

Trade
live animals
anim. products

Import country

Factors:
- Spread- and Infection rates, control measures?
- Direct losses, control costs?
- Social and economic follow-up costs, environmental costs?
QUALITATIVE – QUANTITATIVE RISK ASSESSMENT

Qualitative risk assessment
= collect data including quantitative data and assess the risk using descriptive terms (e.g. low, negligible, high risk)

Scoping study:
Evaluate the availability of good quality numerical data for quantitative risk assessment

Quantitative risk assessment
= assess the risk numerically (2 methods):
  - Deterministic
  - Stochastic
CONTINUUM OF RISK ASSESSMENT TYPES (FAO)

- Qualitative, descriptive, categorical
- Quantitative deterministic
- Specific data, sophisticated models
- Generic numbers, simple model(s)
- Quantitative stochastic

Resource requirements

Complexity
<table>
<thead>
<tr>
<th>Output</th>
<th>Qualitative</th>
<th>Quantitative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Output</td>
<td>words</td>
<td>Numbers</td>
</tr>
<tr>
<td>Advantages</td>
<td>relatively simple to do</td>
<td>more information</td>
</tr>
<tr>
<td></td>
<td>reasonable input demands</td>
<td></td>
</tr>
<tr>
<td></td>
<td>easy to communicate</td>
<td></td>
</tr>
<tr>
<td>Disadvantages</td>
<td>cannot include uncertainty</td>
<td>high data demands</td>
</tr>
<tr>
<td></td>
<td>well</td>
<td>more expertise</td>
</tr>
<tr>
<td></td>
<td>low level of detail</td>
<td>more difficult to communicate</td>
</tr>
<tr>
<td></td>
<td>simplistic (unrealistic)</td>
<td></td>
</tr>
</tbody>
</table>

**ADVANTAGES / DISADVANTAGES**
STEPS (PROCESS) IN DEVELOPMENT OF QRA

- **Qualitative RA**
- **Sufficient Risk?**
  - yes
  - no
  - Relevant data available?
    - yes
    - no
      - Sufficient data quality?
        - yes
        - Quantitative RA
        - no
          - Gather data

- **Quantitative RA**
POSSIBLE INTERPRETATION in QUALITATIVE/QUANTITATIVE RISK ASSESSMENTS

<table>
<thead>
<tr>
<th>QUALITATIVE</th>
<th>INTERPRETATION</th>
<th>QUANTITATIVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>The probability of occurrence is ...</td>
<td>Occurrence can <em>nearly be excluded</em></td>
<td>P &lt; 10^-6</td>
</tr>
<tr>
<td>negligible</td>
<td>Can occur <em>rarely</em></td>
<td>P &lt; 10^-5</td>
</tr>
<tr>
<td>low</td>
<td>Can occur <em>occasionally</em></td>
<td>P &lt; 10^-3</td>
</tr>
<tr>
<td>moderate</td>
<td>Can occur <em>often</em></td>
<td>P &gt; 10^-3</td>
</tr>
<tr>
<td>high</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

P = Probability of occurrence

Source: Stärk. C., BMTW 05/06, 2004, 182-187
VARIABILITY AND UNCERTAINTY

VARIABILITY:
- determined by the real existing variability of a system
- can be assessed and described, but cannot be reduced

UNCERTAINTY:
- due to accidental and systematic errors in data collection
- due to lack of knowledge about the system and the quality characteristics of the data as well as due to the dependency of results on the choice of model
- can theoretically be reduced by more measurements
VARIABILITY:

- refers to differences attributable to true heterogeneity or diversity in a population or parameter that is irreducible by additional measurement
- is an objective property of a population

SOURCES OF VARIABILITY

- **Natural random processes**
  - that stem from environmental/genetic differences among humans, animals, plants, cells, or microbes:
    1. Physiological variations (age, bodyweight, height, blood pressure, heat rate, water intake rates, immunity levels, microbial growth factors, etc)
    2. Climatic variability, variations in soil types, differences in contaminant and distribution of disease morbidities/mortalities, etc
UNCERTAINTY:

- is the **lack of knowledge** by an assessor about specific factors, parameters, models, etc

**KINDS OF UNCERTAINTY**

1. **Parameter uncertainty:**
   - Examples: *Measurement, sampling* and *systematic errors*, and availability of little/scarce data to enable estimation of input true values* of unknown parameters

2. **Scenario uncertainty:**
   - Errors: *Descriptive* and aggregation errors in *professional judgements*, and *incomplete analysis* (e.g. outline of pathways)

3. **Extrapolation uncertainty:**
   - arises when *experts disagree* over whether study *findings can be extrapolated* to real world situations
QUANTITATIVE RISK ASSESSMENT (QRA) USING MONTE CARLO SIMULATION

- *Probability distributions* are used to describe uncertainty as
  - lack of precise knowledge (uncertainty)
  - random effects of chance (variability)

- The combined impact of various uncertainties is calculated in order to determine the probability distribution(s) of the model outcome(s)

- The most critical inputs in the final model are identified by performing a *sensitivity analysis*
PROBABILITY DISTRIBUTIONS OFTEN USED IN MICROBIAL QRA

• BINOMIAL PROCESS
  - discrete independent trials
  - \( s = \text{Binomial} \ (n,p) \)
  - \( p = \text{Beta} \ (s+1,n-s+1) \)
  - \( n = s + \text{Negative Binomial} \ (s,p) \)
  * if last trial was a success, else
  - \( n = s + \text{Negative Binomial} \ (s+1,p) \)
  - \( P(s\geq1) = 1-(1-p)^n \)

• POISSON PROCESS
  - continuous exposure, e.g. bacteria in litres of milk
  - \( t = \) distance moved
  - \( x = \) number of events in \( t \)
  - \( \lambda = \) mean number of events in \( t \)
  - \( \beta = 1/\lambda = \text{MIBE} \)
  - \( x = \text{Poisson} \ (\lambda) \)
  - \( \lambda = \) from Central Limit Theorem = \( N\sim(x,\sigma/\sqrt{n}) \)
  - \( t = \text{Gamma} \ (x,\beta) \)
  - Gamma \ (1,\beta) = \) time until next event
PROBABILITY DISTRIBUTIONS OFTEN USED IN MICROBIAL QRA

- HYPERGEOMETRIC
- NORMAL
  - CLT, measurement errors, symmetric values
- LOGNORMAL
  - CLT, skewed variables (bacterial counts)
- DISCRETE and UNIFORM
  - discrete events, composite distributions
- GENERAL
  - expert opinion
- CUMULATIVE or HISTOGRAM
QUANTITATIVE MICROBIOLOGICAL RISK ASSESSMENT (outline)

- Prevalence in primary production
  - Presence of the agent in raw product
    - Concentration of agent in raw product
    - Concentration in ready-to-eat product
    - Frequency and extent of exposure
      - Disease rate

- Survival and inactivation

- Food consumption

- Dose-response
4 COMPONENTS OF RISK-ASSESSMENT (CAC):

HAZARD IDENTIFICATION

HAZARD CHARACTERIZATION

HAZARD

HUMAN

CONTAMINATION

CONSUME

RISK CHARACTERIZATION
Microbiological risk assessment (MRA) (FOOD SAFETY MRA)

MRA approaches on and along the „qualitative-quantitative continuum“

- Defining the problem: „RISK PROFILES“ (see Word document), prior to commencing a risk assessment
- Qualitative and „semi-quantitative“ MRA
- Quantitative MRA – deterministic and stochastic (probabilistic)
- Complete food chain vs. Product-process MRA
- Risk ranking
- Combination of approaches

- But most important: MRA is to be „fit-for-purpose“
**CODEX definitions of quantitative microbiological food safety metrics used in MRM**

**Food safety objectives (FSO):**

The maximum frequency and/or concentration of a hazard in a food at the point of consumption that provides, or contributes to, achievement of the ALOP (appropriate level of protection)

**Performance objectives (PO):**

The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain that provides, or contributes to, achievement of the ALOP

E.g. for bottled water level of salmonellae after microbiocidal treatment less than \(-2.0 \log_{10}\text{cfu/ml}\)

**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 performance objective (PO)

E.g. less than a 1-log increase in *L. monocytogenes* during refrigerated distribution of a ready-to- eat-food
Further CODEX definitions used in MRA

**(Risk-based) microbiological criterion (MC):**

is based on the examination of foods at specific point in the food chain to determine if the frequency and/or level of a pathogen in a food exceed a pre-established limit.

**Process criterium (PcC)**

physical control measure, e.g. time, temperature, at a step, or a combination of steps, that can be applied to achieve a PO.

E.g. milk pasteurisation requirement of 72° for 15 seconds.

**Product criterium (PdC)**

specifies a chemical or physical characteristic of a food, e.g. pH, water activity / $a_w$, similarly serves as a physical control measure.
General principles for microbiological risk management (MRM)

1. Protection of human health is primary objective in MRM
2. MRM should take into account the whole food chain
3. MRM should follow a structured approach
4. MRM process should be transparent, consistent and fully documented.
5. Risk managers should ensure effective consultations with relevant interested parties.
6. Risk managers should ensure effective interaction with risk assessors.
7. Risk managers should take account of risks resulting from regional differences in hazards in the food chain and regional differences in available risk management options.
8. MRM decisions should be subject to monitoring and review and, if necessary, revision.
PRELIMINARY MICROBIOLOGICAL RISK MANAGEMENT ACTIVITIES

- IDENTIFICATION OF A MICROBIOLOGICAL FOOD SAFETY ISSUE
- MICROBIOLOGICAL RISK PROFILE
- RISK ASSESSMENT POLICY
- MICROBIOLOGICAL RISK ASSESSMENT
IDENTIFICATION OF MRM OPTIONS

for Codex: elaboration of standards and related texts

for Countries

- establish regulatory requirements;
- develop (or encourage the development of) specific documents and guides e.g. GAP, GMP, GHP, HACCP;
- adopt or adapt Codex standards and related texts to the national situation;
- define an FSO for a particular food safety issue (flexibility for industry);
- establish requirements for inspection, audit, certification, approval procedures;
- promulgate awareness and develop educational and training programs to communicate
  - prevention of contamination and/or introduction of hazards should be addressed at relevant stages in the food/feed chain;
  - rapid withdrawal/recall of food/feed procedures are in place, including appropriate traceability/product tracing for effectiveness;
  - properly labelling includes information that instructs the consumer regarding safe handling practices and, where appropriate, briefly informs the consumer of the food safety issue;
When selecting options consider

- planned control of hazards (e.g. with HACCP) is more effective than detecting and correcting
- food safety control system failures (e.g., lot-release microbiological testing of finished products);
- the population may be exposed to multiple potential sources of a particular hazard;
- the suitability of the option to be monitored, reviewed and revised during subsequent implementation;
- the capacity of the food businesses to manage food safety (e.g. human resources, size, type of operation).

➢ a more traditional approach may be selected for small and less developed food businesses, rather than an FSO driven approach
MRM options based on risk

The increasing adoption of risk analysis
• is allowing more transparent approaches
  • for relating ALOP to the required stringency of the food safety control system,
  • and for the comparison of MRM options for their suitability and, possibly, equivalence.

This has allowed the use of traditional MRM options as well as the development of new MRM tools, e.g.
• FSO,
• PO
• PC
  • and the enhancement of the scientific basis of existing MRM tools, e.g. microbiological criteria (MC).
IMPLEMENTATION OF MRM OPTIONS

INTERNATIONAL INTERGOVERNMENTAL ORGANISATIONS

Developing countries may need specific assistance in developing and selecting implementation strategies as well as in the area of education. Such assistance should be provided by international intergovernmental organisations, e.g. FAO and WHO, and developed countries in the spirit of the SPS Agreement.

COUNTRIES

Implementation can occur at different points in the food/feed chain and may involve more than one segment of the industry and consumers.

Governments should ensure

• appropriate regulatory framework and infrastructure,
• including adequately trained personnel and inspection staff, in order
• to enforce regulations and verify compliance.
• Inspection and targeted sampling plans may be applied at different steps of the food chain.

The competent authorities should ensure

• that industry applies the appropriate good practices and,
• within the application of the HACCP system, effectively monitor CCPs and
• implement corrective actions and verification steps.
INDUSTRY is responsible for developing and applying food safety control systems to give effect to decisions on MRM options.

Depending on the nature of the MRM option, this may require activities such as:

- Establishing metrics that will achieve or contribute to established FSOs or other regulatory requirements;
- The identification of PC and design and implementation of appropriate combinations of validated control measures;
- Monitoring and verification of the food safety control system or relevant parts thereof (e.g. control measures, good practices);
- Application, as appropriate, of sampling plans for microbiological analyses;
- Development of plans for corrective actions, that may include withdrawal/recall procedures, traceability/product tracing etc;
- Effective communication with suppliers, customers and/or consumers, as appropriate;
- Training or instruction of staff and internal communication.
CONSUMER

- Consumers can enhance both their personal and the public’s health by being responsible for, adhering to, being informed of and following food safety-related instructions.
- Multiple means of providing this information to consumers should be undertaken, such as public education programs, appropriate labelling, and public interest messages.
- Consumer organisations can play a significant role in getting this information to consumers.