The Hygiene package was adopted in 2004 and it comprises of 5 Regulations and a Directive. The table underneath shows the “umbrella shape” of the package, with general regulations on top and more specific one’s underneath.

### Regulation (EC) 178/2002

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

Guidance of the implementation of Articles 11, 12, 16, 17, 18, 19 & 20 of Regulation 178/2002 on general food law- Conclusions of the Standing Committee on the Food Chain and Animal Health.

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| **Competent authorities:** |
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| Commission Regulation 1665/2006 |
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| Commission Regulation 1666/2006 |

Guidelines to assist MS for single integrated multi-annual national control plan

| **Regulation (EC) 853/2004** laying down specific hygiene rules for the hygiene of foodstuffs of animal origin |
| Guidance document on the implementation of certain provisions of Reg No 853/2004 on the hygiene of food of animal origin |

| Commission Regulation 2074/2005 |
| Commission Regulation 2075/2005 |
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| 2006/766/EC                    | 2006/765/EC                      | 2006/766/EC                     |

**Repealing**

**Directive 2004/41/EC**
Repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending council directives 89/662/EEC and 92/118/EEC and council decision 95/408/EC

**Animal health**

**Directive 2002/99/EC**
laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption

concerning the animal health conditions governing the placing on the market of aquaculture animals and products (1), and in particular Article 19(1), 20(1) and 21(2).

Also Commissions Decisions 2003/804/EC and 2003/858/EC leading to:

- 2006/767/EC

**Chemical contamination**

**Labeling and nutrition**
Overview Food Safety Legislation

Animal Feed Manufacture

Primary Production

Harvest & Cutting

Processing & Wholesale

Retail & Catering

Consumption

178/2002
General Food Law

852/2004
Food Hygiene

853/2004
Animal Origin FBO

854/2004
Animal origin Official Control

2073/2005
Microbiological Criteria

2075/2005
Trichinella

2074/2005
Implementing

2076/2005
Transitional

882/2004
Official Controls
### Rules for all foods

**Hygiene of Foodstuffs**

- *Hygiene Rules for Food of Animal Origin (853/2004)*

### Rules for animal origin foods

- *Hygiene of Foodstuffs*
- *Official Control on products of Animal Origin (854/2004)*

### Rules for industry

- **Hygiene of Foodstuffs (852/2004)**

### Rules for official controls

- **Official Control of Feed and Food (882/2004)**
- **OCFF +**

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Tables page 3 + 4 overview hygiene legislation from Séan O’Laoide (Presentation Riga 2007).
In detail:

**Regulation (EC) 178/2002** (General Food law)

This Regulation establishes common definitions and lays down overarching guiding principles and legitimate objectives for food law in order to ensure a high level of health protection and the effective functioning of the internal market. It has been applied fully since 1 January 2005.

**Guidance document** on the implementation of articles 11, 12, 16, 17, 18, 19 and 20 of Regulation 178/2002 on general food law, conclusions of the standing committee on the food chain and animal health: [http://ec.europa.eu/food/food/foodlaw/guidance/guidance_rev_7_en.pdf](http://ec.europa.eu/food/food/foodlaw/guidance/guidance_rev_7_en.pdf)

**Regulation (EC) 852/2004 on the hygiene of foodstuffs**

This Regulation lays down general hygiene requirements to be respected by food businesses at all stages of the food chain. It has to be implemented by food business operators.

In addition a guidance document has been published on the implementation of certain provisions of this Regulation. It gives an extensive explanation on the meaning of “primary production” and “primary products”. This guidance document has already been modified by SANCO/628/2006.

Other topics discussed in this document are:
- The terms “where necessary”, “where appropriate”, “adequate” and “sufficient”
- Flexibility (traditional methods of production, HACCP)
- The registration and approval of food businesses
- Guides to good practice (hygiene and HACCP)
- Documentation
- Technical issues (heat treatment and training)

Article 5 of Regulation 852/2004 requires food business operators to put in place, implement and maintain a permanent procedure based on HACCP principles. A guidance document has been drafted on the implementation of procedures based on the seven HACCP principles, and on the facilitation of the implementation of the HACCP principles in certain food businesses. (Flexibility particularly in small food businesses.)

**Commission Regulation 2073/2005 on microbiological criteria for foodstuffs.**

This Regulation lays down the microbiological criteria for certain micro-organisms and the implementing rules to be complied with by food business operators when implementing the general and specific hygiene measures referred to in Article 4 of Regulation (EC) No 852/2004.
**Regulation (EC) 853/2004** laying down specific hygiene rules for the hygiene of foodstuffs of animal origin

Food business operators that handle food of animal origin must, in addition to Regulation (EC) 852/2004, also implement the appropriate requirements of this Regulation.

In addition a [guidance document](#) has been published on the implementation of certain provisions of regulation 853/2005. It gives amongst others, information on food containing both products of plant origin and products of animal origin (for example pizza, ice cream, bakery) These types of products fall only under regulation 852/2005 and not also under 853/2005, as long as the product of animal origin used has been obtained in accordance with 853/2005. The document also covers some technical issues, like the cleanliness of the animal that is presented for slaughter and the evaluation of the food chain information by the slaughterhouse operator.


Especially regarding:
- Packaging and wrapping
- Skinning
- Tonsils
- Fish oil for human consumption
- Raw milk, colostrums, dairy products and colostrums based products
- Identification marking

**Regulation (EC) 882/2004** on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

Definitions included in this Regulation are amongst others:
- “surveillance”
- “sampling for analysis”
- “physical check”
- “control plan” & “control body”
- “official control”
- “competent authority”
- “inspection”

It describes the organization of official controls, designation of the competent authorities, staff performing official controls and control and verification procedures.


This Regulation includes amongst others the definitions of:
- “official control”
- “official veterinarian”
- “health mark”
- “audit” – “inspection”

It also has details regarding the approval of establishments (conditional and full) in art 3 and gives the general principles for audits of good hygiene and HACCP in art 4.


This Regulation lays down specific rules on official controls for Trichinella in meat. This is in addition to the rules already set in Regulations 854/2004, 853/2004 and 882/2004. It requires the examination for the presence of Trichinella parasites in all slaughtered pigs, wild boar and horses, except for pigs originating from Trichinella-free farms or regions declared as having a negligible risk. **Commission Regulation (EC) No 1665/2006** amending Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for Trichinella in meat


Especially regarding:
- Raw milk, colostrum, dairy products and colostrum based products


**Directive 2002/99/EC** laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption

This Directive lays down the general animal health rules governing all stages of the production, processing and distribution within the Community and the introduction from third countries of products of animal origin and products obtained from them intended for human consumption.
The implementing and transitional measures of hygiene rules are provided for in the following documents:

**Commission Regulation 2073/2005** on microbiological criteria for foodstuffs (see above)


It shall apply from 1 January 2006, except for Chapters II and III of Annex V (access to list of approved food establishments on national websites), which shall apply from 1 January 2007.

This Regulation includes amongst others measures concerning:
- Food Chain Information to the slaughterhouse (853/2004)
- List of approved establishments (882/2004)
- Model health certificates for frogs’ legs, snails, gelatine, collagen (853/2004)
- Derogation for foods with traditional characteristics (852/2004)
- Amendments


Especially regarding:
- Model health certificates
- Testing methods for raw and heat treated milk
- Detection method PSP
- Annex IV to Regulation (EC) No 2074/2005 is replaced

**Amendments SANCO 2696/2006 rev.8**

**Commission Regulation (EC) No 2075/2005** laying down specific rules on official controls for Trichinella in meat (see above)


This Regulation lays down some transitional arrangements until 31 December 2009 to permit the change-over from the old to the new regime.
The measures include in particular provisions concerning:

**853/2004:**
- Stocks of food of animal origin;
- Placing of food of animal origin on national markets, e.g. direct supply of small quantities of meat from poultry and lagomorphs;
- Placing on the market food of animal origin pending approval of establishments;
- Materials bearing pre-printed health or identification marks
- Marking equipment
- Health import conditions
- Food chain information
- Meat of farmed non–domestic ungulates
- Composition of minced meat
- Clean water
- Raw milk and dairy products
- Eggs and egg products

**854/2004:**
- Training of slaughterhouse staff assisting with official controls
- Certification of establishments using staff assisting with official controls in slaughterhouses
- Model certificate for meat from farmed non domestic ungulates
- Health import conditions

**882/2004:**
- Accreditation of laboratories


Especially regarding:

- Import of fish-oil
- Import of products in Annex VI to Regulation (EC) 2074/2005
- Import of special products from third countries or territories


Draft legislation

SANCO/628/2006 Rev.1 Modification of guidance document on the implementation of certain provisions of this Regulation. It gives an extensive explanation on the meaning of “primary production” and “primary products”.

SANCO/3316/2006 Strategies for control of antibiotic residues in bulk milk


SANCO/2006/0048 Rev. 4 Draft Commission Regulation laying down specific conditions for the antimicrobial treatment of fresh poultry carcasses.


