

Food Safety Regulation: Comparing the EU and Japanese systems

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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

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%



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Global trade in food increasing

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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")

POSSTRI E

Food concerns

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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

World Trade Organisation Agreements

- 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.

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

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

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

Detailed statistical breakdown published annually

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

OSSTRI E

- 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

COMMISSIO	N DECISION		
of 27 Ma	arch 2002		(
concerning certain protective measures with reg culture products intended for human co	ard to poultrymeat and certain fishery and aqua- insumption and imported from Thailand		
(notified under document	number ((2002) 1319)		
(Text with H	EA relevance)		
(2002)3	251/BC)		concerning certain protective measure
THE COMMISSION OF THE EUROPIAN COMMUNITIES,	(6) This Decision will be reviewed in the light of the guaran- tees offered by the competent Thai authorities and on	2002	(notified and
Having regard to the Treaty establishing the European Community,	the basis of the results of the tests carried out by the Member States.	2002	
Having regard to Regulation (EC) No 178/2002 of the Euro- pean Parliament and of the Council of 28 January 2002 laying	(7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,		THE COMMISSION OF THE EUROPEAN COMMUNITIES,
down the general principles and requirements of bood law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (¹), and in particular Article 53(1) there of,			Having regard to the Treaty establishing the E Community,
	HAS ADOPTED THIS DECISION		, , , , , , , , , , , , , , , , , , ,
Having regard to Council Directive 97/78/EC of 18 December 1997 Jaying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (*), and in particular Article 22(1) thereof.	Artide 1		Having regard to Council Directive 97/78[0C of 18 Ib 1997 laying down the principles governing the organi veterinary checks on product entering the Communi third countries (1, and in particular Article 22[1] thereo
Whereas:	This Decision shall apply to poultrymeat and shrimps imported from Thailand.		Whereas
(1) As regards, in particular, food, Artide 53(1)(b)(iii) of Regulation (BC) No 17/2002 provides for the adoption of any appropriate interim measure where it is erident	Artide 2		 Under Directive 97/78/EC the necessary measure be adopted as regards the import of certain p from third countries where any cause likely to or
that food imported from a third country is likely to constitute a serious risk to human health, animal health or the environment	 Member States shall, using appropriate sampling plans and detection methods, subject each consignment of positry- meat and each consignment of shrimps imported from Thai- 		a serious risk to animat or naman neutin appea spreading.
(2) In accordance with Directive 97/78/EC, the necessary measures must be adopted as regards the import of certain products from third countries where anything likely to constitue a sectious danger for animal or human health appears or develops.	concerned do not present a danger to human built. This text must be carbied on it, in particular, with a view to describe the presence of antimicrohidi substances and in particular nitro- turns and their metabolites. 2. Member States shall immediately inform the Commission		(2) Under Council Directive '99(5)/16. of 2) October Richtg the principles growming the organization characteristic of the second second second second characteristic of the second second second second second Parliament and of the Council (), the necessary must be adopted as regards the import of produces from third councilies and limiteded for produces from third councilies and immediad for produces from third councilies and second second second second produces from third councilies and second seco
(3) The presence of nitrofiarans has been detected in poal- trymeat and shrings intended for human consumption and imported from Thailand.	of the results of the test referred in paragraph 1, making use of the Rapid Afert System for Food set up by Regulation (EC) No 178/2002		nutrition, where any cause likely to constitute a danger to animal or human health appears spreading.
(4) Since the presence of this substance presents a potential risk for human health, all consignments of poultrymeat	Artide 3		(3) Under Council Directive 96/23/EC of 29 April 1 measures to monitor certain substances and thereof in live animals and animal produce to the second statement of the second statement of the second second statement of the
and analysed in order to demonstrate their wholesome- ness.	Member States shall not authorise the importation into their territory or the consignment to another Member State of the products referred to in Article 1 unless the results of the tests referred to in Article 2 are frowardse.		repeaning uncertiers 533554EC and 84469/E Decisions 89/187/EEC and 91/664/EEC (*), the tion process of animals and primary products of origin shall be monitored for the purpose of d
(5) Regulation (BC) No 178/2002 has set up the Rapid Alert System for Food and recourse to it is appropriate for implementing the mutual information requirement laid down in Directine 92/78/EC	Artilde 4		animals, their excements and body fluids and in animals, their excements and body fluids and in animal products, animal feed and drinking water
(5 00 1 31, 1.2.2002, p. 1.	All expenditure incurred in applying this Decision shall be		f) OJ L 24, 381.1998, p. 9. f) OJ L 265, 811.1995, p. 17. f) OJ L 234, 1.92001, p. 55.

Thai aquaculture and poultry products undergo mandatory testing at importers expense Prohibition on import of Chinese aquaculture products

21.12.2002

Controls extended to food of non-animal origin Waters

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

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 <u>must</u> be subject to <u>voluntary</u> 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

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