Risk Assessment for Food Safety in Japan

Submitted by: Japan
Introduction of Risk Analysis Framework

Enacted the Food Safety Basic Law
(May, 2003)
and
Established the Food Safety Commission
(July, 2003)

With priority placed on the protection of public health, the Food Safety Commission was established in the Cabinet Office under the framework of risk analysis for food safety and to conduct food safety risk assessments independently from risk management ministries.
Risk Analysis and the Government Organizations

Risk Communication

Risk Assessment
(Food Safety Commission)
- Hazardous substances in food products
- Scientific knowledge
- Implements risk assessment of the health effects resulting from intake

Risk Communication
- Considering assessment results
- Cost effectiveness
- Technical feasibility
- Public sentiment

Risk Management
(Ministry of Health, Labour and Welfare & Ministry of Agriculture, Forestry and Fisheries)
- Determine maximum use levels, residue limits, etc.

Slide provided by Food Safety Commission

Risk Management
Risk Managers

Primary production

• Food Chain Approach
• Codes of Practice

Consumption

MAFF

Production materials
(such as pesticides, veterinary medicines etc)

MHLW

Regulation of sales and manufacture
• Sanitary measures
• Quarantine

For MAFF & MHLW
– Especially for inexperienced officers
– Including risk communication with stakeholders
– Consistent with internationally agreed framework (CAC/GL 62-2007)
– Transparency
– Integrity
– Consistency
– Science-based
Risk management activities of MHLW

Preliminary risk management activities of MHLW

- Recognition of food safety problems
- Preparation of risk profiles
- Consideration on the needs for risk assessments to be requested to the Food Safety Commission, and if yes, on the risk management questions
Preliminary risk management activities of MHLW - Source of information (example): food poisoning statistics

From MHLW database

Physician Consultation Rate:
By e.g. telephone population based survey data

Stool sampling rate:
By e.g. telephone population based survey data

Laboratory test sensitivity rate, coverage in the target population

Kubota, Kasuga et al. by research budget from MHLW
Risk management activities of MAFF

Developing
- Priority list
- Risk Profile
- Guidelines for Surveillance/Monitoring
- Guidelines for Total Diet Study

Conducting
- Surveillance/Monitoring Plans
  - middle-term
  - annual

Available on our Web site (in Japanese)

Slide provided by MAFF
Risk Assessment

14 Expert Committees

- Planning
- Emergency responses
- Risk communication

Chemical substance assessment groups: pesticides, food additives, etc.

Biological agents assessment groups: microorganisms/viruses, prions, etc.

Emerging foods assessment groups: genetically modified foods, etc.

Experts: in total 245

Structure of the Food Safety Commission

Secretariat (60 personnel, 32 technical counselors)

Slide provided by Food Safety Commission

As of April, 2009
Risk Assessment
Based on scientific data, assesses the probability and severity of adverse health effect associated with consumption of food.

Emergency Response
Collects and disseminate relevant information to general public in food-related emergency situations such as the outbreak of food poisoning.

Risk Communication
Interactive exchange of information and opinions concerning food related risks with stakeholders, including consumers.

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### Risk Assessment Activities

<table>
<thead>
<tr>
<th>Classification</th>
<th>No. of requests (including self-tasking assessments)</th>
<th>No. of completed assessments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food additives</td>
<td>93</td>
<td>79</td>
</tr>
<tr>
<td>Pesticides</td>
<td>475</td>
<td>257</td>
</tr>
<tr>
<td>(Positive list-related pesticide included)</td>
<td>(189)</td>
<td>(92)</td>
</tr>
<tr>
<td>Veterinary medicines</td>
<td>313</td>
<td>220</td>
</tr>
<tr>
<td>(Positive list-related v/m included)</td>
<td>(90)</td>
<td>(35)</td>
</tr>
<tr>
<td>Chemical substances/contaminants</td>
<td>56</td>
<td>29</td>
</tr>
<tr>
<td>Microorganisms/viruses</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Prion</td>
<td>13</td>
<td>11</td>
</tr>
<tr>
<td>Genetically modified foods, etc.</td>
<td>87</td>
<td>73</td>
</tr>
<tr>
<td>Novel foods, etc.</td>
<td>64</td>
<td>57</td>
</tr>
<tr>
<td>Others</td>
<td>50</td>
<td>35</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1156</strong></td>
<td><strong>765</strong></td>
</tr>
</tbody>
</table>

◆ Including risk assessments conducted on FSC’s own initiative (As of June 3, 2009)

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Slide provided by Food Safety Commission
Self-tasking risk assessment

- Without requests from risk management ministries
- The Food Safety Commission identifies and prioritizes food safety issues for risk assessment targets by its own evaluation, and collects and generates data for risk assessments as well as possible risk management questions to consider.

Examples
- Interim report on BSE measures (completed)
- Risk assessment of *Campylobacter* in poultry (completed)
- Risk assessment on beef imported to Japan
- Risk assessment of lead in food
- Risk assessment of deoxynivalenol and nivalenol

Scientific data for chemical risk assessments

**Safety data**
1. Disposition (absorption, distribution, metabolism, excretion and degradation)
2. Toxicity
   - Acute toxicity
   - Repeated-dose toxicity
   - Genotoxicity
   - Carcinogenicity
   - Other carcinogenicity (combined administration with a known carcinogen)
   - Reproductive and developmental toxicity
   - Local irritation
   - Sensitization

**Evaluation by international organizations**
1. JECFA
2. Science Committee on Food (SCF)
3. U.S. Food and Drug Administration (FDA)
4. International Agency for Research on Cancer (IARC)
**Campylobacter risk assessment model and used data**

- Prevalence: surveillance data at farms
- Cross contamination: rates back-calculated
- Processing plant
- Imported chicken
- Prevalence, concentration: surveillance data at ports
- Retailers
- Prevalence: surveillance data at retailers
- Raw consumption: Insufficient heating - cooking practices - consumption patterns, frequency
- Home/Restaurants
- RTE foods
- Chicken
- Exposure
- Dose-Response: from literatures
- Infection

Hasegawa, Kasuga et al. and Report by Expert Committee

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**Other risk assessment-related activities by the Food Safety Commission**

- **Developing guidelines**
  - Standards for safety assessments
    - Genetically modified foods (plants, microorganisms)
    - Genetically modified feeds and feed additives
    - Food additives produced by genetically-modified microorganisms
  - Consideration on safety assessments
    - Ranking of the importance of antimicrobials against bacteria which affect human health through food commodities
    - Antimicrobial-resistant bacteria selected by antimicrobial use in food animals
  - Guidelines for risk assessments
    - Microorganisms transmitted by foods

- **Follow-up reviews on the risk management activities after risk assessment results were published**
  - About twice a year for the assessments completed in the previous year
How risk assessment results were used
- some examples

- Pesticide residues, food additives, contaminants, etc.
  Food Safety Commission
  - Determines ADI, TWI, etc.
  MHLW
  - Determines maximum use levels, residue limits, etc.

- BSE test for cattle in Japan
  Food Safety Commission
  - The risk in human would be limited to a very low degree of increase or no increase at all when older cattle above certain age were targeted by the testing.
  MHLW
  - Amended regulation on the testing age for the younger cattle

- Micro criteria for frozen bread dough
  Food Safety Commission
  - Removing ‘E. coli negative’ does not affect safety of the products
  MHLW
  - Amended Food Safety Law to remove ‘E. coli negative’

Risk Communication
Risk Communication by Risk Management Agencies

**MHLW**
- Public meetings of its own and joint meetings with MAFF and FSC
- ca. 50 calls for public comments in the past 12 months
- Brochures, on-line videos, etc.

**MAFF**
- Public meetings of its own and joint meetings with MHLW and FSC
- Public comments
- Website specific to the consumers or kids
- Internet surveys

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Transparency and Risk Communication Activities of the Food Safety Commission

- Commission and Expert Committee meetings are basically open to the public and the meeting minutes and other information are available on the website.
- Public meetings: 344 times
- Calls for information and public opinion regarding risk assessments, etc.: 459 times
- Food Safety Monitors’ meeting: 60 times
- Opinion exchange meetings between Commission members and consumer groups, food businesses, public entities, etc.: 36 times
- Lectures given at various locations by FSC commissioners: 112 times
- Community Food Safety Leader Training Course: 66 times
- Information provided in various formats (website, quarterly journal, brochures, DVDs, etc.)
- E-mail magazine distribution: weekly
- Food Safety Hotline

**Food Safety Hotline**
TEL 03-6234-1177
Mon–Fri 10:00–17:00
(except for public and year-end holidays)

As of June 1, 2009

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Photos from MHWL and MAFF HP

Slide provided by Food Safety Commission
Lessons learnt

- Communications among stakeholders including those between risk managers and risk assessors are continuously encouraged.

- More people, including researchers and industries, are needed to be involved to fill data gaps for risk analysis.

- Advantage of quantitative risk assessment would be recognized by the practical conduction.

- Link between epidemiology and risk assessment should be discussed.

- Discussions on the use of FSO and other metrics should be enhanced.

- Cost-benefit analysis, risk-risk analysis are urgently needed for risk management.

- International, especially regional cooperation is an urgent issue.