

Food Safety Regulation: Comparing the EU and Japanese systems

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- 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.

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 - Food safety scares have high profile in the media
 - Rapid growth in sales of premium priced organic produce

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 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

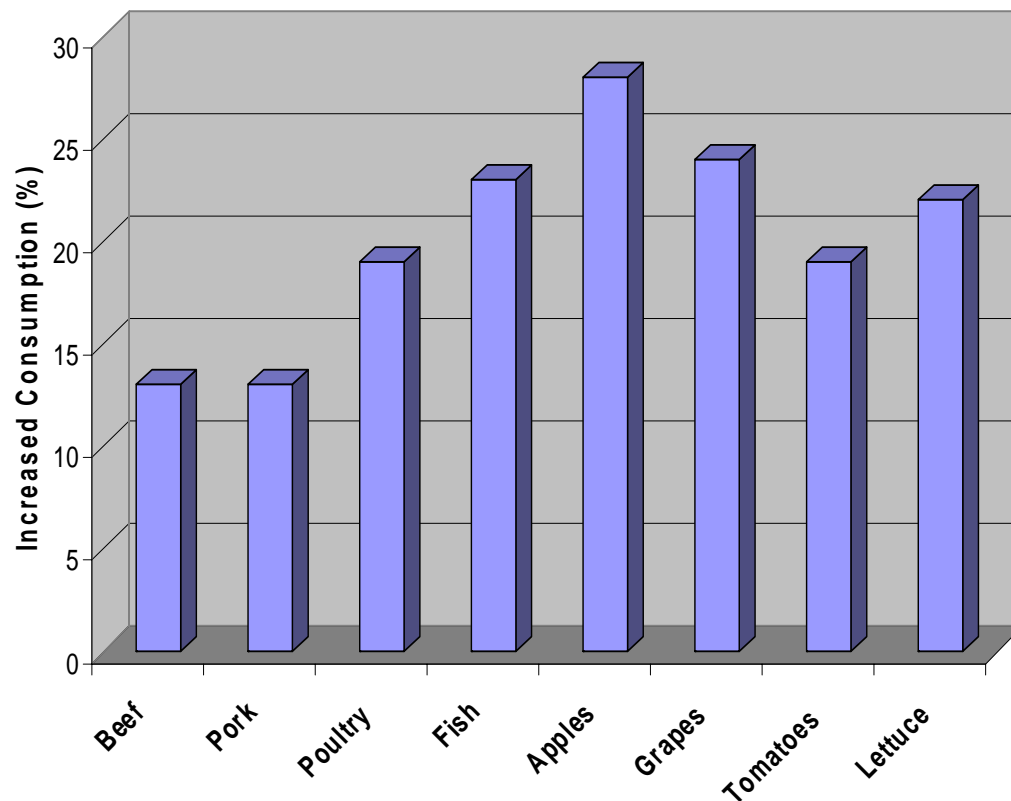
- An effective programme requires collaboration
 - Collaboration between governments
 - Collaboration between government, industry and technology leaders

Increasing demand for food

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%

US Projected Market Growth 2000 - 2020

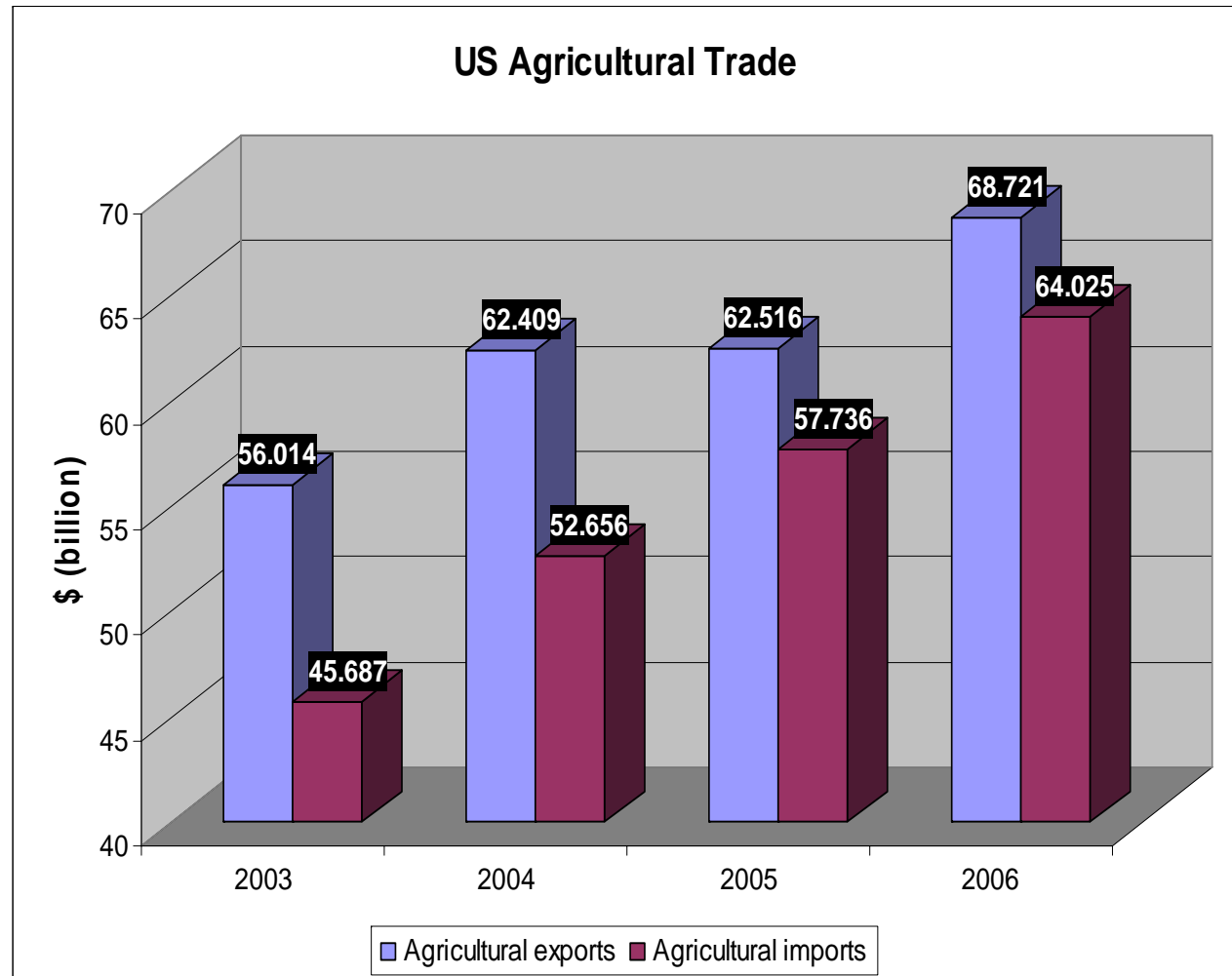


Source: USDA ERS (<http://www.ers.usda.gov/publications/FoodReview/May2002/frvol25i1a.pdf>)

Global trade in food increasing

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

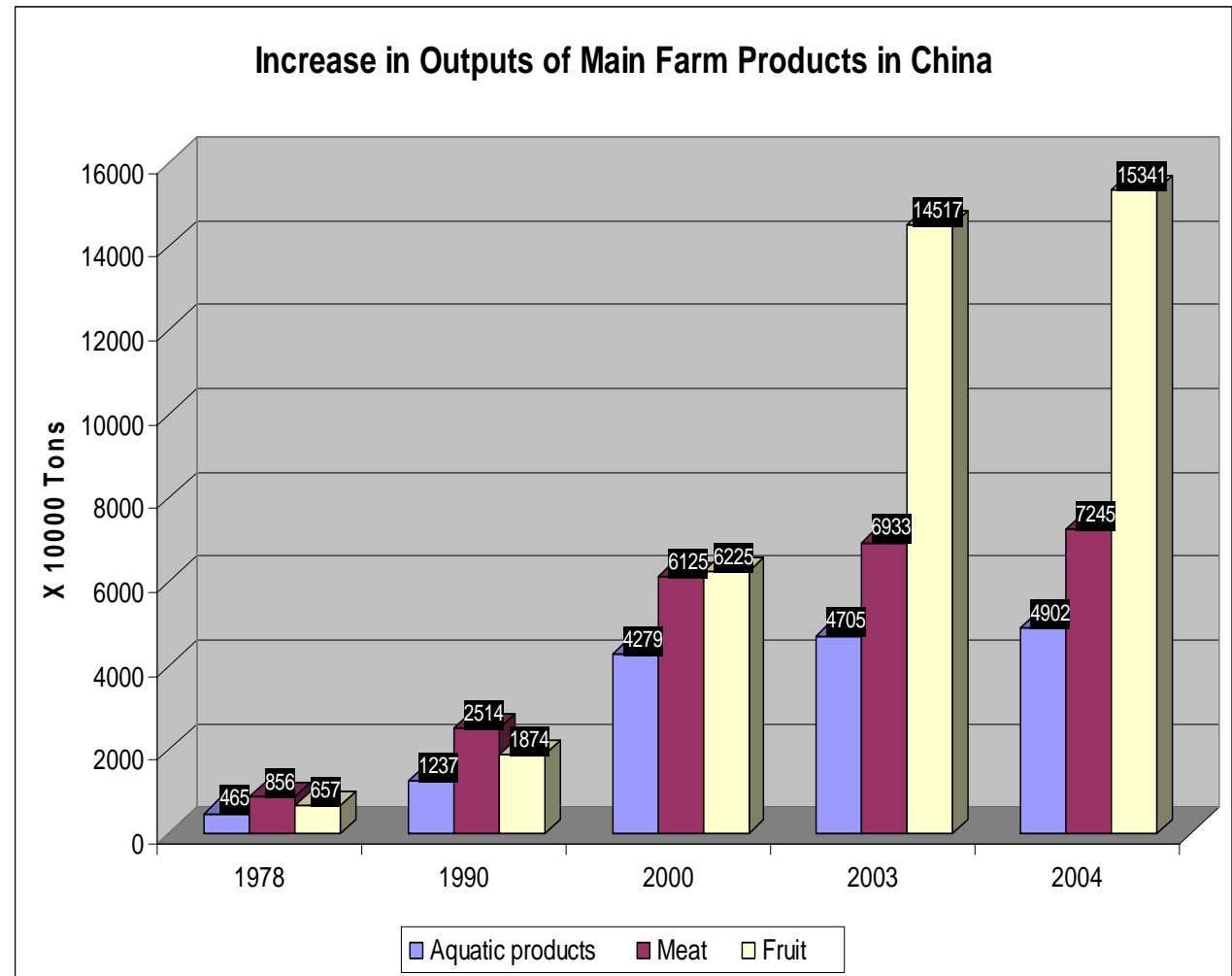
US exports to "high income" markets are declining. Now shifting towards developing markets (China and Mexico currently account for >25% of exports)



Increased agricultural exports is goal in many countries

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

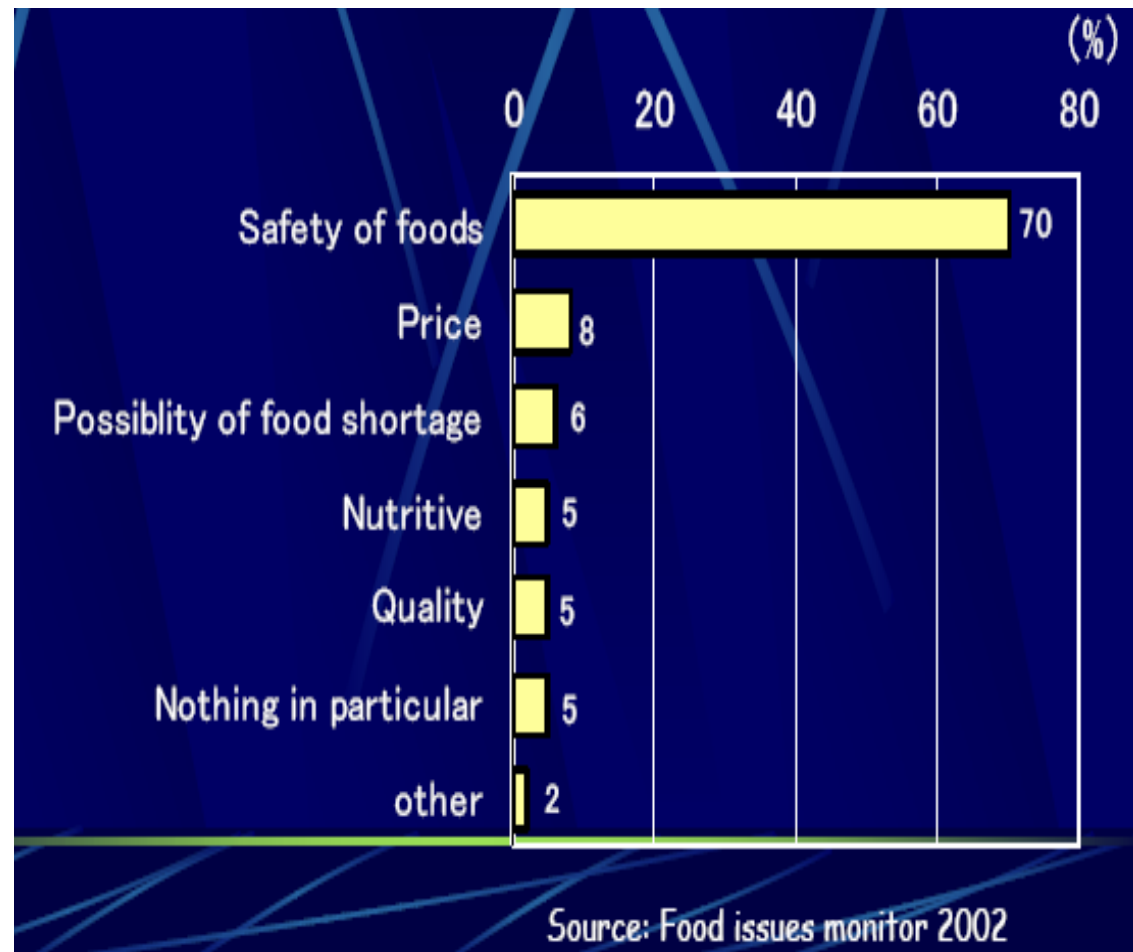
This is a frequently stated goal of many countries (Thailand Department of Fisheries mission statement – “To increase aquaculture production by 5 % per year”)



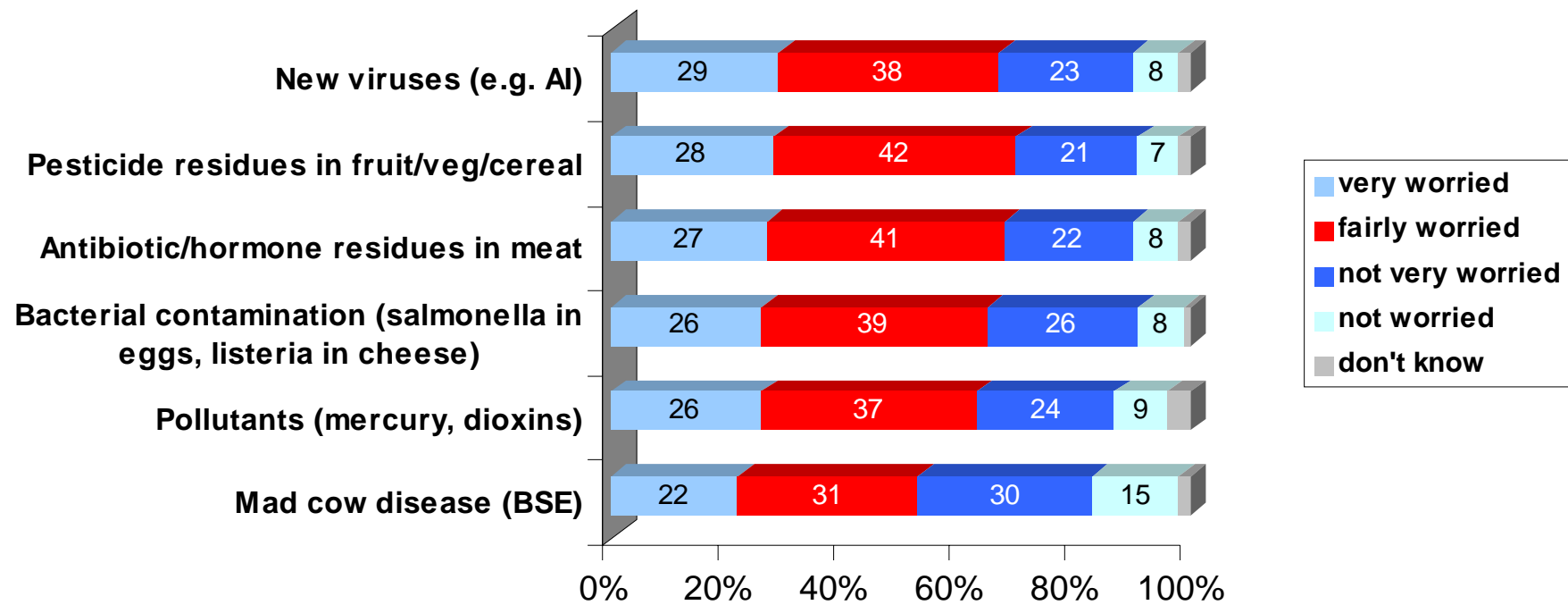
Food concerns

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



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.

Establishment of European Food Safety Authority

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REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 28 January 2002

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

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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

on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC

- **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

Method used must be fit for purpose

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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

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(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)



EUROPEAN COMMISSION

HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate F - 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.....

RASFF notifications issued weekly

- Import testing carried out for verification of control programmes

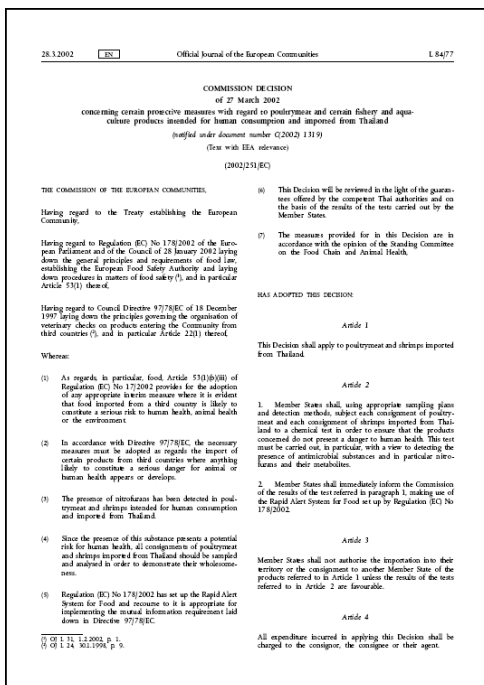
DATE:	NOTIFIED BY:	REF.:	REASON FOR NOTIFYING:	TYPE OF CONTROL:	STATUS
22/08/2007	the Netherlands	2007.BZL	aflatoxins (B1 = 26.3; Tot. = 35.9 µg/kg - ppb) in peanuts from China	border control - import rejected	no distribution / destination of the product changed
22/08/2007	the Netherlands	2007.BZM	aflatoxins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

- Detailed statistical breakdown published annually

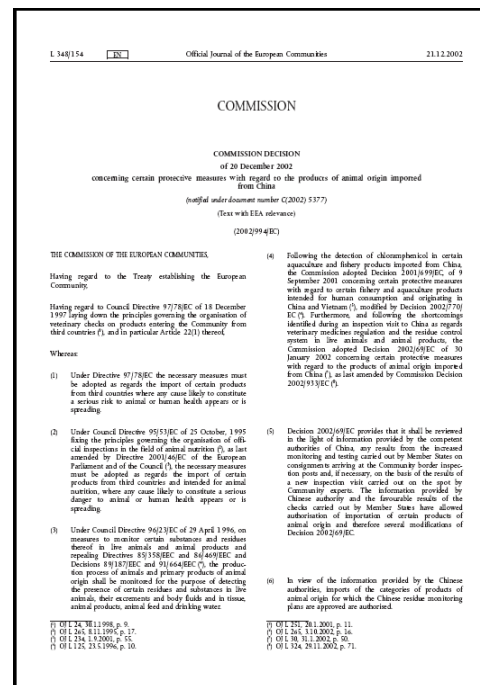
COUNTRY	Number		COUNTRY	Number		COUNTRY	Number	
CHINA	263	↑	AUSTRALIA	17	↓	SWEDEN	6	↓
TURKEY	254	↑	LATVIA	16	↑	SWITZERLAND	6	↓
IRAN	244	↓	HUNGARY	14	↓	F.Y.R.OF MACEDONIA	6	↓
THE UNITED STATES	236	↑	IRELAND	12	↑	ECUADOR	5	=
GERMANY	117	↑	MALAYSIA	12	↑	GEORGIA	5	=
SPAIN	117	↓	PORTUGAL	12	↑	GREENLAND	5	-

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



2002



Thai aquaculture and poultry products undergo mandatory testing at importers expense

Prohibition on import of Chinese aquaculture products

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

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

Consequences of violation

- Details of violations published quarterly

ITEM	EXPORTING COUNTRY	NAME OF MANUFACTURERS	ARTICLE	CONTENTS OF VIOLATION	QUARANTIN STATION	NAME OF IMPORTERS	CAUSE OF VIOLATION	DIPOSAL OF THE CARGO	REMARKS
frozen peeled culture shrimp	Indonesia	WINDUBLAMBANGAN SEJATI	11	violation of element standard (aoz 5 ppb detection)	tokyo	MITSUBISHI CORP. (MITSUBISHI SHOJI KAISHA, LTD.)	under investigation	we directed abandonment or return of the cargo(the whole quantity is kept)	monitoring inspection
heated meat products, heat-pasteurized after packed in container-packages): beef tongue	China	TIANJIN JINXIN FOOD CO.,LTD.	11	violation of element standard (coliform bacteria positive)	sendai airport	TOHOKUNIKATSUSYO LTD.	under investigation	we directed abandonment or return of the cargo(the whole quantity is kept)	independence inspection
dried white fungus	China	HUANGSHAN LVRUN FOOD CO.,LTD.	11	violation of element standard (methamidophos 0.2 ppm detection)	kawasaki	PACIFIC TRADING CO.,LTD.	under investigation	we directed abandonment or return of the cargo(the whole quantity is kept)	ordered inspection-monitoring inspection

- 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

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