Food Safety Regulation: Comparing the EU and Japanese systems

Paul B Young, PhD

Waters Corporation
paul_young@waters.com
Waters is a technology-based company focused on separation science, mass spectrometry and informatics.

Waters creates business advantage for laboratory-dependent organizations, such as healthcare delivery, environmental management, food safety, and water quality worldwide.

Waters has driven scientific discovery and operational excellence with customers worldwide for nearly 50 years.

Waters prides itself in pushing the boundaries of scientific possibilities and is committed to providing our customers novel tools that address the real needs that they face.
Consumers are focused on food safety
  Food safety scares have high profile in the media
  Rapid growth in sales of premium priced organic produce

Regulatory food safety analysis serves 2 main purposes
  1. Protects consumer health
  2. Protects agricultural export markets

An effective programme must be comprehensive
  Relying on 3rd country assurances alone is risky
  Relying on testing of imports alone is expensive

An effective programme requires collaboration
  Collaboration between governments
  Collaboration between government, industry and technology leaders
USDA Predict that by 2020, US consumption of many food commodities will increase by more than 10% over 2000 rates.

Horticultural product demand is expected increase by around 20%.

Many countries are actively pursuing the expansion of export markets. This is reflected in the declining US trade balance.

US exports to “high income” markets are declining. Now shifting towards developing markets (China and Mexico currently account for >25% of exports).
Increased agricultural exports is goal in many countries

The increase in production is mirrored in an increased volume of exports.

This is a frequently stated goal of many countries (Thailand Department of Fisheries mission statement – “To increase aquaculture production by 5% per year”)
In a Japanese survey around 70% of consumers rated food safety as the most important issue.

By contrast, only 8% thought price was the major concern.
EU concerns about food contamination

- **New viruses (e.g. AI)**: 29% very worried, 38% fairly worried, 23% not very worried, 8% not worried, 0% don't know
- **Pesticide residues in fruit/veg/cereal**: 28% very worried, 42% fairly worried, 21% not very worried, 7% not worried, 0% don't know
- **Antibiotic/hormone residues in meat**: 27% very worried, 41% fairly worried, 22% not very worried, 8% not worried, 0% don't know
- **Bacterial contamination (salmonella in eggs, listeria in cheese)**: 26% very worried, 39% fairly worried, 26% not very worried, 8% not worried, 0% don't know
- **Pollutants (mercury, dioxins)**: 26% very worried, 37% fairly worried, 24% not very worried, 9% not worried, 0% don't know
- **Mad cow disease (BSE)**: 22% very worried, 31% fairly worried, 30% not very worried, 15% not worried, 0% don't know

*European Commission Special Eurobarometer 238*
Article 20 of the General Agreement on Tariffs and Trade (GATT) allows governments to act on trade in order to protect human, animal or plant life or health, provided they do not discriminate or use this as disguised protectionism.

Sanitary and Phytosanitary Measures Agreement (SPS) allows countries to set their own standards. Regulations must be based on science, but “precautionary principle” may be applied.

The Technical Barriers to Trade Agreement (TBT) tries to ensure that regulations, standards, testing and certification procedures do not create unnecessary obstacles. It encourages countries to recognize each other’s procedures for assessing whether a product conforms.
laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

- EFSA – Independent scientific point of reference for risk analysis
- Ensures scientific basis for food law
- Establishes the Rapid Alert System for Food and Feed (RASFF)
- Requirement for traceability for all stages of production
COUNCIL REGULATION (EEC) No 2377/90
of 26 June 1990
laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin

(OJ L 224, 18.8.1990, p. 1)

- Defines Maximum Residue Limits (MRLs; tolerances)
  Applies precautionary principle where safe level has not been established

COUNCIL DIRECTIVE 96/23/EC
of 29 April 1996

- Defines the sampling and testing frequencies for domestic produce
  e.g. 0.4 % of all cattle slaughtered must be tested for the presence of veterinary drugs and other contaminants
COMMISSION DECISION
of 12 August 2002
implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results
(notified under document number C(2002) 3044)
(Text with EEA relevance)

2002/657

- EU Does not prescribe analytical techniques
  Allowing labs to improve efficiency through the use of new technologies
- Methods must be demonstrated to be fit for purpose
  Validation procedures are defined to demonstrate suitability
- Methods must be capable of detection and confirmation at level of interest
  Strict criteria must be applied to ensure unequivocal confirmation
- Control laboratories must be accredited under ISO 17025
EU Demands equivalent assurances from 3rd countries wishing to export

COUNCIL DIRECTIVE 96/23/EC
of 29 April 1996


(OJ L 125, 23.5.1996, p. 10)

- EU Maintains lists of establishments in each 3rd country which are approved to export a given commodity

- Approval is subject to submission of acceptable control programmes

- Programme implementation is verified by regular monitoring inspection visits (DG-SANCO Food and Veterinary Office)
FINAL REPORT OF A MISSION CARRIED OUT IN CHINA FROM 22 MARCH TO 30 MARCH 2006 CONCERNING THE EVALUATION OF THE CONTROL OF RESIDUES AND CONTAMINANTS IN LIVE ANIMALS AND ANIMAL PRODUCTS, INCLUDING CONTROL ON VETERINARY MEDICINAL PRODUCTS

- Mission results and recommendations published

- 1. To further improve the design of the NRCP and its implementation, taking into account the deficiencies made in the report

- 5. To ensure the development and validation of analytical methods which are capable of meeting the community requirements......
Import testing carried out for verification of control programmes

<table>
<thead>
<tr>
<th>DATE</th>
<th>NOTIFIED BY</th>
<th>REF.</th>
<th>REASON FOR NOTIFYING</th>
<th>TYPE OF CONTROL</th>
<th>STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>22/08/2007</td>
<td>the Netherlands</td>
<td>2007.BZL</td>
<td>aflatoxins (B1 = 26.3; Tot. = 35.9 µg/kg - ppb) in peanuts from China</td>
<td>border control - import rejected</td>
<td>no distribution / destination of the product changed</td>
</tr>
<tr>
<td>22/08/2007</td>
<td>the Netherlands</td>
<td>2007.BZM</td>
<td>aflatoxins (B1 = 7.5; Tot. = 8.2 µg/kg - ppb) in cleaned medium runner groundnuts from the United States</td>
<td>border control - import rejected</td>
<td>no distribution / physical treatment</td>
</tr>
<tr>
<td>22/08/2007</td>
<td>the Netherlands</td>
<td>2007.BZN</td>
<td>aflatoxins (B1 = 4.1 µg/kg - ppb) in groundnuts from the United States</td>
<td>border control - import rejected</td>
<td>no distribution / product (to be) re-dispatched</td>
</tr>
<tr>
<td>22/08/2007</td>
<td>France</td>
<td>2007.BZO</td>
<td>prohibited substance nitrofurans (metabolite) furazolidone (AOZ) (1.7 µg/kg - ppb) in salted pork casings from China</td>
<td>border control - screening sample</td>
<td>no distribution / destination of the product identified</td>
</tr>
<tr>
<td>22/08/2007</td>
<td>France</td>
<td>2007.BZP</td>
<td>cadmium (0.615 mg/kg - ppm) in fresh shark (Xiphias gladius) from Chile</td>
<td>border control - screening sample</td>
<td>product expired (exceeded use-by date) / reinforced checking</td>
</tr>
</tbody>
</table>

Detailed statistical breakdown published annually

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>Number</th>
<th>COUNTRY</th>
<th>Number</th>
<th>COUNTRY</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHINA</td>
<td>263</td>
<td>AUSTRALIA</td>
<td>17</td>
<td>SWEDEN</td>
<td>6</td>
</tr>
<tr>
<td>TURKEY</td>
<td>254</td>
<td>LATVIA</td>
<td>16</td>
<td>SWITZERLAND</td>
<td>6</td>
</tr>
<tr>
<td>IRAN</td>
<td>244</td>
<td>HUNGARY</td>
<td>14</td>
<td>F.Y.R. OF MACEDONIA</td>
<td>6</td>
</tr>
<tr>
<td>THE UNITED STATES</td>
<td>236</td>
<td>IRELAND</td>
<td>12</td>
<td>ECUADOR</td>
<td>5</td>
</tr>
<tr>
<td>GERMANY</td>
<td>117</td>
<td>MALAYSIA</td>
<td>12</td>
<td>GEORGIA</td>
<td>5</td>
</tr>
<tr>
<td>SPAIN</td>
<td>117</td>
<td>PORTUGAL</td>
<td>12</td>
<td>GREENLAND</td>
<td>5</td>
</tr>
</tbody>
</table>
Consequences of violation

- If product has reach the market a recall is issued
- Frequent violation may result in protective measures
  1. Increased testing frequency
  2. Complete ban on importation

Thai aquaculture and poultry products undergo mandatory testing at importers expense

Prohibition on import of Chinese aquaculture products

©2007 Waters Corporation
REGULATION (EC) No 882/2004 OF THE EUROPEAN PARLIAMENT
AND OF THE COUNCIL
of 29 April 2004

on official controls performed to ensure
the verification of compliance with feed and food law,
animal health and animal welfare rules

- Regulation 882/2004 extended the rules to cover additional foods

- Cost recovery
  All costs resulting from the official controls at the
designated points of introduction and entry should be borne
by the feed and food business operator responsible for the
consignment or its representative.
Japan is one of the least self-sufficient developed countries in the world, importing more than 60 % of its food.

In 2002, the domestic consumer organization identified that high concentrations of some agricultural chemicals were found in some imported crops.

Many of these agricultural chemicals found in imported crops were unauthorized for use in Japan.

There was therefore not an effective system to monitor and make decisions on the safety of this produce.
Japanese response

The Food Safety Basic Law (Tentative Translation)

Law No. 48, May 23, 2003
Last amendment: No. 50, Jun 2, 2006

- **Establishment of Food Safety Commission**

  **Ministry of Health, Labour and Welfare Notification No. 499**

  The Minister of Health, Labour and Welfare has partially revised the Specifications and Standards for Food, Food Additives, Etc. (Ministry of Health and Welfare Notification No. 370, 1959), as given below, based on the provision of Paragraph 1, Article 11 of the Food Sanitation Law; this revision will take effect on May 29, 2006.

- **Revision for food and food additive standards to create “Positive List System” of 799 substances which must be controlled in all imported foodstuffs**
How do Japanese procedures differ from Europe

- Regulations place onus on importer to ensure imported food is compliant

- Japan does not demand equivalence

- Compliance is ensured through very high level of import testing (laboratory tests > 10% of imports)

- For substances not permitted to be present in food at any concentration, MHLW have prescribed analytical methods for use in Japanese control labs
Details of violations published quarterly

- At first import, products must be subject to voluntary tests
- Violations result in inspection orders – increased testing
- Repeat violation may result in a ban on importation
- In practice, importers demand test certificates from exporters
### Conclusions

- **Consumers are focused on food safety**
  - Food safety scares have high profile in the media
  - Rapid growth in sales of premium priced organic produce

- **Regulatory food safety analysis serves 2 main purposes**
  1. Protects consumer health
  2. Protects agricultural export markets

- **An effective programme must be comprehensive**
  - Relying on 3rd country assurances alone is risky
  - Relying on testing of imports alone is expensive

- **An effective programme requires collaboration**
  - Collaboration between governments
  - Collaboration between government, industry and technology leaders
- Paul Young – paul_young@waters.com
- Jeff Tarmy – jeff_tarmy@waters.com