

GUIDELINES ON FLEXIBILITY RULES WITHIN THE IMPLEMENTATION OF THE HYGIENE PACKAGE



Funded by
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**EU FOOD SAFETY
AB GIDA GÜVENLİĞİ**

Turkish Cypriot Community Food Safety Project

Funded under the EU Aid Program for the Turkish Cypriot community (TCc), the “TCc Food Safety Project” executed under the contract 2021/423-933 “Technical assistance to improve implementation of food safety standards and disease crisis preparedness”, strives to support faster social and institutional development of the Turkish Cypriot community and higher economic growth of its agri-food chain sector. The aim is to achieve improved food safety, public health, animal health, and protection of the environment, and to mitigate the impact of potential exotic animal diseases, in particular those posing imminent threats. The project started in May 2021 and will be completed in April 2024.

For more information about the project, you can visit the project’s website, and follow its social media account and contact the project team through the following communication channels:

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1. BACKGROUND

The “TCc Food Safety Project” executed under Contract 2021/423-933 “Technical assistance to improve implementation of food safety standards and disease crisis preparedness” strives to support a faster social and institutional development of the Turkish Cypriot community (TCc) and a higher economic growth of its agri-food chain sector.

The project aims to achieve improved food safety, public health, animal health and protection of the environment, and to mitigate the impact of an imminent threat of potential exotic animal diseases.

This document was produced within the following project activity:

Prepare guidelines for stakeholders to complement the input delivered in specific trainings, workshops, and other capacity building activities.

The reform of the European Regulations on food hygiene, which came into force on 1 January 2006, simplified and harmonised the legislation applicable in the European Union. This set of regulations, known as the “Hygiene Package”, concerns the entire food chain from primary production (both animal and plant) to the consumer and including the food industry, catering, trade, transport and distribution (“from farm to fork”). Its aim was to harmonise the level of food safety by involving all stakeholders in the food chain, subjecting them to the same requirements, by formalising the responsibility of the professionals, and by optimising the controls of the authorities.

The “Hygiene Package” consists of the following parts:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin
- Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (Repealed by Regulation (EU) 2017/625 (the Official Control Regulation) on 14 December 2019).

The Hygiene Regulations above allow the competent authorities to take national measures to provide flexibility in relation to structure, layout, equipment, operational practices, food business operators (FBO)’s obligations and their controls.

The hygiene rules include flexibility for certain establishments e.g. micro-enterprises. In particular, these flexibility provisions have been tailored to facilitate the trade of foods produced at a local level and/or by traditional methods.

Further explanation and guidance are needed for better understanding and use of these provisions of the Hygiene Regulations.

2. INTENDED AUDIENCE

The intended audience of these guidelines are small-scale food business operators who should continue operating without being negatively affected by the provisions of the Food Hygiene Package and, at the same time, ensure the rights of the consumers to safe food, as well as the local bodies.

3. AIM OF THE GUIDELINES

These guidelines aim to provide information on the diverse possibilities to adapt the technical requirements of the Food Hygiene Package in function of the nature of the food businesses concerned.

It should be stressed that the flexibility of the Hygiene Regulations covers only rules under the Hygiene Regulations and not the other relevant legal texts like animal health requirements, residue controls and labelling. The local Turkish Cypriot community (TCc) legal texts regarding “Hygiene Package” requirements have just been approved and are on a very early stage of implementation, so maybe these guidelines for flexibility rules in the application of hygiene package during production and marketing of any kind of food are premature. However, this document will be a useful tool for both FBOs especially Small and Medium Sized Enterprises (SMEs) and local bodies.

For the purpose of this document, instead of “Hygiene Package”, “hygiene of foodstuffs and specific hygiene of food of animal origin rules” will be used.

This document has been prepared taking into account the good international practice, EU Regulations 852/2004, 853/2004 and the draft of the local legal texts that are expected to be approved.

The guidelines are also available to the public on the project’s Online Food Safety Platform <http://tccfoodsafetyproject.eu/>.

4. INTRODUCTION

In order to protect food diversity and serve consumers and the needs of small-scale producers, the legal texts regarding hygiene of foodstuffs and the specific hygiene of food of animal origin rules provide enough possibilities to adapt the technical requirements regarding food hygiene depending on the nature of the food business concerned. Flexibility provisions concern:

- implementation of procedures based on hazard analysis and critical control point (HACCP)
- traditional food products
- continued use of traditional methods
- food businesses situated in regions that are subject to special geographic constraints
- small businesses
- implementation of regulation (EU) 2073/2005
- ‘official’ control

The HACCP system should be implemented for the control of hazards in food businesses carrying out operations that may pose a danger to food safety. However, in traditional products where it is not possible to implement the HACCP system, and in small and medium-sized enterprises (SMEs) where it is not possible to define the critical control points, some flexibility may be applied in the implementation of the hygiene of foodstuffs and specific hygiene of food of animal origin rules, and 'official' controls.

Of course, although some flexibility is applied, it is necessary to comply with the minimum technical and hygienic conditions specified in the local legal texts on production and marketing of the specified foods.

Therefore, in these enterprises it is possible to apply the prerequisite programs within the scope of the Good Manufacturing Practices (GMP) rather than implement the system based on HACCP principles. The prerequisites for good hygiene practices are actually the implementation of food hygiene requirements which are listed below:

1. Infrastructure and equipment requirements
2. Requirements for raw material
3. Safe handling of food (including packaging and transport)
4. Food waste management
5. Pest control procedures
6. Sanitation procedures (cleaning and disinfection)
7. Water quality
8. Maintaining the cold chain
9. Health status of employees
10. Personnel hygiene
11. Education
12. Ensuring traceability
13. Withdrawing and recalling the food from the market and informing the local bodies.

Flexibility can be applied in some of the above points according to the type of enterprise, capacity of the production, process applied to food and type of the food.

5. FLEXIBILITY PROVISIONS

Small and Medium Size Enterprises (SMEs) have an important place in the food sector, especially in rural areas.

Many SMEs in the food sector are family businesses. They have close ties with their customers and prioritize quality of the product. In the EU Regulations, there are provisions for the flexible implementation of the requirements for SMEs and the good practice could be used and adopted for the local small business, as well. However, in order to implement this flexibility, the objectives of the legal texts must be fully met and therefore food safety must not be compromised.

Flexibility provisions contained in the rules on the hygiene of foodstuffs and the specific hygiene rules for food of animal origin hygiene offer the following possibilities:

- to grant:
 - derogations/exemptions from certain requirements
 - adaptations of certain requirements

- to exclude certain activities from the scope

When making use of flexibility provisions, local bodies should generally adopt national measures.

The leading principles for implementing flexibility provisions are subsidiarity and transparency.

Some examples to national measures for foods with traditional characteristics are listed below.

MEMBER STATE	PRODUCT	DEROGATION
Spain	Cheese, sausages, bakery prod., olive oil, alcoholic drinks	infrastructure, equipment
Poland	List of products	infrastructure, equipment
Germany	Sausages, eintöpfe, fruchtaufstriche, milk prod., etc.	infrastructure, equipment

5.1 DEROGATIONS/EXEMPTIONS

Derogations/Exemptions mean that the local bodies authorize food business operators not to apply specific requirements of the hygiene of foodstuffs and specific hygiene for food of animal origin rules in certain situations which are specified in advance.

The situations in which derogations for certain cases can be adopted should be exhaustively defined in the relevant legal texts.

5.2. ADAPTATIONS

Adaptations give the possibility to the local bodies to adapt the requirements specified in the hygiene of foodstuffs and the specific hygiene for food of animal origin rules in certain situations.

Local bodies may adopt national measures in order to adapt the requirements laid down in the legal texts. The main purpose of those national measures is limited to the following:

- To enable the continued use of traditional methods of production

Examples:

- Traditional dried reindeer meat in Finland and Sweden.
 - local sale (“near food”)
 - without veterinary supervision (Finland)
 - only in Lapland (Sami people)
 - sale directly to consumers
 - 200.000 kg of meat/year
 - national stamp (Finland) or 3 villages (Sweden)
- Raw-dried meat products from minced and non-minced meat in Bulgaria.
- Immediate evisceration of poultry in France.

- To accommodate the needs of food businesses situated in regions that are subject to special geographic constraints

Examples:

- Washbasins with hot and cold running water on farms producing cheese in mountain areas in Germany.
- Facilities for washing foodstuffs separately from washbasins on farms producing cheese in mountain areas in Germany.

- To adapt requirements on the construction, layout, and equipment of establishments

Example:

- Special facilities for cutting of meat in food businesses with slaughterhouses of low (specified) capacity in Czechia
- Slaughter on farm in Luxembourg
 - slaughter on the farm
 - 30 well-equipped farms
 - slaughter of 1200 pigs/year
 - slaughter of 4500 piglets/year
 - slaughter of 250 calves/year
- National measures taken for small slaughterhouses in Austria and Slovenia
 - lairage facilities or waiting pens
 - cleaning & disinfection of transport vehicles
 - slaughter room and cutting room
 - storage of detained meat
 - minced meat at 4°C (national market in Austria)

5.3 EXCLUSIONS

These include:

- Primary production for private domestic use
- Domestic preparation, handling or storage of food for private domestic consumption
- Direct supply, by the primary producer, of small quantities of primary products to the final consumer or to the local retail establishment directly supplying the final consumer (e.g. raw milk, eggs, honey, fruit, vegetables, wild game).

5.3.1. Small Quantities of Products Other Than Primary Products

- Direct supply, by the farmer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer.
- Hunters who supply small quantities of wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer.

The term “small quantity” varies from country to country and is subjective. The criteria for this term need to be defined by the local bodies.

5.3.2. Retail

- Retail establishments directly supplying food of animal origin to the final consumer (e.g. butcher shops, supermarkets, production of cheese at the farm etc) do not need to be approved.
- When operations are carried out with a view to supplying another retail establishment (e.g. a butcher shop delivering meat to a restaurant or to a school canteen), retail establishments need to be approved.
- When supplying another retail establishment but this activity is recognised as “marginal, localised and restricted”, retail establishments benefiting from this provision do not need to be approved.

“Localised” means that food is destined for the local market only and that the supplied establishment should be in the immediate vicinity.

“Marginal activity” refers to cases where the supply of food is only a small part of the supplying establishment’s business, or such activity is the main trade activity of the establishment’s business, but it represents a small amount of food in absolute terms.

“Restricted” is the supply concerning only certain types of products or establishments.

MEMBER STATE	MARGINAL	LOCALISED	RESTRICTED
Austria	< 5 tons/week; 250 tons/year	county	%25
Ireland	< 1000 kg	100 km	RTE, mincemeat, < 25%
Belgium	< 800 kg	80 km	< 30%
Sweden	< 150 tons meat; 100 tons milk	county	< 50%
Denmark	< 3000 kg deboned meat	region	

6. IMPLEMENTATION OF FLEXIBILITY PROVISIONS

Implementation of flexibility provisions:

- Food business operators implement the legal requirements.
- Local bodies are responsible for providing flexibility (if any) to food business operators and local bodies should verify its implementation.

7. FLEXIBILITY FOR MICROBIOLOGICAL CRITERIA AND IMPLEMENTATION OF HACCP

All food business operators shall implement a “permanent procedure based on the HACCP principles”. However, flexibility can be applied for small food businesses:

- Operators can choose frequency and method of testing based on the risk and in the context of HACCP.
- For small establishments sampling frequency can be reduced.

In this context, HACCP may not be applied for market stalls, mobile sale vehicles, bars, coffee shops, small retail shops, storage, transport (pre-packed foods). However, these establishments should comply with the general hygiene requirements.

8. FLEXIBILITY ON THE BASIS OF FOODS

8.1 .TRADITIONAL FOODS

Traditional foodstuffs are recognised as a valuable and irreplaceable heritage of any country. For this reason, the hygiene requirements should provide flexibility especially for the production of this type of products, provided that the product is safe.

Foods with traditional characteristics are:

- recognised historically as traditional products, or
- manufactured according to registered technical references to the traditional process, or according to traditional production methods, or
- protected as traditional food products by EU, national, regional or local legal texts.

With regard to the foods with traditional characteristics protected by the EU law, traditional specialities guaranteed (TSGs) registered under Regulation (EC) No 509/2006 and protected designations of origin (PDOs) and protected geographical indications (PGIs) produced in a traditional way under Regulation (EC) No 510/2006 might qualify for the derogations.

For this type of food the legal rules enable local bodies to grant derogations from:

- general hygiene requirements on premises where such products are exposed to an environment necessary for the development of their characteristics (in particular walls, ceilings and doors that are not smooth, impervious, non-absorbent or of corrosion-resistant material and natural geological walls, ceilings and floors)
- the cleaning and disinfecting measures for such premises and the frequency with which they are carried out in order to take into account a specific ambient flora
- requirements on materials of which the instruments and the equipment used specifically for the preparation, packaging and wrapping of these products are made. Instruments and equipment must be maintained at all times in a satisfactory state of hygiene and be regularly cleaned and disinfected.

In the case that the product fulfils the requirements mentioned above, the local body can apply flexibility.

8.2. MEAT AND MEAT PRODUCTS

8.2.1. Butcher Shops

Butcher shop has not been defined in the hygiene rules. Therefore, the activities carried out by these type of establishments (registered or approved) should be defined to apply the hygiene rules.

Registration: Establishment must send information on its activities to the local bodies.

Approval: Following request of the establishment, the local bodies must visit and approve before establishment can start operations.

In general, butcher shops that only supply meat or meat products directly to the final consumer (no slaughter of animals), are considered as retail establishments. This type of establishments only need to be registered. Approval of such shops is not required. This should be checked with the local bodies against the national rules.

However, general hygiene requirements including the HACCP based procedures are applicable for butcher shops. It should be noted that especially in small shops the HACCP based procedures may be implemented in a flexible way.

For more information refer to the Guidance document developed in collaboration between all EU Member States and the Commission in order to provide guidance on the flexibility in the implementation of the HACCP based procedures in food businesses depending on the size and activities:

https://food.ec.europa.eu/safety/biological-safety/food-hygiene/guidance-platform_en#ec-guidance

https://www.row-minvws.nl/binaries/row-minvws/documenten/publicatie/2017/11/23/guidance-document-haccp/guidance_doc_haccp_en.pdf

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:2022:355:FULL&from=EN>

In addition, some national guides to good practices have been developed by the food sectors and assessed by the local bodies. These guides may be used on voluntary basis and may serve as a good and practical tool for the implementation of hygiene requirements in food businesses.

In conclusion, for butcher shops flexibility provisions and national measures may be used in order to adapt the requirements on their construction, layout, and equipment.

8.2.2. Slaughtering at the Farm

Only primary production and retail activities do not need to be approved. Slaughter of animals is not a primary production and cannot be considered as retail.

Slaughter activities at the farm must be carried out in accordance with the appropriate general hygiene rules and specific hygiene rules for slaughterhouses. Slaughter facilities on the farm must be approved by the local body.

Whether at the farm or not, slaughter facilities must always be approved by the local body and comply with requirements for slaughterhouses if slaughtering activities are carried out by operators running butcher shops.

However, the local body may use the flexibility provisions and adopt national measures in order to adapt the requirements on the construction, layout and equipment for these establishments.

8.2.3. Small Capacity Slaughterhouse

Small food businesses have not been defined in the hygiene rules and no specific requirements are applicable to them. Food businesses must comply with the rules, and must be approved by the local body, as provided in the hygiene rules.

However, flexibility may be used for this type of establishment such as adaptation of requirements for their construction, layout, and equipment.

8.3. MILK AND DAIRY PRODUCTS

8.3.1. Selling Raw Milk at the Farm and Shop

Milking and storage of milk at the farm is considered to be a primary production and raw milk is considered to be a primary product. Therefore, exclusion from the requirement is possible under certain conditions.

The conditions for the exclusion from the requirements in the case of direct supply of raw milk are:

- Raw milk (not processed) is delivered by the farmer, or
- Raw milk is delivered directly to the final consumer or to the local retail shop, and
- Raw milk is delivered in small quantities.

If raw milk is delivered in small quantities directly to the final consumer or to the local retail establishment directly supplying this milk to the final consumer, such activity is excluded from the general and specific hygiene requirements. No approval is required. In this case, flexibility provided in the hygiene rules can be used for this type of establishment (adaptation of the requirements for construction, layout and equipment).

However, national measures must be adopted for these activities.

In addition, raw milk must, without exception, come from herds of bovine, including buffaloes, ovine and caprine animals that are in accordance with legal requirements officially free of bovine brucellosis, ovine and caprine brucellosis, and bovine tuberculosis.

8.3.2. Cheese Production on Farm

Cheese is the result of processing raw or heat treated milk so cheese is not a primary product, even when made at the farm.

Therefore, cheese production at the farm must in principle comply with the appropriate general and specific requirements on food hygiene and an approval of the establishment is needed.

But when cheese is manufactured and sold entirely at the farm or at a local market (e.g. weekly market, farmers market etc.) directly to final consumers, this activity is covered by the notion of retail. Only general hygiene requirements are therefore applicable and in this case no approval is needed.

Also, flexibility provisions can be used and national measures can be adapted in order to adapt the requirements on the construction, layout and equipment for these establishments. The existence of such national measures should be checked with the local body.

8.4. HONEY

The beekeeping and production of honey is considered to be a primary production and honey is considered to be a primary product. Therefore, there is an exclusion from the hygiene rules under certain conditions. Direct supply of honey is excluded from the scope of the hygiene rules if i) honey is delivered by producer, or ii) honey is delivered directly to the final consumer or to the local retail shop supplying directly the final consumer, and iii) honey is delivered in small quantities.

This means that if honey is manufactured and sold entirely at the farm or at a local market (e.g. weekly market, farmers market etc.), in small quantities directly to final consumers, general and specific hygiene requirements are not applicable and no approval is needed. In that case, national measures must be adopted for these activities.

In case farmer also wants to deliver honey to an establishment where honey is packaged (or mixed with other honey and packaged) and then delivered to retail shops, the rules for direct supply of small quantities of honey are not applicable for this establishment. The general hygiene requirements should be applied.

8.5. FRUIT AND VEGETABLES

8.5.1. Raw Fruit and Vegetables

The harvesting of fruit and vegetables in the forest/wild and transporting them to the local market are considered to be a primary production. Therefore, under certain conditions these types of foods can be excluded from the requirement.

Direct supply of fruit and vegetables, is excluded from the scope of the hygiene rules if fruit and vegetables (not processed) are:

- delivered by the person who harvested them, or
- delivered directly to the final consumer or to the local retail shop, and
- delivered in small quantities.

If primary products are delivered by the producer, in small quantities directly to the final consumer or to the local retail establishment directly supplying these products to the final consumer, such activity is excluded from the general hygiene requirements.

8.5.2. Juice and Jam from Fruits

Production of fruit juice or jam even from the own harvest of a farmer for selling exceeds the level of primary production. The production of fruit juice or jam is to be considered as an activity after primary production and is therefore subject to the appropriate general hygiene requirements.

The local body may, however, use the flexibility provisions and adopt national measures in order to adapt the requirements on the construction, layout, and equipment for these establishments. The existence of such national measures should be checked with the local body.





9. REFERENCES

European Commission - Commission Notice on the implementation of food safety management systems covering prerequisite programs (PRPs) and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses. Official Journal of the European Union 2016/C 278/01

FAQ (Frequently Asked Questions) on flexibility for food business operators” and “Flexibility provisions for competent authorities”

Guidance document for the implementation of certain provisions of Regulation (EC) No 853/2004 (specific hygiene requirements for products of animal origin)

Guidance document on the implementation of certain provisions of Regulation (EC) No 852/2004 (general hygiene requirements)

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

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Local legal text on ‘Official’ Food Control and Hygiene for Consumer Protection, 1/2020

General Food and Feed local legal text, 56/2014

[Some notes about EU food hygiene regulations](#)

The general EU Hygiene requirements: Regulation (EC) No 852/2004

The specific EU Hygiene requirements: Regulation (EC) No 853/2004

Food Hygiene Package:

Regulations (EC) of 852/2004, 853/2004

Commission Delegated Regulation (EU) 2019/624 (Official controls of products of animal origin)

Commission Delegated Regulation (EU) 2019/625 (Import conditions)

Commission Implementing Regulation (EU) 2019/627 (Practical arrangement official controls products of animal origin)

Commission Implementing Regulation (EU) 2020/2235 (Import certificates)

Commission Implementing Regulation (EU) 2021/405 (Lists of third countries authorised to import products of animal origin)



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