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POLICY DEPARTMENT **A**
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Economic and Monetary Affairs

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Food Safety: State-of-Play, Current and Future Challenges

In-depth Analysis for the ENVI Committee



DIRECTORATE GENERAL FOR INTERNAL POLICIES
POLICY DEPARTMENT A: ECONOMIC AND SCIENTIFIC POLICY

Food Safety: State-of-Play, Current and Future Challenges

IN-DEPTH ANALYSIS

Abstract

Food safety seeks to strike a balance between guaranteeing a high level of public health, environmental and consumer protection, while at the same time providing a stable regulatory environment for actors in the food chain. Food safety challenges relate to cross-cutting issues such as globalisation and climate change, as well as to specific cases – e.g. persistent episodes of food borne illness, Endocrine Disruptors and nanotechnology, particularly in the context of current and future regulation and non-regulatory actions. This document was provided by Policy Department A for the Environment, Public Health and Food Safety Committee (ENVI).

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LIST OF ABBREVIATIONS

AGRI	Agriculture and Rural Development Committee
AMR	Antimicrobial Resistance
BSE	Bovine Spongiform Encephalopathy
BTV	Blue Tongue Virus
CAP	Common Agricultural Policy
ED	Endocrine Disruptors
EDC	Endocrine Disrupting Chemicals
EEA	European Environment Agency
ENVI	Environment, Public Health and Food Safety Committee
FAO	Food and Agriculture Organisation of the United Nations
GAEC	Good Agricultural and Environmental Conditions
GM	Genetically-modified
HACCP	Hazard Analysis and Critical Control Points
OIE	World Organisation for Animal Health
RASFF	Rapid Alert System for Food and Feed
REFIT	Regulatory Fitness Check
sCMO	Single Common market organisation
SME	Small- and Medium sized Enterprise
SMR	Statutory Management Requirements
SPS	Sanitary and Phytosanitary Agreement
TTIP	Transatlantic Trade and Investment Partnership
WHO	World Health Organisation
WTO	World Trade Organisation

EXECUTIVE SUMMARY

This document was prepared for the European Parliament Committee for Environment, Public Health and Food Safety (ENVI) of the European Parliament. Its main aim is to assist Members of the ENVI Committee in their preparation for the hearings of Commissioner-Designates. To do so, this document provides an overview of the EU institutional and regulatory framework for food safety and discusses some of the main current and future food safety challenges by using illustrative examples.

The EU approach to food safety aims at ensuring the highest level of food safety, plant health, animal health and animal welfare. The food sector is important for the economy, both in relation to the internal market, and imports and exports to and from third countries, as the EU is both the largest importer and exporter of food. Legislation on food safety is increasingly being weighed against its impact in terms of compliance costs and administrative burden, especially for SMEs, in the face of increasing global competition and global trade.

Although jurisdiction of Food Safety Policy lays mainly within the Directorate-General for Health and Consumer using independent risk assessment from the European Food Safety Authorities, it cuts across other policy areas such as agriculture, environment and trade and requires analysis and assessment from other independent EU agencies. Since the mid-1990s, changes to the EU food safety framework have been far reaching, mainly as a result of the BSE crisis. EU food safety policy differs from other countries because it employs a 'farm-to-fork' or whole food chain approach and uses the precautionary principle to deal with scientific uncertainties. This approach has recently come under pressure due to the increase in global standard setting, private standards and regulatory coherence in free trade agreements.

Cross-cutting issues such as globalisation, climate change, private food standards and current trade negotiations are expected to put pressure on current and future EU food safety policy. Globalisation of food chains combined with climate change may contribute to increased incidences of food-borne diseases and toxins in food, making international cooperation even more important. New vectors of disease due to climate change are already emerging and will require reinforced emphasis on early warning and monitoring systems at both EU and global levels. Current and future trade negotiations and international standard setting can put additional pressure on the European food safety approach, characterised by a whole food chain approach and utilisation of the precautionary principle.

Food borne pathogens such as salmonella and campylobacter are, despite ongoing progress, persistent and evolving into antibiotic resistant strains. Antimicrobial Resistance (AMR) poses therefore a particularly troubling food safety challenge. AMR is related to animal husbandry practices and complex production systems, and will thus require a multi-sectoral and interdisciplinary approach.

Similarly, Endocrine Disruptors (ED) pose challenges to developing regulation. Current risk-based approaches do not adequately assess potential risks because exposure levels are not as important as duration of exposure and time of exposure in the human life cycle. Current work on regulation of EDs also illustrates the importance of applying the precautionary principle to deal with "scientific uncertainty". The specific case of nanotechnology is not only a food safety challenge in itself, but also brings to question the ability of the current legislative framework on novel foods to deal with the growing array of issues relating to new food technologies and the complexity of issues like nanotechnology and animal cloning.

1. INTRODUCTION

KEY FINDINGS

- Historically, the EU approach to food safety aims at providing the highest level of public health, environmental and consumer protection.
- EU food safety policy is grounded in the principles of the 'farm-to-fork' approach and precautionary principle, differing from other countries food safety approach.
- The EU food sector is an important part of the EU economy, both in terms of jobs and trade.

1.1. Aim and methodology

The aim of this document is to provide an overview of the institutional framework, key legislation and challenges relating to food safety in the EU. Because of the scope of this document, it is by no means meant that the challenges presented in this are exhaustive. Instead, illustrative examples will be used to highlight current and future challenges relating to food safety, set against the EU institutional and legislative framework.

Institutional and legislative frameworks were identified by searching websites, policy documents and recent reports. Challenges were identified using policy documents, foresight studies and scientific literature. Key challenges were chosen not only as challenges, but because they are illustrative of policy dilemmas or illustrate key features or challenges relating to EU food safety legislative and non-legislative action.

1.2. Background

The EU approach to food safety aims at ensuring the highest level of food safety, plant health, animal health and animal welfare. An EU-wide food safety framework contributes to the effective functioning of the internal market, ensuring public health and consumer protection. Implementation involves both legislative and non-legislative actions to maintain an effective control system and ensure compliance with EU standards by third countries.

The objective of the European Union's food safety policy is to protect consumer health and interests while guaranteeing the smooth operation of the single market. In order to achieve this objective, the EU strives to ensure that control standards are established and adhered to as regards food and food product hygiene, animal health and welfare, plant health and preventing the risk of contamination from external substances. The EU also lays down rules on appropriate labelling for foodstuffs and food products. EU Food Safety policy underwent reform in the early 2000s, incorporating a 'farm-to-fork' approach to providing a high level of safety for foodstuffs and food products marketed within the EU at all stages of the production and distribution chains. This approach involves both food products produced within the European Union and those imported from third countries.

The food sector is an important component of the EU economy. The EU is the biggest global exporter and importer of food and drink, with total annual exports of EUR 85 billion and imports of EUR 89 billion¹. The food and drink sector (including agriculture) also play a substantial role in EU employment, employing over 48 million or approximately one-fifth of the EU workforce. Food safety regulation impacts on the food sector, and is often perceived by as a source of additional administrative burden. At the same time, high food safety

¹ Comext 2011 (Trade since 1988 by SITC, Food and live animals + beverages).

standards are important for maintaining consumer confidence in both EU domestic markets (European Commission 2010) and export markets. High food safety, environmental and animal welfare standards thus allow Europe to compete on world markets where it is difficult to compete on price alone.

2. STATE-OF-PLAY

KEY FINDINGS

- Current EU food safety policy is based on a series of principles established in legislation on general food law and the precautionary principle, and incorporates a whole food chain approach to identifying and managing risks.
- Food safety policy includes food safety per se, but also animal and plant health and animal welfare.
- Food Safety policy cuts across sectors and requires a collaborative approach.
- Horizontal legislation set out in the White Paper on Food Safety has been largely implemented; remaining horizontal legislation on animal and plant health is expected to be passed during 2014/2015, and additional specific legislation is expected in several areas.
- Food safety regulation and policy is currently being reviewed under the Regulatory Fitness and Performance Programme to reduce regulatory costs and administrative burden.

This section provides an overview of current legislation and non-legislative actions affecting food safety in the EU. Commission and Parliament are assessing potential new legislation in the foreseeable future and cross cutting dimensions such as the Regulatory Fitness Check (REFIT) and regulatory coherence in current trade negotiations.

The current food safety policy is based on a series of principles established or updated at the beginning of the 2000s. These principles, applied in line with the integrated 'farm-to-fork' approach, specifically include transparency, risk analysis and prevention, the protection of consumer interests and the free circulation of safe and high-quality products within the internal market and with third countries. A certain number of bodies, in particular, the European Food Safety Authority, are responsible for helping to guarantee food safety and its scientific basis (see figure 1 for an overview of EU food safety institutional framework). Research is also an important element of the food safety policy.

Table 1: Overview of institutional framework

Institution	Function
Directorate-General Health and Consumers (SANCO)	Main responsibility for proposing EU Food Safety, animal health and Plant Health legislation and policy
Standing Committee on Plants, Animals, Food and Feed	The Standing Committee on Plants, Animals, Food and Feed was set up by Regulation 178/2002 on food law and food safety. The Committee's mandate covers the entire food supply chain - from animal health issues on the farm to the product on the consumer's table - helping the EU deal effectively with health risks at every stage of the production chain.

Institution	Function
European Food Safety Authority (EFSA)	EFSA provides independent scientific advice on all matters with a direct or indirect impact on food safety. EFSA's remit covers food and feed safety, nutrition, animal health and welfare, plant protection and plant health.
European Environment Agency (EEA)	The European Environment Agency (EEA) role is to provide sound, independent information on the environment. Although not dealing with food safety provides information on issues like EDCs and Precautionary Principle science base.
European Center for Disease Control	The ECDC works in partnership with national health protection bodies to strengthen and develop continent-wide disease surveillance and early warning systems. Through such collaboration the ECDC pools Europe's health knowledge, in order to develop authoritative scientific opinions on risks posed by new and emerging infectious diseases.
Eurostat	Provides and communicates statistics on food borne illness like salmonella and BSE

Source: Adapted from various sources.

2.1. Legislative and Institutional Framework

Since the mid-1990s, changes to the EU food safety framework have been far reaching, mainly as a result of the BSE crisis (van Zwandenberg & Millstone 2005). The guiding principles for the EU Food Safety framework were laid out in the 2000 White Paper on Food Safety and the subsequent General Food Law (Regulation (EC) No 178/2002). Previously separated units dealing with food were merged in the Directorate-General for Health and Consumer Protection (now DG Health and Consumers). This allowed for the separation of food safety, animal and plant health and animal welfare from agriculture and markets (trade, competition and internal market).

This also included institutional and legislative changes at the multiple levels of governance:

- EU level – establishment of EFSA and comprehensive legislation covering all stages of the food chain.
- Member State level – harmonisation of standards and establishment of responsibility for control.
- Food chain operators - food business responsibility for food safety (HAACP), traceability requirements and reporting.

In addition to the legislative framework directly linked to the food sector, the actors in the food supply chain are also subject to legislation in other policy areas. This includes agriculture (DG Agriculture and Rural Development), specifically the Single Common Market Organisation (sCMO)² and cross compliance measures³ relating to Statutory Management

² Single common market organisation (sCMO) is a set of measures that enables the European Union to monitor and manage, either directly or indirectly (via producer organisations supported by operational programmes), the markets of agricultural products. The purpose of market management is to stabilise markets (in terms of quantity offered and purchased and the price at which transactions take place) and thus to ensure, on the one

Requirements (SMR) and Good Agriculture and Environment Conditions (GAEC). Other relevant areas are internal market legislation (DG Internal Market and Services), international obligations such as in agreements and standards (DG Trade), environmental protection and sustainability (DG Environment), industrial policy and SMEs (DG Enterprise and Industry), competition and its impact on choice and innovation (DG Competition) and the research and innovation agenda (DG Research and Innovation and the Joint Research Centres).

Since the new framework for food safety was set out in the White Paper, horizontal legislation has to a large extent been implemented. Remaining horizontal legislation e.g. Animal Health law (European Commission 2013) and Plant health law (European Commission 2013a, European Commission 2013b) are expected to be concluded during 2014. As part of the revision on the EU strategy on Endocrine Disruptors, specific legislation defining criteria for identifying Endocrine Disruptors in the context of the Plant Protection Product Regulation (Council Regulation (EC) No 1107/2009) and Biocidal Products Regulation (Council Regulation (EU) No 528/2012) is underway.

The EU Food (Safety) legislative framework is currently being reviewed and consolidated, and wider use of regulations in lieu of directives is expected to continue towards 2020 in line with the Commission's Smart regulation agenda (European Commission 2010a). Food safety and the food chain have been identified as priority areas for reducing administrative burden (European Commission 2012) and regulatory fitness checks (REFIT) (European Commission 2012a) respectively. The REFIT processes looks at evaluating whether current regulations are 'fit for purpose' and seeks to make EU law simpler, reduce regulatory costs and administrative burden for economic operators that contributes to a clear, stable and predictable regulatory framework supporting jobs and growth. The Commission has outlined the state of play and next steps in their staff working paper Fitness Check of the Food Chain (European Commission 2013c), where it highlighted the need to balance efforts to reduce regulatory costs, repeal unnecessary legislation and reduce administrative burden with a high level of public health, environmental and consumer protection, and ultimately consumer confidence.

The EU uses a prevention-oriented 'farm-to-fork' approach to food safety, as opposed to the 'end-of-pipeline' approach. This means a systematic approach to maintaining safety of foods throughout the food supply chain; e.g. establishing good agricultural and environment conditions as condition for direct payments (cross compliance). In this sense, the precautionary principle (European Commission 2000) is a cornerstone of EU food safety policy, as it helps deal with scientific uncertainty. However the precautionary principle is being challenged as being non-scientific or for its lack of science base in addressing food safety risks.

hand, that farmers do not suffer from excessively low prices and, on the other, that consumers have a safe and secure supply of food at reasonable prices.

³ Farmers are required to respect certain rules. This requirement is known as cross-compliance. These rules concern food safety, animal health, plant health, the climate, the environment, the protection of water resources, animal welfare and the condition in which farmland is maintained. There are two components of these rules: statutory management requirements and good agricultural and environmental conditions. If a farmer is found not to respect these rules, his or her direct payments may be reduced.

3. FOOD SAFETY CHALLENGES

KEY FINDINGS

- Globalisation of food chains combined with climate change may contribute to increased incidences of food-borne diseases and toxins in food, and increase the necessity of identifying emerging food safety issues and international cooperation.
- International trade agreements, new norms for standard setting and regulatory coherence are putting pressure on EU food safety policy.
- Food-borne pathogens such as salmonella and campylobacter are persistent and evolving, while at the same time new threats are emerging.
- Antimicrobial Resistance (AMR) is perhaps the most daunting public health challenge of our time and is intrinsically related to food production systems. Addressing this challenge requires a broad-based strategy.
- Endocrine disruptors (ED) pose challenges to developing regulation, as traditional risk-based approaches cannot adequately assess the potential risk and illustrates the importance of the precautionary principle to deal with “scientific uncertainty”.
- Nanotechnology also brings to question the adequacy of the current legislative framework on novel foods to deal with the complexity of issues like nanotechnology and animal cloning, and whether specific legislation on nanotechnology is necessary in light of this complexity.

3.1. Globalisation, climate change and free trade agreements

The scope and speed of global food trade has increased dramatically during the past 20 years. Food safety issues can have an international and even a global dimension, as international trade increases and emerging countries assume an increasing share of global GDP (FCEC 2013). This interconnectedness allows contaminated food to be distributed far and wide, and makes tracing contamination increasingly difficult. At the same time, international cooperation and standard setting is increasing and private standards for food safety are gaining importance compared to public standards.

Warmer climates, in combination with the globalisation of food chains, may contribute to increased incidence of food-borne diseases and toxins in food. A number of food safety issues relating to climate change have been identified, such mycotoxins⁴ formed on plant products in the field or during storage, increased residues of pesticides in plant products affected by changes in pest pressure; and the presence of pathogenic bacteria in foods following more frequent extreme weather conditions, such as flooding and heat waves (Miraglia, M. et al. 2009). Climate change may affect zoonoses (diseases and infections which are naturally transmitted between vertebrate animals and humans; e.g. salmonella and campylobacter) by increasing the transmission cycle, range and prevalence of vectors of disease, and by increasing the animal host populations of disease. In some regions, climate change will contribute to the establishment of diseases not historically associated with the region (FAO 2010).

⁴ The term 'mycotoxin' refers to toxic chemicals produced by funghi (molds), and usually reserved for products produced by fungi that readily colonize crops.

The spread of Bluetongue virus (BTV)⁵ into Northern Europe is an alarming example of an 'exotic' vector-borne livestock established within new geographical region, with little understanding of its origin, presenting a new and significant risk to livestock production (Jones K. E. et al. 2008).

Both increased speed and scope of globalisation of food trade and climate change will affect the vectors for food borne illness. Although the World Health Organisation (WHO), the World Organisation for Animal Health (OIE) and the European Commission and its agencies are already active in monitoring and evaluating some infections, there is much more to be done to fill gaps in the evidence base, build capacity within public health authorities and raise the political profile of the issue, and to examine the possible emergence of new threats as well as the expansion of diseases already present in Europe.

Because of globalisation, climate change and new international agreements more focus will need to be placed on identifying emerging food safety issues and international cooperation. One of the key tools to ensure the cross-border follow of information to swiftly react when risks to public health are detected in the food chain is RASFF – the Rapid Alert System for Food and Feed. The legal basis of the RASFF was established Regulation (EC) N° 178/2002. The RASFF is one the areas to be reviewed in a external study as part of the REFIT process. The purpose of the RASFF is to avert or mitigate food safety risks they cause harm to European consumers. Increasing globalization of food chains and emerging risks due to new vectors of disease exacerbated by climate change increases the reliance on early warning and alert systems like the RASSF increased international cooperation. Besides its main role of ensuring food safety, the 2013 RASFF annual report (European Commission 2013d), shows that the RASFF a crucial tool to trace back and withdraw products where fraud was detected.

It is predicted at global level that the number of free trade agreements (Menon, J. 2009) and the number of countries involved in setting food safety standards and private food standards will increase (Henson S. & Humphrey J. 2009). The EU is currently negotiating a number of bilateral free trade agreements, most notably the free trade agreement with the USA, the Transatlantic Trade and Investment Partnership (TTIP). This process has been associated with a decline in the costs of cross-border trade in farm and other products (Anderson, K. 2010). Tariffs between the EU and US are already low (about 4% on average). This means that the focus is on removing non-tariff barriers (NTBs) to trade such as Sanitary and Phytosanitary measures going beyond the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS). In simple terms, this agreement allows countries to set their own standards, to protect human, animal or plant health, but requires that these standards should be based on science and should not unjustly discriminate between countries where there are identical or similar standards.

Harmonising regulation and standards on Food Safety poses a variety of challenges to the EU's current food safety approach, which is based on the farm-to-fork approach and the precautionary principle. In the current TTIP negotiation, for instance, the principle has been criticised by food industry groups in both the EU and US as well as US government trade representatives for lacking a 'sound scientific basis' being used inappropriately and "lacking proportionality". In contrast, the European Environmental Agency (EEA) provides a different narrative in their "Late lessons from early warnings" (EEA 2013) on the use, or rather neglect, of the precautionary principle. This report documents many cases in which

⁵ Bluetongue is a non-contagious, insect-transmitted, viral disease of domestic and wild ruminants. It is not known to affect humans. Bluetongue situation in the EU has considerably changed in recent times with incursions of new serotypes and outbreaks in the EU regions where outbreaks have never been reported before and which was not considered at risk of bluetongue.

societies failed to act in time to prevent serious harm to health and the environment, and contends that over-regulation due to the precautionary principle is the exception, whereas under-regulation tends to be the rule.

Increasing globalisation and increasingly complex food chains are also likely to lead to (more) food fraud and adulteration. Food fraud and adulteration does not always entail a food safety risk or public health threat, but often is often involves substituting a cheaper product or component in composite foods. However, a number of food fraud or adulteration incidents such as melamine in milk in China have had a clear public health threat. The recent horsemeat incident illustrates a fraudulent activity that does not bear a public health threat or food safety risk, but undermines consumer confidence in food. It also illustrates the concerns of consumers about product contents and increasing complex food chains, and concerns relating to traceability. The legal basis for preventing fraudulent or deceptive practices, the adulteration of food, and any other practices, which may mislead the consumer is established in Article 8 of Regulation 178/2002 (General Food Law). The Commission is currently working on strengthening its efforts to prevent fraud and adulteration by Mapping existing tools and mechanism available to prevent fraud, creating a dedicated IT tool (like the RASFF) for tracking fraud, and creating Food Fraud team at DG SANCO.

3.2. Persistent problems and new health threats

Although globalisation and climate change as described above will bring changes in vectors of disease and in some cases new diseases, food-borne illness such as salmonellosis and campylobacteriosis are persistent in the EU. Salmonella and campylobacter are the most frequently reported cause of foodborne outbreaks with known origin in the EU. Salmonella especially antibiotic-resistant salmonella, is increasingly linked to industrial and intensive livestock production systems. Although there has been some success in reducing salmonella and campylobacter in livestock, outbreaks remain a persistent problem. Despite changes in food production practices to mitigate risks, these and other food-borne pathogens, seem able to evolve quickly, thus contaminating fresh produce and even generating new public health challenges such as antimicrobial resistance (Newell, D.G. et al. 2010).

Successful programs for controlling salmonella in poultry and pigs exist. In Denmark, major reductions in the incidence of foodborne human salmonellosis were possible using an integrated approach to control of farms and food processing plants. This has been achieved by monitoring the herds and flocks, eliminating infected animals, and diversifying animals (animals and products are processed differently depending on salmonella status) and animal food products according to the determined risk. The program controlling salmonella has resulted in an estimated net savings of EUR 21.7 million (25.5 million USD). The control principles used are applicable to most industrialized countries with modern intensive farming systems (Wegener, H.C. et al. 2003).

One overall challenge is the generation and maintenance of constructive dialogue and collaboration between public health, veterinary and food safety experts, bringing together multidisciplinary skills and multi-pathogen expertise. Such collaboration is essential to monitor changing trends in the well-recognised diseases and detect emerging pathogens⁶. It will also be necessary to understand the multiple interactions these pathogens have with their environments during transmission along the food chain in order to develop effective programmes and solutions.

⁶ Converted from 25.5 million USD using conversion rate for June 2003.

As discussed above microbial pathogens are constantly evolving, which has created new public health problems. Imprudent use of antibiotics in both humans and animal husbandry has led to new challenges relating to antimicrobial resistance. According to WHO, this is one of the major public health challenges of our time 'in which common infections and minor injuries which have been treatable for decades can once again kill'.

Antimicrobial resistance (AMR) presents a substantial challenge to food safety both in terms of impact on public health in general and the capacity of health care systems to deal with infections. It also illustrates the importance of food safety policy that is collaborative across policy areas and sectors. The European Centre for Disease Prevention and Control estimates that AMR results each year in 25 000 deaths and related costs of over EUR 1.5 billion in healthcare expenses and productivity losses (ECDC/EMEA 2009). The European Commission's Action Plan proposes a 12-point action plan against the rising threat of AMR (European Commission 2011); and legislation on Veterinary Medicines and Medicated feed will be proposed in 2014. In addition, it is expected that the EU proposal on animal health law (European Commission 2013) will be adopted in 2014.

The EU was an early mover in banning antibiotics as growth promoters for livestock. An EU-wide ban on the use of antibiotics as growth promoters in animal feed entered into effect in 2006. (REGULATION (EC) No 1831/2003) The ban is the final step in the phasing out of antibiotics used for non-medicinal purposes as part of the Commission's overall strategy to tackle the emergence of bacteria and other microbes resistant to antibiotics, due to their overexploitation or misuse. Banning the use of antibiotics has led to a decrease in resistant bacteria, but the problem persists.

AMR is intrinsically related to the way livestock is treated for disease, production methods and animal husbandry practices. Intensive production systems, livestock density and animal husbandry practices increase the dependency on antibiotics (the so-called sub-therapeutic use). The current action plan and legislation do not address the relationship between production systems, animal husbandry practices and the sub-therapeutic use of antibiotics.

3.3. Use of chemicals and rise of new technologies – Stretching the limits of current regulation

Endocrine disrupting chemicals (EDC) are found in a range of products from plastics used for packaging food and drinks to commonly used pesticides. EDCs or just EDs (Endocrine Disruptors) interfere with hormone systems in humans, animals and plants, and cause 'adverse health effects in an intact organism, or its progeny, or (sub)populations' according to the position adopted by the WHO's International Programme on Chemical Safety (IPSC 2002, UNEP/WHO 2012). EDs are known or suspected to cause a number of health problems such as learning disabilities, attention deficit disorders, cancer and are increasingly linked to obesity and metabolic disorders such as type II diabetes. Recent research suggests that ED effects can even be transmitted to future generations. In relation to food and food safety, exposure to EDs is mainly related to migration through food and drink packaging, pesticide residues in food and environmental exposure in pesticide application.

As part of the revision of its strategy on EDs, the European Commission is currently weighing whether to propose changing EU legislation governing the use of pesticides (Council Regulation (EC) No 1107/2009). The Commission's 2013 work programme (European Commission 2012b) included plans to revise the strategy on endocrine disruptor chemicals (EDCs) to better protect public health and the environment, however no legislation has been proposed as of yet. The proposals have been delayed due to evolving science and divergent views among scientists and stakeholders on criteria for identifying EDs

and incorporating into legislation on biocides and pesticides. A roadmap (European Commission 2014) has been published and a public consultation is expected in 2014. In addition to difficulties related to definition and identification, legislating on ED is challenging because traditional risk-based approaches do not appear suitable to establish appropriate thresholds for exposure: dose is less important compared to exposure and time of exposure in the human lifecycle. Scientists have therefore called for hazard-based cut-off criteria for EDCs.

Legislation on EDCs provides an illustrative example of the importance of the precautionary principle, providing justification for acting in the face of scientific uncertainty and as a tool for acting on the basis of early warnings (EEA 2013). While support for targeted research is a high priority, the need for further research should not delay necessary policy and regulatory decisions to protect public health. Technologies are no longer presumed safe simply because evidence of risk or adverse effect is unavailable. Precautionary approaches presume that an induced adverse response in animals is a reliable indicator of potential harm in humans, unless informed otherwise by multiple studies.

New food chain technologies may increase productivity of the food chain and quality of foods, and can help address a number of societal challenges. However, concerns remain about the safety and acceptability of these technologies in the food chain. Concurrent incremental innovations in conventional technologies can also be anticipated.

The use of nanotechnology in the food chain is increasing, but uncertainties over risks remain. While still at an early stage of development, spending on nanotechnology - technology associated with particles of 1-100 nm in size - is rapidly increasing and the number of nanotech patents is on the rise. Nanotechnologies in the food industry have multiple functions: their first application is in food packaging, where they improve functionality. Other applications of nanotechnology include improving taste, enhancing the bioavailability of certain ingredients, reducing the content of some elements such as sugar and salt, and slowing down microbial activity (SCAR 2011). In addition, nanotechnology could bring about radical new approaches to assist crop production and storage (Office, Government, & The Government Office for Science 2012), and disease and pest control⁷. However, uncertainty persists in the EU on how to accurately define nanotechnology in the EU (in relation to the importance of particle size) (European Commission 2012c). This lack of an accurate definition compounds difficulty in regulating the technology. In addition, the unique features of nanomaterials are not fully explored and raise concerns about potential environmental, health and general safety hazards. For example, some new nanomaterials may have the potential to enter the human body through mucous membranes or the skin and migrate via the blood stream to vital organs, or the brain, interacting with other cells in unpredictable ways, which may have potential cytotoxic or genotoxic effects.(Kearney, J. 2010)

Nanotechnology and other new products or technologies fall under the jurisdiction of novel food legislation (REGULATION (EC) No 258/97). The Commission adopted a proposal for a Regulation of the European Parliament and of the Council on Novel Food in 2007, but the Commission and the Parliament failed to reach an agreement, mainly because of controversy around the inclusion of animal cloning. The regulation on novel food and novel food ingredients is currently under review and the commission has proposed new regulation on novel foods (European Commission 2013e) that aims to streamline the authorisation procedure and to improve its efficiency and transparency. It clarifies the definition of novel food, including new technologies like nanotechnology which have an impact on food.

⁷ Robinson D. K. R. And Morrison M. J. (2009) Nanotechnology Developments for the Agrifood Sector - Report of the Observatory NANO.

The general criteria for the novel food definition remain unchanged in the new proposal.

Nanotechnology use in food illustrates a specific element of novel foods legislation and related challenges. Nanotechnologies are emerging with the capacity to impact both the food industry and consumers (e.g. food processing and packaging, production of agrochemicals and seed). Like other new or modern technologies, nanotechnology can bring significant risks which are hard to assess due to its recent nature. Both animal cloning and nanotechnology are stretching the limits of novel food legislation. More rigorous checks may need to be developed and applied to adequately assess new food technology's impact on food safety and public health. This also raises the question of whether the current framework can effectively deal with the complexity of issues like nanotechnology, and whether additional specific legislation is required.

Genetically modified organisms (GMOs) constitute another key theme for food safety authorities: the authorisation process of GMOs for import or cultivation remains controversial and takes up a significant proportion of EFSA's workload. (Waigmann, E. et al. 2012). Despite EFSA's opinions on authorisation of GMOs indicating no negative environmental or public health impacts of authorized GM crops, public opinion and many Member State governments continue to have concerns about GM crops.

Food and Feed are generally derived from plants and animals, which have been grown and bred by humans for several thousand years. Plant and animal breeding has developed species and animals selecting desirable characteristics. More recently, biotechnology has made it possible to modify genetic material of living cells and organisms. Organisms whose genetic material (DNA) has been altered, are called genetically modified organisms (GMOs). Food or feed which contain and consist of GMOs or are produced from GMOs are referred to as genetically modified (GM) food or feed. Transferring Genes from one species to another (horizontal gene transfer) are particularly problematic for EU citizens. According to a Eurobarometer poll EU citizens do not see the benefits of horizontal gene transfer, have strong reservations about safety, feel that special labelling of food products is necessary, and do not feel that it should be encouraged; while they see some degree of benefit for vertical gene transfer, but have reservations about impact on the environment and safety aspects of the technology. (European Commission 2010b)

EU legislation on GMOs has been in place since the early 1990s. Specific legislation (Regulation (EC) 1829/2003 and Regulation (EC) 1831/2003) has two main objectives: to protect health and environment and to ensure the free movement of GM products in the European Union. GMOs and food products derived from GMOs, which are placed on the market, must also satisfy labelling and traceability conditions.

EU legislation on GM food and feed is currently at an impasse. After a decade of legal battles, the European Union reached an agreement in June 2014, allowing its member states to restrict or ban GMO crops in their territory. In June 2014, the European Council made an important step by reaching political agreement (European Commission 2014a) allowing Member States to restrict or ban GMO cultivation in their territory. A majority of EU member countries backed a compromise agreement on GMO authorisation, which maintains an EU-wide approval scheme but allows national cultivation bans.

The case of GM food and feed illustrates the importance of consumer confidence and complexity of establishing the burden of scientific proof. Critique of the GMO authorization procedure evolves around the lack of "public" studies that meet the criteria from EFSA and that most studies are industry funded or conducted by companies applying for authorisation.

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ANNEX: OTHER FOOD SAFETY CHALLENGES

This annex provides an overview of other food safety challenges, which were not possible to cover in the document because of the scope of the paper. It attempts to provide a list of other challenges with a short description, relevant legislation if possible and links to more information.

Direct marketing and short food supply chains

The Common Agricultural Policy (CAP) rural development strategy envisages a number of new possibilities for the economic development of small and medium size farmers in local and regional markets. Food Safety and Hygiene legislation is an important element of this strategy, particularly with regard to the implementation of relevant hygiene legislation applying to short food supply chains.

Current legislation provides some degree of flexibility, but there is a need to better use the existing provisions of relevant EU legislation adapted to small-scale food operators and direct sales and increased cooperation of farmers/small food business operators with competent authorities responsible for hygiene.

Blue tongue virus (BTV)

BTV is a non-contagious, insect-transmitted, viral disease of domestic and wild ruminants. BTV situation in the EU has considerably changed in recent times with incursions of new serotypes and outbreaks in the EU regions where outbreaks have never been reported before and which was not considered at risk of bluetongue.

Although BTV is not known to affect humans, it imposes a significant risk for animal health and highlights the changing dynamics of food safety, animal and plant health in relation to increasingly globalized food chains and climate change's impact on vectors of disease.

For more information:

- [Council Directive 2000/75/EC](#) lays down specific provisions for the control and eradication of Bluetongue.
- Implementation measures of Directive 2000/75/EC are established on [Commission Regulation \(EC\) No 1266/2007](#).

Avian influenza

Avian influenza (also 'avian flu' or 'bird flu') is a highly contagious viral disease which occurs primarily in poultry and other birds. The spread of highly pathogenic avian influenza from Asia to the west is an area of concern in the EU and globally. This disease can have devastating consequences for the health of birds and can also pose a threat to human health if not controlled. The EU has increased preventive and control measures to ensure early detection of infected birds and help contain the disease in the event of an outbreak.

Legislation in this area has been complemented by emergency measures to guarantee a swift, efficient and coherent response to avian influenza outbreaks. The EU works closely with international partners in the fight against avian influenza. Regular contact and information exchange occurs between the European Commission, the World Organisation for Animal Health (OIE) and the World Health Organisation (WHO).

For more information:

- COUNCIL DIRECTIVE 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC Council Directive 2005/94/EC.

Pandemic (H1N1) 2009 influenza virus

The pandemic (H1N1) 2009 influenza virus is a new virus subtype of influenza A (H1N1) viruses that spreads from human to human and caused a human influenza pandemic in 2009. The pandemic (H1N1) 2009 influenza virus contains gene segments from pig, bird and human influenza viruses in a combination that has never been observed before. Apart from humans, the virus has been found on some rare occasions in pigs in North America, South America, Australia and Europe including some Member States. So far there is no evidence that animals play a role in the spread of this pandemic influenza, which is primarily a human disease. However, it is expected that more infections will occur in pigs given the wide circulation of the virus in the human population.

While pandemic (H1N1) 2009 influenza virus detections in animals are to date rare events, classical swine influenza (SI) viruses circulate widely in many pig populations around the world, including the EU. There is no evidence suggesting that the pandemic (H1N1) 2009 virus behaves in pigs in a different way from the other classical influenza viruses of pigs that only cause a mild respiratory disease.

For more information:

- SANCO/6211/2009 Rev.7 Working document on Surveillance/monitoring and control measures for the pandemic (H1N1) 2009 influenza virus in pigs.

NOTES

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