

ORIGINAL ARTICLE

The contemporary governance of food safety: taking stock and looking ahead

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Abstract

The food safety sector has grown extensively during the last two decades. Both in Europe and in the United States, we can observe a surge of regulatory activity on the one hand, and institutional proliferation accompanied by technological expertise for the purpose of monitoring, on the other hand. At the same time, mechanisms have been installed to allow a faster and more effective reaction to food-related infection outbreaks. Where do we stand today with respect to food safety regulation? And what are the main challenges faced for the future? This is the question addressed by this article. We first consider the European food safety legislative system, as this has emerged over the last years. The European system represents the first comprehensive food safety regulation framework that is tailored to modern challenges. The second section considers the governance structures operating at national and international levels as well as in the private sector for dealing with food safety. The third section compares the different approaches to food safety in two key sub-sectors, namely chemical contamination and microbiological safety. Based on this analysis, we outline in the concluding section the main challenges facing the food safety sector in the future.

European food safety law – a first comprehensive framework

The current European food safety policy regime dates back to the Green Paper on the 'General Principles of Food Law' (COM 97, 176) from 1997 and the subsequent consultation with relevant stakeholders. The 1997 Green Paper and the follow-up White Paper on Food Safety (COM, 99, 719) were elaborated in the midst of the BSE crisis. The latter led to a major inquiry on BSE and government failure in the United Kingdom as well as the re-formulation of food policy at EU level, away from the earlier emphasis on productivity and trade to a focus on public health and animal welfare.

The White Paper on Food Safety lays down the key principles for governing food law in the EU – these principles were translated into law through the General Food Law, Regulation EC 178/2002:

(a) The implementation of an effective food safety policy is only possible following a comprehensive 'farm to table' approach in food legislation; in other words, legislation

must cover all stages of the food chain (production, processing, retail and consumption), all relevant stakeholders and all levels of government.

(b) Given the dynamics of the internal market hence the cross-boundary character of food consumption, food safety must be addressed at EU level. This means that product and process standards must be harmonized or defined with reference to a common legislative framework.

(c) Considering subsidiarity, the responsibility for control procedures must rest with the Member States or at the regional/local levels in federal systems.

(d) The primary responsibility for food safety lies with the food and feed operators and manufacturers as well as with farmers.

(e) The primary responsibility of food and feed operators and manufacturers must come to bear through the implementation of hygiene and quality control systems at the farm and enterprise levels as well as through the implementation of comprehensive traceability procedures allowing the withdrawal of food or feed products when a risk to health is identified.

(f) The precautionary principle may be applied if necessary, hence it should be possible to withdraw feed and food products from the market if there is evidence that these products are harmful.

The key themes of the White Paper on Food Safety are discussed below.

Governance and regulation

The BSE crisis of the 1990s is widely recognized as representing a major instance of government failure both at the national (UK) and EU levels. Most importantly, it demonstrated the shortcomings of the regulatory framework.

The real problem is not necessarily due to a lack of legal instruments, but the broad disparity in the means to respond to situations in specific sectors, or the multiplicity of actions which need to be triggered in the case where a problem spills over from one sector to another. One of the weakest links in the system is the lack of a clear commitment from all interested parties to give an early warning about potential risk, so that the necessary scientific evaluation and protective measures can be triggered early enough to ensure a proactive rather than reactive response at EU level (White Paper, 2000, p. 22).

There were two main problems: first, the existing supposedly harmonized legislation developed in accordance with scientific evidence was put together as a set of directives. The main weakness of directives (as opposed to regulations) is that these must still be transposed into national law. The implementation was weak and, likewise, the monitoring of this process. As a result, there was extensive variation with respect to food safety standards and related procedures, such as traceability, monitoring and control. The second related problem with food safety legislation before 2000 was that it had the status of secondary legislation next to legislation targeting the removal of barriers to competition and the internal market. This was not alone a problem for the food safety sector, but more generally of all those so-called 'positive integration' sectors, i.e. policy sectors concerned with the setting of standards (limits or restrictions) as opposed to their removal.

The decision to make food safety law an EU priority is reflected in the several pieces of legislation that followed the publication of the White Paper. The White Paper also made it clear that in accordance with the principle of subsidiarity, the responsibility of the implementation of food law had to be shared between European and national institutions. In

practice, this meant that the law would be harmonized at European level, and that European institutions would be in charge of audit and oversight. National institutions, on the other hand, would be in charge of implementation and national controls. Taking a step further, the White Paper proposed the establishment of a European Food Authority to act as a clearing house with respect to risk assessment.¹ The European Food Safety Agency (EFSA) was established in 2002 through the General Food Law 178/2002. It is an autonomous agency. This is meant to safeguard scientific independence.

Food traceability

Traceability is 'the ability to trace any food, feed, food-producing animal or substance that will be used for consumption, through all stages of production, processing and distribution' (Informational material from DG-SANCO). The necessity for traceability was illustrated by the problems that arose with dioxin contamination and BSE in the 1990s that resulted in the massive withdrawal of products from the internal market and, in the case of BSE, the killing of animals.

Traceability was made compulsory through the general food law in 2002. In addition there has since been specific legislation for certain categories of food such as fruit and vegetables, beef, fish, honey, olive oil and GMOs as well as for animals.² Traceability typically involves the labelling of batches of products and/or animals as well as the obligation on behalf of food and feed operators to collect and maintain information on the origin of raw materials and/or other relevant stages of the food production chain.

Labelling

Labels of foodstuffs are meant to provide comprehensive information to consumers on the composition of food products, thus contributing to informed decisions. This is of particular relevance for persons suffering from food-based allergies. An evaluation study commissioned by the European Commission in 2003 (TEEC 2003) identified labelling as an important factor for increasing and maintaining public trust in food, and called for further harmonization in the field.

Understood as a reporting requirement, labelling is closely linked to traceability and contributes to the self-regulation of the food industry. Following this logic, the new regulations about beef labelling – regulations 1760 and 1825 dating from 2000 – require that beef labels indicate place of fattening, slaughtering and cutting and information about

where the animal was born and reared. GMO-labelling is regulated through regulations 1830/2003 and 641/2004, while the labelling of all other foodstuffs is regulated through directives.

Rapid alert system for food and feed (RASFF)

Article 50 of the General Food Law from 2002 established the legal basis for the RASFF. This is run by the EFSA in collaboration with DG-Health and Consumer Affairs and national contact points in each member state. The overall objective of RASFF is to notify the European Commission and Member States about risks to human health arising out of foodstuff products already in the market or in the process of importation. There are three types of notifications:

- Alert notifications are sent when the food or feed presenting the risk is already on the market, thus requiring immediate action. Following an alert, the countries affected are called upon to take steps to withdraw and recall the product affected. Following confidentiality provisions, the name of the companies affected by the alert are not publicly released, but are known to the national authorities.
- Information notifications concern food and feed for which a risk has been identified and measures already taken; thus it is not necessary for other member countries to react or take further action. Typically information notifications concern products rejected at the border.
- Finally, news notifications covers all other types of information distributed among members but being neither an alert nor an information notification.

The RASFF system applies to the EU but also to imports into the EU. The countries of origin of products checked and rejected at the border are notified and asked to deal with the problem. When the problem recurs, the Commission suspends imports.³

In 2006, four out of ten notifications concerned market controls (42%), an equal number (45%) resulted from border controls. Notifications brought forward by companies following own checks amounted to 5%, those resulting from consumer complaints to 4%. Germany, Italy, the United Kingdom and Spain tend to display the largest number of notifications, which is not surprising given their size. In terms of the country of origin of the product, China and Turkey are the most problematic, followed by Iran and the United States and, at a lower level, Germany, Spain, Italy, Brazil and France. The largest number of notifications in 2006 (874) were made for mycotoxins.

Precautionary principle

In accordance with the precautionary principle, the EU and its Member States may impose restrictions on the trade of specific foods in the event of a potential (not actual) risk. The legal basis for the application of this principle is only established in the Treaty of the European Communities with respect to the environment, albeit in rather vague terms. However, it is generally recognized that the precautionary principle applies more generally – that is, also for food – but that it is not sensible for legal reasons (and considering liability implications) to establish it more firmly at the regulatory level within law or at the constitutional level.⁴ The applicability of the precautionary principle was established also at the international level through decisions by the Appellate Body of the World Trade Organization (WTO).⁵

An EC Communication from 2000 (EC 2000/1) outlines the procedures and principles to be followed when invoking the precautionary principle. For the European Commission the precautionary principle is part of risk management and thus of political decision-making. It applies to those cases when scientific uncertainty precludes the full assessment of risk. In this case, the precautionary principle may be invoked but only after the scientific data has been evaluated. Its application should follow the principle of proportionality, meaning that any measures taken must be proportional to the level of protection sought. Moreover, measures must be non-discriminatory, consistent with measures adopted in similar circumstances, and – to the extent possible – balancing costs and benefits.

The preferred application of the precautionary principle is by shifting responsibility for the production of scientific evidence to countries or businesses placing products on the market. This implies that when, for instance, a product is withdrawn from the market through invocation of the precautionary principle, the product remains withdrawn till that time when the production company or country of origin supplies verifiable evidence that it is not dangerous to health. This applies in particular to those substances considered ‘a priori’ hazardous.

Proactive approach through HACCP

HACCP stands for ‘hazard analysis for critical control points’ and delineates a quality control system to be used proactively by the food or feed operator for testing the safety of its products. HACCP builds on the systematic identification and elimination of risks at different points of the food chain. This includes the setting of critical points at which

regular checks are carried out for establishing that certain hazardous limits are not exceeded.⁶

Following the General Food Law from 2002, all European food and feed operators are obliged to apply the HACCP system. In response, several private certification procedures were amended according to HACCP principles.⁷ The UN Food & Agriculture Organization (FAO) has also published numerous HACCP manuals targeting specific commodities and hazards. However, insofar as the HACCP represents a best-practice system, what it implies with respect to specific procedures (like sampling, number of control points, frequency of controls) or analytical methods is open to interpretation. This makes the application of penalties for dissenting operators difficult.

Governance – a multi-level system of parallel structures

The food safety sector is a complex institutional regime comprising risk assessment agencies and monitoring bodies operating at different levels and with approaches that are similar but still distinct. The *effectiveness* of this system is not always warranted. Its justification derives from the larger context of socioeconomic and trade relations in which the food sector is embedded.

EFSA

The EFSA was established in 2002 as an autonomous agency following the decision in the framework of the European food safety law to separate the two tasks of risk management and scientific risk assessment. EFSA took over the task of carrying out and coordinating risk assessment and communication at European level. This was previously carried out by the various scientific committees of DG-SANCO. The Agency is located in Parma, Italy and is governed by a 15-member management board comprising scientists, industry and policy representatives. The scientific work of EFSA is carried out by 10 panels.⁸ Each of the panels may initiate a study on their own or upon request by one of the risk managers at Member State level or the European Commission. The European Commission will almost always ask the EFSA to carry out a scientific assessment when confronted with a request for an authorization of a product or company.

For example, in 2007, the EC asked the Panel on Food Additives (AFC) to evaluate the use of additives in energy drinks. This followed a dispute in France about the distribution of an energy drink of Austrian origin. Another expertise commissioned in 2007 concerned the use of

nanotechnologies in food and feed. In 2008 EFSA was asked to assess the evidence released by the UK Food Safety Agency on the link between food colours and hyperactivity in children.

The current big issue for the panel dealing with contaminants (CONTAM) is that of melamine. In May 2007, the EC asked the panel to evaluate the risks associated with the presence of melamine in food and feed. Melamine is an industrial chemical high in nitrogen that is used in plastics and which was intentionally added to wheat gluten and other protein sources produced in China in order to enhance the latter's protein sources. This, in turn, led to several deaths of pets in the United States. Currently melamine contamination is affecting the Chinese domestic market and specifically milk and eggs. The contaminations are thought to have occurred through the contamination of animal feed.

National food safety regimes⁹

National food safety regimes have followed a similar development to that observed at EU level. Several European countries proceeded to establish a food agency equivalent to the EFSA in the years 1999–2004. The competencies on food safety, control and monitoring continue to remain divided among the ministries of agriculture, health, consumer protection, trade and finances. The dominating position of ministries of agriculture and trade are, however, on the decline.

It is possible to compare the different national approaches in the food safety sector according to the following four criteria: (a) the prevalence of HACCP, (b) the organization of control, (c) the approach to risk assessment, and (d) the overall effectiveness of the national food safety systems.

The degree to which *HACCP* has been implemented varies strongly between member states, between food industry sectors and between types of firms. Most countries have granted flexible grace periods for small enterprises and/or firms operating in specific food sub-sectors. The notable exceptions appear to be Finland and Norway. More generally, HACCP is well established among bigger food operators and, especially multinational companies, and, by default, their suppliers. Industrial standards have here a major role to play.

The enforcement of law requires the effective coordination of control functions and activities at different levels. In the food sector, the *organization of control* remains variable. A distinction can be drawn between those countries that

have accrued the control function to one institution – often the national agency also in charge of risk assessment – and countries where this function remains under the authority of one or several ministries. The former case has been observed in Northern Europe (United Kingdom, Finland, the Netherlands, Belgium, Sweden) as well as Austria. The latter is the case in Southern Europe (France, Italy, Greece) and in Eastern Europe (Hungary, Poland, Bulgaria).¹⁰ Germany stands out as a specific example where the control mechanisms are decentralized in the *Länder*. The choice to place the control-function with a national independent agency is often a signal that food control should be carried out in an integrated manner throughout the food chain. The underlying rationale is that fragmented institutionalization might create overlaps of controls, or in the worst case, lead to the absence of controls due to misunderstandings between different ministries or governmental agencies. The opposite case where the control-function remains under the authority of one or several relevant ministries reflects the historically strong position of sector ministries.

In terms of the country-specific approach to *risk assessment*, three groups of countries stand out. In the United Kingdom, France, Germany, Italy, Greece and Finland, which all experienced BSE-outbreaks on their territory,¹¹ we find a strict institutional separation between risk assessment and risk management. Belgium, the Netherlands and Spain stand out as a group of countries where the separation of functions is less visible. The Netherlands is an example of a case where risk communication is carried out by a third authority. In most other cases, risk communication is part of risk assessment. In Sweden and Austria, which were largely excluded from food-borne scandals on their territory, the separation has been less visible perhaps due to the success of the already established and well-functioning institutional structures before the scandals. Hungary, Poland and Bulgaria are newly acceding member countries to the EU and have all experienced great difficulties in aligning their institutional set-up with that of their neighbours.

Whether the institutional separation between risk assessment and risk management is really the ‘golden path’ is a question that attracts much discussion. The underlying rationale for the division of risk analysis into risk assessment, risk management and risk communication is that this allows to ‘differentiate the scientific process from the political/administrative process’, thus making it possible to provide the public with an ‘independent view about the magnitude of a risk through scientific analysis’ (Dreyer *et al.*, 2006, p.13) and helping restore and strengthen political accountability. In practice, this strict separation of

responsibilities is difficult to maintain given that communication is necessary between the fields. In other words, the provision of a strict separation of responsibilities does not alone suffice to ensure a comprehensive and effective handling of risk.

In all countries, the BSE-crisis represents a turning point with regard to food safety regulation, acting as a driver for change at the global level. Therefore, when measuring the *effectiveness* of the country-specific systems, it is important to do this against the backdrop of the pre-food-scandal institutional set-up. For some countries, particularly those which experienced a number of food scares on their own territories such as the United Kingdom, France and Germany, the prime objective of the institutional reform was to restore consumer confidence. In countries like Sweden restoring consumer trust was not as important. Nevertheless these countries had also to align their legislation to the evolving EU framework. Even though every country continues to display its own approach to the handling of food safety, not least as a result of the ‘culture dependency’ of the food sector (van Waarden, 2006, p. 8) convergence is clearly visibly and quite rapidly progressing.

It is here useful to also consider the situation in the United States. The United States has, in fact, a longer record in the regulation of food safety. The first comprehensive piece of legislation in America was the *Federal Food and Drugs Act* of 1906. This was replaced in 1938 by the *Federal Food, Drug and Cosmetic Act (FFDCA)*. Since that time, implementation rests with the Federal Drug Administration (FDA) and a few other specialized institutions. The Center for Food Safety and Applied Nutrition (CFSAN) is the biggest of the designated FDA centres in charge of risk assessments and as such responsible for the safety of up to 80% of all foods consumed in the United States (Arvanitoyannis *et al.*, 2006).¹² The longer history of food safety regulation in the United States, explains the country’s more consolidated institutional framework around a single powerful organization and its scientific centres. This is only a recent achievement in the EU. On the other hand, the United States is less advanced than the EU with respect to the harmonization of standards and reporting requirements (such as labelling) and it, too, faces implementation deficits due to its federal structure. The governance differences between the U.S and Europe, in conjunction with conflicting trade interests, explain the differences between the two countries in terms of standard setting. These are examined in the fourth section of this article. Before this, we look at the international regulatory framework and the role of the private sector.

WTO framework

The international food policy regime as it relates to trade is defined by two WTO-agreements: the Agreement on the application of sanitary and phytosanitary measures (hereinafter referred to as the SPS agreement) and the agreement on technical barriers to trade (hereinafter referred to as the TBT Agreement).

The SPS agreement

When adopting sanitary and phytosanitary (SPS) measures, each country is entitled to establish an own appropriate level of protection, under the condition that this is 'applied only to the extent necessary to protect human, animal or plant life or health', is based on scientific principles (SPS, Article 2.2), and does not discriminate between members (SPS, Article 2.3), that is, it is not used for protecting domestic markets from international importers. The obligation to base SPS measures on scientific principles obliges members to either base their measures on international standards (SPS, Article 3), or on scientific risk assessment (Articles 5.1, 5.2, and 5.3). While Article 5.1 obliges members to base their measure on an 'appropriate' risk assessment, Article 5.2 explains that available scientific knowledge should be taken into account, and Article 5.3 points to the fact that economic factors should also play a role when carrying out risk assessments. Finally, according to Article 5.5, which is also called the consistency requirement, members must avoid measures that result in discrimination while also ensuring that the measure is 'not more trade-restrictive than required to achieve their appropriate level of protection' (Article 5.6).

If a member chooses to base its SPS measure on international standards, guidelines and recommendations, the SPS agreement recommends three standard-setting reference organizations, also called the 'three sister organisations': in the case of human health this is the Codex Alimentarius Commission (CAC); in the case of animal health it is the World Organization for Animal Health (OIE); and in the case of plant health it is the International Plant Protection Convention (IPPC). Adopting the standards of the WTO reference organizations is not obligatory.

The CAC was established as a subsidiary body by the UN Food and Agriculture Organization (FAO) and World Health Organization (WHO) in 1962. It is today a 'crucial channel' for developing standards and guidelines in the food safety sector (Boutrif, 2003; König, 2006). Standards, guidelines and recommendations are drafted by either Codex committees or coordinating committees. Codex committees are organized as either 'general subject' or 'commodity

committees'.¹³ Decisions are taken by a majority vote, however in cases where the relevant standard is specific to a region, only members from that region are allowed to vote. The EU is a member of the CAC since 2003. Member states are also members (Poli, 2004). A number of NGOs have observer status.

The *World Organization for Animal Health (OIE)* was established in 1924 on the basis of an international agreement as the Office International des Epizooties and enjoys today the status of an intergovernmental organization with 169 members. The OIE is in charge of international standards in the field of animal health. The OIE consists of five regional commissions and four specialist committees on animal health standards, on animal diseases, on aquatic animal health and on biological standards.

The *IPPC* was adopted in 1951 in the framework of the FAO and amended twice (last time: 1997). As of October 2007, it comprises 165 member states. The Convention recognizes member states' autonomous right to adopt phytosanitary measures as long as they are consistent with the Convention's main principles of necessity, technical justification and transparency. The objectives of the Convention are implemented by the Interim Commission on Phytosanitary Measures (ICPM), membership of which is open to all FAO members and its contracting parties.

The technical barriers to trade (TBT) agreement

TBT measures cover technical regulations, standards, and conformity assessment procedures. The difference between SPS and TBT measures is important to keep in mind. Essentially, the TBT Agreement covers all technical regulations, standards and conformity assessment procedures except when these are sanitary or phytosanitary measures. In other words, the *type* of the measure determines whether this falls under the TBT provisions, while its *purpose* establishes whether it is an SPS measure. Food labelling is a measure that relates to both agreements. Whereas the TBT Agreement attends to labels established for reasons other than those intended to protect human, animal or plant health, the SPS Agreement attends to labels intended to protect human, animal or plant health. Examples of SPS measures include standards on contaminants, additives, residue pesticides, toxic substances in food and drinks, food safety certification, processing methods with implications for food safety, but also labelling requirements directly related to food safety. Examples of TBT measures are standards on labelling regarding the composition or quality

of food as well as quality requirements for fresh foods, and volume, shape and appearance of packaging.¹⁴

Standardization agencies

Standards institutes exist in most countries and are in charge of elaborating technical standards and guidelines in various sectors. Today most national standards institutes operate in a coordinated way within the international framework established by ISO and CEN.

The *European Committee for Standardization (CEN)* develops technical standards (EN standards) for analytical methods used for establishing levels of contamination, or methods applied in sampling and analysis. CEN members are the national standardization organizations from 30 European countries. The members have voting rights in the General Assembly responsible for providing national expertise to the technical committees in which decisions for new standards are made. CEN has also associate members from industry-, consumer-, environmental- and worker associations/unions. Associate members have no voting rights.

Once a standard has been adopted by CEN, national members are obliged to implement it and refrain from developing own standards that are in conflict with the CEN standard. At present, in the food domain, seven CEN Technical Committees¹⁵ are responsible for outlining new standards. Recent standards developed by these Committees encompass, among others, a standard on the determination of aflatoxins in peanuts, pistachio and figs (EN 14123:2003) and on the detection of GMOs (EN ISO 21572:2004). Both of these standards are typical horizontal methods applying to all food products. CEN also develops vertical methods applicable to specific types of food (like EN ISO 1735:2004 on milk and milk products – methods of sampling and analysis).

At the international level, the *International Standardization Organization (ISO)* brings together standards institutes from 157 countries from either government or industry (one member per country). It is set up as a non-governmental organization and claims to occupy 'a special position between the public and private sectors'.¹⁶ The ISO has 237 technical committees in charge of elaborating industrial and commercial standards and procedures for accreditation. Members of these technical committees are appointed by the standards institutes from member countries (OECD, 1999). Comprising 53 participating countries, Technical Committee No. 34 is in charge of standardization in the food sector and has till now come up with 717 standards. Principally, ISO standards are developed on the request of an industry sector. The standard is considered adopted after

two-thirds of the members that actively engaged in the standard-development agree and after 75% of all voting members agree. All ISO standards are revised within every five years.¹⁷

Industrial approaches

During the course of the food scandals of the past decade, consumer confidence in food safety declined. This spurred a change in consumer awareness giving a significant impetus to regulation but also industrial reform. Product liability through the much used concept 'due diligence' came to play a major part in the development of food safety and quality standards.¹⁸ In parallel with the issuing of public mandatory standards, a shift towards 'more voluntary forms of governance' emerged (Henson, 2006, p. 6).

A key component of a credible standard is the proof or certification that a firm complies with the requirements laid down in the description of the standard. Certification is a process whereby certification bodies, in many cases private national standards organizations, control the buyers of the standard, and where accreditation bodies, usually government-controlled authorities, control the certification bodies so as to ensure consistency in compliance with the standard. Within Europe, operational transparency and a common interpretation of standards is assured through the European Co-operation for Accreditation (EA).¹⁹ At the international level, several national accreditation bodies are also members of the International Accreditation Forum (IAF)

Public standards can be either mandatory or voluntary. Private standards, on the other hand, are either collective or individual – collective standards are those developed by private standard-setting bodies while individual standards are established at the firm- and/or product-level. Table 1 shows how private standards compare with public standards at national and regional level.

One of the most well known collective standards in the food sector is the *British Retail Consortium (BRC) Global Standard – Food* developed by the trade association BRC and dating back to 1998. The BRC standard builds on the 'due diligence' obligation introduced by the UK Food Safety Act of 1990.²¹ The certification of the BRC is provided through external auditors, who must satisfy the requirements of the ISO standard no. 65. Today, compliance with the BRC Global Standard – Food requires adoption and implementation of the HACCP system. The German/French equivalent of the BRC is the *International Food Standard (IFS)* established by the German and French industries in 2003. Upon launch, the IFS was most commonly used in France and

Table 1 Selection of public and private food safety and quality standards²⁰

	Public standards		Private standards	
	Public mandatory	Voluntary consensus	Collective	Individual
Scope				
National	National legislation	Standards developed by national standards institutes	BRC Global Standard – Food	Carrefour Filière Qualité Tesco's finest brand
Regional	EU regulations		IFS	
International		ISO 22000	Global gap	

IFS, International Food Standard; BRC, British Retail Consortium.

Germany but, in the meantime, it has gained foothold also in Italy, Poland and Spain, (Food Manufacture, 2005). To ensure uniform auditing, certification agencies are required to be in conformity with the CEN Standard EN 45011. Collective standard schemes are meant to serve as a guarantee for retailers that their suppliers conform to certain safety, hygiene, and production requirements (DG JRC IPTS, 2005). The impact of these 'retailer brands' from downstream to upstream has been significant. This is especially true in the United Kingdom where both exporters and importers conform to the BRC.

While the BRC and IFS share many commonalities, they both lack recognition on a pan-European scale.²² In contrast, *GLOBALGAP* (former EUREPGAP) has a more international scope but it is primarily 'a pre-farm gate standard' as compared to the BRC and IFS standards which target packing and processing facilities (WTO, 2007). A private standard with possibly greater international scope is the *ISO 22000* launched in 2005. This is a food safety management system incorporating elements of the HACCP system to cover the whole spectrum of the food supply chain in the sense that it is applicable to all food suppliers and producers but also to producers of machines and wrapping. The *ISO 22000* provides companies with an integrated tool to implement risk analyses and critical control points throughout the whole supply chain. In addition to *ISO 22000:2005*, a new standard *ISO/TS 22003:2007* has been launched laying down the requirements for bodies providing audit and certification of food safety management systems like *ISO 22000:2005*. The emergence of the *ISO 22000* has contributed to the hope for an international standard with a wide application and operation in the food supply chain.

Recently, there have been discussions at WTO level about the consequences of industrial standards on developing countries' access to exporting markets.²³ In legal terms, private standards are not mandatory, but several private standards have become the norm in specific industries. Developing countries fear that without compliance with

these private standards their farmers will eventually be excluded from global supply chains (UNCTAD, 2007). The tightening of both public and private standards and the implications of this for developing countries is one of the major challenges for the future of the food safety sector.

Parallel processes of convergence and divergence

Understanding the contemporary food safety regime in Europe, the United States and internationally is a complex task that must consider history, the socioeconomic context as well as institutional practices. In combination, these factors give rise to differences in safety standards. These differences impact, in turn, on trade relations and competition as well as on public health. However, the differences in terms of food safety standards do not only reflect non-technical barriers to trade instituted intentionally or unintentionally within the competitive environment. They are often also based on different risk assessment approaches and a different philosophy regarding the role of the state (and regulation) with respect to safety. The two cases presented below illustrate these underlying differences. The first relates to chemical contaminants, the second to microbiological safety.²⁴

Chemical contaminants

The chemical contamination of food has been recognized as a worldwide public health concern as well as a principal cause of international trade disagreements.²⁵ The chemical safety of food covers several kinds of hazards. Chemical substances in food products can be present in food in different forms: *unintentionally* through contamination either by contact with materials used for packaging (plastic) or food processing (machines, cutlery); or by *pollutants* present in the environment under specific conditions; as *residues* of veterinary medical products in food producing animals or pesticides in plants; or *intentionally* as food

additives (in order to prolong shelf life or for improving appearance or taste as colours and flavourings).

The regulation of contaminants is dealt with differently in the United States and the EU. In line with the precautionary principle, the EU has approached the problem of chemical contaminants through the so-called ALARA principle. *ALARA stands for 'as low as reasonably achievable'*. This assumes that harmful effects may occur at very low levels of contamination. Therefore, the ALARA principle is closely connected to the precautionary principle in the sense that both principles emphasize that even low harmful levels or threats should be a motivator for regulators to prevent a substance from being marketed. In contrast, the United States follows instead the *risk-benefit analysis approach*. In some cases, this has led to an increase in permitted tolerance levels due to the cost burden of removing crops (Post, 2006). Consequently, rather than prescribing maximum acceptable levels of contamination, the FDA lays down so-called action levels in the form of ranges (FDA, 2000). The Codex seeks a reconciliation between the two approaches. Thus, while in theory it favours limits which are 'as low as reasonably achievable', it recommends a toxicological risk assessment and the adoption of higher rather than lower levels (Post, 2006).²⁶

To illustrate the impact of these three different approaches on the setting of maximum levels on chemical contaminants, Table 2 displays the maximum and action levels for aflatoxins in different kinds of nuts in the EU, United States and Codex.

Recently, the European Commission asked EFSA [the Scientific Panel on Contaminants in the Food Chain (CONTAM)] to issue an opinion on the potential impact on consumer health of an increase from the current level of 4 to 8 or 10 µg/kg. The CONTAM Panel found that the potential increase from 4 to 8 µg/kg would have overall minor effects. However, it spoke against a reduction of the standard (through an increase of the maximum levels) with the argument that even though the overall risk of an increase in maximum acceptable levels is minimal, stronger effects can be expected for those population groups with high nut consumption as well as children (EFSA, 2007). At Codex level, the committee in charge (JECFA) recently concluded that there

would be little impact on the dietary exposure of enforcing aflatoxin maximum levels of either 15, 10, 8, or 4 µg/kg.

The aflatoxin case is also a good example of how trade-related concerns influence regulators. As the United States is the world's largest exporter of almonds, the sixth largest exporter of hazelnuts and the second largest exporter of pistachios worldwide, it is not surprising that it took a different stance on the setting of aflatoxin action levels in comparison with the EU, which is among the top of nut-importing countries.²⁷

Microbiological safety of foods

Microbiological hazards is one other area where we can observe differences in approach between the EU, U.S. and the Codex. The EU uses the 'microbiological criterion' approach while the U.S. relies on 'food safety objectives' and 'performance targets'. Both approaches aim at consolidating the HACCP food management system across the food chain. Their difference lies in the extent to which they are prescriptive about individual steps and analytical methodologies.

Before 2006, legislation on microbiological criteria in the EU was laid down in several directives. Following the recommendations of the EFSA Committee on Veterinary Measures (SCVPH), and using the *Codex Principles for the establishment and application of microbiological criteria* (1997), a new legislation was enacted in 2006. This is *Regulation 2073/2005/EC* on microbiological criteria for foodstuffs. *Regulation 2073/2005/EC* distinguishes between 'food safety criteria' and 'process hygiene criteria'. The food safety criterion is mandatory and defines 'the acceptability of a product or a batch of foodstuffs applicable to products ready to be placed on the market'. The process hygiene criterion applies to the production process and is not mandatory. The expectation, of course, is that given the mandatory nature of food safety criteria and assuming an adequate number of controls, process hygiene criteria will be established by default.

The Annex to *Regulation 2073/2005/EC* specifies for several food categories a set of relevant criteria such as the microbiological limits, the analytical reference method, the sampling design and the frequency of sampling. In the majority of cases, the analytical reference method relies on ISO or EN standards. It is worth noting that the analytical methods are *reference* methods, which, in practice, means that food business operators can use other analytical methods, in particular rapid methods, if these are shown to provide equivalent results.²⁸

Table 2 Maximum/action levels for aflatoxin

	EU (µg/kg)	US (µg/kg)	Codex (µg/kg)
Brazil nuts	4	20	–
Pistachios	4	20	–
Peanuts	4	20	15

In the United States, the need to address pathogenic microorganisms in both raw and ready-to-eat products already appeared in the 1980s, and in 1995 the FSIS initiated a proposal on Pathogen Reduction and HACCP (or the so-called 'HACCP Rule'). The HACCP-Rule was based on three parts: first, HACCP was mandated in all federally inspected meat and poultry slaughter and processing plants producing raw ground products; second, 'microbiological food safety objectives' or tolerance levels of hazards were laid down; and third, 'food safety performance standards' were established as a means for the FSIS to verify plants' compliance with the food safety objectives (cf. Billy, 2002). Analytical methods and testing procedures were listed in the Bacteriological Analytical Manual (BAM).²⁹

How the American system works can be illustrated in the case of *Salmonella*. The performance standards for *Salmonella* are based on the national prevalence of *Salmonella* which is determined by baseline data collected by the FSIS.³⁰ The *Salmonella* performance standard for ground turkey can be found in the Code of Federal Regulations (CFR9/§381.94). Here it is stipulated that large federally inspected establishments producing ground turkey must meet the 49.9% performance standard, which is equivalent to a maximum of 29 positive *Salmonella* samples in a 53-sample set.³¹ If more than 29 of the 53 samples are found to be *Salmonella*-positive, official *Salmonella* tests are conducted. If no corrective actions are instituted, the FSIS may suspend inspection. This is tantamount to temporary closure.

The 'food safety objective' was defined by the Codex in 2004 as 'the maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the *appropriate level of protection* (ALOP).³² Because food safety objectives only express concentrations at the point of consumption, the concept of 'performance standard' was developed for other parts of the food chain (Havelaar *et al.*, 2004). The FAO defines a performance standard as 'the frequency and/or concentration of a hazard in a food at any point in the food chain [other than at the moment of consumption] required to achieve a food safety objective'.³³ As such, food safety objectives and performance standards are interlinked in the sense that the performance standard is the means to achieve the food safety objective. The microbiological criterion used instead by the EU is defined by Codex³⁴ as delineating 'the acceptability of a product or a food lot, based on the absence or presence, or number of micro-organisms including parasites, and/or the quantity of their toxins/metabolites per units of mass, volume, area or lot'. One of the main differences between microbiological criteria and food safety objectives/perfor-

mance standards is that a microbiological criterion prescribes a sampling plan and analytical method unlike the food safety objective and performance standard.³⁵

Conclusions

The food safety sector has made tremendous progress during the past decade but it still faces major challenges. This was recently illustrated by the melamine contamination outbreak – first observed in the United States and Canada in relation to pet food imported from China, currently affecting milk, eggs and meat products in China and the neighbouring Asian countries. In many ways the globalization of the food market has brought to light not only the perils associated with trade liberalization under a weak regulatory framework, but also the weaknesses of domestic food markets and monitoring institutions.

On the ground, the biggest challenge today is that of prevention – by overcoming the rather serious implementation deficit in the application of the HACCP system and good agricultural and hygiene practices. Within the EU this is especially a problem for new member states and some of the associated states like Croatia and Turkey. Internationally, least developed countries keen to engage in international trade are often desperately in need of support in the form of capacity building, the transfer of know-how and infrastructural assistance for upgrading their food chains and production processes. The problems faced by the fast developing nations such as China or India are rather more similar to those faced in Europe following the technologically driven increase of agricultural production (at the expense of environmental and food safety concerns) after the end of the Second World War.

At the level of policy (formulation and response), the challenge today is not that of knowing too little; it is rather that of knowing too much. We face the fundamental problem of how to best use information towards the production of knowledge. Our societies have witnessed an information revolution and the term 'knowledge society' has been used to describe them. But the transition from an information society to a knowledge society has still to be fully realized. In this connection, there are three distinct, even if interrelated, problems that deserve attention:

The first concerns uncertainty of scientific evidence. Today, the task of risk management – deciding upon the best or better policy option – is more complicated because the available scientific evidence is often inconclusive given that a lot depends on context and factors external to food chemistry. The extent of scientific uncertainty is quite

common and explains often the different standards between the EU, the United States and Codex Alimentarius about chemical contaminants or microbiological hazards. Indeed, the different approaches between the EU, U.S and Codex reflect differences in terms of the valuation of risks associated with uncertain scientific results. In the competitive context of international trade where food safety standards are often viewed with suspicion as non-tariff trade barriers, and against the background of growing concerns about public health, scientific uncertainty is often politicized both by states and civil society organizations. The implications of this, is that the food safety field has become a contested policy field and is likely to remain so for some time.

The second issue concerns specialization. This too has tended to increase with the increase in information and its diffusion. Specialization, however useful at the technical and scientific levels, is not always helpful for strategic assessments. Information overflow in conjunction with the over-reliance on specialized jargon language also aggravates the task of risk communication and contributes to the spread of disinformation. For all its relevance for citizens' everyday lives, food safety policy and technology speech is extremely non-transparent. Try reading the HACCP principles or specific guidelines (for any product or contaminant) from the perspective of a farmer or a small-size food operator/retailer. The guidelines are even more complicated than the tax declaration documents released by finance offices, yet in terms of contents they are often pretty straightforward and simple.

The third problem and challenge is that of the persisting variation in institutional and monitoring regimes even within nation-states and especially in federal states like the EU and the United States. This problem was recognized as the root of the government failure to deal with the BSE crisis in the United Kingdom and the EU in the 1990s. As discussed, the European Commission adopted a three-fold strategy to deal with this problem of lack of harmonization: first, it reinforced its legislative framework by opting for regulations rather than directives and by clarifying competences between the European and national levels: under the current food safety regime, both risk assessment and risk management are centralized at European level, while member states are entrusted with monitoring; second, it established the EFSA to do away with the extensive fragmentation within the Commission and across nation states in terms of processing scientific evidence; thirdly, it introduced a range of new mechanisms to assist with the monitoring and reaction to crises (such as harmonized traceability rules and the rapid alert system for food and feed). In the United States similar steps are planned with the National Uniformity

for Food Act. Assuming this is eventually enacted, it is expected to provide the means to deal with various outbreaks, such as e.coli in spinach or, more recently, *Salmonella* in tomatoes. This bill was introduced in 2005 and passed the House in 2006. A vote in the Senate never occurred. This is because at the end of each congress session, all resolutions that are not passed are cleared from the books. In order to pass, the bill would have to be reintroduced.

Food safety is one of those sectors which stand to gain from harmonization in terms of standard setting, legislation and monitoring. We are however still far away from achieving this despite the convergence that is obviously taking place within Europe but also world-wide. It will not suffice to alone strengthen the European regulatory framework and its implementation procedures. The ultimate success of the European food safety approach in regulation will depend on the extent to which this forms part of a robust international framework. It is the latter that is currently weak. The first step towards the strengthening of the international framework is better coordination among key players – from the policy to the technical level. But next to coordination activities it is equally important to invest time and resources into the elaboration of transitional arrangements for those countries and/or enterprises, which are unable to meet specific requirements without governmental support. Support in this context means training but also the provision of financial incentives in conjunction with infrastructure and technology upgrading. There is no one instrument that guarantees success in all cases and countries. The precise policy-mix and implementation pathway will have to be defined separately for different commodity groups and countries taking into account economic development, industrial structure and institutional capacity. These are factors that are in some ways 'external' to the food safety regime. But only their inclusion in an integrated manner will ensure long-term sustainable development in the food safety sector.

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Notes

¹The Regulation from 2002 explicitly considers the 'lack of an effective system of collection and analysis at Community level of data on the food supply chain . . . a major shortcoming'

(Preamble, paragraph 49) and provides this as a justification for the establishment of the European Food Safety Agency. A large part of the White Paper is devoted to the question whether this new European Food Authority should be entrusted with the task of risk management besides risk assessment. The White Paper makes a case against mandating this autonomous authority with risk management. Risk management involves legislation and control and as such has to be the task of democratically accountable institutions.

²The Trade Control and Expert System (TRACES) established in 2004 by DG-SANCO allows further the traceability of animals across borders.

³In 2006, the trade was suspended with China for candy using unauthorized colour additives and the use of unauthorized radiation in various food products; with Vietnam for the use of carbon monoxide treatment in tuna and swordfish; with Philippines for the illegal import of various meat products; and with Bangladesh for the use of metabolites in shrimps.

⁴The exception here is France which recently wrote the precautionary principle on its constitution.

⁵The dispute about hormones in bovine meat between the EU, the United States and Canada were instructive in this respect. This case revolved around the ban imposed by the EU in 1988 on the use of hormones in animal growth. The USA and Canada contested this decision and in the absence of a solution in their favour proceeded to impose duties on meat imported from the EU. The case was brought to the WTO. In its first decision in 1997, the WTO declared the bans imposed by the EU as not in conformity with the SPS provisions. The WTO Appellate body to which the EC appealed reversed the decision of the WTO in part and, in doing so, declared the legitimacy of the applicability of the precautionary principle also when the scientific evidence is not complete or quantifiable.

⁶HACCP is based on the following principles: (1) identify any hazards that must be prevented, eliminated or reduced to acceptable levels; (2) identify the critical points at the step or steps at which control is essential to prevent or eliminate a hazard or reduce it to acceptable levels; (3) establish critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards; (4) establish and implement effective monitoring procedures at critical points; (5) establish corrective action when monitoring indicates that a critical control point is not under control; (6) establish procedures to verify that the measures outlined above are complete and working effectively and carry out verification procedures regularly; (7) establish documents and records commensurate with the size of the business to demonstrate the effective application of measures.

⁷See also section on private standards below.

⁸In addition to the 10 panels, there are six 'units' dealing with overarching or cross-sectional issues. These are the 'Pesticide Risk Assessment Peer Review Unit', the 'Animal Diseases Unit', the 'Scientific Cooperation Unit', the 'Data Collection and Exposure Unit', the 'Emerging Risks Unit' and the 'Assessment Methodology Unit'.

⁹The background information used for the analysis reported in this section was compiled with the help of the partners of the MONIQA Network of Excellence. The authors wish to thank the MONIQA partners for their collaboration.

¹⁰This also characterizes trade partners such as Turkey, China, Indonesia and Egypt.

¹¹Besides the United Kingdom, since 1999 cases of BSE have been confirmed in the following countries: Austria, Belgium, Canada, Czech Republic, Denmark, Falkland Islands, France, Finland, Germany, Greece, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, the Netherlands, Oman, Poland, Portugal, Slovakia, Slovenia, Spain, Switzerland and the United States of America (FSA, <http://www.eatwell.gov.uk/healthissues/factsbehindissues/bse/>)

¹²While FDA's responsibilities cover almost the whole food chain, two other regulatory agencies share responsibilities in the field of food safety. Tolerances for pesticide residues in foods is under the authority of the *US Environmental Protection Agency* (EPA), and meat, poultry, and frozen, dried and liquid eggs belong under the authority of the *US Department of Agriculture's* (USDA's) *Food Safety and Inspection Service* (FSIS). The FSIS is responsible for conducting inspections of all meat, poultry and eggs while also being responsible for developing analytical methods for detecting microbiological and chemical contaminants.

¹³Commodity Committees are vertical in the sense that commodity standards lay down specific prescriptions on what constitutes, for instance, processed cheese or olive oils, whereas General Subject committees operate horizontally, drafting standards on food hygiene or labelling (Post, 2006)

¹⁴WTO, http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c1s4p1_e.htm

¹⁵These seven technical committees are: CEN/TC 174, Fruit and vegetable juice, CEN/TC 194, Utensils in contact with food, CEN/TC 275, Food analysis - Horizontal methods, CEN/TC 302, Milk and milk products, CEN/TC 307, Oilseeds, vegetable and animal fats and oils and their by-products, CEN/TC 327, Animal feeding stuffs, CEN/TC 338, Cereals and cereal products

¹⁶ISO, <http://www.iso.org/iso/about.htm>

¹⁷See http://www.iso.org/iso/standards_development/processes_and_procedures/

¹⁸This article deals primarily with food safety standards. In the food quality sector we find a prevalence of private individual labels relating to safety or the origin of products and used as brands and targeting consumer attention. Some – but not all – of these quality labels are explicitly linked to food safety standards through established certification and accreditation procedures. As of yet there does not exist a comprehensive and thorough assessment of the performance of these individual labels with respect to established food safety performance targets.

¹⁹See EA, <http://www.european-accreditation.org/content/ea/EuropNetwork.htm>

²⁰CEN standards have been left out of this comparison table as they are mainly in the analytical field laying down prescriptions on methods of sampling and analysis.

²¹See http://www.brc.org.uk/standards/downloads/food_std_background.pdf, p. 1

²²For retailers, who are present in many different countries, this means that their suppliers are subject to a number of different standards. According to a study carried out by the International Supplier Auditing (ISA), the main differences between BRC and IFS relate to their different approaches to auditing protocols, where critical elements during BRC-audits are determined by the auditor whereas they are pre-determined. See Joppen (2003).

²³The issue was first raised at an SPS Committee meeting on 29–30 June 2005 where Saint Vincent and the Grenadines were concerned about a EurepGAP (now GlobalGAP) scheme and its implications on trade in bananas with supermarkets in the United Kingdom. (WTO – Secretariat of the Committee on Sanitary and Phytosanitary Measures (2007), ‘Private Standards and the SPS Agreement’, G/SPS/GEN/746, p. 1)

²⁴An elaboration of this argument and more examples can be found in Lindner (2007).

²⁵WHO, ‘Chemical Risks in Food’, <http://www.who.int/foodsafety/chem/en/>

²⁶Still the Codex sets specific maximum limits for mycotoxins (aflatoxins (total) in peanuts, aflatoxins M1 in milk, patulin in apple juice), and heavy metals (arsenic, cadmium in various products, lead in various products, mercury in natural mineral waters and salt, methylmercury in fish, and tin in various products). Besides laying down maximum contaminant levels, the Codex standard also prescribes related Codes of Practice for each contaminant/toxin. One Code of Practice which is mentioned for several contaminants/toxins is the *Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)*.

²⁷Against this background, the European Commission recently issued *Decision 2006/504/EC* imposing special import obligations on certain foodstuffs carrying the risk of aflatoxin contamination as a means of protecting consumers. The commodities included in the Decision are: Brazil nuts from Brazil; peanuts from China and Egypt; pistachios from Iran; dried figs, hazelnuts (whole, in powder, or cut), pistachios, dried fruits, and fig- and hazelnut paste from Turkey. The Decision requires that these commodities are imported into the EU only through specific designated points of import listed in Annex II of the Decision. Import is only allowed if the consignment of commodities is accompanied by a health certificate (which is provided for in Annex I of the Decision) signed by specified authorities in the above-mentioned countries as well as the results from sampling and analysis.

²⁸The *Regulation* also lays down a sampling plan for each criterion, however, food business operators may also choose other procedures as long as such sampling and testing schemes provide equivalent guarantees of food safety. The frequency of sampling is not laid down in the Annex but should be decided by the food business operator on a case-by-case basis, however, for foodstuffs of very high microbiological risks, it may be necessary to set ‘harmonised sampling frequencies’ (Note 23).

²⁹FDA – Center for Food Safety and Applied Nutrition, ‘About the Bacteriological Analytical Manual Online’, <http://www.cfsan.fda.gov/~ebam/bam-mm.html>

³⁰For an overview of the microbiological baseline data see: http://www.fsis.usda.gov/Science/Baseline_Data/index.asp

³¹USDA – FSIS ‘HACCP Implementation: First Year *Salmonella* Test Results’, <http://www.fsis.usda.gov/OPHS/salmdata.htm>

³²Codex Alimentarius Commission, 27th Session 2004, Appendix II.

³³FAO (1997), ‘Principles for the establishment and application of microbiological criteria for food’, CAC/GL 21–1997.

³⁴Codex Alimentarius, *The Codex Principles for the establishment and application of microbiological criteria* (1997).

³⁵FAO/WHO (2004) ‘Principles and Guidelines for incorporating quantitative risk assessment in the development of microbiological food hygiene standards guidelines and related texts’, Background paper no. 6, ftp://ftp.fao.org/esn/jemra/kiel_paper5.pdf, p. 6.

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