Risk analysis

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SATREPS/OHEPP

The aim of this talk

- To understand frameworks and significance of WOAH (OIE) and Codex Alimentarius Commission (CAC) Risk Analysis and HACCP
- To study applications of WOAH (OIE) and CAC Risk Analysis

Outline

- Framework and significance of risk analysis
  - WOAH
  - Codex Alimentarius Committee
  - Other frameworks
- Application of risk assessments

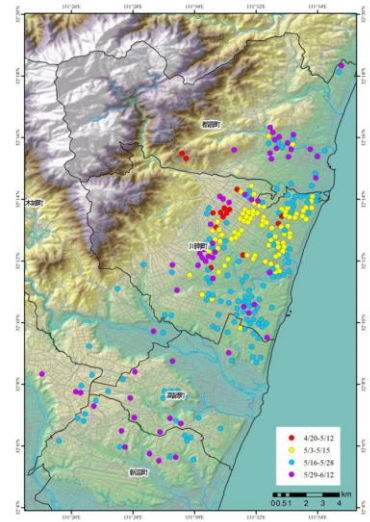
What is “risk”?

- Risk is a probability of occurrence of a scenario and its size of impact

Covid-19
2020 June 21

大勢の家族連れでにぎわう稲毛海浜公園内のビーチ＝千葉市美浜区の稲毛海浜公園「いなげの浜」で

Great East Japan Earthquake and explosion of Fukushima Daiichi plant
2011 March 11



Foot-and-mouth disease in Miyazaki in 2010

WOAH Importation Risk Analysis

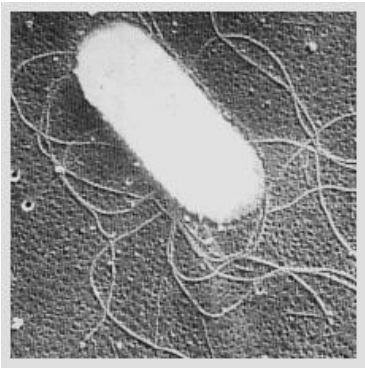
Risk estimation

- **Release assessment** ← Probability of a pathogen enters to my country by importing animals or products
- **Exposure assessment** ← Probability of animals in my country are exposed to the pathogen
- **Consequence assessment** ← Estimation of damage caused by the exposure

Hazard identification → **Risk assessment** → **Risk management**

Risk communication

WOAH Risk analysis for antimicrobial resistance



Risk estimation

- Release assessment ← Use of antimicrobials at farm and selection of resistant bacteria
- Exposure assessment ← Food chain and consumption of the foods contaminated
- Consequence assessment ← Weaker response of antimicrobials in treatment

Hazard identification → **Risk assessment** → **Risk management**

Risk communication

Codex Alimentarius Commission
Food safety risk analysis
A tool for decision-making under uncertainty

*Risk is a probability of occurrence of a scenario and its size of impact (Vose, 2008)

World Trade Organization (WTO)
SPS Agreement: Agreement on the application of Sanitary and Phytosanitary Measures

- Took effect in 1995
- Assessment of equivalence of food safety criteria between two or multiple countries should be based on risk analysis
- After this agreement, risk analysis has been used for food safety standards and criteria in Codex Alimentarius Commission (established in 1962 jointly by the FAO and WHO)

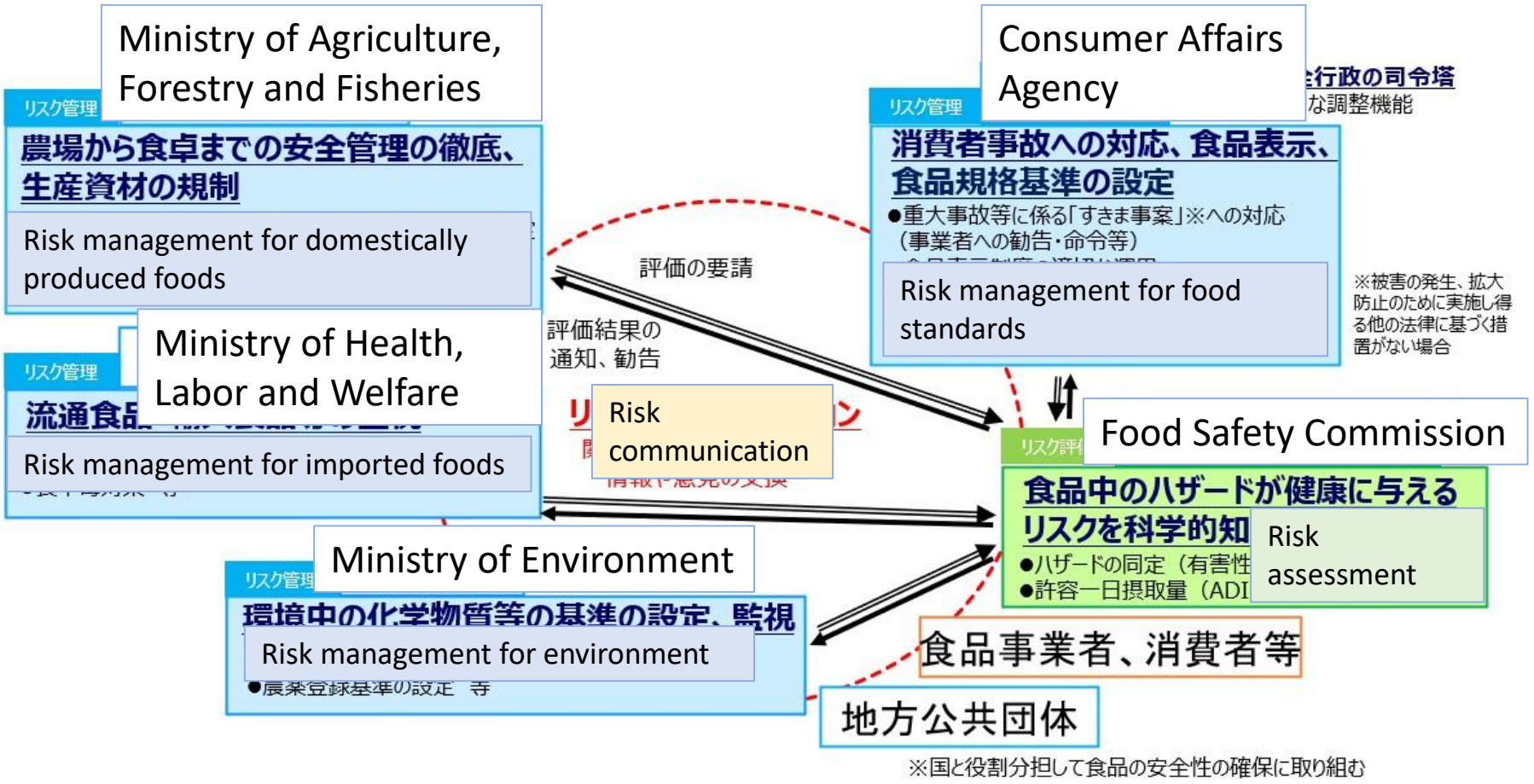
Why food safety?

- Every year, at least 2 billion cases of diarrhea occur and 1.5 million children under 5 yrs die worldwide
- Poor, young, elderly, pregnant women and immune-suppressed most affected
- Food borne diseases include non-diarrheal severe zoonoses

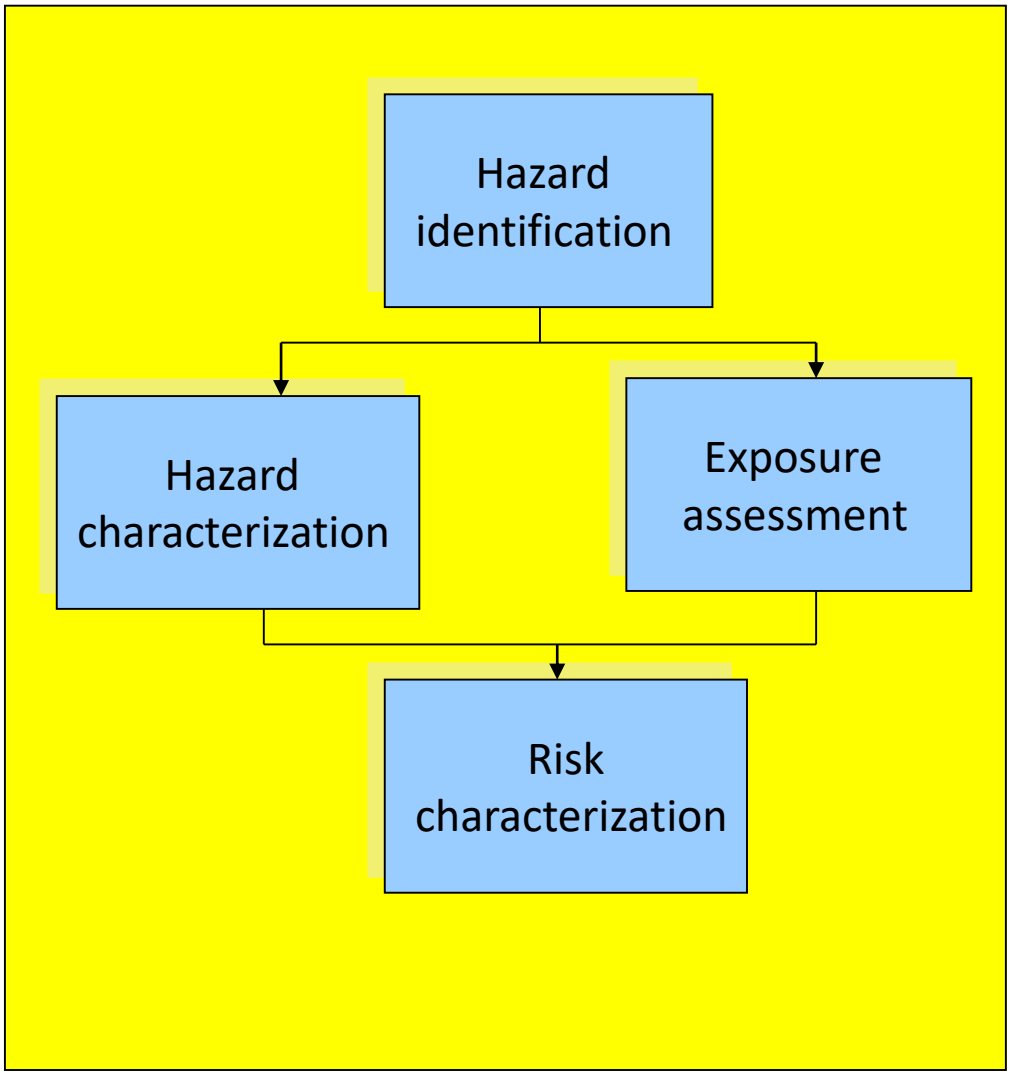
Why animal source foods?

- Two-thirds of human pathogens are zoonotic – many of these transmitted via animal source food
- Animal source food is a single most important cause of food-borne disease
- Many food-borne diseases cause few symptoms in animal host
- Many zoonotic diseases controlled most effectively in <u>animal host/reservoir</u>

Food safety administration system in Japan



Codex Alimentarius Commission
Risk assessment framework
(CAC/GL-30 (1999))

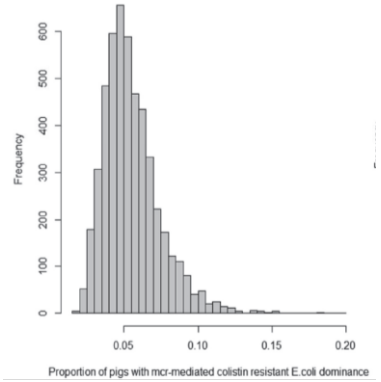


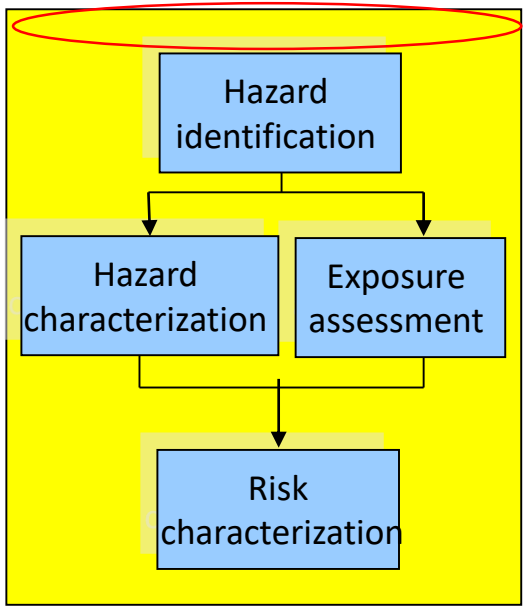
Types of risk assessment and their outputs

- Qualitative
  - Eg). High, middle, low, negligible
- Quantitative
  - Deterministic (point estimate)
  - Stochastic (probability distribution)

Risk estimate matrix

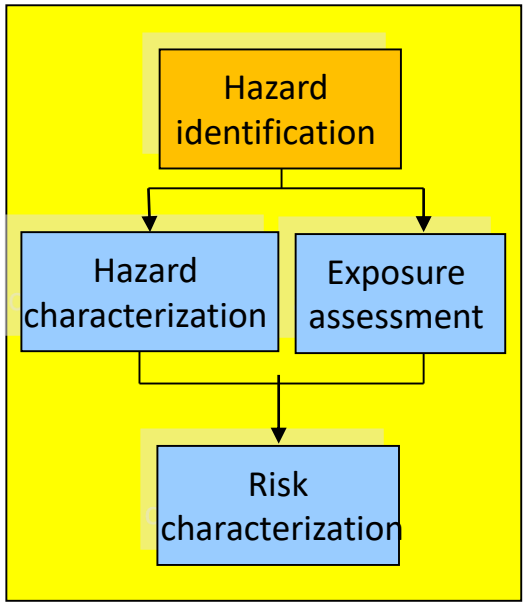
Probability	Consequences					
High	Negligible	Very low	Low	Moderate	High	Extreme
Moderate	Negligible	Very low	Low	Moderate	High	Extreme
Slight	Negligible	Very low	Low	Moderate	High	Extreme
Low	Negligible	Negligible	Very low	Low	Moderate	High
Very low	Negligible	Negligible	Negligible	Very low	Low	Moderate
Extremely low	Negligible	Negligible	Negligible	Negligible	Very low	Low
Negligible	Negligible	Negligible	Negligible	Negligible	Negligible	Very low
	Negligible	**Very low**	**Low**	**Moderate**	**High**	**Extreme**





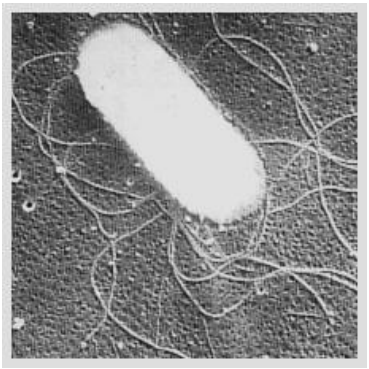
Statement of purpose of risk assessment

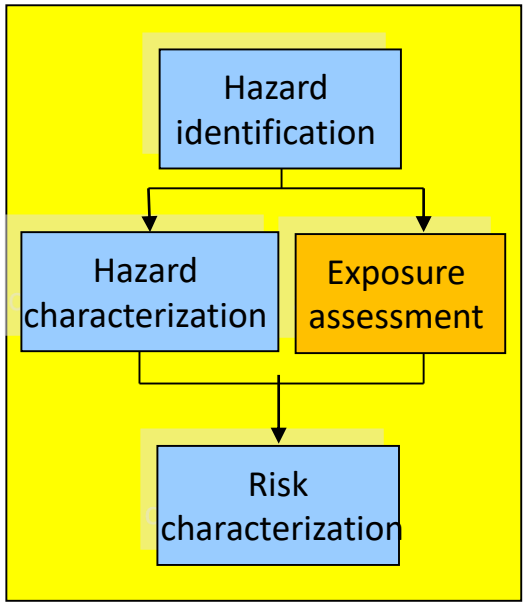
- Clear statement of the specific purpose of the particular risk assessment
  - Why the risk from the hazard in a food item needs to be assessed for the target population
- Output form
  - Qualitative risk (high or low)
  - Annual incidence rate (eg. case/10,000)
- Preliminary investigation phase may be required



Hazard identification

- The identification of biological, chemical, and physical agents –
- capable of causing adverse health effects –
- in food

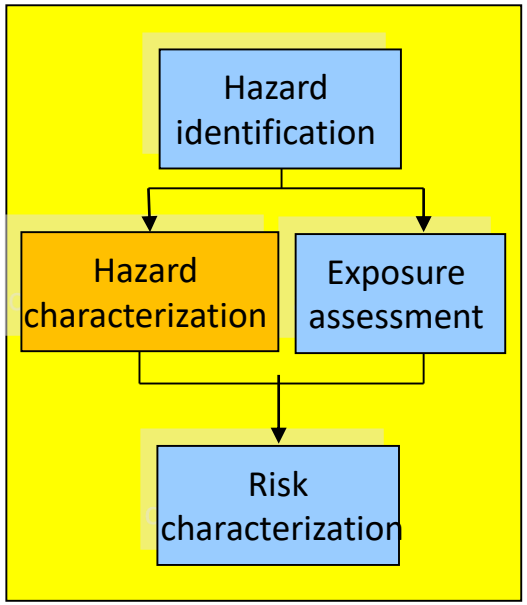




Exposure assessment

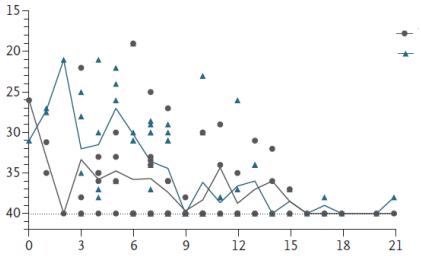
- Assessment of the extent of actual or anticipated human exposure

- Based on the level of **food contamination**, and on **dietary** information
  - Concentration of hazard in a unit food
  - Frequency of ingestion (exposure)
  - Volume of ingestion



Hazard characterization

- Qualitative or quantitative description of the **severity and duration** of adverse effects



- A **dose-response** assessment should be performed if the data are obtainable

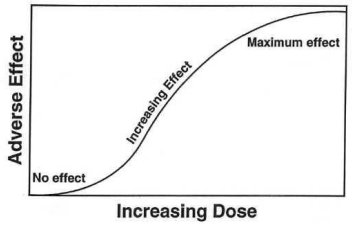
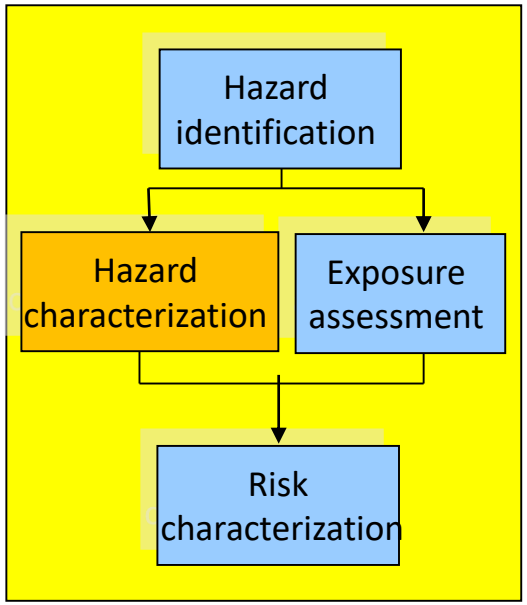
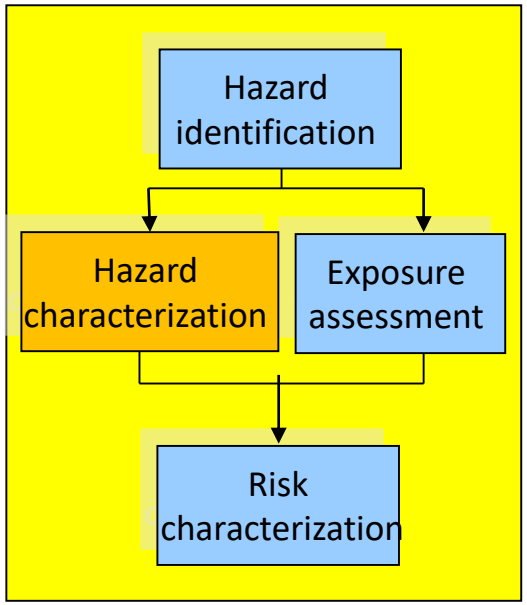


FIGURE 3.1. Adverse response as a result of increasing dose.



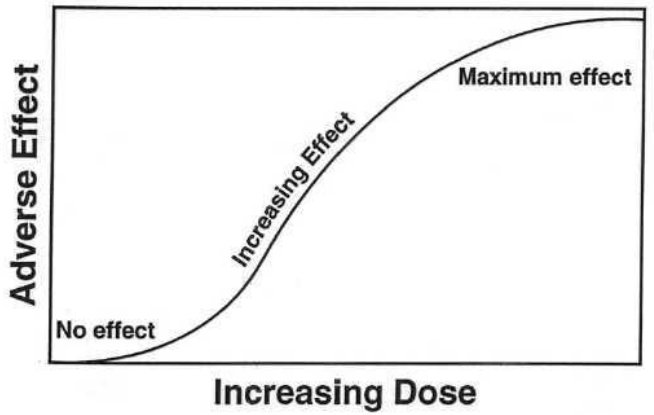
Factors that need to be considered in hazard characterization

- Factors related to the microorganism
  - Speed of replication
  - Virulence and infectivity
  - Delay of onset following exposure
  - Attributes altering pathogenicity, e.g., high fat content of a food vehicle
- Factors related to the host
  - Genetic factors
  - Host susceptibility characteristics
    - Age, pregnancy, nutrition, immune status etc.
  - Population characteristics
    - Population immunity, access to and use of medical care etc.



Dose-response Assessment

- Determination of the relationship between the **magnitude of exposure** (dose) to a hazard and the **severity and/or frequency of associated adverse health effects** (response)



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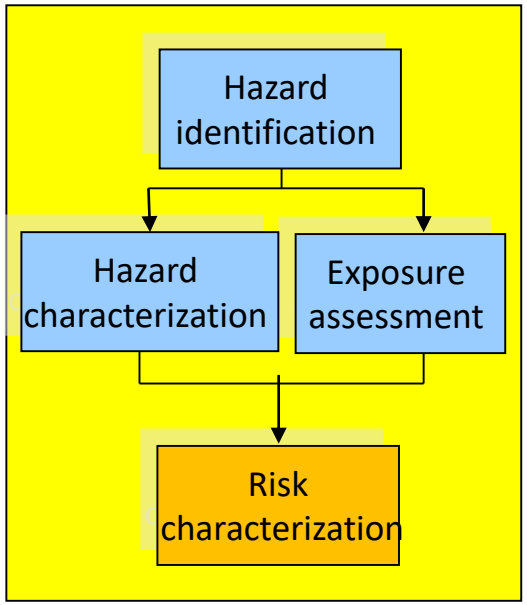
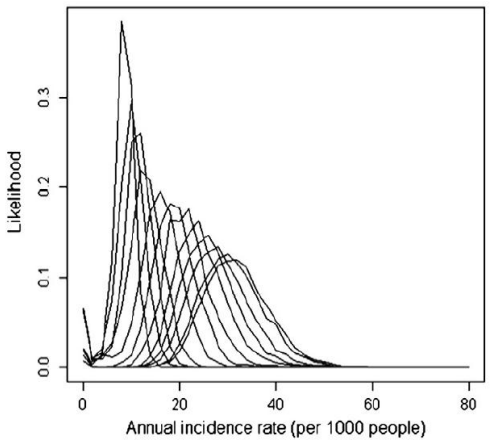


Risk characterization

- Integration of previous three steps
- A qualitative or quantitative estimate of the **likelihood and severity** of the adverse effects in a given population
- Degree of confidence: **uncertainty* and variability*** (stochastic model)
- Influence of factors to the risk estimate: **sensitivity analyses**



*Uncertainty: lack of knowledge

*Variability: variation of a system (eg. temperature)

Risk management

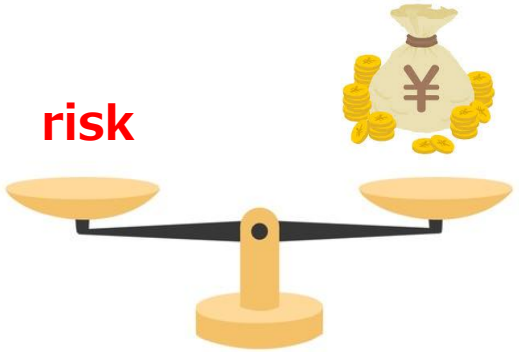
- The process of comparing policy proposals against the results of risk assessment and selecting and implementing appropriate control options, including regulatory measures if necessary (FAO/WHO : Risk Management and Food Safety , 1997)

Table: Elements of risk management

A. Initial risk management activities
Identifying food safety issues
Creating a risk profile
Ranking of hazards to be risk assessed and risk management priorities
Formulation of risk assessment policy for carrying out risk assessment
Commissioning a risk assessment
Review of risk assessment results
B. Evaluating risk management options
Understand available management options
Selection of preferred management options, including consideration of appropriate safety measures
Finalizing management options
C. Implementation of management options
D. Monitoring and review
Evaluation of the effectiveness of implemented policies
Review risk management and/or assessment as necessary

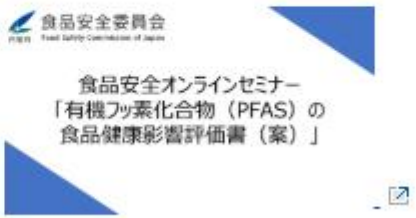
Appropriate Level of Protection: ALOP

- A defense level set by comparing the size of the risk with the economic and other situations

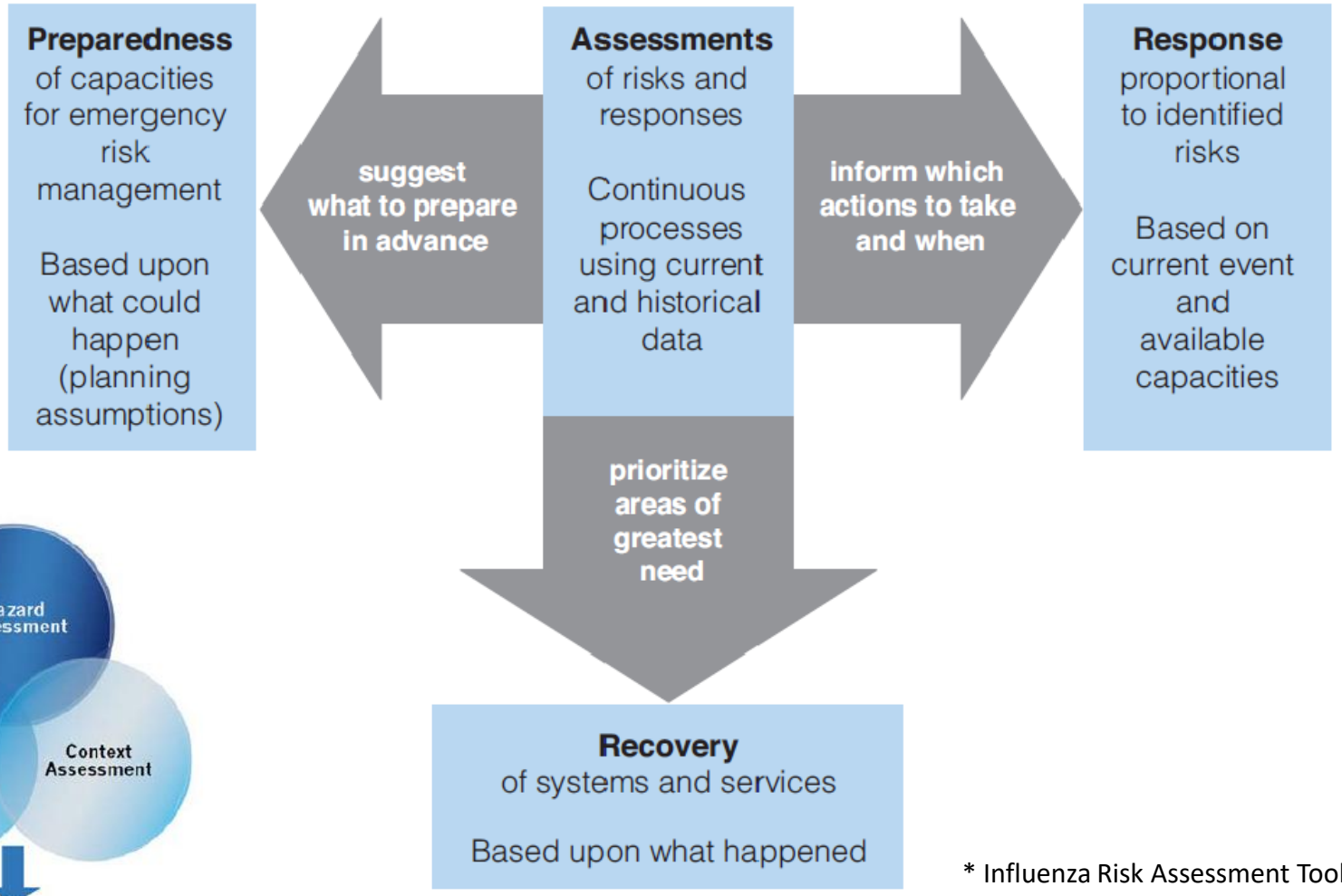


Risk communication

- Two-way communications of opinions regarding risks among risk assessors, risk managers, consumers and other interested parties (FAO/WHO : CAC Report of the 22nd session , 1997)
- Risk communication messages should include information about the nature and the benefit of the risk, the uncertainties of the risk assessment results, and risk management options.
- Strive to tailor content to the recipient, use experts, establish communication expertise, build credibility as a source of information, divide roles, distinguish between scientific and value-based perspectives, ensure transparency, and weigh risks.

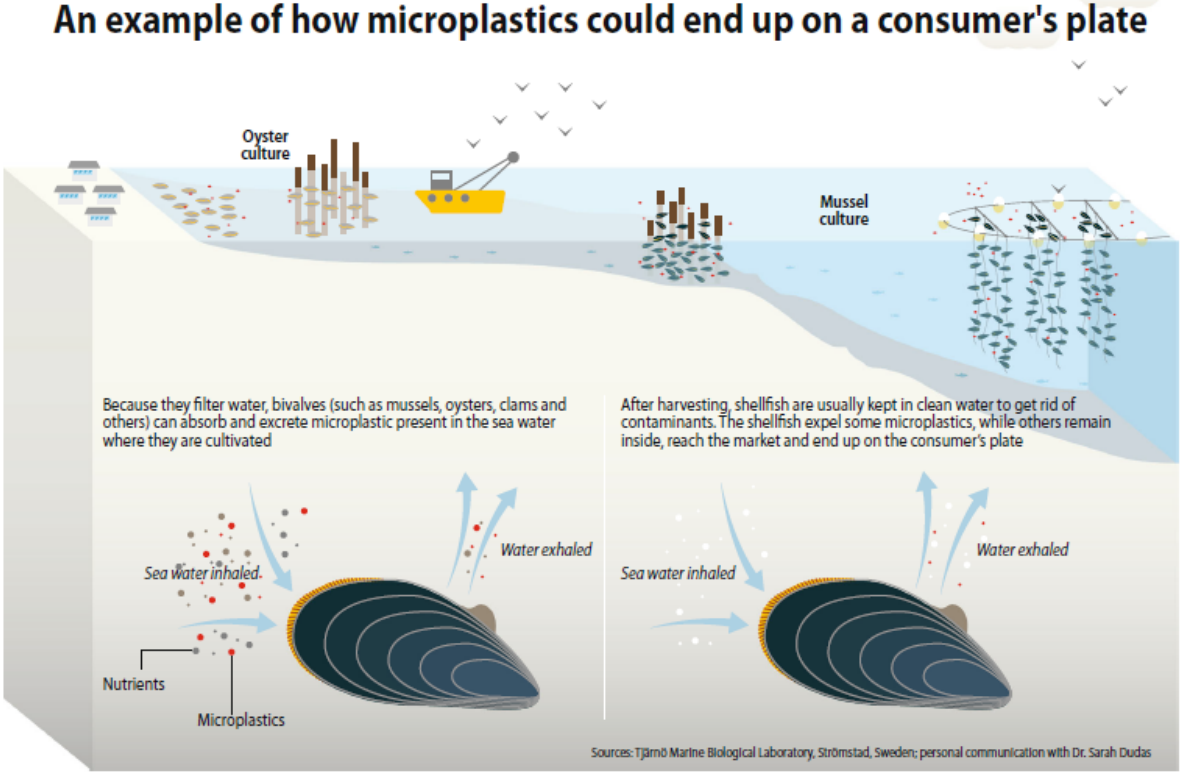
「農薬の再評価に係る食品健康影響評価の進展」～イミダクロプリドを例に～	「アニサキスのリスクプロファイル」についてオンラインセミナー	食品安全オンラインセミナー「有機フッ素化合物（PFAS）の食品健康影響評価書（案）」	加熱と調理～トンカツ編～
			

Pandemic influenza risk assessment (TIPRA), WHO



* Influenza Risk Assessment Tool (IRAT), CDC of vaccine candidates with pandemic potential Monitoring is underway.

Environmental risk assessment and food hygiene



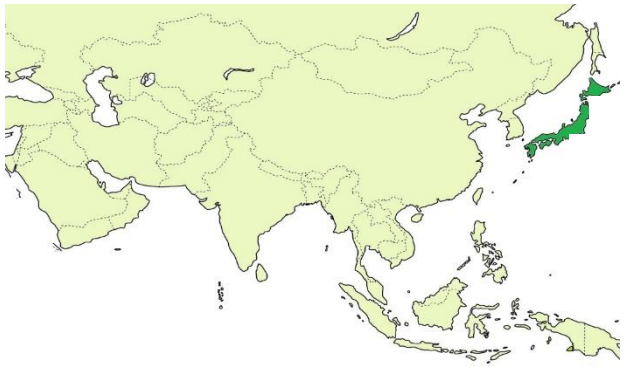
Smith et al., 2018. Current Environmental Health Reports 5, 375-386.

Outline

- Framework and significance of risk analysis
  - WOAH
  - Codex Alimentarius Committee
  - Other frameworks
- Application of risk assessments

Potential routes of ASFV/CSFV incursion to Japan

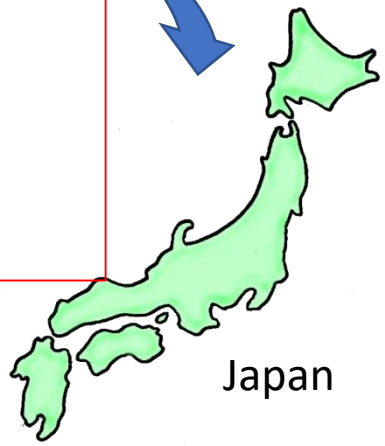
Countries of origin



Aircrafts

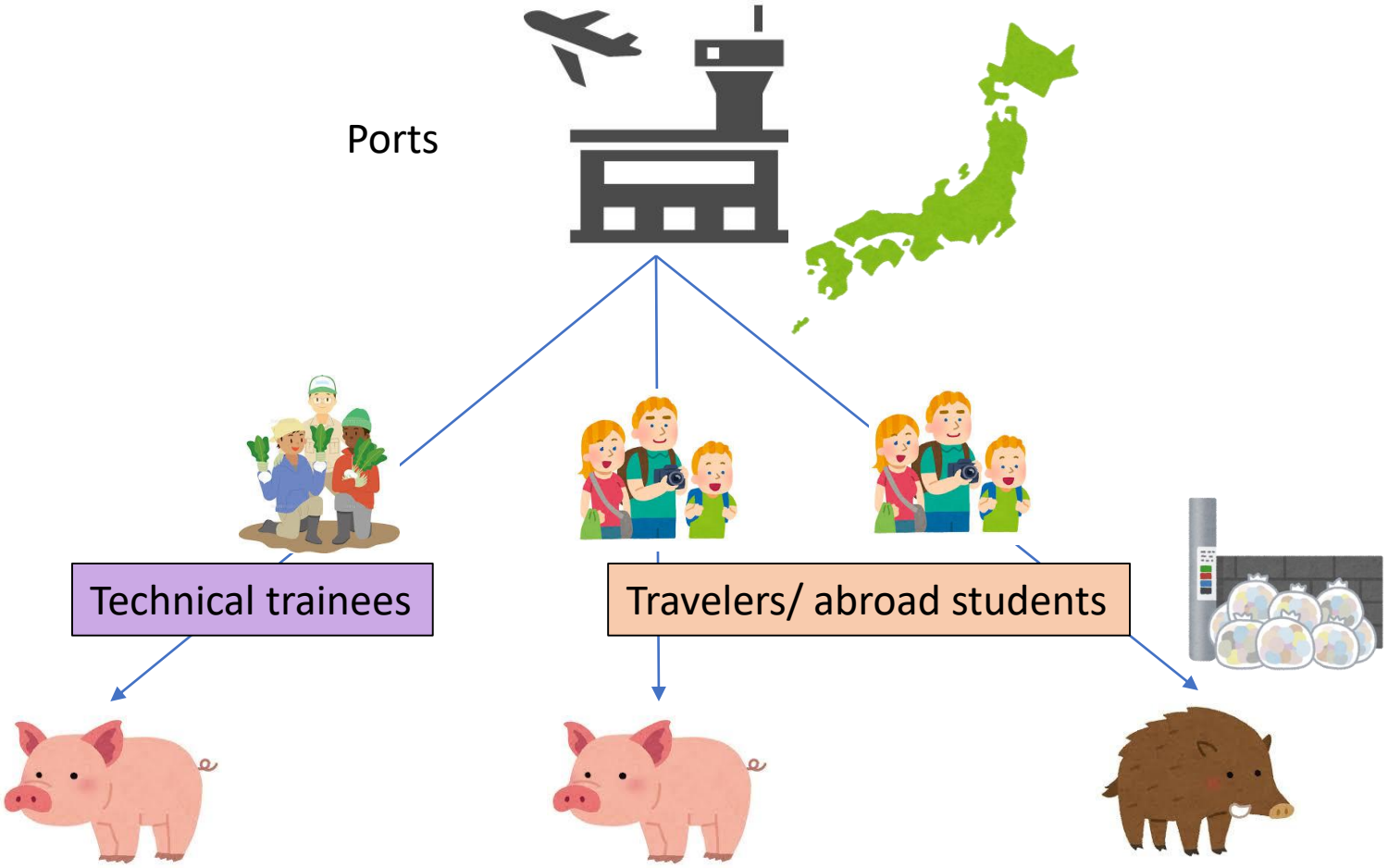
Hand luggage
Animal
Pork products of marketing/ souvenir purposes
Pig feeds

Ship



Japan

Potential routes of exposure of ASFV/CSFV to susceptible hosts



DOI: 10.1111/tbed.13414

ORIGINAL ARTICLE

Transboundary and Emerging Diseases WILEY

Quantitative risk assessment of African swine fever virus introduction to Japan via pork products brought in air passengers' luggage

Satoshi Ito[1,2] | Cristina Jurado[2] | José Manuel Sánchez-Vizcaíno[2] | Norikazu Isoda[1,3]

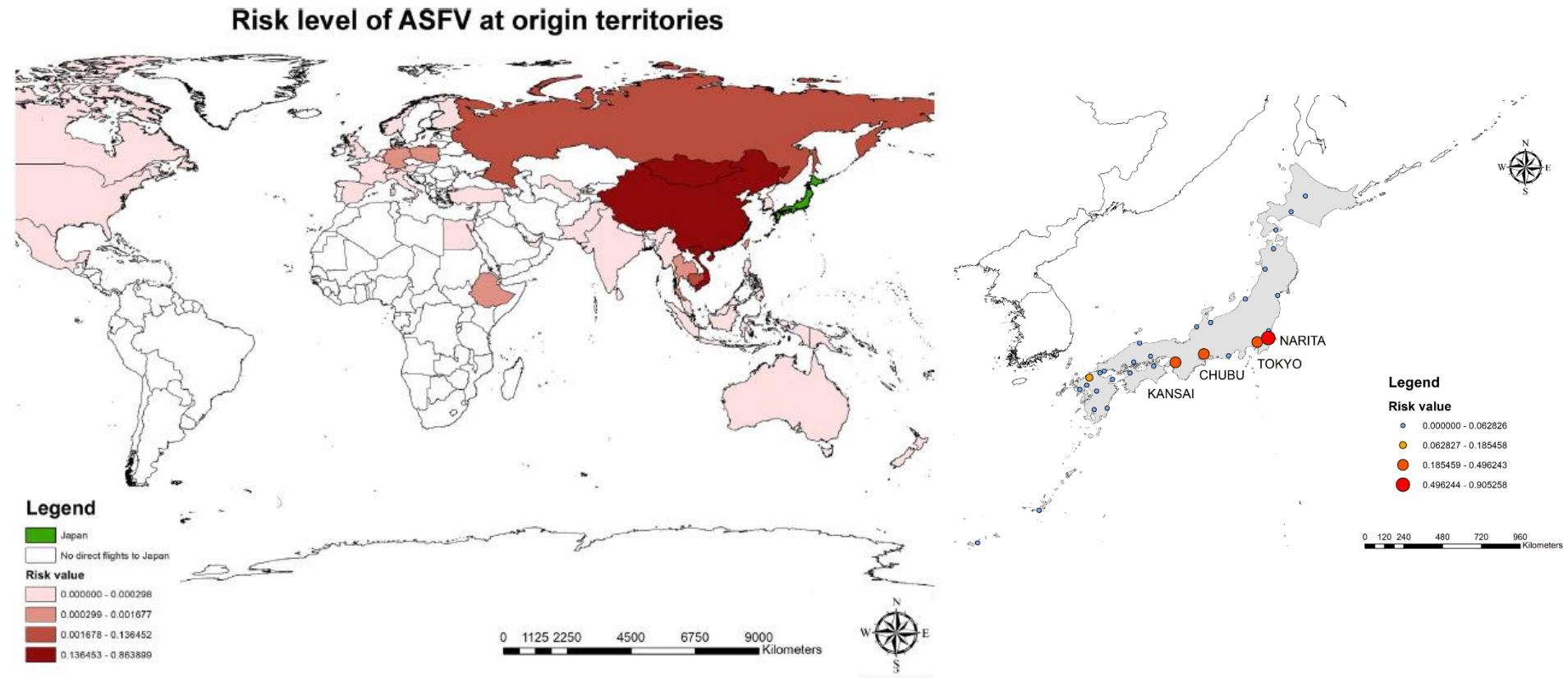
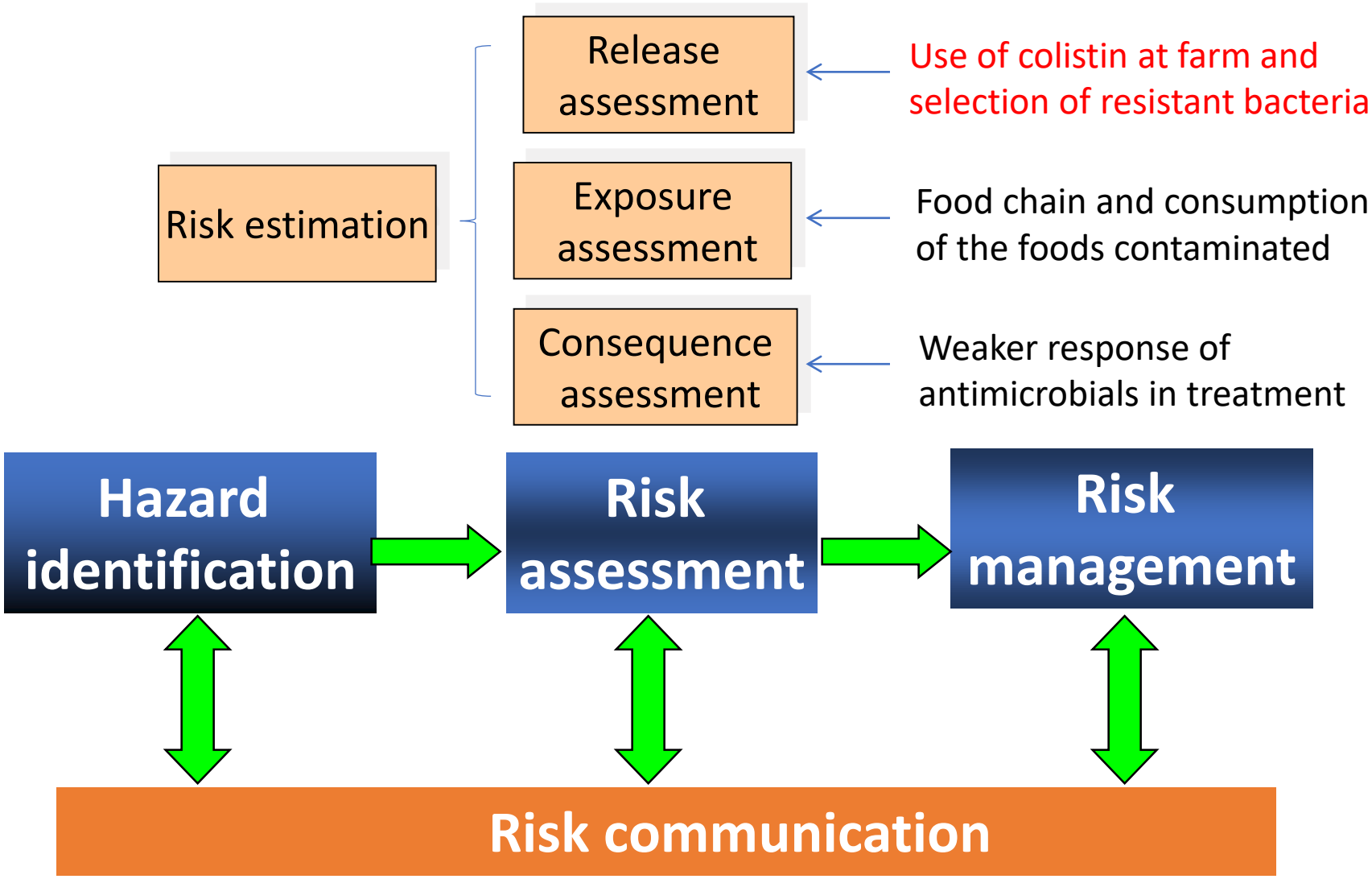


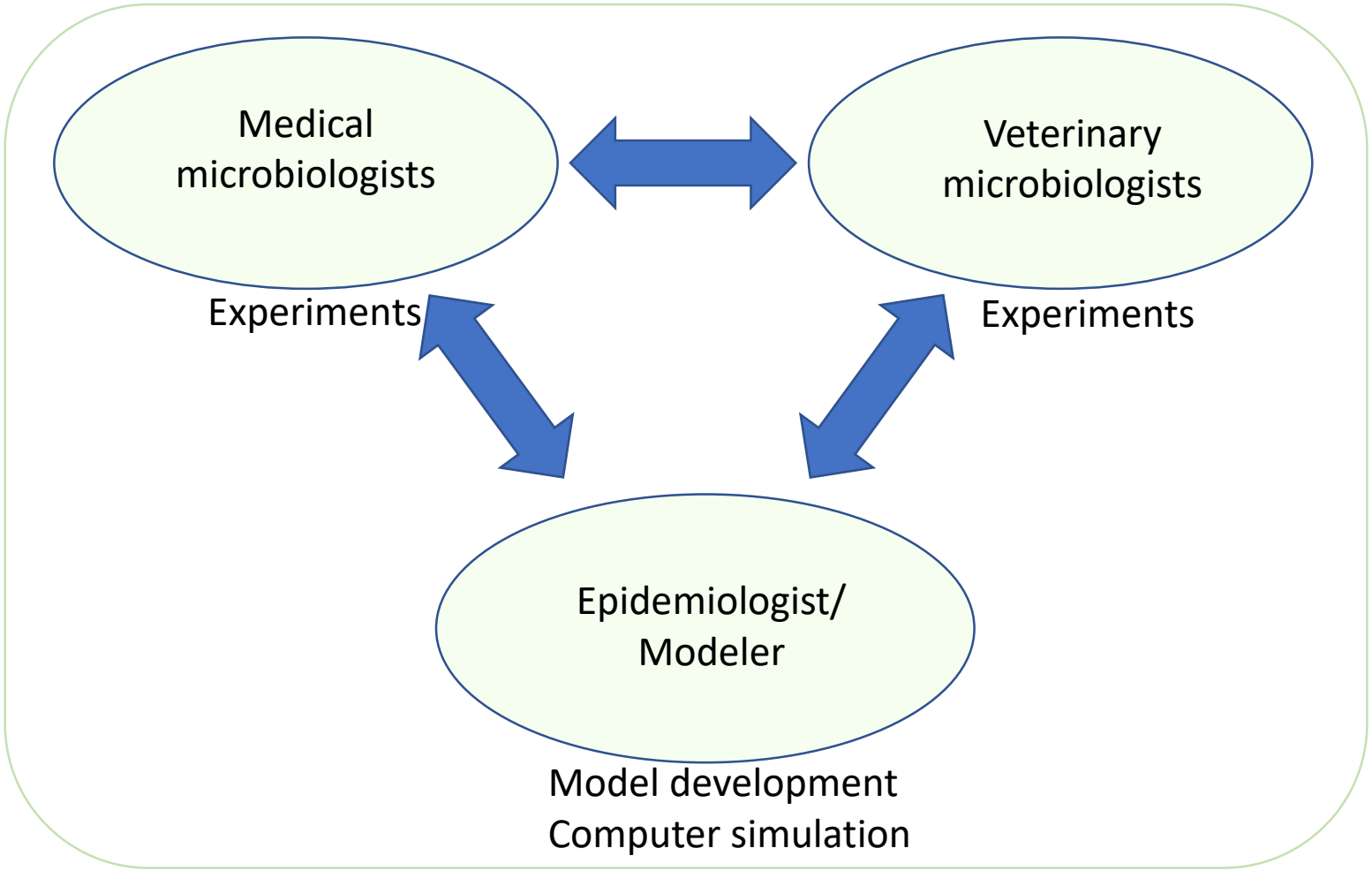
FIGURE 2 The risk results of ASFV introduction into Japan via pork products brought in air passengers' luggage at origin territory level. The graduated colour map represents the annual risk from the highest (darker) to the lowest (lighter)

Release assessment for plasmid-mediated colistin resistance in *Escherichia coli* in pigs at harvesting



The team assembled

Food Safety Commission
Cabinet Office, Japan

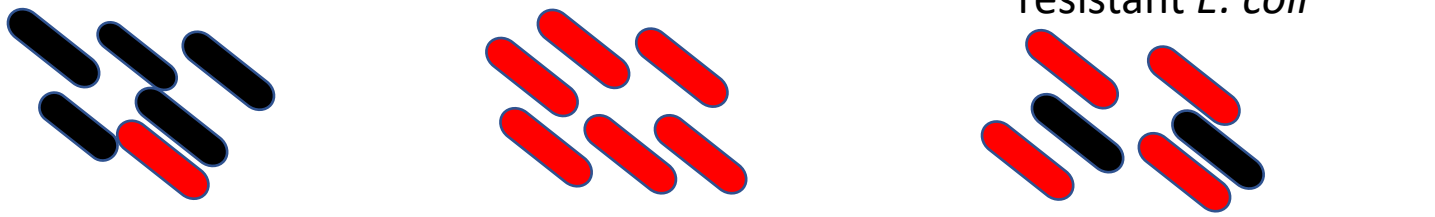


The model

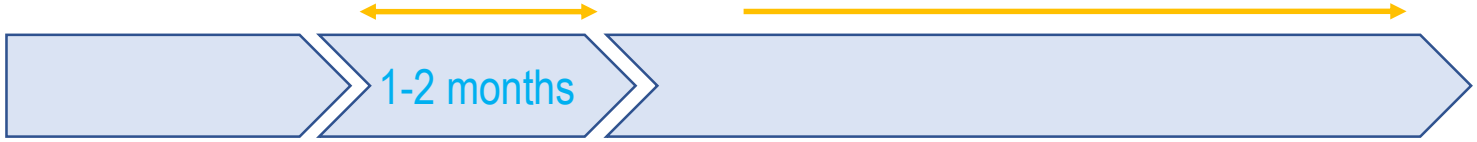
Weaning diarrhea
Edema disease

Treatment with
colistin (selection)

Maintenance of dominance
of selected colistin
resistant *E. coli*



Growth promoter
(selection?)



Weaning

Harvesting

ちくさんクラブ21 No. 27より出典

Risk =
Proportion of pigs with
mcr-mediated colistin resistant
E. coli dominance at harvesting

FOOD SAFETY

doi: 10.14252/foodsafetyfscj.D-20-00004
Food Safety 2020; Vol. 8, No. 2, 13–33

Original Article

Quantitative Release Assessment of *mcr*-mediated Colistin-resistant *Escherichia Coli* from Japanese Pigs

Kohei Makita[1], Yuri Fujimoto[1], Nami Sugahara[1], Takeshi Miyama[1], Masaru Usui[2], Tetsuo Asai[3], Michiko Kawanishi[4], Manao Ozawa[4], Yutaka Tamura[2]

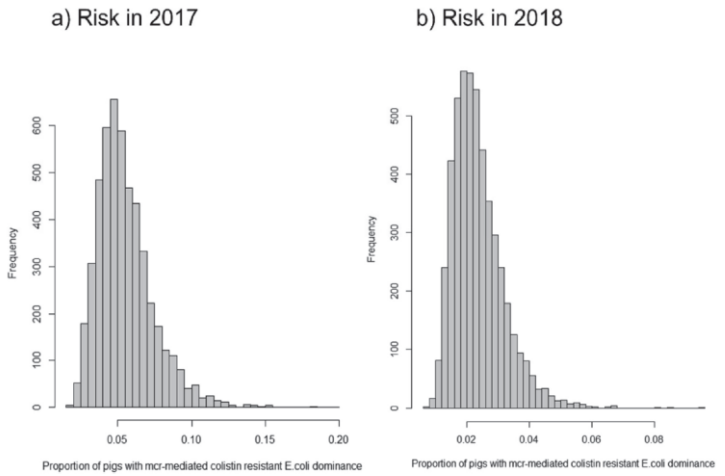


Table 7. Results of scenario analyses showing the proportion of finisher pigs with *mcr-1-5*-mediated colistin-resistant *E. coli* dominant in the gut using the 2017 model (mean, median and 95% credible interval)

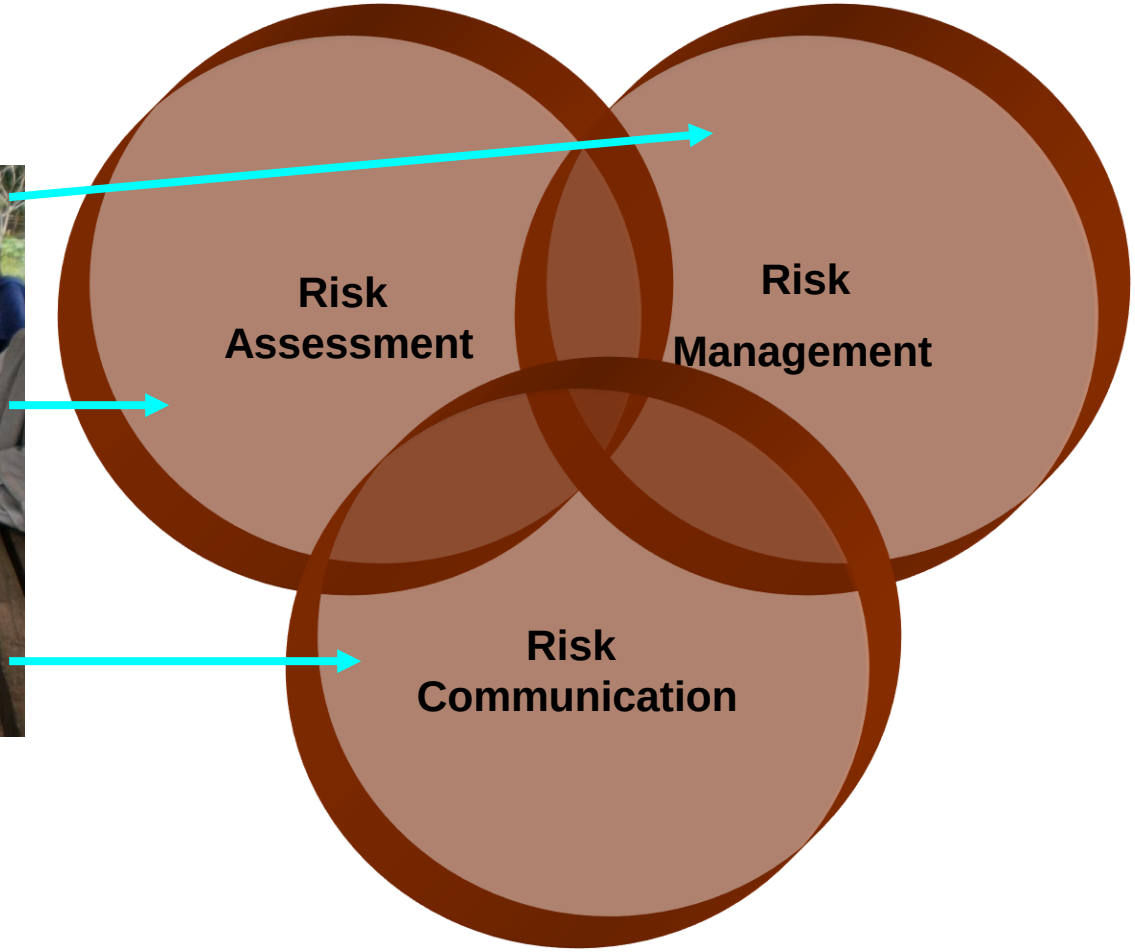
Scenario	Overall	Small-scale farms	Medium-scale farms	Large-scale farms
Default	5.5%, 5.2% (4.2 – 10.1%)	4.6%, 4.3% (3.3 – 9.0%)	5.2%, 4.8% (3.9 – 9.6%)	5.8%, 5.4% (4.3 – 10.5%)
Reduction of edema disease				
50% reduction	5.5%, 5.2% (4.2 – 10.0%)	4.6%, 4.3% (3.3 – 9.0%)	5.1%, 4.8% (3.8 – 9.6%)	5.7%, 5.4% (4.4 – 10.4%)
80% reduction	5.5%, 5.2% (4.2 – 10.1%)	4.6%, 4.2% (3.3 – 9.0%)	5.0%, 4.7% (3.7 – 9.6%)	5.8%, 5.4% (4.4 – 10.5%)
Reduction of diarrhea				
50% reduction	5.2%, 4.9% (3.9 – 9.7%)	4.6%, 4.2% (3.3 – 8.9%)	4.9%, 4.6% (3.6 – 9.3%)	5.3%, 5.0% (4.1 – 9.9%)
80% reduction	5.0%, 4.7% (3.7 – 9.4%)	4.6%, 4.2% (3.3 – 8.9%)	4.8%, 4.5% (3.5 – 9.1%)	5.1%, 4.8% (3.8 – 9.7%)
Reduction of therapeutic colistin				
50% reduction	5.1%, 4.8% (3.9 – 9.4%)	4.6%, 4.3% (3.3 – 9.0%)	4.9%, 4.6% (3.6 – 9.2%)	5.2%, 4.9% (4.0 – 9.7%)
80% reduction	4.8%, 4.5% (3.6 – 9.2%)	4.6%, 4.3% (3.3 – 9.1%)	4.7%, 4.4% (3.5 – 9.1%)	4.9%, 4.5% (3.6 – 9.1%)
Stoppage of therapeutic use	4.6%, 4.3% (3.4 – 8.7%)	4.6%, 4.3% (3.3 – 9.1%)	4.6%, 4.3% (3.4 – 8.9%)	4.6%, 4.3% (3.4 – 8.8%)
Pen level treatment (20% of pigs)	4.7%, 4.4% (3.5 – 8.7%)	4.6%, 4.3% (3.3 – 9.0%)	4.7%, 4.4% (3.5 – 8.7%)	4.7%, 4.4% (3.6 – 8.7%)

- Risk management seems to be effective
- Change of treatment style can further reduce the risk

Food safety risk analysis

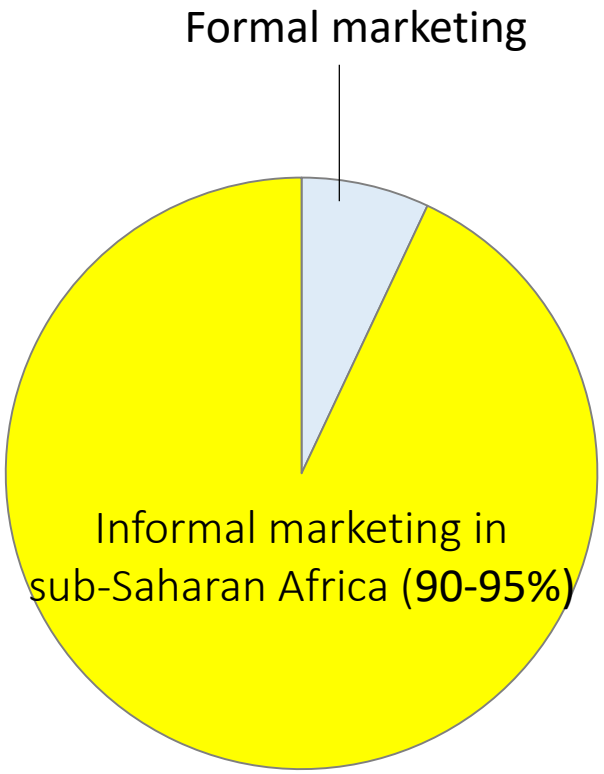
in informal marketing system
Participatory risk analysis

Participatory methods



Dominance of informal markets in developing countries

"Absence of structured sanitary inspection"



Informal ≠ Illegal

What are participatory methods?

- Participants discuss problems
- Several formats:
  - Rapid rural appraisal
  - Participatory rural appraisal
  - Key-informants interview

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Risk assessment of staphylococcal poisoning due to consumption of informally-marketed milk and home-made yoghurt in Debre Zeit, Ethiopia

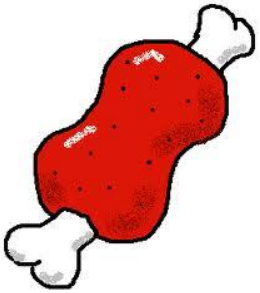
Kohei Makita [a,b,*], Fanta Desissa [c], Akafete Teklu [c], Girma Zewde [c], Delia Grace [a]

[a] Improving Market Opportunities Theme, International Livestock Research Institute (ILRI), PO Box 30709, Nairobi, Kenya
[b] School of Veterinary Medicine, Rakuno Gakuen University, 069-8501, Ebetsu, Japan
[c] Faculty of Veterinary Medicine, Addis Ababa University, PO Box 34, Debre Zeit, Ethiopia

Hazard identification

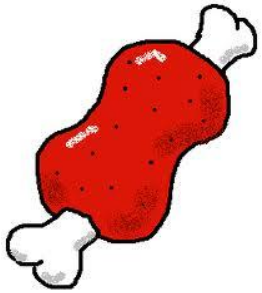
- Hazard
  - *Staphylococcus aureus* enterotoxin
  - Produced by *S. aureus* when the concentration in milk exceeds $10^{6.5}$ CFU/ml
- *S. aureus* is known to be prevalent in milk in Ethiopia by previous reports

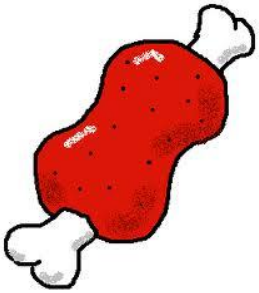
Value chain



A producer ⟶ ⟵ A consumer

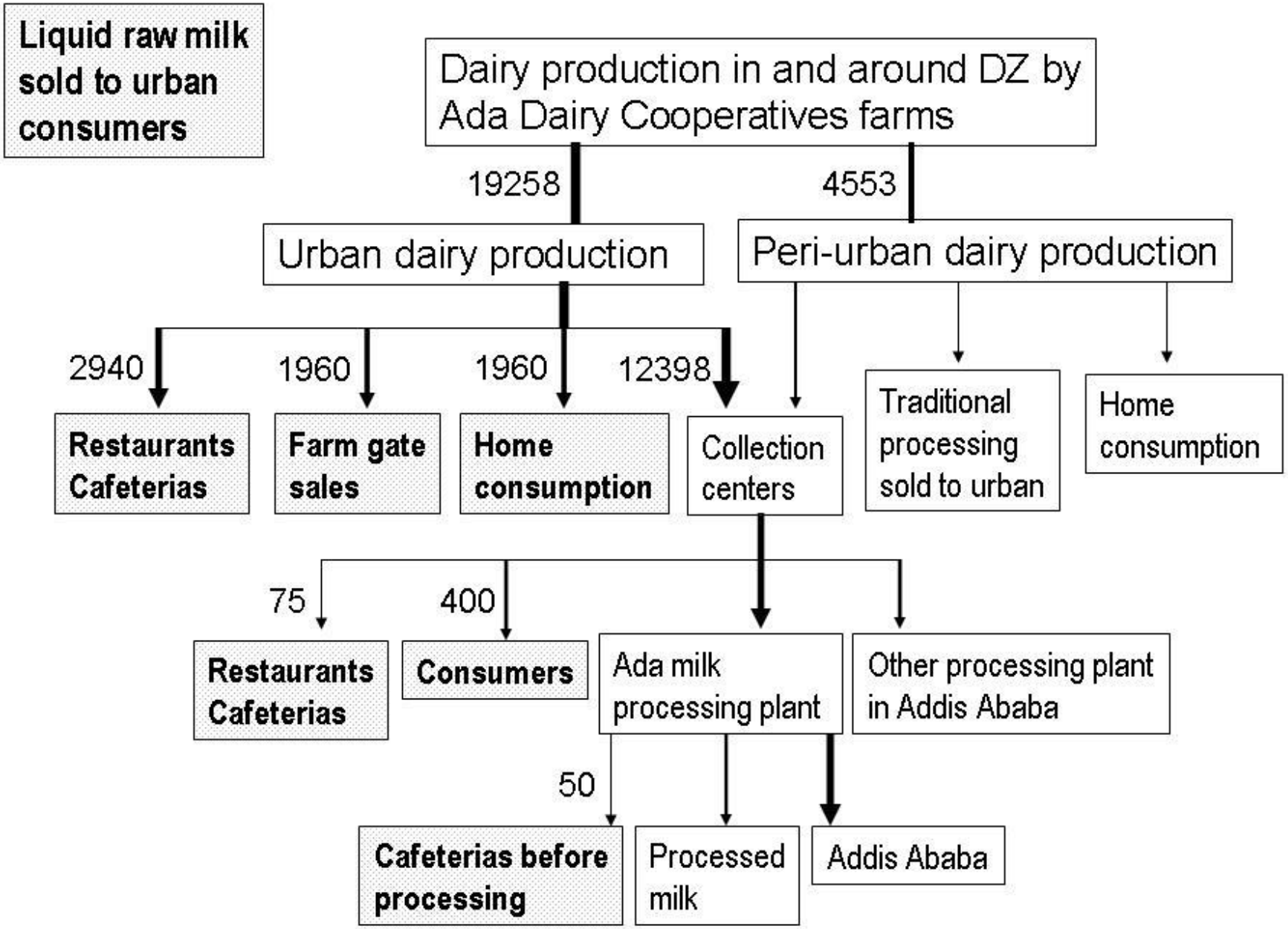
Value chain





Producers → ← Middle men → ← Consumers

Exposure assessment



Dairy value chain- RRA and interviews

Exposure assessment

Contamination rate - a survey

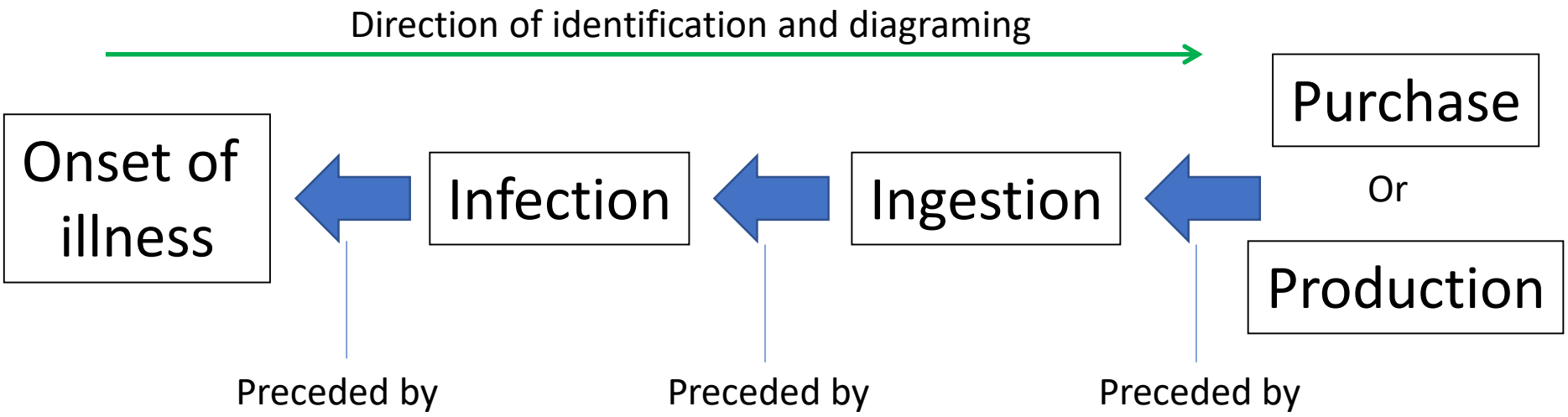
	Isolation of *S aureus*	Boiling before sales
Milk collection centre (n=25)	18 (70.4%)	0
Dairy farm (n=170)	74 (43.6%)	0

Risk mitigation by consumers -participatory and interviews

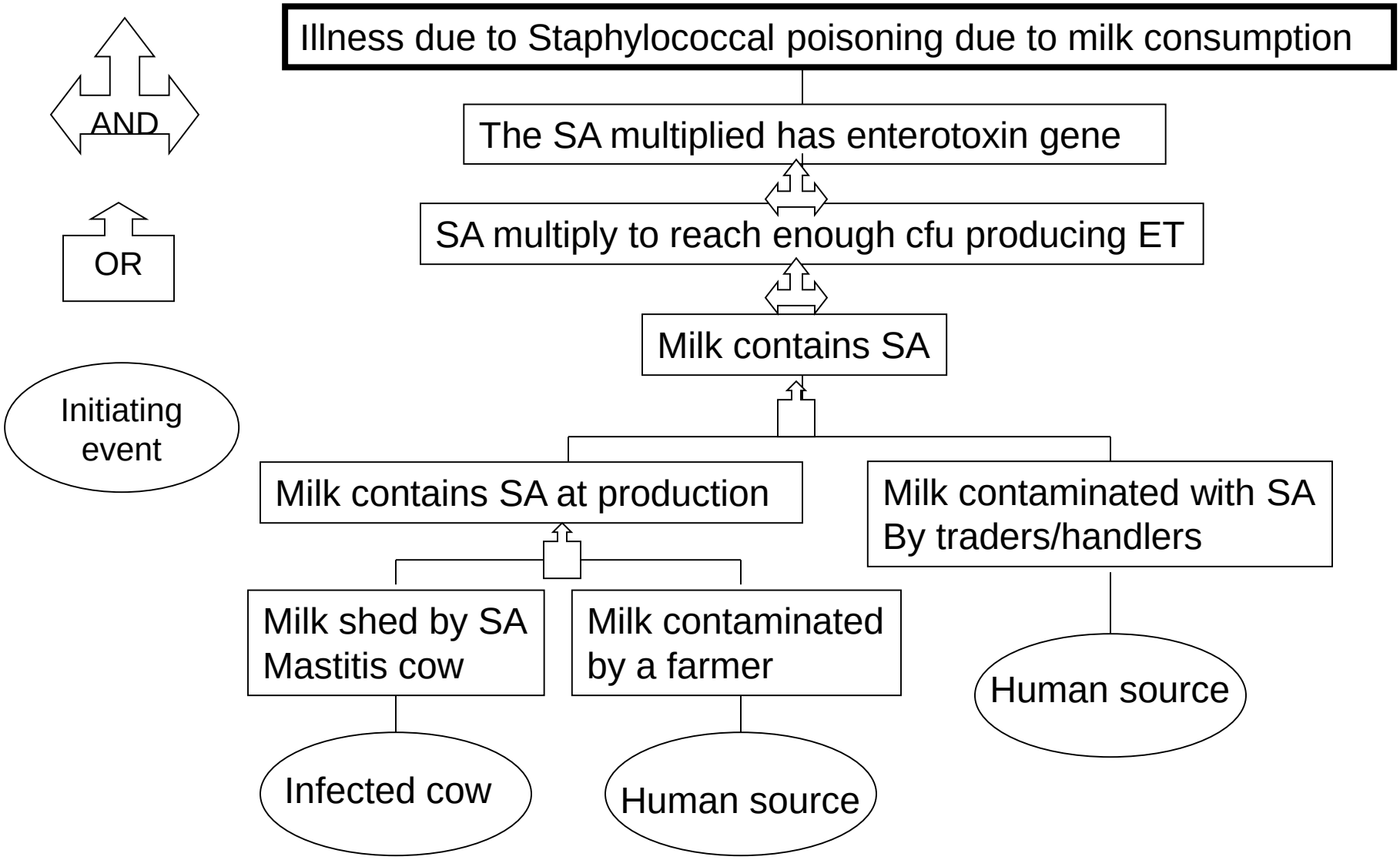
	Boil milk before consumption	Percentage
Dairy farming households (n=170)	116	68.2
Consumers (n=25)	16	64.0

Fault tree analysis in food safety

- How the illness can occur

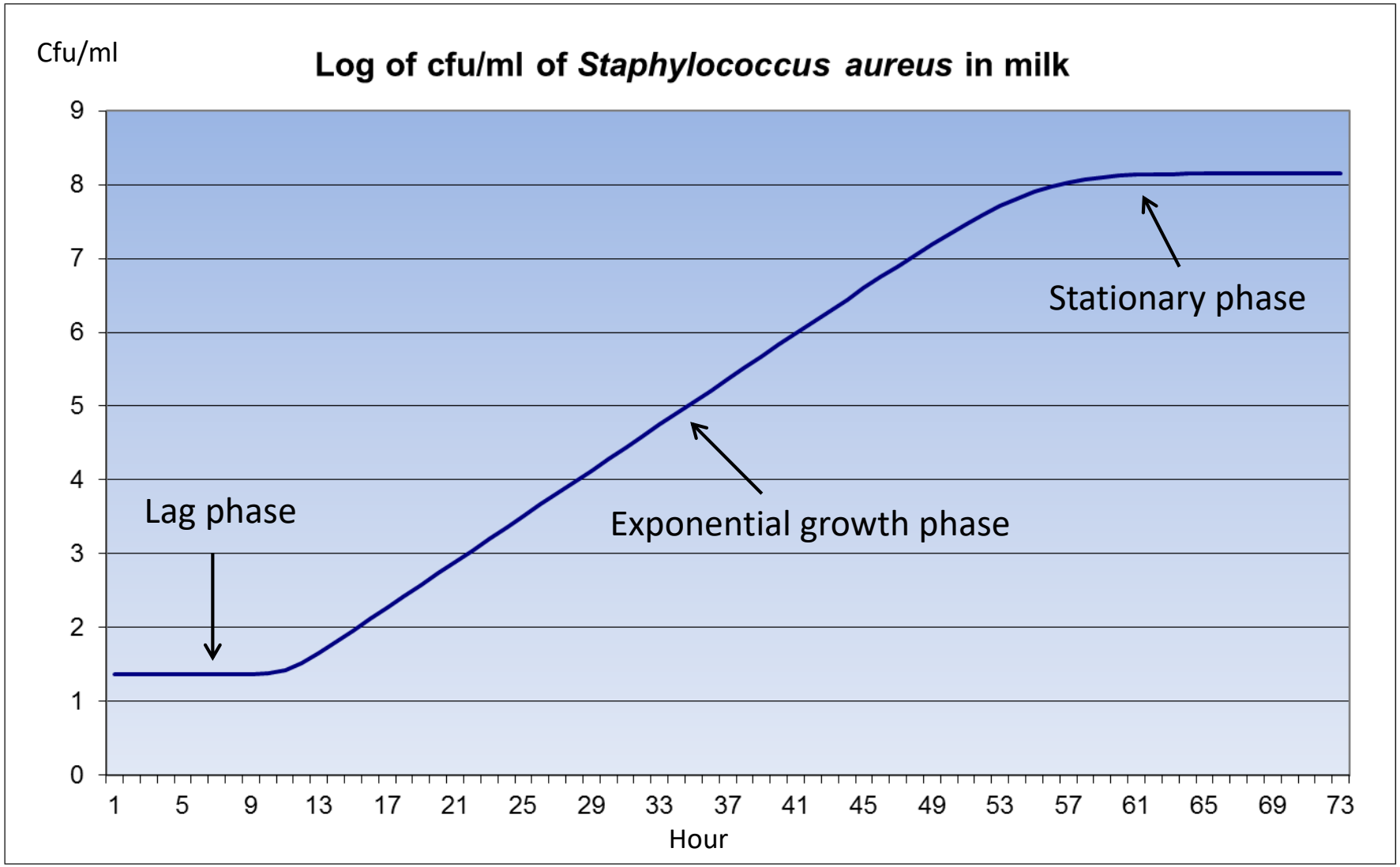


Fault tree: understanding the logic of illness

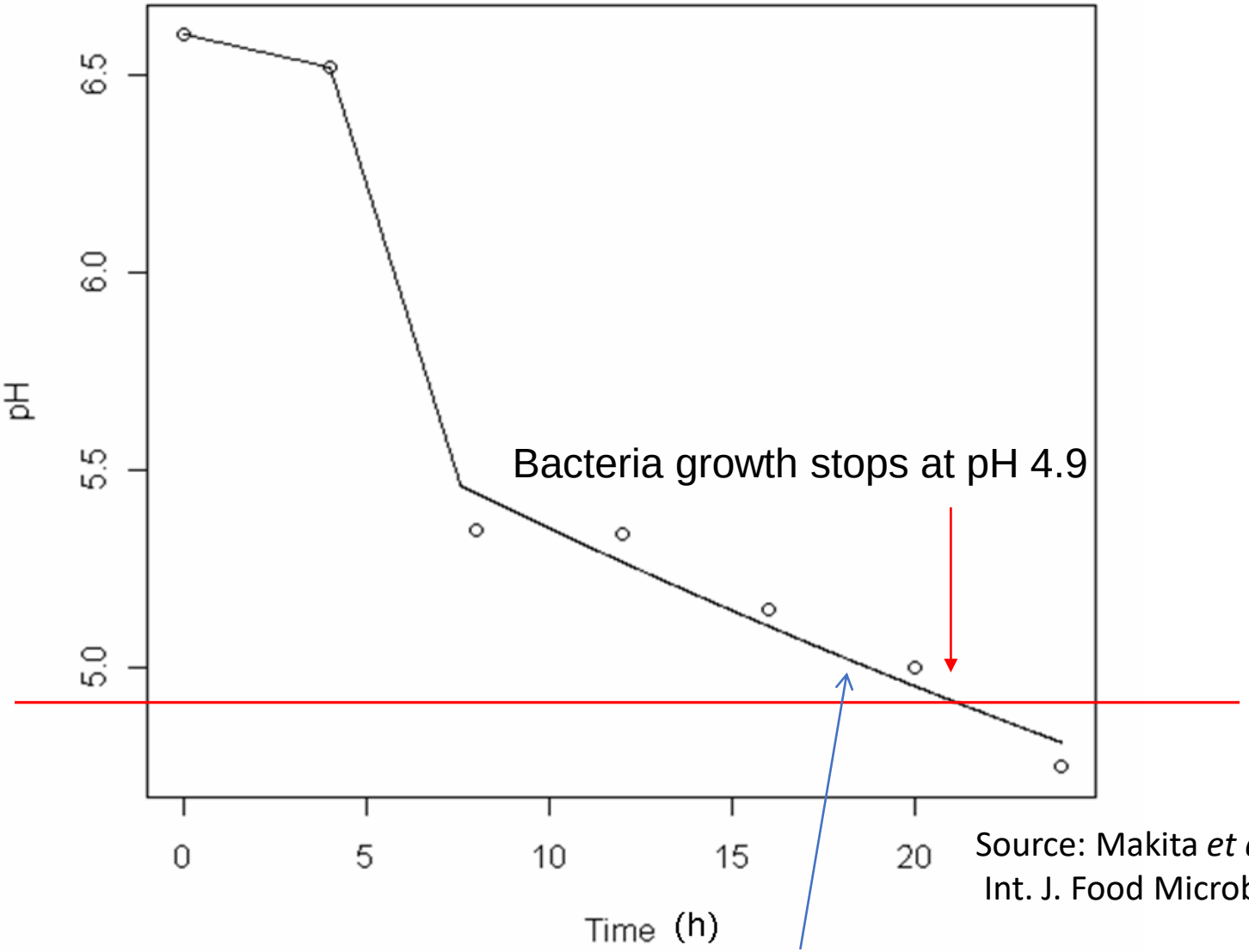


Growth model:

Fujikawa and Morozumi (2006)
modified logistic model



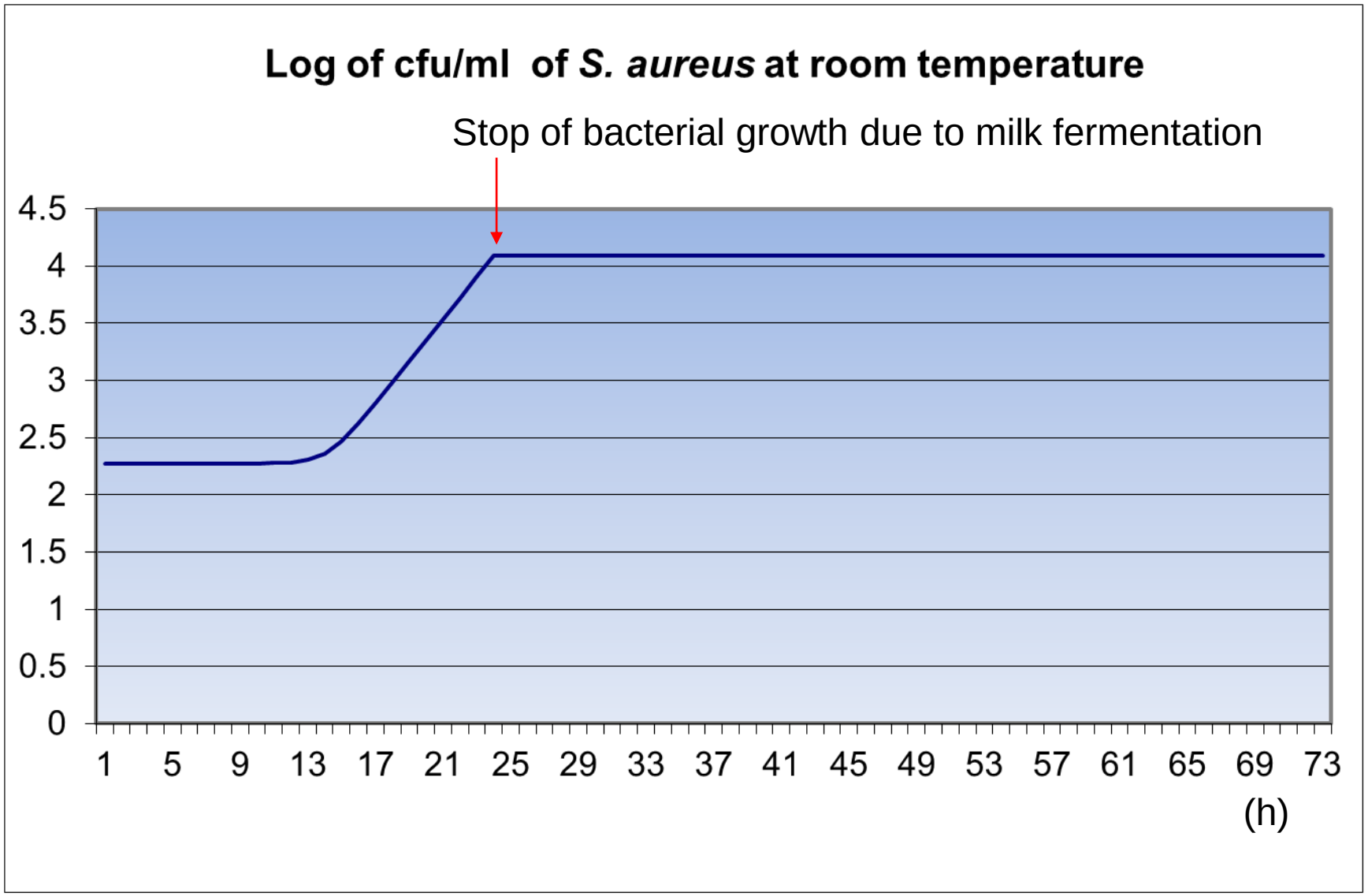
Risk mitigation by traditional milk fermentation- Modeling using reported data (Gonfa et al., 1999)



Source: Makita *et al.*, 2012 Int. J. Food Microbiol.

1/pH=0.002 t (h)+1.187 (df=3, r2=0.90, p=0.009)

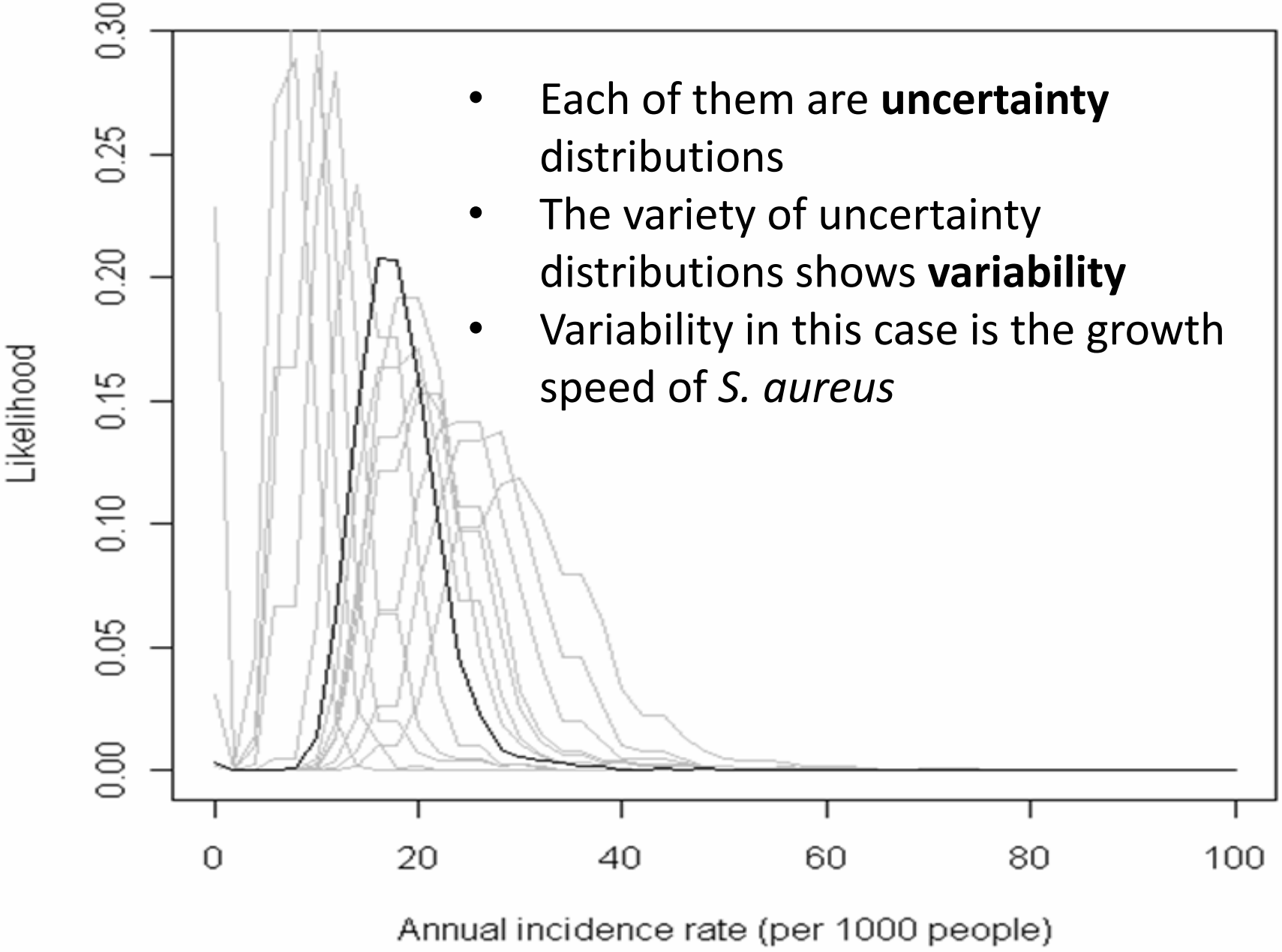
Stop of growth of *S. aureus* in milk by low pH



Constructing a risk model in a computer

- Model value chains which include
  - Mixing
  - Separation
  - Growth
  - Inactivation
- In a stochastic model, computer simulation is used

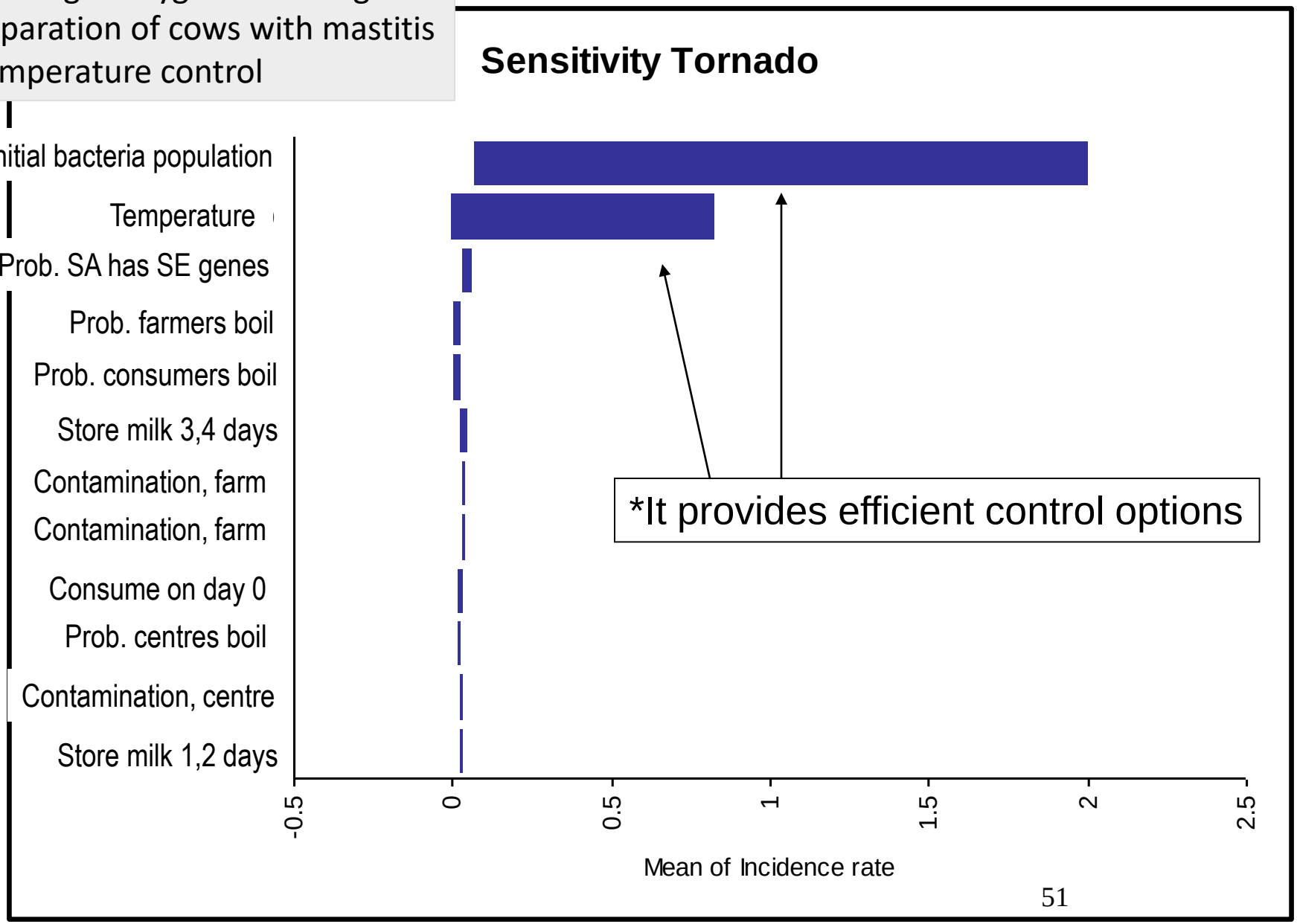
Risk characterization



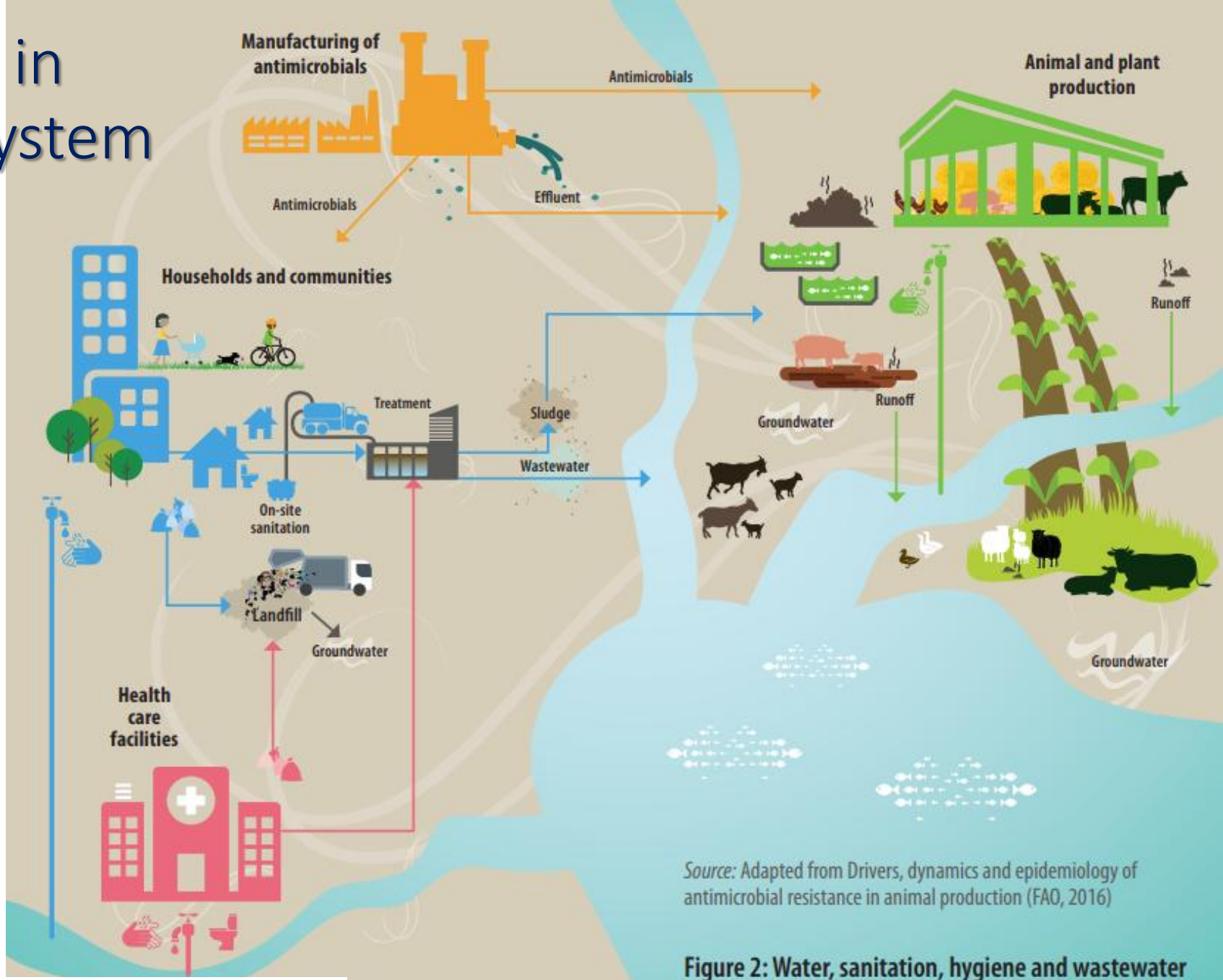
- Each of them are **uncertainty** distributions
- The variety of uncertainty distributions shows **variability**
- Variability in this case is the growth speed of *S. aureus*

Sensitivity analysis

- Training for hygienic milking
- Separation of cows with mastitis
- Temperature control

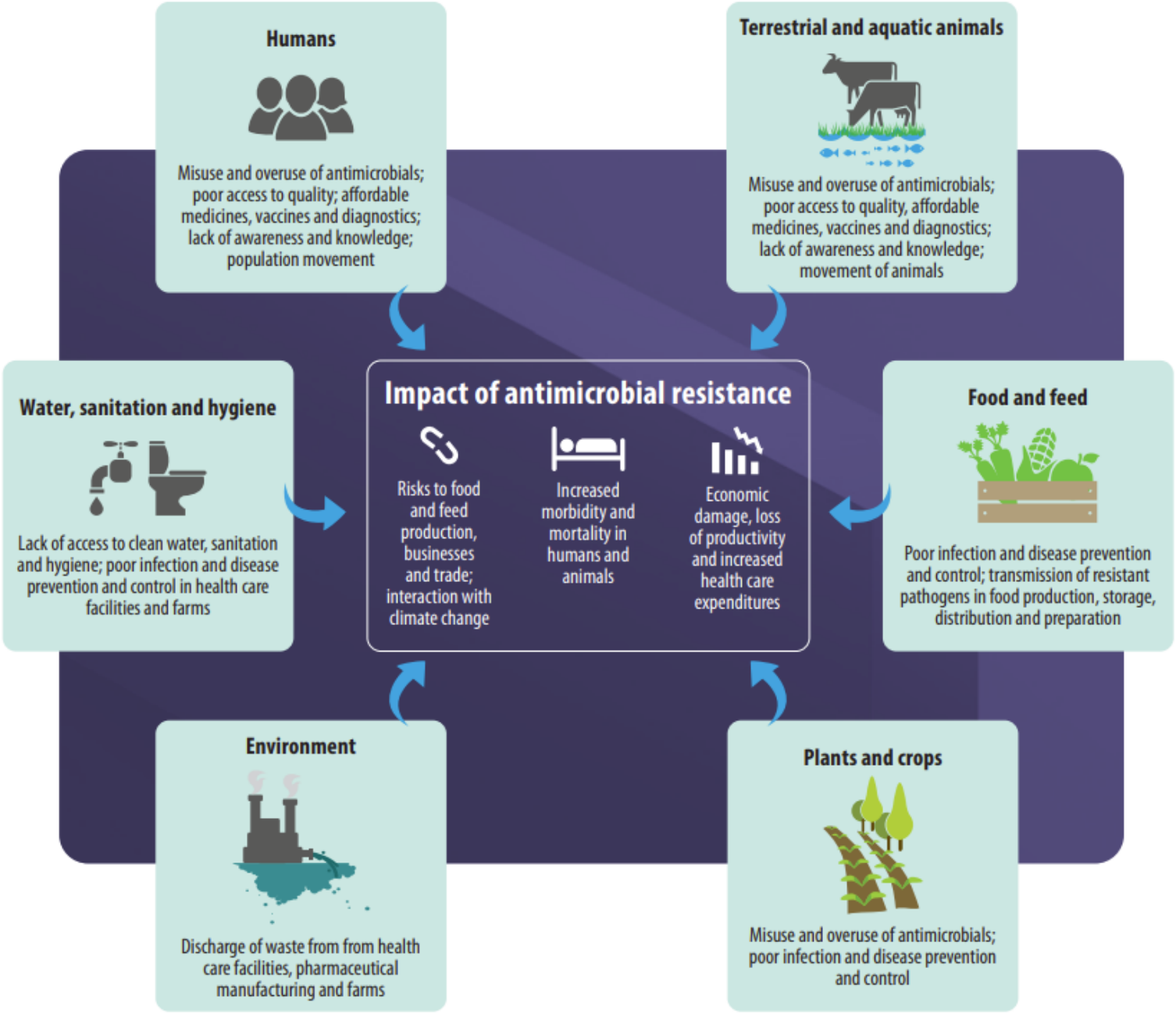


AMR in ecosystem



Source: Adapted from Drivers, dynamics and epidemiology of antimicrobial resistance in animal production (FAO, 2016)

Figure 2: Water, sanitation, hygiene and wastewater treatment influences on antimicrobial resistance

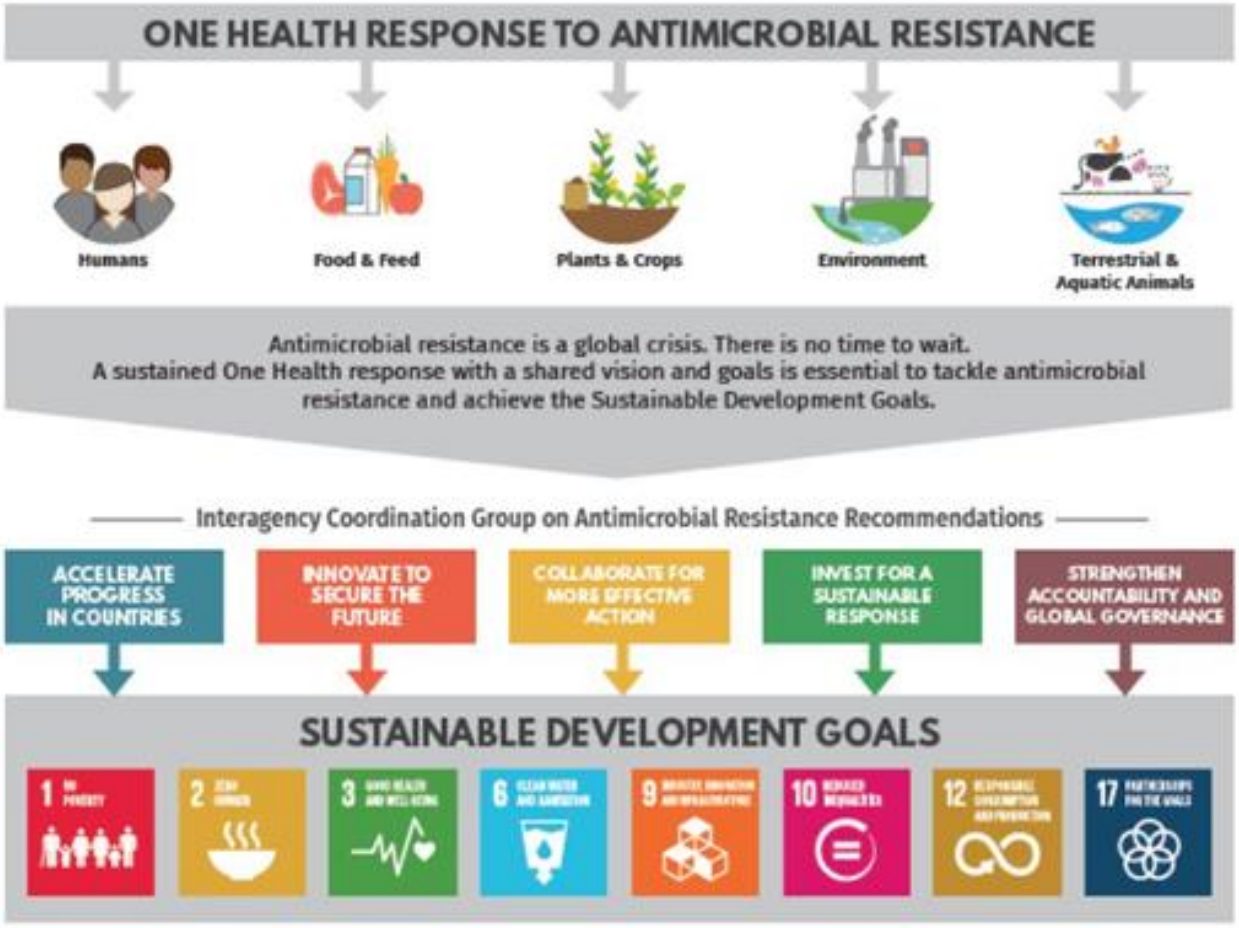


Source: Adapted from Inter-Agency Coordination Group (2019). No time to wait: Securing the future from drug-resistant infections. Report to the Secretary-General of the United Nations.

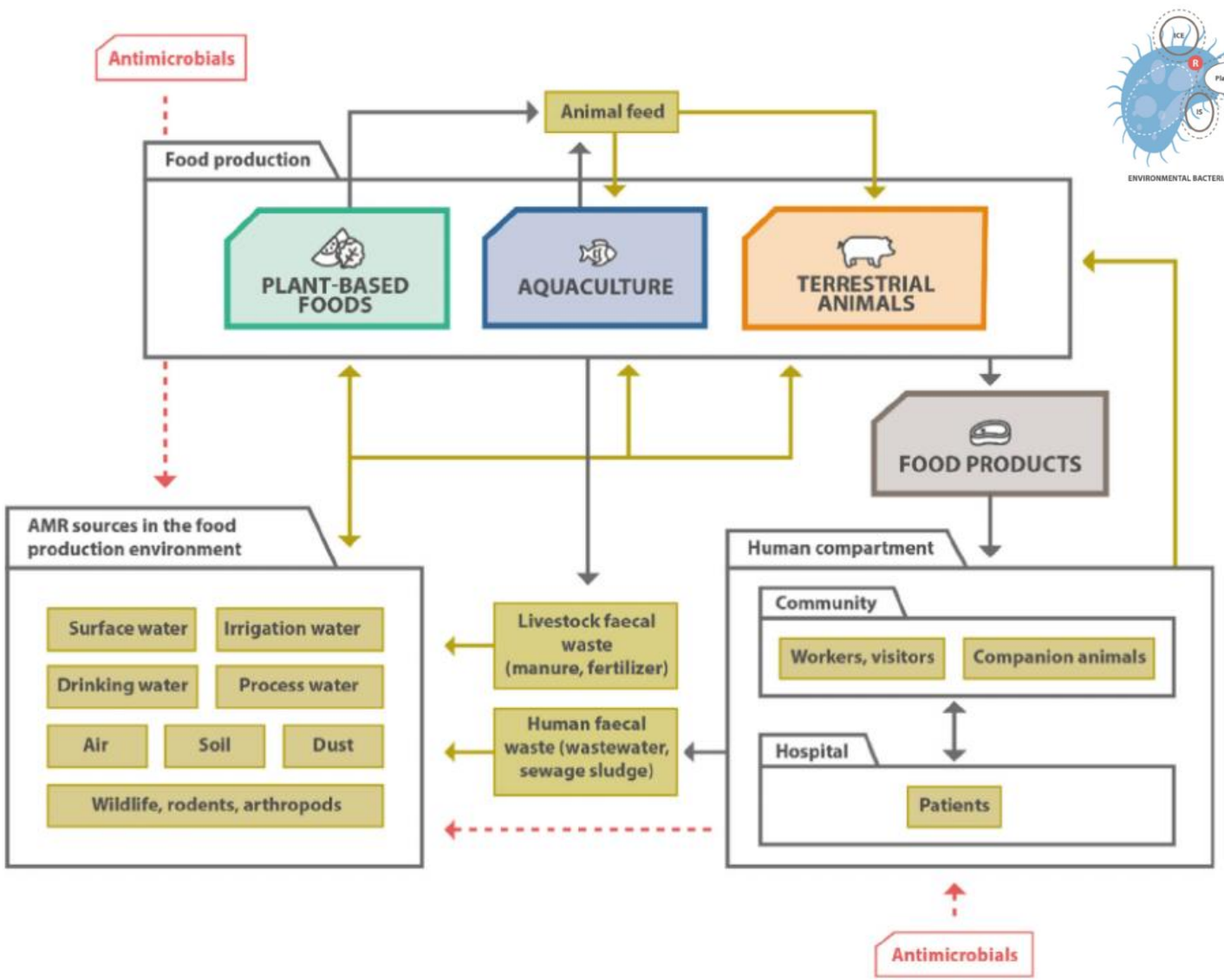
AMR and SDGs

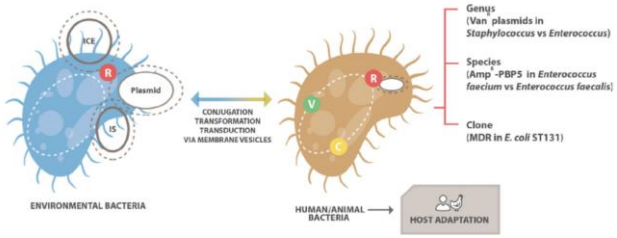
NO TIME TO WAIT:
SECURING THE FUTURE FROM DRUG-RESISTANT INFECTIONS

REPORT TO THE SECRETARY-GENERAL OF THE UNITED NATIONS
APRIL 2019



System approach: EFSA





EFSA BIOHAZ (2021) Role played by the environment in the emergence and spread of antimicrobial resistance (AMR) through the food chain. Doi: 10.2903/j.efsa.2021.6651

Another example
Risk in vegetables

Conclusion

- Risk is a probability of occurrence of a scenario and its size of impact
- By applying entire or a part of a risk assessment framework, you can assess most of the risks you are facing to
- Risk assessment result is extremely helpful in communicating the risk with citizen and between stakeholders, and making decision for preparation and/or intervention (risk management)

Any questions?