

“Piloting of eco-innovative fishery supply–chains to market added–value Adriatic fish products”

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Summary

The study of standard classifications in the development of new products in the fishing industry provides an overview of the legislation as well as the standards included in order to place a product on the market except in the retail categories.

The subject study deals exhaustively with compliance with legal requirements (national laws and adopted EU legislation) for the introduction of new products within new and existing markets.

It equally handles compliance with international standards, regulations and their revisions. The regulations stipulate that when placing goods on the market, the greatest responsibility lies with the manufacturer, so that safety and quality assurance (in relation to product and process specifications) is health, safety and quality of food and sanitary procedures at the manufacturer.

In order to facilitate and harmonize market access, guidelines of minimum sanitary and hygienic practice recognized by the FAO, such as Good Hygienic Practice (GHP) and Good Manufacturing Practice (GMP), are of great help.

The guidelines should otherwise contain essential information during their life cycle and critical points in production (e.g., packaging, storage and transport). In the case of defined products, it is necessary to pass all special requirements for labeling, traceability and all other labeling categories - for unprocessed and for packaged processed products.

Procedures should be defined in terms of "from farm to fork" - that is, all legislation and good practice that accompanies high quality and safety, from the deck to the final stage of food processing, should be defined and respected.

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1. Introduction

The industry of fish and other marine organisms as well as the industry of other food products for direct human consumption has been gaining more and more demands over the decades, therefore nowadays there is a high level of standards for the preparation and control of such products. Such a practice is extremely important because it is always possible for individual entities to introduce into the market the practice of consumer fraud, misinformation and mislabeling, which may be done not out of false intent but ignorance. Therefore, in EU practice, it is important to have standardized procedures for products placed on the market, with unique criteria for goods produced within the EU as those imported.

There are mandatory requirements that need to be adhered to in order for products to be placed on the single European market. The basic categories for these requirements are the framework of the competent authority, accredited facilities in the food business, proper food labeling and other controls.

The basis of the approach to the classifications of legislation and standards in this study refers to three selected species of marine organisms: sardines within the organization of producers Omega 3, shrimp within the organization of producers Istria, and shellfish within the organization of producers Bivalvia. Given the new moments in the market related to catch restrictions as well as seasonal catches, producer organizations seek to consolidate and strengthen their position by introducing changes in process steps that will improve quality and consequently price, as well as by designing value-added products. This study will show all the rules that sea fishery products must meet in order to be placed on the market, with representations for other types of organisms (shellfish).

The main technical innovative activity within this project is to initiate changes in catch handling, selection at sea and designing the process of processing and confectioning of fish as a category of high value-added products, i.e., fishery products ready for consumption in the category of semi-finished dishes of high nutritional value. Process changes for sardines and anchovies refer to a complete change in the technology of fishing on board using pumps. The use of pumps raises the quality and makes it easier to do the job as well as shortening the process with increased safety of fishermen in manipulating the catch. In bivalve molluscs, the selection is applied on board during the catch, and juveniles are returned to the sea with as little stress as possible. For seasonal catches, we chose shrimp, which the Italian side catches in thousands of tons, and mullet, which is one of the most frequent species in the catch of Istrian fisheries. Innovative technology through the processing process is the adaptation of existing machines for deboning

production. Unfortunately, it must be stated that the great opportunity in a different form of sea fish processing in Italy and Croatia has not been fully used and therefore this study opens the possibility of contributing to a new approach to the processing and handling of catches. The scope of this study deals with the issue of standard classification, i.e., the necessary legal conditions for placing a product on the market, with an emphasis on the steps that need more attention.

2. Basic requirements related to the placing on the market of fishery products in the European Union

EU legislation on food trade stipulates that each member state must have an accredited - authorized institution at the national level, i.e., a competent body authorized by the European Commission. This is followed by the transposition and implementation of European legislation as well as the strengthening of national laws, if necessary. The competent authority is responsible for the development and implementation of regulations that meet European requirements. It is usually a government department within the ministries mainly of agriculture, fisheries and aquaculture with which the European Union enters into an agreement, giving them responsibility for mandatory control measures prior to export to other member states. The competent authorities further review and approve the facilities on the basis of the criteria and propose the listing of approved facilities for export to Europe. The competent authorities and the European Commission continuously carry out inspections of approved facilities to check that they comply with regulations and standards for placing food on the market. Through these regular inspections, the existing systems are audited and the correct implementation of regulations is checked. In case of identified deficiencies, changes are proposed or the facility is temporarily closed if major irregularities are observed.

The key requirements to be met before placing food on the market are the proven application of hazard analysis standards and critical control points (HACCP) and the traceability or possibility of traceability of products back to registered fishing vessels or aquaculture farms.

HACCP (Hazard Analysis and Critical Control Point) is a method for controlling processing operations carried out by a professional team of producers. It is subject to audit and places responsibility on the producer for incidents in the food trade. The application of HACCP helps to

identify possible problems and provides instructions on how to prevent and solve them, in order to ensure hygiene, safety and traceability of products.

EU food hygiene regulations cover all stages of production, processing, distribution and placing on the market of products intended for human consumption.

The hygiene rules of the European Union include the following:

- The primary responsibility of the food business operator for food safety;
- Food safety should be ensured throughout the food chain, starting with primary production;
- Application of procedures based on the principles of hazard analysis and critical control points (HACCP);
- Application of basic hygiene requirements, possibly additionally determined for certain food categories.

There are obligations that competent authorities must meet for certain seafood products in terms of national analysis in order for them to be placed on the EU single market. Approval is obtained based on the Residue Monitoring Plan (RMP).

Europe has one of the world's highest food safety standards. Products found to be non-compliant are registered and reported to the Rapid Alert System for Food and Feed (RASFF).

3. Compliance with legislation (national and European legislation)

Legal norms related to the placing of new foodstuffs on the market (the subject of this study are fish and other marine organisms - whole and processed) are significantly represented in the wider European legislation, especially related to production practices and food safety on the market. Within food production and marketing, we distinguish between processed and unprocessed marine organisms.

3.1. Basic legislation related to food production

The most important European regulations related to food production are as follows:

- Regulation (EC) 178/2002 laying down the general principles and requirements of food law
- Regulation (EC) 852/2004 on the hygiene of foodstuffs
- Regulation (EC) 853/2004 laying down specific hygiene rules for food of animal origin (including fish and aquaculture products)
- Regulation (EC) 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

European regulations are based on several unique principles, and one of the most important principles is that food safety is primarily the responsibility of producers. The manufacturer must ensure that his product is safe for consumption and that it does not leave or cause harmful effects on human health or the health of consumers. In addition to prescribing its own production measures, the responsible official competent authority monitors production through regulations, requires compliance with procedures based on HACCP principles and encourages compliance with codes of good practice. The manufacturer must ensure that his products are safe and must be in the control system of the competent authorities.

Fishery products may be placed on the market if they meet the provisions of the Marine Fisheries Act (OG 62/2017, 14/2019).

3.2. Registration and approval of facilities in the food business

Food business operators (FBO), i.e., crafts and companies that decide to produce and place food on the market, must be registered or approved by the competent authorities before starting their activities. A registration / approval number is assigned to each food business facility upon request and official inspection. All food business operators, except those in the retail business, must ensure that the food they produce is marked with their approved number, i.e., it is traceable.

An operator of fishery products may, after obtaining the necessary authorizations, place products on the market only if they have been prepared and / or processed exclusively in establishments which comply with the provisions on general hygiene rules and the provisions on special hygiene rules for food of animal origin. Such facilities must be approved by the competent body of the Ministry of Agriculture - Veterinary and Food Safety Administration, by entry in the Register of approved facilities dealing with the food of animal origin.

According to Regulation (EC) No 178/2002 „food business operator,, means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control. FBO at all stages of production, processing and distribution, which are under its control, must ensure that the food or feed meets all the requirements of food regulations relevant to its business and prove that it has met the prescribed requirements.

FBO is also, within the scope of production, responsible for defining and ensuring the traceability of food, feed, food-producing animals or any other substance intended for incorporation or can be expected to be incorporated into food or feed at all stages of production, processing and distribution. If the FBO considers that the food it has imported, produced, processed, packaged or distributed does not meet the food safety requirements in any important aspect for human health, it must immediately initiate the procedure of withdrawal of that food from the market and inform the competent authority. If the food has already reached the consumer, the FBO must inform the consumers of the reason for the withdrawal of the food and, if necessary, recall the products from the consumers to whom they have already been sold. Withdrawal depends on the product defect, but in the case of product defects dangerous to human health, the recall must be carried out categorically.

3.3. Official process and production controls - legal frameworks for environmental aspects

- **Legislation determining the environmental aspects of fishing and processing of fishery and aquaculture products**

The Environmental Protection Act (OG 80/13, 153/13, 78/15, 12/18 and 118/18) and the Decree on Environmental Impact Assessment (OG 61/14 and 3/17) prescribe implementation of the procedure for assessing the impact of interventions on the environment, mainly in the case of

products from processing facilities and aquaculture facilities. By adopting these regulations, the procedure is systematically regulated and harmonized with the relevant EU directives:

- Council Directive 85/337/EEC from 27th of June 1985. on the assessment of the effects of certain public and private projects on the environment
- Council Directive 97/11/EC from 3rd of March 1997. amending Directive 85/337/EEC on the assessment of the effects of certain public and private projects on the environment
- Directive 2003/35/EC of the European Parliament and of the Council from 26th of May 2003.

The adopted regulations are also based on the provisions of an international agreement, which the Republic of Croatia adopted by adopting the Act on the Ratification of the Convention on Environmental Impact Assessment in a Transboundary Context (OG 6/96).

Impact assessment is a process of assessing the acceptability of the planned project in relation to the environment, and based on that, determining the necessary environmental protection measures. The procedure is carried out in order to minimize the impact of the project and achieve the greatest preservation of environmental quality. The assessment procedure, depending on the need to prepare an environmental impact study, is carried out at an early stage of project planning, before the issuance of a location permit or other approval for the project for which the issuance of a location permit is not mandatory.

The List of interventions in Annex I, which is an integral part of the Regulation, lists the interventions for which the procedure of environmental impact assessment is mandatory. In the List of projects in Annex II the interventions for which the assessment of the need for environmental impact assessment is carried out and for which the Ministry is responsible are listed, and in the List of interventions in Annex III the interventions for which the assessment of the need for environmental impact assessment is carried out and for which the administrative body in the county is competent are listed. The criteria on the basis of which it is decided on the need to assess the impact of the project on the environment are listed in Annex V of the Regulation on the assessment of the impact of the intervention on the environment.

The study, in case of its mandatory adoption, must assess the impact of the planned project on the environment based on factors of imagined and planned production or operation which, depending on the project and environmental characteristics, determine the spread, intensity and

duration of the impact. The study must be made on the basis of the latest, reliable and available data, and it is made by an authorized legal entity.

The impact of the project on the environment, its evaluation and acceptability is assessed by the commission on the basis of a study. The Commission is appointed by the Ministry of Economy and Sustainable Development for the interventions specified in the Lists of Interventions from Annex I and Annex II of the Regulation, and the administrative body in the county, for the interventions listed in Annex III of the Regulation on environmental impact assessment. After the public hearing, the commission issues an opinion on the acceptability of the project and sends it to the competent authority for a decision which is the mandatory content of future permits for the interventions.

The decision on the acceptability of the intervention for the environment determines that the intended interventions are acceptable for the environment with the application of environmental protection measures and may also contain a program for monitoring the environment.

ANNEX I

LIST OF INTERVENTIONS FOR WHICH THE ENVIRONMENTAL IMPACT ASSESSMENT IS OBLIGATORY, RELATED TO FISHERIES

45	<p>Marine farms:</p> <ul style="list-style-type: none"> – whitefish farms in a protected coastal area (PCA) with an annual production greater than 100 t – fish farms outside the PCA, up to a distance of 1 Nm, and of annual production greater than 700 t – fish farms outside the PCA, up to a distance of 1 Nm, and of annual production greater than 3500 t
46	Shellfish farms in PCA with an annual production greater than 400 t

ANNEX II

LIST OF INTERVENTIONS FOR WHICH THE ESTIMATION OF THE NEED FOR THE ASSESSMENT OF THE ENVIRONMENTAL IMPACT IS BEING CARRIED OUT, UNDER THE AUTHORITY OF THE MINISTRY

1.3	Marine farms: – whitefish farms in PCA with an annual production lesser than 100 t – fish farms outside the PCA with an annual production greater than 100 t
6.2	Installations for the production, processing (canning) and packaging of products of plant or animal origin with a capacity of 1 t / day and more

Environmental protection measures define the procedures that need to be taken before construction, during use, and sometimes prescribe measures after the cessation of interventions.

The environmental monitoring program usually prescribes the determination of certain parameters of the marine environment before the intervention in order to determine the so-called zero condition and then prescribes the obligations of their monitoring at several points of coverage of the intervention, obliged to be carried out by the project holder through an authorized person and/or an accredited laboratory.

Due to other economic activities, marine ecosystems are exposed to numerous constant impacts and changes that are important for their functioning and stability (Source: <http://www.fao.org/3/y4773e/y4773e05.htm#TopOfPage>)

When fishing without proper control, overfishing occurs with a significant impact on ecosystems as well as social and economic consequences for the further performance of this activity.

Fishing can significantly affect environmental processes. Excessive fishing disturbs the balance of ecosystems, changing the number of individuals of a particular species in the food chain or the topography of the sea bed and associated habitats.

Habitat change, due to various human activities, can be physical (artificial reefs, fish farm cages, pipelines, port construction, marinas, etc.), mechanical (the impact of trawling on the seabed, sand extraction, wells, etc.) or chemical (addition of pesticides, drugs, hormones, oils, petroleum, etc.). Fishing can positively or negatively affect changes in the amount of fish stock as well as other species in the ecosystem. Some aspects of fisheries can have significant and long-lasting negative effects, such as destructive and prohibited fishing techniques or inappropriate fishing practices; pollution from fish processing plants or farms; use of ozone-depleting refrigerants;

throwing plastic waste into the sea, loss of fishing equipment, threats to endangered species, etc.

In fisheries, related and dependent species must be taken care of in order to maintain balance in the food chain of a particular ecosystem.

Also, fishing can have a significant impact on genetic diversity and can permanently change the characteristics of the population of certain habitats.

Fishing gear can affect living and non-living environments. Environmental damage can arise from the inappropriate use of fishing gear or due to the very nature of fishing technology. Deliberate discarding or loss of fishing gear also affects seabirds, marine mammals and turtles.

Most fishing activities are not selective enough to catch only the desired species leading to accidental catches of other species of which one part has little or no value and will be thrown back into the sea. Part of it will serve as food for seabirds while most will end up on the seabed where, by settling over time, it can cause a decrease in oxygen due to excessive organic load of the seabed (Source in Croatian: <https://euribarstvo.hr/mjera-i-15-ogranicavanje-utjecaja-ribolova-na-morski-okolis-i-prilagodavanje-ribolova-zastiti-vrsta/>).

- **Limiting the impact of fishing on the marine environment and adapting fishing to protection of species**

Sustainable fishing must take into account the specificity of the fishing area in order to adapt techniques, catch different species and respect seasonal biological patterns of fish behavior, reduce unwanted catches, create only small amounts of discarded fish and reduce the impact on marine habitats. (Source: <https://lifeplatform.eu/our-mission/>).

Fishing capacities need to be focused on low-impact fishing methods without exceeding a sustainable level of pressure on the fish stock. One of the preconditions should therefore be fisheries management based on the state of the ecosystem in order to protect the marine environment.

Investments in equipment to limit and, if possible, eliminate the physical and biological effects of fishing on the ecosystem or the seabed are of particular importance.

Through the pilot project, the use of fish extraction pumps as well as a possible selector can be considered as an investment in equipment that improves the selectivity of fishing gear in terms

of size or species, as it will be able to ensure the return of juveniles back to the sea. That has an effect of reducing discards and thus the impact of fishing on the marine environment, ensuring the sustainable exploitation of marine biological resources.

- **EU legislation – fisheries policy**

- Regulation (EU) No 1380/2013 of the European Parliament and of the Council from 11th of December 2013. on the Common fisheries policy
- Commission Implementing Regulation (EU) No 404/2011 from 8th of April 2011. laying down detailed rules for the implementation of Council Regulation (EC) No 1224/2009 establishing a Community control system for ensuring compliance with the rules of the Common fisheries policy
- Council Regulation (EC) No 1224/2009 from 20th of November 2009. establishing a Community control system for ensuring compliance with the rules of the common fisheries policy
- Council Regulation (EC) No 1967/2006 from 21st of December 2006. concerning management measures for the sustainable exploitation of fishery resources in the Mediterranean Sea

4. Official process and production controls - legal frameworks for aspects of safety and quality assurance and sanitary procedures

- **Existing legislation determining food safety control in the fish industry**

By joining the European Union, the Republic of Croatia has developed a general legislative framework in the field of food safety for the purpose of implementing EU regulations:

- The Food Act (OG 81/13, 14/14, 30/15, 115/18) fully ensures the implementation of Regulation (EC) No 178/2002 and other relevant EU regulations.

- The Food Hygiene and Microbiological Criteria for Food Act (OG 81/13, 115/18) ensures the implementation of Regulation (EC) No 852/2004 and Regulation (EC) No 2073/2005, as well as other relevant EU regulations.
- Implementation of Regulation (EC) No 853/2004 and Regulation (EC) No No 854/2004, along with other relevant EU regulations, is provided by the Veterinary Law (OG 82/13, 148/13, 115/18)
- Implementation of Regulation (EC) No 882/2004, as well as the implementation of other relevant decisions of the European Commission, is ensured by the Law on Official Controls conducted in accordance with the Regulations on Food, Feed, Animal Health and Welfare. (OG 81/13, 14/14, 56/15, 32/19)
- The Law on Consumer Information on Food (OG 56/13, 14/14, 56/16, 32/19) ensures the implementation of Regulation (EU) No 1169/2011.

Food Act (OG 81/13, 14/14, 30/15, 115/18) for the purpose of implementing Regulation (EC) No 178/2002 and other relevant EU regulations prescribed provisions at national level governing:

- responsibilities for establishing and implementing food safety policy;
- competencies in the field of risk analysis;
- general rules of the rapid alert system for food and feed at national level;
- general crisis management rules in the field of food and feed safety;
- establishment and coordination of a network of institutions;
- providing scientific and professional opinions and providing scientific and technical assistance;
- national measures needed to implement food safety policy.

Regulation (EC) No 178/2002, the implementation of which is ensured by the Food Act, provides the basis for ensuring a significant level of protection of human health and consumer interests in relation to food, while respecting the efficient functioning of the internal market. Regulation (EC) No No 178/2002 lays down the general principles governing food and feed in general, and food and feed safety in particular at European Union and national level. These principles, which are applied in accordance with an integrated "field-to-table" approach, i.e., through all stages of production, processing, and distribution of food and feed, include in particular risk analysis and prevention, the precautionary principle and the protection of consumer interests.

It is not allowed to place on the market food that is unsafe and food that is harmful to health and / or unfit for human consumption. In determining whether a food is unsafe, harmful or risky, the following must be taken into account: normal conditions of use of the food, information provided to the consumer, possible immediate or delayed effects on human health, possible cumulative toxic effects and particular health sensitivities of certain categories of consumers.

4.1. “Hygiene package”

After the adoption of the European food law or Regulation (EC) No 178/2002, in 2004. the so-called “Hygiene package” decrees were passed which entered into force on 1st of January 2006.

The regulations of the "Hygiene package" prescribe the rules of hygiene of foodstuffs, and the package includes three basic regulations:

- Regulation (EC) No 852/2004 of the European Parliament and of the Council on 29th of April 2004. on the hygiene of foodstuffs;
- Regulation (EC) No 853/2004 of the European Parliament and of the Council on 29th of April 2004. laying down specific hygiene rules for food of animal origin;
- Regulation (EC) No 854/2004 of the European Parliament and of the Council on 29th of April 2004. laying down special rules for the organization of official controls on products of animal origin intended for human consumption.

Regulation (EC) No 852/2004 (general rules - hygiene of foodstuffs) and Regulation (EC) No 853/2004 (specific rules - hygiene rules for food of animal origin), refer to food business operators (FBO), while Regulation (EC) No 854/2004 (controls on products of animal origin) refers to competent authorities and it applies together with Regulation (EC) No 882/2004 of the European Parliament and of the Council on 29th of April 2004. on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Generally, Regulation (EC) No 882/2004 applies on all food business operators (including FBO on the primary production level). Regulation (EC) No 853/2004 is additionally applied on certain FBO dealing with food of animal origin.

Regulation (EC) No 852/2004 establishing a Community control system for ensuring compliance with the rules of the Common fisheries policy

Regulation (EC) No Regulation (EC) No 852/2004 whose implementation is ensured by the Food Hygiene Act and microbiological criteria for food, lays down general rules for food business operators on the hygiene of foodstuffs, taking particular account of the following principles:

- (a) primary responsibility for food safety rests with the food business operator;
- (b) it is necessary to ensure food safety throughout the food chain, starting with primary production;
- (c) it is important, for food that cannot be stored safely at ambient temperatures, particularly frozen food, to maintain the cold chain;
- (d) general implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility;
- (e) guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain with compliance with food hygiene rules and with the application of the HACCP principles;
- (f) it is necessary to establish microbiological criteria and temperature control requirements based on a scientific risk assessment;
- (g) it is necessary to ensure that imported foods are of at least the same hygiene standard as food produced in the Community, or are of an equivalent standard.

FBO must ensure that all stages of production, processing and distribution of food under its control meet the requirements of food hygiene.

Regulation (EC) No 852/2004 prescribes the hygiene requirements that must be met by all FBO, regardless of whether they produce food of animal or non-animal origin. In the case of the production of food of animal origin, FBO must, in addition to the requirements laid down in Regulation (EC) No 1774/2002. 852/2004, also comply with the special rules of hygiene of food of animal origin prescribed by Regulation (EC) No 853/2004, the implementation of which is ensured by the Veterinary Act.

Food business operators carrying out primary production and those associated operations listed in Annex I Regulation (EC) No 852/2004 shall comply with the general hygiene provisions laid down in Part A of Annex I and any specific requirements provided for in Regulation (EC) No 853/2004.

FBO carrying out any stage of production, processing and distribution of food after primary production must comply with the general hygiene requirements laid down in Annex II Regulation (EC) No 852/2004, as well as all with the special requirements prescribed by Regulation (EC) No 853/2004.

Regulation (EC) No 852/2004 states that the registration of establishments and the cooperation of food business operators are necessary to allow the competent authorities to perform official controls efficiently. Every food business operator shall notify the appropriate competent authority, in the manner that the latter requires, of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each such establishment. Food business operators shall also ensure that the competent authority always has up-to-date information on establishments, including by notifying any significant change in activities and any closure of an existing establishment.

FBO performing any stage of food production, processing and distribution, after primary production and related activities, must establish, implement and maintain a system and procedures based on HACCP principles.

FBO must ensure compliance with the provisions of Commission Regulation (EC) No 2073/2005 of 15 November 2005 regarding microbiological criteria for foodstuffs.

Regulation (EC) No 853/2004 establishing a Community control system for ensuring compliance with the rules of the Common fisheries policy

Regulation (EC) No 853/2004 of the European Parliament and of the Council from 29th of April 2004. laying down specific hygiene rules for food of animal origin lays down certain rules on the hygiene of food of animal origin which the FBO must comply with. These rules complement those laid down in Regulation (EC) No 852/2004.

Regulation (EC) No 853/2004 applies to unprocessed and processed products of animal origin.

Regulation (EC) No 853/2004 does not apply to food containing both products of plant origin and processed products of animal origin. However, processed products of animal origin used for the preparation of such food must be produced and handled in accordance with the conditions of this Regulation.

Regulation (EC) No 853/2004 applies to food business operators including: general obligations of FBO, health and identification marking, responsibilities of FBO regarding products of animal origin from outside the Community.

Regulation (EC) No 853/2004 has three annexes:

Annex I. provides the definitions of food of animal origin.

Annex II. provides the requirements concerning several products of animals and they include: application of the identification mark; objectives of haccp-based procedures; food chain information.

Annex III. Provides specific requirements for particular categories of food of animal origin in which there are: meat of domestic ungulates; meat from poultry and lagomorphs; meat of farmed game; wild game meat; minced meat, meat preparations and mechanically separated meat (msm); **live bivalve molluscs; fishery products**; raw milk and dairy products; eggs and egg products; frogs' legs and snails; rendered animal fats and greaves; treated stomachs, bladders and intestines, gelatine, collagen.

4.2. Official controls

General rules for the conduct of official controls are laid down in 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, the implementation of which is ensured by the Official Controls Act which are carried out in accordance with the regulations on food, feed, animal health and welfare. (OG 81/13, 14/14, 56/15, 32/19).

Official controls are carried out at all stages of the production, processing and distribution of food or feed, and on animals and products of animal origin. Official controls include the control of food

and feed business, the use of food and feed, the storage of food and feed, all processes, materials, substances, actions or processes, including transport related to food or feed, and to live animals. Official controls are also carried out on exports from the EU, on placing on the EU market as well as on entry from third countries.

The bodies responsible for the implementation of official controls in the field of food safety are the Ministry of Agriculture, the Ministry of Health and the State Inspectorate, in accordance with the division of competencies referred to in Article 7 of the Law on Official Controls which are carried out in accordance with the regulations on food, feed, animal health and welfare.

Official controls on health and hygiene / food safety are carried out:

a) at the level of primary production and related activities:

- of food of animal origin, veterinary inspection
- of food of plant origin, agricultural inspection

b) at the level of production and processing:

- of food of animal origin, veterinary inspection
- of food of non-animal origin, sanitary inspection
- of food containing ingredients of animal and non-animal origin, sanitary inspection, except in the case when the business with food of animal origin requires the approval of the facility or part of the facility, in which case the veterinary inspection is also competent

c) at the retail level, sanitary inspection, unless a special regulation issued by the Minister responsible for agriculture with the consent of the Minister responsible for health stipulating that official controls are carried out by the veterinary inspection

d) at the import:

- of food of animal origin, border veterinary inspection
- of food of non-animal origin, sanitary inspection at the border

- of food containing ingredients of animal and non-animal origin, border veterinary inspection according to a special regulation on food subject to mandatory veterinary inspection and sanitary inspection at the border.

Special rules for the organization of official controls on products of animal origin are laid down in Regulation (EC) No 1774/2002, which is applied together with Regulation (EC) No 882/2004. Regulation (EC) No 854/2004 shall apply only in respect of those activities and persons to which Regulation (EC) No 853/2004 applies.

4.3. Food analysis and health controls

Healthy food within the regulations is considered to be food acceptable for consumption and free of harmful substances in quantities that could acutely or chronically endanger human health. Criteria for food safety depend on the type of food and ingredients, and all risks posed by the environment with potential contaminants, use of agronomic measures, storage, production technology, storage before and after delivery to the customer and in the household.

In accordance with food regulations, it is not allowed to place on the market food that is unsafe, i.e., food that is harmful to health and / or unfit for human consumption.

Article 10 of the Food Act defines unhealthy food, i.e., food harmful to human health, as prescribed by Article 14 Regulation (EC) No 178/2002.

Food safety testing services in fish processing and production of fish products are carried out in authorized laboratories by accredited methods, which includes:

- Microbiological tests
- Mycotoxicological tests
- Rheological tests
- Testing of heavy metals
- Determination of pesticide residues
- Alkaloid testing
- GMO analysis
- Declaration check (nutritional value)
- Review of the declaration according to the legal regulations
- Validation of product shelf life

- Determination of additives, dyes, preservatives
- Allergen testing

Catalog of laboratory tests according to accreditation and flexible accreditation area HAA ISO / IEC 17025. (Example: Inspecto <https://www.inspecto.hr/en/laboratory/food-analysis/>)

FISH AND FISH PRODUCTS

TYPE OF ANALYSIS	METHOD
Declaration verification	according to the applicable legislation
Moisture	RU-403-01
Crude protein ¹	ISO 1871:2009
Crude fat	RU-412-01
Trace elements - Calcium (Ca)	RU-305-05 (ICP-MS)
Trace elements - Sodium (Na)	RU-305-05 (ICP-MS)
Trace elements - Potassium (K)	RU-305-05 (ICP-MS)
Trace elements - Magnesium (Mg)	RU-305-05 (ICP-MS)
Trace elements - Iron (Fe)	RU-305-05 (ICP-MS)
Trace elements - Manganese (Mn)	RU-305-05 (ICP-MS)
Trace elements - Zinc (Zn)	RU-305-05 (ICP-MS)
Trace elements - Copper (Cu)	RU-305-05 (ICP-MS)
Trace elements - Phosphorus (P)	HRN ISO 6491:2001
Determination of heavy metals Lead (Pb) ²	RU-305-05 (ICP-MS)

Determination of heavy metals Cadmium (Cd) ²	RU-305-05 (ICP-MS)
Determination of heavy metals Arsenic (As) ²	RU-305-05 (ICP-MS)
Determination of heavy metals - Mercury (Hg) ²	RU-305-05 (ICP-MS)
Determination of other heavy metals - Selenium (Se)	RU-305-05 (ICP-MS)
Determination of other heavy metals - Nickel (Ni)	RU-305-05 (ICP-MS)
Determination of other heavy metals - Chromium (Cr)	RU-305-05 (ICP-MS)
Determination of other heavy metals - Cobalt (Co)	RU-305-05 (ICP-MS)
Determination of other heavy metals - Tin (Sn) ²	RU-305-05 (ICP-MS)
Determination of sugar content ¹	RU-357-02 (HPLC-RID); RU-307-01(HPLC-RID)
Determination of nitrite content ¹	RU-308-01 (HPLC-DAD)
Determination of nitrate content ¹	RU-308-01 (HPLC-DAD)
Determination of anorganic arsenic ¹	RU-311-01 (ICP-MS/HPLC)
Aerobic mesophilic bacteria ¹	HRN ISO 4833-1:2013
Aerobic mesophilic bacteria ¹	HRN ISO 4833-2:2013
Yeasts and molds ¹	HRN ISO 21527-1:2012; HRN ISO 21527-2:2012
Salmonella spp. ¹	HRN ISO 6579-1:2017
Salmonella spp.	RU-191-01 (ELISA)
<i>Clostridium perfringens</i>	HRN EN ISO 7937:2005
Coagulase positive staphylococci ¹	HRN EN ISO 6888-2:2004
Sulfite-reducing clostridia ¹	HRN ISO 15213:2004

<i>Escherichia coli</i> ¹	HRN ISO 16649-2:2001
Detection of Enterobacteriaceae ¹	HRN EN ISO 21528-1:2017
Staining of Enterobacteriaceae ¹	HRN EN ISO 21528-2:2017
Detection of <i>Listeria monocytogenes</i> and other <i>Listeria</i> spp. ¹	HRN EN ISO 11290-1:2017
<i>Listeria monocytogenes</i> and other <i>Listeria</i> spp. counts ¹	HRN EN ISO 11290-2:2017
<i>Bacillus cereus</i> ¹	HRN EN ISO 7932:2005
<i>Enterococcus</i> spp. ¹	HRN EN 15788:2010
Coliform bacteria ¹	HRN ISO 4832:2008
Allergen - Gluten ¹	RU-326-01 (ELISA)
Allergen - Soy ¹	RU-325-01 (ELISA)
Allergen - Milk protein	RU-421-01 (ELISA)
Allergen - Hazelnuts	In-house method (ELISA)
Artificial colors - E102 (Tartazine)	RU-342-01 (HPLC-DAD)
Artificial colors - E104 (Quinoline Yellow)	RU-342-01 (HPLC-DAD)
Artificial colors - E110 (Sunset Yellow FCF/Orange Yellow S)	RU-342-01 (HPLC-DAD)
Artificial colors - E122 (Azorubine/Carmoisine)	RU-342-01 (HPLC-DAD)
Artificial colors - E123 (Amaranth)	RU-342-01 (HPLC-DAD)
Artificial colors - E124 (Ponceau 4R/ Cochineal Red A)	RU-342-01 (HPLC-DAD)
Artificial colors - E127 (Erythrosine)	RU-342-01 (HPLC-DAD)

Artificial colors - E129 (Allura Red AC)	RU-342-01 (HPLC-DAD)
Artificial colors - E132 (Indigotine)	RU-342-01 (HPLC-DAD)
Artificial colors - E133 (Brilliant Blue FCP)	RU-342-01 (HPLC-DAD)
Artificial colors - E142 (Brilliant Green BS)	RU-342-01 (HPLC-DAD)
Artificial colors - E151 (Brilliant Black BN)	RU-342-01 (HPLC-DAD)
Artificial colors - E143 (Fast Green FCF)	RU-342-01 (HPLC-DAD)
Artificial colors - E131 (Patent Blue V)	RU-342-01 (HPLC-DAD)
Natural colors - E100 (Curcumine)	RU-342-01 (HPLC-DAD)
Natural colors - E120 (Carmine)	RU-342-01 (HPLC-DAD)
Food sampling for microbiological testing ¹	HRN CEN ISO/TS 17728:2015
Histamine (one elementary unit) ¹	RU-355-02 (HPLC)
Histamine (nine elementary units) ¹	RU-355-02 (HPLC)
<i>Proteus</i> spp.	RU-422-01
<i>Listeria ivanovii</i>	HRN EN ISO 11290-1:2017

Remark:

¹ accredited method according to the requirements of the standard HRN EN ISO/IEC 17025

² flexible accreditation area

4.4. Sampling plan

Regulation (EC) No 178/2002/EC of the European Parliament and of the Council from 28th of 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 ensured

by the Food Act (OG 81/13, 14/14, 30/15, 115/18) is the basis for ensuring a high level of protection of human health and consumer interests related to food.

Pursuant to the Act on Official Controls carried out in accordance with regulations on food, animal feed, animal health and welfare (OG 81/13, 14/14, 56/15, 32/19), the Sampling Plan for Food of Animal Origin is adopted, in order to ensure the protection of the health of consumers and to check that food ready for placing on the market and food already placed on the market comply with the regulations on:

- microbiological criteria for food of animal origin
- food additives of animal origin, allergens in food of animal origin
- the maximum permitted amounts of certain contaminants in food
- food subjected to ionizing radiation
- GMO in food
- control of resistance of zoonotic and commensal bacteria to antimicrobial agents at the level of food production, processing and placing on the market

FROM THE PLAN OF SAMPLING FOOD OF ANIMAL ORIGIN

a) Official sampling plan for food of animal origin under the Regulations (EC) 2073/2005, 2074/2005, 2019/627 i 2019/624.

FOOD	SCREENING	SAMPLING	REMARK
CATEGORY	PARAMETER	PLACE	
Cooked crustaceans and molluscan shellfish Criterion	Salmonella spp.	Approved facilities – warehouses	Cooked crustaceans and molluscan shellfish Criterion
1.16 of the Regulation 2073/2005		of finished product ready for shipment	1.16 of the Regulation 2073/2005

<p>Processed fisheries products (Marinated, smoked or otherwise processed fisheries products</p>	<p><i>Listeria monocitogenes</i></p>	<p>Approved facilities</p>	<p>Ready-to-eat foods - processed fisheries products (marinated, smoked or otherwise processed fisheries products, fish salads, spreads, and other products able to support the growth of <i>Listeria monocitogenes</i>).</p>
<p>Shelled and shucked products of cooked crustaceans and molluscan shellfish</p>	<p><i>E. coli</i></p>	<p>Approved facilities</p>	<p>Shelled and shucked products of cooked crustaceans and molluscan shellfish</p>
<p>Fisheries products and fresh fish</p>	<p>Coagulase-positive staphylococci</p>	<p>Approved facilities</p>	<p>Shelled and shucked products of cooked crustaceans and molluscan shellfish</p>
	<p>Histamine (Pelagic fish)</p>	<p>Approved facilities – warehouses of finished product ready for shipment, Fish markets</p>	
	<p>TVB-N whitefish, frozen</p>	<p>Approved facilities – warehouses of finished product ready for shipment,</p>	<p>Categories of fish species according to the Regulation 2019/624 chilled, frozen,</p>

	fish or organoleptically altered fish	Fish markets	deep frozen or thawed, organoleptically altered
Fisheries products - shellfish	Salmonella spp.	Approved facilities – warehouses of finished product ready for shipment, and Approved facilities - fish markets	Live bivalve molluscs, echinoderms, tunicates and marine gastropods Criterion 1.17 Regulation 2073/2005
	Toxins (DSP, PSP, ASP)	Approved facilities – warehouses of finished product ready for shipment, fish markets	
	<i>E. coli</i>	Approved facilities – warehouses of finished product ready for shipment, fish markets	

Sample of live bivalve molluscs and live echinoderms, tunicates and marine gastropods food safety criterion for the E. coli parameter to be sampled in the approved establishment at the stage before the bivalve mollusc production batch leaves the direct control of the food business operator who produced it or in the retail trade.

b) Official sampling plan for food of animal origin pursuant to Regulation 1881/2006

FOOD CATEGORY	SCREENING PARAMETER	SAMPLING PLACE	REMARK
Freshly caught fish	Lead Cadmium Mercury	Approved facilities and fish markets	
Smoked fish and smoked fishery products	benzo(a)pyrene and sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene	Approved facilities and fish markets	Matrix: Muscle meat of smoked fish and smoked fish products, shellfish
Crustaceans, shellfish, cephalopods	Lead Cadmium Mercury	Approved facilities and fish markets	Matrix: Crustaceans: the flesh of muscle from appendages and abdomen. In case of crustaceans like <i>Brachyura</i> and <i>Anomura</i> , meat from pendant muscles, shellfish, cephalopods
Canned food of animal origin	Anorganic tin		Matrix: Durable cans with fishery or meat products packaged in cans

The selection of fishery products for sampling for the purpose of checking the amount of polycyclic aromatic hydrocarbons (PAH compounds) is based on the production process and only smoked products are sampled, traditionally smoked products deriving from small producers as well as traditionally smoked products produced by industrial producers.

c) Official sampling plan for controls of food additives of animal origin pursuant to Commission Regulation (EC) No 1333/2008 of the European Parliament and of the Council from 16th of December 2008. on food additives, with all amendments.

FOOD CATEGORY	SCREENING PARAMETER	SAMPLING PLACE
Frozen crustaceans and molluscan shellfish	Phosphates (E338-452)	Approved facilities and fish markets
Fresh or frozen shrimps, prawns, etc.	Sulfites (E220-228) Sulphur dioxide	Approved facilities and fish markets
Processed fishery products (surimi sticks and similar products)	Group III dyes - dyes with combined maximum permitted quantities	Approved facilities and fish markets
Fish roe	Group III dyes - dyes with combined maximum permitted quantities	Approved facilities and fish markets
Frozen fish fillet	Phosphates (E338-452)	Approved facilities and fish markets
Thawed or fresh tuna fillet	nitrites (E249-250) nitrates (E251-252)	Approved facilities and fish markets

d) Official sampling plan for food of animal origin for the control of food subjected to ionizing radiation and reporting on the results of controls pursuant to Article 7(3) of Directive 1999/2/EC from 22nd of February 1999. on the approximation of the laws of the Member States relating to food and food ingredients exposed to ionizing radiation

FOOD CATEGORY	SCREENING PARAMETER	SAMPLING PLACE
Frozen or thawed shrimps or prawns (not cleaned)	Total average absorbed dose of ionizing radiation	Approved facilities and fish markets
Frozen or thawed fishery products (fish and/or shellfish), not cleaned		Approved facilities and fish markets

Sampling of fish for the purpose of screening the total average absorbed dose of ionizing radiation - meat with bones, shellfish, fish, mechanically deboned meat for bone fragments, etc. (For crustaceans, shellfish and molluscs, claws and shells are important).

Sampling of caught Pectinidae, sea gastropods and holothuroids (Holothuroidea), other than filter feeders, originating from unclassified catch areas shall be carried out in fish auction halls, dispatch centers or processing facilities - compliance with the following shall be checked:

- *the health standards for live bivalve molluscs laid down in Section VII. Chapter V of Annex III. Regulation (EC) No 853/2004 (organoleptic properties, compliance with microbiological criteria and total amounts of biotoxins);*
- *special requirements for Pectinidae, sea gastropods and holothuroids (Holothuroidea), other than filter feeders, originating from unclassified production areas of Chapter IX. of that section.*

4.5. RASFF – Rapid Alert System for Food and Feed

RASFF - Rapid Alert System for Food and Feed is a necessary element of consumer protection and ensures effective monitoring of food and feed by the competent authorities and serves as a means of exchanging information on the measures taken, in order to respond as soon as possible to serious risks detected in food or feed.

This exchange of information helps Member States to respond more quickly and in a coordinated way to threats to human health caused by food or feed.

Basic regulations of the RASFF system:

1. 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
2. Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components (the IMSOC Regulation)
3. Food Act (OG No 81/13, 14/14, 30/15, 115/18)
4. Ordinance on the rapid alert system for food and feed (OG 155/13)

Other regulations of the RASFF system:

Regulations at EU level

1. Commission Regulation (EC) No 2073/2005 from 15th of November 2005. on microbiological criteria for foodstuffs
2. Commission Regulation (EC) No 1881/2006 from 19th of December 2006. setting maximum levels for certain contaminants in foodstuffs
3. Regulation (EC) No 396/2005 of the European Parliament and of the Council from 23rd of February 2005. on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC
4. Regulation No 1935/2004 of the European Parliament and of the Council from 27th of October 2004. on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
5. Commission Regulation (EU) No 10/2011 from 14th of January 2011. on plastic materials and articles intended to come into contact with food
6. 2017/752 from 28th of April 2017. amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food
7. Commission Regulation (EU) 2017/2158 from 20th of November 2017. establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food
8. Commission Implementing Regulation (EU) No 828/2014 from 30th of July 2014. on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food
9. Regulation (EC) No 1332/2008 of the European Parliament and of the Council from 16th of December 2008. on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97
10. Regulation (EC) No 1333/2008 of the European Parliament and of the Council from 16th of December 2008. on food additives

11. Regulation (EC) No 1334/2008 of the European Parliament and of the Council from 16th of December 2008. on flavorings and certain food ingredients with flavorings properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC

12. Commission Regulation (EC) No 669/2009 on 24th of July 2009. implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC

Regulations at national level – transposed:

1. The Food Hygiene and Microbiological Criteria for Food Act (OG 81/13, 115/18)
2. Contaminants Act (OG 39/13, 114/18)
3. Act on the implementation of Regulation (EC) No 396/2005 on maximum levels of pesticide residues in and on food and feed of plant and animal origin (OG 80/13, 115/18, 32/20)
4. Act on materials and articles in direct contact with food (OG 25/13, 41/14, 114/18)
5. Act on food additives, flavorings and food enzymes (OG 39/13, 114/18)
6. The Law on Consumer Information on Food (OG 56/13, 14/14, 56/16, 32/19)
7. Act on official controls carried out in accordance with regulations on food, animal feed, animal health and welfare (OG 81/13, 14/14, 56/15, 32/19)

4.6. Requirements for fishing vessels fishing for fish and other marine organisms

The following requirements are set out in Annex II to Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down certain **hygiene rules for food of animal origin** and apply to **all vessels used for fishing**.

LEGAL REQUIREMENTS

BEST / GOOD PRACTICE RECOMMENDED

CHAPTER I: REQUIREMENTS FOR VESSELS

I. STRUCTURAL AND EQUIPMENT REQUIREMENTS

A Requirements for all vessels

1. Vessels must be designed and constructed so as not to cause contamination of the products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances.

Premises where fishery products are located must be separated from the boiler room and sanitary facilities. Adequate and sufficient natural or artificial air exchange must be ensured. Artificially induced airflow from a contaminated area to a clean area must be avoided. The air exchange system must be designed in such a way that the filters and other parts that must be cleaned or replaced are easily accessible.

Wastewater drainage systems must be suitable for the purpose for which they are intended.

They must be designed and constructed in such a way as to avoid the risk of contamination.

If the drainage channels are fully or partially open, they must be designed in such a way as to ensure that water does not flow from the contaminated area towards the clean area or into a clean area, especially into the area where food is handled.

2. Surfaces with which fishery products come into contact must be of suitable corrosion-resistant material that is smooth and easy to clean.

Surface coatings must be durable and non-toxic.

3. Equipment and material used for working on fishery products must be made of corrosion-resistant material that is easy to clean and disinfect.

4. When vessels have a water intake for water used with fishery products, it must be situated in a position that avoids contamination of the water supply.

B Requirements for vessels designed and equipped to preserve fresh fishery products for more than twenty-four hours

1. Vessels designed and equipped to preserve fishery products for more than

The materials or coatings from which the tanks, equipment and surfaces that come into contact with the fish are made should be waterproof, resistant to abrasion and deterioration, smooth and resistant to chemicals. They should be shaped in such a way as to prevent the accumulation of dirt and facilitate drainage.

Painted surfaces must not be in such a state that the paint peels or peels and poses a risk of contamination.

The materials or coatings from which the tanks, equipment and surfaces that come into contact with the fish are made should be waterproof, smooth, resistant to wear and decay, and resistant to chemicals. They should be shaped in such a way as to prevent the accumulation of dirt and facilitate drainage.

Painted surfaces must not be in such a state that the paint peels or peels and poses a risk of contamination.

Refrigerated storage facilities for fishery products should be equipped with a

twenty-four hours must be equipped with holds, tanks or containers for the storage of fishery products at the temperatures laid down in Annex III, Section VIII, Chapter VII of Regulation (EC) No 853/2004: “Fresh fishery products, thawed unprocessed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at a temperature approaching that of melting ice.”

2. Holds must be separated from the engine compartments and from the crew quarters by partitions which are sufficient to prevent any contamination of the stored fishery products. Holds and containers used for the storage of fishery products must ensure their preservation under satisfactory conditions of hygiene and, where necessary, ensure that melt water does not remain in contact with the products.

3. In vessels equipped for chilling fishery products in cooled clean seawater, tanks must incorporate devices for achieving a uniform temperature throughout the tanks. Such devices must achieve a chilling rate that ensures that the mix of fish and clean seawater reaches not more than 3oC 6 hours after loading and not more than 0oC after 16 hours and allow the monitoring and, where necessary, recording of temperatures.

II. HYGIENE REQUIREMENTS

temperature data recording device, which is connected to a computer in the wheelhouse for continuous monitoring. Such premises should be adequately insulated to prevent fish from heating up and heat from entering the engine room, the surrounding air and sea, or from the cabins.

When constructing a vessel, it is important to use marine-resistant stainless steel, aluminum or food-safe plastic when making holds and equipment that will be in contact with fishery products. The tanks must have a sufficient number of drainage openings and the water flushing hoses must be of sufficient length to be able to reach all the areas to be cleaned and must have sufficient jet pressure for effective flushing.

1. When in use, the parts of vessels or containers set aside for the storage of fishery products must be kept clean and maintained in good repair and condition. In particular, they must not be contaminated by fuel or bilge water.

2. As soon as possible after they are taken on board, fishery products must be protected from contamination and from the effects of the sun or any other source of heat. When they are washed, the water used must be either potable water or, where appropriate, clean water.

3. Fishery products must be handled and stored so as to prevent bruising. Handlers may use spiked instruments to move large fish or fish which might injure them, provided that the flesh of the products suffers no damage.

Stale or contaminated ice should be discarded immediately and the holds cleaned. Cleaning should be carried out in the prescribed order in which the required chemicals and the manner of their use are listed. Before departure, the responsible person should inspect the condition of all premises where fish are handled.

The catch should be placed in storage as soon as possible, and if this is not possible, the deck must have a roof or awning. Tanks containing fish can be covered with thermal insulation covers.

If trawl netting takes a long time, the fish is crushed in the mesh codend, the tissue is damaged, the spine cracks and bleeds, which leads to inferior quality of fish. While the mesh codend is in the sea, the content is seemingly lighter due to buoyancy, but when the net is taken out on deck, the true weight of the catch is shown. Therefore, the mesh codend should be emptied as soon as possible and crustaceans and other echinoderms should be picked up immediately so that they do not sting the catch. Throwing or crushing should be avoided when handling fish, and equipment should be shaped so as not to damage the fish. If the fish are slid down the chute, it must be of a small enough slope so that the fish are not physically damaged. Sorting and

4. Fishery products other than those kept alive must undergo chilling as soon as possible after loading. However, when chilling is not possible, fishery products must be landed as soon as possible.
5. Ice used to chill fishery products must be made from potable water or clean water.
6. Where fish are headed and/or gutted on board, such operations must be carried out hygienically as soon as possible after capture, and the products must be washed
- storage of catches should be done as soon as possible after the fish are pulled onto the deck.
- The refrigerator compartment should be chilled to 0 °C to + 4 °C before the fish is caught, which means that cooling should be turned on beforehand. If the temperature is too low, the catch may freeze. If there are no appliances for refrigerating, it is necessary to provide a sufficient amount of ice for the duration of the entire voyage. In case the vessel does not have special storage facilities, containers and covers with thermal insulation should be used.
- Ice must be kept in a clean container, covered with a clean cover such as foil or plastic. Under no circumstances should the possibility of ice contamination with bird droppings, chemicals on deck or glass be allowed. Larger ships can be fitted with ice-makers, in which case they should be cleaned regularly. Ice containers and shovels for distributing ice must be clean and disinfected. Ice can also be made from seawater, however ice made from drinking water is recommended, as the temperature of ice from seawater can be as low as -6 °C, which can lead to partial freezing of the fish.
- Rinsing must be done under running water long enough to be done thoroughly. The crew must have clean hands, gloves and clothing, and smoking is strictly prohibited. It

immediately and thoroughly with potable water or clean water. In that event, the viscera and parts that may constitute a danger to public health must be removed as soon as possible and kept apart from products intended for human consumption. Livers and roes intended for human consumption must be preserved under ice, at a temperature approaching that of melting ice, or be frozen.

would be best to do the evisceration and bleeding within one hour after the catch. When opening the abdominal cavity, only one incision should be made, taking care not to damage the meat / fillet. Knives must be extremely sharp and rinsed regularly during use.

CHAPTER II: REQUIREMENTS DURING AND AFTER LANDING

1. Food business operators responsible for the unloading and landing of fishery products must: (a) ensure that unloading and landing equipment that comes into contact with fishery products is constructed of material that is easy to clean and disinfect and maintained in a good state of repair and cleanliness; and (b) avoid contamination of fishery products during unloading and landing, in particular by:

Under no circumstances should the catch be allowed to be left unattended for long periods of time. Any delay in landing and loading can lead to heating and spoilage of fishery products.

(i) carrying out unloading and landing operations rapidly;

(ii) placing fishery products without delay in a protected environment at the temperature specified in Annex III, Section VIII, Chapter VII of Regulation (EC) No 853/2004;

and (iii) not using equipment and practices that cause unnecessary damage to the edible parts of the fishery products.

The materials from which the fish transfer pumps are made are waterproof, wear-resistant, smooth, corrosion-resistant, easy to clean and the devices are designed in such a way as to prevent the accumulation of dirt and facilitate drainage.

LIST OF REGULAR CHECKS

Adherence to the standards of sustainable management and environmental protection requires regular analysis in authorized accredited institutions using accredited methods.

Farms

Based on the environmental impact study, the Ministry of Environment and Energy prescribed environmental monitoring at each location. Measurements are performed at the time of maximum sea water and sediment load, at several positions on the farm at least once a year.

Biological parameters for the usual inspection:

1. on the seabed: biological-diving inspection of vegetation and animal communities and the condition of seagrass beds
2. in the seawater column: transparency, dissolved oxygen, chlorophyll-a
3. in the seabed sediment: redox potential, organic carbon, total nitrogen, total phosphorus

Fresh fish

1. Sampling on farms is performed twice a year at each location:
2. microbiological quality
3. chemical analysis (heavy metals, polycyclic aromatic hydrocarbons, heavy metals, polychlorinated biphenyls)
4. antibiotic residues
5. parasite detection
6. nutritional values of fish meat (especially the content of fat, the ratio of omega 3 and 6 fatty acids is monitored)

Finished products - Fresh fish and derived products

Product health:

1. four times a year for each product category
2. microbiological testing according to EU and Croatian legislation

Smoked fish

Product health - twice a month

Smoked, marinated fish

1. chemical analysis (heavy metals, polycyclic aromatic hydrocarbons, polychlorinated biphenyls) - once a year
2. nutritional value of fish meat - once a year

According to the HACCP plan, and in order to ensure product quality and care for food safety, special attention is paid to hygienic conditions in the production process and the workers themselves - on each line (for certain product categories) swabs (surfaces, equipment, people) are taken by authorized institutions: microbiological quality.

Shellfish

1. health (microbiological examination) - four times a year
2. chemical testing - nutritional values, analysis of heavy metals

According to the Plan for monitoring the sea and shellfish quality, at least twice a month (depending on the period of the year), the authorized institutions monitor the phytoplankton composition of sea water.

Shellfish meat

1. benzo(a)pyrene - twice a year
2. heavy metals - twice a year
3. *Escherichia coli* - once a month
4. biotoxins - once a week

5. Traceability and withdrawal of food products

It is important to know all the regulations related to the activity, and especially the following:

-Regulation (EU) 1169/2011 on the provision of food information to consumers.

-Regulation (EU) 1379/2013 on the common organization of the markets in fishery and aquaculture products

-Regulation (EC) No 2065/2001 laying down detailed rules for the application of Council Regulation (EC) No 104/2000 as regards informing consumers about fishery and aquaculture products, with all amendments.

Key legal requirements are:

- Ensure proper product labeling with all necessary information.
- Ensure that all raw materials, ingredients and materials used in production or incorporated into the product can be monitored and linked to their primary source through all stages of the food chain (catches / farming, processing and distribution).
- Ensure that all products are properly labeled and the declarations contain the appropriate information.
- Ensure the rapid retrieval and withdrawal of raw materials and products suspected of not being safe from the distribution chain.
- Ensure that in cases of product withdrawal the competent authority and the public are informed.

Food business operators have the primary responsibility for food production and processing. They should ensure that procedures are in place to effectively withdraw a product or food from the market when it poses a serious risk to consumer health. When a foodstuff is found to pose a serious risk, it shall be immediately withdrawn from the market and notified to the competent authority. The Regulation also requires food business operators to ensure adequate traceability of food or food ingredients.

Products imported into the EU must comply with EU hygiene standards. Products exported from the EU must comply with the requirements applicable within the EU (in case they are placed on the EU market), as well as with all the requirements of the importing country.

Article 46 of the Marine Fisheries Act stipulates that all fishery products must be traceable from catching or harvesting, landing, transport and storage, processing and distribution to retail stage, and must have a mark identifying the batch or lot in all stages of traceability.

Proper declaration is of great importance, as it is the basic element by which the product is identified and thus forms the key to the implementation of traceability. It is important to ensure that data on the origin of raw materials and processing conditions can be linked to a specific product, so that product data is transmitted through all stages of production, processing and distribution (“from farm to fork”) allowing rapid removal of potentially harmful products from the distribution chain.

5.1. Maximum amounts of residues in food

The European Union has strict and complex legislation on maximum residue levels (MRLs) for fish and seafood. These levels are recorded in various regulatory documents. Depending on the species and source (fishery or aquaculture), it is necessary to prove for each consignment that the products placed on the market do not exceed the MRL. The same is proven based on analyzes from authorized laboratories.

It is necessary to have established systems in processing plants, but also in the internal supply chain. Raw materials entering the plant must not be previously contaminated. Therefore, supplier control is also required.

Regulations relating to the export of fish or seafood to the EU:

- Regulation (EZ) No Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council
- Regulation (EC) No 37/2010 from 22nd of December 2009. on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin

- Regulation (EZ) No 396/2005 of the European Parliament and of the Council from 23rd of February 2005. on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC
- Commission Regulation (EC) No 1881/2006 from 19th of December 2006. setting maximum levels for certain contaminants in foodstuffs

Some other substances classified as “food additives” in the European Union (cocciostats and histomonostats drugs) can also be found as residues in food obtained from animals farmed on feed containing them. Reference point - EU Register of Feed Additives.

5.2. Official process and production controls - legal frameworks

List of possible contaminants and regulations:

Contaminants Act (OG 39/13, 114/18 in force from 01/04/2019) which determines the competent authorities, tasks of the competent authorities, official controls and procedures and reporting to the competent authorities and the European Commission as well as obligations of official laboratories and food business operators, for implementation:

- Council Regulation (EEC) No 315/93 from 8th of February 1993. laying down Community procedures for contaminants in food 2. 13.2.1993, pp. 1-3), with all amendments
- Commission Regulation (EC) No 1881/2006 from 19th of December 2006. setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20. 12. 2006), with all amendments
- Commission Regulation (EC) No 401/2006 from 23rd of February 2006. laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs (OJ L 70, 9. 3. 2006), with all amendments
- Commission Regulation (EC) No 252/2012 from 21st of March 2012. laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006 (OJ L 84, 23. 3. 2012), with all amendments

- Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs (OJ L 88, 29. 3. 2007), with all amendments
- Commission Regulation (EC) No 1882/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs (OJ L 364, 20. 12. 2006), with all amendments

Article 4, paragraph 2 of this Act prescribes that the State Inspectorate adopts and implements inspection plans, i.e., official controls based on risk assessment, which must include monitoring plans pursuant to Article 9 of the Regulation (EC) No 1881/2006, taking into account the guidelines of the Ministry

In addition to the obligations prescribed by the Article 1 of the Regulation (EC) No 1881/2006, a food business operator that imports, processes, produces food or carries out the activity of wholesale food services is obliged to carry out internal controls of operations according to the risk assessment, including the development of a sampling plan for contaminants prescribed by Regulation (EC) No 1881/2006, in accordance with the scope and type of its business, which is prescribed by the Article 5, paragraph 3 of the same Act

Commission Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs(<https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:32006R1881&from=HR>) prescribes the maximum permitted levels of contaminants, with the values shown relating to fish and marine organisms. Key contaminants related to sardines, shrimp and shellfish products are listed below:

5.3. Section 3: Metals

Foodstuffs		Maximum levels (mg/kg wet weight)
3.1.		Lead
3.1.5	Muscle meat of fish	0.30
3.1.6	Crustaceans, excluding brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (Nephropidae and Palinuridae)	0.50
3.1.7	Bivalve molluscs	1.5
3.1.8	Cephalopods (without viscera)	1.0
3.2.		Cadmium
3.2.5	Muscle meat of fish, excluding species listed in 3.2.6 and 3.2.7	0.050
3.2.6	Muscle meat of the following fish: anchovy (<i>Engraulis</i> sp.) bonito (<i>Sarda sarda</i>) common two-banded seabream (<i>Diplodus vulgaris</i>) eel (<i>Anguilla anguilla</i>) grey mullet (<i>Mugil labrosus labrosus</i>)	0.10

	<p>horse mackerel or scad (<i>Trachurus</i> sp.)</p> <p>louvar or luvar (<i>Luvarus imperialis</i>)</p> <p>sardine (<i>Sardina pilchardus</i>)</p> <p>sardinops (<i>Sardinops</i> sp.)</p> <p>tuna (<i>Thunnus</i> sp., <i>Euthynnus</i> sp., <i>Katsuwonus pelamis</i>)</p> <p>wedge sole (<i>Dicologlossa cuneata</i>)</p>	
3.2.7	Muscle meat of swordfish (<i>Xiphias gladius</i>)	0.30
3.2.8	Crustaceans, excluding brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (Nephropidae and Palinuridae)	0.50
3.2.9	Bivalve molluscs	1.0
3.2.10	Cephalopods (without viscera)	1.0
3.3.		Mercury
3.3.1	Fishery products and muscle meat of fish, excluding species listed in 3.3.2. The maximum level applies to crustaceans, excluding the brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (Nephropidae i Palinuridae).	0.50
3.3.2	<p>Muscle meat of the following fish:</p> <p>monkfish (<i>Lophius</i> sp.)</p> <p>atlantic catfish (<i>Anarhichas lupus</i>)</p>	1.0

<p>bonito (<i>Sarda sarda</i>)</p> <p>eel (<i>Anguilla species</i>)</p> <p>emperor, orange roughy, rosy soldierfish (<i>Hoplostethus species</i>)</p> <p>grenadier (<i>Coryphaenoides rupestris</i>)</p> <p>halibut (<i>Hippoglossus hippoglossus</i>)</p> <p>marlin (<i>Makaira sp.</i>)</p> <p>megrin (<i>Lepidorhombus sp.</i>)</p> <p>mullet (<i>Mullus sp.</i>)</p> <p>pike (<i>Esox lucius</i>)</p> <p>plain bonito (<i>Orcynopsis unicolor</i>)</p> <p>poor cod (<i>Tricopterus minutes</i>)</p> <p>portuguese dogfish (<i>Centroscymnus coelolepis</i>)</p> <p>rays (<i>Raja species</i>)</p> <p>redfish (<i>Sebastes marinus, S. mentella, S. viviparus</i>)</p> <p>sail fish (<i>Istiophorus platypterus</i>)</p> <p>scabbard fish (<i>Lepidopus caudatus, Aphanopus carbo</i>)</p> <p>seabream, pandora (<i>Pagellus sp.</i>)</p> <p>shark (sve vrste)</p> <p>snake mackerel or butterfish (<i>Lepidocybium flavobrunneum, Ruvettus pretiosus, Gempylus serpens</i>)</p> <p>sturgeon (<i>Acipenser species</i>)</p> <p>swordfish (<i>Xiphias gladius</i>)</p>	
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	tuna (<i>Thunnus</i> sp., <i>Euthynnus</i> sp., <i>Katsuwonus pelamis</i>)	
3.4.		Tin (inorganic)
3.4.1	Canned foods other than beverages	200

5.4. Section 5: Dioxins and PCBs

Foodstuffs		Maximum levels	
		Sum of dioxins (WHO-PCDD/F-TEQ)	Sum of dioxins and dioxin-like PCBs (WHO-PCDD/F-PCB-TEQ)
5.3.	Muscle meat of fish and fishery products and products thereof, excluding eel. The maximum level applies to crustaceans, excluding the brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (Nephropidae and Palinuridae)	4.0 pg/g wet weight	8.0 pg/g wet weight
5.10.	Marine oils (fish body oil, fish liver oil and oils of other marine organisms intended for human consumption)	2.0 pg/g fat	10.0 pg/g fat

5.5. Section 6: Polycyclic aromatic hydrocarbons

Foodstuffs		Maximum levels (µg/kg wet weight)
6.1.		Benzo(a)pyrene
6.1.3	Muscle meat of smoked fish and smoked fishery products, excluding bivalve molluscs. The maximum level applies to smoked crustaceans, excluding the brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (Nephropidae i Palinuridae).	5.0
6.1.4	Muscle meat of fish, other than smoked fish	2.0
6.1.5	Crustaceans, cephalopods, other than smoked The maximum level applies to crustaceans, excluding the brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (Nephropidae i Palinuridae).	5.0
6.1.6	Bivalve molluscs	10.0

Remark: See the regulation for more details

5.6. Legislation at European Union level

Regulations on maximum levels for contaminants:

The maximum levels for contaminants at the European Union level are harmonized and apply to the edible parts of foodstuffs placed on the Community market, as well as to food imported into the Community. This area is regulated by:

Commission Regulation (EC) No 1881/2006 from 19th of December 2006. setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20. 12. 2006), with all amendments

<http://eur-lex.europa.eu/legalcontent/EN/TXT/?qid=1508499429988&uri=CELEX:02006R1881-20170728>

- Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 37, 13. 2. 1993)

<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1508500508784&uri=CELEX:01993R0315-20090807>

Regulations on sampling of individual contaminants and methods of their determination:

Depending on the type of contaminants to be sampled, as well as the methods of their analysis, the following regulations are applied at EU level:

Commission Regulation (EC) No 401/2006 from 23rd of February 2006. laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs (OJ L 70, 9. 3. 2006), with all amendments <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1508499638254&uri=CELEX:02006R0401-20140701>

Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the control of the levels of trace elements and processing contaminants in foodstuffs (OJ L 88, 29. 3. 2007), with all amendments <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1508499701523&uri=CELEX:02007R0333-20160506>

Commission Regulation (EC) No 1882/2006 from 19th of December 2006. laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs (OJ L

364, 20. 12. 2006.) <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1508499815646&uri=CELEX:32006R1882>

Commission Regulation (EU) 2017/644 of 5 April 2017 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 589/2014. <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1508499901388&uri=CELEX:32017R0644>

Recommendations for contaminants whose levels are not prescribed at the community level through the maximum permitted levels:

There are a number of contaminants that do not have the maximum prescribed levels, but which can pose a health risk at elevated concentrations. Sometimes there is insufficient incidence data for these contaminants, no analytical methods developed or no data on whether it is possible to reduce their levels with good manufacturing practice, and sometimes they are included in the monitoring recommendations for a number of reasons: http://ec.europa.eu/food/food/chemicalsafety/contaminants/index_en.htm

Although EU regulations are already quite elaborated, not all types of residues are included or clearly set up for monitoring. Every now and then, regulations change as European authorities begin to monitor certain residues more closely. That part of the responsibility, in case of suspicion of residues, rests with the competent authorities of each Member State.

Chlorate levels in imported fish and seafood were one of the residues in the spotlight in 2019., and a tightening of the MRL is expected soon. Processing facilities with no access to clean water use chlorate to purify water before it is used in processing plants. Increased levels of chlorate in imported products may raise concerns in some Member States, such as Germany, which are debating what levels of chlorate should be allowed. For example, this debate could result in a change of acceptable levels of chlorate in food exported to the EU. Chlorate-based pesticides are already banned. These types of changes can have a major impact on business, so it is crucial to have information before regulations change. As the fish and seafood industry becomes more significant, competent authorities are becoming more aware of the problems affecting imported fish and seafood trade, such as the levels of certain substances found in products as labeling for these substances. European regulations are likely to become stricter in the future. Chlorate is just one example; another example is the use of antibiotics in farmed fish, where regulations change on a regular basis.

6. Guidelines for health control during the product life cycle - critical points

For each production segment, it is necessary to develop a HACCP plan for the processes from catching, through processing to placing the finished product on the market. It is necessary to identify all the production steps, corrective actions and checks in order for the company to achieve maximum results in creating a healthy product. This is where most of the controls are taken, but they also need to be implemented in sales chains.

For sardines, the primary point after catching is taking a catch on board, followed by proper ice chilling on board. The introduction of pumps in fishing is a big step towards preserving and standardizing the quality of fish in the initial step of taking fish from the sea. Squeezing and crushing of fish was avoided, and manipulation was accelerated without mechanical damage to the fish. As already mentioned, the second step or critical point is ice chilling of fish and maintaining the temperature in the thermal insulation tanks during transport. This is followed by commissioning, where the fish must be processed quickly in terms of cleaning, filleting or freezing. Each processing process has to be very fast and done at the lowest possible temperatures.

For shrimp, it is very important to carry out fast ice chilling on board and transport with as few heat-cold shocks as possible. Processing in the plant, i.e., descaling, is a very fast process due to the exceptional machine capacities and the amount of catch. However, it is necessary to process the semi-finished product very quickly and freeze it.

Catch of shellfish as a very sensitive food due to the need for immediate manipulation significantly differs from the application of the cold chain category because it starts with commissioning. An attempt to implement a cold chain on ships (critical point) is underway and experiments are being conducted to determine quality differences by seasonal periods.

6.1. Regulations for the placing on the market of the Republic of Croatia of food with health claims

The basic legislation dealing with this area includes

Act on nutrition and health claims and food fortified with nutrients (OG 39/13, 114/18 in force since April 1st, 2019.

- “Health claim” means any claim that states, suggests or leads to the conclusion that a category of food, a particular food or a food ingredient affects human health.
- The food business operator must ensure at all stages of food production, processing and distribution that the food complies with food regulations and is responsible for the labeling of packaged food.
- The conditions for labeling, advertising and presentation of food with nutrition or health claims are prescribed in the Ordinance on nutrition and health claims and apply to all forms of commercial communication.
- Article 10 of the Act states:

(2) Food business operators that for the first-time places food supplements, food fortified with vitamins, minerals and other substances, and food with nutritional and health claims on the market of the Republic of Croatia shall act in accordance with the implementing regulation referred to in Article 6 paragraph 1 subparagraph 3 of this Act.

(5) Food business operator claims referring to the recommendations of national associations of doctors, nutritionists, as well as other health-related associations referred to in Article 11 of Regulation (EC) No 1924/2006, may be used only with the approval referred to in Article 7, paragraph 4 of this Act.

- References to general, non-specific health-related benefits from nutrients or products, as well as the use of general non-specific claims (e.g., for bone health) are only allowed if accompanied by a specific approved health claim, however there must be a link between general and specific approved claims.
- The health claim must always be made for the nutrient, food or category of food for which it is approved and not for the product containing it.
- The following information must be provided when stating a health claim:
 - Nutritional value in accordance with Article 7.
 - In accordance with Article 10 paragraph 3

- a) a statement pointing out the importance of a balanced and varied diet and a healthy lifestyle
 - b) the amount of food and the manner of its consumption that are necessary to obtain the beneficial effect that that food is claimed to have
 - c) where applicable, a statement concerning persons who should avoid that food
 - d) an appropriate warning for products that are likely to pose a health hazard in the event of excessive consumption
- If a claim for disease risk reduction is made (Article 14) when labeling, advertising and presenting food, a statement must be made stating that the disease to which the claim relates has multiple risk factors and that changing one of these risk factors may or may not have a beneficial effect.

6.2. Submission of notification concerning the placing on the market

For the purpose of effective monitoring of foods bearing health claims that comply with Annex II. Of the Ordinance on nutrition and health claims, a food business operator must inform the Ministry thereof when placing such food on the market of the Republic of Croatia for the first time.

Notice of placing food with a health claim on the market of the Republic of Croatia is submitted to the e-mail: dodaci.prehrani@miz.hr and should have attached:

- a) completed FORM-ZT-1
- b) text labeling the product in the Croatian language
- c) conceptual design of packaging
- d) a copy of the payment slip for covering monitoring costs

7. Special requirements regarding labeling, traceability and all other labeling categories - for unprocessed and for packaged processed products

It is very important for the final consumer who uses food for immediate consumption that the food is safe for human consumption and that it is properly labeled. The aim of proper food labeling is to enable the consumer to obtain accurate and complete information about the product, in particular about its composition, manner of use and shelf life, and about the manufacturer and / or the seller. This makes it easier for the consumer to make the right decision regarding buying the desired product.

It is the obligation of each FBO in the food business to ensure that these products meet the prescribed requirements at all stages of production, processing and distribution within the business it manages, i.e., to check whether the production, processing and distribution requirements are complied with.

Packaged food placed on the market of the Republic of Croatia must be labeled with data and in the manner prescribed by the provisions of the Act on the provision of food information to consumers (OG No 56/13, 14/14, 56/16, 32/19), Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers (hereinafter: Regulation) with all subsequent amendments, the Ordinance on the nutrition declaration of food, the Ordinance on labels or marks determining the batch or lot to which the food belongs (OG 26/13), and in the case of non-prepacked food, the Ordinance on informing consumers about non-prepacked food (OG No 144/14, 64/20), Instructions on the manner of application of the exemption from stating the nutritional declaration on food (OG No 79/2017).

As of 13rd of December 2016., food placed on the market of the Republic of Croatia, for which it is obligatory to state the nutritional declaration or data on the nutritional value of food, must be labeled as prescribed by the provisions of Regulation (EU) No 1169/2011 on the provision of food information to consumers with all subsequent amendments on how and with what data each prepacked and non-prepacked food that is placed on the market must be labeled.

The above-mentioned regulations, as well as other regulations prescribing additional mandatory information related to certain foods, shall apply to informing consumers about pre-packaged and non-prepacked foods.

In addition to the prescribed mandatory food information, food business operators may label food with additional and voluntary food information, but even then, it must be in accordance with prescribed fair information practices, and information provided on a voluntary basis must not be ambiguous and confusing to the consumer.

7.1. Declaration / labeling of fishery products

Declaration or labeling of fishery products is carried out from the very beginning of the catch or the phase of primary production (filling and labeling of packaging units, etc.) through the production process (labeling of semi-finished products: declaration of finished products: smaller and larger packaging units), and represents a series of marks, trade names, trademark, brand name (product name), product characteristics, storage conditions, pictorial representations or symbols related to the fishery product itself.

Proper declaration is a key part of traceability that allows product information to be easily and clearly transferred to the next link in the supply chain.

The declaration or labeling of fishery products as part of internal traceability should include information on origin / supplier, time of catch, method and date of processing and storage, method and staff who handled it. All these data on the supplier, method, time and area of catch, and qualitative characteristics of the received product must be recorded during receipt and included in the unique number to identify each received batch / lot (it entails fishery products from a particular species that have undergone the same procedure and may originate from the same fishing area and from the same vessel). The proof is the implementation of a sea fishing logbook and the category of first buyers.

The declaration informing consumers of fishery products in packaged products should contain the name of the food, a list of ingredients, a list of all ingredients or excipients that cause allergies or intolerances, which were used in the production or preparation of food and are present in the finished product, even in a modified form, quantity of certain ingredients or categories of

ingredients, net quantity of food, shelf life, special storage conditions and / or conditions of use, company name and address of the food business operator responsible for food or country of origin information or data. Instructions for use are also needed if simple food use is not possible without additional instructions as well as the nutritional value of the food.

Product information, which consumers receive through declarations, must be sufficient to ensure the traceability of the product to the supplier, i.e., it must be such that it contains the name of the supplier and a unique identification number of the production batch (batch, lot).

European labeling regulations are very clear. However, there may be slight differences between labeling of unprocessed and processed fish and other seafood and labeling of wild and farmed fish and other marine organisms. In general, all products should be labeled. Pre-packaged products must have additional information that is not required for non-prepacked products.

All products must have declared:

- Product name, including commercial and scientific names;
- List of ingredients (including all relevant E-numbers, i.e., identification numbers given to substances for which the EU allows addition to food);
- Method of production - it must be mentioned whether it is a farmed product or a wild catch;
- Origin - stating the country in which they were produced;
- Net weight - net weight must be stated on prepacked products;
- The date of minimum durability, consisting of the day, month and year, in that order and preceded by the words “best before” or “best before the end” or “use by” date;
- Seller in the EU - name or company name and address of the manufacturer, packaging plant or seller based in the EU;
- The packaging must contain the EU approval number;
- The packaging must also contain a “batch number”, which is the number given to products belonging to the same batch by the same exporter;
- Nutritional values - ingredients and nutritional value must be stated.

Additional information for prepacked products:

- List of ingredients (including all relevant E-numbers) to be added to the consumer packaging label;
- Quantity of ingredients (as % of total net weight);
- Net weight;
- Company name and address;
- Country of origin or place of provenance;
- Instructions for use (only if necessary);
- Nutrition statement;
- Packed in a protective atmosphere;
- The date of the first freeze (which is considered to be the actual date of freezing, must be agreed with the customer. Some customers prefer the first date of freezing of raw materials; e.g., when fish are caught and frozen on board, even if not yet in the final form. Other customers may want the freezing date to be the first time the product is frozen in its final form; e.g., fish fillets, not whole fish frozen on board);
- Added proteins of various origins;
- If the product is processed, such as surimi or fish balls, this information should be provided (e.g, a preparation of...);
- Identification mark;
- Added water must be included as an ingredient

Added water has recently been a topic of discussion among importers and European authorities. Although it is clear that water should be mentioned on the packaging, it is not always clear how the water content should be measured and how it should be labeled. Also, there are differences in interpretation between Member States.

Water should always be mentioned in the list of ingredients in the order of its share in the total weight of the product compared to the other ingredients. E.g., if 7% water is added, the label should contain 93% fish, 7% water, and then the other ingredients, if any.

In the case of processed fish, if less than 5% water is added, the order in which water is mentioned in the list of ingredients is not important. However, if more than 5% water is added, water must not only be mentioned in the correct order in the list of ingredients, but must be explicitly mentioned in the name of the product to be read e.g., “Norway lobster with added water”.

In some countries, if more than 12% of water is added to crustaceans, the seller may no longer call the product crustaceans. Instead, a product with more than this amount of added water should be labeled as a “preparation of” crustaceans (Germany).

All these interpretations of individual Member States may or may not be acceptable to other Member States. However, they significantly affect everything related to, for example, customs and the tax rate. The most important thing is that the consumer is not misled when it comes to price manipulation and that the end result is a healthy and safe product.

8. Implementation of traceability - origin

According to Regulation (EC) No 178/2002 “traceability” means the possibility of tracing food, feed, food-producing animals or substances intended for incorporation or expected to be incorporated into food or feed, through all stages of production, processing and distribution. This means that business entities must have information about the step before and the step after, that is, about the person who supplied them and the person to whom they delivered their products.

The traceability system can serve different purposes, and the one who applies it can have different benefits:

- ensured rapid product recall or recall and prompt consumer protection
- reduction of the impact of product withdrawal on the market supply of a given product (withdrawal of only a certain batch)
- strengthening consumer confidence, through the industry’s ability to immediately identify and recall potentially defective products
- providing internal logistical support regarding information quality and improving efficiency
- establishing feedback and its impact on improving product quality, conditions and delivery
- ensuring transparency in the distribution of routes and improving the efficiency of supply chains and cooperation between food trade partners
- providing reliable information:

- company to company
- companies to end consumers
- companies to state inspection bodies
- companies to financial or technical auditors
- determining responsibilities and obligations for a particular problem
- providing protection to the company and / or product brand.

In accordance with the principle of consumer protection, consumers must be fully and accurately and clearly and unambiguously informed about the food placed on the market and offered to them in order to enable them to choose the food they will buy and consume.

Responsibility for information on packaged or pre packaged food lies with the entity under whose name or company name the food is placed on the market, which is usually the producer or brand owner that is based in the EU. In the case of food imported into the EU market from third countries, the importer for the EU market is responsible for the food information.

The food business operator that offers or sells food to the final consumer, i.e., the retail store and public catering establishments, is responsible for informing consumers about unpackaged or non-prepacked food.

Council Regulation (EC) No 1224/2009 states that all batches of fishery products must be traceable at all stages of distribution, which includes identification marks on the packaging (baskets or boxes) during transport. The minimum required data is the identification number of each batch; external identification number and name of fishing vessel; FAO three-letter code for each species; catch date; the quantity of each species, expressed in kilograms net weight or, where appropriate, the number of individuals; name and address of the supplier; consumer information provided for in Article 8. Regulation (EC) No 2065/2001: trade name, scientific name, relevant geographical area and method of production and whether the fishery products have been previously frozen.

For each batch of fishery products, a unique number - LOT is indicated, consisting of:

- L designation; document type designations (LOG - electronic logbook of commercial fishing at sea, LB - logbook of commercial fishing at sea, CR - catch report);
- numerical codes consisting of the last two digits of the year, the last five digits of the vessel's CFR number and, in the case of an electronic logbook, the last three digits of the

serial number or, in the case of a paper logbook or report, the last four digits of the logbook or report serial number; FAO marine organism species codes.

9. Category of illegal catch and trade in fish

The European Union Regulation on the prevention and elimination of illegal, unreported and unregulated (IUU) fishing entered into force on 1 January 2010. According to the EU, IUU fishing is any fishing that takes place in prohibited areas, uses illegal methods or is not reported. IUU fishing has a negative effect on the sustainable management of global (and local) fish stocks and creates unfair competition against those who fish legally and responsibly.

It is necessary to prove that fish and other marine organisms do not originate from IUU fisheries. Therefore, fish can only be placed on the market through proof of origin and a logbook approved by the competent authority. The catch certificate must contain all the information given in the model shown in Annex II of the European IUU legislation.

Requirements for fishing vessels

Requests for support of a beneficiary are inadmissible if it has committed a serious offense under Article 42 (1) of the Council Regulation (EC) No 1005/2008 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing, amending Regulations (EEC) No 2847/93, (EC) No 1936/2001 and (EC) No 601/2004 and repealing Regulations (EC) No 1093/94 and (EC) No 1447/1999 (OJ L 286, from 29. 10. 2008) (hereinafter: Regulation (EC) No 1005/2008) or Article 90 paragraph 1 of the Regulation (EC) No 1224/2009, as determined by the competent authority:

1. Vessel owner and / or license holder of a vessel included in the Union IUU vessel list as provided for in Article 40 (3) of the Regulation (EC) No 1005/2008 or flagged to countries identified as non-cooperating third countries referred to in Article 33 of this Regulation, when
2. A serious infringement of the rules of the Common Fisheries Policy has been committed, as defined in other legislation adopted by the European Parliament and the Council.

The applicant and the responsible persons in charge of the certificate on individual vessels must prove that they are familiar with the legal regulations related to fishing and reporting on catches.

It is especially important that they are familiar with all technical measures and restrictions of fishing (spatial and temporal) related to their fishing practice, fishing tools, minimum sizes for certain species, fishing closure, etc.

Applicants need to prove that their fishing gear complies with the legal framework and EU regulations (measured mesh size, length, width, etc.).

Applicants should have a system on board that ensures traceability - print labels with LOT numbers or write on the containers labels that can be used to identify their catch on landing. If the vessel is at sea for more than one day, the batches should be separated and marked with dates in order to know how many hours fish was stored on ice. Of course, there are additional criteria that can be applied for fishing vessels and processing plants.

10. Processing procedures - procedures that follow high quality and safety

They involve processes from the deck to the final stage of food processing, and where important, the variables are temperature (“cold chain”) and time. Cold chain is a well-known category whose goal is to quickly lower the caught fish and other seafood to an adequate temperature and keep this regime as long as possible in the process of production, processing, storage, presentation to the customer, etc. with as few hot-cold temperature jumps as possible.

Processing processes are mainly related to preserving foodstuffs. They consist of various processes whose purpose is to preserve the original quality of a food as much as possible and for as long as possible, i.e., to prevent its spoilage and degradation. There are many factors that cause food spoilage, starting with autolytic enzymes, the activity of microorganisms, the presence of insects, rodents and other pests and other factors that promote food degradation, such as temperature (outside a certain optimal area), air (presence of oxygen - oxidation), light, water content and time.

The basic concept of food preservation means the prevention of spoilage that occurs as a result of the activity of microorganisms. In order to prevent their action which leads to the unusability and harmfulness of the product, various preservation procedures and techniques are applied.

Knowing the properties and needs of microorganisms, classical preservation procedures can eliminate their activity, or extend the shelf life of food. The methods used must be effective, must not impair the nutritional value of the food and lead to undesirable changes in its sensory properties.

Consumers demand that the taste and color of food produced is as natural as possible and that the shelf life allows for a reasonable period of storage before consumption. Therefore, new food processing methods have been developed and applied, which have enabled the production of minimally processed food while retaining all or almost all of its original characteristics.

New methods of food processing and preservation include: pulsating electric field, oscillating magnetic field and high hydrostatic pressure, as well as methods whose commercial exploitation is on the rise; ultrasound as a method of food homogenization, pulsed light and ultraviolet light used for surface food treatments and in packaging.

Common to all these techniques is that the treatment of the material takes place at room temperature, i.e., there is a slight increase in temperature as a result of processing and the process itself takes a short time (from 1 to 10 minutes).

By applying some of non-thermal food processing procedures in certain branches of the food industry, energy can be significantly saved and the duration of the production process shortened, milder heat treatment conditions can be applied and products with better organoleptic characteristics and higher nutritional value can be obtained.

Minimal food processing

Thermal methods	Non-thermal methods
Thermal conduction, convection and radiation	Ionizing radiation
Heat processing	High pressure

Aseptic and semi-aseptic processing	Pulsating white light
Infrared heating	Laser light
Ultraviolet light	Pulsating electric field
Processing by heating in volume	Oscillating magnetic field
Electrical resistance / ohmic heating	Ultrasound
High frequency or radio frequency heating	Ion bombardment
Microwave heating	Plasma sterilization at atmospheric pressure

10.1. Packaging requirements

Thanks to the development of the food industry, there has been an expansion in the production of new packaging materials for food products and a modern way of selling groceries. Success in the market largely depends on the type of packaging, design, its quality, preservation of original freshness and quality of food with emphasis on health (food safety), protection from various chemical, mechanical and microbiological influences in order to increase the shelf life (durability) of packaged content. The food manufacturer must take care that the food is packed in appropriate packaging.

In accordance with the provisions of the Ordinance on packaging and packaging waste (OG No. 88/15, 78/16, 116/17, 14/20) the manufacturer is obliged for each packaging material, according

to the type and composition in which it packs the products it places on the market, to have a certificate on the content of heavy metals in the packaging material. A manufacturer who places a product on the market in packaging from the European Union may have a Declaration of Conformity instead of a certificate stating that the packaging material in which he places the product on the market meets the requirements for heavy metal content, and appropriate documentation must be available.

Additional inspections of packaging that come into contact with food are performed in accordance with the Act on materials and articles in direct contact with food (OG 25/13) and the Ordinance on materials and articles in direct contact with food (OG 125/09 and 31/11 - 1.7.2013 Article 1, subparagraphs 1 and 2, Article 3, Articles 5, 6 and 7, Annexes I, II, III, and V, Figure 1, and Appendices 4 and 5 ceased to be valid).

11. Customer requirements for fish trade

After meeting the requirements of the competent authorities, it is increasingly necessary to adapt to the special requirements of customers. Today, in addition to the requirements of European and national legislation, there are a number of common requirements that most customers will have. Individual customers will want proof that the company and its facilities meet certain food safety standards and that they have social and environmental responsibilities. E.g., Sustainability certification is required to enter the retail markets of northwestern Europe and is also required in other regional and end-consumer markets.

11.1. Food safety certificates

Although European Commission food safety regulations are considered one of the strictest, if not the strictest legal standards for food safety, most European customers will have additional food safety requirements. Certainly, in retail, but also in most food and wholesale markets, European customers will require certification from third parties or independent certification companies. IFS and BRC standards are most often requested.

It should be emphasized that the industry is working to harmonize food safety standards and increase mutual acceptance by comparing third-party food safety schemes by the Global Food Safety Initiative (GFSI). As GFSI is compared to multiple schemes, retailers as well as other distributors are likely to adopt more schemes, reducing pressure on suppliers to establish more independent food safety programs because the same practice is unsustainable in the long run for production cost and management.

11.2. Certificates of social issues

Large companies today often have their own audits and certificates of social compliance. However, some European supermarkets often require their supplier to be certified by a third party for social compliance. As with the food safety certificate, the social compliance certificate is generally relevant for processing plants. These certificates relate to labor and social rights, health and income of people working in processing plants, as well as in the wider supply chain.

In Europe, the most accepted third-party accreditation programs are SA8000 International Accountability International (SAI) and the Business Social Compliance Initiative (BSCI). While the SA8000 is indeed a compliance tool, the BSCI goes much further and requires accredited companies to demonstrate that they are making continuous efforts to improve the situation where a shortcoming is identified. The fewer shortcomings and more progress, the better the BSCI score will be.

With recent scandals over workers' rights and even accusations of slave labor in several fisheries around the world, looking at social responsibility and potentially issuing certificates of social conformity are increasingly desirable in the European market.

11.3. Sustainability certificates

Unlike the certificates on food safety and social compliance, the certificates on sustainability refer to the primary place of production, fishing vessel, processing plant and other related to production. An increasing number of European customers require certification of primary production facilities.

Sustainability certification can no longer be considered a necessary requirement. Although previously only needed in the retail market in north-western Europe, retailers in other parts of Europe and in the food-services market today have also started to use the sustainability certificate as a market access requirement.

In Europe, the most widely accepted sustainability certification system for caught marine organisms (MSC) from catch and (ASC) in aquaculture management. Although there are other certification systems (Friends of the Sea, GLOBALG.A.P., Best Practice Aquaculture Practices), they are still considered standard market requirements.

Market acceptance of sustainability schemes could change again as traders and other distributors commit to seafood certified only from schemes compared to the Global Sustainable Seafood Initiative (GSSI). Once the reference schemes are compared, it is unlikely that traders will commit to a single system, but will instead commit to any program that has been positively rated by GSSI.

To be present in European retail markets, it is necessary to invest in the certification of our own production facilities and the facilities of our suppliers. In the long run, this trend applies not only to the retail market, but also to the food services and wholesale markets.

12. Innovation and organization in placing new products on the market

New technologies applied to improve the level of monitoring and management are the driving force behind the requirements of individual market niches. E.g., levels of traceability that are not common customer requirements are sought by those customers, especially in retail, who want to promote sustainability.

Consumers are most interested in the source of their seafood, traceability in retail, and increasingly in organic certified seafood.

Traceability offers an increasing number of services, and the market is showing interest even though it is mostly just a niche market. This segment is mainly related to the IUU market category. Traceability, associated with the exclusion of the risk of IUU practices and fraud, is becoming

increasingly important in the European retail market. DNA tracking is another way to increase product traceability. It has long been used in other sectors related to animal proteins but is now being developed for caught and farmed fish as well as other marine organisms.

Many European traders tend to look beyond the traceability of the consumer products themselves and consider the ingredients needed to produce these consumer products, such as the composition of fish feed mixtures.

For farmed fish, the risks observed by retail chains often relate to the use of fishmeal and oil from unsustainable or irresponsible sources.

The organic seafood market is relatively stable. The largest markets are in the UK and Germany, followed by France, Italy and Spain. All these years, the assumption has been that this market will grow rapidly. Although this has not happened and consumption is relatively even, given the trends in health and sustainability, we can expect growth in that market in the long run.

Organic seafood can only be obtained from aquaculture, because European Union regulations on organic products, which must comply with all imported organic seafood, do not allow seafood caught in the wild to be certified as organic seafood.

For the sale of organic seafood on the European market, the minimum requirement that must be met is the European Union Organic Seafood Regulation. This harmonization will make it possible to put the EU green leaf on the packaging. Depending on the target market, the client can request certification of the originating plant and manufacturers Naturland (mostly sought after in Germany) or AB (mostly sought after in France).

12.1. Basic instructions before placing the product on the market

It is necessary to:

- Investigate the effect of the presence of chlorate in food and water on living organisms
- Investigate the niche market and whether there is a sensitivity to this issue
- Ensure shipments shipped to any EU Member State to cover financial losses in the event of a shipment being rejected.

- Talk to customers in order to guide them regarding amendments of the European legislation
- Observe maximum residue levels
- Strictly follow the labeling regulations
- Prove that fish and seafood come from legal sources
- Introduce a new system of certificates concerning the country of origin
- Issue food safety and sustainability certificates
- Issue certificates of social compliance
- Comply with increased traceability requirements in supply chains of wild and farmed fish and other marine organisms
- Provide evidence for the organic products market

13. Italian case on standards' qualifications

Abbreviations

ASSAM: Agenzia Servizi Settore Agroalimentare delle Marche – Agency of Services Agrifood Sector of Marche Region

CSM: Centro di Spedizione/Smistamento Molluschi (Center for delivery and sorting of molluscs)

EMAS: Eco-Management and Audit Scheme

OdC: Organismo di Controllo privato o pubblico (Public or private control)

Si. Tra.: Traceability system for agricultural and food products in the Marche Region

UNI: Ente Nazionale Italiano di Unificazione (The Italian Standards Organization for the industrial, commercial and tertiary sectors)

Introduction

Seafood certification for many Italian companies means an opportunity to compete on both national as well as the international market. The need of qualitative and other characteristics' demonstration to consumers, has led these companies to follow the context of regulation and

certification. There is a sharp increase in fishery production companies that have adopted accredited and non-accredited systems, especially since the adoption of the Ministerial Decree of 18 July 2000 by the Italian Ministry for Agricultural Policies, when fishery products were included into quality branding among traditional agro-food products.

The legislative and regulatory provisions governing the production and marketing of the fishery products in both Italy and Croatia are set out in applicable EU and national laws. The UNI EN ISO voluntary certification system in Italy is a country-recognized and widely accepted method. Besides the ISO voluntary certification, the adoption of a formal system of environmental management (EMAS) is also used to conform to environmentally sustainable operations.

In 2007., a national project named „Implementation and certification of a seafood chain traceability was launched by *Organizzazione Interprofessionale Filiera Ittica* in an attempt to set up a certified system for seafood products which could be identified by a collective trademark. It was recognized by the European Union and supported by the Ministry of Agricultural Policies. It included ten producer organizations from four Italian regions, including Emilia Romagna and Marche. Its main objective was to develop a *traceability system* under UNI 10939:2001 regulation, so there could be a guarantee of the products' freshness and food safety for the final consumer.

The quality and safety of seafood products are, as already mentioned, guaranteed by a set of international and national laws, represented by compulsory technical rules and are mandatory for the subject companies. On the other hand, voluntary certifications are regulatory standards produced by Certification Bodies that serve as an additional guarantee for consumer's safety and health. There is a rough division between quality system certification (that involves the productive process of a company) and product certification (which refers to product's characteristics, productive organization and environmental aspects' management). The standards of the system/process certification are those of product chain traceability UNI 10939 and the ISO 9000 series, while for the latter the reference standards are the ISO 14000 series and the EMAS regulations.

It is worth mentioning that Good Manufacturing Practices (GMPs) are also voluntary standards and serve as guidelines, governed by the operations in a company during the product's handling and processing. The best known GMP Standards referring to seafood production sector is certainly The Codex Standard for Fish and Fishery Products (volume 9 Codex Alimentarius, 1999).

The regulated product certification standards have already been mentioned and presented in our previous deliverables (eg. D4.4.2. *Certification scheme for new innovative products and processes*). Such systems include: PDO (Protected Designation of Origin), PGI (Protected Geographical Indication) and TSG (Traditional Speciality Guaranteed), as the most prominent ones.

PDO-related Regulation - Council Regulation (EC) No. 510/2006 on the protection of geographical indications and designations of origin for agricultural products, and the following implementation Commission Regulation (EC) No. 1898/2006.

PGI-related Regulation - Council Regulation (EC) No. 510/2006 on the protection of geographical indications and designations of origin for agricultural products, and the following implementations: Commission Regulation (EC) No. 1898/2006 of 14 December 2006 and Commission Regulation (EC) No. 1216/2007.

TSG-related Regulation - Council Regulation (EC) No. 509/2006 on agricultural products and foodstuff as traditional specialities guaranteed, and the following implementation Commission Regulation (EC) No. 1216/2007.

In Italy, voluntary product certification schemes are usually found in terms of the *regional collective trademark*, with a wide application in the agrofood sector, including seafood products. Here, the peculiarity lies in the fact that the ownership of the mark belongs to a public entity, namely the Region. This mark is able to demonstrate that the products involved possess certain quality characteristics and the existence of a control system, and can be used in conformity with the regulations adopted by the management body, R.D No. 929 from 21st of June 1942.

Besides collective trademarks, there is also a *company mark* with a product distinguished from the solely commercial point of view by belonging to a specific producer. The company mark is regulated by arts. 2569-2574 of the Civil Code as well as by R.D. No. 929 of 21 June 1942, as subsequently amended by D. Lgs No. 480/92 and D. Lgs 198/1996.

Third is the *mark of conformity* that may be compulsory, such as the EC mark that guarantees safety requirements are satisfied by certain products, as laid down in EU directives.

Before any company can make statements of its product's quality, traceability or environmentally friendly practices used - there is a need for mandatory third-party certification and national accreditation to verify claims about seafood sustainability.

Three bodies in Italy have a control task in the accreditation processes. Those are:

- SINCERT (National System for the Accreditation of Certification Bodies) - carries out the formal recognition of the certification body for products and/or quality systems, and verifies whether it is operating under pre-defined procedures;
- SINAL (National System for Laboratory Accreditation) - aims to verify if the tests done by accredited national laboratories are in scrutiny with the protocols recognized nationally and abroad;
- SIT (Italian Calibration Service) - responsible for accrediting test laboratories.

14. Quality certification of the Italian seafood products

For a country like Italy, which is mostly surrounded by the sea, there are not many certified fishery products on the market. In the same time, quality schemes such as the PGI (Protected Geographical Indication) possess massive opportunities for the products' added value in terms of recognizability within and outside the Italian borders. In addition, implementation of such schemes could mean better protection against possible unfair competition from products proposed as similar.

However, the experiences of the existing product brands in Italy so far have shown some distinct obstacles and challenges after registering their products as certified. For example, salted anchovies from the Ligurian Sea (*Acciughe sotto Sale del Mar Ligure IGP*), 13 years after registration of the European mark continue to be almost untraceable, a sort of a ghost brand, despite the enthusiasm and initial commitment to obtain certification. Also, there is the Italian fish sauce made from anchovies (*Colatura di Alici di Cetara DOP*), which is competing on the market with other products with its quality and promotion to be more recognizable on the market. It has a precise geographical reference to Cetara, a small town on the Amalfi Coast, a community inextricably linked to fishing activity. On 21st of October 2020., Colatura di Alici di Cetara became the first PDO product processed from the sea with its publication in the Official Journal of the European Union (L 349/3). The Association for the valorisation of Colatura di Alici di Cetara is the promoting body that, together with the Municipality of Cetara, followed the procedure for the PDO recognition, which officially started on 28th of October 2015., with the

establishment of the Association to which 4 producers, 3 restaurateurs and 2 fishermen from Cetara belong.

In Italy, more than 1.200 different fish species are sold weekly as fresh, frozen and processed products, with more than ten thousand references. And yet, unlike other sectors relating to animal-based food, fish products continue to lack recognition in terms of particular brands or trademarks. Even if we consider domestic fish products, which today account for about one-third of imported products, there are still no species or products recognized and recognizable to the general public as 'excellence' in this sector.

Aiming for quality should represent the added value that a given product has, compared to the conventional one. This added value needs to be clearly and easily communicated to the consumer. Ideally, it should conform to a guideline or specification drawn up by a technical-scientific committee, possibly governed by legislation and in any case controlled and therefore verifiable by competent official bodies. In practice, it would be useful if, for the interests of market fairness and consumer protection, a process could begin as soon as possible on outlining a system of rules for the fisheries sector that would guarantee not only the quality of hygiene and health and proper traceability, as it is today, but also quality relating to other aspects and defined by 'institutional specifications or guidelines' that would clarify more objectively the real added value of a given product.

15. Regional brands' quality control procedures

The aforementioned regional collective trademarks guarantee quality and traceability of seafood products. For the scope of our work, we will use two such brands from the Marche and Emilia-Romagna region - „Prodotto Certificato dell'Alto Adriatico “(PCAA) and „QM - Qualità garantita dalle Marche “. All critical points in production (eg. packaging, storage and transport) and important supply chain actors (eg. retailers, restaurants, wholesalers, fish markets) will be analyzed, so that the framework of production rules and regulations, important for the scope of our project, is fully understood.

Besides these two programmes, in the region of Emilia Romagna, pursuant to regional law L.R. 28/1999, another collective regional quality label was launched called „QC - Qualità controllata “, which promotes aquaculture fish and shellfish production.

16. Marche region fishery products certification

Terms and acronyms

Below are some of the terms and definitions used in the specification.

Adherent to the chain: a person who enters into agreements with the concessionaire to use the QM mark, even though they are not linked to it by a membership obligation.

Self-check: verification and documentation activities carried out before, during and after the production process and performed by the Licensee and each member to ascertain the conformity of the products with the rules for using the *QM* mark and the specific specifications.

Sizing: distribution of the product in homogeneous batches concerning the size.

Marketing channel: The distribution system of the fish product from the producer to the consumer is operated by the chain members who sell/purchase the product without making any modification other than refrigeration.

Market leader: The natural or legal person who coordinates the product chain's activity about traceability and safety aspects.

Timely loading: insertion of data in the server in time for its use by the chain's next link.

Cold room (or cold storage room): a room used to store fish, equipped with a machine or thermodynamic system capable of producing cold, i.e., removing heat from a low-temperature system and transferring it to a higher temperature environment.

Shellfish dispatch center (MMC): the on-shore or floating establishment for the reception, finishing, washing, cleaning, grading, wrapping and packaging of live bivalve molluscs fit for human consumption.

Certificate of conformity: a document issued by the authorised inspection body in accordance with the rules of its certification system, indicating with sufficient certainty the conformity of a product/service with the rules for the use of the QM mark and the specific specifications.

Final consumer: the ultimate consumer of a food product who does not use that product as part of a food business's operation or activity (EC Reg. 178/2002).

Retailer: A commercial operator engaged in selling fisheries products directly to the consumer; this includes both small traders and operators belonging to the large-scale retail trade.

Product/service specification: a document issued or endorsed by the Marche Region and available to the public, which lays down the methods for obtaining and specifying a product and/or processing the product and/or providing a service. The product/service specifications of the QM mark are documents that contain binding specifications, objective and measurable requirements, production, processing and marketing rules that guarantee maximum transparency to the consumer regarding all stages of the production process.

Third-party certification body: a public or private third-party body accredited or compliant with the UNI CEI EN 45011 standard, which issues product and/or service certifications.

Labelling: the set of terms, indications or trademarks, images or symbols, referring to the food product and appearing directly on the packaging or a label attached to it or on the closing device or on signs, rings or bands tied to the product itself, or, failing this, on the documents accompanying the food product.

Fish supply chain: the defined set of organizations (or operators) with the relative material flows that contribute to the formation, distribution, marketing and supply of a fish product. The term supply chain identifies, in this context, all activities and flows that are critical to the characteristics of the product.

Material flows: raw materials, additives, semi-finished products and packaging materials which, at any point in the chain, enter the production process.

Wholesaler: A commercial operator dealing with wholesale quantities of fish product, acting as an intermediary between the fish market and retail traders and/or caterers.

Fish market: a wholesale market for the production of fish products where, by means of public auction or other, the products supplied by individual producers and cooperatives are traded between producers and their consortia, wholesale traders, retailers and caterers.

Final operator: the party who transfers a QM-certified product to another party to carry out a subsequent stage of the production process (intermediate operator) or places a QM-certified product directly on the market.

Dish: part of the menu codified by each restaurateur and approved by the licensee, consisting of one or more branded fish species. The plate must indicate the quantity (in grams) of product required for its preparation.

Primary product: products of primary production, including products of the land, livestock, hunting and fishing.

Fishery product: products of catches at sea or in inland waters. Fresh fishery product: a whole or prepared fishery product which, for the purpose of preservation, has not undergone any treatment other than chilling.

Chilling: the process of lowering the temperature of fishery products to a temperature approaching that of melting ice.

Refinishing: the storage of live bivalve molluscs coming from class A production areas, purification centers or dispatch centers, in tanks or any other installation containing clean seawater or in natural reservoirs to remove sand, mud or slime, preserving or improving organoleptic qualities and ensuring a good state of vitality before wrapping or packaging.

Supply chain traceability: the ability to trace the history and track the use of a product using documented identifications (relating to material flows and supply chain operators).

Traceability: The ability to produce information on a product's characteristics and its use through documented identification.

Third-party transporters: Operators recognised by the concessionaire who transport goods by means of vehicles suitable for transporting fish products on behalf of commercial operators belonging to the brand circuit.

User: the subject who affixes the QM mark directly under their responsibility; this may be the concessionaire themselves or their delegate.

Fishing or catch area: the name of the place where the catch was done. Marine area classified as type "A": marine waters bordering the coast are classified as type "A" production areas when the harvesting and use for direct human consumption of bivalve molluscs are permitted.

Production area: those parts of the sea, lagoon or estuary where there are natural beds of bivalve molluscs or places used to cultivate bivalve molluscs, where the latter are harvested alive.

16.1. Legislative and regulatory references

National Law

- Framework Law No. 963 from 14th of July 1965. and subsequent amendments concerning the regulation of sea fishing;
- Presidential Decree No. 1639 from 2nd of October 1968. on the minimum size of mussels;
- Presidential Decree from 1st of June 1987. on the regulation of professional underwater fishing (for the collection of mussels from the wild);
- Legislative Decree No. 108 from 25th of January 1992. implementing Directive 89/109/EEC on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs;
- Legislative Decree No. 109 from 27th of January 1992. implementing Directives 79/112/EEC, 89/395/EEC and 89/396/EEC on the labelling, presentation and advertising of foodstuffs;
- D.Lgs. No. 530/92 water classification;
- D.Lgs. 11. 531 of 30/12/1992 implementation of Directive 91/493/EEC laying down the health rules applicable to the production and marketing of fishery products;
- Decree of the Ministry of Agriculture and Forestry of 12/01/95 entrusting the management of bivalve mollusc resources to Consortia set up between fishing enterprises;
- Law No. 164 from 21st of May 1998. 'Measures on fishing and aquaculture';

- Ministry of Agriculture and Forestry Policy Decree from 21/07/98 defining the number of units authorised to fish with a hydraulic dredger and the decision-making powers of the Consortium concerning technical fishing stoppages of bivalve molluscs;
- Ministry of Agriculture and Forestry Policy Decree from 14/09/1999 regulating small-scale fishing of bivalve molluscs from 14/09/1999 small-scale governing fishing;
- Decree of the Ministry of Agriculture and Forestry from 27/03/02 and subsequent amendments and additions relating to the labelling of fish products and the control system;
- Circular of the Ministry of Agriculture and Forestry No. 21329 from 27/05/02 relating to the rules for the application of Council Regulation (EC) No. 104/2000 as regards the fishing of bivalve molluscs. No. 104/2000 of the Council as regards consumer information on fishery and aquaculture products;
- Legislative Decree No. 181 from 23/06/03 implementing Directives 2000/13/EC, 2001/101/EC and 2002/67/EC on the labelling, presentation and advertising of foodstuffs;
- Lgs. 11. 114 from 08/02/06 implementation of directives 2003/89/EC, 2004/77/EC and 2005/63/EC on the indication of ingredients contained in foodstuffs.

Regional Law

- Regional Law No. 23 from 10/12/2003 laying down rules on interventions for the support of quality certification systems and traceability of agricultural and agri-food production;
- Resolution of the Regional Council No. 1594 of 21/12/04 - Regional Law 23/03 "Interventions to support quality certification systems and traceability of agricultural and agri-food production" - art. 8.1 - Approval of the regional trademark "QM - Quality guaranteed by the Marche" and related regulations;
- Resolution of the Regional Council No. 725 from 13th of June 2005. which defines the new sanitary classification of the marine waters of our region, for the production of bivalve molluscs;
- DDS Veterinary Service No. 147 of 03/08/2005 and No. 23 from 05/07/2005. Classification of the production area of live bivalve molluscs pursuant to Article 4 of Legislative Decree No. 530/92. Integration of the resolution of the regional council No. 925 from 13th of June 2005.;

- D.G.R. No. 257 from 13/03/2006, modified by the D.G.R. No. 1375 from 11/26/2007 for the adoption of the text definitive of the regulations for the use of the regional brand “QM-Quality guaranteed by the Marche”;
- Resolution of the Regional Council No. 339 from 27/03/06 which incorporates some guidelines of the EC Regulation No. 852/2004 and 853/2004 of the European Parliament;
- Resolution of the Regional Council n. 536 of 08/05/06 - Regional Law 23/03 "Interventions for the support of quality certification systems and traceability of agricultural and agri-food production" - adoption of the definitive text of the guidelines for the drafting of the specifications of the "QM" trademark;
- Transposition of the agreement pursuant to art.8 paragraph 6, of L. No. 131/2003, between the Government, the Regions and the Autonomous Provinces of Trento and Bolzano No.7/CSR/2007 relating to the guidelines on bivalve molluscs and the new EU Regulation;
- D.D.P.F. No. 68/CSI 10 from 14/03/2008 - Regional law 23/03 "Interventions to support quality certification systems and traceability of agricultural and food production" - revision of lines guide for the management of the *Si.Tra.* traceability system.

Compliance with this specification does not exempt adhering subjects from the obligation to comply with laws and regulations (even not expressly reported) under their own responsibility, and are always subjected to, without prejudice, the rights of third parties.

16.2. Definition of the product(s)

Under the QM mark, only those species of bivalve and gastropod molluscs intended for fresh consumption are marketed and for which the product data sheets summarise the characteristic requirements subjected to certification.

QM molluscs are characterized by:

- **production methods:** sea fishing or farming coming exclusively from ZONE A waters according to Reg. EC 854/2004 or for the species fished beyond three miles from the coast (snails, murexes, pelican feet) in the projection zone orthogonal to the coast referred exclusively to ZONE A;
- **commercial sizes** required for the QM circuit greater than the minimum legal sizes (mussels, snails and oysters);

- codified **presentation and marketing** methods for the QM product;
- **guaranteed communication of traceability** to the final consumer.

16.3. Identification and labelling of QM-labelled molluscs

The product *Molluschi QM* must comply with the legislation requirements in force. As additional indications, the documents accompanying QM-branded products, where relevant, must include the following:

- Name of the fishing company/vessel identification or CSM identification;
- Fishing or farming location;
- Date of fishing or harvesting;
- Registration number of the batch;
- Name of the retailer or restaurateur;
- Wording "QM - Qualità Garantita dalle Marche";
- Indication of the site *www.gm.marche.it* for traceability purposes;
- *Si. Tra.* traceability, if possible, in the same visual field as the QM logo;
- Lot traceability code (possibly also expressed by a bar code if recognized by the *Si. Tra.* system);
- QM license No... (optional);
- Live product at the time of purchase (optional).

The third-party certification body (CB) logo and any other certifications obtained may also appear on the labels. The indications on the label must be given in the Member State language in which the product is marketed; they may also be given in several languages. In the case of indications that do not have a correspondent in the Member State language in which the product is marketed, the original indications may be used.

End operators, such as retailers and caterers, shall display the QM mark on their sales premises in such a way that it is clearly visible to consumers. The QM mark shall be used exclusively in the full form, colours and characters described in the annexe to the rules on use (D.G.R. n. 1375 from 26/11/2007) and shall be of a size that according to the specific nature of a packaging is such as to make it visible.

It shall also always be affixed in such a way that it cannot:

- a) be confused with additional graphic elements, underlining, ornaments or text additions that make it difficult to read;
- b) distort the original character of the logo or its meaning;
- c) be confused or associated with other wording present on the product label (e.g. producer's name, private brands, etc.).

Without prejudice to the prerogatives of the inspection bodies, the Marche Region (and on its behalf the position) reserves the right to revoke the license in cases of blatant non-compliance with these requirements.

The Trademark Licensees and the Mollusc Chain members are obliged to comply with any subsequent provisions on consumer information that the Region will communicate through the website www.qm.marche.it.

Traceability

Complete traceability must be ensured at all stages of production by using the *Si.Tra.* regional computer system supplied free of charge to the sectors in the Regional QM brand circuit. If companies already have a computerized traceability system, the regional *Si. Tra.* system can be interfaced with compatible software capable of ensuring the necessary information flow and compliance with the Marche Region and ASSAM's technical specifications. In particular, for each minimum unit of product, access to information on traceability (product characteristics, type of organizations involved, commercial aspects between them) must be guaranteed at the time of purchase.

Packaging

The label's information shall also be contained on the packaging in bags on an irremovable label of impermeable material. QM certificates relating to the batches of molluscs on sale must be displayed at the retail level, together with appropriate signage identifying the QM-labelled product.

Marketing

The Fish Market and/or CSM markets the QM-labelled product following assessment of its conformity with this specification's requirements. The product may be QM-labelled at any marketing stage as long as the various parties are part of the QM chain. Each actor in the chain is obliged to separate the QM-labelled fish product from the non-QM-labelled product.

The Trademark Licensee

The Licensee has the function of coordinating the activities of the Subjects belonging to the chain and of guaranteeing the correct functioning of *Si.Tra.* by providing fulfilments directly or by entrusting them in full or in part to specifically delegated subjects. Also, the Licensee of the mark will have to prepare the following lists concerning the different Subjects composing the chain:

- a) list of the adherent fishing enterprise¹ that carry out local or close coastal fishing and related vessels with which it stipulates conventions (concessionaire-adherent QM fishery supply chain);
- b) list of farming facilities²;
- c) list of any recipients (wholesalers, retailers or restaurants) who place the QM-branded product on the market and thus form part of the chain;
- d) list of the relevant fish markets and mollusc dispatch/sorting centers (CSM);
- e) list of third-party transporters;
- f) list of mollusc species that can be marketed under the QM mark, indicating the commercial name, the scientific name of the species and its FAO alphanumeric code. These lists shall be communicated to the third-party certification body at the beginning of the certification process (recognition phase). They shall be kept, updated and made available upon request of the Certification Body (CB) or other competent authority. In addition, the licensee is obliged to communicate any changes to the lists mentioned above before the annual inspection by the CB. The Licensee identifies a quality manager who supervises the application of the regulated

¹ Required data: owner, boat registration number, number of registration with the RIP (*Registro delle imprese di pesca*) and/or Chamber of Commerce, number of fishing license.

² Copy of the license authorization.



procedures by the components of the supply chain, which interfaces with the third-party Control Body and is generally in charge of second-level controls.

Critical traceability points in the supply chain

1 FISHING ENTERPRISES

2 IDENTIFICATION OF THE FISHING OR FARMING AREA

3 PULLING THE CATCH ON BOARD

4 SORTING

5 WASHING

6 PLACING IN BOXES OR CONTAINERS

7 STORAGE OF BOXES OR CONTAINERS IN CONTROLLED TEMPERATURE

8 LANDING

9 POTENTIAL STORAGE AT PORT



TRANSPORT TO FISH MARKET



TRANSPORT TO A DISPATCH CENTER

Control of documentation accompanying the lot and verification of transporter’s compliance

Control of boxes or other types of containers and their contents

Rejection of non-compliant products

Entry of data in the server for the traceability

Repackaging of the product in mesh bags with labels

Eventual sale auction at the fish market

Restaurateur	Wholesaler	Retailer
Control of bags and their contents and verification of transporter’s compliance	Control of bags and their contents	Carrier conformity check
Rejection of non-compliant products	Rejection of non-compliant products	Control of the bags and their contents
Loading of accepted lots	Storage of the products at a temperature of 0-6 °C	Rejection of non-compliant products
Issue of certificate to the customer	Recording data for the traceability	Loading of purchased lots or batches

Fishing enterprises

QM-marked molluscs pass through dispatch centers and/or fish markets; at the moment of passage through the dispatch center (or fish markets, if there has not been a previous passage through the dispatch center), the data needs to be uploaded into the system.

Within the company, it is necessary to identify a quality manager, who guarantees the application of the procedures provided for by the Specification and who interfaces with the Licensee and with the third-control Body; the Licensee shall be promptly informed of his designation.

The obligations for the fishing enterprises are:

- to locate the type "A" fishing zone and write down the coordinates or use another registration system;
- to arrange the product, free of product defects, in boxes or bags according to size in order to have batches/lots of homogeneous size;
- to separate the branded product from other products;
- to carry out the landing of the product at the port and the transport until the arrival to the fish market or to the dispatch center, preserving the product from possible contaminations;
- transporting the product to the market by suitable means and equipped with a refrigerator (in the case that a market or dispatch center are situated in a different area from that of the landing).

Shellfish farms

The obligations for enterprises with a license for shellfish farms are as follows:

- a. farming in areas exclusively of type "A";
- b. harvest the molluscs when they reach the commercial size and the size required by this specification as per technical datasheet for each species;
- c. place the product, free of product defects, in boxes or bags according to size in order to have batches/lots of homogeneous size;
- d. separates the certified product from other products;
- e. in the case of transport of the product to the fish market, use transporters that comply with the regulations and are equipped with refrigerators if the fish market is located in a different area from that of the landing.

A quality manager must be identified within the company, who shall guarantee the implementation of the procedures laid down in the specifications, and who shall be mediator between the Licensee and the third-party Control Body; the Licensee shall be informed of their designation in a timely manner.

Fish Markets/Mollusc Dispatch/Sorting Centre (CSM)

Upon receiving the product from the fishing enterprise, the persons in charge of the fish market and the CSM will:

- a. checks the product concerning the arrangement in the boxes and the visual and olfactory characteristics;
- b. transport the product using means (their own and/or those of third-party transporters) suitable for the transport of live molluscs;
- c. ensures the presence and maintenance of the product *Molluschi QM* in identified and recognizable containers so as to guarantee at every stage the separation of the generic product from the certified one;
- d. excludes from the circuit the products that do not comply with the specification, promptly notifying the Licensee of the exclusion;
- e. enters in the server the data necessary to guarantee traceability, including the purchaser's reference;
- f. excludes the certified product not sold within 36 hours of collection/invoicing.

Wholesalers

The obligations for wholesalers who market the branded product are:

- a. to verify the product with regard to visual and olfactory characteristics and receive a copy of the certificate of conformity when leaving the CSM (endorsement with indications of the *QM* System and the Licensee);
- b. if it is impossible to confirm it at the market or at the shipping center, exclude from the circuit the products that do not comply with the specification, promptly communicating the exclusion to the fish market, to the CSM and the Licensee;
- c. transport the product using their means (their own and/or third-party transporters) suitable for the transport of live molluscs;

- d. insert in the server the data necessary to guarantee the computer traceability, including the reference of the buyer;
- e. separates in every phase the generic product from the certified one;
- f. excludes the certified product not sold within 36 hours from the harvesting/invoicing.

Retailers

The obligations of retailers marketing the branded product are:

- a. checks the product with regard to the suitable packaging and to the visual and olfactory characteristics and receive a copy of the conformity certificate at the CSM's exit (endorsement with indications of the *QM* system and of the Licensee);
- b. if it is impossible to confirm it at the market or at the CSM, exclude from the circuit the products that do not comply with the specification, communicating the exclusion promptly to the fish market, to the CSM and the Licensee;
- c. transport the product using their means (their own and/or third-party transporters) suitable for the transport of live molluscs;
- d. check in the computer system the purchase of certified products;
- e. display appropriate identification signs and any other information of the brand in the manner prescribed by the Licensee;
- f. records each movement for each minimum unit of the *QM* product;
- g. separate at each stage the generic product from the certified one;
- h. excludes the certified product not sold within 36 hours from the collection/invoice.

Restaurateurs

The obligations of restaurateurs marketing the branded product are:

- a. purchases the product from the actors in the chain that use this specification;

- b. checks the product with regard to suitable packaging and visual and olfactory characteristics and receive a copy of the CSM's certificate of conformity (endorsement with indications of the *QM* system and the Licensee);
- c. excludes from the circuit the products that do not comply with the specification by promptly informing the Licensee and the company from which the product was purchased (fish market, shipping center, retailer) of the exclusion and exclude them from the brand circuit;
- d. excludes the unmarked product within 48 hours of collection/invoicing;
- e. check or directly register the purchase of certified products in the computer system and record each unloading of each minimum unit of the *QM* product;
- f. transport the product using their means (their own- or third-party transporters) suitable for the transport of live molluscs;
- g. display suitable identification signs and any other information of the brand in the manner prescribed by the Licensee;
- h. prepares a list of dishes based on *QM* products, also indicating the quantity of the species used for the preparation of the dish;
- i. for mixed platter dishes (e.g., fried, roasted, grilled, broths, etc.) it is possible to use fish products individually certified with the *QM* mark;
- j. indicates in the menu proposed to customers, the different components of the dishes, specifying the type of product (caught, farmed).

Definition of the supply chain

The marketing system of *QM*-branded molluscs involves the following subjects:

- fishing enterprises and related vessels (local and close coastal fishing) and mussel/ oyster farming facilities with related vessels;
- fish markets;
- Mollusc Shipping/Sorting Centers (CSM);
- wholesalers;
- retailers;

- restaurateurs.

The activity of the actors is supervised by the Licensee, who shall comply with the obligations undertaken towards the Marche Region (as subscribed in the agreement for the use of the label) and towards the actors of the chain (as subscribed in the second-level agreements), namely:

- comply with the regulations for the use of the label;
- comply with the provisions of the *QM* label document system with the specifications approved by the responsible management body;
- respect the procedural guideline approved by the Regional Council;
- use the label only after the release of the license for use by the management body;
- use the *QM* label in all cases where labeling is required, respecting the procedures established by the Decree of the Regional Council No. 1375 of 26/11/2007 and in compliance with the current trademark legislation;
- be subjected to control by the specifically identified Control Body;
- allow and facilitate checks on the *QM* brand at its headquarters and operational facilities by authorized public and private entities;
- allow access to its headquarters and production units concerned to those responsible for the activity of supervision (auditors);
- use the information system for the traceability of the production (*Si.Tra.*) or guarantee, by means of compatible software, the flow of information necessary for it, in accordance with the technical specifications communicated by the Marche Region and ASSAM;
- to maintain the legal requirements laid down and the company characteristics that formed the basis for the favourable assessment of the application by the responsible body and to notify the Commission of any changes that are beyond the control of the Licensee or of the members of the supply chain;
- stipulate a specific contract with the chosen Control Body;
- enter into agreements with all the members of the chain;
- play the role of the leader in managing the information system for product traceability (*Si.Tra.*) and coordinate actions aimed at achieving greater food safety, without prejudice to the responsibilities of the members of the supply chain;
- comply with internal audit procedures and prepare guidelines for company's internal audits for the benefit of members of the supply chain who request them;

- carry out second-party audits in compliance with the specification by the members of the supply chain in the manner provided for by the specification itself;
- promptly notify the management body and the Control Body of any change in the composition of the statutory bodies or the supply chain;
- supervise the correct operations of the authorized parties for the purpose of affixing the QM label;
- upon the expiry of the agreement, submit the documentation required for its renewal.

Relations between the supply chain actors

The fishing enterprises included in the circuit must be duly registered in the register of fishing enterprises and have the fishing license issued by the Directorate of the Ministry of Agricultural, Food and Forestry Policies responsible for Fisheries and Aquaculture. As suppliers of the raw material, fishing enterprises must always market the products through the dispatch centers that, as a rule, upload the data into the computer system; there may also be a passage through the fish market.

16.4. Conditions for admission to use the regional trademark under the license

Minimum requirements to guarantee the hygiene, conservation and traceability of the catch for fishing enterprises and boats intended for collection of farmed mussels/oysters

Vessels shall:

- a) have a system for recording the fishing or harvesting area;
- b) use, for the wild/farmed mussels/oysters, boxes or bags suitable for the storage of the products recognizable and identifiable and provided by or on behalf of the Licensee;
- c) always keep QM-marked products separated from non-certified products;
- d) have suitable facilities for storing the catch at the optimum temperature at any time of the day or period of the year;

e) have an ice compartment purchased ashore, or an ice machine installed on the vessel with characteristics that comply with Presidential Decree 236 of 24 May 1998.

The obligations under points d) and e) do not apply to boats intended for harvesting from farms.

Minimum requirements to ensure the hygiene, conservation and traceability of fish for Shellfish Dispatch/Sorting Centers

CSMs shall have:

- a) premises and facilities that comply with the legal requirements for EC approval by the Ministry of Health;
- b) certified internal audit system;
- c) a weighing and/or paper-based or electronic recording system for the automatic loading/unloading of the batches of certified products purchased/sold;
- d) a networked computer system for daily upload of certified products to the server.

Minimum requirements to guarantee the hygiene, conservation and traceability of the fish for fish markets, wholesalers, retailers and caterers

- a) a weighing system and/or paper or computer-based recording system for the automatic loading/unloading of the batches of certified products purchased/sold;
- b) a networked computer system for the timely upload of the certified products to the server.

Management system and internal audits

The maintenance and verification of the conformity of the marketing system with the provisions contained in this specification is implemented through three levels of control.

- Self-checks carried out by individual operators in the supply chain adhering to the specification;
- Second-party checks carried out by the Licensee or their delegate;

- Third-party checks carried out by a third-party certifying body, public or private, compliant with/accredited to UNI CEI EN 45011 standards, identified by the Licensee.

Self-check

The individual operators in the chain must implement self-checking procedures to ensure compliance with the points set out in the specification.

Second-party control

The Licensee carries out a second-party control activity on its members by means of initial checks for joining the system and subsequent surveillance checks to ensure that the requirements are maintained. The control can be conducted by an internal or external team whose composition must be communicated to the third-party certification body together with any non-conformities found.

Analytical checks on the product

The Licensee may carry out random sampling of the product at each segment of the chain to ascertain whether the product, particularly in relation to its freshness, complies with the parameters indicated in these specifications. The tests will be carried out by public and/or private laboratories complying with and/or accredited under UNI CEI EN ISO/IEC 17025. Samples must be taken in such a way as not to pollute the product. Transport to the laboratory must take place in compliance with the sector legislation.

Third-party checks (Certification Body throughout the supply chain)

Third-party audits, aimed at issuing and maintaining certification, are carried out by a third-party certification body, public or private, identified by the Licensee and authorised by the Marche Region.

Table 1. Example of the mussel product details, for species considered for the certification by the PRIZEFISH project.

Product Datasheet by Species

GENERAL COMMERCIAL NAME: Striped venus clam

SCIENTIFIC NAME: *Chamelea gallina*

PRODUCTION METHOD: Wild capture

CATCHING AREA: Identification of fishing area FAO, ZONE A (EC Reg. 853/04)

FRESHNESS CATEGORY: Fresh, sold not later than 48 hours from packaging

MINIMUM SIZE PER QM: 2,5 cm

CATCHING METHODS:

- **FISHING PERIOD:** Year-round

PERMITTED CATCHING SYSTEMS: Hydraulic dredge

CLEANING AND SCREENING TREATMENT: Yes

PACKAGING CHARACTERISTICS:

Nylon net bag

Type: For food use

Identification to CSM: As required by the Specification

STORAGE CHARACTERISTICS:

COLD CHAIN

Storage temperature 0-6 °C

17. Emilia-Romagna region fishery products certification

With the aim to improve product quality and to increase competitiveness on the EU market, the Emilia Romagna Regional Authority decided to design a regional brand of certified quality, named “Prodotto Certificato dell’Alto Adriatico – PCAA” (Certified Upper (Northern) Adriatic Product). This collective brand serves to enhance product differentiation based on its origin and production requirements, promote vertical coordination and increase profitability. The beneficiaries of the brand are mainly economic agents, fishing and aquaculture enterprises, processing industries, wholesalers, restaurants and fishmongers.

The purpose of this system’s procedure is to determine and control the critical points of the production, adopting any corrections to non-conformities and at the same time guaranteeing the transparency and traceability of all the transformations that the product has undergone in the supply chain until final consumption.

The specification in question applies to the fishery products according to definition given in the EC Reg. 853/2004, which includes:

- fresh fishery products which are “unprocessed fishery products, whether whole or prepared, including products packaged under vacuum or in a modified atmosphere, that have not undergone any treatment to ensure preservation other than chilling”;
- prepared fishery products as “unprocessed fishery products that have undergone an operation affecting their anatomical wholeness, such as gutting, heading, slicing, filleting, and chopping”;
- processed fishery products as “processed products resulting from the processing of fishery products or from the further processing of such processed products”.

Reg. 852/2004 also defines:

- unprocessed products as “foodstuffs that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed”;

- processing as “any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes”.

This specification concerns the following types of products from fishing:

- fresh;
- prepared;
- processed.

Certain production rules specified by the Regional Authority of Emilia-Romagna region will be outlined in the following subchapters, with an example of the species product of concern for the PRIZEFISH project.

17.1. Legislative and regulatory references

Regulation (EC) No. 178/2002 of the European Parliament and of the Council from 28th of January 2002. lays down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in food safety matters;

- Regulation (EC) No. 852/2004 of the European Parliament and the Council from 29th of April 2004. "On the hygiene of foodstuffs";

- Regulation (EC) No. 853/2004 of the European Parliament and the Council of 29th of April 2004. "Laying down specific hygiene rules for food of animal origin";

- Regulation (EC) No. 854/2004 of the European Parliament and the Council from 29th of April 2004. "Laying down specific rules for the organization of official controls on products of animal origin intended for human consumption";

- Regulation (EC) No. 882/2004 of the European Parliament and the Council from 29th of April 2004. on official controls performed to ensure compliance with feed and food law, animal health and animal welfare rules;

- Commission Regulation EC 2073/05 on microbiological criteria for foodstuffs;

- Decree from 27th of March 2002. "Labelling of fishery products and control systems";

- Agreement from 28th of July 2005.: the agreement between the Minister of Health and the Presidents of the Regions and Autonomous Provinces on the document entitled "Guidelines for traceability of food and feed for public health purposes", aimed at facilitating the implementation of Regulation (EC) No. 178/2002 of the Parliament and of the Council of 28 January 2002;
- Legislative Decree No. 109 from 27th of January 1992. "Implementation of Directives 89/395/EEC and 89/396/EEC concerning the labelling, presentation and advertising of foodstuffs";
- EC Regulation No. 1935/2004 of the European Parliament and the Council, on materials and articles intended to come into contact with foodstuffs and repealing Directives 80/590/EEC and 89/109/EEC;
- UNI EN ISO 22000:2018 Traceability in the agri-food chain - General principles and basic system design and implementation requirements;
- EC Reg. 2065/2001 of the Commission: laying down detailed rules for the application of EC Reg. No. 104/2000 of the Council regarding consumer information in the field of fishery and aquaculture products.

Terms and acronyms

Below are some of the terms and definitions used in the specification.

Clean seawater: natural, artificial or purified seawater or brackish water that does not contain micro-organisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food (EC Reg. 852/2004);

Drinking water: water that meets the minimum requirements set out in EC Regulation 98/83 from 3rd of November 1998., on quality water intended for human consumption;

Food: any substance or product partially processed, fully processed or unprocessed, intended to be ingested, or of which it is reasonably expected that it can be ingested by human beings. Includes drink, chewing gum and any substance, including water, intentionally incorporated in foods during their production, preparation or treatment (EC Reg. 178/2002), including prepared live animals for placing on the market for human consumption;

Extensive farming: the one in which the farmer does not administer artificial fish food;

Central competent authority: the Ministry of Health;

Competent local authorities: the Regions, the Autonomous Provinces, the Local Health Unit Companies;

Marketing: possession and displaying for sale, the listing, sale, delivery or any other form of placing on the market fish products intended for human consumption raw or processed in the European Communities, with exclusion of the direct sale by the coastal fishermen, on municipal market, of small quantities to the retailer or to the consumer, and which need to be accompanied by a sanitary certificate issued by the local health unit territorially competent and subjected to the health checks prescribed for control by retailers;

Retail trade: handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets (Reg. EC 178/2002);

Packaging: the placement of one or more wrapped foodstuffs in a second container, and the latter container itself (Reg. EC 852/2004);

Stages of production, transformation and distribution: any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed (Reg. CE 178/2002);

Packing: the operation intended to protect the products using a wrapper, container or other suitable material;

Food business: any public or private entity, for-profit or non-profit, which carries out any of the activities related to one of the stages of production, transformation and distribution of food;

Lot: the quantity of fishery products obtained in practically identical circumstances;

Means of transport: by motor vehicles, railway vehicles, aircraft as well as the containers onboard the fishing vessels for transportation by land, sea or air;

Non-Conformity (NC): an alleged or real characteristic of the product or production process that does not correspond to what is established by the rules of the system;

Food business operator: a natural person or legal entity responsible for ensuring compliance with the provisions of the food law in the food business under their control;

Batch: a group or series of identifiable products obtained by a certain process in practically identical circumstances and produced in a specified place within a period of definite production;

First marketing: marketing phase subsequent to primary production;

Primary products: products of the primary production including produce of the land, farming, hunting and fishing;

Producer: a natural person or legal entity who professionally raises, fishes and collects fishery products according to procedures provided for by the current legal provisions on the subject;

Refrigeration: the procedure which consists in lowering the temperature of the fishery products so as to approach that of melting ice;

Traceability: the possibility of reconstructing and following the path of a food, a feed, an animal intended for food production or a substance intended or likely to enter to be part of a food or feed, through all stages of production, transformation and distribution;

Establishment: each unit of a company in the food sector.

Identification and labelling of PCAA-marked products

The packaging of the PCAA-marked products besides complying with the legislation requirements in force for all indications, also need to contain an irremovable label made of waterproof material, showing the following information:

- PCAA Brand Authorization No.;
- Fishing or farming location;
- Date of fishing or harvesting;
- The indication "Superior Quality Guaranteed until / / ...";
- Nutritional value (water, proteins, lipids, carbohydrates) and caloric value.

Fishing and harvesting regulations

The manager of the fishing enterprise (owner, chief executive officer, chairman or manager in charge) adhering to the PCAA label may delegate other people to carry out the execution of the activities by appointing a Quality Assurance Manager (RAQ). The fishing boat master responsible for the structure, the installations, the sailors and all the activities that take place on board of the boat can assume the function of the RAQ. Food business operators (FBO) must ensure that fishery products placed on the market for human consumption meet the health and hygiene requirements of the EC Reg. 853/04.

Fishing must be carried out with environmentally-friendly equipment that, as far as possible, minimizes discards, the capture of non-target species and the impact on by-catch species.

The tools used for fishing shall in particular ensure:

- a) selectivity in regard to the commercial size;
- b) low percentage of product damage;
- c) low sediment presence.

Waste resulting from the handling of the product onboard must be stored in appropriate boxes and placed in a position that cannot create contamination of the fish product already sorted and intended for consumption and disposed of according to the regulations in force (EC Reg. 1774/2002).

How fish products are stored immediately after being caught or harvested is of strategic importance for maintaining a quality product throughout the supply chain. Up to this point, the first sorting and washing operations must take place in boxes that are protected from atmospheric agents or in special cells at a temperature that does not affect their quality. Those boxes must comply with all applicative hygiene standards and in particular, shall be such as (EC Reg. 853/2004):

- not to alter the organoleptic characteristics;
- not to transmit substances to the fishery products that are harmful to human health (EC Reg. 1935/2004 and subsequent amendments);
- to be sufficiently solid to guarantee adequate protection of the products.

It is forbidden to pack different fish species in the same container; it is also prohibited to stack boxes containing different fish products. At the landing time, the boatmaster draws up a document accompanying the product.

Wholesale markets and collective auction facilities

These production and marketing units must comply with EC Reg. 852/2004 and EC Reg. 853/2004.

The Director responsible for the structure, the facilities, the personnel and all the activities taking place in the system can assume the function of Quality Assurance Manager (RAQ).

The structure of the premises should at least include:

- 1) Department or functional area where products are stored before inspection and sale;
- 2) Department or functional area where the products are displayed and sold (auction);
- 3) Department or functional area for the storage of the sold product, pending the buyer's collection.

Installations must be kept in good working order at all times by setting up a maintenance programme to prevent them from decaying. Maintenance operations must always be documented. Existing equipment for storage, display, handling and preservation of the product must meet quality requirements.

The consignment of fishery products arriving at the wholesale market or collective auction facility must be accompanied by the document drawn up by the fishing operator stating that the product has been processed and packaged to be sold as PCAA.

Fish processing facilities

Enterprises wishing to join the PCAA circuit must comply with the provisions of EC Reg. 852/2004 and 853/2004 and be duly registered or approved.

The company structure's most important functions are those of the Quality Assurance Manager (RAQ) and the Processing Sector Manager (RL).

The RAQ is directly answerable to the legal representative of the company for the total technical and economic management of the sectors; carries out the planning and organisation of the company's activities, including the constant updating and training of personnel; carries out or arranges for the carrying out of suitable inspections to guarantee the control of the company's entire PCAA system, guaranteeing the achievement of the objectives; plans the self-check activity on the PCAA products.

The RL has the task of supervising all the product processing activities up to packaging; takes care of staff training; guarantees the correct maintenance and operation of equipment and tools; controls the correct execution of the cleaning and sanitising procedures of the premises, operating machines and equipment used in product processing, according to what is established by the plan prepared by the RAQ.

The premises, complying with EC Reg. 853/04, must have at least:

- 1) Department or functional area where fish products are stored before processing;
- 2) Department or functional area where the fish products are processed and packaged;
- 3) A cold room where the product is stored before the transport.

The facility must also have a storage area reserved for the product delivered directly from a boat and awaiting sanitary inspection.

The procedures adopted in the facility that adheres to the PCAA system must be planned, sufficiently detailed, brought to staff's attention, documented and filed in an orderly manner. The RAQ must prepare operational procedures to be applied in cases of non-conformity (NC). Any corrective or preventive action taken to eliminate the causes of actual or potential "non-conformities" must be of an appropriate level about the importance of the problems and commensurate with the relative risks, and documented. NCs are also those that may arise from customer complaints.

The consignment of fishery products arriving at the plant must be accompanied by the document drawn up by the fishing operator as well as the required fiscal document issued by the wholesale market or collective auction facility, or directly by the fisherman. The manager inspects the incoming product and checks that it complies with the specification, then registers it in the "Incoming Products Register", assigning it an internal lot/batch number.

The Plant RAQ takes note of the document accompanying the fish product, verifies its conformity with the PCAA system and gives the appropriate instructions for the subsequent phases of product processing by compiling a paper or computerised "Work Sheet".

The Worksheet must contain:

- a) Lot/batch number assigned at registration;
- b) Name of the species of fishery product;
- c) Date and area of fishing;
- d) Date of delivery of the product to the factory;
- e) Type of processing to which it is to be subjected.

17.2. Molluscs harvesting regulations

Food business operators (FBOs) must ensure that bivalve molluscs placed on the market for human consumption meet the hygiene and health requirements laid down in EC Regulation 853/04. The production areas of bivalve molluscs must be classified in advance by the Regional Health Authority according to the predefined health and hygiene requirements.

Alive bivalve molluscs shall only be conveyed to Dispatch Centres or Purification Centres approved by the competent authority, following Regulation (EC) 852/2004. Each batch transported to the CDM/CSM must be accompanied by the "Registration document for the transfer of batches of alive bivalve molluscs" (MBV Guidelines) drawn up by the collector.

The premises, complying with Regulation (EC) 853/2004 must have at least: a department or functional area where bivalve molluscs are stored before purification; a department or functional area where bivalve molluscs are processed and purified; a department or functional area where bivalve molluscs are stored after purification; a department or functional area where bivalve molluscs are processed and packaged; a department or functional area where the product is stored before dispatch.

The Processing Manager (RL) who receives the product checks that the worksheet's data is correct. If the instructions on the product processing and purification steps are clear, the product processing can begin. The worksheet must be displayed in the department and visible to staff.

If the product does not comply with the PCAA system's specifications during the processing and cleaning operations, the RL must stop the processing and immediately inform the RAQ.

The RAQ must determine whether the non-conformity can be remedied through other product handling operations, or otherwise withdraw the product definitively from the PCAA system, informing the producer.

The NC and the interventions and/or corrective actions taken must be documented and archived.

It is forbidden to process bivalve molluscs belonging to different batches, let alone different species, on the same line at the same time. The processing of different batches must necessarily entail complete emptying of the processing line. The processing phases of bivalve molluscs, up to packaging and labelling, must be carried out without interruption, except as provided for in the specification.

The transport of the goods must be guaranteed against any possible risk of interruption of the cold chain. For this purpose, the person in charge will have to draw up a hazard analysis and codify the procedures to minimise the risk concerning the product as foreseen in art. 5 of EC Reg. 852/04. The transporter is responsible for the correct transport of PCAA products to the customer.

Freezing process regulations

The IQF freezing company that uses PCAA-labelled fishery products, whether bought with a brand or self-certified, must document and keep on record all the supply chain stages that the product has undergone. The date of purchase of the product, the quantity of the product purchased, the date and area of fishing, and the name of the fishing boat are essential elements of knowledge.

Waste management

Processing factories that adhere to the PCAA label must implement separate waste collection and in particular, must document the correct disposal of processing residues as indicated by legislative references.

Table 2. Example of the sardine product details, for species considered for the certification by the PRIZEFISH project.

Product Datasheet by Species

GENERAL COMMERCIAL NAME: European pilchard (sardine)

SCIENTIFIC NAME: *Sardina pilchardus*

PRODUCTION METHOD: Wild capture

FRESHNESS CRITERIA: EXTRA category (EC Regulation No. 2406/96 and subsequent amendments)

MINIMUM SIZE PER PCAA: 12 cm

PACKAGING CHARACTERISTICS:

- within 3 days from the time of fishing

Type: Disposable boxes made of wood, polystyrene or other material suitable for containing this type of food product. The container must be constructed in such a way as to facilitate the evacuation of meltwater.

STORAGE CHARACTERISTICS:

COLD CHAIN

Storage temperature: 0-4 °C

18. References & useful links

- Editorial board. Certificare la qualità delle produzioni ittiche italiane, in «Consortium» 20, 2004. Ed. Qualivita, pp. 16-21.
- Production Guidelines. Certified Product of the Northern Adriatic (PCAA). Emilia-Romagna Region.
- Production Guidelines. Regional Trademark QM - "Qualità garantita delle Marche". Resolution 588, 22/04/2013.
- Tepedino V. Pesci in cerca di un riconoscimento, in «Consortium» 20, 2004. Ed. Qualivita. pp. 14-15.

Useful links

- Guidance documents on the introduction of European hygiene rules, adopted by the Health and Consumer Protection Directorate-General for producers in the food industry
http://ec.europa.eu/food/food/biosafety/hygienelegislation/guide_en.htm
- Herceg Z. (2009): Food conservation processes
(<https://www.tehnologijahrane.com/knjiga/procesi-konzerviranja-hrane>)
- EU Register of National Guides to Good Hygiene Practice for fish and aquaculture products produced in Member States
http://ec.europa.eu/food/food/biosafety/hygienelegislation/good_practice_en.htm
- Codex Alimentarius: business code for fish and fish products
http://www.codexalimentarius.net/web/publications_fr.jsp
- FAO: assessment and management of seafood safety and quality: contains information on HACCP principles) <http://www.fao.org/docrep/006/y4743e/y4743e00.htm>
- Sea fish: guide to good hygiene practice (pelagic, demersal, live crustaceans)
http://rfs.seafish.org/good_practice
- Vujković I, Galić K, Vereš M (2007): Food packaging
<https://www.tehnologijahrane.com/knjiga/ambalaza-za-pakiranje-namirnica>
- EU best practice guidelines for voluntary certification schemes
http://ec.europa.eu/agriculture/quality/policy/quality-package-2010/certification-guidelines_en.pdf
- Guide to the Nutritional Aspects of Fish, Ireland's seafood development agency (BIM)
http://www.bim.ie/uploads/text_content/docs/553Nutritional%20Aspects%20of%20Fish.pdf