



What does FLEXIBILITY mean?

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Do we talk about the same thing when we say FLEXIBILITY?

- In the hygiene regulations, there is not a clear definition
- Flexibility provisions are referred to in:
 - Article 13 of Reg. 852/2004
 - Article 10 of Reg. 853/2004, and
 - Article 7 of Reg. 2074/2005
- Member States wishing to adopt national measures on flexibility shall notify The Commission and other Member States.
- In cheese dairies, Flexibility has to be granted by the competent authorities. That's not the case of flexibility regarding HACCP based procedures (doesn't need to be granted)
- In next slides we'll explain this:



FLEXIBILITY in the hygiene package: there is not a clear definition.

- Reg. (EC) No. 852/2004, recital (15):

*“The HACCP requirements should take account of the principles contained in the Codex Alimentarius. They should provide sufficient **flexibility** to be applicable in all situations, including in small businesses. In particular, it is necessary to recognise that, in certain food businesses, it is not possible to identify critical control points and that, in some cases, good hygienic practices can replace the monitoring of critical control points. Similarly, the requirement of establishing ‘critical limits’ does not imply that it is necessary to fix a numerical limit in every case. In addition, the requirement of retaining documents needs to be **flexible** in order to avoid undue burdens for very small businesses”*



FLEXIBILITY in the hygiene package: there is not a clear definition.

- Reg. (EC) No. 852/2004, recital (16):

*“**Flexibility** is also appropriate to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food and in relation to structural requirements for establishments.*

***Flexibility** is particularly important for regions that are subject to special geographical constraints, including the outermost regions referred to in Article 299(2) of the Treaty. However, **flexibility** should not compromise food hygiene objectives. Moreover, since all food produced in accordance with the hygiene rules will be in free circulation throughout the Community, the procedure allowing Member States to exercise **flexibility** should be fully transparent. It should provide, where necessary to resolve disagreements, for discussion within the Standing Committee on the Food Chain and Animal Health established by Regulation (EC) No 178/2002.*



FLEXIBILITY in the hygiene package: there is not a clear definition.

- Reg. (CE) No. 854/2004, recital (7):

*“It is appropriate to provide for the adaptation of certain specific control rules, through the transparent procedure provided for in Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004, to provide **flexibility** in order to accommodate the specific needs of establishments which use traditional methods, have a low throughput or are located in regions that are subject to special geographical constraints. The procedure should also allow pilot projects to take place in order to try out new approaches to hygiene controls on meat. However, such **flexibility** should not compromise food hygiene objectives.”*



FLEXIBILITY in the hygiene package: which is the “*procedure provided for in Regulations 852/2004 and 853/2004 to provide flexibility*”, referred to in the previous slide?

- Reg. (CE) No. 852/2004, article 13: DEROGATIONS/ADAPTATIONS

3. Member States may, without compromising achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4 to 7 of this Article, national measures adapting the requirements laid down in Annex II.

4. (a) The national measures referred to in paragraph 3 shall have the aim of:

- (i) enabling the continued use of traditional methods, at any of the stages of production, processing or distribution of food;
- or

- (ii) accommodating the needs of food businesses situated in regions that are subject to special geographical constraints.

(b) In other cases, they shall apply only to the construction, layout and equipment of establishments.

5. Any Member State wishing to adopt national measures as referred to in paragraph 3 shall notify the Commission and other Member States. The notification shall:



FLEXIBILITY in the hygiene package: which is the “*procedure provided for in Regulations 852/2004 and 853/2004 to provide flexibility*”, referred to in the previous slide?

- Reg. (CE) No. 853/2004, article 10: similar possibilities for ADAPTATIONS/DEROGATIONS
- Member States wishing to adopt national measures on flexibility regarding Regulations (EC) No. 852/2004 and 853/2004, shall notify The Commission and other Member States, which shall have 3 months to send written comments.

The national measures may be adopted by Member States only if consensus is reached.

National measures without notification may lead to the opening of an infringement procedure.



Reg. (EC) No. 2074/2005 also mentions the necessity of applying flexibility for foods with traditional characteristics

Recital (18):

“Flexibility is needed so foods with traditional characteristics can continue to be produced. Member States have already granted derogations for a wide range of such foods under the legislation in force before 1 January 2006. Food business operators should be able to continue without interruption to apply existing practices after that date. A procedure allowing Member States to exercise flexibility is provided for in Regulations (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004.

However, in most cases where derogations have already been granted it is only a question of continuing established practices, so applying a full notification procedure, including a complete hazard analysis, may place an unnecessary and disproportionate burden on the Member States. Foods with traditional characteristics should therefore be defined and general conditions applicable to such foods should be laid down, by way of derogation from the structural requirements laid down in Regulation (EC) No 852/2004, with due regard to food health objectives.”



Reg. (EC) No. 2074/2005 offers another way of granting derogations, with a simple notification (faster and less burden for Member States) for Foods with traditional characteristics

Article 7

Derogation from Regulation (EC) No 852/2004 for foods with traditional characteristics

1. For the purposes of this Regulation, 'foods with traditional characteristics' means foods that, in the Member State in which they are traditionally manufactured, are:

3. Member States granting the derogations provided for in paragraph 2 shall notify the Commission and the other Member States of this no later than 12 months after granting individual or general derogations. Each notification shall:

This procedure for FOODS WITH TRADITIONAL CHARACTERISTICS is simpler and easier. Member States shall notify The European Commission and other Member States, but no period of time to send comments is applied.



DOES FLEXIBILITY always NEED TO BE GRANTED BY COMPETENT AUTHORITIES?

Yes

(except for the implementation of HACCP based procedures, which are flexible by its nature)

Let's see how the flexibility in the HACCP system works



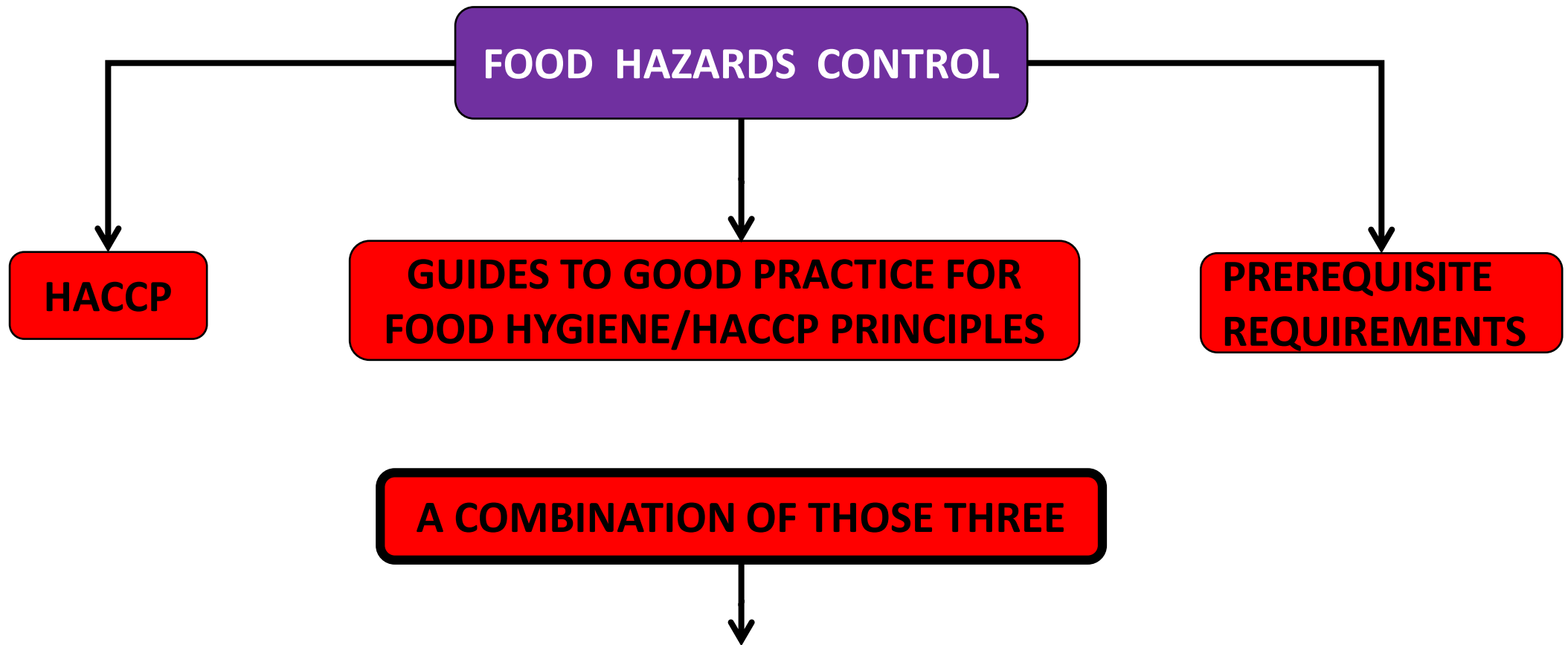
- The HACCP methodology is flexible by its very nature
- *FBO doesn't have to ask for it*
- FBO is not compelled to comply with rules or to implement procedures not relevant or not adapted to the specific context for his activity

Guidance document on the implementation of certain provisions of Regulation (EC) No 853/2004 On the hygiene of foodstuffs

ALL CHEESEDAIRIES MUST

Put in place a system to identify and control significant hazards on a permanent basis and adapt that system whenever necessary

This can be done by different ways



Farmhouse and Artisan Cheese and dairy producers' European Guide for Good Hygiene Practices



So, cheesemakers wishing to implement their own HACCP based system or equivalent method:

- Do not need to be allowed to apply flexibility: no critical control points identified; no critical limits; good hygiene practices instead of HACCP procedures; own decision about keeping written documents and records .

Cheesemakers wishing to implement any official guide to good practices (like the GGHP) on a voluntary basis:

- Do not need to ask for it



Sometimes, the hygiene regulations offer “food business operators” the possibility to choose by themselves whether to implement or not a specific requirement. Is it flexibility?

NO

This is just a proper implementation of the regulations and cheesemakers don't need either to apply for it nor to be allowed to do it

Let's see how it works and some examples



Decided by the Food Business Operator

- ✓ *Where the words “where necessary”, “where appropriate”, “adequate” or “sufficient”, are used, it is up to the FBO to decide whether a requirement is necessary, appropriate, adequate or sufficient to achieve the objectives.*

Guidance document on the implementation of certain provisions of Regulation (EC) No 853/2004 on the hygiene of foodstuffs

- ★ ***“Adequate working space to allow for the hygienic performance of all operations”***
- ★ ***“Storage conditions of sufficient capacity for maintaining foodstuffs at appropriate temperatures and designed to allow those temperatures to be monitored and, where necessary, recorded”***
- ★ ***“An adequate number of washbasins and, suitably located ”***
- ★ ***“Adequate facilities are to be provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment ”***



Decided by the Food Business Operator

As the expressions “where necessary”, “sufficient”, “appropriate”, are difficult to interpretate in small-scale premises, some countries have written guidance documents intended to facilitate the task to producers and inspectors:

- **France: “note de flexibilité**
- **Spain: “Document for a good implementation of Hygiene Package in artisan and farmhouse cheese dairies**

... SOME EXAMPLES in next slides... And in the presentation “premises and equipments”



“Food premises are to provide adequate working space to allow for the hygienic performance of all operations” (Reg. No 852/2004)

Cleaning area in processing room



Multipurpose washbasin in processing room



“An *adequate number of washbasins* is to be available, suitably located and designated for cleaning hands. *Where necessary*, the facilities for *washing food* are to be *separate from the hand-washing facility*. *Adequate facilities* are to be provided, *where necessary, for the cleaning, disinfecting and storage of working utensils and equipment*”. (Reg. No 852/2004)



“An adequate number of flush lavatories are to be available and connected to an effective drainage system” (Reg. No 852/2004):

- The toilet of the cheesemaker house may be “adequate”



“During transport the cold chain must be maintained and, on arrival at the establishment of destination, the temperature of the milk and the colostrum must not be more than 10° C”. (Reg. No 853/2004)

- But the means to achieve the objective can be various



Granted by the Competent Authority: there are three possibilities

DEROGATIONS/EXEMPTIONS

ADAPTATIONS

EXCLUSIONS



Granted by the Competent Authority

DEROGATIONS/EXEMPTIONS

These situations are usually introduced by wording, such as:

- ✓ *"if the competent authority so permits",*
- ✓ *"unless otherwise authorized by the competent authority",*
- ✓ *"with authorization of the competent authority", etc*

Food business operators are authorized to not apply specified requirements of the Hygiene Package in specified circumstances

EXAMPLE:

- ✓ A Member State may, of its own initiative, maintain or establish national rules **permitting the use, with the authorisation of the competent authority, of raw milk not meeting the criteria laid down in Annex III, Section IX, as regards plate count and somatic cell count of the manufacture of cheeses with an ageing or ripening period of at least 60 days.**

(Reg. No. 853/2004, art. 10.8.a)



Granted by the Competent Authority

CHEESES WITH TRADITIONAL CHARACTERISTICS

DEROGATIONS/EXEMPTIONS

Reg. (EC) No. 2074/2005. art. 7

1

Premises where such products are exposed to an environment necessary for the part-development of their characteristics:

- a) Walls, ceilings and doors that are not smooth, impervious, non-absorbent, or of corrosion-resistant material
- b) Natural geological walls, ceilings and floors
- c) Cleaning and disinfecting measures and the frequency carried out, shall be adapted to the activity, to take account of their specific ambient flora

2

Type of materials of which the instruments and the equipment for the preparation, packaging and wrapping of these products are:

- a) Not smooth/corrosion-resistant
- b) Maintained at all times in a satisfactory state of hygiene and regularly cleaned and disinfected



Granted by the Competent Authority

CHEESES WITH TRADITIONAL CHARACTERISTICS

DEROGATIONS/EXEMPTIONS

Reg. (EC) No. 2074/2005. art. 7

For the purpose of this regulation, in the Member State in which they are traditionally manufactured, are:

- a) Recognised historically as traditional products, or
- b) **Manufactured according to codified or registered technical references to the traditional process, or according to traditional production methods, or**
- c) Protected as traditional food products by a Community, national, regional or local law.



Granted by the Competent Authority

CHEESES WITH TRADITIONAL CHARACTERISTICS

DEROGATIONS/EXEMPTIONS

Reg. (EC) No. 2074/2005. art. 7

- ✓ FARMHOUSE AND ARTISAN CHEESES AND DAIRY PRODUCTS are foods with traditional characteristics because they are manufactured according to traditional production methods (see page 5 of the Guide - English version)
- ✓ Associations representing farmhouse and artisan cheese and dairy producers could request their competent authorities for collective exemptions for cheeses with traditional characteristics



Granted by the Competent Authority

CHEESES WITH TRADITIONAL CHARACTERISTICS

DEROGATIONS/EXEMPTIONS

Reg. (EC) No. 2074/2005. art. 7

What kind of exemptions can be requested?

- 1. Walls, floors, ceilings, windows and doors surfaces do not need to be flat, corrosion resistant or water proof**
- 2. Equipment and materials for production and/or packaging do not need to be flat, easy to clean and corrosion resistant**

Walls, floor, ceiling, windows, doors



Stone floor
and walls

Walls, floor, ceiling, windows, doors

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Natural cave





Wooden ceiling and door

Walls, floor, ceiling,
windows, doors



Wooden material and equipment



Plant material (esparto matting, thatched shelves, straw, etc; leaves for covering, etc)



Stones for pressing



Copper equipment



Granted by the Competent Authority

ADAPTATIONS

Member States may adopt national measures in order to adapt requirements laid down in Annex II (Reg. 852/2004) and III (Reg. 853/2004):

- a) To enable the continued use of traditional methods of production, processing or distribution of food, or
- b) To accommodate the needs of food businesses situated in regions that are subject to special geographic constraints
- c) In other cases, they shall apply only to the construction, layout and equipment of establishments

➤ A Member State may, of its own initiative, maintain or establish national rules prohibiting or restricting the placing on the market within its territory of raw milk or raw cream intended for direct human consumption

(Reg. No. 853/2004, art. 10.8.a)





Granted by the Competent Authority

EXCLUSIONS

The Hygiene Package excludes certain activities from its scope

Member States may authorize or not these activities with national rules

RETAIL

Excluded from Reg. 853/2004

- ✓ **Cheeses sold entirely at the place of production or at a local market to final consumers,**

Must comply with:

- a) Reg. 852/2004**
- b) Only the requirements for raw milk of Reg. 853/2004**



Granted by the Competent Authority

EXCLUSIONS

- The European Guide is addressed to cheese dairies under the European Regulations.
- The cheese dairies under the European Regulations can sell their products across the EU.
- In some Member States there are cheese dairies excluded from the European Regulations. In that case, they can sell only locally (each Member State shall define “locally”). Nevertheless, those premises may also apply the Guide on a voluntary basis
- **FACEnetwork position regarding the method of selling: foods must be safe regardless the way of selling.** From a hygiene approach, the differences on the level of requirements should only be based on the way of production, not in the route to market.



So, are our productions protected and within the scope of the European Regulations?

Yes

The European Regulations offer different means:

- Flexibility:
 - a) Adaptations/Derogations (Member States have to apply for it)
 - b) Exemptions for foods with traditional characteristics (a simple notification by Members States)
 - c) HACPP based systems
- The possibility given to producers to choose their methods for many requirements of Reg. (EC) n° 852/2004 and n° 853/2004

So, are exclusions a good solution, considering the limitation to local market only, and that those foods must be safe as well?



HOW CAN A PRODUCER ASK FOR FLEXIBILITY?

- Flexibility granted by the competent authority:
 - Individually
 - Collectively (better option):
 - Through associations of producers, PDO, etc.
 - Depending on the Member State, the request shall be done at local, regional or national level.
- For exceptions concerning foods with traditional characteristics under the Regulation (EC) N° 2074/2005 see tool 9.9