

# iMIS Food Safety Status Legislation

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QAssurance

# Legislation table - EU

Regulation	Directive	Animal by-products	Animal feed	Eggs	Hospitality and craft production	Foodstuffs animals	Foodstuffs vegetable	Composite foodstuff	Fish and seafood	Specific target groups	Special food and drink	Supplements and herbs	Dairy
(EC) No. 999/2001		x	x										
(EC) No. 1069/2009		x	x	x									x
(EU) No. 142/2011		x	x	x									x
(EC) No. 178/2002			x	x	x	x	x	x	x	x	x	x	x
(EC) No. 183/2005			x										
(EC) No. 767/2009			x										
(EC) No. 1831/2003			x										
	2002/32/EC		x										
(EC) No. 396/2005			x										

# Legislation table - EU

Regulation	Directive	Animal by-products	Animal feed	Eggs	Hospitality and craft production	Foodstuffs animals	Foodstuffs vegetable	Composite foodstuff	Fish and seafood	Specific target groups	Special food and drink	Supplements and herbs	Dairy
(EC) No. 669/2009			x										
(EC) No. 1829/2003			x										
(EC) No. 1830/2003			x										
(EC) No. 142/2011			x										
(EC) No. 852/2004				x		x	x	x	x		x		x
(EC) No. 853/2004				x		x		x	x				x
(EC) No. 2073/2005				x	x	x	x	x	x				x
(EC) No. 1169/2011				x	x	x	x	x		x			x
(EC) No. 1333/2008				x	x	x		x			x		x

# Legislation table - EU

Regulation	Directive	Animal by-products	Animal feed	Eggs	Hospitality and craft production	Foodstuffs animals	Foodstuffs vegetable	Composite foodstuff	Fish and seafood	Specific target groups	Special food and drink	Supplements and herbs	Dairy
(EC) No. 2160/2003				x									
(EC) No. 882/2004			x			x		x					
(EC) No. 854/2004						x		x	x				
(EC) No. 2074/2005						x		x					
(EC) No. 1881/2006								x	x		x		x
	2006/88 / EC									x			
	39/2009/EC									X			
	141/2006/EC									x	x		
	125/2006/EC									x			

# Legislation table - EU

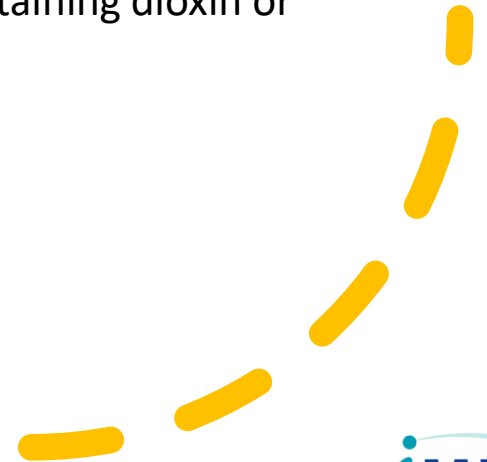
Regulation	Directive	Animal by-products	Animal feed	Eggs	Hospitality and craft production	Foodstuffs animals	Foodstuffs vegetable	Composite foodstuff	Fish and seafood	Specific target groups	Special food and drink	Supplements and herbs	Dairy
	21/1999/EC									x	x		
	96/8/EC									x	x		
(EC) No.609/2013										x			
(EC) No. 258/97											x	x	
	2002/46/EC										x	x	
(EC) No. 1924/2006											x	x	
(EC) No. 1925/2006											x		
(EC) No. 37/2010													x
(EC) No. 589/2008				x									

# Legislation table - EU

Regulation	Directive	Animal by-products	Animal feed	Eggs	Hospitality and craft production	Foodstuffs animals	Foodstuffs vegetable	Composite foodstuff	Fish and seafood	Specific target groups	Special food and drink	Supplements and herbs	Dairy
(EC) No. 543/2008						x					x		
(EC) No. 953/2009												x	
	125/2006/EC										x	x	
(EC) No. 609/2013											x	x	
(EU) No. 2016/127												x	
(EU) No. 2016/128											x	x	

# Animal by-products

- Materials that are not fit or intended for human consumption.
- Sources:
  - Livestock farms
  - Slaughterhouses (slaughter by-products)
  - Food production
  - Supermarkets/restaurants/ households (waste and food scraps)
- Authorities must prevent the incorrect use and processing of the animal by-products. The animal by-products must not be present in the feed or food chain.
  - The incorrect use can lead to major public and animal health risks and economic consequences. (e.g. products containing dioxin or BSE)



# Laws and Regulations

Regulation	Directive	Description
(EC) No. 999/2001		TSE Regulation
(EC) No. 1069/2009		The legal framework for control and supervision of animal products
(EC) No. 142/2011		Implementing regulation

- **National Framework:** the Animals Act, the Animal Products Decree and the Animal Products Regulation
- Administrative enforcement: Enforcement and Other Cases of the Animals Act and the Enforcement and Other Cases of the Animals Act
  - Supervision of safeguarding the trade of animal by-products in the international chains will be further extended.
- Tools used for the monitoring of animal by-products: inspections, laboratory research and enforcement communication.



# Supervision and Risks

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- The tools used for the monitoring of animal by-products:
  - inspections
  - laboratory research
  - enforcement communication
- Also supervision at the companies that receive, store, process, process or destroy animal by-products from the sector.
- Public health risks:
  - Pathogens, chemical and physical contaminants in foodstuffs that end up in food via the feed track or via the fertilizer track.
  - Use of banned animal proteins in feeds for farm animals.
  - 'Leaks' of unsound animal material into the environment, such as cadavers or laboratory waste.
  - Recycling of inadequate animal material for use in the human food chain.
  - Physical contacts with animal by-products.



# Animal feed

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- Role: safe food production of animal origin (meat, eggs and milk).
- Harmful substances (e.g. aflatoxin) can accumulate in the animals through the feed:
  - End up in the products: milk, eggs and meat.
- Improper feed chain can lead to major financial consequences and food safety risks.
  - Supervision of animal feed is essential.
- The animal feed sector for farm animals consists of hundred different raw materials. Large quantities come from Asia and America, but there is also important trade within the EU.

# Raw materials

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- The raw materials can be divided according to origin and use into:
  - by-products primary raw materials
  - minerals
  - additives and premixtures
  - fats and oils
  - other raw materials
- Raw materials may contain dangerous or undesirable substances (cleaning and disinfection agents, fungi, *Salmonella*, dioxin, pesticides, antibiotics and PCBs (polychlorinated biphenyls), mycotoxins, toxic substances) which can enter the human food chain.
  - This can compromise the safety and quality of end products.
- Authorized additives are used in the EU, however, there are indications that non-EU approved additives are also frequently present on the European market.
- No residues of veterinary medicines and additives must be present in other feeds than the feeds for which these products are intended in order to ensure the safety of animal feed.
- Feed labels must contain clear information about composition and origin for traceability purposes in order to prevent feed from being fed to non-target animals.

# Laws and Regulations

Regulation	Description
(EC) No 999/2001	TSE Regulation
(EC) No 1069/2009	The legal framework for control and supervision of animal products
(EU) No. 142/2011	Implementing regulation
(EC) No 178/2002	General principles and requirements of food law establishing a European Food Safety Authority and laying down procedures in food safety matters
(EC) No 183/2005	Feed hygiene requirements
(EC) No 767/2009	Market regulation: marketing and use of animal feed
(EC) No. 1831/2003	Feed additives
2002/32 / EC	Undesirable substances in animal feed
(EC) No. 396/2005	Standards for residues pesticides: Maximum levels
(EC) No 669/2009	Official controls on imports of certain feed and food of non-animal origin
(EC) No 1829/2003	Genetically modified food and feed
(EC) No 1830/2003	Traceability and labeling of genetically modified organisms and traceability of foodstuffs produced from genetically modified organisms
(EC) No 142/2011	Animal by-products: implementing regulation

**National legislation:** Animals Act, Animal Feed Decree 2012, Animal Feed Regulations 2012, Veterinary Medicines Decree

# Supervision

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- The following enforcement methods are used for supervision of the Animal Feed domain:
  - Supervision (horizontal and repressive supervision)
  - Investigation
  - Services.
- The following enforcement instruments are used:
  - Inspections, including sampling in the context of the National Animal Feed Plan
  - Administrative checks
  - Audits
  - Reality checks
  - Interventions
  - (enforcement) communication.

# Compliance picture

Target group	Target	Focus points
Food processing companies creating byproducts that will be used as animal feed	Moderate, partly unknown	Quality focus is inadequate developed and not all companies are known by the NVWA or registered as feed company.
Primary Producers (agriculture)	Partly unknown	Usage of pesticides and additives. On the other side is information available from the sectoral monitoring plan and program.
Companies producing food products for the processing of cereals, seeds, oils and fats	Moderate to sufficient	Traceability, purchase behaviour in relation with countries of origin and safe feed.
Production companies specific for animal feed	Moderate to sufficient	HACCP, traceability, labelling, claims and transport.
Production companies for pets	Moderate to sufficient	HACCP, Labelling and claims
Production companies for other animals (For example fur animals)	Sufficient	
Production companies for additives	Moderate to sufficient	Production of unapproved additives, traceability, labelling and transport.
Production companies for premixtures	Moderate to sufficient	Labelling and transport (Cross contact)
Self mixing (by livestock keepers)	Unclear	Companies possessing a digester, overdose of additives, usage of illegal components and transport/cross contamination.
Storage and transshipment companies	Inadequate to sufficient	Traceability, crosscontamination, companies storing waste.
Transportation companies	Moderate to sufficient and partly unknown	Traceability, crosscontamination, cleaning and disinfecting and not all transporters are known by the NVWA.
Merchants	Moderate to sufficient and partly unknown	Not all merchants are known by the NVWA (especially online merchants). Merchants with a own storage and diverse trade items (food, feed, waste) and traceability
Importers	Moderate to sufficient	Gatekeeper system, traceability and safety of raw materials.
Wholesale and retail	Unknown	
Consumer	Unknown	
Other animal keepers (zoo's etc)	Sufficient	
Insurers	Partly unknown	Bringing insufficient quality of products to the market without further treatment.
Animal feed laboratories	moderate	Duty to report and inspect quality.
Other companies	Unknown	

# Eggs

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- The egg chain: means the primary phase (laying-egg farms) and the processing phase which includes storage and trade.
  - Supervised by Dutch Control Authority Eggs (NCAE)
- Food safety in the egg chain:
  - Antibiotics – veterinary medicines use
  - Dioxin – via animal feed
  - *Salmonella*



Laying egg farms



collectors



packing stations



egg product  
manufacturers / egg  
product traders

# Fraud and Food Safety risks

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- Types of fraud:
  - transferring poultry products (destination)
  - fraud with a best before date
  - fraud with classification of eggs
- Eggs fraud leads to food safety risks:
  - High risks:
    - Illegal use of antibiotics in the poultry chain (residue exceedances in eggs).
    - Eggs that are not intended for human consumption (category 3) are incorrectly changed into eggs intended for humans.
    - The 'best before (Best before) date 'of eggs is changed
  - Low risk:
    - Sales of regularly produced eggs as organic.



# Laws and Regulations

Regulation	Description
(EC) No 1069/2009	The legal framework for control and supervision of animal products
(EU) No 142/2011	Implementing regulation
(EC) No 178/2002	General principles and requirements of food law establishing a European Food Safety Authority and laying down procedures in food safety matters
(EC) No 852/2004	Food hygiene
(EC) No 853/2004	Hygiene in the production of products of animal origin
(EC) No 2073/2005	Microbiological criteria for food
(EC) No 1169/2011	Provision of food information to consumers
(EC) No 1333/2008	Food additives
(EC) No 2160/2003	Salmonella control

**National legislation:** Commodities Act: Commodities Act Decree on food hygiene, Commodities Act Decree on the preparation and treatment of foodstuffs, Wet animals, Animal products, Animal products regulation

# Supervision

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Laying egg farms



collectors



packing stations



egg product  
manufacturers / egg  
product traders

- Laying egg farms:
  - A private quality system for hygiene package – IKB Ei.
  - The frequency of inspections differs. Inspections and any re-inspections take place unannounced. The controls focus on administration, housing, drinking water cross-contamination, animal by-products and samples are taken from eggs.
- Collectors:
  - Inspections are performed unannounced once a year.
  - Focus on: hazard identification and risk assessment, food safety, traceability, general hygiene, specific regulations with regard to design and environment, transport, waste, personal hygiene, packaging, training, eggs and supplier.

- Packing stations:
  - Announced audit once a year where at least 80% is assessed (design and maintenance of the business premises and equipment, hygiene, cleaning and disinfection, water quality, HACCP including documentation, quality of the raw materials, pest control, risk of cross-contamination, personal hygiene, training and instruction of personnel, cold chain, packaging, transport, sampling and testing, and the proper handling of animal by-products). All components to be covered at least once in every 3 years.
  - Unannounced inspections twice a year
  
- Egg product manufacturers:
  - Audit every year where at least 80% is assessed (design and maintenance of the business premises and equipment, hygiene, cleaning and disinfection, water quality, HACCP including documentation, quality of eggs and other raw materials, pest control, risk of cross-contamination, personal hygiene, training and instruction of personnel, cold chain, packaging, transport, sampling and testing, and the correct handling of animal by-products). All components to be covered at least once in every 3 years.
  - Microbiological samples.
  
- Egg product traders:
  - An announced audit once a year and an unannounced inspection once a year. For the audit at least 80% is assessed design and maintenance of the business space, hygiene, cleaning, pest control, risk of cross-contamination, personal hygiene, training and instruction of personnel, cold chain, transport and the correct handling of animal by-products. All components to be covered at least once in every 3 years.

# Hospitality and craft production

- The government uses laws and regulations to protect consumers against unsafe food in the catering industry and craft products.
- Risks:
  - Pests: mice, rats (insufficient hygiene).
  - Microbiological: during the entire chain.
    - Production and processing: inadequate hygiene and cross-contamination lead to contamination with bacteria or viruses.
    - Transportation: improper conditions (temperature, humidity) lead to bacterial (*Clostridium perfringens*, *Bacillus cereus* and *Clostridium botulinum*), fungi and mycotoxins growth.
  - Chemical: processing process – contamination with additives, other substances, chemicals, disinfectants, preservatives, detergents, pest control products etc.



# Laws and Regulations

Regulation	Description
(EC) No. 178/2002	General Food Regulation
(EC) No. 852/2004	Food Hygiene
(EC) No. 2073/2005	Microbiological criteria for food
(EC) No. 1169/2011	Provision of food information to consumers

**National legislation:** Commodities Act, Commodities Act Decree on food hygiene, Commodities Act Decree on the preparation and treatment of food stuffs, Nature Conservation Act

# Supervision

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- The Food Safety Authority supervises compliance with the laws and regulations.
- In addition to food safety, there is (increasingly) self-regulation by the business community and participation in private (self) control systems.
- Top three violations:
  - Insufficient hygiene (equipment and space).
  - Temperature control (cold chain and hot/cold storage).
  - Insufficient assurance of the food safety of critical processes (cooling down and uncooled sales, engineering and pest control).

# Food of animal origin

- This describes part of the meat chain:
  - Industrial companies that produce, import, process, store, distribute and transport foodstuffs of animal origin
  - Except: slaughterhouses, cutting plants and approved cold stores that are linked to a slaughterhouse
- The chain covers all stages of the production, processing and distribution of foodstuffs: food production companies (large and small), importers of foodstuffs (large and small) and storage, transport and distribution companies
- Meat chains:
  - Red meat chain: cattle, pigs, sheep, goats, horses.
  - White meat chain: chicken.
  - Game chain: meat from hunted animals.
  - Processed meat: meat products.



# Fraud

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- Meat fraud: conscious or deliberate adaptation or change of a certain characteristic of meat in order to obtain a financial benefit.
  - Case: horse meat for beef
  - Fraud in the meat products trade
  - Illegal additives to meat
- Types of meat fraud:
  - Covering the destination of the meat, such as upgrading meat. (meat that is classified as category 3 can still be traded as meat intended for human consumption).
  - Upgrading meat by illegal processing, (treating poultry lower legs with acetic acid and / or adding hydrogen peroxide or sulphite to spoiled meat to give it a nice colour again).
  - Calculate the production date of the meat.
  - Including the animal species (horse to beef, from buffalo to beef or from turkey to lamb).
  - Converting the production method of the meat ( form regular meat to organic meat or regular meat to halal meat).
  - Covering the origin of the meat (changing the country of origin or interchanging different breeds).

***Meat scandals are causing consumer confidence to fall.***



# Food Safety risks

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- Food safety risks related to meat fraud (meat conversion). This leads to an unknown product or a product of unknown origin, hence the traceability of the meat is compromised. As a result, checks cannot be done correctly.
  - if a control assumes that it is dealing with beef, it will not test for drugs administered to horses that could be harmful to humans, therefore safety can no longer be guaranteed.
- Food safety risks resulted from meat fraud:
  - Unsafe food (spoiled food, contaminated food) that pose a threat to consumers.
  - There is a direct risk to food safety if residues of veterinary medicines (including antibiotics) are unintentionally left in meat.
  - The presence of resistant bacteria in animals, animal products and the environment poses a risk because these resistant germs can be transferred to humans.
  - Tracking and tracing problems lead to no correct recalls (recall of batches of meat); there is also the risk that meat that has to be taken away for destruction can no longer be located and still ends up on the consumer's plate.

# Laws and Regulations

Regulation	Description
(EC) No 178/2002	General principles and requirements of food law establishing a European Food Safety Authority and laying down procedures in food safety matters
(EC) No 852/2004	Food hygiene
(EC) No 853/2004	Hygiene in the production of products of animal origin
(EC) No 2073/2005	Microbiological criteria for food
(EC) No 1169/2011	Provision of food information to consumers
(EC) No 1333/2008	Food additives
(EC) No 882/2004	Official controls on compliance with feed and food law, animal health and animal welfare rules
(EC) No 854/2004	Official controls on food from animal products
(EC) No 2074/2005	Implementing measures for special animal products
(EC) No 543/2008	Rules for implementing Council Regulation (EC) No 1234/2007 as regards marketing standards for poultry meat

**National legislation:** "Commodities Act "Wet animals, "Animal products regulation "Animal Products Decree

# Supervision

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- Based on European regulations, food safety risks must be prevented, eliminated or reduced to an acceptable level throughout the food chain in accordance with the HACCP principles.
- HACCP plan mandatory.
- The Food Safety Authority's role:
  - Ensure and increase compliance with food safety legislation throughout the food chain.
  - Ensure that companies work according to the HACCP principles.
  - Ensure that companies comply with specific regulations (microbiological criteria, allergen information etc).
- The Food Safety Authority's supervision of the producers is twofold: both supervision of the production processes and of the foodstuffs.
  - The Food Safety Authority supervises to what extent producers of foodstuffs comply with the HACCP principles during production. In addition, the Food Safety Authority supervises the traceability of foodstuffs and the correct and timely notification of unsafe foodstuffs.
  - Companies producing food of animal origin must be approved and accredited by the Food Safety Authority.
  - An audit is carried out at the company for correct application of the HACCP principles.
  - In addition, the Food Safety Authority supervises the correct labelling of foodstuffs.

# Foods of vegetable origin

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- This describes the chain of foodstuff of vegetables origin:
  - Industrial companies that produce, import, process, store, distribute and transport these foods.
  - It covers all stages in the food supply chain.

# Fraud and Risks

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- Types of fraud:
  - Convert: giving the batch a different identity on paper (forging documents or fraudulent use of samples analyses).
  - Upgrade: the batch is physically changed (mixing with another qualitatively better batch).
- Food safety risks related to fraud: *Salmonella*, dioxin, pesticides or other toxic substances can end up in the food chain.
- Other hazards that can arise on vegetable products:
  - Mycotoxins (Aflatoxins, ochratoxin A, Patulin)
  - Heavy metals (lead, cadmium, mercury, arsenic)
  - Biocides and perchlorate
  - Polycyclic aromatic hydrocarbons (PAHs)
  - Pesticide residues
  - Nitrate

# Laws and Regulations

Regulation	Description
(EC) No 178/2002	General principles and requirements of food law establishing a European Food Safety Authority and laying down procedures in matters of food safety
(EC) No 852/2004	Food hygiene
(EC) No 2073/2005	Microbiological criteria for food
(EC) No 1169/2011	Provision of Food Information to Consumers

**Relevant legislation:** Commodities Act, including: Commodities Act Decree on the preparation and treatment of foodstuffs, Commodities Act Decree on food hygiene and Other relevant Commodities Act Decrees

# Supervision

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- Based on European regulations, food safety risks must be prevented, eliminated or reduced to an acceptable level throughout the food chain in accordance with the HACCP principles.
- HACCP plan mandatory.
- The Food Safety Authority's role:
  - Ensure and increase compliance with food safety legislation throughout the food chain.
  - Ensure that companies work according to the HACCP principles.
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- The Food Safety Authority's supervision of the producers is twofold: both supervision of the production processes and of the foodstuffs.
  - The Food Safety Authority supervises to what extent producers of foodstuffs comply with the HACCP principles during production. In addition, the Food Safety Authority supervises the traceability of the products the correct report of unsafe products.
  - Companies producing food of animal origin must be approved and accredited by the Food Safety Authority.
  - In addition, the Food Safety Authority supervises the correct labelling of foodstuffs.

# Composite foodstuff

- This describes the chain of the compound foodstuffs:
  - Companies that produce, import, process, store, distribute and transport composite foodstuffs.
  - Composite = foods contain products of both vegetable and animal origin.
  - It covers all stages of food production, processing and distribution.
- The production of composite foodstuffs is a complex network of chains.
- The large number of ingredients, the long chains with many (international) links and the pressure to keep prices low can encourage fraud, make traceability more difficult and hinder supervision.





# Laws and Regulations

Regulation	Description
(EC) No 852/2004	Food hygiene
(EC) No 853/2004	Hygiene in the production of products of animal origin
(EC) No 2073/2005	Microbiological criteria for food
(EC) No 1169/2011	Provision of food information to consumers
(EC) No 1333/2008	Food additives
(EC) No 882/2004	Official controls on compliance with feed and food law, animal health and animal welfare rules
(EC) No 854/2004	Official controls on food from animal products
(EC) No 2074/2005	Implementing measures for special animal products
(EC) No 1881/2006	Determining maximum levels of certain contaminants

**National regulations:** Commodities Act, Animals Act, Animal products regulation, Animal Products Decree

# Supervision

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- Based on European regulations, food safety risks must be prevented, eliminated or reduced to an acceptable level throughout the food chain in accordance with the HACCP principles.
- HACCP plan mandatory.
- The Food Safety Authority is responsible for the supervision of production processes and foodstuffs.

# Fish and seafood

- This refers to the domain fish chain:
  - From catch and aquaculture to industrial processing and distribution.
- Within aquaculture, the use of antibiotics and the transport of fish are important for food safety.
- The Food Safety Authority supervises the fish chain by means of inspections (food safety, microbiological samples, tests for harmful chemical substances). Besides it also performs landing inspections, recognition and registration of ships and companies etc, as well as focuses on compliance with regulations.
  - When fish is traded illegally, the food safety cannot be guaranteed and therefore may pose a threat to consumers.



# Fraud and Food Safety risks

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- Types of fish fraud:
  - Converting: fish species such as bluefin tuna, cod and sole are replaced with cheaper options.
  - Upgrading: Improper handling, the use of additives and colouring agents to make the fish look fresher.
  - Quotas can be changed (keeping fish off the book).
- Food safety risks:
  - Microbiological (*Salmonella*, *Listeria*, *E.coli*, etc)
  - Chemical (heavy metals, histamine)

# Laws and Regulations

Regulation	Description
(EC) No 178/2002	General principles and requirements of food law establishing a European Food Safety Authority and laying down procedures in food safety matters
(EC) No 853/2004	Hygiene in the production of products of animal origin
(EC) No 852/2004	Food hygiene
(EC) No 2073/2005	Microbiological criteria for food
(EC) No 854/2004	Official controls on food from animal products
(EC) No 1881/2006	Determining maximum levels of certain pollutants

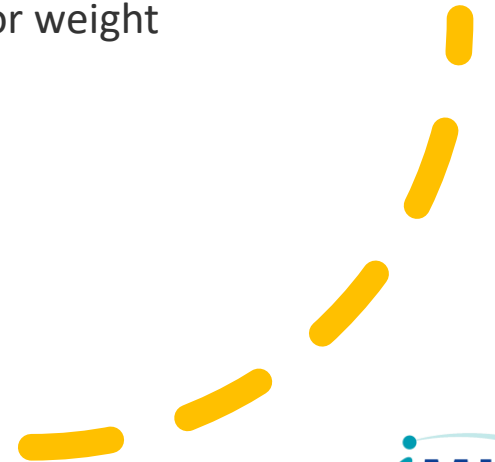
# Supervision

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- Supervision has been tightened up in the past years.
- When official controls are carried out at the fish and fish processing companies, points for improvement have often been identified to which the intervention policy applies, leading to a large number of measures. A distinctive feature of the supervision of the fishing sector is the closure of production areas when contamination is detected (certain areas are closed to fishing due to high levels of dioxins).
- The Food Safety Authority publishes the results of inspections. Moreover, the inspection results of the other EU-approved fish processing companies follow as well. The risk images will be discussed on the basis of the different target groups. The target groups with the greatest risk of non-compliance will be discussed first; target groups with a relatively high risk of non-compliance with the regulations.

# Specific target groups and Special food and drink

- European food law for specific groups is developing rapidly. This certainly also applies to special foods which are a separate category of foods intended for specific groups of consumers.
- In 2013, the EU Regulation on nutrition for specific groups was adopted (Regulation No 609/2013). The regulation is a framework of legislation covering four subjects:
  - Infant formula and follow-on formula;
  - Processed cereal-based foods and baby foods;
  - Food for medical purposes;
  - The daily diet complete replacement products for weight management.



# Laws and regulations for specific target groups

Directive	Description
39/2009 EC	On special nutrition.
141/2006 EC	On infant formulas and follow-on formulas.
125/2006 EC	On processed cereal-based foods and baby foods for infants and young children.
21/1999 EC	On dietetic foods for special medical purposes.
96/8/ EC	On foods intended for use in energy-restricted diets for weight reduction.

As of 20 July 2016, with a certain transition period, these guidelines have been replaced by **Regulation (EC) No 609/2013** on nutrition for specific groups.

**Regulation (EC) No 1169/2011** on the provision of food information to consumers is the basis of the labelling requirements.

**National legislation:** Commodities Act Decree on food information regulates additional regulations and criminalization; Commodities Act regulation on allergens for non-prepacked foodstuffs makes it possible to provide information about allergens orally.



# Laws and regulations for special food and drink

Regulation	Directive	Description
(EC) No 178/2002		General principles and requirements of food law establishing a European Food Safety Authority and laying down procedures in food safety matters
(EC) No 852/2004		Food hygiene
141/2006 / EC	Infant formulas and follow-on formulas	141/2006 / EC
21/1999 / EC	Dietary foods for special medical purposes	21/1999 / EC
96/8 / EC	Foods intended for use in energy-restricted diets for weight reduction	96/8 / EC
(EC) No 258/97		Novel foods and food ingredients
2002/46 / EC	On the approximation of the laws of the Member States relating to food supplements	2002/46 / EC
(EC) No 1924/2006		Nutrition and health claims made on foods
(EC) No 1925/2006		The addition of vitamins and minerals and certain other substances to foods
125/2006 / EC	Processed cereal-based foods and baby foods for infants and young children	125/2006 / EC
(EC) No 1881/2006		Determining maximum levels of certain contaminants
(EC) No 1333/2008		Food additives
(EC) No 953/2009		Substances which may be added to foods for particular nutritional uses for specific nutritional purposes
(EC) No 1169/2011		Provision of food information to consumers
(EC) No 609/2013		Food intended for infants and young children, food for special medical purposes and the daily diet are complete replacement products for weight management, and repealing Council Directive 92/52 / EEC
(EU) No. 2016/127		Concerns the special compositional and information requirements for infant formulas and follow-on formulas and regarding information requirements regarding the nutrition of infants and young children
(EU) No. 2016/128		Special compositional and information requirements for food for special medical purposes

**National legislation:** Commodities Act Decree herbal preparations, Commodities Act Decree on the addition of micro-nutrients to foodstuffs, Commodities Act Decree on information on foodstuffs, Commodities Act regulation for contaminants in food

# Supplements and herbs

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- Products:
  - Foods for special groups (including infants, patients, people who want to lose weight)
  - Herbs and herbal preparations
  - Dietary supplements
  - Medicines
- Supervision falls under the Food Safety Authority.
  - Besides the production, import and distribution of special food and drink products, the composition (quality and type of ingredients) are also supervised.
- Nutrition and Health Claims:
  - There is targeted supervision for nutrition and health claims made on the label or in advertising for food supplements and herbal preparations.

# Fraud and Food Safety risks

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- Types of fraud:
  - Prohibited substances: Nutritional supplements and herbal preparations can contain harmful toxins such as aristolochic acids, PA<sub>s</sub>, PAH<sub>s</sub>1 or lead.
  - Upgrading: Manufacturers "upgrade" their product with a substance that is effective, but it is prohibited. Therefore, this substance is not mentioned on the ingredients list of the packaging. This is referred to as "adulteration".
  - Smurfs: Smurfs means that different parcel shipments with smaller quantities of a certain product are divided among various customers over a longer period of time. Eventually, all packages come together again at one customer. This is done deliberately to not draw attention to the trade flows (to stay under the "customs radar").
- These types of fraud can lead to risks for food safety and public health. Higher risks apply for vulnerable groups: babies, the elderly or the sick. These risks are caused by:
  - the presence of hazardous substances and / or illegal ingredients in products, (sibutramine, sildenafil and ephedrine)
  - contamination ( heavy metals and acids)
  - counterfeit agents
  - too high concentrations of (raw or auxiliary) substances.

# Laws and Regulations

Regulation	Directive	Description
(EC) No 178/2002		General principles and requirements of food law establishing a European Food Safety Authority and laying down procedures in food safety matters
(EC) No 258/97		Novel foods and food ingredients
2002/46 / EC	On the approximation of the laws of the Member States relating to food supplements	
(EC) No 1924/2006		Nutrition and health claims made on foods

The following legislations are especially relevant: General Food Regulation, Directive 2002/46 / EC on the approximation of the laws of the Member States relating to food supplements, Commodities Act Decree on the addition of micro-nutrients to foods, Regulation on novel foods and novel food ingredients, Commodities Act Decree on novel foods, Medicines Act, Commodities Act Decree herbal preparations, Claims Regulation.

# Supervision

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- The inspections at companies mainly focus on the following topics:
  - System inspection at producers and importers of special food and drink products
  - Labelling
  - New foods
  - Prohibited herbs
- The specific label checks focus on the following topics:
  - Claims (medical, nutrition and health claims)
  - Other labelling requirements.



# Dairy

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- The dairy chain - the primary phase (dairy farms) and the processing phase, including storage and trade is supervised by Central Body for Quality Matters for Dairy.
- The retail trade (consumer phase) is supervised by Food Safety Authority.
- Food safety in the dairy chain:
  - Microbiological hazards occur more often than chemical and physical (*L. monocytogenes*, *S. aureus*, *Salmonella* and *E.coli*)

# Laws and Regulations

Regulation	Description
(EC) No. 1069/2009	The legal framework for control and supervision of animal products
(EU) No 142/2011	Implementing regulation
(EC) No 178/2002	General principles and requirements of food law establishing a European Food Safety Authority and laying down procedures in matters of food safety
(EC) No 852/2004	Food Hygiene
(EC) No 853/2004	Hygiene in the production of products of animal origin
(EC) No 2073/2005	Microbiological Criteria for Foodstuffs
(EC) No 1169/2011	Provision of consumer food information
(EC) No 1333/2008	Food additives
(EC) No. 37/2010	Residues of veterinary medicinal products
(EC) No 1881/2006	Determining maximum levels of certain contaminants

**National legislation applicable:** Commodities Act Decree on dairy, Commodities Act Decree on the hygiene of foodstuffs, Commodities Act Decree on the preparation and treatment of foodstuffs, Animals Act, Animal Products Decree, Animal products regulation

# Supervision

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- Dairy farms: mainly produce for their own use or for direct sale to the consumer through their own stores, also supply milk to dairy companies.
  - Inspections are unannounced and focus on functioning of the company's quality system.
- Recipients of farm milk: divisions of dairy companies or independent traders who purchase the farm milk from dairy farms and take care of the transport from the farm to the dairy.
  - Audits to determine whether the standards are exceeded with regard to bacterial count, somatic cell count and bacteria-inhibiting substances.
- Factory dairy producers: dairies that receive raw milk and process it into dairy products.
- Successive processors: cheese processors who further ripen and cut cheese.
  - One regular audit is carried out annually. During this annual audit, at least 80% of the following components are assessed (design and maintenance of the business premises and equipment, hygiene, cleaning and disinfection, water quality, HACCP including documentation, quality of the raw materials including raw milk, pest control, risk of cross-contamination, personal hygiene, training and instruction of personnel, cold chain, packaging, transport, sampling and research and the correct handling of animal by-products). All these parts must be discussed at least once every three years.
  - In addition to inspections, microbiological samples are taken to verify whether dairy products meet the hygiene standards.
- Small-scale dairy and farm dairy producers: small-scale production of dairy products.
  - Same as the above, one regular audit is carried out each year to assess whether they comply with the code.





# iMIS Food Safety Status Legislation

