

Special Report

Chemical hazards in our food: EU food safety policy protects us but faces challenges

(pursuant to Article 287(4), second subparagraph, TFEU)



EUROPEAN
COURT
OF AUDITORS

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TERMS AND ABBREVIATIONS

ADI:	Acceptable Daily Intake
ARfD:	Acute Reference Dose
Botanicals:	Botanicals made from plants, algae, fungi or lichens have become widely available on the EU market in the form of food supplements. Examples include ginkgo, garlic and ginseng. Such products are typically labelled as natural foods. They can be bought over the counter in pharmacies, supermarkets, specialist shops and via the internet.
Codex:	The Codex Alimentarius, or 'Food Code' is a collection of standards, guidelines and codes of practice adopted by the Codex Alimentarius Commission (the CAC). The CAC is the central part of the Joint FAO/WHO Food Standards Programme and was established by FAO and WHO to protect consumer health and promote fair practices in food trade.
DG SANTE:	Directorate-General for Health and Food Safety
DPEs:	Designated Points of Entry
DPIs:	Designated Points of Import
EFSA:	European Food Safety Authority
EMA:	European Medicines Agency
Endocrine disruptors:	Chemicals that can interfere with endocrine systems (i.e. with the glands and the hormones these glands produce) at certain doses. These disruptions can cause cancerous tumours, birth defects, and other developmental disorders.
FAO:	Food and Agriculture Organisation of the United Nations
FBOs:	Food or Feed Business Operators
FDA:	U.S. Food and Drug Administration
GATT:	General Agreement on Tariffs and Trade
HACCP:	Hazard Analysis and Critical Control Points
Import tolerance:	Means an MRL set for imported products to meet the needs of international trade where: <ul style="list-style-type: none"> — the use of the active substance in a plant protection product on a given product is not authorised in the Community for reasons other

than public health reasons for the specific product and specific use;
or
— a different level is appropriate because the existing Community MRL was set for reasons other than public health reasons for the specific product and specific use.

MRL:	Maximum Residual Levels
Rapid Alert System for Food and Feed (RASFF):	Rapid Alert System for Food and Feed - allows Member States food and feed control authorities (EU-28 Member States food safety authorities, Commission, EFSA, ESA, Norway, Liechtenstein, Iceland and Switzerland) to share information about measures taken in response to serious risks detected in relation to food or feed. It provides a round-the-clock service to ensure that urgent notifications are sent, received and responded to collectively and efficiently.
Regulated food ingredient:	Regulated food ingredients are those food ingredients which currently require market authorisation. These comprise chemical substances which are used as food additives, food enzymes, flavourings, smoke flavourings and sources of vitamins and minerals added to food.
Risk assessment:	A scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation.
Risk communication:	The interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food business, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.
Risk management:	The process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options.
SPS agreement:	Sanitary and Phytosanitary Measures
WHO:	World Health Organization
WTO:	World Trade Organization

EXECUTIVE SUMMARY

I. Food safety is a high priority for the EU, affects all citizens and is closely linked to trade policies. EU food safety policy aims to guarantee a high level of protection of human life and health and seeks to protect its citizens from three types of hazards in food: physical, biological and chemical.

II. This audit concentrated on chemical hazards, and our audit question was **“Is the EU food safety model soundly based and implemented to keep the products we consume in the EU safe from chemical hazards?”** We found that the model is soundly based and, indeed, that it is respected worldwide. However, we also found that it is currently over-stretched, as the Commission and Member States do not have the capacity to implement it fully.

III. The EU’s food safety model in respect of chemicals is considered a point of reference around the world and, according to the World Health Organization (WHO), European citizens enjoy one of the highest levels of assurance on the safety of their food in the world. The strength of the EU food safety model is based on:

- (a) its governance structure, with the division of responsibilities between EU decentralised agencies and the Commission, which separates risk assessment from risk management;
- (b) its goal to assess the safety of chemicals before they are used in the food chain; and
- (c) its clear allocation of responsibilities between the private sector and public control authorities.

In addition, the EU requires non-EU countries to comply with EU standards in order to guarantee that food imported to the EU fulfils the same high standards of safety.

IV. However, we identified challenges currently faced by the model regarding its implementation. In particular, we found that:

- (a) The EU legal framework governing chemicals in food, feed, plants and live animals remains a work in progress and has not yet achieved the level of implementation envisaged in the EU food law. In addition, the European Food Safety Authority (EFSA),

which provides scientific advice to inform European law, rules and policymaking, suffers backlogs in its work including in relation to chemicals. This affects the proper functioning of parts of the system and the sustainability of the model as a whole. Furthermore, the checks carried out by public bodies can only ever make up a small proportion of all checks carried out. We found that some Member States' controls cover certain groups of chemical substances more frequently than other, and that the legal framework is so extensive that public authorities alone find it difficult to fulfil all of the responsibilities placed upon them. The EU model can best remain credible by complementing public control systems with private-sector ones. However, the synergies between public and private control system have only started to be explored.

- (b) The EU aims to guarantee that imported food respects the European high safety standards. Currently the EU has limited the use of pesticides based on hazard criteria. Nevertheless, residues of such pesticides may be tolerated in products imported into the EU if a risk assessment has shown that there is no risk to consumers.
- (c) There are limitations in the control system as Member States faced difficulties in determining the nature of enforcement action to be taken in case of non-compliance. Furthermore, the Commission identified opportunities to enhance its procedures for the monitoring and enforcement of food legislation.

V. Based on these findings, while encouraging the Commission to continue to develop the legal framework in a way that maintains the protection of citizens from chemical hazards, we make three recommendations. The Commission should:

- (a) As a part of the current Regulatory Fitness and Performance Programme (REFIT) exercise on the legal framework governing food, feed, live animals and plants, assess potential changes to the legislation governing chemical hazards in the light of the capacity to apply it consistently. It should build upon the work already started to encourage complementarity identifying the way forward so that Member State public authorities can, where justified, rely more extensively on the checks carried out by the private sector to improve the co-ordination and efficiency of checks and the sustainability of the EU food safety model.

- (b) For pesticide residues in food, the Commission should explain what action it will take to maintain the same level of assurance for both EU produced and imported food while remaining compliant with WTO rules.

- (c) The Commission should give Member States further guidance on the application of enforcement measures. The Commission should also put into action the opportunities it has identified to enhance its procedures for monitoring compliance with EU food rules.

INTRODUCTION

1. Food safety is a high priority for the EU and all its citizens. EU food safety policy, founded on the primary responsibility of private operators¹, aims to keep people safe from illness caused by the food they eat. Food safety potentially affects the health of all citizens and is closely linked both to ensuring free movement of food and animal feed within the Union and facilitating global trade² of safe feed and safe, wholesome food. European food law aims to, “Guarantee a high level of protection of human life and health”³. The Commission has emphasised the importance of the policy, stating that “guaranteeing that food sold in the EU remains safe is at the centre of a *Europe that protects*”⁴.
2. According to the WHO estimates on global burden of foodborne diseases⁵, Europe is one of the safest places in the world to eat.

¹ Operators are primarily responsible to (a) ensure compliance with all Union and national food law requirements (including but not limited to those on food safety) that are relevant to their activities and within the businesses under their control, and (b) perform to this end their own controls. This is a key element in the prevention of food crises, especially when related to food safety, as it introduces multiple control points throughout the food chain.

² Global trade is governed by WTO rules. Both the EU and the individual EU Member States are members of the WTO.

³ Article 5 of 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 (OJ L 31, 1.2.2002, p. 1) (General Food Law Regulation).

⁴ European Commission, “Food safety EU budget for the future”, 7 June 2018 (https://ec.europa.eu/food/sites/food/files/future_budget_factsheet_en.pdf).

⁵ World Health Organisation, “WHO estimates of the global burden of foodborne diseases, Foodborne Diseases Burden Epidemiology Reference Group 2007-2015”, Figure 12, p. 80.

What are chemical hazards in food

3. The aim of a food safety model is to combat three types of hazards⁶: physical⁷, biological⁸ and chemical. This audit focused on chemical hazards.

4. All food consists of chemicals. Chemical hazards are substances with the potential to cause adverse health effects that either occur naturally or are added during food production or handling (see **Table 1**). Examples include some additives, pesticides and certain metals. Residues of certain substances may remain and have an impact further down the food supply chain or on various categories of products. For example, residues of pesticides used when growing plants as feed may be detected later in tests on food of animal origin. For this reason, the EU's food safety model takes an integrated approach, encompassing actions that cover the entire food chain from animal feed, animal health, plant protection and food production to processing, storage, transport, import and export, as well as retail sales. Chemical hazards can be present in all food, including organic food⁹.

⁶ Article 3(14) of Regulation (EC) No 178/2002 defines a 'hazard' as a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect on humans.

⁷ Physical hazards are objects in food that may cause injury if eaten. They usually occur because of unsafe food handling practices or accidental contamination.

⁸ Biological hazards are germs that can make people sick. They include parasites, viruses and bacteria. Proper implementation of HACCP (Hazard Analysis Critical Control Points) system is the main tool used to prevent biological hazards.

⁹ Organic food is food certified as having produced by methods that comply with the standards of organic farming. Compliance with these standards does not mean that the presence of all chemical hazards, such as contaminants, is excluded.

Table 1 – Groups of chemical hazards subject to EU regulation that are included in the scope of this audit

Regulated food ingredients	Food additives Food enzymes Food flavourings Nutrient sources (food supplements / botanicals)
Food chain residues	Feed additives Veterinary medicines Pesticides
Contaminants	Environmental pollutants Natural contaminants Process contaminants
Food contact materials	

5. The European Union’s legal corpus governing chemicals in relation to food safety is extensive and fragmented. The EU has adopted numerous pieces of legislation¹⁰, including directives, regulations, decisions and agreements, for each specific area (food additives, flavourings, feed additives, pesticides, etc.). Overall, this legal corpus regulates around 8 000 chemical substances (see [Annex I](#)).

Health risks associated with chemical hazards in food

6. The effects of food containing chemicals at toxic levels are difficult to quantify. Studies of food-borne diseases often contain fewer figures on illnesses or deaths due to chemical

¹⁰ Three of the most important pieces of legislation that are not specifically on chemical hazards but rather food safety as a whole are:

- The Treaty on the Functioning of the European Union provides the basis for the EU food safety policy as the Treaty empowers the EU to act for public health and consumer protection.
- Regulation (EC) No 178/2002 lays down the general principles and requirements of food and feed law (General Food Law Regulation). This sets out a framework for the development of food and feed legislation both at EU and Member State level and covers all stages of food and feed production and distribution.
- Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

hazards¹¹ than on food-borne infections. This may be because the harm caused by many chemical hazards becomes apparent only over the long term, in some cases resulting from their interaction and cumulative effect on our bodies.

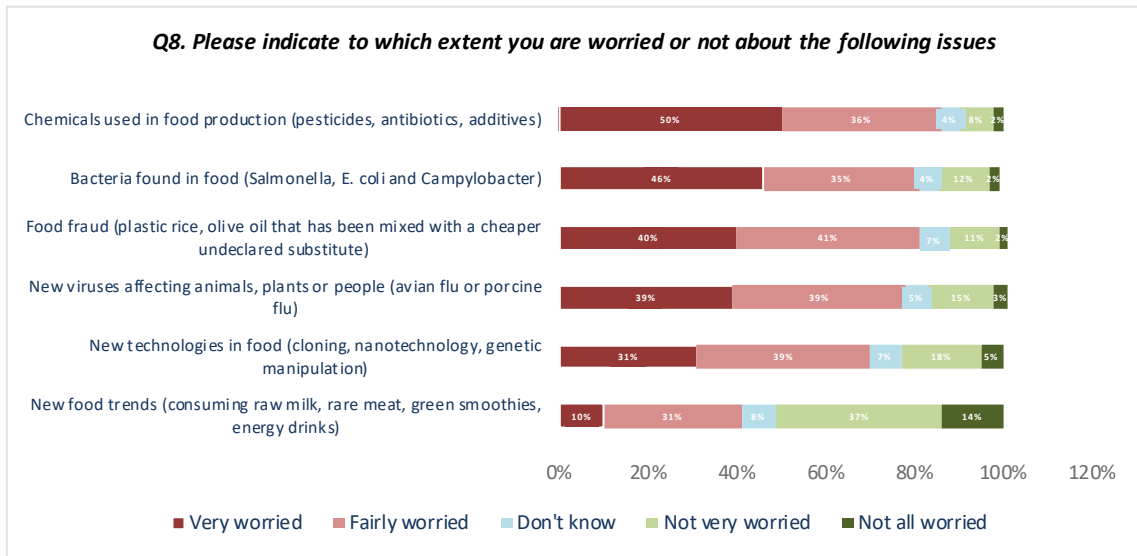
7. Spontaneous complaints about a specific product on the market exceeding toxicity limits are therefore relatively rare. The control system operated by public authorities (see **paragraphs 13 to 17**) have a key role to play in protecting consumers from potential risks.

8. Chemicals in food – including naturally occurring substances – can act as endocrine disruptors and antibiotics used on animals can boost anti-microbial resistance. **Annex II** provides examples of non-negligible health risks associated with chemicals in food.

9. When asked about a restricted number of issues in relation to food, citizens perceived the use of pesticides, antibiotics and additives in food production as the issue that worries them the most. A recent study commissioned by the EFSA found that 86 % of respondents were very or fairly worried about the use of such substances in food production (see **Figure 1**).

¹¹ WHO, “WHO estimates of the global burden of food-borne diseases: Food-borne disease burden epidemiology reference group 2007-2015”, 3.12.2015. This is the first and, currently, most complete WHO study on food-borne diseases estimates. It includes data on four chemical substances (aflatoxin, cassava cyanide, dioxin and peanut allergens).

Figure 1 – Perceptions of risk associated with different issues – EU wide



Source: Etienne, J. et al., EU Insights – Consumer perceptions of emerging risks in the food chain, EFSA, 18.4.2018. doi:10.2903/sp.efsa.2018.EN-1394 ICF.

Why chemical hazards are present in food

10. Food may be exposed to toxic levels of chemicals via several pathways, including agricultural practices, industrial processes, inappropriate storage, environmental contamination and natural toxins. Chemical hazards occur at any point in the food supply chain. The **Coffee cup 1** below shows which chemical hazards a common product may contain. Through the report we have included two more Coffee cups which exemplify how this same product is impacted by the EU food safety model.

Coffee cup 1



Source: ECA.

Do the coffee beans used in your coffee contain any chemical hazard?

The roasted coffee beans used to prepare your daily cup of coffee may contain, for example:

- residues of pesticides applied to the plant and present in the beans (e.g. heptachlor),
- environmental contaminants such as heavy metals that are present in the coffee beans through the uptake by the plant of heavy metals from the soil,
- process contaminants generated during the roasting process (e.g. acrylamide).

Coffee cup 2 (below paragraph 34) explains how these are checked.

11. As well as a legal obligation, food business operators have a strong reputational and economic interest in ensuring that the food they sell is safe. Chemicals, such as disinfectants and preservatives can help them in this. Food business operators also have economic interests which can lead them to use chemicals to, for example, cut costs or offer new products, textures or tastes.

12. The chemical substances that are subject to EU food law represent only a share of the total number of chemicals on the market. The exact proportion is unknown. Most of the chemicals used in food are subject to pre-market authorisation procedures to ensure compliance with EU food law requirements, including food safety. The number of authorisation requests for new substances is growing every year¹². The EU has traditionally been a leading player on the global market in agri-food chemicals. EFSA is the EU body responsible for the risk assessment in all matters covering the food chain.

How the EU food safety control system works

13. The majority of food safety provisions are decided at EU level. The Commission, taking account of the advice of specialised EU agencies, proposes the rules to be followed to

¹² Observed by Ernst and Young in its external review of EFSA 2012.

guarantee the safety of the food consumed in the EU. The Directorate-General for Health and Food Safety (DG SANTE) is the responsible part of the Commission in charge of this policy.

14. Member State authorities are responsible for the enforcement of agri-food chain legislation within their territories. Competent authorities organise official controls systems on their territory to verify that operators' activities and goods placed on the EU market comply with relevant standards and requirements. The Commission is responsible for adopting measures towards non-EU countries (e.g. by de-listing establishments) and for taking legal action when Member States do not fulfil their responsibilities.

15. The Official Food and Feed Controls Regulation (EC) No 882/2004 forms the basis for the checks carried out. The regulation aims at an integrated and uniform approach to official controls along the agri-food chain. It provides the framework for competent authorities to verify compliance with food and feed law and to prevent, eliminate and reduce to acceptable levels risks to human beings and animals. The regulation also lays down specific rules for official controls on imported products. The area of chemical hazards is additionally regulated through a vast number of sectoral legal instruments.

16. The EU is the world's largest importer and exporter of agricultural and food products. Checks on imports aim at ensuring that imports are compliant with EU legislation in the same way that food produced in the EU are. The underlying principle is that all food products on EU markets must be safe, irrespective of their origin¹³.

17. Businesses involved in the food chain have primary responsibility for food safety and frequently have assurance systems that extend to the point of supply.

¹³ "The European Commission works to ensure that Europe's food supply is the safest in the world and that the same standards of food safety apply to all products regardless of origin" - Quote from the Directorate-General for Health and Food Safety's webpage https://ec.europa.eu/food/safety/international_affairs/trade_en. The principle is also reflected in the joint reading of the General Food Law, Articles 11 (imported food and feed) and 14 (food must be safe).

AUDIT SCOPE AND APPROACH

18. Our audit looked at the basis and functioning of the EU's food safety model in respect of chemical hazards. Several factors were taken into account when deciding the scope of the audit: the relevance of the risks associated with the area of chemical hazards, the relevance of the EU's responsibility as regards chemicals, the high relevance and potential impact of an audit with such focus as well as the scope covered by other recent and on-going audits of the Court. The overall audit question was:

Is the EU food safety model soundly based and implemented to keep the products we consume in the EU safe from chemical hazards?

19. In particular we examined:

- whether the EU food safety model for chemicals is considered to be in line with international best practice;
- whether the EU has a sound legal base to guarantee that the key EU requirements regarding chemicals in food, animal feed, live animals and plants are respected for imports;
- the implementation of the model, particularly the completeness of the legal framework, the functioning of the control system and whether the model is viable at medium term.

The audit did not seek to re-evaluate the scientific assessments on food safety issues.

20. When assessing the operation of control systems in Member States, we considered the most recent year for which complete planning, implementation and monitoring documents were available (i.e. 2016).

21. We carried out the audit between December 2017 and May 2018. We collected audit evidence through:

- Documentary reviews and interviews with the Commission (Directorate-General for Health and Food Safety) and with the EFSA, the EU authority which, together with the

European Medicines Agency, provides scientific advice on food safety¹⁴; we also reviewed and analysed the Commission's procedures, guidelines, correspondence with Member States and meeting minutes as well as external evaluations and audit reports.

- Visits to three Member States: Italy, the Netherlands and Slovenia¹⁵. In each of these Member States, we visited relevant government ministries, food business operators and key points in the Member States' control systems (such as border inspection posts). During the visits to Member States we checked the operation of their control systems as well as the flow of information to the Commission and the EFSA on the results of the checks and scientific data.
- Meetings with experts who, as part of their jobs in Member States or the EFSA, sit on international fora and have access to up-to-date information in the area of chemical hazards and food safety in general.

OBSERVATIONS

The EU's food safety model in respect of chemicals is a point of reference around the world

22. This section of the report presents the elements that make the EU model a point of reference around the world. The section also describes the EU legal basis for requiring non-EU countries to comply with EU standards when exporting to the EU in order to guarantee that products from within the EU and those imported fulfil the same high standards of safety.

¹⁴ EFSA is responsible for food safety risk assessment while EMA is responsible for assessing EU medicinal products (which includes veterinary medicines).

¹⁵ The selection of the three Member States was done on the basis of the following criteria: (1) balance between Member States with high volumes of imports and Member States with much lower volumes, (2) Member States having different substances as main concerns when considering chemical hazards on food, and (3) location of the main EU agency providing scientific advice on chemicals in food (EFSA in Parma). A geographical balance was also sought in the selection of the countries. In Italy, due to its regional organisation, we concentrated most of our checks in only one region (Liguria).

The EU model's strength is based on a number of distinctive elements

23. In the context of the Commission Regulatory Fitness and Performance Programme (REFIT)¹⁶ exercise, the recent results of the Fitness Check on the General Food Law¹⁷, the main piece of EU legislation governing the food sector, acknowledge a number of positive attributes of the EU food safety model. The studies we reviewed and the experts we met (see **paragraph 21**) all regarded the EU food safety model as a point of reference^{18 19 20}. Despite the EU model being one of the most well developed, costs of compliance for farmers in the EU are in general in line with those in other parts of the world²¹. Several elements are considered as being distinctive and characteristic of the strength of the EU model. This section discusses three of these elements.

¹⁶ Regulatory Fitness and Performance Programme is part of the Commission better regulation agenda. It aims to keep EU law simple, remove unnecessary burdens and adapt legislation without compromising on policy objectives.

¹⁷ SWD(2018) 38 final, "Fitness Check on the General Food Law (Regulation (EC) No 178/2002)".

¹⁸ Spiric, D. et al., "Convergence on EU and USA Food safety Regulation approach, regarding foodborne outbreaks", International 58th Meat Industry Conference "Meat Safety and Quality: Where it goes?", *Procedia Food Science* 5(2015) 266-269. The report indicates that EU food law is a reference for the US.

¹⁹ Humphrey, J., "Food Safety, Private Standards Schemes and Trade: The Implications of the FDA Food Safety Modernization Act", IDS Working Paper Volume 2012 No 403, September 2012.

²⁰ EIOP: Text 2008-006 - European governance still technocratic? New modes of governance for food safety regulation in the European Union. Robert Fischer. 2018. "Inspired by the EU, a number of countries, e.g. France and Germany, have established independent evaluation agencies and have taken over the principle of organisational separation of risk assessment and risk management."

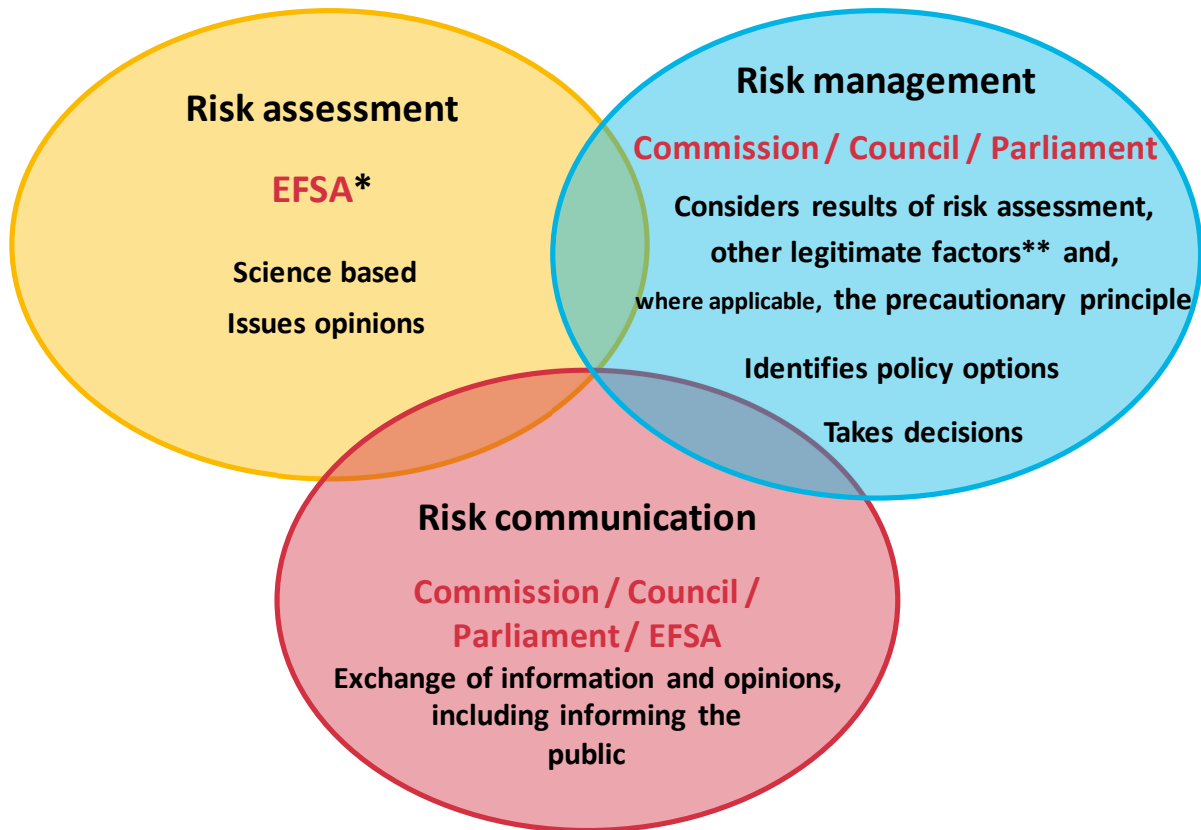
²¹ Assessing farmers' cost of compliance with EU legislation in the fields of environment, animal welfare and food safety, CPRA for the European Commission. AGRI 2011-EVAL-08.

The EU model clearly recognises and distinguishes three components of risk analysis

24. EU law, and in particular the General Food Law (Regulation (EC) No 178/2002)²², distinguishes three components of risk analysis at EU level: risk assessment, risk management and risk communication (see **Figure 2**).

²² In particular, recital 17 of Regulation (EC) No 178/2002 states: “Where food law is aimed at the reduction, elimination or avoidance of a risk to health, the three interconnected components of risk analysis — risk assessment, risk management, and risk communication — provide a systematic methodology for the determination of effective, proportionate and targeted measures or other actions to protect health”. Recital 19 of the same Regulation states: “It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.” Article 3 includes definitions of these three components.

Figure 2 – The three components of risk analysis at EU level



* EMA has responsibility for EU risk assessment in the area of medicinal products (in particular veterinary medicine).

** Societal, economic, traditional, ethical and environmental factors as well as the feasibility of controls.

Source: ECA.

25. In order to ensure the separation of these three components, the General Food Law in 2002 established an independent European Agency for the purpose of providing scientific risk assessments on food safety: the EFSA²³. Establishing this body has enabled EU food safety policymakers not only to respond to public health crises but also to put in place a full food safety system encompassing standards and mechanisms for ensuring compliance with those standards. The General Food Law envisaged that this body would have sufficient powers to lay the foundations for a scientifically based food safety model.

²³ EMA was established by Regulation (EC) 726/2004, but already existed since 1995 based on older Directives. It has responsibility for EU risk assessment in the area of medicinal products.

The EU approach to food safety applies the precautionary principle where necessary

26. The 'precautionary principle' is a risk management tool recognised in the EU's General Food Law²⁴ (see **Box 1**). Where there are reasonable grounds for concern and scientific uncertainty persists, the principle may be invoked during the risk management process and caution may be exercised.

Box 1 – The precautionary principle as defined in the General Food Law

The precautionary principle refers to specific situation where:

- there are reasonable grounds for concern that an unacceptable level of risk to health exists
- the available supporting information and data are not sufficiently complete to enable a comprehensive risk assessment to be made.

When faced with these specific circumstances, decision makers or risk managers may take measures or other actions based on the precautionary principle, while seeking more complete scientific and other data. Such measures have to comply with the principles of non-discrimination and proportionality and should be provisional until the time when more comprehensive information concerning the risk can be gathered and analysed.

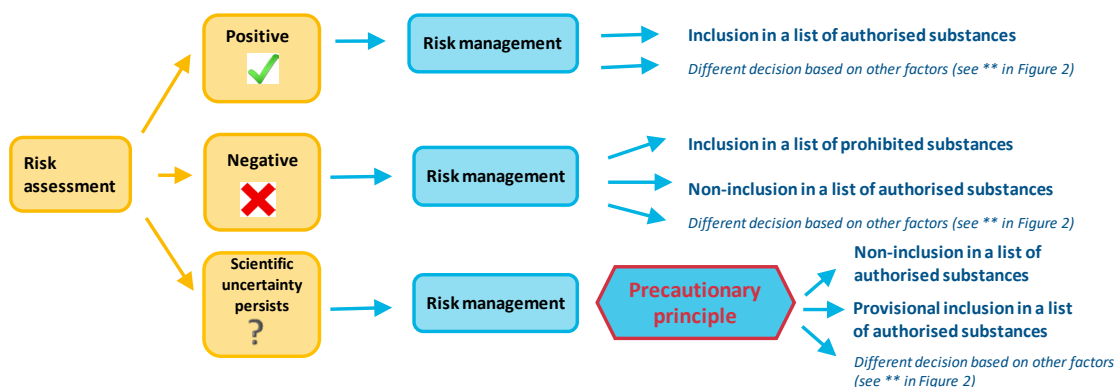
27. In its 2000 Communication on the precautionary principle, the Commission specified that the principle should be applied with a number of restrictions²⁵. The principle may be applied where a risk assessment has been carried out and concluded that, even though a concrete risk exists, further scientific information is still needed to determine the extent of

²⁴ Recital 21 and Article 7 of Regulation (EC) No 178/2002.

²⁵ According to the Communication from the Commission on the precautionary principle (COM(2000) 1 final of 2.2.2000), the measures taken in applying the precautionary principle should be: proportional to the chosen level of protection, non-discriminatory in their application, consistent with similar measures already taken, based on an examination of the potential benefits and costs of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis), subject to review, in the light of new scientific data, and capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.

this risk (see **Figure 3**). “The precautionary principle (...) provides a basis for action when science is unable to give a clear answer²⁶.” It thus allows the risk manager to take provisional measures while waiting for further scientific information needed in order to conduct a comprehensive risk assessment.

Figure 3 – The use of the precautionary principle



Source: ECA, based on the Commission Communication.

28. The precautionary principle has both supporters and detractors. Supporters claim that it is a good tool for protecting the public from potential adverse effects (in this case, chemical hazards). Detractors fear that applying the principle stifles innovation and is unnecessarily expensive. In its 2000 Communication, the Commission tried to balance the “freedom and rights of individuals, industry and organisations with the need to reduce the risk of adverse effects to the environment, human, animal or plant health”.

29. Under the Agreement on the Application of Sanitary and Phytosanitary Measures (the ‘SPS agreement’)²⁷, WTO Members undertake to develop their health standards on risk based criteria²⁸. This has important benefits to the EU as a major food exporter. The current

²⁶ European Commission - Press release - Commission adopts Communication on Precautionary Principle.

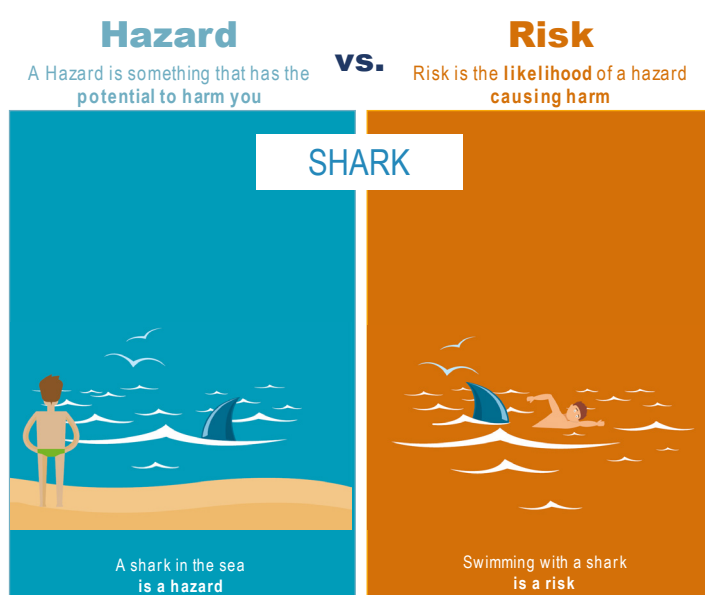
²⁷ The WTO Agreement on Sanitary and Phytosanitary Measures (the “SPS Agreement”) entered into force with the establishment of the World Trade Organization on 1 January 1995. It concerns the application of food safety and animal and plant health regulations.

²⁸ Article 5 of the SPS Agreement.

EU legal framework combines two types of criteria: risk based (in most cases) and hazard-based 'cut-off' criteria in the legislation governing the marketing and use of pesticides (see **Box 2**). Risk based criteria mean that a specific substance has to go through the entire risk assessment process²⁹ to determine its safety limits, while hazard based criteria bans certain substances³⁰ purely on the basis that it considers them potentially hazardous (e.g. carcinogenic), without the need for a full risk assessment.

Box 2 – Difference between hazard and risk

The EU legal framework differentiates between hazard and risk-based criteria. Pesticides that do not meet hazard based cut-off criteria, cannot be marketed or used in the EU. Residues of such pesticides may be tolerated in imported products if a risk assessment has shown that there is no risk to consumers.



Source: EFSA.

²⁹ A full risk assessment includes four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation.

³⁰ 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 (OJ L 309, 24.11.2009, p. 1).

30. Under WTO rules, importing countries cannot use hazard-based criteria alone as a basis for excluding potential imports³¹. The Commission has recently held discussions with the Member States, which assess requests of import tolerances (see **paragraph 38**), on how to implement the legal requirements laid down in the two EU Regulations applicable to pesticides authorisations and pesticides residues³², while adhering to their commitments under the SPS agreement³³.

EU law allocates primary responsibility for food safety to food businesses

31. Food and feed business operators include, for example, farmers, fishermen, processors, distributors, importers, and retailers. They are all subject to general and specific legal requirements³⁴. According to EU food law, responsibility for ensuring compliance with this legislation – and in particular the safety of food – lies primarily with food (or feed) business operators³⁵. To complement and support this principle, Member State authorities are required to ensure adequate and effective controls and the Commission is required to monitor the framework as a whole to ensure that it functions properly (see **Figure 4**).

³¹ WTO ANALYTICAL INDEX, SPS Agreement – Preamble (Jurisprudence). Item 1.5.2 Relationship of the precautionary principle with the SPS Agreement. January 2018.

³² Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005 respectively.

³³ Summary report of the Standing Committee on plants, animals, food and feed held in Brussels on 16-17 February 2017: “Member States highlighted the difficulties that this may create at international level (Codex Alimentarius) and the issues of responsibilities for such policy decisions at their level, given their role as first evaluator in the procedure for the handling of import tolerance requests” and Summary report of the Standing Committee on plants, animals, food and feed held in Brussels on 13-14 June 2018, agenda item A.14.

³⁴ Food and feed business operators at all stages of production, processing and distribution within the businesses under their control must ensure that foods or feeds satisfy those food law requirements which are relevant to their activities and verify that such requirements have been met.

³⁵ The “clear allocation of responsibilities between FBOs and public authorities along the food chain” is recognised in the results of the Fitness Check on General food law as an efficiency gain.

Figure 4 – Structure of private and public checks on food safety



Note: Food business operators could also be subjected to additional controls under private certification schemes and include them into the structure of checks on food safety, however they are not subject to Member States official controls or Commission monitoring.

Source: ECA.

32. Given the large volume of food, feed, live animals and plants that are subject to EU laws on (chemical) food safety, good coordination of both private³⁶ and public checks is important in order to make efficient use of resources. To give an example on the number of checks involved³⁷, in 2016, Member States competent authorities analysed 84 657 samples for pesticide residues (including samples checked by Iceland and Norway) and 706 764 samples for substances and residues covered by Directive 96/23/EC³⁸.

33. In 2016, the Commission examined whether Member States could plan their official controls on feed based on checks carried out by the private sector³⁹ and in 2017, it explored

³⁶ In line with Article 17(1) of Regulation (EC) No 178/2002.

³⁷ Figures based on EFSA reports.

³⁸ Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products (OJ L 125, 23.5.1996, p. 10).

³⁹ A number of benefits are recognised for competent authorities establishing interactions with private assurance schemes in the Overview report “Interaction Between the System of Official

possible synergies between official controls, food business operators' internal controls and private certification schemes⁴⁰. As an outcome of the 2016 feed exercise, the Commission identified both potential benefits from, and challenges to, establishing closer interaction between the system of official feed controls and private assurance schemes.

34. While Member State authorities agreed that properly monitoring the quality of such private schemes and food business operators' internal controls is important, at least two Member State authorities have expressed concerns over these developments⁴¹. One is "the fact that there is a financial relationship between food business operators and certification bodies and that audits for schemes are mainly announced", since "advance notice can negatively affect the reliability of information (...)". Another is that "certain legal requirements are not exactly replicated in the Private Sector Food Safety Standards systems e.g. residue limits".

Feed Controls and Private Assurance Schemes" DG Health and Food Safety-2016-8975.
http://ec.europa.eu/food/audits-analysis/overview_reports/

⁴⁰ Health and Food Audits and Analysis Programme 2017. Directorate-General for Health and Food Safety.

⁴¹ For example DG SANTE 2017-6072. Final report of a fact-finding mission carried out in Germany from 28 November 2017 to 6 December 2017 in order to gather information concerning synergies of official controls with food business operators' own-checks and third party certification schemes. http://ec.europa.eu/food/audits-analysis/audit_reports/. The Netherlands also expressed similar concerns during the audit visit carried out in the context of this audit.

Coffee cup 2**How does the coffee company check your coffee?**

The coffee beans used for your coffee are almost certainly imported and may have been processed by a food business operator in the EU.

This food business operator has a HACCP (Hazard Analysis and Critical Control Points) management system to identify, among other things, any chemical hazards related to its business. The operators put in place specific procedures such as regular cleaning of facilities (to prevent environmental contaminants), laboratory tests on each shipment of raw product upon arrival, computerised systems to control maximum levels of heat during the roasting process (to control the generation of acrylamide), and many others.

Additionally, the operators generally perform additional checks to satisfy specific requests from their direct customers (e.g. to guarantee the absence of a specific substance).

If you want to find out what public authorities check, go to [Coffee cup 3](#) (below paragraph 61).

Imported food from non-EU countries has to meet EU standards

35. Around 13 % of the products consumed in the EU are imported⁴². Outside the EU, food safety standards may differ from those applied within the EU. Together with 188 countries, the EU works for the development of the Codex Alimentarius, which is a collection of standards, guidelines and codes of practice. The Codex provides an essential framework, aligning many food standard issues. But, while a number of countries apply the standards

⁴² Estimated consumption = production in the EU + imports – exports. Data as regards production in the EU - 734 million tonnes (source: “EU agricultural production volumes for 2013 in million tonnes”, Faostat). Data as regards imports - almost 93 million tonnes in 2016, and exports – 91 million tonnes (source: <http://ec.europa.eu/eurostat/web/products-eurostat-news/-/EDN-20171016-1?inheritRedirect=true>).

agreed in the Codex, there are limitations to the standardisation it can provide⁴³. According to the Commission, for example, around half of the maximum residue levels for pesticides established in recent years were equal in the Codex and EU legislation.

36. The Commission states on its website and in its public communications that “strict import rules with respect to food and feed hygiene, consumer safety and animal health status aim at assuring that all imports fulfil the same high standards as products from the EU itself”⁴⁴. The latest annual report of the EFSA on pesticide residues indicates that imports are twice as likely to be subject to testing as domestic production. This reflects the application of a food safety risk model⁴⁵.

37. The EU maintains trade relations with non-EU countries in two ways: 1) through bi-lateral agreements, and 2) without specific bi-lateral agreements. In both cases, non-EU countries are required to comply with EU standards when exporting to the EU.

38. In justified cases, non-EU countries can request that the EU modify certain limits (e.g. Maximum Residual Levels for a specific pesticide or a specific food product). This mechanism is known as ‘import tolerance’. A designated Member State first assesses the request and the documentation sent by the non-EU country. Then, based on the Member State’s risk assessment, the EFSA issues an opinion. If this opinion is favourable and it establishes that the safety of consumers is not put at stake, the Commission may decide to grant the non-EU country’s import tolerance request and amend the EU legal framework to meet its needs (e.g. by setting a specific EU MRL). Non-EU countries may also apply for import tolerances for food containing active substances not authorised in the EU⁴⁶. Hence, in the case of

⁴³ For example, the lists of chemical substances included in CODEX may not be exhaustive or the member countries may still have different legal limits in relation to a particular substance (e.g. different MRL).

⁴⁴ https://ec.europa.eu/food/safety/official_controls/legislation/imports_en

⁴⁵ While 13 % of the products consumed in the EU are imported (see footnote 42), 26.4 % (22 345) of the total number of samples (84 657) concerned products imported from non-EU countries and 67 % (56 749) of the total originated from the reporting countries (EU, Iceland and Norway). The 2016 European Union report on pesticide residues in food European Food Safety Authority.

⁴⁶ If, for instance, those substances were not authorised due to other than health reasons.

import tolerances, the EU has developed a legal framework in order to require non-EU countries exporting to the EU to comply with the same food safety standards as those required of EU products (see [paragraph 30](#)).

The model faces challenges

39. This part of the report identifies challenges currently faced by the EU food safety model. The following sections explain the level of completeness of the legal framework; a number of elements that exist and which put at risk the sustainability of the food safety model in the medium term; and the limitations of the control system.

Some elements of the EU legal provisions still require implementation or action

40. In the years since the General Food Law was adopted in 2002, different regulations governing chemical hazards in food, feed, live animals and plants have entered into force. Some elements of the EU legal provisions still require implementation and Commission action (see [paragraph 53 and Annex III](#)). Some of these elements are therefore covered by national measures. We found that this affected the enforceability of the legal framework and the proper functioning of the market, and may compromise the level of protection from chemical hazards that EU lawmakers envisaged in 2002. [Table 2](#) provides examples of elements of EU legal provisions that still require Commission implementation or action.

Table 2 – Elements of EU legal provisions pending implementation and action

Type of substance	Elements pending
Food additives	Complete re-evaluation Methodology to measure food additive intake
Food enzymes	Adoption of list of authorised food enzymes
Food flavourings	Updating list of food flavourings Methodology to measure food flavouring intake
Nutrient sources (food supplements/botanicals)	Establish maximum and minimum levels of vitamins and minerals
Residues of pesticides	Harmonisation of processing factors Methodology to set MRL for cumulative exposure

41. We found that, currently, EU law covers some groups of substances (e.g. residues of pesticides, veterinary medicines) in greater detail than others (e.g. enzymes, food contact materials). The Commission has not undertaken or commissioned a cross-cutting risk assessment that would justify such differences.

The sustainability of the EU's food safety model is being tested

42. While elements of the legal framework on chemicals in food, feed, plants and live animals remains under development (see **paragraph 40 and Annex III**), the chemical industry continues to grow. There is considerable pressure to authorise new substances. As Ernst & Young observed in its 2012 external evaluation of the EFSA, the number of products authorised has been gradually increasing since 2006, along with the number of applications made and approved. The evaluator's report also noted that "applications cover more than 60 % of EFSA's output. More than one third of these applications concern new products". This stretches the EFSA's capacity and may entail devoting resources to assessments requested by industry. Indeed, various EFSA departments have confirmed the existence of major backlogs, especially in the area of regulated food ingredients. However, despite recent progress, such backlogs have not yet been effectively addressed.

43. Member States do not always provide the data needed for carrying out scientific assessments⁴⁷, despite being required to do so by law or requested to do so by the EFSA. Delays in scientific assessments, including those by EFSA, affect the lawmakers' ability to pass new laws or amend existing ones. Reasons for these delays include limited resources and scientific bodies having problems maintaining a high level of scientific expertise, e.g. due to insufficient number of experts.

44. The legal framework is now so extensive that public authorities are not able to carry out extensive testing for all regulated substances (see **paragraph 50 and Annex I**).

45. These factors threaten the viability of the model in the longer term, because more is expected of it than it can deliver in its current form. The EFSA has already recognised

⁴⁷ Such as occurrence data or food consumption data.

sustainability as an area requiring focus in the years ahead. The Commission has also started reflecting on this through the REFIT exercise and sectoral evaluations.

Limitations in the control system

The control system for products produced or grown in the EU

46. Member States are responsible for enforcing the legislation that applies to the full agri-food chain “from farm to fork” (see **Figure 5**). Under EU law, the relevant Member States’ authorities carry out checks to verify that operators’ activities and goods placed on the EU market comply with relevant standards and requirements. They should carry out these checks regularly, based on risk and with appropriate frequency⁴⁸.

⁴⁸ In principle, the Member States are free to decide on the appropriate number of checks, but EU legislation may specify frequencies for specific products, e.g. Annex IV to Council Directive 96/23/EC establishes “sampling levels and frequency” for live animals and animal products.

Figure 5 – Member State control system for the agri-food chain



Source: European Commission.

47. We found that Member State authorities inspect control systems that food business operators have put in place to address chemical risks and the results obtained⁴⁹. Inspections may detect weaknesses in the use of regulated food ingredients or plant protection products and veterinary medicines that could lead to excessive residues of these, or to residues of non-authorised substances in foodstuffs. In addition, Member State authorities may take samples for laboratory analyses based on control plans.

⁴⁹ Article 10 of Regulation (EC) No 882/2004.



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Member States' tests on food marketed in the EU cover some groups of chemicals more frequently than others

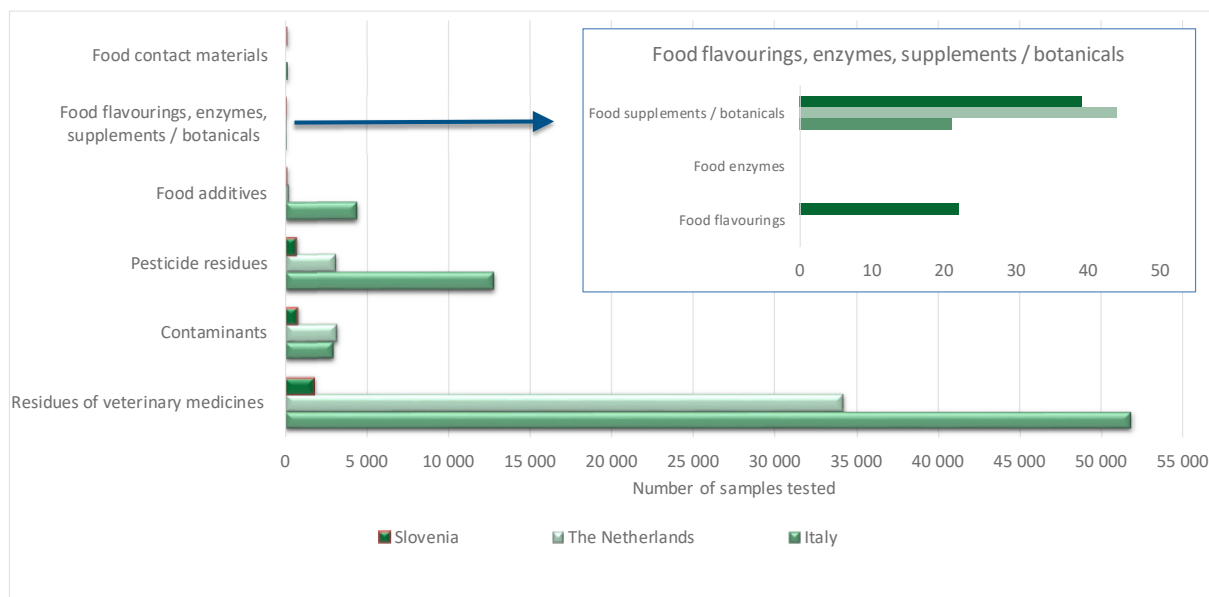
48. Member States are not obliged to include all the substances regulated by the EU in their plans but should plan their checks based on risk. The three Member States we visited carry out a risk analysis for each individual plan, i.e. usually separately for different groups of substances. However, none of these Member States has carried out a cross-cutting risk assessment to rank the different groups of chemical substances by their level of risk.

49. We reviewed reports on laboratory analyses for different groups of chemical substances in the three Member States we visited⁵⁰. We found that these Member States cover some groups of substances in greater depth than others. They focus their checks on residues of

⁵⁰ The information presented refers only to the three Member States visited during the audit. For regulated food ingredients and contaminants not included in Directive 96/23/EC, no reports exist at EU level. For residues of pesticides and veterinary medicines, the EFSA prepares annual reports on the results of Member States' testing.

pesticides, veterinary medicines and contaminants⁵¹ but do not always cover regulated food ingredients, such as food flavourings and food enzymes. **Figure 6** shows samples⁵² carried out in 2016 for different groups of chemical substances in the three Member States visited.

Figure 6 – Samples tested in 2016 by Member States visited



Source: ECA, based on Member State control reports.

50. The incomplete harmonization of legal provisions at EU level (see **paragraphs 40 and 41**) may partly explain the low number – and in some cases the absence – of checks on certain substances (e.g. in enzymes and food contact materials, see **Figure 6**). While the current EU legal framework allows Member States to carry out certain checks on additives and flavourings, Member States carry out a low number of checks in relation to these substances. This reflects the fact that Member States have limited resources and it is not feasible for them to test for all substances⁵³. **Table 3** presents a summary of potential risks

⁵¹ However, these tests do not address all aspects of chemical risks such as accumulation of pesticides (see **paragraph 7 in Annex III**).

⁵² A sample can include several tests for different substances.

⁵³ Conditions of use in Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives occupy 314 pages (Annexes 2-4).

that Member States will not cover if they exclude certain regulated food ingredients from their checks.

Table 3 – Potential risks related to certain substances added to food

Group of substances	Risks
Food additives	<ul style="list-style-type: none"> • Additives other than authorised may be used • Used additives may not comply with purity criteria • Authorised additives may be used in excessive quantities • Insufficient verification of quantum satis (no specified maximum level, to be used in accordance with good manufacturing practice)
Food flavourings (including smoke flavourings)	<ul style="list-style-type: none"> • Flavourings other than authorised may be used • Authorised flavourings may be used in excessive quantities
Food enzymes	<ul style="list-style-type: none"> • Harmful enzymes may be used • Enzymes may be used in excessive quantities

Source: ECA based on an analysis of current legislation.

Further guidance on dealing with infringements

51. If Member State authorities identify an infringement during official inspections, they must take action to ensure that unsafe food does not make it onto the market and that the operator remedies the situation. Possible enforcement measures at Member State level include destroying a particular product or withdrawing it from the market, suspending or shutting the activity down. Furthermore, Member States must lay down their own rules on sanctions, which should be effective, proportionate and dissuasive⁵⁴.

52. We examined the national rules and enforcement actions applied by the Member States we visited. We noted that they have established rules on sanctions for infringements related to chemical hazards. If laboratory tests show that a sample exceeds a limit set in EU law, Member States follow up the infringement and carry out a safety assessment. If Member States assess the product in question as safe, in the first instance they normally apply a

⁵⁴ Articles 54 and 55 of Regulation (EC) No 882/2004.

warning or increased checks. Where the safety assessment shows a risk to health, they apply fines.

53. However, we found that where Member States had identified a non-compliance they faced difficulties in determining the enforcement action that they could take for a specific infringement. Member States cannot refer to a set value as a basis for determining the nature of the enforcement actions to be taken in case of non-compliance.

The Commission reviews action taken by Member State authorities

54. The Commission visits Member States to check action taken by national authorities to implement EU legislation. It may make recommendations to national authorities and follows up on the implementation of these recommendations. It may also identify issues affecting the implementation of EU rules through other mechanisms, such as complaints, monitoring of reporting from Member States, notifications of draft national legislation and transposition checks.

55. Where the Commission identifies non-compliance, it has a number of options ranging from dialogue at any appropriate level to formal infringement procedures. It can also send high-level letters, initiate legal proceedings and can also either suspend, or impose special conditions on the sale of certain foodstuffs. The Commission must take such measures when these foods are likely to constitute a serious risk to human health and when there is evidence of a serious failure in a Member State's control systems. To date, it has done so in at least one case when it prohibited the sale of cheese produced using milk containing antibiotic residues.

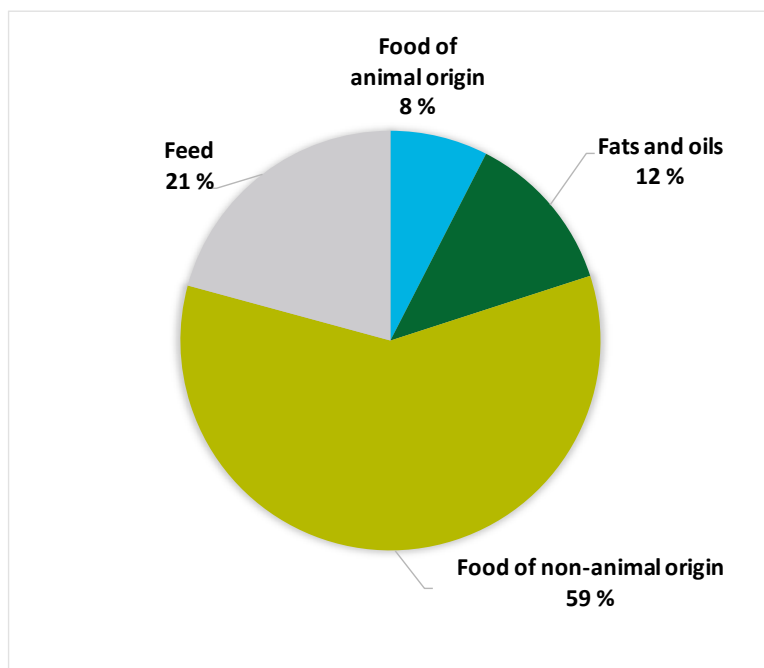
56. We reviewed the recommendations arising from audits carried out by the Commission in 2016. We found audit recommendations on pesticides, contaminants and veterinary medicines. The Commission did not make any recommendations or apply any enforcement measures against Member States in relation to regulated food ingredients.

The control system for products consumed in the EU but produced or grown elsewhere

57. Border checks are important because the moment the products from non-EU countries reach the EU is the first at which they are available for checks by Member States authorities.

Imports, once they are within the EU territory, are subject to the same control regime as domestic production. Most of the food we import is of non-animal origin, including grains, fruits and vegetables, coffee, tea and spices (see **Figure 7**).

Figure 7 – Imports of different types of food and feed in 2016



Note: Fats and oils can be both animal and non-animal origin and could be for human consumption and for non-human consumption.

Source: ECA, according to Eurostat, based on weight.

58. The EU control system for imports is based on risk to human, animal and plant health. Higher-risk imports require stricter conditions for the entry into the EU and therefore a higher level of controls than lower-risk imports. The EU’s approach considers that food of animal origin involves a higher degree of risk⁵⁵ than food of non-animal origin. As a result, imports of food of non-animal origin are normally subject to fewer checks than those of animal origin unless there is a specifically regulated risk (see **paragraph 60**).

⁵⁵ “Imported products of animal origin and live animals present a high level of risk as they can transmit serious human and animal diseases”. DG SANTE web page: https://ec.europa.eu/food/safety/official_controls/legislation/imports/animal_en

59. Food of animal origin can enter the EU once the Commission approves its country of origin⁵⁶ and approves establishments in non-EU countries based on lists proposed from these countries^{57 58}.

60. In general, EU legal provisions leave determining the frequency and nature of checks on imports of food of non-animal origin to the Member States. **Box 3** provides information about the exceptions to this general rule and summarises the special control procedures and import conditions applicable in these cases to consignments of food of non-animal origin at the EU's external borders.

⁵⁶ According to Article 11(4) of Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206), the Commission reviews the public and animal health situation in the relevant non-EU country by requesting and examining documents and, as a general rule, visiting the country. In relation to chemical risks, this review covers the non-EU country's laws on products of animal origin, use of veterinary medicinal products, preparation and use of feedstuffs and approval of the residue monitoring programme

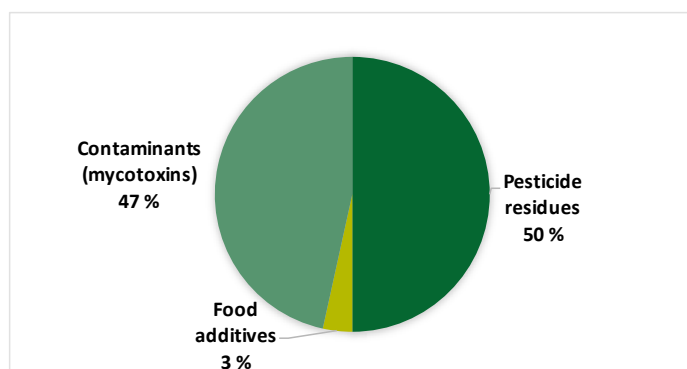
⁵⁷ The Commission inspects a sample of these establishments during audits in non-EU countries. The Commission also informed us that it is preparing a report on the outcome of its evaluation of establishments in one non-EU country that have been approved to export to the EU.

⁵⁸ According to Regulation (EC) No 853/2004 and Articles 11 and 12 of Regulation (EC) No 854/2004, the authorities in non-EU countries are responsible for checking and guaranteeing that establishments meet EU requirements for each category of food products.

Box 3 – Exceptions for products of non-animal origin

The EU has increased the level of controls on certain feed and food of non-animal origin posing a known or emerging risk⁵⁹. **Figure 8** describes the chemical hazards the increased controls cover⁶⁰.

Figure 8 – Chemical risks covered by the increased controls for food of non-animal origin



Source: ECA, based on the Regulation (EC) No 669/2009.

Furthermore, the EU has set special conditions for high-risk food of non-animal origin⁶¹. These conditions require non-EU countries to provide a health certificate, together with the results of laboratory checks.

⁵⁹ Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased levels of official controls on imports on certain feed and food of non-animal origin and amending Decision 2006/504/EC (OJ L 194, 25.7.2009, p. 11).

⁶⁰ Regulation (EC) No 669/2009 currently covers 35 different products and 24 non-EU countries. The most common products include nuts, vegetables, herbs and spices. The regulation sets frequencies for identity and physical checks including laboratory tests (5, 10, 20 or 50 %) The list of the products and the frequencies of the checks are reviewed every six months on the basis of the results of the checks.

⁶¹ According to the Commission Implementing Regulation (EU) No 884/2014 of 13 August 2014 imposing special conditions governing the import of certain feed and food from certain third countries due to contamination risk by aflatoxins and repealing Regulation (EC) No 1152/2009 (OJ L 242, 14.8.2014, p. 4); Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10) and Commission Implementing Regulation (EU) No 885/2014 of 13 August 2014 laying down specific conditions applicable to the import of okra and curry leaves from India and repealing Implementing Regulation (EU) No 91/2013 (OJ L 242, 14.8.2014, p. 20), Commission

61. Member States are responsible for controls at the EU's external borders. They carry out documentary, identity and physical checks to verify that products of animal and non-animal origin are as described and meet EU import conditions (see **Figure 9**).

Figure 9 – The different types of checks

Documentary checks	Identity checks	Physical checks
<ul style="list-style-type: none"> • Examination of commercial documents and required documents such as health certificates 	<ul style="list-style-type: none"> • Visual inspection to ensure that documents tally with the labelling and the content of the consignment 	<ul style="list-style-type: none"> • Check on the food itself • May include sampling for analysis and laboratory tests

Source: ECA, based on Article 2 of Regulation (EC) No 882/2004.

Implementing Regulation (EU) 2017/186 of 2 February 2017 laying down specific conditions applicable to the introduction into the Union of consignments from certain third countries due to microbiological contamination (OJ L 29, 3.2.2017, p. 24), the EU has set these special conditions for certain products from 12 non-EU countries, mainly due to risk of contaminants in nuts and dried fruits.

Coffee cup 3



How do public authorities check the coffee beans used in your coffee?

Coffee beans grown outside the EU can enter the EU through, for example, a port in a Member State. Since EU law does not include any checks on coffee, public authorities in Member States are free to decide whether to carry out checks on coffee at the EU external borders.

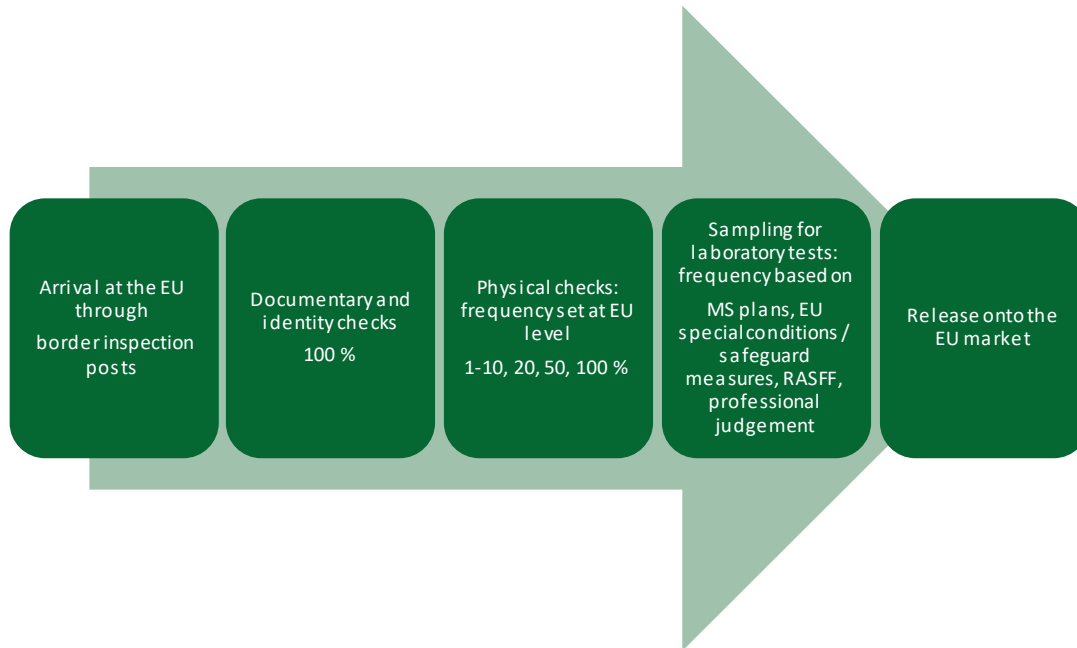
Once inside the EU, the coffee beans are subject to official controls in the same way as products grown/produced in the EU. Public authorities, based on their sectoral plans (for pesticides, contaminants, etc.), inspect the premises of food business operators (factories, storage facilities, supermarkets, restaurants, etc.) and check their procedures for preventing and detecting chemical hazards. Inspectors may also take samples and send them to a laboratory to find out whether raw or roasted coffee beans contain harmful pesticide residues, contaminants and/or unauthorised regulated food ingredients.

Checks to identify chemical hazards are primarily decided by Member States

62. EU law imposes frequencies for physical checks of imported products of animal origin (see **Figure 10**) and for certain products of non-animal origin (see **Figure 11**). Physical checks include taking samples for laboratory tests but minimum frequencies are not generally established at EU level, except for a limited number of imported products⁶². Laboratory tests to identify chemical hazards are therefore primarily decided by each Member State.

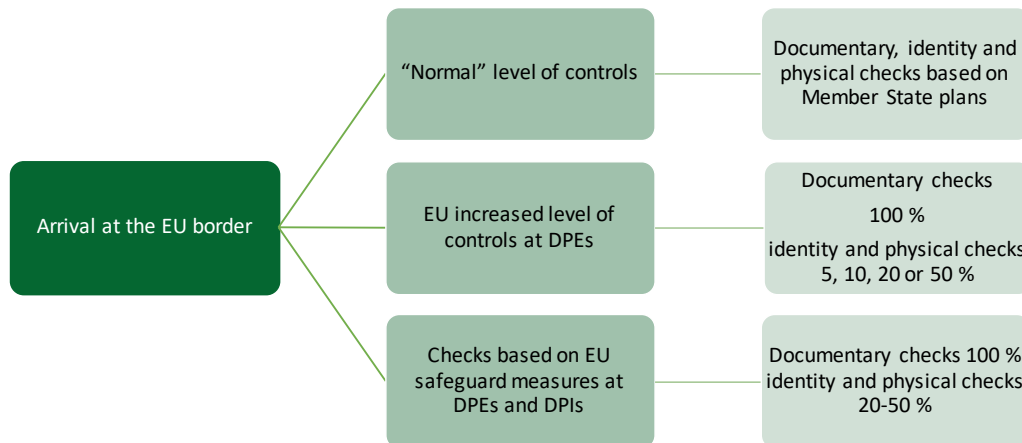
⁶² In addition to the provisions referenced in Box 3, Commission Decision 2002/805/EC of 15 October 2002 concerning certain protective measures with regard to certain products of animal origin for animal nutrition and imported from Ukraine (OJ L 278, 16.10.2002, p. 24); Commission Decision 2010/381/EU of 8 July 2010 on emergency measures applicable to consignments of aquaculture products imported from India and intended for human consumption (OJ L 174, 9.7.2010, p. 51); Commission Decision 2010/220/EU of 16 April 2010 on emergency measures applicable to consignments of farmed fishery products imported from Indonesia and intended for human consumption (OJ L 97, 17.4.2010, p. 17) and Commission Decision 2002/251/EC of 27 March 2002 concerning certain protective measures with regard to poultry meat and certain fishery and aquaculture products intended for human consumption and imported from Thailand (OJ L 84, 28.3.2002, p. 77).

Figure 10 – Border checks on food safety for food of animal origin



Source: ECA, based on Directive 97/78/EC of the Council, Decision No 94/360/EC of the Commission and Regulation (EC) No 882/2004.

Figure 11 – Border checks on food safety for food of non-animal origin



Source: ECA, based on the EU provisions.

63. The Rapid Alert System for Food and Feed (RASFF) is a tool, set up by the EU, to swiftly exchange information between national authorities on health risks related to food and feed. We found that the RASFF was widely used as a source of information for planning laboratory tests in the three Member States we visited as it provides important information on risks.

64. Our audit revealed that Commission and Member State control procedures focus on detecting residues of veterinary medicines, some contaminants and pesticides based on Directive 96/23/EC for products of animal origin. Physical checks on imports of food of non-animal origin at the EU's external borders mainly cover pesticide residues and contaminants.

65. We also found that, in the Member States visited, checks on food flavourings, food enzymes and food supplements are particularly absent both for products of animal and non-animal origin. In addition, food of animal origin is rarely checked in relation to additives and in relation to pesticides and contaminants regulated by EU legal instruments other than Directive 96/23/EC. **Box 4** provides an example of a Member State plan not including tests on all groups of chemical hazards.

Box 4 – Example of a Member State plan not including tests on all chemical hazards for products of animal origin

The Netherlands defines its laboratory tests on chemical hazards in its residues plan. The 2016 plan envisaged the testing of 1 % of consignments imported for residues of veterinary medicines, a small number of contaminants and pesticide residues. There were no checks planned on regulated food ingredients or pesticides and contaminants regulated by EU legal instruments other than Directive 96/23/EC.

Enforcement measures are not used to the fullest possible extent

66. We reviewed the actions Member States take when they identify imported food that does not comply with EU requirements. Member State authorities assess the safety of imported food products in the same way as they do for products of EU origin (**paragraphs 52 and 53**). Member States either reject the consignment or withdraw the products from the market and order the importers to pay the laboratory costs. None of the three Member States visited impose further penalties on importers.

67. The Commission can address deficiencies with audit recommendations, follow-up audits, high-level letters and meetings with representatives of non-EU countries involved. Unlike the Member States, the Commission can suspend or impose special conditions on

imports⁶³ and actually uses these tools⁶⁴. It has also laid down special conditions requiring authorities in the non-EU countries to carry out certain checks, such as laboratory analyses, before they export food products⁶⁵.

68. EU law also empowers the Commission to delist establishments based in non-EU countries producing food of animal origin⁶⁶. The Commission relies on non-EU countries for the listing and de-listing of establishments. However, the Commission may delist them in the case where the competent authorities in the non-EU countries do not give sufficient guarantees in relation to establishments. Until recently, the Commission did not use this prerogative of de-listing⁶⁷. Commission services have suggested that the current legal procedure for de-listing an establishment deserves to be reconsidered.

69. Commission services have identified opportunities to improve the way that the Commission deals with non-EU countries' challenges in meeting EU import requirements. These include strengthening its use of existing audit and follow-up activities in order to encourage compliance and resolve the problems identified.

⁶³ Article 53(1)(b) of Regulation (EC) No 178/2002.

⁶⁴ For example: Commission Implementing Regulation (EU) 2015/943 of 18 June 2015 on emergency measures suspending imports of dried beans from Nigeria and amending Annex I to Regulation (EC) No 669/2009 (OJ L 154, 19.6.2015, p. 8).

⁶⁵ For example: Commission Implementing Regulation (EU) 2015/175 and Commission Implementing Regulation (EU) No 885/2014.

⁶⁶ Article 12(4)(c) of Regulation (EC) No 854/2004.

⁶⁷ The first establishment the Commission de-listed at its own initiative was one in Brazil. It was de-listed because of salmonella and fraud related to laboratory certification for meat and meat products exported to the EU.

CONCLUSIONS AND RECOMMENDATIONS

70. This audit concentrated on chemical hazards, whose damaging effects may often not be immediately apparent because they are long-term and cumulative. Our main audit question was “Is the EU food safety model soundly based and implemented to keep the products we consume in the EU safe from chemical hazards?” We found that the model **is** soundly based, considered as a reference model around the world and provides EU citizens with a high level of food safety. However, we also found that it is currently over-stretched, as the Commission and Member States do not have the capacity to implement it fully.

71. We identified a number of inconsistencies and challenges currently facing the EU food safety model.

72. The legal framework governing the safety of chemicals in food, feed, plants and live animals remains a work in progress and has not yet achieved the level of implementation envisaged in EU food law (see **paragraph 40**). In addition, the various EFSA departments that assess requests to use chemicals in food and provide scientific advice to inform European law, rules and policy making are suffering major backlogs (see **paragraph 42**). This affects the proper functioning of parts of the system and the sustainability of the model as a whole (see **paragraphs 46 to 69**).

73. The checks carried out by public bodies can only ever make up a small proportion of all checks carried out. We found that some Member States’ controls cover certain groups of chemical substances more frequently than others (see **paragraphs 48 to 50 and 62 to 65**), and that the legal framework is so extensive that public authorities alone find it difficult to fulfil all of the responsibilities placed upon them (see **paragraphs 43 to 45**). The EU model can best remain credible by complementing public control systems with private-sector ones. However, the synergies between public and private control system have only started to be explored (see **paragraphs 32 to 34**). Therefore:

Recommendation 1 – Reviewing the legislation and improving complementarity between private and public control systems

(a) The Commission should as a part of the current Regulatory Fitness and Performance Programme (REFIT) exercise on the legal framework governing food, feed, live animals and plants, assess potential changes to the legislation governing chemical hazards in light of the capacity to apply it consistently.

Target implementation date: 2020.

(b) The Commission should build upon the work already started to encourage such complementarity identifying the way forward so that Member State public authorities can, where justified, rely more extensively on the checks carried out by the private sector to improve the efficiency of checks and the sustainability of the EU food safety model.

Target implementation date: 2020.

74. A strength of the EU model is that it aims to guarantee that products from within the EU and those imported fulfil the same high standards of safety, thereby protecting the consumer. We found that the EU has sufficient legal basis and a system of checks in place to ensure that products comply with EU standards regardless of their country of origin.

75. We also found that to assure EU safety standards are met for food imports, a risk assessment is made, and import tolerances granted, for certain pesticide residues, where safe for consumers. This takes account of specific conditions in non-EU countries (see **paragraphs 29, 30 and 38**). Therefore:

Recommendation 2 – Maintaining the same level of assurance for both EU produced and imported food

For pesticide residues in food, the Commission should explain what action it will take to maintain the same level of assurance for both EU produced and imported food while remaining compliant with WTO rules.

Target implementation date: 2019.

76. While noting the interest of food and feed business operators in maintaining a high level of food safety, Member States public authorities face difficulties in determining the nature of enforcement action to be taken in case of non-compliance (see paragraphs 51 to 53 and 66). The Commission has identified opportunities to enhance its procedures for the monitoring and enforcement of food legislation (see paragraphs 54 to 56 and 67 to 69). Therefore:

Recommendation 3 – Facilitating consistent application of EU food law

(a) The Commission should give Member States further guidance on the application of enforcement measures.

Target implementation date: 2020.

(b) The Commission should put into action the opportunities it has identified to enhance its procedures for monitoring compliance with EU food rules.

Target implementation date: 2020.

This Report was adopted by Chamber I, headed by Mr Nikolaos MILIONIS, Member of the Court of Auditors, in Luxembourg at its meeting of 14 November 2018.

For the Court of Auditors

Klaus-Heiner LEHNE
President

ANNEX I**Chemical substances regulated in the EU food and feed legal provisions**

	Authorised	Not authorised
Food Additives	<p>334 E food additives <i>Source:</i> Regulation 1333/2008 of 16 December 2008 ANNEX II Union list of food additives approved for use in foods and conditions of use. Part B - List of all Additives</p>	
Food Flavourings	<p>2549 substances approved on food flavourings <i>Source:</i> Regulation 1334/2008 of 16 December 2008 Annex I Table I: List of flavourings and source materials approved for use in and on foods. 10 authorised smoke flavourings <i>Source:</i> Regulation 1321/2013 of 10 December 2013 – List of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings</p>	<p>15 substances <i>Source:</i> Regulation 1334/2008 of 16 December 2008 (consolidated version). Annex III Part A: Substances, which shall not be added as such to food.</p>
Feed Additives	<p>1584 feed additives <i>Source:</i> Register of Feed Additives of 11 October 2017 pursuant to Regulation (EC) No 1831/2003. Annex I: List of additives 236 additives no application for re-evaluation was submitted <i>Source:</i> Register of Feed Additives of 11 October 2017 pursuant to Regulation (EC) No 1831/2003. Annex II – List of additives for which no application for re-evaluation was submitted before the deadline of 8 November 2010 Regulation 1831/2003 of 22 September 2003/Art. 17: The Commission shall establish and keep up to date a Community Register of Feed Additives</p>	

Food Contact Materials	<p>885 authorised FCM substances <i>Source:</i> Regulation 10/2011 of 14 January 2011 (consolidated version): Annex I “Union list of authorised monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids”, Table I - List of authorised substances in the manufacture of plastic FCMs</p> <p>34 groups restriction of FCM substances <i>Source:</i> Regulation 10/2011 of 14 January 2011. Annex I / Table II - Group restriction of FCM substances</p> <p>Art. 5 – Regulation 1935/2004 of 27 October 2004</p> <p>105 substances or groups of substances <i>Source:</i> Directive 2007/42 of 29 June 2007. Annex II – List of substances or groups of substances from which <u>regenerated cellulose films</u> used as food contact materials are allowed</p>	<p>3 non-authorised substances <i>Source:</i> Regulation 1895/2005</p> <p>1 non-authorised substance <i>Source:</i> Regulation (EU) No10/2011 and Regulation (EU) 2018/213</p>
Pesticides	<p>492 active substances Parts A and B – List of approved active substances</p> <p>20 Part C – Basic substances</p> <p>13 Part D – Low risk active substance</p> <p>71 Part E – Candidates for substitution</p> <p><i>Source:</i> <u>EU Pesticides database (October 2018)</u></p>	<p>833 active substances not approved under Regulation 1107/2009</p> <p>38 substances pending</p> <p>20 substances “Not a plant protection product”</p> <p><i>Source:</i> <u>EU Pesticides database (October 2018)</u></p>
Contaminants	<p>59 Contaminants /undesirable substances</p> <ul style="list-style-type: none"> - Inorganic contaminants and nitrogenous compounds (including metals): 9 substances - Mycotoxins: 9 substances - Inherent plant toxins : 7 substances - Organochlorine compounds (except Dioxins and PCBs) 10 substances - Dioxins and PCBs 3 substances - Processing contaminants: 3 substances - Harmful botanical impurities 7 substances - Authorised feed additives (coccidiostats) in non-target feed following unavoidable carry-over: 11 substances <p><i>Source:</i> Directive 2002/32 of 7 May 2002 (consolidated version)</p> <p>Feed: Commission Recommendation 2006/576/EC of 17 August 2006 (consolidated version)</p> <p>Food: Regulation (EC) 1881/2006 of 19 December 2006 (consolidated version)</p>	

<p>Veterinary medicines (including hormones)</p>	<p>666 pharmacologically active substances <i>Source:</i> Regulation 37/2010 of 22 December 2009 Annex Table 1 – Allowed substances 1 group of substances <i>Source:</i> Directive 96/22/EC of 29 April 1996 (consolidated version). Annex II: List of prohibited substances: List B: prohibited substances with derogations</p>	<p>9 substances <i>Source:</i> Regulation 37/2010 of 22 December 2009 Annex Table 2 – Prohibited substances 3 substances or groups of substances <i>Source:</i> Directive 96/22/EC of 29 April 1996 (consolidated version). Annex II List of prohibited substances. List A: prohibited substances 1 group of substances <i>Source:</i> Directive 96/22/EC of 29 April 1996. Annex III List of provisionally prohibited substances ----- 6 groups of substances Group A — Substances having anabolic effect and unauthorized substances 3 groups of substances Group B — Veterinary drugs and contaminants <i>Source:</i> Directive 96/23/EC of 29 April 1996. Annex I</p>
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Examples of chemicals and their associated outcomes

Substance	Examples of products in which substance may be present	Examples of associated outcomes
Pesticides (when used illegally)	Plants (cereals, vegetables, fruits) feed, animals	Low birth-weight and pre-term infants, various birth defects, numerous cancer sites, ischaemic heart disease, cerebrovascular disease
Unauthorised colour Red 2G (128)	Certain sausages and burger meat	Genotoxicity, carcinogenicity
Methylmercury	Fish (tuna, marlin, sword fish, northern pike)	Affected cognitive development, mental retardation, Parkinson disease, attention-deficit disorder, minamata disease
Lead	Food / water / soil contamination, plants	Various birth defects, anaemia, methaemoglobinemia, cognitive development affected, mental retardation, parkinson disease, attention-deficit disorder, minamata disease, hearing loss, ischaemic heart disease, cerebrovascular disease, calculus of kidney, chronic renal disease
Cadmium	Plants (rice and other cereals, root crops, vegetables)	Ischaemic heart disease, cerebrovascular disease calculus of kidney, chronic renal disease, osteoporosis, gout
Dioxins	Feed, products of animal origin (dairy products, meat, eggs)	Numerous cancers, including of the lung, skin, liver, brain, kidney, prostate, bone marrow and bladder
Aflatoxin	Plants (resulting from mould affecting cereals, oilseeds, spices, nuts), dairy products	Numerous cancers, including of the lung, skin, liver, brain, kidney, prostate, bone marrow and bladder

Source: Table inspired on Prüss-Ustün, A. et al., "Knowns and unknowns on burden of disease due to chemicals: a systematic review". Table 1 – Examples of sources and pathways of human exposure to a few selected chemicals and Table 2 – Main disease groups with suspected or confirmed linkage to chemicals. Published online 21.1.2011 doi: [10.1186/1476-069X-10-9](https://doi.org/10.1186/1476-069X-10-9).

Examples of elements of EU legal provisions pending implementation and action

1. Food additives are substances added intentionally to foodstuffs to perform certain technological functions, for example: to colour, sweeten or help preserve them¹. In 2011, the EU established a Union list of additives authorised for use in foods² replacing the provisions of previous Directives on food additives. Currently the list contains 334 food additives³. However, Regulation (EC) No 1333/2008 deemed a mandatory re-evaluation necessary for 316 of these additives in order to decide whether to keep them on the list. By August 2018, 175 additives had been re-evaluated. The legal deadline to complete the re-evaluation programme is the end of 2020 but this may be affected by backlogs at the EFSA.

2. The regulation⁴ requires the EU to draw up a list of authorised food enzymes. However, ten years after it was passed, the Commission has not yet drawn up any such list. This is because the regulation⁵ envisaged its establishment as a single step, meaning it cannot happen until all the enzymes considered for inclusion in the Union list have been assessed for their safety by the EFSA. However, by the time of our audit, the EFSA had issued conclusive scientific assessments only for 13 enzymes (having completed assessments for only 18 enzymes out of the 281 for which it had received complete applications).

¹ <https://www.efsa.europa.eu/en/topics/topic/food-additive-re-evaluations>

² Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives (OJ L 295, 12.11.2011, p. 1–177).

³ Annex II of Regulation (EC) No 1333/2008 includes the Union list of food additives approved for use as such in foods and conditions of use.

⁴ Article 1 of Regulation (EC) No 1332/2008.

⁵ Recital 14 and Article 17 of Regulation (EC) No 1332/2008.

3. Out of the 2 546 authorised flavourings⁶ on the EU list, 318 were in May 2018 marked with footnotes⁷, indicating that they are allowed on the market but their evaluation is still pending completion. The EFSA had completed the final evaluation for 117 of these 318 substances at the time of the audit.

4. Member States are required to monitor the consumption and use of food additives and flavourings. This information is useful for the EFSA to evaluate food flavourings and re-evaluate food additives, and in particular to carry out “exposure assessments”, one of the four elements of any risk assessment. Under EU law⁸, the Commission should, by 20 January 2011, have adopted a common methodology for Member States to collect this required information for flavourings (no deadline was given for food additives). However, no such methodology had yet been adopted at the time of our audit.

5. In the area of food supplements, Directive 2002/46/EC requires the Commission to set maximum levels of vitamin and mineral content in supplements. However, even though the EFSA published the “tolerance upper intake levels for vitamins and minerals” in 2006, the Commission has not yet set any such limits. Therefore, Member States’ limits continue to apply. According to the Commission, the issue is on stand-by and it has not planned action in the near future. The Member State authorities we visited during our audit expressed the view that these values should be set at EU level in order to give the food and feed industry clear indications on what is allowed and what is not, and to ensure that all businesses operating on the EU market are treated equally. They further explained that the current situation, with each Member State setting different levels or none at all, also has a negative impact on consumers’ perceptions of the safety of these products.

⁶ Source: [Commission’s database on food flavourings](#).

⁷ Part A of the EU list has four different footnotes : 1. “evaluation to be completed by the Authority”; 2) “additional scientific data shall be submitted by 31 December 2012”; 3. “additional scientific data shall be submitted by 30 June 2013”; and 4. “additional scientific data shall be submitted by 31 December 2013”.

⁸ Article 20(2) of Regulation (EC) No 1334/2008.

6. In the area of food contact materials, the EFSA explains that: “the safety of food contact materials must be evaluated as chemicals can migrate from the materials into food”.

However, a number of the specific legal provisions governing the production of food contact materials are not yet harmonised across the EU.

- Under Article 4 of Directive 84/500/EEC, the Commission had until 1987 to re-examine the limits laid down in Article 2 for ceramic articles. However, by the time of our audit, this re-examination had not yet been completed or resulted in any decision.
- Regulation (EC) No 450/2009, on active and intelligent materials and articles intended to come into contact with food, provided that the Commission should adopt an EU list of active and intelligent food contact materials after the EFSA had delivered its opinion on the applications. The EFSA adopted the last opinion for the initial batch of applications in 2013, but the Commission has not yet drawn up the EU list.
- For recycled plastic materials, between 2008 and 2018, the EFSA received 156 applications on recycling processes. The EFSA’s safety assessment for each recycling process should be followed by a risk management decision on whether to authorise it. By the time of our audit, there were still 138 decisions pending adoption. As a transitional measure when Regulation (EC) No 282/2008 entered into force, the Commission established an EU register listing these valid applications. As a result, all recycling processes listed in the register may currently still be used, regardless of the EFSA’s final assessment.

7. In addition, even though the EU legal framework already contains a number of provisions on risks linked to cumulative exposure, e.g. for pesticide residues, the methodology itself is not yet ready to be used in an MRL setting.

8. As regards botanicals, the EFSA Scientific Committee compiled a “Compendium of botanicals that are reported to contain toxic, addictive, psychotropic or other substances that may be of concern”⁹. The purpose of the compendium was to draw attention to issues

⁹ EFSA Journal 2012;10(5):2663.
<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2012.2663>

that need to be taken into account when assessing the safety of botanicals. However, no rules have yet been adopted at EU level, and botanicals remain subject to Member State rules. A system of mutual recognition exists allowing a company marketing in one country a specific product containing certain botanicals to request the authorisation to market that same product in another country, but the process of obtaining this mutual recognition is lengthy and not exempt of risks as the authorisation in the second country may be finally denied. In view of this situation, some Member States have cooperated to establish their own joint lists of botanicals that can or cannot be used in dietary supplements. The main example in this regard is the BelFrit project¹⁰, jointly created by Belgium, France and Italy, and which has been used as the basis for new regulations in Italy and in Belgium.

¹⁰ <https://effl.lexxion.eu/article/EFFL/2013/3/241>

**REPLIES OF THE COMMISSION TO THE SPECIAL REPORT OF THE
EUROPEAN COURT OF AUDITORS**

**“CHEMICAL HAZARDS IN OUR FOOD: EU FOOD SAFETY POLICY PROTECTS
US BUT FACES CHALLENGES”**

EXECUTIVE SUMMARY

I. The production and consumption of food plays a central role in the European Union's economy. The Commission fully recognises that food safety is therefore a matter of great public concern. It is always a key policy priority for the Commission to ensure that the EU has the highest standards of food safety. This priority is particularly reflected in one of the main objectives of the General Food Law Regulation (GFL Regulation)¹, the foundation of a vast array of specific EU food legislation introduced in 2002, namely a high level of protection of public health.

III. Overall, the Fitness Check² concluded that the objective of a high level of protection of public health has been attained. The level of protection of public health has been overall raised. Current food safety levels are more favourable than in 2002. The scientific basis of EU measures has also been improved considerably. These are due to the creation of the European Food Safety Authority (EFSA) responsible for providing scientific advice in all matters relating to food chain, the strict separation of the risk assessment and risk management at EU level and the systematic implementation of the risk analysis principle in EU food law. The Commission notes that no systemic inconsistencies in the application of the risk analysis principle at EU level have been identified.

The food safety framework has also served, in some cases, as a source of inspiration for non-EU countries developing their national legislation. Similarly, EU standards relating to the food chain are considered as being amongst the highest in the world. This is largely due to the strong and sound science-based risk assessments, delivered by EU decentralised agencies.

IV.

(a) The Commission acknowledges certain legal provisions are not yet implemented (maximum levels of vitamin and mineral content in supplements) and certain scientific methodologies such as the methodology for assessment of cumulative exposure for substances with the same effect is not yet available due to scientific complexity.

Article 14(9) of General Food Law provides that where there are no specific Union provisions, food shall be deemed safe when it conforms to the specific provisions of national food law of the Member State in the territory of which the food is marketed taking into account the Treaty provisions on the free movement of goods. Therefore, in the areas where implementation is pending the level of protection from chemical hazards is not compromised.

The Commission agrees on the existence of backlogs especially in the area of regulated food ingredients. The REFIT exercise for pesticides legislation is currently ongoing and the Commission's legislative proposal amending the General Food Law addresses, amongst

¹ 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, (OJ L 31, 1.2.2002, p. 1).

² The Commission has recently completed a comprehensive evidence-based policy evaluation of the GFL Regulation (Fitness Check) for the entire food sector under the Regulatory Fitness and Performance Programme (REFIT); Commission Staff Working Document – The REFIT Evaluation of the General Food Law (Regulation (EC) No 178/2002), ('Fitness Check') SWD(2018)38, 15.1.2018.

others, the sustainability of the EU risk assessment in the food chain, and more specifically the scientific capacity of the EFSA³.

The Fitness Check established that the division of responsibilities between the private sector and the public control authorities has also ensured efficiency gains. The private sector is primary responsible for compliance with food law and for carrying out 'own controls'. The public control authorities are responsible for carrying out official controls. This division has allowed the public control authorities to develop a more harmonised and better targeted, risk-based approach to official controls, taking into account the private controls where reliable.

(b) To ensure a level playing field also in terms of food safety, food imported into the EU must comply with the relevant requirements of EU legislation or with conditions recognised by the EU to be at least equivalent thereto. The EU has made considerable efforts to ensure alignment of EU food law with international standards. Moreover, as a major global trader of food and feed, the EU has on many occasions significantly contributed to the development of international standards on the basis of EU standards. Where, however, harmonised EU standards are stricter than those established at international level, the EU communicates its position in a transparent manner, allowing exporters to the EU to prepare accordingly to meet the EU standards.

(c) The Commission has systematic procedures in place for follow-up of audit recommendations since 2005 and incremental enforcement actions can be used where non-compliance with EU rules persists.

The Commission is working to enhance its procedures for the monitoring and enforcement of all food and health legislation which will cover the follow up to recommendations arising from Commission audits.

V. The Commission accepts all of the ECA's recommendations.

(a) The Commission is firmly committed to the constant evaluation of EU law to identify areas of improvement through its REFIT programme. A number of sectoral evaluations are currently being carried out, or planned in the near future in the area of food law.

The Commission has recently adopted a legislative proposal amending the General Food Law and other eight sectoral acts, which addresses the long-term sustainability of the EU risk assessment in the food chain, and more specifically the scientific capacity of the EFSA⁴.

In the Commission's view, in the areas where implementation is pending the level of protection from chemical hazards is not compromised.

³ Proposal for a Regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) No 178/2002 [on general food law], Directive 2001/18/EC [on the deliberate release into the environment of GMOs], Regulation (EC) No 1829/2003 [on GM food and feed], Regulation (EC) No 1831/2003 [on feed additives], Regulation (EC) No 2065/2003 [on smoke flavourings], Regulation (EC) No 1935/2004 [on food contact materials], Regulation (EC) No 1331/2008 [on the common authorisation procedure for food additives, food enzymes and food flavourings], Regulation (EC) No 1107/2009 [on plant protection products] and Regulation (EU) No 2015/2283 [on novel foods], COM/2018/0179 final, dated 11.4.2018.

⁴ Proposal for a Regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) No 178/2002 [on general food law], Directive 2001/18/EC [on the deliberate release into the environment of GMOs], Regulation (EC) No 1829/2003 [on GM food and feed], Regulation (EC) No 1831/2003 [on feed additives], Regulation (EC) No 2065/2003 [on smoke flavourings], Regulation (EC) No 1935/2004 [on food contact materials], Regulation (EC) No 1331/2008 [on the common authorisation procedure for food additives, food enzymes and food flavourings], Regulation (EC) No 1107/2009 [on plant protection products] and Regulation (EU) No 2015/2283 [on novel foods], COM/2018/0179 final, dated 11.4.2018.

The Commission notes that the new Official Controls Regulation (Regulation (EU) 2017/625) which applies from 14 December 2019 specifies in its Article 9 (1)(d) that competent authorities shall perform official controls taking account of – inter alia – where appropriate, private quality assurance schemes.

The Commission will – within its mandate – endeavour to support Member State competent authorities in the implementation of this provision. The current work to prepare the tertiary legislation takes into account the needs expressed in the Regulation and in particular the complementarity of the responsibilities of Member States' authorities and the private sector.

(b) In the area of pesticides residues, the EU Regulation on maximum residue levels provides the same level of consumer protection for all foods, independently of their origin, as there is only one set of MRLs for all products. A REFIT evaluation is currently ongoing regarding this legislation. A report to the European Parliament and the Council will be prepared in 2019 regarding pesticides and residues thereof. In more general terms, the EU framework will continue to provide the same level of assurance for both EU produced and imported food by strictly following the already established legal requirements.

(c) The Commission will consider providing such guidance where appropriate. The Commission has already strengthened its use of existing audit and follow-up activities as means to encourage third countries' compliance with EU import requirements.

INTRODUCTION

1. Food law, both at Union and national level, aims at a high level of protection of human life and health at all times and the effective functioning of the internal market. To this end, certain general principles and requirements have been established in the General Food Law Regulation that are applicable both at Union and national level, e.g. risk analysis principle, primary responsibility of private operators, imported food and feed complying with all EU law requirements, traceability and that only safe food and feed can be placed on the Union market⁵.

11. Food business operators, including importers, are legally obliged under the General Food Law to ensure that food placed on the Union market, regardless of its origin, is safe and that it complies with all requirements of food law, established at Union and national level⁶.

13. According to the risk analysis principle, on the basis of the EFSA's risk assessment (provision of scientific advice), it is for the EU/national risk managers⁷ (depending on whether the area is harmonised or not) to take appropriate measures, including on food safety, for example, to authorise a food, under which conditions, or to prohibit it).

These measures take into account the results of the risk assessment (and at EU level in particular the opinions of the EFSA) as well as other legitimate factors⁸ and the precautionary principle where the applicable conditions are met.

⁵ 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 (OJ L 31, 1.2.2002, p. 1) (General Food Law Regulation).

⁶ Articles 14 and 17(1) of the General Food Law Regulation.

⁷ The risk managers are mainly the Commission with the assistance of Member States' representatives in the Standing Committee for Plant and Animal Health and Food and Feed (PAFF) and, depending on the applicable procedures, the Council and the European Parliament. The directorate general of Health and Food Safety (DG SANTE) is the responsible part of the Commission in charge of risk management in the food area as far as the Commission is concerned.

⁸ The General Food Law provides a non-exhaustive list of legitimate factors in recital (19), e.g. societal, economic, traditional, ethical and environmental factors as well as the feasibility of controls. The use of legitimate factors in the

OBSERVATIONS

23. The Fitness Check of the General Food Law found among others, that the current food safety levels are more favourable than those prior to 2002. The scientific basis of EU measures has improved considerably. No systemic inconsistencies in the application of the risk analysis at EU level were identified. The EU food law model has inspired non-EU countries in developing their national legislation and contributed to the EU product safety recognition worldwide. There is also a high degree of harmonisation of EU food law which has contributed to the effective functioning of the internal market.

Box 1 – The precautionary principle as defined in the General Food Law

Pursuant to the precautionary principle, EU (but also national) risk managers may take provisional risk management measures, where, following an assessment of available information the possibility of harmful effects on health is identified but scientific uncertainty persists.

The application of the precautionary principle requires a scientific evaluation as well as an evaluation and balancing of the risks involved, i.e. whether the potential risks identified exceed the threshold of what is acceptable for society as well as the consequences of non-action by the EU/national risk managers. Therefore, the application of the precautionary principle is a particular tool of risk management.

28. According to the Fitness Check findings, EU managers have opted for the application of the precautionary principle in very few cases. No evidence was found on concrete adverse impacts of any of these measures on innovation and trade.

In recent years and with respect to politically sensitive issues, stakeholders and especially certain NGOs as well as certain Member States have called for total bans notably for endocrine disruptors, plant protection products or GMOs in accordance with the precautionary principle. Nevertheless, these calls do not fulfil the two conditions for the application of the precautionary principle. Therefore, these requests seem to pertain to calls for considering other legitimate factors rather than the application of the precautionary principle.

Box 2 – Difference between hazard and risk

Imported products will undergo a risk assessment that must demonstrate that food is safe for consumers before those substances can be tolerated in imported products. Moreover, legal limits (MRLs) must be respected.

30. The Commission continues to provide assurance that all food sold in the EU, regardless of origin, meets the same safety standards: there is only one set of MRLs applicable to all products on the EU market regardless of their origin. Where a substance is not approved in the EU for reasons other than public health reasons (e.g. environmental reasons) import tolerances may be established in well justified cases, but only if fully supported by data and if safe for consumers.

33. The Fitness Check further established that the division of responsibilities between the private sector and the public control authorities has also ensured efficiency gains. The private sector is primary responsible for compliance with food law and for carrying out 'own controls'. The public control authorities are responsible for carrying out official controls. This division has allowed the public control authorities to develop a more harmonised and better targeted, risk-based approach to official controls, taking into account the private controls where reliable.

EU decision-making process is not static; the exact range of factors and the weight attributed to them varies on a case-by-case basis depending on the subject matter and the measure concerned.

34. The Fitness Check on General Food Law showed that national differences are not systematic but appear rather on a case-by-case basis. The Commission endeavours to alleviate these national differences through discussions within the Working Groups composed of Member States' representatives, through the work of the audit and inspection service of DG SANTE and last but not least, through the issuing/updating where possible of general guidelines.

35. While Codex food safety texts are used as references in the WTO/SPS agreement, it does not prevent WTO members to adopt different standards provided that it is scientifically justified.

40. In the years following the introduction of General Food Law in 2002, a high degree of harmonisation has taken place in the area of food law⁹.

Relatively few areas remain as partially harmonised in the area of food law¹⁰. In the absence of full harmonisation in this area, the risk analysis is carried out at national level. While the level of protection is not jeopardised in those cases since any national measure must pursue a high level of protection of human and health and be taken on the basis of the risk analysis principle, pursuant to the General Food law, the adoption of such national measures may result in disparities that may impact negatively the internal market¹¹. This impact is currently being assessed in a number of sectoral evaluations in more detail.

41. The Commission aims at ensuring safety without imposing an unnecessary burden or level of complexity and fully ensuring the safety of the final application of the substances. It does not consider it necessary to undertake a cross-cutting risk assessment.

42. See the Commission's reply to paragraph 40.

According to the Fitness Check, the EFSA's scientific capacity has progressively been increased. This overall matched the increased demand for scientific advice. The EFSA has over time reduced its number of backlogs and continues to do so by taking appropriate measures. Moreover, the Commission has recently adopted a legislative proposal which, amongst others, addresses the long-term sustainability of the EU risk assessment in the food chain¹².

43. According to the Fitness Check of the General Food Law, for the most part national food law has been adopted on the basis of a risk analysis. Where this has not taken place, according to the consulted Member States' competent authorities, it is attributed to the challenges faced in the application of the risk analysis principle, such as restricted available resources. The intensity of those challenges varies on a case-by-case basis. There is also some evidence that

⁹ Commission Staff Working Document, The REFIT Evaluation of the General Food Law (Regulation (EC) No 178/2002),SWD(2018)38 final, dated 15.1.2018, ('Fitness Check'), at p. 89.

¹⁰ Such as food contact materials other than plastics, food supplements and foods with added vitamins and minerals as regards the setting of maximum levels of substances as well as lack of full implementation at EU level with respect to health and nutrition claims as regards botanicals.

¹¹ Commission Staff Working Document, The REFIT Evaluation of the General Food Law (Regulation (EC) No 178/2002),SWD(2018)38 final, dated 15.1.2018, ('Fitness Check'), at p. 89.

¹² Proposal for a Regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) No 178/2002 [on general food law], Directive 2001/18/EC [on the deliberate release into the environment of GMOs], Regulation (EC) No 1829/2003 [on GM food and feed], Regulation (EC) No 1831/2003 [on feed additives], Regulation (EC) No 2065/2003 [on smoke flavourings], Regulation (EC) No 1935/2004 [on food contact materials], Regulation (EC) No 1331/2008 [on the common authorisation procedure for food additives, food enzymes and food flavourings], Regulation (EC) No 1107/2009 [on plant protection products] and Regulation (EU) No 2015/2283 [on novel foods], COM/2018/0179 final, dated 11.4.2018.

where national measures were not adopted on the basis of risk analysis, they were subsequently amended or repealed¹³.

44. The framework under which Member States operate – Regulation (EC) No 882/2004 – enshrines the concept of risk-based controls as opposed to a testing for all regulated substances.

45. The Fitness Check exercise identified a shortcoming in long-term sustainability. The EFSA has been working on capacity building training, and the Commission is also supporting risk assessment training via the Better Training for Safer Food initiative.

48. See the Commission's reply to paragraph 41.

49. Indeed, all groups of substances shall be subject to official controls. However, at the time of enforcement it is important to apply a risk based approach which may lead to a different depth and frequencies of controls for different groups of substances.

50. In the limited partially harmonised areas, any national measures taken must be based on the risk analysis principle and pursue a high level of protection of public health. The Commission agrees with the ECA that Member States should not exclude regulated products from their checks.

53. According to Article 6 of the GFL, national food law must be based on the risk analysis principle; therefore food safety is not jeopardised.

56. As no audits were carried out on regulated food ingredients there was no occasion for the Commission to make recommendations (if any) to the Member States. However the Commission did carry out a number of fact-finding missions on food additives and smoke flavourings in 2015 and 2016. By their nature, fact-finding missions do not contain recommendations. The results of these missions fed into an overview report which was published in 2017. This report detailed a range of actions taken by the Commission on foot of the results of the missions and highlighted opportunities for improvement in Member States' performance of official controls. Furthermore, in 2018 the Commission commenced an audit series in six Member States evaluating their official control system on food improvement agents (food additives, (smoke) flavourings and certain food ingredients with flavouring properties), the reports of which include recommendations to the Member States.

58. Overall there is sufficient evidence that food of animal origin has generally more potential to be of risk for public and animal health (mainly microbiological) than food of plant origin.

60. Competent authorities in the Member States carry out regular official controls on food of non-animal origin imported into the Union, at an appropriate place, including the point of entry of the goods into the Union, on the basis of national control plans in light of potential risk and these controls must cover all aspects of food law (cf. Article 15 (1) and (2) of Regulation (EC) 882/2004).

66. The measures taken by Member States, i.e. to reject the consignment and invoice laboratory costs (plus associated delays of entry), are not "cost-free" and act as a deterrent or de facto penalty. They can also have potential contractual implications between the operators concerned.

CONCLUSIONS AND RECOMMENDATIONS

72. The Commission acknowledges certain legal provisions are not yet implemented (maximum levels of vitamin and mineral content in supplements) and certain scientific

¹³ Commission Staff Working Document, The REFIT Evaluation of the General Food Law (Regulation (EC) No 178/2002), SWD(2018)38 final, dated 15.1.2018, ('Fitness Check'), at p. 39.

methodologies such as cumulative exposures is not yet available due to scientific complexity. Article 14(9) of General Food Law provides that where there are no specific Union provisions, food shall be deemed safe when it conforms to the specific provisions of national food law of the Member State in the territory of which the food is marketed taking into account the Treaty provisions on the free movement of goods. Therefore, in the areas where implementation is pending the level of protection from chemical hazards is not compromised.

The Commission agrees on the existence of backlogs especially in the area of regulated food ingredients. The REFIT exercise for pesticides legislation is currently ongoing and the recently adopted Commission legislative proposal amending the General Food Law addresses, amongst others, the long-term sustainability of the EU risk assessment in the food chain, and more specifically the scientific capacity of the EFSA¹⁴.

73. The Fitness Check established that the division of responsibilities between the private sector and the public control authorities has also ensured efficiency gains. The private sector is primary responsible for compliance with food law and for carrying out 'own controls'. The public control authorities are responsible for carrying out official controls. This division has allowed the public control authorities to develop a more harmonised and better targeted, risk-based approach to official controls, taking into account the private controls where reliable.

Recommendation 1 – Reviewing the legislation and improving complementarity between private and public control systems

(a) The Commission accepts the recommendation.

The Commission is firmly committed to the constant evaluation of EU law to identify areas of improvement through its REFIT programme. A number of sectoral evaluations are currently being carried out, or planned in the near future in the area of food law.

The Commission has recently adopted a legislative proposal amending the General Food Law and other eight sectoral acts, which addresses, amongst others, the long-term sustainability of the EU risk assessment in the food chain, and more specifically the scientific capacity of the European Food Safety Authority (EFSA)¹⁵.

In the Commission's view, in the areas where implementation is pending the level of protection from chemical hazards is not compromised.

(b) The Commission accepts the recommendation.

The Commission notes that the new Official Controls Regulation (Regulation (EU) 2017/625) which applies from 14 December 2019 specifies in its Article 9 (1)(d) that competent

¹⁴ Proposal for a Regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) No 178/2002 [on general food law], Directive 2001/18/EC [on the deliberate release into the environment of GMOs], Regulation (EC) No 1829/2003 [on GM food and feed], Regulation (EC) No 1831/2003 [on feed additives], Regulation (EC) No 2065/2003 [on smoke flavourings], Regulation (EC) No 1935/2004 [on food contact materials], Regulation (EC) No 1331/2008 [on the common authorisation procedure for food additives, food enzymes and food flavourings], Regulation (EC) No 1107/2009 [on plant protection products] and Regulation (EU) No 2015/2283 [on novel foods], COM/2018/0179 final, dated 11.4.2018.

¹⁵ Proposal for a Regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) No 178/2002 [on general food law], Directive 2001/18/EC [on the deliberate release into the environment of GMOs], Regulation (EC) No 1829/2003 [on GM food and feed], Regulation (EC) No 1831/2003 [on feed additives], Regulation (EC) No 2065/2003 [on smoke flavourings], Regulation (EC) No 1935/2004 [on food contact materials], Regulation (EC) No 1331/2008 [on the common authorisation procedure for food additives, food enzymes and food flavourings], Regulation (EC) No 1107/2009 [on plant protection products] and Regulation (EU) No 2015/2283 [on novel foods], COM/2018/0179 final, dated 11.4.2018.

authorities shall perform official controls taking account of – inter alia – where appropriate, private quality assurance schemes.

The Commission will – within its mandate – endeavour to support Member State competent authorities in the implementation of this provision. The current work to prepare the tertiary legislation takes into account the needs expressed in the Regulation and in particular the complementarity of the responsibilities of Member States' authorities and the private sector.

Recommendation 2 – Maintaining the same level of assurance for both EU produced and imported food

The Commission accepts the recommendation.

In the area of pesticides residues, the EU Regulation on maximum residue levels provides the same level of consumer protection for all foods, independently of their origin, as there is only one set of MRLs for all products. A REFIT evaluation is currently ongoing regarding this legislation. A report to the European Parliament and the Council will be prepared in 2019 regarding pesticides and residues thereof. In more general terms, the EU framework will continue to provide the same level of assurance for both EU produced and imported food by strictly following the already established legal requirements.

76. The Commission has systematic procedures in place for follow-up of audit recommendations since 2005 and incremental enforcement actions can be used where non-compliance with EU rules persists.

The Commission is working to enhance its procedures for the monitoring and enforcement of all food and health legislation which will cover the follow up to recommendations arising from Commission audits.

Recommendation 3 – Facilitating consistent application of EU food law

(a) The Commission accepts the recommendation and will consider providing such guidance where appropriate.

(b) The Commission accepts the recommendation.

The Commission has already strengthened its use of existing audit and follow-up activities as means to encourage third countries' compliance with EU import requirements.

AUDIT TEAM

The ECA's special reports set out the results of its audits of EU policies and programmes, or of management-related topics from specific budgetary areas. The ECA selects and designs these audit tasks to be of maximum impact by considering the risks to performance or compliance, the level of income or spending involved, forthcoming developments and political and public interest.

This report was adopted by Audit Chamber I — headed by ECA Member Nikolaos Milionis — which specialises in sustainable use of natural resources. The audit was led by ECA Member Janusz Wojciechowski, supported by Kinga Wisniewska-Danek, Head of Private Office and Katarzyna Radecka-Moroz, Private Office Attaché; Michael Bain, Principal Manager; Maria Eulàlia Reverté i Casas, Head of Task; Päivi Piki, deputy Head of Task; Ioannis Papadakis, Manuel Dias Ferreira Martins and Ermira Vojka, Auditors; and Terje Teppan-Niesen, Assistant. Linguistic support was provided by Philippe Colmant, Vesna Marn and Michael Pyper.



From left to right: Eulàlia Reverté i Casas, Katarzyna Radecka-Moroz, Janusz Wojciechowski, Michael Bain, Päivi Piki, Manuel Dias Ferreira Martins.

Event	Date
Adoption of Audit Planning Memorandum (APM) / Start of audit	29.11.2017
Official sending of draft report to Commission (or other auditee)	27.9.2018
Adoption of the final report after the adversarial procedure	14.11.2018
Commission's (or other auditee's) official replies received in all languages	6.12.2018

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Food safety is a high priority for the EU and affects all citizens. EU aims to protect its citizens from hazards that may be present in food. We checked whether the EU food safety model, specifically as regards chemical hazards, is soundly based and implemented. We found that the model is soundly based, respected worldwide and that European citizens enjoy one of the highest levels of assurance on the safety of their food in the world. However, we also found that EU food safety model is currently over-stretched, and faces certain challenges. We make recommendations to the Commission on how to address these challenges and improve the functioning of the food safety model.



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