



# **Better Training for Safer Food** *FOOD HYGIENE AND FLEXIBILITY*

**Dissemination of  
the contents of the  
training**

**BTSF**

*Unless otherwise noted the reuse of this presentation is not authorised. For any use or reproduction of elements that are owned by the EU, permission may need to be sought directly from the respective right holders. All statements and references in this presentation come from of the Training coordinator and tutors and do not represent the official position of the European Commission.*

# **• COURSE BACKGROUND, OBJECTIVES & EXPECTED RESULTS**

## BACKGROUND

In order to protect food diversity and to serve consumers and the needs of small-scale producers, EU legislation provide ***ample possibilities*** to adapt the technical requirements of the Food Hygiene Package in function of the nature of the food business concerned

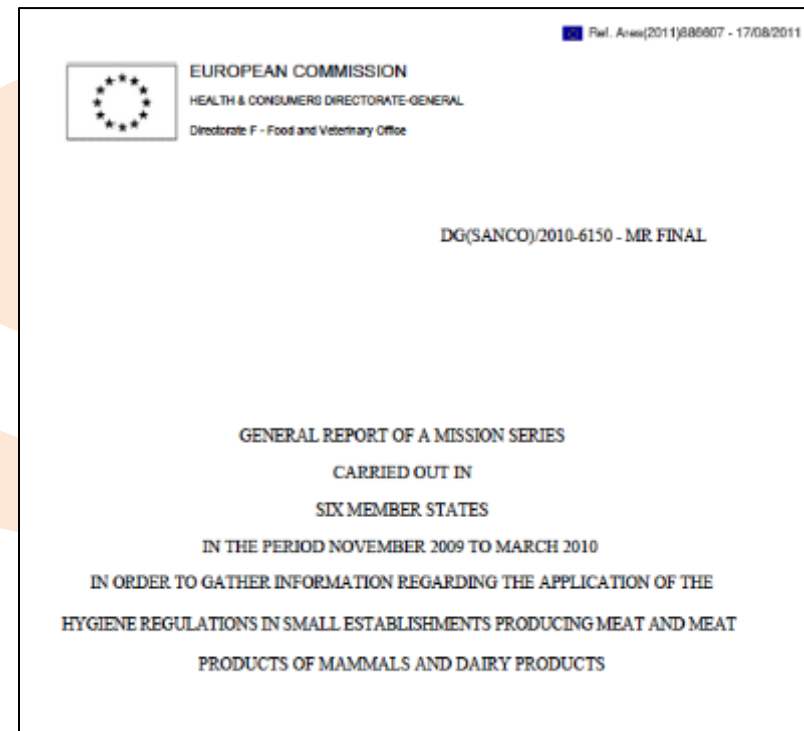
# BACKGROUND

Flexibility provisions for

- implementation of procedures based on 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 2073/2005

## BACKGROUND

- Commission report in 2009: Competent Authorities in MS may not have availed of all flexibility possibilities offered in the legislation
- FVO report DG(SANCO)/2010-6150 confirmed the difficulties and shortfalls in the application of flexibility provisions



# TRAINING CONTENTS

1. Flexibility in the Hygiene Regulations; DG SANTE reports
2. Activities excluded from the scope of the hygiene Regs
3. Flexibility and small businesses
4. Flexibility and the HACCP principles
5. Flexibility with regard to Reg. 2073/2005
6. Flexibility and traditional foods
7. Flexibility and traditional methods
8. Flexibility related to geographic constraints
9. Assessment of the implementation of flexibility by CAs
10. The notification process, analysis of notifications

# • FLEXIBILITY THROUGH THE HYGIENE REGULATIONS; DG SANTE REPORTS

# FLEXIBILITY IN THE FOOD HYGIENE PACKAGE

- EU Food legislation is objective oriented: flexibility means to move focus from requisites/stringent requirements to objectives
- FBO can decide how to reach the objectives
- The terms 'where necessary, 'where appropriate'... mean where necessary to achieve the objectives of the Regulation



# FLEXIBILITY ADDRESSED TO FBO: EXAMPLES

- Regulation 852/04, Annex II: Where necessary, adequate changing facilities for personnel are to be provided



# FLEXIBILITY ADDRESSED TO FBO: EXAMPLES

- Regulation 853/04, Annex III, Section I: Slaughterhouses: *separation in space or time of packaged and exposed meat*



# FLEXIBILITY DOESN'T MEAN

- To give up the consumers' health and interests protection because of FBOs' interest
- To forget Good Practices, because business is business, and a flexible approach is always possible...

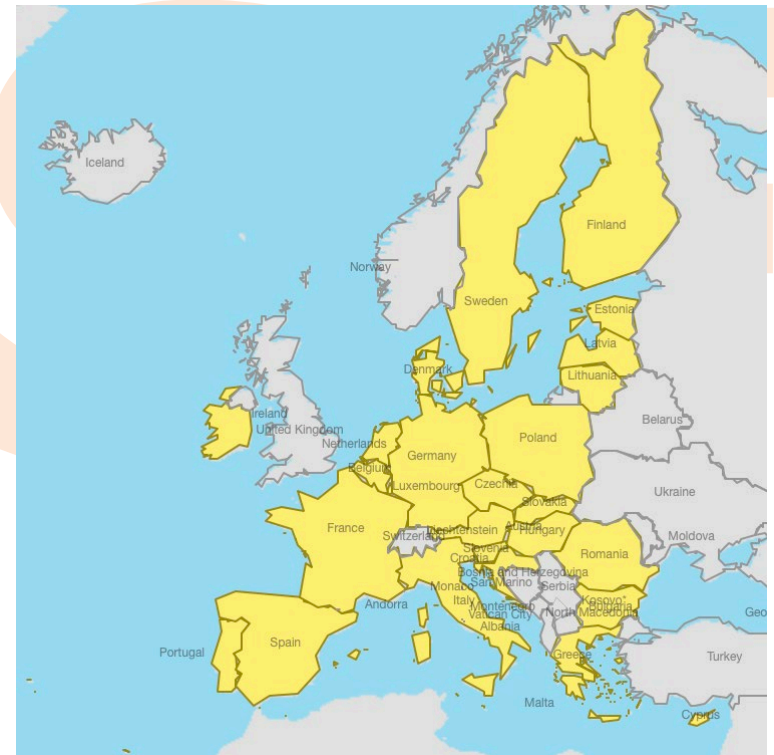


***Flexibility should not compromise food hygiene objectives***

# LEADING PRINCIPLES FOR IMPLEMENTING FLEXIBILITY PROVISIONS

## SUBSIDIARITY PRINCIPLE

*Member States are best placed to find solutions to local situations*



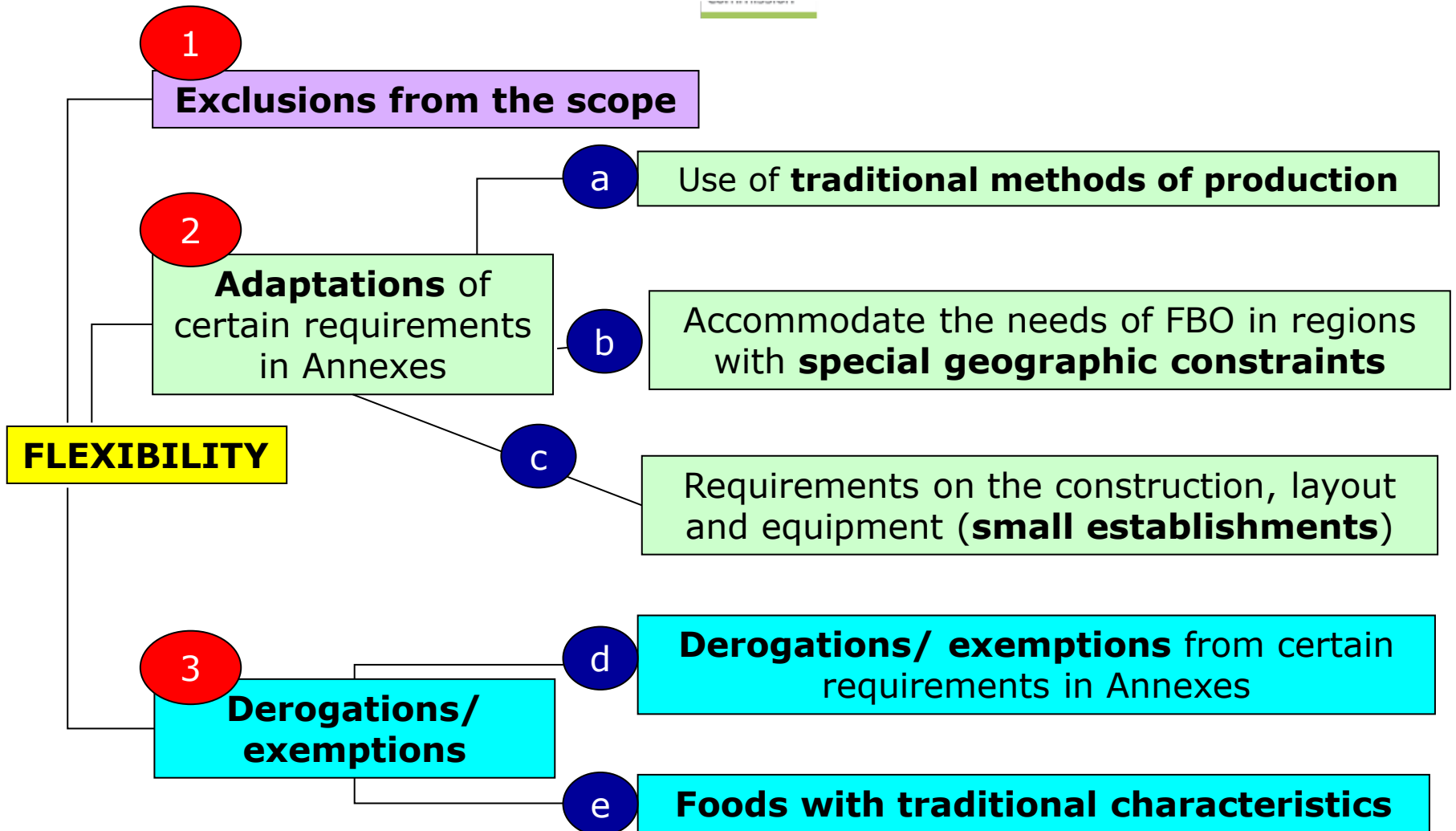
# LEADING PRINCIPLES FOR IMPLEMENTING FLEXIBILITY PROVISIONS

## **TRANSPARENCY PRINCIPLE**

*Each draft of national measures must be notified to the Commission and to the other Member States*

Food will be in free circulation throughout the Community: the procedure allowing Member States to exercise flexibility should be fully transparent

# LEGAL BASES: FLEXIBILITY AND POSSIBILITIES OFFERED IN THE FHP



2

## **Adaptations**

Member States are given the possibility to adapt the requirements laid down in the Annexes of the Hygiene Package in specified circumstances

3

## **Derogations/ exemptions**

Member States are given the possibility to authorise Food Business Operators not to apply specified requirements of the Hygiene Package in specified circumstances

## 2 ADAPTATIONS

Art. 13 Reg. 852  
Art. 10 Reg. 853

3. Member States may adopt national measures **adapting** the requirements laid down in Annex II of Reg. 852 and Annex III of Reg. 853:

- 2a aim of enabling the continued use of traditional methods (production, processing or distribution)
- 2b aim of accommodating the needs of food businesses situated in regions that are subject to special geographical constraints
- 2c in other cases, they shall apply only to the construction, layout and equipment of establishments



3

3d

## DEROGATIONS

Reg. 852/04,  
art. 13 paragraph 2

Derogations from Annexes I and II may be granted, in particular in order to facilitate the implementation of Art. 5 (HACCP) for small businesses, *in accordance with the procedure referred to in Article 14(2)*, taking into account the relevant risk factors, provided that such derogations do not affect the achievement of the objectives of this Regulation

## 3 3d DEROGATIONS/EXEMPTIONS

### ***From the Guidelines on flexibility for the Competent Authorities***

- In certain cases, the Hygiene Regulations provide for the Competent Authority to authorise a certain flexibility
- Situations usually introduced by wording, such as
  - ✓ "if the Competent Authority so permits"
  - ✓ "unless otherwise authorised by the Competent Authority"
  - ✓ "with authorisation of the Competent Authority"

*You can find several examples in Reg. 853/04, not in Reg. 852/04 (see syllabus)*

# 3 3d DEROGATIONS - EXEMPTIONS

## EXAMPLES

- Reg. 853, Annex III  
Section I: slaughterhouses  
need not have separate  
place for the cleaning,  
washing and disinfection of  
means of transport for  
livestock if the Competent  
Authority so permits...



# 3 3d DEROGATIONS - EXEMPTIONS

## SOME EXAMPLES

Reg. 853/04, Annex III, Section I (meat of domestic ungulates ), Chapter II, paragraph 2, letter b)

- slaughterhouses must have a separate room for the emptying and cleaning of stomachs and intestines, unless the Competent Authority authorises the separation in time of these operations within a specific slaughterhouse on a case-by-case basis

# 3 3d DEROGATIONS/EXEMPTIONS

- It is up to Member States to grant the derogations at national level on a case-by-case basis
- Drafts of national measures which will enable the use of derogations must be notified to the Commission and other Member States

# 3<sup>3e</sup> DEROGATIONS

Reg. 2074, food with traditional characteristics

2. Member States may grant establishments manufacturing foods with traditional characteristics individual or general derogations from the requirements concerning:

- *premises*
- *materials of instruments and equipment*





# 3<sup>3e</sup> DEROGATIONS

Reg. 2074,  
traditional food

Premises where products are exposed to an environment necessary for the part development of their characteristics (walls, ceilings and doors; natural geological walls, ceilings and floors)



*Cleaning and disinfection: adapted to the activity in order to take account of their specific ambient flora*

3

3e

## DEROGATIONS

Reg. 2074, traditional food

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





# GUIDANCE DOCUMENTS OF THE EC

COMMISSION STAFF WORKING DOCUMENT (2010)  
on the Understanding of certain provisions  
on flexibility provided in the Hygiene Package

❑ Guidelines for Food Business Operators

❑ Guidelines for the Competent Authorities

# GUIDELINES FOR FOOD BUSINESS OPERATORS

- Basis for a better understanding of certain provisions for flexibility provided in the Hygiene Regulations
- Flexibility of the Hygiene Regulations is not limited to the points mentioned in this document

# 2010-6150 REPORT: MOST COMMONLY USED FLEXIBILITY MEASURES

## General

- Replacement of HACCP by good hygiene practices; sometimes, relevant documentation was very limited or non-existent
- Level of detail of HACCP-based own-check programmes
- Lighter microbiological sampling programme

# DG(SANCO) 2010-6150 REPORT

*Examples of National measures possibly affecting the achievement of the objectives of the Hygiene Regulations*

- Sale of uninspected wild game meat to the final consumer
- Voluntary testing for *Trichinella* in wild boar
- 'Cold inspection'
- Absence of carcass sampling or reduced carcass sampling
- Reduced/absent microbiological sampling in minced meat
- HACCP replaced by GHP

# DG(SANCO) 2010-6150 REPORT

*Compliance issues which could have been addressed through flexibility measures (in general)*

- Separation between retail and EU-eligible activities
- Separation in time of different activities in the same place
- Changing rooms and hygiene barrier at the entry
- Access from changing rooms to working rooms
- Storage of cleaning and disinfection equipment
- Requirement to establish HACCP-based procedures
- Documentation of own controls, temperature registration

# DG(SANCO) 2010-6150 REPORT

*Compliance issues which could have been addressed through flexibility measures: abattoirs, cutting plants, meat processing*

- Housing of live animals before being slaughtered
- Carrying out all dressing operations in the same place
- Post-mortem after the carcass is cut in quarters
- Temperature in the cutting rooms
- Freezing of meat after maturation
- Exit of the meat in the absence of docking facilities
- Storage of animal by-products
- Location of slaughterhouses within the perimeter of a farm

## 2010-6150 REPORT: OUTCOMES

- The level of application of flexibility measures was very different in the six MS visited
  - ✓ *In some cases the CCA has provided guidelines for application of national measures to its authorities*
  - ✓ *In other MS it was solely left to the local authorities to apply flexibility at local level*
- Also within MS the flexibility measures applied were different between the regions and the CCA was not always aware about the details of the flexibility measures applied in all parts of the MS

## 2010-6150 REPORT: OUTCOMES

- Notification not consistently applied, not all national measures had been notified
- The documentation of the application of flexibility measures in individual establishments did not in all cases allow for verification on-the spot
- In some MS flexibility measures seem to go beyond the provisions foreseen in the Hygiene Regulations
- In other areas where flexibility could provide ad-hoc solutions in small capacity establishments the CA have so far not taken any action



## 2010-6150 REPORT: RESULTS

*In small establishments visited which could not benefit from flexibility measures non-compliance was more frequent*

**Very few cases where flexibility was applied could lead to possible health risks**

# **ACTIVITIES EXCLUDED FROM THE SCOPE OF THE HYGIENE REGULATIONS**

1

## Exclusion from the scope

2

**Adaptations** of  
certain requirements  
in Annexes

a

Use of **traditional methods of production**

b

Accommodate the needs of FBO in regions  
with **special geographic constraints**

c

Requirements on the construction, layout  
and equipment (**small establishments**)

3

**Derogations/  
exemptions**

d

**Derogations/ exemptions** from certain  
requirements in Annexes

e

**Foods with traditional characteristics**

**FLEXIBILITY**

## EXCLUSIONS FROM THE SCOPE: PRIMARY PRODUCTS

Reg. 852/04

c) direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer

- General provisions of Regulation 178/2002 and Regulation 2017/625 apply to regulate these activities
- MS are obliged to adopt national rules

# SMALL QUANTITIES = SUBSIDIARITY

It is up to MS to further refine this notion depending on the **local situation**, and to lay down under national law the rules necessary to ensure that the safety of the food is guaranteed

**National Rules**



# PRIMARY PRODUCTS

- Products of plant origin  
*e.g. grains, fruits, vegetables, herbs,*
- Products of animal origin  
*e.g. eggs, raw milk, honey*
- Products harvested wild either from  
plant or animal origin  
*e.g. mushrooms, berries, snails etc.*



## NATIONAL RULES. Direct supply – small quantity. EGGS



2012 526 B: 60.000 /year



2016 584 LV: Maximum  
1000 laying fowl



2015 629 FIN:  
20.000kg/year



2015 567 LT: Eggs from  
2,000 laying hens



2013 167 P: 350/week



## NATIONAL RULES. Direct supply – small quantity. HONEY



2013 332 B; amount produced by 24 hives



2012/476/CZ: 2000 Kg/ year



2016 302 FIN: 2500 kg/year



2009/042/SK: honey from the own production of an individual primary producer intended for direct sale



2013 167 P: 500kg/year





# NATIONAL RULES.

## Direct supply – small quantity. RAW MILK



2012 526 B: 15.000 liters/year



2007 52 CZ: daily consumption in the household of the consumer



2011 132 FIN: 2500 kg/year



2009/042/SK: 1,000 kg (cow's milk), 200 kg (sheep's, goat's milk)



2013 167 P: 80 lt per day



# EXCLUSIONS FROM THE SCOPE: MEAT FROM POULTRY AND LAGOMORPHS

Reg. 853/04

d) direct supply, by the producer, 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 as fresh meat

- Regulations 178/2002, 852/2004 and 2017/625 apply
- MS are obliged to adopt national rules

## Direct supply, small quantity POULTRY AND LAGOMORPHS

	Small quantity (Maximum)				
Country					
Notification	2012 526 B	2009 42 SK	2015 82 PL	2010 197 BG	2013 167 P
Poultry	7.500/year	10.000/year	10.000/year	800/month	100/week
Lagomorphs	1.000/year	5.000/year	5.000/year	50/month	50/week
Local	80 Km	100 Km	Province and neighboring Provinces	Administrative area	Municipality and adjoining municipalities

# EXCLUSIONS FROM THE SCOPE: WILD GAME or WILD GAME MEAT






Reg. 853/04

e) hunters who supply small quantities of wild game or wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer

- Regulations 178/2002 and 2017/625 apply
- In case of wild game meat, also Reg. 852/2004 applies
- MS are obliged to adopt national rules

# Direct supply, small quantity

## WILD GAME

	Small quantity (Maximum)				
					
	2012 526B	2015 82 PL	2009 42 SK	2010/197/BG	2016 141 DK
<b>Large wild game (by hunters)</b>	1/hunting day	10.000 Kg/year	2 tons of boned game or a reasonable quantity of unboned game per week	50/year	15/year
<b>Small wild game (by hunters)</b>	10/hunting day	10.000 Kg/year		1500/year	500/year
<b>Local</b>	80 Km	Province and neighboring Provinces	100 Km	Administrative area	50 Km

# EXCLUSIONS

## Retail



Reg. 853/04

It shall ***not*** apply to retail supplying another retail establishment recognised as: marginal, localised and restricted activity

# LOCALISED, MARGINAL, RESTRICTED ACTIVITIES

## **Combination of three criteria**

- Localised: immediate vicinity
- Marginal: amount/percentage from the usual production
- Restricted: certain products or establishments only

*Notification procedure according to Directive 2015/1535*

## AN EXAMPLE: IRELAND

### Marginal

total supply less than 2000 kg/ week, or supply to other retail establishments no more than 25% of the total

### Localised

within 100km of the supplying establishment



### Restricted

the FBO does not supply other retail establishments with either ready-to-eat food of animal origin, or more than 250 kg per week in total of minced meat, meat preparations made from minced meat or meat products made from minced meat, prepared or processed in his or her establishment



# CHEESE PRODUCTION AT THE FARM

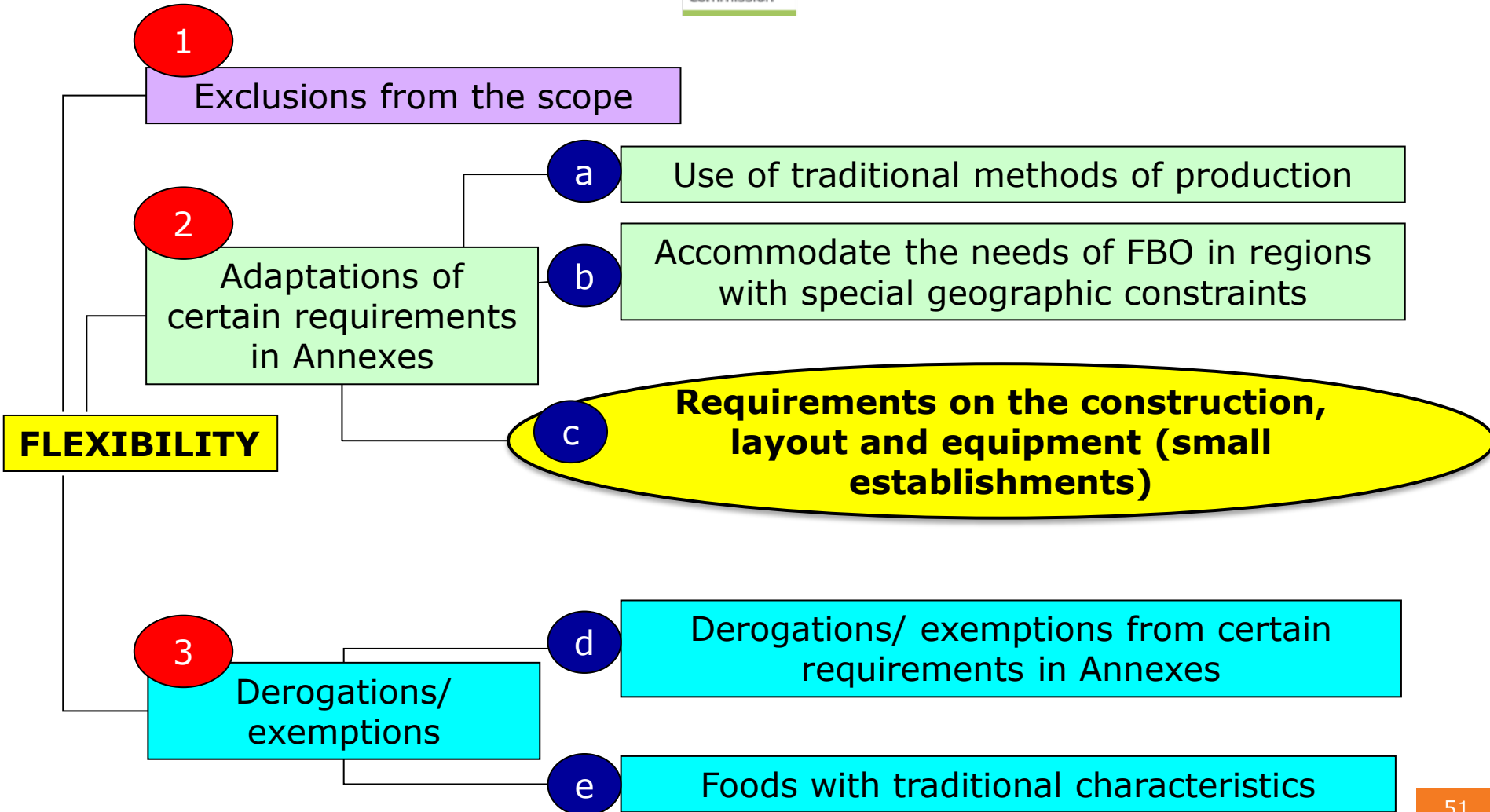
Cheese manufactured  
and sold at the farm or  
at a local market to final  
consumers



**RETAIL**



# **• FLEXIBILITY IN RELATION TO BUILDING, LAY OUT AND EQUIPMENT OF ESTABLISHMENTS**



# FLEXIBILITY AND SMALL ESTABLISHMENTS

There is no definition of small food businesses in the EU hygiene legislation and no specific requirements are applicable only to them

*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*

## SLAUGHTERHOUSES and FLEXIBILITY: LEGAL FRAMEWORK

**If «authorised», by the CA, flexibility concerning:**

- separate facilities for sick or suspect animals
- separate room for the emptying and cleaning of stomachs and intestines (case-by-case basis)
- separate place for the cleaning, washing and disinfection of means of transport for livestock
- lockable facilities reserved for the slaughter of sick and suspect animals
- meat temperature (transportation after PM)

# SLAUGHTERHOUSES and FLEXIBILITY: LEGAL FRAMEWORK

## **Flexibility already included in the FHP:**

- sufficient number of rooms, appropriate to the operations being carried out
- separation in space or time of slaughtering operations (including dispatching of meat)
- slaughter lines (where operated) that are designed to allow constant progress and to avoid cross-contamination
- lockable facility or, where needed, room for the exclusive use of the veterinary service

# SLAUGHTERHOUSES and FLEXIBILITY: LEGAL FRAMEWORK

## **Flexibility already included in the FHP:**







- storage of packaged and exposed meat: separation in space or time
- meat temperature during cutting etc.: maintained by means of an ambient temperature of 12 °C or an alternative system
- premises approved for the cutting of meat of different animal species: separation of the operations in either space or time

**In red: derogations/exemptions**

**In green: flexibility in FHP, no need for notification**

**In black: Small establishments (SE)**

## SMALL SLAUGHTERHOUSES: NOTIFICATIONS

Country							
Notification		2005 536 A	2013 190BG, 2015 582BG	2014 454 HR	2008 433 CZ	2011 54FIN; 2015 601FIN	2009 553 PL
Limit/year (Livestock Units)			480		1000	1000 (5000)	1000
Limit/week (Livestock Units)				20	20	20	20
Facilities adopted	lairage facilities or waiting pens	SE	SE	SE	SE	SE	SE
	separate facilities for sick/suspect animals		SE	X			
	separate place for the cleaning, washing and disinfection of means of transport for livestock	SE	SE	X	SE	SE	
	use of the slaughtering room as a cutting room (separation in time)	SE	SE	SE	SE	SE	SE
	refrigerated storage of detained meat in an area of the chilling room	SE	SE	X	X	SE	SE
	single changing room for staff employed in the clean and unclean parts			SE			
	no separate room for authorised persons		SE	SE			
	emptying and cleaning of stomachs and intestines in the room used for slaughtering and/or cutting up meat		SE	SE			



# FLEXIBILITY IN SMALL ESTABLISHMENTS



2014 454 HR

**Finalised**

- Small slaughterhouse for poultry and lagomorphs: up to 10,000 units per month; facilitations: evisceration and further dressing may be carried out in the same room as the scalding and plucking
- Mobile slaughterhouses: adapted vehicle or mobile modular business unit used for slaughtering poultry and lagomorphs or domestic ungulates and farmed game

# SMALL ESTABLISHMENTS

- Processing milk: maximum 10,000 litres/ day
- Meat and/or fishery products: maximum 5,000 kg/week
- Egg packing centres: maximum 3,000,000 eggs/ year



# SMALL ESTABLISHMENTS FLEXIBILITY MEASURES

- Carry out different production steps and/or production of different products in the same room: separation in time
- Store raw materials, finished products and detained products in the same room: separation in space
- Use the same entrance/exit for raw materials, finished products and non-compliant products: separation in time
- Facilities located on the same grounds as a private residential building: use a private area as changing and washing area

# **FLEXIBILITY WITH REGARD TO THE IMPLEMENTATION OF PROCEDURES BASED ON THE HACCP PRINCIPLES**

# KEY ISSUES FOR SIMPLIFIED HACCP

**Reg. (EC) No 852/2004**

*Food business operators should establish and operate food safety programs and procedures based on the HACCP principles*

**No need for unnecessary  
complicated HACCP-  
System**



## KEY ISSUES FOR SIMPLIFIED HACCP

Article 5 (2) (g) : *documentation and records must be commensurate to the nature and the size of the food business*

Requirement of generating documents needs to be flexible in order to avoid undue burdens for very small businesses



# KEY ISSUES FOR SIMPLIFIED HACCP

Official Journal  
of the European Union

C 278



English edition

Information and Notices

Volume 59

30 July 2016

## 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 (2016/C278/01) - **CNHACCP**

# WHAT ARE SIMPLIFIED HACCP-BASED PROCEDURES?

- **7 principles:** practical model to identify and control significant hazards
- Where that objective can be achieved by equivalent means that substitute in a simplified but effective way some (!) of the seven principles: the obligation to establish permanent procedure(s) based on HACCP is fulfilled (*Article 5, paragraph 1 of Regulation (EC) No 853/2004*)



# FLEXIBILITY

## Food Safety Management System

### **POSSIBILITIES FOR FLEXIBILITY:**

1. Prerequisites Programs
2. Preliminary HACCP activities
3. HACCP principles: HA, CCP's, CL, Monitoring, Documents and records

1

# *FLEXIBILITY AND PREREQUISITES*

## SOME EXAMPLES

- Reg. 853/2004: Exclusions from the scope for the direct supply of small quantities of meat from poultry and lagomorphs slaughtered on the farm
- Exclusion of most retailers from Reg. 853/2004
- Adaptations for traditional methods, geographical constraints, small establishments

## *FLEXIBILITY AND HACCP: Preliminary HACCP activities*

- No permanent HACCP team, one person responsible for HACCP/FSMS
- Product description: use of existing product information (label, internet)
- Simple flow diagram (*nature of business!*)

3

## ***FLEXIBILITY AND HACCP: CRITERIA***

*As to Article 5(2)(g) of the Regulation (EC) No 852/2004*

Two main criteria to be eligible for flexibility:

**NATURE AND SIZE** of the business,

**to be considered separately**

- A. NATURE: risk-based approach, hazard analysis plays a crucial role
- B. SIZE: reflected in a reduction of administrative burden

3

## *FLEXIBILITY AND HACCP*

- Recital 15 of Reg. 852/2004 clearly recognises that not in all cases CCP might be identified
- In such case the application of procedures based on the HACCP principles is limited to the first principle
- **A hazard analysis is needed** to justify in a risk-based manner why NO CCP is needed and demonstrating that PRPs are sufficient to control the risks

*Flexibility on the hazard analysis is not directly linked to the size of the establishment*

3

## *FLEXIBILITY AND HACCP*

When CCPs are identified in small enterprises, proportionality in administrative burden justifies additionally a simplified approach to comply with the other HACCP principles

# SCENARIOS FOR “PROCEDURES BASED ON HACCP PRINCIPLES”

1. Guides to Good Practice (GHP/GMP)
  - when all hazards are controlled by Good Practices / prerequisite Programs (PRPs)
2. Sector specific guides (e.g. meat, milk, etc.)
  - good practice and the principles of HACCP are already included
3. Generic HACCP-guides
4. Developing own, full HACCP system

# 1 - GUIDES TO GOOD PRACTICE

- All hazards are controlled by Good Practices/PRPs: requirements of Art.5 have been met
- It can be considered that a hazard analysis has been performed e.g. serves the purpose/ objective of HACCP: no need to implement a full HACCP system
- Basic monitoring, verification and record keeping should be carried out





## 2 – SECTOR SPECIFIC GUIDES

- A simple and practical description of the way how to control hazards
- Guidelines for the practical implementation of the PRPs
- HA already done, all significant hazards covered
- Pre-determined CCPs
- Clearly defined procedures for monitoring, corrective actions and verification
- Requirements for documents and records



## 3 – GENERIC HACCP GUIDES

- All 7 principles of HACCP applied
- Flexibility can also be applied
- Follow Annex II of the Commission Notice
- Use of adopted generic HACCP-guides
- Suitably trained person should be available
- When using generic HACCP guides: analysis for the possible presence of additional hazards and the methods to control them is required

# REGISTER(S) OF EU- AND NATIONAL GUIDES TO GOOD PRACTICE

[https://ec.europa.eu/food/food/biological-safety/food-hygiene/guidance-platform\\_en](https://ec.europa.eu/food/food/biological-safety/food-hygiene/guidance-platform_en)



EN English

Search

## Food Safety

[Home](#) [Food](#) [Animals](#) [Plants](#) [Horizontal topics](#)

[European Commission](#) > [Food Safety](#) > [Food](#) > [Biological safety](#) > [Food Hygiene](#) > [Guidance Platform](#)

## Guidance Platform

### PAGE CONTENTS

[About the platform](#)

[EC guidance](#)

[Stakeholder guidance](#)

[National guidance](#)

## About the platform

In order to assist Member States and food business operators to better understand the food hygiene rules and how to implement them in specific sectors, a selection of representative full guides at EU and national level for different aspect are made available through the links below.

For detailed information about national guidelines in different sectors users should check the [EU Register of National Guides to Good Hygiene Practice](#) which provides an overview of all guides.

EC guidance

# EFSA - FLEXIBILITY RELATED TO FSMS

***Hazard analysis approaches for certain small retail establishments in view of the application of their food safety management systems***

SCIENTIFIC OPINION



**SCIENTIFIC OPINION**  
**ADOPTED: 18 January 2017**

*EFSA Journal 2017;15(3):4697*

# NEW COMMISSION NOTICE

The approach of both EFSA Scientific Opinions is incorporated

Commission Notice  
(CN) providing guidance  
on

**food safety  
management  
systems for food  
retail activities,  
including food  
donations**

Official Journal  
of the European Union

C 199



English edition

Information and Notices

Volume 63

12 June 2020

Contents

IV Notices

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

European Commission

2020/C 199/01

Commission Notice providing guidance on food safety management systems for food retail activities, including food donations ..... 1

# EFSA - FLEXIBILITY RELATED TO FSMS

**Guidance on food safety management systems for small food retailers (SFR-FSMS)**: application of hazard identification, ranking and control in butcher, grocery, bakery, fish and ice cream shops

[https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety\\_fh legis\\_guidance\\_mngt-systems-sfr-fsms\\_en.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_fh_legis_guidance_mngt-systems-sfr-fsms_en.pdf)

- Extracted from the EFSA opinion
- Available in all EU languages

# EFSA - FLEXIBILITY RELATED TO FSMS

## Recommendations

- Butcher, grocery, bakery, fish and ice cream shops shall apply the 'simplified approach'
- Retail establishments need to tailor their SFR-FSMS in a clear and user friendly way based on the specific processes (stages) and products relevant to their business
- 'Simplified approach' would also overcome issues encountered by other small food businesses
- To be considered for wider application within the food industry

# CONCLUSIONS

- The Food Hygiene Package, CNHACCP and relevant guidelines give the possibility to implement flexibility in HACCP and own-check implementation
- FSMS: all implemented measures to control hazards
- Basic role covered by GHP and HACCP generic Guides
- Main goal: flexibility for small businesses
- Main trend: replacement of HACCP principles with prerequisites – general control measures
- Record keeping sometimes limited to non compliances and relevant corrective actions



# **FLEXIBILITY WITH REGARD TO REGULATION (EC) N. 2073/05 ON MICROBIOLOGICAL CRITERIA FOR FOODSTUFFS**

# FLEXIBILITY AND REGULATION 2073/05

- Sampling and analyzing: verification procedures that each FBO shall put in place to assess their FSMS effectiveness and efficacy
- Food Safety Criteria and Process Hygiene Criteria are strictly linked to the concepts and to the procedures based on the HACCP principles put in place by the FBOs
- Accordingly, a flexible approach to microbiological testing may also be applied

# FLEXIBILITY

May be addressed to any of the different aspect of the micro criteria laid down in Reg. 2073/05:

- Microorganism of interest
- Sampling plan & frequency
- Sample dimension
- Analytical methods

# SAMPLING FREQUENCY REDUCTION

May be granted when:

- risk analysis has been carried out (following an overview of the present conditions and preventive actions planned and carried out by the concerned FBO) with favourable outcomes
- low risk profile is connected to a small throughput establishment
- Competent Authority permits it
- additional measures are in place (ie. National Monitoring Program)

## LESS SAMPLE UNITS (REDUCTION OF THE SAMPLE SIZE)?

*"The number of sample units of the sampling plans set out in Annex I may be reduced if the food business operator can demonstrate by historical documentation that he has effective HACCP-based procedures"*

Reg. (EC) n. 2073/05, art. 5. 3

## REGARDLESS any Reduction of the sampling frequency or sampling size

CORRECTIVE ACTIONS/MEASURES have always to be taken if results are unsatisfactory/non-compliant!

- FS-criterion: Withdrawal, product recall, review of production processes (HACCP), re-process
- PH-criterion: Improvements and review of hygiene processes at the level of production and earlier stages (farm level)

according DOCUMENTATION needs to be provided!

# ROLE OF THE GUIDES TO GOOD PRACTICE FOR HYGIENE AND FOR THE APPLICATION OF HACCP PRINCIPLES

Guides play a significant role in granting support to the FBOs asked to decide and justify the:

- matrix to be sampled
- sampling frequency
- microorganism of interest
- corrective actions and specific measures to be taken in case unsatisfactory results are obtained

# ROLE OF THE GUIDES

Guidelines may support FBO in justifying their verification plan:

- sampling frequency and samples' dimension can be reduced in some circumstances
- sampling locations to be addressed should be tailored on the actual situation
- alternative analytical methods may help in managing processes in a better way



# SAMPLING FREQUENCY REDUCTION: EXAMPLES

## SLAUGHTERHOUSES (UNGULATES)

Guidelines Red Meat



Microcriteria/PHC	Average amount of slaughtered LSU*/past 2 years	Frequency/amount of samples/year
<i>Aerobic colony count,</i> <i>Enterobacteriaceae;</i> <i>Salmonella</i>	999 - 500	5% of LSU slaughtered in prev. year (LSU/20)
	499 - 250	4% of LSU slaughtered in prev. year (LSU/25)
	249 - 150	3% of LSU slaughtered in prev. year (3*LSU/100)
	149 - 100	3 carcasses
	99 - 50	2 carcasses
	49 - 20	1 carcasses
	19 - 1	1 carcass in 2 years

\*Livestock Unit

- ie. **199 LSU** slaughtered:  $3 \times 199 / 100 = 6$  **samples**
- Proportional allocation when more than one category slaughtered



2013/167/P

**Finalised**

# SAMPLING FREQUENCY REDUCTION: EXAMPLES

## SLAUGHTERHOUSES (UNGULATES)

### PROCESS HYGIENE CRITERIA

N. SLAUGHTER/YEAR	INITIAL FREQUENCY	FREQUENCY REDUCED
Cattle: 5,000 to 10,000 Horses: 200 to 1,000 Sheep/Goats: 10,000 to 20,000 Pigs: 10,000 to 50,000 Piglets: 2,000 to 20,000	<b>Aerobic colony count and <i>Enterobacteriaceae</i>:</b> 5 carcasses once every fortnight, for 4 consecutive fortnights <b>(5 x 4= 20 samples)</b>	<b>Aerobic colony count and <i>Enterobacteriaceae</i>:</b> 5 carcasses every 4 weeks
	<b><i>Salmonella</i>:</b> 5 carcasses once every fortnight, for 15 consecutive fortnights <b>(5 x 15= 75 samples)</b>	<b><i>Salmonella</i>:</b> 5 carcasses every 4 weeks
Cattle: less than 5,000 Horses: less than 200 Sheep/Goats: less than 10,000 Pigs: less than 10,000 Piglets: less than 2,000	<b>Aerobic colony count and <i>Enterobacteriaceae</i>:</b> 5 carcasses once a month, for 4 consecutive months <b>(5 x 4= 20 samples)</b>	<b>Aerobic colony count and <i>Enterobacteriaceae</i>:</b> 5 carcasses per quarter
	<b><i>Salmonella</i>:</b> 5 carcasses once a month, for 15 consecutive months <b>(5 x 15= 75 samples)</b>	<b><i>Salmonella</i>:</b> 5 carcasses per quarter

# SAMPLING FREQUENCY REDUCTION: EXAMPLES

## SLAUGHTERHOUSES (POULTRY) PROCESS HYGIENE CRITERIA



2013/167/P

**Finalised**

N° of slaughter/year	Initial frequency	Frequency reduced
Chickens: 250,000 to 5,000,000 Turkeys: 50,000 to 200,000	<u>Salmonella:</u> 5 samples once every fortnight, for 15 consecutive fortnights <i>(5 x 15 = 75 samples)</i>	<u>Salmonella:</u> 5 samples every 4 weeks.
Chickens: less than 250,000 Turkeys: less than 50,000	<u>Salmonella:</u> 5 samples once a month, for 15 consecutive months <i>(5 x 15 = 75 samples)</i>	<u>Salmonella:</u> 5 samples per quarter

**Already reduced!** (in case of satisfactory results, Salmonella control, low prevalence)



2013/167/P

**Finalised**

# SAMPLING FREQUENCY REDUCTION: EXAMPLES

## POULTRY MEAT, MINCED MEAT, MEAT PREPARATIONS

Average monthly production	SAMPLING FREQUENCY (PROCESS HYGIENE CRITERIA)		SAMPLING FREQUENCY (FOOD SAFETY CRITERIA)	
	Initial frequency	Frequency reduced	Initial frequency	Frequency reduced
Higher than 1,000 kg and lower than 4,000 kg per product	<b>Aerobic colony count and <i>E . coli</i>:</b> 5 samples once a month, for 4 consecutive months (5 x 4= 20 samples)	<b>Aerobic colony count and <i>E . Coli</i>:</b> 5 samples once every quarter	<b><i>Salmonella</i>:</b> 5 samples once a month, for 10 consecutive months (5 x 10= 50 samples)	<b><i>Salmonella</i>:</b> 5 samples once every quarter
Less than 1000 kg per product	<b>Aerobic colony count and <i>E . coli</i>:</b> 5 samples once every six months	<b>Aerobic colony count and <i>E . coli</i>:</b> No reduction	<b><i>Salmonella</i>:</b> 5 <sup>(3)</sup> samples once every six months	<b><i>Salmonella</i>:</b> No reduction



2013/167/P

**Finalised**

# REDUCTION OF SAMPLING UNITS: EXAMPLES

Establishments producing small quantities of **cheese and dairy products** (up to 50,000 lt/year) - **Process hygiene criteria**

TYPE OF END PRODUCT	MICROORGANISMS	PURPOSE	SAMPLING PLAN		LIMITS	
			n	c	m	M
Cheese made from milk or whey that has undergone heat treatment	<b><i>E.coli</i> count</b>	For process validation purposes	5	2	100 cfu/g	1000 cfu/g
		For monitoring while results remain in compliance	1	0	100 cfu/g	
Cheese made from raw milk	<b><i>Coagulase-positive staphylococci</i></b>	Exempt from sampling				
Cheese made from milk that has undergone a heat treatment lower than pasteurisation and ripened cheese made from milk or whey that has undergone pasteurisation or a stronger heat treatment	<b><i>Coagulase-positive staphylococci</i></b>	Exempt from sampling				
Unripened soft cheese (fresh cheese) made from milk or whey that has undergone pasteurisation or a stronger heat treatment	<b><i>Coagulase-positive staphylococci</i></b>	Exempt from sampling				

93



2013/167/P

**Finalised**

# REDUCTION OF SAMPLING UNITS: EXAMPLES

Establishments producing small quantities of **cheese and dairy products** (up to 50,000 lt/year) – **Food Safety Criteria**

TYPE OF END PRODUCT	MICROORGANISMS	PURPOSE	SAMPLING PLAN	
			n	c
Various cheeses that are able or unable to support the growth of <i>Listeria. monocytogenes</i>	<b><i>Listeria monocytogenes</i></b>	For process validation purposes	5	0
		For monitoring while results remain in compliance	1	0
Cheese made from raw milk or milk that has undergone a heat treatment lower than pasteurisation	<b><i>Salmonella</i></b>	For process validation purposes	5	0
		For monitoring while results remain in compliance	1	0
Cheese made from raw milk or whey, or heat-treated milk	<b><i>Staphylococcal enterotoxins</i></b>	For process validation purposes	5	0
		For monitoring while results remain in compliance	1	0



2013/167/P

**Finalised**

# REDUCTION OF SAMPLING UNITS: EXAMPLES

Establishments producing small quantities of **meat and meat products** (average monthly production: up to 4000 kg per product)

## Food Safety Criteria

TYPE OF END PRODUCT	MICROORGANISMS	PURPOSE	SAMPLING PLAN	
			n	c
RTE foods, made from meat or meat products able or unable to support the growth of <i>L. monocytogenes</i> , other than those intended for infants and for special medical purposes	<b><i>Listeria monocytogenes</i></b>	For process validation purposes	5	0
		For monitoring while results remain in compliance	1	0
Fresh poultry meat	<b><i>Salmonella</i></b>	For process validation purposes	5	0
		For monitoring while results remain in compliance	1	0
Minced meat and meat preparations, made from poultry meat, intended to be eaten cooked	<b><i>Salmonella</i></b>	For process validation purposes	5	0
		For monitoring while results remain in compliance	1	0



2013/167/P

**Finalised**

# REDUCTION OF SAMPLING UNITS: EXAMPLES

Establishments producing small quantities of **meat and meat products** (average monthly production: up to 4000 kg per product)

## Food Safety Criteria

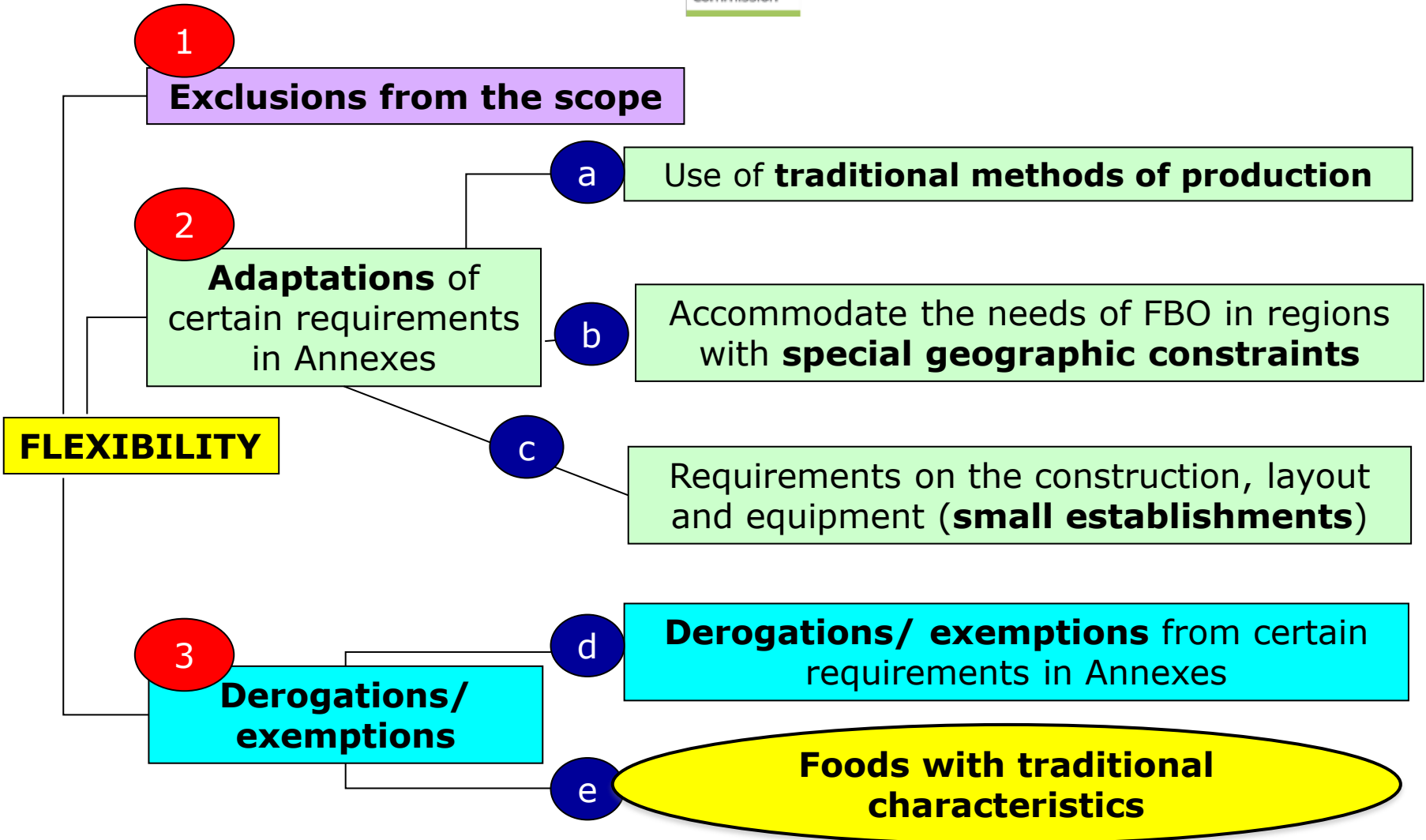
TYPE OF END PRODUCT	MICROORGANISMS	PURPOSE	SAMPLING PLAN	
			n	c
Minced meat and meat preparations (other species than poultry meat), intended to be eaten cooked	<b>Salmonella</b>	For process validation purposes	5	0
		For monitoring while results remain in compliance	1	0
Meat products intended to be eaten raw, excluding products where its manufacturing process or composition will eliminate the risk of Salmonella	<b>Salmonella</b>	For process validation purposes	5	0
		For monitoring while results remain in compliance	1	0
Meat products, made from poultry meat, intended to be eaten cooked	<b>Salmonella</b>	For process validation purposes	5	0
		For monitoring while results remain in compliance	1	0



## SUMMARISING

- Sampling and analysing are part of the measures and instruments FBOs shall put in place to achieve the Food Law objectives
- Sampling and analysis are not standing alone activities, but are part of a wider approach including the implementation of the GHP and HACCP based procedures
- Micro testing, as a consequence, shall be implemented according to the same flexible approach
- Each element of the micro criteria *may be tailored on the effective needs*

# **FLEXIBILITY PROVISIONS PURSUANT TO ARTICLE 7 OF REG. 2074/05 FOODS WITH TRADITIONAL CHARACTERISTICS**



# FLEXIBILITY AND TRADITIONAL FOODS

1. Flexibility is needed so traditional foods can continue to be produced
2. MS have already granted derogations before 01/01/2006
3. FBO should be able to continue to apply existing practices
4. Foods with **traditional characteristics** should therefore be defined
5. General conditions [derogation from the structural requirements Reg. 852/04] applicable to such foods should be laid down

*[Reg. 2074/05]*

# WHAT DOES IT MEAN TRADITIONAL?



**FOOD SAFETY**

**Reg. 2074/05**

**To be considered  
for flexibility  
purposes**

**FOOD QUALITY**

**Reg. 1151/12**

*On protected  
traditional food*

# WHAT DOES IT MEAN TRADITIONAL?

**According to Reg. 2074/05**

***FOOD SAFETY***

*Foods that, 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

# WHAT DOES IT MEAN TRADITIONAL?

## According To Reg. 1151/2012 On Protected Traditional Food

*FOOD  
QUALITY*

*For the purpose of this Regulation, 'traditional' means proven usage on the domestic market for a period that allows transmission between generations; this period is to be at least 30 years*



# PROTECTED TRADITIONAL FOOD

REGULATION 1151/2012 on quality schemes for agricultural products and foodstuffs

**The objective is to promote and protect names of quality agricultural products and foodstuffs and not to protect consumers health**





# PROTECTED TRADITIONAL FOOD

## ***Protected Designation of Origin - PDO:***

agricultural products and foodstuffs which are produced, processed and prepared in a given geographical area

## ***Protected Geographical Indication - PGI:***

agricultural products and foodstuffs closely linked to the geographical area. At least one of the stages of production takes place in the area

## ***Traditional Speciality Guaranteed - TSG:***

highlights traditional character, either in the composition or means of production

# LIST OF THE PRODUCTS



AGRICOLTURA E SVILUPPO RURALE  
**DOOR**

ARCHIVED ON  
20/12/2019

As from 1<sup>st</sup> January 2020, information on food PDO, PGI and TSG can be found on the eAmbrosia electronic register

English (en)

European Commission > Agriculture and Rural Development > Agriculture and food > DOOR > Browse

- Latest [registered](#) designations
- Latest [published](#) designations
- Latest [applied](#) designations



10 rows view 17 - 32 from 181 rows.

Search on EUROPA | Contact | Cookies | Legal notice | Privacy statement English (en)

Dossier Number	Country	Name
<a href="#">IT/PDO.0005/0661</a>	Italy	
<a href="#">FR/PDO.0005/0542</a>	France	
<a href="#">ES/PDO.0005/0605</a>	Spain	
<a href="#">FR/PDO.0005/0563</a>	France	
<a href="#">IT/PDO.0005/0686</a>	Italy	
<a href="#">IT/PDO.0005/0466</a>	Italy	
<a href="#">ES/PDO.0005/0497</a>	Spain	



EUROPEAN COMMISSION

eAmbrosia – the EU geographical indications register

Home > Food, Farming, Fisheries > Food safety and quality > Certification > Quality labels > Geographical Indications register

Search

Wine Register

Food Register

Spirit drinks

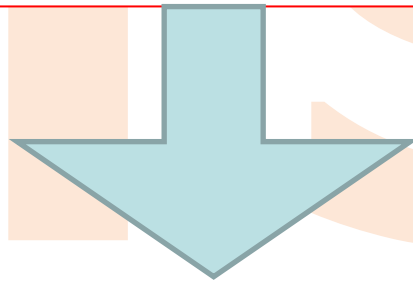
Aromatised Wine Register

3719 Records

Product Type	Country	Type	File number	Name	Product Category	Status	Date	
Food	Cyprus	Protected Geographical Indication (PGI)	PGI-CY-02369	Λουκάνικο Πιτσιλιάς / Loukaniko Pitsilias	Class 1.2. Meat products (cooked, salted, smoked, etc.)	Published	17/06/2020	<a href="#">i</a>
Wine	Italia	Protected Designation of Origin (PDO)	PDO-IT-02176	Friuli / Friuli Venezia Giulia / Furlanija / Furlanija Juljska krajina	Wine	Published	16/06/2020	<a href="#">i</a>
Food	Cyprus	Protected Geographical Indication (PGI)	PGI-CY-02368	Χοιρομέρι Πιτσιλιάς / Hiomeri Pitsilias	Class 1.2. Meat products (cooked, salted, smoked, etc.)	Published	16/06/2020	<a href="#">i</a>
Food	Greece	Protected Designation of	PDO-GR-02389	Ρόδι Ερμιόνης / Rodi Ermionis	Class 1.6. Fruit, vegetables and	Published	15/06/2020	<a href="#">i</a>

# WHY FLEXIBILITY FOR TRADITIONAL FOOD?

EU supports the diversification of agricultural production and the promotion of traditional products



***Specific provisions for Flexibility measures***

3

## DEROGATIONS

3f

Reg. 2074/05, food with traditional characteristics

2. Member States may grant establishments manufacturing foods with traditional characteristics individual or general derogations from the requirements concerning:

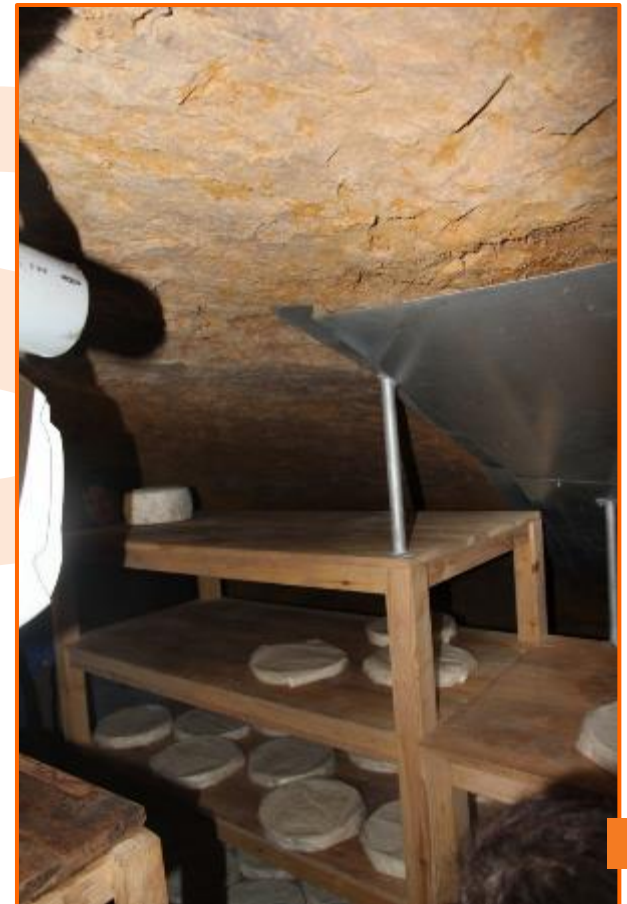
- *premises*
- *materials of instruments and equipment*

# PREMISES

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

- ✓ walls, ceilings and doors that are not smooth, impervious, non-absorbent or of corrosion resistant material
- ✓ natural geological walls, ceilings and floors

Art 7 Reg. 2074/05  
point 2 letter (a)



# WALLS CEILINGS DOORS

Rooms with  
tiles or porous  
natural stone in  
walls, ceilings  
and floor or  
other natural  
material in the  
floor



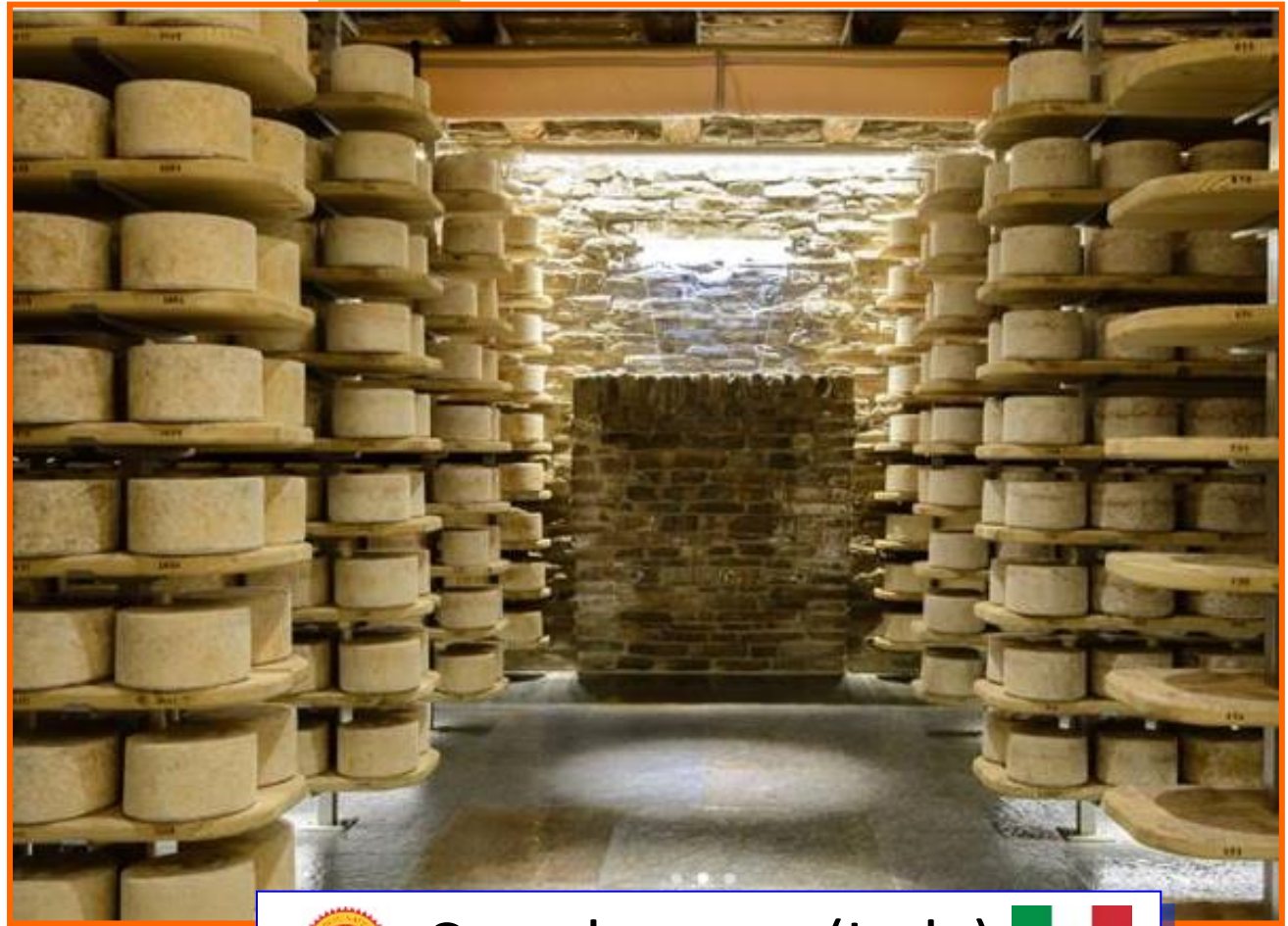
Abondance (France)





# WALLS CEILINGS DOORS

Stone cellars  
for ripening of  
milk products



Castelmagno (Italy) 



# WALLS CEILINGS DOORS

Natural caves  
for ripening of  
milk products



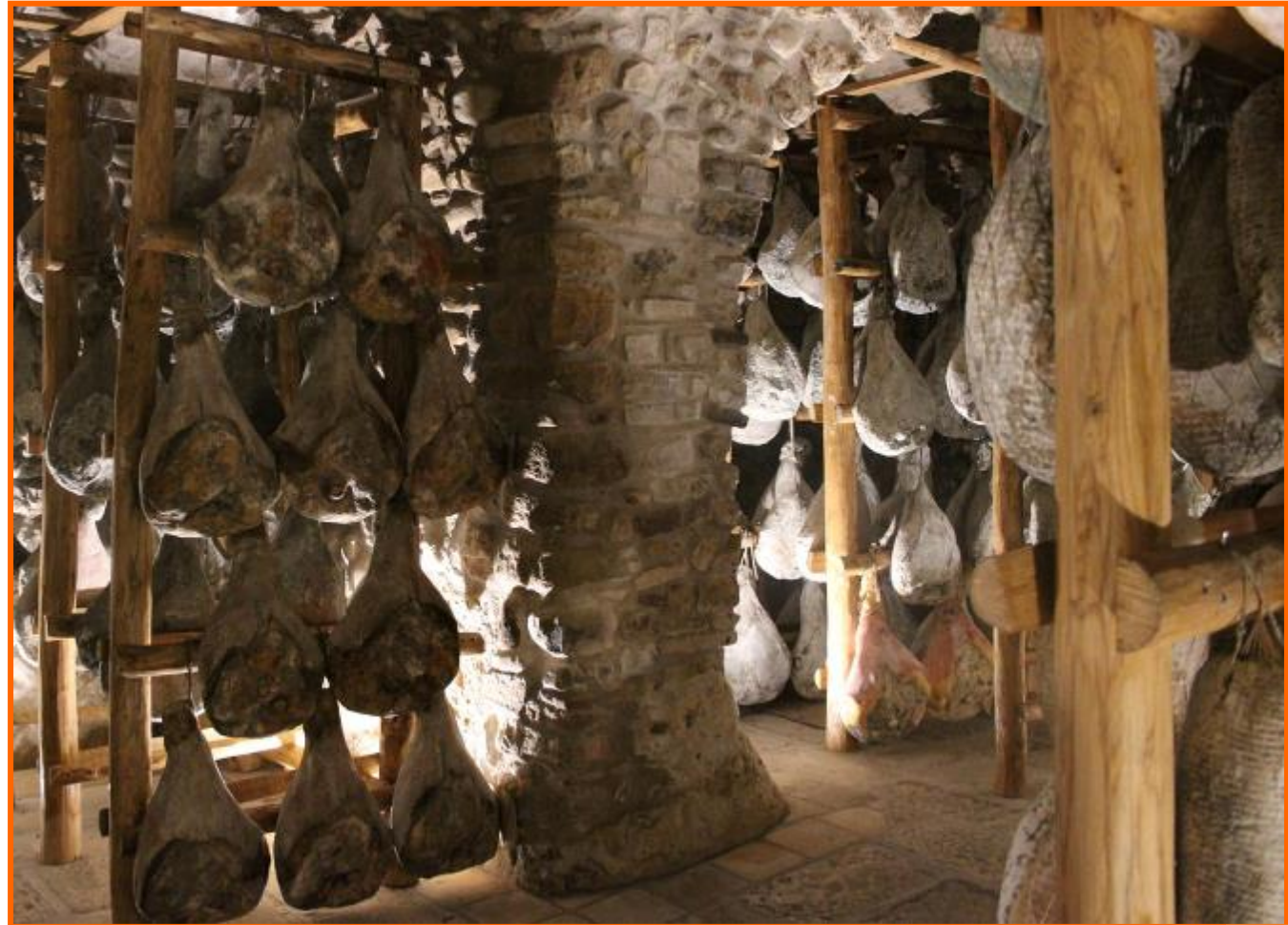
Picòs Bejes-Tresviso (Spain)





# WALLS CEILINGS DOORS

Natural  
caves or  
stone  
cellars for  
ripening  
(meat  
products)



Prosciutto di Trevico (Italy)



# TRADITIONAL PREMISES

- a) measures for cleaning and disinfecting*
- b) frequency with which they are carried out*

*shall be adapted to the specific ambient flora activity*



# TRADITIONAL PREMISES

- *Products complete their evolution during the ageing process*
- *Necessary to have a suitable environment taking in account the specific ambient flora*
- *These conditions aren't simply achievable in a cave or using wooden surfaces*
- *Products evolve through the microbial flora in part transmitted to the environment in which they are located*



# TRADITIONAL EQUIPMENT

Art 7 Reg. 2074/05  
point 2 letter (b)

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

- use of copper vats
- use of wooden equipment
- use of wrapping material made of natural fibers or other material of plant origin in the production, storage and wrapping of milk products

# TRADITIONAL EQUIPMENT

Equipment  
made of wood  
for smoking of  
naturally  
fermented raw  
sausages and  
raw smoked  
meat products



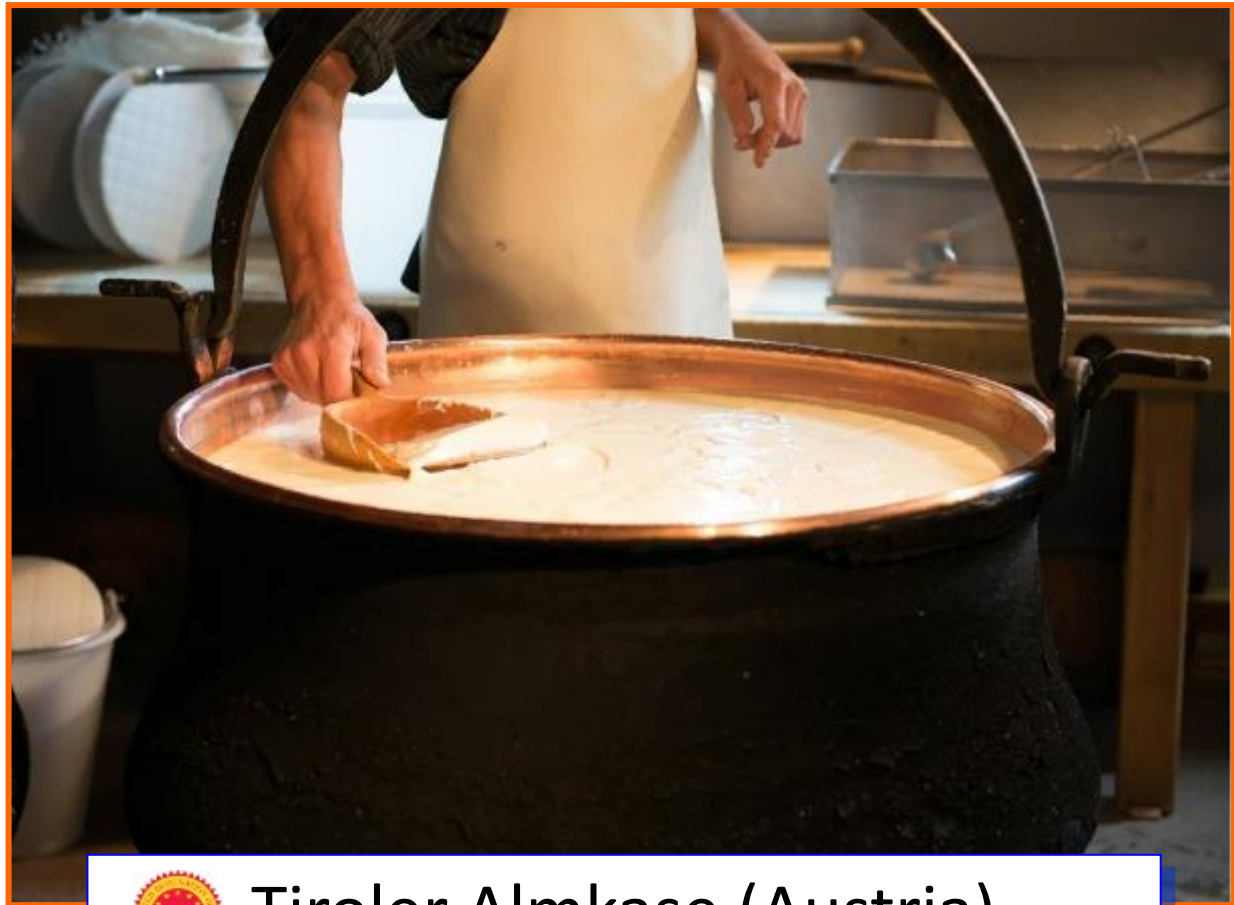
Gornooryahovski sudzhuk (Bulgaria)





# EQUIPMENT MATERIALS

Copper vats in  
cheese  
production



Tiroler Almkase (Austria)

# EQUIPMENT MATERIALS

Wooden  
equipment in  
cheese  
production



Mozzarella di bufala Campana (Italy)



# EQUIPMENT MATERIALS

Wooden  
equipment in  
cheese ripening



Paški sir (Croatia)





# EQUIPMENT MATERIALS

Wooden  
equipment  
(pasta  
production)



NATIONAL  
LAW

Pasta Caldes de Montbui (Spain)



121

# EQUIPMENT MATERIALS

Equipment  
made of straw  
(cheese  
production)

This photo is copyright protected and reproduction, modification and republication on any means are prohibited, even partially. However, it can be used for non-profit purposes provided that: 1) the watermark is not removed 2) the author and source are mentioned 3) a link to our home page is created (<http://www.archart.it>)



**Puglia**



**Campania**



**Sardegna**



**Sicilia**



Ricotta di fuscella (Italy)



# WRAPPING MATERIALS

Wrapping  
material  
made of  
natural  
fibers



Queijo Picante de Beira Baixa (Portugal)

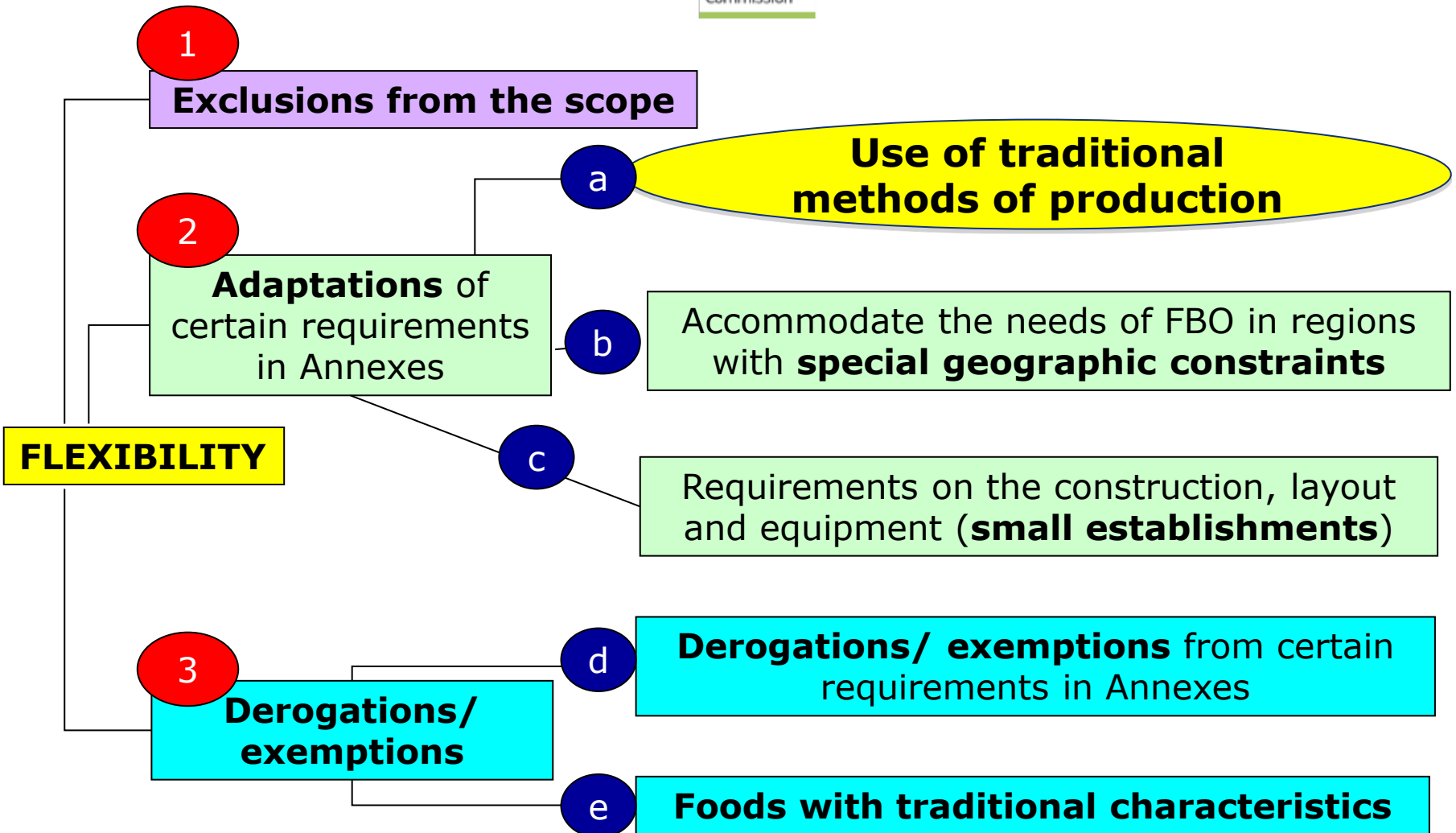




## CONCLUSIONS

- Flexibility is needed so traditional foods can continue to be produced
- The FHP provides flexibility for the production of traditional foods, limited to premises and equipment
- Traditional does NOT mean dirty
- Basic hygiene rules must be respected at ALL stages

# **FLEXIBILITY MEASURES TO ENABLE THE CONTINUED USE OF TRADITIONAL METHODS**



# FOOD HYGIENE PACKAGE

Flexibility shall have the aim  
of enabling the continued  
use of traditional methods,  
at any of the stages of  
production, processing or  
distribution of food



**Paragraph 4 (a)(i) of Article 13 of Regulation (EC) No 852/2004**  
**Paragraph 4 (a)(i) of Article 10 of Regulation (EC) No 853/2004**

# TRADITIONAL PRODUCTS AND TRADITIONAL METHODS

Whenever “tradition”  
is connected with  
premises (walls,  
doors, ceilings, floors)  
or material of  
equipment, flexibility  
shall refer to  
Regulation 2074





# TRADITIONAL PRODUCTS AND TRADITIONAL METHODS

*If the “tradition” is  
connected with other  
requirements and  
particularly with the  
process, flexibility  
applies for  
«traditional methods»*



# TRADITIONAL METHODS

Examples in the Guidelines on flexibility for the  
Competent Authorities

- Traditional dried reindeer meat (FI)
- Raw-dried meat products from minced and non-minced meat (BG)
- Immediate evisceration of poultry (FR)

# TRADITIONAL DRIED REINDEER MEAT



## “PORON KUIVALIHA”

- **Prepared outdoors** by hanging salted strips of meat in the open air, facing south (for sunshine)
- Solid floors, net walls keep birds and other animals away; no insect during the cold period
- Preparation is done during late winter (specific weather conditions), the drying process takes 1 – 1,5 months
- Temperature above freezing during the day, below-freezing at night and dry wind, sunlight ripens the meat

# TRADITIONAL DRIED REINDEER MEAT



- Need for flexibility concerning premises
- Flexibility is needed to allow a traditional method of production to continue, also a traditional product (Reg. 2074/05 art. 7)



# NOTIFICATION OF TRADITIONAL METHODS

## Traditional summer pasture

- Seasonal production of milk products using traditional methods in milk processing facilities on high mountains
- Milk processing facilities: in areas at least 750 meters above sea level producing milk for the purpose of milk products by means of seasonal pasture



2008/274/SI

**Finalised**





# NOTIFICATION OF TRADITIONAL METHODS

## SITUATION

- Traditional activities are carried out in simple rooms frequently made of timber
- Often there is no electricity, town water and drainage systems for waste water
- Products made from raw milk are often cooled and saved in milk containers submerged in cold water
- Most common products: cheeses that mature more than 60 days



# NOTIFICATION OF TRADITIONAL METHODS

## **Necessary to amend the requirements for:**

- plan, shape, structure, position and size of processing rooms
- toilets with a flushing system connected to a sewage system
- hot and cold running water for hand hygiene
- building materials for floors and walls, ceilings, windows, doors and other surfaces
- cleaning and disinfection aids and tool storage
- drinking water



# NOTIFICATION OF TRADITIONAL METHODS

- Milk products can be sold directly to the end consumer at the location of their production
- The operators shall provide evidence in their HACCP plans that they can ensure the safety of produced milk products using special or similar procedures set out in their own plans

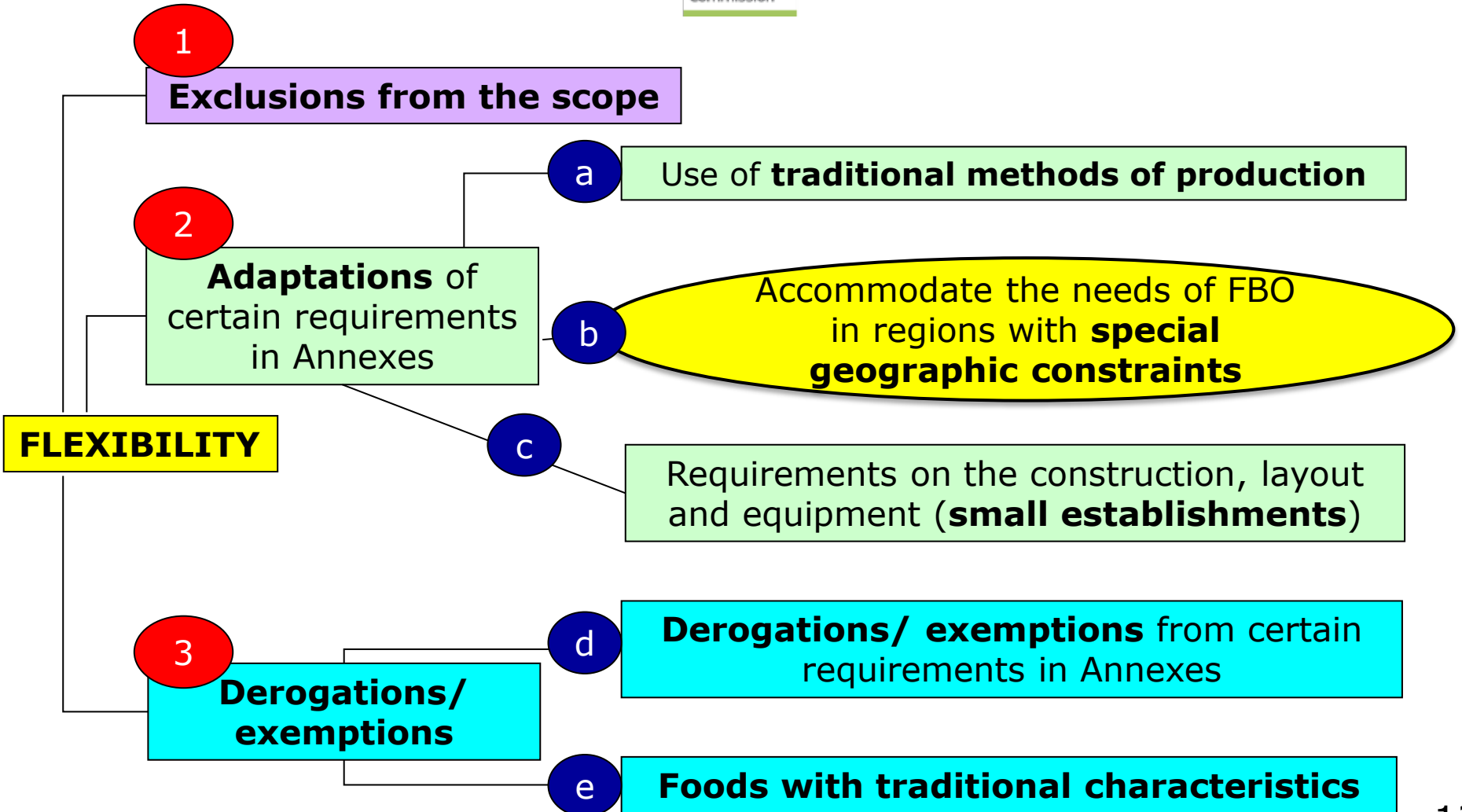




# SUMMARISING

- Different interpretation of the wording «traditional methods»
- According to the legal framework, for «traditional methods» adaptations are foreseen, not exemptions or derogations
- In some cases, confusion between “traditional food” and “traditional methods”
- In other cases, no distinction among different flexibility provisions (geographic constraints, small businesses)

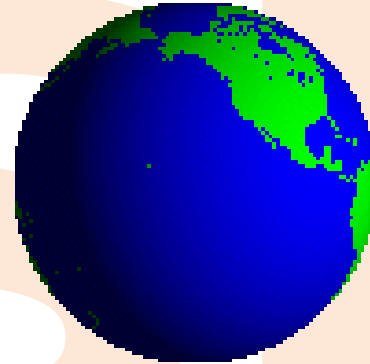
# **FLEXIBILITY MEASURES TO ACCOMMODATE THE NEEDS OF FOOD BUSINESSES SITUATED IN REGIONS THAT ARE SUBJECT TO SPECIAL GEOGRAPHIC CONSTRAINTS**



# REGIONS/AREAS SUBJECT TO SPECIAL GEOGRAPHIC CONSTRAINTS

## LOCATED

- in small isles
- in mountain areas
- in areas with poor logistic infrastructures
- mostly supplying local market



## SMALL ISLES

- Geographical distribution and the size of certain Greek islands
- Small number of animals intended for slaughter on these islands
- Difficulties to transfer these animals to other locations with approved slaughterhouses



# MOUNTAIN AREAS

**Reg. 1151/2012 – Art. 31**

**Reg. 1257/99/CE - Art. 18**

a) Areas characterised by **limitation of the possibilities for using the land** and an appreciable increase in the cost of working it, because:

- HIGHER ALTITUDE - very difficult climatic conditions that shorten the growing season
- LOWER ALTITUDE - presence of slopes too steep for the use of machinery

b) Areas north of the **62nd Parallel** and certain adjacent areas shall be treated in the same way as mountain areas



# LESS-FAVOURABLE AREAS

## Reg. 1257/99/CE - Art. 19



Areas, that could be be considered also as mountains areas, characterized by:

- poor productivity
- difficult cultivation
- limited potential
- productivity appreciably lower than the average
- need to preserve the countryside
- in danger of abandonment
- with low or dwindling population
- with possible reduction of the population living








# LESS-FAVOURLED AREAS


## **Reg. 1257/99/CE - Art. 20**

May include other areas affected by specific handicaps in which farming should be continued in order to:

- ✓ conserve or improve the environment
- ✓ maintain the countryside
- ✓ preserve tourist potential of the area
- ✓ protect the coastline



	LEGAL ACT	LAYOUT, DESIGN, CONSTRUCTION SITING AND SIZE OF FOOD PREMISES	FLOOR, WALL, CEILING, WINDOWS, DOORS, SURFACES (INCLUDING EQUIPMENT)	TOILETS	WASHBASIN WITH HOT AND COLD RUNNING WATER	DRAINAGE FACILITIES, WASTE WATER DISCHARGE SYSTEM
	Erste Verordnung 08/05/2010	X	X		X	X
	Rozporządzenie 910 07/07/2010		X		X	X
	Uradni list RS, št. 3/2009 – 16/01/2009	X	X		X	
	DGAL/SDSSA/N201 1-8239 ; Arrêté 7/11/2012	X	X	X	X	X
	Several regional laws	X	X	X	X	X
	Reg. 22/05/2007 Reg. 21/05/2013	X	X		X	X
		X	X		X	X

	FACILITIES FOR WASHING FOODSTUFFS SEPARATED FROM WASHBASINS	AVAILABILITY OF POTABLE WATER	TCP AND SCC RAW MILK CHECK	RESPECT TCP AND SCC RAW MILK CRITERIA	MEASURES
	X	X	X	X	HARD OR SEMI-HARD CHEESES RIPENING MORE THAN 60 DAYS
	X		X		
	X	X			DIRECT SALE TO FINAL CONSUMERS
	X	X	X		
	X	X	X	X	TRADITIONAL PRODUCTS
	X	X	X	X	DIRECT SALE TO FINAL CONSUMERS AND HARD OR SEMI-HARD CHEESES RIPENING MORE THAN 60 DAYS
	X		X		

# MOUNTAIN AREAS - FLEXIBILITY MEASURES

## Milking equipment and premises

- Containers and equipment drying must be done in a protected area and protected from dust



# MOUNTAIN AREAS - FLEXIBILITY MEASURES

## **Walls, ceilings and doors**

- Walls, ceilings and doors that are not in smooth materials, waterproof, non-absorbent and resistant to corrosion
- Walls, ceilings and natural soils of geological origin
- Use of concrete as floor (tiles recommended)



# PREMISES AND MINIMUM STRUCTURAL REQUIREMENTS

PREMISES	NEW BUILDING	OLD BUILDING (RENOVATED)	ACCESSORY PREMISES
Milking area or room	YES	YES	YES
Milk storage room	YES	AREA	AREA
Processing room	YES	YES	YES
Ripening room	YES	AREA	NO
Toilet	YES	YES	NO
Changing facilities	YES	AREA	AREA

# MOUNTAIN AREAS FLEXIBILITY MEASURES

## Washing facilities

- Time-separated use of facilities for washing hands and washing foodstuffs and prevention of adverse effects on foodstuffs





# MOUNTAIN AREAS FLEXIBILITY MEASURES

## **Material, equipment**

- Wooden or copper curdling or maturation tanks
- Wooden churns or kneading cuvelles (cuvelles de malaxage)
- Wooden seasoning boards, draining desk, containment or decurdling wood



# MOUNTAIN AREAS FLEXIBILITY MEASURES

## Material, equipment

- Utensils made of wood, cane, copper or brass
- Wooden molds, circles, boxes or wooden boxes
- Straw, plant straw, reeds, raffia, vegetable leaves





# MOUNTAIN AREAS FLEXIBILITY MEASURES

## Changing facilities and flush lavatories

- Possibility to have only an area for changing clothes
- In case of buildings subject to particular constraints, and in family business (no employee): possibility to use home flush lavatories if they are located in the immediate neighbourhood



# MOUNTAIN AREAS - FLEXIBILITY MEASURES

## Water supply

- Premises located in mountains areas seldom equipped with connection to the public water supply
- Water supply finalized at cleaning of premises and equipment or at cooling the milk in sealed containers



# MOUNTAIN AREAS - FLEXIBILITY MEASURES

## Raw milk criteria

Impossibility to guarantee, on time and with the appropriate delivery method, the analysis of milk samples taken in mountainous areas (difficult to reach)



# MOUNTAIN AREAS - FLEXIBILITY MEASURES

## Raw milk criteria

1. Milk can be processed for a specific period (summer pasture) without checking raw milk criteria (TPC/SCC)
2. TPC cannot be checked and SCC could be checked using alternative system (CMT test)
3. Milk is considered to fulfil criteria of Reg. 853/04 on the basis of the result of a test on a single sample of raw milk



# CONCLUSIONS

- Food businesses situated in regions that are subject to special geographical constraints need to have a certain degree of flexibility
- Member States have adopted similar provisions in similar contexts (mountain areas)
- Flexibility provisions allowed the protection of our cultural heritage and avoided depopulation in specific areas

# **ASSESSMENT OF THE IMPLEMENTATION OF FLEXIBILITY PROVISIONS BY COMPETENT AUTHORITIES**

# THE SYMMETRY OF THE FHP

Proportionality and Flexibility are principles governing Official Controls' organization and implementation:

-*"The frequency of official controls should be regular and proportionate to the risk"*(°)

as well as enforcement measures to be taken in case a non conformity is identified:

-*"The sanctions provided for must be effective, proportionate and dissuasive"* (\*)

(°) Reg. 882/04, 13<sup>th</sup> whereas

(\*) Reg. 882/04, art. 55

# BEST PRACTICES: FROM THE DG SANCO REPORT 2010-6150

*When carrying out  
Official Control activities,  
Competent Authority  
shall be fully aware of  
flexibility adopted in the  
company and relevant  
legal framework*





# BEST PRACTICES FOR OFFICIAL CONTROL AND FLEXIBILITY

- Official Control shall be carried out against requirements of the FHP as adapted according to National provisions



# BEST PRACTICES FOR OFFICIAL CONTROL AND FLEXIBILITY

## ***Record-keeping***

- When carrying out Official Control activities, records should be kept of specific flexibility provisions applied in the food business
- Use of a specific check list or adapted check lists is suggested



# BEST PRACTICES FOR OFFICIAL CONTROL AND FLEXIBILITY

## ***KEY QUESTIONS***

- Are specific conditions established in the legislation respected?
- Are flexibility provisions compromising the achievement of objectives of the Regulations?
- Are adequate procedures adopted by the FBO in the own-check plan to ensure the achievement of objectives of the Hygiene Regulations?
- Is the FBO following a Guidelines/ Guide to GHP/ Generic HACCP guide?

# BEST PRACTICES FOR OFFICIAL CONTROL AND FLEXIBILITY

## ***FBO producing traditional foods***

- Experimental trials should be conducted to collect evidences leading to processes' and products' standardisation
- This information is essential to demonstrate the objectives' achievement and shall be taken into consideration in the framework of Official Controls



# BEST PRACTICES FOR OFFICIAL CONTROL AND FLEXIBILITY: OWN-CHECK AND HACCP

Regulatory assessment should be carried out taking into account the means that have been chosen by food businesses for ensuring compliance with the HACCP requirement

- using prerequisite programs only
  - ✓ correct implementation of these requirements has to be verified
- using Guides to good practice for hygiene and for the application of HACCP principles
  - ✓ assessment against the used guides

# GUIDES TO GOOD PRACTICE AND OFFICIAL CONTROLS

- CAs shall take into consideration the procedures and systems laid down in Guides to manage pre-requisite programmes and HACCP principles
- CAs shall focus on the implementation and on the possible adaptations of the Guides to the actual situation





# OBJECTIVES OF THE REGULATIONS

- To secure a high level of consumer protection with regard to food safety
- To ensure the proper functioning of the internal market

# ACHIEVEMENT OF THE OBJECTIVES OF THE REGULATIONS

## ***Food safety objectives***

- Provide justifications and demonstration that measures will not affect safety of food products and consequently consumer health



# EU FHP: IMPORTANCE OF OWN-CHECK

EU FHP: objective oriented legislation

How to demonstrate compliance and achievement of objectives?

***Through the own-check plan***

Manual may help FBOs in deciding whether the adopted solution is “appropriate, adequate or sufficient”

# ACHIEVEMENT OF THE OBJECTIVES OF THE REGULATIONS

## Examples

- Evidences that the adopted derogation/ adaptation do not compromise the achievement of the Food Law objectives
- Demonstration that products processed in such a way are safe and wholesome
- Studies carried out on products and production processes

# DOCUMENTATION IN THE ESTABLISHMENTS

DG(SANCO)/2010-6150 REPORT

*The documentation of the application of flexibility measures in individual establishments did not in all cases allow for verification on-the spot*

BEST PRACTICE: The national measures that are availed of should be documented in the approval/official file of the establishment

# DOCUMENTATION: BEST PRACTICE

## **Derogation granted to individual establishment**

*Documentation on the flexibility measures granted to the establishment should be included in the approval document or in an attachment*

Statements on the approval document :

- reference to the relevant national legislation
- declaration on specific derogations/adaptations granted to the individual establishment

# DOCUMENTATION: BEST PRACTICE

**Derogation granted to a «category» of establishments (i.e. small slaughterhouses, cutting plants etc.)**

Documentation on the flexibility measures granted should be available in the establishment, i.e.

National guidelines or Law or Order, and a reference should be included in the approval file

# DOCUMENTATION: BEST PRACTICE

Reference should be available in the approval document or in attached file to the derogation/adaptation granted for:

- special geographic constraints
- foods with traditional characteristics
- traditional methods of production
- small businesses

# CONCLUSIONS

- Flexibility provisions foreseen for the FBO should be mirrored by flexibility in Official Control
- In Official Control, account should be taken of the approach chosen by FBO to comply with hygiene requirements
- When adopting flexibility for official control, achievement of objectives of the Regulations should always be considered

# **NATIONAL MEASURES AND NOTIFICATION PROCESS - THE NOTIFICATIONS IN THE TRIS DATABASE**

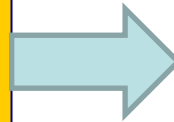


# MAIN PRINCIPLES

- The internal market comprises an area without internal frontiers (free movement of goods)
- For the smooth functioning of the internal market, transparency should be ensured as regards national initiatives for the establishment of technical regulations
- Notification procedures provide a certain level of "harmonisation" of rules at EU level

A

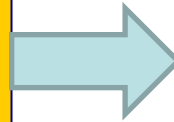
- DEROGATIONS/  
EXEMPTIONS  
FROM ANNEXES
- EXCLUSIONS



*Notification according  
Directive 2015/1535  
(98/34/EC)*

B

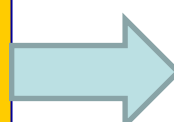
- ADAPTATIONS OF  
ANNEXES



*Notification according  
the Hygiene Package*

C

- TRADITIONAL  
FOODS



*Simplified notification  
procedure*

<p><i>Notification procedure in accordance with Directive 2015/1535 (98/34/EC)</i></p>	<p><i>Notification procedure in accordance with the Hygiene Package</i></p>
<p>DEROGATIONS, EXEMPTIONS EXCLUSIONS</p>	<p>ADAPTATIONS</p>
<ul style="list-style-type: none"> <li>• <u>All drafts national measures</u> with the aim of laying down technical measures or specifications are covered</li> <li>• Member States notifying the draft national measures must send the draft via their national contact point to the <u>Commission</u></li> <li>• Managed by DG GROW, the translations are dealt with by DG GROW</li> <li>• Managed by TRIS system, a software used by the Member States and the Commission to transmit the draft measures</li> </ul>	<ul style="list-style-type: none"> <li>• <u>Only</u> National measures adapting the requirements of the <u>Food Hygiene Package</u> are covered</li> <li>• Member States notifying the draft national measures must send the draft to the <u>Commission and other Member States</u></li> <li>• The translations are dealt with by the Member States notifying the draft</li> </ul>

C

## NOTIFICATION PROCEDURE FOR TRADITIONAL FOODS

Simplified notification procedure:  
simple information

- When? no later than 12 months after granting individual or general derogations: notify the Commission and the other Member States
- Neither a standstill period nor comments from other Member States and the Commission are applicable



# C NOTIFICATION PROCEDURE FOR TRADITIONAL FOODS

## Notification

- derogations granted
- description of the requirements adapted
- foodstuffs and establishments concerned



# NOTIFICATION: HAZARD ANALYSIS IN CASE OF

- ✓ *Traditional methods of production*
- ✓ *Regions with geographical constraints*
- ✓ *Layout and equipment of establishments*

# HOW TO FIND NOTIFICATIONS

<http://ec.europa.eu/growth/tools-databases/tris/en/search/>



The screenshot shows the TRIS website interface. At the top, there's a header with the European Commission logo and the word "GROWTH" in large blue letters, followed by the subtitle "Internal Market, Industry, Entrepreneurship and SMEs". Below this is a navigation bar with the breadcrumb "European Commission > Growth > Single Market and Standards > Tools and Databases > TRIS". A row of social media icons (Twitter, Facebook, Google+, YouTube, RSS) is followed by a menu with five items: "Single Market and Standards" (highlighted), "Industry", "Entrepreneur and SMEs", "Access to finance for SMEs", and "Sectors".

The main content area is titled "Prevention of technical barriers to trade". It features a video player with a red play button. Below the video, the text reads: "Don't let barriers stop your success".

The left sidebar contains a "TRIS" section with links: "About the 2015/1535", "The 2015/1535 and You", "Search the database", "FAQ", and "Contact". Below this is a "Single Market and Standards - links" section with links for "News", "Events", "Tools and Databases", "Contracts and grants", "Public consultations", and "Publications".

The main text below the video explains the importance of business success and the role of the TRIS system in preventing technical barriers. It states that the (EU) 2015/1535 procedure aims to prevent creating barriers in the internal market before they materialize. Member States notify their legislative projects regarding products and Information Society services to the Commission, which analyses these projects in the light of EU legislation. Member States participate on the equal foot with the Commission in this procedure and they can also issue their opinions on the notified drafts.

The Technical Regulation Information System:

- helps you to be informed about new draft technical regulations and
- allows you to participate in the 2015/1535 procedure.

# INTRODUCTION

- An analysis of the notification available on the TRIS system has been carried out
- 145 notifications have been taken in consideration in the first phase; further new notifications analysed in the second phase (total: **181**)
- Trends have been analysed:
  - ✓ year of notification
  - ✓ notifying MS
  - ✓ foodstuffs concerned
  - ✓ subject of flexibility



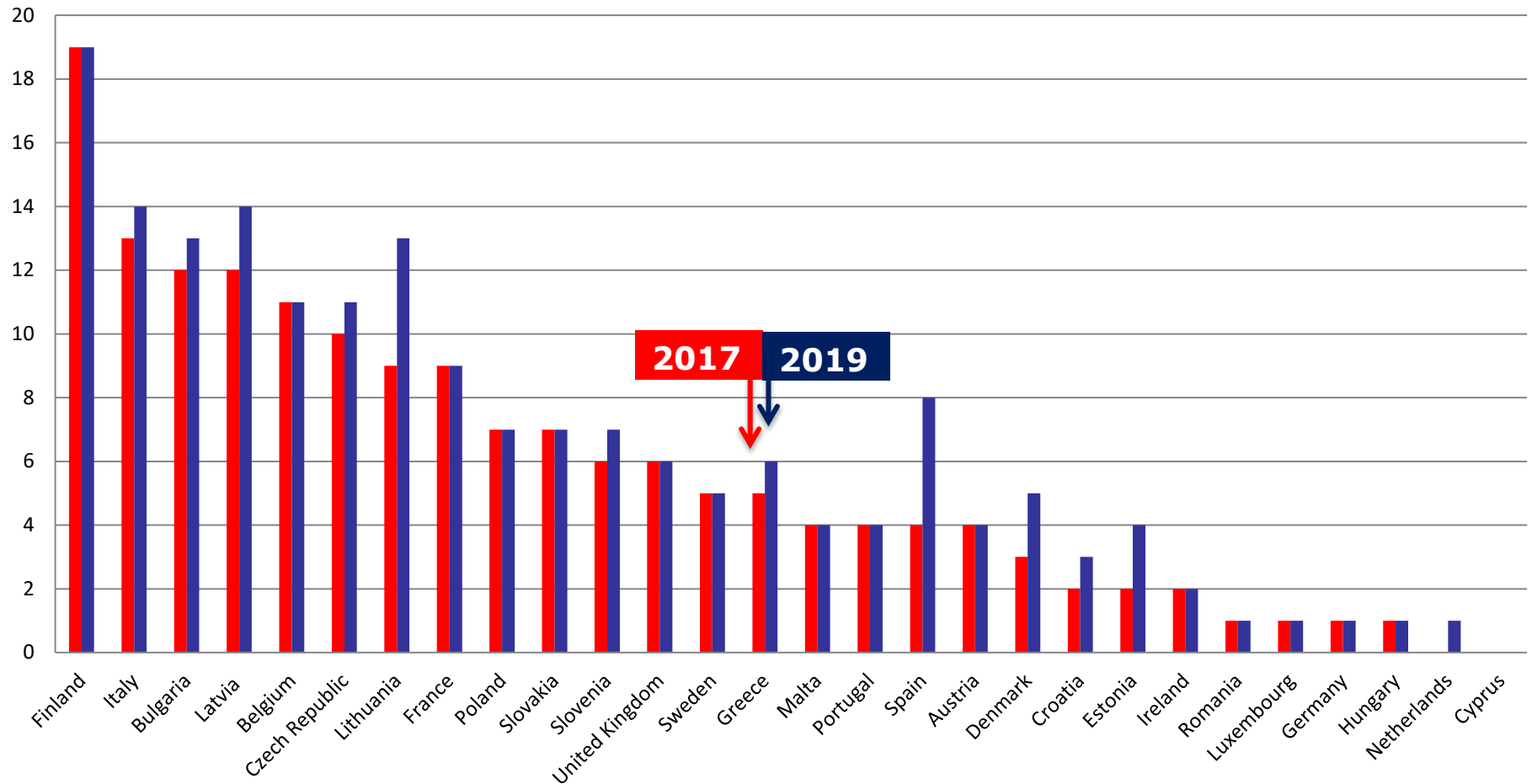
## TO BE CONSIDERED

- It is not always easy to search for information in the TRIS database
- The database includes national measures regarding products and Information Society services
- Research in the database has to be done using key words (i.e. «food safety», «HACCP» etc.)
- Some notifications might not be retrievable
- Adaptations are not always in the Tris database

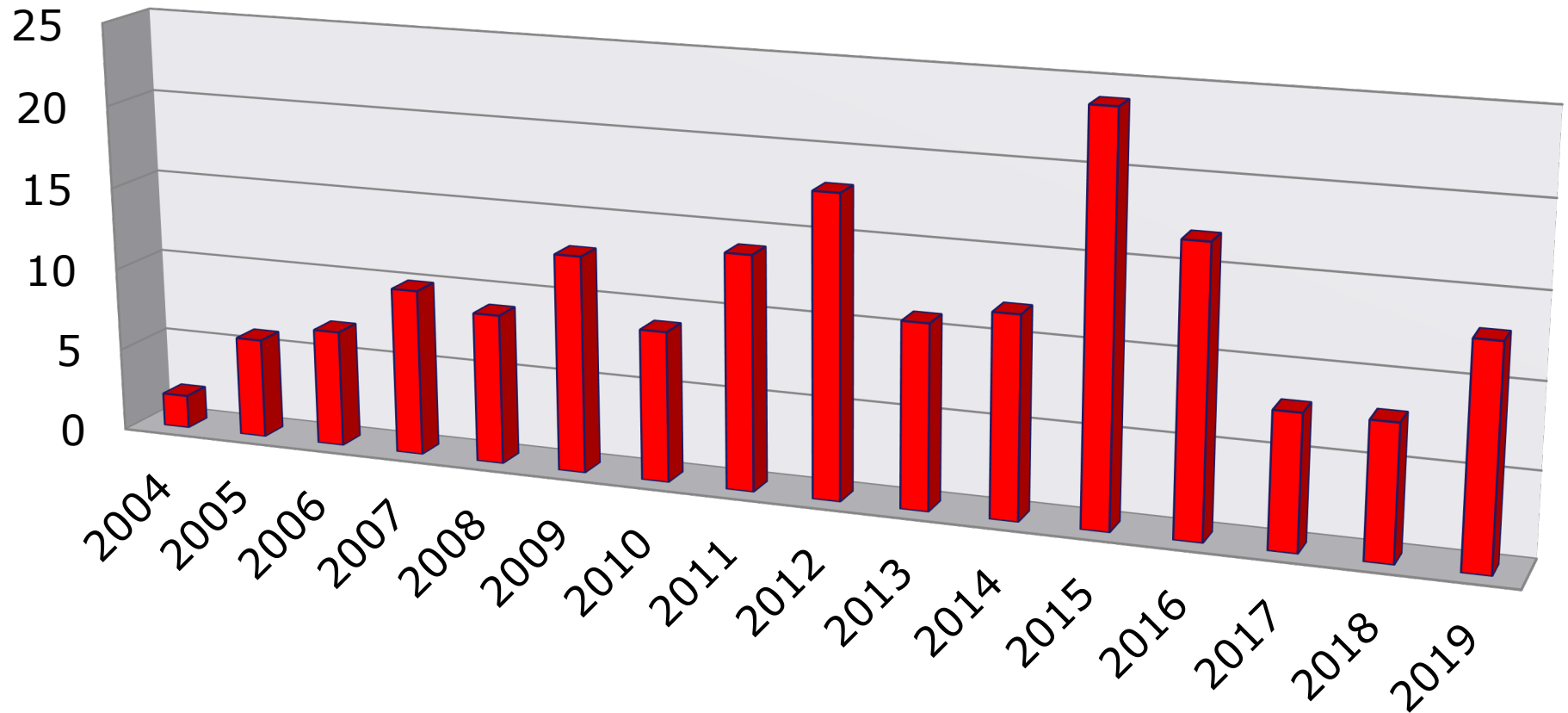
## TO BE CONSIDERED

- After receiving comments, the draft of the legal act might be changed, or the notification withdrawn
- Some notifications are amending previously finalised notifications
- Some others are making specific reference to National legal acts, and therefore are not understandable

# NOTIFICATIONS IN 2004 – 2019 COUNTRY DISTRIBUTION

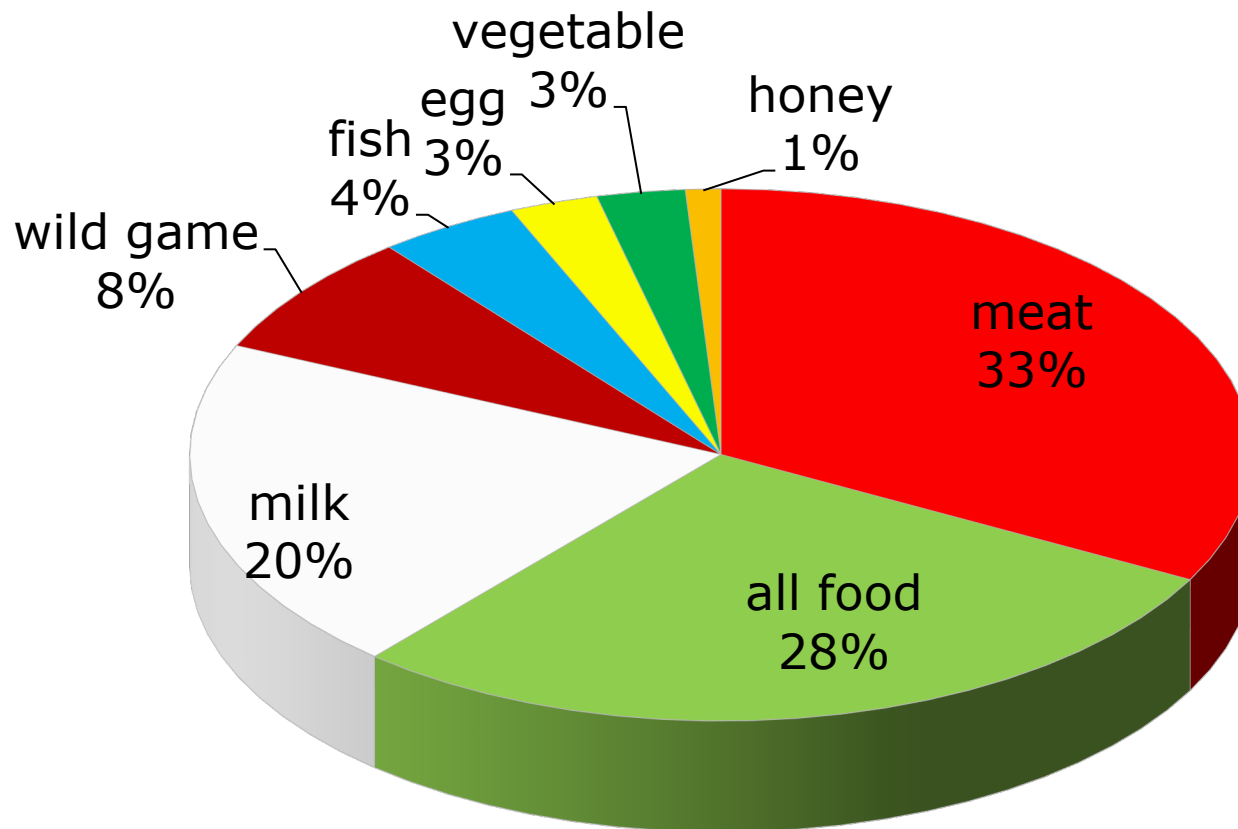


# NOTIFICATIONS IN 2004 – 2019



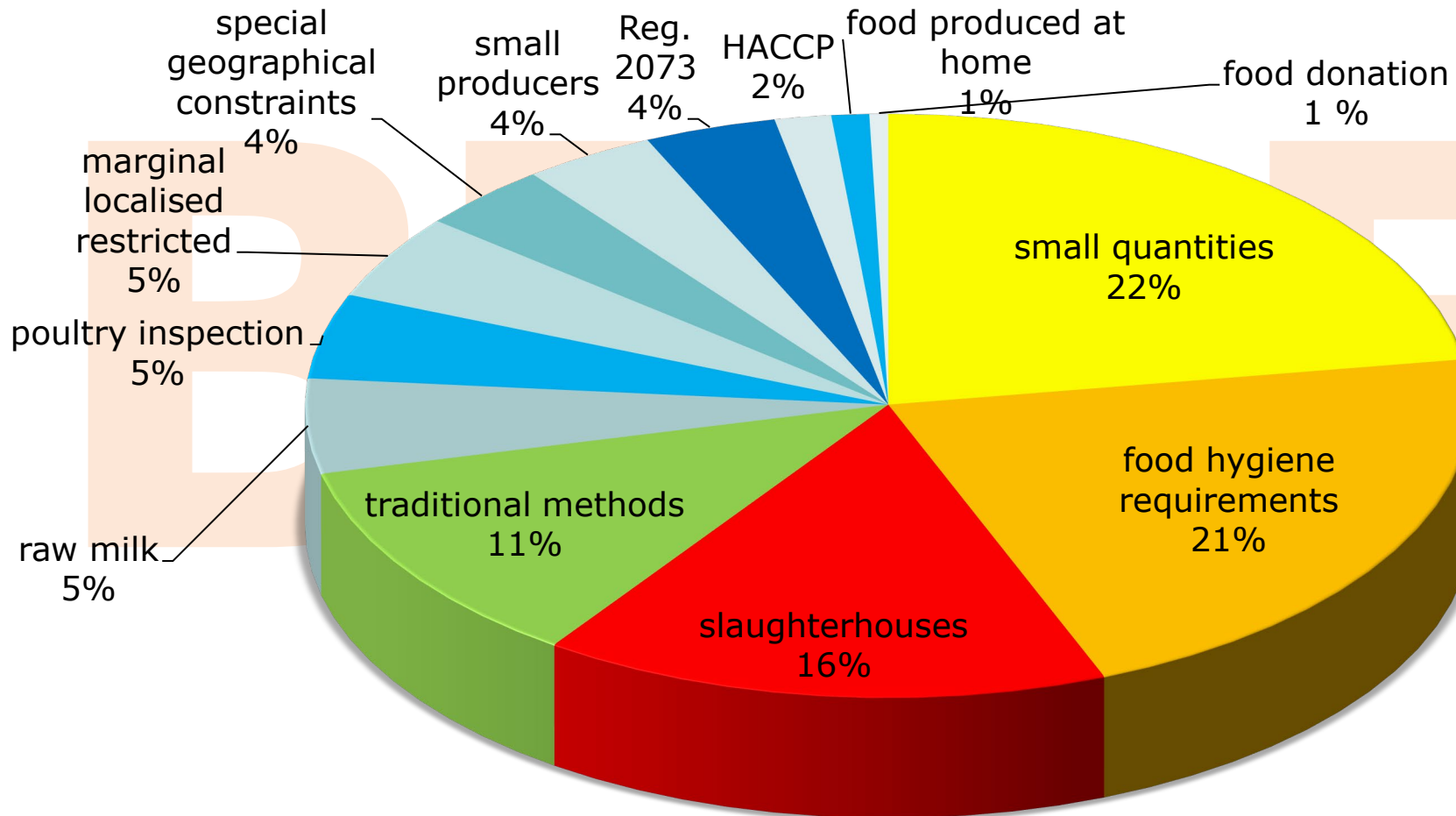
# NOTIFICATIONS IN 2004 – 2019

## FOODSTUFFS DISTRIBUTION

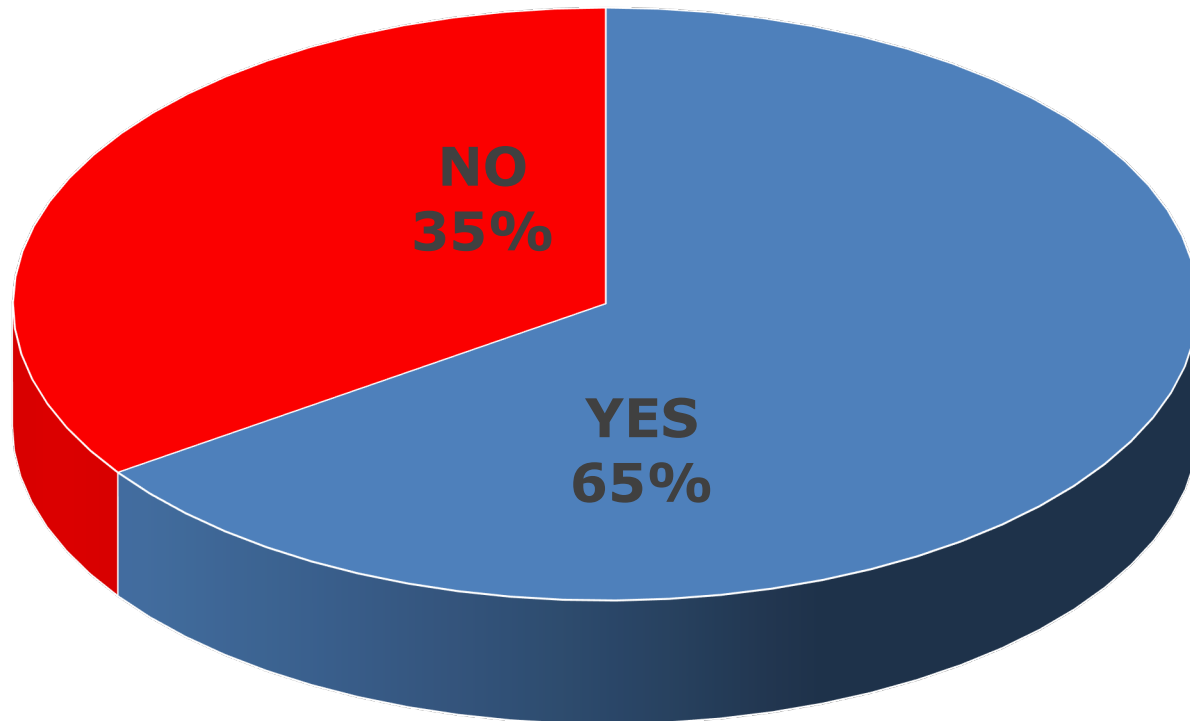




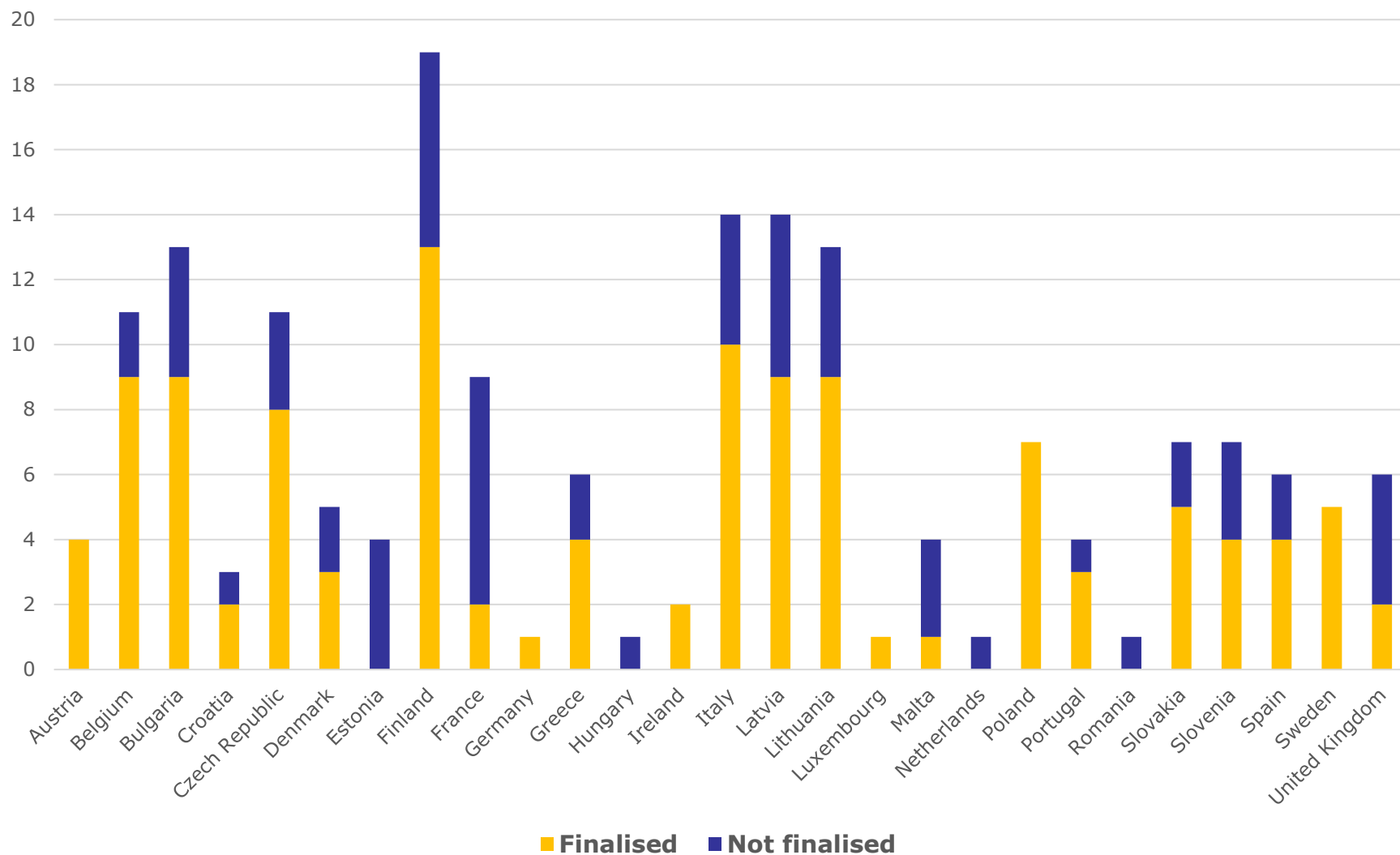
# NOTIFICATIONS IN 2004 – 2019



# FINALISED NOTIFICATIONS 2004 – 2019



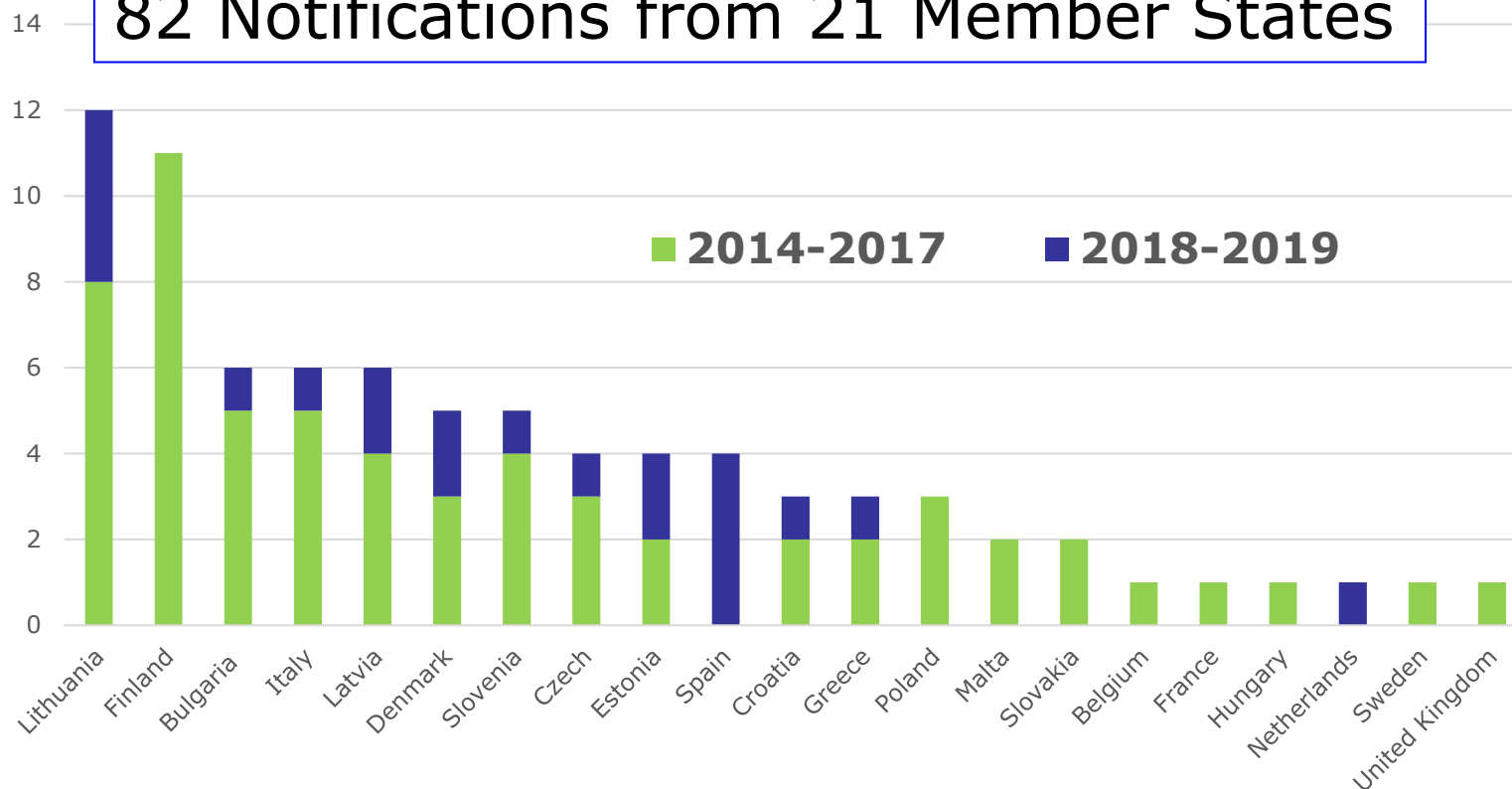
# FINALISED NOTIFICATIONS 2004 – 2019





# NOTIFICATIONS IN 2014 - 2019

82 Notifications from 21 Member States



# CONCLUSIONS

## The Food Hygiene Package offers several possibilities for flexibility

- traditional methods
- traditional foods
- small businesses
- geographical constraints
- HACCP
- microbiological criteria



## WE CAN CONCLUDE THAT...

- ...FHP provides sufficient platform for flexibilities
- ...flexibility shall be encouraged
- ...in most of the cases, flexibility implementation has no impact on food safety
- ...safety rules included in the food hygiene package must always be respected



Unless otherwise noted the reuse of this presentation is not authorised. For any use or reproduction of elements that are owned by the EU, permission may need to be sought directly from the respective right holders. All statements and references in this presentation come from of the Training coordinator and tutors and do not represent the official position of the European Commission.

**Opera S.r.l.**

# QUESTIONS?

Viale Parioli 96 - 00197 Roma - Italy  
Tel +39 06 8080111  
info@opera-italy.eu; [www.btsftraining.com](http://www.btsftraining.com);  
[www.opera-italy.eu](http://www.opera-italy.eu)

## Better Training for Safer Food BTSF

- *European Commission  
European Health and Digital Executive Agency  
Covent Garden Building*
- *Place Charles Rogier, 16*
- *B-1210 Brussels - Belgium*