



EUROPEAN UNION

Delegation of the European Commission to the USA

European Union Rules for Food Imports and the Concept of Equivalence

**Presentation for the National Advisory Committee on Meat and Poultry
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Scope of the presentation

■ General rules, domestic and imported foods

- The General Food Law
- Official controls and certification
- Imports from third countries.

■ Equivalence

- The multilateral system
- EU approach
- Experience

■ Sources of Information

The notion “Food”

- **Food of animal origin**
 - Raw products (meat, fish, eggs, milk etc)
 - Processed products (ham, cheese, pies)
- **Food of non-animal origin**
 - Fruits, vegetables, cereals, tubers
 - Drinks
 - Minerals (e.g. Salt)
- **Shelf-stable, composite foods**
(cakes, pasta, chocolate)

The legal basis: Farm to fork, food and feed

General Food Law:

Regulation 178/2002

Official controls

Regulation (EC) No 882/2004

Food hygiene:

H I: Regulation (EC) No 852/2004

H II: Regulation (EC) No 853/2004

Residue monitoring

Directive 96/23, Regulation 396/2005

Animal Health:

Directive 2002/99

Plant Health:

Directive 2000/29

(these are only the major elements – see Import Guidance document for more detail)

General Food Law (Reg 178/2002)

- **Article 17 – Liability**

All operators must ensure safety of food and feed.

- **Article 18 – Traceability**

All food, feed and animals: One step up, one step down.

- **Article 20 – Recall**

All recalls must be reported to authorities.

- **Article 11 - Imports**

Food and feed imported into the Community must comply with food law or conditions recognised as equivalent or, where a specific agreement exists, with requirements contained therein.

- **Article 12 - Exports**

Food and feed exported shall comply with the food law.

Hygiene – EU Domestic Production

- **Food of animal origin**
 - Production and handling only by approved operators and after inspection;
 - HACCP-based self controls mandatory;
 - Regular inspection on risk basis.
- **Food of non-animal origin**
 - Operators must notify authorities;
 - HACCP-based self controls mandatory;
 - Regular inspection on risk basis.

Principles for Official Food and Feed Control

- Regulation 882/2004
 - Authorities at all levels must have adequate staff, resource, training, free of conflicts of interest.
 - Accredited laboratories, international testing standards.
 - Risk-based controls in all sectors of food and feed production, based on multi-annual control plans.
 - **Control plans are reviewed by EU Commission.**
 - **Authorities are audited by EU Commission.**

Food Imports - Same Principles

- **Food of animal origin**

- Positive lists of eligible countries and businesses.
- Country listing based on compliance or equivalence.
- Initial audit by FVO. Re-inspections on risk basis.
- Official veterinary certification. Entry via border inspection posts.

- **Food of non-animal origin**

- No country listing.
- Importer is liable for safety (general food law).
- Import without certification via any port of entry.
- Exceptions apply for high-risk foods (aflatoxin).

Country Listing: Food of animal origin

- Competent Veterinary Authority is organised and equipped in-line with Regulation 882/2004.
- Animal health and zoonoses requirements met.
- Approved businesses meet EU hygiene requirements and are regularly inspected.
- A monitoring system for residues is in place.
- Confirmatory inspection of the FVO.
- Official Certification agreed.
- Member States agree in Standing Committee.

Food businesses listing (food of animal origin)

- Country listing establishes a relationship of trust between the EU27 and the country:
 - Yearly submission of residue monitoring plan;
 - Exporting country can list further businesses after inspection by their own competent authority;
 - 4 weeks commenting period, then automatic inclusion on EU list of approved establishments; establishment is then eligible for imports;
 - FVO re-inspects occasionally or 'for reason'.

Equivalence - the principle

- **Equus valere:** Different measures may have the same value, i.e. lead to the same result.
- **Equivalence assessment is an obligation since 1995, under the world trade rules:**
 - SPS Agreement, Article 4: Members shall accept ... measures of other Members as equivalent, even if these measures differ from their own ... if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection.
 - Members shall, upon request, enter into consultations with the aim of achieving ... agreements on recognition of the equivalence.
- ... **but it is difficult to implement it.**

Equivalence - implementation

- **In the multilateral system**

- **CODEX Guideline 53/2003,
Additional guidance agreed in June 2008:**

- **Segmented, measure-by-measure approach
'cutting the process into many slices'.**
 - **Scope can be limited to selected measures.**
 - **Verification issues do not jeopardize equivalence.**
 - **Isolated assessments of individual measures may not
appropriately consider the performance of the whole
system.**

- **The procedures proposed in CODEX provide a systematic
framework, but may favour a too narrow view.**

Equivalence - implementation

- **The EU strategy**
 - Outcome-oriented assessment
 - **Table-top exercise to compare objectives, legal basis, infrastructure, individual measures;**
 - **Emphasis on control system, to reliably guarantee compliance with rules of the exporting country;**
 - **Weight of evidence assessment of the overall performance, to compare the resulting level of protection rather than individual measures;**
 - **On site visit to verify;**
 - **Discussion and joint decision with Member States;**
 - **Verification issues jeopardize equivalence.**

EU Experience

- **One size does not fit all**
 - Equivalence Agreements with USA, Can, NZ, Chile, Switzerland are different in scope and ambition.
- Massive trade facilitation is possible (NZ, CH).
- Regulatory work becomes more complex.
- Success in one area helps to create momentum and to overcome concerns and skepticism.

EU Experience (II)

- Maintenance of equivalence:
 - Changes in legislation of both, importing and exporting country may affect equivalence status. But is it lost?
 - Each side evaluates impact of its own legal changes and informs the trade partner of the assessment.
 - Other side may comment.
 - Equivalence is maintained until proven otherwise.
- Reciprocity
 - Reciprocity is not automatic.
 - But it helps to win goodwill and stakeholder support.
 - As always, win-win situations are preferable.

EU Experience (III)

- Equivalence determination remains a judgement:
 - ‘Equivalent’ is not ‘identical’ – but what is it then?
 - Different measures may have similar results;
 - Zero tolerances do not necessarily mean zero risk;
 - Sometimes quantitative data is difficult to generate and even if available, difficult to compare.
- Some goodwill is necessary – i.e. a broader view.
- History of collaboration helps to build goodwill.
- Stakeholder support is important.
- Equivalence is not a solution for measures with strong political implications.

An example

Salmonella in hog carcasses

- US sampling of skin swabs results in 3-4% Salmonella positive carcasses (2002-2006 data).
- EU sampling of ileo-caecal lymph nodes results in 10% positive carcasses (2006/07 baseline study).

Is this 'equivalent'?

- Legal tolerances for Salmonella are similar (EU 5/50 carcass swab samples positive, US 6/55).
- US and EU are concerned about Salmonella.
- Programs are in place to bring figures further down.
- Authorities have the means and the power to implement and enforce these programs.

This is equivalent, if both sides collaborate.

Another example

Salmonella in poultry carcasses

- US performance standard 20% positive samples, based on carcass wash sampling method.
- EU performance standard 7/50 positive samples, based on 25g neck skin samples.
- Most businesses perform much better than that, but US and EU are committed to bring prevalence further down:
 - US categorization of businesses;
 - EU food chain-oriented reduction strategy.
- Again, authorities do not do the same things, but they address the same problem with similar vigor (and probably similar success).

Is this equivalent? If both sides collaborate, it can be.

Food borne illnesses 2004 – 2006

Incidence per 100.000 population extrapolated from diagnosed and reported cases:

	EU (EFSA)	US (foodnet)
Salmonella (estimated 'true' incidences are higher and less different)	2004: 42.2 2005: 38.2 2006: 34.6	14.6 14.6 14.8
Campylobacter (estimated 'true' incidences are higher and less different)	47.6 51.6 46.1	12.9 12.7 12.7
Listeria	0.3 0.3 0.3	0.3 0.3 0.3
E. Coli	1.3 1.2 1.1	0.9 1.1 1.3

Sources of Information

General Information:

http://ec.europa.eu/food/index_en.htm

Food and Veterinary Office:

http://ec.europa.eu/food/fvo/index_en.html

Guidance Document for Imports

http://ec.europa.eu/food/international/trade/guide_thirdcountries2006_en.pdf

Rapid Alert Reports:

http://ec.europa.eu/food/food/rapidalert/index_en.htm

List of establishments:

http://ec.europa.eu/food/food/biosafety/establishments/index_en.htm

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