

Process: food safety law in action

EU Food Law – Renmin 26 March 2017

Bernd van der Meulen



WAGENINGEN UNIVERSITY
WAGENINGEN **UR**



European Institute for Food Law
European Institute for Food Law

Overview

- Background / Food Safety in General
- Prevention
 - FBOs: Hygiene
 - Hygiene 1
 - Hygiene 2/4 food of animal origin
 - Hygiene feed
- Preparedness
 - FBOs: Traceability
- Response → repetition from lecture on enforcement
 - FBOs: recall
 - MS: enforcement & controls (Hygiene 3)
 - EU: emergency measures



Some tools

■ Sources

- Hygiene 1 (852/2004)
- Hygiene 2 (853/2004)
- Hygiene 3 (854/2004)
- Hygiene Feed (183/2005)
- Official controls (882/2004)
- ECJ 6-10-11 C-382/10

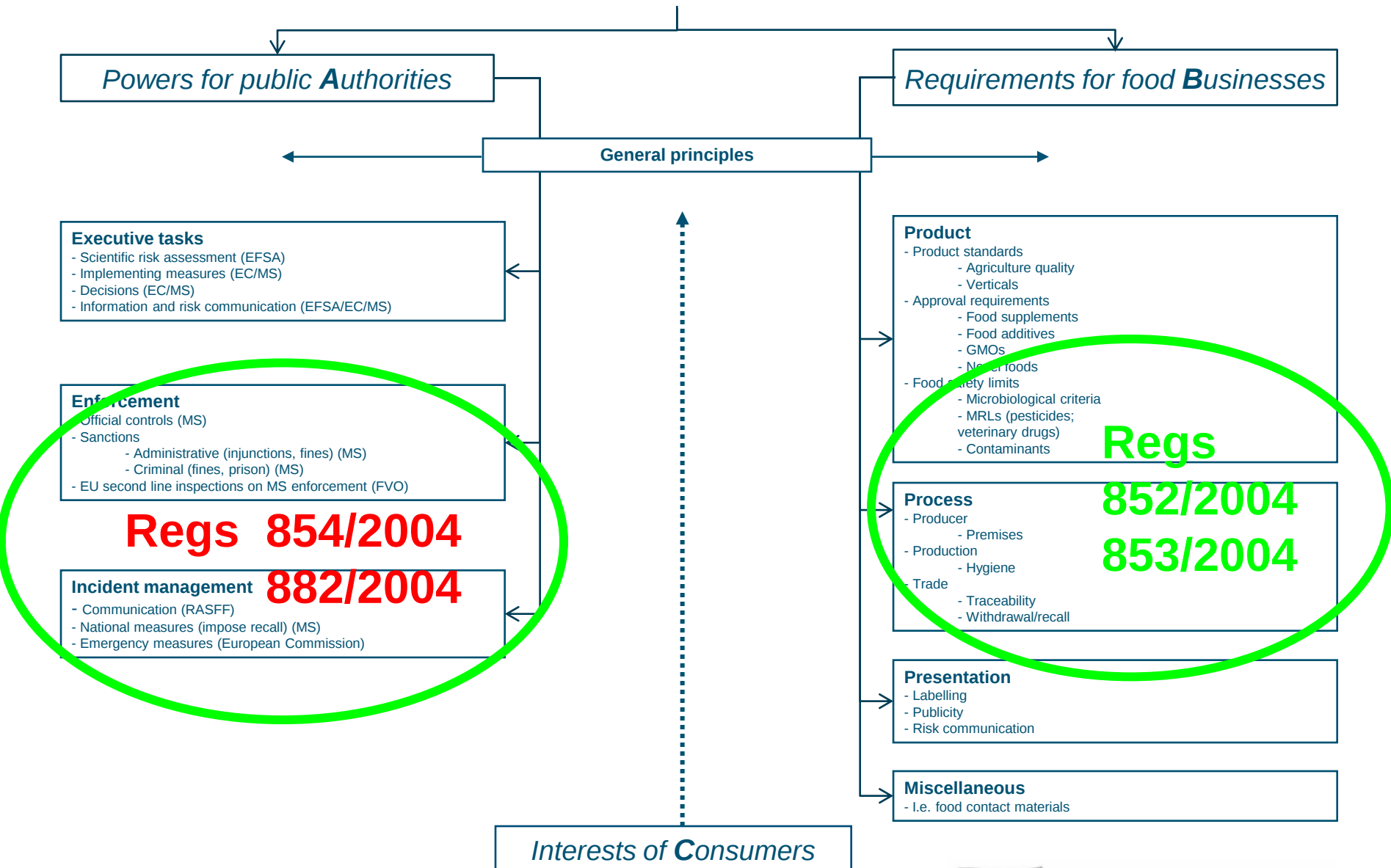


■ Literature

- Bernd van der Meulen, Is current EU food safety law geared up for fighting food fraud?
<http://link.springer.com/article/10.1007/s00003-015-0992-2>



Framework of analysis for European Food Law



Regulation 178/2002 (GFL)

■ Definitions

- Food
- Food business operator

■ General ban on unsafe food: Article 14

- General sanction on non-compliance with food safety law → food may not be brought to the market

■ Principles

- Holism: feed & food from farm to fork
- Apply international standards → Codex Alimentarius
- Business is responsible for food safety → performance standards / process standards
- Member States responsible for enforcement



Food safety risks

- Article 3(9/14) GFL:

9. 'risk' means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;

14. 'hazard' means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;



Risk management: responsibilities

- Article 6: risk management is based on scientific risk assessment
- Article 17(1) GFL: FBOs responsible for food safety
 - Prevention: hygiene
 - Preparedness: traceability
 - Response: recall
- Article 17(2) GFL: MS responsible for controls & enforcement
- Article 53 GFL: emergency measures by the European Commission



1) Prevention - Food hygiene

'hygiene', means the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use

- **Achieve Article 14 GFL**
- **Achieve food safety objectives**
- Regulation 852/2004 Article 2(1)(a)
Definitions



Biological Safety: Food Hygiene

http://ec.europa.eu/food/safety_en

http://ec.europa.eu/food/safety/biosafety/food_hygiene_en

European Commission > Food Safety > Food > Biological safety > Food Hygiene

 **HEALTH** **FOOD** **ANIMALS** **PLANTS** **AMR**

BIOLOGICAL SAFETY

- Antimicrobial Resistance
- Crisis Preparedness & Management
- Food Hygiene**
- Legislation
- Guidance
- Microbiological Criteria
- Approved EU food establishments
- Approved Third Country food establishments
- Feed Hygiene
- Food-borne diseases (Zoonoses)
- Food Irradiation
- EU Reference Laboratories

Food Hygiene

Rules on hygiene of foodstuffs were adopted in April **2004** by the European Parliament and the Council (Regulation (EC) No [852/2004](#), [853/2004](#) and [854/2004](#)). They became **applicable on 1 January 2006**.

In order to explain to everyone concerned, the approach that has been taken on the hygiene of foodstuffs since 1 January 2006, the Commission published an online **magazine FOOD Hygiene & Safety** that explains and documents the rules.

The 2004 rules **merged, harmonised and simplified** detailed and complex **hygiene requirements** previously contained in a number of Council Directives covering the hygiene of foodstuffs and the production and placing on the market of products of animal origin.

The rules in place since 2006 innovate in making a **single, transparent hygiene policy** applicable to all food and all food operators right through the food chain ('from farm to fork'), together with effective instruments to manage food safety and any future food crises throughout the food chain.

This Commission report (2009) recounts the experience gained, including the difficulties encountered (in 2006, 2007 and 2008) from the implementation of the hygiene package by all interested actors. It does not suggest any detailed solutions to the difficulties reported and is, therefore, not accompanied by proposals.

The report is accompanied by a [Staff Working Document](#) where annexes referred to in the report can be found.

The hygiene rules include flexibility for certain establishments e.g. micro-enterprises explained in the following document:

 [Share](#)

RELATED LINKS

-  [Food Hygiene related press releases](#)

QUICK LINKS

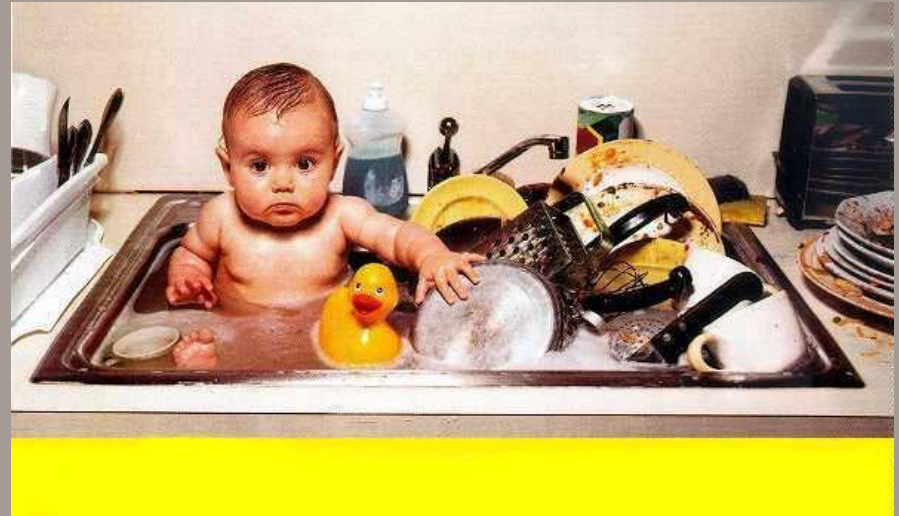
-  Rapid Alert for Food and Feed (RASFF)
-  Health and food audits and analysis
-  European Food Safety Authority (EFSA)
-  Better Training for Safer Food (BTSF)
-  E-News
-  Events
-  Videos



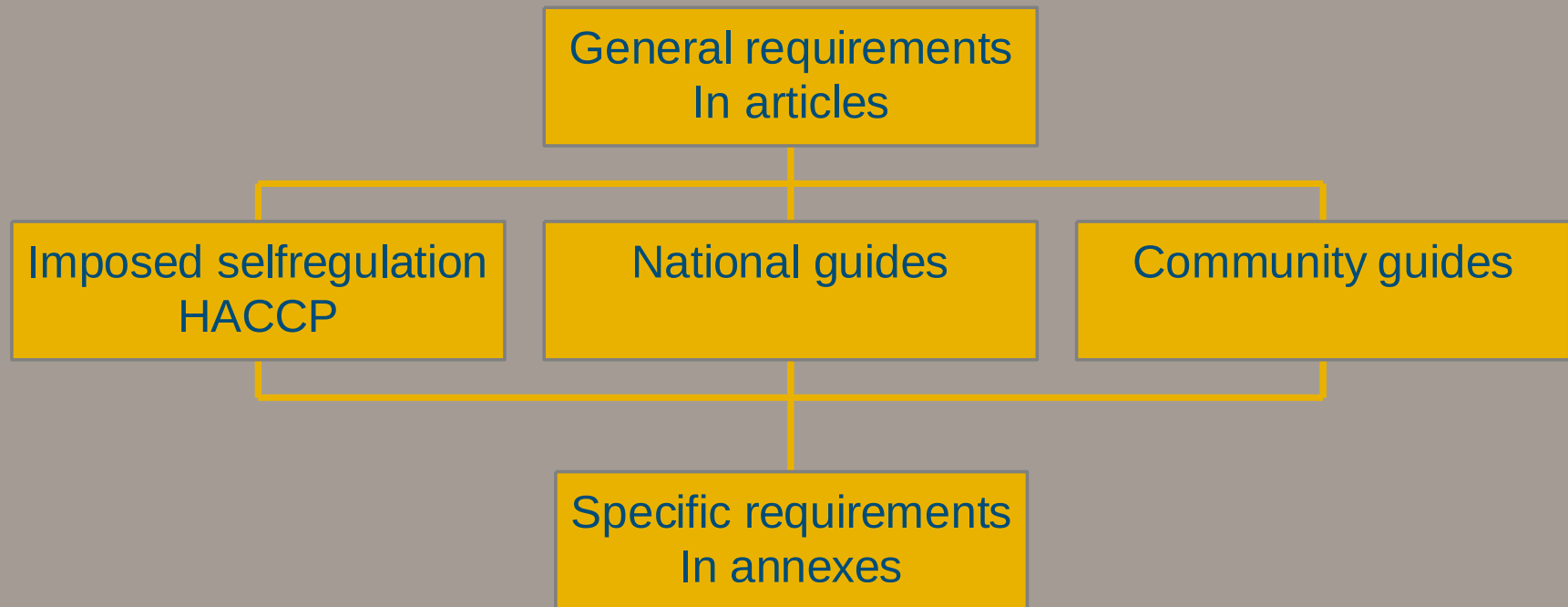
WAGE

Hygiene 1 (I)

- Regulation 852/2004
- General principles
 - Business responsible
 - Chain integration
 - HACCP
- Scope
 - All food (**including** animal origin)
 - All stages of production, processing, distribution
 - Except: primary production for private use, domestic preparation
- Definitions: GFL & specific



Hygiene 1 (II) Structure



Hygiene 1 (III)

- General obligations
 - Registration of establishments
 - Satisfy Regulation's requirements
 - Comply with applicable annex and Hygiene 2
 - Comply with criteria set by Commission
 - Implement and maintain permanent procedure based on HACCP-principles
 - Co-operate with authorities



Hygiene 1 (IV) HACCP

Article 5(2) Hygiene 1

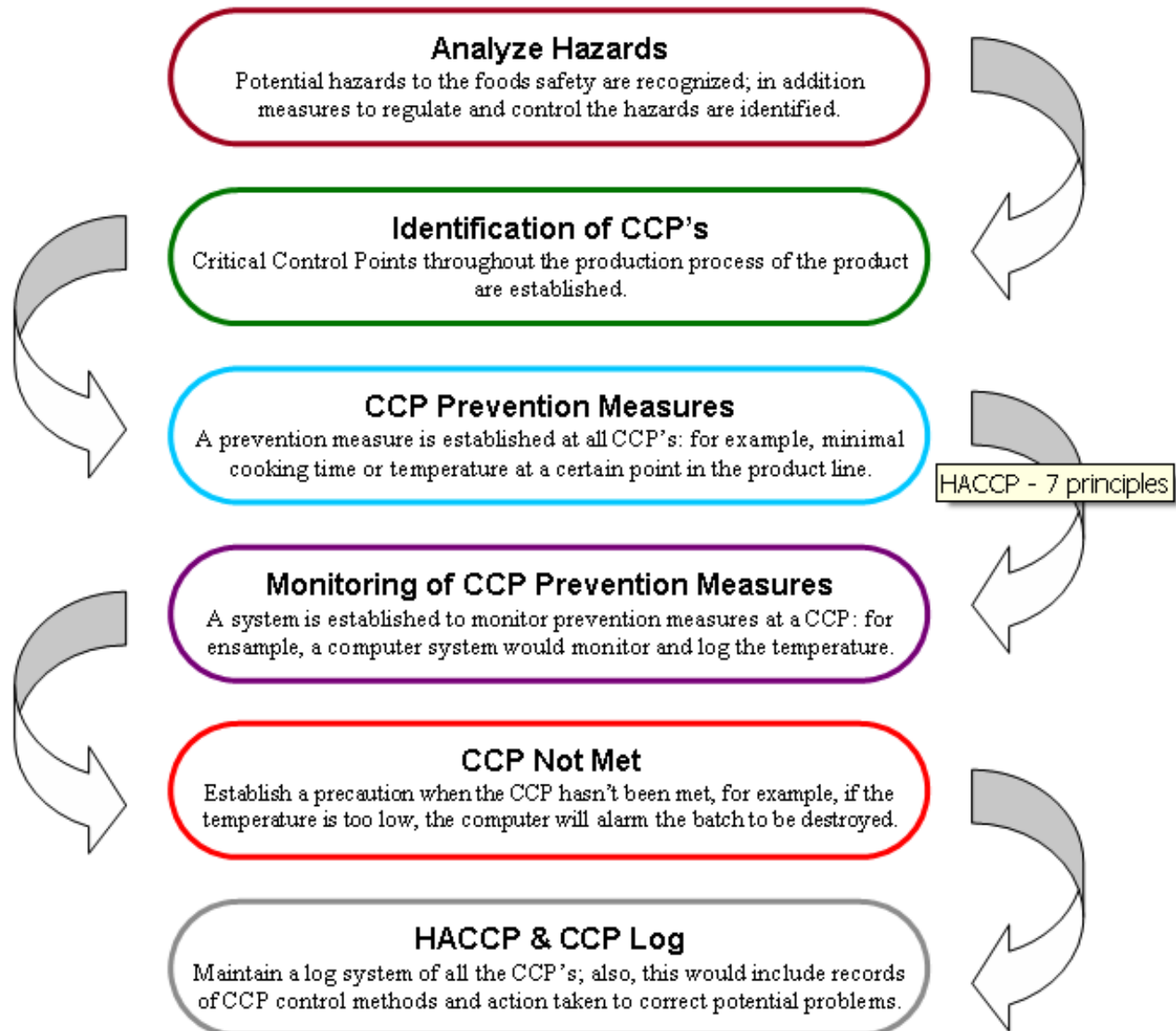
- A) Identify hazards
- B) Identify critical control points
- C) Establish critical limits
- D) Establish monitoring procedures
- E) Establish corrective actions
- F) Verification
- G) Documentation

Primary producers exempted
→ often corrected by private standards



Hygiene 1 (IV) HACCP cont'd

In simple terms a 7 point process needs to be followed



Hygiene 1 (V) Annexes

- Updated through Commitology
- Annex I: primary production
- Annex II: others
- Practical details
 - Sinks, personal hygiene
 - waste water, etc.



ECJ 6-10-11 C-382/10: Responsibility

- At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.



ECJ 6-10-11 C-382/10: Resp. cont'd

- 20: FBO is responsible
- 22: It follows that (...) where the competent authorities do not appear to have concluded that there was actual contamination, it cannot be concluded that food business operators have infringed (...) on the basis only of the finding that a potential purchaser could conceivably have touched the foodstuffs by hand or sneezed on them, without **considering the measures** taken by those operators (...) in order to prevent, eliminate or reduce to acceptable levels the hazard which the contamination (...) may present and without **determining that the measures** taken in that regard were insufficient in the light of all the available relevant data.
- **I.e. check the system.**



Cross compliance

- Primary sector receiving Single Farm Payment
- Regulation 73/2009 → comply with requirements mentioned in Annex
- Articles 14, 15, 17(1), 18, 19, 20 GFL businesses responsible to satisfy the food and feed safety requirements of food law → includes food hygiene legislation



Hygiene 2

- **Regulation 853/2004 laying down specific hygiene rules for food of animal origin**
- **Food of animal origin processed and unprocessed**
 - **Composite products excluded**
- **Health and identification marking**
- **Vertical rules in annexes: molluscs, fish, etc.**

UK

AB 007

EC



Hygiene 4



- Council *Directive* 2002/99
- Animal health rules for human consumption
 - production, processing, distribution, etc.
- No spreading diseases
- Only use of healthy animals

Hygiene feed

- Regulation 1831/2003
- Feed for food
- Feed hygiene &
- Traceability of feed
- Structure similar to H 1
 - Registration of establishments
 - Follow annexes
 - Implement HACCP



I

(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 2073/2005**of 15 November 2005****on microbiological criteria for foodstuffs****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs ⁽¹⁾, and in particular Articles 4(4) and 12 thereof,

- (4) Microbiological criteria also give guidance on the acceptability of foodstuffs and their manufacturing, handling and distribution processes. The use of microbiological criteria should form an integral part of the implementation of HACCP-based procedures and other hygiene control measures.

**European Institute for Food Law**

European Institute for Food Law

Food safety criteria

Microbiology of foods and animal feeding stuffs. Horizontal method for the detection and enumeration of *Listeria monocytogenes*

Chapter 1. Food safety criteria

Food category	Micro-organisms/ their toxins, metabolites	Sampling-plan ¹		Limits ²		Analytical reference method ³	Stage where the criterion applies
		n	c		M		
1.1 Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes ⁴	<i>Listeria monocytogenes</i>	10	0	Absence in 25 g		EN/ISO 11290-1	Products placed on the market during their shelf-life
1.2 Ready-to-eat foods able to support the growth of <i>L. monocytogenes</i> , other than those intended for infants and for special medical purposes	<i>Listeria monocytogenes</i>	5	0	100 cfu/g ⁵		EN/ISO 11290-2 ⁶	Products placed on the market during their shelf-life
		5	0	Absence in 25 g ⁷		EN/ISO 11290-1	Before the food has left the immediate control of the food business operator, who has produced it

Regulation 2075/2005 Trichinella

- **Systematic sampling of carcasses**
 - Freezing
 - Trichinella free holdings
- **Training**
- **Sampling methods**
- **Import examination in 3rd country**



Food Safety in FBOs

- Preparedness
- Response



GFL Food safety requirements

- EU food safety law applies to imports & exports
- Traceability
 - One step up, one down
 - Internal traceability?? → often corrected in private standards
- Withdrawal & recall
 - Food not in compliance with food safety requirements



2) Preparedness

Traceability: aims

- Retrace origin of food safety problems
 - 'Normal' / Bio terrorism
 - Trace affected products of safety problems
 - Prepare recall
- information must be suitable to reconstruct the chain

Other uses

- Guarantee quality
 - inform consumers about invisible aspects (org. kosher, BRC, GM, origin, child labour, sustainable, etc.)
- Identify liability (Reg. 1935/2005 on packaging)

GRAIN
CROP

VINEYARD

ORCHARD

COWS

HENS

C U L T I V A T I O N

B R E E D I N G

WHEAT

SUGAR
BEET

GRAPES

CITRUS

MILK

EGGS

P R O C E S S I N G

P R O C E S S I N G

FLOUR

SUGAR

SULTANAS

CANDIED
FRUIT

BUTTER

YOLK



Panettone

Traceability: responsibilities

- Food business operator
 - Have system in place
 - Decide on kind of system
 - Decide on batch size



3) Response

Identification of food safety problem

- Extent of the problem

- Art. 14(6) GFL

Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.

- Where is the rest of the lot?

- Art. 18 GFL: traceability

- One step up, one down
- Information to authorities on demand



Consequences of food safety problem I

- Company level
- 14(1) GFL no placing on the market
- 19(1)
 - Withdraw from the market
 - Inform authorities (19(3))
 - Inform consumer
 - Recall from consumer
- 19(4) collaborate with authorities
- 18(2/3) make traceability information available on demand of competent authorities



Recall

- GFL 19
- Who is responsible?
 - Importer
 - Producer
 - Processor
 - Manufacturer
 - Distributor
- When?
 - Has reason to believe that a food is not in compliance with food safety requirements
- What?
 - Take measures to restore high level of food safety
 - Withdraw from customer
 - Recall from consumer



Consequences of food safety problem II

- Member State level
- 17(2) GFL have national legislation in place
 - Inspections
 - Communication
 - Sanctions
- Subsidiarity principle / 53 GFL
 - First responsibility: Member States
- Art. 34 TFEU: no quantitative trade barriers
- Art. 36 TFEU: exception for protection of health
 - Borders may be closed
- 18 GFL: demand traceability information
- 10 GFL: public information



Consequences of food safety problem III

- The European Commission
- 53 GFL interim measures
 - Suspension of placing on the market
 - Suspension of imports
 - Conditions
 - Any other
- 54 GFL Member States may act when Commission does not



Official Controls

- Regulation 882/2004
- Scope
 - Food and feed law
 - Animal health & animal welfare law
 - Not included: common market agriculture
- Objectives
 - Prevent risks to humans and animals
 - Protect consumers' interests



Hygiene 3

- Regulation 854/2004 on official controls on products of animal origin
- On site visit prior to approval of establishment
- Obligation to co-operate
 - Give access
 - Provide documentation
- Audits on correct use of HACCP / guides



Thank you for your kind attention

Q&A

Bernd.vanderMeulen@wur.nl



© B.M.J. van der Meulen Wageningen UR / European Institute for Food Law

www.law.wur.nl - www.food-law.nl - www.nvfr.nl



WAGENINGEN UNIVERSITY
WAGENINGEN **UR**



European Institute for Food Law
European Institute for Food Law