UNIVERSITÀ DEGLI STUDI DI TERAMO

UNITE

BASIC EU FOOD SAFETY REGULATIONS

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EU FOOD SAFETY POLICY

The EU's food safety policy covers food “from farm to fork”.

Its three general objectives are:

- to ensure that food and animal feed are safe and nutritious
- to ensure a high level of animal health, welfare and plant protection
- to ensure adequate and transparent information about the origin, content/labelling and use of food

- The basic principles for the EU’s food safety policy are defined in the EU’s General Food Law.

- Its general objectives are to facilitate the free trading of food across all EU countries by ensuring the same high level of consumer protection in all Member States.

- European law is divided into 'primary' and 'secondary' legislation.
- The treaties (primary legislation) are the basis or ground rules for all EU action.
- Secondary legislation – which includes regulations, directives and decisions – are derived from the principles and objectives set out in the treaties.

PRIMARY LEGISLATION

A treaty is a binding agreement among the EU Member States. It sets out EU objectives, rules for EU institutions, how decisions are made and the relationship between the EU and its member countries.

Under the treaties, EU institutions can adopt legislation, which the Member States then implement.

SECONDARY LEGISLATION

There are five types or forms of EU secondary legislation:

- Regulations – these are binding and directly applicable in all Member States

- Directives – these are binding as to the result to be achieved but leave Member States to decide on the method of achieving that result. The method is decided by Member States when they transpose the Directive into their national legislation

SECONDARY LEGISLATION

- Decisions – these are binding upon those to whom they are addressed (e.g. one, several or all Member States or an individual company) and are directly applicable

- Recommendations – these have no binding force

- Opinions – these have no binding force

COUNCIL DIRECTIVE 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs

This Directive lays down the general rules of hygiene for foodstuffs and the procedures for verification of compliance with these rules

SOME BASIC PREMISES…

Whereas the free movement of foodstuffs is an essential pre-condition for the completion of the internal market; whereas this principle implies confidence in the standard of safety of foodstuffs for human consumption in free circulation, and in particular their standard of hygiene, throughout all stages of preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the consumer

SOME BASIC PREMISES…

Whereas the general rules of hygiene for foodstuffs to be observed at the time of preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the consumer must be harmonized in order to protect human health

Whereas, however, a food business operator is responsible for the hygiene conditions in his food business; whereas this Directive does not therefore impose observance of guides to good hygiene practice, which have no legal force

Whereas food business operators must ensure that only foodstuffs not harmful to health are placed on the market and appropriate powers should be granted to the competent authorities to protect public health

ARTICLE 3

Food business operators shall identify any step in their activities which is critical to ensuring food safety and ensure that adequate safety procedures are identified, implemented, maintained and reviewed on the basis of the following principles, used to develop the system of HACCP (Hazard analysis and critical control points):

— analysing the potential food hazards in a food business operation

— identifying the points in those operations where food hazards may occur

— deciding which of the points identified are critical to food safety — the 'critical points'

— identifying and implementing effective control and monitoring procedures at those critical points, and

— reviewing the analysis of food hazards, the critical control points and the control and monitoring procedures periodically and whenever the food business operations change

ARTICLE 8

Inspections by competent authorities shall include a general assessment of the potential food safety hazards associated with the business. Competent authorities shall pay particular attention to critical control points identified by food businesses to assess whether the necessary monitoring and verification controls are being operated.

ARTICLE 16

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 months after adoption. They shall forthwith inform the Commission thereof.

Member States adopt these provisions, the provisions shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication.

Decreto Legislativo 26 maggio 1997, n. 155

"Attuazione delle direttive 93/43/CEE e 96/3/CE concernenti l'igiene dei prodotti alimentari"

pubblicato nella *Gazzetta Ufficiale* n. 136 del 13 giugno 1997 - Supplemento Ordinario n. 118

COMMISSION DIRECTIVE 96/3/EC of 26 January 1996 granting a derogation from certain provisions of Council Directive 93/43/EEC on the hygiene of foodstuffs as regards the transport of bulk liquid oils and fats by sea

Repealed by

Commission Regulation (EU) No 579/2014 of 28 May 2014

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 30.04.1997
COM(97) 176 final

THE GENERAL PRINCIPLES OF FOOD LAW

IN THE EUROPEAN UNION

Commission Green Paper

Commission Green Paper

General Background

- Food law is a matter of great public concern. A high level of security and effective public control is necessary to ensure that the food supply is safe and wholesome and to ensure the effective protection of the other interests of consumers.

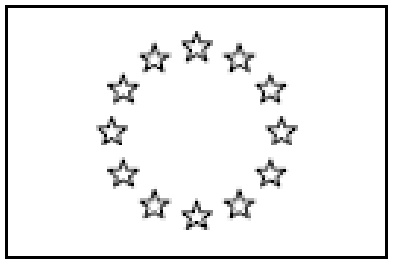
- With every household spending on average about 20% of its disposable income on food and drink, the sector is of vital importance to the European economy. The food and drink processing industries alone employ some 2. 3 million people, and in 1996 consumption within the Community will reach about ECU 500 000 million.

The Green Paper identifies six basic goals for Community food law:

- to ensure a high level of protection of public health, safety and the consumer
- to ensure the free movement of goods within the internal market
- to ensure that the legislation is primarily based on scientific evidence and risk assessment
- to ensure the competitiveness of European industry and enhance its export prospects
- to place the primary responsibility for safe food on industry, producers and suppliers using hazard analysis and critical control points (HACCP) type systems, which must be backed up by effective official control and enforcement
- to ensure the legislation is coherent, rational and user friendly

According to the Codex Alimentarius Guidelines for the Application of the Hazard Analysis Critical Control Point System, HACCP is a system which identifies specific hazards and preventative measures for their control. The system consists of seven principles:

- Identify the potential hazards associated with food production at all stages, from growth processing, manufacture and distribution until the point of consumption. Assess the likelihood of occurrence of the hazards and identify preventative measures for their control.
- Determine the points/procedures/operational steps that can be controlled to eliminate the hazards or minimize their likelihood of occurrence (Critical control point (CCP).
- Establish critical limits which must be met to ensure the CCP is under control.
- Establish a system to monitor control of the CCP by scheduled testing or observations.
- Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
- Establish procedures for verification which include supplementary tests and procedures to confirm that the HACCP system is working effectively.
- Establish documentation concerning all procedures and records appropriate to these principles and their application.



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 12 January 2000
COM (1999) 719 final

WHITE PAPER ON FOOD SAFETY

- Food production is extremely complex.
- Products of animal and plant origin present intrinsic hazards, due to microbiological and chemical contamination.
- Nevertheless, the current legal framework and operational set-up has in general afforded the EU consumer a high level of health protection.

- ***European Food Authority***
- The establishment of an independent European Food Authority is considered by the Commission to be the most appropriate response to the need to guarantee a high level of food safety.

- ***Food Safety Legislation***
- The setting up of the independent Authority is to be accompanied by a wide range of other measures to improve and bring coherence to the corpus of legislation covering all aspects of food products from “farm to table”.

- Responsibility for safe food production is shared between operators, national authorities and the European Commission. Operators are responsible for compliance with legislative provisions, and for minimising risk on their own initiative.

- National authorities are responsible for ensuring food safety standards are respected by operators. They need to establish control systems to ensure that Community rules are being respected and, where necessary, enforced.

Consumer information

- *Risk communication*

- A more pro-active approach needs to be introduced concerning the communication of unavoidable risks for certain parts of the population. For instance women of childbearing age, pregnant women, infants, the elderly and immunodeficient people should be warned more actively about the possible risks of certain foods.

Consumer information

- *Labelling and advertising*
- Consumers are to be provided with essential and accurate information so that they can make informed choices.

- *Nutritional value of food*
- Ensuring the protection of public health is not restricted to chemical, biological and physical safety of food. It should also aim at ensuring the intake of essential nutrients while limiting intake of other elements in order to avoid adverse health effects, including anti-nutritional effects. Scientific information has shown that an adequate and varied diet are very important factors in maintaining good health and overall well being.

CONCLUSIONS

- Legislation will be reviewed and amended as necessary in order to make it more coherent, comprehensive and up-to-date. Enforcement of this legislation at all levels will be promoted.

“HYGIENE PACKAGE”

Regulation (EC) No 178/2002	
Food business operators	Competent authorities
Regulation (EC) No 852/2004	Regulation (EC) No 882/2004
General rules on hygiene	General rules for official controls
Regulation (EC) No 853/2004	Regulation (EC) No 854/2004
Specific rules on hygiene for products of animal origin	Specific rules for official controls on products of animal origin

“HYGIENE PACKAGE”

- Regulation (EC) No 178/2002 of **28 January 2002** laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

- Rules on hygiene of foodstuffs were **published on 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**.

- 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.

DIRECTIVE 2004/41/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption

The following Directives shall be repealed with effect from the relevant date*:

- 1) Council Directive 64/433/EEC of 26 June 1964 on health conditions for the production and marketing of fresh meat;
- 2) Council Directive 71/118/EEC of 15 February 1971 on health problems affecting the production and placing on the market of fresh poultry meat;
- 3) Council Directive 72/461/EEC of 12 December 1972 on health problems affecting intra-Community trade in fresh meat;
- 4) Council Directive 77/96/EEC of 21 December 1976 on the examination for trichinae (*Trichinella spiralis*) upon importation from third countries of fresh meat derived from domestic swine;

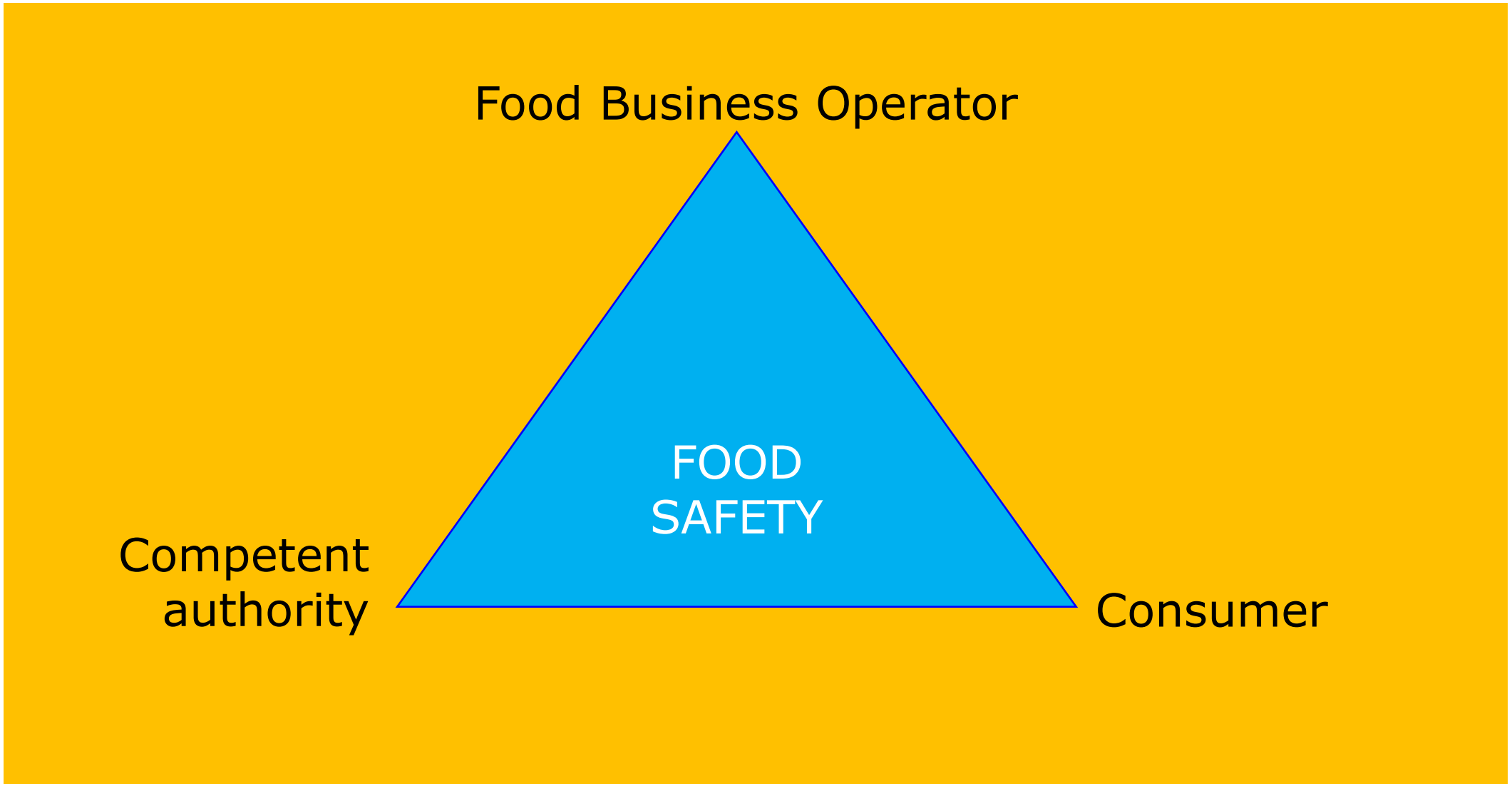
*the "relevant date" shall mean the date of application of Regulations (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004.

- 5) Council Directive 77/99/EEC of 21 December 1976 on health problems affecting the production and marketing of meat products and certain other products of animal origin;
- 6) Council Directive 80/215/EEC of 22 January 1980 on animal health problems affecting intraCommunity trade in meat products;
- 7) Commission Directive 89/362/EEC of 26 May 1989 on general conditions of hygiene in milk production holdings;
- 8) Council Directive 89/437/EEC of 20 June 1989 on hygiene and health problems affecting the production and the placing on the market of egg products;

- 9) Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs;
- 10) Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products;
- 11) Council Directive 91/494/EEC of 26 June 1991 on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultry meat;
- 12) Council Directive 91/495/EEC of 27 November 1990 concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat;

- 13) Council Directive 92/45/EEC of 16 June 1992 on public health and animal health problems relating to the killing of wild game and the placing on the market of wild-game meat;
- 14) Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products;
- 15) Council Directive 92/48/EEC of 16 June 1992 laying down the minimum hygiene rules applicable to fishery products caught on board certain vessels in accordance with Article 3(1)(a)(i) of Directive 91/493/EEC;
- 16) Council Directive 94/65/EC of 14 December 1994 laying down the requirements for the production and placing on the market of minced meat and meat preparations.

FOOD SAFETY


Food Business Operator
FOOD
SAFETY
Competent
authority
Consumer


SAFE FOOD
???

REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

Food that complies with specific Community provisions governing food safety shall be deemed to be safe…

Article 1 - Aim and scope

This Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market.

For the purposes of paragraph 1, this Regulation lays down the general principles governing food and feed in general, and food and feed safety in particular, at Community and national level.

Article 1 - Aim and scope

This Regulation shall apply to all stages of production, processing and distribution of food and feed. It shall not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption.

Article 2 - Definition of ‘food’

For the purposes of this Regulation, ‘food’ (or ‘foodstuff’) means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. ‘Food’ includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment.

Article 2 - Definition of ‘food’

‘Food’ shall not include:

a) feed

b) live animals unless they are prepared for placing on the market for human consumption

c) plants prior to harvesting

d) medicinal products

Article 2 - Definition of ‘food’

‘Food’ shall not include:

e) cosmetics
f) tobacco and tobacco products
g) narcotic or psychotropic substances
h) residues and contaminants

Article 3 - Other definitions

‘food law’ means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals

Article 17 – Responsibilities

Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.

Article 17 – Responsibilities

Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution.

Article 17 – Responsibilities

For that purpose, they shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution.

Article 17 – Responsibilities

Member States shall also lay down the rules on measures and penalties applicable to infringements of food and feed law. The measures and penalties provided for shall be effective, proportionate and dissuasive.

REGULATION (EC) No 852/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the hygiene of foodstuffs

Article 1 – Scope

This Regulation lays down general rules for food business operators on the hygiene of foodstuffs, taking particular account of the following principles:

primary responsibility for food safety rests with the food business operator

Article 1 – Scope

general implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility

Article 1 – Scope

it is necessary to ensure food safety throughout the food chain, starting with primary production

Article 2 – Definitions

'primary products' means products of primary production including products of the soil, of stock farming, of hunting and fishing

Regulation (EC) No 178/2002 – article 3

'primary production' means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products

Article 4 – FBO's obligations

Food business operators carrying out primary production and those associated operations listed in Annex I shall comply with the general hygiene provisions laid down in part A of Annex I and any specific requirements provided for in Regulation (EC) No 853/2004.

Article 4 – FBO's obligations

Food business operators carrying out any stage of production, processing and distribution of food after those stages to which paragraph 1 applies shall comply with the general hygiene requirements laid down in Annex II and any specific requirements provided for in Regulation (EC) No 853/2004.

Annex II

- CHAPTER I
- General requirements for food premises
- (layout, design, construction, siting and size of food premises)

General requirements for food premises

- The layout, design, construction, siting and size of food premises are to:

- (a) permit adequate maintenance, cleaning and/or disinfection, avoid or minimise air-borne contamination, and provide adequate working space to allow for the hygienic performance of all operations;
- (b) be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces;
- (c) permit good food hygiene practices, including protection against contamination and, in particular, pest control;
- (d) where necessary, provide suitable temperature-controlled handling and storage conditions of sufficient capacity for maintaining foodstuffs at appropriate temperatures and designed to allow those temperatures to be monitored and, where necessary, recorded.

General requirements for food premises

- An adequate number of flush lavatories are to be available and connected to an effective drainage system. Lavatories are not to open directly into rooms in which food is handled.

- An adequate number of washbasins is to be available, suitably located and designated for cleaning hands. Washbasins for cleaning hands are to be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. Where necessary, the facilities for washing food are to be separate from the hand-washing facility.

General requirements for food premises

- There is to be suitable and sufficient means of natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area is to be avoided. Ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.

- Sanitary conveniences are to have adequate natural or mechanical ventilation.

- Food premises are to have adequate natural and/or artificial lighting.

General requirements for food premises

- Drainage facilities are to be adequate for the purpose intended. They are to be designed and constructed to avoid the risk of contamination. Where drainage channels are fully or partially open, they are to be so designed as to ensure that waste does not flow from a contaminated area towards or into a clean area, in particular an area where foods likely to present a high risk to the final consumer are handled.

- Where necessary, adequate changing facilities for personnel are to be provided.

- Cleaning agents and disinfectants are not to be stored in areas where food is handled.

Annex II

- CHAPTER II
- Specific requirements in rooms where foodstuffs are prepared, treated or processed

General requirements for rooms

- (a) floor surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate. Where appropriate, floors are to allow adequate surface drainage;

- (b) wall surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials and require a smooth surface up to a height appropriate for the operations unless food business operators can satisfy the competent authority that other materials used are appropriate;

General requirements for rooms

- (c) ceilings (or, where there are no ceilings, the interior surface of the roof) and overhead fixtures are to be constructed and finished so as to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable mould and the shedding of particles;

- (d) windows and other openings are to be constructed to prevent the accumulation of dirt. Those which can be opened to the outside environment are, where necessary, to be fitted with insect-proof screens which can be easily removed for cleaning. Where open windows would result in contamination, windows are to remain closed and fixed during production;

General requirements for rooms

- (e) doors are to be easy to clean and, where necessary, to disinfect. This will require the use of smooth and non-absorbent surfaces unless food business operators can satisfy the competent authority that other materials used are appropriate;

- (f) surfaces (including surfaces of equipment) in areas where foods are handled and in particular those in contact with food are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of smooth, washable corrosion resistant and non-toxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate.

Annex II

- CHAPTER VIII
- Personal hygiene

- No person suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted, for example, with infected wounds, skin infections, sores or diarrhoea is to be permitted to handle food or enter any food-handling area in any capacity if there is any likelihood of direct or indirect contamination. Any person so affected and employed in a food business and who is likely to come into contact with food is to report immediately the illness or symptoms, and if possible their causes, to the food business operator.

Article 4 – FBO's obligations

Food business operators shall, as appropriate, adopt the following specific hygiene measures:

(a) compliance with microbiological criteria for foodstuffs;
(b) procedures necessary to meet targets set to achieve the objectives of this Regulation;
(c) compliance with temperature control requirements for foodstuffs;
(d) maintenance of the cold chain;
(e) sampling and analysis.

Article 5 – HACCP

Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.

Article 5 – HACCP

The HACCP principles referred to in paragraph 1 consist of the following:
(a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;
(b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;
(c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;

Article 5 – HACCP

(d) establishing and implementing effective monitoring procedures at critical control points;
(e) establishing corrective actions when monitoring indicates that a critical control point is not under control;
(f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively;
and
(g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

Article 6 – Official controls, registration and approval

Food business operators shall cooperate with the competent authorities in accordance with other applicable Community legislation or, if it does not exist, with national law.

In particular, every food business operator shall notify the appropriate competent authority, in the manner that the latter requires, of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the ***registration*** *of each such establishment.*

Article 6 – Official controls, registration and approval

However, food business operators shall ensure that establishments are approved by the competent authority, following at least one on-site visit, when ***approval*** *is required:*

(a) under the national law of the Member State in which the establishment is located;
(b) under Regulation (EC) No 853/2004;
(c) by a decision adopted by the Commission.

Article 4 – FBO's obligations

Food business operators shall, as appropriate, adopt the following specific hygiene measures:

(a) compliance with microbiological criteria for foodstuffs;
(b) procedures necessary to meet targets set to achieve the objectives of this Regulation;
(c) compliance with temperature control requirements for foodstuffs;
(d) maintenance of the cold chain;
(e) sampling and analysis.

Regulation (EC) No 2073/2005

on microbiological criteria for foodstuffs

Premises….

- Regulation (EC) No 178/2002 lays down general food safety requirements, according to which food must not be placed on the market if it is unsafe. Food business operators have an obligation to withdraw unsafe food from the market. In order to contribute to the protection of public health and to prevent differing interpretations, it is appropriate to establish harmonised safety criteria on the acceptability of food, in particular as regards the presence of certain pathogenic micro-organisms.

Premises….

- Foodstuffs should not contain micro-organisms or their toxins or metabolites in quantities that present an unacceptable risk for human health.

- Microbiological hazards in foodstuffs form a major source of food-borne diseases in humans.

- Sampling of the production and processing environment can be a useful tool to identify and prevent the presence of pathogenic micro-organisms in foodstuffs.

Premises….

- 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.

Article 1
Subject matter and scope

- This Regulation lays down the microbiological criteria for certain micro-organisms and the implementing rules to be complied with by food business operators when implementing the general and specific hygiene measures referred to in Article 4 of Regulation (EC) No 852/2004.

Article 1

- The competent authority shall verify compliance with the rules and criteria laid down in this Regulation in accordance with Regulation (EC) No 882/2004, without prejudice to its right to undertake further sampling and analyses for the purpose of detecting and measuring other micro-organisms, their toxins or metabolites, either as a verification of processes, for food suspected of being unsafe, or in the context of a risk analysis.

Article 2
Definitions

- ‘microbiological criterion’

- means a criterion defining the acceptability of a product, a batch of foodstuffs or a process, based on the absence, presence or number of micro-organisms, and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch

Article 2

- ‘food safety criterion’

- means a criterion defining the acceptability of a product or a batch of foodstuff applicable to products placed on the market

Article 2

- ‘process hygiene criterion’

- a criterion indicating the acceptable functioning of the production process. Such a criterion is not applicable to products placed on the market. It sets an indicative contamination value above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law

- It is appropriate to lay down implementing measures concerning the foodstuff to which the criterion applies, the points of the food chain where the criterion applies, as well as the actions to be taken when the criterion is not met.

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	Vm	M		

Chapter 2. Process hygiene criteria

2.1 *Meat and products thereof*

Food category	Micro-organisms	Sampling plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			

Article 2

- ‘compliance with microbiological criteria’

- means obtaining satisfactory or acceptable results set in Annex I when testing against the values set for the criteria through the taking of samples, the conduct of analyses and the implementation of corrective action, in accordance with food law and the instructions given by the competent authority

Article 7

- 2. When testing against food safety criteria set out in Chapter 1 of Annex I provides unsatisfactory results, the product or batch of foodstuffs shall be withdrawn or recalled in accordance with Article 19 of Regulation (EC) No 178/2002. However, products placed on the market, which are not yet at retail level and which do not fulfil the food safety criteria, may be submitted to further processing by a treatment eliminating the hazard in question. This treatment may only be carried out by food business operators other than those at retail level

Article 7

- The food business operator may use the batch for purposes other than those for which it was originally intended, provided that this use does not pose a risk for public or animal health and provided that this use has been decided within the procedures based on HACCP principles and good hygiene practice and authorised by the competent authority

Article 7

- 4. In the event of unsatisfactory results as regards process hygiene criteria the actions laid down in Annex I, Chapter 2 shall be taken

Chapter 2. Process hygiene criteria

2.1 *Meat and products thereof*

Food category	Micro-organisms	Sampling plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			

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	Vm	M		
1.1	Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes (4)	*Listeria monocytogenes*	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 *L. monocytogenes*, other than those intended for infants and for special medical purposes	*Listeria monocytogenes*	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
1.3	Ready-to-eat foods unable to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes (4) (8)	*Listeria monocytogenes*	5	0	100 cfu/g		EN/ISO 11290-2 (6)	Products placed on the market during their shelf-life

- (1) n = number of units comprising the sample; c = number of sample units giving values between m and M.
- (2) For points 1.1-1.25, 1.27a and 1.28 m = M.
- (3) The most recent edition of the standard shall be used.
- ‘dietary foods for special medical purposes’ means a category of foods for particular nutritional uses specially processed or formulated and intended for the dietary management of patients and to be used under medical supervision. They are intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two.

	Food category	Micro-organisms/their toxins, metabolites	Sampling plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies
			n	c	Vm	M		
1.1	Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes (4)	*Listeria monocytogenes*	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 *L. monocytogenes*, other than those intended for infants and for special medical purposes	*Listeria monocytogenes*	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
1.3	Ready-to-eat foods unable to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes (4) (8)	*Listeria monocytogenes*	5	0	100 cfu/g		EN/ISO 11290-2 (6)	Products placed on the market during their shelf-life

- (4) Regular testing against the criterion is not required in normal circumstances for the following ready-to-eat foods:
- — those which have received heat treatment or other processing effective to eliminate *L. monocytogenes*, when recontamination is not possible after this treatment (for example, products heat treated in their final package)
- — fresh, uncut and unprocessed vegetables and fruits, excluding sprouted seeds
- — bread, biscuits and similar products
- — bottled or packed waters, soft drinks, beer, cider, wine, spirits and similar products
- — sugar, honey and confectionery, including cocoa and chocolate products
- — live bivalve molluscs
- — food grade salt

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

- (5) This criterion shall apply if the manufacturer is able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life. The operator may fix intermediate limits during the process that must be low enough to guarantee that the limit of 100 cfu/g is not exceeded at the end of shelf-life.

- (6) 1 ml of inoculum is plated on a Petri dish of 140 mm diameter or on three Petri dishes of 90 mm diameter.

	Food category	Micro-organisms/their toxins, metabolites	Sampling plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies
			n	c	Vm	M		
1.1	Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes (4)	*Listeria monocytogenes*	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 *L. monocytogenes*, other than those intended for infants and for special medical purposes	*Listeria monocytogenes*	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
1.3	Ready-to-eat foods unable to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes (4) (8)	*Listeria monocytogenes*	5	0	100 cfu/g		EN/ISO 11290-2 (6)	Products placed on the market during their shelf-life

- ISO 11290-1:2017
- Microbiology of the food chain -- Horizontal method for the detection and enumeration of *Listeria monocytogenes* and of *Listeria* spp. -- Part 1: Detection method

- ISO 11290-2:2017
- Microbiology of the food chain -- Horizontal method for the detection and enumeration of *Listeria monocytogenes* and of *Listeria* spp. -- Part 2: Enumeration method

	Food category	Micro-organisms/their toxins, metabolites	Sampling plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies
			n	c	Vm	M		
1.1	Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes (4)	*Listeria monocytogenes*	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 *L. monocytogenes*, other than those intended for infants and for special medical purposes	*Listeria monocytogenes*	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
1.3	Ready-to-eat foods unable to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes (4) (8)	*Listeria monocytogenes*	5	0	100 cfu/g		EN/ISO 11290-2 (6)	Products placed on the market during their shelf-life

- (7) This criterion shall apply to products before they have left the immediate control of the producing food business operator, when he is not able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit of 100 cfu/g throughout the shelf-life.

- (8) Products with pH ≤ 4,4 or a w ≤ 0,92, products with pH ≤ 5,0 and a w ≤ 0,94, products with a shelf-life of less than five days shall be automatically considered to belong to this category. Other categories of products can also belong to this category, subject to scientific justification.

Interpretation of the test results

- *L. monocytogenes* in ready-to-eat foods intended for infants and for special medical purposes:
- — satisfactory, if all the values observed indicate the absence of the bacterium,
- — unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

Interpretation of the test results

- *L. monocytogenes* in ready-to-eat foods able to support the growth of *L. monocytogenes* before the food has left the immediate control of the producing food business operator when he is not able to demonstrate that the product will not exceed the limit of 100 cfu/g throughout the shelf-life:
- — satisfactory, if all the values observed indicate the absence of the bacterium,
- — unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

Interpretation of the test results

- *L. monocytogenes* in other ready-to-eat foods:
- — satisfactory, if all the values observed are ≤ the limit,
- — unsatisfactory, if any of the values are > the limit.

Chapter 2. Process hygiene criteria

Food category	Micro-organisms	Sampling plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.1.1 Carcases of cattle, sheep, goats and horses (4)	Aerobic colony count			3,5 log cfu/ cm^2 daily mean log	5,0 log cfu/ cm^2 daily mean log	ISO 4833	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
	Enterobacteriaceae			1,5 log cfu/ cm^2 daily mean log	2,5 log cfu/ cm^2 daily mean log	ISO 21528-2	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls

- (1) n = number of units comprising the sample; c = number of sample units giving values between m and M.
- (2) For points 2.1.3-2.1.5 m = M.
- (3) The most recent edition of the standard shall be used.
- (4) The limits (m and M) shall apply only to samples taken by the destructive method. The daily mean log shall be calculated by first taking a log value of each individual test result and then calculating the mean of these log values.

Interpretation of the test results

- The test results demonstrate the microbiological quality of the process tested.

- *Enterobacteriaceae* and aerobic colony count in carcases of cattle, sheep, goats, horses and pigs:
- — satisfactory, if the daily mean log is ≤ m,
- — acceptable, if the daily mean log is between m and M,
- — unsatisfactory, if the daily mean log is > M.

How a food regulation is adopted….

Ordinary legislative procedure

- It is based on the principle of parity between the directly-elected European Parliament, representing the people of the Union, and the Council, representing the governments of Member States.

- The ordinary legislative procedure gives the same weight to the European Parliament and the Council of the European Union on a wide range of areas (for example, economic governance, immigration, energy, transport, the environment and consumer protection).

- The procedure starts with a legislative proposal from the Commission and consists of up to three readings.

- The two co-legislators (i.e. EU Parliament and Council) adopt legislation jointly, having equal rights and obligations - neither of them can adopt legislation without the agreement of the other, and both co-legislators have to approve an identical text.

Commission proposal

- The European Commission is the only EU Institution which has the right to initiate legislation. Consequently, it is responsible for drafting appropriate legislative proposals.

- Before the Commission proposes new initiatives it assesses the potential economic, social and environmental consequences that they may have.

- Ahead of adopting formal proposals, the Commission will consult with relevant interest groups, such as non-governmental organisations, local authorities and representatives of industry and civil society.

- Citizens, businesses and organisations can participate in the consultation procedure via the website “Public consultations".

- Following this initial consultation the Commission will usually publish a Green Paper or a White Paper.

- A Green Paper is essentially the Commission putting down some broad policy thinking in a particular area and asking for comments from interested parties.

- A White Paper will contain more detailed policy proposals from the Commission.

- The Commission’s draft legislative proposal (for a regulation, a directive or a decision) is submitted to both the European Parliament and to the Council and also to all Member State Parliaments and where appropriate the Committee of the Regions and the Economic and Social Committee.

The EU Parliament’s first Reading

- The European Parliament review proposals by the Commission and propose amendments.
- Adoption of any amendments of the Commission’s proposal requires only a simple majority.
- This revised proposal is sent to the Council.

The EU Council's first Reading

There are three possible scenarios:

- The Council accepts without alteration the Commission's proposal, which the European Parliament has not amended, and the act can be adopted.
- The Council accepts all the European Parliament's amendments which the Commission has incorporated into its amended proposal, and the act can be adopted.
- In all other cases, the Council adopts a "common position" that is forwarded to the European Parliament.

- It is, however, the Parliament that has to act first, by adopting the Commission's proposal without amendments, amending it, including as a result of a first reading agreement, or rejecting it.

- Then the Council may decide to accept Parliament's position, in which case the legislative act is adopted, or it may amend Parliament's position and communicate its position at first reading to Parliament for a second reading.

- During the whole first reading stage, neither the Parliament nor the Council are subject to any time limit by which they must conclude their first reading.

The EU Parliament's second Reading

- When the European Parliament receives the Council's "common position" it has three months to take the legislation forward. Failure to meet the three month deadline allows the Council to adopt the legislation based on their common position.

- In terms of possible amendments to the Council's common position, EU Parliament should include amendments proposed at the first reading but not accepted by the Council or should relate to a section of the common position which is substantially different from the Commission's original proposal.

Also in this case there are three possibilities:

- Passed – if the Parliament approves the Council's common position by an absolute majority or fails to take a decision within the three month time limit.
- Rejected – if the Parliament rejects the common position by an absolute majority. This would result in the proposal not being adopted and the procedure ending.
- Amended – if the Parliament chooses to adopt the common position with amendments by an absolute majority. If this happens the text is forwarded to the Council for further consideration and to the European Commission to provide an opinion.

The EU Council's second Reading

- The Council is allowed three months (which can be extended to four months) to consider the European Parliament's amendments to their common position.

- If the Council approves the amended common position by a qualified majority, the proposal will be deemed to have been adopted.

- If the Council rejects some of the Parliament's proposed amendments to the common position, the Presidents of the Council and the European Parliament will convene a Conciliation Committee.

- In second reading the two co-legislators (i.e. EU Parliament and Council) are bound by strict time limits laid down in the Treaty: each of the co-legislators has three months extendable by one month.

- If there is a common intention of the co-legislators to conclude in second reading, informal negotiations with the Council and the Commission start after the vote of the draft recommendation for second reading.

in other words…..

- The European Parliament and the Council review proposals by the Commission and propose amendments. If the Council and the Parliament cannot agree upon amendments, a second reading takes place.
- In the second reading, the Parliament and Council can again propose amendments. Parliament has the power to block the proposed legislation if it cannot agree with the Council.
- If the two institutions agree on amendments, the proposed legislation can be adopted. If they cannot agree, a conciliation committee tries to find a solution. Both the Council and the Parliament can block the legislative proposal at this final reading.

Conciliation: the final stage

- The Conciliation Committee is made up of an equal number of representatives of the European Parliament and the Council and is chaired by the European Commission.

- The aim of the Committee is to jointly agree finalised legislation.

- The Conciliation Committee must be convened within six weeks (or eight weeks, if an extension has been agreed) of the Council concluding its second reading and officially notifying Parliament that it is not in a position to accept all the Parliament’s second reading amendments.

- It is constituted separately for each legislative proposal requiring conciliation and has six weeks (or eight weeks, if an extension has been agreed) to reach an overall agreement in the form of a 'joint text’.

- In practice, given the relatively short time frames to reach an agreement, informal negotiations generally start before the Conciliation Committee is formally convened.

Third reading

- If the conciliation procedure is successful the jointly agreed text must be approved within six weeks of the conciliation process starting.

- A simple majority of the votes cast is required for approval; otherwise the joint text is rejected.

- If the Parliament and the Council cannot agree the text within the stipulated timeframe the legislation is not adopted and the proposal falls.

"GAME OVER!"

The legislative procedure can only be re-started by a new proposal from the Commission.

Procedure 2013/0140/CODCOM (2013) 265

Leading person:	Tonio BORG
Leading service:	Directorate-General for Health and Consumers
Procedure:	Ordinary legislative procedure (COD)
Type of file:	Proposal for a Regulation
Documents:	COM/2013/265/FINAL IP/2013/400

- Adopted act:

Regulation (EU) 2017/625

Procedure 2013/0140/CODCOM (2013) 265

- **06/05/2013 : Adoption by Commission**
- **06/05/2013 : Transmission to Parliament**
- **06/05/2013 : Transmission to Council**
- **06/05/2013 : Supplements:**
- **SWD/2013/166**
- **SWD/2013/167**

Procedure 2013/0140/CODCOM (2013) 265

- **16/10/2013 : European Economic and Social Committee opinion**
- **29/11/2013 : Committee of Regions opinion**

- **15/04/2014 : EP opinion on 1st reading**
- Approval with amendments

- **09/07/2014 : Commission position on EP amendments on 1st reading**
- Partial agreement

Procedure 2013/0140/CODCOM (2013) 265

- **15/12/2014 : Discussions within the Council or its preparatory bodies**
- **20/10/2015 : Discussions within the Council or its preparatory bodies**
- **26/10/2015 : Council agreement**

Procedure 2013/0140/CODCOM (2013) 265

- **11/07/2016 : Discussions within the Council or its preparatory bodies**
- **26/09/2016 : Discussions within the Council or its preparatory bodies**
- **07/12/2016 : Discussions within the Council or its preparatory bodies**

Procedure 2013/0140/CODCOM (2013) 265

- **08/12/2016 : Discussions within the Council or its preparatory bodies**
- **09/12/2016 : Discussions within the Council or its preparatory bodies**
- **12/12/2016 : Discussions within the Council or its preparatory bodies**

Procedure 2013/0140/CODCOM (2013) 265

- **13/12/2016 : Discussions within the Council or its preparatory bodies**
- **14/12/2016 : Discussions within the Council or its preparatory bodies**
- **16/12/2016 : Discussions within the Council or its preparatory bodies**

Procedure 2013/0140/CODCOM (2013) 265

- **19/12/2016 : Council's position at 1st reading and statement of reasons**
- **19/12/2016 : Discussions within the Council or its preparatory bodies**
- **06/01/2017 : Adoption by Commission of its communication on Council's position at 1st reading**

Procedure 2013/0140/CODCOM (2013) 265

- **09/01/2017 : Discussions within the Council or its preparatory bodies**
- **19/01/2017 : Discussions within the Council or its preparatory bodies**
- **19/01/2017 : Receipt by the Parliament of the Council's position at 1st reading**

Procedure 2013/0140/CODCOM (2013) 265

- **15/03/2017 : Discussions within the Council or its preparatory bodies**

- **15/03/2017 : EP opinion on 2nd reading**
- Approval without amendment

- **15/03/2017 : Signature by the President of the EP and by the President of the Council**

REGULATION (EU) 2017/625 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 March 2017

on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)

Regulation EU 2017/625 on official controls

- The Commission recognised the need to strengthen the instruments available to the competent authorities in the Member States to check compliance with EU legislation on the ground (through controls, inspections and tests).

- Recent food scandals have shown once more the need for more effective action on the part of enforcement authorities to protect consumers and honest operators alike from the risks (also in economic terms) which may arise from breaches of the rules along the chain.

- The new rules follow a more risk based approach thus allowing competent authorities to focus their resources on the more relevant issues.

- *Article 167* - **Entry into force and application**

- 1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

- Unless otherwise provided for in paragraphs 2 to 4, it shall apply from 14 December 2019.

- *Article 167* - **Entry into force and application**

- 2. In the area governed by the rules referred to in point (g) of Article 1(2), Article 34(1), (2) and (3), point (e) of Article 37(4) and Article 37(5) shall apply from 29 April 2022.
- 3. Articles 92 to 101 of this Regulation shall apply from 29 April 2018, instead of Articles 32 and 33 of Regulation (EC) No 882/2004, which is repealed by this Regulation.
- 4. Article 163 shall apply from 28 April 2017.