





3 - Food safety

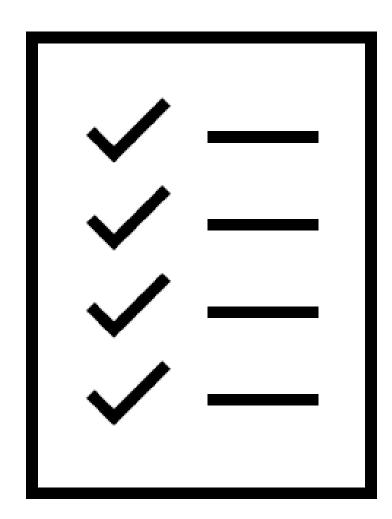
CONTENT 2 - EU FOOD LAW

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# Program

- 1. General overview
- 2. Legal framework
- 3. Food safety
- 4. Hygiene package
- 5. Plant protection products and use of pesticides
- 6. Food contact materials
- 7. OGMs Novel Foods
- 8. The European Food Safety Authority



#### 1. General overview

Food safety: "Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use"

Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP 1-1969)

Food safety concerns the general conditions that products that are consumed must possess in order to be suitable for human consumption and not harmful to health.



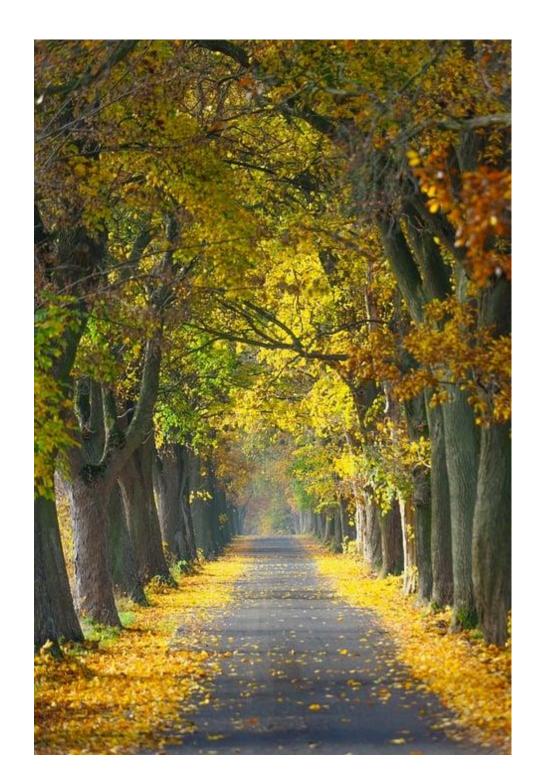
### 2. Legal framework

**EUROPEAN GENERAL FOOD LAW** ⇒ Regulation (EC) No 178/2002, of the European Parliament and of the Council of 28 January 2002:

- lay down the general principles and requirements of food law;
- establish the European Food Safety Authority;
- and lay down procedures in matters of food safety.

#### SCOPE - Article3(1):

- 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.



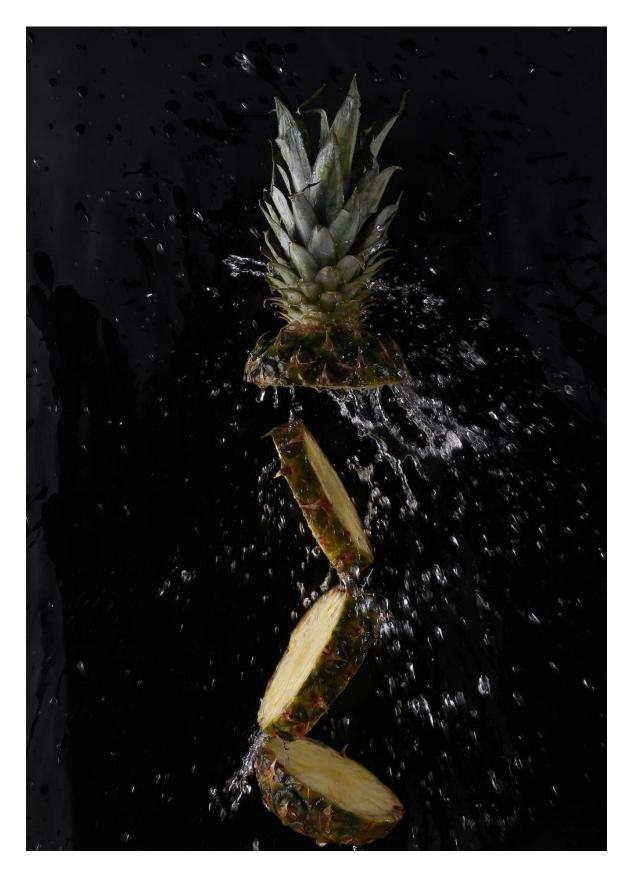
## 2. Legal framework



#### Other important legal documents:

- Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed
- Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms
- Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
- Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
- Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food

## 2. Legal framework



#### Other important legal documents:

- Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene
- Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin
- Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market
- Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain
- Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides
- Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food
- Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles

#### THE LEGAL NEGATIVE CONCEPT

The general principal regarding food safety is establish in Article 14(1) of Regulation 178/2002, in a negative perspective. This is, the European Regulation give a negative concept of food safety describing **when food is unsafe** 

According with Article 14(1) of Regulation 178/2002: "Food shall not be placed on the market if it is unsafe."

Food **is unsafe** if it is considered to be:

- (a) injurious to health;
- (b) unfit for human consumption

Article 14(2) of Regulation 178/2002





#### FOOD IS INJURIOUS TO HEALTH if:

- (a) Have probable immediate and/or short-term and/or long-term effects if consumed, but also on subsequent generations;
- (a) Have probable cumulative toxic effects;
- (a) Have particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.

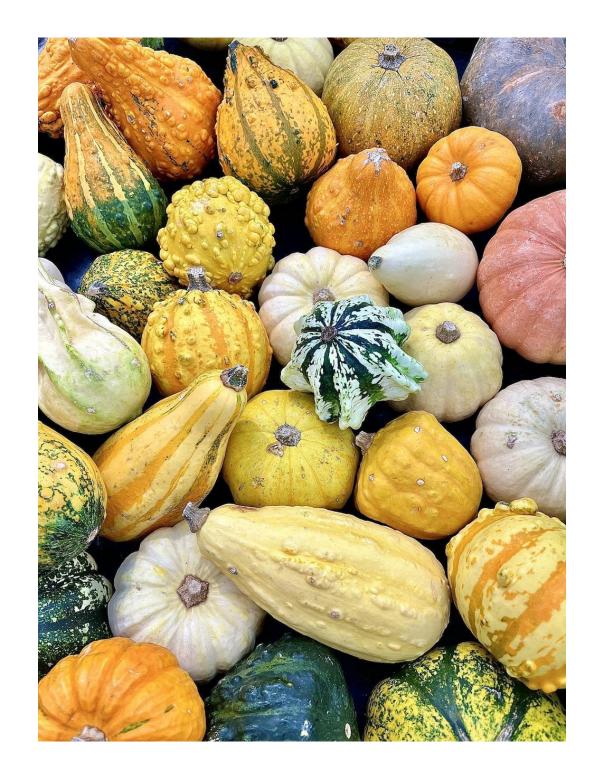
Article 14(4) of Regulation 178/2002



#### FOOD IS UNFIT FOR HUMAN CONSUMPTION

if it is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.

Article 14(5) of Regulation 178/2002





#### **RISK ANALYSIS**

"the probability of harmful effects needs to be established through risk assessment as set out in Article 6 GFL including the precautionary principle codified in Article 7 GFL"

Alfred Hagen Meyer and Rudolf Streinz, LFBG - Basis VO

Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

Article 6(2) of Regulation 178/2002



#### PRECAUTIONARY PRINCIPLE

In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

Article 7(1) of Regulation 178/2002

## 3.2. Hygiene Package

Food can be a favourable environment for the development of micro-organisms and, consequently, for food contamination and transmission of diseases, so prevention and control of micro-organisms is necessary

"FOOD 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

Article 2(1)(a) of the Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs



## 3.2. Hygiene Package



#### SPECIFIC HYGIENE REQUIREMENTS

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

- compliance with microbiological criteria for foodstuffs
- compliance with temperature control requirements for foodstuffs
- maintenance of the cold chain
- sampling and analysis

Article 4(3)(a) of the Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

## 3.3. Plant protection products and use of pesticides





REGULATION (EC) NO 396/2005 of the European Parliament and of the Council, of 23 February 2005 establishes the maximum residue levels of pesticides in or on food and feed of plant and animal origin

Important concepts [article 3(2)]:

- 'pesticide residues' means residues, including active substances, metabolites and/or breakdown or reaction products of active substances currently or formerly used in plant protection products as defined in Article 2, point 1 of Directive 91/414/EEC
- MRL 'maximum residue level' means the upper legal level of a concentration for a pesticide residue in or on food or feed set in accordance with this Regulation, based on good agricultural practice and the lowest consumer exposure necessary to protect vulnerable consumers;

#### 3.4. Food contact materials



Food is delivered to the consumer packaged and even when it is bought in bulk it has been transported in boxes or packaging. The material of this type of packaging, called Food Contact Materials (FCM), comes into contact with food products and can contaminate them with particles that are not beneficial for health.

Thus, the EU has published legislation that regulates the materials used in the production of packaging and all materials that may come into contact with food:

- Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food;
- Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food when placed on the European market.

#### 3.5. OGMs – Novel Foods

According with the European Commission, 'Novel Food' "can be newly developed, innovative food, food produced using new technologies and production processes, as well as food which is or has been traditionally eaten outside of the EU.

Examples of Novel Food include new sources of vitamin K (menaquinone) or extracts from existing food (Antarctic Krill oil rich in phospholipids from *Euphausia superba*), agricultural products from third countries (chia seeds, noni fruit juice), or food derived from new production processes (UV-treated food (milk, bread, mushrooms and yeast)".

Novel Food that may be placed on the market in the EU pursuant to Regulation (EC) No. 258/97 are available on <a href="https://food.ec.europa.eu/safety/novel-food/authorisations/list-authorisations-under-former-novel-food-regulation\_en">https://food.ec.europa.eu/safety/novel-food/authorisations/list-authorisations-under-former-novel-food-regulation\_en</a>



## 3.6. The European Food Safety Authority

In European terms the European Food Safety Authority is the competent authority in this sector.

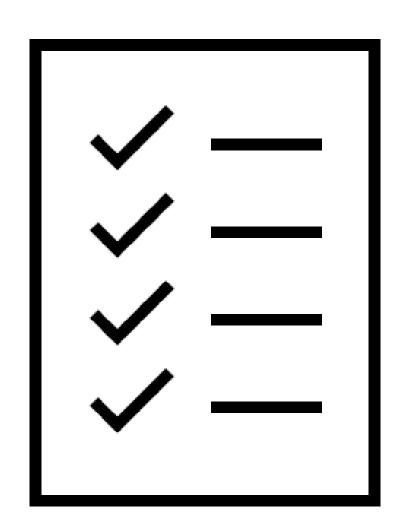
EFSA is governed by a <u>Management Board</u> whose members are mandated to act in the public interest.



The <u>Management Board</u> is composed of 27 Member State representatives (with alternates), 4 representatives of civil society and of interests in the food chain (with alternates), 2 representatives of the European Commission (with alternates), 2 representatives of the European Parliament (without alternates), 2 representatives of the EFTA/EEA countries and 1 representative of the EFTA Surveillance Authority (with alternates).

## Key messages of the lecture

- 1. Bernd van der Meulen, EU Food Law Handbook, European Institute for Food Law series, Volume 9, 2020
- 2. Harry Bremmers, Kai Purnhagen (eds.), Regulating and Managing Food Safety in the EU: A Legal-Economic Perspective, Springer, 2018
- 3. A. Alemanno, S. Gabbi, Foundations of EU Food Law and Policy: Ten Years of European Food Safety Authority, Routledge, 2016
- 4. Caduff, L., & Bernauer, T. (2006). Managing Risk and Regulation in European Food Safety Governance. Review of Policy Research, 23(1), 153–168.
- 5. Holm, L., & Halkier, B. (2009). Eu Food Safety Policy. European Societies, 11(4), 473–493. <a href="https://doi.org/10.1080/14616690802592589">https://doi.org/10.1080/14616690802592589</a>



## Thank you for your attention

Any question? Doubts?

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