

The Past and Future of Risk Assessment for Food Safety - Perspective from FSCJ's Experience -



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Susumu Kumagai
(Chair, FSCJ)

The Past

Chronology of Events Relating to Risk Assessment for Food Safety

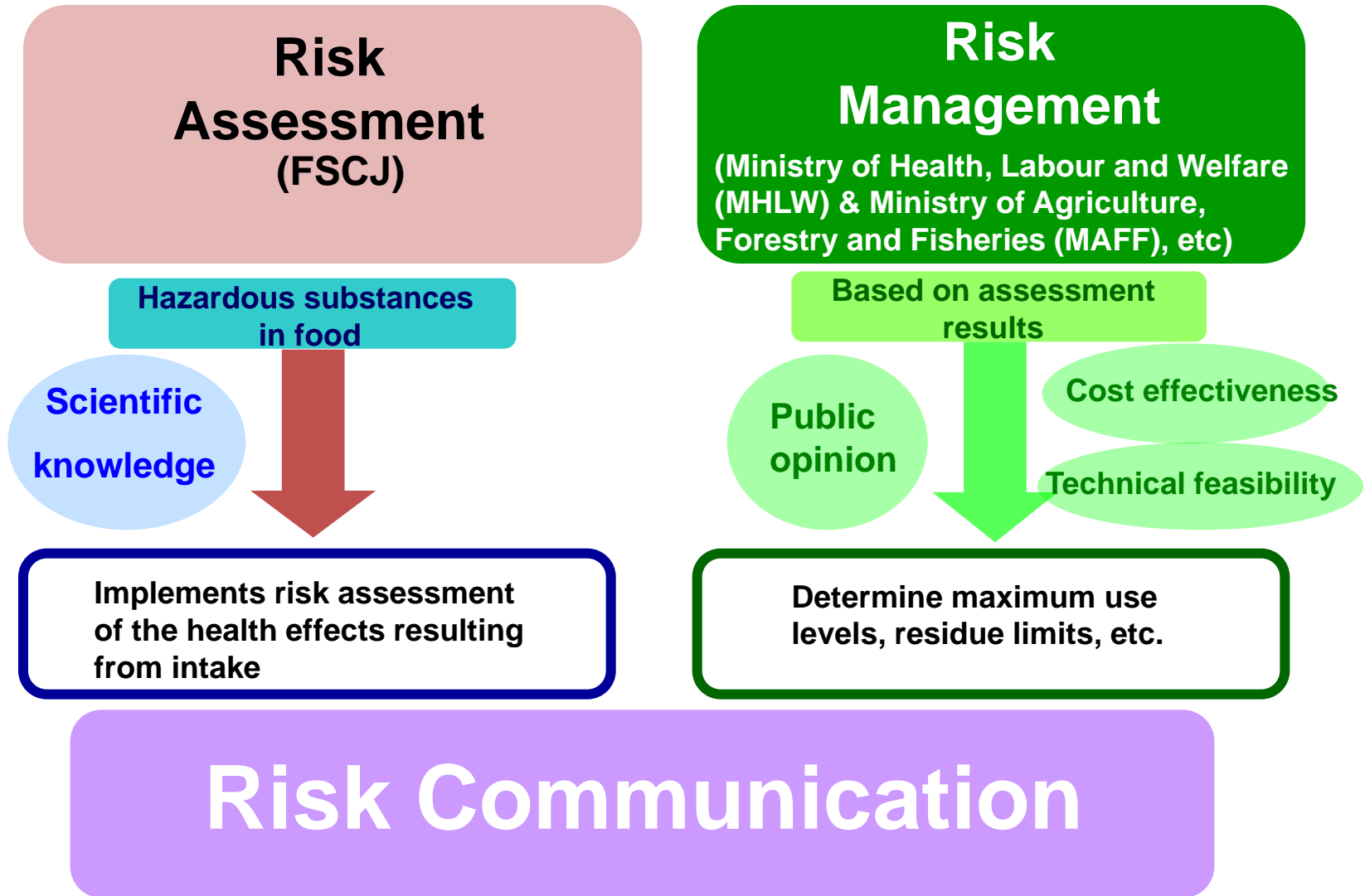
Japan	International organizations
<p>1949 Food Sanitation Investigation Council (MHW), Expert panels, Expert Committees, etc</p>	<p>1956 JECFA 1963 CODEX Alimentarius Commission 1965 IARC 1967 JMPR</p>
<p>1995 Incorporation of HACCP to the Food Sanitation Act</p>	<p>1993 FAO/WHO “HACCP System and Guidelines for its Application” 1995 FAO/WHO “Application of Risk Analysis to Food Standard Issues”</p>
<p>2001 Pharmaceutical Affairs & Food Sanitation Council (MHLW)</p>	<p>1999 JEMRA</p>
<p>2003 FSCJ Expert committees</p>	<p>2002 EFSA, FSANZ 2003 “Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius”</p>

Background of FSCJ's Foundation



- **Food Safety Basic Act enacted (May 16th 2003)**
- **Top priority focused on protecting public health**
- **Proposed introduction of risk analysis method to food safety administration**
- **FSCJ, a risk assessment agency, established in Cabinet Office, separately from the administrative authorities (July 1st, 2003)**
- **Carry out unbiased, independent and science-based risk assessment for food safety**

Three Elements of the Risk Analysis Method



Roles of FSCJ

Risk Assessment

Based on scientific data, assesses the probability and severity of adverse health effect associated with consumption of food.

Emergency Response

Collects and disseminates relevant information to general public in food related emergency situations such as food poisoning outbreaks.

Risk Communication

Interactively exchanges information and opinion concerning food related risks with stakeholders, including consumer.



FSCJ Organization

Food Safety Commission of Japan(FSCJ): 7 Commissioners

12 Expert Committees (Approximately 200 experts)

- Planning

Chemical Substances

- **Food additives**
- **Pesticides**
- **Veterinary Medical Products**
- **Apparatus and containers/
packages**
- **Chemical and Contaminants**

Biological Materials

- **Microorganisms and Viruses**
- **Prions**
- **Natural toxins and mycotoxins**

Novel Foods

- **Genetically modified foods**
- **Novel foods**
- **Feed, Fertilizers**

Secretariat

- **Director-General**
- **Deputy Director-General**
- **General affairs Division**
- **First Risk Assessment Division**
- **Second Risk Assessment Division**
- **Information, Recommendation
and Public Relations Division**
- **Director for Information Analysis**
- **Director for Risk Communication**



Flow of Assessment

Requests from risk managers

Opinions from general public
(Self-tasking assessment)

FSCJ

Hearing of the background and details of
Assessment requests

Deciding assessment
subjects

Discussion at Expert Committees

Drafting of assessment reports

Call for the public comments (generally for 30 days)

Public meetings

Additional discussion at Expert Committees as necessary

Finalizing of risk assessment report (FSCJ decision)

Notification of assessments

Risk Management Organization

Risk Assessment Achievements

Classification	Number of requests (The number indicated includes the self-tasking assessments)	Number of completed assessments
Food additives	135	124
Pesticides	840	539
(Including positive list-related pesticides)	(421)	(198)
Veterinary medicinal products	363	305
(Including positive list-related v/m)	(104)	(57)
Chemical substances/contaminants	60	54
Apparatus and containers/packages	16	7
Microorganisms/viruses	9	8
Prions	21	28
Natural toxins/mycotoxins	8	6
Genetically modified foods, etc.	180	159
Novel foods, etc.	76	71
Feed, Fertilizers, etc.	153	85
(Positive list-related feed+etc. included)	(94)	(45)
Other	6	4
Total	1,867	1,390

(As of May 2013)

FSCJ Assessments and their results

- Pesticides -

FSCJ < Risk Assessment >

Accepted Daily Intake: (mg/kg bw/day)



MHLW

< Risk Management >

Maximum Residue Limits
in Food
(vegetables, fruits, etc.)
(ppm)
[Food Sanitation Act]



MAFF

< Risk Management >

Conditions on usage
↓
Approval of agricultural
chemicals
[Agricultural Chemicals
Control Act]

FSCJ Assessments and their results

- Trichloroethylene in drinking water -

FSCJ <Risk Assessment>

Tolerated Daily Intake : 1.46 $\mu\text{g}/\text{kg}$ bw/day
Cancer Risk* : $8.3 \times 10^{-3}/\text{mg}/\text{kg}$ bw/day



*Cancer Risk when exposed to
1mg/kg bw/day through a life

MHLW <Risk Management>

Limit in Drinking Water
0.01 mg/l (\leftarrow 0.03 mg/l)
[Waterworks Act]

FSCJ Assessments and their results

- 2,3,5,6-Tetramethylpyrazine

(Internationally commonly used food additives “flavourings”) -

FSCJ < Risk Assessment >

No safety concern when used for a flavouring agent



MHLW < Risk Management >

- Condition of use : only for flavourings
- Approval of food additives
[Food Sanitation Act]

FSCJ Assessments and their results

- EHEC and *Salmonella* in Beef for Raw-Eating -

MHLW <Request of risk assessment>

- Target bacteria in beef for raw-eating : EHEC and *Salmonella*
- Indicator microorganisms : Enterobacteriaceae
- Standard for processing



FSCJ <Risk Assessment>

- Food Safety Objective (FSO) for EHEC and *Salmonella* is <0.04 cfu/g
- Validation for processing condition to give the FSO value is required.



MHLW <Risk Management>

- Microbiological standard : Enterobacteriaceae negative
- Processing standard : Beef-chunk surface must be heated at 60 °C for >2min.

[Food Sanitation Act]

FSCJ Assessments and Their Results

- Revision of Control Measures for BSE-

MHLW <Request of risk assessment>

- Domestic
 - ① Age limits for BSE test of slaughtered cattle
 - ② Specified risk materials (SRMs)
- Imported from USA, Canada, France, Netherlands
 - ① Age restriction on cattle meat & offal import
 - ② SRMs



FSCJ <Risk Assessment>

Differences in risk are negligible between

- Domestic
 - >30 mo & >20 mo for BSE test; >30 mo & all ages for SRM
- Imported from USA, Canada, France, Netherlands
 - 30 mo & 20 (0) mo for upper limit of import; >30 mo & all ages for SRM



MHLW <Risk Management>

Regulation based on the risk assessments

Risk Assessments and Their Results

(2003-2011)

Numbers of Assessments Conducted by FSCJ

Food additives	Pesticides	Vet. medicines	Prions	GM Foods	Feed, Fertilizers	Others	Total
101	351	264	19	110	37	119	1001



Numbers of Assessments Led to Regulatory Actions by Risk Management Authorities

Food additives	Pesticides	Vet. medicines	Prions	GM Foods	Feed, Fertilizers	Others	Total
100	274	226	16	127	26	88	857

Risk Communication Activities

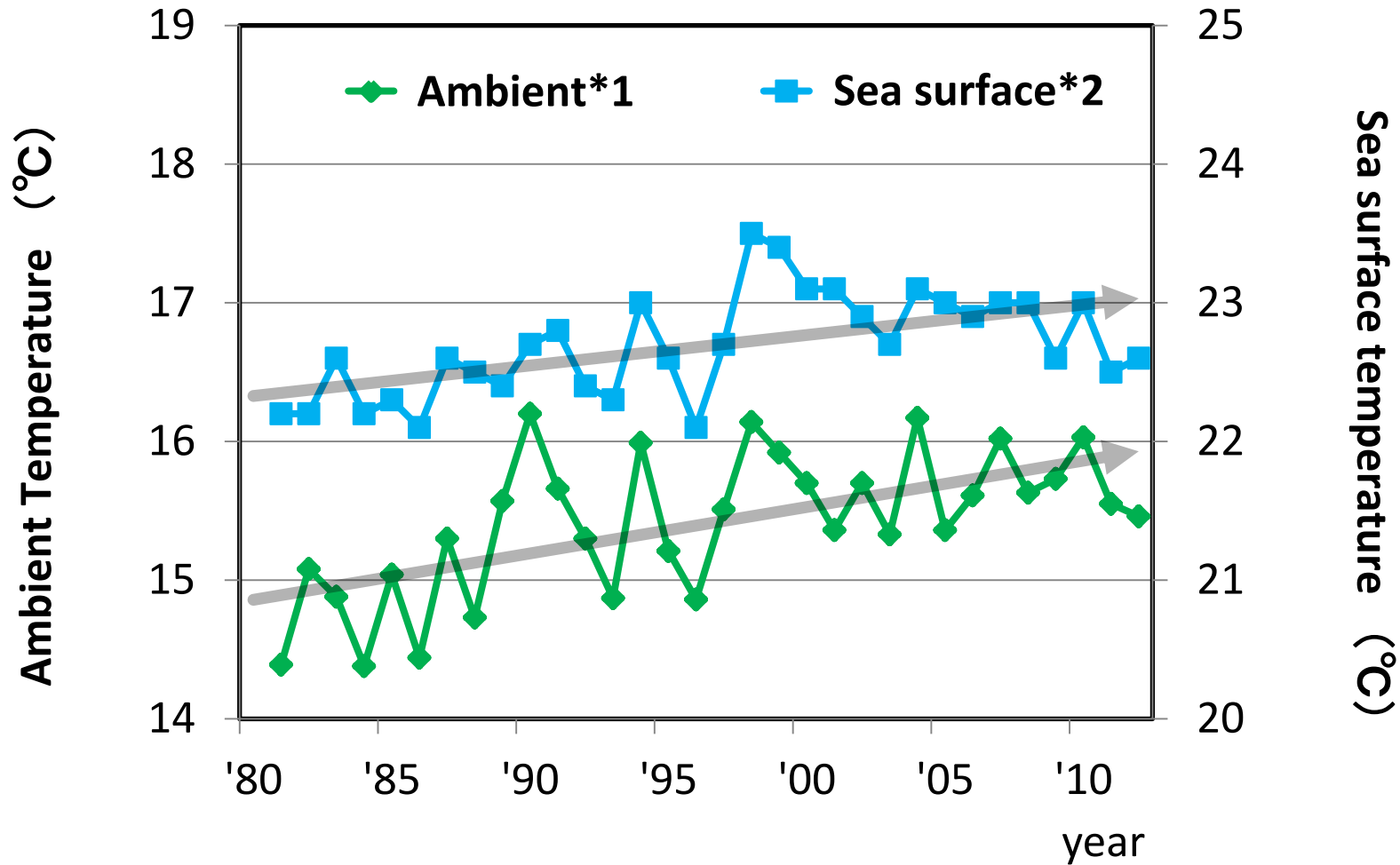
- Commission and Expert Committee meetings are in principle open to the public and the meeting minutes and relevant information are available on the website.
- Public meetings : **512**
- Calls for information and public opinion regarding risk assessments, etc. : **774**
- Food Safety Monitors' meetings : **99**
- Opinion exchange meetings between Commission members and consumer groups, food businesses, public entities, etc. : **40**
- Lectures given at various locations by FSC commissioners : **163**
- Information provided in various formats (website, quarterly journal, brochures, DVDs, etc.)
- E-mail magazine distribution : **weekly**
(General public version : **twice a month**)
- Food Safety Hotline receive inquiries by telephone and e-mail



Food Safety Hotline
TEL +81-3-6234-1177
Mon~Fri 10:00~17:00
(except for public and year-end holidays)

The Future

Trend on Annual average Ambient and Sea Temperatures around Japan over the last three decades



Source : Japan Meteorological Agency

*1:Choshi City, Chiba Pref., *2:Southern part of the sea off Kanto

Global Warming

Warming averaged for 2011-2030 compared to 1980-1999 is $+0.64-0.69^{\circ}\text{C}$
(Climate Change 2007: IPCC Fourth Assessment Report)

Environmental Change

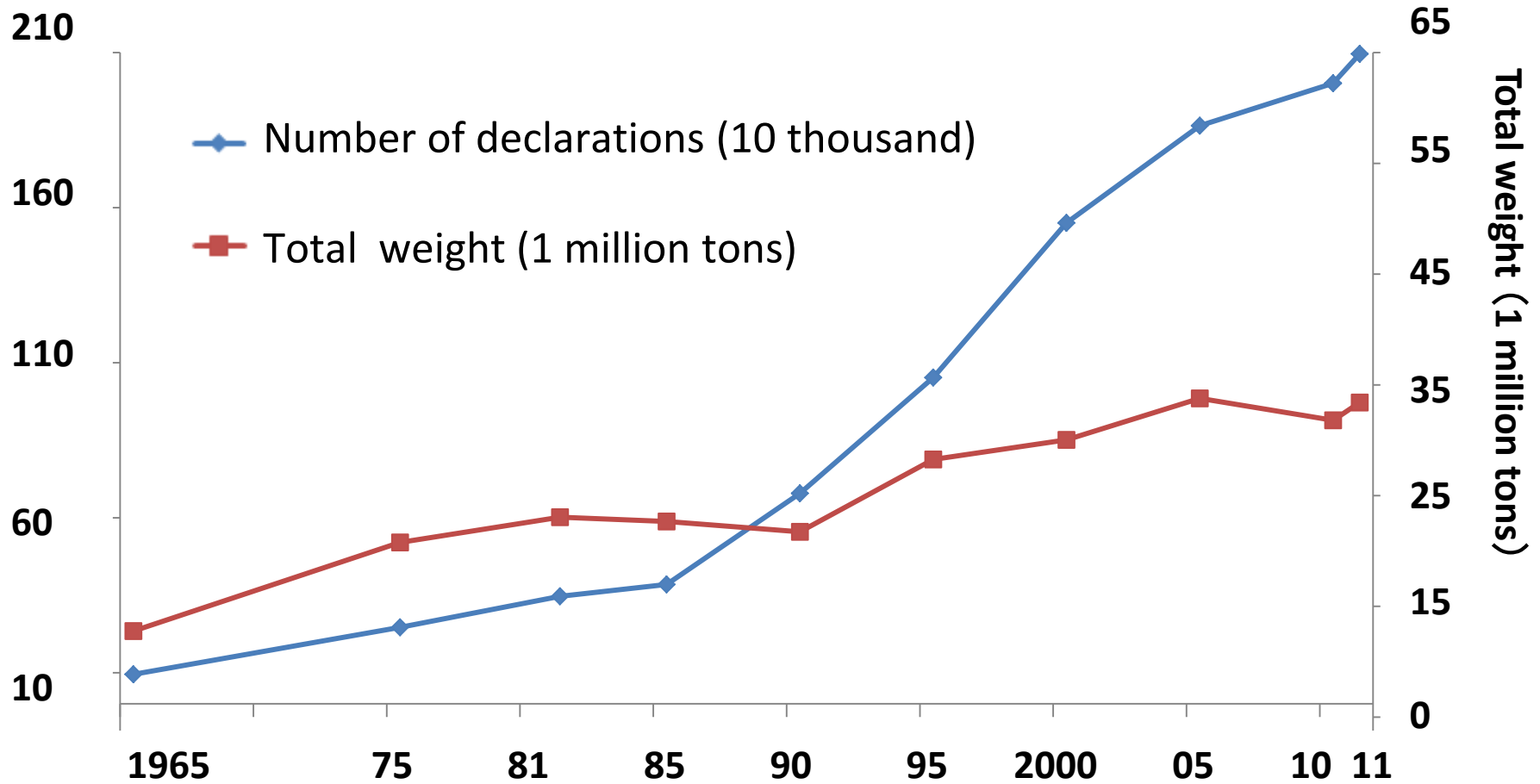
- Changes in ecosystems
- Sea level rise
- Increase in bacterial proliferation
- Changes in distribution of pathogens

Impaired yields of
crops, livestock & fish

Anticipated increase of health risk by
Marine toxins : Ciguatoxin, Palytoxin, etc.
Mycotoxins : Aflatoxin, Fusarium toxins, Zearalenone, etc.
Food-borne pathogens : VTEC, *Salmonella*, *Listeria monocytogenes*, HEV, etc.

Trends of Imported Foods

- Total weight and Number of declarations to quarantine offices -



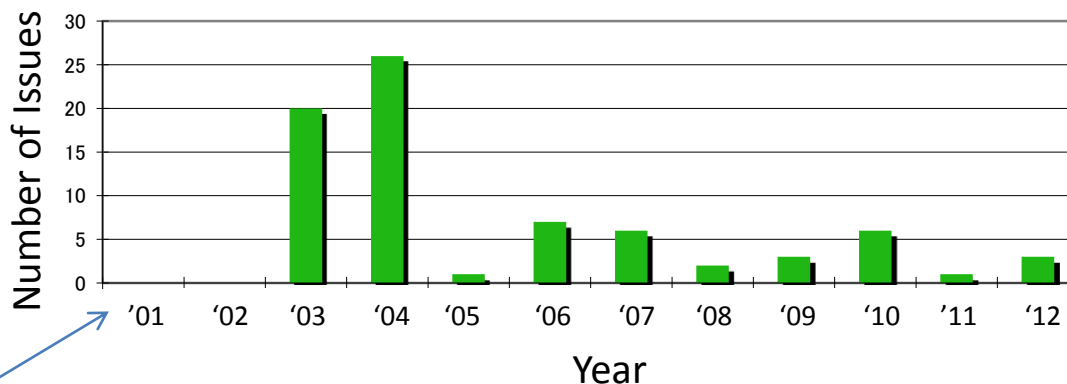
Source : statistics on inspection of imported foods,2011, MHLW

Major Outbreaks of Food-borne Infection and Food Poisoning Caused by Imported Food and Food Materials

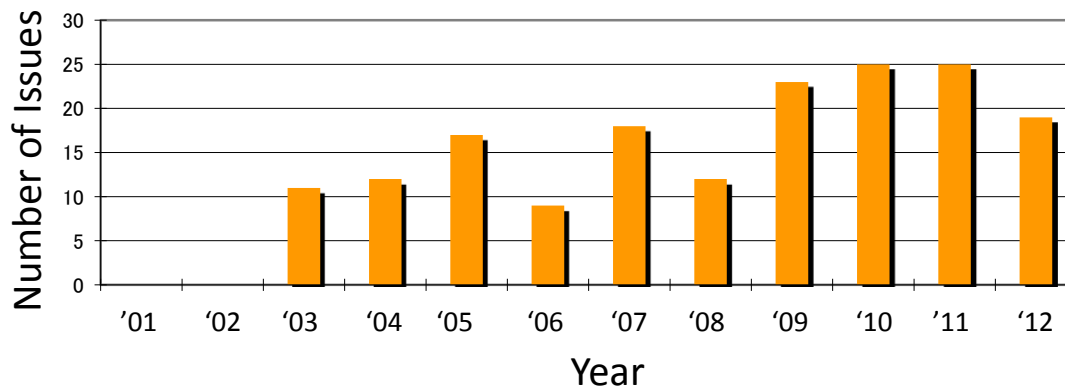
Year	Country	Agent	Implicated food or food material
2012	USA	<i>Salmonella</i> Bareilly, <i>S. Nechanga</i>	frozen tuna fish
2011	Europe	VTEC O104:H4	fenugreek seeds
2011	Switzerland	<i>Listeria monocytogenes</i>	cooked ham
2011	USA	<i>Salmonella</i> Agona	papaya
2009	Finland	<i>Salmonella</i> <i>Bovismorbificans</i>	alfalfa seeds
2009	Japan	<i>Shigella sonnei</i>	oval squid
2008	Europe	<i>Salmonella</i> Agona	ready-to-eat meat
2008	Japan	methamidophos	Chinese dumpling
2008	Japan	histamine	tuna fish

Requested Risk Assessment Issues of Novel Foods in Each Year

Food for Specified Health Uses



Genetically Modified Foods



Start of
Systems
for Review &
Permission

Increased Risk Assessment

- Climate changes
- Diversification of preference for food
- Expansion of trade
- Increase of novel foods
- Innovation & development of technology for food production & supply
- Hunger & malnutrition
- Increasing life-style related diseases



Increase of items for risk assessment to ensure food safety



The need of more accurate and cost-effective risk assessment

Future issues of research and mutual understanding

- Toward more accurate and cost effective risk assessment -

- Metabolism of chemicals in human body
- Threshold of Toxicological Concern
- Benchmark dose
- Margin of exposure
- Risk assessment methods of
 - genotoxic carcinogen
 - pathogens
 - drug-resistant microorganisms
 - chemical related allergy

Development of Research and Data Collection Systems

- Future Direction of Risk Assessment -



Future Challenges in FSCJ

- Toward more accurate and cost effective risk assessment to be in time for effective management –

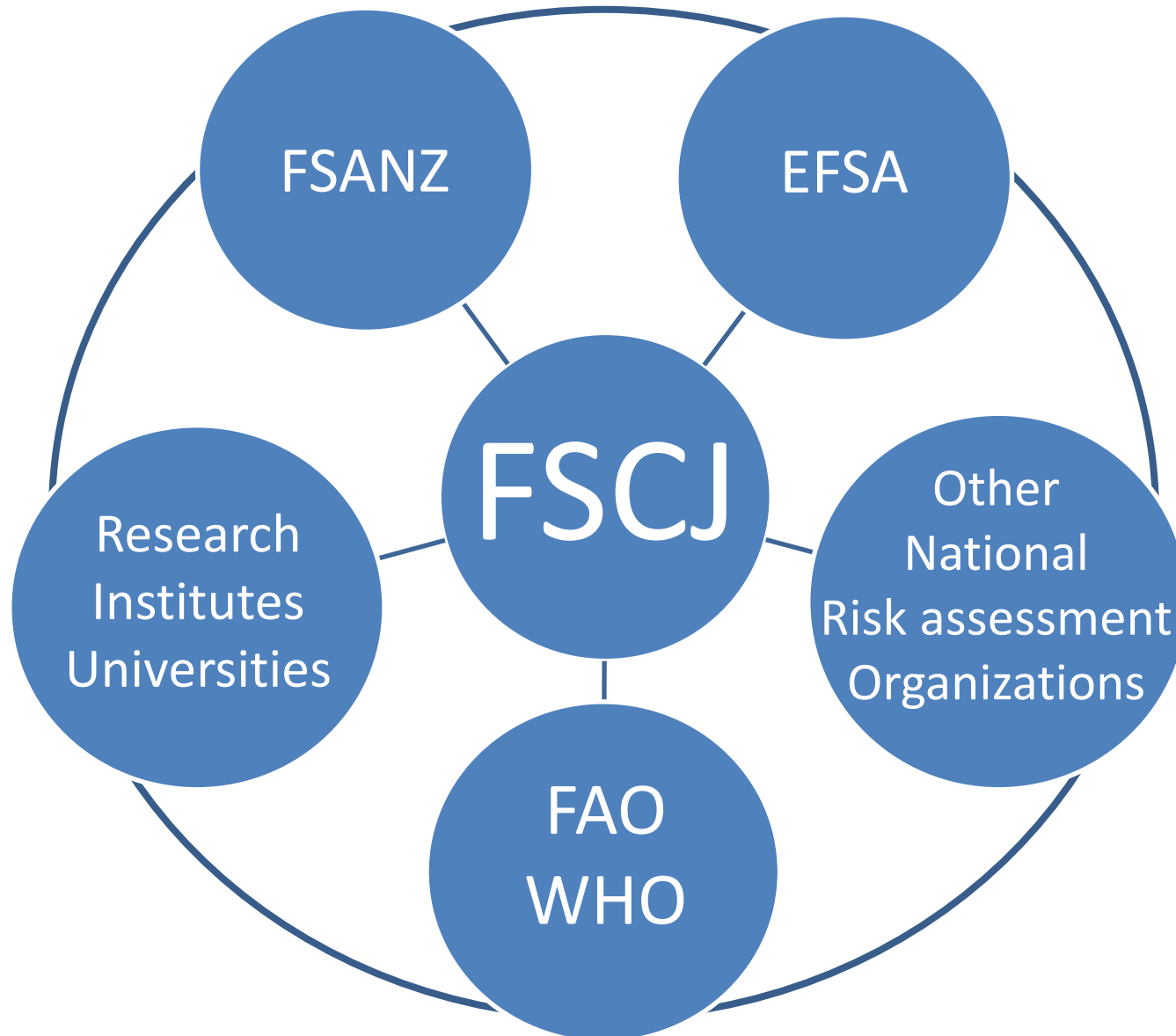
1. Developing an integrated research field specific for risk assessment
2. Increase of professionals responsible for risk assessment for food safety
3. International collaboration in risk assessment
4. Sharing data and collaboration in data collection with other national and international risk assessment organizations
5. Collaboration in research required for risk assessment with laboratories of universities and institutes
6. Promotion of science and technology for risk assessment through publication of on-line journal and holding meetings for information exchange
7. Enhancement of secretariat for risk assessment

Future Challenges in FSCJ

- Toward more effective risk communication -

1. Broad dissemination of scientific information relating to risk assessment for food safety through the mass media
2. Frequent exchange of opinion and information with the mass media to facilitate common understanding
3. Dissemination of scientific knowledge to consumers and students
4. Production of text books and on-line text for education of food safety and distribution of them to interested parties
5. Exchange of opinions and information with persons in a leading position on food safety issues
6. Development of skills of interpreter to communicate on scientific information

The need of International Network in Risk Assessment and Research, and Sharing of Data and Experience





Thank you
for your
attention