

JENS KARSTEN

*FOOD GOVERNANCE, FOOD LAW AND THE THIRD LEVEL
IN THE HIERARCHY OF NORMS*

SUMMARY: 1. Introduction. – 2. Food Law. – 2.1. Pillars of Food Law. – 2.2. Development of Food Law. – 2.3. Food law – An attempt to give Union law a structure and to relate it to relevant Italian law. – 2.4. Food 2030 - Food 2050. – 2.5. Case study: Parma Ham – a very Italian contribution to European food law. – 3. Tertiary Law. – 3.1. Comitology. – 3.2. Delegated acts. – 3.3. Implementing acts. – 3.4. Useful web-links. – 4. Food Governance.

1. Introduction

In this short treatise or compilation, three topics will be presented, two of which are closely related and rooted in the tangible – and ‘tastetable’ – subject of food, while the third appears abstract. Food is the bracket that holds the narrative together. EU law’s hierarchy of norms, and in particular its third level, can well be explained on the subject of food and the law and policy that governs its production, processing and consumption.

European Food Law regulates areas as diverse as primary food production in agriculture and fisheries, trade in food, food security (safety of supply) and food defence, food safety, food information as well as nutrition. In the TFEU, reference is made to the internal market, to agriculture, to health and consumer protection, but no single provision provides the foundation for food law – which was no obstacle for food law, more even than other fields of law, of becoming heavily communiterised, with a recent tendency towards re-nationalisation. Food and drink was the area of law on which the European Court of Justice originally developed its free movement of goods doctrine on products like whisky (*Dassonville*), liquor (*Cassis de Dijon*), margarine (*De Smet*), beer (*Reinheitsgebot*), pasta (*Drei Glocken*) and cheese (*Deserbais*). Reaching maturity (and saturation point) it becomes perceived as an area of law in its own right.

EU Tertiary Law is law adopted by the EU-Executive (the European Commission) on the basis of express empowerments in secondary law adopted, mostly, by the EU co-legislator (the European Parliament and the

Council). The Commission also completes the law, by delegated act (to supplement or amend) and implementing act (to establish uniform conditions). Tertiary law is adopted in a procedure known as ‘comitology’ that has thoroughly changed with the Lisbon Treaty 2009. Labelled ‘underground law’ due to opaque procedures and inaccessible Commission *interna*, it is often of paramount importance regarding the decisions taken. Comitology, having developed in the 1960s in the area of agricultural law, has the biggest legislative output in the area of farm law and food law. This is also the area where most cases occurred for the scrutiny of the Commission by European Parliament and Council.

Food Governance is the art of shaping the regulatory environment by various strata of government for food business operators, consumers and the general public. It is both law and a branch of political science and follows the structures of EU.

2. Food Law

Food law is everywhere but not well known as a branch of law. Rooted in the agricultural *acquis communautaire* but developed on the internal market provisions of the Treaty, it forms a body of law that governs food security and food defence, food safety, food information and nutrition. While highly relevant in societal terms and for the sheer base needs of each and everybody, it only recently emerged as an independent field of law. The chapter will present key elements of food law, its basis, its current predicaments and an outlook for the future (“Food 2030”/“Food 2050”), thereby ‘wetting the taste’ as it is hoped for the subject.

In Union law, “food law” as a body of law is defined as “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”¹.

2.1. Pillars of Food Law

Distinguishing four strands of food policy helps to structure food law and understand its background.

¹ Article 3 No 1 of Regulation (EC) No 178/2002.

a) Food Security and Food Defence

Food security (safety of supply), by the 1996 World Food Summit, was stated to “exists when all people, at all times, have physical and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life”. It has been made food-related priority by the Council Presidency Trio of Romania-Finland-Croatia 2019-2020.

Food defence can be described as anti-crime and anti-terrorism in the food chain. The European Parliament offers the following description: “Food defence is generally defined as the protection of food from intentional contamination or adulteration by biological, chemical, physical, or radiological agents and includes measures regarding prevention, protection, mitigation, response and recovery from intentional acts of food contamination. Food defence is different from food safety as the latter deals with unintentional contamination. In 2007, the World Health Organisation identified intentional food contamination as one of the main global health threats of the 21st century and stated that food has become an instrument for terrorist attacks. In the EU, food defence is a rather new concept, as opposed to the USA where food defence originated and is extensively regulated. Past incidents such as terrorist attacks and food fraud have contributed to food defence systems development in some Member States. In the aftermath of the 2001 terrorist attacks in the US, the Health and Security Committee was set up in the EU. This informal group was given a formal status and assigned specific tasks in 2013, when Decision 1082/2013/EU on serious cross-border threats was adopted, reinforcing coordination of preparedness measures across the EU for communicable diseases and other serious health threats (including intentional food contamination)”.

b) Food Safety (food composition)

Food safety, in law, is the body of rules describing the handling, preparation, and storage of food in ways that prevent food-borne illness and avert health hazards. Food safety law deals with biological safety (hygiene), chemical safety (residues and contaminants), radiological safety (radiation) and physical safety (foreign body contamination, imitates).

c) Food Information (commercial communication)

Food information law means the “Union provisions governing the food information, and in particular labelling, including rules of a general nature

applicable to all foods in particular circumstances or to certain categories of foods and rules which apply only to specific foods”².

d) Nutrition

Nutrition deals with people’s diets. WHO-Europe defines the challenge as follows:

“Tasty, nutritional food adds years to life and life to years. Nevertheless, the burden of disease associated with poor nutrition continues to grow in the WHO European Region. Poor diet, overweight and obesity contribute to a large proportion of non-communicable diseases, including cardiovascular diseases and cancer, the two main killers in the Region. National surveys in most countries indicate excessive fat intake, low fruit and vegetable intake and an increasing problem of obesity, all of which not only shorten life expectancy, but also harm the quality of life”.

e) Neighbouring areas

A holistic view of food law must include primary production, that is, agriculture and fisheries³. Feed law, plant health and animal health, therefore, are part of the picture.

2.2. Development of Food Law

The table below provides an overview over the development of EU food law in the shortest possible fashion:

² Article 2(2)(b) of Regulation (EU) No 1169/2011.

³ Article 3 No 1 of Regulation (EC) No 178/2002: “primary production” means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of “wild products”.

Food	Nutrition
<p><i>“Free movement of food” (→ Directives)</i></p> <p>Vertical Directives Horizontal (Dir. 79/112 – 1st Labelling Directive)</p> <p>6/11/1985: Commission Communication “Completion of the Internal Market: Community legislation on foodstuffs” (COM(85) 603 final of 8/11/1985)</p> <p>24/10/1989: Communication on the free movement of foodstuffs within the Community (OJ C 271, 24/10/1989, p. 3)</p> <p><i>Crisis response (→ Regulations)</i></p> <p>30/4/1997: Green Paper on general principles of EU food law (COM(97) 176 final)</p> <p>12/1/2000: White Paper on Food Safety (COM (1999) 719 final) — “Farm to Fork” 14/12/2000: Council Resolution on health and nutrition (OJ C 20, 23/1/2001, p. 1)</p> <p>28/1/2002: Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety (General Food Law)</p>	<p>24/9/1990: Directive 90/496/EEC on nutrition labelling 3/12/1990: Council Resolution on an action programme on nutrition and health (OJ C 329, 31/12/1990, p. 1)</p> <p>28/6/1994: Council of Europe Recommendation on food and health</p> <p>20/5/2000: WHO (Europe) first action plan for food and nutrition policy</p> <p>2003: establishment of the Network on Nutrition and Physical Activity</p> <p>23/9/2002: EP and Council adopting a programme of Community action in the field of public health (2003-2008)</p> <p>8/12/2005: Commission Green Paper “Promoting healthy diets and physical activity: a European dimension for the prevention of overweight, obesity and chronic diseases”</p> <p>16/11/2006: WHO European Charter on counteracting obesity</p> <p>30/5/2007: Commission White Paper on nutrition, overweight and obesity-related health issues</p> <p>2007: “EU Pledge” of food industry (www.eu-pledge.eu)</p> <p>... in the making: product reformulation</p>

2.3. Food law – An attempt to give Union law a structure and to relate it to relevant Italian law

The table below lists the items of the *acquis communautaire* forming together the body of Union food law. The reader is invited to complete the list by references to Italian law.

Food law proper

Area covered	Union law	Italian law
General Food Law	Regulation 178/2002 (2019 amendments to be adopted)	
Food Defence	Decision 1082/2003	
Food Information Law	Article 16 Reg. 178/2002	
	FIC-Reg. 1169/2011 <i>Before 13/12/2014: Dir. 2000/13</i>	
	NHCR 1924/2006 (health claims)	
	Article 5 Reg. 853/2004 (identity marks)	
Food information law of agricultural law	Product denominations (CMO) Quality labels Eco labels Beef labelling	
Food (and non-food) advertisement	UCP Dir. 2005/29	
	MCA Dir. 2006/114	
Food (and non-food) packaging	Dir. 75/107 (bottles as measuring containers)	
	Dir. 76/211 (weigh or volume of pre-packed products)	
	Dir. 2007/45 (nominal quantities for pre-packed products)	
	Dir. 2009/34 (weights and measures)	
	Dir. 2011/91 (lot identification)	
Food (and non-food) price indication	Price Indication Dir. 98/6	
Functional food (<i>physiological effect</i>)	Food Supplements Dir. 2002/46 (<i>creates food subcategory</i>)	
	Food for specific groups (FSG) Reg. 609/2013 <i>Before 20/7/2016: PARNUTS-Dir. 2009/39 (creates food subcategory)</i>	
	Fortified Food Reg. 1925/2006 (Reg. 307/2012)	

(segue)

Area covered	Union law	Italian law
Food composition	Food Improvement Agents Package (“FIAP 2008”) Common authorisation procedure of Reg. 1331/2008 + Reg. 234/2011 Enzymes Reg. 1332/2008 Additives Reg. 1333/2008 Flavourings Reg. 1334/2008	
	Smoke flavourings Reg. 2065/2003 Reg. 1321/2013	
	Novel Food Reg. 2015/2283 <i>Before 1/1/2018:</i> Novel Food Reg. 258/97	
	Genetically modified organisms GMO-Reg. 1829/2003	
Biological safety	General food hygiene Reg. 852/2004	
	Hygiene animal products Reg. 853/2004	
	Microbiological criteria Reg. 2073/2005	
	QuickFrozenDir 89/108 QuickFrozenReg 37/2005	
	Biocides (food and non-food) Reg. 520/2012	
	Reg. 2016/2031 (phytosanitary)	
Chemical safety	Contaminants Reg. 315/93 Reg. 1881/2006 (recast under way)	
	Residues incl. pesticides Reg. 396/2005	
	Food contact material Reg. 1935/2004	
	Extraction solvents Dir. 2009/32	
Radiological safety	Irradiation Dir. 1999/2	
Market surveillance	Reg. 882/2004 and Reg. 854/2004 <i>as of 19/12/2019:</i> Official Controls Reg. 2017/625	
RASFF	Article 50 <i>et seq.</i> Reg. 178/2002	

...	Product reformulation (EU action in pipeline)	
Criminal liability	Food fraud (EU action in pipeline)	
Product safety	Food Imitations Dir. 87/357	
Civil liability	Dir. 85/374, amended by Dir. 1999/34	
Enterprise	Food SMEs (EU action in pipeline)	

Agricultural food law

Area	Union law	Italian law
Common Market Organisation	Single CMO-Reg. 1308/2013 (marketing standards)	
	CMO-Implementation (<i>tertiary law</i>) Reg. 1850/2006 (hops) Reg. 445/2008 (spreading fats) Reg. 543/2008 (poultry) Reg. 566/2008 (baby beef) Reg. 589/2008 (eggs) Reg. 617/2008 (hatching eggs) Reg. 1333/2011 (bananas) Reg. 29/2012 + 1335/2013 (olive oil) Reg. 543/2011 (fruit+vegetable) Reg. 1666/1999 Reg. 85/2004 (apples) UNECE Food Standards ⁴	
	CMO-Fish Reg. 1379/2013	
School milk and fruit	Reg. 2017/39	

⁴ UNECE Food Standards and Recommendations of the Working Party on Agricultural Quality Standards (WP.7).

For the morning:

Vertical rules for specific foods	Union law	Italian law
“Breakfast Directives”	Coffee Dir. 1999/4	
	Chocolate Dir. 2000/36	
	Honey Dir. 2001/110	
	Sugar Dir. 2001/111	
	Fruit Juice Dir. 2001/112	
	Marmalade Dir. 2001/113	
	Sour milk Dir. 2001/114	

For the entire day:

	Mineral Water Dir. 2009/54	
	Water Quality Dir. 98/83	

For the evening:

Alcoholic beverages	Union law	Italian law
Common Market Organisation Wine	Reg. 1308/2013	
Aromatised wines	Reg. 251/2014	
Spirits	Reg. 110/2008 (2019 amendments to be adopted)	

Quality Policy	Quality-Reg. 1151/2012: Protected Designation of Origin (PDO) Protected Geographical Indication (PGI) Traditional Speciality Guaranteed (TSG) Island products Mountain products Local food (Article 55)	
	POSEI-Reg. 228/2013	
	Organics Reg. 834/2007 + Reg. 889/2008 and Reg. 1235/2008 <i>as of 1/1/2021:</i> Reg. 2018/848	
Beef registration and labelling	Reg. 1760/2000	
Aquaculture	Dir. 2006/88	

2.4. Food 2030 - Food 2050

Food's future is uncertain and impacted by the challenges for sustainable production and consumption. Two target dates have been set by the European Commission and its scientific arm, the Joint Research Centre (JRC). Under the label of "Food 2030" and "Food 2050", reflection papers have been published:

2030:

Research and innovation policy⁵ of the European Commission
Bioeconomy – Agri-Food Chain
Future-proofing of the food system

2050:

Joint Research Centre (LRC) 28/11/2016 "Looking into the future of European food safety and nutrition policy"⁶.

⁵ <https://ec.europa.eu/research/bioeconomy/index.cfm?pg=policy&lib=food2030>.

⁶ <https://ec.europa.eu/jrc/en/news/looking-future-european-food-safety-and-nutrition-policy>.

2.5. Case study: Parma Ham – a very Italian contribution to European food law

The subject of Parma ham provides an insightful illustration for the link between national and European food law:

- 1963: Consorzio del Prosciutto di Parma
- 1970: Law No. 506
- 1978: Ministerial Order
- 1990: Law No. 26
- 1996: Commission Regulation (EC) No 1107/96 of 12 June 1996 on the registration of geographical indications and designations of origin under the procedure laid down in Article 17 of Council Regulation (EEC) No 2081/92
- 2003: Case C-108/01 [2003] ECR I-5121
- 2006: Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs
- 2012: Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs
- 2008, 2010, 2013: tertiary law amendments to product specification of Prosciutto di Parma (PDO = Protected Designation of Origin)
- 2017: Annex 20-A of Comprehensive Economic and Trade Agreement (CETA⁷) EU-Canada
- 2019: Annex 14-B of the Agreement between the European Union and Japan for an Economic Partnership⁸
- 2019: EU joining the Geneva Act of the Lisbon Agreement to better protect Gis.

3. Tertiary Law

Primary law is the law of the Treaties. Secondary law is the law adopted (mostly) in the ordinary legislative procedure, proposed by the European

⁷ OJ L 11, 14/1/2017.

⁸ OJ L 330 of 27/12/2018, p. 884.

Commission and adopted by the European Parliament and the Council («*méthode communautaire*»). Tertiary law is the law adopted by the Commission, controlled, to various degrees, by committees of Member States' experts. Sometimes, therefore, dubbed 'underground law' (because its procedures are removed from the public eye) it is a denomination for the tertiary level of Union law-making by delegated acts and implementing acts as introduced by the Lisbon Treaty (Article 290 TFEU and Article 291 TFEU). Both are often poorly understood in their importance as regulatory tools and in the complexity of the processes required for their adoption.

Procedures shall be explained on the basis of food and farm law which provide rich pickings for examples. The following is a compilation of material.

3.1. Comitology

"Comitology" is a neologism derived from the French term «Comitologie», itself (obviously) derived from «Comité». But, if this notion is so central, what really is a committee?

Standing Committee Plants, Animals, Food and Feed (SCoPAFF)

The Standing Committee "Plant, Animals, Food and Feed" (SCoPAFF⁹) – organised in "Sections" (general food law, biological safety of the food chain, novel food and toxicological safety, etc.), and its off-shots (expert groups and working groups) provide a forum for discussion between Commission and Member States on food-law matters. The SCoPAFF also decides on 'Lisbon Comitology' (implementing acts) and, in expert groups, discusses delegated acts.

Expert Groups and Committees

Experts sent by Member States meet in different constellations fulfilling different functions.

N.B.: Expert Group ≠ Working Party (even though the persons attending meetings might be the same).

⁹ Article 58(1) of Regulation (EC) No 178/2002.

Example animal feed:

Expert Groups ¹⁰	Standing Committee
- to discuss policy issues - to discuss → delegated acts	- to discuss and vote on → implementing acts
Substances indésirables – Nutrition animale (E00910): Directive 2002/32/EC on undesirable substances in animal feed	SCoPAFF – Section “Animal Nutrition”
Regulatory Committee (archive): Standing Committee for Animal Nutrition	Animal Health and Welfare section of the Standing Committee on SCoPAFF

3.2. Delegated acts

Purpose: completion or amendment of certain non-essential elements of a legislative act.

Primary law: Article 290 TFEU (auto-sufficient, that is, no need of completion by secondary legislation).

- A legislative act may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act.
The objectives, content, scope and duration of the delegation of power shall be explicitly defined in the legislative acts. The essential elements of an area shall be reserved for the legislative act and accordingly shall not be the subject of a delegation of power.
- Legislative acts shall explicitly lay down the conditions to which the delegation is subject; these conditions may be as follows:
 - (a) the European Parliament or the Council may decide to revoke the delegation;
 - (b) the delegated act may enter into force only if no objection has been expressed by the European Parliament or the Council within a period set by the legislative act.

¹⁰ <http://ec.europa.eu/transparency/regexpert> – Commission Decision C(2016) 3301 final of 30/5/2016 establishing horizontal rules on the creation and operation of Commission expert groups.

For the purposes of (a) and (b), the European Parliament shall act by a majority of its component members, and the Council by a qualified majority.

- The adjective “delegated” shall be inserted in the title of delegated acts.

Secondary law:

- Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making (OJ L 123, 12/5/2016, p. 1) incl. Common Understanding on Delegated Acts;
- Rules set out in the basic act (Articles 51/52 FIR; recital 58 in the example of the FIC-Regulation – below);
- Legislative delegation in FIC-Regulation (12-times);
- Article 105 of the Rules of Procedure of the European Parliament.

Example: *Regulation (EU) No. 1169/2011 on the provision of food information to consumers* (FIC-Regulation)

Recital 58

“The power to adopt delegated acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of, *inter alia*, the availability of certain mandatory particulars by means other than on the package or on the label, the list of foods not required to bear a list of ingredients, the re-examination of the list of substances or products causing allergies or intolerances, or the list of nutrients that may be declared on a voluntary basis. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council”.

Article 51

Exercise of the delegation

- “1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 9(3), Article

10(2), Article 12(3), Article 13(4), Article 18(5), Article 19(2), Article 21(2), Article 23(2), Article 30(6), Article 31(2), Article 36(4) and Article 46 shall be conferred on the Commission for a period of 5 years after 12 December 2011. The Commission shall draw up a report in respect of the delegation of power not later than 9 months before the end of the 5-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than 3 months before the end of each period.

3. The delegation of power referred to in Article 9(3), Article 10(2), Article 12(3), Article 13(4), Article 18(5), Article 19(2), Article 21(2), Article 23(2), Article 30(6), Article 31(2), Article 36(4) and Article 46 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or on a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 9(3), Article 10(2), Article 12(3), Article 13(4), Article 18(5), Article 19(2), Article 21(2), Article 23(2), Article 30(6), Article 31(2), Article 36(4) and Article 46 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or of the Council”.

Article 52

Urgency procedure

“1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 51(5). In such a case, the Commission shall repeal the act without delay following the no-

tification of the decision to object by the European Parliament or by the Council”.

Soft law:

- Communication on Delegated Acts of the Commission (COM (2009) 673 final of 9/12/2009);
- Many more statements and declarations by EU organs.

Procedure:

- Basic legislative act is the FIC-Regulation with which the Union legislator has granted legislative delegation;
- The Commission, advised by EFSA (Article 5 FIC-Regulation), presents a proposal for a delegated act;
- Without being obliged to do so (note, however, recital 58 (2nd sentence) FIC-Regulation) the Commission may consult the expert committee;
- The European Parliament and/or the Council exercise political control subsequently through a right to object within a fixed period of 2x2 months (Article 51(5) FIC-Regulation) against the coming into force of adopted delegated acts, but need to mobilise an absolute majority respectively a qualified majority;
- The European Parliament and/or the Council exercise political control through a right to revoke (Article 51(3) FIC-Regulation), but need to mobilise an absolute majority respectively a qualified majority.

N.B.: Scrutiny (objection and revocation) is exercised *ex post*; no possibility for amendments.

3.3. Implementing acts

Purpose: Efficacy in the application of Union law.

Primary law: Article 291 TFEU (*to be completed by act of secondary law*).

- Member States shall adopt all measures of national law necessary to implement legally binding Union acts.
- Where uniform conditions for implementing legally binding Union acts are needed, those acts shall confer implementing powers on the Com-

- mission, or, in duly justified specific cases and in the cases provided for in Articles 24 and 26 of the Treaty on European Union, on the Council.
- For the purposes of paragraph 2, the European Parliament and the Council, acting by means of regulations in accordance with the ordinary legislative procedure, shall lay down in advance the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.
 - The word "implementing" shall be inserted in the title of implementing acts.

Secondary law:

- Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers ("Comitology Regulation");
- FIC-Regulation.

Article 48
Committee

"1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Article 58(1) of Regulation (EC) No 178/2002. That Committee is a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply".

- Article 106 of the Rules of Procedure of the European Parliament;
- Rules of Procedure of the Appeal Committee (OJ C of 24/6/2011, p. 13).

Advisory Procedure
= fall-back procedure

Examination procedure – FIC-Regulation-style

1. The Union legislator provides for a legislative delegation in a “binding legislative act” – here the FIC-Regulation.
2. The Commission submits a draft implementing act to the responsible Examination Committee – here the SCoPAFF (Article 48 FIC-Regulation in conjunction with Article 3(3) of Regulation (EU) No 182/2011).
3. Then, in the particular design of the examination procedure of the FIC-Regulation, three scenarios are possible:
 - a. In case the SCoPAFF approves the proposal by qualified majority, the implementing act is adopted (Article 6(1) and 2 of Regulation (EU) No 182/2011).
 - b. In case there is neither a qualified majority in the SCoPAFF for the proposal nor a simple majority against it (that is, there is no opinion from the Examination Committee), the Commission cannot, as usually possible, adopt the implementing act or present and amended version of the proposal, but is obliged under Article 48(2)(2nd subpara.) FIC-Regulation to proceed according to Article 5(4) (3rd subpara.) of Regulation (EU) No 182/2011. Should the Commission therefore consider the implementing act to be necessary, it has two options:
 - The Commission can elaborate a modified proposal and present it to the Examination Committee for fresh negotiations within two months.
 - The Commission can refer its original proposal to the Appeal Committee within a delay of one month (Article 1(5) of the Rules of Procedure of the Appeal Committee: regularly the COREPER = Committee of Permanent Representatives of the Member States). If the Appeal Committee approves the draft or does not vote on it, the implementing act will be adopted. If the Appeal Committee votes with qualified majority against the draft, the implementing act will not be adopted. It is worthy of note that recital 14 of Regulation (EU) No 182/2011 requires of the Commission in the “particularly sensitive sectors” of “consumer health” and “food safety” to “act in such a way as to avoid going against any predominant position which might emerge within the appeal committee against the appropriateness of an implementing act”.

- c. In case the SCoPAFF rejects the proposal by simple majority, the Commission has the options as under b).

Scrutiny of implementing acts outside Comitology:

Rights of the Legislator

According to Article 10(3) and (4) of Regulation (EU) No 182/2011, the European Parliament and the Council have the right to be informed by the Commission.

According to Article 11 of Regulation (EU) No 182/2011 the co-legislators have the right to indicate that a draft implementing measure exceeds implementing powers.

The rest of us (Article 11 TEU)

The general public is informed via the on-line Comitology register (Article 10(5) of Regulation (EU) No 182/2011).

“Feedback mechanism”: citizens and other stakeholders can provide feedback on the draft text of an implementing act for four weeks before the relevant committee votes to accept or reject it.

3.4. Useful web-links

European Commission “Implementing and delegated acts”:

https://ec.europa.eu/info/law/law-making-process/adopting-eu-law/implementing-and-delegated-acts_en

Ordinary legislative procedure – Complete text:

www.europarl.europa.eu/external/html/legislativeprocedure/default_en.htm

Ordinary legislative procedure – Glossary:

www.europarl.europa.eu/external/appendix/legislativeprocedure/eu-roparl_ordinarylegislativeprocedure_glossary_en.pdf

“Level 2” measures in financial services regulations:

https://ec.europa.eu/info/business-economy-euro/banking-and-finance/financial-reforms-and-their-progress/regulatory-process-financial-services/regulatory-process-financial-services_en

4. Food Governance

Governance of food markets and food consumption is comprised of legislating, monitoring, enforcing rules and improving nutrition and thus is an interesting case study for the shape and growth of European governance. Largely Europeanised but now shortlisted for partial re-nationalisation, food policy shows a *Wimmelbild* of EU institutions and bodies, national agencies, non-governmental organisations (NGOs) and stakeholder organisation all engaged in making policy choices, carrying out safety assessments and conducting research. Sketching an image of the complexity of food governance and many of its ramifications is the objective of this chapter as well as showing how to engage in the process. The basic questions to ask are: What, actually, is EU law? Who makes food law?

What, actually, is EU law?

A fair question if one thinks of the level of regulation, its authors and its influencers.

Sources of Union food law are:

- The Treaties: Lisbon Treaty – TFEU (primary law);
- Regulations/Directives adopted by the European Parliament and the Council (secondary law);
- Delegated Regulations/Directives of the Commission (tertiary law);
- Implementing Regulations of the Commission (tertiary law);
- Recommendations (*sui generis*);
- ... and on top of all that: a cacophony of guidelines, notices, Q&As, policy papers, etc.

An overview of the sources of EU food law may look as follows:

Primary law – The Treaties	Secondary law – Legislative acts	Tertiary law – Non-legislative acts
Treaty on the European Union – TEU	Regulations – Article 288 TFEU	Delegated acts – Article 290 TFEU
Treaty on the Functioning of the European Union – TFEU	Directives – Article 288 TFEU	Implementing acts – Article 291 TFEU

Annexes – Annex I to the TFEU (Article 38(3) TFEU)	Decisions – Article 288 TFEU	Legal acts directly based on the Treaty – Article 43(3) TFEU ¹¹
Accession Treaties	Uniform international law – Article 216(2) TFEU	“Old Comitology” acts Article 12(2nd subpara.) of Regulation 182/2011 Regulatory procedure with scrutiny («PRAC»)

Recommendations – Article 292 TFEU¹² (example: Recommendation 2013/99/EU on food fraud)

Free Trade Agreements (FTAs, examples: CETA, JAFTA) and Association Agreements – Article 207 and Article 217 TFEU

Mutual Recognition and Equivalence Agreements (organic products)

Categories of soft law¹³:

Guidelines (example: Article 10(4) Health Claims Regulation 1924/2006)

Technical Guidelines (example: Article 14 FSG-Regulation 609/2013)

Commission Notices (example: substances or products causing allergies or intolerances)

Q&As (example: Q&A on FIC-Regulation 1169/2011)¹⁴

Endorsed stakeholder guidance papers (example: European guide to good practice for smoked fishes and/or salted and/or marinated)

EFSA Guidelines (example: Guidance on the preparation and presentation of an application for authorisation of a novel food)

Policy Papers (example: Green and White Papers)

Parliamentary Questions

European region:

Council of Europe¹⁵

UNECE Food Standards (standards and recommendations)

WHO-Europe (nutrition policy)

¹¹ Joined Cases C-124/13 and C-125/13.

¹² Case C-16/16.

¹³ European Parliament resolution of 4/9/2007 on institutional and legal implications of the use of ‘soft law’ instruments (OJ C 187E of 24/7/2008, p. 75).

¹⁴ Case C-113/15 (paragraphs 26, 77, 78) and Case C-541/16 (paragraphs 46 and 47).

¹⁵ Examples: European Convention for the Protection of Animals kept for Farming Purposes; Council of Europe Resolution concerning the transmission of flavour of smoke to food; Resolution on metals and alloys used in food contact materials and articles.

Acquis mondial
 Codex Alimentarius Commission (off-shoot FAO+WHO)
 UNESCO Intangible Cultural Heritage Lists (examples: Belgian beer, Mediterranean diet)

Food law is a good example for Union soft law being influential. Examples for established instruments of EU food law underneath the law are:

Commission notices

Commission Notice relating to the provision of information on substances or products causing allergies or intolerances as listed in Annex II to Regulation (EU) No 1169/2011 (OJ C 428, 13/12/2017, p. 1).

Commission Notice on the application of the principle of quantitative ingredients declaration — QUID (OJ C 393, 21/11/2017, p. 5).

Commission Notice on the classification of Food for Special Medical Purposes (OJ 401, 25/11/2017, p. 1).

Question & Answer-catalogues

ex.: Q&A on FIC-Regulation 1169/2011

Judgement in Case C-113/15 (paragraphs 26, 77 and 78)

Judgement in Case C-541/16 (paragraphs 46 and 47)

Commission guidance papers

ex.: Guidance on food safety management systems for small food retailers (SFR-FSMS): the application of hazard identification, ranking and control in butcher, grocery, bakery, fish and ice cream shops (August 2017)

Currently in the making:

Guidance on Regulation (EU) 2017/2158 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food

Stakeholder guidance papers endorsed by the SCoPAFF

ex.: European Guide for Good Hygiene Practices in the production of artisanal cheese and dairy products

Guide for the hygienic manufacture of processed cheese

Guidance on cheese as a raw material in the manufacture of food products

Currently in the making:

Guidance paper on primary ingredient labelling

EFSA guidelines

ex.: Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283

Written Question

Member of European Parliament (MEP) tabling a question to the Commission; Commissioner obliged to answer

Who makes food law?

Commission echelons/departments influential on food law (Commission 2014/9):

- Political management: Commissioners Juncker, Timmermans, Kaitanen, Andriukaitis
- Horizontal coordination: Secretariat General – SecGen
- Directorate General “Health and Food Safety” (DG SANTE)
- Directorate General “Agriculture and Rural Development” (DG AGRI)
- Directorate General “Internal Market, Industry, Entrepreneurship and SMEs” (DG GROWTH)
- Directorate General “Research and Innovation” (DG RTD)
- Legal Service

Other movers and shakers:

- EFSA
- Standing Committee
- Working Groups
- Expert Groups
- Joint Research Centre – JRC (to, for instance, prepare parameters for EFSA risk assessments)
- Scientific Advice Mechanism – SAM (to, for instance, express views on politically thorny issues)
- Reference Laboratories – EURL
- Permanent Representations of Member States – PermReps

Dual function of European Commission:

- Power triangle of European Commission (holding the right of initiative), European Parliament and Council as co-legislators (amending proposals and adopting the law)

- Steering the Comitology process (see previous chapter) in various constellations.

Commission with Member States

Standing Committee Plants, Animals, Food and Feed – SCoPAFF

(Article 58 of Regulation (EC) No 178/2002)

Expert Groups (ex.: Expert Group on Plant Genetic Resources)

Working Groups (ex.: Working Group on Novel Food)

Example of animal feed:

Expert groups	Committee (Standing Committee SCoPAFF – meeting in sections
To discuss policy issues To discuss delegated acts	To discuss and vote on implementing acts
Substances indésirables – Nutrition animale (E00910): Directive 2002/32/EC on undesirable substances in animal feed	SCoPAFF – Section “Animal Nutrition”
Regulatory Committee (archive): Standing Committee for Animal Nutrition	Animal Health and Welfare section of the Standing Committee on PAFF

Commission with stakeholders

Formalised Commission-(organised) Stakeholder relations

SANTE: Advisory Group on the Food Chain and Animal and Plant Health
(Decision 2004/613/EC)

AGRI: Civil Dialogue Group