

# *Seafood Hygiene :*

## *The new EU regulations and directives*

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### **BACKGROUND**

Food hygiene serves to protect the consumer from foods that might be either damaging to health or unpalatable. To achieve this, food must be produced according to existing laws or scientifically recognised processing methods and hygiene standards.

With the growth of the food industry and the international markets during the recent years production practices have become more and more complex. This demands that all those involved in the production and handling of food has a high degree of knowledge and understanding of hygiene practises and hygiene conditions.

That is why, over the years, legislation concerning hygiene within the food industry has been continuously tight-

ened. As in the rest of the world, this is also the situation in EU.

EU is according to the FAO statistics the biggest importer of fishery products in the world. About 3 million tonnes are imported from third countries annually.

When it is so important for third countries to comply with the EU regulations, it is mainly because of getting easier access to the common market in EU and to avoid the bureaucracy and often stricter veterinary border control of the goods both in the exporting and the importing countries. Products that meet the requirements laid down in EU legislation can be traded in all EU Member States. The basic principle is harmonisation. This means that the rules governing the trade of products are recognised and applied equally in each Member State.

Products originating in third countries are harmonised if the individual producer or the country of origin is approved according to EU legislation and listed on the category II list of approved countries for export to the EU. The list is introduced for an interim period in order to allow the time necessary to carry out the Community inspections in the third countries to verify that their establishments comply with Community provisions and to avoid a disruption in trade from third countries. During the interim period the competent authority in the actual third country should undertake the guarantee of conformity with Community provisions for the protection of public health. It is the responsibility of the competent authority to draw up a list of establishments and vessels approved for export to EU and to assure their compliance with Community rules.

From 1 January 2005 have the new EU food law been in force followed by the EU regulations on official controls and the EU "Hygiene package" being in force from 1 January 2006.

### **THE NEW EU REGULATIONS AND DIRECTIVES**

The total package of laws in relation to food safety originates from the White Book and the related work forms the EU food law (EU 178/2002), the regulation on official control (EU 882/2004) and the 5 regulations/directives as included in the "hygiene package".

The Whitebook was published by the Commission on 12 January 2000 and is the master plan/strategy for the provisions of the community within specific areas – here food safety. The Whitebook describes the principles behind the new rules on food safety in EU and can be summarised in the following 9 main principles. Many of the principles are not new, but have been developed over the years. They will now be confirmed/affirmed in the EU rules. Many subjects are already implemented in national laws.

1. Farm to table or trawl to table for fishery products: The overall and general principle in the Whitebook is that the food safety policy shall be based on an integrated and unified strategy – across all the food sectors, between Member States and Third Countries. The food law applies to all level in the food chain from feed to final product (animal feed production, primary production, processing of food, storage, transport and retail sales). It is new that feed now is included in the food chain. The law of official control also includes feed. Finally will a hygiene regulation for feed be ready in order to be in force from 1 January 2006 EU 882/2004.
2. The processors/food business operators have the primary responsibility for the food safety - principle of own control. This is not a new principle, though there have been demand for own control 94/356, but the new rules fully implements the own control and in all parts of the food chain.
3. The national competent authorities perform official control of the establishments and assures through the control that the food business operators fulfils their responsibilities. The official control have already for a period been planned and carried through as control of the establishments own control, but in the new rules are the principle fully applied and confirmed. Through inspection/control visits in the Member States are the Commission controlling and assuring that the Competet Authorities have been able to fulfil the necessary and efficient control of the establishments.
4. Traceability: As part of the food safety shall all raw mate-



rials and ingredients in food be traced. Therefore shall procedures be implemented making traceability possible. The more rigorous demands, means that the food business operator now shall be able to inform from where the raw material are received and to whom it have been sold. The food business operators shall also have a plan for withdrawal of feed and food from the market in case of health hazards.

5. Initiatives for securing of food safety shall be based on a scientific background – and the same for the risk assesment.
6. The principle of prudence is still in force.
7. It is politically decided to ensure a high level of protection.
8. A fast and efficient early warning system (Rapid Alert). And it is the obligation of the food business operators to inform the authorities in case of a possible health risk for the consumer from a specific product placed on the market.
9. Openness: The statement of the food policies shall be done in public and openness, in order for all interested parties to be able to participate and contribute to the process.

All the rules in the food law have been evaluated and some further explanations and descriptions have been presented in a Guidance on the implementation of articles 11, 12, 16, 17, 18, 19 and 20 of Regulation 178/2002 on General Food Law. Can be downloaded here: [http://europa.eu.int/comm/food/food/foodlaw/guidance\\_rev\\_7\\_en.pdf](http://europa.eu.int/comm/food/food/foodlaw/guidance_rev_7_en.pdf)

The conclusion of the white book is that the proposed arrangements will result in the highest possible level of food safety and health protection by co-ordination and integration of the entire food safety complex.

In the new EU food law is a list of basic and general demands and objectives on food safety given including the establishing of the European Food Safety Authority. The authority prepares scientific evaluations/assesments and provides scientific and technical assistance in relation to the preparation of EU laws and policies on food. The authority makes risk analyses, while the realisation of risk assesments is the responsibility of the Commission and the Council.

## 1.1 Regulation EC no 882/2004 of the 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.

The regulation on official controls (EU 882/2004) lay down the rules for the competent authorities control of the establishments.



Member States shall ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency, so as to achieve the objectives of this regulation taking account of:

1. Identified risks associated with animals, feed or food, feed or food business, the use of feed or food or any process, material, substance, activity or operation that may influence feed or food safety, animal health or animal welfare
2. Feed or food business operators past record as regard compliance with feed or food law or with animal health and animal welfare rules
3. The reliability of any own checks that have already been carried out
4. Any information that might indicate non-compliance

Official control shall be carried through unannounced, but in case where announced visits is an advantage can this also be done.

The Member States are allowed to collect fees or taxes to cover the cost of the Official control.

Establishments shall be registered or approved. All establishments and vessels handling fishery products shall be approved. By approved means authorised.

The Member States shall from 1 January 2007 present multiannual national control plans.

### THE EU "HYGIENE PACKAGE"

The EU "Hygiene package" consists of:

- Two regulations directed towards the Food Business Operator
  - Hygiene rules for food (EU Reg. 852/2004)
  - Specific hygiene rules for food of animal origin (EU Reg. 853/2004)
- One regulation directed towards Authorities of Control
  - Specific rules for the official controls on products of animal origin intended for human consumption (EU Reg. 854/2004)
- One directive on animal health
  - In force since 1 January 2005 (EU Dir. 2002/99)
- One directive on repealing of existing directives
  - (EU Dir. 2004/41)

The regulation 852/2004, 853/2004 & 854/2004 have direct legal effect in all Member States, and shall be in force from 1 January 2006 with a transitional period of 4 years.

The two directives 2002/99 – animal health and the directive 2004/41 on repealing of certain directives shall be implemented by national laws/rules.

EU 2004/41 includes the changing of the directives 89/662 92/118 and decision 95/408.

Directive 2002/99 shall be implemented 1 January 2005 and Dir 2004/41 no later than 1 January 2006.

Dir 2002/99 is integrated in the veterinary announcement.

Regulation 854/2004 gives specific rules on official control as a supplement to the general decisions on official control as presented in the regulation on official control directive 882/2004.

EU documents is published in the EU Bulletin and can be found on EUR-LEX : [www.europa.eu.int/eur-lex/en/](http://www.europa.eu.int/eur-lex/en/)

The directives/regulations is direct in force and shall not be implemented in national laws

In addition to the "hygiene package" are additional 3 regulations prepared and ready to be in force from 1 January 2006:

1. Microbiological criterias for food
2. Official control of trichines
3. Official control with cysticercose-ox tint – tapeworm.

### 1.2 Regulation [EC] no 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs – 29 April 2004.

The regulation applies for all food business operators in all stages of the food chain, production, processing, storage and distribution of food – ie from the fisherman – catching the fish on the sea or the farmer growing the grain in the field to the auction hall, the processor to the supermarket or the shop at the gas station.

The regulation do not apply for primary production for private domestic use nor private preparation, handling or storage for private domestic consumption.

The regulation differs a little in the demands to the primary production and later stages – but it is mainly for other products than fishery products – even though specific rules for proces-



sing and handling on board fishing vessels compared to shorebased processing is present.

**1.3 Regulation (EC) no 853/2004 of the European Parliament and of the Council laying down specific hygienic rules for food of animal origin 29 April 2004.**

The regulation is laying down specific hygienic rules to the food business operators producing food of animal origin, such as meat, milk, egg and fishery products.

The regulation applies first of all to the wholesalers/producers but there are some specific demands regarding trade with bivalve molluscs and fishery products that also applies for the retailers.

For bivalve molluscs (Annex 3, section 7, point 3)

1. Health standards for live bivalve molluscs
2. Wrapping and packaging of live bivalve molluscs
3. The retailer must keep the label attached to the packaging of live bivalve molluscs that are not in individual consumersize packages for at least 60 days after splitting up the contents.
4. Ensure correct storage temperature and that the final consumerpacks are not sprayed or re-immersed in water

5. Specific requirements for scallops (Pectinidae) harvested outside classified production areas.

For fishery products: (Annex 3, section 8, point 2)

1. Requirements for fresh fishery products
2. Requirements for mechanically separated fishery products
3. Requirements concerning parasites (freezing for raw fish consumption)
4. Requirements for processed fishery products
5. Health standards for fishery products
6. Organoleptic properties of fishery products
7. Histamine
8. TVN
9. Parasites
10. Toxins harmful to human health

It can nationally be decided to let other rules applies for retailers too. For example meat cutting and fish filleting in supermarkets.

**1.4 Regulation EC no 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.**

The specific control on bivalve molluscs and fishery products is mainly concentrated on production - and release areas - and on the final products.

Control with specified and determined release and pproduction areas includes amongst other sampling plans to ensure that the control is done within regular periods.

The official control with fishery products especially focuses on control with production and marketing. It means control of hygienic conditions during landing and first auction, inspection of vessels and establishments on shore including fish auctions and wholesale markets.

**WHAT IS NEW?**

There is nothing new or only very limited. It is first and foremost a matter of compilation and simplification of the 17 existing regulations on hygiene related to food. It means that only few rules are repealed/dropped and even fewer new rules have been added.

Nevertheless can it be recognised that the regulation presents a new style with less detailed rules and more emphasis on individual judgement by the Food Business Operator, few new rules regarding primary production and strictening of old rules regarding training of staff and control staff for the meat production and finally shall the regulations be considered a full harmonisation of the EU market unless directly mentioned that national rules shall be applied.

There have been established procedures for mutual accept of certain national rules, securing that specific national rules can only applies if the other Member States and the Commision approves them.

Some examples comparing the existing and new regulations are given in the presentation at the seminar.

**CONCLUSION ON THE NEW LEGISLATION**

A key point of the new legislation is that every operator involved in the food chain will bear primary responsibility for food safety, with a single, transparent hygiene policy being applicable to all foodstuffs and all operators ( from trawl to table), together with effective instruments to guarantee food safety and manage any future crisis in the sector. ■ ■

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