



MONTENEGRO
MINISTRY OF AGRICULTURE AND
RURAL DEVELOPMENT
Directorate for Food Safety,
Veterinary and Fitosanitary Affairs



GUIDELINES

FOR GOOD HYGIENE PRACTICES AND
IMPLEMENTATION OF NATIONAL DEROGATIONS FOR
CONSTRUCTION, LAYOUT AND EQUIPMENT FOR SMALL
VOLUMES OF MEAT PRODUCTION, PROCESSING AND
DISTRIBUTION ESTABLISHMENTS



First edition



MONTENEGRO

MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT
Directorate for Food Safety, Veterinary and Phytosanitary Affairs

GUIDELINES

FOR GOOD HYGIENE PRACTICES AND
IMPLEMENTATION OF NATIONAL DEROGATIONS FOR
CONSTRUCTION, LAYOUT AND EQUIPMENT FOR SMALL
VOLUMES OF MEAT PRODUCTION, PROCESSING AND
DISTRIBUTION ESTABLISHMENTS

First edition

Podgorica, 2017

GUIDELINES FOR GOOD HYGIENE PRACTICES AND IMPLEMENTATION OF NATIONAL DEROGATIONS FOR CONSTRUCTION, LAYOUT AND EQUIPMENT FOR SMALL VOLUMES OF MEAT PRODUCTION, PROCESSING AND DISTRIBUTION ESTABLISHMENTS

Edited by: Biljana Blečić, Assistant Director, Directorate for Food Safety, Veterinary and Phytosanitary Issues, Food Safety Department

Authors: Slobodan Šibalić, Doctor of Veterinary Medicine, consultant of Center for Rural Development and Agriculture "Agrikultura"; Professor Aleksandra Martinović, Center for Rural Development and Agriculture "Agrikultura"; Dragana Tar, Center for Rural Development and Agriculture "Agrikultura";

Reviewers: Emilie Vandecastelaere, Agribusiness Economist and Food Quality Expert, FAO; Lisa Paglietti, Economist, FAO; Stefania Manzo: Consultant, FAO

Publisher: The Ministry for Agriculture and Rural Development

Design: Miroslav Dragin



Food and Agriculture Organization
of the United Nations



European Bank
for Reconstruction and Development



Kneževina
Luksemburg



This Guide was prepared by the Ministry of Agriculture and Rural Development of Montenegro, as the Competent Authority. It was supported by a joint project of the European Bank for Reconstruction and Development (EBRD) and the Food and Agriculture Organization of the United Nations (FAO), "Upgrade of Meat Quality Standards in Montenegro and Exchange of Lessons Learned in the Western Balkans", co-financed by FAO and the Grand Duchy of Luxembourg. Implementation support was provided by the Center for Rural Development and Agriculture "Agrikultura". The project's objective is to facilitate a more efficient and integrated food production chain in Montenegro and upgrade quality and safety in the meat production sector.

Disclaimer

Agribusinesses and food producers are not obliged to follow the advice laid out in this Guide, as other ways of achieving compliance with the requirements of current legislation on food hygiene and safety may be equally valid.

This Guide is an evolving document and will be periodically updated to take into account the experiences and information from scientific bodies, competent authorities and food business operators. To improve the quality and effectiveness of future editions, all critical analysis, comments and suggestions are welcome.

Preface

What is the objective and purpose of the Guide?

The primary objective of this Guide is to provide information and support to food businesses involved in slaughtering, cutting or processing meat for human consumption. It is particularly tailored to those establishments that are subject to official approval and veterinary control.

The requirements of food hygiene legislation with which food businesses in the Montenegrin meat sector have to comply are set out and quoted in this Guide, which also provides practical guidance on implementation and interpretation and advice on how these obligations can be met. However, the advice on the legal requirements are non-binding and should be read in conjunction with the legislation itself. It is the responsibility of individual businesses to ensure their compliance with the law; and in the case of specific queries, businesses should seek advice from the relevant enforcement authority.

Food businesses can use this Guide as a source of information when establishing their own food safety systems, including prerequisite programmes and self-check/self-control plans. The comprehensive information provided will improve businesses' understanding of structural and hygiene preconditions and possible flexibilities of hygiene requirements in order to reduce and control possible hazards at all stages of production, processing and distribution of meat and meat products. This Guide should be particularly helpful for prospective meat businesses in the seeking approval to start operations or to update hygiene conditions of existing premises.

These guidelines cover:

- General hygiene requirements for **all food businesses**
- Specific hygiene requirements for production and processing of meat
- Derogations of specific food hygiene requirements that may be applied in **establishments with small throughput** of production, processing and distribution of meat products and in **establishments that produce traditional products or use traditional methods in production**

Who can use this Guide?

This Guide is intended for all types of establishments operating with meat and meat products, regardless of ownership and volume of production. The Guide is primarily useful to businesses that carry out slaughtering, cutting and/or meat processing operations. However, the guidelines for good manufacturing practices (GMP) and good hygiene practices (GHP) could be applied at various stages of the food chain including retail butcher shops that are subject to the registration procedure.

The guidelines within should be understood as a set of minimum conditions that are subject to inspection during official controls of the food establishments that evaluate the effects of individual food businesses' control programmes and compliance with general and specific hygiene requirements.

¹ According to the regulation on conditions for derogation with respect to construction, layout and equipment in establishments with small volume of production, processing and treatment of food ("Official Gazette of Montenegro", No. 21/2016), the term "derogation" covers (i) adaptations of requirements laid down in the annexes of the Hygiene Package in specified circumstances; and (ii) derogations that may be applied as specified in the requirements of the Hygiene Package in specified circumstances. The Hygiene Package for food consists of 3 Regulations¹ and 2 Directives) and the Feed Hygiene Regulation are an integral part of the EU's "farm to fork" strategy for food safety. They provide for a single, transparent EU hygiene policy, applicable to all food and feed and at every point on the food chain. They seek to provide effective tools to ensure food safety and to manage potential food and feed crises.

Flexibility provisions in Montenegro compared to the possibilities given in the EU legal framework

The following possibilities are given within the flexibility provisions contained in the EU hygiene regulations:

► to grant:

1) **derogations/exemptions** from certain requirements laid down in Annexes - **food with traditional characteristics** (infrastructure, equipment)

2) **adaptations** of certain requirements laid down in some Annexes, including requirements on official controls in order:

- to enable the **continued use of traditional methods** (at any of the stages of production, processing or distribution of food),
- to accommodate the needs of food businesses **situated in regions that are subject to special geographic constraints**, and
- in **establishments with low throughput** (to adapt requirements on the **construction, layout and equipment**).

► to **exclude** some activities from the scope of the Hygiene Package:

• **direct supply of small quantities to the final consumer** or to **local retail establishment directly supplying the final consumer** of:

- primary products (by farmers),
- products collected in the wild (by individuals),
- meat of poultry and lagomorphs (by farmers),
- wild game or wild game meat (by hunters),

• retail establishments directly supplying food of animal origin to the final consumer (e.g. butcher shops, production of cheese on the farm), or to another retail establishment, if this activity is recognized as marginal, localized and restricted.

When making use of flexibility provisions, Member States have in general to adopt National Measures. Montenegro has adopted food hygiene regulations in line with the relevant EU regulations. However, pursuant to the national Law on Food Safety, the Regulation on conditions for derogation in respect to the construction, layout and equipment of facilities with a small volume of production, processing and treatment of food ("Official Gazette of Montenegro", No. 21/2016) was adopted. Granted **derogations** in this Regulation cover the **adaptations** of food hygiene requirements on the **construction, layout and equipment** which could be applied to **small volume establishments** and use of **traditional methods** of production and the **derogations** that could be applied in production of **food with traditional characteristics** (infrastructure, equipment).

Table of Contents

Preface.....	3
Overview	6
Acronyms and abbreviations.....	9
Glossary.....	9
Regulatory framework.....	11
Registration and approval of establishments for meat production and meat processing.....	13
Self-regulation is the main pillar of food safety control.....	17
Chapter 1 Prerequisite hygiene requirements.....	19
1.1 General food hygiene requirements	21
1.2 Conditions on premises where food is prepared, treated or processed	26
1.3 Equipment and materials.....	36
1.4 Temperature controls	38
1.5 Water supply	44
1.6 Establishment and equipment maintenance	46
1.7 Cleaning	47
1.8 Sanitation of tools and equipment.....	50
1.9 Employee health and personal hygiene	51
1.10 Control of pests and other animals.....	53
1.11 Removal of animal by-products	55
1.12 Traceability.....	56
1.13 Reception, packaging and transport of food.....	59
1.14 Labelling information for consumers.....	63
1.15 Training	65
Chapter 2: Specific hygiene requirements.....	67
2.1 Facilities for animal slaughter	37
2.2 Facilities for cutting meat	73
2.3 Establishments slaughtering and cutting small volumes of meat.....	76
2.4 Facilities for meat processing	84
2.5 Small-volume meat processing establishments	91
Chapter 3: Traditional products	95
Chapter 4: Hazard analysis and critical control points.....	99
Annexes.....	105

Overview

of derogations for small meat producers, processors and distributors

This section provides an overview of all derogations laid out in the regulation *Derogations for establishments with low throughput of production, processing and distribution of meat and meat products concerning construction, layout and equipment* (Official Gazette of Montenegro, No. 21/2016).

Establishments slaughtering a small volume of ungulates and farmed game, poultry and domestic lagomorphs may have:

STIPULATED DEROGATION	PLACE IN THE GUIDE
<i>(1) One changing facility for employees working in clean and dirty parts of the establishment, if up to five persons are employed in the production part of the facility,</i>	Part 2, Chapter 2.3 Small slaughterhouses
<i>(2) An adequately-sized cupboard that can be locked for use of the official veterinarian instead of a separate room for the official veterinarian.</i>	Part 2, Chapter 2.3 Small slaughterhouses

Establishments slaughtering small volume of ungulates and farmed game, poultry and lagomorphs do not need to have:

STIPULATED DEROGATION	PLACE IN THE GUIDE
<i>(1) A separate room for the reception and temporary accommodation of animals to be slaughtered in accordance with the regulations on food hygiene and hygiene requirements for products of animal origin, if the slaughter of animals is performed immediately upon arrival at the facility. In establishments slaughtering small volumes of ungulates and farmed game with facilities for the reception and temporary accommodation of animals, the slaughter of animals should be carried out within 21 days of the reception if during that period the animals have not left the lairage facilities.</i>	Part 2, Chapter 2.3 Small slaughterhouses
<i>(2) Separate room for sick and diseased animals.</i>	Part 2, Chapter 2.3 Small slaughterhouses
<i>(3) A separate place with appropriate facilities for the cleaning, washing and disinfection of means of transport for livestock, if the food business operator has a signed contract for washing, cleaning and disinfection of means of transport.</i>	Part 2, Chapter 2.3 Small slaughterhouses
<i>(4) Detained carcasses and carcasses fit for human consumption may be stored in the same room i.e. a cooling chamber provided that:</i> <ul style="list-style-type: none"> ▪ space reserved for detained carcasses is marked and can be locked; ▪ the reason for retaining carcasses is not a contagious disease; ▪ contamination of other meat is prevented. 	Part 2, Chapter 2.3 Small slaughterhouses

STIPULATED DEROGATION	PLACE IN THE GUIDE
<i>(5) Separate room for emptying and cleaning of stomachs and intestines, this can be performed in the slaughter area after the completion of slaughter operations, provided that the area is free of carcasses and that the space is thoroughly cleaned and disinfected prior to use.</i>	Part 2, Chapter 2.3 Small slaughterhouses
<i>(6) In establishments slaughtering small volume of poultry and lagomorphs, evisceration and further dressing of the carcasses may be carried out in the same room where scalding and plucking of feathers is performed, provided that there is sufficient space and adequate physical separation of evisceration and plucking, in order to prevent food contamination.</i>	Part 2, Chapter 2.3 Small slaughterhouses
<i>(7) Special area for meat cutting. Cutting of meat may be carried out in the slaughter room – only if the meat is obtained from animals slaughtered in that establishment – provided that slaughter and cutting operations are separated in time and that after slaughtering and prior cutting, thorough cleaning and disinfection is performed.</i>	Part 2, Chapter 2.3 Small slaughterhouses

In establishments with small volumes of meat processing:

STIPULATED DEROGATION	PLACE IN THE GUIDE
<i>(1) Different technological phases and/or production of different products may be performed in the same room, provided that time separation between production phases is assured.</i>	Part 2, Chapter 2.5 Small volumes of meat processing
<i>(2) Storage of raw materials, finished products and detained products in the same room may be done with adequate spatial separation, so as to prevent possible contamination and ensure that detained products are packaged, sealed and clearly marked.</i>	Part 2, Chapter 2.5 Small volumes of meat processing
<i>(3) The same entrance and exit may be used for raw materials, finished products and unsafe products, with appropriate separation in time.</i>	Part 2, Chapter 2.5 Small volumes of meat processing

In establishments with small volumes of meat processing, the following premises can be placed outside the working area but inside the establishment grounds:

STIPULATED DEROGATION	PLACE IN THE GUIDE
<i>(1) Changing room for employees.</i>	Part 2, Chapter 2.5 Small volumes of meat processing
<i>(2) Storage area for packaging materials.</i>	Part 2, Chapter 2.5 Small volumes of meat processing
<i>(3) Storage premises for materials for cleaning and disinfection of production plant.</i>	Part 2, Chapter 2.5 Small volumes of meat processing

If the small-scale meat processing facility is located in the same ground as residential house:

STIPULATED DEROGATION	PLACE IN THE GUIDE
<i>(1) Changing room and sanitary facilities of residential house may be used for employees' needs.</i>	Chapter 2

In establishments where traditional products are produced or where traditional manufacturing methods are used, facilities and premises may:

STIPULATED DEROGATION	PLACE IN THE GUIDE
<i>(1) Be constructed from natural materials necessary for the development of specific characteristics of that traditional product.</i>	Chapter 3 Production of traditional meat products
<i>(2) Have walls, ceilings and doors that are not of smooth, impervious, non-absorbent or corrosion-resistant materials or may have natural geological walls, ceilings and floors.</i>	Chapter 3 Production of traditional meat products
<i>(3) Adapt the cleaning and disinfection procedures to keep the natural production conditions (e.g. specific ambient flora).</i>	Chapter 3 Production of traditional meat products
<i>4) At all stages of production and packaging use equipment, tools and instruments that are made of materials that are not smooth, corrosion-resistant and non-absorbent, including wood, stone and other materials that are traditionally used in the production, maturation and storage of the product and that are maintained in a satisfactorily hygienic state and are regularly cleaned, washed and, if necessary, disinfected.</i>	Chapter 3 Production of traditional meat products

Acronyms and abbreviations

EBRD	European Bank for Reconstruction and Development
FAO	Food and Agriculture Organization of the United Nations
FBO	Food business operator
GMP	Good manufacturing practices
GHP	Good hygiene practices
HACCP	Hazard Analysis and Critical Control Points
MSM	Mechanically-separated meat
RFH	Regulation on food hygiene ("Službeni list CG", broj 13/2016)
RSHRPAO	Regulation on specific hygiene requirements for food of animal origin ("Službeni list CG", broj 32/2016)
SSOP	Sanitation standard operating procedure
SOP	Standard operating procedure
ZoBH	Law on food safety ("Službeni list CG", broj 57/2015)

Glossary

In this Guide, the following terms are used as defined below:

Food operating activity is part of all phases of production, processing and food distribution, either profitable or non-profitable, private or public.

Food business operator is a legal or physical person or company responsible for fulfilling the legal requirements for food within the scope of its activities.

Risk is the possibility of a harmful effect on health and the consequences to human health.

Hazard/danger is a biological, chemical or physical substance in food or feed or the condition of food and feed that can harm human health.

Traceability is the possibility to trace food, feed and animals that are used for food production, raw materials and substances that are intended to be used in all phases of production, processing and food distribution.

Production, processing and food distribution is any phase including import that is used starting from the primary production of food and ending with its storage, transport, sale and supply to the final consumer.

Food hygiene is a set of measures and conditions necessary to control risks and ensure that food is appropriate for consumption.

Food safety is the absence of all biological, chemical or physical danger that could harm the health of the consumers.

Good hygiene practice is set of procedures used to manage hygiene of the working environment and ensure basic conditions to produce safe food for human consumption and health.

Good manufacturing practice is set of procedures used to manage conditions of the working environment and for the production of safe food.

Standard operating procedures are set of step-by-step instructions compiled by an organization to help workers carry out routine operations. SOPs aim to achieve efficiency, quality output and uniformity of performance, while reducing miscommunication and failure to comply with regulations.

Sanitation standard operating procedures are documented steps that must be followed to ensure adequate cleaning of product contact and non-product surfaces. SSOPs are considered one of the prerequisite programmes of HACCP.

Cleaning is elimination of visible dirt.

Washing is full elimination of all dirt.

Disinfection is use of physical, chemical and mechanical means to eliminate all forms of microorganisms, above all vegetative.

Disinsection and deratization are insect and pest control.

HACCP is method to identify, assess and manage possible risks and dangers that are of importance for food safety. A **HACCP system** consists of structures, procedures, processes and resources necessary to implement HACCP plans and fulfil all the objectives defined in the plan.

HACCP plan is a document that is made according to the HACCP principles. Its function is to ensure control of hazards that are relevant for food safety of the food business operator.

Flow chart is a schematic description of phases (steps in procedures or operations) that are implemented during production, distribution and sale of a particular food product.

Derogations are exemption measures on general and specific food hygiene requirements for establishments with small throughput of production, processing and distribution of meat and meat products concerning construction, layout and equipment and for establishments producing traditional products.

Regulatory framework

The purpose of general and specific regulations for food hygiene is to ensure a high level of consumer protection regarding food safety. Throughout the production process until the product reaches the market, every food business operator has an obligation to implement all measures to prevent potential risks in food that can have adverse effects on human health. These requirements are laid out in the following:

- Law on food safety (Official Gazette of Montenegro, No. 57/2015)
- Regulation on food hygiene (Official Gazette of Montenegro, No. 13/2016)
- Regulation on specific hygiene requirements for food of animal origin (Official Gazette of Montenegro, No. 32/2016)
- Regulation on conditions for derogation with respect to the construction, layout and equipment of establishments with small volumes of production, processing and treatment of food (Official Gazette of Montenegro, No. 21/2016); Regulation on microbiological criteria for food safety (Official Gazette of Montenegro, No. 26/2016);
- Regulation on food information to consumers (Official Gazette of Montenegro, No. 12/2016);
- Regulation on materials and items that come in contact with food (Official Gazette of Montenegro, No. 80/2016)
- Regulation on food additives (Official Gazette of Montenegro, No. 19/2016)
- Regulation on maximum limits of contaminants in food (Official Gazette of Montenegro, No. 48/2016)
- Rulebook on safety requirements for drinking water (Official Gazette of Montenegro, No. 24/2012)
- Rulebook on method of registration and keeping of central register of registered and approved establishments for production, processing and distribution of food (Official Gazette of Montenegro, No. 25/2016)
- Law on veterinary matters (Official Gazette of Montenegro, No. 30/2012, 48/2015)
- Law on protection of animal welfare (Official Gazette of Montenegro, No. 14/2008, 47/2015)
- Rulebook on protection of animals during slaughtering (Official Gazette of Montenegro, No. 54/2015)

Figure 1: Regulations and laws related to food safety

Registration and approval of establishments for meat production and meat processing

In accordance with the law on food safety², food business operators are required to perform activities of production, processing and/or distribution exclusively in registered or approved establishments. This requirement applies to each individual food establishment under the control of a food business operator. Registered and approved establishments are entered in the Central Register of registered and approved establishments, which is kept by the competent authority based on the written decision on compliance with the requirements laid out for registration or approval of the establishment.

In accordance with the law³, food business operators are required to inform the competent authority of any changes regarding the business operator, the establishment or any activity as outlined in the written compliance decision for registration or approval of establishment including the termination of activity.

The rulebook on methods of registration and maintenance of the Central Register of registered and approved establishments for production, processing and distribution of food includes information on the types of establishments where the activities that are subject to registration are performed, the application form for registration and related documentation, the types of establishments where the activities that are subject to approval are performed, and the application form for approval and related documentation.

The Central Register of registered and approved establishments is published on the website of the competent authority.

Table 1: Registration and approval of establishments

Registration of establishments	Approval of establishments
The purpose of registration is to provide the competent authorities with legal information on each food business operator, location of the establishment, type of production and activities performed.	The purpose for approval of establishments dealing with production of food of animal origin is associated with increased risks related to this type of production. Operators must not commence business operations without prior approval of the establishment if the business activity requires approval.

² Official Gazette of Montenegro, No. 57/2015.

³ Official Gazette of Montenegro, No. 25/2016.

What is needed to register the establishment?	What is needed to approve the establishment?
<p>To register the establishment, the food business operator must submit the application form for registration of the establishment to the competent authority</p> <ul style="list-style-type: none"> • proof of ownership (real estate register certificate) or lease contract (for the facility, land, agricultural holding); • drawing of the establishment with the layout, equipment, receipt and movement of raw materials and final products; • description of technological procedures that are carried out in the production, processing, packaging, storage, transport and distribution; • approval of customs authority for customs warehousing (for importers); • proof of payment of fee to competent authority. 	<p>To register the establishment, the food business operator submits to the the application form for registration of the establishment to the competent authority</p> <ul style="list-style-type: none"> • proof of ownership (real estate register certificate) or lease contract (for the facility, land, agricultural holding); • layout drawing of the establishment in 1:100 scale with incorporated rooms and premises for production, equipment, floor drainage channels, water taps, hand washing and sterilization facilities, rail system, premises for employees (changing rooms, toilets, showers and laundry) and marked movement paths for employees, raw materials and finished products, including paths for movement of animal by-products (lines of movement must be marked in different colours); • list and purpose of all the premises in the establishment, their surface size and volume (temperature of all production facilities with temperature-controlled regime, if necessary for the technological process of production); • list and purpose of equipment and tools used in the establishment; • description of all activities performed in the facility and description of the production process and flow chart for each production line and food ingredients (product specification); • type of products that are produced/stored in the establishment; • designed capacities of production/storage, shown on daily/monthly/annual basis; • number of employees (full-time and part-time) handling food; • description of water supply/water control; • approval of customs authority for customs warehousing (for importers); • proof of payment of fee to competent authority.

Which establishments can be registered?	Which establishments can be approved?
<ul style="list-style-type: none"> • establishments for production of animals intended for human consumption (primary production of food of animal origin); • establishments for storage of meat products not requiring temperature controlled storage conditions, are subject to registration 	<ul style="list-style-type: none"> • slaughtering and cutting of meat of domestic ungulates; • slaughtering and cutting of meat or poultry and lagomorphs; • slaughtering/dressing and cutting of meat of farmed game and flightless birds; • slaughtering/dressing and cutting of wild game; • production of minced meat, meat preparations and mechanically-separated meat (MSM); • meat processing; • rendered animal fats and greaves (raw material collection; processing and production of rendered fats and greaves); • treatment/processing of stomachs, bladders and intestines; • gelatine (raw material collection, processing); • collagen (raw material collection, processing); • storage of meat, minced meat, meat preparations, MSM and meat products under temperature-controlled conditions (stand-alone establishment); • wholesale trade of meat, minced meat, meat preparations conditions, MSM and meat products under temperature-controlled conditions; • repacking of meat and meat products.

Source: authors own sistematization

Approval of establishments

In order to obtain the approval for production, processing and/or distribution of food, the establishment must fully meet the requirements of general and special hygiene conditions, as well as other provisions of the law on food safety and the legislations appropriate for the type of the establishment.

Table 2: Procedure for approval of the establishment and responsibilities of each actor To initiate process

Food business operator	Competent authority	Commission for Inspection of Establishments	Competent authority (following Commission proposal)
Submits request for approval with documentation	Forms a Commission for Inspection of Establishments	(1) Inspects the establishment and assesses the compliance with the prescribed requirements in terms of infrastructure, equipment, etc. (2) Prepares a protocol with a proposal for the issuance of a conditional approval for a period of 3 months	(1) Issues a conditional approval (2) Makes an entry in the register of approved establishments (3) Assigns a veterinary control number to FBO

Close to expiration of the 3 month conditional approval			
Commission for Inspection of Establishments			Competent authority
Re-checks the establishment while carrying out the approved activity to verify compliance with requirements	Complies with all the requirements	Proposal of the Commission	Issues the approval for performance of operations at the establishment
	Establishment does not comply with the requirements		Extends the conditional approval for a period not longer than 3 months
Close to expiration of the 3 month deadline conditional approval			
Commission for Inspection of Establishments			Competent authority
	Complies with all the requirements	Proposal of the Commission	Issues the approval for performance of the operations at the establishment, based on the removal of the establishment from the Register
	Not all requirements have been complied with		Donosi rješenje o brisanju objekta iz Registra odobrenih objekata.

Source: authors own sistematization

Table 3: Changes that affect approval of establishment

Change	Food business operator	Competent authority
Changes concerning the operator, change in terms of the establishment or with regard to the approval issued	Obligated to notify the competent authority of any change not later than 15 days after	Upon receiving the notification of the changes, carries out the approval procedure as described in Table 2
Does not perform one or more of the approved operations for up to 6 months	Obligated to notify the competent authority of any change not later than 15 days after suspension of operations	Upon receiving the notification of the changes, carries out the approval procedure as described in Table 2
Does not perform one or more of the approved operations for more than 6 months	Obligated to notify the competent authority of any change not later than 15 days after	Upon receiving the notification of the changes, carries out the approval procedure as described in Table 2

Source: authors own sistematization

Table 4: Revocation of approval

Competent authority	
Issues a decision on revoking approval for the establishment based on:	Request of FBO
	The decision of the inspector to prohibit continuation of operations in the establishment due to non-compliance with the requirements for which the approval was issued
	The information by the FBO or inspector that the business operations in the establishment concerned have been ceased for more than 1 year.
Deletes the establishment from the Registry	

Source: authors own sistematization

Note: Current regulations are regularly being updated and are available at the following website: www.vet.uprava.gov.me/biblioteka/zakoni.

Self-regulation is the main pillar of food safety control

Food contamination is a significant source of disease and the main concern for public health. Food-borne diseases cause huge socio-economic damage through, for example, their negative impact on trade and tourism and the deterioration of consumer confidence in particular. Therefore, in the current food production and food processing system, particular attention is given to product safety.

The primary responsibility for food safety lies with the FBO. To produce safe food for consumers, all important safety hazards that are associated with the production of food need to be prevented, eliminated or reduced to an acceptable level. Therefore, food safety system priorities in food businesses today are directed towards hygiene conditions and operating procedures. Based on the risk analysis, food hygiene legislation encourages every FBO to produce food safely by applying good hygiene and manufacturing practices and food safety management procedures based on Hazard Analysis and Critical Control Point (HACCP) principles. By putting implementing and maintaining permanent procedures based on the HACCP principles, FBOs will be able to use their internal systems to control food safety hazards associated with their production process and to identify the best points in the along the value chain for quality and safety control.



Food safety management steps

- ▶ **PLAN** what needs to be done to maintain food safety and write it down
- ▶ **DO** what you planned to do to maintain food safety
- ▶ **CHECK** that you are doing what you planned to do to maintain 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

Establishing and implementing control in all phases of production, including the sourcing of raw material, and taking samples of intermediate and final products for lab testing to evaluate the presence of microbiological or chemical contamination, allows the producer to confirm the validity of the production process and procedures as well as to document and guarantee the safety of the product sent to market.

Positive effects of the HACCP system 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 institutions:** economic and reliable control of food safety, decreasing costs of health care of the population, and possibility for international food trade.
-

Chapter 1:

Prerequisite hygiene requirements

“Prerequisite programmes” are the obligatory requirements and procedures that result in appropriate conditions and control of the work environment in order to produce safe food. They are defined by the food hygiene legislation⁴ and the objective of their application is the decrease of possibility that the low level risk transforms into serious threat for food safety.

Prerequisite programmes consist of GMPs, GHPs and standard operating procedures (SOPs). It is important to understand that prerequisite programmes need to be applied in a similar manner by all FBOs that produce, process and place the food on the market. Good manufacturing and hygiene practices are the same for all producers within the same scope of activity (e.g. all slaughterhouses, cutting plants, meat processing plants, etc.) Contrary to that, the HACCP plan is specific to one producer for both production processes and the final product.



The word of the law

According to the law on food safety, FBOs are an integral part of the prerequisite programmes through their work on traceability (article 27), recalling substandard food (article 28) and their obligation to inform authorities and public about food safety standards (article 17).

⁴ Legislation includes: Law on food safety (Official Gazette of Montenegro, No. 57/2015); Regulation on food hygiene (Official Gazette of Montenegro, No. 13/2016); Regulation on specific hygiene requirements for food of animal origin (Official Gazette of Montenegro, No. 32/2016)

Table 5: The role of different standards in prerequisite programmes

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 ensure 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		
<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)

Prerequisite programmes need to be established and successfully introduced prior to the development and application of a HACCP system. They represent the base for preparation and effective application of HACCP principles, in particular:

- requests for raw materials
- safe food handling (including packaging and transport)
- handling animal by-products and other waste
- procedures for pest control
- procedures for cleaning and sanitation
- water supply
- wastewater drainage
- control of temperature and maintenance of cold chain
- health and personal hygiene of all employees
- general and personal hygiene training for employees

Implementation of prerequisite programmes can in some cases control food safety risks. When this occurs, the legal requirements regarding food hygiene are considered fulfilled, and there is no need to continue developing and implementing HACCP system procedures. This means that the first step in the development of the HACCP system (risk analysis) is fulfilled

1.1 General food hygiene requirements

Establishments engaged in general food production and processing must meet the conditions defined in food hygiene legislation; while premises where food of animal origin is prepared, treated or processed must meet the same general conditions, but also the specific requirements laid down for food of animal origin. Small-scale meat establishments may be subject to derogations for construction, layout and equipment.

Location

<p>RFH - Annex 2 – Part 1: General requirements for food premises: Point 2. (a–c)</p>	<p><i>The layout, size and siting of premises where food is handled are to:</i></p> <p><i>(a) provide adequate maintenance, cleaning and/or disinfection, prevent or reduce airborne contamination, and provide adequate working space for the hygienic performance of operations;</i></p> <p><i>(b) prevent the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces;</i></p> <p><i>(c) allow good hygiene practices when handling food, including protection against contamination and, in particular, pest control.</i></p>
--	--

Before making a decision on the site of construction of the food establishment, suitability of the ground, possible sources of contamination of food, as well as the impact of the operations on the environment should be considered. If necessary, an assessment of the protective measures preventing a negative environmental impact is carried out.

To build an establishment for food production at a specific location and to meet other spatial planning conditions, approval of the relevant competent authorities is required. The establishment should not be built on the site where preventive measures cannot ensure food safety and environmental protection.

The location for the construction of the establishment should be:

- outside environmentally polluted areas and industries that pose a threat to food safety (e.g. chemical use/production, significant dust) (this may include an assessment of the prevailing winds);
- on ground that is not prone to landslides or flooding (should be on compact and drainable soil with low levels of ground water), unless adequate and durable protection is assured;
- outside areas with neglected and untidy environments, or those constantly burdened with waste materials or conducive to the settlement of pests;
- a place with available necessary infrastructure for operation of the establishment (e.g. sufficient quantity of potable water, wastewater disposal, electric power, availability and quality of access roads).

Construction, layout and arrangements

<p>RFH - Annex 2 – Part 8: Requirements applicable to food: Points 3,7 and 8.</p>	<p>3. <i>At all stages of production, processing and distribution, food must be protected against any contamination likely to render the food injurious to human health.</i></p> <p>7. <i>Food business operators who are manufacturing or packaging processed food should have suitable rooms for the separate storage of raw materials from processed products and provide sufficient separate refrigerated storage premises.</i></p> <p>10. <i>Hazardous and/or inedible substances, including animal feed, must be adequately labelled and stored in separate rooms or containers.</i></p>
<p>RFH - Annex 2 – Part 6: Food waste: Point 3.</p>	<p>3. <i>Storage and disposal of food waste, non-edible by-products and other refuse may be managed in waste premises designed and constructed in such a way as to enable them to be thoroughly cleaned and protected from animals and pests.</i></p>
<p>RFH - Annex 2 – Part 9: Wrapping and packaging of food: Points 2 and 3.</p>	<p>2. <i>Wrapping materials must be stored in such a manner that prevents risk of contamination.</i></p> <p>3. <i>Wrapping and packaging operations must be carried out so as to prevent contamination, ...</i></p>

Land area for the construction of establishment should match the capacity, number and size of buildings constructed to ensure their connection and sufficient distance between the "dirty" and "clean" parts of the establishment.

For construction, hard and durable materials that are easily maintained and cleaned (and, where necessary, disinfected) should be used.

The construction, layout and arrangement of premises and equipping of the facility should allow enough space for the application of GMP and GHP in the production, processing and distribution of food and for the protection of food from contamination.

When designing new or altering existing establishments/premises, the following factors should be taken into account:

- expected daily throughput of the receipt and slaughter of each species in accordance with the planned slaughter schedule (i.e. daily, weekly, monthly, seasonal);
- expected capacity of meat (carcasses/halves, parts, packaged chilled and/or frozen meat), and the capacity of cutting, deboning and meat processing, in accordance with the planned schedule and structure of processing and treatment of meat and meat products (e.g. slicing and packaging of meat products), including possible future expansion;
- need for sufficient space for hygienic handling, production and storage of fresh meat and meat products;

- removal method and the required space for collection and disposal of animal by-products and other waste materials;
- required space and facilities for maintaining general hygiene in the establishment, personal hygiene and other employee needs;
- space needed for means of transport and loading and unloading operations.

Operations that extend over the designed capacity and/or available space, or perform multiple tasks in the same room, increase the risk of food contamination. One should avoid handling too many animals or excessive amounts of products within the available space/facilities, as cramped working conditions compromise GMP and GHP and increase the risk of contamination and its spread between carcasses/halves of slaughtered animals, employees, and the environment/surfaces that come into contact with food. The risk of cross-contamination can be reduced by:

- I) adjusting the real production capacity to the available space (e.g. number of slaughtered animals, quantity of products);
- II) performing tasks that pose a risk for cross-contamination in separate rooms/facilities; or
- III) performing different jobs (this is only true when the fbo has a small production volume) in the same room, but at different times. However, this may only be done between specified jobs and rooms where it was assessed that, with prior cleaning and disinfection between the different tasks at the same place, the risk of cross-contamination would not be increased, and that the possibility of the occurrence or spreading of contamination was reduced to a minimum.

This means that the total volume of work in every room needs to be adjusted based on its size. The number and size of rooms should therefore determine which activities (*what* and *how much*) may be carried out in a high-quality and hygienic way.

In general, "clean" and "dirty" operations should always be separated in space or by physical construction, e.g. carried out in separate rooms. The same principle whenever there is the possibility of direct or cross-contamination in food production, processing and distribution. This especially applies to exposed products and ready-to-eat food directly used by the consumer without prior heat treatment. For these reasons, the provisions of the regulations require that FBOs use separate rooms for certain activities, such as: handling and storage of raw materials, finished products, unpackaged (exposed) or packaged products intended for human consumption, by-products not intended for human consumption, packaging materials, hazardous substances/chemicals, etc.

Box 1: Derogation from the requirements: Use of the same entry and exit bay (shared intake and dispatch facilities)

"Establishments with low volume of meat processing may use the same entry and exit bay for raw materials, finished products and unsafe products, with appropriate separation in time".

When using a single entry/exit bay at different times for both intake (unloading) and dispatch (loading) of unpacked and packed fresh meat; finished products intended for human consumption; and inedible by-products, it is necessary to ensure GHP and the application of measures that will prevent the contamination of food.

In order to avoid contaminating products when being transported from the establishment to the vehicle (e.g. exhaust gases, dust, insects, birds, leaves, adverse weather conditions), structural solutions and clear procedures for loading and unloading are necessary. In addition, any possible negative impact of the environment on the temperature and relative humidity inside the establishment and the vehicle must be maintained at an acceptable level.

Optimum protection of the inside of the building and products, particularly of the exposed meat, may be achieved by using the appropriate bay to establish a direct connection between the establishment and the vehicle or, in cases where this is not possible, a canopy or awning may be sufficient. In exceptional cases, particularly in facilities with low capacity (e.g. when loading/ unloading of the vehicle must be carried out on the street/road), the operator must set out appropriate procedures for protecting exposed meat from contamination (e.g. closed or covered containers).

Establishment grounds

- It is recommended that the establishment grounds be fenced in. Access roads and roads within the grounds should be sufficiently broad and of solid material (e.g. concrete or asphalt).
- Roads within the grounds should be suitable for cleaning and washing and have a sufficient number of hydrants and drains.
- All ground surfaces that are not covered with concrete or asphalt should be covered by vegetation.
- Measures should be taken to control entry to and exit from the grounds.
- Animals should be prevented from accessing the property; pets and other animals should not be kept in any establishment working with food.
- Layout of buildings should ensure that the "clean" area is located near the exit/area that dispatches finished products intended for human consumption. It should also be separate from the "dirty" area, which includes entry routes for animals for slaughter, dispatch of by-products not intended for human consumption, and other waste materials located within this part of the ground.
- "Clean" and "dirty" routes may not be crossed by one another.

If there is a single entrance/exit gate for animals, inedible by-products and products intended for human consumption (e.g. small-scale slaughterhouses, cutting and meat processing facilities), it is necessary to ensure good hygiene practices and application of measures that will prevent food contamination.

1.2 Conditions on premises where food is prepared, treated or processed

Rooms where food of animal origin is prepared, treated or processed must meet the requirements defined in the regulations on general food hygiene and the special requirements for food of animal origin.

However, provisions on derogations and exemptions from food hygiene requirements may apply for the construction and layout of premises on which traditional products are produced or traditional production methods are used (Chapter 24). They may also apply for small-scale establishments that slaughter, cut and process meat. (Chapters 21 and 23).

Floor surfaces

**RFH – Annex 2 – Part 2:
Specific requirements in rooms
where food is prepared, treated
or processed:
Points 1 and (a) 3.**

1. Rooms where food is prepared, treated or processed, excluding dining areas but including rooms contained in means of transport, should be constructed and equipped in such a way as to provide good hygiene practices in food handling and protection against contamination between and during operations:

a) floor surfaces are to be constructed of impervious, non-absorbent, washable and non-toxic materials. They can be made of other materials if the FBO can prove that they are adequate, easy to clean and disinfect, have an adequate slope towards drainage channels and can be maintained in a sound condition.

For construction of floors, resistant materials suitable for erving floor transport that may be easily cleaned, washed and, where necessary, disinfected should be used. Floor surfaces should be non-slip, directed down slopes towards the drainage system, and hygienic, especially in wet areas. Floors must be maintained in a sound condition (e.g. quick repairs of damages/cracks) so that they can be kept clean. For example, concrete floors require more frequent repairs, which increase maintenance costs over time. Damaged floor surfaces may be the cause of product contamination.

Suitable materials are those that are impervious, non-absorbent and non-toxic and that may be washed, such as suitably coated concrete, epoxy resins and/or tiles, or other surfaces that satisfy the competent authority.

Walls

RFH - Annex 2. – Part 2: Specific requirements in rooms where food is prepared, treated or processed: Point 1b.	<i>b) Wall surfaces are to be constructed of impervious, non-absorbent, washable and non-toxic materials, have a smooth surface up to a height appropriate for operations, or can be made of other materials if food business operator can prove that are easy to clean and maintain.</i>
--	---

Walls must be well maintained so that they can be easily cleaned. Materials for outer wall surfaces that are difficult to clean or that are not resistant to moisture should be avoided. Friable materials or those that are readily peel (e.g. an ordinary paint, plaster, peeling laminates or damaged surfaces) may cause contamination and increase maintenance costs over time.

Suitable materials are those that are resistant to moisture (impervious, non-absorbent), non-toxic and that have a smooth surface and are washable, or the competent authority is satisfied that other used materials are appropriate. For example, properly installed ceramic tiles, plaster coated with washable paint (not recommended for walls that are close to work surfaces and equipment), plain or insulated panels, or walls with plastic or metal (stainless steel) coating (not recommended without additional physical protection/bumper in places where impact damage may occur), as well as the epoxy resins and similar coatings of wall surfaces.

Junctions between the walls and the floors, walls and ceilings and walls with each other must be smooth and sealed using an impervious material (e.g. silicone or mastic/waterproof sealant). The junctions should be rounded to reduce the possibility of retention and accumulation of dirt and to facilitate cleaning and sanitation.

It is recommended that the walls be light in colour so that dirt can be seen easily.

For ease of washing, the washable wall surfaces should go to the ceiling. However, smooth wall surfaces in cleaner spaces can go slightly higher than those that could come into contact with food (during handling or storage) or that are likely to become soiled or splashed (by water, blood, the contents of the stomachs and intestines, etc.).

On premises that require controlled temperatures (e.g. refrigeration, freezing, cutting, curing, incubation, etc.), the walls should have appropriate thermal insulation.

It is recommended that, where impact damage may occur (floor and/or suspended transport), the corners of walls and pillars be protected with built-in angle linings/shields made of stainless metal. Shields should be flat with smooth surfaces, built-in at the level equal to wall surface.

In the rooms and corridors where intensive floor transport is carried out, it is desirable to incorporate adequate protection of walls and doors (e.g. metal or parapet bumpers) and prevent subsequent contamination of food.

Ceilings and interior roof surfaces

**RFH – Annex 2 – Part 2:
Specific requirements in rooms
where food is prepared, treated
or processed:
Point 1c.**

(c) Ceilings (or the interior surface of the roof) and overhead fixtures are to be constructed and finished so as to prevent condensation, the growth of undesirable mould and the shedding of particles into food.

Ceilings, interior roof surfaces and overhead structures must be easy to clean and maintain to prevent the risk of product contamination from accumulated dirt or shedding of particles (e.g. old paint, plaster, rust, fibres, peeling or crumbling surfaces). Poorly constructed surfaces will lead to higher maintenance costs over time.

Ceiling materials, design and effective ventilation are all important in protecting against condensation and mould growth.

Suitable ceiling surfaces are those that are durable, cleanable and resistant to the conditions of the working environment (e.g. plastic coatings, concrete coatings, etc.). Polystyrene ceiling tiles are not suitable for ceilings in premises that handle food.

Fitting a suspended ceiling made of a washable material (e.g. plastic cladding) with overhead fixtures and installations above it may be an alternative solution. However, preventive monitoring and maintenance is needed to ensure such installations do not cause contamination, condensation problems, or pest infestations

It is recommended that the colour of the ceiling surfaces be light so that dirt and damage from wastewater leakage, moulds, cobwebs, etc. can be seen easily.

Windows

**RFH – Annex 2 – Part 2:
Specific requirements in rooms
where food is prepared, treated
or processed:
Point 1d.**

(d) Windows and other openings should be constructed to prevent the accumulation of dirt; those that can be opened to the outside environment are to be fitted with insect-proof screens which can be easily removed for cleaning. Where open windows would result in contamination, windows should remain closed and fixed during production.

Windows and other openings need to be capable of being maintained in sound condition (wooden windows should be protected with a waterproof coating/material) and be constructed and installed so to prevent the accumulation of dirt. Windows in rooms where food is handled may compromise the room temperature and product safety if opened for ventilation during production periods. They must therefore be blocked.

Windows that can be opened to the outside environment are to be fitted with insect-proof screens which can be, where necessary, easily removed for cleaning and maintenance.

Doors

RFH – Annex 2 – Part 2: Specific requirements in rooms where food is prepared, treated or processed: Point 1e.	<i>(e) Doors should be easy to clean and disinfect, constructed of impervious, non-absorbent, washable and non-toxic materials – or other materials if the food business operator can prove that they are appropriate.</i>
---	--

Doors should be adequately wide and tall to facilitate the easy movement of employees in accordance with the needs of food handling and equipment. Doors must be constructed and installed so that they can be easily maintained in sound condition and, if necessary, disinfected (smooth, waterproof, non-toxic materials, e.g. stainless steel or coated, plastic panels).

Doors may be made from wood (not recommended in areas with high humidity, low and high temperatures and floor transport), but all parts of the wooden doors should be protected with a waterproof and cleanable coating/paint. Parts of the wooden doors that are exposed to water and/or can be easily damaged should be protected with plastic or stainless steel coating.

Doors that are located in zones with high temperature fluctuations and/or in areas where certain temperature controls (e.g. cooling, freezing, cutting, curing) is required should have adequate thermal insulation. In cases where frequent crossing between rooms with the same temperature environment occurs, the door is not necessary; overlapping plastic strips may also be installed within the door opening (so-called "saloon" doors). This solution requires special attention and maintenance, cleaning and disinfection must be included in the relevant procedures of the operator's self-control system.

External doors must close the door opening tightly (e.g. for pest control, any external light must not be visible from the inside when the door is closed). When external doors are frequently used (e.g. for loading/unloading), additional measures to reduce any negative impact from surroundings such as dust, heat, etc. and to avoid pests may be used (e.g. self-closing mechanisms, air curtains).

Doors located in production rooms that open directly to the outside should be closed and locked during operations. If such doors have a specific purpose (emergency exit, removal of equipment, etc.), they may be used during operations only in accordance with good practices as stipulated in the operator's self-control system.

Food contact surfaces

RFH – Annex 2 – Part 2: Specific requirements in rooms where food is prepared, treated or processed: Point 1f.	<i>(f) Surfaces (including equipment surfaces) in areas where food is handled and in particular those in contact with food are to be constructed of smooth, washable, non-toxic and corrosion-resistant materials (or other materials when the food business operator proves they are appropriate), easy to clean and, when necessary, disinfect in order to be maintained in a sound condition.</i>
---	--

Equipment and surfaces that come into contact with food and inedible by-products, should be of a material that is easily cleaned and disinfected and that is not harmful to human health. In addition, adequate technical maintenance for the construction and materials should be ensured, including the replacement of parts and/or the repair of damages that may retain dirt and prevent effective hygiene procedures.

Construction and installation of equipment should provide its proper disassembling for ease of maintenance, good hygiene practices and appropriate internal/external control.

Angles, junctions and repaired damages of surfaces that come into contact with food should be smooth and rounded for good cleaning and disinfection.

Stainless steel and appropriate plastics that are smooth, non-corrosive, non-toxic and manufactured in accordance with the standards for effective sanitation are suitable for producing parts/surfaces that come into contact with food. The operator has the right to use other materials.

Wood is generally not acceptable as a material in the production, processing and distribution of food, as it can be easily damaged, absorbs liquid and is difficult to clean and disinfect. However, while respecting the principles of good manufacturing and good hygiene practices, wood may be used in some manufacturing processes and storage of food if the operator has demonstrated that its use does not endanger the safety of the product (e.g. ripening/drying of certain types of cheese and fermented/dried meat products).

Galvanized metal is prone to corrosion and should be avoided.

Handwashing facilities

**RFH – Annex 2 – Part 1:
General requirements for
food premises:
Point 3.2.**

2) An adequate number of handwashing basins is to be available, suitably located, and provided with hot and cold running water, materials for cleaning hands and for hygienic drying. The facilities for washing food are to be separate from the handwashing facility

The number of handwashing basins needed depends on the number of employees and the nature and location of the operations being carried out in the establishment.

Position of handwashing basins. Handwashing basins should be placed conveniently close to toilets, entry points for food-handling areas and workstations to encourage staff to wash their hands. Employees should have easy access to basins fitted with taps designed to prevent cross-contamination (e.g. powered by pressing a button with the foot or knee rather than with hands, or activated automatically by sensors).

The supply of hot and cold water. Hot and cold water can be supplied through separate taps, but a mixed supply to provide a moderate temperature is preferable to ensure that employees are not discouraged from using the facilities because of extreme water temperatures.

Handwashing materials. There must be an appropriate agent for handwashing (solid or liquid soap) available next to the tap. Antibacterial soaps and other agents for hand hygiene, including skin protective, unperfumed creams may be used provided they do not pose a threat to food safety. If a nailbrush for washing hands is used, it must be replaced or washed regularly because it can harbour bacteria.

Hand drying. Disposable paper towels for drying hands are recommended. There must be a bin/basket available to discard the used paper towels. Drying with hot air dryers is not recommended because they can create aerosols that may contaminate the environment/food contact surfaces. If cloth reusable towels are used they must be laundered before reuse.

Handwashing basins must be separated from food washing facilities.

Food washing facilities

**RFH – Annex 2 – Part 2:
Specific requirements in rooms
where food is prepared, treated
or processed:
Point 3.**

3. Adequate provisions are to be made, where necessary, for washing food. Every sink or other such facility must have an adequate supply of hot and/or cold potable water and be regularly cleaned and, where necessary, disinfected.

The food-washing facility may simply be a sink supplied with a continuous flow of potable running water (i.e. not occasionally filled and emptied), or may be customized equipment designed for the purpose. Food is not permitted to be washed in containers with standing water.

Facilities provided for washing food should have an suitable supply of hot and/or cold potable water so as to prevent splashing. Washing under high pressure (e.g. a unit with jet spray) should be avoided to prevent possible contamination of adjacent food, surfaces and staff.

Processes around handling washed and unwashed food should prevent contamination of washed food.

Ventilation

**RFH – Annex 2 – Part 1:
General requirements for food
premises:
Point 3.3 and 6.**

3) There are to be suitable and sufficient means of natural or mechanical ventilation which prevent airflow from contaminated areas to clean ones. The ventilation system is to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.

6) Toilets and changing facilities are to have adequate natural or artificial ventilation.

Adequate ventilation in establishments should be provided to minimize the contamination of food through the air, prevent build-up of heat and humidity, and eliminate odours and smoke that may compromise the food.

The ventilation system should be designed and installed so as to allow the entry of fresh air while preventing the entry of contaminants and pests. It should also block airflow from dirty/contaminated areas to clean areas.

Ventilation systems should be constructed and installed in a way that enables easy cleaning and maintenance.

Adequate ventilation may be achieved artificially or naturally. Natural ventilation can be achieved by opening windows, but this is usually sufficient only in very small premises. Artificial (mechanical) ventilation may be provided with a simple wall or window-mounted fan, steam extractors, or local or central ventilation ducted systems. These devices are best situated near sources of heat, steam, smoke and odours to maximize their effectiveness.

The position of air inlets (external and internal) for food-handling areas is important so that dust, doors or fumes are not drawn in. Outside air inlets should be fitted with screens against insects, birds and other pests, and where necessary, with cleanable filters.

Ventilation ducts and air inlets/outlets in rooms subject to cooling temperatures should be regularly cleaned from dust and, if needed, the procedure should involve the cleaning and disinfection or replacement of parts in order to avoid the spread of contamination (e.g. mould spores can accumulate in parts of ventilation system: screens, fans, filters, etc.).

Recommendation: The ventilation systems must be thoroughly checked and, if necessary, disassembled and cleaned as they are complex installations that may have significant consequences in case of failure.

Adequate ventilation should be provided not only in the working areas but also in toilets and in changing facilities.

Lighting

**RFH – Annex 2 – Part 1:
General requirements for food
premises:
Point 3.4**

4) *Should have adequate natural and/or artificial lighting.*

Lighting may be natural or artificial but must be good enough to allow safe food handling, effective cleaning, monitoring of hygiene standards and inspection. Lighting should not distort perception of colours, but allow any discoloration of meat to be identified easily.

Intensity of lighting must be adapted to the nature of the work. High-intensity lighting is recommended and these levels are considered adequate:

- 540 lux at inspection points
- 240 lux in work rooms
- 110 lux in other areas

For poultry welfare reasons, blue lighting should be used for its calming effect while receiving and hanging poultry on hooks for stunning and slaughter. However, lighting must also be sufficiently strong allow adequate inspections to be performed.

Sources of lighting. Lightbulbs/tubes must be protected by covers (protective shatterproof and waterproof covers) to minimise the risk of contamination of food by glass fragments if there are damages/breakages and for easy cleaning

Recommendation: Sources of lighting above the work area must be checked frequently and if necessary, disassembled and cleaned.

Wastewater drainage

**RFH – Annex 2 – Part 1:
General requirements
for food premises:
Point 3.5.**

5) Drainage facilities are to be designed and constructed to avoid the risk of contamination. Where drainage channels are fully or partially open, they should ensure that wastewater does not flow from a contaminated area towards or into a clean area, in particular those area where food likely to present a risk to the final consumer is handled.

The drainage system must be able to dispose of wastewater effectively during the maximum volume of work at any time. In addition, the system should be easy to clean and maintain, the effluents and materials should be carried out toward “dirty” parts of the line and not allow effluent or foul air to enter “clean” areas, and it should prevent the entry of pests.

Wastewater from equipment should be connected to drains via water traps/“siphons” (e.g. hand washing basins, sterilizers, other washing equipment, refrigeration equipment) or via a disconnected drain (e.g. for washing cattle heads, edible offal, carcasses/sides, and washing and sanitizing) so that water does not flow freely on floors. Floor drainage in wet areas, where necessary (e.g. on the slaughter line), must be provided with enough capacity to prevent overflow and splashing of effluents through channels and slopes and the floors should be laid out so that wastewater is directed down slopes into drains to minimize pooling.

Open drainage channels should have removable gratings for easy cleaning and maintenance.

Drains should have removable gratings and effective water traps or sediment traps that are easy to clean and do not allow foul air or effluent to enter food-handling areas. Water traps assist with

rodent control. Sediment traps are buckets to prevent excess solid materials entering the lower drainage system where they can result in blockage.

In accordance with a special regulation, drain traps or sieves in wastewater systems of slaughterhouses at points where specified risk material (SRM) is removed must ensure that the solid particles are no more than 6 millimetres.

Protective gratings/screens should be fitted to drains that open to the outside of the building to prevent the entry of rodents/pests.

If there are internal drain inspection chambers (manholes) within the building, they should be double sealed and secured so that overflow and spread of foul air cannot occur

Changing facilities

**RFH – Annex 2 – Part 1:
General requirements
for food premises:
Point 3.7**

7) Where necessary, adequate changing facilities for personnel are to be provided.

Where the employees need to wear working and protective clothing, adequate changing facilities separate from food-handling areas and the toilets should be provided, with a sufficient number of lockers so that staff can store their outdoor clothing and personal belongings or work clothing. Benches or chairs that are used during changing clothing and footwear may minimize the possibility of getting work and protective clothing dirty.

In order to avoid contamination, there should be a place for:

- keeping protective clothing clean
- disposing of dirty clothing

Laundry and, if necessary, ironing of clothing may be done in a separate room, or can be contracted with an outside service.

It is not acceptable to use changing facilities for other purposes; and other areas may not be used as a changing room.

It is desirable that the changing area be in the same building as or connected to the food operation.

Between the food-handling area and the changing room, a “hygiene Interspace“ should be designed and arranged which may have a handwashing facility and simple facility for washing boots, and may include space for washing and drying/hanging aprons.

Toilets

RFH – Annex 2 – Part 1: General requirements for food premises: Point 3.1.	<i>Premises on which food is handled should have: 1) An adequate number of flush lavatories connected to a drainage system. The toilet areas are not to open directly into rooms in which food is handled.</i>
---	--

Preferably, flush lavatories should be in the same building as or connected to the food operation. However, in small-scale meat processing establishments where staff numbers are very small and the premises are next door to a house, adapted provisions laid down for changing and toilet facilities may be applied.

Toilet doors must not open directly into the room where food is handled.

Handwashing facilities before the toilets is recommended so that staff can remove and hang up their protective clothing before using the toilet.

Toilets should be directly connected to the sewerage system.

The number of flush lavatories should correspond to the number and gender of employees.

Storage of cleaning chemicals

RFH – Annex 2 – Part 1: General requirements for food premises: Point 4.	<i>4. Cleaning agents and disinfectants may be stored in rooms where food is not handled.</i>
---	---

Cleaning and disinfecting chemicals should be kept/stored in a separate and locked room or, exceptionally in small-scale food establishments, in a place (e.g. cupboard, cabinet) that can be locked and used only for this purpose, so that it does not pose a threat to food contamination and human health.

1.3 Equipment and materials

Equipment and materials on premises where food is prepared, treated or processed must meet the requirements laid down in food hygiene legislation.

Provisions on derogations and exemptions from the requirements of food hygiene may be applied when equipping premises on which traditional products are made or traditional production methods are used (Chapter 24).

<p>RFH – Annex 2 – Part 5: Equipment requirements: Points 1b and c, 2 and 3.</p>	<p><i>1. Equipment, articles and fittings with which food comes into contact are to:</i></p> <p style="padding-left: 20px;"><i>(b) be of such material and be maintained in a good condition as to minimize any risk of contamination, with the exception of containers and packaging for single use (non-returnable);</i></p> <p style="padding-left: 20px;"><i>(c) be installed in such a manner as to allow cleaning of the equipment and the surrounding area.</i></p> <p><i>2. Where necessary, equipment must be fitted with an appropriate control device according to the technological requirements of production.</i></p> <p><i>3. Where chemicals have to be used to prevent corrosion of equipment and containers, such chemicals are to be used in a manner to prevent contamination.</i></p>
---	--

Equipment that comes into contact with food (excluding containers and disposable packaging) needs to be constructed so that it can be kept clean, washed, disinfected and maintained in sound condition.

Before purchase and installation of equipment, the following should be carefully considered:

- material surfaces are smooth, washable, easy to clean, corrosion-resistant, and non-toxic;
- suitable materials are stainless steel or food grade plastics; galvanized metal is prone to corrosion and is therefore not acceptable for direct contact with exposed food;
- in general, wood is not acceptable (easily damaged, difficult to clean and disinfect), except for use in cases where derogations from the general food hygiene requirements (wood can be used in some processes and/or procedures the risk level for product safety is acceptable, e.g. in the production of certain types of cheeses and fermented/dried traditional meat products);
- all parts and surfaces coming into contact with food are available for cleaning and disinfection and there is no space where materials/dirt can be trapped;
- the equipment can be disassembled for cleaning and maintenance, pest control and adequate supervision;
- the surfaces are without cracks, ridges or crevices; where possible, joints should be continuously welded, and then junction surfaces smoothed to avoid sharp edges, screws and rivets;
- the corners of equipment are rounded (easy for cleaning);

- the moving parts requiring lubrication (e.g. bearings) are away or protected from food contact surfaces (while ensuring that lubricants do not contaminate product);
- surfaces should allow water and cleaning residues to drain away quickly;
- where the construction of the machinery prevents disassembling or where the contact surfaces are not accessible for adequate cleaning, the equipment should have a clean-in-place (CIP) system for cleaning and disinfection;
- the location and the installation of equipment should allow all parts of the equipment and the surrounding areas to be accessible for maintenance, good hygiene practices and reliable control; fitting equipment in places where access or cleaning is difficult should be avoided;
- equipment should be installed so that the floor surface under the machine can be easily cleaned (e.g. using platforms/holders/carriers rather than floor mounted);
- the equipment for cooling, thermal processing and storage should be designed and constructed so that the pre-set temperature values can be achieved quickly in order to preserve the safety and quality of food;
- where necessary, equipment should have adequate measurement and control instruments to manage and monitor processes and certain critical parameters (e.g. temperature, time, humidity, air circulation), including calibration certificates (attestation of conformity);
- it is recommended that the automatic device for monitoring/recording temperature have an audio and/or visual warning signal when the limit temperature values are endangered or being breached;
- operator shall maintain and keep records when monitoring the parameters established in accordance with the provisions of the regulations or the operator's self-control procedures.

Equipment for collection, temporary storage and transport of animal by-products not intended for human consumption (e.g. containers, vehicles) should be leak-proof and easily cleaned, washed and disinfected and, according to the purpose (risk category), correctly and clearly marked. In addition, the construction, capacity, location and method of installation must all prevent the contamination of food and the environment.

Equipment for the collection, temporary storage and transport of waste materials must correspond to its purpose and allow the application of good manufacturing and hygiene practices.

1.4 Temperature controls

In establishments that produce, process and distribute food, the temperature control should provide adequate cooling (achieve and maintain appropriate levels of cooling or freezing temperatures) and heating (heating of water to sanitize tools and equipment, maintain hygiene within the establishment, and allow for thermal processing at pasteurizing or sterilizing temperatures) depending on the nature of the operations performed.

Importance of chilling

<p>FSL – Food hygiene requirements: Article 37, point 3.</p>	<p><i>Food business operators shall, according to the type of food, implement specific food hygiene measures in order to ensure:</i></p> <p><i>(c) compliance with temperature control requirements for food;</i></p> <p><i>(d) maintenance of the cold chain.</i></p>
<p>RFH – Annex 2 – Part 1: General requirements for food premises: Point 2d.</p>	<p><i>2. The layout, size and siting of premises where food is handled should:</i></p> <p><i>(d) provide temperature-controlled handling and storage conditions of sufficient capacity to maintain food at appropriate temperatures that may be monitored and, when necessary, recorded.</i></p>
<p>RFH – Annex 2 – Part 8: Requirements applicable to food: Points 5 and 7.</p>	<p><i>5. Raw materials, ingredients, intermediate products and finished products likely to support the reproduction of pathogenic microorganisms or the formation of toxins should be kept at temperatures that minimize risks to human health. The cold chain must not be interrupted.</i></p> <p><i>7. Food business operators involved in manufacturing or wrapping processed food should have separate storage rooms for raw materials and processed products and should provide cooling equipment such as cooling chambers with sufficient separate space for storage.</i></p>

Regardless of the type and capacity of the establishment engaged in food production, processing and distribution (including approved and registered establishments), temperature requirements are one of the basic elements of food safety management and must be respected. Procedures related to reaching and maintaining temperatures should be an integral part of the operator's self-control system.

Warm and wet food provides the ideal conditions for the growth of microorganisms that cause food poisoning and spoilage. Low temperatures and dry surfaces will inhibit the growth of bacteria and moulds and extend the shelf life of food products. In order to preserve the safety of foodstuffs, it is important to maintain the temperatures at a predetermined level that is regulated or defined in the operator's self-control system.

Layout, siting, size and arrangements of refrigerated rooms should be designed to achieve and/or maintain the required temperatures of food, particularly for anticipated throughput at peak production periods, including the warmest periods of the year.

Speed and quality of cooling

F

or quick, quality cooling, it is important to ensure the following:

- capacity and functionality of the device and the intensity of cooling, i.e. air temperature;
- temperature of product at the beginning and the end of the process (temperature of product entering and leaving the chilling facility);
- speed/time and frequency of loading and unloading the chamber/equipment;
- relative humidity and airflow;
- quantity/volume of products (loading level);
- spacing between products (free space between the pieces/packaging of products);
- thickness of single or stacked pieces/packaging units.

Food refrigeration units should be adjusted to an appropriate temperature. If different types of food with different chilling rates and storage temperatures are being handled simultaneously, different product groups should be kept apart from each other in separate rooms or refrigeration devices. Poor manufacturing practices (overloading chilling rooms, freezer rooms or chilled storage rooms beyond their designed capacity; long and frequent opening of doors), will delay reaching the pre-set temperature values.

Chilling and condensation

RFH Annex 2 – Part 1: General requirements for food premises: Points 2b and 3.3.	<i>2) The layout, size and siting of premises where food is handled should: (b) prevent ...the formation of condensation or undesirable mould on surfaces;</i> <i>3.3) There is to be suitable and sufficient means of natural or mechanical ventilation.</i>
UPZHPŽP – Prilog I, Odeljak I DIO VII: Skladištenje i prevoz Stav (1), tačka 1)	<i>...after the post-mortem inspection, meat must be chilled in the slaughterhouse ... while providing the adequate ventilation to prevent condensation on the surface of the meat.</i>

Since humidity encourages the growth of microorganisms on the meat, condensation is a sign that quick corrective actions should be undertaken. After analysing the possible causes, preventive measures may be implemented to prevent future condensation on all surfaces including equipment (ceiling, lighting bulbs other equipment, cooling equipment, gauges and upper structure, work surfaces, walls, etc.) and products (e.g. carcasses/halves, unpackaged finished products). By fitting the appropriate insulation materials, increasing the air circulation and cooling intensity in refrigerated rooms, implementing good practices in the handling of products that should be chilled (rate of operation; use of hot water for sanitation of tools and equipment on the slaughter line, and meat cutting), relative humidity and the risk of condensation or direct contamination may be minimized.

Maintaining the cold chain

After cooling food to legal temperatures or below, it is necessary to maintain that temperature during storage, cutting, deboning, processing, wrapping, packaging and transport to minimize the opportunity for growth of microorganisms.

Meat can be kept for a certain time at the required temperature by maintaining the temperature in the room where meat is handled (e.g. cutting room: 12 °C). This temperature provides sufficient time for the necessary cutting/deboning operations of chilled meat, with no significant increase of the meat's surface temperature. However, interruptions of the cold chain should be kept to a minimum by keeping meat (carcasses/halves or packed) in chilled storage until it is ready for the cutting room; and once it is cut/deboned, meat should be promptly transferred to refrigerated storage. Particular care is needed where the rate of accumulation of small meat pieces (e.g. trimmings) may take several hours for containers to be filled and moved to chilled storage. The operator must manage the intake temperature of meat, quantity and the speed/time of meat cutting and retention period in the cutting room, so as to ensure that the meat will remain within the temperature limits of chilled meat.

The cold chain is not to be interrupted. This includes maintaining the temperature of already chilled/frozen products if a standard has already been legally established (e.g. fresh meat according to animal species; meat products according to manufacturers' specifications). However, limited periods outside of temperature control are permitted (at room or so-called ambient temperature), to accommodate the practicalities of handling during preparation, transport, storage, display and service of food, provided that this does not represent a risk to product safety and human health.

Interruption in the established temperature along the food chain accelerates the growth of bacteria and seriously jeopardizes product safety. The time period when there is a risk that the food is out of a certain temperature regime should be as short as possible, and interruptions of the cold chain should be reduced to a minimum. This can be achieved by, for example, rapid loading/unloading, avoiding the accumulation of chilled meat in ambient temperature areas, or having refrigerated dispatch areas. This is of particular importance during hot periods of the year, including for the connection between the vehicle and the building during loading/unloading operations. Finally, good practices may include cooling the transport vehicle before loading, and opening vehicle door as little as possible to help maintain the correct temperature of the product.

Refrigerated transport

**RFH – Annex 2 – Part 4:
Transport:
Point 7.**

7. Where necessary, means of transport and/or containers used for transporting food must be capable of maintaining and monitoring food at the appropriate temperatures.

Since there are special temperature requirements for transporting meat, vehicles and containers that transport meat must be cooled or be able to maintain the cold chain at the regulated temperatures set for the type of food, unless a special exemption is applied under specific conditions and approval by the competent authority (see Chapter 2 – Meat cutting).

Means of transport are used to maintain the cold chain, but not to lower the temperature of meat to the established limit. To this end, temperature limit values should be set with tolerances for transport taking into account the following factors:

- air temperature within the vehicle;
- product temperature at loading and unloading;
- relative humidity and air circulation;
- quantity/volume of products (loading level);
- spacing between product;
- time/frequency of loading and unloading while en route.

Well-constructed, refrigerated means of transport should have good insulation, adequate opportunities for internal allocation of goods, sealing doors, watertight floor surfaces, and an efficient cooling device. The instruments in the driver's cab should show the air temperature in the loading chamber, with the possibility of continuously monitoring and recording the temperature during transport, automatically or manually. Any deviation and subsequent corrective measures should be recorded.

Temperature measurement devices

Where necessary, the temperature on premises with food should be monitored and recorded. It is important that any deviation beyond the established limits be recorded and corrective measures should be taken. There must be a documented procedure to be applied in the case of such deviations.

RFH – Annex 2. – Part 5: Equipment requirements: Point 2.	<i>2. Where necessary, equipment must be fitted with an appropriate control device according to the technological requirements of production.</i>
--	---

For temperature monitoring, manual or automatic instruments/devices that show, write or "remember" the current ambient or internal product temperature can be used. It is recommended that the temperature monitoring system be equipped with a warning device (sound and/or light alarm) when the specified temperature or time limits outside of the specified temperature are in danger of being breached.

In approved establishments with a small business volume, the air temperature can be monitored with thermometers (with or without probes), and the temperature values can be recorded in accordance with the operator's established procedure, including the reading frequency, way of writing the temperature values and corrective measures being taken in case of deviations.

In all cases when temperature deviations are recorded, corrective action taken and their effect must be also recorded.

Although the temperature on the surface of the meat is most important for product safety (microbiological contamination is usually confined to the surface), the product is only cooled to the

required temperature once the measured value of the whole product, including at its thickest point, is equal to or lower than that identified in the operator's self-control documents.

The food temperature can be measured by manual probe or remote thermometer. Reading values are entered in the records in accordance with the procedures of the operator's self-control system. The part of the thermometer that comes into contact with food must be hygienic and cleaned and disinfected after each use so that it does not contaminate the food.

Maintenance and accuracy of measurement and control devices. The operator should insure that measurement and control devices work accurately by checking each one regularly (at the recommended service time intervals) and at any time that there may be a defect, against a recognized standard (calibration). The operator should keep a record of the individual thermometer number and the date and outcome of the check.

Freezing meat

**RSHRPAO – Annex I, Chapter I
Part VII: Storage and transport
Paragraph 3.**

(3) Meat intended for freezing must be frozen without undue delay and, where necessary, after a stabilization period.

Freezing is a food preservation method. Before it is placed in a freezer, meat should be cooled to minimize condensation and temperature fluctuations in the freezer.

With the formation of ice crystals, microorganisms stop growing, but they are not destroyed. Good practices in freezing (freezing immediately after reaching the established temperatures; proper food handling; and the rate of freezing), and maintaining a constant storage temperature in the freezer prevent the growth of microorganisms and the negative impact of ice crystals on meat quality.

Food hygiene regulations do not determine the storage period for frozen meat. If handling alongside fresh meat, the FBO determines the storage life of both (and divisions including halves/quarters, parts, processing categories) in its manufacturing specification. However, the temperature requirements of minced meat, prepared meat and MSM are determined by the provisions of the regulation on specific hygiene requirements for products of animal origin, and the legal temperature conditions must be maintained during storage and transport.

Type of animal, product, and packaging, speed of freezing, and fluctuations in temperature and storage temperature will affect the shelf life of frozen foods.

Thawing meat

<p>RFH – Annex 2 – Part 8: Requirements applicable to food: Point 9.</p>	<p><i>9. Food must be thawed so that there is no growth of pathogenic microorganisms or the formation of toxins; and run-off liquid from the thawing process must be adequately drained to prevent contamination and risk to human health.</i></p>
<p>RSHRPAO – Annex I, Chapter I Part III: Storage and transport Paragraph 1, point 1.</p>	<p><i>7. Defrosted minced meat, meat preparations and MSM must not be refrozen.</i></p>

Thawing meat melts ice and releases liquids, providing the conditions for growth of microorganisms. Liquid from the thawing process should be adequately drained and anytime that packaging containing such liquid is opened it should be removed to prevent its leaking onto other food, packaging or working surfaces. In addition, the thawing process should be done under controlled temperature and time conditions to ensure a stable temperature increase, but only up to the legal temperature limits for meat.

Once defrosted, meat may be refrozen if its bacterial load has been tested, and such meat may only be used for processing in meat products that undergone heat treatment.

Heat treatment: Hermetically-sealed containers

<p>RFH – Annex 2 – Part 10: Heat treatment: Points 1–3.</p>	<p><i>1. Food placed on the market in hermetically-sealed containers should be heat treated to avoid processing an unprocessed product or further processing an already processed product whereby:</i></p> <ul style="list-style-type: none"> <i>(a) every part of the product must be heated to a given temperature for a given period of time;</i> <i>(b) product contamination must be prevented during the thermal process.</i> <p><i>2. Food business operators must regularly check the main parameters (temperature, pressure, container sealing and microbiology criteria) with automatic devices.</i></p> <p><i>3. The thermal process includes food pasteurization, exposure to ultra high temperatures or sterilization in accordance with international standards.</i></p>
--	--

Canning food in a permanently sealed container and subjecting it to heat for a specific period of time before cooling will destroy microorganisms that cause food poisoning. The hermetical seals will prevent re-contamination of the canned product.

Heat treatment regimens are to be determined for each product separately and are to be part of an operator's documented self-control system. When conducting heat treatment, the operator must set the conditions for monitoring temperature and time, including warning devices (audible and/or visible alarm) if the process parameters are at risk of changing (temperature, time, pressure).

1.5 Water supply

Adequate supplies of water that meets potable water quality requirements must be provided for establishments handling food.

RFH – Annex 2 – Part 7: Water supply: Points 1.a and 2.	<p><i>1. Establishments where production, processing and distribution of food is performed must:</i></p> <p style="padding-left: 40px;"><i>(a) be provided an adequate supply of potable water to prevent food contamination.</i></p> <p><i>2. In order to prevent food contamination adequate facilities and procedures must be provided for water supply.</i></p>
--	---

The quality and safety of water are two of the most important conditions of good manufacturing and hygienic practices in food businesses, because water can be a source of different microbiological and chemical hazards. The microorganisms that cause food poisoning can survive for several days to weeks in an aqueous medium.

Water supply systems (public water supply, private wells) can be contaminated with faecal microorganisms and with various chemical substances (e.g. metals, pesticides, nitrates) from sewage and/or wastewater originating from agricultural and other economic activities. Bacteria can reproduce in the water systems, especially if water is standing for a long time in storage tanks or pipes that are not in use.

Using non-hygienic water presents a hazard to food safety and to employees. Therefore, the quality of water used in the production, processing and distribution of food is one of the pre-requisites for food safety.

The water supply of facilities that operate with food may come from a public water supply or from private sources/wells. Water always has to meet the legal requirements.

The use of water from private wells requires special attention, which should include prior verification of the overall quality of water, protection from contamination. During use, regular quality checks and, if necessary, adequate treatment/processing (e.g. filtering, sedimentation, chlorination) should also be carried out.

Water supply system should be of sufficient capacity to meet the peak requirements of working operations and to facilitate good hygiene practices in the establishment.

Plumbing systems should be maintained (e.g. checks and repair of damages, corrosion, leaks, cleaning or filter replacement) and, if necessary, rinsed and cleaned (disinfected). If necessary (e.g. when the water is "hard"), use of approved water softening agents is allowed to reduce the accumulation of deposits (better effect of detergents), but with application of good practices so that they do not become sources of contamination.

Experts should be consulted for high-quality, safe procedures and measures when chlorinating and softening water, including cleaning and disinfection of the water system.

Potable water

Drinking water is water that, in accordance with the special national regulations (Regulation on detailed requirements that drinking water in terms of safety shall meet – Official Gazette of Montenegro, No. 24/2012), meets the minimum requirements laid down for the quality of water intended for public supply, including water intended for the production and processing of food and maintenance of hygiene in the establishment.

Water control

Food operators must establish control plans and procedures to prevent, remove or minimize risks of water contamination and thus prevent consumers' diseases.

Bearing in mind that the water distribution system is unique to each facility, the operator shall, in accordance with the risk assessment, establish and implement an individual plan and procedures for quality/safety control of drinking water.

A water self-control plan should include a schematic plan of water distribution with the appropriate legend, plan/points and frequency of sampling and testing, content of tests, measures in case of non-compliant results and cleaning/maintenance of the water supply system.

A schematic plan of the water distribution in an establishment (joint or separate layout of the establishment location and layout of the production premises) should at least include: point of entry of water into the establishment (from the connection to the public water supply/water gauge, or from its own wells); location of the water treatment (e.g. chlorination), if any; as well as complete distribution pipelines of cold and hot water with taps at the points of use.

Water self-control plans may include a distribution of non-potable water that is clearly marked (e.g. pipes in different colours). Self-control plans are updated in accordance with the construction and technological changes of the establishment in order to ensure the maintenance of the water supply system, its protection from contamination, and the continued effectiveness of internal and external controls.

Use of nonpotable water

**RFH – Annex 2 – Part 7:
Water supply:
Point 3.**

3. Where non-potable water is used (for fire control, steam production, refrigeration and other similar purposes), it should circulate in a separate pipeline system that is not connected with, or allowed reflux into, the potable water system.

To save drinking water, non-potable water may be used for certain purposes and the operation of the systems where water does not come into contact with food (e.g. for fire control, non-food contact steam production, refrigeration equipment). However, if the non-potable water is used in the establishment, non-potable water pipelines must be completely separate from any part of the potable water system and be clearly marked to avoid misuse of non-potable water and the contamination of food. Also, it must be assured that there are no opportunities for non-potable water to enter the potable distribution system (e.g. through siphoning back from a drain, submerged hoses, blocked drain traps).

Use of ice

**RFH – Annex 2 – Part 7:
Water supply:
Point 5.**

5. Ice that comes into contact with food or that may contaminate food must be made from potable water or, when used to chill whole fishery products, must be made from clean water and must be stored in a manner that protect it from contamination.

Ice that comes into contact with food must be produced from potable water. Methods of production, handling and storage of ice must protect the ice from potential contamination. Devices for production and storage containers for ice must be regularly cleaned and disinfected, and manufactured ice must be protected (covered or closed) from contamination.

Use of steam

**RFH – Annex 2 – Part 7:
Water supply:
Point 5.**

6. Steam that comes into contact with food must not contain substances that may present a hazard to health or are likely to contaminate the food.

Steam that comes into direct contact with food must be manufactured from potable water and must not contain harmful substances. Employees who handle food should be trained to know the importance of water quality and its use in working with food, especially regarding the procedures and business operations (hygiene, production, control) that are under their competency. Also, employees must be aware of their obligation to report problems in the water supply system promptly, including deviations in the use and control of water quality.

1.6 Establishment and equipment maintenance

Maintenance is the application of preventive and corrective procedures for appropriate regular control checks; replacement and repairs throughout the facility enabling its functionality and implementation of good hygiene and manufacturing practices; and the assurance of the safety and wholesomeness of food and health and safety of employees.

**RFH – Annex 2 – Part 1:
General requirements for food premises:
Point 1.**

1. Food premises must be maintained...in good condition.

A prerequisite for good and easy maintenance is appropriate structure, construction, layout and equipping of the establishment, where the choice of materials, their durability and installation quality, as well as the selection of equipment, their installation and the possibility for their dismantling are of the utmost importance for the implementation of good hygiene practices.

Although maintenance is related to the whole establishment, it has a special significance for:

- premises where food is handled;
- devices, equipment and surfaces that come into contact with food;
- vehicles and containers for food transport.

Staff who are engaged in checking conditions of the premises and/or are involved in maintenance should be trained and experienced enough to observe and assess the state and acceptable limits or the need for preventive or corrective intervention on defects that can affect performance and/or hygiene conditions for food operations. For some inspection checks and maintenance tasks (e.g. measuring and control devices, pressure vessels), a specially trained person should be engaged.

A preventive maintenance plan should be in place to prevent sudden breakdowns, unexpected repairs and reduce the costs of future maintenance. This plan should include all procedures in the production, processing and distribution of food.

All repairs should be done during breaks or, when necessary, during operations if the food has been removed or protected. Parts and materials used in repairs must not pose a threat to the food safety. Persons responsible for maintenance must follow the rules of the food business operator, including those concerning personal hygiene, and should take into account the impact of their work on the safety of the food. Storage of spare parts and materials for repair should ensure they do not become a source of pollution.

1.7 Cleaning

Dirt, waste, chemicals and pests are a significant potential source of microbiological, physical and chemical contamination of the environment in the food industry.

RFH – Annex 2 – Part 1: General requirements for food premises: Point 1.	<i>1. Food premises must be maintained in a clean...condition.</i>
---	--

Effective cleaning on a regular basis is essential to remove all debris from the food premises. Poorly executed cleaning programmes directly threaten food safety. Therefore, the FBO should establish procedures to prevent or minimize the risks of such hazards causing illness or injury to consumers.

Surfaces in contact with food are considered to be clean if they are:

- physically clean – all visible dirt/impurities have been removed;

- chemically clean – residues of cleaning materials have been removed;
- microbiologically clean – the number of microorganisms have been reduced to a level that does not pose a risk to human health.

To maintain hygiene, different chemicals that dissolve and remove dirt (detergents) or that have an antimicrobial effect (disinfectants) can be used, and there are cleaning materials that have a combined effect. The effect of disinfectant is not complete if the treated surface has not been previously cleaned of grease and protein residues, etc.). All materials have their optimum effect if they are prepared and used correctly and at a certain temperature in accordance with the manufacturer's instructions.

Cleaning plan. Operators need to establish a sanitation plan (cleaning and disinfection), which should encompass the entire premises of the food establishment (e.g. production, storage, transport).

The sanitation plan should outline the appropriate level of cleanliness of the facilities and equipment, as well as the cleaning equipment itself. The plan must be regularly and fully implemented and documented. It should include a sanitation checklist, which will ensure that no area or piece of equipment is missed and which can record problems and corrective measures taken. The sanitation plan can be prepared in cooperation with experts and must be updated in accordance with changes in the chemical substances used, working procedures and preventive measures, as well as changes in the facility and equipment.

Periodically and when necessary (e.g. use of a new chemical), the effects of sanitation and applied procedures should be checked and confirmed before the operations start by sampling and testing the work environment, such as surfaces that come into contact with food.

The sanitation plan should contain at least:

- rooms/surfaces, equipment and device items/parts to be cleaned;
- method and frequency of cleaning;
- responsible party for cleaning and/or individual tasks;
- chemicals, materials and equipment to be used;
- safety precautions and protective measures to be taken;
- responsible party for checking/control.

In accordance with the risk assessment, surfaces that come into contact with ready-to-eat food (consumed without preparation/heat treatment) may be cleaned several times during the shift or day; while surfaces that come into contact with unpacked meat should be cleaned at least once per shift or day; and other surfaces as needed.

Facilities and equipment where food is handled should be clean at the beginning of each shift, and if necessary, after breaks; it is a good practice to sanitize immediately after the end of the operation, during breaks or between shifts. When employees have finished their work, all edible products should be removed and all residual coarse materials/wastes should be cleaned so the workplace is prepared for sanitation. If sanitation is to be done contemporaneously with the work, measures must be taken to protect food from potential contamination.

Unless otherwise stated in the manufacturer's instructions, the cleaning process consists of 5 stages:

- Stage 1: preliminary cleaning and scraping, brushing and wiping of food and dirt residues, followed by a pre-rinse with potable water;
- Stage 2: main cleaning, scrubbing off any remaining food and dirt from surfaces that have been previously soaked in diluted detergent in order to remove grease and residual debris; scrubbing must be done thoroughly from the centre to the outside of the surface;
- Stage 3: rinse with clean water to remove loosened food, dirt and detergent;
- Stage 4: use a disinfectant to reduce or kill microorganisms;
- Stage 5: thorough rinsing with potable water to remove disinfectant (if rinsing is included in the manufacturer's instructions).

Attention should be paid to the cleaning equipment, which must be regularly cleaned and disinfected before reuse, and its maintenance or replacement in order to avoid cross-contamination. Cleaning equipment should be stored in an appropriate place such as a separate room or space, which must be regularly cleaned.

Good practices to prevent the spread of contamination may include separating cleaning equipment according to its place of use (e.g. broom/brush for cleaning the toilets floors or equipment exclusively for cleaning the premises where food is handled). Marking equipment (e.g. colour coding) is an easy way to monitor the purpose and location of equipment.

Food transport vehicles should also be included in the cleaning schedule. The method and frequency of cleaning and disinfecting internal surfaces of the cargo space depend on the type of food being transported (e.g. exposed meat, packaged products), its loading method, the assessed risk of cross-contamination and the possible impact on safety of loaded foods.

Particular attention should be paid to cleaning, washing and disinfecting livestock transport vehicles. These means of transport must be cleaned and disinfected before and immediately after carrying animals according to the documented standard procedure. If needed (e.g. occurrence of infectious diseases), a special procedure with alternative approved chemicals and/or concentrations must be applied.

In some cases, disinfection will not sufficiently reduce the level of microorganisms, mainly for the following reasons:

- insufficient pre-cleaning;
- biofilm build-up preventing penetration and action of disinfectants;
- use of incorrect disinfectants;
- incorrect use of appropriate disinfectants;
- non-rinsing or poor rinsing of disinfectants.

Chemicals for cleaning and disinfection must be stored safely and securely in order to prevent risks to the safety of food or to human health.

1.8 Sanitation of tools and equipment

**RFH – Annex 2 – Part 2:
Specific requirements in rooms
where food is prepared, treated
or processed:
Point 2.**

2. Rooms where food is prepared, treated or processed should have, where necessary, facilities for storing corrosion-resistant working utensils and equipment for cleaning and disinfection, be easy to clean, and hot and cold water.

Facilities for cleaning and disinfecting tools and utensils will be necessary in most food-handling areas. To encourage their regular use, it is recommended to install the equipment for cleaning and sanitation next to food handling areas, provided that measures are in place to avoid risk of cross-contamination or condensation.

This facility may be a sink (preferably double bowled), a machine or a cabinet, depending on the type of tools in use. Facilities are to be made of cleanable, corrosion-resistant materials (e.g. stainless steel).

Hot water baths with stagnant water are not recommended as the water quickly becomes dirty. Clean utensils and equipment must be kept on an extended platform with a grid or perforated plate so that they can dry quickly and without risk of splashing or coming into contact with contaminated surfaces.

Handling procedures for clean and dirty utensils should prevent contamination of the former.

Equipment for cleaning crates for poultry

In the slaughterhouse for poultry there must be facilities for cleaning, washing and disinfecting crates in which the animals are delivered. Good practices require a protected area for washing crates and separation of clean crates from those that are dirty or contain live animals, as well as from the space for stunning and hanging animals.

1.9 Employee health and personal hygiene

<p>FSL – Personal hygiene Article 39.</p>	<p><i>(1) The food business operator shall, at all stages of production, processing and distribution, ensure that persons performing food-handling tasks shall maintain a high degree of personal hygiene and wear suitable, clean and, where necessary, protective clothing and footwear referred to in Article 37 paragraph 6 and 7 of this Law.</i></p> <p><i>(2) The food business operator shall, at all stages of production, processing and distribution, ensure that persons suffering from or being a carrier of a disease likely to be transmitted through food or afflicted with infected wounds or diarrhoea shall not handle food or enter any food-handling area if there is any likelihood of direct or indirect contamination.</i></p> <p><i>(3) Persons referred to in paragraph 2 of this Article shall immediately report the illness, symptoms or causes to the person responsible in the food business facility.</i></p>
--	---

Persons employed in food establishments must be healthy and not suffering from or carrying foodborne diseases, and must maintain a high level of personal hygiene. Their behaviour must not affect the facility hygiene and food safety.

Health status of employees

In order to perform tasks with food, it is necessary for a person to be in good health. Regular medical examinations at the legal time intervals is an obligation for both the employer and the employee. Employees should be provided with a health certificate following the medical examination. Employees should be made aware of their obligation to report illnesses or symptoms, in particular: jaundice, diarrhoea, vomiting, fever, sore throat with fever, visibly infected skin injuries, and discharges from ears, eyes or nose. Otherwise, need for medical examination and/or exclusion from working with or near food should be considered on an individual basis. If an employee is sent on sick leave, return to the same or another working position is possible only with the consent of a doctor.

Personal hygiene and staff behaviour

During work, staff working with food must maintain a high degree of personal hygiene, wear suitable and clean working clothing and footwear and, where necessary, protective clothing and footwear. If employees leave the premises where they work with food in their work clothing and footwear, regular and additional procedures should be conducted such as changing clothing or footwear upon departure and return.

It is forbidden to bring food into the premises, carry mobile phones, watches, jewellery and artificial nails, or work with lacquered nails, perfumed creams, or anything else that might contaminate food. Smoking, chewing gum, eating and drinking (except in designated areas), spitting, sneezing and coughing, particularly around unpackaged or unprotected food, is prohibited.

It is desirable that employees move from clean to unclean areas of the establishment, and not vice versa, in order to minimize the possibility of cross-contamination from dirty working or protective clothing and footwear. However, when it is unavoidable that employees move from dirty to clean area, they are required to use the proper procedures regarding personal hygiene (changing working clothing and footwear, disinfecting footwear, washing and disinfecting hands).

In order for employees to meet the set hygiene standards, it is essential that short and simple written instruction be made available in addition to training on good practices and expectations in terms of cleanliness and behaviour. Positive results in maintaining high levels of hygiene and appropriate behaviour in operation with food could be achieved with tags, stickers, posters, etc. in prominent places to remind employees of the good practices and/or the prohibition of bad ones.

Employees should be encouraged to wash their hands, especially at the beginning of their work with food, after handling raw food or any contaminated material, and immediately after using the toilet. Clean hands are a prerequisite for personal hygiene and it is necessary to instruct the employees how to wash their hands properly. Wearing protective gloves does not change the procedure for handwashing. It is essential that there be a sufficient number of handwashing facilities with detergent and disposable paper towels. Hot air hand dryers that may contaminate surfaces are not desirable.

Working and protective clothing and footwear

Employees should wear appropriate, clean and dry work and protective clothing, in order to protect food from contamination and protect employees from potential hazards from food/materials and the work environment.

Staff working in production areas and coming into contact with raw materials and products must wear designated working clothing and footwear, and when it is necessary, additional protective clothing and footwear. Work and protective clothing include: coats, coveralls, suits, aprons, gloves, hats, helmets, boots and shoe protectors. In rooms where food is handled, personal clothing should be completely covered with working and protective clothing and footwear. All hair needs to be covered with a cap, and facial hair with a mask. It is desirable that the working and protective clothing be made of durable material that can be washed at high temperatures. Clothing and disposable footwear protectors should be sufficiently resistant to be serve its purpose.

Employees should be provided with enough working suits in order to change them daily or as needed. Working and protective clothing and footwear should be kept at a clean, designated place, and soiled ones should be discarded in labelled containers.

Working clothing and footwear should be checked for damages and, if necessary, repaired or changed. It is important to provide employees with the correct size and cut so that they can move and carry out their duties comfortably.

Working and protective clothing and footwear worn in dirty areas need to be clearly differentiated from that worn in food-handling areas.

Visitors

In areas where production, processing and handling with food takes place, visitors are required to wear protective clothing and footwear, and to meet the same requirements as the employees regarding their health, personal cleanliness and hygiene.

1.10 Control of pests and other animals

Insects, rodents, birds, domestic and other animals pose a serious threat to food safety. Many pest species are carriers of microorganisms that can cause food poisoning (e.g. birds carry *Campylobacter spp.*, insects and rodents *Salmonella spp.*). Flies in particular can transfer contamination from dirty to clean areas. Pests are significant sources of foreign objects and materials such as animal hair, feathers, droppings, urine, nesting material, insect eggs and larvae, and the bodies of the pest species themselves may cause physical damage to food products and packaging, including damages to installations, fixtures and equipment. Such damages are health and safety hazards and can contaminate the food. Poorly-executed pest control programmes and careless storage and use of chemicals are also chemical hazards.

Persistent pest infestations often indicate serious failures in maintenance and cleaning or significant weaknesses in the good manufacturing and hygienic practices in the facility.

RFH – Annex 2 – Part 8: Requirements applicable to food: Point 4.	<i>4. The food business operator will perform adequate protection procedures to control pests and establish adequate procedures to prevent domestic animals from accessing places where food is prepared, stored or handled.</i>
--	--

Preventing pest infestations

Design, construction, layout and equipping of facilities should prevent the entry of pests as much as possible. All potential pest entry points should be taken into account (e.g. doors, windows, ventilation inlets/outlets, drains, by-product chutes, lairage/slaughter corridor interface). Additional equipment that minimizes risk of pest entry such as self-closing door mechanisms, fly screens, drain traps, chute end flaps, air curtains, etc. should also be considered. Openings to the outside, drains and other points of pest entry should be physically protected with a seal or proof applied to holes and cracks, open ends of drains, gaps around drains and pipes, opening of roofs.

The application of good practices provide an important level of protection as well through, for example:

- only opening windows with well-fitted fly screens (recommended mesh size less than 2 mm);
- minimum opening and regular closing of external doors;
- maintenance of self-closing door mechanisms and air curtains, if used;
- control of entry/keeping of domestic animals and pets (e.g. guard dogs), under special authorization of the competent authority;

- adequate procedures for receiving/control and storage of delivered goods in order to prevent entry of rodents and insects.

Availability of water and food facilitates the colonization and multiplication of pests. Good practices around incoming materials include checks for insect and rodent infestation before storing); storage of edible materials in rodent-proof conditions, avoiding hidden places; stock rotation to minimize the opportunities for pest infestations; and storage of inedible food by-products and waste in covered containers. When empty, storage bins/premises must be proofed against insects, glodara, birds and other animals. Regular, good maintenance and cleaning are essential for effective pest control.

Control and eradication of pests

For the control and eradication of pests that are present in the workplace, chemicals such as insecticides and rodenticides, physical traps and biological agents may be used. Before the chemical treatment is applied, all food must be removed and all equipment covered. Only specially-trained persons may apply chemical products, in compliance with the requirements, health and safety precautions specified in the manufacturer's instructions.

Traps for flying insects should be installed close to entrances to prevent their entry into the establishment/rooms, but not above exposed food, equipment or packaging. These devices should be cleaned and serviced regularly to ensure their efficacy. If high numbers of insects are found, species identification may help to trace the source of the problem and to apply an effective insecticide.

Rodents are a common problem in or around food premises. Within the pest control programme, FBOs should develop and apply a rodent control plan, which – among the other rodent protective measures within the establishment – should include: boxes with poisonous bait around the yard and premises; chemical substances (the active substance must be approved for use in food handling facilities); frequency of regular and additional trap setting and control; records on the implementation and control of pests, and the name/address of the authorized/contracted organization.

Baits are to be placed in the rodents' direction of movement and regularly checked for signs of their presence. Findings should be recorded following changes to the plan or the implementation of further measures. Baits are not to be placed in rooms with disposed food. Dead rodents should be removed quickly and safely, and the type and number recorded.

Live capture traps for rodents may be used for very small infestations or when there is a high risk of contaminating food with chemicals if rodenticide is used. The capture places can help determine the main routes of rodents

Deterring birds from entering the food establishment may be achieved with protective nets, removal of food sources, nesting and roosting sites or with visual scare devices. Wild birds are protected by the law and poisoning birds is illegal in all circumstances.

1.11 Removal of animal by-products

Collection and disposal of animal by-products and other waste materials

Animal by-products not intended for human consumption, as well as other waste materials originating from food businesses (hereinafter: waste material), can be a significant source of microbiological, physical and chemical contamination of food. Waste material is a potential source of food for pests, which may give rise to further microbiological contamination, so endangering food safety and human health. Therefore, this material must be stored and disposed of in an appropriate way to ensure that waste products do not re-enter the food chain.

RFH – Annex 2 – Part 6: Food waste: Points 1–4.	<ol style="list-style-type: none">1. Food waste, non-edible by-products and other refuse should be removed from rooms where food is present to avoid their accumulation.2. Food waste, non-edible by-products and other refuse are to be deposited in closable containers or other types of containers, if food business operators can prove that they are easy to clean and, where necessary, to disinfect and keep in sound condition.3. Storage and disposal of food waste, non-edible by-products and other refuse may be performed in facilities for waste constructed in such a way as to ensure their thorough cleaning and protection from the entry of animals and pests.4. Food waste, non-edible by-products and other refuse should be removed from rooms where food is present in a hygienic and environmentally-friendly way in accordance with the law in order to avoid contamination.
RFH – Annex 2 – Part 8: Requirements applicable to food: Point 10.	<ol style="list-style-type: none">8. Hazardous and/or inedible substances, including animal feed, must be adequately labelled and stored in separate rooms or containers.

Waste material should be regularly removed from areas where it is produced or placed in containers provided for the purpose. Accumulation of waste material in areas where food is handled, or where its proximity to food endangers safe operations, is not allowed. All removal from work areas, storage and disposal must be carried out hygienically and without the risk of contamination of products for human consumption.

All persons who come into contact with waste material are required to wash their hands immediately, and if they work with food, to undertake other necessary measures to maintain personal hygiene (changing working and protective clothing and footwear, disinfecting footwear and hands).

Capacity of containers and premises for the collection and storage of waste materials in a food establishment must be determined in accordance with the amount and type of materials that are normally produced and collected on a daily basis and with the frequency of delivering this material to approved establishments that handle/process animal by-products. Containers and stores are not allowed to

overflow, to litter the surrounding area or, if liquid, to leak into drains or streams. Containers that are used for collection, storing or transport of any risk category of animal by-products outside the food premises must be made of impermeable and resistant material, suitable for cleaning, washing and disinfection, secured from leaks and preferably closed. Containers used for holding specific risk types of animal byproducts need to be clearly marked (Category I – black, II – yellow and III – green). Labels can get dirty, drop off, or be misread, so colour coding is recommended.

It is necessary for food operators to have a contract with the local/state competent authorities on delivery and disposal of waste materials to designated establishments.

Detained meat and meat declared unfit for human consumption

Detained meat is meat and offal set aside for further detailed inspection in order to check potential disease findings, test results or identification checks.

Detained meat, offal and animal by-products not intended for human consumption must not come into contact with meat that has passed a post-mortem examination or is still awaiting inspection. It is necessary to provide adequate space and equipment to store detained meat and meat declared unfit for human consumption before it is removed as a by-product (Chapter 19 – Slaughterhouses).

Manure

**RSHRPAO – Annex I, Chapter I
Part II: Requirements for slaughterhouses
for domestic ungulates
Paragraph 9.**

9. If manure or digestive tract content is stored in the slaughterhouse, there must be a special area or place for that purpose.

If manure or digestive tract content is stored in the slaughterhouse, there must be a location near the lairage on the dirty side of establishment grounds for that purpose. The floor should slightly slope to the front where a drain should be provided to prevent the overflow of waste.

Removal of hay and straw. Hay and straw contaminated with animal manure classified as a category 2 animal by-product should be removed from the means of transport according the special regulation.

1.12 Traceability

Availability of information on the origin/suppliers and customers at every stage of production, processing and distribution of food provides the ability to trace food backwards or forwards through the food chain. The objective of traceability is that any product, production lot or consignment suspected or found to be unsafe or not of appropriate quality may for a short period of time to be withdrawn or recalled from the market. Use of health marks (for meat) and identification marks (for

meat products) in approved slaughterhouses, meat cutting and processing plants and cold storages; name and address of FBO, production date, use by date and batch identification, etc., are important elements of the operator's traceability system in the food chain.

<p>FSL – Traceability Article 27, Points 1, 2 and 3.</p>	<p><i>1. Food and feed business operators shall put in place traceability at all stages of production, processing and distribution of food, feed, food-producing animals and/or substances added to food or feed.</i></p> <p><i>2. Food and feed business operators shall put in place the traceability system and the procedures to identify the following persons:</i></p> <ul style="list-style-type: none"> • suppliers of food, feed, a food-producing animal or substances added into food or feed; • the other businesses to which their products have been supplied; <p><i>3. Food and feed that is placed on the market must be labelled or identified to enable traceability through relevant documentation or information.</i></p>
<p>RSHRPAO – Annex II: Health and identification marks.</p>	<p><i>Food business operators must only put on the market food of animal origin that is marked with a health mark and/or an identification mark.</i></p>

Implementation of good practices and the availability of information and product traceability data contributes to the acquisition and strengthening of consumer confidence in the national and individual operator's food safety system.

Data on suppliers and customers

FBOs must have "one step back – one step forward" systems in place, as well as records of suppliers and customers. They should be able to quickly and reliably identify suppliers of feed, food-producing animals and food, including any substance incorporated into the food, and procedures to identify the businesses to which their products have been supplied. Each operator shall have in place systems and procedures for this information to be made available to the competent authorities on demand. FBOs do not have to identify the immediate customers when they are final consumers, i.e. if food is used only for personal use and not for any food business activities.

Identification marking

The identification mark must be applied before the product of animal origin leaves the establishment of production. Identification marks are placed on products coming from establishments complying with the relevant requirements. If the original wrapping and packaging material has been removed, a new one is used, or the product is repacked or further processed it is necessary to set a new identification mark.

Identification marks should be:

- clear, legible and visible to the competent authorities with easily recognizable markings;
- oval shaped;
- and contain:
 - name or abbreviation of the country from which the food business operator/product originates;
 - approval number.

Identification marks can be set:

- by embossing the mark directly on the product (with approved colour), on the packaging material or packaging;
- by printing the mark on a label affixed to the product, packaging material or packaging;
- in the form of a permanent/irremovable label made of durable material.

The meat traceability system should contain identification data on each individual or group of animals (e.g. transport documents, ear tags), records on carcasses and related edible and non-edible parts, health marks and identification marks.

If the product is delivered directly to the end users, the identification marks can be placed only on the outer surface of the package. When the product is delivered to other establishments for additional treatment, wrapping and packaging, the identification mark can be placed on the sealed shipping container or on the bulk packaging.

Identification marks/labels should be tightly controlled to reduce the possibility of abuse to a minimum. Identification marks should be applied to a label fixed to the packaging in such a way that it is destroyed when the packaging is opened.

Food withdrawal and recall

FBOs are obliged to prepare and use documented procedures for rapid and complete withdrawal (if the product is not yet available to end consumers) or recall (if the product is available or used by the ultimate consumers) from the market any quantity of products suspected or confirmed to present a microbiological, physical or chemical hazard to consumers.

Where necessary, appropriate records on production, processing and distribution of food should be kept after the expiry date of the product, because the product can remain in the food chain or with the final consumer for a longer period of time.

In the event that the product must be withdrawn or recalled because of a direct, immediate threat to human health, other food produced under similar conditions and that may present a similar threat to public health should be assessed and, if necessary, also be withdrawn. In such cases, public notification through the media should be considered about the type of food and health hazards.

Withdrawn or recalled products should be kept under control until they are:

- destroyed
- used for other purposes, but not for human consumption
- used for human consumption if subsequently found to be safe
- re-processed in a way that ensures their safe use

1.13 Reception, packaging and transport of food

The conditions for receiving raw and other materials in food establishment

Each step in the food chain must be conducted according to the rules of good manufacturing and good hygienic practices and HACCP principles, as this is essential for the quality and safety of products and consumer confidence. Traceability and steady quality and safety of incoming materials contributes to the quality and safety of the finished products.

FBOs should develop and implement a documented system of procurement, selection and reception of raw materials, products and ingredients necessary for production. It is a good practice that all of the materials are supplied according to the established specifications and that applied measures should enable the reception of materials of adequate quality (e.g. composition and shelf life) and safety. Criteria and reception procedures should primarily prevent entry of materials from establishments that have not been approved or registered, whose temperatures are above the determined limits, or that is contaminated with undesirable microorganisms or their toxins, parasites, pesticides and veterinary drugs above the legal limits. The selection procedure should exclude all unverified and unreliable suppliers. Upon arrival or after reception, but before the start of treatment, it is desirable for raw materials and other ingredients to be visually inspected, suspicious lots separated and, if necessary, tested to determine their suitability for use.

Conditions for hygienic wrapping and packaging

The aim of food packaging is to:

- prevent its subsequent contamination (microbiological, physical, chemical);
- prevent physical damages during further handling with food;
- provide proper labelling of products;
- present the product.

Under the conditions laid down for the use and storage of food, materials and gases (modified atmosphere packages) used for wrapping and packaging must be safe, non-toxic and not adversely affect the wholesomeness of food.

When considering the construction, remodelling and equipping of the food establishment, the following should be kept in mind:

- that storage of wrapped and packaged products is maintained in a hygienic manner (not on the floor);
- that appropriate storage conditions for wrapping and packaging materials should be provided before their use;
- that wrapped and packaged food is stored separately from unpackaged food.

It is essential that good practices and regular review of wrapping and packaging materials in the storage area are carried out to prevent contamination by dirt and pests.

Materials for wrapping and packaging

For wrapping and packaging, only those materials that are suitable for contact with foodstuffs and that do not adversely affect the taste and smell of the product may be used. Wrapping material must protect the product during handling and storage and must not be a source of contamination. If wrapping material is strong enough, it may serve as both wrapping and packaging, for example, by using:

- cardboard cartons with a plastic inner coating;
- rigid or flexible containers from which the majority of air can be removed (vacuum packaging), or modified atmosphere packages (combination of gases such as oxygen, carbon dioxide and nitrogen are introduced into the package at the time of closure).

In these cases there is no need for outer packaging, although it is common for vacuum or modified atmosphere packaged products to be transported in plastic reusable containers.

Reusable packaging materials

Only wrapping and packaging containers that are capable of being cleaned (e.g. hard plastic) may be reused for foodstuffs and then only if they are cleaned and disinfected before reuse.

Plastic trays and containers need to be well maintained and carefully handled (e.g. protected from forklift and truck damage, cracking, deep scoring) to keep them in a suitable condition for effective cleaning and disinfection. Containers supplied by customers must also be in a suitable condition before being accepted for use.

Wrapping and packaging operations

It is important that assembling boxes for packaging be done under hygienic conditions and as close to the time of use as possible in order to minimize the risk of contamination while waiting for use. If boxes are assembled and stored for later use, they should be stacked on their sides or opening-to-

opening, so that the wrapping surface inside the boxes is not at risk of contamination. If necessary, piles of assembled boxes may be covered.

To reduce the risk of cross-contamination, packing operations should be done at the place where the products are located. Wrapping and packaging should be finished in the shortest possible time so that the temperature of the food remains within the established limits.

In order to prevent cross-contamination between packaged and unpackaged food, they should be kept:

- in separate rooms;
- in the same room but at different times;
- at the same time, but with a permanent barrier, which can be cleaned and disinfected; or
- at the same time, but with polythene covering to protect unpackaged food from airborne cross-contamination.

Mistakes in wrapping and packaging of food can be related to:

- unsatisfactory quality of wrapping and packaging material (e.g. prone to damage/tearing), providing exposure to the food environment;
- use of wrapping and packaging material whose quality has not been tested;
- poor storage conditions and handling of wrapping and packaging material (e.g. poor keeping practices and damages; material without protection against dirt/dust; low level of hygiene and the presence of pests);
- the use of dusty or damaged materials (e.g. cardboard boxes), without additional protection of internal surfaces before use (polythene liners/bags);
- poor maintenance (e.g. repair or replacement of damaged/wear and tear) and cleaning of reusable packaging;
- poor condition of storage and handling of wrapped or packaged food (e.g. damage to bulk and single packages; low level of hygiene and the presence of pests).

Food transport

During loading, unloading and transport, food must be protected from harmful microbiological, physical and chemical hazards and, where necessary, from high temperatures. Unsatisfactorily cleaned, poorly maintained and inadequate means of transport and containers, including insufficient procedures for the separation of packaged of unpackaged products, create conditions for cross-contamination of food during handling and transport.

Means of transport

In order to avoid transfer of contamination between different consignments, means of transport must be washed and disinfected between two transports within the facility or in an authorized and contracted washing service centre. Vehicles and containers should be cleaned by using water under pressure and disinfected inside and outside. The door for loading washed and disinfected vehicles and containers must be kept closed until the next loading.

The location of loading and unloading and handling practices should facilitate quick work procedures that avoid contamination of food and the negative impact of the environment (e.g. dust, smoke, weather conditions, leaves, pests, etc.).

A vehicle with a cooling device needs to have good thermal insulation including an internal coating that is watertight hygienic (no cracks and sharp corners to build up dirt), air-tight doors, a powerful cooling unit and temperature gauge in the driver's cab for permanent monitoring and, if necessary, temperature recording during transport.

Supervision and training. Drivers and employed staff in loading and unloading should be trained in the food safety hazards associated with transport. It is necessary to instruct the staff about the proper cleaning procedures, separation of clean from dirty loads and packaging from exposed meat, as well as the importance of adherence to guidelines and prompt reporting of failing procedures.

Separation of food. Unpacked food is transported:

- in a separate vehicle; or
- in the same vehicle as packaged food, but:
 - at different times;
 - at the same time, separated from packaged food with a continuous barrier that can be cleaned and disinfected; or
 - at the same time, if it is protected with an impermeable covering. Hanging exposed meat should be placed so as not to come into contact with the floor and walls of the means of transport.

Maintaining the temperature in transport. Vehicles with cooling devices are used to maintain the target temperature, but not for further cooling of the goods. To maintain the food temperature during transport at the desired level, the following should be taken into account:

- temperature of the product during loading and unloading of vehicle;
- duration and frequency of loading and unloading;
- quantity of goods being transported;
- distance between the products; and
- temperature, relative humidity and air circulation inside the vehicle.

Temperature of the product, if necessary/applicable, should be measured manually with a probe thermometer and recorded as often as required in the operator's self-control plan.

1.14 Labelling information for consumers

Labelling information about food hygiene should be informative and clear for consumers so that they can:

- I) understand the importance of the information and how to use the available data;
- II) choose food meeting their personal needs and preferences;
- III) prevent contamination, growth or survival of food pathogens through proper storage, preparation and use.

Food information intended for consumers should be clearly distinguished from the information intended for industry and traders, particularly labelling. Incomplete or incorrect information about food and/or inadequate information about general food hygiene may cause the consumer to mishandle the food. Such mistakes may lead to foodborne diseases or inedible food, even if the previous control measures of hygiene in the food chain were carried out appropriately.

All food products should contain information that will enable consumers to keep, prepare, handle and use the purchased product safely and properly. Training programmes on public health and food hygiene should form the basis of consumer education. Such programmes allow consumers to understand the importance of information about food and to follow the instructions provided with the products, as well as to choose food on the basis of information provided. In particular, consumers should be well informed about the link between the shelf life and the temperature at which the food is kept and the illnesses that can be caused by food.

In order to achieve a high level of health protection and consumer interests, FBOs are obliged to ensure that consumers are appropriately informed regarding the food they consume.

The current regulation on food information to consumers (Official Gazette of Montenegro, No. 57/15) in Montenegro lays out detailed conditions on food information to consumers according to the type and categories of food, food labelling and the manner of providing food information to consumers.

<p>Regulation on food information to consumers Articles 8 and 10.</p>	<p><i>Mandatory food indications for food business operators are:</i></p> <p>(a) <i>the name of the food;</i></p> <p>(b) <i>the list of ingredients;</i></p> <p>(c) <i>all ingredients or processing aids used in the manufacture or preparation of a food that may cause allergies or intolerances and that are still present in the finished product, even if in an altered form;</i></p> <p>(d) <i>the quantity or categories of ingredients;</i></p> <p>(e) <i>the net quantity of the food;</i></p> <p>(f) <i>the date of minimum durability or the “use by” date;</i></p> <p>(g) <i>special storage conditions and/or conditions of use;</i></p> <p>(h) <i>the name and residence or business name and address of the food business operator who placed the food on the market and who is responsible for accuracy and immutability of the food information;</i></p> <p>(i) <i>the country of origin or place of provenance of guaranteed traditional agricultural products and foodstuffs with protected geographical indications and designations of origin according to the specific legislation;</i></p> <p>(j) <i>instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions;</i></p> <p>(l) <i>a nutrition declaration.</i></p> <p><i>Mandatory food information shall be marked in a conspicuous place that is easily visible, clearly legible and, where appropriate, indelible and shall not be hidden, obscured, detracted from or interrupted by any other written or pictorial matter or any other intervening material.</i></p>
---	--

The legal name of the food means the name laid down in the special regulations applicable to that food. If the name of the food is not legally defined, the name used in the country of production or sale can be applied.

If the name of the food is not a legal name, the name by which it is placed on the market can be:

- I) a customary name; or
- II) a descriptive name of the food that is sufficiently clear for consumers to know its true nature and distinguish it from other similar products.

FBOs must provide a list of ingredients on the label or packaging that is clearly identifiable and includes the word “ingredients”. The list of ingredients should include all the ingredients of the food,

in descending order of weight, as recorded at the time of their use in the manufacture of the food.

FBOs are required to indicate the quantity of an ingredient or category of ingredients used in the manufacture or preparation of a food, and where the ingredient or category of ingredients concerned:

- I) appears in the name of the food or is usually associated with that name by the consumer;
- II) is emphasized on the label in words, pictures or graphics; or
- III) is essential to characterize a food and to distinguish it from products with which it might be confused because of its name or appearance.

In the case of foods which, from a microbiological point of view, are highly perishable and are therefore likely after a short period to constitute an immediate danger to human health, the date of minimum durability shall be stated by the "use by" date. After the "use by" date, a food is deemed to be unsafe in accordance with the law on food safety.

The storage conditions and/or use of the food should be marked on the packaging or label.

The storage conditions and/or time limit for consumption of food should be indicated on the packaging or the label to ensure proper storage methods or use of the food after opening. Instructions for use of food must be given in a way that allows the appropriate use of the food.

1.15 Training

**FSL – Staff training
Article 40.**

The food business operator shall ensure that persons handling food are supervised, instructed and/or trained regarding the food hygiene rules related to their work activity.

The level of awareness and responsibility

Employees involved in food production can be a significant source of physical and microbiological contamination if personal hygiene and behaviour do not meet the required standard. Poor working practices and failures to follow instructions increase the risk of contamination of food and its environment. Therefore, employees should undergo and pass training around the importance of hygiene and the consequences of their work, as well as their obligation to report deviations from standard and common practices. High-quality and comprehensive training and clear work instructions for all level of staff, with continuous monitoring, are essential so that they can perform their duty to handle food safely.

Training programmes

Training should be organized for employees in accordance with their field of work and level of food safety competence, so that everyone receives the necessary knowledge and skills (**what** and **how** to

work), so they can perform their work effectively and in accordance with the standards of good practices, i.e. the company's personal hygiene and health procedures.

Employees who do not handle food but need to enter food handling areas and everyone with hygiene responsibilities (quality controllers, store keepers, production managers, cleaners, maintenance staff), should also receive hygiene training and/or a copy of the instructions.

At least one person in the business entity needs to have proper training in the application of HACCP principles and develop and maintain the HACCP-based procedures in the establishment. All food handlers may benefit from HACCP awareness training to help them understand the food safety hazards and the importance of operating the plant's HACCP-based procedures effectively.

Employees, especially new and unexperienced persons, must be supervised until it is clear that they are competent to handle food safely. Supervisors or managers should have a sufficient level of training to give appropriate supervision and instruction of food handlers and to make decisions based on sound knowledge of food safety principles and practices. A record of each individual's training should be kept to show that he or she has received appropriate training and instruction in food hygiene matters commensurate with their work activity.

Follow-up training

Periodical follow-up training (refresher training) is likely to be necessary at least every 2 to 3 years depending on job function, especially if there are significant changes in working practices, technology, equipment or legislation, or if current practices are found to be unsuccessful. If needed, the company food safety training programme may be amended.

Chapter 2: Specific hygiene requirements

A food business operator engaged in the production and/or processing of meat and meat products must meet the general and specific food hygiene requirements given that facilities for slaughtering, cutting and processing and meat processing facilities fall into the high food safety risk category.

2.1 Facilities for animal slaughter

Slaughter of domestic ungulates – Structural hygiene requirements

<p>RSHRPAO – Annex I, Chapter I Part II: Requirements for slaughterhouses for domestic ungulates Paragraph 4.</p>	<p><i>(4) To prevent contaminating meat, slaughterhouses for domestic ungulates should:</i></p> <p><i>(a) have a sufficient number of rooms for the operations being carried out;</i></p> <p><i>(b) have a separate room for the emptying and cleaning of stomachs and intestines;</i></p> <p><i>(c) ensure separation in space or time of the following operations:</i></p> <ul style="list-style-type: none"><i>- stunning and bleeding;</i><i>- in the case of porcine animals, scalding, depilation, scraping and singeing;</i><i>- evisceration and further dressing;</i><i>- handling clean tripe and guts;</i><i>- preparation and cleaning of other offal, particularly the handling of skinned heads if it does not take place at the slaughter line;</i><i>- packaging offal;</i><i>- dispatching meat;</i> <p><i>(d) if more than one slaughter line is operated on the same premises, there must be enough separation of the lines to prevent cross-contamination.</i></p>
--	--

Slaughter of poultry and lagomorphs – Structural hygiene requirements

<p>RSHRPAO – Annex I, Chapter II Part II: Requirements for slaughterhouses for poultry and lagomorphs Paragraph 1.</p>	<p>(1) Slaughterhouses in which poultry and lagomorphs are slaughtered should:</p> <ul style="list-style-type: none"> (a) have a room or covered space for the reception and inspection of the animals before slaughter; (b) have a sufficient number of rooms for the operations being carried out; (c) have a separate room for evisceration and further dressing, including the addition of seasoning to whole poultry carcasses; (d) ensure separation in space or time of the following operations: <ul style="list-style-type: none"> - stunning and bleeding; - plucking or skinning, and any scalding; - dispatching meat; (e) if more than one slaughter line is operated on the same premises, there must be enough separation of the lines to prevent cross-contamination.
---	--

Slaughter of different animal species

<p>RSHRPAO – Annex I, Chapter I Part IV: Slaughter hygiene Paragraph 17</p>	<p><i>(17) If different animal species are slaughtered in the same slaughterhouse, precautions must be undertaken to prevent cross-contamination by separation either in time or in space of operations carried out for the different species. If carcasses of farmed game and other game slaughtered at the farm are handled in the same place, a separate reception and storage space for the unskinned carcasses should be set up as well.</i></p>
<p>RSHRPAO – Annex I, Chapter II Part II: Slaughter hygiene of poultry and lagomorphs Paragraph 2.</p>	<p><i>(2) Where establishments are approved for the slaughter of different animal species or for the handling of farmed ratites and small wild game, precautions must be taken to prevent cross-contamination by separation either in time or in space of the operations carried out for the different species. Separate facilities for the reception and storage of carcasses of farmed ratites slaughtered at the farm and for small wild game must be available.</i></p>

Slaughterhouses can be approved for the slaughter of different animal species, or for the handling of carcasses of farmed game (e.g. ostriches) and wild game (e.g. deer and wild pigs). If a slaughterhouse handles multiple species, the slaughter and dressing of each species needs to be carried out on separate lines or at different times to prevent contamination between species.

Unless there are separate lines for different species, the slaughter and dressing areas are to be cleaned and disinfected between species and between wild and farmed game to prevent cross-contamination. Pigs are to be slaughtered last.

Effective separation of “clean” and “dirty” operations is an important way to eliminate sources of contamination. Only where spatial separation is impossible or not rational or profitable due to the capacity and dynamics of work should time separation be used – and then only with an effective cleaning and disinfecting procedure between operations.

The optimal solution is to design a path leading from dirty to clean areas, allowing easy physical or spatial separation of operations. The proper order of edible or clean products followed by detained or dirty products should be followed without crossovers or doubling back.

In any case, the layout and procedures should prevent the movement of employees from dirty to clean areas, without prior washing and disinfection of hands and footwear, as well as, where necessary, changing working and protective clothing.

Slaughter of sick and suspect animals

Where separate facilities intended for slaughtering animals that are sick or suspected to be suffering from disease are not available, or there are no nearby establishments authorized by the competent authority for this purpose (“sanitary slaughterhouse”), such animals can be slaughtered at the end of the normal slaughter period to minimize the possible spread of infection and followed by a thorough cleaning and disinfection so as not to compromise the hygienic operation of the slaughterhouse. This additional activity within the same slaughterhouse should be approved by the competent authority.

Emergency slaughter

Injured or diseased animals that must be slaughtered or killed on the grounds of animal welfare can only be used for human consumption once they have undergone a veterinary ante-mortem inspection, been stunned and bled in a hygienic and humane manner, and declared fit for human consumption following a post-mortem inspection carried out in the slaughterhouse. Meat of emergency slaughtered animals that has been declared fit for human consumption may only be placed on the domestic market.

Self-control system

An operator’s self-control system must include implementing, maintaining and monitoring good hygiene practices and procedures for livestock handling and slaughter, dressing carcasses and, when necessary, taking corrective actions if there is a failure. Applied procedures must be based on HACCP principles.

Slaughter line equipment and operation

<p>RSHRPAO – Annex I, Chapter I Part II: Requirements for slaughter- houses for domestic ungulates Paragraph 4d</p>	<p><i>In order to prevent meat contamination, slaughterhouses for domestic ungulates, poultry and lagomorphs must have:</i></p> <p><i>(d) equipment that prevents contact between the meat and the floors, walls, installations and fixtures and have slaughter lines that are designed, when in operation, to allow constant progress of the slaughter process and to prevent cross-contamination between the different parts of the slaughter line, ...</i></p>
<p>RSHRPAO – Annex I, Chapter II Part II: Slaughter hygiene of poultry and lagomorphs Paragraph 1e.</p>	<p><i>(e) equipment that prevents contact between the meat and the floors, walls, installations and fixtures and have slaughter lines that are designed, when in operation, to allow constant progress of the slaughter process of poultry and lagomorphs and to prevent cross-contamination between the different parts of the slaughter line, ...</i></p>

It is necessary to set up structures and equipment (e.g. rails, platforms for dressing operations and inspection, equipment for washing hands, containers), including installations at the appropriate height and distance so that the carcasses/halves and meat are far enough from the floor, walls and other potentially dirty surfaces. In addition, the placement of equipment and available working space should be sufficient to ensure safe operations of employees and appropriate application of hygiene measures and maintenance.

The design of the slaughter line should allow a progressive workflow that avoids regular contact between carcasses. After hide/skin removal (cattle, sheep/goat and horses), removal of hair (pig), feathers (poultry) and fur (lagomorphs), carcasses must be separated from each other until post-mortem inspection is completed. Rail systems should allow suspect carcasses to be moved to the detention area, which should be located adjacent to the main slaughter hall. When the post-mortem inspection is complete, the overhead rail should reconnect the detention room with the main slaughter line for the carcasses to continue either to the chill rooms or to the inedible by-product room/container.

Equipment for disinfecting tools

<p>RSHRPAO – Annex I, Chapter I Part II: Requirements for slaughter- houses for domestic ungulates Paragraph 5</p>	<p><i>(5) Slaughterhouses must have facilities for disinfecting tools with hot water not below 82 °C, or another adequate system with an equivalent effect.</i></p>
<p>RSHRPAO – Annex I, Chapter II Part II: Slaughter hygiene of poultry and lagomorphs Paragraph 2.</p>	<p><i>(2) Slaughterhouses must have facilities for disinfecting tools with hot water not below 82 °C, or another adequate system with an equivalent effect.</i></p>

Where hot water is used to disinfect tools and utensils at the slaughter line while in operation, it is necessary to maintain the temperature and water level in each sterilizer by means of a continuous flow of hot water at a minimum temperature of 82 °C with overflow ducted to a drain. Sterilizers

should allow knife blades/junctions and other tools to be fully immersed. Good practices for sterilizers include washing tools and utensils before sanitation, avoiding hot water above 85 °C for steam control (which can cause condensation and mould) and health and safety reasons, as well as complete emptying and cleaning upon completion.

Disinfecting facilities for tools and utensils should be located close to workstations to allow easy use throughout operations.

Handwashing facilities

Staff handling exposed meat should be provided with handwashing basins that are fitted with taps that are not hand operated as this may lead to re-contamination.

Post-mortem inspection

<p>RSHRPAO – Annex I, Chapter I Part II: Requirements for slaughter- houses for domestic ungulates Paragraph 6</p>	<p><i>(6) The handwashing equipment used by the staff engaged in handling exposed meat must have taps designed to prevent the spread of contamination.</i></p>
<p>RSHRPAO – Annex I, Chapter II Part II: Slaughter hygiene of poultry and lagomorphs Paragraph 3.</p>	<p><i>(3) The handwashing equipment used by the staff engaged in handling exposed meat from poultry and lagomorphs must have taps designed to prevent the spread of contamination.</i></p>

Post-mortem inspection points should be located close to the following dressing procedure: head removal (for inspection of the head), evisceration (for inspection of offal), carcass split (for carcass inspection and health marking). For small-scale establishments or individual slaughter, the inspection point may be a single point. In any case, all parts of the animal carcass must be kept together until the post-mortem inspection is completed.

Inspection points/point should have enough space and other conditions (lighting at 540 lux, handwashing facilities and sterilizer, system that allows carcasses to go to the detention room for further inspection) to allow the inspection to be carried out hygienically and effectively and to record post-mortem findings.

Animal welfare

From the farm to the point of slaughter, animals should be treated in a way that does not cause them avoidable excitement, distress, suffering or pain. When possible, they should be provided with an environment that slows them to behave naturally. Procedures used to slaughter animals must be applied in a way that minimizes any pain or distress.

Slaughterhouses present a noisy and unfamiliar environment to animals. Calm and efficient handling reduces stress for animals and handlers, improves safety for workers and raises overall meat quality. If carried out correctly, stunning before slaughter is a painless procedure that permits the slaughtering process to be carried out while the animal is still unconscious. An animal may be slaughtered only if it was stunned first, except in the case of emergency slaughter, or if poultry and lagomorphs are slaughtered at the household for private consumption.

Reception area for poultry and lagomorphs

At the point of unloading and receiving poultry and lagomorphs before slaughter, adequate space and lighting should be provided to allow the appropriate ante-mortem inspection and documentation of animals. At the same time, due to animal welfare reasons, blue lighting should be used at the reception, hanging and stunning areas, provided adequate inspection can still be performed.

Table 6: Good and bad practices for animal reception at slaughterhouse

Good practice – always:	Bad practice – never:
<ul style="list-style-type: none"> • ensure the animal has been effectively stunned; • keep stunning equipment maintained and clean; • have a reserve stunning device in good working order available for immediate use in case the used stunning instrument fails to operate effectively; • stun injured and exhausted animals without delay; • handle animals in a manner that will allow stunning, hoisting and sticking to take place without delay; • complete all operations on one animal before the next is handled if working alone; • stun adult cattle in a stunning or restraining pen that is in good working order; • bleed without delay after stunning. 	<ul style="list-style-type: none"> • leave animals waiting in stunning pens; • place an animal in a stunning pen unless the person who is carry out the stunning is ready to act immediately; • stun an animal unless you are sure you can apply the stunning instrument correctly; • stun an animal unless it is possible for it to be stuck without delay; • use electrical stunning equipment for purposes other than stunning animals; • tie the legs of the animal or suspend it by the legs before stunning.

2.2 Facilities for cutting meat

<p>RSHRPAO – Annex I, Chapter I Part III: Requirements for cutting plants Paragraph 6 and RSHRPAO – Annex I, Chapter II Part III: Requirements for cutting of poultry and lagomorphs Paragraph 1.</p>	<p><i>Establishment for cutting meat of domestic ungulates/poultry and lagomorphs should:</i></p> <ol style="list-style-type: none"><i>1. Be constructed so as to prevent contamination of meat, in particular by: (a) allowing constant progress of the operations; or (b) ensuring separation between the different production batches;</i><i>2. have rooms for the separate storage of packaged and exposed meat, unless stored at different times or in such a way that the packaging material and the manner of storage cannot be a source of contamination for the meat;</i><i>3. have cutting rooms equipped to ensure compliance with the hygiene requirements during cutting and boning (Chapter I, Part V);</i><i>4. have equipment for washing hands with taps designed to prevent contamination for use by staff engaged in handling exposed meat;</i><i>5. have facilities for disinfecting tools with hot water at not less than 82 °C, or another adequate system having an equivalent effect.</i>
--	---

Structural hygiene requirements

In meat cutting establishments, prerequisites of food hygiene are applied in accordance with the nature and volume of operations. Particular attention should be paid to ensure the layout and arrangements of meat cutting lines are in accordance with the capacity and separation of clean and dirty premises and procedures in order to reduce the risk of meat contamination to a minimum.

Where the premises are approved for cutting meat of different animal species, precautions should be taken to avoid cross-contamination by separating the operations for the different species in either space or time as necessary.

When meat storage rooms have adequate capacity, a continuous flow of production may be facilitated before and after cutting in order to prevent the accumulation of exposed meat, the possibility of cross-contamination (e.g. packaged and unpackaged meat) and increasing temperature above the legal standards. This can be achieved by separating lines for cutting meat of different species and different production lots, using good manufacturing and hygiene practices when cutting and deboning meat (meat handling, handling packaging materials and packaged meat, personal hygiene, hygiene of tools and equipment before and during the operation, maintenance and hygiene of premises).

Storage areas

Shortly after arrival, chilled meat for cutting must either be cut or put in refrigerated storage. The conditions must prevent harmful deterioration and protection from contamination. In cases where the meat cutting facilities receive packaged meat for further treatment, there must be adequate premises for unpacking and the hygienic disposal of packaging materials.

Received lots of meat must retain the identification label of their origin and reception for traceability and inventory control (e.g. reception date; approval number of establishment of origin; number of accompanying commercial or veterinary documents; identification of storage location and date).

There must be enough space and room for exposed meat to be stored separately from processed meat and packaged products. This can be assured by keeping them in separate premises or in the same store at different time, or at the same time with either a permanent barrier between them that can be cleaned and disinfected or by using an appropriately placed polythene covering to prevent airborne cross-contamination.


Exposed, packaged and processed meat may be stored in the same cold store and at the same time, provided that there are documented procedures and measures for hygiene and product safety (with a permanent barrier that can be cleaned and disinfected, or with a polythene covering that prevents airborne contamination of unpackaged food). Also, conditions and manufacturing practices during the simultaneous storage of different forms of exposed and packaged meat in plastic foil, bags or vacuum packages must not lead to contamination of exposed meat. It is necessary to protect the meat below the hanging parts or have a spatial separation between hanging meat and meat in containers/racks.

Cutting and use of meat

Meat must attain and remain at the legally-specified temperature during cutting, boning, slicing, wrapping, packaging, storage and transport (3 °C for offal, 7 °C for red meat, 4 °C for poultry meat) with an ambient temperature of not more than 12 °C.

When the cutting room is on the same site as the slaughter premises, meat may be cut and deboned and prior to reaching the legal temperatures, provided that meat is transferred to the cutting room directly from the slaughter premises or after chilling in a refrigerated room.

If cut before chilling, meat must be chilled to the legal temperatures as soon as it is cut and, where appropriate, packaged.



The competent authority may in particular authorize the cutting of meat of ungulates prior to cooling (i.e. “warm” meat) if the meat is intended to be manufactured no more than 2 hours away from the slaughterhouse or cutting room (exemption for a “cold chain interrupted for limited period”). Loading meat for transport must be completed as soon as possible after the slaughter of animals or after meat cutting/deboning. It is the responsibility of the dispatching operator to ensure that all meat is delivered within 2 hours of departure, even if consignments are being delivered to several premises by a single or several vehicles. Also, the dispatching operator needs to confirm that the operator at the receiving establishment is able to refrigerate or cut/debone the warm meat on arrival as a lengthy delay is not covered by this exemption.

Special approval of the competent authority should verify that handling meat that is transported warm at both the dispatching and receiving establishments is in accordance with the necessary information about the establishment to be supplied and the specified final products.

Procedure for meat dropped on the floor

The procedure for meat that has been dropped on the floor depends on the size of the piece and the extent and nature of the meat contamination (e.g. whether it was dropped on a dry surface or in wastewater).

Large pieces of ungulate meat or in-skin poultry carcasses are trimmed in a special place outside the regular meat cutting area so that all visible contamination is removed. The meat is not to be washed before or after trimming.

Small pieces of meat and all those that are not suitable for trimming must be disposed of as food that is unfit for human consumption (non-edible by-product).

Finally, the place where meat is trimmed after each use must be cleaned, washed and disinfected.

Handwashing facilities

For staff handling exposed meat, it is necessary to provide equipment for handwashing with appropriate taps to avoid contamination through manual opening and closing. Taps that are activated by sensors or parts of the leg are recommended over those that are activated by elbows since employees might instead use their hands.

Self-control system

An operator’s self-control system should include implementation, maintenance and monitoring of good hygiene practices and procedures for handling and meat cutting and, when necessary, corrective actions if there is a failure. Applied procedures must be based on HACCP principles.

2.3 Establishments slaughtering and cutting small volumes of meat

Maximum capacities

In accordance with the *Regulation on conditions for the derogation in respect of the construction, layout and equipment of establishments with small volumes of production, processing and treatment of food* (Official Gazette of Montenegro, No. 21/2016):

“establishments slaughtering a small volume of ungulates and farmed game and cutting meat of ungulates and farmed game are establishments slaughtering and cutting up to 10 livestock units per week.

One livestock unit (LSU) is calculated as follows:

- 1 adult bovine animal and soliped; or
- 2 calves or young bulls/heifers; or
- 4 pigs weighing more than 100 kg live weight; or
7 pigs weighing up to 100 kg live weight; or
- 10 sheep and goats; or
- 12 lambs or kids or piglets of less than 15 kg live weight”

“Establishments slaughtering small volumes of poultry and lagomorphs are those that slaughter and cut up to 6 000 animal units per month.

One animal unit is calculated as follows:

- one broiler, one chicken, one farmed game – one unit each;
- one duck – two units each;
- one turkey, one goose, one lagomorph – three units each;
- other poultry – one unit each”

In establishments slaughtering and/or cutting meat of small volumes of ungulates, farmed game, poultry and lagomorphs, the following derogations from certain requirements laid down in the *Regulation on food hygiene* (Official gazette of Montenegro, No 13/2016) and the *Regulation of specific hygiene requirements for food of animal origin* (Official gazette of MN, No 32/2016) are permitted regarding construction, layout and equipment, such as:

One changing room for all employees

Small-volume establishments for animal slaughter and meat cutting **may have:**

"one changing facility for employees working in clean and dirty parts of the establishment, if up to five persons are employed in the production part of the facility".

The separation of changing facilities and other rooms intended for staff needs (e.g. cantina), particularly for employees working in clean and dirty areas of the establishment, may help prevent the spread of contamination from dirty areas (e.g. lariaje – handling live animals; collecting and handling by-products) to areas where unpackaged fresh meat and/or ready-to-eat products are handled (e.g. sliced and vacuum-packed products and products that are not heat treated before consumption).

Simultaneous use of one changing facility by employees working in clean and dirty areas increases the possibility of cross-contamination, especially in establishments with high-volume production. However, in establishments with small production volume, the risk of introducing and spreading contamination may be brought to an acceptable level by applying good hygiene practices. For example, proper personal hygiene, cleaning and disinfecting protective footwear, disinfecting tools and utensils, changing working and protective clothing and footwear will all help avoid the spread of harmful microorganisms. Adherence to these procedures is particularly important in cases where employees working in dirty and clean areas of the establishment use one changing room.

Facilities for veterinary inspection

RSHRPAO – Annex I, Chapter I Part II: Requirements for slaughterhouses for domestic ungulates Paragraph 10	<i>(10) Slaughterhouses must have a separate equipped room for the official veterinarian.</i>
RSHRPAO – Annex I, Chapter II Part II: Requirements for slaughterhouses for poultry and lagomorphs Paragraph 6.	<i>(6) Slaughterhouses for poultry and lagomorphs must have a separate equipped room for the official veterinarian.</i>

Small-volume establishments for animal slaughter and meat cutting **may have:**

"only an adequate cupboard that can be locked for use of the official veterinarian instead of a separate room for the official veterinarian".

In small establishments where a single official veterinarian is normally working for only a few hours a week, a separate room may not need to be provided.

Adequate working conditions must be provided for the official veterinarian while working on the premises (table, chair, electrical outlets and proper lighting, areas for keeping personal and working clothing and footwear and personal belongings) and a cupboard that can be locked for official documents, stamps and marks that the food has been examined and is safe for consumption.

Lairage facilities

<p>RSHRPAO – Annex I, Chapter I Part II: Requirements for slaughterhouses for domestic ungulates Paragraph 3a and c.</p>	<p><i>(3) For construction, layout and equipment, slaughterhouses that process domestic ungulates should have:</i></p> <p><i>(a) adequate and hygienic lairage facilities or, climate permitting, waiting pens that are easy to clean and disinfect, equipped for watering and, if necessary, feeding the animals, with a wastewater drainage system that must not compromise food safety.</i></p> <p><i>(c) lairage facilities of sufficient size to ensure that the welfare of the animals is respected and that there is space for ante-mortem inspections, including a review of the identification marks.</i></p>
<p>RSHRPAO – Annex I, Chapter II Part II: Requirements for slaughterhouses for poultry and lagomorphs Paragraph 1a.</p>	<p><i>(1) Slaughterhouses that slaughter poultry and lagomorphs should have:</i></p> <p><i>(a) a room or covered space for the reception of the animals and for their inspection before slaughter (lairage).</i></p>

Lairages have been shown to be a source of contamination of animal hides/skin/fleeces. Many animals pass through them and can share organisms that, when present on meat, can cause illness in humans. The design, construction and operation of lairages have an important role in the safe production of meat. However, the proportionality principle (that the layout and design of the lairage space depends on the production capacity and organization of the slaughterhouse) must be respected when deciding the characteristics of a lairage space. In small abattoirs where several animals are slaughtered per day or week, there is no need for complex or large infrastructure and equipment. Devices for watering and feeding animals may be simple (e.g. mobile equipment), but during lairaging, animals must have continuous access to water both in terms of quantity and accessibility.

The size of the lairage facilities must ensure that the welfare of the animals is respected. Fences between pens should be appropriate to the species and category of animals (space, height, strength) held on the premises. Stables and pen floors should be made of materials that minimize the risk of animals slipping. Design, construction and maintenance must provide surfaces without sharp or prominent edges that could injure animals. All materials and structures must allow for effective cleaning and disinfection.

For ante-mortem inspections, the conditions should not disturb the animals while providing adequate lighting, space and access to inspect them in motion and at rest. When animals need to be examined in detail, the use of equipment for restraining or the appropriate associated procedure is recommended.

In small slaughterhouses for ungulates and farmed game with facilities for the reception and temporary accommodation of animals, they must be slaughtered within 21 days of reception if the animals have not left the lairage facilities during that period.

An establishment slaughtering small volumes of ungulates, farmed game, poultry and lagomorphs **do not need to have:**

"a separate room for the reception and temporary accommodation of animals to be slaughtered in accordance with the regulations on food hygiene and hygiene requirements for products of animal origin, if the slaughter of animals is performed immediately upon arrival at the facility".

In addition, the veterinarian should be scheduled in advance for the ante mortem examinations to avoid keeping animals in an establishment that does not have lairage facilities for an extended period.

Spaces for sick or suspect animals

**RSHRPAO – Annex I, Chapter I
Part II: Requirements for
slaughterhouses for
domestic ungulates
Paragraph 3b.**

(3) In relation to the construction, layout and equipment that slaughterhouses that slaughter domestic ungulates should have:

(b) separate lockable facilities or, climate permitting, pens for sick or suspect animals with separate draining and sited in such a way as to prevent contamination of other animals.

It is necessary to provide a separate area for sick or suspect animals so that the animal cannot escape and/or mix with other animals and remain under the supervision of the official veterinarian.

Establishments slaughtering small volume of ungulates and farmed game, poultry and lagomorphs **do not need to have:**

"separate room for sick and disease suspect animals"

if appropriate slaughter procedures are applied for sick and suspect animals without affecting hygiene and food safety.

Space/rooms intended for other purposes may be used for sick animals as long as the content can be and is removed immediately.

Facilities for cleaning livestock vehicles

<p>RSHRPAO – Annex I, Chapter I Part II: Requirements for slaughterhouses for domestic ungulates Paragraph 8.</p>	<p><i>(8) Slaughterhouse must have a separate place with appropriate facilities for the cleaning, washing and disinfection of means of transport for livestock or must have a contract with an approved third party for washing, cleaning and disinfecting means of transport in the immediate vicinity.</i></p>
<p>RSHRPAO – Annex I, Chapter II Part II: Requirements for slaughterhouses for poultry and lagomorphs Paragraph 5.</p>	<p><i>(5) Slaughterhouse for poultry and lagomorphs must have a separate place with appropriate facilities for the cleaning, washing and disinfection of means of transport for poultry or to have a contract with an approved third party for washing, cleaning and disinfecting equipment for transport of poultry and lagomorphs.</i></p>

To prevent the spread of infectious disease, facilities for cleaning, washing and disinfecting livestock transport vehicles are normally required on the slaughterhouse site.

These facilities should have:

- impervious hard surface, with space for normal vehicle throughput;
- functionality in all weather conditions (e.g. protection canopy);
- drainage facilities sufficient for the quantity of liquid waste generated during cleaning and disinfection;
- adequate supplies of pressurized, potable water;
- sufficient light in which to work and inspect;
- equipment (i.e. sprays, high-pressure hoses, brushes, etc.) with which to apply disinfectant;
- approved disinfectants for use at approved dilution ratios, for thorough disinfection;
- safe storage of cleaning materials, disinfectants and equipment;

- safe storage facilities for materials removed from vehicles, before its disposal, so that animals have no access to it.

There should be documented procedures and plans for regular and thorough disinfection of vehicles (solution preparation/dilution; cleaning and disinfection method; removal of collected waste materials; records on storage and use of disinfectants; records on cleaned and disinfected vehicles).

Establishments slaughtering small volume of ungulates and farmed game, poultry and lagomorphs **do not need to have:**

"separate place with appropriate facilities for the cleaning, washing and disinfection of means of transport for livestock, if the food business operator has a signed contract for washing, cleaning and disinfection of means of transport".

Contracts for washing, cleaning and disinfection of means of transport can only be signed with an entity that has been approved by the competent authority for cleaning, washing and disinfection of means of transport of animals.

Rooms for detained meat

<p>RSHRPAO – Annex I, Chapter I Part II: Requirements for slaughterhouses for domestic ungulates Paragraph 7</p>	<p><i>7) Slaughterhouses must have separate lockable facilities for the refrigerated storage of detained meat as well as for meat declared unfit for human consumption.</i></p>
<p>RSHRPAO – Annex I, Chapter II Part II: Requirements for slaughterhouses for poultry and lagomorphs Paragraph 4.</p>	<p><i>Meat of slaughtered animals may be detained for further examination, which can include awaiting more information or test results, or verifying the identity of animals.</i></p>

Meat of slaughtered animals may be detained for further examination, which can include awaiting more information or test results, or verifying the identity of animals.

In establishments that slaughter small volumes of animals:

"In a room i.e. one cooling chamber, retained carcasses and carcasses fit for human consumption may be stored, provided that:

- (1) spaces reserved for detained carcasses are marked and can be locked;*
- (2) the reason for retaining carcasses is not a contagious disease;*
- (3) contamination of other meat is prevented".*

It is necessary to provide refrigeration space that can be locked and equipment for storing detained meat. This can be a dedicated room or space (e.g. cage) inside the chiller room, constructed of a corrosion-resistant material that can be cleaned.

Construction and use of the space should prevent leakage of liquids from retained material in the rest of the chilling room. For individual establishments, if such a solution does not endanger the hygiene and safety of meat, the competent authority may permit the use of rail in cold storage, which can be locked/blocked.

Acceptable storage solutions for detained meat depends on the volume of business. The solution is not acceptable if the use of space interrupts or interferes with the process of cooling meat.

Facilities for meat unfit for human consumption

In small-scale slaughtering facilities, unfit meat may be stored in chambers intended to refrigerate meat fit for human consumption provided it is packed, sealed and labelled in accordance with the special hygiene requirements for food of animal origin, and that storage and disposal do not compromise hygiene and food safety. This means that there should be no opportunity for cross-contamination between fit and unfit meat. It is necessary to provide a separate space that can be locked and clearly marked for storing meat declared unfit for human consumption prior to its disposal as an animal by-product.

Documented operating procedures and measures should be in place to prevent the misuse of detained meat and inedible by-products, as well as contamination of meat fit for human consumption.

Emptying and cleaning stomachs and intestines

Small-volume slaughtering establishments **do not need to have:**

"[a] separate room for emptying and cleaning of stomachs and intestines, where emptying and cleaning of stomachs and intestines may be performed in slaughter area after the completion of slaughter operations, provided that the area is free of carcasses of slaughtered animals and that prior to use it is thoroughly cleaned and disinfected".

Emptying and cleaning stomachs and intestines in the slaughter room may be authorized at the premises, provided that the competent authority accepts the operator's written guidelines on how this operation will be carried out, including the procedures of cleaning, washing and disinfecting the premises and equipment used.

This approval may only be applied to a single facility on a case-by-case basis after submitting such a request and must be part of the establishment's approval decision.

Evisceration and dressing of poultry and lagomorph carcasses

In establishments slaughtering small volumes of poultry and lagomorphs:

"evisceration and further dressing of carcasses of poultry and lagomorphs may be carried out in the same room where scalding and plucking of feathers is performed, provided that there is sufficient spatial and adequate physical separation of evisceration and plucking, in order to prevent food contamination".

The operator must have sufficient space for physical separation between the evisceration and plucking operations. Also, documented measures (e.g. work in smaller batches) and hygiene procedures (personal hygiene, cleaning and disinfection of tools/utensils) must be applied to prevent contamination.

Space for cutting meat

Small volume establishments for animal slaughter and meat cutting **should not have:**

"[a] special area for meat cutting; cutting of meat may be carried out in slaughter room, but only if the meat is obtained from animals slaughtered in that establishment, provided that slaughter and cutting operations are separated in time and that thorough cleaning and disinfection is performed after slaughtering and prior to cutting".

In small-scale slaughterhouses in which all slaughter operations are completed before the next animal is admitted (stationary individual slaughter), the facility may be used as a cutting room as well, provided that the slaughtering operations and cutting are carried out at different times and that the facility has been thoroughly cleaned and disinfected after slaughter and/or prior to cutting.

2.4 Facilities for meat processing

Prerequisite requirements

In meat processing establishments, prerequisite requirements of food hygiene are applied in accordance with the nature and volume of operations.

Temperature control facilities

Meat processing establishments need to comply with the temperature requirements for meat and premises and provide sufficient cooling capacity at every stage of production, storage and transport, as well as the adequate devices of monitoring temperatures, in order to guarantee that the chilling process is correct and that the cold chain is being maintained.

Self-control

FBOs involved in meat processing are obliged to establish, implement and maintain permanent self-control procedures based on the HACCP principles. These principles are necessary to ensure that food safety hazards, particularly microbiological cross-contamination during cutting and the growth of microorganisms due to inadequate temperature control, are reduced to a minimum. This is accomplished by applying appropriate criteria and operational procedures for cutting/deboning, maintaining the cold chain, and if required, during storage, transport and thawing.

Regular monitoring and recording is recommended to check that employees are applying the established procedures for meat processing, such as:

- cleanliness of food handling areas, storage and vehicles;
- meat handling procedures, including adequate cleaning and disinfection of tools;
- meat temperature in work premises, warehouses and vehicles;
- adherence to regime and effectiveness of heat treatment, if used;
- maintenance of personal hygiene practices;
- testing of microbiological criteria.

Sampling and laboratory testing can assist in the validation and verification of the effectiveness of the procedures included in the self-control system, as well as the fulfilment of process hygiene and food safety criteria.

It is necessary to apply corrective actions if there is a failure. Such actions may include:

- notification to the meat supplier and, if necessary, change of suppliers;
- removal of contaminated raw materials or products;
- determination of underlying cause and what needs to be done to prevent similar incidents in the future;
- reviewing and improving the guidelines and training employees.

The operator must keep accurately dated records on production monitoring, (e.g. a daily diary) with observations and issues that require special attention and any corrective measures.

Training and instructions

Employees need to complete sufficient training and obtain clear work instructions to know and understand the consequences of their actions, as well as their obligation to report failure of standard and usual practice.

All employees, managers and visitors are required to comply with the internal rules of personal hygiene and health procedures in the meat processing establishment, particularly handwashing and wearing working and protective clothing and footwear.

Raw meat for processing

Meat for meat processing must be sourced from approved slaughterhouses and/or approved cutting plants or establishments approved for production of minced meat or meat preparations, and must have a health or identification mark.

Meat reception. It is necessary to establish an adequate system for accepting deliveries of meat and non-meat raw materials, Good control practices on arrival of each consignment should include answers to the following questions:

- Is there any required/contracted documentation?

- Are meat and other products of animal origin sourced from approved establishments?
- Do the meat and other products meet temperature requirements?
- Are all products of animal origin correctly identified (e.g. health marks/identification mark for meat/products of animal origin)?
- Have the products been contaminated (e.g. visible soil, foreign bodies, pests)?
- Do the products meet the company's quality specifications/agreed quality standards?

If the conditions are not met, especially those that are important for food safety, it is necessary to take measures, which may include:

- holding shipment e.g. awaiting documentation;
- treatment e.g. trimming visible contamination from parts of meat that is otherwise suitable for human consumption;
- diverting raw materials to production of heat treated products;
- returning the shipment to the originating premises (where the meat received is not fit for human consumption, it must be handled as an animal by-product; such meat cannot be returned to the supplier unless they are authorized to receive animal by-product).

If incoming raw materials are sampled for laboratory testing, and a positive release system is in place, these raw materials must be held until the results become available. In all cases, robust arrangements are needed so that test results can be matched to sampled products (traceability).

Batch identification. It is necessary to preserve the identity of incoming batches for stock control and traceability purposes, and it is recommended to use "first in – first out" good storage practice.

Storage. Premises and containers for keeping/storing meat and other products must be kept clean and disinfected, with adequate ventilation so that the risk of contamination is reduced to a minimum.

Hygiene regulations set out the maximum temperature at which meat can be stored. Temperature control is important to minimize the growth of microbiological organisms that may spoil food or cause food poisoning.

All raw meat must be kept separately from processed and or packaged products. This may be done by keeping them in separate stores, in the same store at a different time, or at the same time with either a permanent barrier between them that can be cleaned and disinfected or by using an appropriately placed polythene covering to prevent airborne cross-contamination.

By-products must be kept apart from meat declared fit for human consumption. Storage containers must be clearly labelled and secured in a way that avoids the risk of contaminating food.

Traceability should ensure that all products of animal origin that are used as raw materials come exclusively from establishments with approval, including all necessary identification that will allow traceability/link of raw materials to outgoing processed product.

Meat processing

<p>RFH – Definitions: Article 2 – Points 11–13.</p>	<p>(11) “processing” means heating, smoking, salting, maturing, drying, marinating, extracting, pressing or a combination of those processes or any action that substantially alters the initial product;</p> <p>(12) “unprocessed products” means products that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, skinned, minced, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed;</p> <p>(13) “processed products” means products resulting from the processing of unprocessed products and may contain ingredients that are necessary for their manufacture or to give it certain specific characteristics.</p>
--	---

When establishing a self-control system in meat processing establishments, in addition to the implementation of prerequisite programmes and other issues important for the safety and quality of the finished products, it is required to consider the following:

- **Process flow:** The method and speed of fresh meat delivery before and during processing must be timely, balanced and prevent cross-contamination, e.g. between raw materials and ready-to-eat products. The addition of other ingredients (e.g. flavourings, additives and other non-meat ingredients) must be under constant supervision during receipt, storage, scaling, packaging and labelling for use, handling until use and removal of packaging in order to prevent microbiological, physical or chemical contamination.
- **Process control:** Depending on the type of product and method of processing, the self-control system must define all actions, process and other key elements relating to the ingredients, type of product and production processes. Knowing this information can help prevent the growth of pathogenic microorganisms and toxin production during all stages of processing and ensure appropriate shelf life and product quality.

Every technological process and its effect on the safety and quality of products has its critical parameters that must be monitored/controlled during and at the end of the manufacturing process. The most common parameters are:

- temperature and cooling time (meat, minced meat, meat products, MSM);
- temperature and time of heat treatment of pasteurized and sterilized products;
- temperature and time during and after smoking, ripening and drying;
- pH during, and in particular after the fermentation/ripening and drying;
- water activity (a_w) during, and in particular after fermentation/ripening and drying;
- water to protein ratio after drying;
- formulation and application of curing ingredients, e.g. nitrite quantity.

If heat and/or other processing treatments are insufficient to ensure the shelf life of the product at room temperature, the product should be cooled to an appropriate storage temperature in a manner

that ensures product safety is not compromised by germination and subsequent growth of pathogenic spore formers. Product preparation, such as distribution of antibacterial ingredients throughout cooked sausage emulsions, addition of cultures and adjustment of pH should achieve required levels of pathogen control.

Heat treatment must be carried out within the scheduled time according to each product or until the internal product temperature is reached. The effects should be validated by reducing the presence of pathogens and meeting other specified performance objectives (through heating, heat treatment, pressure and cooling process), performance criteria and microbiological criteria.

The success of pasteurization or other heat processes should be validated for all heat-treated products in hermetically-sealed containers to ensure that product safety is maintained through the end of shelf life, taking into account all preservation factors.

Sterilized, canned products in hermetically-sealed containers must be protected from contamination after the heat treatment and during the product cooling process until the internal product temperature is equal to the ambient temperature (e.g. contamination by suction of contaminated water). As a preventive measure against later contamination that could poison people or spoil the product, it is necessary to check that the seals on each container is secure

Detection of foreign bodies. Process lines that manufacture products containing minced, comminuted or MSM, as well as all mechanically-processed products, should have in-line magnets or other means of detecting and warning of contamination that carries physical hazards.

Taking into consideration that tradition and experience are of special importance in production of safe and quality meat products, expert advice is recommended for meat processing management.

Minced meat and meat preparations

RSHRPAO – Definitions: Article 2 – Points 13 and 15.

13) *“Minced meat“ means boned meat that has been minced into fragments and contains less than 1% salt;*

15) *“meat preparations“ means fresh meat and meat that has been minced, had foodstuffs, seasonings or additives added to it, or undergone processes insufficient to modify the muscle fibre structure of the meat and thus to eliminate the characteristics of fresh meat.*

The opportunity for contamination and interruptions to the cold chain must be minimized by keeping meat intended for minced meat or meat preparations packed and in chilled storage under legal temperatures until it is ready for processing. Meat preparations include *čevapčići* (sausages) and *pljeskavica* (hamburgers).

Minced meat and meat preparations must be chilled to no higher than 2 °C and 4 °C, respectively, and frozen no warmer than -18 °C, provided that the said temperatures are maintained during storage and transport.

Legitimate materials for the production of minced meat and meat products. All meat used in the manufacture of minced meat and meat preparations must come from approved premises and must be either marked for health or bear an identification mark. Meat must comply with the requirements for fresh meat (chilled or frozen) and derive from skeletal muscle, including adherent fatty tissues. Use of small pieces of meat obtained by treatment of whole muscles is acceptable as well.

“Storage time” of chilled meat intended for the production of minced meat and meat preparations is the date of slaughter plus a certain number of days that the operator implements as a good and documented practice, which will vary by species.

Minced meat and meat preparations produced from chilled meat may be frozen, while respecting the conditions of hygiene and the required temperatures. Thawed products must not be refrozen.

Use of frozen meat. Thawing and deboning can be carried out immediately before mincing or meat preparation if carried out hygienically. The process should be included in the HACCP plan, as well as the determination of the storage period for frozen meat, which is largely a quality issue.

Well-maintained records should:

- demonstrate the time when chilled meat was frozen, thawed, deboned and used for the production of minced meat and meat preparations;
- show that the established storage time have not been exceeded;
- ensure that the thawed minced meat and meat preparations will not be refrozen.

Other raw materials like MSM, meat containing bone fragments, cartilages or skin, as well as head meat, with the exception of masseters, the non-muscular part of the linea alba, the region of the carpus and the tarsus, bone scrapings and the muscles of the diaphragm (unless the serosa has been removed), are not appropriate as raw materials for the production of minced meat and meat preparations. Finally, scraps designated “inedible” or “unfit for human consumption” or whose use would not reach the microbiological criteria for minced meat are not acceptable.

Mechanically-separated meat

**RSHRPAO – Definitions:
Article 2 – Point 14.**

(14) “Mechanically-separated meat” (MSM) is the meat obtained by removing meat from flesh-bearing bones after deboning, or from poultry carcasses by using mechanical means resulting in the loss or modification of the muscle fibre structure.

Raw materials for MSM. All meat used in the manufacture of MSM must comply with the requirements for fresh meat. That means that the meat must originate from approved premises and have either health marks or bear an identification mark.

Raw material for deboning from an on-site slaughterhouse may be used no later than 7 days from the date of slaughter; otherwise, raw material for deboning must be no more than 5 days old. Poultry carcasses must be deboned no more than 3 days from the date of slaughter. The meat must be deboned shortly before the production of MSM.

Immediately after manufacture, MSM must be wrapped or packaged and then chilled to a temperature of not more than 2 °C or frozen to an internal temperature of not more than –18 °C. These temperature requirements must be maintained during storage and transport.

Thawed MSM or flesh-bearing bones intended for MSM production must not be refrozen. MSM that complies with the microbiological criteria and calcium content for minced meat may be used in meat preparations that are clearly labelled to be consumed only after first undergoing heat treatment.

MSM with a calcium content that is too high or low or that does not comply with the microbiological criteria for minced meat may only be used in establishments approved to manufacture heat-treated meat products, if the microbiological status allows for it.

The operator must keep adequate records in place to show that the requirements for production, processing and distribution are always met.

Meat products

RSHRPAO – Definitions: Article 2 – Point 47

(47) **“Meat products”** are processed products resulting from the processing of meat or from the further processing of such processed products that no longer have the characteristics of fresh meat.

Minced meat and meat preparations that are used as ingredients for meat products do not have to meet other requirements for raw materials, except for those regarding fresh meat laid down in the *Regulation on specific hygiene requirements for products of animal origin* (Official Gazette of Montenegro, No. 32/2016, Section VI).

Edible by-products

Rendered animal fats and greaves. FBOs that manufacture rendered animal fats and greaves may use only raw materials that:

- (I) are derived from animals that have been slaughtered in a slaughterhouse, and that are fit for human consumption following ante-mortem and post-mortem inspections;
- (II) consist of adipose tissues or bones that are reasonably free from blood and impurities;
- (III) are transported and stored until rendering in hygienic conditions with an internal temperature of not more than 7 °C, or stored and transported without active refrigeration if rendered within 12 hours after the day on which they are obtained.

Treated stomachs, bladders and intestines. FBOs treating stomachs, bladders and intestines may place them on the market only if they are from animals that have been slaughtered in a slaughterhouse, have been found fit for human consumption following ante-mortem and post-mortem inspections, and fulfil the other relevant legal requirements.

Gelatine and collagen. For the production of gelatine or collagen intended for use in food, the following raw materials may be used: bones, according to the special regulation; hides and skins of farmed ruminant animals; skin and bones of pigs; skin and bones of poultry; tendons, skin and bones of fish; and hides and skins of wild game.

In both cases, these raw materials must derive from animals that have been slaughtered in an approved slaughterhouse, and whose carcasses are fit for human consumption or, in the case of wild game, whose hides and skins are found fit for human consumption.

The use of hides and skins is prohibited if they have undergone any tanning process, regardless of whether this process was completed. Establishments for collecting hides and tanneries may also supply raw materials for the production of gelatine and collagen intended for human consumption if the competent authority specifically authorizes them and the establishment fulfils the requirements.

2.5 Small-volume meat processing establishments

In accordance with the *Regulation on conditions for derogations for the construction, layout and equipment of establishments with small volumes of production, processing and treatment of food* (Official Gazette of Montenegro, No. 21/2016), “establishments processing small volume of meat are processing facilities in which up to 1 000 kg of meat per week is processed.”

In establishments processing small volumes of ungulates, farmed game, poultry and lagomorphs, the following derogations from certain requirements laid down in the *Regulation on food hygiene* (Official gazette of Montenegro, No 13/2016) and the *Regulation on specific hygiene requirements for food of animal origin* (Official gazette of Montenegro, No 32/2016) are granted regarding construction, layout and equipment, such as:

Different production phases and/or production of different products in the same room

In establishments with small volume of meat processing, **they may perform:**

“different technological phases and/or production of different products in the same room, provided that time separation between production phases is assured”.

If simultaneous work on different technological phases of production for a single product and/or manufacturing of various products at the same time may adversely affect the safety and quality of products that are prepared/produced, these production phases or products must be produced at different times. For example, work with chilled raw materials and heat processing; chilling and storage of cooked/boiled and fermented/dried products; manufacture of canned products in hermetically sealed containers must be done separately. If time separation is required, the operator should apply documented procedures of good manufacturing practice.

Storage of raw materials, finished products and retained products in the same room

In establishments with small volumes of meat processing, **they may:**

“stor[e] raw materials, finished products and detained products in the same room with adequate spatial separation, so as to prevent possible contamination and that detained products are packaged, sealed and clearly marked”.

Raw materials, unwrapped and wrapped meat and processed meat (finished products) can be stored in the same cold store at the same time, provided that there are documented procedures and measures to ensure hygiene and product safety. In addition to the spatial separation, additional physical barriers may be used to prevent contact and cross-contamination (e.g. a permanent barrier that can be cleaned and disinfected), or plastic film may be used to protect unpackaged raw materials and products from air contamination.

If detained products and inedible by-products (category 3) are stored in the same room, they must be wrapped (e.g. polyethylene bags) and closed in designated and marked containers.

Changing room for employees out of the production area

In establishments with small volumes of meat processing:

“changing room for employees can be placed outside the working area but inside the establishment ground”;

“If the small-scale meat processing facilities are located in the same ground as residential house, changing and sanitary facilities of the residential house may be used for employees’ needs”.

When the changing room for employees is located outside the working area and inside the establishment grounds (e.g. in a residential house), there must be documented procedures and good hygiene practices must be applied with regard to personal hygiene (handwashing and disinfection). Measures must also be taken to prevent the introduction of contamination in establishment (disinfection of protective footwear, replacement of working and protective clothing and footwear).

Storage of packaging materials outside the production area

In establishments with small volumes of meat processing:

“[the] storage area for packaging materials may be placed outside the working area but inside the establishment grounds”.

If the location of storage facilities for packaging materials requires leaving the production premises/crossing the establishment’s grounds or passing through the outside environment, the operator should document and implement best practices for handling and protecting packaging materials during receiving, storing and transport from the storage premises to the point of use in the workplace area. Procedures should cover location and method of handling the packaging according to its purpose and type.

Storage of cleaning and disinfection materials outside the production area

In establishments with small volumes of meat processing:

“storage premises for materials for cleaning and disinfection of production plant may be located outside the working area but inside the establishment grounds”.

It is important that the storage place for cleaning and disinfection equipment is under a permanent operator’s control. This person should ensure that there are no risks to the safety of raw materials and products, prevent unauthorized access and use, and maintain proper conditions for the chemicals.

The operator should document and apply best practice procedures for the receipt, handling and use of all chemical substances.

The same entrance and exit of raw materials, finished products and unsafe products

In establishments with small volumes of meat processing:

“[the] same entrance and exit may be used for raw materials, finished products and unsafe products, with appropriate separation in time.”

If the same entrance and exit are used at different times for loading and unloading packaged and packed fresh meat, finished products intended for human consumption and inedible by-products, it is necessary to ensure good hygiene practices and application of measures that will prevent contamination of food.

With regard to the conditions laid down in the legislations on food hygiene (*Regulation on food hygiene*, Official gazette of Montenegro, No 13/2016) and special hygiene requirements for food of animal origin (*Regulation on specific hygiene requirements for products of animal origin*, Official gazette of Montenegro, No 32/2016), stipulated derogations for meat processing facilities in which 1 000 kg of meat per week is processed may at a minimum include the following elements for construction, layout and equipment:

- One entrance and exit for raw materials, finished products and unsafe products, with an adequate separation in time.
- One room/cold chamber/refrigerator of sufficient size and capacity for reception, chilling and storage of raw materials/meat, finished and detained products with appropriate spatial separation. If space is limited, the simultaneous holding of detained and safe raw materials and finished products is allowed if the detained products are packaged, sealed and clearly marked.
- A room for cutting and/or processing meat, along with adequate time or spatial separation.
- In case of heat treatment, a special room, device or procedures of cutting and/or processing of meat separated in time.
- A room or device for smoking and/or maturing and/or other processes that require special microclimate conditions in production.
- A space, locker and, if necessary, a refrigerator for storing seasonings, additives and other materials needed for production.
- A space or locker for storing materials for wrapping and packaging, and a separate area for packaging may be placed outside the working area but within the establishment's grounds.
- A separate room or space for storing utensils, equipment and materials for cleaning, washing and disinfection may be placed outside the working area but within the establishment's grounds.
- A changing room and toilets for staff may be placed outside the working area but within the establishment's grounds. If the establishment is located on the same grounds as residential housing, the changing and sanitary facilities of the house may be used for the employees.

Chapter 3:

Traditional products

Today, consumers are more demanding than ever before about their food. As education levels rise and food options expand, many people are choosing food products with quality characteristics associated with tradition, skills and knowledge that have been passed through the generations. Local identities can be the result of acquired knowledge and skills incurred over a long period of time, and are often inseparable from natural resources and typical methods of production. Therefore, it is necessary to preserve this heritage since, in addition to conveying culture and history, it adds value on the market for such products whose quality is the result of geographical origin, tradition and speciality of location.

In Montenegro, there is a long practice of consuming typical products directly offered at the farm, at green markets, through small specialized shops, etc. Over the years, a large number of traditional food products have integrated into to the Montenegrin tradition. There is great potential to increase the quantities produced and placed on the market through tourism or export.

There is no inventory of the agricultural and food products and traditional specialties in Montenegro that have the potential for GI protection, so they must be identified on an individual basis. In addition



Njeguška pršuta



to protecting popular Montenegrin products, the possibility of re-establishing the production of some long-time forgotten food specialties should not be ignored.

Traditional agricultural and food products can be protected by the competent government institutions through quality labelling, with three types of quality logos: designation of origin, protected geographical indication or traditional speciality guaranteed (TSG).

Food safety standards in the production of traditional products

In addition to protecting knowledge and skills related to traditional products, it is necessary to ensure an identical or standardized quality respecting the principles of food safety. The Law on Food Safety (Official Gazette of Montenegro, No 57/2015) requires that all food business operators involved in the production and distribution of food, including those making products with traditional characteristics, introduce HACCP as a mandatory requirement, which can potentially lead to a high level of food safety.

Since a significant part of agricultural production is currently performed on family farms, Montenegro has adopted a set of incentives for producers using traditional production methods who are located in rural, hard-to-reach areas. By applying these measures, diversity of food products will be preserved, traditions and historical heritage in food production will be protected, and increased distribution of these products will be enabled.

When are derogations important for traditional food production?

Derogations can be important for both small-volume facilities producing, processing and treating food; and establishments producing traditional products. In many cases, a business will be both small and traditional. It is thus extremely important to understand the main difference and points of overlap between the derogations relating to these two categories. Namely, small-scale facilities for production, processing and food treatment have a maximum capacity of meat they may process, and they must meet certain requirements in terms of construction, layout and equipment (e.g. minimum number of rooms, time separation of different production operations in the same room, etc.). On the other hand, **derogations for production of traditional products and/or using traditional methods do not limit production volume and are applicable to establishments of both large and small capacities.**

**Regulation on conditions for derogations in terms of construction, layout and equipment of establishments with a small volume of production, processing and treatment of food
(Official Gazette of Montenegro, No. 21/2016)**

Article 6.

In establishments where traditional products are produced or where traditional manufacturing methods are used, facilities and premises may:

- (I) be constructed from natural materials necessary for the development of specific characteristics of that traditional product;
- (II) have walls, ceilings and doors that are not of smooth, impervious, non-absorbent or corrosion-resistant materials or may have natural geological walls, ceilings and floors;
- (III) adapt cleaning and disinfection procedures needed to keep the natural production conditions (specific ambient flora);
- (IV) at all stages of production and packaging use equipment, tools and instruments that are made of materials that are not smooth, corrosion-resistant or non-absorbent, including wood, stone and other materials that are traditionally used in the production, maturation and storage of the product and that are maintained in a satisfactorily hygienic state and are regularly cleaned, washed and, if necessary, disinfected.

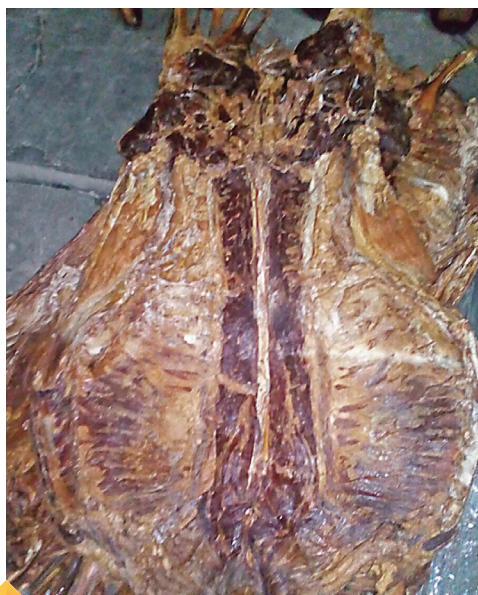
Derogations related to premises

Premises for the production of traditional products may have walls, ceilings and doors that are not smooth, impervious, non-absorbent or made of stainless material. In specific cases, premises made of stone and wood may be used. Cleaning and disinfecting measures for the premises and cleaning frequency can be adapted to the activity in order to protect natural ambient flora as long as the objectives of food safety are achieved.

Derogations related to equipment

Tools, utensils and equipment used in manufacturing, wrapping and packaging traditional meat products may be made of natural materials such as wood and stone. Equipment that comes into contact with food must be clean, regularly maintained and, if necessary, disinfected so as to prevent the risk of contamination.

Specified derogations from food hygiene regulations in establishments producing traditional products or using traditional methods, regardless of the production volume, allow the premises to be made of natural materials, provided they are necessary for the development of the specific characteristics of the traditional products, which must be proved by the food business operator to the competent authority (e.g. data from a document on the protection of geographic indication of origin). Also, materials for tools, utensils and equipment used in various stages of production may be made of stone (e.g. for pressing) or wood (e.g. maturing, drying, storage).



Ovčija stelja



Kastradina

However, derogations specified for small-scale production or processing of meat may be applied only to establishments processing up to 1 000 kg of meat per week for traditional products. In this case, derogations related to construction, layout and equipping this facility may be reviewed in Chapter 23 – Small-scale meat processing establishment.

Derogations in meat production

In order to use the opportunities for derogations, it is essential that manufacturers who are engaged in traditional food production are recognized by the competent authority (Ministry of Agriculture and Rural Development, Veterinary Directorate).

Instruction for the recognition of traditional products Point 2.

Traditional products are foods with traditional characteristics that are traditionally manufactured in Montenegro and that are:

- recognized historically as traditional;
- manufactured according to codified or registered technical references to the traditional process, or according to traditional production methods; or
- protected as traditional food product in line with the special law.

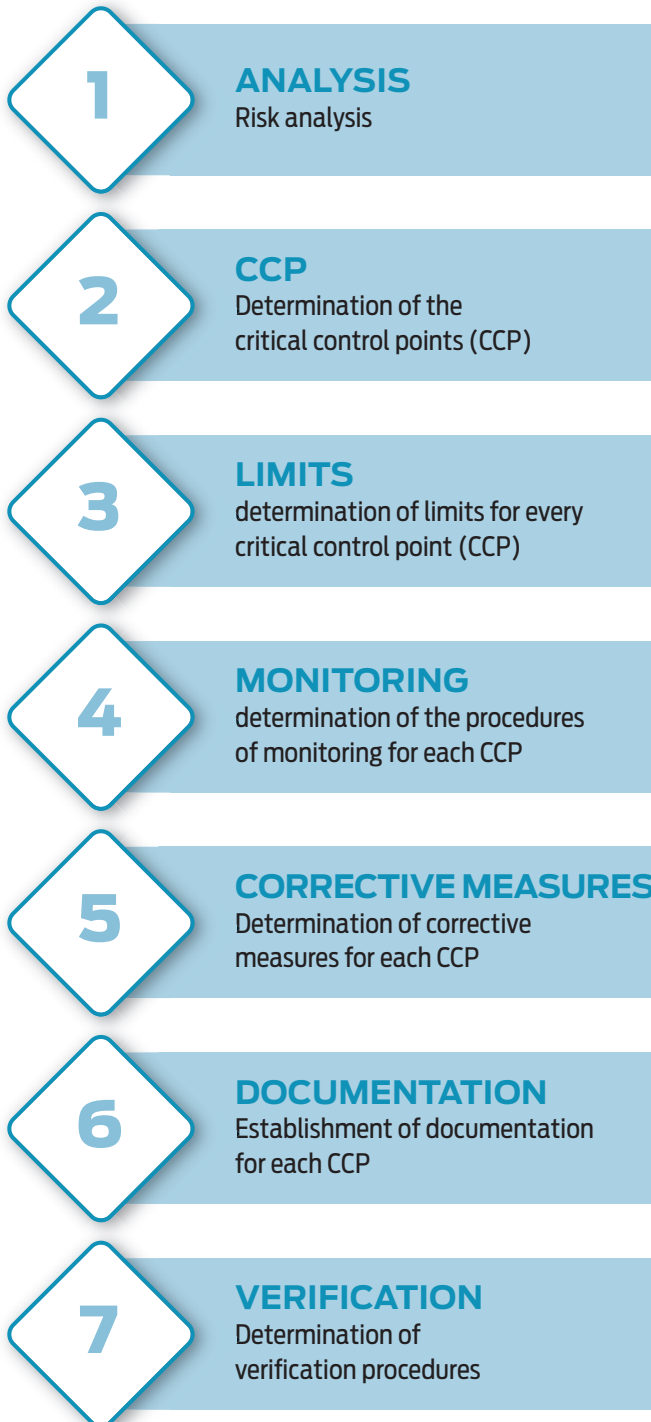
This type of products shall be recognized as traditional by the competent authority responsible for agriculture (hereinafter referred to as the "Ministry") at the request of natural or legal person or association of producers.

Chapter 4:

Hazard analysis and critical control points

HACCP is a scientifically-based system designed to identify and control health hazards that are especially present in the food production process with the aim of ensuring food safety. Internationally-agreed principles are applied to all food and beverage production sectors, distribution, retail and hospitality. Within the context of HACCP, the following definitions are relevant:

- risk is the possibility of a hazard occurring;
- a hazard is the physical, chemical or microbial agent that can make a product unsafe for human health or can lead to its spoilage;
- a critical control point is a step in the production process where the risk cannot be eliminated or reduced to acceptable levels.

Figure 2: The seven principles of HACCP

Source: Authors' elaboration.

How can an effective HACCP system be established?

When first creating a HACCP system, it is necessary to determine the scope of the plan. It should include a description of the production process, as well as an explanation of which part of the process and hazard categories will be subject to analysis (biological, chemical and physical).

Then it is necessary to describe the product and clearly state its composition (raw materials, ingredients, additives), its structure and physicochemical properties, methods of processing (salting, drying, smoking, heat treatment), packaging, storage conditions, distribution shelf life and instructions for use. Normal expected use of the product by consumers should also be clearly defined.

The next step is to create a diagram flow for the product or group of products. It should include all stages of production from receipt of raw materials to the final product, including the preparation, processing, packing, storage and distribution. The diagram flow is checked on-site in the course of production.

Figure 3: How to create a HACCP system

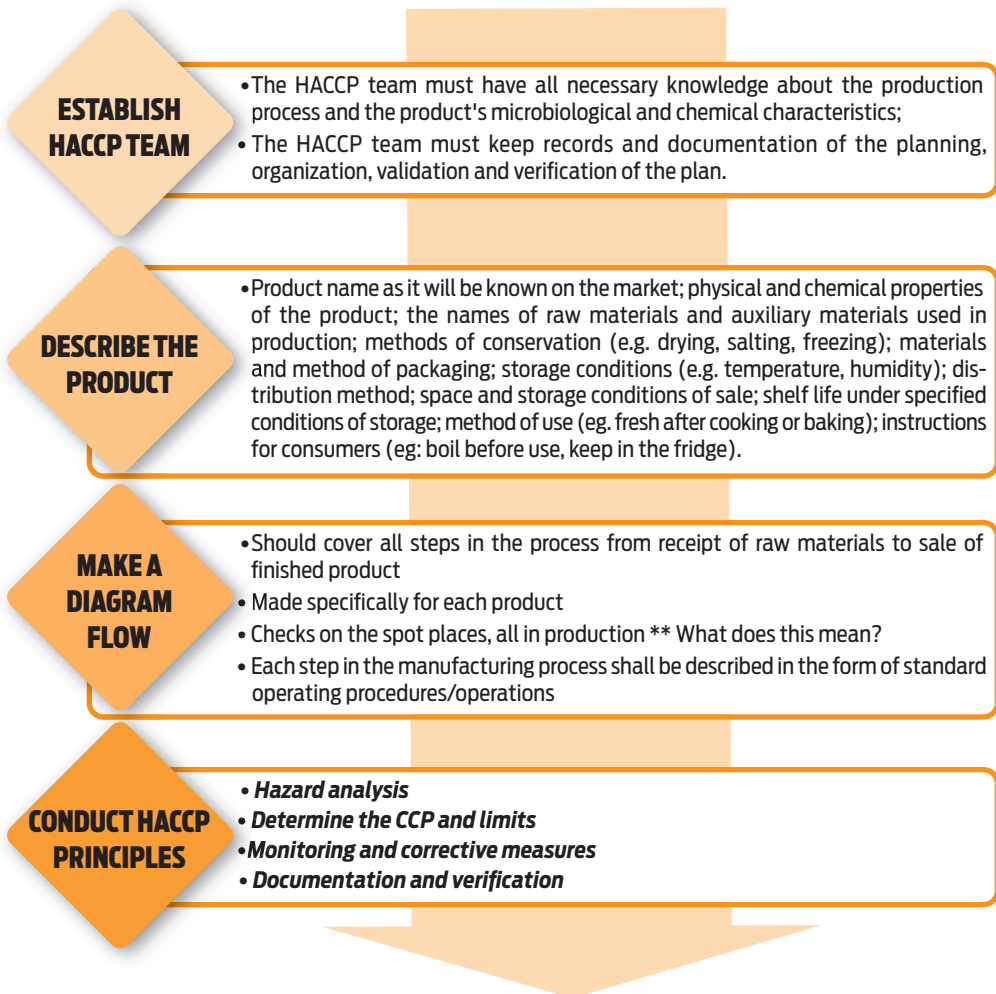


Table 7: The seven HACCP principles

Principle	Description	Examples
1. Hazard analysis	Identification and characterization of risks	Analysis of biological, physical and chemical hazards
2. Identification of critical control points (CCP)	Phase or process that allows elimination or reduction of hazard to an acceptable level	Disinfection, sterilization, product cold storage (temperature), salting
3. Establishing monitoring procedures for critical control points	Determination of measurable values following the CCP	Cooling temperatures, temperature of heat treatment, salt %, ripening time, smoking time
4. Monitoring	Implementation of planned monitoring-control activities if the CCP is under control	What is being checked? Who checks? How is the check conducted? How often is it checked?
5. Corrective measures	Control points that are out of control	Corrective measures must be taken
6. Verification	Verification activities on each CCP	Equipment verification, calibration, control of microorganisms, etc.
7. Documentation	HACCP documentation	Data on risk analysis, critical limits, monitoring of CCPs, date and signature

Microbiological criteria for self-control plans

In their self-control plan, producers must include all required microbiological criteria specific to food businesses. Microbiological criteria define the acceptability of a food product or lot based on the absence, presence, or number of microorganisms including parasites, and/or quantity of their toxins/metabolites per unit of mass, volume, area or lot. When microbiological criteria are included in the self-control plan, all components that constitute the microbiological criterion must be taken into account. These are:

- category of food (product) to which it relates;
- microorganism or toxin/metabolite being tested;

sampling plan (with the number and size of the elementary units comprising the sample);

- limit values;
- testing method;
- phase in which the criterion applies, and corrective measures in case of unsatisfactory results.

All of the above elements must be thoroughly described in a self-control plan.

In addition to microbiological criteria, the FBO must include a self-control plan and sampling frequency. Regulations on microbiological criteria for food safety sampling prescribe frequency for carcasses, minced meat, meat preparations, MSM and fresh meat; FBOs producing these products need to follow the prescribed sampling frequency.

For all other categories of food sampling, frequency is not prescribed, and FBOs can determine it in their self-control plans. The competent authority must endorse the sampling plan (both sampling frequency and number of samples) for meat products.

The self-control plan must describe sampling methods, equipment and tools that are used in sampling, and a description of their proper use and instructions for operation. Sampling must be performed in an appropriate manner to avoid contamination of the sample.

Sampling and testing methods can differ from those defined in the Regulation provided that the FBO proves that the methods are at least as efficient as the benchmarked ones and the competent authority authorizes their use.

In addition to the obligatory microbiological criteria established in the Regulation, the producer may in the course of operations test for other microorganisms, which then have to be included in the self-control plan (e.g. on the basis of required product specifications, recommended parameters from the Guide et al.)

Details and components that define the microbiological criterion (food to which it is related, the microorganism, a sampling plan, limits, testing method, the stage at which the criterion is applied, the corrective action in the case of unsatisfactory results)

What should small producers do?

Small-scale production (up to 10 employees) is quite common in Montenegro, especially in the specialized production of meat and meat products. For these manufacturers, certain modifications to the HACCP plan relating to the definition of risk, the number of CCP, the simplification of procedures for monitoring, and simplified documentation may be necessary, although they should always consider the specific risks associated with their type of production regardless of the production volume itself. Taking into account the provisions of flexibility for small producers, there should not be a formal risk analysis. For certain categories of food businesses, it is possible to determine in advance the danger to be controlled.

In this context, the short guidelines for HACCP establishment are given on the site of the agency for food safety, veterinary and phytosanitary affairs.⁵

⁵ Available at: <http://www.vet.uprava.gov.me>

Critical limits for CCPs can be determined based on experience or international documentation for a number of work processes e.g. food preservation, pasteurization of liquid food, etc., for which there are internationally-recognized standards. Critical limits can also be specified in the guidelines of good manufacturing practices as specified in this document.

Regardless of traditional production methods and derogations, all operators in the food chain are responsible for ensuring the production of safe products without exception.

DAILY TEMPERATURE MONITORING LOG
(Manual records)

MONTH _____

DATE	CHILLER ROOM No ... (5°C or below)		CHILLER ROOM No ... (5°C or below)		REFRIGERATOR (7°C or below)		FREEZER (-15°C to -18°C)		NOTE (e.g. corrective action)	Initials
	Time/Temp	Time/Temp	Time/Temp	Time/Temp	Time/Temp	Time/Temp	Time/Temp	Time/Temp		
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										
17										
18										
19										
20										
21										
22										
23										
24										
25										
26										
27										
28										
29										

SANITATION PLAN

FBO name

Period:

Cleaning/Sanitatio site (premises/equipment)	Frequency	Procedure	Chemical (name)	Working concentration	Contact time	Equipment and devices	Responsible operator and supervisor	Note

RECORDING OF CLEANING AND DISINFECTION CHEMICALS

Chemical compound (Commercial name)	Date of receipt	Supplier (name and phone)	Description (type of chemical, purpose)	Precautions

ELEMENTS AND EXAMPLE OF SSOP FOR CLEANING AND SANITATION OF EQUIPMENT

List of elements that should be included in an SSOP:

- FBO's name;
- Date (effective date or most recent update);
- SSOP number (optional, SSOP number may be combined with the and version) - example: SSOP No 5, version 3; or SSOP: 5-03;
- Procedure/Programme title;
- Scope (what is covered);
- Frequency (how often should be done);
- Procedure: Step-by-step instructions (use a logical/needed order) and add notes as needed for clarification; always specify: chemicals type/brand name), chemical concentration, temperature and time (break into sections for multiple tasks);
- Recordkeeping: identify which forms or logs are used and the way of writing/filing (each important/critical data should be written for effective implementation of SSOP, e.g date and time, concentration and temperature, application site/area);
- Person responsible for the SSOP content and updates. Include signature and date lines;
- Page numbers.

Example SSOP

FBO's name:.....

Number of SSOP: **5-03**

Date issued/Updated: (dd/mm/yy)

Procedure name: **Cleaning and sanitizing of equipment for cutting, salting/curing and processing of meat**

Scope: **Tables, plastic boards, utensils, containers/vats, grinder, mixer, filling device**

Cleaning and sanitizing schedule

Equipment for cutting, salting/curing and meat processing is cleaned at the end of each processing day and sanitized immediately prior to use.

Manual Cleaning (in a sink):

1. Dismantle equipment to be cleaned and rinse parts with warm water (usually around 45 0C).
2. Make cleaning and sanitizing solutions according to manufacturers instructions.
Note: wear appropriate personal protection equipment (gloves, eye protection)
3. Wash all surfaces and parts using a clean brush.
4. Rinse thoroughly with warm water to remove all dirties and cleaner residues.
5. Visually inspect parts for damages, dirties and residual cleaner.
6. Rinse all surfaces and parts with sanitizer solution.

Manual sanitizing

1. Fill appropriate container with 10 liters of room temperature water.
2. Add 1 package/dose of sanitizer (name),(Name of producer) to the bucket and stir to dissolve.
3. Sanitize equipment using a clean brush, making sure to sanitize all surfaces and parts.

Recordkeeping:

Manual cleaning of tables, utensils, containers and dismantled parts is recorded daily in Form – Cleaning and sanitation diary

REFERENCES

- 1) Law on food safety ("Official Gazette of Montenegro", No. 57/2015);
- 2) Regulation on food hygiene ("Official Gazette of Montenegro", No. 13/2016);
- 3) Regulation on specific hygiene requirements for food of animal origin ("Official Gazette of Montenegro", No. 32/2016);
- 4) Regulation on conditions for the derogation in respect of the construction, layout and equipment of establishments with small volume of production, processing and treatment of food ("Official Gazette of Montenegro", No. 21/2016);
- 5) Regulation on microbiological criteria for food safety ("Official Gazette of Montenegro", No. 26/2016);
- 6) Rulebook on method of registration and keeping of central register of registered and approved establishments for production, processing and distribution of food (Official Gazette of Montenegro", No. 25/2016);
- 7) European Commission - Guidance document on the implementation of certain provisions of Regulation (EC) No 852/2004 on the hygiene of foodstuffs;
- 8) European Commission - Guidance document on the implementation of certain provisions of Regulation (EC) No 853/2004 on the hygiene of food of animal origin;
- 9) European Commission - Guidance document on the implementation of procedures based on the HACCP principles, and on the facilitation of the implementation of the HACCP principles in certain food businesses;
- 10) Commission Staff Working Document on the understanding of certain provisions on flexibility provided in the Hygiene Package - Frequently Asked Questions - Guidelines for food business operators;
- 11) Commission Staff Working Document on the understanding of certain provisions on flexibility provided in the Hygiene Package - Frequently Asked Questions - Guidelines for the competent authorities;
- 12) Regulation (EC) No 2074/2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 and for the organisation of official controls under Regulation (EC) No 854/2004 and of the Regulation (EC) No 882/2004, derogating from Regulation (EC) No 852/2004 and amending Regulations (EC) No 853/2004 and (EC) No 854/2004;
- 13) Food Standards Agency (FSA) – Meat Industry Guide, 2009;
- 14) Food Standards Agency (FSA) - Small and low throughput establishments: examples of EU hygiene regulations flexibilities;
- 15) Austrian Food Manual, IV edition, Chapter A2 / Hygiene - Guideline for good hygiene practice and application the principles of HACCP at slaughter and cutting of cattle, pigs, sheep, goats and equines as well as in the production of meat products, BMG-75210/0002-II/B/13/2014.

CIP - Каталогизација у публикацији
Национална библиотека Црне Горе, Цетиње

ISBN 978-86-85799-20-4
COBISS.CG-ID 34499344

