



ANALYSIS OF EU AND MONTENEGRO LEGISLATION FOR ORGANIC AQUACULTURE WITH PROTOCOL FOR ORGANIC SHELLFISH BREEDING

University of Montenegro
Institute of Marine Biology Kotor



CONTENT

<i>ANALYSIS OF EU AND MONTENEGRO LEGISLATION FOR ORGANIC AQUACULTURE WITH PROTOCOL FOR ORGANIC SHELLFISH BREEDING.....</i>	<i>1</i>
<i>1. INTRODUCTION.....</i>	<i>3</i>
<i>2. PRINCIPLES AND STANDARDS OF ORGANIC PRODUCTION</i>	<i>4</i>
<i>4. LEGISLATIVE FRAMEWORK IN MONTENEGRO.....</i>	<i>8</i>
<i>5. ORGANIC BREEDING OF AQUACULTURE ANIMALS</i>	<i>9</i>
GENERAL RULES FOR AQUACULTURE ANIMAL BREEDING	9
CULTIVATION PRACTICE IN ORGANIC AQUACULTURE	11
PREVENTION OF DISEASES.....	12
VETERINARY TREATMENT	14
<i>6. ORGANIC PRODUCTION OF SHELLFISH</i>	<i>14</i>
The cultivation of genetically modified organisms (GMOs), as well as animals in which polyploidy is artificially induced, is prohibited.	15
Shellfish handling	15
Special rules relating to shellfish breeding	15
Shellfish spat	15
Stocking density	15
Control of harmful organisms.....	16
Cultivation shellfish techniques	16
<i>7. ORGANIC CONTROL SYSTEM IN MONTENEGRO</i>	<i>16</i>
<i>8. STEPS AND OBLIGATIONS OF ORGANIC PRODUCERS</i>	<i>18</i>
HOW TO BECOME ORGANIC PRODUCER AND WHAT ARE THE STEPS IN THE CERTIFICATION PROCESS?	18
TRANSITIONAL PERIOD	21
CERTIFICATION.....	22
LABELING OF ORGANIC PRODUCTS	22
DECLARATION OF PRODUCTS	23
MANUFACTURER'S RECORDS.....	24
CONTROL.....	24

1. INTRODUCTION

Organic production is a comprehensive system of farm management (aquaculture) and food production, which combines best environmental practices, high levels of biodiversity, conservation of natural resources, application of high standards of animal welfare, and the method of production is in line with the desire of certain consumers to use products that are produced using natural substances and based on natural processes.

Organic production plays a significant dual social role, providing on the one hand a specific market that responds to consumer demand for organic products, and on the other hand providing public goods that contribute to environmental protection, animal welfare and rural development.

Organic production in Montenegro represents relatively young branch of production, while in other part of the world, organic production is fast growing sector, that actually represents the answer on more pronounced disturbed state of the environment, , on worsen food quality and destruction of human healt and increasing threats to human health.

Organic production is regulated by the law, which includes control and certification of production and its products (control “from field to table”), also represents continuous process that is not at easy at al.

Montenegro has good preconditions for development of qualitative, health safe, organically sertificated food, so its neccessary to work on educating all actors.

Good potential for beginning and developing of **organic aquaculture** in Montenegro is evident, first of all taking in account favorable environmental conditions. On the other hand, taking into account the method of farming of shellfish in Montenegro, as well as achieved standards when is the safety of selling products is questioning, it can be said that shellfish have good potential to be first organically certificated aquaculture product in Montenegro.

For these reasons, there is a need to develop the manual (protocol), which can provide necessary informations and to help farmers who intend to engage organic production.

2. PRINCIPLES AND STANDARDS OF ORGANIC PRODUCTION

The best definition of Organic production is through its **goal**, production of **health-safe, qualitative food in an environmentally sustainable way**. The goal of organic agriculture is to improve the health and productivity of interdependent communities, the environment, plants, animals and people.

It means:

- the use of natural resources in sustainable way (“keep and leave” natural resources for future generations);
- development of organic production with preserving of ecosystem;
- maintaining and increasing environmental protection;
- reduction of all types of pollution.

ADVANTAGES OF ORGANIC PRODUCTION:

1. Sustainable production

- reduction of all types of pollution;
- use natural resources on sustainable way;
- keeping ecosystem;
- maintain and increasing quality of water in which the farming is performed;
- preserve autochthonous species.

2. Benefit for breeders

- added value to production – increasing competitiveness on domestic and regional market;

- subventions (Ministry of Agriculture, Forestry and Water Management of Montenegro, various projects aimed at the development of the organic sector);
- possible higher price of products (regulates the market, has strong influence if there is trust between consumer – organic breeder);
- free inspections and certification services (control body "Monteorganica" for producers in Montenegro);
- better standard of producers.

3. Greater guarantee that the products are of better quality and healthier

- certificated product – consumers trust;
- preservation of human health.

DEFICIENCIES OF ORGANIC PRODUCTION:

- greater involvement of producers;
- lack of information and lack of expertise;
- lower yield, in some situations;
- lack of inputs for organic production (disinfectants and veterinary treatment, on the domestic market);
- poor infrastructure;
- higher price of products from organic agriculture - lower purchasing power of consumers.

ORGANIC PRODUCT is:

- controlled;
- certified.

Product of organic production is an organic product only if it has certificate given by an authorized legal entity- control and certification body, which proves that the entire process of production/product is implemented and controlled (production, processing, packaging, storage and declaration) in the manner prescribed by the Law and following regulations on organic production.

PRINCIPLES OF ORGANIC PRODUCTION

1. The principle of health

Organic production should to maintain and increase health of environment, plants, animals, humans and entier planet.

Animal health is maintained by breeding methods that stimulate natural immunity choice of species, hygienic conditions in facilities, etc.)

2. The principle of ecology

Organic production should be based on living ecosystems and cycles, to work with them, to support and help in its sustain.

Production based on evaluation of risk assesment, measures of precautionary and preventive measures.

The use of GMO (genetically modified ormanisms) and products obtained from or with GMO is not allowed.

They should use renewable sources of energy and recycled materials.

3. The principle of justice

Organic production based on fair treatment of nature and the general environment.

Implemtentation of any action that may mislead consumers about the nature of the product is forbidden!!

4. The principle of nurturing and caring

Organic production needs to be managed in careful and responsible way in order to preserve the health and well-being of present and future generations and ecosystems.

3. EU LEGISLATIVE FRAMEWORK

The first Regulation on the production and labeling organic productions in Europe Union was published in 1991 and only included rules for plant production and food from plant origin. After more than 10 years from addoption of the first Regulation, organic production and the EU market have grown

significantly, and conditions for new 'organic' regulation was created, which proved spreading and introducing new products categories, such as aquaculture and wine.

In 2007 was adopted Regulation (EC) no. 834/2007 on organic production and labeling of organic products, while detailed rules for its application with regard to organic production, labeling and control was defined with Regulation (EZ) no. 889/2008. The sets of organic rules starts to apply on January 1, 2009, but without detailed rules for organic aquaculture. After that, in August 2009, was adopted Regulation (EZ) no. 710/2009 which claim detailed rules of organic production of animals and marine algae in aquaculture, as supplement to Regulation (EZ) no. 899/2008, and applies on July 1, 2010 (EZ 2009). It followed by few changes of mentioned organic regulations, regarding dynamic evolution of organic sector, experience gained in application of this rules and new technical and scientific knowledge.

Organic production in the EU is currently regulated by the following acts:

Regulation (EC) 834/2007 of organic production and labelling organic products, defining goals, principles and standards of organic production. Establishing obligatory use of European logo on the packaging of European products and origin of raw materials. The regulation also sets out specific principles that apply to agriculture and which organic production should follow. Many of them are also related to organic aquaculture, and some are specific to aquaculture:

Regulation (EC) 834/2007 of organic production and labeling of organic products, defining goals, principles and standards of organic production. Establishes mandatory use of European logo on product packaging and origin of raw materials. Regulation also states special principles that apply to agriculture and which organic production should follow it. Many of them also related to organic aquaculture, and some of are specific for aquaculture:

- Organic aquaculture must be in line with principle sustainable exploitation of fisheries resources.
- Animal health should be maintain by stimulating natural immune defenses of animals, as well as choosing appropriate species and breeding methods.
- Respecting high levels of animals welfare by respect the specific needs of species.
- Species should be chosen regard to animals ability to adapt to local conditions, their vitality and resistance to disease or health issues.
- It is necessary to maintain biodiversity of natural aquatic ecosystems, the continuous health of aquatic environment and quality of surrounding aquatic and terrestrial ecosystems in aquaculture production.
- Aquatic animals will be fed with food from sustainable exploitation of fisheries resources or organic food that is composed of agricultural ingredients from organic farming and natural non agricultural substances.

Regulation also establishes general rules of production for all categories of products covered by this Regulation: plants, marine alga (seaweed), animals (including all species from aquaculture), processed food and processed food for animals feed. Also, include the criteria for products and substances that can be used in those products, such as fertilizer, additives or products for cleaning and disinfection. The Regulation clearly states that the use of genetic modified organisms „GMO“ and ionizing radiation is prohibited in organic production, including organic aquaculture.

The regulation also, as a general principle, stipulates that the entire farm (farm) is managed in accordance with the requirements applicable to organic production. However, it is still possible to divide the farm into separate production sites, in a way that not all units are managed in an “organic” way, but if there is a proper separation between the sites. Furthermore, in the case of aquaculture, it is possible to grow the same species in an organic and inorganic way, provided that the individual production units are properly separated and that appropriate records are kept showing that separation.

- **Regulation of European commission (EC) no. 889/2008** determine detailed rules for implementing of Council regulation no. 834/2007 on organic production and labeling of organic products that refer to organic production, labeling and control. This regulation is modified and supplemented by other Commission regulations, few of them especially refer to aquaculture: Reg. (EZ) No. 710/2009; Reg. (EU) No. 505/2012; Reg. (EU) No. 1030/2013; Reg. (EU) No. 1364/2013; Reg. (EU) No. 1358/2014; Reg. (EU) 2016/673; Reg. (EU) No. 2017/838 i Reg. (EU) 2018/1584.

Then, at the end of 2011, European Commission was announced revision of organic regulations. This was long-term process, which reached first turning point in 2018, when was adopted new European legal framework from field of organic production 19 of April 2018, by enacting **European Parliament regulation and Commission no. 848/2018**. The aim of this framework is to ensure import only high-quality organic products, increase of organic production in Europe Union, avoid contamination, illegal pesticides or syntetic fertilizers. One of the new elements to be mentioned is obligation to establish free public database to check availability of organic stock(juveniles) on national level. This regulation was modified on 2020, by Regulation 1693/2020. It was envisaged that new rules should enter into force on January 1, 2022.

4. LEGISLATIVE FRAMEWORK IN MONTENEGRO

Organic production in Montenegro is legally regulated and controlled production. Controlling system of organic production in Montenegro is established according to systems of control which is legitimate by European regulations (The regulation of Commission (EC) no. 834/2007 and the regulation of Commission (EC) br. 889/2008), as follows:

- **The law on organic production** ("Official Gazette of Montenegro", no. 56/2013), which entered into force on December 14, 2013. This law regulates production of agricultural and other products by methods of organic production, goals and principles of organic production, rules of organic production, labeling, inspection and certification in organic production, processing, labeling, storage, transport, trade, import and export of organic products, as well as other important questions relevant to organic production.

Beside the law, following bylaw also was adopted, which regulate in more details the goals and principles of organic production. **The bylaw applicable to organic aquaculture are as follows:**

- Rolebook of rules and conditions of organic production for animals of aquaculture and seaweed ("Official Gazette of Montenegro", no. 84/2017), describe in details the method and issue of organic production in aquaculture, as well as duration of transition period (conversion) from inorganic aquaculture production to organic aquaculture production;
- Rolebook of content and size of the organic production mark ("Official Gazette of Montenegro", No. 60/2016)- describe in details appearance of national organic production mark, as well as method of marking;
- Rolebook on detailed content, manner of registration and guidance of the Register of Entities in organic production ("Official Gazette of Montenegro", no. 26/2015)- describe in details the data contained in Register of Entities in organic production, as well as manner of entry and list of documents required for entry in Register;
- Rolebook of manner and methodology performance of professional control in organic production ("Official Gazette of Montenegro", no. 78/2015)- more closely prescribes the manner and methodology of performing professional control, the content of annual report on performed control activities, content and pattern of certificates and documentation attaches to affirm equivalence of certificates when importing the organic products;
- Rolebook of terms and conditions for processing, packaging, transport and storage of organic products ("Official Gazette of Montenegro", no. 83/2016).

5. ORGANIC BREEDING OF AQUACULTURE ANIMALS

Regulations of European Union and Montenegrin legislation containing wide range of rules that refer to breeding of aquaculture animals (fish, crabs, echinoderms and molluscs, as well as rules refers to zooplankton, micro-crabs, rotifers, worms and other species that feed aquaculture animals), in frame of this chapter, only will be covered aspects that can be applied to shellfish breeding.

GENERAL RULES FOR AQUACULTURE ANIMAL BREEDING

General rules for breeding aquaculture animal refer to ensure sustainability of the aquatic environment in which breeding and plan for sustainable management is carried out, as well as rules of simultaneous organic and non-organic breeding of aquaculture animals.

Rules for ensuring sustainability of the aquatic environment (water quality) in which breeding and plan for sustainable management is carried out, implies that:

- Activity of breeding performed on locations that are not susceptible to be polluted by products or substances that are not approved for organic production or pollutants which can endanger organic nature of products.
- Organic and non-organic production units need to be separated. Separation measures for these units, establishes according to natural state, separate systems for water distribution, distance, tides, upstream and downstream position of organic production unit. Authority can choose locations or areas that are not good for organic aquaculture and also they can specify minimal distance between organic and non-organic production units.
- For all new breeding locations which regist organic production of more than 20 tones of aquaculture products, its requires Environmental impact assessment, for detecting the operating conditions of the production unit and possible effects of its operation. If the unit has already been subjected to an environmental impact assessment then its use is permitted for that purpose.
- Entities are obliged to adopt the sustainable Management Plan that is proportionate to production unit. Plan uptades annualy with detailed influence on environment, parameters that need to be monitored and measures that need to be taken to minimize negative influence on environment.
- Entities engage in organic production nedd to use renewable sourses of energy and recycled materials and within sustainable Management Plan preapare schedule of reducing of litter, that need to be establishet at the beginning of organic breeding. Where it is possible, the use of residual heat is limited to energy from renewable sources.

Measures of defence and prevention taken against natural predators, in accordance with European Union and national rules, need to be included in sustainable Management Plan.

When organic and non-organic breeding of animals is simultaneous, could be performed in same facility, when it comes to hatcheries and breeding ground, need to be clear physical distance and special water distribution system.

In case of production to consumption, competet authorrity can allow existence of organic and non-organic units for breeding aquaculture animals in the same facility under condition that exist clear physical distance and special water distribution system, as well as involveing different production steps and different handling period with animals from aquaculture (taking into account the existing farming systems in Montenegro, this possibility is predominantly related to freshwater fish farming).

ORIGIN OF ORGANIC AQUACULTURE ANIMALS

Organic aquaculture implies the use of local (autochthonus) species and breed using species that are more adapted to the breeding conditions, good health and use of resources of food. Choosing species which can breed without significant bad effects on wild fund.

The cultivation of genetically modified organisms (GMO) is prohibited, as well as animals in which polyploidy is artificially induced.

For the purpose of reproduction (breeding) or to improve the genetic stock and when there is not enough organic animals from aquaculture, animals can be introduced from wild fond (caught) or non-organic animals from aquaculture. Such animals need to be hold under the condition of organic production for least 3 months before they can be used for breeding .

CULTIVATION PRACTICE IN ORGANIC AQUACULTURE

Farm for aquaculture animals need to be designed in accordance with their specific needs and to carried out:

- 1) in suitable environment for living in accordance with specific needs of farmed specie;
- 2) in aquatic ecosystem of good quality, sufficient amount of oxygen, in accordance with specific needs of farmed specie;
- 3) in suitable temperature and amount of light in accordance with specific needs of farmed specie and appropriate geographic location.

The stocking density of breeding animals is determined based on specie or group of related species.

In the system for aquaculture animals production, the flow and physico-chemical parameters of water should ensure health and welfare of animals, while production system need to be projected, located and managed in manner that reduce escaping of aquaculture animals.

Closed recirculation of water in facilities for aquaculture animal production can be used only in case of hatcheries and breeding grounds or production of species that is used as food for animal from organic production.

For the systems for organic breeding aquaculture animals, it should:

- 1) be situated on location where flow of water, depth and water mass circulation lead to reduction of influence of seabed and surrounding water mass.
- 2) in relation to environmental expose, it has appropriately designed, built and maintained holding system.

Natural water springs can be used for heating or cooling in all production stages, while artificial heating and cooling of water is possible only in case of hatcheries and breeding grounds

Handling animals from aquaculture need to be kept in minimum and done with attention, with use of appropriate equipment, in order to avoid stress and physical damage.

For organic breeding of aquaculture animals, artificial lighting can be used:

- 1) to extend daylight but not exceeded maximum of 16 hours of daylight in order to respect ecological needs, geographic conditions and health of breded animals, only if the artificial lighting is used for reproductive purpose.
- 2) in order to avoid disturbing effects of changing light intensity, can be used dim or back light.

Aeration of water is performing when exist health need and in critical periods like reproduction or transport as follows: 1) during increasing of temperature, decreasing of atmospheric pressure or pollution; 2) during sampling or sorting; 3) in case of ensuring of survival of animals.

Mechanical aerator, used for water aeration, is powered from renewable sources of energy.

During organic breeding, use of hormones and their derivatives is prohibited.

In the cultivation of organic spat, as food for animals it can be used non organic phytoplankton and zooplankton.

PREVENTION OF DISEASES

Prevention of aquaculture animals disease is based on keeping the animals in optimal conditions, provide appropriate selection of location, organization of production units, regular cleaning and disinfection of facilities, using high quality food (if it is applicable to the type of breeding), maintain appropriate density during breeding and appropriate choice of breeding species.

Each breeding ground should have written agreement with qualified institution which are responsible for animal health that going to visit the farms at least once a year or once at two years in case of shellfish breeding.

Only following products can be used for cleaning and disinfection:

Table 1. Cleaning and disinfecting substances for equipment and facilities in which aquaculture animals are not present (in absentia) are:

In accordance with Regulations on more detailed rules and conditions of organic production for aquatic animals and marine	In accordance with latest modifications to Regulation 889/2008
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algae (seaweed)	
1) ozone 2) sodium chloride 3) sodium hypochlorite 4) calcium hypochlorite 5) lime (CaO, calcium oxide) 6) caustic soda 7) alcohol 8) hydrogen peroxide 9) organic acids (acetic acid, lactic acid, citric acid) 10) humic acid 11) peracetic acid 12) iodophores 13) copper sulfate - used until December 31, 2015 14) potassium permanganate 15) peracetic and peroctanoic acid 16) tea obtained from natural camellia seeds (use limited to shrimp products);	1) ozone 2) sodium hypochlorite 3) calcium hypochlorite 4) calcium hydroxide 5) lime (CaO, calcium oxide) 6) caustic soda 7) alcohol 8) copper sulfate - used until December 31, 2015 9) potassium permanganate 10) tea obtained from natural camellia seeds (use limited to shrimp products); 11) a mixture of potassium peroxymonosulfate and sodium chloride for the production of hypochlorous acid

Table 2. Substances for cleaning and disinfection of equipment and facilities used in presence of aquaculture animals:

In accordance with Regulations on more detailed rules and conditions of organic production for aquatic animals and marine algae (seaweed)	In accordance with latest modifications to Regulation 889/2008
1) limestone (calcium carbonate) for pH control 2) dolomite for pH correction (use limited to shrimp products).	1) limestone (calcium carbonate) for pH control 2) dolomite for pH correction (use limited to shrimp products). 3) Sodium chloride 4) Hydrogen peroxide 5) Sodium percarbonate 6) organic acids (acetic acid, lactic acid, citric acid) 7) humic acid 8) peroxyacetic acid 9) peracetic and peroctanoic acid 10) iodoform (eggs only)

Also, it requires rest of facilities after each production cycle, before next use, during rest perform emptying and disinfection production installations, however this activity is not obligatory for shellfish breeding.

Ultraviolet light and ozon can be used only in hatcheries and breeding grounds.

VETERINARY TREATMENT

For the cure of aquaculture animals can be used substances of plant, animal or mineral origin in homeopathic solution, plants and their extracts which do not have anesthetic effect and elements in traces, metals, natural immunostimulans or probiotics.

If use of aforementioned substances is not effective in curing of disease, it can be used allopathic treatments, including antibiotic, used twice a year, or one treatment per year in case of animals which production cycle is shorter than one year. In case of exceeding limits of allopathic treatments, aquaculture animals cannot be placed in the market as organic products.

Treatment against parasites is performed in two treatments per year, one treatment per year when the production cycle is shorter than 18 months, excluding treatment which is a part of necessary health care program.

After performing of allopathic veterinary treatments and treatment for parasites, as well as treatment which are included in mandatory health care program, withdrawal period lasts twice longer than withdrawal period in non organic production regard to instructions from drug manufacturer. When the withdrawal period is not determined in instruction drug, the same lasts 48 h.

In case of treatment with veterinary medical products, before placing aquaculture animals on the market, control body is notified, and treated animals are labelled.

6. ORGANIC PRODUCTION OF SHELLFISH

Organic production of shellfish can be performed by company or entrepreneur, first of all if satisfies precondition to have valid licence for mariculture issued in accordance with Law on Marine Fisheries and Mariculture

Species selection

Organic aquaculture involves the use of local (indigenous) species and breeding that focuses on species that are more adapted to the conditions of cultivation, good health and good use of food resources. Species that can be bred without significant damage to the wild fund are selected.

In this sense, the two indigenous species of shellfish currently grown in Montenegro: mussels (*Mytilus galloprovincialis*) and oysters (*Ostrea edulis*) *are fully suitable for organic farming*.

The cultivation of genetically modified organisms (GMOs), as well as animals in which polyploidy is artificially induced, is prohibited.

Shellfish handling

Shellfish handling should be reduced to minimum and performed carefully, with use of appropriate equipment in order to avoid stress and physical damage.

Special rules relating to shellfish breeding

Organic shellfish production can be performed in the same aquatic environment, as organic fish production, seaweed and sea snails, regarding to it can be done in **polyculture**.

Organic production of shellfish carried out in aquatic environment that are: 1) clearly marked with signs or with buoys, 2) organized in a way which does not endanger survival of other species (especially species)

Shellfish spat

Organic spat are used for organic cultivation at production unit.

In organic production of shellfish can be used wild spat for cultivation that do not have originate for organic production units, under following conditions: 1) come from area in which quantity of spat exceed ecosystem needs; and 2) comes from collectors for natural spat.

Its necessary to have notes about how, where and when were collected, in order to ensure their traceability all the way to the collection area.

Stocking density

In organic production, it is used the same density of spat as it is used for non organic cultivated shellfish in same area. Sorting, diluting and adjusting the density will be performed in accordance to biomass as to ensure animal welfare and high quality of products.

Control of harmful organisms

Biofouling organisms are removed physically or manually and when it is possible, return to the sea far away from shellfish farm. During one cultivation cycle, shellfish can be treated with lime solution in order to control competitive biofouling organisms.

Cultivation shellfish techniques

Cultivation practice eligible for organic production implies the use of following cultivation techniques: System of buoys and ropes (cultivation on floating parks), rafts, bottom cultivation, bags from net, cages, lanterns and other cultivation systems.

For shellfish raft cultivations, number of falling ropes (pergolar) should not exceed one pergola per square meter of surface.

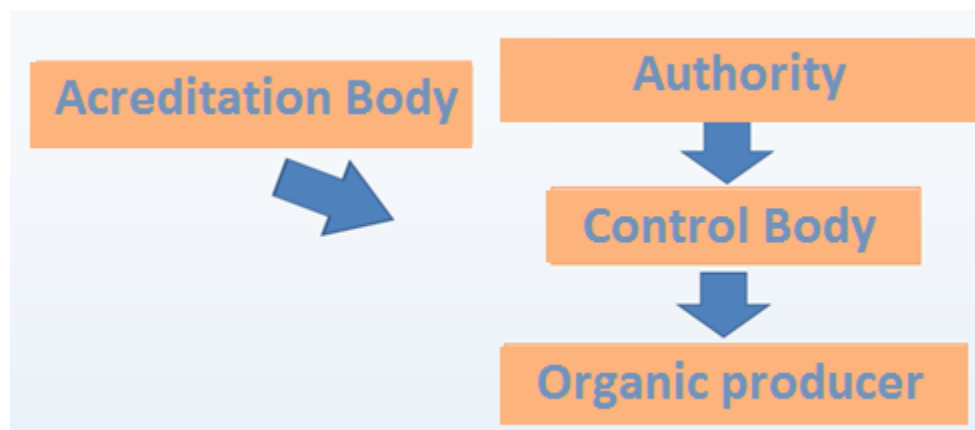
The maximum allowed length of falling rope is 20 m.

Thinning of the pergolar should not be done during the production cycle, while the distribution of the pergolar can be done, but in this way not to increase the prescribed holding density.

In aforementioned, shellfish cultivation techniques currently used in Montenegro, *are fully suitable for organic farming*

Cultivation of shellfish at sea bottom is allowed only if it does not have significant influence on environment at the area of collection and growth.

7. ORGANIC CONTROL SYSTEM IN MONTENEGRO



INSTITUTIONAL FRAMEWORK

➤ **Competent authority**

Ministry of agriculture, forestry and water management, create and implements policies in field of organic production. In terms of Regulation Council (EC) no. 834/2007, the Ministry has the role of competent authority.

Ministry of agriculture, forestry and water management in accordance to Law of organic production have following responsibilities:

- Issue authorization to control bodies (legal entity for performing determination activities of compliance with requirements to establishing of organic production, control of the application of organic production methods and issue certificates for products made by methods of organic production.
- Keeps records of control bodies authorized to perform control in organic production;
- keeps a register of entities in organic production;
- Implements supporting program to organic production;
- Supervise the implementation of the Law of the organic production, through agricultural inspectors.

➤ **Control body**

In accordance with Law of organic production, determining the compliance with requirements for establishing of organic production, control of implementing methods of organic production and issuing authorization to products obtained by methods of organic production perform legal entity- control body authorized by Ministry of agriculture, forestry and water management.

Requirements that legal entity need to fulfill to perform control and certification at organic agriculture are:

- That is registered in the Central Register of economic entities;
- That is accredited in accordance to standard standard MEST EN 45011, to has certificate of accreditation issued by Accreditation body of Montenegro in accordance with required Montenegrin, European and international standards,
- That fulfills requirements in the way of technical equipment and professional staff;
- That have the standard protocol of control that perform and which contain detailed description of control measures and precaution measures for which legal entity undertakes to apply to entities subject to its control;

- That have measures which going to applies when find irregularities or/and delicts.

Until now, one legal entity –control body „Monteorganica“ d.o.o. is authorized by Ministry of agriculture, forestry and water management and accredited by Accreditation Body for activities of control and certification in organic production for: primary production (plant production, animal husbandry, beekeeping and collection of wild plants and forest fruits) and processing of organic products. On the other hand, control body „Monteorganica“ d.o.o. still not accredited for control and certification in organic aquaculture.

Control body is in oblique to keep list of entity under its control, that contains: title and seats, or name and address of subject which it publishes on its webpage, also had obligation to send the entity list to the Ministry by January 31, that was controlled in the previous year.

8. STEPS AND OBLIGATIONS OF ORGANIC PRODUCERS

HOW TO BECOME ORGANIC PRODUCER AND WHAT ARE THE STEPS IN THE CERTIFICATION PROCESS?

Step 1

Education on methods of organic production which includes and good knowledge of the regulations that governing organic production in Montenegro: the Law of organic production and regulations established in accordance to the Law.

Step 2

Decision on engaging in certificated organic production.

Establish the decision after education to: allowed cultivation methods for production, understanding the regulations which governing organic production, as well as obligations carried bz this type of production.

Step 3

Engaging in certificated organic production.

It is necessary to get involved in process of organic production, producer who intends to get involved in organic production need to inform about authorized controll bodies. In accordance with the Law of organic production, Ministry of agriculture authorize control bodies to performing activities of control and certification in organic production. The list publishes in Official Gazzete or on website of Ministry of agriculture.

“Monteorganica” d.o.o. is controlling organization by Ministry of agriculture, Forestry and Water management and accredited by Accreditation Body of Montenegro to perform professional control and certification of organic production for certain types of production.

Step 4

Contact the authorized control body in order to get an application for engage in organic production.

The procedure for involving the producer in organic production starts with apply that producer claim to authorized body. The breeder fills the application and application documentation (if its prescribed) and submit it to the control body.

When it comes to the control body “Monteorganica” d.o.o., is issued the obligation to submit the application by April 1 (for those who apply for the first time and for those who are already in the certification process), otherwise, the control will not be done. Application submitted after the deadline are rejected, except in cases when the delay was caused due to force majeure (illness, professional disability or death of breeder owner, natural disaster, emergency on regional level). In that case, it is necessary to submit the evidence to Certification body within 15 days from the occurrence of force majeure.

For the apply to control body “Monteorganica” d.o.o. uses application forms for specific area of organic production, however the application documents for the area of organic aquaculture has not been defined yet.

Step 5

The certification body reviews the application form, checking the documentation and fulfilment of the conditions for accepting the application.

In case of incomplete documentation, the breeder has deadline to complete it. However, the certification body can reject the apply for certification, and some of reasons can be: incompleteness and untimeliness of the application; the products do not belong in categories defined by the Law of organic production; the products are not intended for placing on the market; the application for certification of product for which certification body is not authored or do not have appropriate completeness; if the production implementing near polluter and have not submitted proves of absence of product contamination or if it applies the production that has not been established yet.

Step 6

Conclude the contract with authorized control and certificated body.

If the application submitted to control body is acceptable, producer and control body conclude an agreement on performance of control and certification in organic production. Linked to that, the producer receive code under which is signed in the register organic producers of the Certification body. After concluding the contract, the producer is involve in organic production and begins the period of conversion in organic production.

Example of the contract with “Monteorganica” d.o.o. can be found in [Annex 2](#) of this document.

Step 7

The controllers of the Certification body performing Initial control and compile the report on control.

The controller „Monteorganica“ d.o.o, with producer concluding appropriate time for performance of initial (first) control. Controllers go to the field at agreed time and control the entire shellfish farm of registered producer during which, observe current state at field, check the datas from application and perform the evaluation of level of accordance with organic production rules.

The controllers, current state and results of control, note in reports of control and on the bases of which the decision on certification is made. The producer is left with a copy of the report with the identified non-compliances, the proposal of the corrective measure by the manufacturer and the set deadlines for its implementation.

Step 8

Making a decision on certification status

The decision on certification is the final assessment and is made on the basis of control results and other available information: data from the application documentation, submitted evidence of non-compliance, etc.

The certification body shall inform the manufacturer of the certification status in the Certification Report or the relevant Decisions.

Decision on issuing a certificate Certification body "Monteorganica" d.o.o. adopts after fulfilling the following conditions:

- *Supervisory control did not identify major non-compliances*
- *Evidence was submitted within the set deadline on the implemented corrective measures for identified non-compliances, the elimination of which was a condition for the issuance of the certificate*
- *submitted form Yield report Z 2.7 (statement that it has products for the market)*
- *submitted example of declaration and method of product labeling*
- *submitted proof of payment of the fee for issuing the certificate.*

Step 9

Entry in the register organic agriculture of

In case of a positive certification report, the producer is obliged to register in the register of organic production kept by the Ministry of Agriculture, Forestry and Water Management. Entry in the Register is made on the basis of the request of a legal or natural person which is in **Annex 2** of this document. The following documentation is attached to the request:

- 1) report of the control body on the fulfillment of the conditions for the inclusion of the subject in the process of organic production;
- 2) proof of registration of the subject in the appropriate register of producers (register of the Food Safety, Veterinary and Phytosanitary Administration and Mariculture License); i
- 3) certificate of registration from the Central Register of Business Entities.

Step 10

Issuance of certificates

The control body issues a certificate as confirmation that the methods of organic production have been implemented, ie that the product, as a result of such production, is organic. The certificate for organic products is issued after the full expiration of the transitional period.

From the Certification Body "Monteorganica" d.o.o. the manufacturer received with the Decision on the issuance of the certificate, the Certificate and the obligatory attachment - the List of certified products. The List of Certified Products contains data on all certified products, quantities and statuses (transition period or organic).

The form of the certificate is defined by the Rulebook on the manner and methodology of performing professional control in organic production ("Official Gazette of Montenegro", No. 78/2015) and is in **Annex 3** of this document.

TRANSITIONAL PERIOD

A transition period (conversion) is a certain period of time required for the transition from non-organic to organic production and in which organic production methods are applied.

The transition period is the time necessary to establish a farm management system, and the producer gains experience in applying organic production methods. The transition period may be shortened and extended depending on certain conditions: specific environmental factors, compliance with the prescribed requirements or internal rules of the Certification Body, as well as the professional and managerial skills of the manufacturer.

After the conclusion of the contract between the producer (entity) and the authorized control body, the producer is obliged to apply the methods of organic production and perform the production in accordance with the regulations on organic production. The transitional period begins from the day of concluding the contract. All means used in production must be in accordance with the permitted for organic production and are in the annexes to the Ordinance on detailed rules and conditions of organic production for aquaculture animals and seaweed ("Official Gazette of Montenegro", No. 84/2017)

The transition period for the transition from inorganic aquaculture production to organic aquaculture production is:

- 1) 24 months, for facilities that cannot be dried, cleaned and disinfected;
- 2) 12 months, for facilities that can be dried;
- 3) six months, for facilities that can be dried, cleaned and disinfected;
- 4) **three months, for facilities in the open system, including facilities for the production of shellfish.**

Animals and products of animal origin produced in the transitional period may not be placed on the market or advertised with organic production labels.

CERTIFICATION

In order for organic products and their producers to be different from others, for them to be able to exercise their rights to certain incentives and for consumers to be protected, certification of organic production is necessary. Certification of organic agriculture is certification of production methods.

Certification is a procedure on the basis of which the authorized control body issues a written certificate confirming that the organic product or production process is in accordance with the Law on Organic Production and regulations adopted on the basis thereof. The certificate must contain: the name of the entity, the type or list of products and the period of validity of the certificate.

*Manner of invoking the certification and use of the Certificate, the control body "Monteorganica" d.o.o. defined in the document Rules of use of the certificate P.4., which is in **Annex 4** of this document.*

In case of non-compliance with the Law and accompanying regulations on organic production, internal procedures of the certification body and the Contract on control and certification and the conditions prescribed by them, **the certificate may be suspended or revoked!**

The producer is also subject to the penal provisions prescribed by the Law on Organic Production and the internal procedures of the certification body.

LABELING OF ORGANIC PRODUCTS

Product labeling represents the use of:

- The terms "organic", "organic", "biological" or their abbreviations ("eco", "bio", "organic") or a statement that a product from the transition period is on the product or advertising material,
- Logo "Organic product of Montenegro".

A **logo** is a mark on a product that is an indicator and confirmation that the product is organically certified in accordance with certain standards and serves to facilitate product identification.

The national mark guarantees that the product has passed the control process and that it has been certified in accordance with the regulations by the certification body (authorized control body) controlled by the Ministry of Agriculture, Forestry and Water Management.

Organic products that are certified in accordance with the Law on Organic Production bear the domestic logo (sign of organic production), which is used in the labeling, advertising and presentation of organic products:



The logo may not be used for products in transition. Also, when labeling the product, the name of the control body to whose control the entity with which the final phase of production or preparation was performed and the number of the certificate are subject must be stated.

DECLARATION OF PRODUCTS

The declaration of organic products must contain:

1. Name (name and surname / name of the company) of the manufacturer;
2. Name of the product (with the prefix ORG, BIO, EKO or organic, biological, ecological);
3. Year of manufacture;
4. Number of the Decision under which the producer is registered in the MAFRD (Ministry of Agriculture, Forestry and Water Management) as an organic producer;
5. Certificate Number;

6. Sentence: "Control of organic production performed by" Monteorganica "d.o.o Podgorica, no. Decisions 060-313 / 07-0205-55 MAFWM

7. Logo "ORGANIC PRODUCT OF MONTENEGRO"

MANUFACTURER'S RECORDS

The producer is obliged to keep records on the manner of applied methods of organic production in the production of organic products and keep all documentation on activities in organic production (purchase of inputs and sale of products - invoices, receipts, declarations, etc.). The manufacturer is obliged to present all of the above, at the request of the certification body or controller during the control process.

The Rulebook on the Manner and Methodology of Professional Control in Organic Production ("Official Gazette of Montenegro", No. 78/2015) prescribes the records that the breeder is obliged to keep, and which when it comes to breeding aquaculture animals, **ie for shellfish farming it is necessary is to keep the following records:**

- the origin, the beginning of the transitional period for aquaculture animals coming to the holding, as well as the date of arrival;
- number of lot, age, weight and destination of aquaculture animals leaving the holding;
- veterinary treatment, with information on the purpose, date of application, method of application, type of product and withdrawal period;
- disease prevention measures, before production, purification and water quality.

CONTROL

Control is the process of determining the compliance of reported production with regulations for organic production (Law and regulations on organic production). Organic production is subject to expert control, which is determined on the basis of an assessment of the risk of non-compliance with the rules established by the Law on Organic Production. Entities are subject to expert control at least once a year. Expert control may be performed by a control body authorized by the Ministry

Types of control:

1. **first (initial) control** - entire farms / farms;
2. **regular inspections** - announced or unannounced. They are carried out at least once a year according to the Annual Control Plan;

3. **extraordinary controls** - announced or unannounced. They are carried out according to the Annual Control and Risk Assessment Plan. The control body conducts 10% of extraordinary controls annually (*out of the total number of manufacturers registered with the control body "Monteorganica" d.o.o.*).

Documentation and records. The control body performs professional control of organic production on the basis of the submitted request and verification of documentation and records kept by the subject of control and which contains:

- 1) description of the production unit (farm), ie activity;
- 2) measures implemented at the level of the production unit for organic production;
- 3) measures taken to reduce the risk of pollution by illicit products or substances in organic production and implemented measures in storage facilities and at all stages of organic production;
- 4) list of legal or natural persons with whom a contract has been concluded for the distribution, storage, transport, packaging and processing of organic products.

In addition to the above data for performing professional control in the production of aquaculture animals, the production entity also submits:

- 1) data on the capacity of fish farms and other aquatic organisms;
- 2) environmental impact assessment, as appropriate.

Expert controls are performed before and during the production of maximum shell biomass.

In the procedure of professional control, the financial documentation is checked for the purpose of control:

- 1) supplier, ie seller or exporter of organic products;
- 2) types and quantities of organic products delivered to the production unit, raw materials and additives purchased, used, including the composition of animal feed;
- 3) types and quantities of organic products stored;
- 4) types and quantities of organic products placed on the market, ie customers, as well as premises or storage facilities;
- 5) types and quantities of purchased and placed on the market organic products, suppliers, sellers or exporters;

6) other documentation at the request of the control authority or control body.

Description of control. Prior to the start of the inspection, the inspector informs the producer about the details of the inspection, inspection of the farm (breeding installation, warehouses, facilities, documentation) and collects information received from the producer, visual inspection and based on the above documentation and records.

During the control, the controller collects evidence, photo-documentation and can take samples for analysis based on the order of the control body or his own decision in case of suspicion of violation, ie. non-compliance. Sample testing is performed by laboratories with which the Certification Body has a contractual relationship. The costs of the analysis are borne by the producer, with the possibility of reimbursing half of the total costs, based on the measure of the Agro-budget allocated for this purpose.

After the control, the control body is obliged to make a report and submit it to the Ministry and the subject of control within 30 days, ie if it finds that there has been non-compliance with the rules or suspects non-compliance with the rules to inform the Ministry and the subject of control.

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REGIONE PUGLIA

Puglia Region, Presidency-Health Marketplace



Molise Region



Univerzitet Crne Gore- Institut za biologiju mora



Crna Gora
Ministarstvo poljoprivrede i ruralnog razvoja

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