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The EU's General Food Law Regulation

An introduction to the founding principles and the fitness check

IN-DEPTH ANALYSIS

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This paper gives an overview of the act underpinning EU food-chain legislation: the General Food Law Regulation (Regulation (EC) No 178/2002). It describes the objectives and principles, obligations and requirements set out in the food law regulation. It also examines the procedures used, such as the Rapid Alert System for Food and Feed (RASFF), emergency and crisis management, as well as the functioning of the committee set up to deal with the regulation's implementation, the Standing Committee on Plant, Animals, Food and Feed (PAFF). Also included is a description of the structure and role of the European Food Safety Authority (EFSA), founded by the regulation in 2002. It concludes with a short description of the forthcoming fitness check of the General Food Law Regulation and a glimpse at the topics likely to be discussed in the coming months.

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EXECUTIVE SUMMARY

As part of its Better Regulation agenda the European Commission is currently finalising the fitness check for the General Food Law Regulation (Regulation (EC) No 178/2002). The review will assess the key components of the founding act for current EU food chain legislation, including its principles, the rules of crisis management and the rules governing the set-up and functioning of the European Food Safety Authority (EFSA). The publication of a Commission staff working document on the results of the fitness check is expected in the course of 2017.

This in-depth analysis gives an overview of the content of the General Food Law Regulation, including its objectives and guiding principles, and requirements and procedures related to food safety and possible emergencies.

The main objectives of EU food law are to guarantee a **high level of protection of human life and health** and the **protection of consumers' interests**, while at the same time ensuring **free movement** of food and feed in the internal market. Following the **'farm-to-fork'** approach, the whole food chain must be included in food safety policy. **Food business operators** bear the main responsibility for ensuring that only safe food is placed on the market. The **Member States** are responsible for checking that food business operators fulfil the requirements of food law, through their system of **official controls**.

The Standing Committee on Plants, Animals, Food and Feed (PAFF) assists the Commission in the preparation of measures in the area of food and feed safety. A rapid alert system (RASFF) is in place to share cross-border information quickly when risks to public health are detected in the food chain.

The General Food Law Regulation is also the founding regulation of the **European Food Safety Authority (EFSA)**, whose tasks include providing **scientific advice**, assessing risks and identifying emerging risks, as well as collecting data on, for example, food consumption patterns, contaminants and residues in food.

In addition to the fitness check on the General Food Law Regulation, there are other ongoing and announced evaluations and initiatives in the pipeline, likely to inspire discussion on various aspects of EU food legislation in the coming months. Some of these are outlined in the final chapter.

TABLE OF CONTENTS

1. Background

The European Union (EU) has some of the highest food safety standards in the world, and the comprehensive EU legislation in place aims to ensure that food and feed are safe for consumers. Much of this legislation is harmonised in the European Union, in order not to pose barriers in the internal market.

The General Food Law Regulation (Regulation (EC) No 178/2002) is the founding act of current EU food and feed legislation. It defines the general principles, requirements and aims of food legislation. It also established the European Food Safety Authority (EFSA), an independent agency tasked with providing the decision makers with scientific advice concerning food safety issues. Furthermore, the General Food Law Regulation lays down the main procedures for the management of emergencies and crises, including the Rapid Alert System for Food and Feed (RASFF), an information-sharing portal designed to enable a swift reaction when risks to public health are detected in the food chain.

The General Food Law Regulation was drafted after a series of food incidents in the late 1990s in the EU, such as the BSE (bovine spongiform encephalopathy) outbreak and the dioxin scare. The BSE epidemic in cattle ('mad cow disease') was found to be a result of using meat and bone meal, made from carcasses of cattle infected with BSE, in cattle feed.[1] Subsequently, a new variant of Creutzfeldt-Jacob disease – a fatal neurodegenerative disorder in humans – was identified, raising concerns that BSE was spreading to humans via consumption of infected meat products.[2] In 1999, dioxin, a highly toxic and carcinogenic substance was detected in eggs, chicken meat and pig meat. The substance was found to be originating from contaminated fat used in animal feed.[3] These scares highlighted the need to establish general principles and requirements concerning food and feed law in the EU, to ensure a high level of protection of human life and consumers' interests.

In its **White Paper on Food Safety**[4] the European Commission announced that a new legal framework would be proposed. The Commission outlined an integrated approach to food safety 'from farm to table', covering the whole food chain and including all aspects, from animal feed production, primary production, food processing, storage and transport to retail sale. The Commission also proposed setting up an independent European Food Authority, which would provide the Commission with the scientific advice needed to guarantee a high level of food safety.

The legislative proposal was published in November 2000, and the regulation of the European Parliament and of the Council laying down the general principles and requirements of food law and establishing the European Food Safety Authority (referred to as the General Food Law Regulation) was adopted in 2002.[5]

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1 Causes of BSE, archived web content of the Department for Environment, Food and Rural Affairs, United Kingdom Government Web Archive.

2 A. Diack et al., 'Variant CJD, 18 years of research and surveillance', *Prion,* Vol. 8, Iss. 4, 2014.

3 A. Covaci et al., 'The Belgian PCB/dioxin crisis – 8 years later: An overview', *Environmental Toxicology and Pharmacology*, Vol. 25, Issue 2, 2008, pp. 164-170.

4 White Paper on Food Safety, European Commission, 12 January 2000.

5 Procedure file 2000/0286(COD).

2. Main elements of the General Food Law Regulation

2.1. Legal basis

Articles 43 (common agricultural policy and common fisheries policy), 114 (approximation of laws of the Member States), 168 (public health protection) and 169 (consumer protection) of the Treaty on the Functioning of the European Union constitute the legal basis for EU general food law. In addition, Articles 191 (environmental protection and precautionary principle) and 207 (common commercial policy based on uniform principles) are relevant primary law provisions related to food law.[6]

The General Food Law Regulation (Regulation (EC) No 178/2002)[7] is the foundation for EU food and feed law. It lays down general **principles, requirements** and **procedures** related to decision making in food and feed safety, covering **all stages of the food chain** from production and processing to transport and distribution. It also covers **feed** produced for, or fed to, **food-producing animals**. It does not cover production for private domestic use or the handling of food at home.

2.2. Objectives and principles of the General Food Law Regulation

The General Food Law Regulation establishes common **definitions** of basic concepts (such as 'food', 'feed' and 'food or feed business operator')[8] and lays down overarching guiding **principles and objectives** to ensure a high level of health protection and the effective functioning of the internal market. It highlights the **'farm to fork'** (or 'field to fork') approach, stressing that an integrated approach to food safety is needed, engaging all actors in the food chain.

2.2.1. Objectives

The general **objectives**[9] of EU food law are:

- to guarantee a **high level of protection of human life and health** and the **protection of consumers' interests**, including fair practices in food trade, taking into account animal health and welfare, plant health and the environment;
- to ensure **free movement of food and feed** manufactured and marketed in the EU; and
- to **facilitate global trade** by taking into account international standards and agreements when developing food law – except where this might undermine the high level of protection pursued by the EU.

2.2.2. Risk analysis principle

Articles 6 to 10 of the regulation lay down the fundamental principles of food law. According to Article 6 of the regulation, food law must be **based on risk analysis**. Risk analysis is defined as a process consisting of three interconnected components: risk assessment, risk management and risk communication. **Risk assessment** must be undertaken in an independent, objective and transparent manner, based on the best available scientific evidence. The role of risk assessor is essentially given to EFSA, whose task it is to undertake scientific and technical evaluations. **Risk managers** (the European

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6 Consolidated version of the Treaty on the Functioning of the European Union.

7 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.

8 Articles 1 to 3 of the regulation.

9 Article 5 of the regulation.

Commission, European Parliament and EU Member States) must take into account the results of risk assessment and, in particular, the opinions of EFSA.

2.2.3. Precautionary principle

The **precautionary principle**[10] is one of the basic principles underlying food and feed law. According to Article 7 of the regulation, 'in specific circumstances, where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment'. Precautionary measures adopted must be 'proportionate and no more restrictive of trade than is required' to protect public health.

2.2.4. Protection of consumers' interests

Food law must be aimed at **protecting consumers' interest**, providing a basis for consumers to make informed choices, and preventing fraudulent practices, the adulteration of food and any other practices misleading the consumer (Article 8 of the regulation).

2.2.5. Principle of transparency

According to the **principle of transparency**, defined in Articles 9 and 10 of the regulation, there has to be **open public consultation**, directly or through representative bodies, during the preparation, evaluation and revision of food and feed law. Where there are 'reasonable grounds to suspect that a food or a feed may present a risk' for human or animal health, public authorities must inform the general public of the nature of the risk.

To fulfil the requirement of public consultation, an **advisory group** on the food chain and animal and plant health was established with Commission Decision 2004/613/EC.[11] The advisory group consists of 45 representative organisations of consumers, farmers, food industry and retailers. The group examines the Commission's policy proposals at its regular meetings: general policy issues are discussed at twice-yearly plenary sessions, and more technical issues in ad-hoc working groups. The latest plenary meeting,[12] held on 25 November 2016, discussed, inter alia, the Commission's strategy to combat antimicrobial resistance, the EU action plan on food and feed eCommerce control, and the update of the criteria for identifying endocrine disruptors.[13]

As from 1 July 2015 there is a new, additional **feedback mechanism** available for stakeholders and citizens: they are invited to give their feedback on new initiatives planned by the Commission (so-called 'Roadmaps', 'Inception impact assessments' and 'Evaluation roadmaps'), as well as on Commission's new legislative proposals, once they

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[10] For a more comprehensive analysis, see 'The precautionary principle', EPRS, December 2015. In 2000, the Commission published a communication establishing common guidelines on the application of the precautionary principle.

[11] Commission Decision 2004/613/EC concerning the creation of an advisory group on the food chain and animal and plant health.

[12] Draft agenda of the plenary meeting of the advisory group on the food chain and animal and plant health.

[13] For more information and a list of the advisory group members, see the webpage Advisory Group – Food Chain and Animal and Plant Health.

have been agreed on by the Commission.[14] The new feedback mechanism is a part of Commission's 'Better Regulation' agenda.[15]

2.3. Obligations and requirements set by the Food Law Regulation

2.3.1. Safety requirements

Articles 11 to 13 of the regulation establish general **obligations of food trade.** According to these provisions, food and feed **imported** into the EU must comply with requirements of food law, as must food and feed **exported** from the EU.

Food and feed safety requirements are set out in Articles 14 and 15 of the regulation, establishing that food or feed is not placed on the market if it is unsafe – that is, if it

- is injurious to health or has an adverse effect on human or animal health,
- is unfit for human consumption, or
- makes food derived from food-producing animals unsafe for human consumption.

The safety requirements also provide that where a food that is unsafe is part of a batch, it shall be presumed that all the food in that batch is unsafe (unless a detailed assessment proves it otherwise).

2.3.2. Operators' responsibilities

The regulation places the **responsibility on food and feed business operators** to ensure that their products satisfy the safety requirements and comply with food law. Operators are responsible for the safety of the food and feed that they produce, transport, store or sell.

The **Member States have the responsibility** to **monitor and verify** that the requirements of food law are fulfilled by the food and feed business operators at all stages of production, processing and distribution. To ensure this, the Member States are required to maintain a **system of official controls**, established through Regulation (EC) No 882/2004.[16] This Regulation on Official Controls sets a legislative framework for the organisation of controls, to ensure that the rules are enforced by Member States across the EU in a harmonised manner. It is currently being revised[17] by the European Parliament and the Council.

When food or feed is found to be unsafe, business operators are obliged to **withdraw** it from the market or **recall** it from consumers. Business operators are also required to **notify** the competent national authorities of the action taken and collaborate with them to prevent risks to the final consumer.

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[14] For more information, see the European Commission's DG Health and Food Safety webpage on Consultations, as well as Commission's general webpage 'Share your views', where the new draft texts are published.

[15] For more information, see European Commission's webpages on 'Better regulation: why and how'.

[16] Regulation (EC) No 882/2004 of the European Parliament and Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules.

[17] Procedure file 2013/0140(COD). The European Parliament and the Council reached a political agreement on the new Regulation on Official Controls on 15 June 2016. The EP plenary vote on the agreed text is scheduled for March 2017. The regulation could then enter into force in the second quarter of 2017 and be applicable by 2020.

The Commission's Directorate-General (DG) for Health and Food Safety carries out **audits and inspections**[18] to verify whether EU food and feed safety legislation is properly implemented in the Member States, focusing mainly on the control system that the Member States – and also non-Member States – have in place.

2.3.3. Traceability

Traceability is of paramount importance in cases where there are problems with the safety of foodstuffs or feed. Article 18 of the regulation makes traceability compulsory for all food and feed businesses at all stages of production, processing and distribution. Traceability allows food business operators and authorities to withdraw or recall products – and trace the source – in cases of possible risk.

Food business operators must have **traceability systems** in place, to be able to identify the supplier of a food, feed, a food-producing animal, or any substance intended to be used in a food or feed – as well as the one to whom their product is going to (**'one step back, one step forward'**). Also **importers** are required to identify from whom the product was exported in the country of origin.

In addition to this general obligation, there is sector-specific legislation for certain categories of food and feed (such as fruit and vegetables, beef, fish, honey, olive oil and genetically modified organisms (GMOs)). Detailed traceability requirements for foods of animal origin are set out in Commission Implementing Regulation (EU) No 931/2011.[19] Animal holders must 'tag' every animal with details of their origin, and when taken to slaughter, the carcasses must be stamped with the traceability code of the abattoir.

Also, after an outbreak of Shiga toxin-producing *E. coli* (STEC) in May 2011, a Commission implementing regulation[20] was drawn up, laying down traceability requirements for sprouts and seeds intended for the production of sprouts.

To enable the traceability of animals across borders, a trade control and expert system (TRACES)[21] was set up in 2004. This is a database tracking the movement of animals, semen and embryos, food, feed and plants both within the EU and from third countries. All consignments of these products must be accompanied by health certificates or trade documents. National competent authorities are pre-notified via the system of the arrival of a consignment and can thus plan their controls in advance.

2.4. Procedures under the General Food Law Regulation

Chapter IV (Articles 50 to 57) of the regulation sets out procedures for a rapid alert system, crisis management and emergencies. Article 58 establishes the Standing Committee on Plants, Animals, Food and Feed (PAFF), assisting the Commission and delivering opinions on measures that the Commission intends to adopt.

2.4.1. Rapid alert system for food and feed (RASFF)

The rapid alert system, a network in place since 1979, was reinforced by the regulation in 2002 (Articles 50 to 52). The aim of this network is to share cross-border information

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[18] For more information on the audits, audit reports and work programmes, see Commission website 'Health and Food Audits and Analysis'.

[19] 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.

[20] Commission Implementing Regulation (EU) No 208/2013 on traceability requirements for sprouts and seeds intended for the production of sprouts.

[21] TRACES: TRAde Control and Expert System.

quickly when risks to public health are detected in the food chain. A notification is also made if a competent authority rejects a batch of food or feed intended to be imported into the EU, at a border post.[22]

Members of the network are the national food safety authorities of the 28 Member States, the European Commission, EFSA, the European Economic Area (EEA) countries Norway, Liechtenstein and Iceland, and Switzerland. To keep the system effective, each of the members has a designated contact point, exchanging information by means of an online system, **iRASFF**. The Commission is responsible for managing the network.

The latest RASFF annual report[23] gives an overview of the types of notification, product and hazard and countries that have been reported through the RASFF system in 2015. Just over a half of the total number of notifications concerned controls at border inspection posts, when a consignment was not accepted for import. The second largest category were notifications concerning official controls in the internal market, and a small number of notifications were triggered by an official control in a non-member country. There was a sharp increase in notifications concerning allergens – mostly milk, egg or sulphite – not declared on the label. The number of notifications concerning mycotoxins[24] (mostly aflatoxins) in food was also significant.

Since June 2014, the RASFF consumer's portal[25] has provided up to date information for citizens on food recalls and public health warnings in different EU countries.

In addition to the RASFF, Member States also exchange information within the **Food Fraud Network**, which, since November 2015, has been equipped with an IT application, the 'Administrative Assistance and Cooperation System'.[26] In October 2016 the European Commission's Joint Research Centre (JRC) launched a new monthly report on food fraud,[27] presenting articles from the media and from the RASFF.

2.4.2. Standing Committee on Plants, Animals, Food and Feed (PAFF)

Article 58 of the regulation establishes the Standing Committee on Plants, Animals, Food and Feed (PAFF). It is composed of representatives of all the Member States and presided over by a Commission representative.[28] The standing committee was set up to assist the Commission in the preparation of measures and provides opinions on the Commission's proposed initiatives in the areas of food and feed safety, animal health and welfare, and plant health. It can also examine issues on the initiative of the chair or at the request of one of its members.

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[22] Regulation (EC) No 16/2011 lays down more detailed implementing measures and procedures. A distinction is made, for example, between notifications requiring rapid action (alert notifications) and other notifications (information notifications and border rejection notifications).

[23] 'The Rapid Alert System for Food and Feed – 2015 annual report', European Commission, Health and Food Safety, 2016.

[24] Mycotoxins are toxic compounds produced by different types of fungus or mould.

[25] For more information, see the Commission webpages on 'RASFF' and 'RASFF information for consumers'.

[26] For more information, see the Commission webpage on 'Food Fraud'.

[27] See JRC webpage 'New monthly report on food fraud and authenticity'.

[28] For more information on comitology procedures, see the Commission webpage 'Comitology in brief'.

The standing committee is divided into 14 sections:[29]

- General Food Law
- Biological Safety of the Food Chain
- Toxicological Safety of the Food Chain
- Controls and Import Conditions
- Animal Nutrition
- Animal Health and Animal Welfare
- Genetically Modified Food and Feed and Environmental Risk
- Phytopharmaceuticals
- Plant Health
- Propagating Material of Ornamental Plants
- Propagating Material and Plants of Fruit Genera and Species
- Seeds and Propagating Material for Agriculture and Horticulture
- Forest Reproductive Material
- Vine

The opinions of the standing committee can be more or less binding on the Commission, depending on the particular procedure specified in the legal act being implemented. Detailed provisions on the procedures are laid down in Regulation (EU) No 182/2011[30] (the Comitology Regulation). In many cases in the area of food and feed law, the Commission may only adopt the implementing decision if it gets a **favourable opinion** from the committee, to be given by a **qualified majority** of the Member States (the 'examination procedure', Article 5 of the Comitology Regulation). If the standing committee delivers a **negative opinion,** the Commission cannot adopt the draft implementing act. If **no opinion** is delivered (no qualified majority either for or against the proposal), the chair may either submit an amended version of the act to the same committee within two months of the vote, or submit the draft implementing act within one month of the vote to the appeal committee for further deliberation.

The **appeal committee** was a novelty introduced by the Comitology Regulation. It was established to create a second layer to address issues on which the standing committee could not find agreement. According to the Commission's report on the implementation of the Comitology Regulation,[31] referral to the appeal committee is a rather exceptional step in the procedure. It is a possibility for moving ahead in the event of a negative opinion or no opinion. The Commission report states that up to now, the appeal committee has been convened mainly in relation to one policy area, namely health and consumer protection, and more specifically genetically modified food and feed and plant protection products. The Commission report observes that in these cases the appeal committee has so far confirmed the 'no opinion' outcome of the standing committee. Where no opinion is delivered, it is for the Commission to take a decision.

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[29] The agendas and reports of the different sections can be accessed via the Commission webpage 'Standing Committees'.

[30] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

[31] Report from the Commission to the European Parliament and the Council on the implementation of Regulation (EU) 182/2011 (COM(2016) 092 final).

It is worth noting that in his State of the Union Address 2016[32], Commission President Jean-Claude Juncker committed to assess the democratic legitimacy of current procedures, referring to the controversies surrounding the renewal process for glyphosate in the spring and summer of 2016. Following this, in its 2017 work programme, the Commission announced a **new legislative initiative: 'Modernisation of Comitology procedures'**, to be published in the first quarter of 2017.[33]

2.4.3. Emergency measures

In case of an emergency, when a food or feed presents a serious risk to human health, animal health or the environment, the Commission can – on its own initiative or at the request of a Member State – put in place **protective measures**. These can include suspension of the placing on the market of products, suspension of imports of a product, laying down special conditions for the food or feed in question, or any other appropriate interim measures. The Commission must consult PAFF before taking such measures (Article 53 of the regulation).

However, if a Member State informs the Commission of the need to take emergency measures, but the Commission does not act, the Member State concerned may itself adopt interim protective measures. It must notify this to other Member States and the Commission. In this case, the Commission must refer the matter to the Standing Committee within 10 working days, with a view to extending, amending or revoking the national interim measure (Article 54 of the regulation).

2.4.4. Crisis management

For situations that cannot adequately be managed solely by using the emergency measures described above or other existing procedures, a **general crisis management plan** has been adopted, in accordance with Article 55 of the regulation, by Decision 2004/478/EC.[34]

In a crisis situation, involving direct or indirect risk to human health deriving from food or feed, the Commission must set up a **crisis unit.** EFSA is tasked with supporting the unit by providing scientific and technical support. The crisis unit must collect and evaluate all relevant information and identify the options available to prevent, eliminate or reduce the risk to human health as rapidly as possible. It will also keep the public informed of the measures taken.

According to the general crisis management plan, each Member State, EFSA and the Commission must designate a crisis coordinator. For the implementation of the general plan, **Member States** are also required to draw up their own operational **contingency plans for food and feed**, setting out measures to be implemented in emergencies (Article 13 of the Official Controls Regulation). The national plans must specify the national administrative authorities to be engaged in crisis management, their powers

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[32] 'State of the Union Address 2016: Towards a better Europe – a Europe that protects, empowers and defends', Strasbourg, 14 September 2016. 'It is not right that when EU countries cannot decide among themselves whether or not to ban the use of glyphosate in herbicides, the Commission is forced by Parliament and Council to take a decision. So we will change those rules – because that is not democracy', Juncker said in his speech.

[33] Annex to the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Commission Work Programme 2017.

[34] Commission Decision 2004/478/EC of 29 April 2004 concerning the adoption of a general plan for food/feed crisis management.

and responsibilities, as well as procedures for communication between the relevant actors.

The Health and Consumer Protection Directorate-General of the Commission (now DG Health and Food Safety) also published in 2006 a 'Modus operandi for management of new food safety incidents',[35] agreed with the standing committee (PAFF), and aiming at a common approach for the management of such incidents.

2.4.5. Further guidance

To help food chain operators to apply the General Food Law Regulation correctly, the Commission has published a **guidance document**[36] giving food chain operators further information on the main food law requirements – including safety requirements, responsibilities, traceability, withdrawals and notifications as well as imports and exports.

In addition to the principles laid down in the General Food Law Regulation, all food business operators need to comply with **good hygiene practices** and procedures based on **Hazard Analysis and Critical Control Point (HACCP) principles**.[37] In July 2016 the Commission published new guidance[38] on these food safety management systems.

3. The structure and role of the European Food Safety Authority

3.1. Mission and tasks

The General Food Law Regulation is the founding regulation of the European Food Safety Authority (EFSA).[39] EFSA started its work on 1 January 2002 and is situated in Parma, Italy. It is an independent European agency, funded by the EU budget, which operates separately from the European Commission, European Parliament and EU Member States.

EFSA's mission is to provide **scientific advice** and scientific and technical support for the EU's legislation and policies in all fields that have a direct or indirect impact on food and feed safety. Scientific opinions drafted by EFSA serve as a scientific basis for the elaboration and adoption of EU measures (Article 22 of the regulation).

EFSA has the role of **risk assessor** in EU's food regulatory system, while Commission, European Parliament and Member States are the risk managers.

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[35] Modus operandi for the management of new food safety incidents, Health and Consumer Protection Directorate-General, 2006.

[36] Guidance on the implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) No 178/2002 on General Food Law. At the request of the European Parliament, the Commission has also issued guidelines on how the traceability requirements apply to charities.

[37] Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for food of animal origin and Regulation (EC) 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (the 'Hygiene Regulations').

[38] Commission notice on the implementation of food safety management systems covering prerequisite programmes (PRPs) and procedures based on the HACCP principles, including the facilitation/flexibility of implementation in certain food businesses.

[39] Chapter III, Articles 22 to 49 of the regulation.

EFSA's core tasks are to provide EU risk managers with independent, up-to-date scientific advice on questions related to food and feed safety, animal health and welfare, plant health, nutrition, and environmental issues related to these. It evaluates food and feed products that require a **safety assessment** before they can be used on the EU market. EFSA is also tasked with **collecting data** in the fields within its brief: in particular, it is required to collect data on food consumption patterns, biological risk, contaminants in food and feed, and also residues (Article 33 of the regulation). EFSA is also tasked with **communicating** on risks to EU institutions and Member States, stakeholders and the public, as well as identifying **emerging risks.**

Most of EFSA's work is undertaken in response to requests for scientific advice from the Commission, Parliament and Member States.[40] It also carries out work on its own initiative, in particular relating to emerging issues and new hazards.

EFSA coordinates working groups of scientists and external experts and networks of EU Member State organisations having expertise in specific scientific fields (for example emerging risks, pesticide residue monitoring, etc.).[41] In accordance with Article 36 of the regulation, a list is drawn up of competent organisations designated by the Member States, which may assist EFSA with its work. These 'Article 36 organisations' can carry out various tasks on EFSA's behalf; in particular preparatory work for scientific opinions, scientific assistance, collection of data and identification of emerging risks. Some of these tasks may be eligible for financial support.[42]

In assessing **pesticide active substances**, EFSA performs an independent **scientific peer review** of the assessment report produced by designated rapporteur Member State. These peer reviews are conducted in cooperation with all Member States.[43]

Article 39 of the regulation concerns the confidentiality of EFSA's work. According to the Article, 'the Authority shall not divulge to third parties confidential information that it receives for which confidential treatment has been requested and justified, except for information which must be made public if circumstances so require, in order to protect public health'. This has been a controversial issue in recent months, with EFSA finally deciding,[44] at a request of a group of Members of the European Parliament, to release some of the raw data from industry studies used in the safety assessment of the pesticide glyphosate.

3.2. EFSA's organisational structure

3.2.1. Management Board

EFSA is governed by a Management Board, composed of 14 members, appointed by the Council after consulting the European Parliament, from a list drawn up by the Commission. Four of the members must have their background in organisations representing consumers and other interests in the food chain. In addition, there is one

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[40] For example, in June 2016 the five Nordic countries requested an opinion from EFSA on whether a dietary reference value could be set for sugar.

[41] EFSA webpage on 'Working groups and Networks'.

[42] Eligibility criteria for these organisations are set out in Commission Regulation (EC) No. 2230/2004, and EFSA's Management Board regularly updates the List of Article 36 organisations.

[43] Article 12 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. See also the Decision of the Executive Director of EFSA concerning pesticide risk assessment peer review.

[44] 'Glyphosate: EFSA to share raw data', EFSA News, 29 September 2016.

representative of the Commission on the Management Board. The members' term of office is four years, and it may be renewed once.

The members of the board are mandated to act independently in the public interest, and do not represent a government, organisation or sector. They are required to submit a declaration of commitment and a declaration of interests annually, indicating the absence of any interests that might be considered prejudicial to their independence. They must represent the highest standards of competence, a broad range of expertise and the broadest possible geographical distribution within the EU.

The board sets EFSA's budget and approves the annual work programme, as well as a multi-annual programme. The current chair of the board, Jaana Husu-Kallio, was elected in October 2016 for the term of office of two years. The board meets four times a year, and its meetings are open to public. It makes its decisions by a majority of its members. The board appoints the Executive Director and members of the Scientific Committee and the Scientific Panels.[45]

3.2.2. Executive Director

The Executive Director is the legal representative of EFSA. He is responsible for all operational and staff matters and drawing up the annual work programme in consultation with the Commission, Parliament and Member States. Current Executive Director, Bernhard Url, was appointed in June 2014, for a period of five years.

3.2.3. Advisory Forum

The Advisory Forum is composed of representatives of the national food safety authorities in the Member States, Iceland and Norway. The Advisory Forum is chaired by the Executive Director. It meets four times a year, to share experience and expertise on issues related to food and feed safety. It advises EFSA on scientific matters, its work programme and priorities, aiming to identify emerging risks as early as possible. The members aim to co-ordinate their work programmes with EFSA and each other, to avoid duplication and to promote sharing of scientific information. Commission and Parliament are invited to participate in the plenary meeting as observers.[46]

The members of EFSA's Advisory Forum signed a Declaration of Commitment[47] in September 2016 in Bratislava, in which they agree to strengthen the relationships between EFSA and the food safety institutions in the Member States, to share information and data and to promote scientific excellence and scientific networking.

3.2.4. Scientific Committee and Scientific Panels

The Scientific Committee and the Scientific Panels are responsible for providing the scientific opinions of EFSA, each within their own spheres of competence. They can also organise public hearings. They are composed of scientific experts with a three-year mandate.[48] The next call of interest for membership of the Scientific Committee and panels will be launched in the second quarter of 2017.

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[45] For more information, see the Rules of Procedure of the Management Board. A list of Management Board members and information about board meetings can be found on EFSA's webpage on 'Governance'.

[46] For more information, see the Management Board decision concerning the operation of the Advisory Forum (of 5 October 2016).

[47] Declaration of Commitment of the members of the EFSA's Advisory Forum.

[48] For more details, see the Decision of the Management Board concerning the establishment and operations of the Scientific Committee, Scientific Panels and of their Working groups (of 15 March 2012) and the Decision of the Executive Director concerning the selection of members of the Scientific

The Scientific Committee is composed of the chairs of the Scientific Panels and six independent scientific experts who do not belong to any of the Scientific Panels. It is responsible for the general coordination of the scientific opinion procedure and harmonisation of working methods. It also provides opinions on multisectoral issues falling within the competence of more than one Scientific Panel.

The Scientific Committee and the Scientific Panels act by a majority of their members. The opinions of these bodies must include any minority opinions expressed by individual members.[49]

The number and names of the Scientific Panels may be adapted in the light of technical and scientific development by the Commission, at EFSA's request. At present, there are ten panels[50] operating:

- Panel on Animal Health and Welfare (AHAW),
- Panel on Food Additives and Nutrient Sources Added to Food (ANS),
- Panel on Biological Hazards (BIOHAZ),
- Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF),
- Panel on Contaminants in the Food Chain (CONTAM),
- Panel on Additives and Products or Substances used in Animal Feed (FEEDAP),
- Panel on Genetically Modified Organisms (GMO),
- Panel on Dietetic Products, Nutrition and Allergies (NDA),
- Panel on Plant Health (PHL), and
- Panel on Plant Protection Products and their Residues (PPR).

4. Fitness check of the General Food Law Regulation and other initiatives

As part of its Better Regulation agenda and Regulatory Fitness and Performance Programme (REFIT) – an ongoing effort to scan EU legislation and identify areas for improvement – the European Commission is currently finalising the fitness check for the General Food Law Regulation.[51] Launched in April 2014, the review will assess the key components of this regulation, including its principles, the rules of crisis management and rules governing the set-up and functioning of EFSA. The aim is to assess whether the regulatory framework is 'fit for its purpose'; that is, whether the EU actions are proportionate to their objectives and delivering as expected. Publication of the Commission staff working document on the results of the fitness check was originally planned for the first semester of 2016, but has been delayed and is now expected to be finalised in early 2017.[52]

Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work (of 13 May 2016).

[49] Article 16 of the Decision of the Management Board concerning the establishment and operations of the Scientific Committee, Scientific Panels and of their Working groups. For example, a minority opinion was annexed to EFSA Panel on Genetically Modified Organisms (GMO) Scientific Opinion of August 2016.

[50] For the draft agendas and minutes of the meetings of the various panels and lists of their members, see the EFSA webpage on 'Scientific Committee and Panels'.

[51] See Commission webpage on the Fitness check of the General Food Law Regulation.

[52] Commission staff working document – Regulatory Fitness and Performance Programme REFIT and the 10 Priorities of the Commission, 25 October 2016.

The General Food Law Regulation was adopted in 2002 and entered fully into force in 2005. The existing national and EU food law principles and procedures had to be adapted at the latest by January 2007 to comply with the general principles (Articles 5 to 10) of the regulation. Since then, the regulation has never been evaluated comprehensively.

EFSA is subject to a regular external evaluation every six years under Article 61 of the regulation. The results of the last evaluation, published in 2012,[53] are being used as part of the data for the now ongoing fitness check. Some of these results need to be updated and completed. The next evaluation of EFSA will be carried out in 2017.

The fitness check will take into account previous evaluations completed in the area of food and feed, as well as two external studies commissioned to support the fitness check:

- an external study on the general part of the General Food Law Regulation (Articles 1 to 21), and
- an external study on the RASFF and the management of emergencies and crises (Articles 50 to 57).

To collect data for the evaluation, an online survey targeted the 28 EU Member States' competent authorities, as well as key stakeholders involved in the food chain, including business operators, international organisations, relevant government bodies in third countries, and consumer organisations. The deadline for responses was 27 March 2015.

Small and medium-sized enterprises (SMEs) were consulted from March to June 2015 via the European Enterprise Network, delivering 925 replies, the majority of which from processors or manufacturers of food products. The summary of these results is available on the Commission webpage.[54]

The Commission has announced that it will decide on the necessity of any follow-up action depending on the results of the fitness check.

4.1. Other ongoing and announced Better Regulation initiatives

In addition to the fitness check of the General Food Law Regulation, other evaluations and initiatives are ongoing in the food safety area, as outlined below.

4.1.1. REFIT evaluation of the regulation on nutrition and health claims made on foods

A roadmap[55] describing the evaluation process was published in October 2015. The initial planned completion date was June 2017, but according to the latest information, it will be finalised only by early 2018.[56] The evaluation is focusing mainly on whether 'nutrient profiles'– which the regulation on nutrition and health claims requires the Commission to establish by January 2009, but which have still not been adopted – should be set, or removed from the regulation, and secondly, how botanical claims (health claims made on plants and their preparations) should be assessed.

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[53] EFSA 10 years on – Independent report says Authority delivering on all fronts, outlines recommendations for further progress, EFSA News, 5 September 2012.

[54] Commission webpage on 'Fitness Check of General Food Law', SME survey, 'Summary of the results'.

[55] Evaluation and Fitness Check (FC) Roadmap – Evaluation of a) Regulation (EC) No 1924/2006 on nutrition and health claims made on food with regard to nutrient profiles and health claims made on plants and their preparations and of b) the general regulatory framework for their use in foods.

[56] Commission Staff Working Document – Regulatory Fitness and Performance Programme REFIT and the 10 Priorities of the Commission, 25 October 2016.

4.1.2. Proposal for a new measure on bisphenol A (BPA) in food contact materials
The roadmap[57] was announced in November 2015. The proposal is expected in the coming months, now that EFSA has accomplished its review[58] of two new studies concerning the possible effects of BPA on the immune system of animals.

4.1.3. Initiative to limit industrial trans fats intakes in the EU
An Inception Impact Assessment[59] was published in October 2016. In December 2015 the Commission published a report regarding trans fats, concluding that a legal limit for industrial trans fats would be the most effective measure, but that further investigation was required. In accordance with Better Regulation principles, the Commission has to carry out an impact assessment and a public consultation before moving forward.

4.1.4. REFIT evaluation of the EU legislation on plant protection products and pesticide residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005)
The evaluation and fitness check roadmap[60] was published in November 2016, with completion scheduled for November 2018.

4.2. Likely topics in future discussion

One of the major topics to be discussed in the context of the fitness check of the General Food Law Regulation is the evaluation of the current pre-market authorisation process for certain products, such as pesticides, genetically modified organisms (GMOs) and novel foods. As mentioned above (in Section 2.4.2.), the Commission has announced in its work programme for 2017 a new legislative initiative on **modernising comitology procedures**.

One issue linked to the previous one is the growing mistrust of citizens towards the EU's science-based systems, such as the pre-market authorisation system used for approval of certain products, referred to by Health and Food Safety Commissioner Vytenis Andriukaitis in a speech given recently.[61]

Another aspect are the changing expectations of EU citizens: tendencies to demand healthier food or quality food, local products, food that is produced in a more environment-friendly and sustainable way, paying attention to animal welfare, etc.

The Council of the European Union, at its June meeting in 2016, adopted conclusions[62] on food product improvement, recalling the importance of reducing levels of salt, saturated fat, trans-fatty acids, added sugar and the energy density of food, given the role these play in the development of non-communicable diseases, weight problems and obesity. The Council called upon the Member States to have a national plan for food product improvement in place by the end of 2017.

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57 Roadmap – Proposal for a new measure on bisphenol A (BPA) in food contact materials.

58 'Bisphenol A: new immune system evidence useful but limited', EFSA news, 13 October 2016.

59 Inception Impact Assessment – Initiative to limit industrial trans fats intakes in the EU.

60 REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005).

61 Speech by Commissioner Andriukaitis on 15 November 2016 in a conference on 'The Future of EU Food Law'. 'We need to address the widely held suspicion, mistrust and even hostility towards science and evidence-based decisions on new products; on substances; and on new methods of food production', Andriukaitis said in his speech.

62 Council conclusions on food product improvement, 17 June 2016.

Reducing food waste[63] is high on the agenda, with the first meeting of the newly created EU Platform on Food Losses and Food Waste held in Brussels at the end of November 2016. New research into the date-marking of food products, such as 'use-by' and 'best-by' marking, has been announced as one priority, as these are poorly understood by consumers[64] and may lead to perfectly edible products being thrown away. Another aim is to come up with EU guidelines on food donation, to clarify the rules and responsibilities under which unsold food can be given to charitable organisations or food banks.

Food labelling rules are also discussed in the context of recent announcements by several Member States to begin mandatory country-of-origin labelling for dairy and meat products. Member States are allowed, under certain conditions, under Article 39 of Regulation (EU) 1169/2011,[65] to adopt additional mandatory labelling requirements, but there are concerns as to how this will affect the internal market.

Discussion is also continuing on the Commission proposals on identifying endocrine disruptors,[66] as well as on a Commission Regulation on reducing the presence of acrylamide in food, expected to be published soon.

5. Further reading

European Commission Food safety portal.

European Food Safety Authority portal.

European Parliament Factsheets on the European Union – Food safety.

Mylona, K. et al., Overview of the food chain system and the European regulatory framework in the fields of food safety and nutrition, Publications Office of the European Union, Luxembourg, 2016.

Summaries of EU legislation: Safe food and animal feed, EUR-Lex.

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[63] See for example the Commission webpage on EU actions against food waste for ongoing initiatives.

[64] See Briefing on 'Best before' date labels – Protecting consumers and limiting food waste, EPRS, February 2015.

[65] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers.

[66] See Briefing on 'Commission proposals on identifying endocrine disruptors', EPRS, July 2016. EFSA and the European Chemicals Agency (ECHA) recently announced that they are developing scientific guidance to enable identification of endocrine disruptors, with the draft guidance document to be prepared during the first half of 2017.

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The General Food Law Regulation (Regulation (EC) No 178/2002) was drafted following a series of food incidents in the EU in the late 1990s, including the BSE (bovine spongiform encephalopathy) outbreak and the dioxin scare. It is the act underpinning current EU food and feed legislation and defines its general principles, requirements and aims.

The regulation also established the European Food Safety Authority (EFSA), an independent agency tasked with providing decision makers with scientific advice on food safety issues. Furthermore, the General Food Law Regulation lays down the main procedures for the management of emergencies and crises, including the Rapid Alert System for Food and Feed (RASFF), designed to enable a swift reaction when risks to public health are detected in the food chain.

As part of its Better Regulation agenda, the European Commission is currently finalising its fitness check of the General Food Law Regulation. The review will assess the key components of this founding act. The results of the review are expected in the course of 2017.

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