Risk Assessment & Risk Management Activities in Japan

Fumiko Kasuga

National Institute of Health Sciences, Japan

Today's topics

- Risk management activities for food safety in Japan
- Risk analysis framework in Japan
- Risk assessment and science
- Future challenges

Food Safety - from Farm to Table

Food Chain

Production | **Processing, Distributing**

Farmers → Products → Foods → Consumers

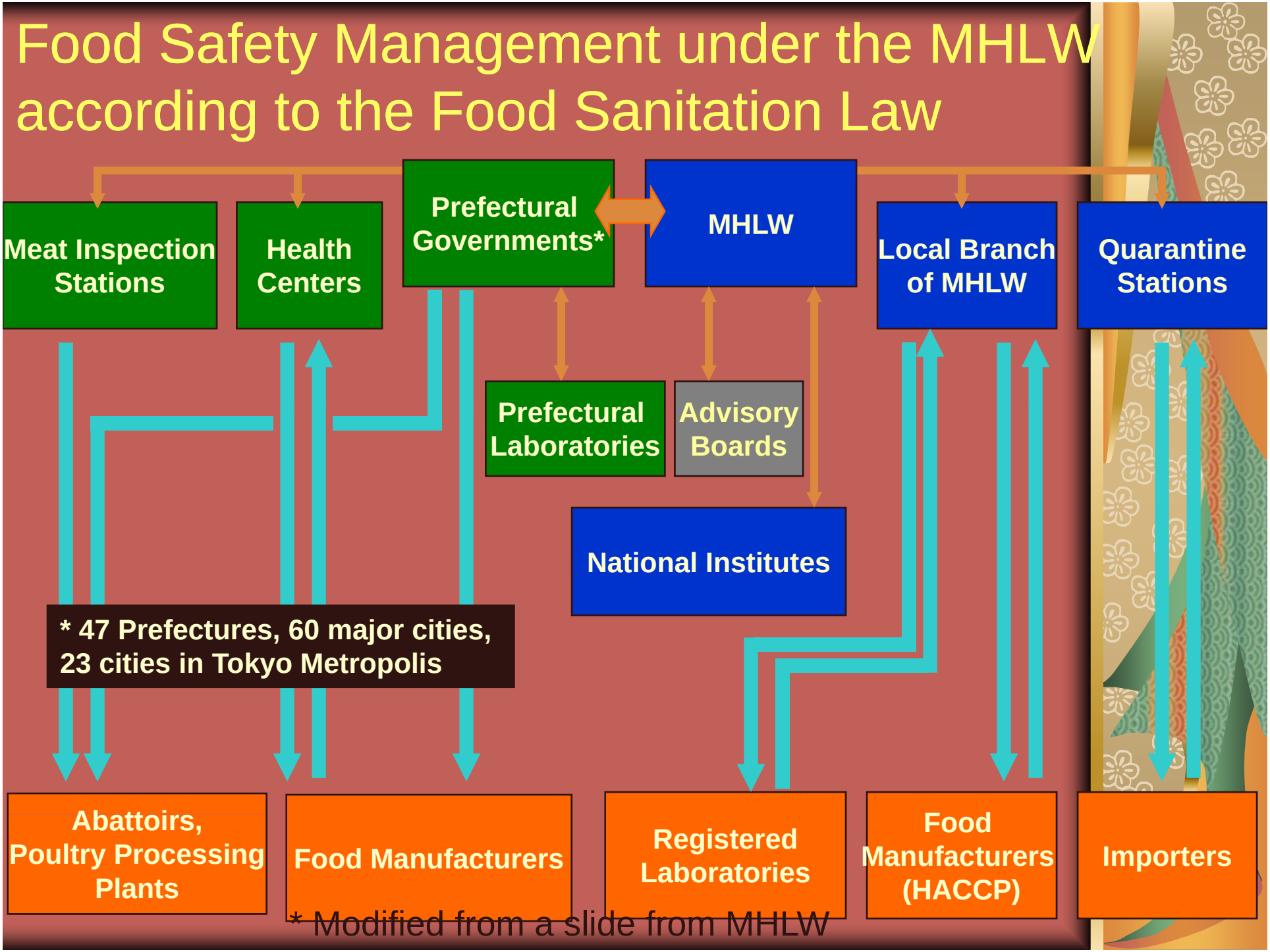
Ministry of Agriculture, Fisheries and Forest (MAFF) (Regulation at production stage)	Cooperation	Ministry of Health, Labour and Welfare (Regulation on foods and food handling)

Food Safety Commission

(Assessment on the impacts on human health)

* Modified from a slide from MAFF

Food Safety Management under the MHLW according to the Food Sanitation Law



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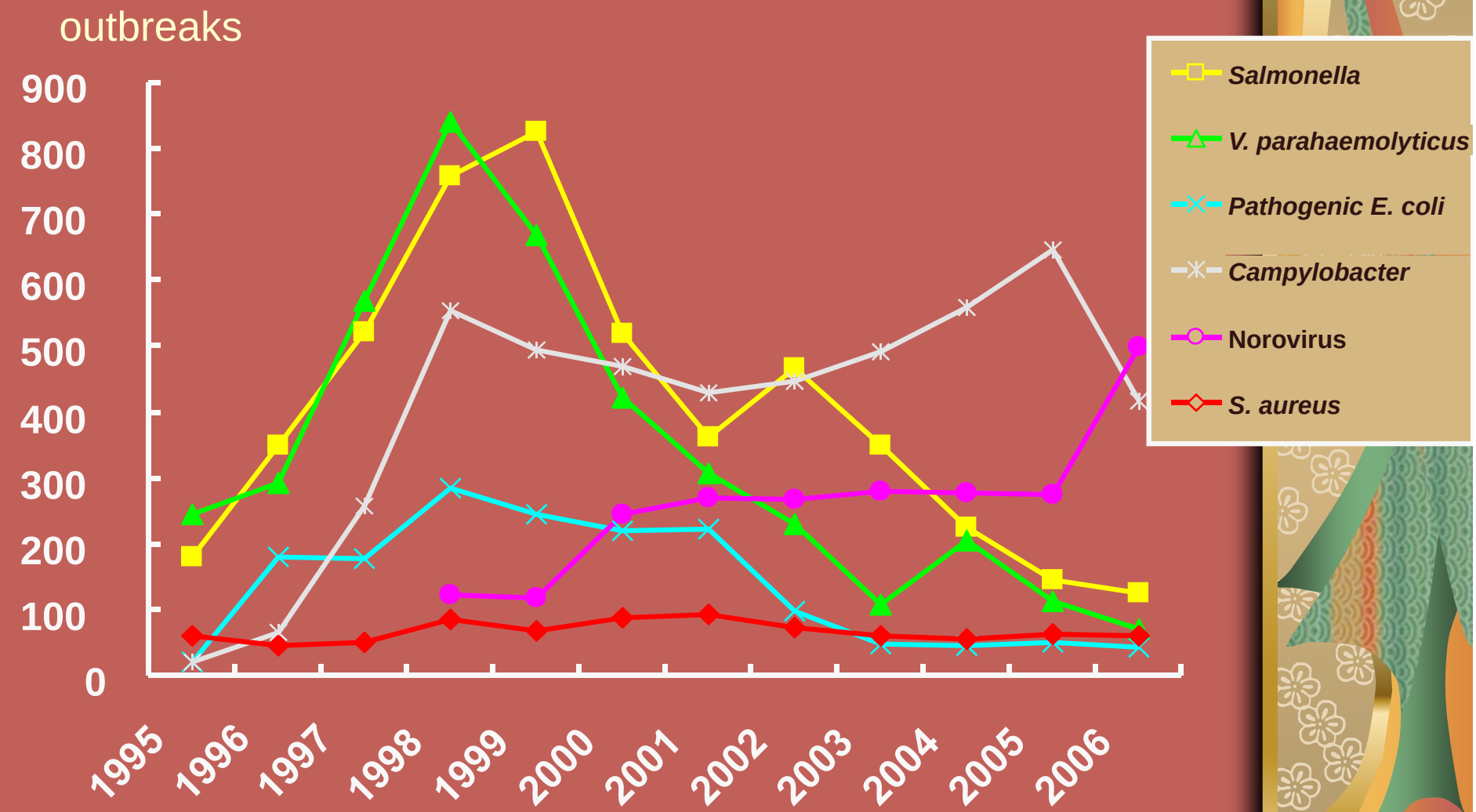
Trends in foodborne outbreaks by causative pathogens (No. of outbreaks)



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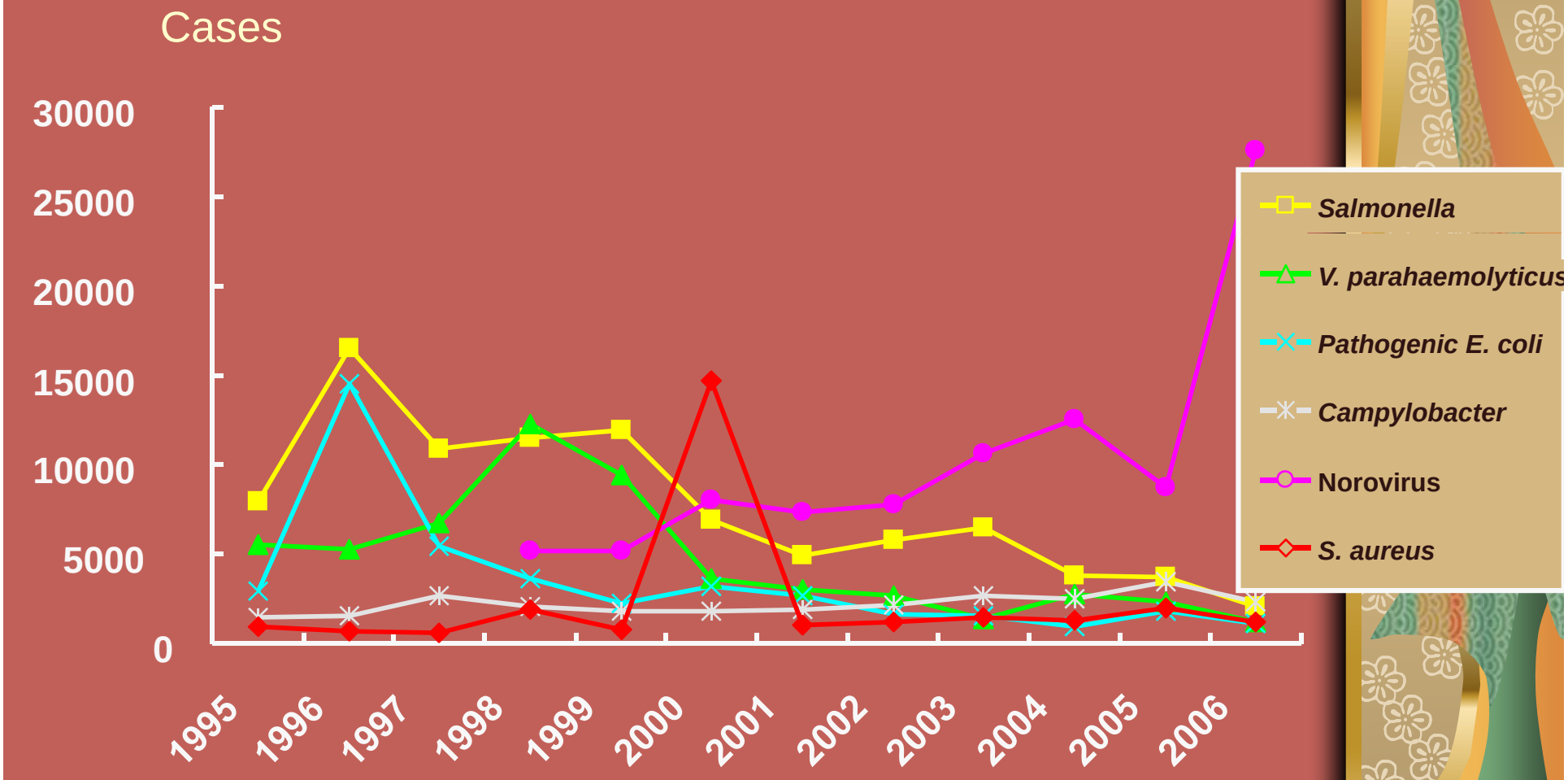
Trends in foodborne outbreaks by causative pathogens (No. of cases)



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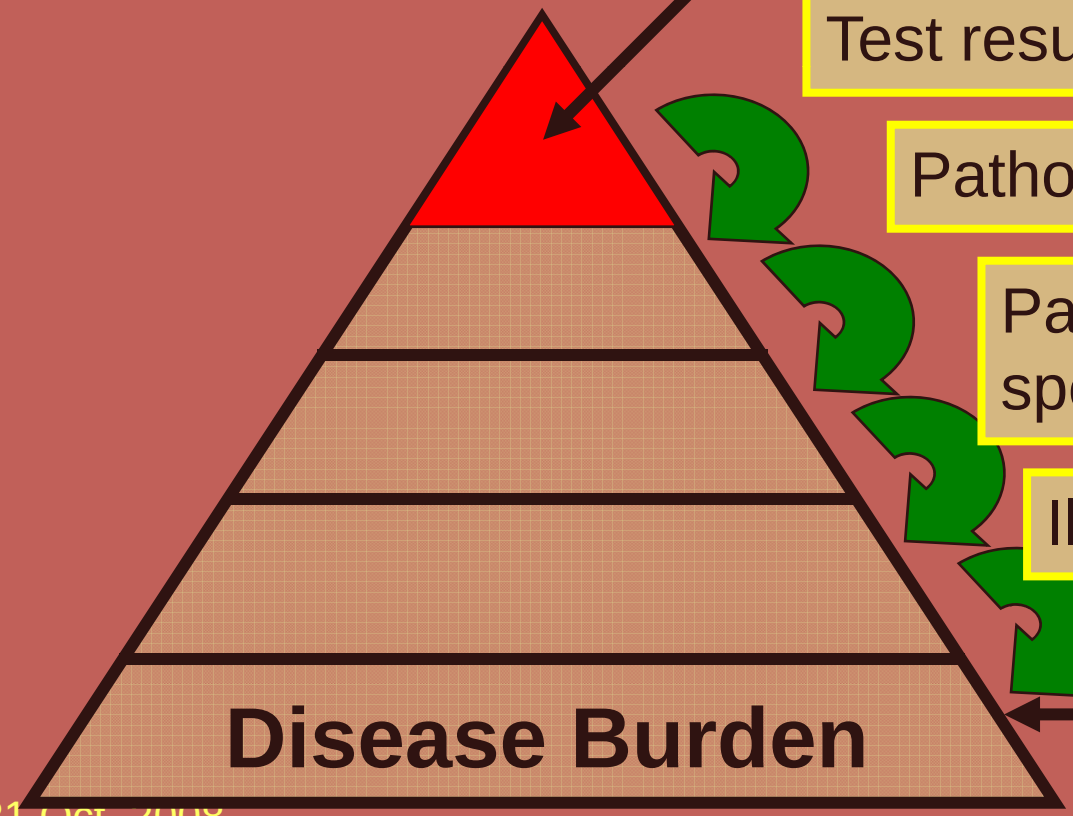
Surveillance of Foodborne Diseases



What we do know…

(reported cases)

Test results reported to the authority

Pathogens detected by test

Patients tested their stool specimens

Ill people seek medical care

What we need to know!

Burden of illness study in Japan

- Pilot studies in Miyagi prefecture, Japan, to estimate acute gastroenteritis associated with *Vibrio parahaemolyticus, Campylobacter*, and *Salmonella* based on the lab confirmed cases.
- GE incidence, physician visit rate, stool sampling rate were obtained by population telephone survey and other methods.
- Ratio of foodborne was assumed according to US paper.

K. Kubota, F. Kasuga, H. Toyofuku, E. Iwasaki, S. Inagaki, T. Nokubo, Y. Sakurai, M. Komatsu, K. Abe, K. Hiroshima, M. Kumagai, M. Oguro, F. J. Angulo, E. Scallan, K. Morikawa

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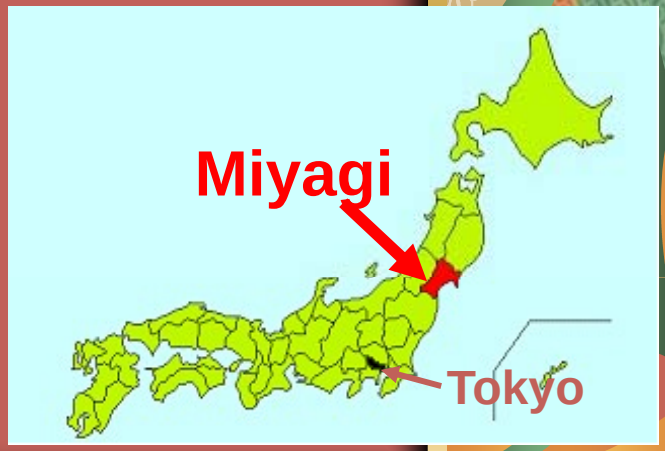

Situation before 2001

- Scientists were providing suggestions through advisory board activities within competent authority agencies, by
  - collecting and reviewing data
  - providing general expert opinions
  - advisory boards still active
- Science-based, but not always risk-based

In 2001 and thereafter

- The 1st case of BSE was detected in Japan, September 10, 2001
- MAFF was criticized of insufficiently incorporating scientific advices on BSE control
- Discussions initiated toward re-organizing government structure for food safety
  - Introduction of Risk Analysis
  - Separation of RAs from RM
  - Establishing a new organization for RAs

The Food Safety Basic Law

Law No. 48, May 23, 2003

Enforced : No. 74. June 11. 2003

Contents

- Chapter I General Provisions (Articles 1-10)
- Chapter II Basic Direction for Policy Formulation (Articles 11-21)
  - Adoption of risk analysis (Articles 11-13)
- Chapter III Food Safety Commission (Articles 22-38)
  - To be established in the Cabinet Office
  - Risk managers ask Commission to conduct risk assessments and/or to provide scientific advices
  - Food Safety Commission can conduct self-task risk assessment

Related Ministries for Food Safety (since July, 2003)

Cabinet Office

Food Safety Commission

Risk Assessment

-**Risk assessments**
-**Risk communication**
-**Emergency response**

e.g. setting ADI

Risk assessment results, Opinions

Questions

Risk assessment results, Opinions

MAFF

Risk Management

MHLW

Risk Management

e.g. setting MRL

Risk Communication

All stakeholders

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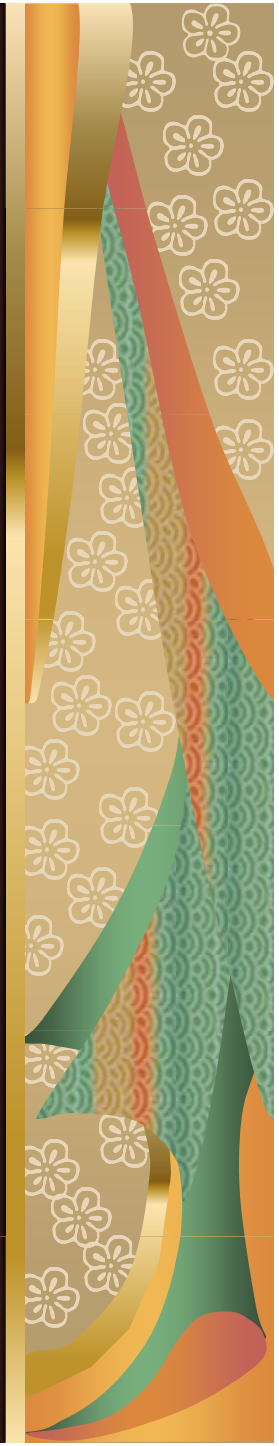
Organization of Food Safety Commission

- Commission
- Expert Committees
  - Planning
  - Risk communication
  - Emergency response (outbreaks, etc.)
  - (Chemical substance assessment groups)
    - Food additives, Pesticides, Veterinary Medicines, Apparatus/Containers and packages, Chemical substances/Contaminants, etc.
  - (Biological materials assessment groups)
    - Microorganisms/Viruses, Natural toxins/Mycotoxins, Prions(BSE, etc.)
  - (Emerging foods assessment groups)
    - Genetically modified foods, Novel foods, Feed/Fertilizer

Opinions provided by the Expert Committee on Microorganisms/Viruses

- Opinions on the changes in the target diseases in Slaughterhouse Sanitation Law and Food Sanitation Law
- Opinions on the establishment of microbiological specification on *Bacillus cereus* in infant formula
- Opinions on the removal of microbiological specification (*E. coli* negative) from frozen bread dough



Guidelines for conducting MRA - Table of Contents

1. Introduction
2. Selection of subjects for food safety risk assessment to be conducted by the Food Safety Commission
   - Food safety issue identification
   - Preparation of risk profile
   - Setting priorities among food safety problems
   - Selection of subjects for assessment and items for confirmation
3. Risk assessment issues raised by risk managers
4. Risk Assessment
   - Components of risk assessment and conduct procedures

[Appendices]

Definitions and interpretations of terms (ALOP, FSO, PO, PC)
Predictive Microbiology
Dose-Response Models
Sensitivity Analysis
Uncertainty Analysis

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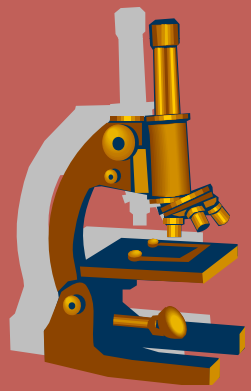
Preparation of risk profiles

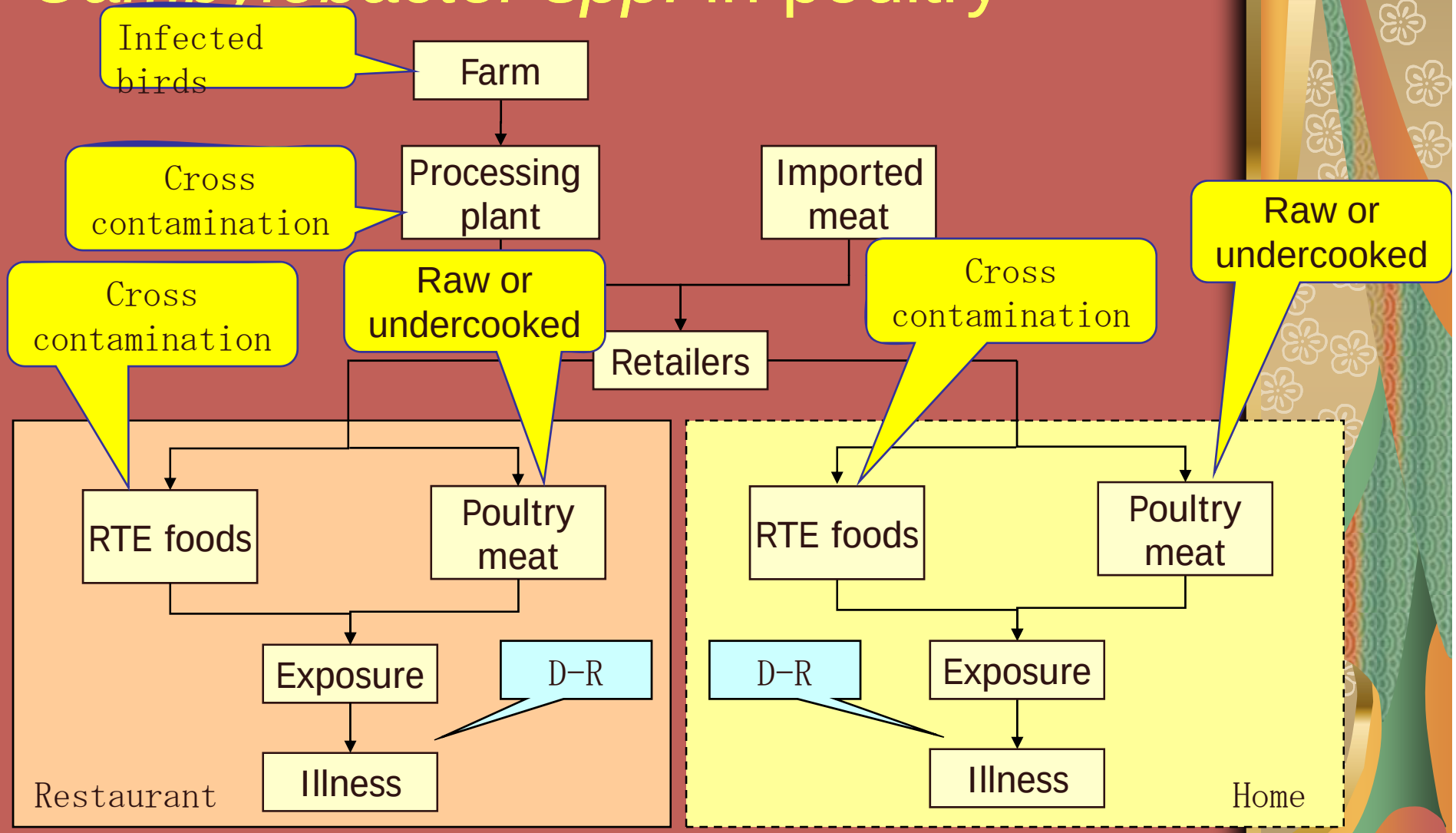
- Currently available information summarized by FSC expert committees
  - *Salmonella* in poultry or eggs
  - *Campylobacter spp.* in poultry
  - *Vibrio spp.* in seafoods
  - *Listeria* in RTE foods
  - EHEC in beef
  - *Norovirus* in bivalves
  - Hepatitis virus A in bivalves
  - Hepatitis virus E in pork



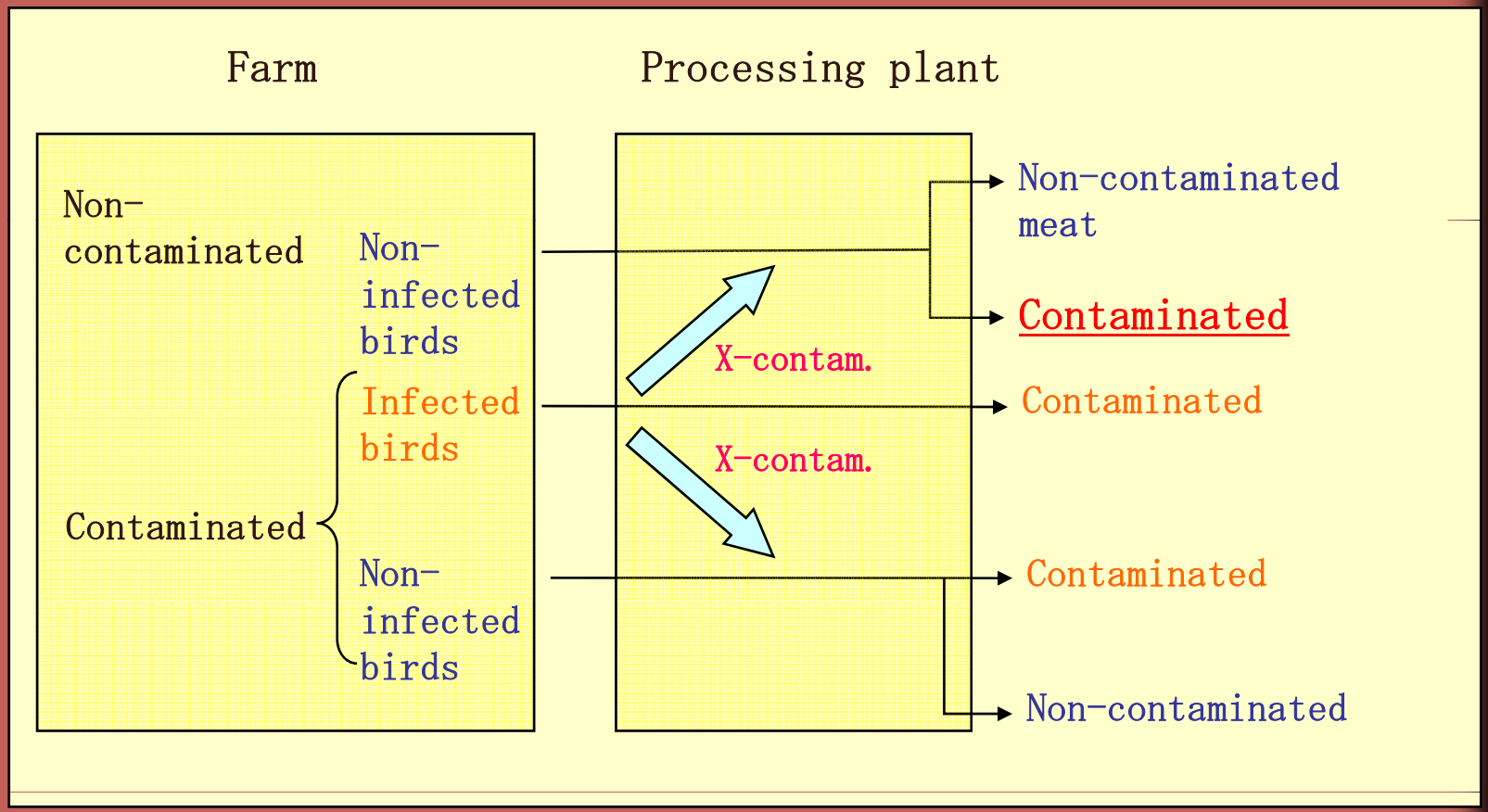
Further prioritization – current activities

- *Salmonella* Enteritidis in eggs
- *Campylobacter spp.* in poultry
- EHEC in beef products
- *Norovirus* in oysters
- Considering whether MRA is needed and feasible
  - Possible RM questions
  - Possible RA structures
  - Data availability
- *Campylobacter spp.* in poultry was selected.

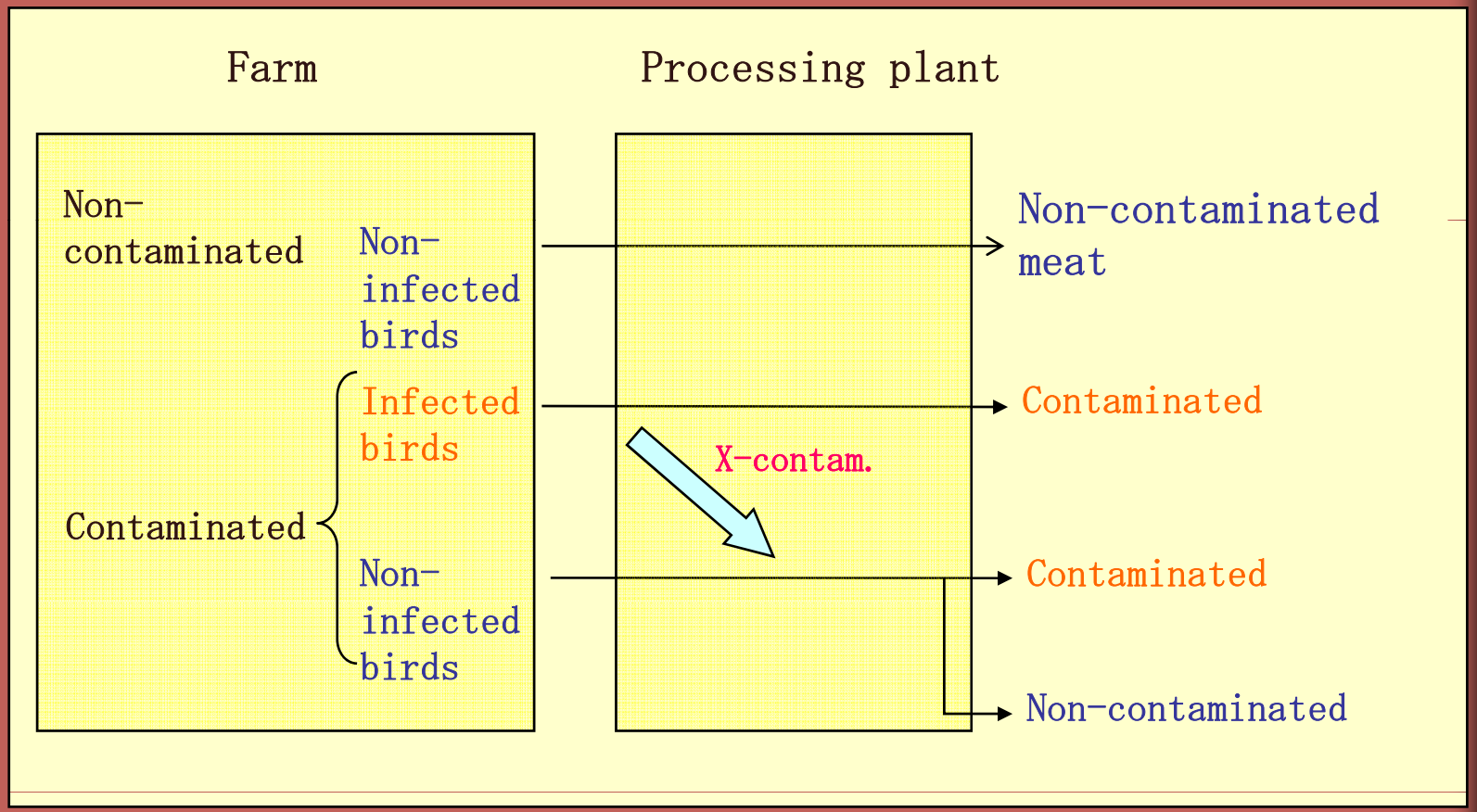
Quantitative risk assessment of *Campylobacter spp.* in poultry



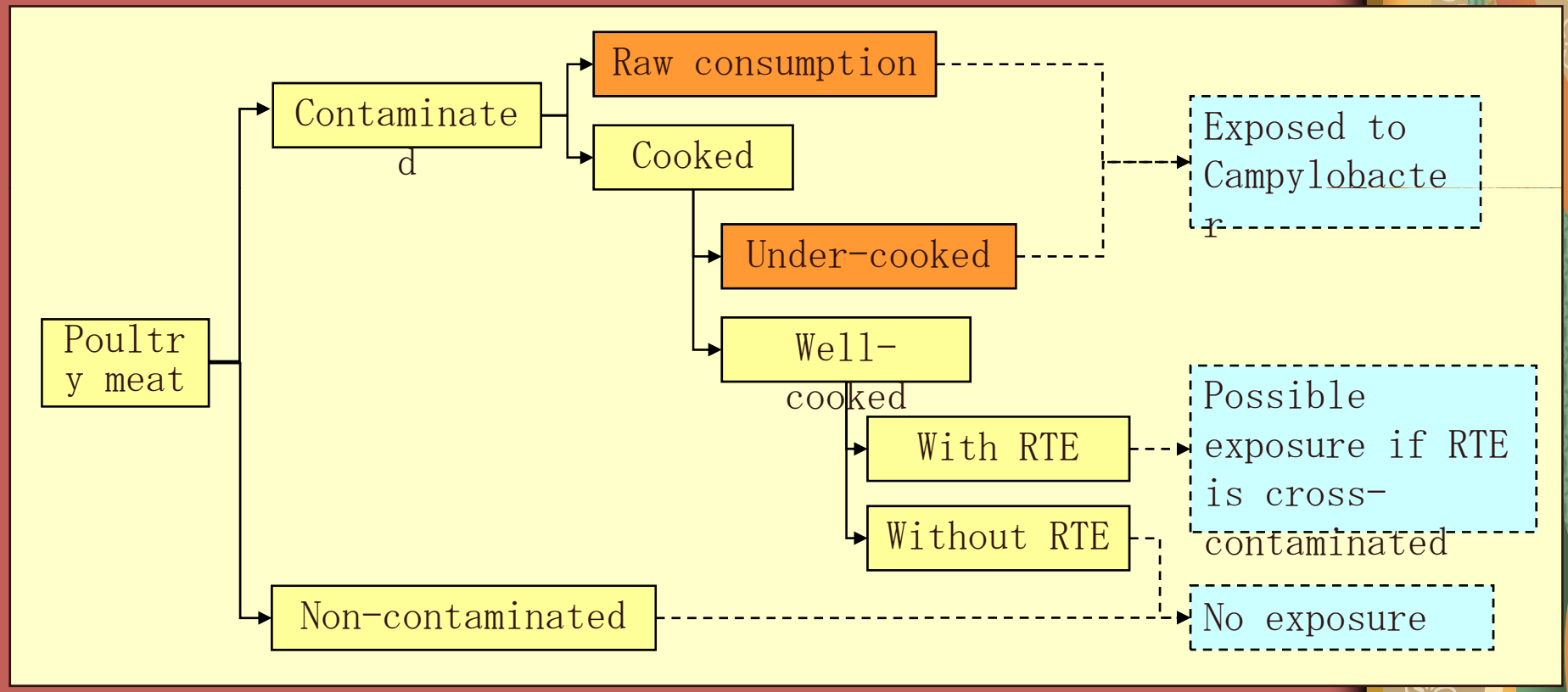
Poultry processing plants
- baseline scenario



Poultry processing plants
- if birds from contaminated and non-contaminated farms can be separated



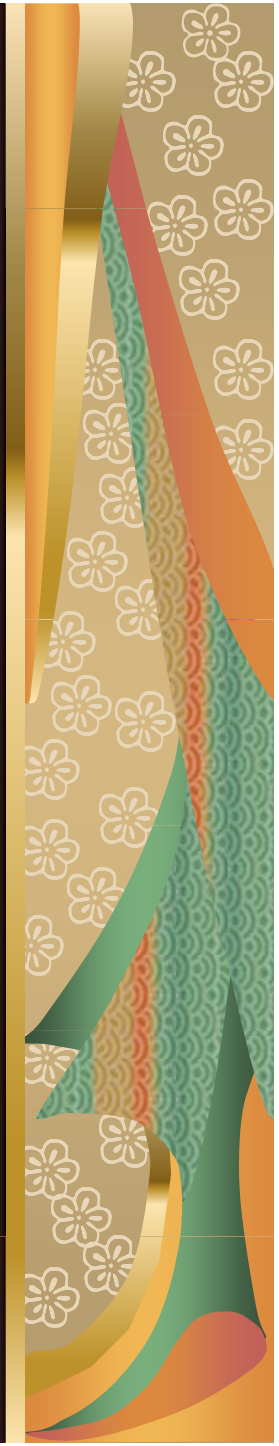
Cooking and consumption stage



Future challenges

Development of QMRA

- Science-based advice can give information that a control measure can cause certain degree of pathogen reduction at certain stage of food chain, which must be good for the consumer.
- However, we still don’t know how many people can be saved by this measure.
- QMRA can answer this question, and can compare the effects of different measures in terms of reducing illnesses.
- QMRA needs integration of multiple disciplines of science and time consuming. Need training and collaboration with new expertise.
- Still needs science-based advice/opinions.



Future challenges (continued)

- Integration in epidemiological issues
  - Estimating burden of illness (real cases) and then to consider source attribution (how much foodborne, or how much beef-related)
  - Improvement of surveillance
    - Various source of surveillance data practically integrated in many countries even for the human illnesses
    - Still challenge to integrate animal and human surveillance systems and food contamination data in Japan
    - Harmonization of detection and testing methods for foods from the international viewpoint
  - Inclusion of severity of illness in burden estimates
    - Metrics of DALY (disability adjusted life years)
    - New project initiated by WHO (Foodborne Epidemiology Reference Group: FERG) – support and collaboration