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**FAO TCP/RER/3301(D)**

**Sustainable Development of the Aquaculture Sector from a Postharvest  
Perspective with a Focus on Quality, Traceability and Safety**

# **Implementation of EU Regulations in Marine Aquaculture and Fish Processing Establishments**

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# EU Food Law



The European Commission works to ensure the safety of EU food supply and that the same standards of food safety apply to all products regardless of origin, **including seafood and other fishery products.**

- ✓ The European Union is by far the world's biggest importer of fish, seafood and aquaculture products.
- ✓ Import rules for these products are harmonised, meaning that the same rules apply in all EU countries.
- ✓ For non-EU countries the European Commission is the negotiating partner that defines import conditions and certification requirements.



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# EU Food Law

- ✓ The European Commission's Directorate-General for Health and Consumers (**DG-SANCO**) is responsible for food safety in the European Union.
- ✓ Our import rules for fishery products and shellfish (bivalve molluscs) seek to guarantee that all imports fulfil the same high standards as products from the EU Member States
- ✓ with respect to hygiene and consumer safety and, if relevant, also to the animal health status.



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# EU Food Law



The legislation system of the EU uses these instruments:

- **Regulations** of the European Parliament and the Council (EC) or the Commission. These apply directly to all member states and are binding as soon as they are adopted and published. They are mandatory for all member states.
- **Directives** of the Council (EC). These describe compulsory objectives but allow member states flexibility in translation into national law through national implementing legislation. A directive may allow specific derogations (exceptions) for national laws or practices. But each directive states when it becomes forbidden to allow non-complying products on the market.
- **Decisions** are documents binding the parties to whom they are addressed. This may be member states, companies or individuals.



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- ✓ **Animal health requirements for aquaculture animals and products thereof:**  
Directive 2006/88/EC
- ✓ **General food law** - Reg. (EC) 178/2002
- ✓ **Hygiene package** - Regulations
  - 852/2004 on food hygiene
  - 853/2004 on food of animal origin
  - 854/2004 rules for official controls on products of animal origin
  - 183/2005 on feed hygiene
  - 882/2004 on official controls - feed and food law
- ✓ **Microbiological criteria for foodstuffs** Commission Regulation EC 2073/2005.
- ✓ **Food labelling** - Directive 2000/13
- ✓ **GMO regulations** - Reg. 1829/2003 and 1830/2003
- ✓ **Packaging and food contact materials** - Reg. 1935/2004
- ✓ **Food additives, colours and sweeteners:**  
Directives 89/107, 94/35, 94/36 EEC and 95/2/EEC
- ✓ **Maximum levels for certain contaminants in foodstuffs**- Reg. 1881/2006.



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## COUNCIL DIRECTIVE 2006/88/EC of 24 October 2006

Directive 2006/88/EC, is already transposed and implemented into Croatian national legislation:

- Veterinary Act (O.G. 41/07)
- Ordinance (OG 42/08) /Council Directive 2006/88 EU - Animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals



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## COUNCIL DIRECTIVE 2006/88/EC of 24 October 2006



### ON ANIMAL HEALTH REQUIREMENTS FOR AQUACULTURE ANIMALS AND PRODUCTS THEREOF, AND ON THE PREVENTION AND CONTROL OF CERTAIN DISEASES IN AQUATIC ANIMALS

#### SCOPE

- ✓ applies to all animals of aquaculture products, where "aquaculture animals" means aquatic animal at all life stages, including eggs and sperm or gametes, reared in a company or in a molluscs farming area, including those from the wild intended for a farm or area.
- ✓ Are excluded from the scope of ornamental animals bred in aquaria non-commercial, wild animals caught for direct entry into the food chain and aquatic animals caught for the production of fishmeal, fish feed, fish oil and similar products



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## COUNCIL DIRECTIVE 2006/88/EC of 24 October 2006



### FIELD OF APPLICATION

- ✓ Aquaculture animals intended for farming and restocking
- ✓ Aquaculture animals and products thereof intended for human consumption
- ✓ Aquaculture animals and products thereof placed on the market for further processing before human consumption
- ✓ Aquaculture animals and products thereof placed on the market for human consumption without further processing



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## COUNCIL DIRECTIVE 2006/88/EC of 24 October 2006



### AQUACULTURE PRODUCTION BUSINESSES AND AUTHORISED PROCESSING ESTABLISHMENTS

- ✓ Each aquaculture production business is duly authorised by the competent authority
- ✓ Where appropriate, such authorisation may cover several aquaculture production businesses for molluscs in a mollusc farming area.
- ✓ However, dispatch centres, purification centres or similar businesses located inside a mollusc farming area shall have an individual authorisation.
- ✓ Each aquaculture production business and authorised processing establishment has a unique authorisation number



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## COUNCIL DIRECTIVE 2006/88/EC of 24 October 2006



### AUTHORISATION CONDITIONS

- Aquaculture production businesses and authorised processing establishments fulfils the relevant requirements of Articles 8, 9 and 10;
  - Art.8 - Recording obligations - Traceability*
  - Art. 9 - Good hygiene practice*
  - Art. 10 - Animal health surveillance scheme*
- has a system in place which enables the operator to demonstrate to the competent authority that those relevant requirements are being fulfilled;
- remains under the supervision of the competent authority, which shall perform the duties laid down in Article 54(1).



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## COUNCIL DIRECTIVE 2006/88/EC of 24 October 2006



### INTRODUCTION OF AQUACULTURE ANIMALS AND PRODUCTS THEREOF INTO THE COMMUNITY FROM THIRD COUNTRIES

- ✓ Only the countries listed or approved by the EU are allowed to export into the Community.
- ✓ To obtain that approval, the third country needs to demonstrate to the EU that the competent authority (CA) provides appropriate guarantees as regards compliance with the EU legislation.
- ✓ An inspection by EU may be required to confirm this.



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# COUNCIL DIRECTIVE 2006/88/EC of 24 October 2006



## DISEASE STATUS (1)

The health status of a country, aquaculture zones or compartments will be determined by the presence or absence of the listed pathogen in its aquaculture stocks and wild animals.

EXOTIC DISEASES		
	DISEASE	SUSCEPTIBLE SPECIES
FISH	Epizootic haematopoietic necrosis	Rainbow trout ( <i>Oncorhynchus mykiss</i> ) and redfin perch ( <i>Perca fluviatilis</i> )
	Epizootic ulcerative syndrome	Genera: <i>Catla</i> , <i>Channa</i> , <i>Labeo</i> , <i>Mastacembelus</i> , <i>Mugil</i> , <i>Puntius</i> and <i>Trichogaster</i> .
MOLLUSCS	Infection with <i>Bonamia exitiosa</i>	Australian mud oyster ( <i>Ostrea angasi</i> ) and Chilean flat oyster ( <i>O. chilensis</i> )
	Infection with <i>Perkinsus marinus</i>	Pacific oyster ( <i>Crassostrea gigas</i> ) and Eastern oyster ( <i>C. virginica</i> )
	Infection with <i>Microcytos mackini</i>	Pacific oyster ( <i>Crassostrea gigas</i> ), Eastern oyster ( <i>C. virginica</i> ), Olympia flat oyster ( <i>Ostrea conchaphila</i> ) and European flat oyster ( <i>O. edulis</i> )
CRUSTACEANS	Taura syndrome	Gulf white shrimp ( <i>Penaeus setiferus</i> ), Pacific blue shrimp ( <i>P. stylirostris</i> ), and Pacific white shrimp ( <i>P. vannamei</i> )
	Yellowhead disease	Gulf brown shrimp ( <i>Penaeus aztecus</i> ), Gulf pink shrimp ( <i>P. duorarum</i> ), Kuruma prawn ( <i>P. japonicus</i> ), black tiger shrimp ( <i>P. monodon</i> ), Gulf white shrimp ( <i>P. setiferus</i> ), Pacific blue shrimp ( <i>P. stylirostris</i> ), and Pacific white shrimp ( <i>P. vannamei</i> )



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NON-EXOTIC DISEASES		
	DISEASE	SUSCEPTIBLE SPECIES
FISH	<del>Spring viraemia of carp (SVC)</del>	<del>Bighead carp (<i>Aristichthys nobilis</i>), goldfish (<i>Carassius auratus</i>), crucian carp (<i>C. auratus</i>), grass carp (<i>Ctenopharyngodon idellus</i>), common carp and koi carp (<i>Cyprinus carpio</i>), silver carp (<i>Hypophthalmichthys molitrix</i>), sheatfish (<i>Silurus glanis</i>) and tench (<i>Tinca tinca</i>)</del>
	Viral haemorrhagic septicaemia (VHS)	Herring ( <i>Clupea</i> spp.), whitefish ( <i>Coregonus</i> spp.), pike ( <i>Esox lucius</i> ), haddock ( <i>Gadus aeglefinus</i> ), Pacific cod ( <i>G. macrocephalus</i> ), Atlantic cod ( <i>G. morhua</i> ), Pacific salmon ( <i>Oncorhynchus</i> spp.) rainbow trout ( <i>O. mykiss</i> ), rockling ( <i>Onos mustelus</i> ), brown trout ( <i>Salmo trutta</i> ), turbot ( <i>Scophthalmus maximus</i> ), sprat ( <i>Sprattus sprattus</i> ) and grayling ( <i>Thymallus thymallus</i> )
	Infectious haematopoietic necrosis (IHN)	Chum salmon ( <i>Oncorhynchus keta</i> ), coho salmon ( <i>O. kisutch</i> ), Masou salmon ( <i>O. masou</i> ), rainbow or steelhead trout ( <i>O. mykiss</i> ), sockeye salmon ( <i>O. nerka</i> ), pink salmon ( <i>O. rhodurus</i> ) chinook salmon ( <i>O. tshawytscha</i> ), and Atlantic salmon ( <i>Salmo salar</i> )
	Koi herpes virus (KHV) disease	Common carp and koi carp ( <i>Cyprinus carpio</i> ).
	Infectious salmon anaemia (ISA)	Rainbow trout ( <i>Oncorhynchus mykiss</i> ), Atlantic salmon ( <i>Salmo salar</i> ), and brown and sea trout ( <i>S. trutta</i> ).
MOLLUSCS	Infection with <i>Marteilia refringens</i>	Australian mud oyster ( <i>Ostrea angasi</i> ), Chilean flat oyster ( <i>O. chilensis</i> ), European flat oyster ( <i>O. edulis</i> ), Argentinian oyster ( <i>O. puelchana</i> ), blue mussel ( <i>Mytilus edulis</i> ) and Mediterranean mussel ( <i>M. galloprovincialis</i> )
	Infection with <i>Bonamia ostreae</i>	Australian mud oyster ( <i>Ostrea angasi</i> ), Chilean flat oyster ( <i>O. chilensis</i> ), Olympia flat oyster ( <i>O. conchaphila</i> ), Asiatic oyster ( <i>O. dense-lammellosa</i> ), European flat oyster ( <i>O. edulis</i> ), and Argentinian oyster ( <i>O. puelchana</i> ).
CRUSTACEANS	White spot disease	All decapod crustaceans (order Decapoda).



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# COUNCIL DIRECTIVE 2006/88/EC of 24 October 2006



## FARM'S HEALTH STATUS

### Category I

Declared disease-free



### Category II

Not declared disease-free but subject to a surveillance programme



### Category III

Not known to be infected but not subject to surveillance programme for achieving disease free status.



### Category IV

Known to be infected but subject to an eradication programme



### Category V

Known to be infected. Subject to minimum control measures



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# COUNCIL DIRECTIVE 2006/88/EC of 24 October 2006



## ADMITTED COMMERCIAL FLOWS

Category	Health status	May introduce animals from	Health certification		May dispatch animals to
			Introduction	Dispatching	
I	Disease-free (Articles 49 or 50)	Only category I	YES	NO when dispatched to category III or V  YES when dispatched to categories I, II or IV	All categories
II	Surveillance Programme (Article 44(1))	Only category I	YES	NO	Categories III and V
III	Undetermined (not known to be infected but not subject to a programme for achieving disease- free status)	Categories I, II, or III	NO	NO	Categories III and V
IV	Eradication Programme (Article 44(2))	Only category I	YES	YES	Only category V
V	Infected (Article 39)	All categories	NO	YES	Only category V



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## COUNCIL DIRECTIVE 2006/88/EC of 24 October 2006



### NOTIFICATION AND MINIMUM MEASURES FOR CONTROL OF DISEASES OF AQUATIC ANIMALS (1)

- ✓ Any suspicion or confirmation of the presence of a listed disease or an increase in mortality needs to be notified at the national level.
- ✓ The obligation to notify is applied to any professional that is aware of the situation (such as the owner or manager), any person to accompany the animals during transportation, veterinary practitioners or aquatic animal health professionals, official veterinarians and private laboratories.
- ✓ In case of suspicion of a listed disease, appropriate sample collection and submission to a designated laboratory has to be carried out.
- ✓ While waiting for the results, the farm/area is placed under official surveillance and no aquatic animals are allowed in or out of the facilities/area.



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## COUNCIL DIRECTIVE 2006/88/EC of 24 October 2006



### NOTIFICATION AND MINIMUM MEASURES FOR CONTROL OF DISEASES OF AQUATIC ANIMALS (2)

- ✓ At this point, an epizootic investigation is performed with the aims of finding out the possible origin and means of contamination, the animal movement prior to notification, the health status of other farms and the establishment of a containment area appropriate to the disease in question, including a protection zone and a surveillance zone around the area.
- ✓ If a listed disease is confirmed, international notification is due to the OIE, trading partners and neighboring countries potentially at risk.

### CONTROL PROGRAMMES: SURVEILLANCE, ERADICATION AND CONTINGENCY PLANS

Depending on the disease status, countries need to have a surveillance or an eradication programme. In any case, the country should have a contingency plan in place.



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## FARMERS AND PROCESSING/PACKING OPERATORS

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

**(EC) 853/2004:**  
Regulation on specific  
hygiene rules for food of  
animal origin

**(EC) 2073/2005:**  
Regulation on microbiological  
criteria for foodstuffs and  
feed production

## EU Hygiene package



## OFFICIAL INSPECTORS VETERINARY POLICE

**(EC) 854/2004:**  
Regulation on official  
controls on foods of animal  
origin

**(EC) 882/2004:**  
Regulation on official  
controls for feed and food,  
animal health and animal  
welfare rules



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# EU Hygiene package

(EC) 178/2002



- Regulation on General principles and requirements of food law
- Establishing EFSA
- Laying down procedures in matters of food safety

*"Assurance of a high level of protection of human health and consumers' interest in relation to food, in the diversity in the supply of food including traditional products" is the proclaimed objective of the regulation. "It establishes common principles and responsibilities, the means to provide a strong science base, efficient organizational arrangements and procedures to underpin decision-making in matters of food and feed safety" and "applies to all stages of production, processing and distribution of food and feed, except the primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption".*



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# EU Hygiene package



(EC) 852/2004

Regulation on the hygiene of foodstuff:

- applies to all stages of food and feed chain
- **food business operators obligations**
- general requirements primary production
- technical requirements
- temperature control requirements
- **HACCP** - all non primary producers
- **registration/approval of food businesses**
- national guides to good practice
- **product recall**



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# EU Hygiene package



(EC) 853/2004

Regulation on specific hygiene rules for food of animal origin

- **spec. hygiene rules** for food of animal origin
- processed and unprocessed, except food consisting partly of products of plant origin
- approval of establishments
- health and identification marking
- imports
- Food Chain Information
- does not apply to retail (certain exemptions)

Amended by Regulation (EC) 1662/2006



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# EU Hygiene package



Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall:



1. **ensure** that foods or feeds satisfy the requirements of food law which are relevant to their activities ;
2. **verify** that such requirements are met;
3. assure the relevant product **traceability**;
4. **withdraw** and/or **recall** food/feed which is not in compliance with the food/feed safety requirements;
5. **notify** the consumers and the competent authorities when the non conforming product may have reached the consumer; the competent authorities if the food placed on the market may be injurious to health, about the measures that he had taken to prevent risk for the final consumer and
6. **cooperate** with the competent authorities to avoid or prevent the risk for the consumer.



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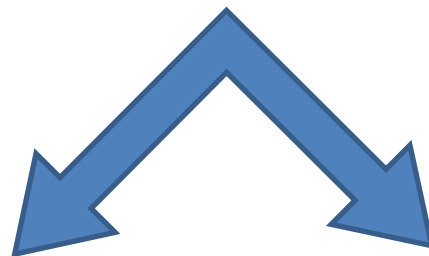
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# EU Hygiene package



## Traceability

Quantitative risk assessments typically aim at covering the whole "farm to fork" or 'ship to dish' chain and at any point in time, one must therefore be able to trace an event or a product

## HACCP

Hazard

Analysis and

Critical

Control

Points



*THANKS !  
HVALA!*

