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INTERACTION AND COMMUNICATION BETWEEN RISK ASSESSOR AND RISK MANAGER

Prof. Samuel Godefroy, Ph.D. *| Full Professor, Food Risk Analysis and Regulatory Policies*

Outline

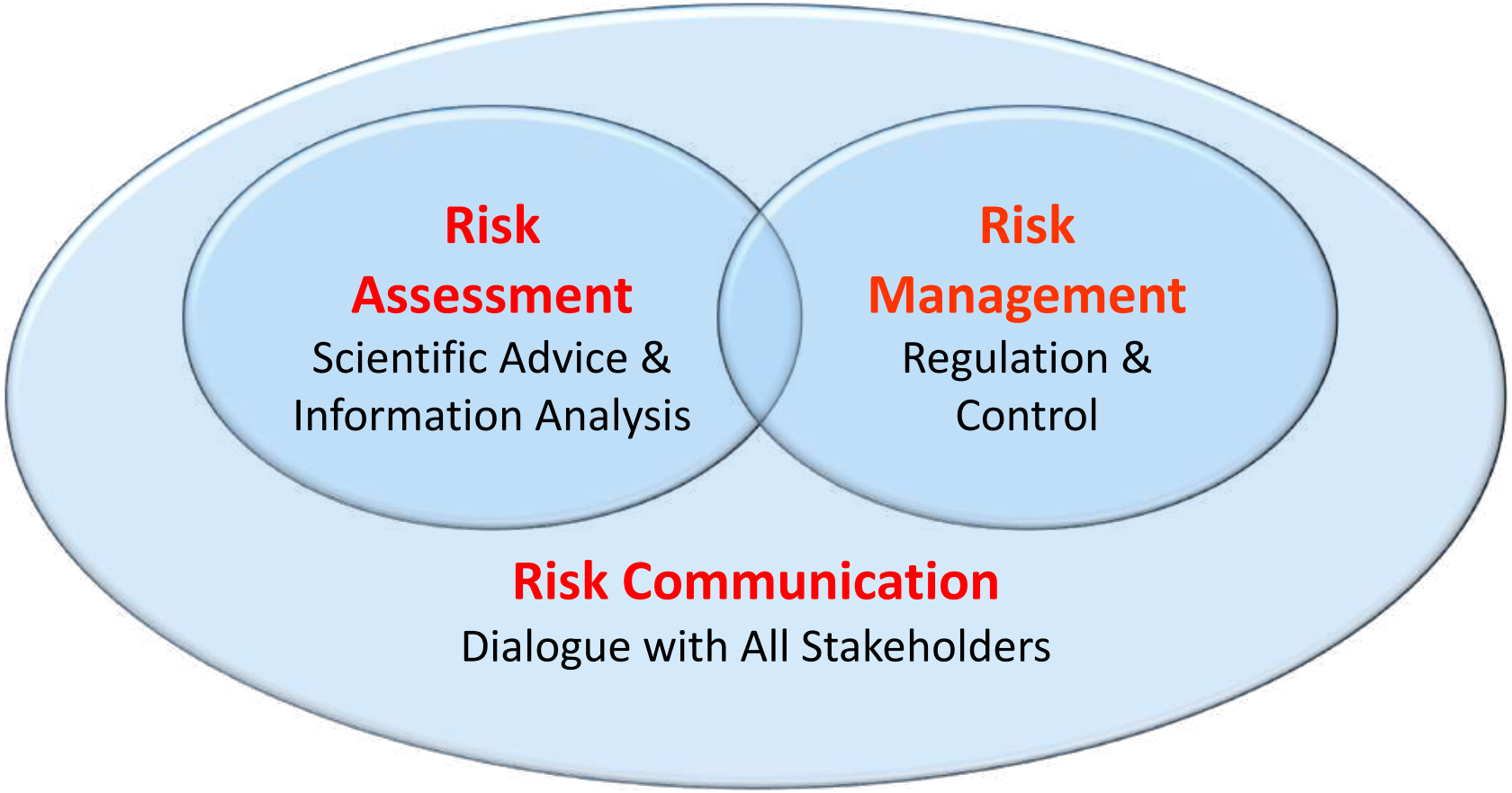
Reviewing situations of use of Risk Analysis Approach in the context of Issues / Food Incident Management

Importance of Dialogue, Clear Governance and Procedures between Risk Assessors and Risk Managers

Conclusions

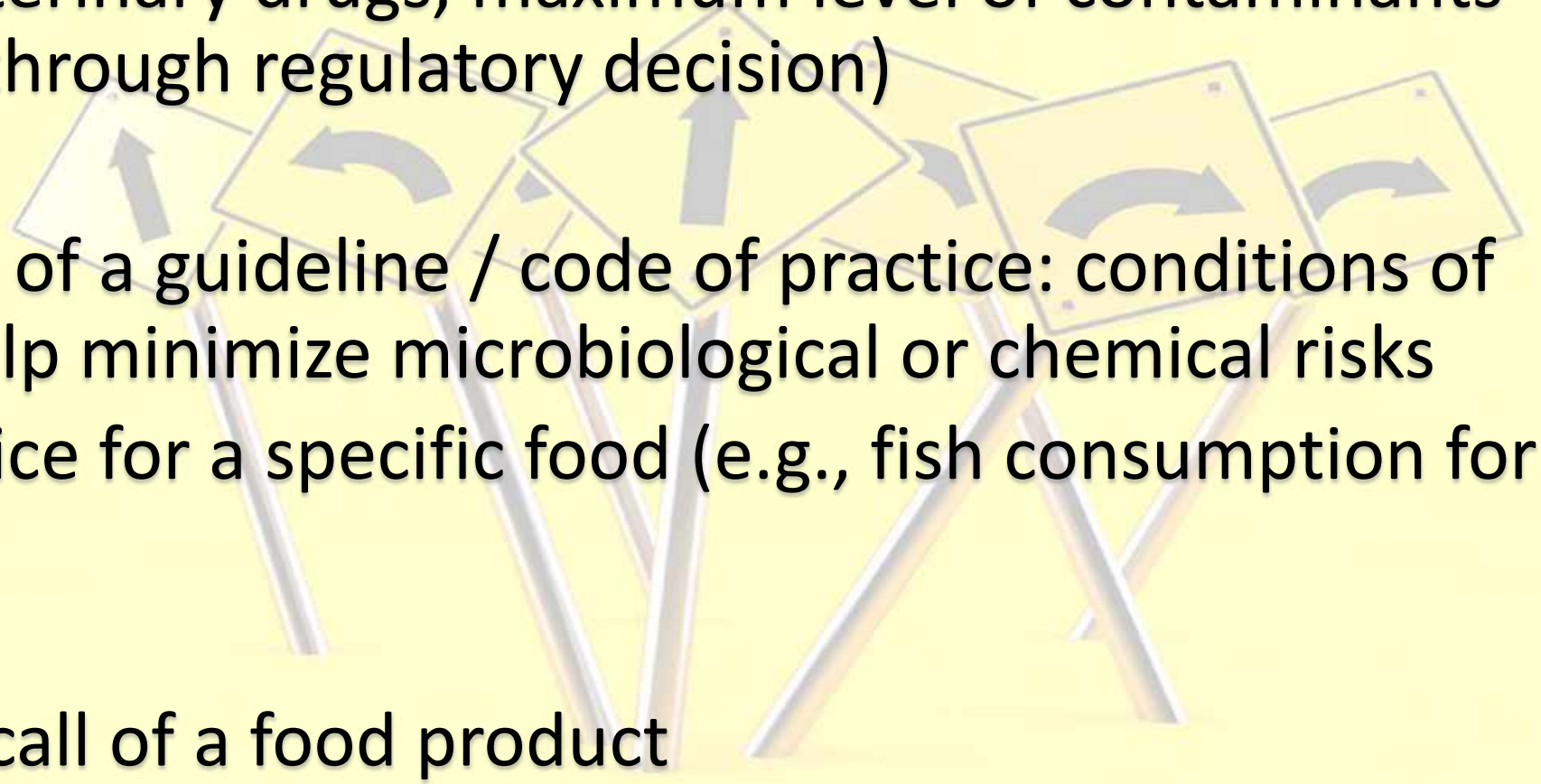
Reminder of the Risk Analysis Framework

FAO / WHO Risk Analysis Paradigm



Example of Food Decisions where Risk Analysis is Needed

- The development of a standard: A maximum residue level for use of pesticides or veterinary drugs, maximum level of contaminants in food (generally through regulatory decision)
- The Development of a guideline / code of practice: conditions of production that help minimize microbiological or chemical risks
- Consumption advice for a specific food (e.g., fish consumption for pregnant women)
- Mandating the recall of a food product



Managing Health Risks

Multiple Levers Of Action

Regulatory And Non-regulatory Measures

Use Various Instruments from a Tool Box of Risk Management Tools

Toolbox of Risk Management Measures

Focusing on Recall Situations


Risk Manager Is
the Coordinator of
the Process

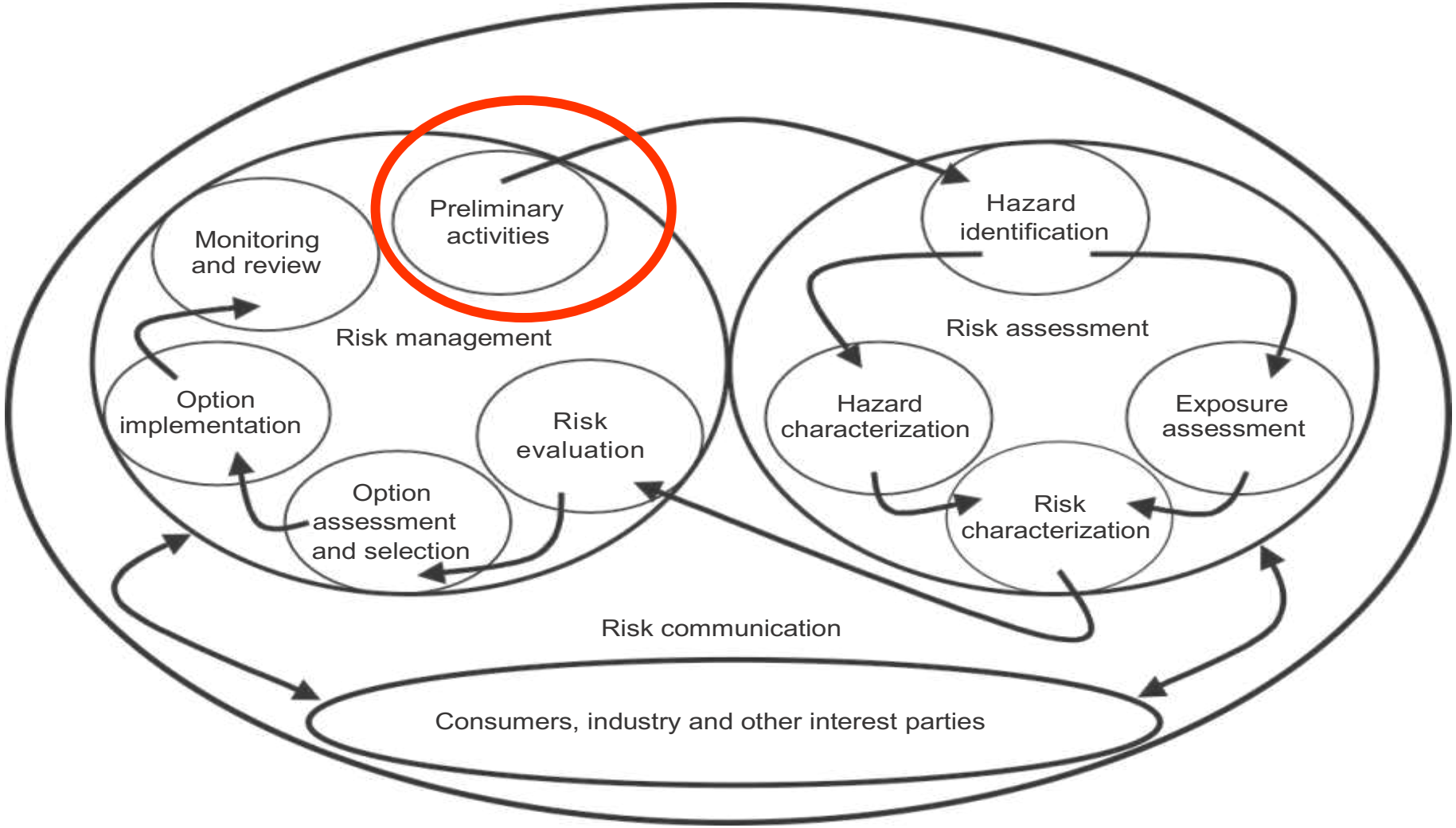
Risk Manager's Role

- ❑ Gathers Data / Evidence
- ❑ Shares Information and Coordinates Communication with all Parties
- ❑ Frames the Risk Question(s) if Warranted
  - There is no standard for each combination food/contaminant
  - Even if there a standard / regulation, a risk assessment may be needed to support further action (risk-driven measures)

Importance of:

- ➢ Structure
- ➢ Clear Roles and Responsibilities
- ➢ Procedures

Risk Analysis continues to offer the right structure…



Other Procedures are needed….

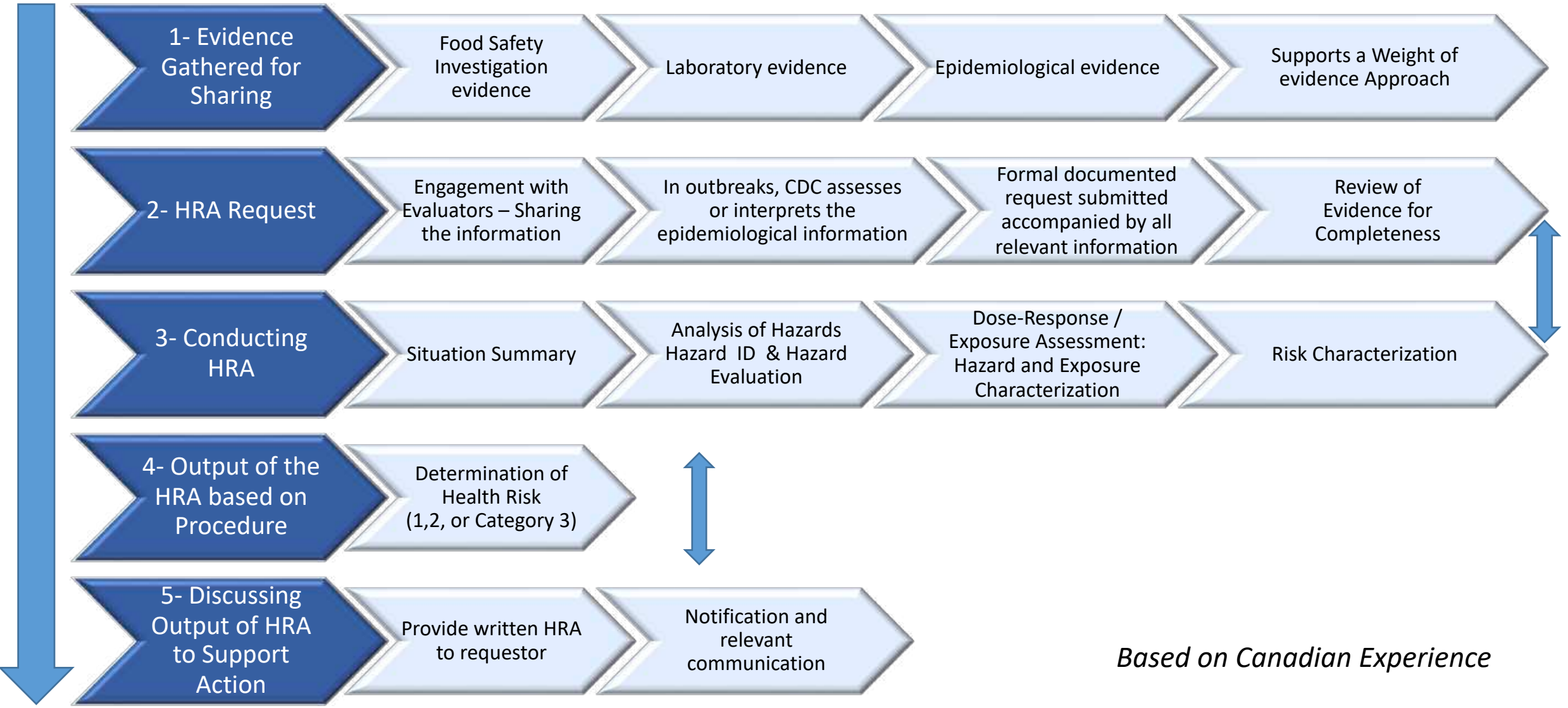
To support Communication between Risk Analysis Partners and Stakeholders

Other Procedures are Warranted….

"The interactive exchange **of information and opinions throughout the risk analysis process concerning hazards and risks, 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." (*Codex, 2001*)

Structure is Needed for the Application of Risk Communication

Example of Process Flow …for Health Risk Assessment (HRA)



Based on Canadian Experience

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A Few Areas of Clarification….

- Initiation
  - The Risk Manager requests a HRA to the risk assessment evaluator on duty

- All data available are to be provided to the scientific evaluator in a precise and documented form

The result of the HRA is contingent on the availability and precision of the information provided

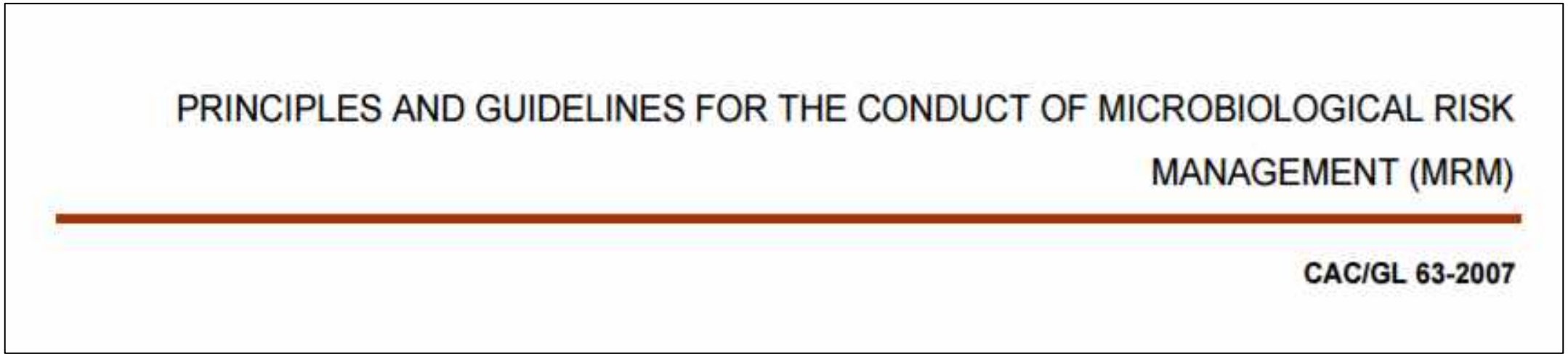
The Process Includes Regular Engagement …

- The evaluator reviews the information provided for adequacy and reliability
  - The evaluator may request additional information (e.g., microbiological data, methodology used, physico-chemical test results, storage conditions of a food, storage temperature, packaging material specifications, etc.)
  - In an outbreak situation, the evaluator may request an Epidemiologist (from a CDC) to assess or interpret the epidemiological evidence
  - A search for similar scenarios is done in the literature, in previous records, etc.

Need to Document Sources / Methods Followed

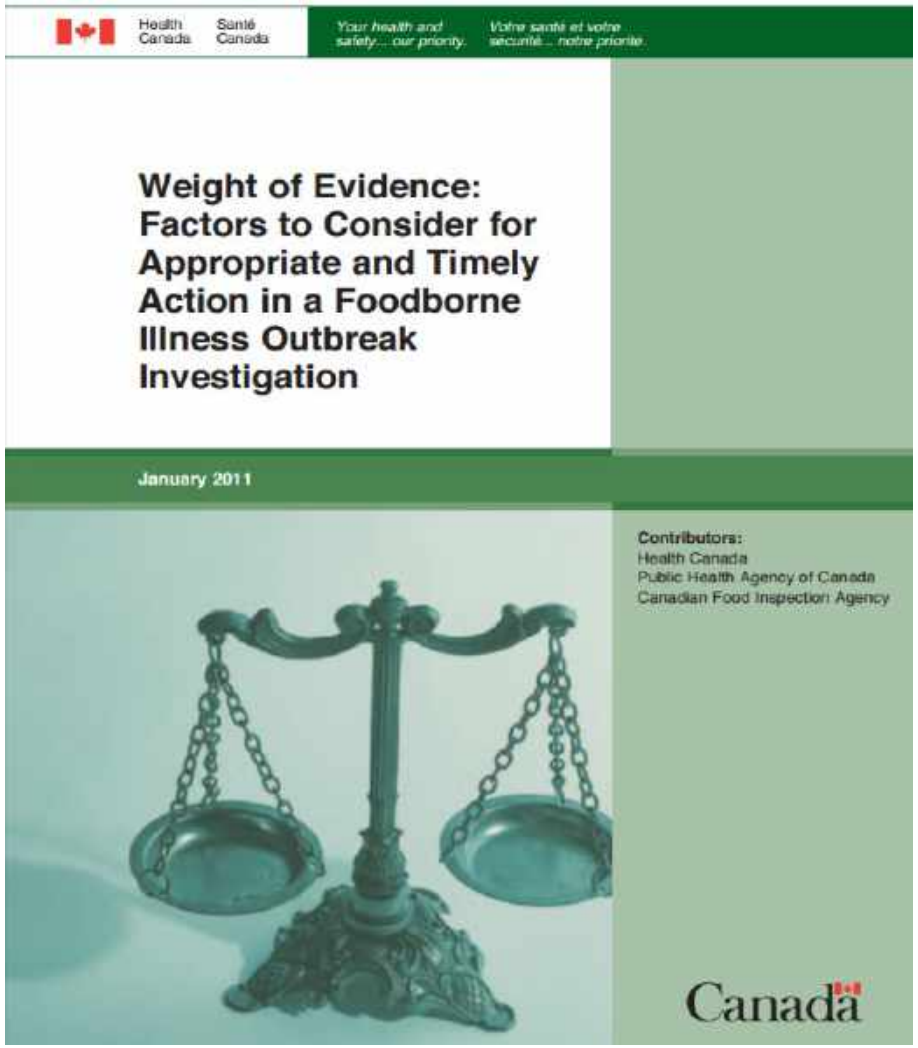
Example:

A health risk assessment is performed following a template based on Codex Alimentarius guidance and following any other health risk assessment policies



Need to Update / Document Methodologies, as Required

- Needed to Develop a Guidance for More Systematic Approach of Weighing in several Data Sources (Epi, Versus Laboratory Results, Food Safety Investigation)
- Develop Decision-Trees where Required
- Use Lessons Learnt from Previous Incidents to Support Enhanced Structure and Coordination



Establish Agreed-Upon Risk Catagorization

(same approach to « read » HRA Result)

Categorization of the Level of Risk is Important

Example: 3 categories from highest to mildest (This can be part of a Health Risk assessment policy/manual)

The level of Health Risk is determined by taking into account the hazard identified, the exposure assessment and the hazard characterization.

❑Health Risk 1

- Represents a situation where there is a reasonable probability that the consumption/exposure of/to a food could lead to adverse health consequences which are serious or life threatening or that the probability of an outbreak situation is considered high.

❑Health Risk 2

- Represents a situation where there is reasonable probability that the consumption/exposure to a food could lead to temporary or not life threatening health consequences or that the probability of serious adverse consequences is considered remote.

Determination of Health Risk 1, 2, or Category 3

❑ Health Risk 3

- Represents a situation where there is a reasonable probability that the consumption/exposure to a food is not likely to result in any adverse health consequence.

The situation identified may be an indication of a breakdown in Good Manufacturing Practices (e.g., sanitation, quality issues, etc.); in Good Agricultural Practices (e.g. pesticide residue in food above the established MRL); in Good Practices in Veterinary Medicine (e.g. animal drug residue in food above the MRL) or some other relevant factor (e.g., food containing non-permitted nutrients or food additives above the permitted levels, nutrients that do not meet label claim, health-related labelling infractions, etc.).

Common Engagement (by Risk assessors and Managers)/ Communication with Stakeholders and Partners

Discussing Examples

Situation Associated with OTA in Children Food

- Risk Manager /enforcer recalled product and issued advisory associated with findings of OTA in Oat containing children food – Prior to having a Risk Assessment
- Decision **reached** based on higher occurrence levels in some products and the “vulnerability of the population” : Children
- Then Asked to have a Risk Assessment to ”Justify” the Decision
- Risk Assessment clearly did not reach the “higher” level of risk (not warranting recall
- Lack of **coordination and transparency** in process did not help interaction with stakeholders & impacted industry

Lessons Learnt … and Recommendations

- Although following the Risk Analysis Approach offer the structure needed, further procedure development and documentation is useful to support systematic and robust decision-making processes associated with food safety.
- Optimum Documentation of Process is critical to:
  - clarify roles & responsibilities (and accountabilities)
  - Ensure consistency and coherence of decision-making
  - support trust

- Addition of guidance may be needed as warranted by encountered situations


thank you
merci
obrigado
gracias
danke
bedankt
dziękuję
go raibh maith agat
terima kasih
kop khun krap
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