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**on the Understanding of certain provisions on flexibility provided in the Hygiene
Package**

**Frequently Asked Questions
Guidelines for food business operators**

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1. INTRODUCTION

This document should serve as a basis for a better understanding of certain provisions for flexibility provided in the Hygiene Regulations and lead to a better use of these provisions by Member States. It should be stressed that the flexibility of the Hygiene Regulations is not limited to the points mentioned in this document.

In addition it should be noted that this document covers only rules under the Hygiene Regulations and not the other relevant legislation like animal health requirements, residue controls and labelling. Therefore your Competent Authorities should be contacted in order to fully understand the relevant provisions applicable for your activity in the different domains.

Flexibility provisions contained in the Hygiene Regulations offers the possibilities:

- to grant:
 - (i) **derogations/exemptions** from certain requirements laid down in Annexes of the Hygiene Regulations;
 - (ii) **adaptations** of certain requirements laid down in Annexes of the Hygiene Regulations;
- to **exclude** some activities from the scope of the Hygiene Regulations.

When making use of flexibility provisions, Member States have in general to adopt national measures.

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

- based on the transparency principle, each draft of such national measures must be notified to the Commission and to the other Member States;
- based on the principle of subsidiarity, Member States are best placed to find solutions to local situations.

These Guidelines should be used together with the Guidance documents for the implementation of the Hygiene Regulations:

- Guidance document on the implementation of certain provisions of Regulation (EC) No 852/2004 (general hygiene requirements);
- 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 procedures based on the HACCP principles, and on the facilitation of the implementation of the HACCP principles in certain food businesses.

Terminology and rules for the implementation of Hygiene Regulations, including flexibility provisions, are explained in these guidance documents which are published on the website of DG SANCO on the following link:

http://ec.europa.eu/food/food/biosafety/hygienelegislation/guide_en.htm

A special account should be also paid to the document "Understanding of certain provisions on flexibility provided in the Hygiene Package - Guidelines for competent authorities" developed in parallel with this frequently asked questions document.

Specific technical terms used in this document and for the purposes of this document can be found in the table below.

Technical term	Understanding
The Hygiene Regulations	Regulations (EC) No 852/2004 / (EC) No 853/2004 and (EC) No 854/2004
The general EU Hygiene requirements	Relevant requirements of Regulation (EC) No 852/2004
The specific EU Hygiene requirements	Relevant requirements of Regulation (EC) No 853/2004

2. QUESTIONS AND ANSWERS

2.1. Traditional foods

Question 1:

"There is a long tradition of production of cheese in my country. Raw material is sheep milk and cheese is produced at the farm in the mountains. Because of the traditional way of production (in sheep huts high in the mountains), it is difficult – nearly impossible – to comply for these premises with the EU rules. Also to achieve full compliance with rules for transport of these products from the mountains to the local shops is difficult. Is the EU banning production of these products?"

ANSWER:

No, the EU recognise the traditional foodstuffs as a valuable and irreplaceable heritage of the Member States and, hence, also the heritage of the European Union. That is why the Hygiene Regulations provide flexibility especially for production of this type of products on condition that the product is safe.

For the rules for the production of cheese on the farm see question 8.

Question 2:

*"When can I consider the food I produce as a **food with traditional characteristics** and what derogations can be granted to such food?"*

ANSWER:

Foods with traditional characteristics are foods traditionally manufactured in Member States which are:

- (a) recognised historically as traditional products, or
- (b) manufactured according to registered technical references to the traditional process, or according to traditional production methods, or
- (c) protected as traditional food products by EU¹, national, regional or local law.

For this type of foods the EU legislation enables Member States **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 your product fulfils requirements mentioned above and you want to know how flexibility is applied in your country, you should contact the competent authority.

Question 3:

*"Is there further flexibility if **traditional methods of production** are used?"*

ANSWER:

Yes. If foods are traditionally produced in Member States and there is a need to adapt other requirements than mentioned in the Answer to Question 2, the EU legislation allows to Member States to adopt national measures in order to **adapt requirements** in Hygiene Regulations.

¹ In 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 in question.

In the case that your method of production, processing or distribution of food is traditional and you want to know how flexibility is applied in your country, you should contact the competent authority.

2.2. Meat and Meat Products

Question 4:

*"I run a **butcher shop**. I was told that my shop must be approved and comply with all EU rules. Could you advise me which requirements I should fulfil in order to comply with this legislation?"*

ANSWER:

There is no definition of "butcher shop" in the Hygiene Regulations. The EU hygiene rules apply depending on the activities actually carried out in establishments.

At first, you need to verify if you need to be just **registered or approved**. (Registration means that you must send information to the competent authority on your establishment/activities, approval means that, following such request, the competent authority must visit and approve before you can start operations) Establishments commonly called "butcher shops", which only supply meat or meat products directly to the final consumer (no slaughter of animals), are considered as retail establishments. They, therefore, only need to be registered. Approval of such shops is not required by EU legislation.

However, Member States may require approval on a national basis in accordance with their national measures. The existence of such national measures should be checked with the competent authority.

Secondly, certain **EU requirements for butcher shops** apply.

General hygiene requirements are applicable including the HACCP based procedures. It should be remembered that especially in small shops the HACCP based procedures may be implemented in a flexible way. A Guidance document was developed in collaboration of all 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.

The Guidance document can be found on the following page of the DG Health and Consumers website of:

http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf

In addition, in some **Member States national guides to good practice** have been developed by the food sectors and assessed by the competent authorities. 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. All national guides to good practice are sent to the register which is run by the Commission. The register is published on the website of DG Health and Consumers at the following address:

http://ec.europa.eu/food/food/biosafety/hygienelegislation/register_national_guides_en.pdf

Finally, Member States may use the flexibility provisions and adopt national measures in order to **adapt the requirements on the construction, layout and equipment** for butcher shops.

Question 5:

*"I have a farm with pigs and cattle. In addition, I would like **to slaughter animals for my butcher shop placed on the farm**, produce meat and some traditional meat products and sell these products directly in my shop to consumers. The capacity of my farm is really small and all my products will be sent only to my shop. I think that my premises should comply only with requirements for butcher shops. Am I correct?"*

ANSWER:

You have to comply with the requirements on butcher shops explained under question 4.

However, only primary production and retail activities do not need to be approved according to the Hygiene Regulations. 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 EU hygiene rules and specific EU hygiene rules for slaughterhouses. Slaughter facilities on the farm must be approved by the competent authority.

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

However Member States may 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 competent authority.

Question 6:

*"I have a **small capacity slaughterhouse** and cutting plant attached to it. Until now the slaughterhouse was approved by the competent authority according to national rules. I was told by the competent authority that from 1 January 2010 the slaughterhouse must be approved in accordance with Regulation (EC) No 853/2004 otherwise I will have to stop operations. I think that it is inappropriate to require small establishments supplying meat only locally to comply with strict EU rules. I also think that there should be a time given to food business operators to comply with EU requirements."*

ANSWER:

There is no definition of small food businesses in the EU hygiene legislation and no specific requirements are applicable only to them. The approach agreed by Member states in 2004 is that all establishments (including small slaughterhouses and cutting plants) may place food on the Community market provided they were approved in accordance with the Hygiene Regulations.

A transitional period of four years was given to small capacity establishments, approved under the previous regime for the national market only, to comply with the EU rules. This transitional period ended on 31 December 2009. From 1 January 2010 food businesses must

comply with the EU rules, including approval by the competent authority, as provided in the Hygiene Regulations.

Member States may, however, use the flexibility provided in the Hygiene Regulations and, if needed, adapt requirements in Annexes of the Hygiene Regulations for this type of establishment – for example adaptation of requirements for the construction, layout and equipment.

This means that in order to continue to operate, certain adaptations of requirements may be introduced, which should be drafted as national measures and notified by the competent authorities.

The existence of such rules should be checked with the competent authority.

2.3. Milk and dairy products

Question 7:

"I have a small farm (10 cows) and I would like to sell (raw) milk at the farm and to the shop in near town. What requirements I should comply with?"

ANSWER:

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 EU requirement is possible under certain conditions.

The conditions for the exclusion from the EU 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 EU hygiene requirements. No approval is required. However, national measures must be adopted in Member States for these activities. In the case that national rules have not been adopted or your activity does not comply with rules set up at national level, general and specific EU hygiene requirements are applicable.

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

You, as a farmer, should, therefore, check:

- Whether the national measures for direct supply of raw milk have been adopted in your Member State;

- What is considered to be a small quantity in your Member State and whether you are allowed to use this possibility;
- What are the rules applicable in your Member State.

Question 8:

*"I have a farm with cows and I **produce cheese on my farm**. I would like to sell my cheese at the farm or to the local shop. With which EU rules for food hygiene do I have to comply with?"*

ANSWER:

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

As a consequence, cheese production at the farm must in principle comply with the appropriate general and specific EU requirements on food hygiene and an **approval is needed**.

However, 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.

In addition to that, Member States may 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 competent authority.

Raw milk dairy products must come from herds of bovine, including buffaloes, ovine and caprine animals that are in accordance with EU legislation officially free of bovine brucellosis, ovine and caprine brucellosis and bovine tuberculosis. However as there are derogations for raw milk cheese with a maturation period of more than two months, you should contact your competent authority.

2.4. Honey

Question 9:

*"I am a beekeeper and I **sell honey from my own production to the final consumer**. In the future I would like to supply my honey to an establishment where honey is **packed and supplied to shops across the whole of my country**. Is there any difference in requirements I have to comply with?"*

ANSWER:

The beekeeping and production of honey is considered to be a primary production and honey is considered to be a primary product. Therefore exclusion from the Hygiene Regulations under following conditions:

Direct supply of honey is excluded from the scope of the Hygiene Regulations if following principles has been applied:

- Honey is delivered by producer, or
- Honey is delivered directly to the final consumer or to the local retail shop supplying directly the final consumer, and
- 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 EU hygiene requirements are not applicable and no approval is needed. National measures must be adopted in Member States for these activities. In the case that national rules have not been adopted or your activity does not comply with rules set up at national level, general EU hygiene requirements are applicable.

You should, therefore, check:

- Whether the national measures for direct supply of honey has been adopted in your Member State;
- What is considered to be a small quantity of honey in your Member State and whether you are allowed to use this possibility;
- Which rules are applicable for you.

In case you also want to **deliver honey to an establishment where honey is packaged** (or mixed with other honey and packaged) and then **delivered to retail shops, the situation** becomes different. As the packaging establishment is not a retail shop, the rules for direct supply of small quantities of honey (see above) are not applicable.

The general EU Hygiene requirements are applicable to your activities as a supplier of honey to such establishment.

2.5. Fruit and vegetables

Question 10:

*"I enjoy going to forest to pick-up **blue-berries and mushrooms**. I would like to sell them to consumers in the local market. Do any EU hygiene rules apply to that?"*

ANSWER:

The harvesting of berries and mushrooms in the wild and their transport to the local market are considered to be a primary production and blue-berries and mushrooms are considered to be primary products. Therefore exclusion from the EU requirement is possible under certain conditions.

Direct supply of blue-berries and mushrooms, as well as other fruit and vegetables, is excluded from the scope of the Hygiene Regulations if following principles has been applied:

- Blue-berries and mushrooms (not processed) are delivered by the person who harvested them, or
- These products are delivered directly to the final consumer or to the local retail shop, and
- These products are delivered in small quantities.

If primary products are delivered by the producer (in this case person who harvested them in the wild), 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 EU hygiene requirements. National measures must be adopted in Member States for these activities. In the case that national rules have not been adopted or your activity does not comply with rules set up at national level, general EU hygiene requirements are applicable.

You should, therefore, check:

- Whether the national measures for direct supply of these products has been adopted in your Member State;
- What is considered to be a small quantity in your Member State and whether you are allowed to use this possibility;
- Which rules are applicable for you.

A special account should be paid to the fact that in some Member States national rules for quality of these products and also obligatory training of people who harvest such products and place them on the market may be laid down in addition to the hygiene rules.

Question 11:

"I am a small farmer and I produce juice and jam from fruits I harvest. I would like to sell it to the shops in my region. Is this possible?"

ANSWER:

If a farm uses its harvest or part of its harvest (e.g. apples or plums) to produce fruit juice or jam at its premises for selling, such farm exceeds the level of primary production. The activity of producing fruit juice or jam is to be considered as an activity after primary production and it is therefore subject to the appropriate general EU hygiene requirements.

Member States 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 competent authority.