

FOOD SAFETY AND FOOD SECURITY

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Legislative framework in EU Food Safety

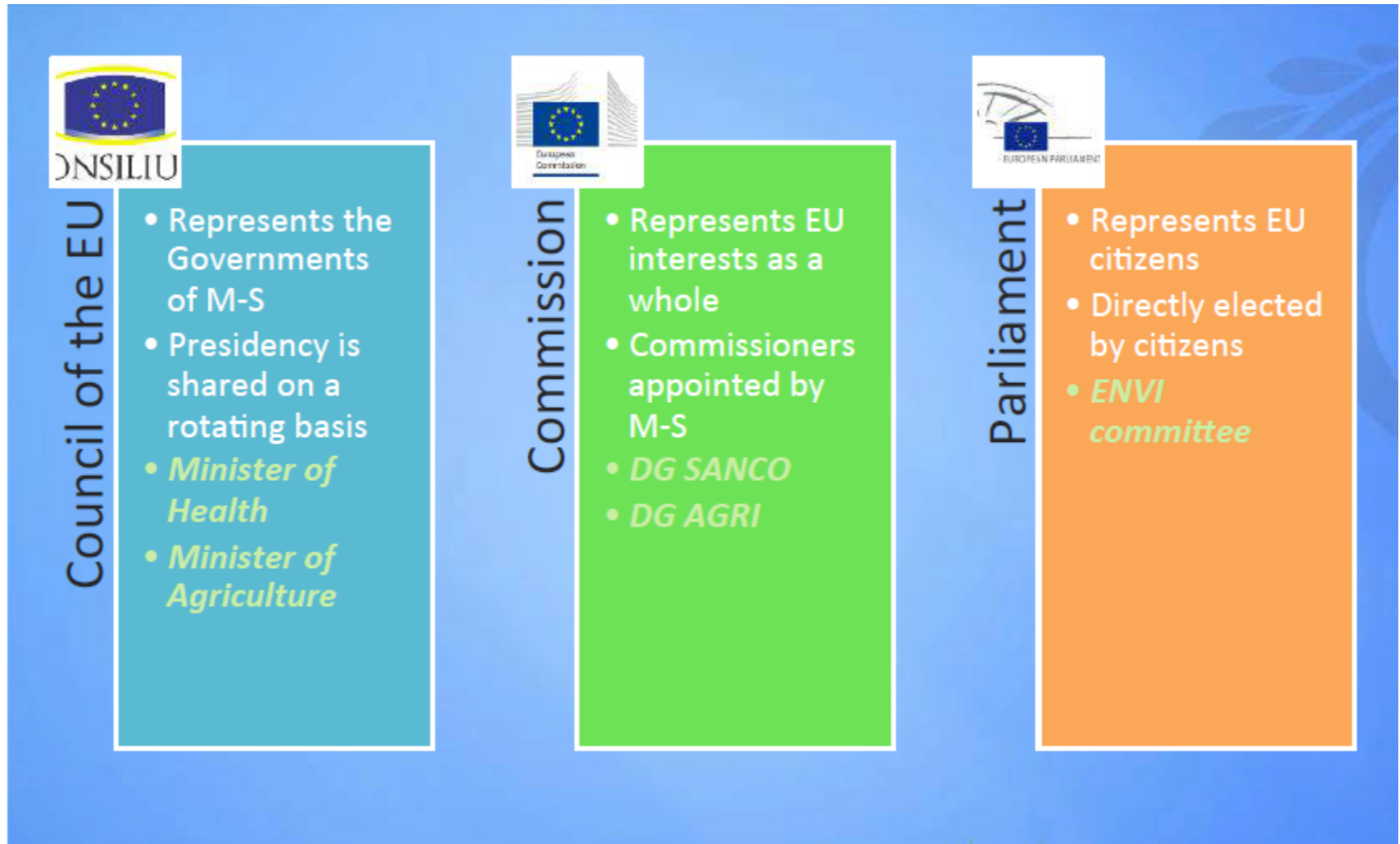
Part I

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EU Institution and policy making

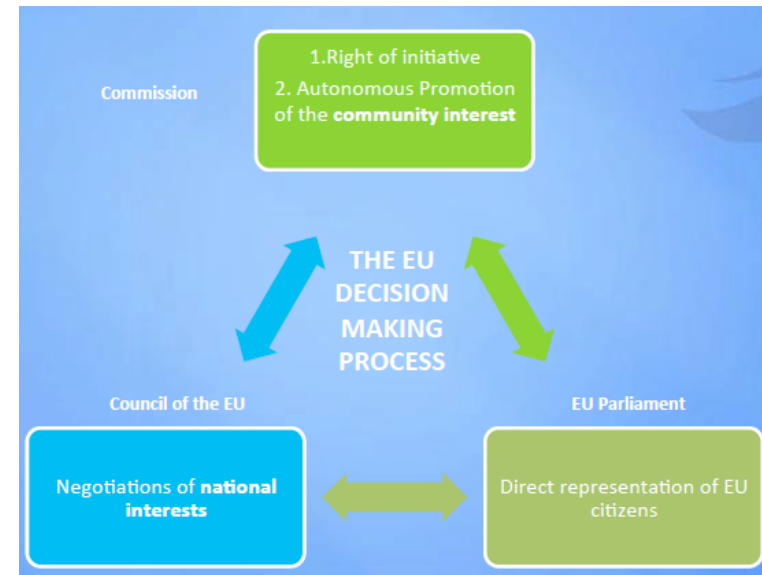


The **Committee on the Environment, Public Health and Food Safety (ENVI)**

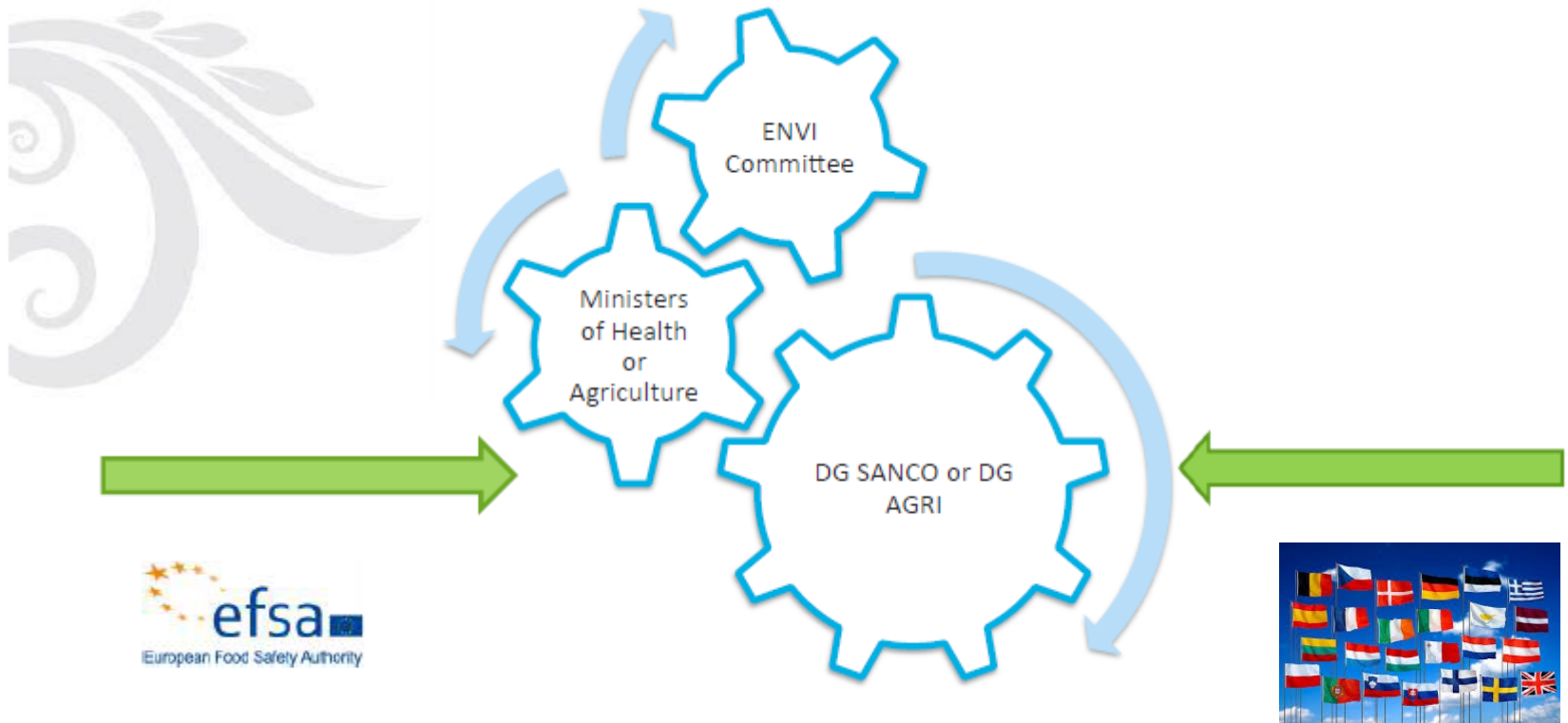
Directorate-General for Health and Consumers (DG SANCO)

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EU Institution and policy making



EU Institution and policy making

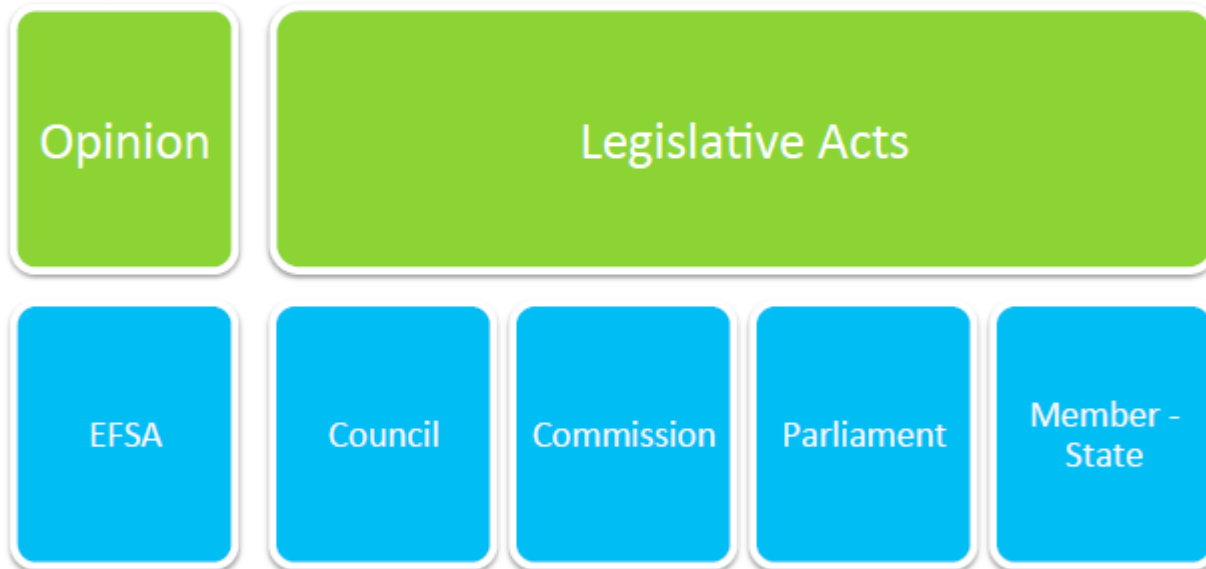


The **Committee on the Environment, Public Health and Food Safety (ENVI)**

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EU Food Law & Decision Making

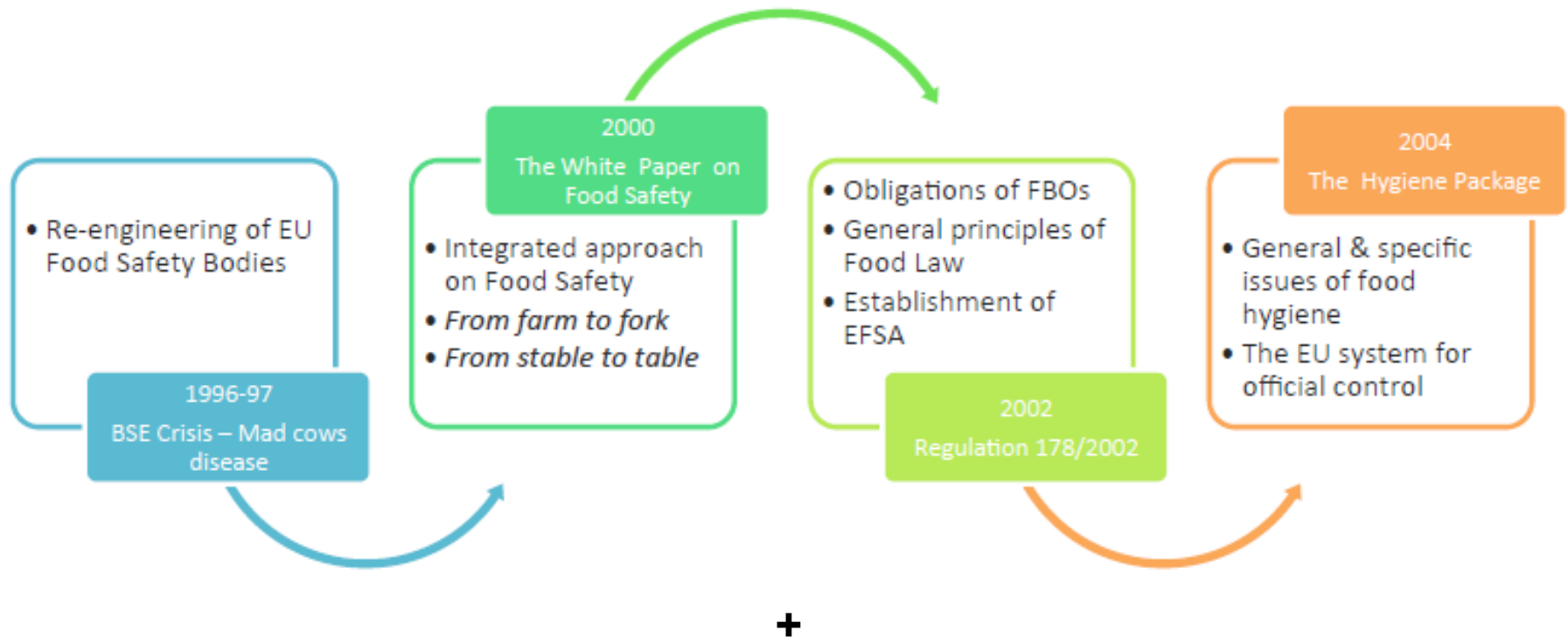
Framework Recall

EU Food Legislation

- **Regulations** → legislative acts applied in their entirety in Member States. They have the power of laws and supersede national laws. They include implementation mechanisms
- **Directives** → establish objectives that are compulsory to Member States, but requires transposition into national law as they do not include implementation mechanisms
- **Decision** → can be addressed to both Member States and specific entities; they are directly applicable but usually cover a narrow topic or issue
- **Implementing acts** → legally binding acts / concern procedural elements

The EU has moved from mostly Directive to Regulations to the control of food safety in order to harmonize the legislation towards Member States

Framework timeline



Regulation 2073/2005 Microbiological criteria for food safety & hygiene monitoring

- **Regulation 2074/2005** Implementing measures for certain products under the provisions of Reg 853/2004

- **Regulation 931/2011** Traceability requirements

Legislation before the White Paper

- Overlaps, repetitions and contradictions
- Different approach for food of animal origin and other foodstuffs
- High level of technical detail
- Extensive involvement of competent authorities in providing guarantees
- Mixture of different skills

The White paper (2000)



FOOD
SAFETY

The White Paper proposes a number of measures to reorganise food safety:

- ✓ the establishment of an autonomous **European Food Authority (EFSA)** to provide scientific opinions on all aspects of food safety;
- ✓ legislation covering all food-related aspects;
- ✓ national control systems which should be carried out in a more harmonised and therefore more effective way within the Community;
- ✓ an appropriate dialogue with consumers and other stakeholders on food safety issues
- ✓ The guiding principle of this new system is that food safety policy should be based on a **comprehensive integrated approach**.

A new cultural and legislative approach

General principles of food safety

- global and integrated approach
- primary responsibility to food and feed business operators (**FBOs**)
- implementation of traceability
- risk analysis underpinning any decision
- precautionary principle

The new global Food Law

- horizontal approach for all foods
- consideration of particular risks related to specific foods
- elimination of many technical details
- separation of texts relating to hygiene, official controls and animal health aspects

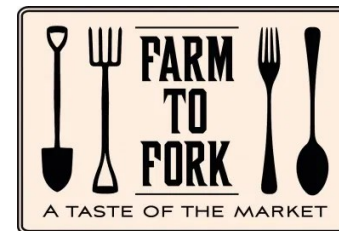
Framework



- White Paper on Food Safety (2000)



- “From-Farm-To-Fork” and “ From Stable to Table” approach



- New EU food legislation



- ✓ Regulation 178/2002
- ✓ Hygiene package

Framework



From Farm to Fork CONTROLLING THE SAFETY OF THE AGRI FOOD CHAIN



NATIONAL ENFORCEMENT
AUTHORITIES PERFORM
CONTROLS ON FARMS,
BUT ALSO...

> THE CONTROLS CHECK FOR

- hormones
- chemical residues
- bacterial / viral contamination
- overall hygiene
- labelling
- proper refrigeration
- animal and plant health requirements
- animal welfare
- fraud

...BORDER CONTROLS
FOR IMPORTED ANIMALS, PLANTS,
SPECIFIC FOODSTUFF
FROM OUTSIDE THE EU
AND...

CONTROLS DURING
TRANSPORT WITHIN
THE EU, AND...

> Controls are performed
on the basis of RISK for health

...CONTROLS ON
FOOD PROCESSING PLANTS,
WHOLESALERS, SUPERMARKETS
RETAILERS AND RESTAURANTS

> 100,000-120,000

IMPARTIAL, INDEPENDENT,
WELL TRAINED STAFF

with specific inspection competences
check 25 MILLION operators
along the agrifood chain for the
safety of 500 million consumers.

Regulation (EC) No 178/2002

“General Food Law Regulation”

- Regulation 178/2002 is the foundation of food and feed law:
 - coherent framework for the development of food & feed legislation (EU/national)
 - common definitions and general principles, requirements & procedures for food & feed safety at all stages of the production, processing & distribution
 - setting of European Food Safety Authority ([EFSA](#))
 - main procedures and tools for the management of emergencies & crises as well as the Rapid Alert System for Food and Feed ([RASFF](#))

Regulation (EC) No 178/2002

“General Food Law Regulation”

- Regulation 178/2002 is composed by:
 1. Field of application and common definitions (Arts 1-3)
 2. General principles, requirements & procedures for food & feed safety at all stages of the production, processing & distribution (Arts 4-21)
 3. setting of European Food Safety Authority (EFSA) (Arts 22-49)
 4. main procedures and tools for the management of emergencies & crises as well as the Rapid Alert System for Food and Feed (RASFF) (Arts 50-54)
 5. Final dispositions and procedures

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 1

Aim and scope

1. 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. It establishes common principles and responsibilities, the means to provide a strong science base, efficient organizational arrangements and procedures to underpin decision- making in matters of food and feed safety

2. 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**

It establishes the **European Food Safety Authority**

It lays down **procedures for matters with a direct or indirect impact on food and feed safety**

3. 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

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 2

Definition of food

‘Food’ or ‘foodstuff’: 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

‘Food’ shall not include: feed, live animals unless they are prepared for placing on the market for human consumption, plants prior to harvesting, medicinal products, cosmetics, tobacco and tobacco products, narcotic or psychotropic substances, residues and contaminants

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 3

Other definitions

‘food law’: 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

‘food business’: any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food

‘food business operator (FBO)’: the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control

‘stages of production, processing and distribution’: any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed

‘traceability’: the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 3

Other definitions

‘**risk**’: a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard

‘**hazard**’: a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect

‘**risk analysis**’: a process consisting of three interconnected components: risk assessment, risk management and risk communication

‘**risk assessment**’: a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation

‘**risk management**’: the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options

‘**risk communication**’: the interactive exchange of information and opinions throughout the risk analysis process

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 5

General objectives

- High level of protection of human life & health and the protection of consumers’ interests
- Fair practices in food trade, taking into account animal health/welfare, plant health & the environment
- Free movement of food and feed manufactured and marketed in the EU
- Facilitate global trade of safe feed & safe and wholesome food by taking into account **international standards & agreements**

Regulation (EC) No 178/2002

“General Food Law Regulation”

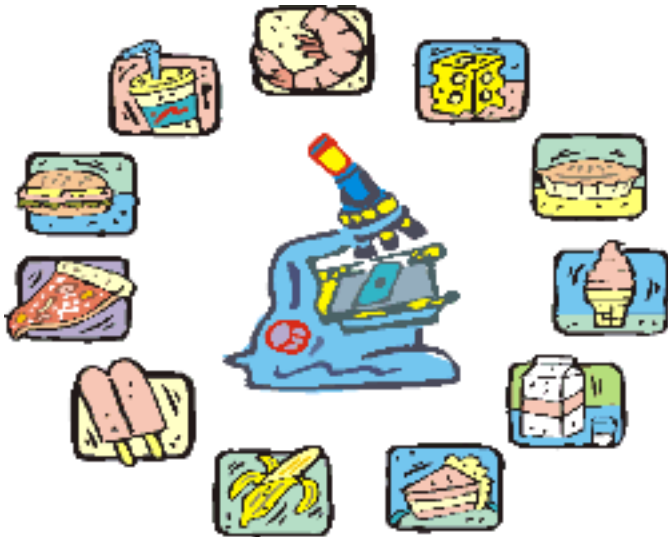
Article 6

Risk analysis principle

1. Risk assessment → independent, objective & transparent, based on the best available science
2. Risk management → select the appropriate actions necessary to prevent, reduce or eliminate the risk
3. Risk communication → the interactive exchange of information and opinion throughout risk analysis

HAZARD and RISK Definitions

HAZARD



biological, chemical or physical agent contained in a food or feed, or condition in which a food or feed is found, capable of exerting a potentially harmful effect on health

HAZARD and RISK Definitions

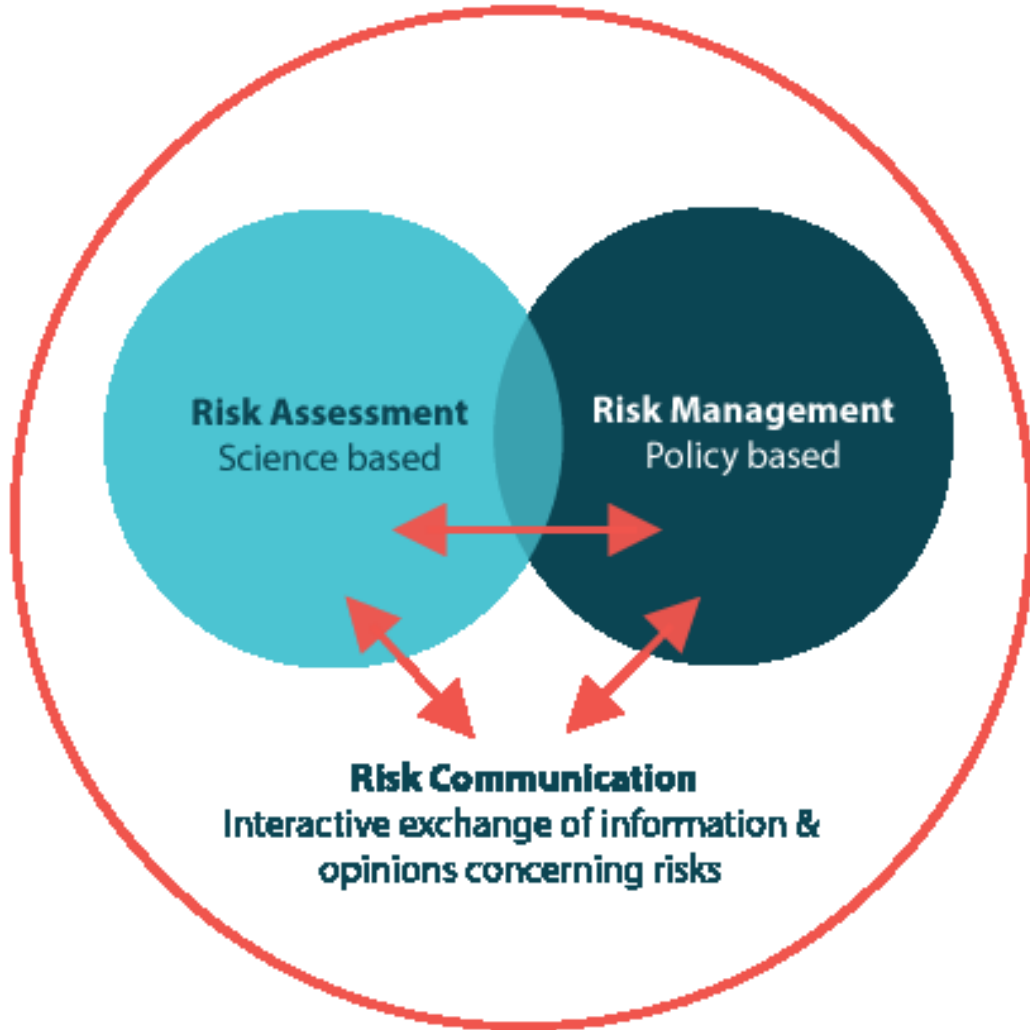


RISK

Risk is an estimate of the probability of that a harmful event occurs

Function of the probability and severity of a harmful effect on health resulting from the presence of a hazard

RISK ANALYSIS



Risk analysis is composed by 3 process:

- **Assessment**
- **Managment**
- **Communication**

RISK ASSESSMENT

Scientific evaluation of known or potential adverse health effects resulting from human exposure to food-borne hazards

The process includes the following steps:

- **Hazard identification**: adverse health effects associated with a particular agent
- **Hazard characterisation**: qualitative and/or quantitative assessment of the nature of the adverse effects
- **Exposure assessment**: qualitative and/or quantitative assessment of the degree of intake likely to occur
- **Risk characterisation**: integration of the previous steps into an estimate of the adverse effects likely to occur in a given population, including pending uncertainties.

RISK MANAGEMENT

- **Preliminary activities**: acquiring information (including that acquired through risk assessment)
- **Assessment of options**: Assess the options available for the management of a food safety problem in the light of scientific information on risks and other factors and cost-benefit analysis. This may include reaching a decision on an appropriate level of consumer protection.
- **Important objective**: optimisation of control measures in terms of effectiveness, efficiency, technological feasibility and practicality along the food chain

RISK MANAGEMENT

- **Implementation of decisions** (standards, HACCP).
Flexibility is a desirable element. It is essential to verify in itinere the application of the measures.
- **Monitoring and review**: obtain and analyse data in order to have an integrated view of food safety and consumer health

If there is evidence that the public health objectives are not being met, a rethink of the measures will be necessary.

RISK COMMUNICATION

- It is an interactive process of exchange of views and information on risk between risk assessors, risk managers and other stakeholders (industry and consumers).
- It is an integral part of the risk analysis process and ideally all stakeholders should be involved from the outset.
- The risk communication strategy should be discussed and agreed between risk assessors and risk managers and understand who should present the information to the public and how this will be done.

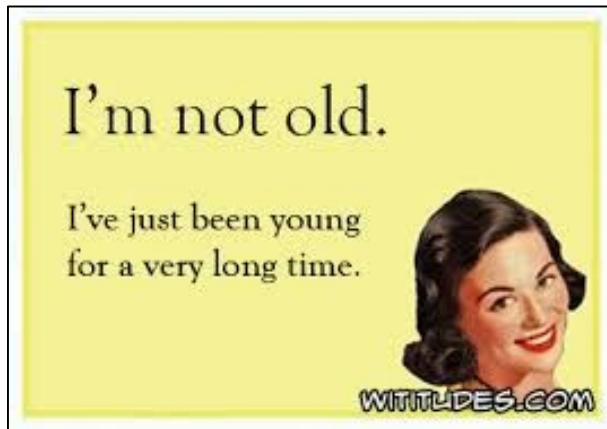


Regulation (EC) No 178/2002 “General Food Law Regulation”

Article 7

Precautionary principle:

Not a new concept



Regulation (EC) No 178/2002
“General Food Law Regulation”

Precautionary Principle

Implementation on the International level

1992 - Rio Declaration on Environment and Development; the United Nations Convention on Climate Change

1992 - Maastricht Treaty amends Treaty of European Community: “Community policy on the environment ... shall be based on the precautionary principle ...” – precautionary principle not Defined

1994 – World Trade Organization Agreement on Sanitary and phytosanitary Measures (SPS)

1998 – ECJ Judgment in BSE case - “When there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks becomes fully apparent” - *First time PP spread to the Food Law area* (C-180/96 United Kingdom v. Commission)

2000 – Biosafety Protocol Implementation In Europe

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 7

Precautionary principle: - reasonable grounds for concern that an unacceptable level of risk to health exists → **Scientific uncertainty**
- available supporting information & data not sufficiently complete to enable a comprehensive risk assessment

→ Decision makers or risk managers may take measures:

- ✓ Proportional
- ✓ Non-discriminatory
- ✓ Consistent
- ✓ Based on the examination of the potential benefits and costs
- ✓ Subject to review
- ✓ Capable of assigning responsibility for producing the scientific evidence

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 7

Precautionary principle

Proportionality → tailoring measures to the chosen level of protection

→ a total ban may not be a proportional response to a potential risk in all cases, but it is the only possible response in certain cases

Non-discrimination → comparable situations should not be treated differently

→ different situations should not be treated in the same way

Consistency → measures should be of comparable scope & nature to those already taken when all scientific data are available

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 7

Precautionary principle

Examining costs & benefits → comparing the overall cost to the Community of action and lack of action, in both the short and long term

→ much broader scope than an economic cost-benefit analysis, considering the efficacy of possible options & their acceptability (the protection of health takes precedence over economic considerations)

Subject to review in the light of new scientific data → measures maintained so long as scientific information is incomplete or inconclusive & the risk is still too high

Assigning responsibility for producing scientific evidence → countries that impose a prior approval requirement on products that they deem dangerous treat them as dangerous, unless and until businesses demonstrate safety

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 8

Protection of consumers' interests

- Protection of the interests of consumers and provision of a basis for consumers to make informed choices in relation to the foods they consume
- Prevention of:
 - fraudulent or deceptive practices
 - the adulteration of food
 - any other practices which may mislead the consumer

Regulation (EC) No 178/2002

“General Food Law Regulation”

Articles 9 & 10

Transparency

- Food safety & protection of consumer interests are of great concern (general public, non-governmental organizations, professional associations, international trading partners & trade organizations) → transparency of decision-making is of paramount importance
- The General Food Law provides for the mechanisms necessary to increase consumer confidence:
 1. Effective public consultations during the preparation, evaluation & revision of food and feed law
 2. Obligation on public authorities to inform the general public, in case of reasonable suspicion that a food or feed may present a risk for human or animal health

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 11

Food and feed imported into the Community

- Food and feed imported shall comply with:
 - the relevant requirements of food law or
 - conditions recognised by the Community to be at least equivalent or
 - where a specific agreement exists between the Community & the exporting country, with agreed requirements
- The traceability provisions of the General Food Law do not have an extra-territorial effect outside the EU → this requirement covers all stages of production, processing and distribution in the EU, namely from the importer up to the retail level
- Traceability is sufficiently fulfilled because the requirement extends to the importer, being able to identify from whom the product was exported in the third country

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 12

Food and feed exported from the Community

- Food and feed exported or re-exported shall comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country (legislation or administrative procedures)
- In other circumstances, except in the case where foods are injurious to health or feeds are unsafe, food and feed can only be exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for which the food or feed concerned could not be placed on the market in the Community
- When there is a bilateral agreement → comply with the agreed provisions
- Rationale → to prevent the “exportation” of crisis

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 13

International Standards

Without prejudice to their rights and obligations, the Community and the Member States shall:

- contribute to the development of international technical standards for food/feed & sanitary/ phytosanitary standards
- promote the coordination of work on food/feed standards undertaken by international organisations
- contribute, where relevant and appropriate, to the development of agreements on recognition of the equivalence of specific food and feed-related measures
- give particular attention to the special development, financial and trade needs of developing countries
- promote consistency between international technical standards and food law

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 14

Food safety requirements

1. Food shall not be placed on the market if it is unsafe
2. Food shall be deemed to be unsafe if it is considered to be:
 - injurious to health or
 - unfit for human consumption
3. In determining whether any food is unsafe, regard shall be had:
 - to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and
 - to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 14

Food safety requirements

4. In determining whether any food is injurious to health, regard shall be had:
 - not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations
 - to the probable cumulative toxic effects
 - to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers

5. In determining whether any food is unfit for human consumption, regard shall be had to whether the food 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

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 14

Food safety requirements

6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence of unsafety
7. Food that complies with specific Community provisions shall be deemed to be safe
8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from imposing restrictions or requiring its withdrawal from the market where there are reasons to suspect that the food is unsafe
9. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 15

Feed safety requirements

1. Feed shall not be placed on the market or fed to any food- producing animal if it is unsafe
2. Feed shall be deemed to be unsafe for its intended use if it is considered to:
 - have an adverse effect on human or animal health, or
 - make the food derived from food-producing animals unsafe for human consumption
3. Where a feed which has been identified as not satisfying the feed safety requirement is part of a batch, lot or consignment of feed of the same class or description, it shall be presumed that all of the feed in that batch, lot or consignment is so affected, unless following a detailed assessment there is no such evidence

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 15

Feed safety requirements

4. Feed that complies with specific Community provisions shall be deemed to be safe
5. Conformity of a feed with specific provisions applicable to that feed shall not bar the competent authorities from imposing restrictions or requiring its withdrawal from the market where there are reasons to suspect that the feed is unsafe
6. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 16

Presentation

Without prejudice to more specific provisions of food law,

- the labelling, advertising and presentation of food or feed, including:
 - their shape, appearance or packaging
 - the packaging materials used
 - the manner in which they are arranged and the setting in which they are displayed and
 - the information which is made available about them through whatever medium
- shall not mislead consumers

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 17

Responsibilities

1. 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
2. Member States shall enforce food law, & monitor and verify that the relevant requirements of food law are fulfilled by food & feed business operators at all stages of production, processing & distribution
 - maintain a system of official controls & other activities as appropriate to the circumstances (public communication on food & feed safety and risk, food & feed safety surveillance & other monitoring activities covering all stages of production, processing & distribution)
 - lay down the rules on measures & penalties applicable to infringements of food & feed law
 - measures and penalties shall be effective, proportionate and dissuasive

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 17

Responsibilities

As a food business is best placed to devise a safe system for supplying food/feed & ensuring that the food/feed it supplies is safe, it holds primary legal responsibility for ensuring compliance with food law & in particular food safety (→ fundamental role of food businesses to the farm to table policy, covering all sectors of the food chain)

Defining responsibilities should consider the fact that interactions between producers, manufacturers & distributors are becoming increasingly complex (in many cases primary producers have contractual obligations to manufacturers or distributors to meet specifications which cover quality and/or safety)

Each link in the food chain should take the measures necessary to ensure compliance with food law requirements within the context of its own specific activities (like applying HACCP-type principles)

Where a product is found failing food law requirements, the liability of each link in the chain should be reviewed according to whether or not it has properly fulfilled its own specific responsibilities

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 18

Traceability

1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution
2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed
→ such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 18

Traceability

3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied → this information shall be made available to the competent authorities on demand
4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 18

Traceability / Guidance on the implementation of 178/2002 on General Food Law (2010)

Rationale: Traceability is a way of assisting in having a food safety problem:

- It facilitates targeted withdrawal and recall of food, thereby avoiding unnecessary disruption of trade
- It enables consumers to be provided with accurate information concerning implicated products, thereby helping to maintain consumer confidence
- It facilitates risk assessment by control authorities
- Apart from its food safety role, traceability also helps to ensure:
 - fair trading amongst operators
 - the reliability of information supplied to consumers in terms of substantiating claims made by manufacturers

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 18

Traceability / Guidance on the implementation of 178/2002 on General Food Law (2010)

Covered operators:

- Traceability requirements apply to food business operators at all stages of the food/feed chain, from primary production, food/feed processing to distribution & supply
- Brokers are included, regardless of physical possession of the food/feed
- Member States should take into account the degree of organisation and continuity of their activities
- Where transportation/storage is integrated within a food/feed business, the business as a whole must comply with the provision of traceability principle
→ for the transport unit, maintaining records may be sufficient as other units would maintain records of products received from suppliers

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 18

Traceability / Guidance on the implementation of 178/2002 on General Food Law (2010)

Impact on food business operators (FBO):

- The obligation to identify the suppliers and direct recipients of their food/feed is stipulated explicitly
- Article 18 is worded in terms of its goal & intended result, rather than in terms of prescribing how that result is to be achieved → allows flexibility
- It affects importers who are required to be able to identify from whom the product was exported in the country of origin
- Traceability obliges businesses to be able to identify at least the immediate supplier of the product in question & the immediate subsequent recipient, with the exemption of retailers to final consumers / **one step back-one step forward**

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 18

Traceability / Guidance on the implementation of 178/2002 on General Food Law (2010)

Implementation of traceability requirements:

- Identification of suppliers & customers by food business operators:
 - suppliers can be individuals or legal persons
 - supermarkets and restaurants are included to customers
 - cold store operators and transporters should also keep traceability records
- Internal traceability:
 - operators are not expressly compelled to establish a link between incoming & outgoing products
 - internal traceability would contribute to more targeted and accurate withdrawals → save costs
 - decision is left to food business operators

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 18

Traceability / Guidance on the implementation of 178/2002 on General Food Law (2010)

Implementation of traceability requirements:

- Traceability systems laid down by specific legislation:
 - beef labelling, fish labelling, GMOs
 - specific regulations laying down marketing & quality standards for certain products
 - any other identification system existing within the framework of specific provisions may be used
- Information to be kept → not specified, but operators should keep at least:
 - name, address of supplier, and identification of products supplied
 - name, address of customer, and identification of products delivered
 - date and, where necessary, time of transaction / delivery
 - volume, where appropriate, or quantity

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 18

Traceability / Guidance on the implementation of 178/2002 on General Food Law (2010)

Implementation of traceability requirements:

- Time of reaction for traceability, data availability:
 - “systems” & “procedures” → a structured mechanism able to deliver the needed information upon request
 - need to provide the important information, not the format in which it is kept
 - the records should be sufficiently organised to enable availability without undue delay
- Time for keeping records → not specified, but it is suggested:
 - highly perishable products (use by date <3 months) → for 6 months after manufacturing/delivery
 - products with “best before” date → for the period of the shelf-life plus 6 months
 - other products → for 5 years

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 19

Responsibilities for food: food business operators (*withdrawal, recall and notification*)

1. If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall :
 - immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that operator & inform the competent authorities
 - effectively and accurately inform the consumers of the reason for its withdrawal if the product has reached the consumer
 - recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection

** if the product is removed before being placed on the market or if it is under the immediate control of a particular food business operator, there are no notification obligations*

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 19

2. A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall :
 - initiate procedures to withdraw from the market products not in compliance
 - pass on relevant information necessary to trace a food
3. A food business operator shall immediately inform the competent authorities:
 - if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health
 - of the action taken to prevent risks to the final consumer
4. A food business operator shall:
 - not prevent/discourage any person from cooperating with authorities to reduce/eliminate food risk
 - collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied

Regulation (EC) No 178/2002

“General Food Law Regulation”

Article 20

Responsibilities for food: food business operators (*withdrawal, recall and notification*)

- The objectives of this Article are the same as those of Article 19, applied to feed *mutatis mutandis*
- In the context of feed, it is important to take into account that some type of feed in some of its raw state prior to processing is not fit for animal consumption
- Mostly similar to those of Article 19, except that Article 20 (1) provides in particular for the destruction of the feed or batch of feed considered as non compliant with the feed safety requirements, unless the competent authority is satisfied otherwise
- In the context of feed, the information on withdrawal will concern the users (farmers) of the feed and not consumers

SUMMARIZING

Key obligations of FBOs (Food Business Operators)

Safety

FBOs shall not place on the market unsafe food

Responsibility

FBOs are responsible for the safety of the food which they produce, transport, store or sell

Traceability

FBOs shall be able to rapidly identify any supplier or owner

Transparency

FBOs shall immediately **inform** the competent authorities if they have a reason to believe that their food is not safe

Emergency

FBOs shall immediately **withdraw** food from the market if they have a reason to believe that it is not safe

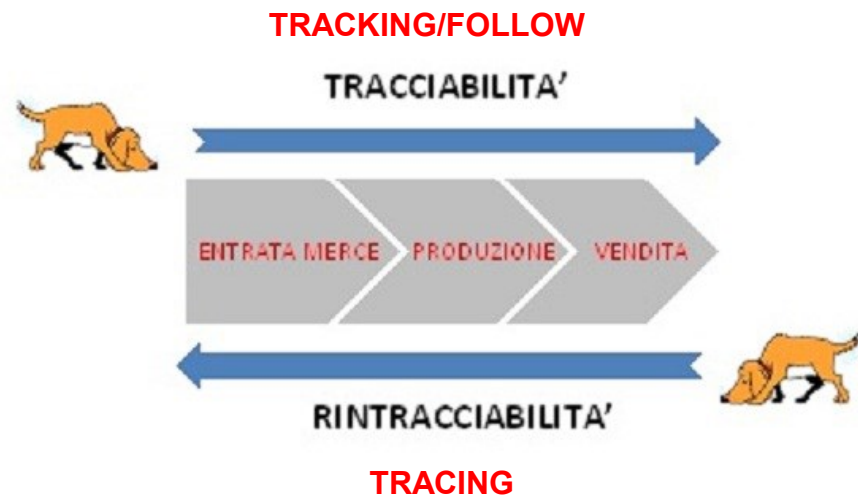
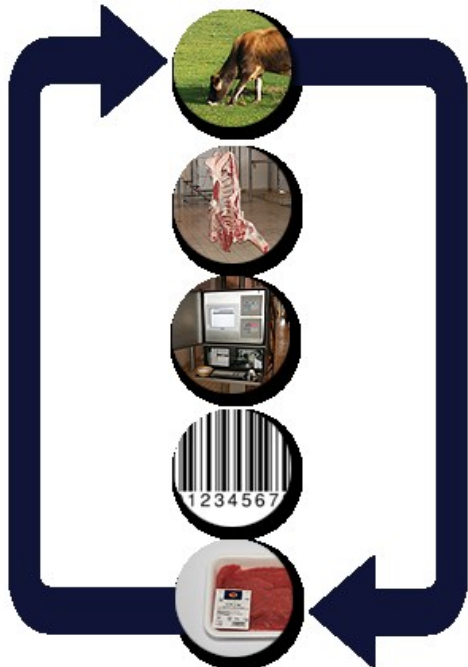
Prevention

FBOs shall identify and regularly review the critical points in their processes and ensure that controls are applied at these points

SUMMARIZING

Traceability

- Means the ability to **trace and follow** a food, at all stages of production
- Traceability facilitates the **identity, history** and **source** of a product
 - It does not make food safe, it is a management tool
 - It enables the assurance of food safety and allows action to be taken if food is found not to be safe, e.g. withdrawal or recall



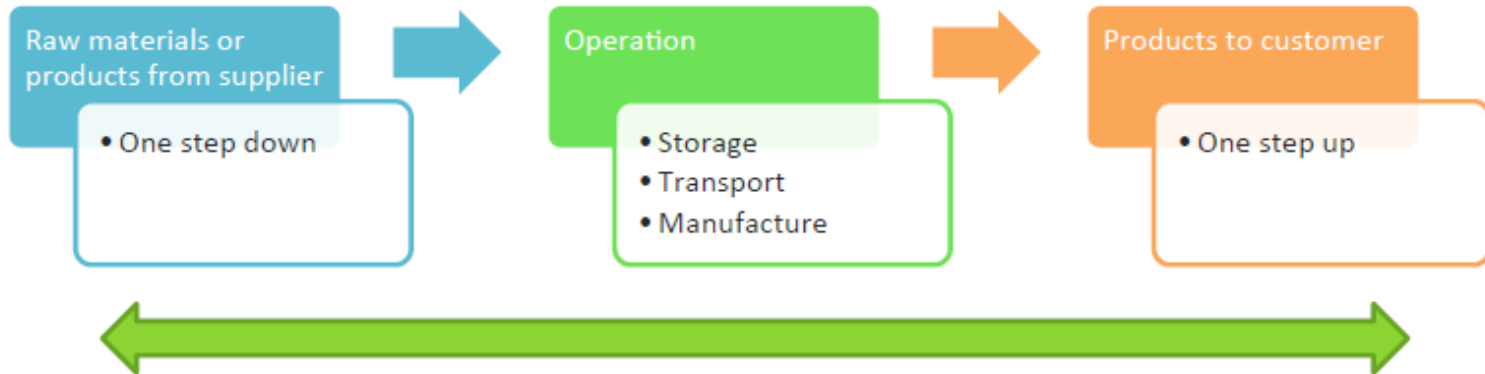
SUMMARIZING

Traceability- the “one up”/ “one down” concept

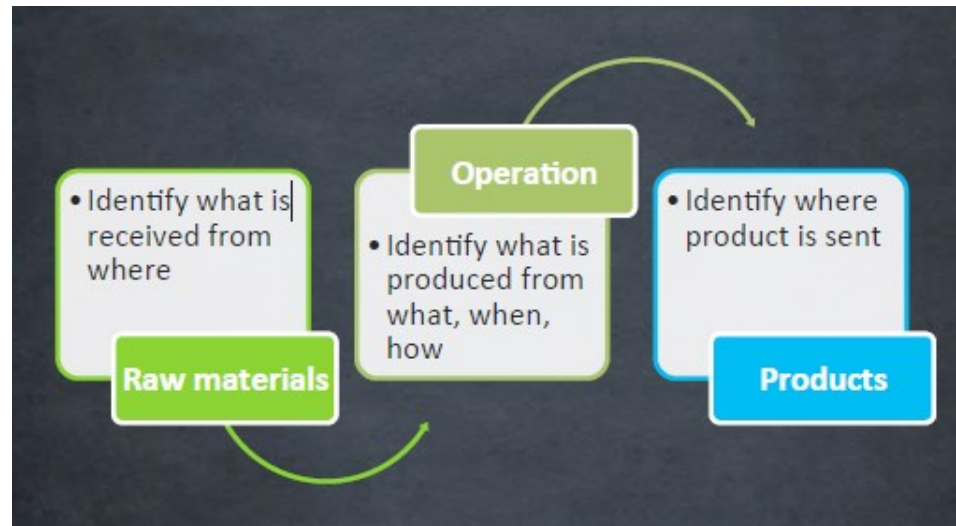
- Each stage in the food chain must
 - Identify **what is received** (raw materials from the previous stage in the chain)
 - Identify **where product is sent** (to the next stage in the chain)
 - Make **information available** on demand
- Each stage in the food chain is responsible for the operations under **their** control
 - No requirement for whole chain traceability

SUMMARIZING

Traceability

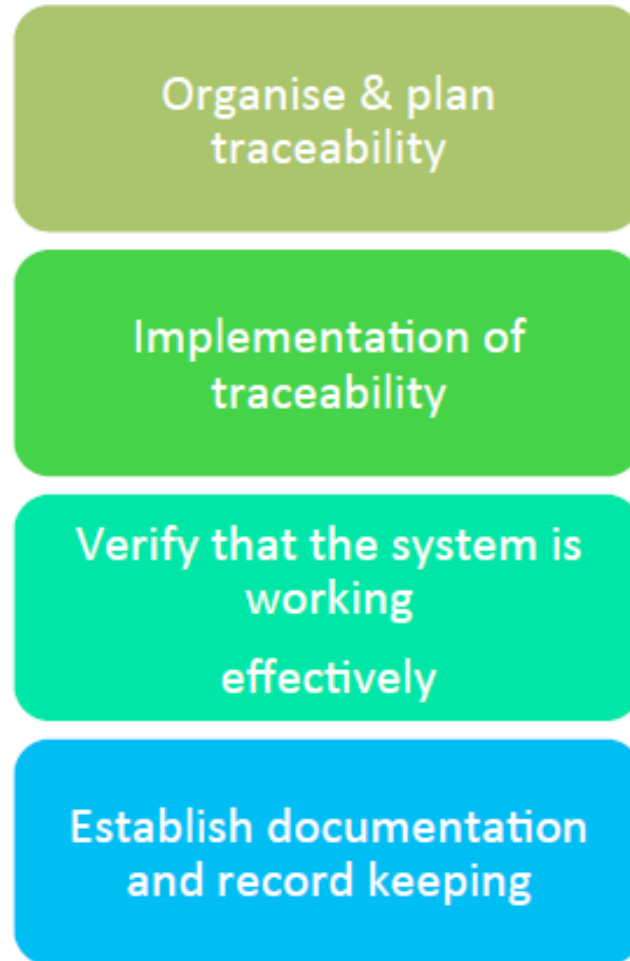


Make information available on demand



SUMMARIZING

Traceability



Food-specific legislation related to traceability

- **Commission Implementing Regulation (EU) No 931/2011**
“on the traceability requirements set by Regulation (EC) No 178/2002 of the European Parliament and of the Council for food of animal origin”
- **Regulation (EC) No 1760/2000 of the European Parliament and of the Council**
“establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97”
- **Commission Regulation (EC) No 1825/2000**
“laying down detailed rules for the application of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the labelling of beef and beef products”
- **Commission Implementing Regulation (EU) No 1337/2013**
“laying down rules for the application of Regulation (EU) No 1169/2011 of the European Parliament and of the Council as regards the indication of the country of origin or place of provenance for fresh, chilled and frozen meat of swine, sheep, goats and poultry”

Food-specific legislation related to traceability

- **Regulation (EC) No 1379/2013 of the European Parliament and of the Council**
“on the common organisation of the markets in fishery and aquaculture products, amending Council Regulations (EC) No 1184/2006 and (EC) No 1224/2009 and repealing Council Regulation (EC) No 104/2000”
- **Commission Regulation (EC) No 589/2008**
“laying down detailed rules for implementing Council Regulation (EC) No 1234/2007 as regards marketing standards for eggs”
- **Commission Implementing Regulation (EU) No 208/2013**
“on traceability requirements for sprouts and seeds intended for the production of sprouts”
- **Regulation (EC) No 1830/2003 of the European Parliament and of the Council**
“concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC”

Food-specific legislation related to traceability



Regulation (EC) No 178/2002

“General Food Law Regulation”

Articles 22-49

European Food Safety Authority (EFSA)

- The Regulation sets up an independent agency responsible for scientific advice and support, the European Food Safety Authority (EFSA)
- EFSA is a European agency funded by the European Union that operates independently of the European legislative and executive institutions (Commission, Council, Parliament) and EU Member States
- EFSA is responsible for risk assessment and also has a duty to communicate its scientific findings to the public
- As the risk assessor, EFSA produces scientific opinions and advice that form the basis for European policies and legislation

Regulation (EC) No 178/2002

“General Food Law Regulation”

Articles 50-52

Rapid Alert System for Food and Feed (RASFF)

- The Regulation establishes the Rapid Alert System for Food and Feed (RASFF)
- It is a rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed
- RASFF is a key tool used to react rapidly to food and feed safety emergencies and incidents, as it enables information to be shared efficiently between its members (EU-28 national food safety authorities, Commission, EFSA, ESA, Norway, Liechtenstein, Iceland and Switzerland)
- Thanks to RASFF, many food safety risks had been averted before they could have been harmful to European consumers

Rapid Alert System for Food and Feed (RASFF)

Commission Regulation (EU) No 16/2011

- Commission Regulation (EU) No 16/2011 lays down the implementing measures for the RASFF
- It stipulates the duties of the RASFF network members and defines the different types of notifications
- It provides that all contact points shall ensure the availability of an on-duty officer reachable outside office hours for emergency communications on a 24-hour/7-day-a-week basis
- Before transmitting a notification to all members of the network, the Commission contact point shall verify the RASFF notifications
- Any member of the network may request a notification withdrawal or amendments
- If the notified product originates from or is distributed to a third country, the Commission shall inform the third country without undue delay
- The Regulation introduces exact deadlines for Member States (48 hours) as well as the Commission (24 hours) for transmitting alert notifications

Regulation (EC) No 178/2002

“General Food Law Regulation”

Articles 53-54

Emergency measures

- Where food or feed originating in the Community or imported presents a serious and uncontrollable risk to human health, animal health or the environment, the Commission can put in place protective measures, following an opinion from the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee, established in Article 58) and:
 - suspend the placing on the market or use of products originating from the EU
 - suspend imports of products originating from third countries
- Such action can be initiated by the Commission itself, or be requested by a Member State
- However, if the Commission does not act after having been informed of the existence of a risk, the EU country concerned may take temporary protective measures
- Within 10 working days, the Commission must refer the matter to the PAFF Committee

Regulation (EC) No 178/2002

“General Food Law Regulation”

Articles 55-57

Crisis management

- A general plan for crisis management shall be followed in cases of direct or indirect risks to human health deriving from food & feed which:
 - are not likely to be prevented, eliminated or reduced to an acceptable level by provisions in place or
 - cannot adequately be managed by defined emergency measures
- The general plan for crisis management is established by Decision 2004/478/EC
- It also specifies the crisis situations involving a serious direct or indirect risk to human health

Regulation (EC) No 178/2002

“General Food Law Regulation”

Articles 55-57

Crisis management

- In the case of a serious risk, the Commission must immediately set up a crisis unit:
 - supported scientifically & technically by EFSA
 - responsible for collecting & evaluating all relevant information & identifying the options available for preventing, eliminating or reducing the risk to human health
- Decision 2004/478/EC also lays down management procedures where the risk is potential but could evolve into a serious risk → a crisis unit will not be set up but adequate provisions will be made to ensure effective management

Regulation (EC) No 178/2002 “General Food Law Regulation”

In 2018 Fitness Check on General Food Law was completed

- assessing whether the legislative framework introduced by the Regulation for the entire food and feed sector is 'fit for purpose' and whether it captures and reflects policy trends of today
- Main findings of the Fitness Check on the General Food Law :
 - The Regulation is still relevant today with respect to the current trends: growth and competitiveness and increased globalization
 - Overall, it has achieved its core objectives, namely high protection of human health and consumers' interests and the smooth functioning of the internal market
 - No systemic failures have been identified. Nevertheless, the GFL is less adequate to address new challenges like food sustainability in general, and more specifically, **food waste**

Regulation (EC) No 178/2002

“General Food Law Regulation”

REVISION

- In April 2018 the European Commission officially proposed a targeted revision of the General Food Law Regulation, drawing also on the Commission's Fitness Check
- The proposal aims to:
 - give citizens greater access to information submitted to the European Food Safety Authority (EFSA) on approvals concerning the agri-food chain
 - provide the possibility for additional studies to be requested by the Commission and will involve Member States' scientists more closely in approval procedures
- The proposal refers to revision of the Regulation coupled to revision of sectoral legislation to strengthen transparency in the area of:
 - GMOs & novel foods
 - feed & food additives, smoke flavourings, food enzymes & flavourings
 - food contact materials & plant protection products

“General Food Law Regulation”

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Food

GENERAL FOOD LAW

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Expert Group on General Food Law

Transparency & sustainability of risk assessment

Implementation of the Transparency Regulation



ALL TOPICS

General Food Law

Brexit

[Notice to stakeholders - Withdrawal of the United Kingdom and EU Food Law](#)

European citizens need to have access to safe and wholesome food of highest standards.

A series of food incidents in late 1990s draw attention to the need to establish general principles and requirements concerning food and feed law **at Union level**. Accordingly, the European Commission developed an **integrated approach to food safety 'from farm to fork'**, primarily set out in its **White Paper on Food Safety**. 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** laying down the general principles and requirements of food law (**General Food Law Regulation**).

The General Food Law Regulation is the foundation of food and feed law. It sets out 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.

It also sets up an independent agency responsible for scientific advice and support, the **European Food Safety Authority** (EFSA).

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).

RELATED LINKS

- [Infographic: The General Food Law - Fitness Check](#)
- [Events](#)
 - [15 years anniversary of the General Food Law](#)
- [Comitology committee](#)

RELATED DOCUMENTS

- [28 February 2018: Technical expert seminar on the preparation of the UK withdrawal in the SPS area - Food and Water](#)
- [From Farm to Fork: Controlling the safety of the agri food chain](#)
- [General Food Law Regulation](#)
- [White Paper on Food Safety, 2000](#)

QUICK LINKS

- [Rapid Alert for Food and Feed \(RASFF\)](#)
- [Health and food audits and analysis](#)