New Risk Assessment Methodologies

in the development of Food Safety Systems

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Food Industry Context

Business Risk Management
ISO 31010/9001
(guidance on selection and application of systematic techniques for risk assessment)

- Food Safety is a business risk for food companies
- The level of consumer protection required should be set by regulators
- Food companies are responsible for the safety of their products

Food Safety Risk Analysis	Food Safety Management Systems
Codex Alimentarius	Food Companies

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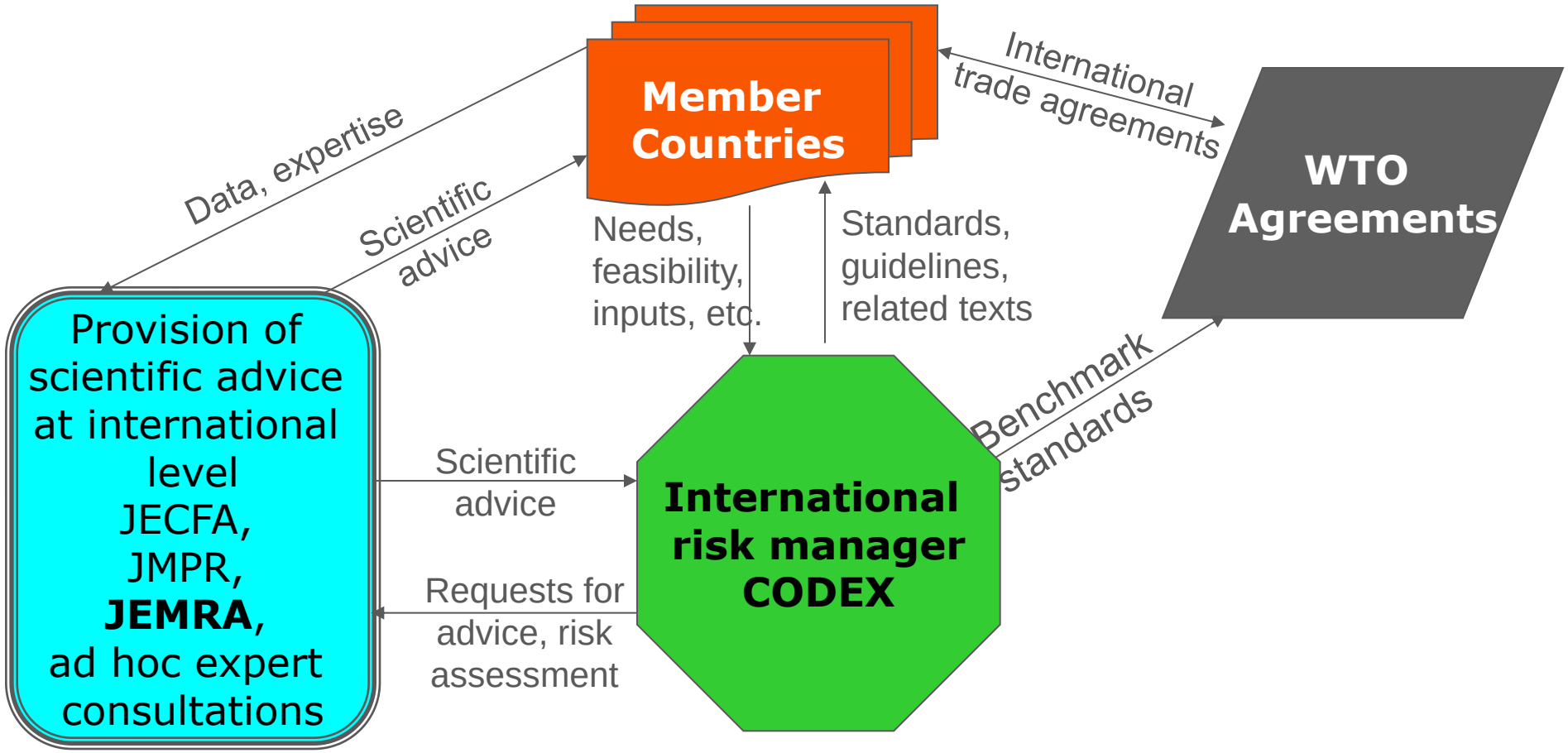
Food Industry Context

- Although responsibilities in the area of food safety are divided between a number of stakeholders the objective is the same ⟹ **consumer protection**.
- Because prevention is better than cure, consumer protection focuses on the prevention of placing on the market products that do not meet food safety requirements.
- In line with the WTO Sanitary and Phytosanitary agreements, science must be the basis for decisions made in the area of Food Safety.

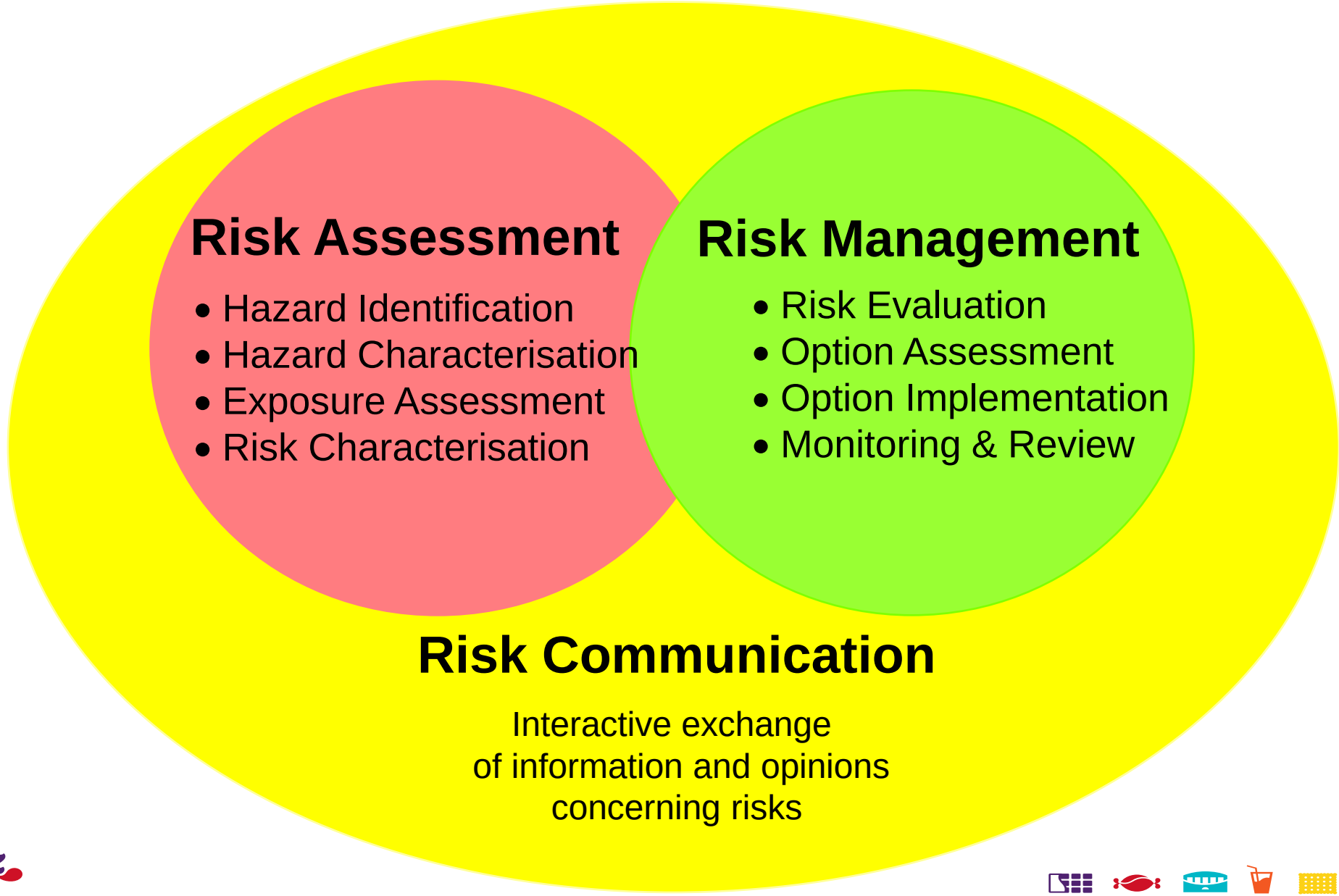
Food Industry Context

- Agreement has been reached at the CODEX ALIMENTARIUS level on keys terms related to food safety. In the interests of simplicity, clarity and harmonisation these definitions should be used by all stakeholders in the food chain:
    - Risk Analysis
        - Risk Assessment
        - Risk Management
        - Risk Communication
- Risk Assessment as defined by CODEX is a complex process and is used by Regulators in conjunction with Risk Management to set Food Safety Objectives.

International level



Risk analysis



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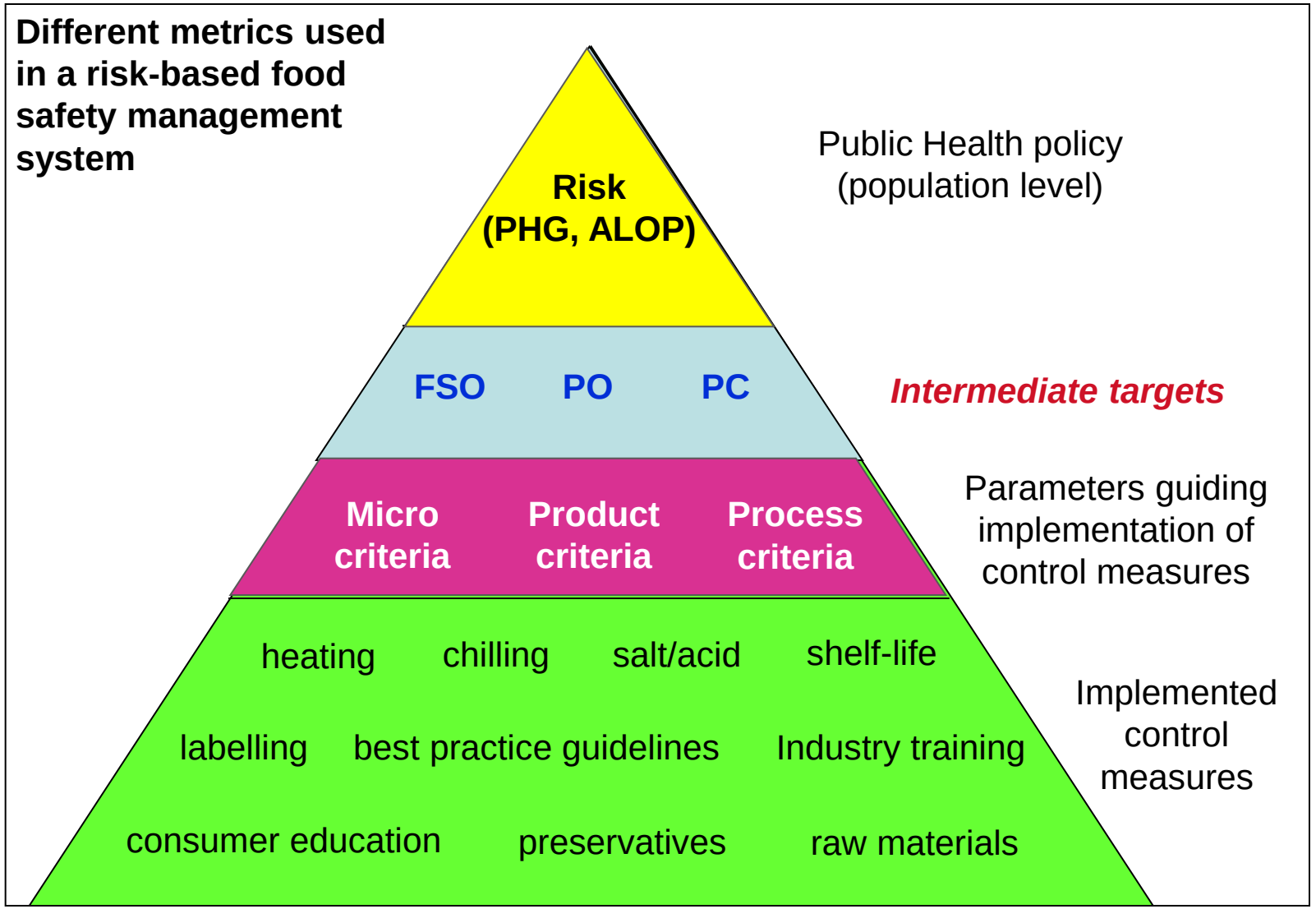

FAO/WHO “Kiel 3”

How risk assessment is relevant for food industry

Food industry can use the results of risk assessment to

- learn about differences in levels of hazard control between (typical) operations
- source appropriate raw ingredients
- appreciate different intervention strategies or management options
- provide insight in critical processes, handling, use
- develop and communicate examples of how to meet government requirements / performance standards

➢ Seen as an enabler to help strengthen food safety management systems

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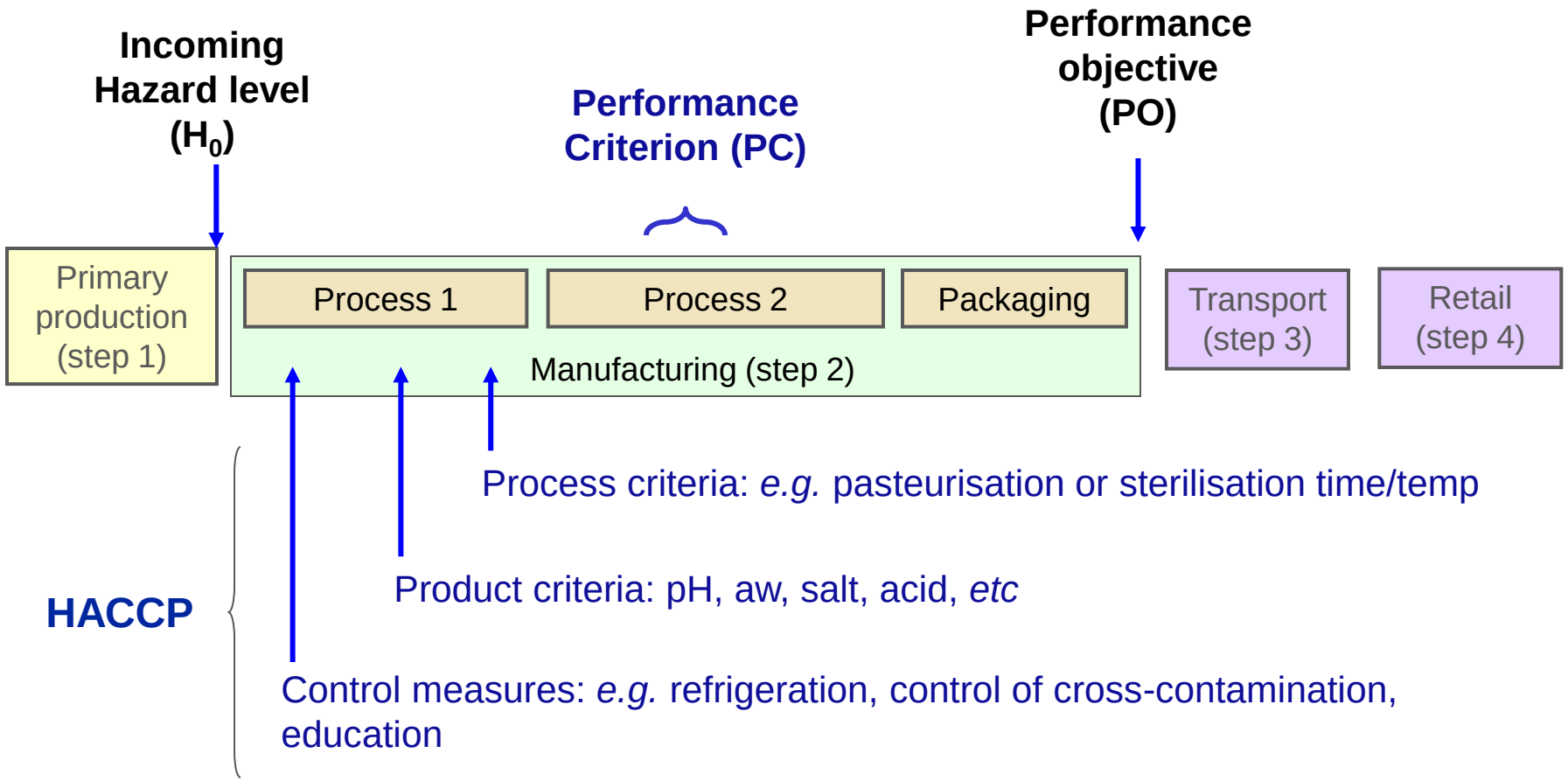
How to work with the risk-based metrics – an example for microbiological hazards



Are All Risk Assessments the same?

No - Fit the complexity risk assessment to the purpose

Basic Risk Assessment

The purpose of the Basic Risk Assessment is to rapidly determine, using the data readily available, whether there is potential human health impact as measured against published guideline values or benchmark criteria. If this question can not be clearly answered using the available date an advanced risk assessment will need to be undertaken. These can be completed in hours.

Are All Risk Assessments the same?

No - Fit the complexity risk assessment to the purpose

Advanced Risk Assessment

The Advanced Risk Assessment uses existing models or supporting tools either to refine data points or to fill in data gaps necessary for reaching a conclusion as to whether there is potential human health impact as measured against published guideline values or benchmark criteria. These can be completed in days.

Are All Risk Assessments the same?

No - Fit the complexity risk assessment to the purpose

Sophisticated Risk Assessment

The Sophisticated Risk Assessment refines either the hazard characterization or the exposure assessment using a combination of specific studies, complex models, mechanistic insights into pathways to further customise the modified criteria values calculated in the Advanced Risk Assessment to achieve a more accurate representation of the risk posed. These may take years to complete.

This tiered approach provides a systematic way of matching the approach used to the need

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Who is developing sophisticated Risk Assessment techniques

Regulatory Bodies (complex and/or mechanistic models)

- ECHA (European Chemicals Agency)
- EFSA (European Food Safety Authority)
- OECD (Organization for Economic Co-operation and Development)
- US-EPA (United States – Environmental Protection Agency)
- US-FDA (United States – Food and Drug Administration)
- WHO (World Health Organization)

What's Changing in Risk assessments?

- **More data:**
  - 120,000 chemicals registered under REACH each with more than 20 data points
- **Modelling**:
  - ECHA **QSAR** (Quantitative Structure-Activity Relationship) **Toolbox** **has 1 590 000 data points on different properties for around 59 000 chemicals**
- **Omics:**
  - **Metabolic simulators**
    - Population modelling using toxicokinetic/toxicodynamic (TK/TD)
    - Flux modelling for metabolic pathways in single organisms
    - Microbial community profiling (taxonomic) also linking to functionality (metabolic)
- **Shifting political priorities:**
  - We have successfully extended life expectancy but not **healthy life years**
    - Burden of obesity to NHS in 2016 was £6.1 billion and by 2050 obesity will cost the NHS £9.7 billion and the wider economy £49.9 billion*
- **Societal demand for transparency whilst being uncomfortable with uncertainty**:
  - Social media and alternative facts – NGOs have become businesses looking for the next story

*NICE (National Institute for Health Care Excellence, UK 2016)

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What's Changing in Risk assessments?

Peter W. Preuss (Director National Center for Environmental Assessment , US-EPA)

- Current toxicity testing can't provide all the data needed for risk assessment. There are simply too many chemicals, too many tests, and too many questions
- Using animals to test chemicals thoroughly is time-consuming and expensive and un-ethical - we just need to move on to something else

2004 US-EPA creates the National Center for Computational Toxicology (NCCT) Anticipating that bioinformatics will be a heavy component of any new risk-assessment

2007 NCCT launches ToxCast to rapidly predict whether chemicals are toxic to humans and to help prioritize which ones should be targeted for further testing. Robotic technologies make it possible to screen the biological activity of high numbers of chemicals.

2016 - EPA lays out a framework for incorporating advances in genomics and computational sciences into toxicity testing and risk assessment. The approach entails examining the network of pathways formed when genes, proteins, and small molecules interact. The goal is to understand how chemical exposures can perturb such pathways and lead to a cascade of events that ultimately cause adverse health effects.

"That starts to get us to predicting toxicity in humans rather than in rats".

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Main areas of impact on the food industry

- Packaging
- Food contact materials
- Additives
- Processing
- Raw materials (animals and zoonosis epidemiological/spread models)
- Pesticides

- Both human health and environmental impact

The opportunity

- Industry needs to meet the dual drive for increasing Transparency and Reducing Uncertainty if it is to maintain public Trust in the Food Supply

Mechanistic models

- OMICs and their integration into biological function
- Quantitative Structure Activity Relationships (QSAR)
- physiologically-based modelling

are key approaches that will reduce uncertainty and increase the scientific basis of risk assessment.

A paradigm shift in chemical and microbiological risk assessment will not be easy. It will require a sustained commitment for resources, collaboration, and the political will to push the effort forward.

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Thank you for your Attention!