The Codex Approach to Risk Analysis of Detection of Contaminants

Especially in food where there is No Regulatory Level

SUSTAINABLE DEVELOPMENT G☉ALS

Overview

- Unpacking the topic
- Boundary: applies for contaminants (undesirable compounds)
- Quick overview on FAO's views of food safety
- How does Codex approach risk assessment and risk analysis
- Additional considerations
- Risk management options in situation where there is no regulatory maximum level

FAO's Food Safety Priorities

- Vision: Safe food for all people at all times

- Mission: To support Members in continuing to improve food safety at all levels by

  - providing scientific advice and
  - strengthening their food safety capacities

  for efficient, inclusive, resilient and sustainable agrifood systems

STRATEGIC OUTCOME 1

Inter-governmental and multi-stakeholder engagement in intersectoral coordination

STRATEGIC OUTCOME 2

Sound scientific advice

FAO Strategic priorities for food safety

within the FAO strategic framework 2022–2031

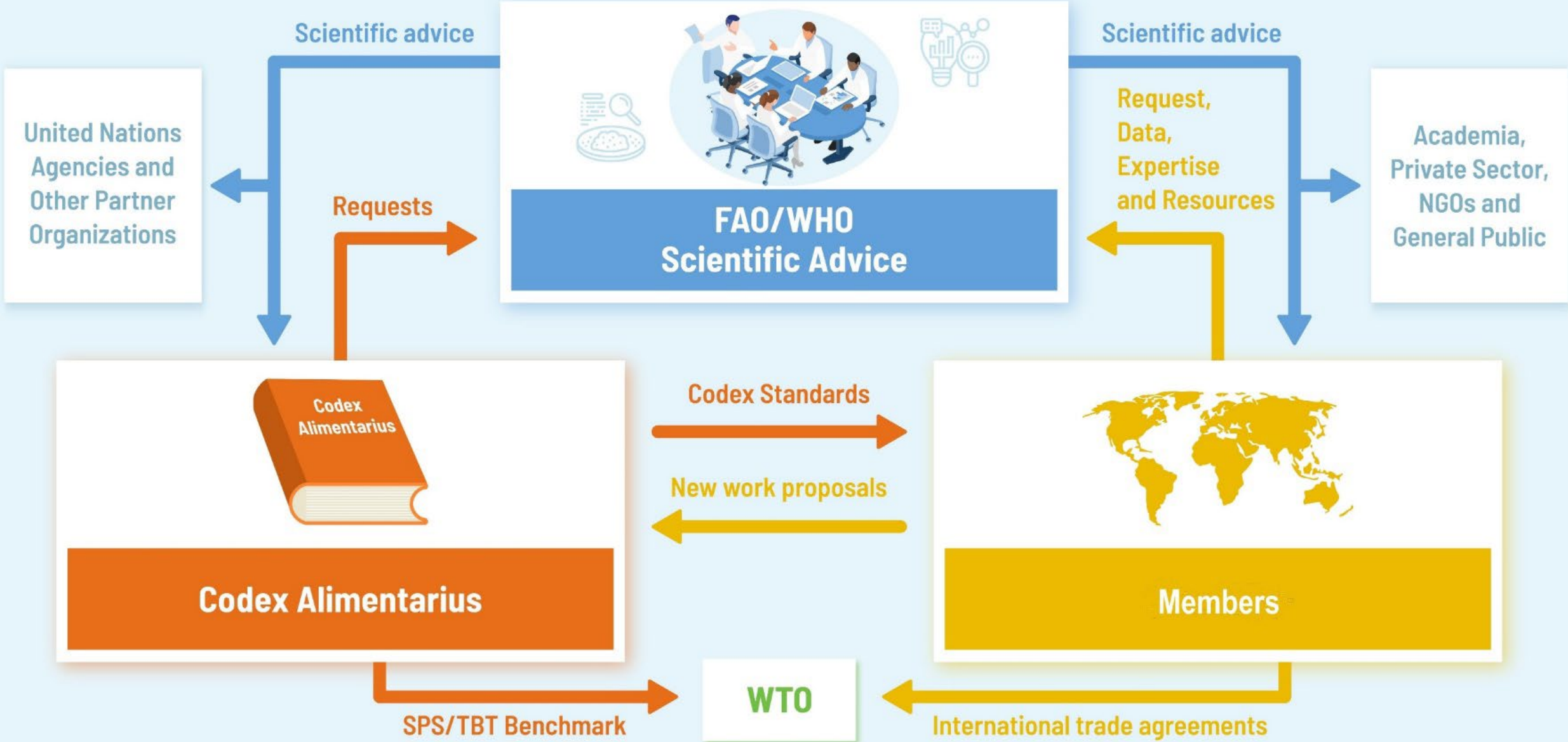**STRATEGIC OUTCOME 4**

Public and private stakeholder collaboration

STRATEGIC OUTCOME 3

National food control systems

Provision of Scientific Advice

Risk Analysis Framework

Risk Assessment

Scientific advice
Information analysis
WHO & FAO
Member countries

Risk Management

Standards,

Code of practices
and control
CAC
Member countries

Risk Communication

Dialogue with
all stakeholders
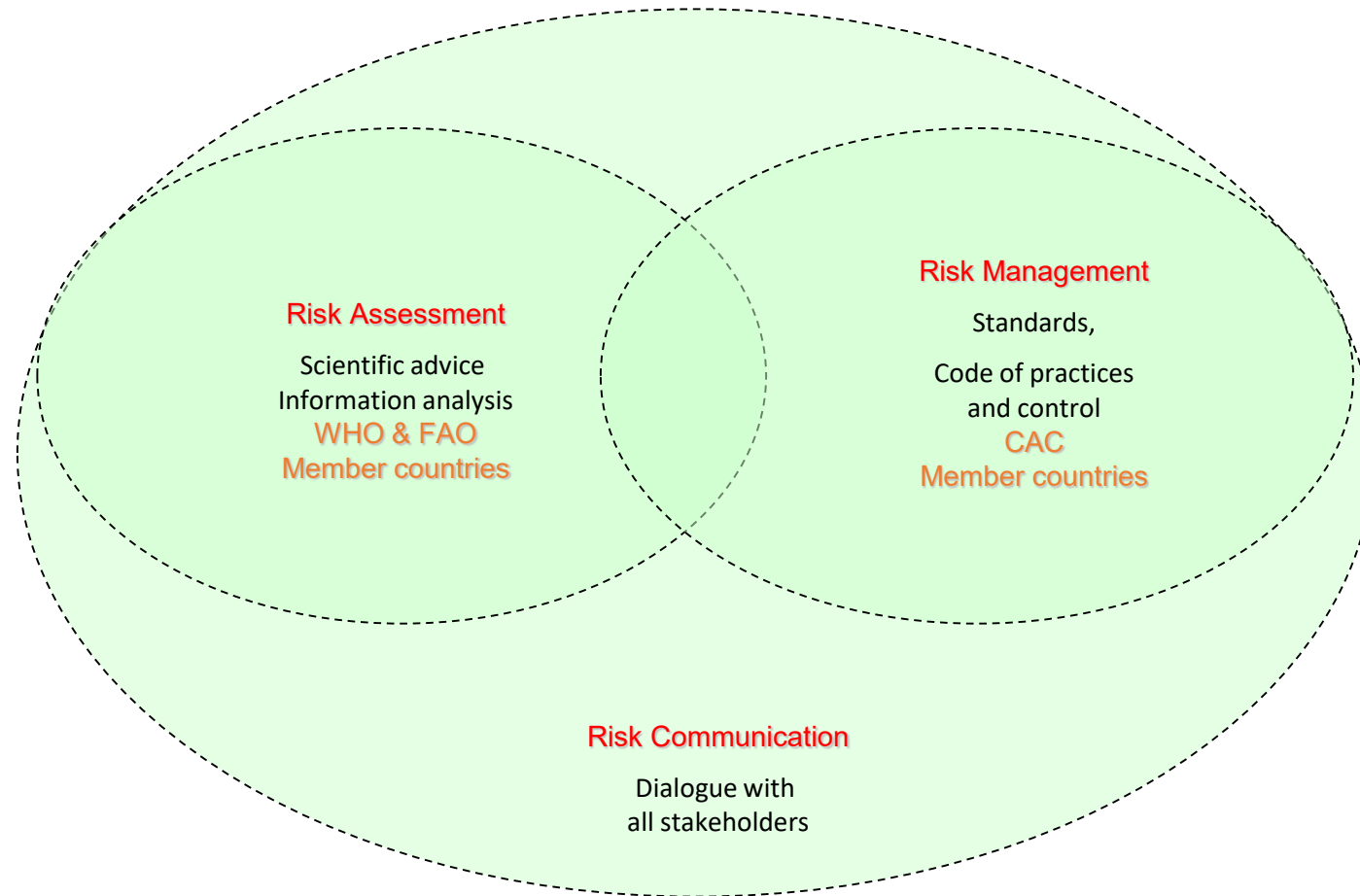
Risk Assessment Process
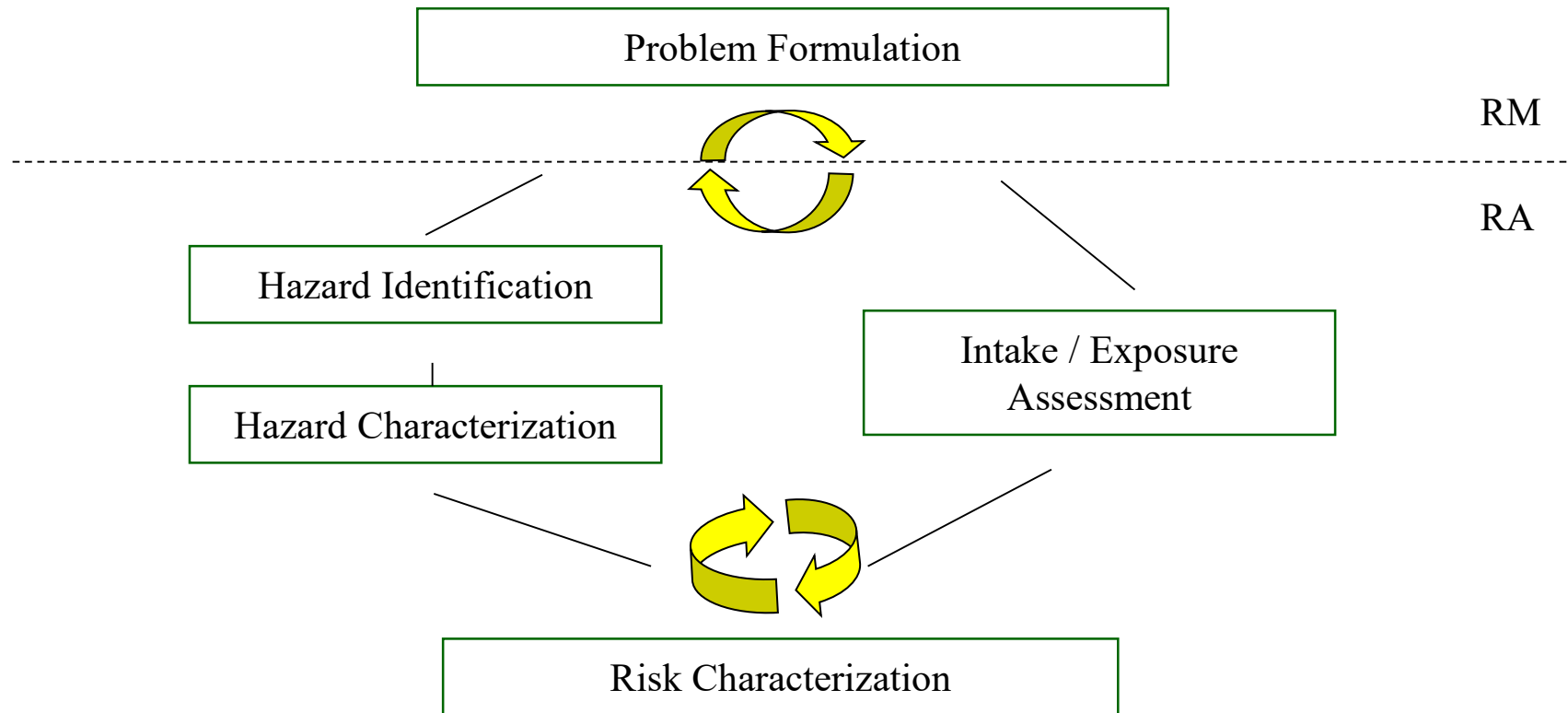
Risk Assessment Process

Hazard Identification

Identify hazards (biological, chemical or physical agents which may cause adverse health effects) in a food or group of foods

Hazard characterisation

Definition of health-based guidance values (nutritional/ toxicological)

Intakes/Exposure assessment

Likely dietary intake /exposure via food as well as from other sources if relevant

Risk/benefit characterisation

Estimation of the probability of occurrence and severity of a potential adverse health effect in a given population (inadequacy or exceedance)

Back to the Question

- **<u>The Codex Approach to Risk Analysis of Detection of Contaminants in Food where there is No Regulatory Level</u>**

Basic clarification:

- Most food regulatory systems are based on an approach that permission must be granted. But what does it mean if a permission has not been granted?
    - Permission revoked?
    - Considered, but not permitted due to demonstrable health risks?
    - Never considered?

- Where does it come from?

- What is the risk we are concerned about?

Considerations:

- Where does it come from?
  - Unintended
  - Intended (incl. food fraud, misuse)
- What is the risk we are concerned about? Public health? Trade?
- Risk tolerance
  - "Innocent until proven guilty?" (nothing is assumed dangerous until evidence demonstrates otherwise, prove of damage)
  - "Guilty until proven innocent"? (everything assumed dangerous to public health until it is proven otherwise, prove of safety)

Considerations:

- Timeframe needed
- What is known about the substance(s)
    - Chemical composition
    - Detection methods
    - Toxicological properties
    - Occurrence
    - Source
- Trade issue vs public health issue
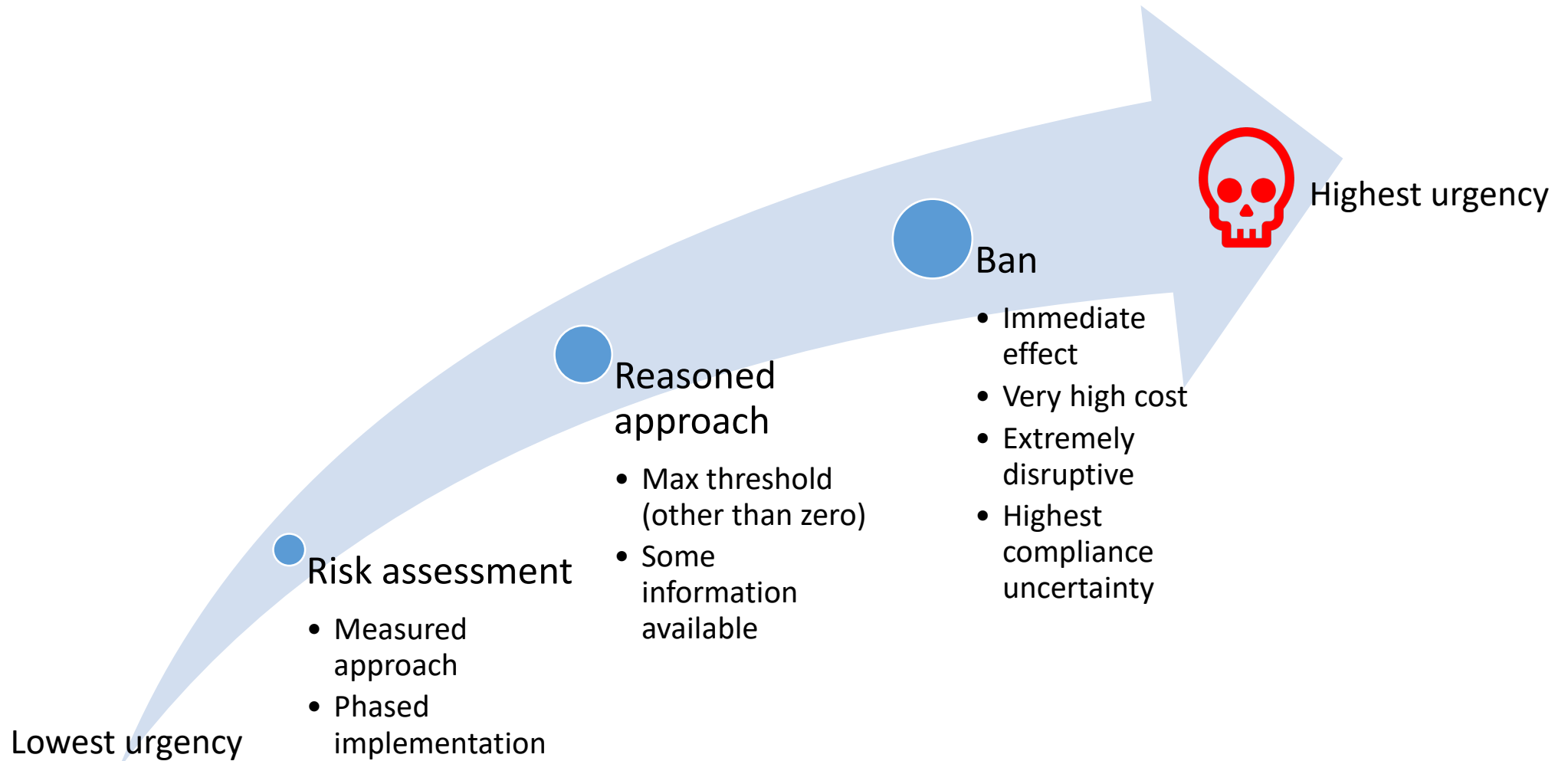
Considerations: Constraints

- Science takes time (formal risk assessment)
- Public crisis demands urgency
- Call for ban:
  - Assumes that agent and mechanisms are understood
  - May be suitable to avoid imminent and immediate harm to consumers
  - Possibly political expedient
  - Normally very costly
  - Very difficult to manage: zero tolerance is always a moving target and will attract ever more sensitive methods
  - Almost impossible to come back from
- All other options require lack of urgency and trigger more nuanced discussion

Risk management decision/options

- Zero-tolerance/ban: no threshold provided

- Tolerance level specified at limit of quantitation (LOQ)

- Tolerance at some higher levels (may apply for groups of compounds where information can be obtained from chemically related compounds); such tolerance levels are too low to allow use, but allow for adventitious presence

- No regulatory action until risk assessment has completed (evidence driven action); may be done in a staged manner: risk categorization/quick assessments before full risk assessment

The urgency to respond

Highest urgency

Ban

- Immediate effect
- Very high cost
- Extremely disruptive
- Highest compliance uncertainty

Reasoned approach

- Max threshold (other than zero)
- Some information available

Risk assessment

- Measured approach
- Phased implementation

Lowest urgency

The Codex Approach to Risk Analysis of Detection of Contaminants in Food where there is No Regulatory Level

- There is no single Codex approach

- The context will be critical

- With the absence of a compliance target, various risk management option exist:
  - Ban
  - Maximum threshold (LOQ or similar)
  - Await availability of more data/full risk assessment

Q&A