FOOD SAFETY ASSESSMENT

Recognition of the significant impact of food borne contaminants (poisonings, diseases etc) in terms of human suffering and economic costs to society and industry, combined with an increasing global food trade has underlined the need for

a structured risk assessment

HACCP is only one part of the risk analysis process
HACCP is a risk management tool not a risk assessment tool

RISK ANALYSIS FRAMEWORK
(Adapted from Benford, 2001)

Codex Alimentarius Commission (CAC)

A four step risk assessment framework

- HAZARD IDENTIFICATION
- HAZARD CHARACTERIZATION
- EXPOSURE ASSESSMENT
- RISK CHARACTERIZATION

RISK – *a function of the probability of an adverse health effect and the magnitude of that effect, consequential to a hazard in food*

HAZARD – *a biological (chemical or physical) agent in or property of food that has the potential to cause an adverse health effect*

HAZARD = a biological, chemical or physical agent with the potential to cause an adverse health effect (e.g. Salmonella could be in food and it could make someone ill) .....CODEX definition

RISK = the likelihood of an adverse event (e.g. a consumer gets food-borne illness) and the severity of that event

RISK ≠ HAZARD

RISK ANALYSIS

RISK ASSESSMENT – a process to scientifically evaluate the probability of occurrence and severity of known or potential adverse health effect resulting from human exposure to foodborne hazards

RISK MANAGEMENT– a process to weigh policy alternative in light of the results of risk assessment and, if required, to select and implement appropriate control option

RISK COMMUNICATION – a process to exchange information and opinions interactively among risk assessors, risk managers and other interested parties

KASUS (1)
Formalin dalam berbagai bahan dan produk olahan pangan lokal

KASUS (2)
Melamin dalam sebuah produk makanan bayi impor

RISK ASSESSOR
RISK MANAGER
OTHER INTERESTED PARTIES

?

RISK ASSESSOR

pihak yang berperan menentukan keberadaan bahaya dalam pangan dan tingkat risikonya terhadap kesehatan konsumen

RISK MANAGER

pihak yang berperan mengambil tindakan (mengelola) untuk meminimalkan risiko gangguan kesehatan karena keberadaan dan paparan bahaya dalam produk pangan.

OTHER INTERESTED PARTIES

semua pihak yang berkepentingan terhadap risiko kesehatan yang berasal dari bahan/produk pangan

1. Prior knowledge on the substance:
   - origin of the substance
   - history of use and consumption
   - chemical identity, characterisation and specification
   - effect of processing on substance and on whole food
   - effect of transport and storage

2. Prior knowledge on exposure

3. Prior knowledge on possible biological effect(s)
   - qualitative aspects
   - quantitative aspects
   - predicted effects

Fig. 2. The systematic collection of prior knowledge.

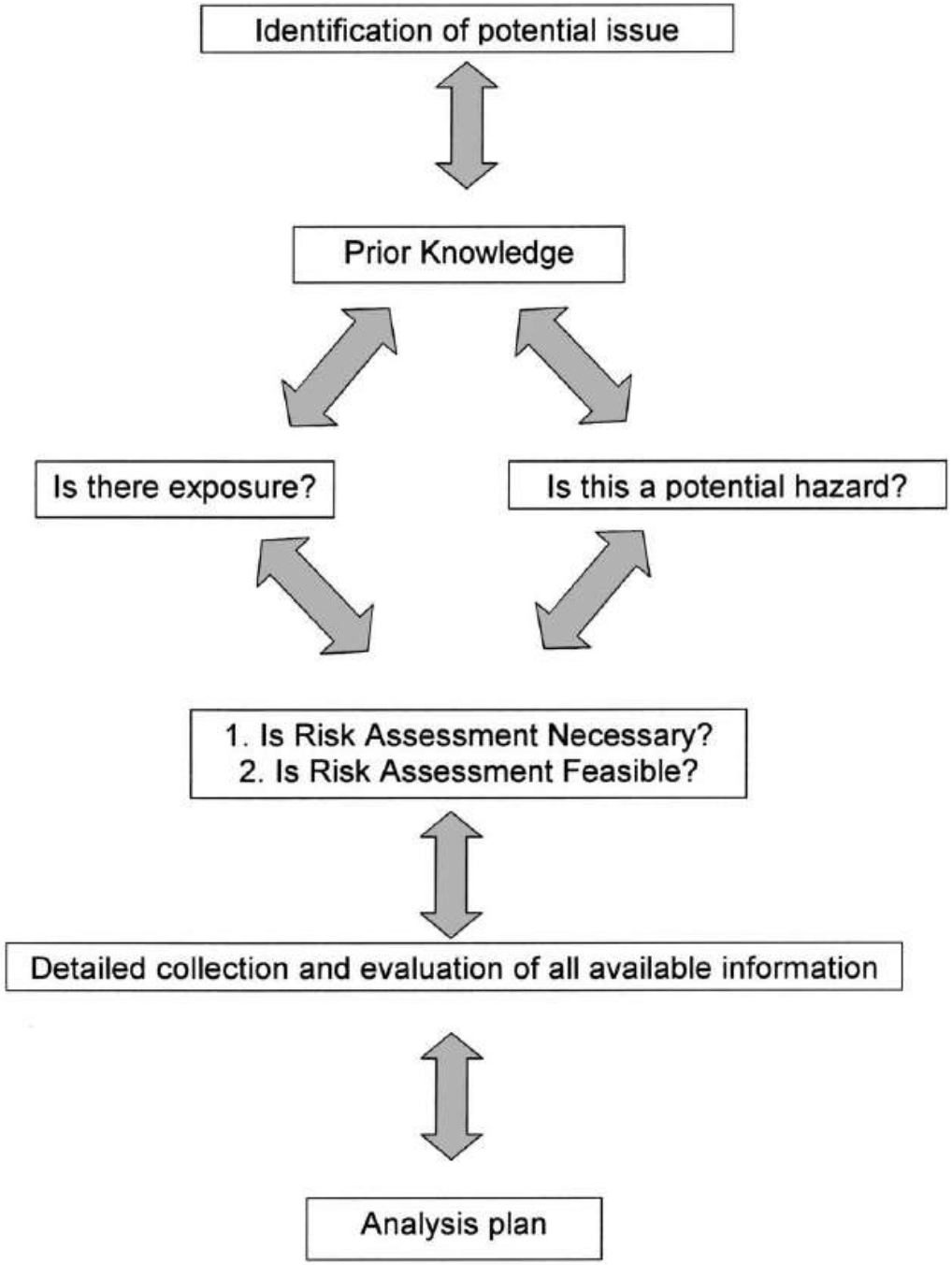
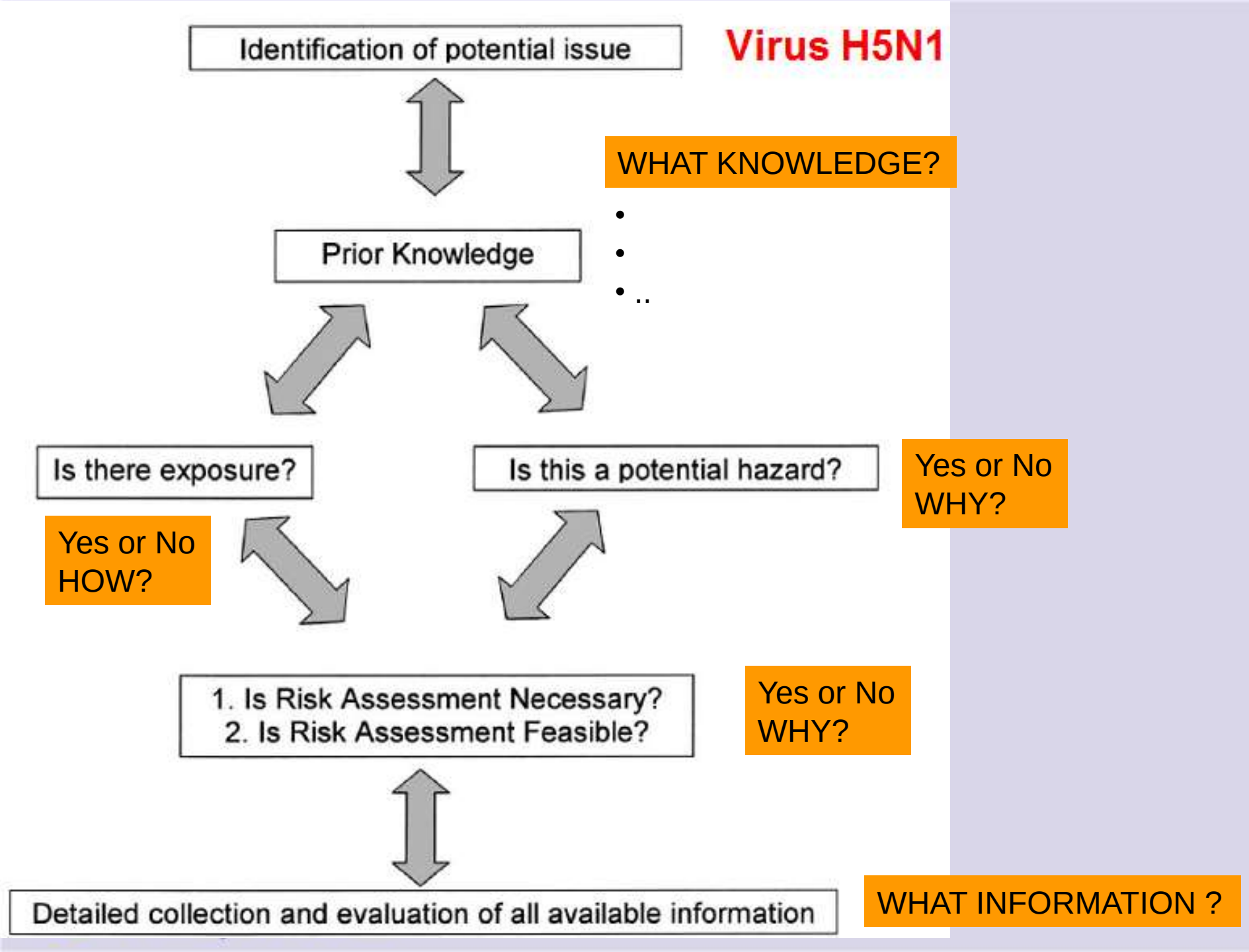


Fig. 3. Problem formulation for risk assessment is an iterative process requiring a dialogue between stakeholders.


Identification of potential issue
Virus H5N1
WHAT KNOWLEDGE?
Prior Knowledge
Is there exposure?
Is this a potential hazard?
Yes or No
WHY?
Yes or No
HOW?
1. Is Risk Assessment Necessary?
2. Is Risk Assessment Feasible?
Yes or No
WHY?
Detailed collection and evaluation of all available information
WHAT INFORMATION ?

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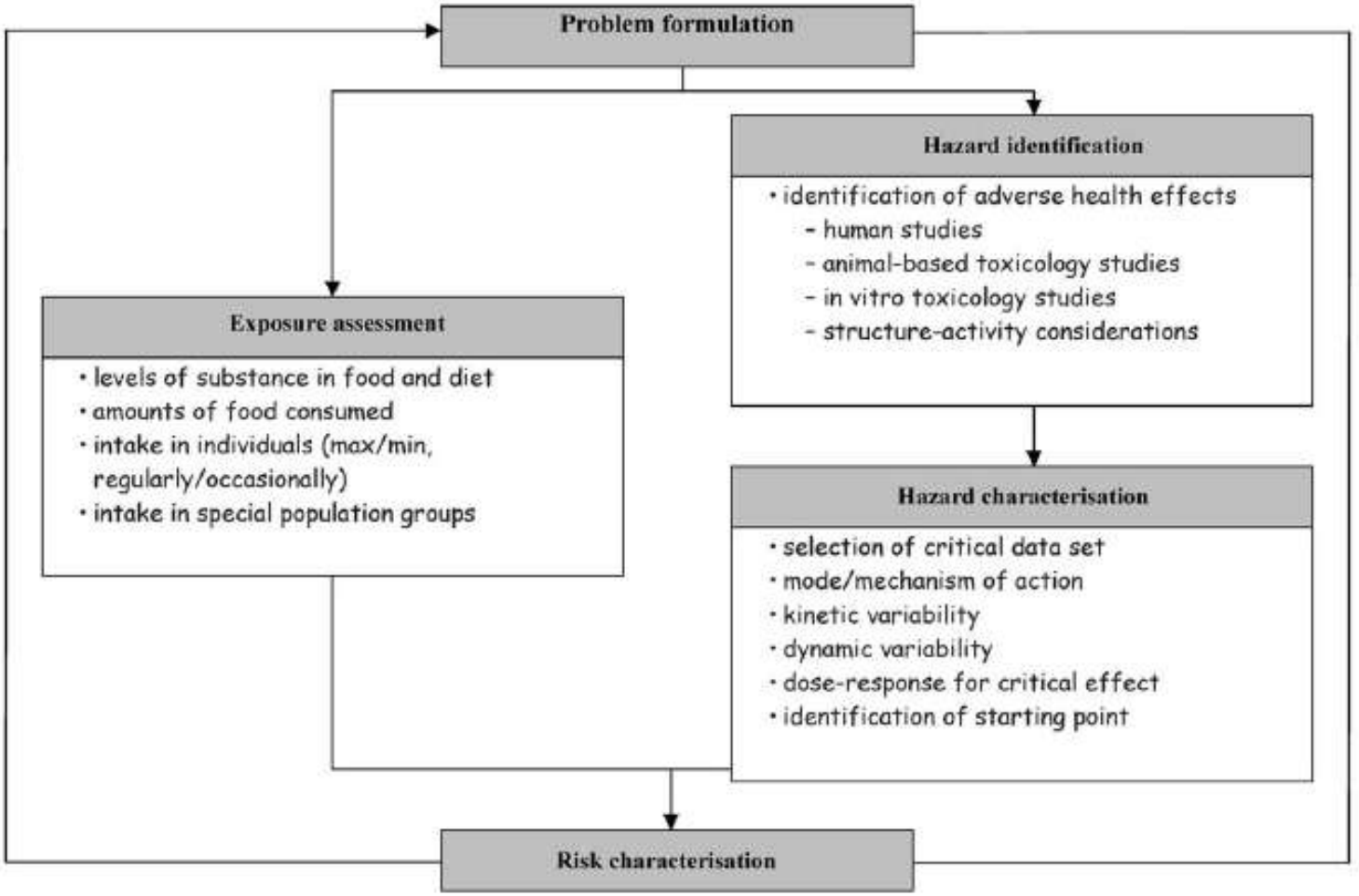


Fig. 1. The risk assessment paradigm.

Renwick *et al.*, 2003

A Four-Step Risk Assessment Framework

1. HAZARD IDENTIFICATION

identification of biological/chemical agents that are capable of causing adverse health effects and may be present in a particular food or group of foods

⇨**Information (biological, epidemiological etc) and expert knowledge on the link between a biological/chemical agent in a specific food and illness in consumers**

2. HAZARD CHARACTERIZATION

the qualitative and/or quantitative evaluation of the nature of the adverse effects associated with biological agents that may be present in food

⇨**Dose response assessment – determination of the relationship between the numbers of the MO ingested (or the concentration of a microbial toxin) and the frequency and severity of defined adverse health effects resulting from ingestion**

3. EXPOSURE ASSESSMENT

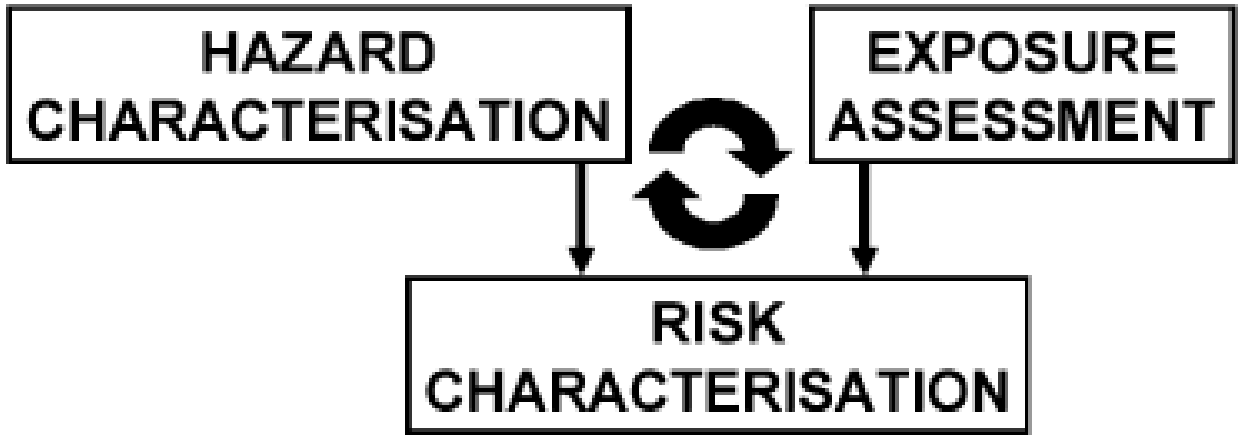
the qualitative and/or quantitative evaluation of the likely intake of the biological agent via a food

⇨**Estimation of the probability of consumption and the amount of biological agent likely to be consumed. All sources of entry of the hazard into the food should be evaluated.**

4. RISK CHARACTERIZATION

the qualitative and/or quantitative estimation of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard indentification, hazard characterization/dose-response, and exposure assessment

⇨**Combines all the information gathered to produce a statement of risk, also includes a summary of uncertainties and variability of the information used to derive the risk estimate**



Is the exposure sufficient to warrant full hazard characterisation?

Is the hazard relevant to the exposed individuals?

Do the hazard characterisation data match the human exposure?

Integration of new data on hazard identification or characterisation

Integration of new data on increased or altered pattern of uses

Integration of new data on the nature of the distribution within food

Fig. 4. The iterative nature of risk characterisation, with examples of questions and information that can affect the outcome.

Decisions about hazards are essential to control, reduce, or eliminate requires definition of limits dictated by acceptable levels of risk.

The notion of an "acceptable" or "tolerable" level of risk is a VALUE-LADEN concept that must be addressed by policy makers together with the public.

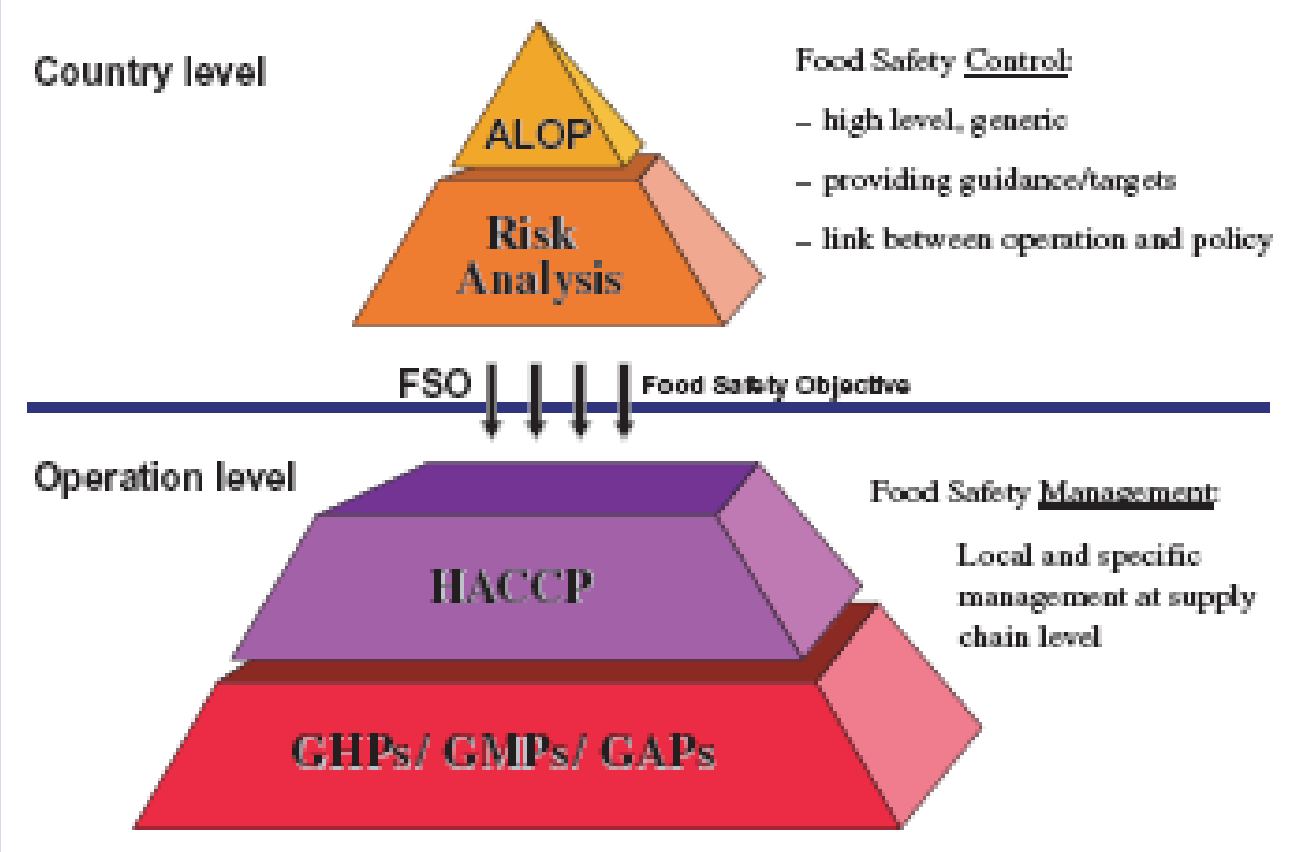


Illustration of how Food safety control at a country level can link into Food Safety Management at the operational level through a Food Safety Objective set by a governmental competent authority on the basis of a public health goal (ALOP) established following the Risk Analysis framework.

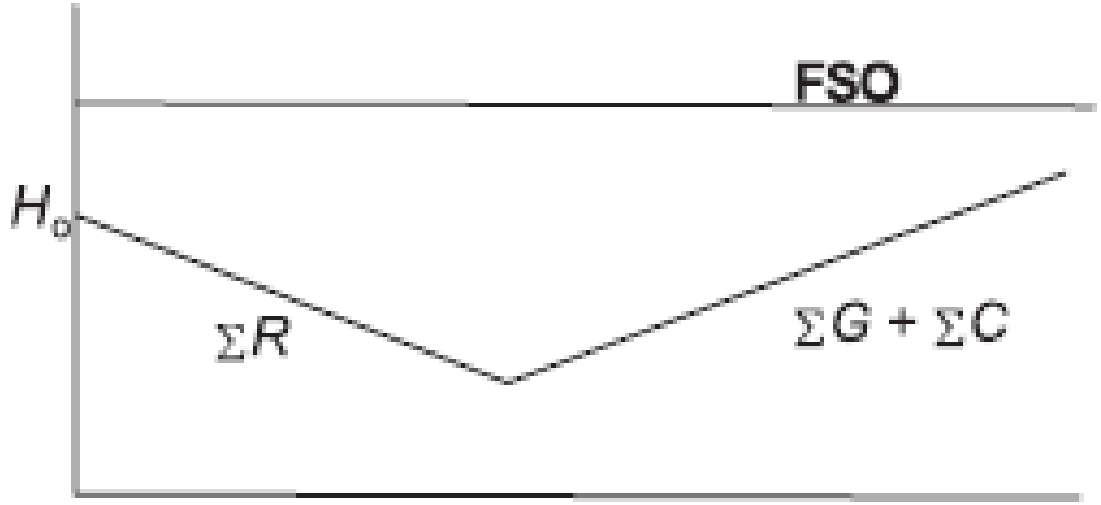
FOOD SAFETY EQUATION

$$(H0 - \sum R + \sum I) \leq PO \text{ (or FSO)}$$

H0 = The Initial Contamination Level
∑R = The Sum of Reductions of Contaminant along the process (*from farm to fork*)
∑I = The Sum of Increases of Contaminant along the process (*from farm to fork*)
PO = Performance Objective
FSO = Food Safety Objective

ICMSF

$$H_o - \Sigma R + \Sigma G + \Sigma C < FSO$$



FSO: Food Safety Objective (cfu/ g or prevalence)

Fig. 1. Schematic representation of the FSO-concept.

ICMSF = International Commission on Microbiological Specification for Foods

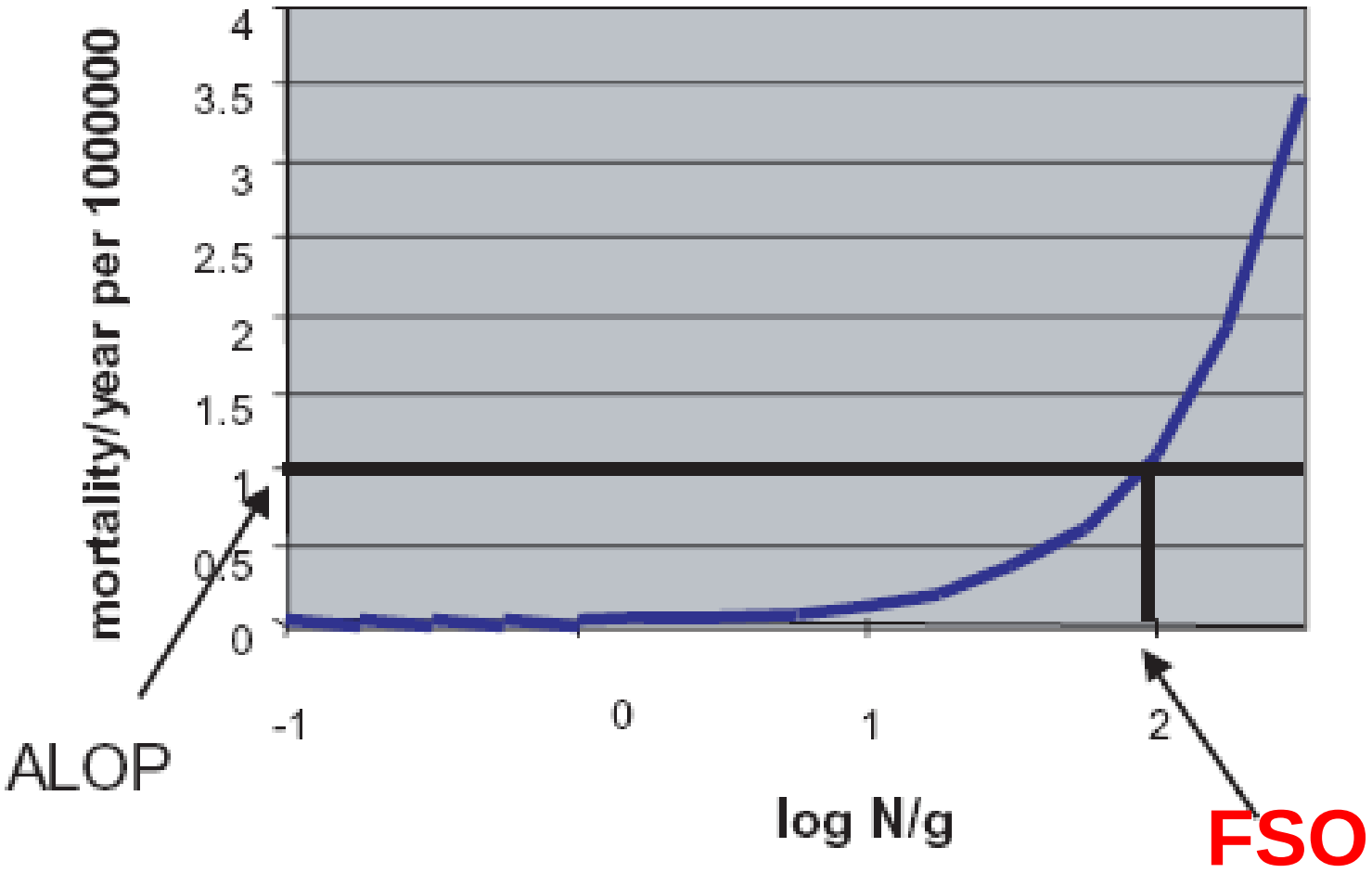


Fig. 2. Relation between ALOP and FSO.

Lecture Material - Food Safety
Budi Widianarko - UNIKA SOEGIJAPRANATA

DIETARY EXPOSURE ASSESSMENT
of Toxic Chemicals

CONSUMPTION SAFETY

based on EXPOSURE ASSESSMENT

- Identification of NOAEL/NEL/NOEC based on results of toxicity tests (human or other mammals) ……. ….Using Toxicological Database

- Application of a safety factor – usually 100
  (a "quick and dirty" method)

⇩

Acceptable Daily Intake (ADI) or Reference Dose (RfD)

NOAEL = no observed adverse effect level
NEL = no effect level
NOEC = no observed effect level

CONSUMPTION SAFETY

based on EXPOSURE ASSESSMENT (Cont'd)

3. (Provisional) Tolerable Weekly Intake

   [TWI = 7 x ADI]

4. Estimation of daily or weekly intake (DI/WI) of toxicant …. based on daily or weekly consumption (DC/WC) of the foodstuff and its toxicant concentration

Reference:

e.g. Trace Elements in Human Nutrition and Health. WHO & FAO. 1996

CONSUMPTION SAFETY

based on EXPOSURE ASSESSMENT (Cont'd)

5. Risk Characterization

……. Calculation of Hazard Quotient (HQ)

HQ = WI/TWI or HQ = DI/ADI

or HQ = DI/RfD

If HQ ≥ 1 …. there is a significant probability that the individual's health will be affected by the toxic substance

CONSUMPTION SAFETY

based on EXPOSURE ASSESSMENT (Cont'd)

Definitions

DC = daily consumption of the contaminated foodstuff (g)

WC = weekly consumption of the contaminated foodstuff (g)

DI = daily intake of the toxic substance (mg)

WI = weekly intake of the toxic substance (mg)

ADI = acceptable daily intake (mg/kg body weight)

TWI = tolerable weekly intake (mg/(x)kg body weight)

Ex. : WHO/FAO - female 55 kg (15-60 yrs)

QUANTIFICATION OF RISK

$$HQ = \frac{WI}{MTWI} \qquad (1)$$

WI = Weekly Intake of metal (µg/kg body weight)
(weekly consumption of seafood x concentration of metal in seafood)

MTWI = Maximum Tolerable Weekly Intake (µg/kg body weight)

(WHO, 1996: Cu & Zn: Upper Limit of The Safe Range)

$$HQ_{(T)-} = \sum_{i=1}^{n} \sum_{j=1}^{k} WI_{ij}/MTWI_{ij} \qquad (2)$$

i = 1 ……. n (index of metal)

j = 1 ……. k (index of seafood)

Table 4. Concentrations of trace metals in four seafood species from the north coast of Central Java

Seafood	Concentration (ug/g dry weight)		
	Cd	Cu	Zn
Cockle	17–165	42–65	750–1030
Mullet	01–04	02–06	391–553
Milkfish	06–08	11–14	27.8–49.2
Shrimp	06–12	165–262	351–375

Source: Widianarko (2004)

Weekly Consumption of Seafood
(3 coastal settlements)

Seafood	Average Consumption (g dry weight/person/week)		
	Tanah Mas	Tambak Lorok	Tri Mulyo
Cockle	9.0	25.9	11.6
Mullet	31.4	NA	11.1
Milkfish	10.4	44.4	22.8
Shrimp	9.4	122.2	22.7




Weekly Dietary Exposures and Hazard Quotients (1)

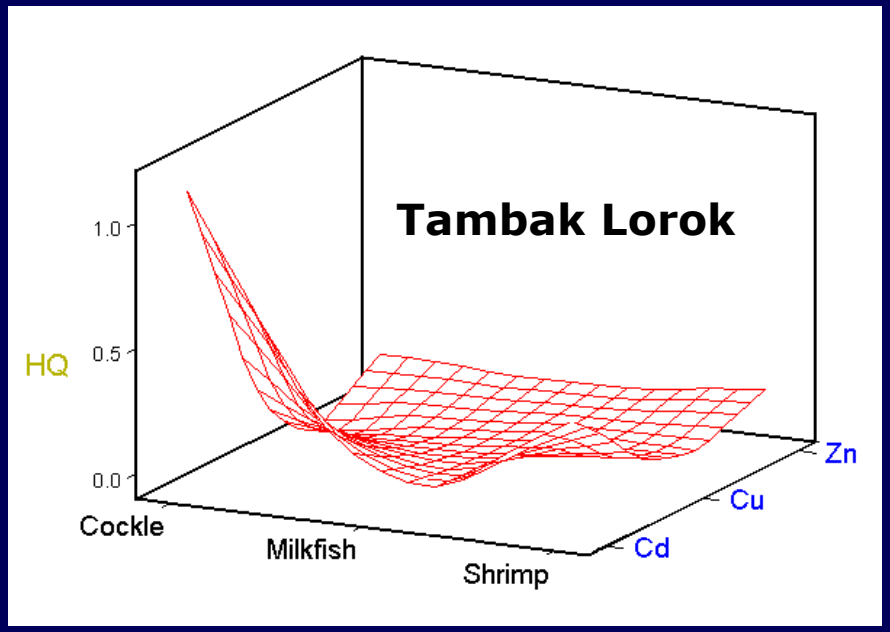
Setlement	Seafood	Level	Weekly Intake (mg)			Hazard Quotient			
			Cd	Cu	Zn	Cd	Cu	Zn	Sub- Total
TM1	Cockle	Min	0.02	0.04	0.68	0.0397	0.0005	0.0193	
		Max	0.15	0.06	0.93	0.3857	0.0008	0.0265	0.41
	Mullet	Min	0.00	0.01	0.12	0.0082	0.0001	0.0035	
		Max	0.01	0.02	0.17	0.0326	0.0003	0.0050	0.01
	Milkfish	Min	0.01	0.01	0.29	0.0162	0.0002	0.0083	
		Max	0.01	0.01	0.51	0.0216	0.0002	0.0146	0.01
	Shrimp	Min	0.01	0.16	0.33	0.0146	0.0022	0.0094	
		Max	0.01	0.25	0.35	0.0293	0.0035	0.0101	0.01
								TOTAL	0.44

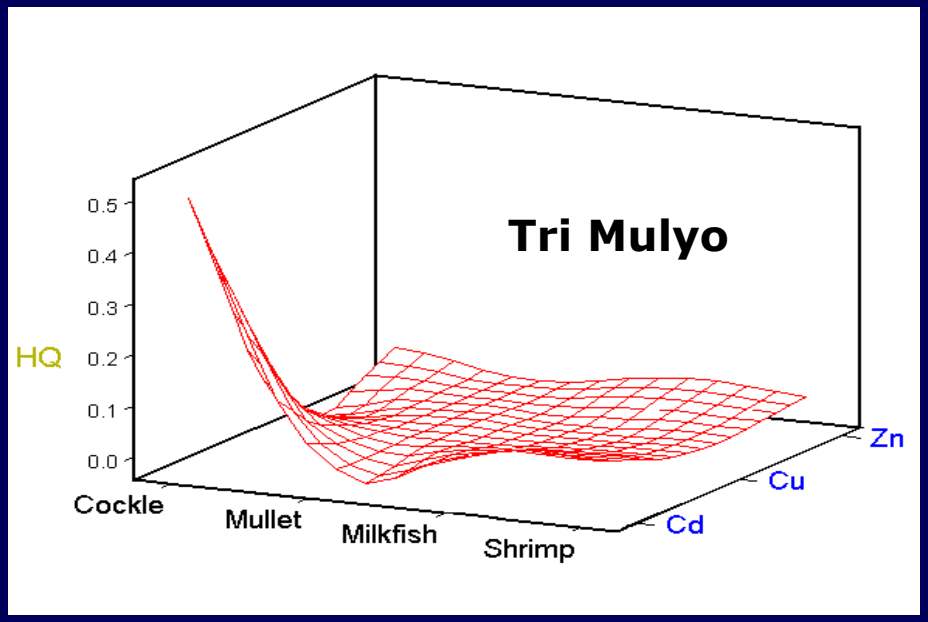
Weekly Dietary Exposures and Hazard Quotients (2)

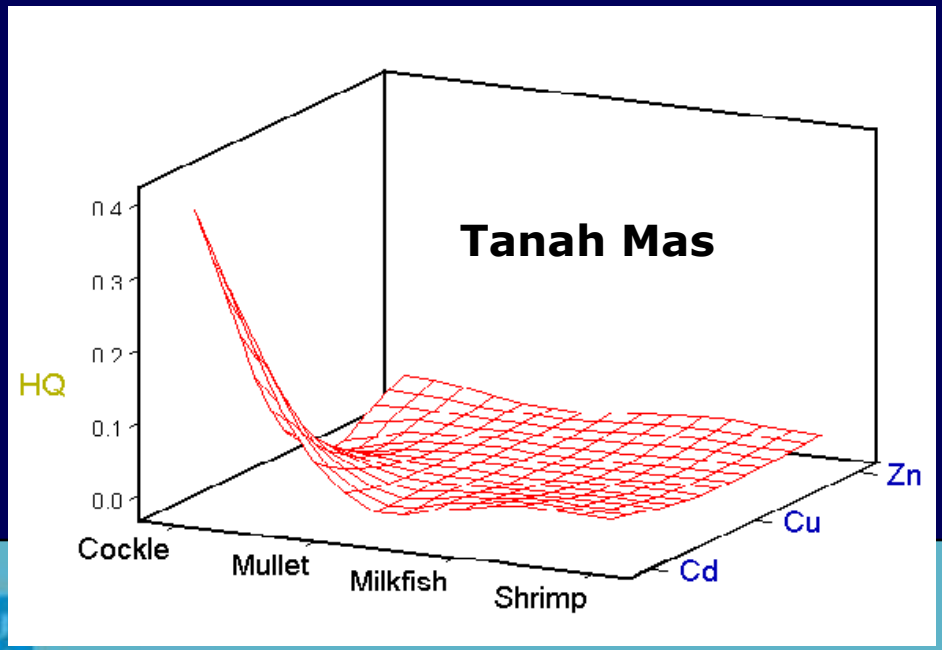
Setlement	Seafood	Level	Weekly Intake (mg)			Hazard Quotient			
			Cd	Cu	Zn	Cd	Cu	Zn	Sub- Total
TL	Cockle	Min	0.04	0.11	1.94	0.1144	0.0016	0.0555	
		Max	0.43	0.17	2.67	1.1100	0.0024	0.0762	1.19
	Mullet	Min	NA	NA	NA	NA	NA	NA	
		Max	NA	NA	NA	NA	NA	NA	NA
	Milkfish	Min	0.03	0.05	1.23	0.0692	0.0007	0.0353	
		Max	0.04	0.06	2.18	0.0923	0.0009	0.0624	0.16
	Shrimp	Min	0.07	2.02	4.29	0.1904	0.0288	0.1225	
		Max	0.15	3.20	4.58	0.3809	0.0457	0.1309	0.56
								TOTAL	1.91

Weekly Dietary Exposures and Hazard Quotients (3)

Setlement	Seafood	Level	Weekly Intake (mg)			Hazard Quotient			
			Cd	Cu	Zn	Cd	Cu	Zn	Sub- Total
TM2	Cockle	Min	0.02	0.05	0.87	0.0512	0.0007	0.0249	
		Max	0.19	0.08	1.19	0.4971	0.0011	0.0341	0.53
	Mullet	Min	0.00	0.00	0.04	0.0029	0.0000	0.0012	
		Max	0.00	0.01	0.06	0.0115	0.0001	0.0018	0.01
	Milkfish	Min	0.01	0.03	0.63	0.0355	0.0004	0.0181	
		Max	0.02	0.03	1.12	0.0474	0.0005	0.0321	0.08
	Shrimp	Min	0.01	0.37	0.80	0.0354	0.0054	0.0228	
		Max	0.03	0.59	0.85	0.0708	0.0085	0.0243	0.10
								TOTAL	0.72


Tambak Lorok
HQ
1.0
0.5
0.0
Cockle
Milkfish
Shrimp
Cd
Cu
Zn


Tri Mulyo
HQ
0.5
0.4
0.3
0.2
0.1
0.0
Cockle
Mullet
Milkfish
Shrimp
Cd
Cu
Zn


Tanah Mas
HQ
0.4
0.3
0.2
0.1
0.0
Cockle
Mullet
Milkfish
Shrimp
Cd
Cu
Zn

CURRENT WEEKLY CONSUMPTION LEVEL (WC) = 25.9 g dw/person

HQ = 1.1

MAXIMUM WEEKLY TOLERABLE CONSUMPTION (MWTC)

= [CONSUMPTION LEVEL THAT LEADS TO AN HQ VALUE OF 1.0]

MWTC = f (HQ, WC)

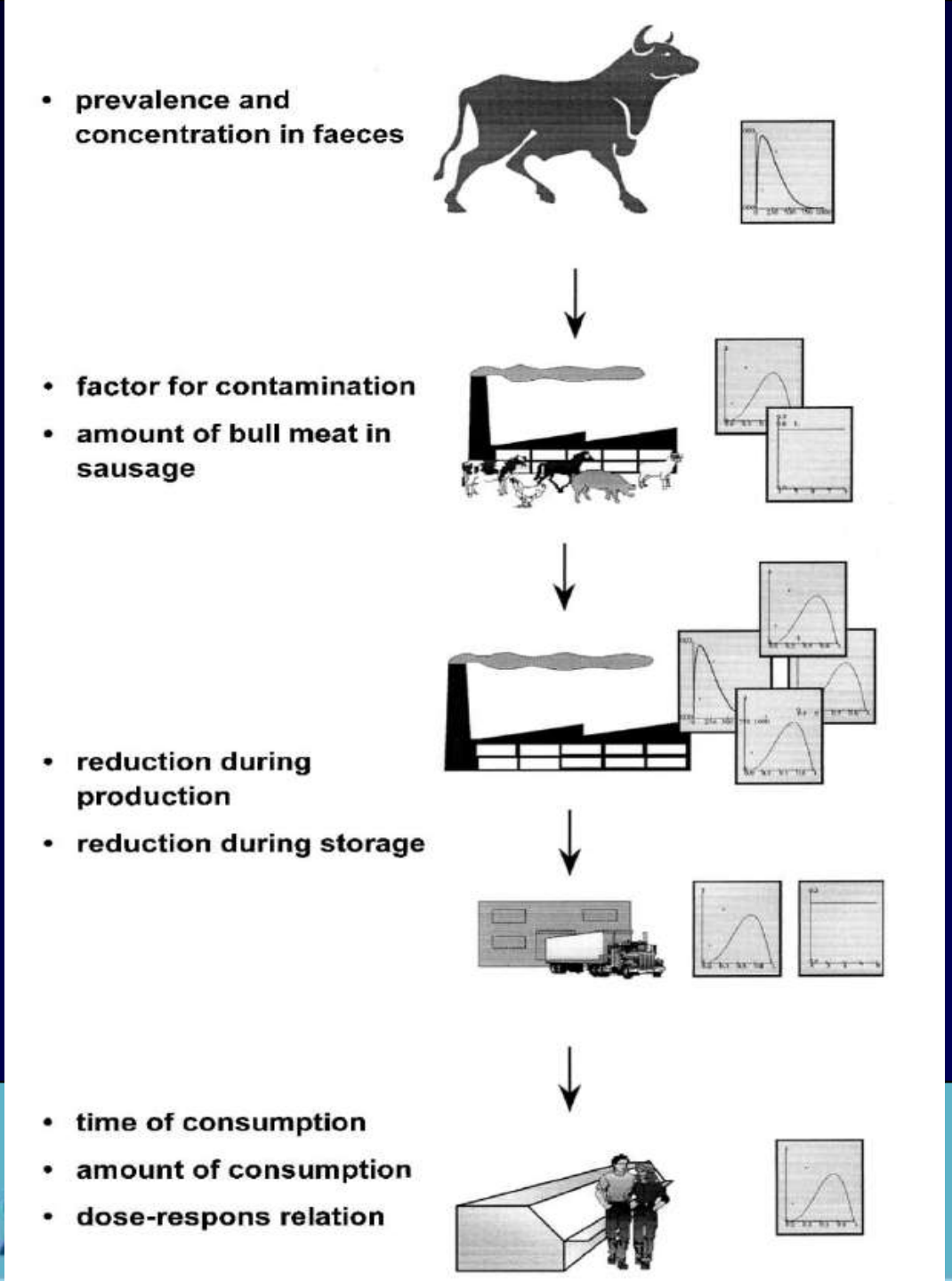
MWTC = (1/HQ) X WC = (1/1.1) 25.9 g dw/person = 23.5 g dw/person

- THE MELAMINE CASE

- In summary, excluding infant formula and assuming that 50% of the diet is contaminated at a level of 2.5 ppm melamine and its analogs, there is a 1000-fold difference between the estimated dietary exposure (intake) and the level of melamine that does not cause toxicity in animals (NOAEL). Thus, levels of melamine and its analogues below 2.5 ppm in foods other than infant formula do not raise public health concerns.

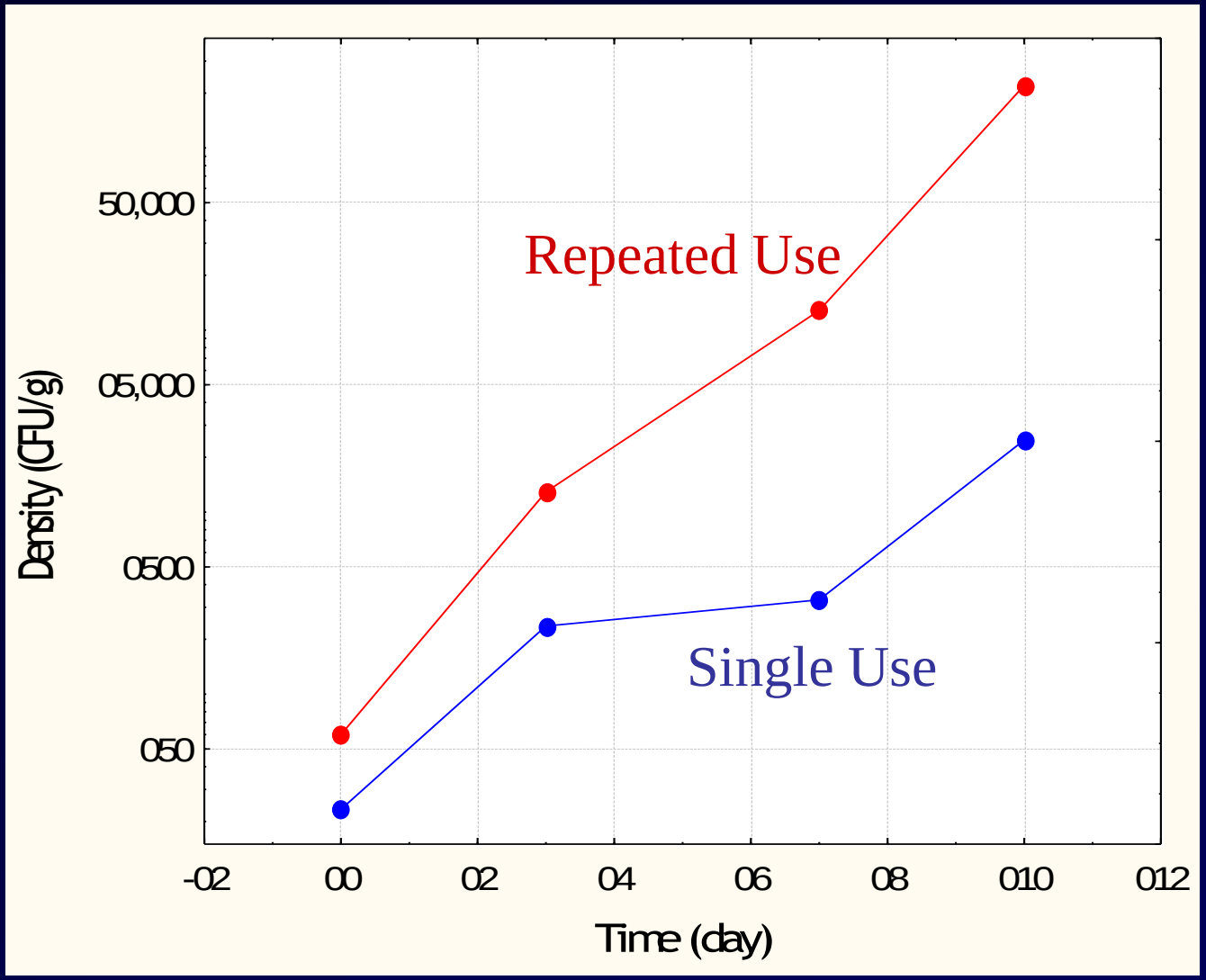
Risk factors in the lifecycle of fermented sausages

Sources: Hoornstra & Notermans (2001)



SPECIAL FEATURES OF MICROBIAL HAZARDS

- Dynamic of growth
- Inactivation of MOs throughout the food chain
- Diversity of MOs and of human immune response to MOs
- The phenomenon of resistance toward antibiotics, sanitizers, pasteurization
- Role of the consumer in altering the potential risk outcome through food handling and preparation



Growth of bacteria in corned beef during storage in the refrigerator

Sources: Mayasari (2004)

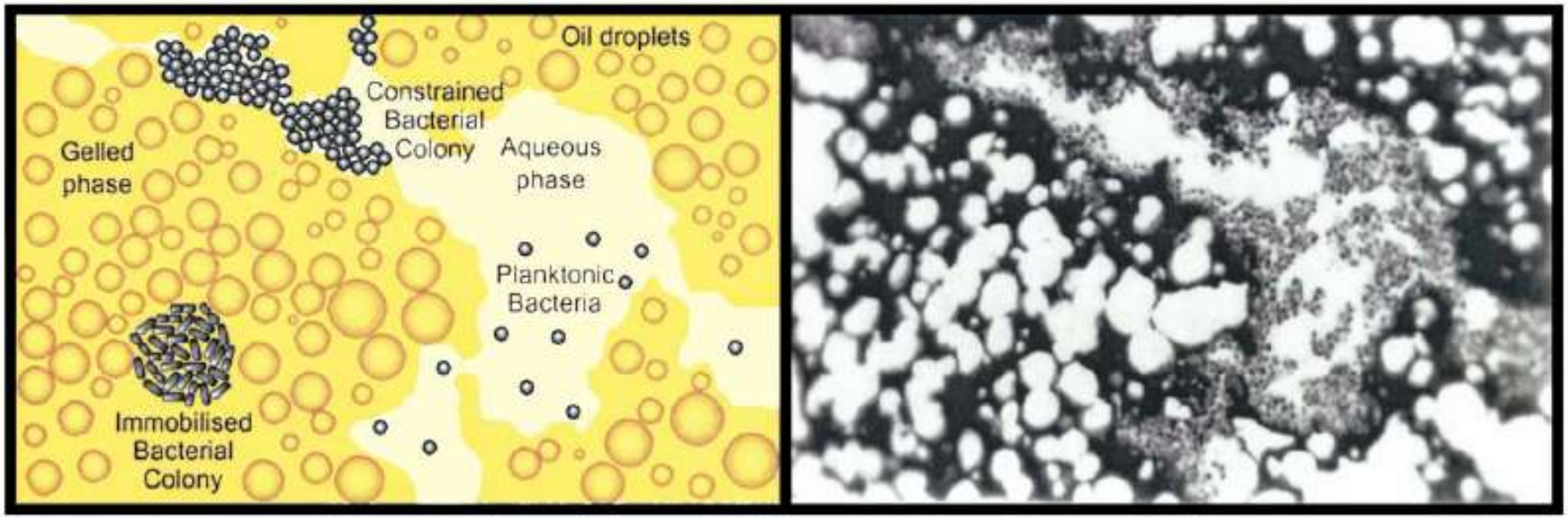


Fig. 1. Schematic diagram (left) and light micrograph (right) showing different environments for microbial growth in a sample of cheese. See Parker et al. (1998) for details.

BUZZ GROUPS

RISK ASSESSMENT

provides the linkages between HACCP criteria and a measure of the associated human health risk to help determine which hazards are eseential to control, reduce, or eliminate and to verify that critical control points (CCPs) and assigned critical limits effectively result in risk reduction.