CHIFSS
CII-HUL Initiative on Food Safety Sciences

Unilever

# Introduction to Modern, Effective Food Safety Management


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# Outline

- Modern, effective food safety management
  - Why is it needed?
  - Evolution in food safety management
  - Risk Analysis as the modern framework
  - Quantitative Microbiology* to make it effective.

[1] Quantitative Microbiology: e.g. predictive microbiology, quantitative risk assessment.

# Why do we need food safety management?

# Government perspective (1)

US-CDC estimates that each year roughly:

- 48 million out of ~300 million people get sick (~1 in every 6)
- 128,000 are hospitalized (~1 in 2500)
- 3,000 die of foodborne diseases (~1 in 100,000).

India, estimates:

- 170,000 are hospitalized (~1 in 7000)
- Cost: 28B$ (5% of GDP).

# Government perspective (2)

**Table 1. Estimated annual number of domestically acquired foodborne illnesses, hospitalizations, and deaths due to 31 pathogens and unspecified agents transmitted through food, United States**

| Foodborne agents | Estimated annual number of **illnesses** (90% credible interval) | % | Estimated annual number of **hospitalizations** (90% credible interval) | % | Estimated annual number of **deaths** (90% credible interval) | % |
|---|---|---|---|---|---|---|
| 31 known pathogens | 9.4 million (6.6–12.7 million) | 20 | 55,961 (39,534–75,741) | 44 | 1,351 (712–2,268) | 44 |
| Unspecified agents | 38.4 million (19.8–61.2 million) | 80 | 71,878 (9,924–157,340) | 56 | 1,686 (369–3,338) | 56 |
| Total | 47.8 million (28.7–71.1 million) | 100 | 127,839 (62,529–215,562) | 100 | 3,037 (1,492–4,983) | 100 |

http://www.cdc.gov/foodborneburden/pdfs/factsheet_a_findings_updated4-13.pdf

# Government perspective (3)

**Table 2. Top five pathogens causing domestically acquired foodborne illnesses**

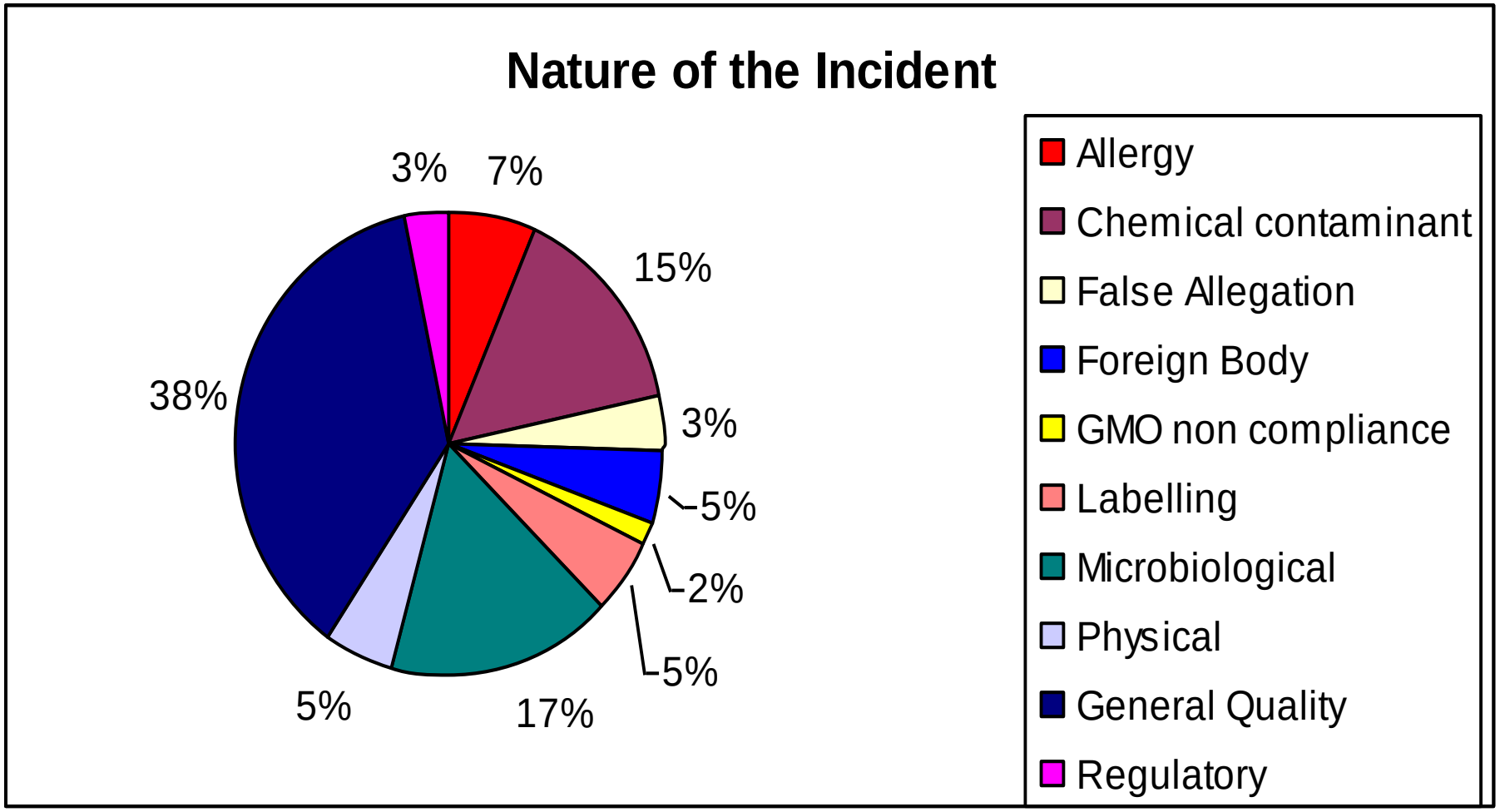
| Pathogen | Estimated annual number of illnesses | 90% Credible Interval | % |
|---|---|---|---|
| Norovirus | 5,461,731 | 3,227,078–8,309,480 | 58 |
| *Salmonella*, nontyphoidal | 1,027,561 | 644,786–1,679,667 | 11 |
| *Clostridium perfringens* | 965,958 | 192,316–2,483,309 | 10 |
| *Campylobacter spp.* | 845,024 | 337,031–1,611,083 | 9 |
| *Staphylococcus aureus* | 241,148 | 72,341–529,417 | 3 |
| Subtotal | | | 91 |

http://www.cdc.gov/foodborneburden/pdfs/factsheet_a_findings_updated4-13.pdf

# Severity of hazards

| Human pathogen | Illnesses (%) | Hospital. (%) | Death (%) |
|---|---|---|---|
| *Bacillus cereus* | 0.198 | 0.014 | 0 |
| *Staphylococcus aureus* | 1.3 | 2.9 | 0.107 |
| *Yersinia enterocolitica* | 0.628 | 1.8 | 0.126 |
| *Clostridium botulinum* | 0.00042 | 0.076 | 0.246 |
| *Vibrio* | 0.038 | 0.203 | 1.7 |
| *E. coli O157:H7* | 1.3 | 4.6 | 4.3 |
| ***Campylobacter*** | **14.2** | **17.3** | 5.7 |
| ***Listeria monocytogenes*** | 0.018 | 3.8 | **27.5** |
| ***Salmonella*** | **9.7** | **25.7** | **30.4** |

# Operational perspective on hazards



# Evolution of food safety management

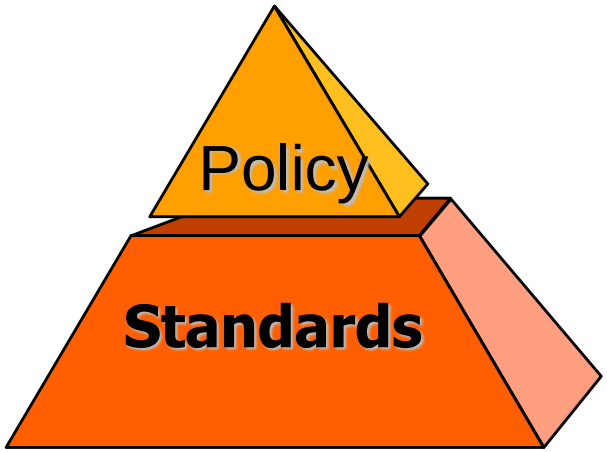
# What is Food Safety Management?

- Ensuring consumer protection

- A joined responsibility with complementary accountabilities
  - **Government**: “controlling” food safety by defining food safety regulations & standards
  - **Industry**: “managing” safe food delivery day-by-day
  - **Consumers**: keeping safe food safe
  - **Academia**: developing science underpinning food safety

# Food Safety *Control* & Foods Safety *Management*

**Country level**




**Food Safety *Control*:**

- High level, generic
- Policy-based guidance
- Specific standards, criteria

**Operational level**

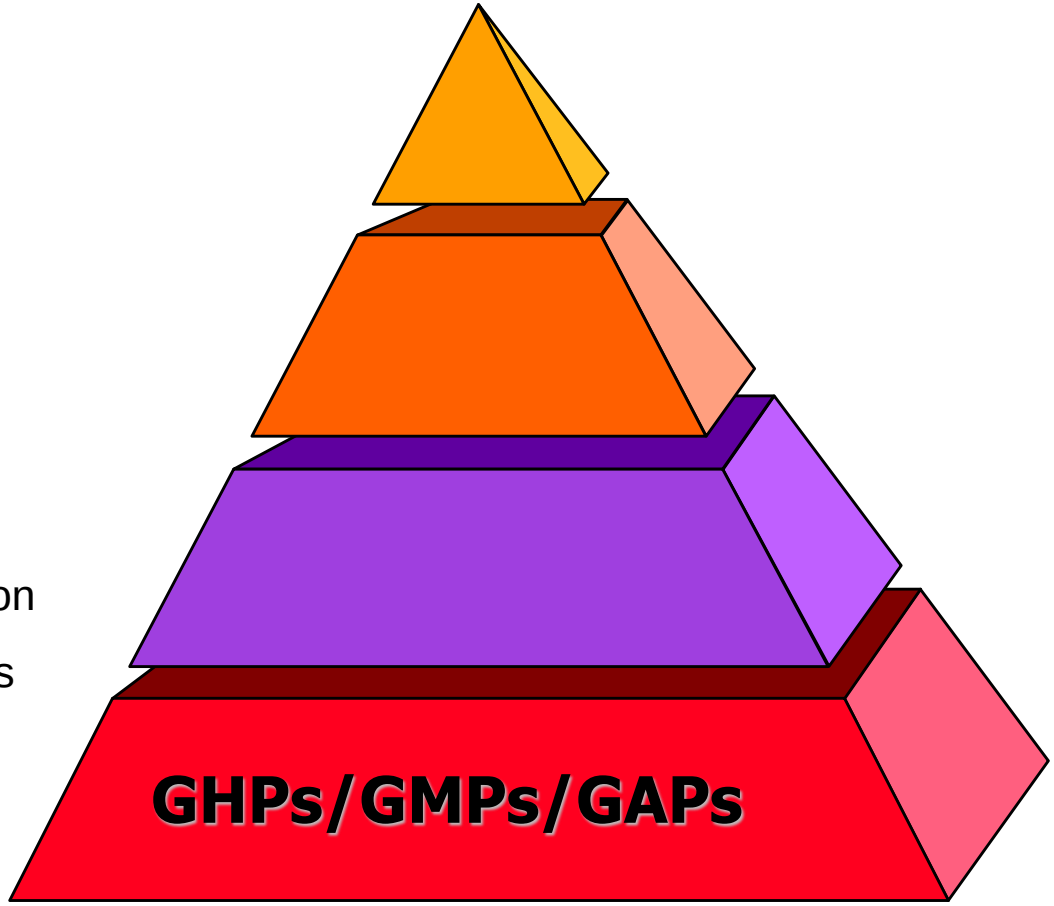

**Food Safety *Management*:**

Local, specific management at supply chain level

**INCLUDES ALL HAZARDS**

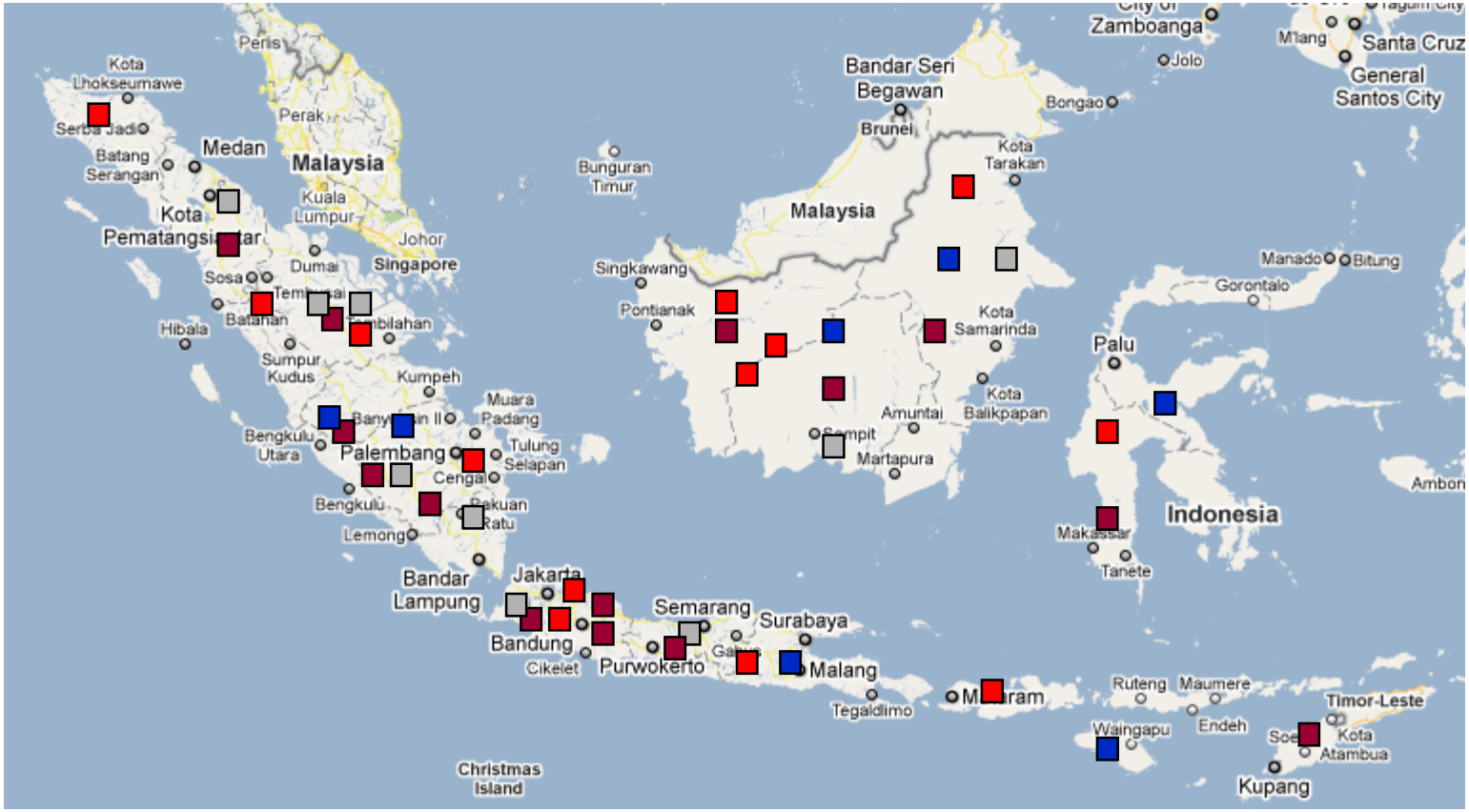
# “Good Practices”

- The foundation of all food safety management systems are Good Practices (Good *Manufacturing* Practices, Good *Hygiene* Practices; Good *Agricultural* Practices)
- They provide general, generic guidance on sanitary practices and on the level of care expected of facilities handling or manufacturing foods



# “Good Practices” are generic

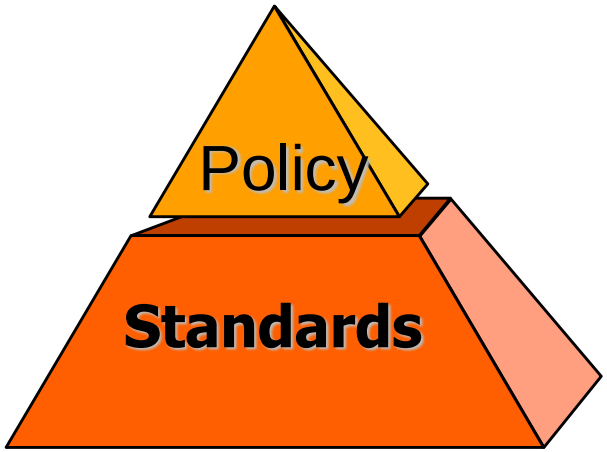
Different types of food operations may have similar/same good practice programs (GAPs, GHPs, GMPs)




*Good practices have helped improve food safety management, but still food-borne disease outbreaks may occur due to lack of specific, critical controls*

# Food Safety *Control* & Foods Safety *Management*

**Country level**

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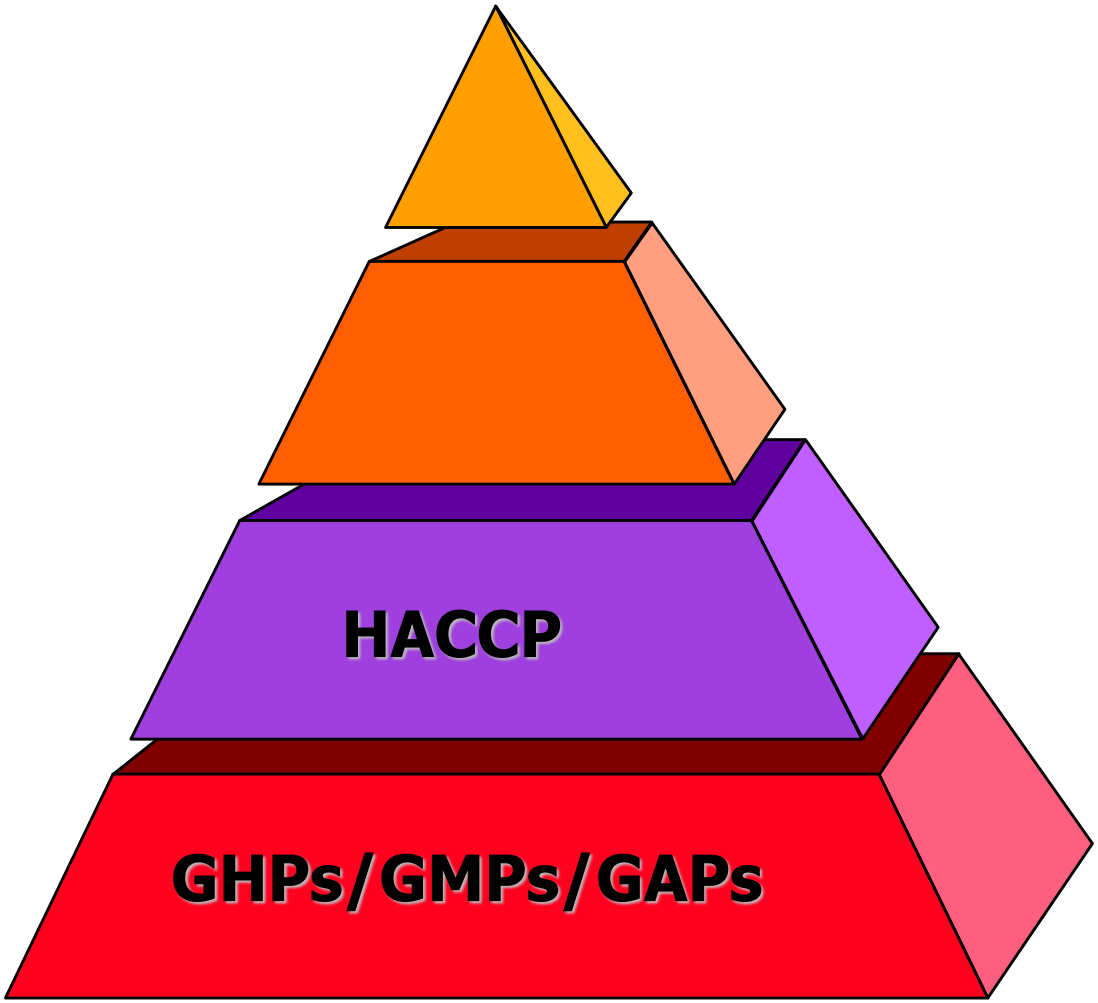
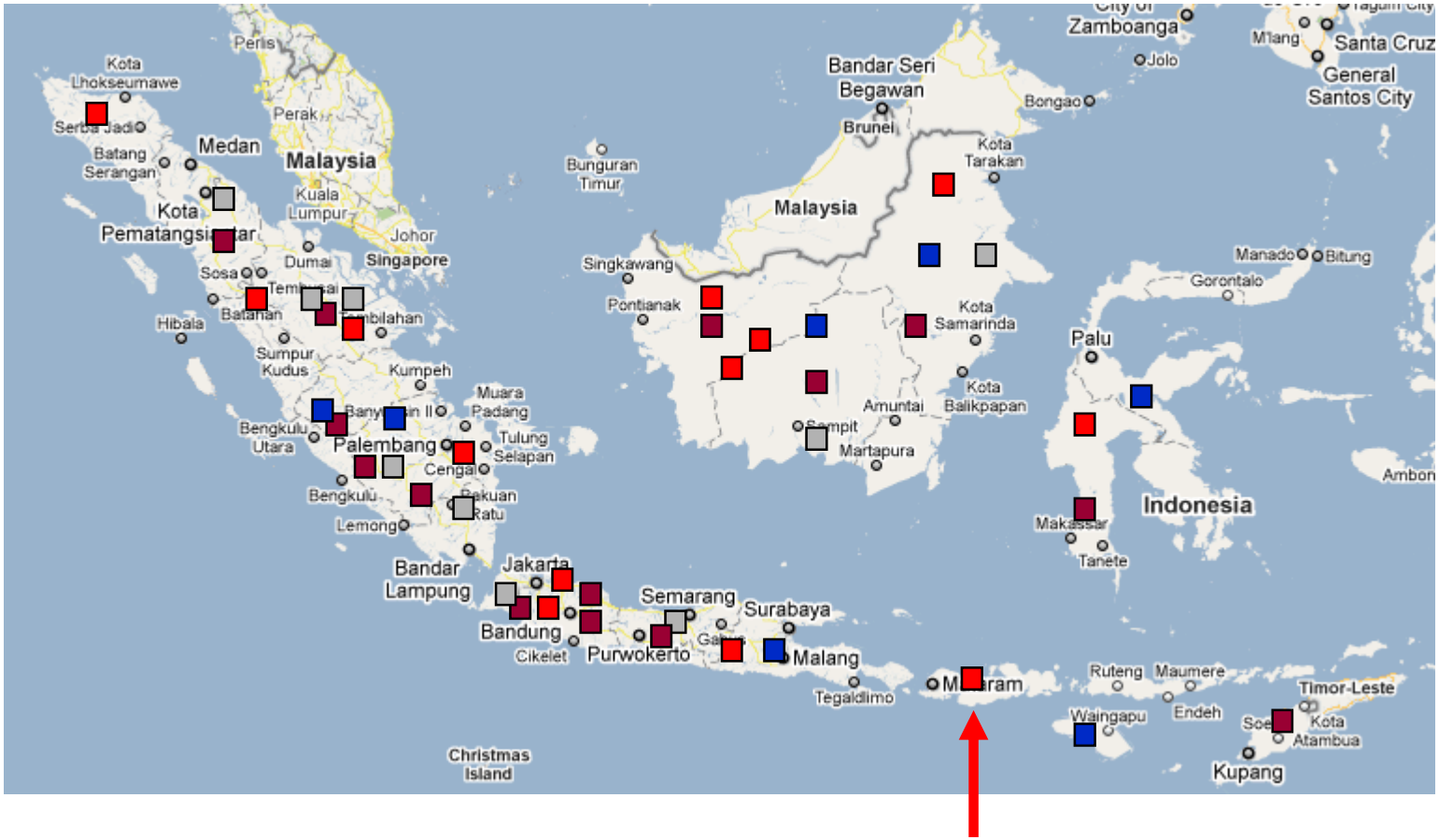
# HACCP

- Hazard Analysis Critical Control Point (HACCP)
- Augments Good Practices with a more systematic, targeted approach to focus control efforts specifically on critical control measures
- HACCP systematically evaluates all possible hazards for a specific operation and establishes the necessary controls for significant hazards
- Control measures at critical points are duly monitored to verify ongoing control during operation



# HACCP is very specific




HACCP concerns a specific product, manufactured on a specific location & production-line & food product-batch

# Food safety management - stringency

- *Stringency* (i.e., required level of hazard control) is often not defined in today's regulations and standards
- Sometimes, Governments give explicit guidance on *stringency* by setting quantitative limits to certain hazards
- *Stringency* is otherwise a result of the (technical) ability of a food business operator to manage their operation

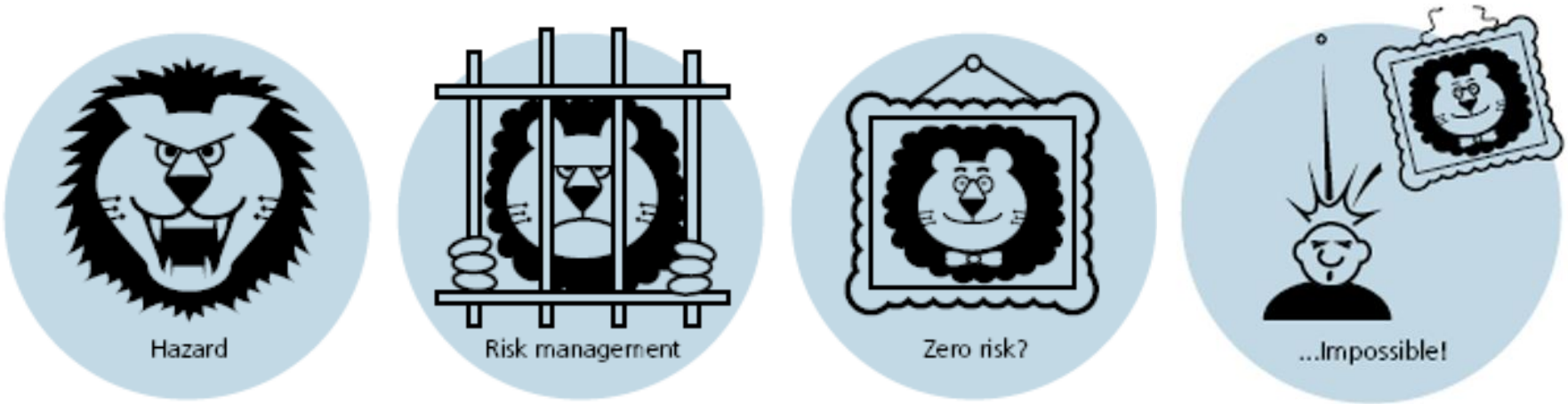
# So are foods then always safe?

- Food safety will depend on:
  - Whether there is any form of management
  - Whether management is by best practices only
  - Whether additionally HACCP is implemented
  - Whether there is quantitative governmental guidance on the “stringency” required for control of specific hazards in foods, e.g.
    - Limits for hazards or microbiological criteria
    - Performance standards for processing

# Modern food safety management?

- Provides risk-based guidance to industry:
  - Explicitly defines *stringency* of hazard control based on the **risk** that the hazard poses to consumers
  - Drives for management that is *proportional* to the **risk**

# Hazard & Risk




**The difference between RISK and HAZARD** (no animals were harmed in the making of this cartoon).

# Modern food safety management?

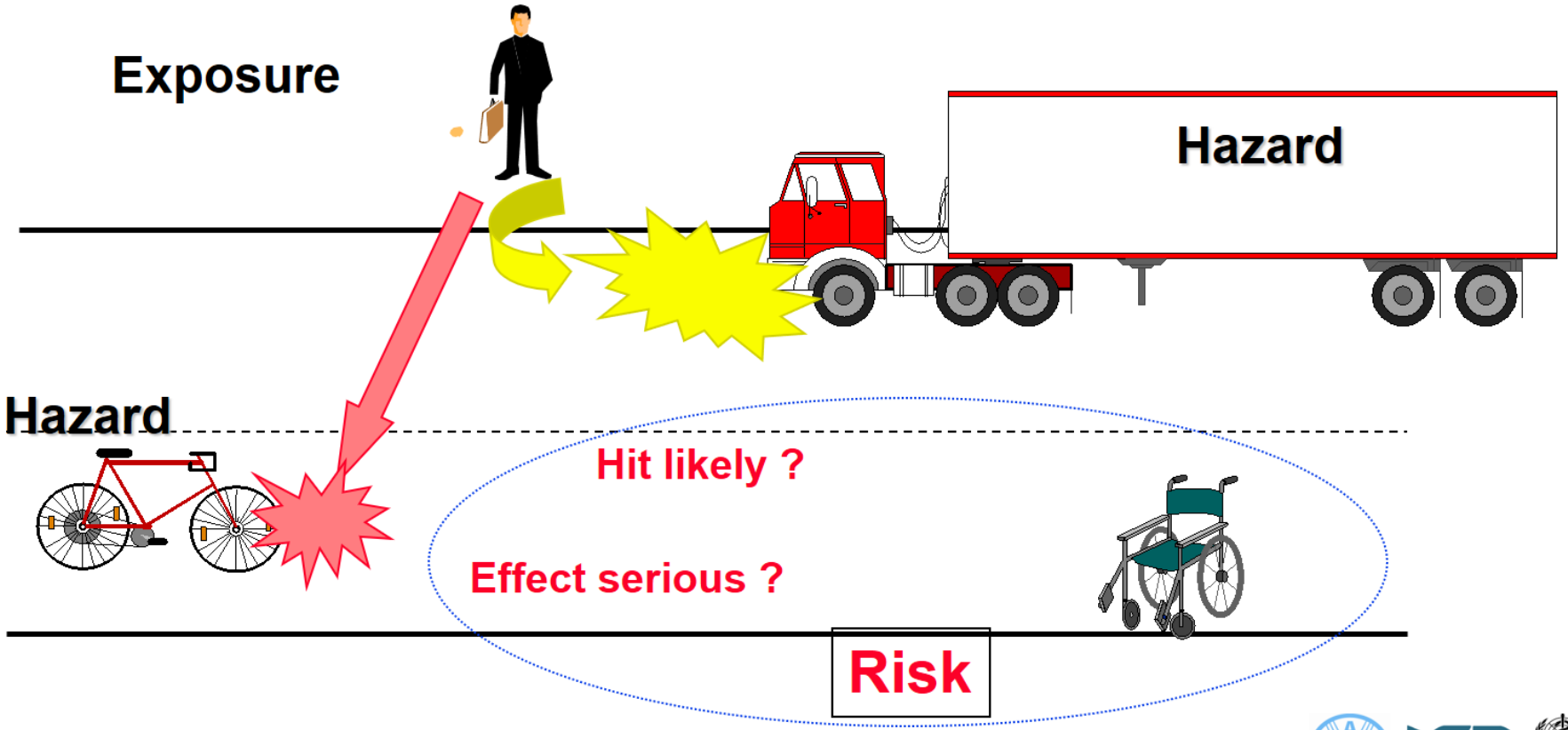
- Provides risk-based guidance to industry:
  - Defines *stringency* of hazard control based on the **risk** that the hazard poses to consumers
  - Drives for management that is *proportional* to the **risk**
  - Moves away from “zero risk” as the ideal as this is not necessarily realistic or needed
  - Recognizes that hazards may not always pose a **risk** that is *unacceptable*

# Risk-based food safety management

# Terminology: Hazard & Risk (microbiology)

- **Hazard:** An agent causing an adverse effect (microbe, toxin)
- **Exposure:** Estimate of the hazard level in the food consumed
- **Severity:** Extent of adverse health effect on the consumer caused by the hazard
- **Risk:** *A combination of* exposure and severity
- **Probability:** a feature of all aspects above, e.g.
  - Probability of the hazard actually being present in a food
  - Probability of the consumer eating that contaminated food
  - Probability of the consumer being sensitive to the adverse health effect of the hazard

# Risk and hazard



# Not every hazard necessarily poses a risk

- Without exposure there is no risk
- Potential hazard presence does not equate to actual presence
- Hazards vary in severity
- Consumers vary in susceptibility
- Low levels of a hazard may not be unsafe for specific consumers
- Capable industries can manage hazards to a defined “acceptable level of risk”

- Sound science can inform on these aspects
- **Risk Assessment** is the best practice approach to assemble the science
- **Risk Management** is the best approach for decision making

Risk Analysis Framework

# What is acceptable risk ?

# Levels of "Risk"

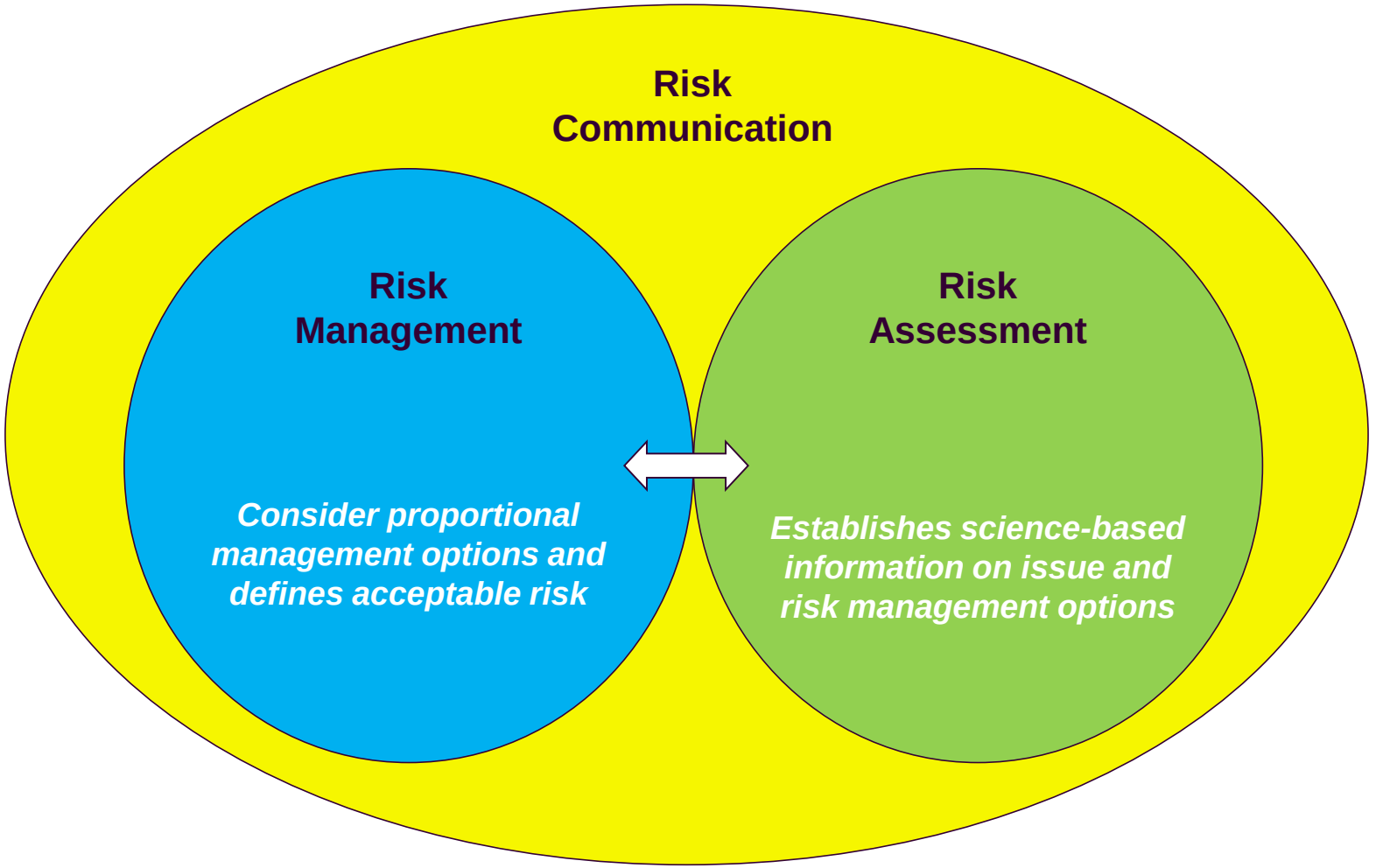
| Term used | Risk range | Example | Risk estimate |
|---|---|---|---|
| *HIGH* | 1:100 | (A) Transmission to susceptible household contacts of measles and chickenpox | 1:2 |
| | | (A) Transmission of HIV from mother to child | 1:6 |
| | | (A) Gastrointestinal effects of antibiotics | 1:10-1:20 |
| *MODERATE* | 1:100-1:1000 | (D) Smoking 10 cigarettes a day | 1:200 |
| | | (D) All natural cause, age 40 | 1:850 |
| *LOW* | 1:1000-1:10.000 | (D) All kind of violence and poisoning | 1:3300 |
| | | (D) Influenza | 1:5 000 |
| | | (D) Accident on road | 1:8 000 |
| *VERY LOW* | 1:10.000-1:100.000 | (D) Leukaemia | 1:12 000 |
| | | (D) Playing soccer | 1:25 000 |
| | | (D) Accident at home | 1:26 000 |
| | | (D) Accident at work | 1:43 000 |
| | | (D) Homicide | 1:100 000 |
| *MINIMAL* | 1:100.000-1:1.000.000 | (D) Accident on railway | 1:500 000 |
| | | (A) Vaccination associated polio | 1:1 000 000 |
| *NEGLIGIBLE* | 1:10.000.000 | (D) Hit by lightning | 1:10 000 000 |
| | | (D) Release of radiation by nuclear power Station | 1:10 000 000 |

1: Risk of an individual dying (D) in any one year or developing an adverse response (A)

KC Calman, 1996

# Risk Analysis Framework

… the latest step in the evolution of food safety management



# Acceptable level of Risk

… a government decision


Public Health Goal

Appropriate Level of Protection (**ALOP**)

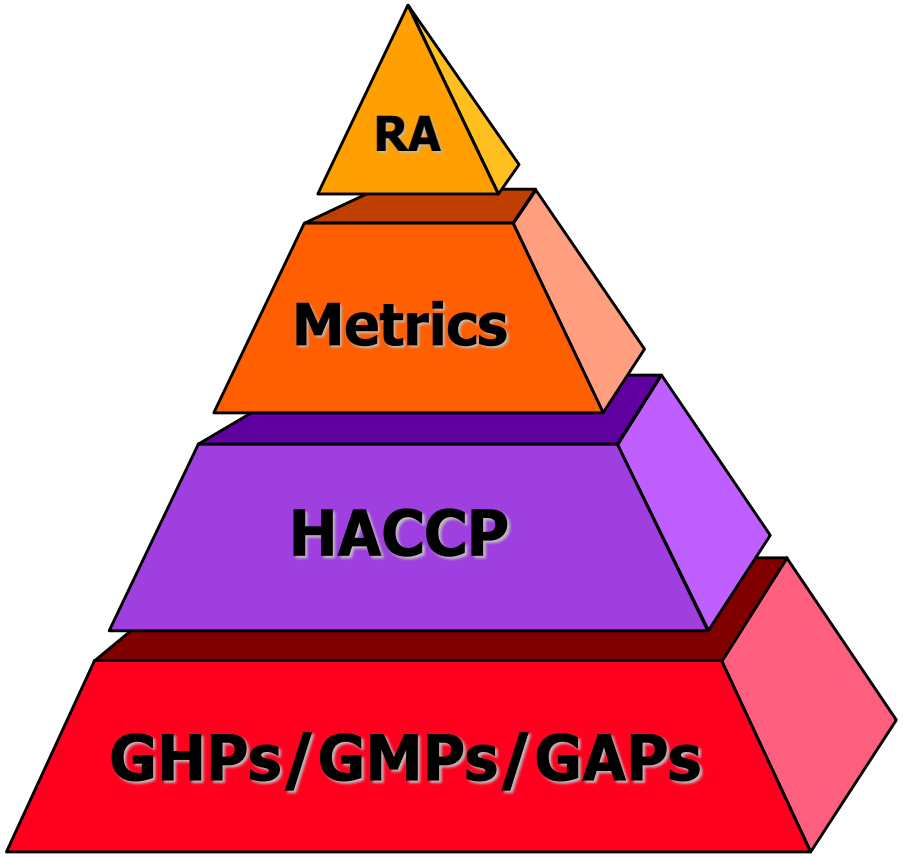
*Tolerable Level of Risk (TLR)*

*Acceptable level of risk (ALR)*

# Risk Analysis Framework

… Modern way to decide on Effective food safety management

- Risk Analysis (RA)
- Triggered by World Trade Organisation (WTO)
- Advocated by many governments and inter-governmental organisations (FAO, WHO, Codex)
- Risk Analysis may be used to define *risk-based metrics* that provide explicit, quantitative guidance (ALOP, FSO, POs, MCs)



# Risk-based metric – example FSO

**Risk Level (RL)**

**RISK ANALYSIS**

Risk Assessment

Risk Management

Risk Communication

Decisions?

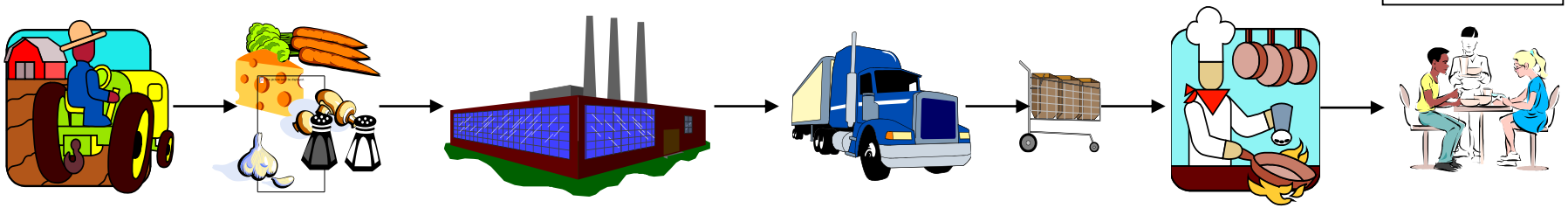
RL < PL: e.g. no action needed

RL = PL: e.g. no action needed

RL > PL: e.g. risk reduction action needed

**Policy Level of risk (PL): ALOP[1] or public health goal**

**FSO[2]**



[1]: ALOP, Appropriate Level Of Protection; [2]: Food Safety Objective

# How do governments use Risk Analysis?

- To develop an estimate of the risk to human health and safety
- To prioritize between risks that require mitigation
- To identify appropriate measures to mitigate a risk, *e.g.* to:
  - identify the various points of control along the food chain at which measures could be applied
  - weigh up the respective costs and benefits
  - determine the most effective one(s)
- To communicate with stakeholders about risks and mitigation options

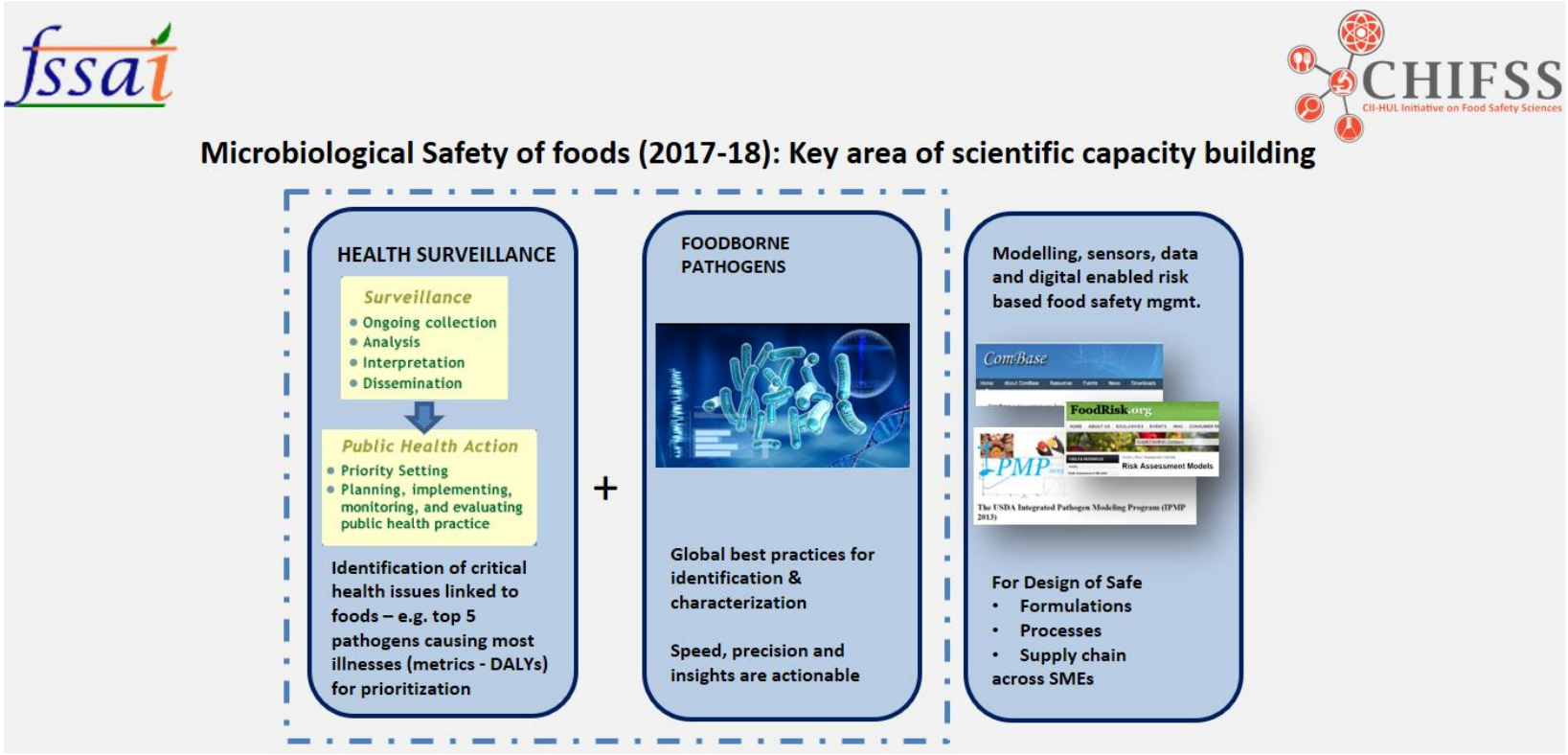
# Risk Analysis benefits?

- *Stringency* of required hazard control is:
  - “articulated”, i.e. quantified
  - “proportional”, i.e. based on risk posed by the hazard
  - “science-based”, i.e. objectively defendable
  - in-line with policies on public health protection
  - providing a measure for equivalence of product safety

# Risk Analysis Pre-requisites

- Data on pathogens & foods (surveillance; incident investigation; epidemiology) - government

- Quantitative methods/approaches for data handling/processing (e.g. Predictive modelling, Risk Assessment; etc)



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# Questions?

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