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FOODQA - Fostering Academia-Industry Collaboration in Food Safety and Quality

Workshops and Seminars to Food Industry in Jordan



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General food laws (principles, hygiene, traceability)

Introduction

- 1) Regulation (EC) No 178/2002
- 2) EU Food Hygiene Legislation
- 3) Food-specific legislation related to traceability



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- White Paper on Food Safety (2000)



- “From-Farm-To-Table” approach



- New EU food legislation



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



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

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

CONTROLS DURING
TRANSPORT WITHIN
THE EU, AND...

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

> THE CONTROLS CHECK FOR

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

> Controls are performed
on the basis of RISK for health

> 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.

EU Food Legislation

- Regulations → binding legislative acts / applied in their entirety
- Directives → legislative acts / countries devise national laws on how to achieve the objectives
- Implementing acts → legally binding acts / concern procedural elements
- <https://eur-lex.europa.eu/homepage.html>



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Regulation (EC) No 178/2002

- 2002 → 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)



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Regulation (EC) No 178/2002

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”



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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



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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



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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’: 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



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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



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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



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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



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Article 7

Precautionary principle:

- reasonable grounds for concern that an unacceptable level of risk to health exists
- 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



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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



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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



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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



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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



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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



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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



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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



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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



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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



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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



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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



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Article 15

Feed safety requirements

4. Feed that complies with specific Community provisions shall be deemed to be safe
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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



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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



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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



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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



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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



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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



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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



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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



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Article 18

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

Impact on food business operators:

- 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**



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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



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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



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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 unduly 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



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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*



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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



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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



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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



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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



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Articles 50-52

Rapid Alert System for Food and Feed (RASFF)

- Without prejudice to other Community legislation, the Member States shall immediately notify the Commission under the rapid alert system of:
 - any measure they adopt which is aimed at restricting the placing on the market or forcing the withdrawal from the market or the recall of food or feed in order to protect human health & requiring rapid action
 - any recommendation or agreement with professional operators which is aimed, on a voluntary or obligatory basis, at preventing, limiting or imposing specific conditions on the placing on the market or the eventual use of food or feed on account of a serious risk to human health requiring rapid action
 - any rejection, related to a direct or indirect risk to human health, of a batch, container or cargo of food or feed by a competent authority at a border post within the European Union



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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



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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



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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



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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



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Fitness Check of Regulation (EC) No 178/2002

- Fitness Checks provide an evidence-based critical analysis of whether Union actions are proportionate to their objectives and delivering as expected
- 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



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Revision of Regulation (EC) No 178/2002

- 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



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EU Food Hygiene Legislation

- EU Rules regarding Food Hygiene (“hygiene package”) cover all stages of the production, processing, distribution and placing on the market of food intended for human consumption
- Rules on hygiene of foodstuffs were adopted in April 2004 by the European Parliament and the Council and they became applicable on 1 January 2006
- They merged, harmonised and simplified detailed and complex hygiene requirements previously contained in a number of Council Directives



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EU Food Hygiene Legislation

- These rules are provided for in the following key acts:
 - **Regulation (EC) 852/2004** on the hygiene of foodstuffs
 - **Regulation (EC) 853/2004** laying down specific hygiene rules for food of animal origin
 - **Regulation (EC) 854/2004** laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
 - **Directive 2004/41/EC** 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 and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC



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EU Food Hygiene Legislation

- Main principles taken into account by the hygiene rules:
 - Primary responsibility for food safety borne by the food business operator
 - Food safety ensured throughout the food chain, starting with primary production
 - General implementation of procedures based on HACCP principles
 - Application of basic common hygiene requirements, possibly further specified for certain categories of food
 - Registration or approval for certain food establishments
 - Development of guides to good practice for hygiene or for the application of HACCP principles as a valuable instrument to aid food business operators at all levels of the food chain to comply with the new rules
 - Flexibility provided for food produced in remote areas & for traditional production & methods



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EU Food Hygiene Legislation

Selected guides provided by the European Commission

- Guidelines on minimum recommendations for official laboratory appointed for the detection of Trichinella in meat
- Guidance on food safety management systems for certain small food retailers
- Commission notice on addressing microbiological risks in fresh fruits and vegetables at primary production through good hygiene
- Commission Notice on Food Safety Management Systems (FSMS), including HACCP
- Guidance document on hygiene of food of animal origin
- Guidance document on rules on food hygiene and official controls
- Guidance document on the hygiene of all food
- Illustrative Guidance on import conditions for composite products



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Regulation (EC) No 852/2004 of the European Parliament and of the Council “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:
 - a. Primary responsibility for food safety rests with the food business operator
 - b. It is necessary to ensure food safety throughout the food chain, starting with primary production



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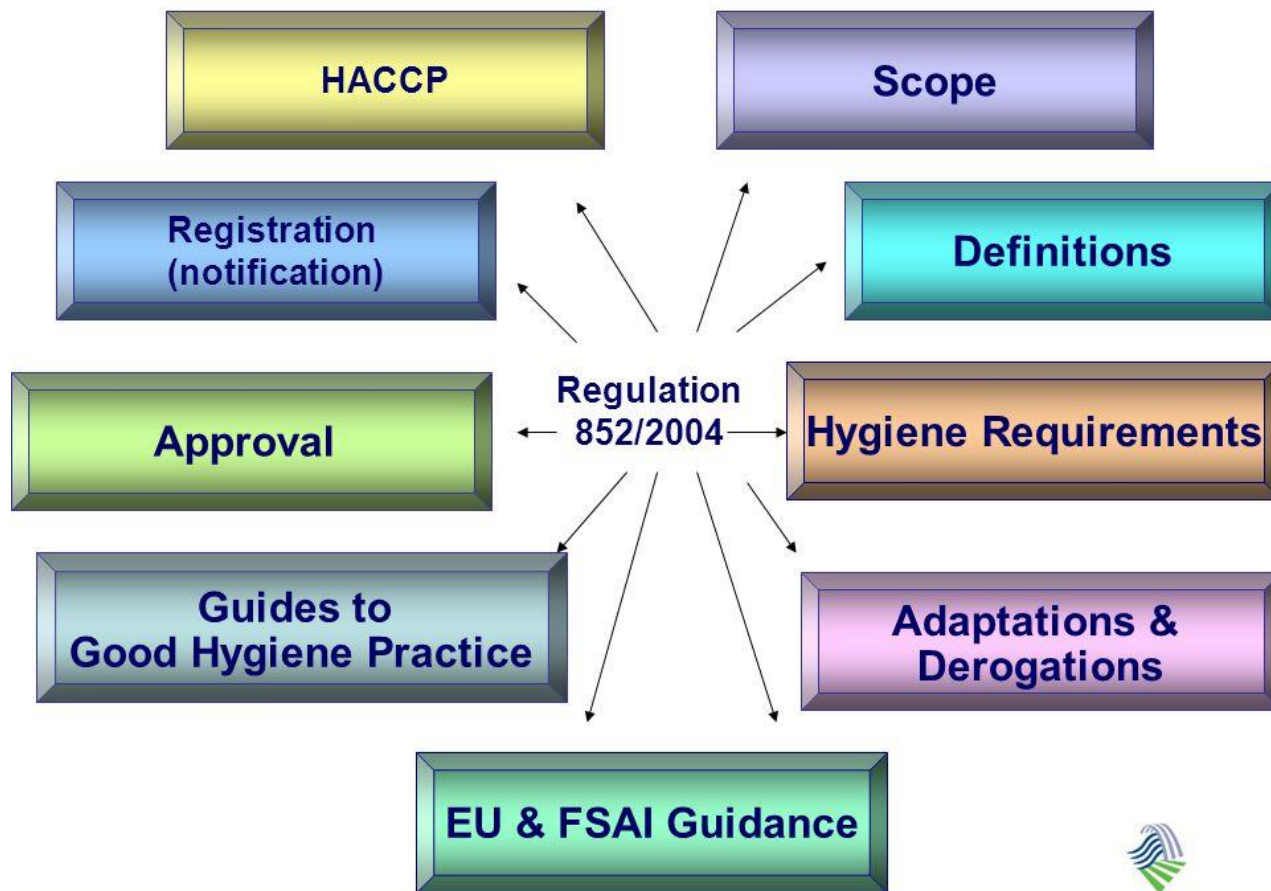
Regulation (EC) No 852/2004

- c. It is important, for food that cannot be stored safely at ambient temperatures, particularly frozen food, to maintain the cold chain
- d. General implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility
- e. Guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain with compliance with food hygiene rules and with the application of the HACCP principles
- f. It is necessary to establish microbiological criteria and temperature control requirements based on a scientific risk assessment
- g. It is necessary to ensure that imported foods are of at least the same hygiene standard as food produced in the Community, or are of an equivalent standard



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Regulation (EC) No 852/2004



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Article 1

Scope

- This Regulation shall apply to all stages of production, processing and distribution of food and to exports, and without prejudice to more specific requirements relating to food hygiene
- The Regulation shall not apply to:
 - a. primary production for private domestic use
 - b. the domestic preparation, handling or storage of food for private domestic consumption
 - c. the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments (national rules shall be established)
 - d. collection centres & tanneries



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Article 2

Definitions

- ‘food hygiene’ or ‘hygiene’: the measures & conditions necessary to control hazards & to ensure fitness for human consumption of a foodstuff taking into account its intended use
- ‘establishment’: any unit of a food business
- ‘equivalent’: in respect of different systems, capable of meeting the same objectives
- ‘potable water’: water meeting the minimum requirements laid down in Council Directive 98/83/EC
- ‘clean water’: clean seawater and fresh water of a similar quality
- ‘wrapping’: the placing of a foodstuff in a wrapper or container in direct contact with the foodstuff concerned, & the wrapper or container itself
- ‘packaging’: the placing of one or more wrapped foodstuffs in a 2nd container, & the latter container itself
- ‘processing’: any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes
- ‘unprocessed products’: foodstuffs that have not undergone processing; divided, parted severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen, thawed products



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Article 3

General obligation for food business operators

- This Regulation shall apply to all stages of production, processing & distribution of food & to exports, & without prejudice to more specific requirements relating to food hygiene

Article 4

General obligation for food business operators

- 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 & analysis (use of equivalent methods where not specified)



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Article 5

Hazard Analysis and Critical Control Points

Food business operators (after primary production & associated operations) shall put in place, implement & maintain a permanent procedure or procedures based on the HACCP principles:

1. identifying any hazards that must be prevented, eliminated or reduced to acceptable levels
2. identifying the CCPs at the steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels
3. establishing critical limits at CCPs which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards
4. establishing & implementing effective monitoring procedures at CCPs
5. establishing corrective actions when monitoring indicates that a CCP is not under control
6. establishing procedures, which shall be carried out regularly, to verify that 1-5 measures are working effectively
7. establishing documents & records commensurate with the nature & size of the food business to demonstrate the effective application of 1-6 measures



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Article 5

Hazard Analysis and Critical Control Points

- When any modification is made in the product, process, or any step, food business operators shall review the procedure & make the necessary changes
- Food business operators shall:
 - provide the competent authority with evidence of their compliance
 - ensure that any documents describing the procedures developed are up-to-date at all times
 - retain any other documents and records for an appropriate period



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ANNEX I: Primary production

Part A: General hygiene provisions for primary production and associated operations

Scope

This Annex applies to primary production & the following associated operations:

- a. the transport, storage & handling of primary products at the place of production, provided that this does not substantially alter their nature
- b. the transport of live animals, where this is necessary to achieve the objectives of this Regulation
- c. in the case of products of plant origin, fishery products and wild game, transport operations to deliver primary products, the nature of which has not been substantially altered, from the place of production to an establishment



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Hygiene provisions

1. As far as possible, food business operators are to ensure that primary products are protected against contamination, having regard to any processing that they will subsequently undergo
2. Food business operators are to comply with appropriate Community & national legislative provisions relating to the control of hazards, including:
 - a) measures to control contamination from the air, soil, water, feed, fertilisers, veterinary medicinal products, plant protection products & biocides & the storage, handling & disposal of waste and
 - b) measures relating to animal health & welfare and plant health that have implications for human health, including programmes for the monitoring & control of zoonoses & zoonotic agents



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Hygiene provisions

3. Food business operators rearing, harvesting or hunting animals or producing primary products of animal origin are to take adequate measures, as appropriate:
 - a. to keep facilities clean and, where necessary to disinfect them appropriately
 - b. to keep clean &, where necessary, to disinfect equipment, containers, crates, vehicles & vessels
 - c. to ensure the cleanliness of animals going to slaughter and, where necessary, production animals
 - d. to use potable water or clean water
 - e. to ensure that staff handling foodstuffs are in good health & undergo training on health risks
 - f. to prevent animals & pests from causing contamination
 - g. to store & handle waste & hazardous substances so as to prevent contamination
 - h. to prevent the introduction & spread of contagious diseases transmissible to humans through food
 - i. to use feed additives & veterinary medicinal products as required by legislation



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Hygiene provisions

4. Food business operators producing or harvesting plant products are to take adequate measures, as appropriate:
 - a. to keep clean &, where necessary, to disinfect facilities, equipment, containers, crates, vehicles, vessels
 - b. to ensure, cleanliness & hygienic production, transport & storage conditions for plant products
 - c. to use potable water or clean water
 - d. to ensure that staff handling foodstuffs are in good health & undergo training on health risks
 - e. to prevent animals & pests from causing contamination
 - f. to store & handle wastes & hazardous substances so as to prevent contamination
 - g. to take account of the results of any relevant analyses that have importance to human health
 - h. to use plant protection products & biocides as required by legislation
5. Operators are to take appropriate remedial action when informed of problems identified during official controls



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Record-keeping

1. Food business operators are to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, & to make them available to the competent authority and receiving food business operators on request
2. Operators rearing animals or producing primary products of animal origin are, in particular, to keep records on:
 - a) the nature & origin of feed
 - b) veterinary medicinal products or other treatments, dates of administration & withdrawal periods
 - c) the occurrence of diseases that may affect the safety of products
 - d) the results of any analyses carried out on samples taken from animals or other samples taken for diagnostic purposes, that have importance for human health
 - e) any relevant reports on checks carried out on animals or products



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Record-keeping

3. Food business operators producing or harvesting plant products are, in particular, to keep records on:
 - a) any use of plant protection products & biocides
 - b) any occurrence of pests or diseases that may affect the safety of products of plant origin
 - c) the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health
4. The food business operators may be assisted by other persons, such as veterinarians, agronomists & farm technicians, with the keeping of records



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ANNEX II: General hygiene requirements for all food business operators

Chapter I: General requirements for food premises

1. Food premises are to be kept clean & maintained in good repair & condition
2. The layout, design, construction, siting & size of food premises are to:
 - a) permit adequate maintenance, cleaning and/or disinfection, avoid or minimise contamination by air, 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 & the formation of condensation or undesirable mould on surfaces
 - c) permit good food hygiene practices, including protection against contamination & pest control
 - d) where necessary, provide suitable temperature-controlled handling & storage conditions of sufficient capacity for maintaining foodstuffs at appropriate temperatures & designed to allow those temperatures to be monitored &, where necessary, recorded



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Chapter I: General requirements for food premises

3. An adequate number of flush lavatories are to be available & connected to an effective drainage system → lavatories are not to open directly into rooms in which food is handled
4. An adequate number of washbasins is to be available, suitably located & designated for cleaning hands, 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
5. There is to be suitable & 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 & other parts requiring cleaning or replacement to be readily accessible



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Chapter I: General requirements for food premises

6. Sanitary conveniences are to have adequate natural or mechanical ventilation
7. Food premises are to have adequate natural and/or artificial lighting
8. Drainage facilities are to be adequate for the purpose intended

They are to be designed & 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

9. Where necessary, adequate changing facilities for personnel are to be provided
10. Cleaning agents & disinfectants are not to be stored in areas where food is handled



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Chapter II: Specific requirements in rooms where foodstuffs are prepared, treated or processed

1. In rooms where food is prepared, treated or processed the design & layout are to permit good food hygiene practices, including protection against contamination between and during operations. In particular:
 - a) Floor surfaces are to be maintained in a sound condition & be easy to clean & to disinfect
Floor materials are to be impervious, non-absorbent, washable and non-toxic (or equivalent)
Where appropriate, floors are to allow adequate surface drainage
 - b) Wall surfaces are to be maintained in a sound condition & be easy to clean & to disinfect
Wall materials are to be impervious, non-absorbent, washable & non-toxic (or equivalent)
A smooth surface up to a height appropriate for the operations is required
 - c) Ceilings & overhead fixtures are to be constructed & finished so as to prevent the accumulation of dirt & to reduce condensation, the growth of undesirable mould & the shedding of particles



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Chapter II: Specific requirements in rooms where foodstuffs are prepared, treated or processed

- d) Windows & 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 during production
- e) Doors are to be easy to clean and, where necessary, to disinfect
This will require the use of smooth and non-absorbent surfaces (or equivalent)
- 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 (or equivalent)



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Chapter II: Specific requirements in rooms where foodstuffs are prepared, treated or processed

2. Adequate facilities are to be provided, where necessary, for the cleaning, disinfecting & storage of working utensils & equipment

These facilities are to be constructed of corrosion-resistant materials, be easy to clean & have an adequate supply of hot and cold water

3. Adequate provision is to be made, where necessary, for washing food

Every sink or other such facility provided for the washing of food is to have an adequate supply of hot and/or cold potable water consistent with the requirements of Chapter VII and be kept clean &, where necessary, disinfected



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Chapter III: Requirements for movable and/or temporary premises (such as marquees, market stalls, mobile sales vehicles), premises used primarily as a private dwelling-house but where foods are regularly prepared for placing on the market and vending machines

1. Premises & vending machines are, as applicable, to be so sited, designed, constructed & kept clean & maintained in good repair & condition as to avoid contamination (animal, pests)
2. In particular, where necessary:
 - a) Appropriate facilities are to be available to maintain adequate personal hygiene
 - b) Surfaces in contact with food are to be in a sound condition and be easy to clean &, where necessary, to disinfect
This will require the use of smooth, washable, corrosion-resistant & non-toxic materials (or equivalent)
 - c) Adequate provision is to be made for the cleaning &, where necessary, disinfecting of working utensils & equipment



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Chapter III: Requirements for movable and/or temporary premises (such as marquees, market stalls, mobile sales vehicles), premises used primarily as a private dwelling-house but where foods are regularly prepared for placing on the market and vending machines

- d) Where foodstuffs are cleaned as part of the food business' operations, adequate provision is to be made for this to be undertaken hygienically
- e) An adequate supply of hot and/or cold potable water is to be available
- f) Adequate arrangements and/or facilities for the hygienic storage & disposal of hazardous and/or inedible substances and waste (whether liquid or solid) are to be available
- g) Adequate facilities and/or arrangements for maintaining & monitoring suitable food temperature conditions are to be available
- h) Foodstuffs are to be so placed as to avoid the risk of contamination as applicable



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Chapter IV: Transport

1. Conveyances and/or containers used for transporting foodstuffs are to be kept clean & maintained in good repair & condition to protect foodstuffs from contamination & are, where necessary, to be designed & constructed to permit adequate cleaning and/or disinfection
2. Receptacles in vehicles and/or containers are not to be used for transporting anything other than foodstuffs where this may result in contamination
3. Where conveyances and/or containers are used for transporting anything in addition to foodstuffs or for transporting different foodstuffs at the same time, there is, where necessary, to be effective separation of products



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Chapter IV: Transport

4. Bulk foodstuffs in liquid, granulate or powder form are to be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs
Such containers are to be marked in a clearly visible and indelible fashion, in one or more Community languages, to show that they are used for the transport of foodstuffs, or are to be marked 'for foodstuffs only'
5. Where conveyances and/or containers have been used for transporting anything other than foodstuffs or for transporting different foodstuffs, there is to be effective cleaning between loads to avoid the risk of contamination
6. Foodstuffs in conveyances and/or containers are to be so placed and protected as to minimise the risk of contamination
7. Where necessary, conveyances and/or containers used for transporting food stuffs are to be capable of maintaining foodstuffs at appropriate temperatures & allow temperature monitoring



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Chapter V: Equipment requirements

1. All articles, fittings & equipment with which food comes into contact are to:
 - a) be effectively cleaned & disinfected at a sufficient frequency to avoid any risk of contamination
 - b) be so constructed, be of such materials and be kept in such good order, repair & condition as to minimise any risk of contamination
 - c) with the exception of non-returnable containers & packaging, be so constructed, be of such materials & be kept in such good order, repair & condition as to enable them to be kept clean &, where necessary, to be disinfected
 - d) be installed in such a manner as to allow adequate cleaning of the equipment & surrounding area
2. Where necessary, equipment is to be fitted with any appropriate control device to guarantee fulfilment of this Regulation's objectives
3. Where chemical additives have to be used to prevent corrosion of equipment and containers, they are to be used in accordance with good practice



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Chapter VI: Food waste

1. Food waste, non-edible by-products & other refuse are to be removed from rooms where food is present as quickly as possible, so as to avoid their accumulation
2. Food waste & other refuse are to be deposited in closable containers (or equivalent), which are to be of an appropriate construction, kept in sound condition, be easy to clean &, where necessary, to disinfect
3. Adequate provision is to be made for the storage & disposal of food waste & other refuse
Refuse stores are to be designed and managed in such a way as to enable them to be kept clean &, where necessary, free of animals & pests
4. All waste is to be eliminated in a hygienic & environmentally friendly way in accordance with Community legislation & is not to constitute a direct or indirect source of contamination



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Chapter VII: Water supply

1.
 - i) There is to be an adequate supply of potable water, which is to be used whenever necessary to ensure that foodstuffs are not contaminated
 - ii) Clean water may be used with whole fishery products; clean seawater may be used with live bivalve molluscs, echinoderms, tunicates & marine gastropods; clean water may also be used for external washing

When clean water is used, adequate facilities & procedures are to be available for its supply to ensure that such use is not a source of contamination for the foodstuff
2. Where non-potable water is used, for example for fire control, steam production, refrigeration & other similar purposes, it is to circulate in a separate duly identified system
Non-potable water is not to connect with, or allow reflux into, potable water systems



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Chapter VII: Water supply

3. Recycled water used in processing or as an ingredient is not to present a risk of contamination
It is to be of the same standard as potable water, unless the competent authority is satisfied that the quality of the water cannot affect the foodstuff wholesomeness in its finished form
4. Ice which comes into contact with food or which may contaminate food is to be made from potable water or, when used to chill whole fishery products, clean water
It is to be made, handled & stored under conditions that protect it from contamination
5. Steam used directly in contact with food is not to contain any substance that presents a hazard to health or is likely to contaminate the food
6. Where heat treatment is applied to foodstuffs in hermetically sealed containers it is to be ensured that water used to cool the containers after heat treatment is not a source of contamination for the foodstuff



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Chapter VIII: Personal hygiene

1. Every person working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean &, where necessary, protective clothing
2. 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 & employed in a food business & who is likely to come into contact with food is to report immediately the illness or symptoms, & if possible their causes, to the food business operator



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Chapter IX: Provisions applicable to foodstuffs

1. A food business operator is not to accept raw materials or ingredients or any other material used in processing products, if they are known to be, or might reasonably be expected to be contaminated with parasites, pathogenic microorganisms or toxic, decomposed or foreign substances to such an extent that, even after hygienically applied normal sorting and/or preparatory or processing procedures, the final product would be unfit for human consumption
2. Raw materials & all ingredients stored in a food business are to be kept in appropriate conditions designed to prevent harmful deterioration & protect them from contamination
3. At all stages of production, processing & distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed
4. Adequate procedures are to be in place to control pests & to prevent domestic animals from having access to places where food is prepared, handled or stored



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Chapter IX: Provisions applicable to foodstuffs

5. Raw materials, ingredients, intermediate products & finished products likely to support the reproduction of pathogenic micro-organisms or the formation of toxins are not to be kept at temperatures that might result in a risk to health

The cold chain is not to be interrupted, but limited periods outside temperature control are permitted, to accommodate the practicalities of handling during preparation, transport, storage, display & service of food, provided that it does not result in a risk to health

Food businesses manufacturing, handling & wrapping processed foodstuffs are to have suitable rooms, large enough for the separate storage of raw materials from processed material & sufficient separate refrigerated storage

6. Where foodstuffs are to be held or served at chilled temperatures they are to be cooled as quickly as possible following the heat-processing or final preparation stage, to a temperature which does not result in a risk to health



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Chapter IX: Provisions applicable to foodstuffs

7. The thawing of foodstuffs is to be undertaken in such a way as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins in the foods
During thawing, foods are to be subjected to temperatures that would not result in a risk
Where run-off liquid from the thawing process may present a risk to health it is to be adequately drained
Following thawing, food is to be handled in such a manner as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins
8. Hazardous and/or inedible substances, including animal feed, are to be adequately labelled and stored in separate and secure containers



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Chapter X: Provisions applicable to the wrapping and packaging of foodstuffs

1. Materials used for wrapping & packaging are not to be a source of contamination
2. Wrapping materials are to be stored in such a manner that they are not exposed to a risk of contamination
3. Wrapping & packaging operations are to be carried out so as to avoid contamination of the products

Where appropriate & in particular in the case of cans & glass jars, the integrity of the container's construction & its cleanliness is to be assured

4. Wrapping & packaging material re-used for foodstuffs is to be easy to clean &, where necessary, to disinfect



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Chapter XI: Heat treatment of food placed in hermetically sealed containers

1. Any heat treatment process used to process an unprocessed product or to process further a processed product is:
 - a) to raise every party of the product treated to a given temperature for a given period of time
 - & b) to prevent the product from becoming contaminated during the process
2. To ensure that the process employed achieves the desired objectives, food business operators are to check regularly the main relevant parameters (particularly temperature, pressure, sealing and microbiology), including by the use of automatic devices
3. The heat process used should conform to an internationally recognised standard



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Chapter XII: Training

Food business operators are to ensure:

1. that food handlers are supervised & instructed and/or trained in food hygiene matters in relation to their work activity
2. that those responsible for the development & maintenance of the HACCP-based procedure or for the operation of relevant guides have received adequate training in the application of the HACCP principles
3. compliance with any requirements of national law concerning training programmes for persons working in certain food sectors



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Regulation (EC) No 852/2004



Regulation (EC) No 853/2004 of the European Parliament and of the Council “laying down specific hygiene rules for food of animal origin”

Article 1

Scope

- This Regulation lays down specific rules on the hygiene of food of animal origin for food business operators, which supplement those laid down by Regulation (EC) No 852/2004
- They shall apply to unprocessed and processed products of animal origin
- Unless expressly indicated to the contrary, this Regulation shall not apply to food containing both products of plant origin and processed products of animal origin



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Article 1

Scope

- The Regulation shall not apply in relation to:
 - a. primary production for private domestic use
 - b. the domestic preparation, handling or storage of food for private domestic consumption
 - c. the direct supply, (i) by the producer, of small quantities of primary products or (ii) small quantities of meat from poultry and lagomorphs slaughtered on the farm or (iii) small quantities of wild game (by the hunter) to the final consumer or to local retail establishments (national rules established)
 - d. retail, unless expressly indicated to the contrary
- This Regulation shall apply without prejudice to:
 - a. relevant animal and public health rules
 - b. animal welfare requirements
 - c. requirements concerning animal identification & the traceability of products of animal origin



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Article 5

Health and identification marking

- Food business operators shall not place on the market a product of animal origin handled in an establishment subject to approval in accordance with this Regulation unless it has either:
 - a health mark applied in accordance with Regulation (EC) No 854/2004 or
 - when that Regulation does not provide for the application of a health mark, an identification mark applied in accordance with Annex II, Section I, of this Regulation
- Food business operators may apply an identification mark to a product of animal origin only if the product has been manufactured in accordance with this Regulation in establishments meeting the requirements of Article 4 concerning registration and approval
- Food business operators may not remove a health mark applied in accordance with Regulation (EC) No 854/2004 from meat unless they cut or process it or work upon it in another manner



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ANNEX I: Definitions

- ‘Products of animal origin’ means:
 - food of animal origin, including honey and blood
 - live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods intended for human consumption and
 - other animals destined to be prepared with a view to being supplied live to the final consumer



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ANNEX II: Requirements concerning several products of animal origin

Section I: Identification marking

A. Application of the identification mark

1. The identification mark must be applied before the product leaves the establishment of production
2. However, when a product's packaging and/or wrapping is removed or it is further processed in another establishment, a new mark must be applied to the product, indicating the approval number of the establishment where these operations take place
3. An identification mark is not necessary on packs of eggs when a packing centre code is applied in accordance with Council Regulation (EC) No 1234/2007
4. Food business operators must, in accordance with Regulation (EC) No 178/2002, have in place systems & procedures to identify food business operators from whom they have received & to whom they have delivered products of animal origin



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B. Form of the identification mark

1. The mark must be legible and indelible, and the characters easily decipherable
It must be clearly displayed for the competent authorities
2. The mark must indicate the name of the country in which the establishment is located, which may be written out in full or shown as a two- letter code according to the relevant ISO standard
*In the case of Member States these codes are BE, BG, CZ, DK, DE, EE, GR, ES, FR, HR, IE, IT, CY, LV, LT, LU, HU, MT, NL, AT, PL, PT, SI, SK, FI, RO, SE & UK
3. The mark must indicate the approval number of the establishment; if an establishment manufactures both food to which this Regulation applies and food to which it does not, the food business operator may apply the same identification mark to both types of food
4. When applied in an establishment located within the Community, the mark must be oval in shape and include the abbreviation CE, EC, EF, EG, EK, EO, EY, ES, EÜ, EK, EB, EZ or WE

Those abbreviations must not be included in marks applied on products imported in the EU from establishments located outside the Community



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C. Method of marking

1. The mark may be applied directly to the product, the wrapping or the packaging, or be printed on a label affixed to the product, the wrapping or the packaging
The mark may also be an irremovable tag made of a resistant material
2. In the case of packaging containing cut meat or offal, the mark must be applied to a label fixed to the packaging, or printed on the packaging, in such a way that it is destroyed when the packaging is opened

This is not necessary, however, if the process of opening destroys the packaging

When wrapping provides the same protection as packaging, the label may be affixed to the wrapping



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C. Method of marking

3. For products that are placed in transport containers or large packages & are intended for further handling, processing, wrapping or packaging in another establishment, the mark may be applied to the external surface of the container or packaging
4. In the case of liquid, granulate and powdered products of animal origin carried in bulk, and fishery products carried in bulk, an identification mark is not necessary if accompanying documentation contains the information required
5. When products are placed in a package destined for direct supply to the final consumer, it is sufficient to apply the mark to the exterior of that package only
6. When the mark is applied directly to products, the colours used must be authorised in accordance with Community rules on the use of colouring substances in foodstuffs



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Section II: Objectives of HACCP-based procedures

1. Food business operators operating slaughterhouses must ensure that the procedures that they have put in place in accordance with the general requirements of Regulation (EC) No 852/2004 meet the requirements that the hazard analysis shows to be necessary and the following requirements
2. The procedures must guarantee that each animal or, where appropriate, each lot of animals accepted onto the slaughterhouse premises:
 - a) is properly identified
 - b) is accompanied by the relevant information from the holding of provenance referred to in Section III
 - c) does not come from a holding or an area subject to a movement prohibition or other restriction for reasons of animal or public health, except when the competent authority so permits
 - d) is healthy (as far as the food business operator can judge) and clean
 - e) is in a satisfactory state as regards welfare on arrival at the slaughterhouse
3. In the event of failure to comply with any of the above requirements, the food business operator must notify the official veterinarian and take appropriate measures



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Section III: Food chain information

Food business operators operating slaughterhouses must, as appropriate, request, receive, check and act upon food chain information as set out in this Section in respect of all animals, other than wild game, sent or intended to be sent to the slaughterhouse:

1. Slaughterhouse operators must not accept animals onto the slaughterhouse premises unless they have requested, and been provided with, relevant food chain information contained in the records kept at the holding of provenance in accordance with Regulation (EC) No 852/2004
2. Slaughterhouse operators must be provided with the information no less than 24 hours before the arrival of animals at the slaughterhouse



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Section III: Food chain information

3. The relevant food chain information is to cover, in particular:

- a) the status of the holding of provenance or the regional animal health status, & whether the holding is officially recognised to apply controlled housing conditions in relation to Trichinella (EC 2075/2005)
- b) the animals' health status
- c) veterinary medicinal products or other treatments administered to the animals within a relevant period together with their dates of administration & withdrawal periods
- d) the occurrence of diseases that may affect the safety of meat
- e) the results, of any analysis carried out on samples taken from the animals or other samples taken to diagnose diseases that may affect the safety of meat
- f) relevant reports about previous ante- and post-mortem inspections of animals from the same holding of provenance including, in particular, reports from the official veterinarian
- g) production data, when this might indicate the presence of disease &
- h) the name and address of the private veterinarian normally attending the holding of provenance



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Section III: Food chain information

4. However, it is not necessary for the slaughterhouse operator to be provided with
- a) the animals' health status & relevant information, if the operator is already aware of this information or
 - b) the information related to the holding of provenance, if the producer declares that there is no relevant information to report

The information need not be provided as a verbatim extract from the records of the holding of provenance, but it may be provided through electronic data exchange or in the form of a standardised declaration signed by the producer

5. Food business operators deciding to accept animals onto the slaughterhouse premises after evaluating the relevant food chain information must make it available to the official veterinarian without delay and, no less than 24 hours before the arrival of the animal or lot



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Section III: Food chain information

6. If any animal arrives at the slaughterhouse without food chain information, the operator must immediately notify the official veterinarian
7. If the competent authority so permits food chain information may arrive less than 24 hours before the arrival of the animals at the slaughterhouse or accompany these animals to the slaughterhouse However, any item of food chain information, knowledge of which may result in serious disruption of the slaughterhouse activity, is to be made available to the food business operator operating the slaughterhouse in sufficient time before arrival
The food business operator operating the slaughterhouse must evaluate the relevant information and must submit the food chain information received to the official veterinarian
The slaughter or dressing may not take place until the official veterinarian so permits
8. Food business operators must check passports accompanying domestic solipeds & if they accept the animal for slaughter, they must give the passport to the official veterinarian



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Section IV: Requirements applicable to frozen food of animal origin

1. For the purposes of this Section, ‘date of production’ means:
 - a) the date of slaughter in the case of carcasses, half carcasses or quarter carcasses
 - b) the date of killing in the case of bodies of wild game
 - c) the date of harvesting or catching, in the case of fishery products
 - d) the date of processing, cutting, mincing or preparation, as appropriate, for any other origin
2. Until the stage at which a food is labelled or used for further processing, food business operators must ensure that in the case of frozen products, (i) the date of production & (ii) the date of freezing, if differs, are made available to the food business operator to whom the food is supplied &, upon request, to the competent authority
Where a food is made from a batch of raw materials with different dates of production & of freezing, the oldest dates of production /freezing, as appropriate, must be made available
3. The appropriate form in which the information must be made available is up to the supplier



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ANNEX III: Specific requirements

- | | |
|--|--|
| I. Meat of domestic ungulates | X. Eggs & egg products |
| II. Meat from poultry & lagomorphs | XI. Frogs' legs & snails |
| III. Meat of farmed game | XII. Rendered animal fats & greaves |
| IV. Wild game meat | XIII. Treated stomachs, bladders & intestines |
| V. Minced meat, meat preparations & mechanically separated meat | XIV. Gelatine |
| VI. Meat products | XV. Collagen |
| VII. Live bivalve molluscs | XVI. Highly refined chondroitin sulphate, hyaluronic acid, other hydrolysed cartilage products, chitosan, glucosamine, rennet, isinglass and amino acids |
| VIII. Fishery products | |
| IX. Raw milk, colostrum, dairy products & colostrum-based products | |



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Regulation (EC) No 854/2004 Directive 2004/41/EC

Regulation (EC) No 854/2004 of the European Parliament and of the Council

“laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption”

- Requirements for competent authorities:
 - Official controls to verify food business operators' compliance with the requirements of Regulations (EC) No 852/2004, 853/2004 & 1069/2009
 - The official controls shall include audits of HACCP-based procedures & any particular auditing & inspection tasks required for different food categories
 - Auditing & inspection tasks, health mark, action after controls, responsibilities & frequency of controls, professional qualifications, food-specific requirements of inspections, specific hazards

Directive 2004/41/EC of the European Parliament and of the Council

“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 and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC”



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Implementing and delegated acts of hygiene package

- **Commission Regulation (EC) No 2073/2005**

“on microbiological criteria for foodstuffs”

- **Commission Regulation (EC) No 2074/2005**

“laying down implementing measures for certain products under Regulation (EC) No 853/2004 & for the organisation of official controls under Regulations (EC) No 854/2004 & 882/2004, derogating from Regulation (EC) No 852/2004 and amending Regulations (EC) No 853/2004 & 854/2004”

- **Commission Implementing Regulation (EU) No 2015/1375**

“laying down specific rules on official controls for *Trichinella* in meat”

- **Commission Implementing Regulation (EU) No 2016/759**

“drawing up lists of third countries, parts of third countries & territories from which Member States are to authorise the introduction into the Union of certain products of animal origin intended for human consumption, laying down certificate requirements, amending Regulation (EC) No 2074/2005 & repealing Decision 2003/812/EC”



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Key rules related to hygiene package

- **Regulation (EC) No 178/2002 of the European Parliament and of the Council**
- **Regulation (EC) No 882/2004 of the European Parliament and of the Council**
“on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules”
- **Council Directive 2002/99/EC**
“laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption”



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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”



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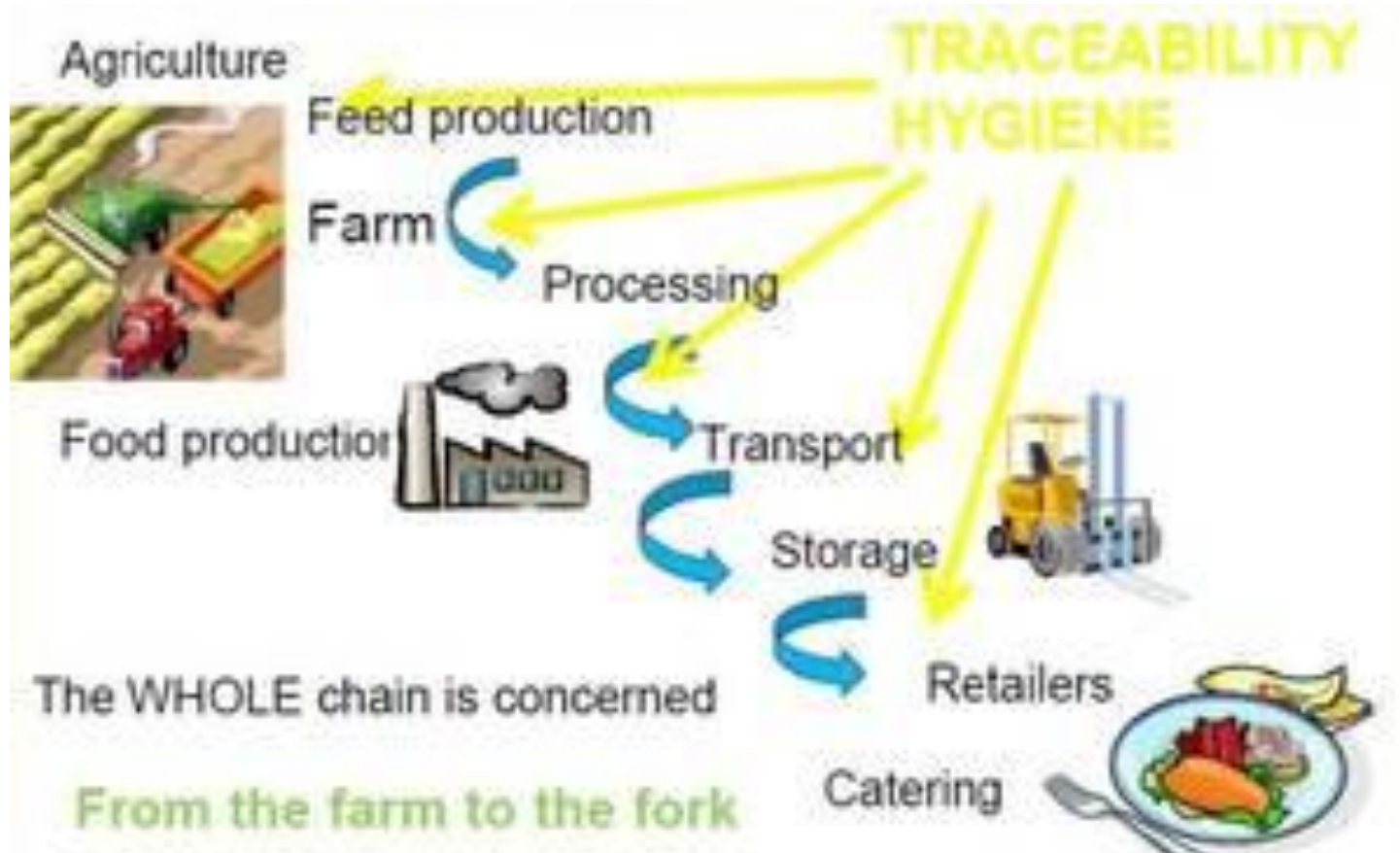
Food-specific legislation related to traceability

- **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”



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Food-specific legislation related to traceability



Thanks you for your attention!



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