



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs  
Single Market Enforcement  
Notification of Regulatory Barriers

Message 201

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Forwarding of the response of the Member State notifying a draft (Croatia) to request for supplementary information (INFOSUP) of European Commission.

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4. 2024/0604/HR - C50A - Foodstuffs

5.

6. In the Republic of Croatia a total of 1360 establishments have been entered in the Register of Approved Establishments Operating with Food of Animal Origin. Out of the total number of establishments, 452 are small capacity establishments, approved under the implementation of the Ordinance on measures for the adaptation to the requirements of the regulations concerning food of animal origin notified by the EC under the notification numbers: 2014/454/HR and 2018/322/HR.

The need to adopt the regulations on adaptation measures arose from the fact that in the Republic of Croatia we have a large number of small-capacity production establishments that produce food intended mainly for the local and national market and that have only a few employees (mainly 1-3). Given that production is very small, in order to operate and be profitable, they are granted to apply derogations when constructing establishments and forming infrastructure, in accordance with the provisions of Article 13(4)(a) and (b) of Regulation (EC) No 852/2004 and Article 10(4)(a) and (b) of Regulation (EC) No 853/2004, provided that food safety is not compromised.

Adaptation of requirements in approved establishments located in regions subject to special geographical constraints Under the provisions of Article 13(4)(a)(ii) of Regulation (EC) No 852/2004 and Article 10(4)(a)(ii) of Regulation (EC) No 853/2004, the Republic of Croatia has laid down national provisions for milk processing establishments located in regions subject to special geographical constraints. Special geographical constraints refers to islands not connected by a bridge to the mainland of the Republic of Croatia and mountainous areas defined by a special regulation on mountainous areas (located at an altitude above 1 000 meters). Only cheeses with a maturation period of more than 60 days may be produced in such establishments.



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Conditions to be met by the raw material for production (raw milk):

— if the control of raw milk for somatic cells and the total number of microorganisms cannot be ensured or if the milk does not meet the requirements set out in Annex III, Section IX, Chapter I, Item 3 of Regulation (EC) No 853/2004 as regards somatic cells and the total number of micro-organisms, products may be placed on the market for public consumption if the milk:

1. has no visible changes, and
2. was previously subjected to a mastitis test which did not yield a positive result;

Conditions to be met by establishments:

— in relation to the provisions of Annex II, Chapter I of Regulation (EC) No 852/2004, the following conditions must be ensured in a milk processing establishment:

1. one washbasin that may be used for washing food, equipment and hands, provided that precautions have been taken to prevent food contamination;
2. food is not directly or indirectly exposed to waste water;

— in relation to the provisions of Annex II, Chapter VII, Item 1 of Regulation (EC) No 852/2004, a sufficient quantity of water must be provided in the milk processing establishment that shall be tested to meet the requirements in accordance with the regulation governing water for human consumption at the lowest frequency.

The production of hard cheeses with a maturation period of more than 60 days reduces the risk to human health arising from the use of raw milk that does not meet the prescribed criteria (micro-organisms, somatic cells), and the above provisions of Regulation (EC) No 853/2004 refer to this type of milk processing as an effective option for exploiting non-compliant milk. In addition, the quantity of non-compliant milk compared to the total quantity of milk produced in the Republic of Croatia is less than 1 %. Although this provision has been in force since 2015 (and has been notified through the TRIS procedure), to this day no establishment has been approved in the Republic of Croatia with the application of these provisions.

Production of food of animal origin with traditional characteristics

In accordance with the provisions of Article 13(4)(a)(i) of Regulation (EC) No 852/2004 and Article 10(4)(a)(i) of Regulation (EC) No 853/2004, the Republic of Croatia has laid down national provisions under which the production of food of animal origin with traditional characteristics is permitted. Such production shall be permitted only if it is established that the production does not jeopardise the public health interest and that compliance with food hygiene requirements is not compromised.

The production of food of animal origin with traditional characteristics shall be permitted in establishments constructed from natural materials necessary for obtaining a specific characteristic of the product, and/or with the adaptation of cleaning and disinfection measures in establishments, taking into account the natural conditions of production (specific ambient flora) and using equipment and tools, at all stages of production and packaging, which are made from natural materials that are necessary for obtaining the traditional characteristic of the product.

In order to authorise the production of food of animal origin with traditional characteristics, the food business operator must submit an application to the competent authority, which shall include the following, in accordance with the requirements of Article 7 of Regulation (EC) No 2074/2005:

- name of the product;
- geographic origin;
- description of the product, of the technological production process, and of the storage and maturation conditions;
- materials, equipment and instruments used for the production of the product;
- description of the establishment or production premises, and of the storage and maturation conditions;
- history and traditional aspects of the product and/or production;
- any other information that the food business operator considers important.

The competent authority shall assess the application of the food business operator and the information provided and, in the case of a positive assessment, the competent authority shall enter the name of the product in the national list of products with traditional characteristics of the Republic of Croatia.

The competent authority shall keep and update a list of national traditional products drawn up in accordance with the provisions of this Ordinance and shall inform the European Commission and the Member States of adaptation measures, products and establishments producing such products.

The competent authority of the Republic of Croatia has established a committee for the assessment of documentation for



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the approval of the production of food of animal origin with traditional characteristics, but to date, no approved establishment in the territory of the Republic of Croatia has submitted an application for the approval of the production of food of animal origin with traditional characteristics.

Consequently, the Republic of Croatia still does not have a list of national traditional products that have been approved in accordance with the provisions of the Ordinance on measures for adaptation to the requirements of regulation concerning food of animal origin, therefore, and within the meaning of Article 7 of Regulation (EU) No 2074/2005, the competent authority of the Republic of Croatia has not notified the European Commission and the Member States of adaptation measures, products, and establishments for the production of such products.

### Small-capacity slaughterhouses

The slaughter capacity of ungulates, equines, poultry, lagomorphs and farmed game, and game processing capacity of establishments shall be based on, or comply with, the capacities referred to in Article 13(3) of Regulation (EU) 2019/627. Small-capacity slaughterhouse for ungulates, equines, and farmed game means an establishment for the slaughter of ungulates, equines, and farmed game with a slaughter capacity not exceeding 20 livestock units per week, and a total slaughter capacity not exceeding 1 000 livestock units per year. In order to determine the number of animals constituting one livestock unit, the provisions laid down in Article 17(6) of Regulation (EC) No 1099/2009 were used, and the table of coefficients and species/categories of animals was defined in the draft Ordinance. In addition, it is nationally determined that an adult bovine animal means an animal of 300 kg or more.

A small-capacity slaughterhouse for poultry and lagomorphs means an establishment for slaughtering poultry and lagomorphs with a slaughter capacity not exceeding 12 500 animal units per month, calculated as follows: chickens, hens, and farmed feathered game represent one unit, ducks represent two units, turkeys, geese, and lagomorphs represent three units, and other poultry represent one unit.

An establishment with a small processing capacity of small wild game means an establishment for the processing of small wild game with a processing capacity not exceeding 12 500 units of animals per month, calculated as follows: wild feathered game represents one unit and lagomorphs represent three units.

Small-capacity establishment for the processing of large wild game means an establishment for the processing of wild game with a processing capacity not exceeding 20 livestock units per week and a total processing capacity not exceeding 1 000 livestock units per year.

The provisions of Article 13(4)(b) of Regulation (EC) No 852/2004 and Article 10(4)(b) of Regulation (EC) No 853/2004 prescribe national adaptations for establishments with a small slaughter capacity of ungulates, equidae, farmed game, poultry, lagomorphs, and game processing relating to the construction, layout, and equipment of establishments, which may be applied provided that the public health interest is not jeopardised and that compliance with food hygiene requirements is not compromised.

The conditions to be met by small-capacity establishments for slaughter of ungulates, equidae, farmed game, poultry, lagomorphs, and game processing shall comply with the requirements of Annex II to Regulation (EC) No 852/2004 and, as applicable, Annex III to Regulation (EC) No 853/2004, with the exception of the following:

- a single changing room for staff employed in the so-called clean and unclean parts of the establishment may be used provided that they have no more than 5 employees in the production area of the establishment;
- if no room is provided for the authorised person, an adequate changing area in the changing room for employees and an adequate space within the slaughterhouse establishment with a desk, chair and locker, which can be locked, must be provided for the authorised person's needs;
- facilities for the reception and temporary storage of animals for slaughter referred to in Annex III, Section I, Chapter II, Item 1(a) and Annex III, Section II, Chapter II, Item 1 of Regulation (EC) No 853/2004 do not need to be provided if the slaughter of animals takes place immediately after their arrival at the establishment, without prejudice to the provisions of animal welfare legislation;
- it is not necessary to provide a separate space for diseased animals and suspected diseased animals if an appropriate written slaughter procedure is applied that describes the handling of diseased animals and suspected diseased animals without prejudice to food hygiene and safety;
- it is not necessary to provide a separate area with adequate equipment for cleaning, washing and disinfecting the means of animal transport referred to in Annex III, Section I, Chapter II, Item 6 and Annex III, Section II, Chapter II, Item 6 of Regulation (EC) No 853/2004 in slaughterhouses if there are officially approved places for cleaning, washing and disinfecting the means of animal transport within a distance of no more than 20 km;
- emptying and cleaning of stomachs and intestines may be carried out in the area for slaughtering animals and/or



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cutting meat after slaughter when there are no more carcasses/meat of slaughtered animals in the area; furthermore, the area for slaughtering and/or cutting must be thoroughly washed and, if necessary, disinfected before each use;

- cutting meat in premises where slaughtering and dressing is carried out is allowed provided that the slaughtering and dressing operations are separated by time and that thorough cleaning and disinfecting has been carried out after slaughtering and before cutting; in this case the cutting capacity must not exceed 250 tonnes of meat per year;
- in small slaughterhouses for poultry and lagomorphs, the evisceration and further processing of poultry and lagomorph carcasses may be carried out in the same room as the scalding and plucking, provided that the evisceration and plucking are sufficiently distanced one from another and appropriately physically separated in order to avoid food contamination;
- in small slaughterhouses for poultry and lagomorphs, the competent veterinary inspector may at the request of the food business operator, in individual cases, allow that the evisceration and further processing of poultry and lagomorph carcasses is carried out in the same area where the scalding and plucking of poultry is carried out, provided that the scalding and plucking are separated by time and that the premises are thoroughly washed and disinfected between these procedures;

- detained and healthy carcasses/meat may be stored in the refrigeration room/chamber provided that the following conditions are met: the space provided for the detained carcasses/meat is clearly marked and lockable; the reason for detaining is not suspicion of an infectious disease; the contamination of other meat is prevented.

In addition, in small slaughterhouses for ungulates, equines and farmed game in which the animals that originate from or have been reared in the Republic of Croatia for more than three months are slaughtered, the slaughtering shall be carried out no later than 21 days from the delivery of the animals, provided that they did not leave the rooms for the reception and temporary accommodation of animals in the slaughterhouse during this period and that the welfare and health of the animals were not jeopardised. Taking into account the current epidemiological situation in the Republic of Croatia, the occurrence of African swine fever and the possible occurrence of other diseases of the listed susceptible animal species, in order to reduce the risk, a national restriction of this provision is laid down. It provides that if animals intended for slaughter originate from protection and surveillance zones, and zones of infection established in accordance with the regulations governing the protection of animal health, the animals must be slaughtered without delay, at the latest within 72 hours of arrival at the slaughterhouse.

### Mobile slaughterhouses

Mobile slaughterhouses may carry out approved activities if they meet the conditions referred to in the proposed Article 12 of the notified draft Ordinance and if the conditions laid down in the regulations governing food hygiene and animal welfare are met.

The conditions to be met by mobile slaughterhouses shall comply with the requirements of Annex II to Regulation (EC) No 852/2004 and, as applicable, Annex III to Regulation (EC) No 853/2004. A mobile slaughterhouse must be constructed in such a way that the following operations can be carried out within the establishment: restraining, stunning and slaughtering of animals, skinning, hair or feather removal, processing of carcasses and organs, post-mortem inspection of carcasses and organs, cooling of carcasses, and it must have a separate changing and sanitary area for employees.

In view of the adaptation measures provided for the construction, layout, and equipment of the mobile slaughterhouse establishment, and in accordance with Article 13(4)(b) of Regulation (EC) 852/2004 and Article 10(4)(b) of Regulation (EC) 853/2004, the mobile slaughterhouse is not required to have:

- facilities for the reception and temporary storage of animals for slaughter as laid down in Annex III, Section I, Chapter II, Item 1(a) of Regulation (EC) No 853/2004,

- room for an authorised person. The health stamps shall be kept in the lockable section of the mobile slaughterhouse and, after marking the carcasses, the competent authorised person shall return them to the designated section and ensure that only authorised persons have access to the stamps. The next slaughter may be carried out only if the seal previously affixed to the section for storing stamps is not damaged.

Although this provision has been in force since 2015 (and has been notified through the TRIS procedure), to this day no establishment has been approved in the Republic of Croatia with the application of these provisions.

### Cutting of domestic pigs older than 5 weeks in the slaughterhouse

Pursuant to Article 15(3) of Commission Implementing Regulation (EU) 2019/627, and taking into account national eating habits (spit-roasting of piglets), a national provision was provided under which the cutting of domestic pigs older than 5 weeks in a slaughterhouse before delivery is not mandatory if the results of ante-mortem and post-mortem inspection are satisfactory and the pigs are not older than 4 months.

Cutting of bovine carcasses not older than 12 months



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Pursuant to Article 15(3) of Commission Implementing Regulation (EU) 2019/627, and taking into account national eating habits (roasting of oxen on a spit on special, rare occasions such as Christmas and Easter), a national provision was provided under which it is not mandatory to cut the carcass of bovine animals into half carcasses if the bovine animal is not older than 12 months. Permission not to cut a bovine carcass shall be granted by a person authorised for ante-mortem and post-mortem inspection only at the request of the food business operator with appropriate justification and only for a specific occasion. However, if the inspection of the carcasses raises suspicion of the presence of a possible hazard, a post-mortem inspection shall be carried out in accordance with the provisions of Article 12 of Commission Implementing Regulation (EU) 2019/627.

### Adaptation of requirements for other small-capacity establishments

Pursuant to the provisions of Article 13(4)(b) of Regulation (EC) No 852/2004 and Article 10(4)(b) of Regulation (EC) No 853/2004 national adaptations are prescribed for all establishments with a small slaughter capacity relating to the construction, layout, and equipment of establishments, which may be applied provided that the public health interest is not jeopardised and that compliance with food hygiene requirements is not compromised. The establishments subject to adaptations in question shall have a maximum production capacity per unit of time which shall not be exceeded.

Establishments that may use national adaptations are:

- small-capacity establishments for cutting meat of ungulates, equidae, poultry, lagomorphs, game, and/or farmed game – capacity of 5 000 kilograms per week;
- small-capacity establishments for the production of minced meat, meat preparations, and mechanically separated meat – capacity of 5 000 kilograms per week;
- small-capacity storage establishment for fresh fishery products – an establishment for storing up to 5 000 kilograms of fresh fishery products per week;
- small-capacity establishment for processing meat and/or fishery products – an establishment for processing meat or fishery products with a raw material input that does not exceed 5 000 kilograms of meat or fishery products per week;
- small-capacity establishment for processing milk – a milk processing establishment with a raw material input that does not exceed 10 000 litres of milk per day;
- small-capacity milk collection centre – an establishment that collects milk from two or more producers under a system of buying-in from one establishment approved for milk processing;
- small-capacity egg packing centre and small-capacity egg processing establishment – an egg packing establishment where up to 3 000 000 eggs are packed per year;
- small-capacity establishment for processing snails and frogs – an establishment processing up to 10 000 kilograms of snails or frogs per year;
- small-capacity establishment for the production of rendered animal fats and greaves – an establishment producing rendered animal fat and greaves with a raw material input that does not exceed 5 000 kilograms per week.

In order to further ensure that such establishments are indeed of small capacity, a further restriction is laid down under which in establishments with multiple activities referred to in Article 4(1)(2), points 5, 6, 8, 9, 10, 11 and 15 of the notified draft Ordinance, the total amount of raw material input must not exceed 5,000 kilograms per week.

The conditions to be met by small capacity establishments in respect of the activity they carry out shall comply with the requirements of Annex II to Regulation (EC) No 852/2004 and, as applicable, Annex III to Regulation (EC) No 853/2004, with the exception of the following:

- carry out different technological production stages and/or production of different products in the same room provided that the production stages are separated by time and that the room is appropriately cleaned and, if necessary, washed and disinfected between the individual stages;
- storage of raw materials, finished products and detained products may be carried out in the same room with adequate spatial separation, in such a way as to prevent possible contamination and provided that the finished and detained products are prepackaged, closed and clearly labelled;
- changing and sanitary areas for workers, storage space for packaging, and space for cleaning and disinfection of the establishment may be located separately from the working area if they are within the premises of the establishment, provided that workers have a separate entrance to the establishment with an anteroom where it is possible to carry out disinfection of footwear and hygienic hand washing;
- entry/exit for workers must be separated from entry/exit for raw materials, finished products, and non-compliant products;
- use the same entrance/exit for raw materials, finished products and non-compliant products if they are separated by



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time;

- in establishments located on the same grounds as a private residential building, use a private area located on the establishment grounds as changing and sanitary areas;
- milk collection centres with a total daily working time of up to three hours are not required to have sanitary areas for workers on the premises, but such areas must be available to them.

In the period since the application of the notified Ordinance (notification numbers: 2014/454/HR and 2018/322/HR), the majority of approved small-capacity establishments were approved in accordance with the above-mentioned national provisions. All of the permissible derogations relating to the construction, layout and equipment of establishments must be substantiated by the food business operator through appropriate written procedures, which are part of the self-control system and ensure compliance with the hygiene requirements of food regulations and the production of safe food in the establishment.

Adaptation of requirements for small capacity dispatch centres for live bivalve molluscs situated on the coast and small capacity purification centres for live bivalve molluscs

Establishments that may use national adaptations are:

- small capacity dispatch centres for live bivalve molluscs situated on the coast – an establishment for the dispatch of live bivalve molluscs with a dispatch capacity of up to 5,000 kilograms of live bivalve molluscs per week;
- small-capacity centres for the purification of live bivalve molluscs, an establishment in which up to 5,000 kilograms of live bivalve molluscs are purified per week.

The conditions to be met by small capacity dispatch centres for live bivalve molluscs on the coast and small capacity purification centres for live bivalve molluscs shall comply with the requirements of Annex II to Regulation (EC)

No 852/2004 and, as applicable, Annex III to Regulation (EC) No 853/2004, with the exception of the following:

- changing and sanitary areas for workers, storage facilities for packaging, and facilities for cleaning and disinfection of the establishment may be located away from the work area if they are within the perimeter of the establishment, provided that workers have access to the establishment where it is possible to carry out disinfection of footwear and hygienic hand washing;
- in establishments located on the same grounds as a private residential building, a private area located on the establishment grounds may be used as changing and sanitary areas provided that workers have access to the establishment where it is possible to carry out disinfection of footwear and hygienic hand washing.

Small-capacity dispatch centres for live bivalve molluscs situated on board vessels

Small-capacity dispatch centre for live bivalve molluscs situated on board vessels – a watercraft intended for the dispatch of live bivalve molluscs from a farm of the same food business operator or a monitored production area for which the operator is authorised to harvest, with a capacity of up to 1 000 kilograms of live bivalve molluscs per day.

The conditions to be met by small capacity dispatch centres for live bivalve molluscs on board vessels shall comply with the requirements of Annex II to Regulation (EC) No 852/2004 and, as applicable, Annex III to Regulation (EC) No 853/2004, with the exception of the following:

- solid walls and windows do not need to be provided, on the condition that live bivalve molluscs are protected from pests and air contamination during operations;
- appropriate areas/devices for personal hygiene (including hygienic hand washing, sanitary facilities, and changing rooms for staff) shall be provided;
- cleaning, washing and disinfection equipment may be stored in an area where live bivalve molluscs are handled, provided that adequate separation is ensured in such a way as to prevent contamination.

In conclusion, it should be noted that throughout all these years, from 2015 until today, i.e. since the existing Ordinance on measures for the adaptation to the requirements of regulations concerning food of animal origin (notified by the EC under the notification numbers: 2014/454/HR and 2018/322/HR) has been in force, no significant incident involving food of animal origin produced in small-capacity establishments was directly linked to the adaptation measures provided for the requirements of food regulations, which confirms that the legislative framework and on-site control measures have ensured that the adaptation to the requirements of the regulations in question did not jeopardise the achievement of the objectives of those regulations.

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