



Food and Agriculture
Organization of the
United Nations



European Bank
for Reconstruction and Development

GENERAL AND SPECIFIC REQUIREMENTS FOR THE REGISTRATION, HYGIENE AND EQUIPMENT OF FACILITIES FOR FOOD PRODUCTION AND PROCESSING

in collaboration with



MONTENEGRO

MINISTRY OF AGRICULTURE
AND RURAL DEVELOPMENT



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MINISTRY OF SUSTAINABLE
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REGIONALNA RAZVOJNA AGENCIJA
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ABBREVIATIONS

HACCP	Hazard Analysis and Critical Control Points
GMP	Good Manufacturing Practice
GHP	Good Hygienic Practice
DFH	Decree on Food Hygiene (Official Gazette of Montenegro, No 13/2016)
DSRHPAO	Decree on special requirements for hygiene for products of animal origin (Official Gazette of Montenegro, No 32/2016)
LFS	Law on Food Safety (Official Gazette of Montenegro, No 57/2015)

PURPOSE AND USE OF THE BOOKLET

The primary objective of this booklet is to inform and support the producers and food processors of the existing legislation on food safety and good hygienic practices, and their obligations for placing safe products on the market.

The booklet includes:

- Glossary of terminology
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- What are the legal requirements for all food business operators
- How food business operators can meet the prescribed requirements;
- Application of the flexibility criteria the possibility of adapting or applying the prescribed rules in terms of the construction; arrangement and equipping of facilities with a small volume of production (flexibility).
- List of relevant institutions and contacts
- List of Legal references

DEFINITIONS

- Cleaning is the elimination of visible impurities.
- Disinfection is the use of physical, chemical or mechanical means to eliminate, all forms of microorganisms, above all vegetative.
- Disinfection and pest control is the destruction of insects and rodents.
- Entrepreneur as a legal basis for registration includes a natural person that: (i) performs business activities on his own account for the purpose of gaining profit; (ii) is liable with all its property for business activities; (iii) has to be registered within Central Registry of Business Entities for statistical purposes.
- Food business is a profitable or non-profitable activity, public or private, which covers all stages from production, to processing and distribution of food.
- Food business operator is any company, other legal person, entrepreneur or natural person responsible for the implementation and carrying out prescribed requirements for ensuring safety of food and feed within their businesses.
- Food hygiene is a set of measures and conditions necessary to control hazards and ensure is appropriate for consumption.
- Food safety is the absence of biological, chemical and physical hazards that could harm consumer health.
- Good hygienic practice (GHP) is a set of procedures that manage the hygiene of the working environment and ensure basis conditions for the production of safe food.
- Good Manufacturing Practice (GMP) is a set of procedures that govern the working environment and provides the basis for the production of safe food.
- Hazard Analysis Critical Control Point (HACCP) is a method to identify assess and manage possible risk and hazards that are of important for food safety.
- HACCP Plan is a document that serves to control the dangers of importance for the food safety of a given entity (plant, production line) and it is made in accordance with the HACCP principles.
- Hazard/danger is a biological, chemical, or physical agent in food or feed material that can harm human health.
- Natural person as a legal basis for registration is a person that is an individual human being, as opposed to a legal person, which may be a private (i.e., business entity or non-governmental organization) or public (i.e., government) organization. Montenegro allows individual producers

(natural persons) to be food business operators, food processors, provided they have approved establishments and processing facilities

- Production, processing and food distribution is any phase, including food import, starting from food production to food storage, transport, sale or supply to the end consumer.
- Risk is the possibility of a harmful effect on health and the consequences to human health.
- Traceability is the possibility to trace food, feed and animals that are used for food production. raw materials that are intended to be used in all phases of production, processing and food distribution.
- Washing is the complete removal of impurities.

THE MAIN PRINCIPLE OF FOOD SAFETY CONTROL- SYSTEM OF SELF REGULATION

Food contamination is a significant source of diseases and constitutes a major problem for public health. Food-related diseases cause high socio-economic damage, a negative impact on trade and tourism, and reduce consumer confidence. Therefore, in the modern food system special attention is placed to the safety of products. Modern food safety systems focus on the hygiene of working conditions and operating procedures.

1) The Montenegrin existing law places the primary responsibility for food safety on the food business operators (FBO).

The regulations set out the obligations to establish, implement and maintain a self-control system based on Hazard Analysis and Critical Control Points (HACCP) principles or the implementation of good manufacturing and good hygienic practices, while performing. The fulfilment of general conditions of hygiene of food related to:

**Arrangement of the
production spaces**

**Waste disposal
management**

**Water supply and waste
water management
system**

Production equipment

**Hygiene, training and
health of the employees**

Transport



GENERAL REQUIREMENTS FOR THE FOOD BUSINESS OPERATORS

There are prerequisite programs that are obligatory requirements to produce safe food. They consist of Good Manufacturing Practice (GMP), Good Hygienic Practice (DHP) and Standard Operational Procedures (SOP). The main features are presented in the box below

GMP	GHP	SOPs
<ul style="list-style-type: none"> • GMP is the set of recommendations that must be implemented in production, processing, storing and distribution of food in order to prevent microbiological, chemical or physical contamination of the product. • In other words, GMP indicates what is necessary to be done to prevent the food contamination, who should do it and when it should be done. • GMP is not related to particular risks and factors, so not adhering to it would not necessarily jeopardize the health of the consumers, but it would increase the risks linked to food safety. 	<ul style="list-style-type: none"> • Cleaning and sanitation have very important places within the prerequisite programmes and are main elements of the good manufacturing practice. • GHP is a set of procedures that ensures a clean environment for production, processing, storage and distribution of food at the market. In other words, GHP defines what is necessary to be done regarding cleaning and hygiene, as well as who needs to act and when to implement these tasks. 	<ul style="list-style-type: none"> • SOPs are step by step procedures on how to do something that is critical to safety, quality and/or security.
Topics/areas of application	Topics/areas of application	Topics/areas of application
<ul style="list-style-type: none"> • Establishment and premises: location, infrastructure, layout, equipment, maintenance and working environment (temperature, ventilation, lighting) • Employees/staff: organization structure, Job description, structure and working tasks, application of working procedures, training • Equipment: construction, installation, technical maintenance and calibration • Raw material: live animals, raw material, additives, materials for packing • Traceability of products: including their recall from the market • Documentation 	<ul style="list-style-type: none"> • Cleaning and sanitation of the rooms and equipment • Health and hygiene of the employees that are involved in tasks of food production, processing and distribution • Hygiene of the raw material for production including health of live animals • Packed, marked and stored materials as well as means and substances for sanitation, application according to instructions and documented procedures 	<ul style="list-style-type: none"> • Standard operating procedure (SOP) for personal hygiene • SOP for cleaning and sanitation of premises (SSOP) • SOP for sanitation of filling machine (SSOP)

2) The HACCP system prevents the occurrence and/or control of a problem that can endanger hygiene and safety at any point of business along the food chain.

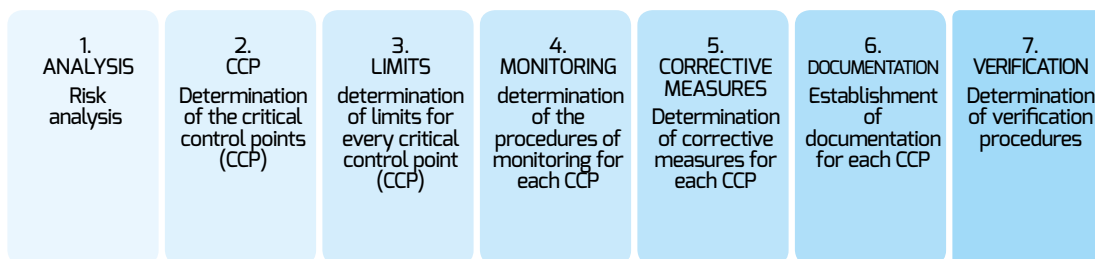
Food safety management plan:

- PLAN what needs to be done to ensure food safety
- DO what you are planned to do to ensure food safety
- CHECK that you are doing what you planned to do to ensure food safety and write down what was checked and when
- ACT to correct any food safety problems and write down what has been done about the problem and when

The Risk Analysis and Critical Control Points (HACCP) is required by the Law on Food Safety No. 57/15

The effective use of HACCP is linked to the compliance of principles of Good Manufacturing Practice (GMP) and Good Hygiene Practice (GHP). These two norms ensure the adequate application of the hygienic principles.

The HACCP system acts as a preventive tool in advance to anticipate possible risks and hazards and ways of controlling them, and it is characterized by 7 principles presented in the below diagram:



The microbiological criteria for food safety for all types of food are set in the Rulebook on microbiological criteria (Official Gazette of Montenegro, No. 26/2016”). The aim of the legislation is the production of safe food and this is achieved through the identification and effective control of food-related risks. The most important food hazards are those microorganisms, primarily bacteria, that can cause various diseases in humans who consume contaminated foods, and fatalities are often noticed.

Producers and food business operators in general must include in the self-control plan all required microbiological criteria and other microbiological requirements specific to food business. The Rulebook determines the

frequency of sampling for specifically:

- carcasses,
- minced meat,
- meat products,
- mechanically separated meat and fresh meat,

All food business operators are obliged to include such a sampling frequency in their self-control plan.

The frequency of sampling foreseen by its plan by the FBO is necessary to verify the competent authority that performs official controls.

Positive effects of the HACCP systems introduction:

- For food business operators: production of safe food, less business risk, improved competitiveness; better work organization and use of time
- For consumers: decreased risk of food borne diseases and more confidence in food safety and quality
- For institution: economic and reliable control of food safety



PROCEDURES FOR REGISTRATION OF FACILITIES DEALING WITH FOOD PRODUCTION AND PROCESSING

The food business operator is obliged to submit a request for registration of the establishment to the Food Safety Authority, before commencing the activity in the facility subject to the Registration. The registration of facilities is regulated by the Rulebook on the way of registration and management of the central registry of registered and/or approved facilities for the production, processing and distribution of food or feed (Official Gazette of Montenegro 39/2017).

The registration process and the necessary documentation are detailed below:

- **Procedure for submitting a request for approval of facilities in food business – Information booklet** (<http://www.ubh.gov.me/vijesti/174686/Uputstvo-o-nacinu-upisa-u-centralni-registar-registrovanih-odnosno-odobrenih-objekata-za-proizvodnju-preradu-i-distribuciju-hran.html>)
- Application for registration in the register of registered facilities for production, processing and distribution of food – Form 1
- Application for the approval of an establishment for the production, processing and distribution of food of animal origin – Form 2A
- Request for approval of a facility for the production, processing and distribution of non-food foods - Form 2B
- Application for the approval of facilities that have a small volume of production, processing and processing or which produce traditional products or use traditional methods of food production- Form 3.

CATERING FACILITIES

The operation and registration of the facilities engaged in the hospitality sector is defined by the „Rulebook on minimal technical requirements, registration of the facilities providing a services in closed type buildings” (“Official Gazette of Montenegro” No. 31/2004). This Rulebook prescribes the minimum technical conditions, content and form of the application form and the manner of keeping the Registry on provision of catering services of companies, other legal entities and entrepreneurs in closed type buildings.

Catering facilities must be equipped, and staffed to allow: rational use of space, smooth movement of guests and staff, smooth transfer of things, proper storage of goods, food and drinks, protection of the health of guests and staff, and professional service guests. At the main entrance to the catering facility, the type and the name of the catering facility must be clearly displayed. The equipment and the equipment must be kept in a proper and functional state.

Food business operators engaged in the production, processing and distribution

of food, after primary production, subject to registration, are also facilities for retail sale of food to the end consumer (retail shops, pharmacies and other specialized stores, catering facilities and markets /markets).

Catering facilities are subject to the registration process by submitting a request for registration of the facility to the Food Safety Administration, Veterinary and Phytosanitary Affairs.

The procedure for submitting a request for approval of facilities in food business is explained in the Information booklet (<http://www.ubh.gov.me/vijesti/174686/Uputstvo-o-nacinu-upisa-u-centralni-registar-registrovanih-odnosno-odobrenih-objekata-za-proizvodnju-preradu-i-distribuciju-hran.html>)

The Food Safety, Veterinary and Phytosanitary Administration, in cooperation with the Chamber of Commerce, have developed a Guideline for good hygiene deficiencies in the catering sector. The Guideline is intended for food business operators in the catering, trade and public catering sector in order to easily and legally fulfil the statutory requirements by applying procedures based on the principles of good hygiene practice. Procedures regulated by this Guide replace procedures established on HACCP principles

The Guideline can be found on the following link: <http://www.ubh.gov.me/vijesti/174162/Vodic-za-dobru-higijensku-praksu-u-poslovanju-sa-hranom.html>



FOOD INFORMATION TO CONSUMERS

Food business operators have the obligation to provide information about the food to ensure a high level of protection of health and consumer interests.

In Montenegro, the new Regulation on consumer food information is in force (Official Gazette of Montenegro, No. 22/18). This regulation sets conditions for informing consumers about food, compulsory and other information on food, content of information and data on food according to species and food categories, food labelling and the way consumers provide information about food.

Food information required are:

- 1) the name of the food;
- 2) a list of ingredients;
- 3) all ingredients or excipients used in the process of producing or preparing foods that may cause allergies or intolerances or are obtained from substances or products that may cause allergies or intolerances and which are present in the finished product and in a modified form;
- 4) quantity of ingredients or category of ingredients;
- 5) the net quantity of food;
- 6) the date of minimum durability, or “use up to_____ (date);
- 7) special conditions of storage and / or use;
- 8) the name and the seat, or the name and address of the food business operator whose name or the name of the food is placed on the market and who is responsible for food information, their accuracy and immutability;
- 9) country or place of origin for agricultural and food products guaranteed traditional specialties and with a geographical indication in accordance with a special regulation;
- 10) instructions for use or preparation of food for food that cannot be used properly without instructions;
- 11) the actual alcoholic strength by volume, for beverages containing more than 1,2% vol. alcohol;
- 12) nutritional declaration (labelling of nutritive values).

In addition to this information, it is mandatory to provide guidance and additional mandatory information for a particular type or category of food, as defined in the Regulation.

REQUIREMENTS FOR SMALL- SCALE PRODUCERS INCLUDING TRADITIONAL PRODUCTION AND SELLING OF THE PRODUCTS ON THE HOUSEHOLD

This information concerns the requirements that small scale and traditional producers must meet. These Regulations also prescribe the requirements relating to the direct sale of such products to consumers on the household.

1. REGULATION ON CONDITIONS FOR DEROGATION IN THE CONSTRUCTION, DEVICE AND EQUIPMENT OF FACILITIES WITH LOW VOLUME OF FOOD MANUFACTURING, AND PROCESSING (“OFFICIAL LIST OF MNE”, No. 21/16).

This Regulation applies to food business operators who perform activities in establishments with a low volume of production, processing and processing of products, as well as food business operators that produce traditional products or use traditional methods of production.

The requirements set out in this Regulation relate to:

- Slaughtering and cutting of fennel meat, equidae and farmed game up to ten conditional throats per week;
- Slaughtering and cutting meat of poultry and lagomorphs to 6,000 units of animals per month;
- Processing of milk in which up to 750 l of raw milk is processed daily;
- Processing of meat and / or fishery products in which up to 1,000 kg of meat or fishery products is processed on a weekly basis;
- Removing live bivalve molluscs from a floating facility from their own farm, with a capacity of up to 500 kg of live bivalve molluscs per day;
- Packaging of eggs with a capacity of up to 1,500,000 eggs per year;
- Processing of fruits and vegetables in which up to 30,000 kg of fruit is processed annually;
- Processing of olives in which up to 6,000 kg of olives are processed annually, i.e. 500 liters of oil annually;
- Production of wines in which up to 10,000 kg of grapes are processed annually, i.e. they produce 5,000 liters of wine per year;
- Processing of other non-animal products in which is processed to 3 t of raw material annually.

This Regulation applies to food business operators that produce traditional products or use traditional methods of production.

2. REGULATION ON HYGIENE REQUIREMENTS FOR FACILITIES AND SPACES IN WHICH SMALL QUANTITIES OF PRIMARY PRODUCTS ARE MANUFACTURED (“OFFICIAL LIST OF MNE”, NO. 08-1847 / 16)

This regulation defines the requirements for the hygiene of the facilities, premises and equipment in which small quantities of primary food products are produced for the supply of end-users or retail outlets in the local market, special requirements for hygiene for primary products, types of primary products and criteria for determining small quantities of primary products and the local market.

This Regulation applies to primary food products for people who are produced, processed and processed on a family farm.

Hygiene requirements for facilities, premises and equipment:

- production can be carried out in special facilities located on agricultural holdings or in premises that are part of a residential facility of a household and which are protected from pests;
- facilities must have a sufficient amount of warm and / or cold water that meets the requirements of drinking water;
- It is necessary to ensure adequate space for maintenance of the product at the prescribed temperature.
- Equipment and accessories used in production should be made of suitable material and clean.

The primary products of a small manufacturer can only be sold:

- 1) if they are produced on their own agricultural holding;
- 2) the ultimate consumer or retail facility on the local market;
- 3) in the quantities defined by the regulation.

Special requirements for hygiene for eggs. They must be of healthy livestock. The collection of eggs must be carried out at least once a day and they must be clean, dry and protected from impacts and direct sunlight. Storage and transport must be at a temperature that ensures maintenance of the quality and safety of eggs. The eggs must be delivered to the final consumer no later than 21 days after the day of collection.

Special requirements for hygiene for raw milk. The milk must be from a healthy animal that meets health requirements and must be stored in a room that is separate from the place where the animals are located. After milk milking it is necessary to wash down and store in a clean and covered container in a cool place. The milk must be controlled four times a year on the total number of microorganisms and somatic cells. Raw milk must be delivered to the final consumer within 24 hours if stored at a temperature of 6 ° C to 8 ° C, and if it is stored without cooling within 2 h after milking.

Special requirements for hygiene for cheese, whey, sour cream and kajmak. A small producer can produce and sell cheese, whey, sour cream and kajmak only if:

- Produced from raw milk from a healthy animal in accordance with a special regulation;
- processed in clean rooms that are separated from the rooms where the animals are housed.
- Up to 50 liters of raw milk per day can be processed in the processing industry if it is produced in premises that are part of the residential household.
- More than 100 liters of raw milk can be processed per day if the processing is done in a separate facility located on the farm.

Special requirements for honey. It can be sold only if it originates from healthy bees and does not contain unauthorized substances. A maximum of 300 kg of honey can be stored and packed in a room within the housing unit of the household. More than 300 kg of honey can be stored and packed in a special facility located on a farm.

Special requirements for fruits, vegetables and cereals. The small producer can process up to 50 kg of fruits, vegetables and cereals daily in the premises of the residential household. A small producer can process more than 50 kg of fruits, vegetables and cereals daily in a separate facility located in the agricultural holding.

At the web site of the Directorate of Food Safety, Veterinary and Phytosanitary Affairs the more detailed information for small scale producers can be found:

- **Deviations in the construction, arrangement and equipping of facilities that have a small amount of production and processing of food – Information booklet**
(http://www.ubh.gov.me/biblioteka/sektor_1/informativni_materijal/)
- **Hygiene requirements for buildings and premises where small quantities of primary products for human consumption are produced- Information booklet**
(http://www.ubh.gov.me/biblioteka/sektor_1/informativni_materijal/)

II INFORMATION ON PRIMARY PRODUCTS AT THE PLACE OF SALE

Primary products during delivery and / or sale to the final consumer or retail establishments should follow the following information:

- 1) the name and surname of the small producer;
- 2) the name of the product;
- 3) the address of the agricultural holding;
- 4) number of decisions on entry in the register of agricultural holdings;
- 5) number of decisions on registration in the register of registered food establishments;
- 6) date of manufacture.

INFORMATION ON RELEVANT INSTITUTIONS

FOOD SAFETY DIRECTORATE

Adresa: Serdara Jola Piletića 26,

81000 Podgorica, Crna Gora

Tel. +382 20 201 945; +382 20 621 111

Fax: +382 20 201 946; +382 20 621 008;

<http://www.ubh.gov.me/uprava>

EMAIL: upravazabezbjednosthrane@ubh.gov.me

- **Registration of the facilities for the production, processing and distribution of food**
- **Approval of the facilities for the production, processing and distribution of food of animal origin**
- **Approval of the facilities for the production, processing and distribution of food of non-animal origin**
- **Approval of facilities that have a small scale production and processing or which produce traditional products or use traditional methods of food production**

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- **Micorbiological analysis of the food**
- **Physical-chemical analyses**

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- **Micorbiological analysis of the food of animal origin**
- **Parasitology analyses**

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- **Analyses of the quality of honey-authorized by Ministry of Agriculture**

LEGAL FRAMEWORK

CONCERNING FOOD SAFETY

- Law on Food Safety (“Official Gazette of Montenegro”, No. 57/2015);
- Decree on Food Hygiene (“Official Gazette of Montenegro”, No. 13/2016);
- Decree on microbiological criteria for food safety (“Official Gazette of Montenegro”, No. 26/2016);
- Regulation on informing consumers about food (“Official Gazette of Montenegro”, No. 22/2018);
- Regulation on additives that can be used in food (“Official Gazette of Montenegro”, No.19/2016);
- Decree on maximum allowed quantities of contaminants in food (“Official Gazette of Montenegro”, No. 48/2016);
- Decree on materials coming into contact with food (“Official Gazette of Montenegro”, No. 80/2016);
- Ordinance on requirements for potable water (“Official Gazette of Montenegro”, No. 24/2012);
- Decree on the use of health and nutritional claims in labelling, advertising and presentation of food (“Official Gazette of Montenegro” No. 06/17)
- Rulebook on how to register and maintain a central register of registered or approved facilities for the production, processing and distribution of food or feed (Official Gazette of Montenegro, No. 39/2017).

CONCERNING PRODUCTS OF ANIMAL ORIGIN

- Decree on special requirements for hygiene for products of animal origin (“Official Gazette of Montenegro”, No. 32/2016);
- Ordinance on requirements for the traceability of food of animal origin (“Official Gazette of Montenegro”, no. 48/16);
- Decree on the types of substances used to reduce the surface contamination of animal by-products of animal origin (“Official Gazette of Montenegro” No. 80/16);
- Veterinary Law (“Official Gazette of Montenegro”, No. 30/2012 and 48/15);
- Law on Animal Welfare (“Official Gazette of Montenegro”, No. 14/2008 and 47/15);
- Ordinance on detailed conditions for the protection of animals during slaughter (“Official Gazette of Montenegro”, number 54/2015).

CONCERNING DEROGATIONS FOR SMALL-SCALE OR TRADITIONAL PRODUCTION

- Decree on conditions for deviation in terms of the construction, arrangement and equipping of facilities with a small volume of production, processing and processing of food (“Official Gazette of Montenegro”, No. 21/2016) and
- Decree on the requirements of hygiene for buildings and premises in small quantities produces small quantities of primary products for human consumption. (“Official Gazette of Montenegro, No. 6/2018) - with amendments.