International Food Regulations

Katrina Campbell Professor in Food Security & Diagnostics

E-mail: katrina.campbell@qub.ac.uk









Key Players





EUROPEAN COMMISSION





Food and Agriculture Organization of the United Nations







Learning Outcomes

- To obtain an understanding about policy, regulations and legislation
- To know who the key organisations in food safety
- To gain an insight into the breadth and depth of regulations
- To understand why regulations are important globally
- To comprehend EU Food Law
- Distinguish between a contaminant and an additive





Food policy

- A food policy is any legislative or administrative decision made by a government agency, business, or organization which effects how food is produced, processed, distributed, and purchased, designed to influence the operation of the food and agriculture system
- Food policy has both political and economic factors that contribute to the challenges it faces





Food Safety Legislation

- The production, processing, distribution, retail, packaging, and labelling of foodstuffs are governed by a mass of laws, regulations, codes of practice and guidance.
- Food safety legislation places an obligation on food business operators to ensure that all their activities are carried out in a hygienic way and makes it an offence to supply food which is unsafe or harmful to human health.





What is a regulation?

- A regulation is a rule based on and meant to carry out a specific piece of legislation.
- Regulations are enforced usually by a regulatory agency formed or mandated to carry out the purpose or provisions of a legislation.





Who is responsible for Food Safety Regulations?

- The making of national food safety legislation is the function of an individual country's government.
- Food regulations are based on domestic laws, but they also operate within an international framework of rules and agreements.
- The enforcement of regulations on food standards, safety and hygiene is primarily the responsibility of local authorities, specifically Environmental Health Officers (EHO) and Trading Standards Officers (TSO).





History

- World Food Council was a United Nations organization established by the UN General Assembly in December 1974
- Food policy came about after the first meeting of the World Food Council (WFC) in 1974
- WFC was officially suspended in 1993
- WFC's functions were absorbed by the Food and Agriculture Organization (FAO) of the United Nations and the World Food Programme





FAO of the United Nations

- Serving both developed and developing countries, FAO (Food and Agriculture Organisation) established in 1945 acts as a neutral forum where all nations meet as equals to negotiate agreements and debate policy
- The World Food Programme (WFP) is the food aid branch of the UN, and the world's largest humanitarian organization addressing hunger worldwide



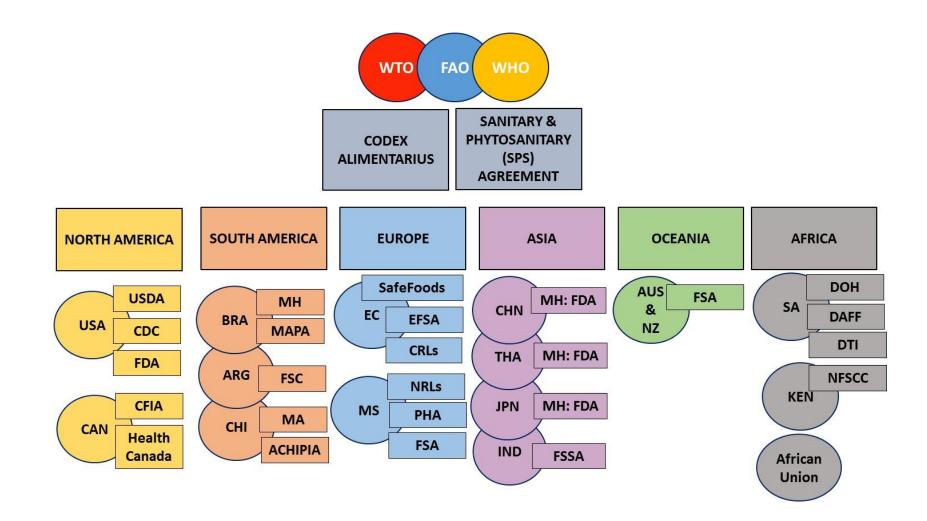


Who are the Key Organisations in Food Safety?

- Food and Agriculture Organization of the United Nations (FAO)
- Health Organisation (WHO)
- World Trade Organisation (WTO)
- Codex Alimentarius Commission (CAC)
- European Union (EU)
- European Food Safety Authority (EFSA)
- Safe Foods
- Food Standards Agency (FSA)
- United States Department of Agriculture (USDA)
- U.S. Food and Drug Administration (FDA)
- Centers for Disease Control and Prevention (CDC)
- China Food and Drug Administration (CFDA)











Codex Alimentarius



International "Food Law" or "Food Code"









- Developed Codex Commission in 1961
- Subsidiary of Food and Agriculture Organization (FAO), United Nations (UN)and World Health Organization (WHO)
- Joint venture between FAO and WHO to formulate internationally accepted food safety standards for protection of human health and to ensure fair trade practices





Codex Alimentarius

- Impacted quality and safety of world food supply
- Upgraded standards for manufacturing, processing, safety and quality throughout world
- Increased international trade 800% since 1962
- Contributes to lowering of trade barriers and protectionism





Purpose of Codex Alimentarius

To protect consumer health and economic interests and to secure fair trade practices in the food industry





Codex Commission

- Coordination of all food standards
- Initiation and supervision of draft standards
- Finalization of food standards
- Publication of standards worldwide
- Amend standards in face of new technology





Harmonization of International Trade

- Differences in food laws and standards developed independently can cause barriers to trade between nations
- Often disguised as health or safety measures but really designed to protect local farm products or consumer misconceptions (Genetic modifications)





Economic Impact Statements

- Required since 1979
- Member nations required to declare possible economic impacts of their standards while in draft form
- Designed to help prevent trade barriers
- GATT General Agreement on Tariffs and Trade
- NAFTA North American Free Trade Agreement





Codex Alimentarius

- Ensures that products complying with Codex standards can be bought and sold on the international market without compromising health or interests of consumers
- Codex standards ensure product is <u>safe</u> internationally
- Review of member laws based in *internationally* accepted scientific and technological standards





What is covered in the Codex?

- Codex standards cover all the main foods, whether processed, semi-processed or raw that are intended for sale for the consumer or for immediate processing.
- Codex provisions concern the hygienic and nutritional quality of food, including microbiological norms, contaminants, food additives, pesticide and veterinary drug residues, labelling and presentation, and methods of sampling and risk analysis.





"Food" under the Codex:

"*any* substance, whether processed, partly processed or raw, which is *intended* for human consumption and includes drink, *chewing gum* and *any* substance which has been used in the manufacture, preparation or treatment of food but *does not* include cosmetics, tobacco or substances used *solely* as drugs"

Is the circular economy included here ?





Structure of Codex Commission

- Inter-governmental body
- Open to all UN member nations
- Currently 165 members (98% of world)
- Executive Committee oversees Commission activities (Chair, 3 vice chairs and 6 others)
- Secretariat oversees Executive Committee
 - Located at FAO in Rome
 - Corresponds with member states re: standards





Codex Committees

- Commodities Committees
 - Eg.Fats and Oils
- General Subject Committees
 - Eg.Food Additives
- Regional Committees
 - Intra-regional matters and trade
- Regional Coordinating Committees
 - Africa, Europe, South West Pacific,
 Latin America, Caribbean, Near East, North America



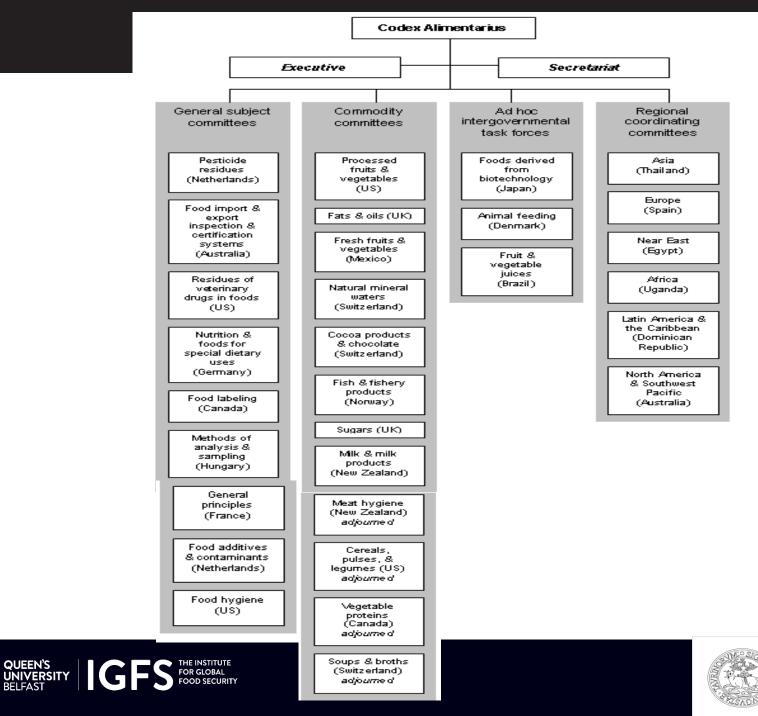


Subsidiary Bodies in the Codex

- The structure of the Codex Alimentarius Commission (CAC) consists of the Commission, the Executive Committee and the subsidiary bodies.
- Two kinds of subsidiary bodies can be established and these are classified as general subject committees and commodity committees.
 - General Subject Committees are so called because their work has relevance for all Commodity Committees .
 - **Commodity Committees** have the responsibility for developing standards for specific foods or classes of food.









Subsidiary Bodies in the Codex

General Subject Committees

- Food Additives (China)
- Food Hygiene (USA)
- Food Labelling (Canada)
- Methods of Analysis and Sampling (Hungary)
- Pesticide Residues (China
- Residues of Veterinary Drugs (USA)
- Food Import and Export Inspection and Certification Systems (Australia)
- Contaminants in Foods (Netherlands)
- Nutrition and Foods for Special Dietary Use (Germany)

Commodity Committees

- Milk and Milk Products (New Zealand)
- Processed Fruit and Vegetables (USA)
- Meat Hygiene (New Zealand)
- Fish and Fishery Products (Norway)
- Fresh Fruit and Vegetables (Mexico)
- Fats and Oils (Malaysia)
- Sugars (United Kingdom)
- Cereals, Pulses and Legumes (USA)
- Vegetable Processes (Canada)
- Natural Mineral Waters (Switzerland)
- Cocoa Products and Chocolate (Switzerland)





Codex Legal Tools:

- Codex Standards
- Codes of Practices
- Guidelines and Recommendations





Codex Standards

- Food requirements intended to provide consumers with a sound, wholesome food product free from *adulteration*, correctly *labeled* and *presented*.
- Explicitly quantifies and specifies *in* acceptable form, exactly what is considered to be *in compliance* with regards to certain commodities





Codex Standards

- International acceptance most importance consideration next to safety
- Prescribed format used to develop each standard. Must include:
 - Name, scope, description, essential composition and quality factors, food additives, contaminants, hygiene, weights and measures, labeling and methods of analysis and sampling





Codex Standards

- Use HACCP in development of standards
- Flexible enough to allow member incorporate them into existing legislation
- Strive for *"international consensus"*
- Now incorporate *"risk analysis"* methods
- 8 step procedure to pass a standard
 - Reviewed twice by CAC, twice by member and twice by government and other interested parties





- Food and feed can become contaminated by various causes and processes.
- This Standard contains the main principles which are recommended by the Codex Alimentarius in dealing with contaminants and toxins in food and feed.
- It lists only the maximum levels and associated sampling plans of contaminants and natural toxicants in food and feed.
- It only includes those that can be transferred to food of animal origin and can be relevant for public health.





Definition of Contaminants

"Any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter."





Definition of Contaminants

This standard applies to any substance that meets the terms of the Codex definition for a contaminant, including contaminants in feed for food-producing animals, except:

- 1. Contaminants having only food quality significance, but no public health significance, in the food(s).
- 2. Pesticide residues, as defined by the Codex definition that are within the terms of reference of the CCPR. Pesticide residues arising from pesticide uses not associated with food production may be considered for inclusion in the General Standard for Contaminants if not dealt with by the CCPR.
- 3. Residues of veterinary drugs, as defined by the Codex definition, that are within the terms of reference of the CCRVDF.
- 4. Microbial toxins, such as botulinum toxin and staphylococcus enterotoxin, and microorganisms that are within the terms of reference of the CCFH.
- 5. Processing aids (that by definition are intentionally added to foods).

CCFAC – Codex Committee on Food Additives and Contaminants CCPR – Codex Committee on Pesticide residues CCRVDF - Codex Committee on Residues of Veterinary Drugs in Foods CCFH – Codex Committee on Food Hygiene





Maximum and Guideline levels

The **Codex maximum level (ML) for a contaminant in a food or feed commodity is the** maximum concentration of that substance recommended by the CAC to be legally permitted in that commodity.

A **Codex guideline level (GL) is the maximum level of a substance in a food or feed** commodity which is recommended by the CAC to be acceptable for commodities moving in international trade. When the GL is exceeded, governments should decide whether and under what circumstances the food should be distributed within their territory or jurisdiction.





Index of Contaminants

- Natural toxins
- Phycotoxins
 - Saxitoxin
 - Lipophilic toxins
 - Domoic acid

• Mycotoxins

- Aflatoxins, Total
- Aflatoxin M1
- Ochratoxin A
- Patulin

- Radionuclides
- Heavy Metals
 - Arsenic
 - Cadmium
 - Lead
 - Mercury
 - Methylmercury
 - Tin
- Others
 - Acrylonitrile
 - Chloropropanols
 - Melamine
 - Vinyl Chloride monomer





A-Z Veterinary Drug Residues

Α	D
<u>Abamectin</u>	Danofloxacin
<u>Albendazole</u>	Deltamethrin
<u>Amoxicillin</u>	Dexamethasone
<u>Avilamycin</u>	Diclazuril
<u>Azaperone</u>	Dicyclanil
В	Dihydrostreptomycin/Streptomycin
Benzylpenicillin/Procaine benzylpenicillin	<u>Diminazene</u>
C	<u>Doramectin</u>
<u>Carazolol</u>	E
<u>Ceftiofur</u>	Eprinomectin
Chlortetracycline/Oxytetracycline/Tetracycline	<u>Erythromycin</u>
<u>Clenbuterol</u>	Estradiol-17beta
<u>Closantel</u>	F
<u>Colistin</u>	Febantel/Fenbendazole/Oxfendazole
<u>Cyfluthrin</u>	<u>Fluazuron</u>
<u>Cyhalothrin</u>	<u>Flubendazole</u>
Cypermethrin and alpha-Cypermethrin	<u>Flumequine</u>





A-Z Veterinary Drug Residues

<u>Gentamicin</u> I <u>Imidocarb</u> <u>Isometamidium</u> Ivermectin

G

L Levamisole Lincomycin M Melengestrol acetate Monensin Moxidectin N

<u>Narasin</u> <u>Neomycin</u> Nicarbazin

Ρ

Phoxim Pirlimycin Porcine somatotropin Progesterone R R Ractopamine hydrochloride S Sarafloxacin Spectinomycin Spiramycin

<u>Sulfadimidine</u>

T <u>Testosterone</u> <u>Thiabendazole</u> <u>Tilmicosin</u> <u>Trenbolone acetate</u> <u>Trichlorfon (metrifonate)</u> <u>Triclabendazole</u> <u>Tylosin</u> Z Zeranol





Pesticide Residues in Food and Feed

- These standards contain Codex maximum residue limits for pesticides and extraneous maximum residue limits.
- Pesticides included in the Standards are: -

Acephate (095) Iprodion (111) Chlorpyrifos-methyl (090) Methamidophos (100) Dichlorvos(025) Permethrin (120) Fenitrothion (037) Chlorpyrifos (017) Metalaxyl (138) Diazinon (22) Parathion-methyl (059) Dimethoate (027) Azinphos-methyl (002) Malathion (049) Cypermethrin (118) Parathion (058) Dicofol (026) Phenthoate (128)

Disulfoton (074) Phosalone (060) Phorate (112) Ethion (034) Endosulfan (032) (Total) Pirimicarb (101)

Pirimiphos-methyl (086)

Quintozene (064) Vinclozolin (159)





Pathogens addressed in the Codex

• Codex standards aim to reduce microbial food safety risks associated with various pathogens

Included are:-

- Escherichia Coli 0157
- Listeria Monocytogenes
- Salmonella
- Mycobacterium Tuberculosis
- Clostridium Botulinum
- Cryptosporidium parvum

- Brucellosis spp
- Pathogen psychrotrophs)
- Shigella spp
- Cyclospora cayetanensis
- Norwalk-like Virus
- Hepatitus A Virus

E Coli 0157



Salmonella







Food Additives under the Codex:

- Codex General Standard for Food Additives
 - "any substance not normally consumed as a food on its own and normally constituting a typical food ingredient, whether or not it has any nutritional value, the intentional additional of which to food for a technological purpose in the manufacturing.....or may reasonably be expected to result...in it or its byproducts becoming a component of or otherwise affecting the characteristics of such foods"





Codes of Practice

- Advisory text issued to all members
- Designed to assist members in achieving purposes of Codex
- Individual members decide how to use code
- Typically describe "hygiene" requirements

 "Adequate" / "Acceptable"
- Considered "checklist" of requirements for enforcement authorities (Jurisdictional Prerequisites)





Guidelines and Recommendations

- Basic tool used to help member nations in elaboration of their standards to conform to Codex
- Not binding but accepted worldwide
- Very useful to developing countries
- Example: "Code of Ethics for International Trade in Food"
- Commission can make guidelines "quasi-binding"
 - i.e. SPS Agreement guidelines





Acceptance

- Member nation must formally accept Codex standard
- Types of acceptance:
 - <u>Full Acceptance</u>:
 - Product distributed freely under standard name if complies with Codex standard
 - Acceptance with specified variations:
 - Product distributed freely only if complies with standard and variation





Acceptance

- <u>Target Acceptance</u>
 - Conforming product distributed freely but standard not accepted until certain date
- <u>Free Distribution</u>
 - Replaced "Target Acceptance"
 - Free distribution of conforming products so long as complies with national standard
- <u>Non Acceptance</u>
 - Country refuses to accept standard in any form and indicates whether or not it will allow free distribution of Codex products





Enforcement of Codex Standards

- Codex regulation not binding until adopted by member.
- Member ratification of Codex standards is mandatory
- Violation would then be violation of the member country's national law and punishment accordingly





Codex Summary

- Codex Alimentarius is designed to ensure *international acceptance* in terms of quality and economic interest of consumer and to *ensure fair trade practices*
- Standards based on *scientific principles* such as HACCP (Hazard analysis and critical control points)





Codex Summary

- Flexible so can be integrated into member's National law
- SPS Agreement, GATT and NAFTA all encourage acceptance of Codex standards
- Codex reflects *international consensus* on food law issues





EU Policy



The EU member countries have transferred some of their law-making authority to the EU in certain policy areas, such as agriculture and fisheries.





EU Agriculture Policy

- European Commission
 - Agriculture and Rural Development
- European Parliament
 - Committee on Agriculture and Rural Development
- Council of the European Union
 - Agriculture and Fisheries Council (ministers of all EU Member states)





European Parliament

 The Committee on Agriculture and Rural Development (AGRI) is primarily responsible for examining and amending the European Commission's legislative proposals by preparing reports on agricultural policy for subsequent adoption by the European Parliament in plenary. It has 45 full members and 45 substitute members.





What is the role of the EU in Food Safety?

- The EU is a major global trader of food and feed. It has entered into international trade agreements and contributed to the development of international standards which underpin food law.
- It also supports the principles of free trade in safe food and feed following fair and ethical trading practices. This is of enormous importance to citizens in Europe and around the world whether they are politicians, traders or consumers.
- The EU is a member of the WTO, which is the leading organisation that sets the international rules for trade.
- All 27 EU countries are members of the Codex Alimentarius Commission (International Food Standards).





EU Regulations in Food Safety

- The EFSA produces risk assessment and scientific advice to provide a good foundation for European policies and legislation.
- EU regulations cover all stages of the production and distribution chain, adopting the approach 'from the farm to the fork'.
- EU regulations concern food and food product hygiene, animal health and welfare, plant health and preventing the risk of contamination from external substances. They also lay down rules on appropriate labelling for these foodstuffs and food products.
- Many of the EU regulations are mandatory for member states and therefore must be incorporated into individual countries' national legislation.





EU Regulations in Food Safety

The main EU Regulations in Food Safety are:-

- General Food Law
 - (EC) No 178/2002
- Food Hygiene Controls
 - (EC) No 852/2004
 - (EC) No 853/2004
 - (EC) No 854/2004
- Official Feed and Food Control Regulations
 - (EC) No 882/2004
- Microbiological Criteria for Foodstuffs
 - (EC) No 2073/2005

EU legislation on contaminants in food are in <u>Council Regulation</u> <u>315/93/EEC</u>

Maximum levels for certain contaminants in food are set in <u>Commission</u> <u>Regulation (EC) No 1881/2006</u>.

nitrate, mycotoxins (aflatoxins, ochratoxin A, patulin, deoxynivalenol, zearalenone, fumonisins and citrinine), metals (lead, cadmium, mercury, inorganic tin), 3-MCPD, dioxins and dioxin-like PCBs, non dioxin-like PCBs, polycyclic aromatic hydrocarbons (PAH) (benzo(a)pyrene) and sum of 4 PAHs), melamine and erucic acid.





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	FOOD	ropa Search on Europa en English	
European Commission > Food Safet	FOOD ANIMALS PLANTS AMR	Share	
Principles	General Food Law		
Requirements	European citizens need to have access to safe and wholesome food of the highest standard.	RELATED LINKS	
Procedures	A series of food incidents in late 1990s draw attention to the need to establish general	• Events	
Fitness Check of General Food Law	principles and requirements concerning food and feed law at Union level. Accordingly, the European Commission developed an integrated approach to food safety 'fromfarm to table', primarily set out in its White Paper on Food Safety $\mathbb{A}^{[0]}$ and $\mathbb{A}^{[0]}$.	15 years anniversary of the General Food Law Comitology committee	
Expert Group on General Food Law	It covers all sectors of the food chain, including feed production, primary production, food processing, storage, transport and retail sale. In 2002, the European Parliament and the Council adopted Regulation (EC) No 178/2002 [aying down the general principles and requirements of food law (General	RELATED DOCUMENTS	
ALL TOPICS	Food Law Regulation). The General Food Law Regulation is the foundation of food and feed law. It sets outs an overarching and coherent framework for the development of food and feed legislation both at Union and national levels. To this end, it lays down general principles, requirements and procedures that underpin decision making in matters of food and feed safety, covering all stages of food and feed production and distribution.	Erem Farm to Fork: Controlling the safety of the agri food shain b General Food Law Regulation White Paper on Food Safety, 2000 b Control	
	It also sets up an independent agency responsible for scientific advice and support, the European Food Safety Authority (EFSA).	QUICK LINKS	
	Moreover, it creates the main procedures and tools for the management of emergencies and crises as well as the Rapid Alert System for Food and Feed (RASFF).	Rapid Alert for Food and Feed (RASFF)	
	The General Food Law Regulation ensures a high level of protection of human life and consumers' interests in relation to food, while ensuring the effective functioning of the internal market.	Health and food audits and analysis European Food Safety Authority (EFSA)	
		Better Training for Safer Food (BTSF)	





EU Food Law

- The food law aims at ensuring a high level of protection of human life and health, taking into account the protection of animal health and welfare, plant health and the environment. This integrated "farm to fork" approach is now considered a general principle for EU food safety policy.
- Food law, both at national and EU level, establishes the rights of consumers to safe food and to accurate and honest information. The EU food law aims to harmonise existing national requirements in order to ensure the free movement of food and feed in the EU.
- The food law recognises the EU's commitment to its international obligations and will be developed and adapted taking international standards into consideration, except where this might undermine the high level of consumer protection pursued by the EU.





EU Food Law – Risk Analysis

- The Regulation establishes the principles of risk analysis in relation to food and establishes the structures and mechanisms for the scientific and technical evaluations which are undertaken by the European Food Safety Authority (EFSA).
- Depending on the nature of the measure, **food law**, and in particular measures relating to food safety must be **underpinned by strong science**. The EU has been at the forefront of the development of the risk analysis principles and their subsequent international acceptance. Regulation EC 178/2002 establishes in EU law that the three inter-related components of risk analysis (risk assessment, risk management and risk communication) provide the basis for food law as appropriate to the measure under consideration.
- Clearly not all food law has a scientific basis, e.g. food law relating to consumer information or the prevention of misleading practices does not need a scientific foundation.
- Scientific assessment of risk must be undertaken in an independent, objective and transparent manner based on the best available science.





EU Food Law – Risk Analysis

- Risk management is the process of weighing policy alternatives in the light of results of a risk assessment and, if required, selecting the appropriate actions necessary to prevent, reduce or eliminate the risk to ensure the high level of health protection determined as appropriate in the EU.
- In the risk management phase, the decision makers need to consider a range of information in addition to the scientific risk assessment. These include, for example, the feasibility of controlling a risk, the most effective risk reduction actions depending on the part of the food supply chain where the problem occurs, the practical arrangements needed, the socio-economic effects and the environmental impact. Regulation EC/178/2002 establishes the principle that risk management actions are not just based on a scientific assessment of risk but also take into consideration a wide range of other factors legitimate to the matter under consideration.



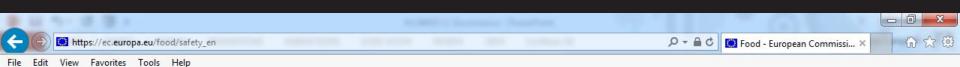


EU Food Law - Transparency

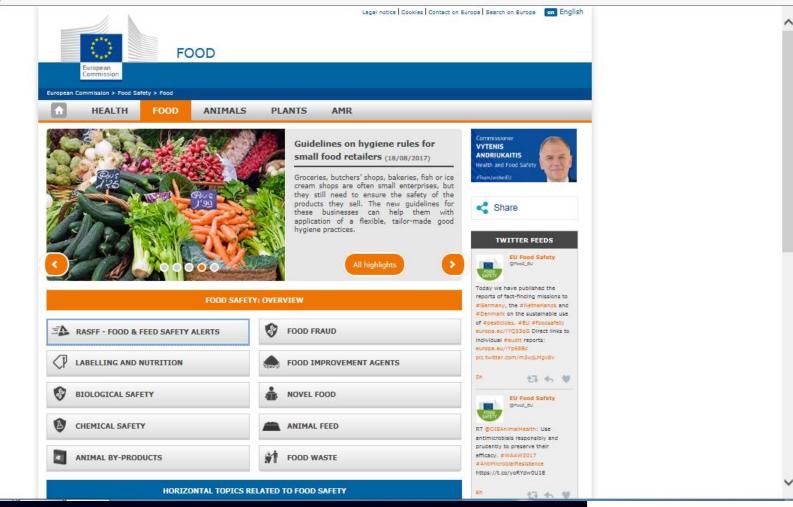
- Food safety and the protection of consumer interests are of increasing concern to the general public, non-governmental organisations, professional associations, international trading partners and trade organisations. Therefore, the **Regulation** establishes a framework for the greater involvement of stakeholders at all stages in the development of food law and establishes the mechanisms necessary to increase consumer confidence in food law.
- This consumer confidence is an essential outcome of a successful food policy and is therefore a primary goal of EU action related to food. Transparency of legislation and effective public consultation are essential elements of building this greater confidence. Better communication about food safety and the evaluation and explanation of potential risks, including full transparency of scientific opinions, are of key importance.







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International Food Regulations

Katrina Campbell Professor in Food Security & Diagnostics

E-mail: katrina.campbell@qub.ac.uk







