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Food Safety, Private Standards Schemes and Trade: The Implications of the FDA Food Safety Modernization Act

John Humphrey

Summary

Food safety standards for the production of fruit and vegetables that are developed and administered by private sector actors have become a common requirement for producers and exporters of fresh produce in the past two decades. Instead of relying on inspection after produce has been harvested, preventive controls identify sources of food safety risks and introduce procedures to eliminate them or reduce them to acceptable levels. This approach has been criticised for its reliance on controls over the way food is produced and the use of third-party certification to monitor and enforce compliance. The criticisms frequently imply that public controls over production and trade of fresh produce are less onerous and more science-based. The FDA Food Safety Modernization Act (FSMA), passed by the US Congress in January 2011, adds a new element to the discussion of private standards. In a radical departure from past practice it introduces mandatory on-farm preventive controls on US farms for those categories of fresh produce for which the risks to human health from food borne illness outbreaks are considered substantial. Food imported into the United States must be shown to have been produced to an equivalent level of safety, and the responsibility to verify this is placed on food importers. The use of preventive controls backed up by audit and inspection moves US public regulations much closer to the approach used by private standards developers and adopters.

This paper compares and contrasts the development of private standards in Europe and the approach developed by the FSMA. It uses the framework of different regulatory strategies – performance-based, technology-based and management based – to analyse the regulatory choices made in both cases and their implications for producers and exporters in developing countries. It argues that the adoption of mandatory on-farm controls by the FSMA reflects the seriousness of microbial contamination of fresh produce as a food safety risk and the shortcomings of performance-based regulation. The impacts on exporters will be similar to the impact of private standards. The nature of these impacts will depend, first, upon the choice of on-farm controls by the FDA for domestic production in the United States and the balance between technology-based and management-based regulation. The second factor is how the FDA will determine whether private standards and public regulations in exporting countries provide an equivalent level of safety to that in the US.

Keywords: standards, trade, food, food safety, certification

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List of Acronyms

AFFSA	Agence Française de Sécurité Sanitaire des Aliments
AFS	Assured Food Standards
APS	Assured Produce Scheme
ANSES	Agence Nationale de Sécurité Sanitaire de l'Alimentation, de l'Environnement et du Travail
BRC	British Retail Consortium
BSE	Bovine spongiform encephalopathy
CAC	Codex Alimentarius Commission
CSC	California Strawberry Commission
FDA	Food and Drug Administration (US Federal government)
FDAGA	Food and Drug Administration Globalization Act
FD&CA	Federal Food, Drug, and Cosmetics Act
FSA	Food Safety Act, 1990 (United Kingdom)
FSIS	Food Safety and Inspection Service (of the USDA)
FSLC	Food Safety Leadership Council
FSMA	FDA Food Safety Modernization Act
FSVP	Foreign Supplier Verification Program
GAPs	Good Agricultural Practices
GFSI	Global Food Safety Initiative
GMA	Grocery Manufacturers Association (of the United States)
GMPs	Good Manufacturing Practices
HACCP	Hazard Analysis and Critical Control Point
IFS	International Food Standard
IPPC	International Plant Protection Convention
ISO	International Organization for Standardization
LGMA	California Leafy Green Products Handler Marketing Agreement
MCS	México Calidad Suprema
MPE	Model Plan of Excellence (developed by the Guatemalan Berry Commission)
NLGMA	National Leafy Greens Marketing Agreement
OIE	Organisation Mondiale de la Santé Animale (World Organisation for Animal Health), previously Office International des Epizooties
SAGARPA	Secretaría de Agricultura, Ganadería. Desarrollo Rural, Pesca y Alimentación (Mexico)
SPS	Sanitary and Phytosanitary
SQF Institute	Safe Quality Food Institute (Washington DC)
TBT	Technical Barriers to Trade
UFPA	United Fresh Produce Association (of the United States)
USDA	United States Department of Agriculture
US GAO	United States Government Accountability Office
WTO	World Trade Organization

1 Introduction

In the past three decades, exports of food, and in particular non-traditional agricultural exports, have been one of the success stories for developing countries. Over the 20-year period from 1980 to 2000, developing country exports of fish products and horticultural products (fruit, vegetables and flowers) expanded rapidly. The share of these products in the total value of agricultural trade jumped from 21.6 per cent to 40.9 per cent (World Bank 2005: 2). Nevertheless, alongside this generally positive picture there have been concerns about food safety standards and their capacity to act as non-tariff measures - restraining trade and preventing developing countries taking full advantage of their comparative advantages in the production of such products. Concerns about this issue (and associated issues relating to technical standards for non-food products) led to the inclusion of the Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) agreements within the WTO.

More recently, debates have arisen about the impacts on developing country food producers and exporters of private standards schemes[1] developed by food businesses, business coalitions and private standards setters. In the past 10-15 years, a wide variety of private standards aimed not only at food safety, but also issues such as environmental impact, employment and working and animal welfare, have been developed and adopted. One particular characteristic of Europe, above all Northern Europe, has been the predominance of collective private standards, developed by business coalitions and aimed at securing food safety in complex value chains. These standards have introduced farm-level audits and third party certification as central features of the food safety systems demanded by many supermarkets in Europe.[2]

The potential negative impacts of such standards on food exporters in developing countries have been raised on numerous occasions at the WTO and in the Codex Alimentarius Commission (WTO 2007b; WTO 2007a; Codex Alimentarius Commission 2010; Henson and Humphrey 2009). While government controls over food of animal origin already greatly restrict international trade in such products, low risk foods, which have included fresh produce (fruit and vegetables), have been subject to fewer regulatory controls. There is concern that private standards based on audit and third party certification developed by companies or coalitions of companies increase costs for farmers and rely on complex compliance mechanisms that are difficult for small farmers to meet. Further private food safety standards have been criticised not only for introducing HACCP-based controls on farms and along the value chain, but also for lacking accountability and undermining the legitimacy of public standards (ISO 2010; Fuchs and Kalfagianni 2010). Equally, however, a number of authors have challenged this critical view of private food safety standards, pointing the ways that increased compliance costs may be offset by improvements in farming practices, the role of larger exporters in facilitating small farm access to export markets and the efforts made by the owners of private standards to facilitate market access (Jaffee and Masakure 2005; Jaffee, Henson and Dias Rios 2011; Will 2011).

Up to now, this issue has been characterised predominantly in terms of public regulations versus private standards, with the focus on the adoption of private standards in Europe, particularly food safety standards by European supermarkets. This is because such

[1] This report distinguishes between ‘‘regulations’’, ‘‘standards’’ and ‘‘standards schemes’’. Regulations are controls with legal force adopted by governments. Standards are sets of rules that are not mandatory. Anyone can develop a standard. Organisations (businesses, business associations, etc.) may decide to adopt the standard, but it is not legally binding unless governments create regulations that require the adoption of a particular standard. This paper is concerned with standards schemes: these are standards that have mechanisms for management, monitoring and enforcement. Many of the criticisms of private standards refer to their characteristics as schemes (audit, certification, etc.) rather than the standards themselves. For further discussion of these issues, see Henson and Humphrey (2009).

[2] For a discussion of third party certification, see Hatanaka *et al.* (2005). This issue is discussed further in Section 2.2.

standards have been developed most extensively in Europe,[3] with GLOBALG.A.P. (known prior to 2008 as EUREPGAP) being particularly relevant because it applies to pre-farmgate activities. Many studies have analysed the impact of GLOBALG.A.P. on farmers in developing countries (Graffham, Karehu and MacGregor 2007; Mithöfer, Asfaw, Ehlert, Mausch and Waibel 2007; Maertens and Swinnen 2009 among many others). The issue of certification at the farm level has been seen as a consequence of private standards, with the development of widely adopted industry, or collective standards, being a particular feature of private standards development in Europe.

However, the signing of the FDA Food Safety Modernization Act (FSMA) by President Obama in January 2011 introduces a significant new element into the discussion of developed country food safety standards. The FSMA (United States Congress 2010) mandates the US Food and Drug Administration (FDA) to introduce mandatory rules and procedures to apply to the production and harvesting of fresh fruit and vegetables associated with foodborne illness outbreaks in the Unites States. Such products would, on the basis of recent foodborne illness outbreaks in the United States, be likely to include at least melons, raspberries spinach, lettuce and green onions. These mandatory controls over farm level practices will affect exporters to the United States, as FDA is mandated to establish equivalent levels of safety for imported fresh fruit and vegetables. The mechanisms that will be used to achieve this include obligations on importers to verify that the food safety practices of their overseas suppliers match US requirements. The FSMA specifically refers to the use of audit and third party certification as a means of verifying compliance with its requirements.

In other words, the use of audit and certification at the farm level is not confined to private standards. The FSMA demonstrates that standards and compliance are best understood as involving choices of regulatory strategies in the face of the increasing complexity of food production systems and the perception that consumers face new or increased risks from food that require new forms of control. These choices face both public regulators and private standards designers and implementers.

The analysis begins with a consideration of changing regulatory strategies for food safety in Section 2. Section 3 considers the evolution of public regulation of food safety in Europe and the interrelationships between public regulation and private standards. Section 4 analyses how approaches to food safety have changed in the United States in response to illness outbreaks related to microbial contamination of fresh produce and the likely impact of the FSMA. Section 5 concludes with a discussion of the way the FSMA casts new light on the framing of debates on private standards.

2 Food safety and regulatory strategies

Over the past few decades there has been a change in thinking about food safety. This can be summed up as a shift in the balance of food safety strategies away from reliance on inspection and towards prevention. This is exactly the terminology used by the FDA in its 2007 strategy document: ‘Building safety into products is described in one word: prevention. This shift to an increased emphasis on prevention is at the core of FDA's Food Protection Plan’ (U.S. Food and Drug Administration 2007). Similarly, EU Regulation 178/2002, often referred to as the General Food Law, uses the terminology of ‘risk assessment, risk management, and risk communication’ and the ‘reduction, elimination or avoidance of a risk to health’ (CEC 2002: Preamble, paragraph 17). Such changes are part of a broader trend

[3] See, for example, the special issue of *Food Policy* edited by Henson and Reardon (2005), the extensive survey of private standards in Europe by Aragrande *et al.* (2005) and the report on private standards by Fulponi (2006).

that is not confined to food. They reflect ideas about quality-at-source and quality management, and the development of standards relating to manufacturing production, such as ISO 9000 and its precursors, which can be traced back as far as the 1950s. According to Unnevehr:

> There is growing adoption in the food industry of management practices that focus on prevention and control of food safety hazards. Many hazards are expensive to test for and may enter food products during growing, harvesting, processing and transport. Therefore, documented and verified practices that are designed to prevent or control hazards are becoming accepted as the most cost-effective means of reducing food safety hazards. While testing and verification are essential for establishing good process controls, testing can never be practical as the only means of monitoring safety.
> (Unnevehr 2000: 235)

This shift in perspective is often characterised as a change from product controls to process controls. Product controls are based on inspection of products after they have been produced. Product regulations specify particular characteristics that products must possess (for example, absence of harmful chemicals). Process controls, in contrast, define how products should be made, transported or preserved. The goal is to establish controls, procedures and responsibilities to ensure that the product is produced correctly first time. In food safety, this shift would be the difference between inspecting products at some point along the value chain (when leaving the farm, or after processing) and developing procedures at different points in the value chain designed to identify risks to food safety and introduce mechanisms that either prevent them happening or reduce their occurrence and impact to acceptable levels. This is what the use of HACCP in food processing and the adoption of good agricultural practices (GAPs) are designed to achieve.[4] The further corollary of this process-based approach is that traceability is required so that products can be identified as originating from well-regulated processes.

The distinction between product controls and process controls is widely made (see, for example, Nadvi and Wältring 2004: 56-58) and provides a useful contrast between the two approaches. However, it does not offer a sufficiently strong analytical basis for understanding key choices about the design of regulations and standards. These design choices, it will be argued, substantially affect the way in which regulations and standards impact upon value chains.

This paper employs the analytical framework provided by Coglianese and Lazer (2003) for the discussion of the design of regulatory frameworks (and by extension, private standards, as will be discussed below). Instead of distinguishing two options (product and process controls), they distinguish three approaches to public regulation:

- Performance-based regulation. In this case, the regulatory authority specifies outcomes that must be achieved: for example, that certain food should not contain detectable levels of many pesticides or should be free of microbial contamination. The focus is on achieving particular food safety outcomes and no particular route to achieving these outcomes is ruled in or out. Performance-based regulation need not be restricted to products. Environmental regulations, for example, might establish limits for emissions of chemicals into the environment.
- Technology-based regulation. This form of regulation specifies ‘technologies to be used or steps to be followed’ (Coglianese and Lazer 2003: 694). This name derives from the

[4] The distinction between HACCP and GAPs relates to differences in the extent to which the external environment can be controlled. HACCP is effective in controlled environments where risks become predictable. On farms, where there are more varied risks and less capacity to control them, GAPs form the basis of recommended practices. These are often referred to as HACCP-based.

application of such systems in the pursuit of environmental protection: they mandated particular technologies to be used to achieve particular environmental goals. However, any set of defined rules or procedures or behaviours would fall into this category. Examples would include the requirement for surfaces used in food processing to be made of non-absorbent materials or a rule that specifies a minimum separation distance between fresh produce fields and concentrated animal feeding operations. Such regulations may focus on particular procedures as well as on hard technologies.

- Management-based regulation. According to Coglianese and Lazer, this form of regulation does not specify specific outputs or processes, but rather requires firms to produce 'plans to comply with general criteria designed to promote the targeted social goal' (2003: 694).[5] A requirement for firms to introduce HACCP would be an example of management-based regulation. In this case, the specific outputs, processes and technologies required would be established on the basis of the HACCP process itself.[6]

With respect to the third type of regulation, Coglianese and Lazer (2003: 713-17) provide additional discussion about the ways in which management-based controls might be enforced. Legislation mandating management-based regulation might simply require that a business conduct a risk assessment and develop a food safety plan based upon it. More stringently, the legislation (or the authorities mandated to develop and enforce it) might specify detailed procedures for scenario planning and hazards assessment. The enforcement agency might go a step further and require plans to be filed and/or subjected to detailed appraisal. Finally, the regulatory authority might complement the risk assessment with inspections and specific technology requirements. Each of these choices has implications for how compliance to the regulation is to be achieved.

According to Coglianese and Lazer, the choice of control strategies by the regulatory authority is likely to depend on the likelihood of non-conformance with management-based regulation and the consequences of this non-conformance. As the likelihood of non-conformance increases and as the adverse effects increase, then the more the authority will take steps to assess the rigour and validity of the risk analysis and the implementation of the safety plans resulting from it. As the regulatory authority increases the level of its oversight and also the level of guidance (or instructions) about how management-based controls are to be implemented, then the degree of prescription rises and the gap between management-based regulation and technology-based regulation diminishes.

Coglianese and Lazer discuss the circumstances in which one type of regulation would be more effective than another. This issue, and the extent to which choices about regulatory models might be relevant to current trends in the global agri-food industry, are set out in Table 2.1. The limitations of both performance- and technology-based regulation are exacerbated by increasing internationalisation of agri-food businesses and trade. Inspection becomes less effective and more expensive as more and more food is traded and new risks arise. Equally, specification of particular (hard or soft) technologies becomes less efficient in the face of increasing heterogeneity of production. These same processes also create challenges for management-based regulation, as this relies on the capacity of the governments both to specify appropriate managerial practices with respect to the design of food safety systems and to be able to ensure that such practices are applied effectively in enterprises.

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5 The term 'social goal' indicates that the goal of the regulation is to affect something which has consequences external to the enterprise. If all the costs and benefits of a firm's actions impacted clearly, directly and unambiguously on the firm, there would be no need for regulation.

6 See Appendix 1 for a brief description of the HACCP system.

Table 2.1 Three types of regulation in the food industry

Type of regulation	Most appropriate when	Global agri-food trends
Performance-based	Outcomes are clear and easily measurable	Increasing quantity and diversity of food trade means that inspecting outputs of the food system is increasingly expensive. For certain types of food safety threats, such as microbiological contamination, testing is not very efficient because contamination may be confined to a small part of a batch.
Technology-based	'Most private actors have similar operations and the technology used by these actors tends to be stable over time' (Coglianese and Lazer 2003: 705)	Technological innovation is rapid in the food industry. At the farm level, in particular, environments are heterogeneous and a single technology or process will not work in different economic, social or environmental contexts. Detailed specification of good practices is a good way to eliminate hazards introduced as a consequence of poor practices. It works less well when hazards derive from complex and differing external environments, and it can obstruct the introduction of new and more efficient technologies.
Management-based	Outputs cannot be measured nor appropriate technologies specified	Rapidly increasing agri-food trade means that appropriate management practices have to be identified and enforced across national boundaries. Regulators need to be sure that firms design and implement appropriate systems for food safety.

These discussions of regulatory strategies raise issues of direct concern for both public and private food safety regimes. This can be seen in the approaches taken in the formulation of both Codex Alimentarius Commission (CAC) guidelines and private standards. These formulations, in turn, have consequences for food producers.

2.1 Regulatory strategies in the Codex Alimentarius

Discussions on food safety regulations within the CAC have, in effect, focused on the relative merits of technology- and management-based standards that are linked to particular types of food safety challenges. A paper by Claus Heggum for the Third Australian Food Safety Conference in September 2010 characterises the two types of regulation as 'old' and 'new' approaches to food safety (Heggum 2010). Table 2.2 summarises the distinction between them. The old approach is based on the elimination of hazards through the adoption of specific 'technologies' or procedures. The new approach is based on the ideas of acceptable levels of protection and the validation of processes (of which there may be more than one) to achieve this level of protection.

Table 2.2 Old and new approaches to food safety

Old approach	New approach
Language is 'avoid, minimise or eliminate' hazards	Risk management with validated controls
Unsafe food result of errors, which can be eliminated by control points	Inherent risks in food from endemic pathogens Modelling of problems to achieve acceptable levels of protection.
Inspection/testing at pre-identified, mandated points in the chain Focus on control points rather than final outcome	Reliance on validation of processes Quantified metrics and modelling of risks Metric-driven with quantification of outcomes
Focus on situation at particular points in the chain. Focus on specific procedures. Highly prescriptive	Focus on performance and outcomes Food safety objectives at the end of the chain (acceptable level of protection) Multiple routes to achieving same objective allowed
First-generation HACCP Safety an absolute - yes/no	Second-generation HACCP based on ISO 22000 and derived from CAC dairy code Safety a continuum - more or less
Government responsibility. Government does quantitative risk assessment for food products in general	Industry responsibility. Food business operators design systems appropriate for particular products/plants/processes

Source: Constructed from Heggum (2010).

Equally, however, the Codex discussions on milk hygiene, from which Heggum derives his analysis,[7] can be seen as linking regulatory approaches to different types of risks, along the lines suggested by Coglianese and Lazer. The new approach is particularly relevant for new food safety risks such as endemic pathogens (bacteria and viruses present in the food chain). It is most appropriate for controlled environments, such as food processing establishments, where validation through metrics and modelling can be achieved. The introduction to the Code concludes by stating:

> The Code takes into consideration, to the extent possible, the various product and processing procedures as well as the differing characteristics of milk from various milking animals used by member countries. It focuses on acceptable food safety outcomes achieved through the use of one or more validated food safety control measures, rather than mandating specific processes for individual products. (Codex Alimentarius Commission 2004: 1)

The point is repeated later in the document:

> As is the case with the rest of this code, this section also does not mandate or specify the use of any one set of controls to be used, but leaves it up to those responsible for

[7] Heggum and others argue that the new approach is reflected in the 2004 Codex Alimentarius Commission Code of Hygienic Practice for Milk and Milk Products (Codex Alimentarius Commission 2004).

> assuring the safety of the finished product to choose the most appropriate set of control measures for the particular situation.
> (Codex Alimentarius Commission 2004: 13)

Clearly, the 'new' approach has the characteristics of management-based regulation. Nevertheless, the new approach does not completely supersede the old. The 2004 code of hygienic practice recognises there are situations where preventive controls are valid:

> A distinction can be drawn between the types of control measures used for microbiological hazards and those used for chemical and physical hazards. The control measures used with chemical and physical hazards in food are generally preventive nature, i.e. they focus on avoiding the contamination of food and chemical or physical hazards in the first place rather than reducing or eliminating such hazards once they have been introduced into the product.
> (Codex Alimentarius Commission 2004: 22)

In other words, when risks arise from hazards introduced into the food system by poor practices, it is perfectly legitimate for technology-based regulation to minimise the likelihood of such events happening. The same considerations apply with respect to controls for staff hygiene. The CAC milk hygiene guidelines include statements about how to handle staff with illness, washing of hands and forearms, staff with abrasions, use of water resistant bandages and cleaning of clothing (Appendix 1, section 3.2.4). These types of control, which prescribe particular procedures (hence they are called prescriptive), are typical of technology-based regulation. They suggest a specific set of procedures designed to avoid risks introduced by agri-food businesses themselves because of the way they handle or process food.

These issues were discussed in relation to public regulatory strategies, but many of them also apply to private standards. To the extent that private standards and the standards schemes that enforce them reflect the desire of food businesses to exercise control down the value chain, they face the same challenges as public regulations. Private standards, too, have to face new challenges arising from globalisation and new food safety risks.

2.2 Collective private standards and their impacts on production systems

Private standards have been widely adopted by companies in the EU and enforced along supply chains that stretch out to many different parts of the world. Therefore, it is important to understand how they operate and the choices made on regulatory strategies. These decisions and their consequences for production systems can be clarified by breaking down standards into five distinct processes: design, adoption, implementation, conformity assessment and enforcement.[8]

Standards design. Private standard-setters make decisions about the horizontal scope of the standard – the ranges of issues and which products are covered by the standard – and vertical scope – which parts of the value chain are covered by the standard. Decisions are made about how the standard is to be enforced and the combinations of regulatory strategies (performance-, technology- or management-based regulation) to be used. Some of these design issues are resolved by reference to international norms and guidelines. Both the CAC and the International Organization for Standardization (ISO) provide specific standards and guidelines for standard schemes.

The main purpose of food safety standards is to create systems that operate on farms and in processing establishments to ensure compliance with buyers' requirements. Private standards are more than good practice: they are schemes for ensuring suppliers (farms in

[8] This discussion draws considerably on Henson and Humphrey (2009).

the case of pre-farmgate standards) conform to approved practices in food production and processing. The website of the IFS standard refers to it as 'intended to allow the assessment of suppliers' food safety and quality systems, in accordance with a uniform approach' (IFS 2010). However, standards primarily concerned with food safety may also address broader corporate social responsibility agendas because buyer requirements are not necessarily confined to food safety. Environmental impact and worker welfare are sometimes included, and issues such as community rights and animal welfare may be relevant for some food products.[9]

The choice between technology-based standards and management-based standards has consequences for implementation. Technology-based standards provide an unambiguous basis for conformity assessment and clear guidelines to implementers about what they need to do. They are prescriptive: specific hazards and control points are specified in the design of the standard and should be applicable in all places and for all producers. For this reason, they also run the risk of being inappropriate in heterogeneous environments. Procedures designed in and for one location or one type of farming system may be applied and enforced in another.[10] This problem may be mitigated by the development of national standards benchmarked to international standards (such as the national GAPs benchmarked to GLOBALG.A.P., van der Valk and van der Roest 2008). Second, as will be discussed below, a shift in emphasis from technology-based regulation to management-based regulation – particularly at the farm level – may provide more scope for adjusting implementation of standards to specific circumstances.

Given the importance of standards for how production is organised and the costs of compliance, as well as for protecting brand image, competition develops in standards design. The design, ownership, conformity assessment and enforcement of standards schemes are frequently conducted as business propositions. Businesses compete to establish credible standards that are widely adopted. Equally, food businesses, and particularly farms and food processors, will be affected not only by the broad choices of regulatory strategy, but also by the specific ways in which standards are implemented and assessed. For this reason, different business coalitions will also attempt to create standards in order to gain control over regulatory choices and, in some cases, use the standard as part of a broader branding exercise.

Standards adoption. Private standards only have force when they are adopted by companies. The entities involved in the setting of private standards have no legal or regulatory power to compel implementation of these standards. The power to bring about compliance is wielded by adopters that see value in using the standard. In some cases, adoption of private standards for both primary production and food processing by retailers is an important factor in the spread of private standards. For standards developed by producers, the producer group itself can decide to implement the standard, but ultimately its success depends upon the adoption or recognition of the standard by buyers of food products. The same applies for standards developed by organisations not directly involved in the relevant food value chain. Such standards are prevalent in areas such as sustainability and environmental and social impacts. Examples include the Rainforest Alliance, the Marine Stewardship Council standard, and many others. In addition, governments may also adopt private standards, by accepting them as indicators of food safety.[11]

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9 For example, aquaculture has been associated in some countries with the denial of community rights to resources that have hitherto been publicly available. Some supermarkets might not wish to be associated with such practices.

10 The issue of the application of prescriptive procedures in heterogeneous environments does not arise solely in the context of international standards. It has been one of the main areas of contention in the discussion of good agricultural practices and how they might be enforced in the United States. This issue is discussed further below.

11 See, for example, the discussion of the use of private standards by the Competent Authority for food safety in the Netherlands to identify where checks should be more or less stringent (van der Meulen 2011).

The widespread adoption of private standards by large retailers and processors means that they may become a market entry requirement for some market segments. In the case of Kenya, for example, fresh vegetables were exported predominantly to the UK and the Netherlands in the late 1990s, and the adoption of EUREPGAP by leading UK and Dutch supermarkets meant that the standard was critical for continued export success.

Standards implementation. The private standards discussed in this paper are predominantly technology-based and management-based. In other words, they set out rules for how companies should carry out certain activities. At the farm level, this usually means implementing HACCP-based good agricultural practices designed to eliminate risks. This will involve a combination of attention to production practices (for example, the implementation of integrated pest management to reduce pesticide use), purchases of new equipment (for example, secure storage facilities for crop protection products) and the development of the systems for monitoring and record-keeping that make internal and external audits possible.

Implementation is the area that critics of private standards and their impacts tend to focus on, because of the additional costs and capacity challenges that arise from implementation. These include capital expenditure, new skills, training for workers and investments in management systems. However, other researchers have pointed to the ways in which these increased costs may be offset by reductions in pesticide use and more efficient production techniques. It is also far from clear that the costs associated with private standards are predominantly borne by small farmers at all. Small farmers operating in outgrower schemes may find most of the additional costs are borne by the exporting company (see Humphrey 2008: 65-72).

Conformity assessment. Standards acquire force when their implementation is verified. Management- and technology-based standards define rules and procedures to be followed at certain points in the process. The standard is made effective through further provisions. These include, first, prerequisite schemes, which establish in general terms that the company or the facility has the management systems in place to operate the standard and systems of monitoring compliance to the standards, and second, assessments of conformity. In the many collective private food safety standards, this is achieved through third party certification carried out by independent certification bodies recognised by the owner of the standard. This has become the norm for many private food safety standards. In addition to this, further testing of soil and water may be required, as well as some testing of product. These costs can be considerable. To the extent that certification and testing costs do not increase proportionately to farm size, small farms may be at a considerable disadvantage.

Enforcement. This refers to the actions to be taken in cases of non-compliance with the standard, which may range from implementation and corrective actions to deregistration – withdrawal of the right of the offending establishment to claim that it is certified to the standard. Conformity assessment and enforcement though sanctions and corrective measures are the devices that turn a standard (a series of rules) into a ‘standards scheme’ – a system of effectively enforcing conformance to the rules.

3 Food safety law and the development of private standards in the European Union

This section of the paper is concerned with the link between public regulations, the development of private standards in Europe and the implications for trade in food. EU food safety legislation distinguishes between food of animal and non-animal origin. Controls are extensive for food of animal origin. For production and processing of such food within the EU,

food hygiene regulations, specifically Regulation 853/2004, mandates the use of HACCP in processing establishments and a range of other hygiene measures (CEC 2004c). For imported food of animal origin, there are specific requirements relating to the listing of approved countries, the registration of approved establishments and facilities, advance notice of importation, border inspections, documentation and health identification markings. In addition to this, EU legislation places particular requirements on the food safety authorities of exporting countries (usually referred to as the 'Competent Authority') to demonstrate that effective controls over food establishments exporting food of animal origin to the EU. Regulation 882/2004 refers to exporting establishments being 'the subject of regular and effective controls by the competent authority of the third country' (CEC 2004a: Article 48 para. 4(e)(iv)). Further, companies importing food into the EU should verify that products of animal origin come from approved countries and establishments and have the necessary marks and certificates, and that they comply with animal health requirements.

In contrast, controls over food of non-animal origin – the subject of this paper – are considerably less strict. The general obligations on importers and food business operators remain in force, as summarised by the UK government's guidance notes for food importers:

> It is the responsibility of the importer to ensure that there are sufficient quality controls in place in the country of origin where the product is produced. It is also the importer's responsibility to ensure that the food they import to the UK is fit for human consumption and that no-one will become ill if they eat it.
> http://www.food.gov.uk/foodindustry/imports/imports_advice/

Nevertheless, official controls in the exporting countries are noticeably less stringent for food of non-animal origin, and the EU guidance notes on food imports and the hygiene regulations state that, 'with regard to food of non-animal origin, it is in many cases sufficient that exporting establishments in third countries are known to and accepted as suppliers by importers of food into the community' (European Commission 2006: 10). This position was taken in 2006 even though, for example, regulations concerning food safety and fruit and vegetables had been considerably tightened up in the preceding decade. In this context, the growth of private standards requires some explanation. Why have private controls been developed for production and processing of food of non-animal origin if government controls do not appear to be stringent?

3.1 Food safety and private standards in the UK

The development of private standards in the food industry has been most evident in the United Kingdom. As discussed by Loader and Hobbs (1999), the European Commission introduced a number of directives relevant to food safety in the 1980s and early 1990s. These included the product-liability directive in 1985, a directive concerning the consistency of inspection and standards across member states in 1989 and a directive on food hygiene in 1993 (Loader and Hobbs 1999: 686-87). When the European Commission issues a directive, EU Member States are obliged to introduce legislation to put it into effect. The UK Food Safety Act (FSA) in 1990 and the General Hygiene Act (1995) met this obligation in a way that promoted a specific private sector response. The FSA (and, subsequently, the EU's General Food Law of 2002) did not mandate particular policies or procedures to achieve food safety. It did not even mandate implementation of HACCP systems. Instead, it placed a significant burden of responsibility on food business operators to supply safe food. The FSA:

> extended legal liability for the safety and standards of food to all downstream firms in the food chain, regardless of where the food safety problem originated. This meant that the food retailer could be held liable for selling food that was tainted by the actions of an upstream food manufacturer if the retailer could not show that they had

> taken all reasonable precautions, i.e. exercised due diligence.
> (Loader and Hobbs 1999: 687-88)

The introduction of the due diligence requirement was a significant change. Prior to the 1990 Act:

> food legislation contained the so-called 'warranty' defence. A person accused of an offence would escape conviction if he could prove that, when he bought the product, he obtained a written warranty from his supplier that the product could be lawfully sold or dealt with; that there was no reason to believe, when the offence was committed, that the true position was otherwise, and that the product was in the same state as when he bought it.
> (Humber Authorities Food Liaison Group n.d.: 4-5)

The 1990 Act removed this defence, putting food business operators under 'strict liability' to sell safe food: in other words, they could be held responsible for selling unsafe food irrespective of how the food became unsafe. However, the Act allowed one defence for food business operators: they would not be found to have committed an offence if they could show that they had exercised ‘due diligence’ in ensuring that the supply chain was delivering safe food. Section 21 of the Food Safety Act makes this clear:

> In any proceedings for an offence under any of the preceding provisions of this Part... it shall... be a defence for the person charged to prove that he took all reasonable precautions and exercised all due diligence to avoid the commission of the offence by himself or by a person under his control.
> (UK Government 1990: Section 21, para. 1)

Paragraph 3 of the same section refers to ‘carrying all such checks on the food in question as were reasonable in all the circumstances, or that it was reasonable in all the circumstances for him to rely on checks carried out by the person who supplied the food to him.’

In response to this challenge, some UK food retailers increased monitoring of their supply chains. Supply chain management as a form of brand defence continues to be a widely used approach. In some cases, companies have backed up their supply chain management practices with inspection and third-party certification to a company-developed standard (Swoffer 2005: 26). The Nature's Choice scheme developed by Tesco is one example. The real innovation in the UK and the Netherlands in the 1990s was to collectivise these concerns about supply chain management through **collective** private standards that could be developed, adopted and enforced by and for multiple companies. These could complement or substitute for both company-level supply chain supervision and single-company standards schemes. The collective private standards introduced in the late 1990s enabled retailers to simplify their control procedures, establish proper procedures for accreditation and certification in line with international norms, outsource some monitoring and control processes, pass on much of the burden of compliance to suppliers and, most importantly, demonstrate due diligence.

In the late 1990s, three different private standards were developed in the UK:

- In 1996, a working group consisting of retailers, inspection bodies, trade bodies and the UK accreditation service began work on the British Retail Consortium (BRC) standard for food processing plants, and the first edition of the standard was produced in 1998 (Swoffer 2005: 27). The standard was, according to Swoffer, developed by retailers in order to govern autonomous processing plants that manufactured their own-label products.

- In 1997, the Assured Produce Scheme (APS) for horticulture was implemented (Kirk-Wilson 2002). This was a specific standards scheme developed for British farming. In 2000, a multi-stakeholder initiative that included various farmer organisations and the British Retail Consortium developed the Assured Food Standards (AFS) family of standards that operate under the 'Red Tractor' logo. This family of schemes provides farm-level controls for a range of products, including cereals, fruit and vegetables, beef, lamb, poultry and dairy.
- In 1997, large European food retailers, supermarkets, produced the EUREPGAP standard, discussed in Section 3.3.

The owner the first of these standards, the BRC, introduced auditable food safety controls into food processing plants. It was, and continues to be, based on HACCP principles. In fact, the requirements of the BRC Global Standard are closely aligned with the Codex standards on food safety and processing plants, and are very similar to many other certification schemes used in processing plants.[12]

The BRC was very clear about the standard's relation to the legal obligations imposed by the 1990 Food Safety Act:

> In 1998 the British Retail Consortium (BRC), responding to industry needs, developed and introduced the BRC Food Technical Standard to be used to evaluate manufacturers of retailers own brand food products. ***It is designed to assist retailers and brand owners to produce food products of consistent safety and quality and assist with their 'due diligence' defence, should they be subject to a prosecution by the enforcement authorities***. Under EU food Law, retailers and brand owners have a legal responsibility for their brands.
> (British Retail Consortium website, http://www.brcglobalstandards.com/globalstandards/GlobalStandards/About.aspx, emphasis added)

The BRC was also clear about the function of the standard as a means of facilitating control over the food value chain:

> Certification to a Global Standard, which is achieved through audit by a third party Certification Bodies [sic], reassures retailers and branded manufacturers of the capability and competence of the supplier, and reduces the need for retailers and manufacturers to carry out their own audits, thereby reducing the administrative burden on both the supplier and the customer.
> (British Retail Consortium, website, http://www.brcglobalstandards.com/Conference.aspx)

This reference to audit and certification is particularly important. A standard on its own is a set of rules. As Brunsson and Jacobsson (2000) have observed, anyone can create a standard. The critical point is that the standards schemes developed at this time combined the standard with mechanisms for implementation, monitoring and enforcement. Audit and third-party certification are essential features of these mechanisms. Through them, vigilance is maintained over food value chains.

The second of the three schemes mentioned above, the APS, was developed to address a second challenge facing the UK food industry – declining consumer confidence in the safety of British food. The 'Red Tractor' standards were specifically designed to restore the confidence of ***British*** consumers in ***British*** produce – identified by the scheme's Union Jack

[12] A comparison between the standards adopted by nine certification schemes the food processing plants and the Codex general principles of food hygiene showed that five of the schemes adopted all 37 of the Codex requirements, five adopted 36, and one 34 (Murray 2009).

logo – as well as to bring some rationalisation and greater clarity to the proliferating number of standards and schemes:[13]

> AFS and the Red Tractor mark were set up to help harmonise the approach to standard setting and inspection throughout the supply chain and to give the public a mark of quality, safe, affordable food that they could recognise and trust. (http://www.redtractor.org.uk/site/REDT/Templates/GeneralWho.aspx?pageid=21&cc=GB#established)

The AFS schemes extend the idea of monitoring and some third-party certification bodies from food processing plants (as in the case of the BRC standard) to the farm level. The same principles of risk assessment, preventive measures, monitoring and audit by third parties are applied to the farm practices. Coverage of these schemes became very broad, as can be seen in Table 3.1.

Table 3.1 UK coverage of Red Tractor schemes

Red Tractor Farm Assurance Scheme	Approximate Coverage
Fresh Produce	67%
Dairy	95%
Pigs	90%
Poultry	95%
Beef and Lamb	65%

Source: Kirk-Wilson (2008: 15).

The third of the standards listed above, the EUREPGAP standard, was developed by UK and Dutch supermarkets. It was specifically designed to introduce controls on the production and harvesting of fresh produce imported by adopting companies (the UK and Dutch supermarkets). In many respects, EUREPGAP applied the same principles used in the APS to suppliers in other countries.[14] Having the legal responsibility to provide safe food and facing a legal liability and damage to brand reputation if they failed to meet this responsibility, food businesses created standards schemes designed to increase the safety of the food they sold and reduce their risk exposure. The strategy to achieve this goal at the farm level was technology-based regulation. In the first decade of its existence, EUREPGAP adopted a prescriptive approach that instructed farmers to adopt particular methods to control the risks associated with fresh produce production, as will be discussed below. Given the dominant role of UK supermarkets in fresh produce imports, this approach to food safety was implemented extensively in sub-Saharan Africa, Southeast Asia and Latin America.

These responses from food processors, retailers, and farmers in the UK were not determined by the Food Safety Act itself. This prescribed no particular routes to securing food safety. This remains the case across the EU. The UK and other member states approve a large number of hygiene guides – both generic and product specific – which identify good practices that, if followed, would ensure compliance with the law, but companies are free to develop their own food safety plans (Appelhof and van den Heuvel 2011: 114). The legal requirement is only that there should be a food safety plan: the state regulatory strategy continues to be management-based regulation. In response to this however, and in order to maintain control

[13] See http://www.redtractor.org.uk/site/REDT/Templates/GeneralWho.aspx?pageid=14&cc=GB.
[14] There are close similarities between the APS and EUREPGAP, although the former is not benchmarked to the latter.

along the supply chain, private standards in the UK adopted technology-based regulation. They prescribe particular rules and regulations that are designed to produce a desired outcome – food that is safe, or at least food produced and processed with a degree of oversight that meets the requirement of exercising 'due diligence'. Had the suppliers taken the route of management-based regulation – obliging their suppliers to develop adequate food safety plans, they would still have had to introduce a means of verifying the design and implementation of these plans.

3.2 EU law and the development of private standards

One of the most notable features of private standards development in Europe has been its ***lack*** of uniformity. It appears to be strongest in northern Europe, but much weaker in southern Europe and weaker still in the new accession states in Eastern Europe. Analysts have generally attributed this to different patterns of retail concentration and retail strategies. Food retailers, particularly supermarkets, are more likely to adopt private standards when two conditions are satisfied. The first is that the retailers have sufficient market power to be able to impose private standards as a condition of access. In other words, supermarkets have to be able to act as gatekeepers to consumers. This gives them the power to demand the conformance with standards schemes that suppliers may find onerous. This power is closely linked to retail concentration.

The second condition is that the benefits of adoption exceed the costs of introducing such schemes. The adoption of private standards in food processing is associated with the development of supermarkets' own brands (usually referred to as private label or own label). With the increasing prevalence of own label produce in supermarkets (again, particularly in northern Europe, see Dobson Consulting 1999: 50), the retailers became the repositories of customer confidence in the safety and quality of food. To the extent that companies offered themselves and their brands as the basis of consumer trust, they gained consumer loyalty and became the gatekeepers to these consumers. As a result, maintaining brand reputation was essential, and exercising controls along the value chain was a means of doing this. The implementation of HACCP-based standards along the value chain provided both a due diligence defence in the context of the 1990 Food Safety Act and a degree of brand protection. Industry concentration provided both the motive for this strategy (defence of brands) and the market power to require suppliers to comply with the standards.[15] For the supermarkets, legal obligations and brand protection made some form of supply chain controls necessary, and the key issues were how to do this effectively while keeping their costs in check.

If these factors alone were sufficient to explain the development of private standards, one might expect differences to persist across the European Union. Convergence of national retail systems is likely to take place very slowly, if at all. However, the past 10-15 years have also seen a considerable transformation in EU food safety legislation and the implementation of new regulations designed to ensure equivalence of food safety practice across member states. To what extent do these changes promote a more widespread adoption of private standards across the EU?

In the course of the 1990s there was a substantial shift in the stance taken by food safety authorities in the European Union towards food safety and how it should be achieved. This was reflected in the 1997 Green Paper on the general principles of food law and in the White Paper on Food Safety, published in 2000. The latter not only proposed the establishment of the European Food Safety Authority, but also proposed 'a wide range of other measures to improve and bring coherence to the corpus of legislation covering all aspects of food

[15] The role of brands in the development of standards is discussed by Graz and Nölke (2008) and by Mayer and Gereffi (2010).

products from “farm to table”’ (CEC 2000b: 3). In the following five years, not only was the European food safety authority itself established, but a broad range of legislation (discussed below) was introduced.

Table 3.2 Summary of significant European food scares, 1988-1999

Year	Microbial	Contaminants	Animal diseases
1988	Salmonella in eggs (UK)		
1989	Listeria (UK) Salmonella (UK) Botulism (UK)	Alar (pesticide)	BSE (UK)
1990		Benzene in bottled water (EU)	
1992	Listeria (France)		
1995	Campylobacter (UK) E. coli (Sweden)		
1996	E. coli (Sweden and UK)		CJD deaths in the UK
1998	Salmonella (Germany) Salmonella (France) Botulism (Italy France UK Norway)		
1999	Salmonella (France) Listeria (France)	Dioxins in animal feed (EU)	

Source: Knowles *et al.* (2007: 46)

The catalyst for this reform process was, undoubtedly, the repeated food safety scares in the EU in the 1990s. Knowles *et al.* (2007: 46) list a series of significant food safety issues in the European Union running from 1988 through to 1999, as shown in Table 3.2. The BSE crisis, in particular, is widely considered to have led to the EU White Paper on food safety and the subsequent establishment of the European Food Safety Authority (Caduff and Bernauer 2006: 153-7).[16] As Vogel notes:

> While both the Commission and its scientific advisory body eventually re-certified British beef as safe for human consumption, the EU's failure to recognise its health hazards severely undermined public trust in EU food safety regulations and the scientific expertise on which they were based. To date, approximately one hundred Europeans have died from BSE. Though this number is far lower than had been earlier feared, as one British scholar put it, ‘the BSE scandal represents the biggest failure in UK public policy since the 1956 Suez crisis’.
> (Vogel 2003: 17)

Vogel argues that this was more than a crisis of food safety. It was a crisis of European food safety regulation in the context of the single market. European integration meant that food should travel freely across national boundaries within the EU, but consumer confidence in

[16] See also, Vincent (2004).

food safety in Member States was undermined by the scandals. Furthermore, the BSE scandal pointed to shortcomings in decision-making processes within the EU and the balance of responsibility between the Commission and the Member States. It highlighted the need to reformulate the EU's basic approach to food safety: 'In face of the crisis the EU initiates crucial reforms in the field of risk regulation in order to restructure the whole system of food safety regulation drawing the consequences [sic] of the failure of early warning systems, of insufficient risk management procedures, and of insufficient capacities to estimate the development of potential dangers' (Janning 2008: 71).

The food scandals eventually led to a tightening up of national regulations and food safety institutions in various European countries. The Belgian government created the Federal Agency for the Security of the Food Chain, the French the Agence Française de Sécurité Sanitaire des Aliments (AFFSA),[17] and the British the Food Standards Agency. In Germany, consumer protection was made a more explicit responsibility of the Ministry of Agriculture and Forestry (Knowles *et al.* 2007: 56).

However, the European Commission needed to develop an EU-wide response in order to sustain the continuing development of the single market. The 2000 White Paper resulted in Regulation 178/2002, also known as the General Food Law, which set out the general principles of European food law and established the European Food Safety Authority. It defined the challenge as follows:

> There are important differences in relation to concepts, principles and procedures between the food laws of the Member States. When Member States adopt measures governing food, these differences may impede the free movement of food, create unequal conditions of competition, and may thereby directly affect the functioning of the internal market.
> (CEC 2002: Preamble, para. 20)

Existing legislation had to be harmonised and rationalised. Seventeen EC Directives relating to food hygiene were eventually repealed in January 2006 after the creation of a series of new regulations. The shift in instruments itself is significant. Directives can be interpreted by Member States and incorporated into domestic law, allowing for variation. Regulations have to be applied directly, without any interpretation or adaptation (although enforcement is shaped by the differing national legal systems).

The guiding philosophy for the new system was set out in the 2002 General Food Law which identifies key principles:

1. Food safety is to be ensured by focusing on the food value chain as a whole: 'In order to ensure the safety of food, it is necessary to consider all aspects of the food production chain as a continuum from and including primary production and production of animal feed up to and including sale or supply of food to the consumer because each element may have a potential impact on food safety' (CEC 2002, preamble, para 12).
2. Food safety is based upon the principle of containing risk. Elimination or avoidance of risks to health requires risk assessment, risk management and risk communication (paragraph 17). The HACCP methodology is central to this.
3. The precautionary principle is established as part of food law: 'In those specific circumstances where a risk to life or health exists but scientific uncertainty persists, the precautionary principle provides a mechanism for determining risk management measures or other actions in order to ensure the high level of health protection chosen in the Community' (paragraph 21).

[17] In 2010 AFFSA was integrated into a broader agency focusing on the safety of food, the environment and work, the Agence Nationale de Sécurité Sanitaire de l'Alimentation, de l'Environnement et du Travail (ANSES).

4. Traceability. Control of risk and rectification of problems requires traceability. This is secured through identification of suppliers and customers for all products incorporated into food or feed (paragraph 29). This in turn requires record-keeping and labelling (article 18, paragraphs 1 and 2), so that information can be supplied to the authorities on demand.
5. Private sector responsibility. Paragraph 30 of the preamble to the General Food Law legislation states that: 'A food business operator is best placed to devise a safe system for supplying food and ensuring that the food it supplies is safe; thus, it should have primary legal responsibility for ensuring food safety' (CEC 2002). Furthermore, 'feed and food business operators at all stages of production, processing and distribution within the businesses under their control are responsible for ensuring that feed and food satisfy the requirements of feed and food law which are relevant to their activities' (CEC 2004a: preamble, para. 4). The precise impact of this legislation varies from country to country, as this liability is implemented in particular EU countries and depends upon national legal orders.

The emphasis on the primary legal responsibility of food business operators does not mean that the governments withdraw from food safety. As Graffham (2006b: 6) notes, public authorities have an important role to play. Food businesses are responsible for running their establishments and ensuring that food is safe. This responsibility extends to taking reasonable steps to ensure that the inputs they purchase are safe. Governments – or more specifically the Competent Authorities responsible for food safety – have the task of approving and registering food establishments where necessary and 'establishing control systems and verifying compliance with food law and food hygiene' (2006b: 6). Unusually for the EU, the Commission (through the Food and Veterinary Office of DG Sanco) has the power to check to see that governments are meeting these responsibilities effectively.

The General Food Law was followed by further regulations:

- Regulation EC/882/2004: feed and food law, animal health and animal welfare rules. This replaces and rationalises various directives (CEC 2004a). This sets out official control mechanisms to ensure compliance with rules concerning food, feed, and animal health and welfare.
- Regulation (EC) No 852/2004, which sets out general hygiene requirements for all food business operators. The Regulation couches food hygiene objectives in general terms, allowing food business operators the option to implement as they see fit. For example, the law states that 'Food business operators producing or harvesting plant products are to take adequate measures, as appropriate... to ensure, where necessary, hygienic production, transport and storage conditions for, and the cleanliness of plant products' (CEC 2004b: Annex II, chapter 1, para. 2d). HACCP principles are specified, but not for primary producers.
- Regulation (EC) No 853/2004 complements 852/2004 by setting out specific rules relating to hygiene requirements for food of animal origin.
- Regulation (EC) No 854/2004 specifies the official controls to be implemented by governments to ensure that establishments are meeting the legal requirements for production and processing of food of animal origin.

In addition to this, in the case of horticulture, regulations concerning pesticide residues were considerably tightened in the 1990s and early part of the twenty-first century. Directive 2000/24/EC tightened up requirements (CEC 2000a), and legislation in 2005 harmonised standards across the EU (CEC 2005). Private standards offered a way of meeting these stricter regulations. EUREPGAP (rebranded as GLOBALG.A.P. in 2008) had developed on-farm practices and procedures backed up by certification to impose controls relating to pesticide application, farm hygiene, etc.

The link between EU legislation and private standards is made more plausible by the steady development and adoption of private standards in the early part of the twenty-first century. In the last decade private standards have been developed in more European countries. French and German retailers developed The International Food Standard (IFS). The IFS website provides another clear statement of the role of rationalisation in the development of collective private standards, referring to increasing consumer demands, legal requirements and globalisation as the motivation for developing a quality and food safety standard applying to post-farm gate processing (IFS 2010).[18]

Similarly, the widespread adoption of the GLOBALG.A.P. standard by German retailers after 2005 does not appear to be directly attributable to legislative changes. It was much more about brand protection and consumer confidence. German retailers were late adopters of private standards at the farm level, but there was a radical change in policy following an exposé by Greenpeace of pesticide residue levels in fruit and vegetables in 2005:

> The main drivers of the implementation of GLOBALG.A.P. in Germany were publications by Greenpeace revealing pesticide residues levels on fresh fruit and vegetables which exceeded the permitted MRLs [maximum residue levels]. The first of these reports was published in 2005. Out of 658 samples purchased from different retailers in Germany, Austria and Switzerland, 163 samples (25 per cent) were classified as non-recommendable and out of these 100 samples (15 per cent of the total) even reached or exceeded the permitted MRLs.
> (Rodman 2008: 33)

The challenge for German supermarkets was not only that they appeared to be supplying customers with food that was dangerous – a conclusion that customers would be likely to make, given that Greenpeace's findings suggested that the some fresh fruits and vegetables on offer exceeded the maximum residue levels set down by the EU – but also that the Greenpeace report, and its follow-up in 2007, ranked supermarkets from good to bad. Supermarkets risked losing market share if customers felt that some of their competitors were safer. The response of German supermarkets to this bad publicity was to revise value chain practices. By 2007, all of the major German supermarkets had become members of GLOBALG.A.P. (Rodman 2008: 35). In parallel with this, they also competed with each other on the basis of reducing pesticide residues below the EU legal requirements.

There is not an unambiguous link between EU legislation and private standards development. The European Commission has been at pains to emphasise that much of this legislation merely harmonises previous legislation across the EU, and it has been seen that major changes in UK food law and practice predated these changes by some considerable time. Nevertheless, the link between the proliferation of private food safety standards and their wider adoption across some EU states and EU legislation needs further attention.

The direct implications of EU food safety law arise from the overall responsibilities of governments and food business operators not to place unsafe food onto the market. This responsibility also extends to imported food:

> Food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein.
> (CEC 2002: Article 11)

[18] Around the same time, a further standard, Qualität und Sicherheit, was developed in Germany. This covers the whole of the food chain, including farms. The label presents itself to German consumers as a guarantee of quality and safety (Rodman 2008: 33).

The general responsibility placed on all food business operators to ensure that food is safe lies not only with importers, but with subsequent handlers of food along the chain. In fact, in some ways the responsibility is even greater than for food originating from within the EU. Food business operators handling food produced within the EU may be able to presume that it has been produced in accordance with EU food legislation that would be enforced in the country of origin. It is not so easy to make (and more importantly, to justify) this presumption in the case of food imported from third countries.[19]

What are the implications of this responsibility? A literal reading of EU food safety regulations might suggest that importers have a responsibility to ensure that food of non-animal origin imported from third countries has been produced in conditions that conform to EU food hygiene regulations (852/2004). This is the conclusion reached by Graffham (2006a), who argues that importers do, in fact, have such a responsibility, with the implication that they might adopt private standards and certification as a means of meeting it. He bases this view on interviews with staff at the Commission's Directorate-General for Health and Consumers (DG SANCO).[20]

The implication of this interpretation is that importers of food of non-animal origin should be obliged to take direct steps to verify that the conditions of production in exporting countries conformed to EU regulations. In particular, they would be obliged to verify that quality controls are in place in the country of origin, including during harvesting. Private standards and third-party certification would be one means of doing this.

In practice, it is hard to believe that this is the way import controls operate. There are clearly numerous examples of importers acting on a consignment basis, buying and selling produce about which they have limited knowledge. There is still a considerable amount of ‘arm’s length’ trading in food of non-animal origin. When the fresh produce importers stress the need for stringent controls, they generally refer to the customers' requirements, not those of EU legislation.

An alternative interpretation of the legal position is possible, and it was suggested by the case of Lidl Italia. The supermarket was selling a product whose contents had been mislabelled. It sold these products in sealed jars, and the question arose whether in the circumstances it could be held responsible for incorrect labelling under consumer protection legislation. When this case was referred to the European Court of Justice, the Advocate General argued that the attribution of responsibility depends upon relationships along the value chain. If, for example, a supermarket was sourcing own label products, its responsibilities would be greater than if it were merely a small retailer selling a product made by a large manufacturer (Klaus and Meyer 2008: 10). Responsibility has to be related to the capacity of the person involved to verify that something conforms to legislation. By extension, the general responsibility on food business operators to ensure safety of food has to be assigned according to the extent that the food business operator could reasonably be able to exercise such responsibility. This might vary according to the nature of the importer relationship. In some cases it may be more reasonable to expect the importer to verify whether imported fresh produce has been produced in accordance with the EU regulations. In other cases it may be impossible, or unreasonable.

Much food of non-animal origin is imported into the EU without importers being able to verify that has been produced in accordance with EU food hygiene regulations as they apply at farm level. At most, the importer is likely to be familiar with the exporter and to have some

[19] The Italian court of appeal in the Lidl Italia case decided that for products imported from third countries the importer cannot make a presumption of it matching Italian or European regulations and so the importer should check that the food conforms (Klaus and Meyer 2008: 409).

[20] Personal communication from Andrew Graffham.

experience of previous imports of food that have not been shown to be unsafe. In the absence of specific problems arising with such food, food safety authorities are not likely to take action. Therefore, importers will continue to import such food and there will be no specific pressure to introduce other private standards to control practices at farm level. Even if problems do arise, the specific penalties would depend on national legislation.

3.3 Farm-level standards in practice: the case of GLOBALG.A.P.

European food companies are under an obligation to provide safe food to consumers. They do not have to adopt private food safety standards in order to satisfy this requirement, even in the case of imported food. Nevertheless, private food safety standards have been adopted widely, and the GLOBALG.A.P. standard provides a good illustration of the specific characteristics of private standards and the particular choices that have been made by predominantly European standard-setting organisations in the area of food safety standards. It is a widely-adopted pre-farmgate standard that has a direct impact on farmers that meet its requirements. GLOBALG.A.P. is managed by GLOBALG.A.P. in Cologne, under the legal identity of FoodPLUS GmbH.

Private standards do not remain constant. For the purposes of this discussion, attention is focused on EUREPGAP Revision 2, operated from January 2005, which is when many retailers in Europe required African exporters to comply with the standard. The key characteristics of the standard are:

1. It is a voluntary standard. No producer or retailer has to comply with it, and its use is not even mandatory for GLOBALG.A.P. members.[21] However, it is widely adopted and therefore access to substantial segments of markets in some European countries is dependent upon being certified.
2. It is a HACCP-based standard (see Appendix 1), aimed at regulating practices on farms. The standard identifies specific hazards and control points, so it was largely prescriptive in nature in the period from 1995 to 2008. The standard identifies risks, procedures and control points. In the case of pesticide residues, the standard identifies ways in which excessive residues might accrue and remain on fresh produce, specifying a number of measures designed to prevent/avoid/eliminate such an outcome. These include ensuring that staff making decisions about applications are properly trained, chemicals are properly mixed in a suitable environment, only permitted chemicals are used, application equipment is properly checked and calibrated, and proper intervals between application and harvesting are maintained. The control points are means of ensuring that these measures to control risks have been taken. However, more recent versions of GLOBALG.A.P., particularly version 4,[22] have paid more attention to microbial contamination, where there is a greater emphasis on identifying and responding to the heterogeneous environments and consequent risks facing different types of farms or products. The relationship between different types of food safety risks and appropriate regulatory strategies was discussed in Section 2.1.
3. Conformity assessment is based on internal audits carried out on the farm and by external audits conducted by third-party auditors (certification bodies). This means, for example, verifying that suitable storage is in place, documenting the training of staff responsible for decisions about pesticide applications, and establishing that records have been kept. Such audits are conducted at least annually.
4. The enforcement process responds to the seriousness of non-conformance items. EUREPGAP Revision 2 distinguished between ‘major musts’, ‘minor musts’ and ‘recommendations’ (EUREPGAP 2005b: 11). Major musts have to be complied with 100 per cent, and in cases where non-compliance is detected in an audit (indicating that the

[21] Retailer members of GLOBALG.A.P. are not obliged to source fresh produce solely from certified farms.
[22] See GLOBALG.A.P. (2012b; 2012a; 2012c).

farm's own systems failed to detect and correct it) certification is suspended immediately for three months, and permanently in cases of a repeat offence. At least 95 per cent of minor musts should be complied with, and levels greater than this have to be corrected within 28 days. Recommendations are included in the audit process but are not obligatory (EUREPGAP 2005b: 21-22).

5. GLOBALG.A.P. is revised at regular intervals. Part of this evolution reflects the changing regulatory environment. For example, following the introduction of EU hygiene regulations, EUREPGAP introduced further specifications with respect to hygiene practices during harvesting. The 2001 version of EUREPGAP included two 'minor musts' and one recommendation. Revision 2 of EUREPGAP, effective from 2005, included six 'major musts' and one 'minor must' relating to food hygiene (EUREPGAP 2001; EUREPGAP 2005a).[23] However, as a food standards business, GLOBALG.A.P. also responds to customer needs. Its revenues depend upon the take-up of the standard, and so it considers the interests of existing retailers and suppliers and potential new ones. The response of GLOBALG.A.P. to changing market circumstances will seen in the discussion of the evolution of standards in the United States.

EUREPGAP Revision 2 covers 14 areas of good farming practices. The focus is predominantly on crop protection and hygiene, as can be seen in Table 3.3. Of the 49 major musts, 15 are concerned with crop protection, while 19 are concerned with harvesting and post-harvest treatments. The major musts for harvesting are concerned with hygiene issues – preventing contamination from workers, equipment or the environment – and for post-harvest treatments they are mostly focused on contamination – from workers, from washing and from product treatments. Similarly, more than half (57 out of 99) minor musts occur in the crop protection and post-harvest treatment sections.[24]

[23] Revision 4 of GLOBALG.A.P. includes ten major musts and two minor musts in this section (GLOBALG.A.P. 2012a).

[24] Revision 3 of GLOBALG.A.P. in force until 2012, is more stringent with respect to employment and working conditions, waste and pollution management than earlier versions. In these categories, some items that were Recommendations in Revision 2 were reclassified as minor musts (GLOBALG.A.P. 2009). From 2005, GLOBALG.A.P. worked with the German technical cooperation agency, GTZ, and Coop Switzerland to develop a voluntary module on social standards that could be certified simultaneously with GLOBALG.A.P. (GLOBALG.A.P. 2010). The GLOBALG.A.P. Risk Assessment on Social Practice (GRASP) is now part of the GLOBALG.A.P. family of standards (see http://www.globalgap.org/cms/front_content.php?idcat=126).

Table 3.3 EUREPGAP Revision 2, control points for fresh fruit and vegetables

Chapter	Major musts	Minor musts	Recommendations
1. Traceability	1	0	0
2. Record-keeping and self-inspection	3	1	0
3. Varieties and rootstocks	1	6	4
4. Site history and management	2	2	1
5. Soil and substrate management	1	3	6
6. Fertiliser usage	2	15	4
7. Irrigation	1	0	15
8. Crop protection (pesticides)	15	43	6
9. Harvesting	6	1	2
10. Post-harvest treatments	13	14	5
11. Waste and pollution management	0	0	6
12. Worker health, safety & welfare	2	13	9
13. Environmental issues[(a)]	0	1	8
14. Complaint form	2	0	0
TOTAL	49	99	66

Source: EUREPGAP (2005a).
Note: (a) Environmental impact issues such as soil erosion are treated in other chapters of the standard.

The standard operationalises a widely used approach to food safety, but it is not the only possible one. It was determined by the following factors:

1. This standard was developed primarily to meet the needs of retailers. Their interpretation of the best way that they should satisfy regulatory requirements, meet consumer expectations and address pressures from NGOs and other pressure groups determined the hierarchy of concerns expressed in Table 3.3, even though the government structure of GLOBALG.A.P. has evolved to include greater representation for producer members. The standard aims to limit the risk exposure of the buyers, erring on the side of caution. This same issue arises in the framing of the CAC guidelines on dairy hygiene, discussed in Section 2. A large part of these guidelines is couched in terms of how an enterprise assesses its own risks and the strategies it might use to achieve desirable food safety outcomes. However, when businesses depend upon the performance of suppliers, the guidelines imply that it is possible to be much more prescriptive.
2. Various accounts of the introduction of EUREPGAP (see, for example, Swoffer 2005) emphasise that prior to the standard being introduced retailers were already directly monitoring their supply chains. Therefore, the new standard did not necessarily introduce completely new requirements for farmers. It codified existing practices and harmonised them across different retailers. In doing so, it created a collective private standard – one developed initially by multiple stakeholders and which was independent of any one of

them. Later, the standard setting organisation expanded its membership and developed more inclusive governance.
3. GLOBALG.A.P. allows some consistency of control over increasingly internationalised supply chains. It has the advantage for the buyer of allowing, in principle, easy substitution of one supplier for another, as long as both are certified. In practice, however, many companies continue to complement certification by inspection visits, long-term relationships, etc.

In the context, therefore, of consumer concerns about food safety, increasing retail concentration and retailer power, and a legal framework that placed some legal obligations on food business operators without specifying precisely how these might be met, retailers in some European countries developed collective private standards as a means of meeting these multiple responsibilities and protecting their brand images. This strategy has had substantial impacts (both positive and negative) on exporters of fruit and vegetables to the EU.

In the United States, in the same period, the response of food businesses was markedly different. As will be discussed in the next section, it was more fragmented and heterogeneous. However, the FSMA, passed in January 2011, opens the way for a government-led system of technology-based or management-based regulation of both domestically-produced and imported fresh produce in cases for products associated with serious health risks. How this has come about, what the legislation states and what it might imply for exporting countries is the subject of the next section.

4 Food safety regulation and private standards in the United States

Food safety is a big issue in both Europe and the United States, creating challenges for both governments and businesses. But the approach to food industry regulation and the division of responsibilities between public and private actors are very different in the United States. This section begins with a discussion of the how the public food safety system is organised in the USA, and then examines how the leafy greens marketing agreement in California represents a radical shift in policy. Section 4.3 then considers how public approaches to food safety for both domestically-produced and imported food have evolved since 2006. Subsequent sections analyse the impact of the FSMA on domestic fresh production, imports of food and fresh produce exporting countries.

4.1 Food safety regulation in the United States

The regulation of food safety in the United States is divided between multiple Federal agencies and individual States. At the Federal level, the main agencies responsible are the Food Safety and Inspection Service (FSIS) and the FDA, although Knutson and Ribeira observe that the National Marine Fisheries Service, the Environmental Protection Agency and the Centers for Disease Control and Prevention also have food safety responsibilities (Knutson and Ribeira 2011: 2-3). The FSIS, which is part of the US Department of Agriculture (USDA), has specific responsibilities for the safety of domestically-produced meat, poultry and some egg products. The regulatory system for these products is strict, and it has been strengthened since the 1990s. Controls on imported meat and poultry are also stringent, and similar in many respects to those operating in the European Union. FSIS inspectors are present in processing plants, and since 1996 all the meat and poultry processing plants have to develop pathogen reduction programmes based on HACCP principles.

> The 1996 PR/HACCP rule shifted emphasis from visual inspection of carcasses to control of pathogens using a system of checks at critical control points where food safety is at risk, required plant operators to conduct tests for generic *Escherichia coli* (*E. coli*), and imposed *Salmonella* performance standards. Implementation of the regulation began in 1997 and was mandated by early 2000 in all sizes and types of meat and poultry slaughter and processing plants in the United States.
> (Ollinger, Moore and Chandran 2004: iv)

As summarised by Plunkett and de Waal (2008: 658-59), import regulations require foreign countries to have equivalent levels of sanitary protection to those applicable in the United States. This involves documentation, questionnaires and on-site audits of the food safety system. This is complemented by a certification by the food safety authorities in the exporting country and inspections at port of entry.

Other food products are largely regulated by the FDA. Here, the levels of control are more varied. The FDA mandates the use of HACCP in processing for three specific products – low acid canned food, fruit juices and shrimp. In the case of fresh produce, and in particular on-farm controls for fresh produce, the FDA pays particular attention to the issue of microbial contamination and establishes and recommends good agricultural and handling practices. The key guidelines for controlling microbial contamination on-farm were issued in 1998. These laid out very clearly the hazards relating to the four main vectors of microbial contamination in fresh produce – soil, water, humans and animals. However, these guidelines were not mandatory:

> The produce guide is guidance and it is not a regulation. As guidance and if applied as appropriate and feasible to individual fruit and vegetable production operations, the guide will help to minimize microbial food safety hazards for fresh produce. Because it is guidance, and not a regulation, the guide does not have the force and effect of law and thus is not subject to enforcement.
> (U.S. Food and Drug Administration 1998: 2)

The framing of the guidelines clearly reflects their intention to provide advice rather than instruction. For example, with respect to water quality: 'Growers with older wells (e.g. wells constructed 30–40 years ago, and especially wells constructed before 1925), or who have other reasons for concern about the condition of their well and possible contamination, may want to have their well examined by a water quality expert' (U.S. Food and Drug Administration 1998: 10-11). Having offered sound advice, the FDA leaves it up to farmers to decide if and how to respond.

Calvin (2003: 77) argues that there were two good reasons for adopting this approach. First, agricultural production is very heterogeneous. The guidelines recognise that risks very considerably from product to product even within the fresh fruit and vegetables category. For example, products growing in the ground, or close to it, will be at greater risk from animal faecal contamination than tree crops.[25] At the same time, farm practices and farm environments vary considerably from one part of the United States to another. Therefore, technology-based regulation would be inappropriate in the context of such heterogeneity. The guidelines were written in a way that allows different responses according to the different risks faced and accepts that some risks can only be minimised rather than eliminated.

[25] Microbial contamination from soil comes through soil amendments added to fields. The risks associated with these can be reduced by avoiding certain risky products, controls over origin and treatment of the soil prior to application. The human vector for microbial contamination relates to poor hygienic practices in the fields, illness, etc., which can also be reduced or eliminated through provision of suitable facilities and identification of and response to disease symptoms. Contamination through the animal and water vectors are more difficult to control.

Second, the FDA was very aware of its responsibility as a government organisation and the need to provide a sound scientific base for its recommendations. According to Calvin, 'guidelines do not outline specific testing and monitoring regimes because scientific data is lacking for establishing more specific guidelines' (Calvin 2003: 77). However, this meant that the main regulatory approach was performance-based – food should be free of microbial contamination – even though testing for such contamination is widely accepted as ineffective.

The development and use of non-enforceable, industry-specific guidelines is illustrated by the California Strawberry Commission (2005). The CSC developed guidelines for good agricultural practices for strawberry growing in the late 1990s, following problems with contamination (Richards and Patterson 1999), amending them further in 2005. These were comprehensive, covering pesticide usage as well as control of four vectors associated with microbial contamination: soil, water, field sanitation, and worker health and hygiene.[26] The food safety programme also provided guidance for shippers and processors in such areas as processing facilities, pest control and transport. A section on traceback procedures was also included.

The CSC programme (California Strawberry Commission 2005) facilitated implementation of good practices by providing procedures, checklists and forms to be used by farmers. For example, with respect to composted soil, the CSC guidelines included detailed questions that farmers should ask of compost producers, including the make-up of the composted material, dates, temperature readings and microbiological testing, etc. However, the programme consisted of recommendations for good practices, not a standards scheme. It was not prescriptive (farmers were encouraged to adapt the guidelines to their circumstances) and it stated explicitly that it had no regulatory function: 'This guideline is not intended, nor should it be interpreted, to create an industry-wide standard against which growers, shippers or processors will be measured, regardless of whether they choose to follow any or all of the suggestions in the guideline' (California Strawberry Commission 2005: 3). It follows that there was no mechanism to monitor or enforce compliance.

The result of all this was that early in the twenty-first century there was recognition of continuing problems with respect to food safety, particularly relating to microbial contamination and widely-accepted general principles for good agricultural practices, recommended by the FDA and by the industry. The FDA's 2004 Action Plan for fresh produce, for example, highlighted the problems and made a call to action:

> Over the past decade, the federal government has focused significant resources on reducing foodborne illness from all sources. However, despite these efforts, foodborne illness associated with fresh produce continues to be documented. The persistence of foodborne illness associated with fresh produce may be attributable to a number of factors, but many cases are preventable. Given the importance of produce consumption and its central role in a healthy diet, it is imperative that the incidence of foodborne illness cases associated with produce be reduced.
> (U.S. Food and Drug Administration 2004)

There was, however, no consensus on how to develop a system for enforcing good practice. The 2004 Action Plan recommended more guidance, education and support for farmers as the solution to continuing foodborne illnesses associated with fresh produce. It appears that the FDA had the authority to regulate on-farm processes (Burrows 2008), but it chose not to do so.

[26] The CSC food safety programme only mentions animal intrusion into fields in passing and refers to dogs and livestock rather than wild animals. Preventing animal intrusions in processing facilities is given more consideration.

Private standards in the United States

In this context, were food companies developing and using private standards? In fact, many leading food companies in the United States do require their supply chains to implement HACCP-based systems of food safety. This is particularly evident in the foodservice sector, where companies such as McDonald's and Yum! Brands impose stringent conditions on suppliers, backed up by inspections. For example, suppliers to McDonald's are required to develop and implement HACCP plans, and facilities are inspected by both company representatives and third-party auditors (Gale 2006). The size of the largest companies in the food service sector and the importance of brand image to these companies are drivers that incentivise the development of food safety controls along the value chain and enable the food service companies to insist on supplier compliance. In some areas, such as animal welfare, large companies such as McDonald's have been active in developing and promoting private standards (Mench 2008).

Food service companies were by no means the only ones to develop supply chain controls. In the fresh produce sector for example, Fresh Express, a processor and packager of ready-to-eat packaged salads located in California, developed a system based on GAPs, GMPs and HACCP for its farm suppliers (Gale 2004). The checks applied to suppliers prior to incorporation in the value chain would be familiar to many European firms: pre-audit questionnaire, on-site inspection by company staff, identification of corrective steps and timescale, and renewed inspection. The account of the Fresh Express system provided by Gale gives no indication, however, of whether and how these procedures were codified into a standard or if any use was made of third-party certification. Alongside such company initiatives, providers of third party standards were active in the United States at the beginning of the twenty-first century. These included Davis Fresh and Primus Labs, and in 2003 the Food Marketing Institute purchased the SQF standard.

The nature of standards and their enforcement varied considerably. One source of information on this issue is a study of the adoption of third-party certification by retailers and wholesalers in relation to imports of fresh produce from developing countries. Interviews were conducted with ten major retailers and three wholesalers about the use of third-party certification in 2004-5 (Busch, Thiagarajan, Hatanaka, Bain, Flores and Frahm 2005). They found:

- There is considerable diversity of practices among the firms interviewed. Some of the companies required or requested suppliers to meet certain standards, while others prefer to rely on personal relationships or direct inspections on suppliers' facilities.
- The application of standards was heterogeneous. The report refers to three different situations: encouragement to suppliers to follow the GAP and GMP guidelines issued by the FDA; second- or third-party certification to standards that embody the principles set down by the FDA[27]; enforcement of FDA GAPs complemented by further food safety requirements, through second-party audit (i.e. by the buyer) or third-party audit.
- The standards themselves were varied. Sometimes they were developed by the buyers themselves, and in other cases suppliers are expected to obtain certification from one of the available certification bodies. Third-party certifiers in the United States used a number of different standards, ranging from internationally-available standards such as EUREPGAP and SQF to standards developed by companies in the United States.
- Different companies took different approaches to achieving food safety, varying in their use of second- and third-party audit and applying a range of different standards. As a result, there was no uniformity of either practice or the standards themselves.

[27] The USDA has developed an audit process for assessing farm compliance with FDA guidelines (USDA 2009). It is offered as a service to farmers who might need it to satisfy themselves or their customers about compliance with the guidelines (Shipman 2009). There appear to be no specific consequences of audit failure.

Further, the use of management-based approaches to regulation was not accompanied by strict monitoring of the outcomes. In the view of one European fresh produce consultant with experience of applying GLOBALG.A.P. in many countries, farms in California frequently adopted risk-based self-assessments. The farms themselves assessed the level of risks and the adequacy of their responses. In this way they had food safety plans, but the plans were not subject to external discipline, leaving the system dependent on the willingness and ability of farmers to assess risks and take action to contain them.

4.2 The spinach crisis: introducing enforced, prescriptive food safety controls

In the United States, as elsewhere (including the EU), illnesses and deaths from foodborne pathogens occur frequently. One widely-cited study by the Centre for Disease Control in 1999 estimated that there were about 5,000 deaths annually from foodborne diseases, and that known pathogens accounted for 1800 deaths, 60,000 hospitalisations and 14 million illnesses (Mead, Slutsker, Dietz, McCaig, Bresee, Shapiro, Griffin and Tauxe 1999: 607). Food kills, although the numbers should be put into perspective: there were approximately 42,000 deaths per annum from road traffic accidents in the United States in the late 1990s and over 600,000 deaths from heart disease alone in 2006.

Most food sold to consumers in the United States is safe, but food safety problems persist. A number of the widely-documented food illness outbreaks in the 1990s and early part of the twentieth century were associated with imported food. Calvin (2003: 80-8) describes three such cases: cyclospora in raspberries imported from Guatemala in 1996 and 1997; hepatitis A in strawberries imported from Mexico (although processed in California) in 1997; and salmonella in cantaloupe melons imported from Mexico in 2000, 2001 and 2002. When imported food is identified as the source of food safety risks, then the response of consumers and government is to consider tightening up import controls. There is a widespread belief in many developed countries that imported food is less safe than that produced domestically.

Nevertheless, clearly documented problems with some imported food should not obscure or downplay serious instances of microbial contamination of domestically-produced food. In California, the acceptance of mandatory controls began to occur in response to persistent food safety problems. In 2004, pistachio growers supported a Federal marketing *order* (mandatory for all growers) to control aflatoxins and almond growers supported pasteurisation following salmonella outbreaks in 2001 and 2004 (Carman 2007: 182). However, the outbreak associated with E. coli O157:H7 in spinach in 2006 marked a turning point. While problems relating to leafy greens produced within the United States were not uncommon(see, Falkenstein 2010), the 2006 outbreak was unusual in its scale. In all, over 100 people were hospitalised as a result of the outbreak, and 31 suffered from a serious complication associated with E. coli, haemolytic-uremic syndrome.[28] The impact on the industry was also unusually severe. The FDA took strong action:

> On September 14, 2006, the U.S. Food and Drug Administration (FDA) announced that consumers should not eat bagged spinach… The next day FDA expanded the warning to include all fresh spinach. FDA had never before made such a sweeping statement about any U.S.-grown produce item. Stores and restaurants immediately removed spinach from their shelves and menus. Spinach harvesting and marketing ceased and there was no U.S. spinach on the market for five days.
> (Arnade, Calvin and Kuchler 2009: 734)

[28] This syndrome was the reason why the health consequences (more than 30 deaths) of an outbreak associated with a different strain of E. coli in Germany in 2011 were so serious.

Sales of spinach, both bagged and fresh, were suspended for five days, and spinach from California was kept out of the market for a further ten days. This had a big impact on sales. In early 2007, five months after the outbreak, sales of bagged spinach were 27 per cent down on the previous year, and sales of bagged salads containing spinach down 24 per cent. Sales of bagged salads not containing spinach fell by only 5 per cent in the same period (Calvin 2007: 29). Further, The Canadian Food Inspection Agency banned imports of spinach from all US sources in September 2006.

The FDA's assessment of the outbreak drew attention to repeated problems with E. coli in fresh produce and suggested action would be imminent:

> Although the current outbreak may ultimately trace back to a specific field(s), there has been a long history of *E. coli* O157:H7 outbreaks involving leafy greens from the central California region... FDA and the State of California have previously expressed serious concern with the continuing outbreaks of foodborne illness associated with the consumption of fresh and fresh-cut lettuce and other leafy greens. After discussions with industry, FDA and the State of California, as part of a longer term strategy, now expect industry to develop a plan to minimize the risk of another outbreak due to *E. coli* O157:H7 in all leafy greens, including lettuce. The Grower Shipper Association of Central California, the Produce Marketing Association, the United Fresh Produce Association, and the Western Growers Association, said today...'We will work aggressively with the Food and Drug Administration and state regulatory authorities to ensure the industry's growing and processing practices continue to be based on the very best scientific information available, and that we are doing everything possible to provide the nation with safe and healthy produce.' Implementation of these plans will be voluntary, but FDA and the State of California are not excluding the possibility of regulatory requirements in the future.
> (U.S. Food and Drug Administration 2006)

The distinctive feature of the industry's response was that it involved enforcing new standards, group audit and certification. In the immediate aftermath of the crisis, various competing proposals to restore consumer confidence in California leafy greens (spinach, lettuce, etc.) were proposed. The Food Safety Leadership Council proposed a standards scheme for on-farm produce safety (FLSC 2007) that matched or exceeded FDA guidelines and would be backed up by third party certification. FLSC was an industry group whose members included Avendra LLC, Darden Restaurants, McDonald's Corp., Wal-Mart Stores Inc., Walt Disney World Co. and Publix Super Markets (Paggi 2008: 5). A different industry group, consisting of eight buyers (Safeway, Wegman's, Supervalu, Kroger, Sysco, Denny's, Costco, Amerifresh and Markon Cooperative) also announced a food safety initiative in 2006 (Jim Prevor's Perishable Pundit 2006).

However, it was an initiative developed by the producer side of the industry, and more specifically the large companies involved in packing and shipping of leafy greens that prevailed. Faced with pressure from the FDA, the possibility of standards being developed by their customers, and a ban on leafy green exports to Canada, the big players in the California industry responded. The shippers in the leafy greens sector, in collaboration with the California State government, introduced the California Leafy Green Products Handler Marketing Agreement (LGMA). This provided a system of controls designed to minimise the risks of microbial contamination and reassure consumers about the safety of leafy greens produced in California. The innovative features of this initiative (and that of the FLSC) were prescription and enforcement:

> The goal of the LGMA food safety program is to protect public health by the minimizing risk of introducing food borne pathogens into the fields and farms producing leafy greens. The LGMA continually reviews and updates an accepted set

> of food safety standards designed to identify potential hazards on leafy greens and requiring members to perform certain operations which will mitigate risks to an acceptable level. The LGMA works with government auditors to determine whether or not a member of the LGMA is in compliance with the required LGMA food safety practices. Members must be in compliance with all LGMA standards. Members are required to make corrective action on any and all findings cited during government audits and measures must be taken to prevent future infractions for any practice found to be out of compliance. All member audits performed by government inspectors are reviewed by the LGMA's Compliance Officer. (http://www.caleafygreens.ca.gov/certification/enforcement)

In some respects, the LGMA has similarities with private standards in Europe. Five characteristics of the LGMA would be familiar:[29]

- It is a voluntary arrangement, but it is binding on those who adopt it. The signatories to the agreement are handlers (the shippers/distributors, who often also own large farms), and they are obliged (for one year at a time) to source produce solely from farms that have been certified to the LGMA standard. The LGMA quickly gained the adherence of shippers responsible for distributing 99 per cent of California-produced leafy greens. The shippers, therefore, are the route through which a much larger group of farmers are incorporated into the scheme. In terms of the different functional elements of standards discussed in Section 2.2, various parts of the industry have designed the standard, while it is adopted by the shippers, implemented by the growers and monitored and enforced by the LGMA and the California State Department of Agriculture.
- The main impact of the scheme is at farm level. The LGMA identified and codified product-specific GAPs. These are specified in a periodically updated 54-page document (LGMA 2010a) that provides specific instructions about issues such as water quality, water testing, worker hygiene and sanitation, and safe separation distances between crop production and other specified land uses, etc.[30] It is prescriptive – in the case of controls over water, for example, the LGMA specifies particular procedures for water testing, a written compliance plan, instructions on remedial actions to be taken in the event of permissible levels of pathogens being exceeded, and extensive reference to water management and water controls in the audit checklist.[31]
- The approach is science-based, but pragmatic. Where there is no unambiguous scientific basis for some of the recommended practices, they are justified pragmatically, with a promise that they will be amended once better science is available (for example, LGMA 2010a: 49). As might be expected, a comparison of the LGMA and FSLC standards by Paggi (2008: 21) shows that in areas such as the separation of produce fields from grazing cattle or concentrated animal feeding operations the FSLC standard was markedly more stringent than the LGMA standard.
- The LGMA scheme incorporates traceability requirements in order to facilitate trace back of produce to particular farms or blocks.
- The scheme has enforcement mechanisms. Farms incorporated into the scheme have to maintain records, and farms are audited regularly. The LGMA has made an audit checklist publicly available (LGMA 2010b). The mandatory inspections of farms are carried out by inspectors from the California Department of Food and Agriculture. The LGMA website emphasises that inspectors will issue citations for even minor infringements and that corrective actions have to be undertaken and subsequently

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29 Information can be found at http://www.caleafygreens.ca.gov/. There is also a scheme in Arizona, and a proposal was made to create a national scheme (National Leafy Greens Marketing Agreement 2009), although this stalled.

30 The latest version of the document is 2011 (LGMA 2011).

31 This is not the only possible approach. The controls introduced in the tomato sector by the State of Florida (with the support of the industry) are also based on an audit approach, but lean more to management-based regulation, with auditors verifying, for example, written standard operating procedures (Florida Department of Agriculture and Consumer Services: Division of Fruit and Vegetables 2011).

monitored. Farms may be de-certified for persistent violations, and the LGMA website provides information on cases of decertification.

The LGMA differs in one important respect from private standards in Europe – public regulatory involvement. The particular administrative device employed to develop the LGMA scheme was a marketing agreement. This long established mechanism for ordering the activities of producers and distributors of agricultural products is administered by the State government – in this case by the California State Department of Agriculture. The Department of Agriculture is a signatory to the agreement and provides inspectors to audit farms.

The implementation of the LGMA programme does not necessarily define more stringent or novel GAPs compared to those previously available. Its importance lies in three aspects. First, it specifies certain specific ways in which these good agricultural practices are to be operationalised. In other words, it adopts a prescriptive, technology-based approach. While the 1998 FDA guidelines (U.S. Food and Drug Administration 1998) recommend that farmers should check water supplies, the LGMA states precisely what steps farmers had to take to test water quality.[32] Second, compliance with the standard is checked through audit and certification. Third, signatories to the agreement will not source produce from farms that do not meet the standard. Clearly, the reputational and economic damage to all growers associated with foodborne illness outbreaks is a strong incentive to collective action. The FDA's reference to regulatory action if the industry was not able to come up with a scheme (U.S. Food and Drug Administration 2006) would have been another incentive. The setup of the scheme addresses the problems of free riding (benefiting from the scheme without joining it) and shirking (joining the scheme but not fully meeting its requirements), as discussed by Prakash and Potowski (2010). While there was some resistance by agricultural producers in the United States to the use of third-party certification, as discussed above, in the case of leafy greens the need to restore business and consumer confidence was clearly judged to outweigh the likely costs.

Events in California highlighted the extent of the food safety problems related to certain types of fresh produce. Microbial contamination presents particularly severe challenges for food safety:

1. The potential health consequences from certain types of microbial contamination can be severe: serious illness and death.
2. Inspection is particularly ineffective for detecting microbial contamination. When excessive pesticide residues appear on fresh produce, it is reasonable to expect that they will be distributed fairly extensively across any single batch. Microbial contamination may affect (at the time of inspection) only a small part of a batch, meaning that even extensive sampling may be unlikely to detect it. These low levels of contamination can still lead to serious outbreaks of foodborne illness. In other words, performance-based regulation is likely to be ineffective – more so than for pesticide contamination, for example.
3. Problems with microbial contamination appeared to be increasing, although this may be an artefact of more effective public health screening.
4. Farms exist in environments where there are natural reservoirs of infection in soil, or in water, or in animals, or in humans. It is impossible to eliminate the risk of contamination from the environment, although it can be minimised.
5. It has not yet been possible to devise acceptable ‘kill steps’ for microbial contamination in fresh produce that eliminate contamination (or reduce it to acceptable levels) at some point in processing (the equivalent of pasteurisation for milk).

[32] The same applies in the case of the tomato marketing order in Florida. The GAPs are not novel, but the means of enforcement through mandatory audits certainly is.

The implications of all this for certain types of fresh produce are considerable. They may pose serious health risks and it may be impossible to reduce these to acceptable levels through product inspection. This then justifies the development of technology-based or management-based controls at the farm level. The fact that the controls were industry-specific and largely applied in a single state with some homogeneity in production mitigated some of the drawbacks of technology-based regulation.

4.3 Public initiatives on food safety: inspection to prevention

How did these concerns translate into public policy and new legislation? In the early part of the twenty-first century, but not in direct response to the leafy green E. coli outbreak, the issue of food safety was also moving up the public agenda in the United States. A significant part of this increasing concern with food safety focused on food imports. As is shown in Table 4.1, both per capita consumption by weight and the import shares of domestically consumed produce increased substantially across a wide range of fruit and vegetables between 1975 and 2000. A presentation from the United States Government Accountability Office (GAO) on food safety and the FDA started by observing that food was imported from 150 countries, that 15 per cent of all the US food supply was imported, and that this included 60 per cent of fresh fruit and vegetables and 80 per cent of seafood (2010: 1).

Table 4.1 Fresh fruit and vegetable consumption and import shares of consumption, United States 1975 and 2000

	Per capita consumption (pounds, farm weight)		Import share of consumption (%)	
Year	**2000**	**1975**	**2000**	**1975**
Fruit				
Bananas	28.4	17.6	99.6	99.9
Apples	17.4	19.5	7.2	2.2
Grapes	7.3	3 .6	44.1	5.9
Strawberries	5.0	1.8	5.8	8.9
Cantaloupe	10.8	5.2	37.4	12.4
Vegetables				
All lettuce	32.0	23.5	0.7	0.0
Onions	18.3	10.5	9.3	4.0
Tomatoes	17.6	12.0	32.9	21.9
Bell peppers	7.0	2.5	19.6	12.6
Cucumbers	6.4	2.8	41.4	21.6

Source: Calvin (2003: 79).

Border inspections and inspections of overseas facilities were seen as inadequate to ensure the safety of imported food. Many reports have pointed to inadequate levels of inspection of overseas food facilities and also the limits of border inspections (see, for example, United States Government Accountability Office (GAO) 2010). In response to these recognised shortcomings, various proposals were made to improve the efficiency of inspection regimes, particularly, but not solely, with respect to imported products. Policymakers and

commentators argued in favour of increasing the resources available to the FDA, increasing the number of inspections of foreign facilities, stronger prior notice arrangements for shipments, greater deterrence to attempts to import unsafe food through higher fines, introducing systems to more effectively identify shipments with high risk so that border inspections can be focused on these products, and improving recall systems in the United States. One clear prerequisite for achieving the latter, traceability, was introduced by the US government, but as a result of concerns with bio-terrorism and deliberate contamination of food after 2001 rather than food safety concerns as such.

The FDA also recognised the limitations of border inspections. Mike Leavitt, the Secretary of Health and Human Services, was quoted as stating that 'we cannot inspect our way to safety' (Plunkett and DeWaal 2008: 657-58). The FDA's 2007 strategy (U.S. Food and Drug Administration 2007) highlighted trends that increased food-related risks, such as rising numbers of older people who are susceptible to foodborne illnesses, increased consumption of convenience foods, increased consumption of fruit and vegetables, rising imports of food and threats from new pathogens (citing 14 pathogens 'newly associated with foodborne illness since the mid-1970s'). The core elements of the FDA's approach to food safety were presented in terms of 'prevention, intervention and response' (see Figure 4.1), and the document highlighted prevention and the role of the private sector:

> The FDA will work with the private sector to build on the actions of the food industry to ensure product safety. Building safety into products is described in one word: prevention. This shift to an increased emphasis on prevention is at the core of FDA's Food Protection Plan, and will be evident immediately as the FDA begins an industry-wide effort to focus attention on prevention, from general best practices for all foods to the possibility of additional measures for high-risk foods.
> (U.S. Food and Drug Administration 2007)

Further, the document included reference to the use of voluntary third-party inspections as a means of providing FDA with assurances about food safety so that it could 'allocate inspection resources more effectively'. Such measures would apply to both domestic and foreign food establishments.

Figure 4.1 FDA Food Protection Plan, 2007

Source: U.S. Food and Drug Administration (2007).

In adopting this approach to food safety, the FDA signalled its intent to shift from performance-based regulation, based on controlling output through inspection, towards technology- or management-based regulation, which focuses on regulating processes. Given the recognition by the FDA of the heterogeneity of farm situations, it would be logical to implement management-based regulation rather than technology-based regulation (as was discussed in Section 2, see Coglianese and Lazer 2003). However, the impact of such a change in approach would depend very much on how it is implemented, and the FDA strategy did not state explicitly how this would be put into practice. In fact, the strategy made very little reference to controls at farm level, which left open the extent to which regulation of farming practices would be introduced and how they would be enforced.

The theme of prevention was further highlighted by the Interagency Working Group on Import Safety, set up in 2007 by the Bush Administration. This addressed issues relating to the safety of imported products in general in a report and an implementation plan (Interagency Working Group on Import Safety 2007b; Interagency Working Group on Import Safety 2007a). These reports recommended both risk-based strategies that would identify those products where efforts should be concentrated and also the use of prevention rather than inspection. Familiar themes reoccur:

- The responsibility of the private sector for import safety: 'All entities involved in the import life cycle are responsible for ensuring the safety of the products they produce, distribute, export, import or sell' (Interagency Working Group on Import Safety 2007a: 13). Similarly, 'the US importing community... must share a commitment to ensure that products brought into the United States are manufactured in accordance with US safety standards' (Interagency Working Group on Import Safety 2007a: 13). It is less clear how this responsibility is to be enforced and the precise nature of the obligations on the private sector.
- Recognition of the role of third-party certification. The strategy refers to the 'Creation of mandatory and voluntary third-party certification programs for foreign producers that are based on product risk to verify compliance with US safety standards' (Interagency Working Group on Import Safety 2007a: 15).
- Recognition by US authorities of certification programmes and incentives for exporters to use them. The Action Plan recommends that the FDA should be provided 'with the authority to require certification or other assurance that the product under its jurisdiction complies with FDA requirements' and that the 'FDA would accept certifications from either relevant government agencies or accredited third parties' (Interagency Working Group on Import Safety 2007a: 18).[33]
- Development of good import practices in partnership with 'the importing community' and to 'partner with the import community to foster the creation of voluntary certification programs for importers', which would be private-sector based and established conformity with good import practices (Interagency Working Group on Import Safety 2007a: 21). It is not clear precisely what might be certified.

Some businesses supported this approach. In particular, the Grocery Manufacturers Association (GMA) produced a position paper on food safety in 2007 that highlighted 'four pillars' of public-private partnership for the safety of imported food. These were a mandatory foreign supplier quality assurance programme, a voluntary qualified imported food safety programme, building the capacity of foreign governments in the area of food safety and expanding the capacity and resources of the FDA (Grocery Manufacturers Association 2007). However, these plans were not implemented during the Bush administration.

[33] This is not new, particularly with respect to the use of foreign government certification. The FSIS relies on the equivalency of the safety systems of exporting countries (United States Government Accountability Office (GAO) 2010: 2). This is also a central element of the EU's controls on imported food.

In parallel to these Executive Branch initiatives, Congress also focused on food safety, with legislative proposals multiplying. In 2007, Representative John Dingell introduced the Food and Drug Import Safety Act, citing many of the limitations of the FDA and food safety policy in the United States (Chen and Dunnegan-Mallat 2008). This proposed increasing the capacity and vigilance of the FDA, as well as introducing more restrictions on imports in general. It also proposed to enhance the role of importers in establishing the safety of imported food by creating a 'Safe and Secure Food Importation Program', which 'would offer expedited passage of importer's food products through the inspection process in exchange for adherence to certain food safety and security measures' (Chen and Dunnegan-Mallat 2008: 1346).

The Food and Drug Administration Globalisation Act (FDAGA), introduced in 2009, proposed greatly increased powers for the FDA over both domestic and imported food, along with proposals for regulating domestic production of fresh produce. It included a proposal to mandate the FDA to establish and enforce minimum standards for safe growing, harvesting, packing, sorting and storage operations for fruit and vegetables (United States Congress 2009a). While the FDAGA did not go beyond Committee in the House, a similar Act, the Food Safety Enhancement Act of 2009 (United States Congress 2009b) was passed by the House of Representatives, but did not go through Senate.

By this time, food businesses and associations were also looking for government to take the lead. The White Paper on food safety produced by the United Fresh Produce Association (2009) emphasised three points that recur frequently in discussions of regulation in the United States. First, government, and particularly the FDA, should be at the centre of food safety initiatives: 'the produce industry also supports a strong role by the federal government in ensuring that produce sold in the United States is grown, packed and distributed in accordance with appropriate science-based safety standards.' The White Paper further argued that 'the law requires, and the public demands, that FDA as an independent, public health agency be the final arbiter of what is safe enough' (United Fresh Produce Association 2009: 1). The UFPA goes further, suggesting that within the regulatory system for fresh produce public authorities should not only establish general requirement relating to the safe production, harvesting, processing and distribution of food, but that they should also be involved in defining the specific means of meeting these requirements. The UFPA suggests that 'USDA/state department of agriculture GAP audits could be designed to certify against FDA standards' (United Fresh Produce Association 2009: 4).[34] Second, a commodity-specific approach should be adopted because of the diversity of crops within the fresh produce sector and their different risk profiles. Third, the UFPA is mindful, however, of the cost implications of standards. The White Paper recommends that due attention be given to containing costs through a targeted approach that avoids adding 'regulatory costs and burdens to sectors where those requirements are unneeded, without doing anything to enhance safety where most critical' (United Fresh Produce Association 2009: 2).

By 2009, the FDA itself was seeking powers to introduce mandatory fresh produce standards. A notification on consultation on new regulations stated, 'The Food and Drug Administration is proposing to promulgate regulations setting enforceable standards for fresh produce safety at the farm and packing house. The purpose of the proposed rule is to reduce the risk of illness associated with contaminated fresh produce' (U.S. Food and Drug Administration 2009). This was a marked change of direction. This thinking and many of the provisions of the FDAGA and the Food Safety Enhancement Act were incorporated into a new bill on food safety proposed by Representative John Dingell. This bill, and Senate bill

[34] The corollary of this position is that movement towards private sector food safety standards should be curtailed. The UFPA argues that the third party standards and certification should 'be based on a harmonized set of FDA endorsed standards, and have industry-wide public recognition to preempt additional redundant audits' (United Fresh Produce Association 2009: 4).

S 510, became the FDA Food Safety Modernization Act, which was signed into law in January 2011.

4.4 The FDA Food Safety Modernisation Act (FSMA), 2011: domestic market

The FSMA amended the existing Federal Food, Drug, and Cosmetic Act (FD&CA) (21 USC 301 and subsequent chapters), instructing the FDA to undertake consultations prior to introducing changes in food safety legislation.[35] The new Act addressed some well-known shortcomings in food safety legislation, giving the FDA the power to issue mandatory recalls, and requiring it to significantly expand inspection and testing of both domestic and foreign food facilities.[36] More generally, it incorporated the prevention approach, applying this to both food processing facilities and the production and harvesting of fruit and vegetables.

Three issues are particularly relevant for the discussion of fresh produce: (i) new regulations for food facilities, (ii) the introduction of new, enforceable GAPs for some domestically-produced fresh produce, and (iii) the safety of imported food.

Regulation of food facilities

Section 103 of the FSMA adds a new Section 418 that introduces new and enhanced regulations relating to food 'facilities'. Registration and re-registration of such facilities is tightened up, and they will be required to analyse hazards, introduce preventive controls, monitor the effectiveness and establish procedures for taking effective corrective actions. The new Section 418 of the FD&CA (set out in Section 103 of the FSMA) extends the use of risk-based preventive controls from high-risk operations (for example, meat processing plants) to all food facilities not exempted by the Act.

According to Michael Taylor, the Deputy Commissioner for Foods at the FDA, 'Facilities that process human food will be required to establish modern preventive controls that are consistent with internationally recognised principles of Hazard Analysis and Critical Control Points (HACCP) and address supplier verification activities that relate to the safety of food' (Taylor 2012). Processing plants will be required to develop food safety plans, implement preventive controls and enhance record keeping. This will greatly increase management-based regulation in food facilities, although some establishments will have exemptions given from the requirements for hazard analysis and preventive controls.

The impact on farms of Section 418 is much more limited. The new Section 418 of the FD&CA only applies to food facilities, which Section 415 of the same Act defines as 'any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. Such term does not include farms.' However, existing FDA guidelines on microbial contamination in fresh-cut vegetables do include operations involving minimal processing in the category of food facilities. Therefore, any facility that includes the following activities is likely to fall under the provisions of Section 418:

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[35] The FSMA is solely concerned with provisions for food (Chapter IV of the FD&CA), imports and exports (Chapter VIII) and the authorities granted to the FDA. This is in contrast to the earlier FDAGA, which included sections on drugs and cosmetics safety (United States Congress 2009a). Certain key provisions of the FSMA add new sections to Chapter IV of the FD&CA and are numbered sequentially to previous parts of Chapter IV. Section 103 of the FSMA introduces the new Section 418 of the FD&CA which defines controls for food establishments, while the new Section 419 of the FD&CA instructs the FDA to introduce mandatory controls for fresh produce. These parts of the FD&CA are also incorporated into the US Code (21 USC) Chapters 341 to 350, and these numbers are sometimes used to refer to the provisions.

[36] The FDA is mandated to 'inspect at least 600 foreign facilities within a year of enactment and to double those inspections every year for the next five years'. For this and other information about the act, see http://www.fda.gov/Food/FoodSafety/FSMA/ucm239907.htm. This compares to an annual average of 240 inspections of food firms in foreign countries carried out by the FDA from 2001 to 2008 (United States Government Accountability Office (GAO) 2010: 8).

> fresh-cut fruits and vegetables that have been minimally processed (e.g., no lethal kill step), and altered in form, by peeling, slicing, chopping, shredding, coring, or trimming, with or without washing or other treatment, prior to being packaged for use by the consumer or a retail establishment. Examples of fresh-cut products are shredded lettuce, sliced tomatoes, salad mixes (raw vegetable salads), peeled baby carrots, broccoli florets, cauliflower florets, cut celery stalks, shredded cabbage, cut melon, sliced pineapple, and sectioned grapefruit.
> (U.S. Food and Drug Administration 2008)

Domestic fresh produce production and the FSMA

Section 105 of the FSMA makes changes to produce safety by adding a new section, Section 419, to Chapter IV of the FD&CA. This instructs the FDA to develop and introduce safety standards for the production and harvesting of fruit and vegetables within two years following the signing of the Act (in other words, by January 2013). The FDA's online frequently asked questions about the Act emphasise how the new act will lead to mandatory on-farm controls for at least some categories of product:

> This new law puts prevention up front for FDA. For the first time, FDA will have a legislative mandate to require comprehensive, science-based preventive controls across the food supply. Under the Act, implementation of mandatory preventive controls for food facilities and compliance with mandatory produce safety standards will be required. FDA is in the process of developing a proposed rule that will establish science-based minimum standards for the safe production and harvesting of fruits and vegetables and will address soil amendments, worker health and hygiene, packaging, temperature controls, water, and other issues.
> (U.S. Food and Drug Administration 2010)

In other words, the FDA is mandated by the Act to establish regulations for controlling microbial contamination of fruits and vegetables, replacing the voluntary guidance of the 1998 Guidelines with mandatory rules: ‘Since 1998, produce growers have had available the 'Good Agricultural Practices' issued by FDA and the U.S. Department of Agriculture (USDA). But this guidance is not an enforceable regulation like the Produce Safety Regulation will be, says [the FDA's senior adviser for product safety] Gorny’ (U.S. Food and Drug Administration 2011: 1).

The provisions do not apply to all fresh produce farms:

- The FSMA instructs the FDA to produce proposed rules for ‘those types of fruits and vegetables that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death’ (United States Congress 2010: Section 105 (a)(1)(A)).
- Exemptions will apply to farms whose turnover is below $500,000 and at least half of whose sales go to the ‘qualified end-users’.[37]
- There is a provision for US states and foreign countries to request variances in provisions in response to local conditions as long as the same level of public health protection can be shown to be achieved (United States Congress 2010: Section 419 (a)1(A)).

For non-exempted farms, failure to comply with Section 419 is a prohibited act (United States Congress 2010: Section 419 (c)). Violations leave businesses and individuals subject to criminal and civil penalties. The Act also refers to enforcement of these standards:

[37] Qualified end-users can be direct purchasers of produce from the farm for consumption (businesses do not qualify), or restaurants or retail food establishments located in the same state or less than 275 miles from the farm.

> The Secretary [of Health and Human Services] may coordinate with the Secretary of Agriculture and, as appropriate, shall contract and coordinate with the agency or department designated by the Governor of each State to perform activities to ensure compliance with this section.
> (United States Congress 2010: Section 419 (d))

The most obvious routes to achieving this would be through some form of inspection and certification. This might be along the lines already used by the USDA to audit compliance with FDA GAPs (USDA 2009), but blogs and website discussions from legal firms also raise the possibility of applying other existing schemes, including the LGMA. A posting on the Food Liability Law blog, published by the law firm Stoel Rives LLP, suggests that:

> The fear among many small farm and 'ag-in-the-middle' proponents who are not exempt is that FDA will impose standards similar to those adopted by the National Leafy Greens Marketing Agreement (NLGMA) proponent group.
> (Odza 2011)[38]

The blog goes on to suggest that farms in such a position should be (i) arguing that their product is low risk, (ii) laying the groundwork for state-level variance, and/or (iii) contacting Congressmen so that pressure is put on the FDA. While the final implementation of the FSMA with respect to fresh produce is far from being defined, and while final practices will almost certainly be subject to political bargaining, some form of risk-based preventive controls at the farm level are inevitable.

4.5 The FSMA and imported food

The FSMA increases controls over imported food. The underlying reasons for this were made clear earlier. As the Federal government tightens controls on domestic food production, processing and distribution, it is logical to seek equivalent levels of control for imported produce, and particularly so when imported food is under suspicion of not being of as high a standard as domestically-produced food. Sections 301 to 309 of the FSMA add a number of sections to Chapter VIII of the FD&CA, which refers to the safety of imported food. As with the provisions of the FSMA in relation to domestically-produced food, many of these provisions relate to food facilities, but there are also implications for farms that suggest a shift to technology- or management-based regulatory frameworks.

The FSMA requires food importers to verify that they have adequate food safety measures in place. In particular, Section 301 of the Act states that 'each importer shall perform risk-based foreign supplier verification activities for the purposes of verifying that the food imported by the importer or agent of an importer is produced in compliance with the requirements of section 418 or section 419 as appropriate' (United States Congress 2010: Section 301). Michael Taylor summarises this as 'FSMA makes importers accountable for verifying, in a manner transparent to FDA, that the food they import has been produced in accordance with U.S. standards, or under modern preventive controls that provide the same level of public health protection' (Taylor 2012). Although most discussions of the FSMA focus on certification of foreign facilities, the reference to Section 419 in the quote above implies that farms will also be affected.[39] The FSMA's Foreign Supplier Verification Program makes it obligatory for importers 'to verify that their foreign suppliers have adequate preventive controls in place to ensure that the food they produce is safe' (U.S. Food and Drug

[38] The NLGMA was a proposal to reproduce the standard scheme developed by the LGMA in California at a national level. It did not come to fruition.

[39] The exemptions from the obligations on importers are very tightly drawn. The law does not apply to products already subject to HACCP regulations, nor to small quantities of food imported for research and evaluation purposes. The law does allow foreign governments to claim variances in compliance in the same way that states of the union are allowed to (but these may be rejected by the Secretary).

Administration 2010). It becomes a prohibited act (i.e. illegal) not to have a foreign supplier verification programme in place. The Act suggests various ways in which this responsibility might be quitted:

> Verification activities under a foreign supplier verification program under this section may include monitoring records for shipments, lot-by-lot certification of compliance, annual on-site inspections, checking the hazard analysis and risk-based preventive control plan of the foreign supplier, and periodically testing and sampling shipments. (United States Congress 2010: Section 301(c)(4))

From the point of view of non-tariff measures, there is a considerable difference between these options: monitoring records or periodic testing and sampling of shipments, on the one hand, and checking the preventive control plans of the foreign supplier on the other. The Act does not specify whether acceptable verification activities will vary according to the risk profile of particular products or as a result of the FDA's confidence in the food safety systems of particular exporting countries.

The precise impact of the legislation will depend to a large extent on how the provisions of Sections 418 and 419 are operationalised (what foods are considered high risk, how controls are implemented, etc.). Nevertheless, some substantial impact on exporters seems inevitable. First, fresh produce farms in the United States will be subject to enforceable standards, and it is unlikely that exporters to the United States will be subject to less stringent controls. Even if the FDA recognises equivalent standards (public or private) in exporting countries, they are not likely to be less stringent. Second, in the lead up to the definition of the proposed rule, risks involved with fresh produce once again came to the fore. In September 2011, an outbreak of Listeria responsible for over 20 deaths was unequivocally linked to cantaloupe melons produced in Colorado. This was the worst outbreak of illness and death related to contaminated food for more than 20 years, far outweighing the 2006 spinach crisis. The FDA is unlikely to downplay risks. Third, the Act will introduce and enforce standards that will take past experience of outbreaks as one indicator of which foods should be classified as high risk. In the past 15 years, serious disease outbreaks have been associated with cantaloupe melons (domestic and imported), raspberries, strawberries, spinach, lettuce, etc., so the range of fresh produce that will be affected by the new controls is likely to be broad.

The FSMA also discusses third party certification as one of the instruments to be used to tighten up food safety, but with three important riders. First, this is raised in the context of food facilities: ‘FDA will be able to accredit qualified third party auditors to certify that foreign food facilities are complying with US food safety standards’ (U.S. Food and Drug Administration 2010). Second, the requirement for third-party certification appears to apply only to high-risk foods and where the overall food safety system is deemed inadequate (U.S. Food and Drug Administration 2012: Question G.6; U.S. Food and Drug Administration 2010: Section 303). Third, subsequent FDA presentations emphasised the *process* of certification, and the recognition of foreign accreditation bodies that will regulate third-party auditors: ‘the third party auditors will be authorized to certify that foreign facilities meet the requirements of the Act’ (Hogan Lovells US LLP 2011). The FDA will delegate the process of accrediting auditing bodies, but these discussions do not make clear precisely what obligatory standards (or rules in FDA terminology recognised certifiers will be auditing. This issue is discussed further in Section 4.6.

Finally, the Act mandates the FDA to establish a Voluntary Qualified Importer Program that links expedited import to controls over food facilities. The ‘FDA must establish a voluntary program for importers that provides for expedited review and entry of foods from participating importers. Eligibility is limited to, among other things, importers offering food from certified facilities’ (U.S. Food and Drug Administration 2010). Here, the Act explicitly makes eligibility

dependent upon the risk profile of the food, past history of compliance, the exporting country's food safety standards and risks related to intentional adulteration of food. The reference to ‘certified facilities’ means that this provision will not apply to farms, but it may apply to off-farm storage and packaging and to minimally processed fresh produce.

4.6 Impacts on food exporters and exporting countries

The impacts of these measures will not become clear until the FSMA has been fully implemented. However, it is possible to see three factors that will affect the way it impacts on exporters and exporting countries. The first relates to exporting country capacity. There are various examples of exporters in developing countries failing to meet new regulations. This was seen clearly in the case of measures taken to combat cyclospora in raspberries from Guatemala. In the late 1990s, there were a number of outbreaks of cyclospora associated with raspberries from Guatemala. After a second outbreak, in 1997, the FDA introduced a blanket ban on the import of raspberries from Guatemala. In order to regain access to the US market, the Guatemala Berry Commission, supported by the Guatemalan government, introduced the Model Plan of Excellence (MPE), which became a mandatory requirement for export to the United States. The MPE standard had detailed food safety practices enforced by government inspections and FDA audits. It was prescriptive, specifying particular safety procedures – even to the extent of indicating filter sizes to be used for irrigation and water for hand washing – and traceability requirements were also included. While this programme was successful in eliminating microbial contamination, it also drastically reduced the number of exporting firms, from 85 in the 1990s to only three in 2002 (Calvin 2003: 82).

At the same time, however, the introduction of clear guidelines and models for action for exporters to the United States may allow them to develop cost-effective forms of compliance. Rather than having to develop bespoke systems designed to meet particular challenges in the US market, exporters will know what certification is required to meet the requirements of the FSVP. Experience from Europe suggests that while certification requirements will favour larger and more organised exporters, whether or not these exporters will choose to source from small farms or not depends on a range of factors, including access to land and risk diversification strategies.[40]

In this respect, countries that have invested in the development of food safety standards and the capacity of businesses to meet their requirements will be in a stronger position to meet any new requirements for exports into the United States. Mexico, for example, has developed the México Calidad Suprema (MCS) scheme. Sponsored by government entities – the Economics Ministry, the Bank of Mexico and the Ministry of Agriculture and Rural Development (SAGARPA) – it was first established in 1999 as a voluntary scheme aimed predominantly at production for the domestic market (van der Valk and van der Roest 2008). Between 2004 and 2008, MCS was benchmarked to the GLOBALG.A.P. standard, acquiring the characteristics of a standards scheme with its associated enforcement. The rationale for the scheme's development was outlined in a presentation by its Technical Director in 2006 (Villegas 2006). This pointed to the increasing adoption of standards by buyers in major markets, including supermarkets in Europe, the United States, Canada and Mexico, the positioning of the MCS alongside other internationally-accepted standards, and the recognition of the food safety priorities of governments in developed countries. Although the scheme was developed with the support of government agencies, a range of certification bodies – both Mexican and non-Mexican, public and private – are accredited for certifying to the standard.

[40] Among the extensive literature on the impact of private food safety standards on exporters and farmers in developing countries, see Will (2011), Jaffee and Masakure (2005) and Henson and Jaffee (2008).

Clearly, there are existing schemes operative in exporting countries that are designed to meet, or facilitate compliance with, standards adopted by leading companies in the US and European export markets. Such standards were only implemented by a minority of exporting companies in any one country. Such standards **may** be recognised as sufficient to meet the requirements of the FSMA, but this will depend not only on decisions made by the US government, but on the dynamics of operationalisation of the FSMA in North America. This introduces the second factor, which is the influence on FSMA implementation of private sector designers, adopters, implementers and certifiers of standards. As was noted above, the standards environment is a dynamic one, driven not only by the changing regulatory environment but also by competition between entities involved in the process of creating standards schemes and implementing or administering such schemes. There has been a lot of activity in this area.

The FDA Deputy Commissioner for Food, Michael Taylor, suggested in March 2012 that the rule for produce safety will be 'closely aligned with the Codex Code of Hygienic Practice for Fresh Fruit and Vegetables' (Taylor 2012).[41] It would be surprising if the FDA diverged substantially from the Codex Alimentarius, and avoiding divergence minimises the risks of challenges brought by other countries to the WTO. However, the Codex, by itself, does not indicate just how the Codex Code will be implemented. The Code, for example, states that:

> Growers should identify the sources of water used on the farm (municipality, re-used irrigation water, well, open canal, reservoir, rivers, lakes, farm ponds etc.). They should assess its microbial and chemical quality, and its suitability for intended use, and identify corrective actions to prevent or minimize contamination (e.g. from livestock, sewage treatment, human habitation).
> (Codex Alimentarius Commission 2003b: 3)

In other words, the Codex defines a standard, but does not define the nature of the *standards scheme* that will enforce it, including the choice about the degree of prescription or the specific ways in which (in this case) the quality and suitability of water will be defined, measured and verified. Where the FDA's documentation does make references to standards and certification, these refer primarily to the process of accreditation and ISO standards for inspections at accreditation bodies (see, for example, U.S. Food and Drug Administration 2012: Question I4.6). Therefore, there is scope for lobbying about the precise nature of the regulations and the regulatory strategy to be employed:

- In the case of water quality, will the FDA adopt the LGMA strategy to meet the general Codex requirement for water suitability through establishing specific criteria for what constitutes suitability for intended use and indicating precisely how the assessment of water quality is to be carried out, documented and verified through third-party audit? In other words, will it go down the route of technology-based regulation?
- Or, will the new produce rule work along the lines of GLOBALG.A.P. Revision 4, adopting a management-based strategy, instructing farms to have competent bodies to identify water hazards, and respond to the challenges identified by developing suitable water safety plans?
- If a management-based regulatory strategy is adopted, choices still remain, discussed in Section 2. How will such safety plans be registered, evaluated and audited? Will farms, for example, be required to document their assessment process or use recognised companies to carry out the assessments?
- How will the FDA determine how compliance with either of these approaches is to be audited?
- For food exporting countries, in particular, the question of recognition of the equivalence in food safety systems is particularly important. Will the FDA recognise many national or

[41] See Codex Alimentarius Commission (2003b).

private systems as equivalent to the rules developed for the US farms, and how will such equivalence be established?

- More generally, the inclusion of certain foods in the category that requires application of the new fresh produce safety rule is based on the threat to human health. There is reference in the FSMA to allowing variances where 'necessary in the light of local growing conditions' (United States Congress 2010: Section 105 (c)1(F)), as long as the same level of protection is achieved. To what extent will safety controls be adjusted to reflect the incidence of different sources of contamination of food in different countries, positively as well as negatively?

Just how the new rules impact on farmers and certifiers in the United States and in food exporting countries will depend upon how the general requirements set out by the Codex are translated into an auditable and enforceable scheme and the extent to which other schemes are recognised as providing the same level of protection. These same issues arise with respect to private standards. Within GLOBALG.A.P., for example, decisions are made about appropriate forms of regulation and what constitutes equivalence in different contexts when national GAPs are developed and benchmarked.

Given all of these uncertainties, it is not surprising that different entities in the United States operating in the farming and food safety industries, or representing businesses in the sectors, have been pushing for their standards to be recognised. The LGMA, for example, would like to see its standard for leafy greens in California adopted by the FSMA. Reporting on a visit by FDA staff to the LGMA, the LGMA's website concluded by stating that 'LGMA is encouraging the FDA to consider adopting this comprehensive food safety program [the LGMA] as a means of meeting requirements of new FSMA legislation which will soon go into effect'.[42] Similarly, GLOBALG.A.P. has been working to make the GLOBALG.A.P. standard more attractive to North American food businesses. It has stripped out the social and environmental elements of GLOBALG.A.P. because these are, generally speaking, not priorities for the US food industry. At the same time, Revision 4 of GLOBALG.A.P. has shifted towards a more management-based approach which would be compatible with twin challenges of diverse farming systems and addressing the North American food safety priority, which is microbial contamination.[43] The goal is to benchmark the US version of GLOBALG.A.P., referred to as the Produce Safety Standard, to the Global Food Safety Initiative (GFSI). The logic behind this is that GFSI benchmarked pre-farmgate standards would be accepted by the FDA as indicating compliance with the mandatory fresh produce rule to be introduced as a result of the FSMA. This would then allow private standards to be offered as a means of satisfying both the needs of US domestic producers and future US import requirements.

There are good reasons to suppose that the requirement under the Foreign Supplier Verification Program to verify that foreign suppliers produce imported food using 'reasonably appropriate risk-based preventive controls' will promote increased use of certification. Even if certification is not mandatory, importers might well decide to use it, because it would provide a clear indication that reasonable steps had been taken to implement risk-based preventive controls. For the same reason, the importers' customers might demand certification. An alternative strategy might be for importers to choose to work with fewer, well-known foreign suppliers, acquiring confidence from direct knowledge of the companies they deal with. Even this might not make certification redundant. In Europe, the consequences for importers of supplying unsafe food to large customers (financial penalties, delisting, etc.) mean that certification and other supply chain oversight strategies are best seen as complementary.

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42 http://www.caleafygreens.ca.gov/blog/fda-officials-tour-spinach-farm-gain-insights-fsma-implementation

43 Note, however, that this move to a management-based approach makes GLOBALG.A.P. very different to the technology-based approach used by the LGMA.

It is likely that the FSMA will lead to increased application of standards schemes based on audit and certification at the farm level, both in the USA and in exporting countries. There will be many cases in which such schemes are already in place. In fact, the law will address the current anomaly that large retailers in the United States frequently require a GFSI-benchmarked standard for imported produce, but no auditable standard for domestically-sourced produce. It is also the case that following particular food safety problems, specific arrangements were made in the past to introduce enhanced food safety controls – for example, the MPE in Guatemala. However, the FSMA is likely to lead to a considerable extension of such controls. They will be applied to more countries and to a greater range of import channels. However, the precise impact of these controls depends to a large extent on how adoption of a fresh produce standard (or a series of product-specific standards) is translated into standards schemes and the regulatory choices made in the course of this translation.

5 Conclusion: public and private responses to food safety challenges

This paper took as its starting point the impact of private food safety standards on farms and farmers in developing countries. Within discussions on this issue there have been a number of commonly accepted assertions. In particular:

1. Private standards are different to public regulations. They are more intrusive at the farm level and create more problems for compliance.
2. Private standards are overly prescriptive, and therefore lead to inefficiencies and increased costs. The use of farm-level certification is particularly problematic because of its cost and complexity. Private standards introduce requirements that are significantly more onerous than those associated with public regulations.
3. The European Union is ahead of the United States in terms of food safety. If the United States wants to catch up, it will need to emulate the best practices found in Europe.[44]

All these assertions are thrown into doubt by the examination of the FSMA and its likely impact on the production and import of fresh produce in the United States. They will be considered in turn.

5.1 What is the difference between private standards and public regulations?

Generally speaking, fresh produce has been treated as low risk from the point of view of food safety. It was shown in Section 3.2 that the EU's guidance notes on food of non-animal origin did not consider it necessary to apply the same level of vigilance as applied to food of animal origin. This difference in treatment goes a long way to explaining why public regulations and private standards have appeared to be so different. Public regulations for food of animal origin are very strict. They include mandatory HACCP in food processing establishments, inspections (including permanent on-site government inspectors in the United States), testing regimes, etc. Private standards for fresh produce are certainly no more stringent than this, but they have stood out because public regulation of fresh produce safety has, hitherto, been ‘light touch’.

If, however, some fruits and vegetables are considered to be high risk, and if performance-based regulation through inspection is not effective in detecting food safety problems, then on-farm controls have to be adopted. These controls could be public, or private, or a mixture

[44] This view is sometimes expressed by practitioners working in the field of standards, particularly in the United Kingdom.

of the two. The two forms of control can interact. The FDA could create a new auditable standard for production and harvesting of fresh produce. It could use the existing USDA audit system aimed at verifying compliance with the 1998 guidelines on microbial contamination, possibly with modifications to reflect current best practice. Equally, it could recognise a range of public and private standards, in the United States and abroad, as providing an equivalent or acceptable level of protection for the public. Various bodies have already tried to develop equivalent standards. In Peru, for example, the government agency, SENASA, developed a standard aimed at complying with FDA guidelines. Private standards developers, such as GLOBALG.A.P., have developed new versions of their standards with the requirements of the US market in mind.

In this context, the apparent gap between public regulation and private standards narrows substantially. Both the public and private sectors look to develop technology-based and management-based approaches to food safety regulation. Implementing new systems will require public-private partnerships or recognition of private standards as establishing compliance to public regulations.

5.2 Prescription

Private standards have been criticised for their degree of prescription. These criticisms have been vocal in the United States, where the resistance of producers and producer associations to private standards has frequently pointed to the inefficiencies of the ‘one size fits all’ approach to food standards. It is argued that it inhibits innovation by being overly prescriptive and it can introduce unnecessary costs into the value chain. The critique of the prescriptive approach tends to imply that ‘farmers know best’ and that they are best placed to decide how to ensure that the food they produce is safe.

There are two problems with this view. The first relates to an appreciation of the suitability of technology-based and management-based regulation in different circumstances, as discussed in Section 2. Management-based regulation (i.e. a prescriptive approach) is more appropriate and effective when food safety problems are caused by poor practices relating to the design or operation of farms or facilities. Where it is businesses and people that introduce risks into the food safety system, prescriptive practices can eliminate them, although even here there may be alternative routes to achieving food safety, as recognised by the benchmarking of national GAPs. Management-based regulation is more appropriate to situations where the nature and level of risk varies according to the external environment. In such situations, the ‘one size fits all’ approach is inefficient.

The second issue relates to the relative merits and impacts of a prescriptive approach. There are some advantages to it. It provides clear guidelines to farms and facilities about how to comply with food safety regulations/standards. As long as the operator follows the rules, compliance is achieved. Management-based regulation is more challenging to implement. The farm or facility has to go through the process of identifying hazards, developing a food safety plan, showing how it is implemented, and showing how it is enforced through monitoring and corrective action. This requires a greater level of competence, and is potentially more open to uncertainty about compliance.

In practice, there may be convergence between the two approaches. On the one hand, it may be easier to develop risk profiles for different types of situations and to produce more standardised models of compliance with management-based regulation. To the extent that this is done, there is a move back towards prescription. On the other hand, prescriptive standards themselves adapt to changing food safety hazards and requirements. Revisions 3 and 4 of GLOBALG.A.P. have not adopted a prescriptive approach in relation to irrigation water quality. Farms are (simplifying somewhat) asked if they have undertaken an annual risk analysis relating to water for irrigation (with specifications of the kinds of risks that should

be assessed), whether water testing is undertaken by a suitable laboratory in line with the risk analysis and whether adverse results have been acted upon (GLOBALG.A.P. 2012c: Part 6.3). This is not prescriptive. It allows a tailored approach to water safety. It is less prescriptive than the LGMA, for example.

5.3 The United States and Europe

How do the United States and Europe compare with respect to initiatives on food safety, and what are the implications of the FSMA? A view taken by some food safety experts in Europe is that the reworking of European food safety legislation in the late 1990s and early twenty-first century created an EU system more effective at ensuring food safety than that of the United States. Furthermore, to the extent that EU food safety legislation has encouraged the development of private standards, the effectiveness of controls over farms and food facilities in some parts of Europe, particularly in northern Europe, has been notably higher than for many parts of the US food safety system. Foodborne illness outbreaks in the United States such as the case of salmonella in eggs in Iowa in 2010 reinforced the impression that the poor hygiene practices found in the substantial food operation at the heart of this outbreak would not have been left undetected by third-party certification in Europe. The lesson drawn from this and other examples would be that the United States needs to catch up with Europe and that the best way to do this would be through the development of private standards. Some critics of the FDA in the United States would agree with this view (see, for example, Williams 2010).

This view is mistaken for two reasons. First, the FSMA represents a significant change in food safety legislation and approaches in the United States. It will significantly change how fresh produce food safety is controlled both domestically and with respect to imported food – notwithstanding the possibility that the changes proposed for domestic production are so significant that there will, inevitably, be pressure to moderate new controls. The means by which controls will be put into effect, however, are not the same as in Europe. The government, at both federal and state level, will continue to have an important role in food safety, particularly as a legitimiser of new rules. The nature of this role was foreshadowed by the development of the LGMA in California. However, private companies will also have a role to play in the new food safety system because of the likely need for extensive monitoring and enforcement of the new fresh produce rules being developed by the FDA. It was argued above that the application of management-based regulation to imported produce would create such a strong requirement for verification that third-party certification to either FDA standards or standards accepted by the FDA as equivalent to them would be essential. This possibility is foreshadowed in the FSMA itself.

The second caveat with respect to the comparison between the United States and Europe relates to the challenges facing European regulators. At the farm level, private standards such as GLOBALG.A.P. initially focused most of their attention (in the original standard and in Revision 2) on the issue of excessive pesticide residues. This reflected the concerns of the EU authorities. It was also shown that the EU's own guidance on the application of hygiene controls did not appear to be overly concerned with health problems arising from fresh produce. While a literal reading of EU legislation might suggest that imported food should be subject to verification of on-farm hygiene practices, there is no evidence that such requirements are enforced across the EU, even if many large companies choose private standards as a way of doing precisely this. However, microbial contamination of fresh produce and the serious health impacts that arise from it does occur in Europe, even if the widespread publicity given to the E. coli outbreak in Germany in 2011 was exceptional. If

European authorities come to consider microbial contamination of fresh produce as seriously as the authorities in the United States, then it may be Europe that needs to catch up.[45]

To sum up, the FSMA represents a radical shift in food safety legislation in North America. It is likely to have a very substantial impact on both the domestic production of fresh produce and on production of food that is subsequently imported into the United States. Precisely what the impact will be depends upon how the provisions of the Act are translated into practical rules, regulations and guidance. The FDA has been left with a very demanding set of challenges. It is expected to design and implement effective and enforceable science-based food safety controls while at the same time recognising the heterogeneity of farm systems in the US and not placing too onerous a burden on farmers. Nevertheless, once it is accepted that some types of fresh produce contamination are both difficult to detect and can be the cause of serious illness and death, the logical step is to use technology-based or management-based regulation as the only possible response. The consequences for importers of fresh produce into the United States, and hence the producers and exporters of these products, are likely to be substantial.

[45] It should not be assumed that the challenges of microbial contamination will be the same in Europe as in North America, or in the countries from which food is imported into the two regions. Different types of farming practices may play an important role in determining the extent of the microbial contamination problem. However, foodborne illness outbreaks associated with microbial contamination of fresh produce have occurred in both Europe and North America.

Appendix 1: Basic HACCP principles

The US Department of Agriculture's Food Safety Inspection Service identifies the seven HACCP principles in the following terms. These are used for establishing HACCP programmes in processing plants. It is generally considered that the same level of control is not possible right across farm environments because there are too many external influences that are not under control, as is discussed by Baines *et al*. (2004) For this reason, pre-farmgate standards are usually referred to as 'HACCP-based'.

Principle 1: *Conduct a hazard analysis*.

- Plants determine the food safety hazards identify [sic] the preventive measures the plant can apply to control these hazards.

Principle 2: *Identify critical control points.*

- A critical control point (CCP) is a point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to an acceptable level. A food safety hazard is any *biological, chemical,* or *physical* property that may cause a food to be unsafe for human consumption.

Principle 3: *Establish critical limits for each critical control point*.

- A *critical limit* is the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level.

Principle 4: *Establish critical control point monitoring requirements.*

- Monitoring activities are necessary to ensure that the process is under control at each critical control point. FSIS is requiring that each monitoring procedure and its frequency be listed in the HACCP plan.

Principle 5: *Establish corrective actions.*

- These are actions to be taken when monitoring indicates a deviation from an established critical limit. The final rule requires a plant's HACCP plan to identify the corrective actions to be taken if a critical limit is not met. Corrective actions are intended to ensure that no product injurious to health or otherwise adulterated as a result of the deviation enters commerce.

Principle 6: *Establish record keeping procedures.*

- The HACCP regulation requires that all plants maintain certain documents, including its hazard analysis and written HACCP plan, and records documenting the monitoring of critical control points, critical limits, verification activities, and the handling of processing deviations.

Principle 7: *Establish procedures for verifying the HACCP system is working as intended.*

Source: http://www.fsis.usda.gov/OA/background/keyhaccp.htm

These seven HACCP principles are the bedrock of the food safety systems around the world. They were, for example, incorporated into the Codex Alimentarius Commission general principles of food hygiene in 1969 (Codex Alimentarius Commission 2003a: 22-3). The precise specifications of the principles are subject to variation.

Appendix 2: Websites for standard-setting organisations

A lot of information about private standards can be obtained from the websites of standards developers. In some cases, extensive documentation about standards is publicly available. Relevant websites include the following.

AIB International

AIB International's website provides information about its products, although most have to be purchased.

http://www.aibonline.org/

BRC Global Standards Food

'In 1998 the British Retail Consortium (BRC), responding to industry needs, developed and introduced the BRC Food Technical Standard to be used to evaluate manufacturers of retailers own brand food products. It is designed to assist retailers and brand owners produce food products of consistent safety and quality and assist with their "due diligence" defence, should they be subject to a prosecution by the enforcement authorities. Under EU food Law, retailers and brand owners have a legal responsibility for their brands.'

http://www.brcglobalstandards.com/standards/food/

FSSC Food Safety System Certification 22000

Based on ISO 22000, complemented by the British Standards Institute PAS 220 Prerequisite Programme. For a discussion of this standard, see Appelhof and van den Heuvel (2011).

http://www.fssc22000.com/en/

Global Food Safety Initiative (GFSI)

'The Global Food Safety Initiative is a business-driven initiative for the continuous improvement of food safety management systems to ensure confidence in the delivery of safe food to consumers worldwide. GFSI provides a platform for collaboration between some of the world's leading food safety experts from retailer, manufacturer and food service companies, service providers associated with the food supply chain, international organizations, academia and government.'

GFSI is not a standard like the other examples in this Appendix. One of the activities of GFSI is to benchmark existing standards so that buyers can accept different certifications as being equivalent.

http://www.mygfsi.com/

On benchmarking specifically, see http://www.mygfsi.com/gfsi-benchmarking-general.html

GLOBALG.A.P.

GLOBALG.A.P. provides extensive documentation of its standards, and this can be found at http://www.globalgap.org/cms/front_content.php?idcat=9

GLOBALG.A.P. also provides a list of its current members by category: see http://www.globalgap.org/cms/front_content.php?idcat=4

IFS Food

'The IFS Food is a Standard for auditing retailer and wholesaler branded food product suppliers and only concerns food processing companies or companies that pack loose food products.'

http://www.ifs-certification.com/index.php?page=home&content=public_content&desc=ifs_standards_food_5&language=english

QS, Qualität und Sicherheit

The QS site, http://www.q-s.de/en/ provides extensive documentation of the standard. See also Appelhof and van den Heuvel (2011: 125-26).

SCV De Stichting Certificatie Voedselveiligheid (Dutch HACCP)

http://www.foodsafetymanagement.info/net-book.php?op=cms&pageid=1&pageid_up=0&nnl=english

SQF
The owners of the SQF standard, the SQF Institute, provide extensive resources at its website, http://www.sqfi.com/. This includes the latest versions of the SQF 1000 and SQF 2000 codes.

Appendix 3: List of sources

The following people were interviewed in the course of the research. None of them have reviewed the Working Paper and they bear no responsibility for its contents.

Name	**Position at the time of the interview**
Richard Baines	Royal Agricultural College, UK
Linda Calvin	Economics Research Service, USDA
Roberta Cook	Department of Agricultural and Resource Economics, University of California, Davis
Nigel Garbutt	Chairman, GLOBALG.A.P.
Donna Garren	Global Food Safety Initiative, Washington DC
David Gombas	Sr Vice President, Food Safety and Technology, United Fresh Produce Association, Washington DC
Steve Homer	Managing Director, SMHProjects, UK
Scott Horsfall	California Leafy Greens Marketing Agreement
Kristian Moeller	Secretary, GLOBALG.A.P.
Belinda Mohr	U.S. Food and Drug Administration
Kevin Swoffer	Director, KPS Resources Ltd
Rick Pasco	Attorney, McLeod, Watkinson and Miller, Washington DC
Bernd van der Meulen	Professor of Law and Governance, Wageningen University and Chairman of the Dutch Food Law Association
Richard Williams	George Mason University, formerly U.S. Food and Drug Administration

The Working Paper draws on previous work on standards and fresh produce, particularly that which led to the production of Dolan and Humphrey (2000; 2004), Humphrey (2008) and Henson and Humphrey (2009).

Extensive use was made of websites. The FDA has an extensive programme of public engagement for the FSMA with many documents and consultations about how to implement the Act. Other interested parties, such as the Grocery Manufacturers Association and the United Fresh Produce Association have made submissions to the FDA, developed policy initiatives and organised conferences.

References

Appelhof, T. and van den Heuvel, R. (2011) 'Inventory of Private Food Law', in B. van der Meulen (ed.) *Private Food Law*, Wageningen, Wageningen Academic Publishers: 113-48

Aragrande, M.; Segre, A.; Gentile, E.; Malorgio, G.; Giraud Heraud, E.; Robles Robles, R.; Halicka, E.; Loi, A. and Bruni, M. (2005) *Food Supply Chains Dynamics and Quality Certification*, Final Report, Brussels: EU DG Joint Research Centre (last accessed February 2008)

Arnade, C.; Calvin, L. and Kuchler, F. (2009) 'Consumer Response to a Food Safety Shock: The 2006 Food-Borne Illness Outbreak of E. Coli O157: H7 Linked to Spinach', *Review of Agricultural Economics* 31.4: 734-50

Baines, R.N.; Ryan, P. and Davies, W.P. (2004) 'HACCP at the Farm Level: The Missing Link in Food Safety & Security', paper presented at IFAMA Conference, Montreux, June, available https://www.ifama.org/events/conferences/2004/cmsdocs/Baines1095.pdf (last accessed October 2011)

Brunsson, N. and Jacobsson, B. (2000) 'The Contemporary Expansion of Standardization', in N. Brunsson and B. Jacobsson (eds), *A World of Standards*, Oxford, Oxford University Press: 1-17

Burrows, V. (2008) *FDA Authority to Regulate on-Farm Activity*, CRS Report for Congress RS22939, Washington DC: Congressional Research Service, available http://www.nationalaglawcenter.org/assets/crs/RS22939.pdf (last accessed July 2012)

Busch, L.; Thiagarajan, D.; Hatanaka, M.; Bain, C.; Flores, L. and Frahm, M. (2005) *The Relationship between U.S Food Retailers and TPC*, RAISE SPS Global Analytical Report 9, Washington DC: USAID, available http://cs3.msu.edu/d/pubs/The%20Relationship%20of%20TPC%20to%20SPS%20Measures--Final%20Report%20+%20Annexes.pdf (last accessed July 2012)

Caduff, L. and Bernauer, T. (2006) 'Managing Risk and Regulation in European Food Safety Governance', *Review of Policy Research* 23.1: 153-68

California Strawberry Commission (2005) *Food Safety Program*, Watsonville, CA: California Strawberry Commission, available http://www.calstrawberry.com/fileData/docs/FSP_English.pdf (last accessed July 2012)

Calvin, L. (2007) 'Outbreak Linked to Spinach Forces Reassessment of Food Safety Practices', *Amber Waves* 5.3: 25-31, available http://webarchives.cdlib.org/sw1vh5dg3r/http://ers.usda.gov/AmberWaves/June07/Features/Spinach.htm (last accessed July 2012)

—— (2003) 'Produce, Food Safety, and International Trade: Response to U.S. Foodborne Illness Outbreaks Associated with Imported Produce', in J. Buzby (ed.) *International Trade and Food Safety: Economic Theory and Case Studies*, Washington D.C., United States Department of Agriculture, Economics Research Service: 74-96, available http://www.ers.usda.gov/Publications/AER828/ (last accessed July 2012)

Carman, H. (2007) 'California Farmers Adapt Mandated Marketing Programs to the 21st Century', *California Agriculture* 61.4: 177-183, available http://ucce.ucdavis.edu/files/repositoryfiles/ca6104p177-65681.pdf (last accessed July 2012)

CEC (2005) 'Regulation (EC) No 396/2005 on Maximum Residue Levels of Pesticides in or on Food and Feed of Plant and Animal Origin and Amending Council Directive 91/414/Eec', *Official Journal of the European Communities*, 16 March 2005, available http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:070:0001:0016:en:PDF (last accessed July 2012)

—— (2004a) 'Corrigendum to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on Official Controls Performed to Ensure the Verification of Compliance with Feed and Food Law, Animal Health and Animal Welfare Rules', *Official Journal of the European Union*, 28 May 2004, available http://europa.eu./comm/food/food/controls/index_en.htm (last accessed July 2012)

—— (2004b) 'Corrigendum to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the Hygiene of Foodstuffs', *Official Journal of the European Communities*, 25 June 2004, available http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:226:0003:0021:EN:PDF (last accessed July 2012)

—— (2004c) 'Corrigendum to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 Laying Down Specific Hygiene Rules for Food of Animal Origin', *Official Journal of the European Communities*, 25 June 2004, available http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:226:0022:0082:EN:PDF (last accessed July 2012)

—— (2002) 'Regulation (EC) No 178/2002 Laying Down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority and Laying Down Procedures in Matters of Food Safety', *Official Journal of the European Communities* L 31/1. available http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF (last accessed July 2012)

—— (2000a) *Commission Directive 2000/24/EC*, L 107/28, Brussels: Commission of the European Communities, available http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:107:0028:0037:EN:PDF (last accessed July 2012)

—— (2000b) *White Paper on Food Safety*, COM (1999) 719 final, Brussels: Commission of the European Communities, available http://ec.europa.eu/dgs/health_consumer/library/pub/pub06_en.pdf (last accessed July 2012)

Chen, K. and Dunnegan-Mallat, R. (2008) 'H.R. 3610, the Food and Drug Import Safety Act of 2007', *International Law* 42.4: 1339-56

Codex Alimentarius Commission (2010) *Consideration of the Impact of Private Standards*, CX/CAC 10/33/13, Rome/Geneva: FAO/WHO, available ftp://ftp.fao.org/codex/Meetings/CAC/cac33/cac33_13e.pdf (last accessed July 2012)

—— (2004) *Code of Hygienic Practice for Milk and Milk Products*, CAC/RCP 57-2004, Rome/Geneva: FAO/WHO, available http://www.codexalimentarius.net/web/standard_list.do?lang=en (last accessed July 2012)

—— (2003a) *Recommended International Code of Practice General Principles of Food Hygiene*, CAC/RCP 1 1969, R.4-2003, Rome/Geneva: FAO/WHO, available http://www.codexalimentarius.org/ (last accessed July 2012)

—— (2003b) *Code of Hygienic Practice for Fresh Fruit and Vegetables*, CAC/RCP 53-2003, Rome/Geneva: FAO/WHO, available http://www.codexalimentarius.org/ (last accessed July 2012)

Coglianese, C. and Lazer, D. (2003) 'Management-Based Regulation: Prescribing Private Management to Achieve Public Goals', *Law & Society Review* 37.4: 691-730

Dobson Consulting (1999) *Buyer Power and Its Impact on Competition in the Food Retail Sector of the European Union*, Report prepared for the European Commission - DGIV Study contract number IV/98/ETD/078, Nottingham: Dobson Consulting

Dolan, C. and Humphrey, J. (2004) 'Changing Governance Patterns in the Trade in Fresh Vegetables between Africa and the United Kingdom', *Environment and Planning A* 36.3: 491-509

—— (2000) 'Governance and Trade in Fresh Vegetables: The Impact of UK Supermarkets on the African Horticulture Industry', *Journal of Development Studies* 37.2: 147-176

EUREPGAP (2005a) *EUREPGAP Control Points & Compliance Criteria Fruit and Vegetables Version 2.1-Oct04*, Cologne: EUREPGAP

—— (2005b) *EUREPGAP General Regulations Fruit and Vegetables Version 2.1-Oct04*: EUREPGAP, available http://www.sativa.pt/Uploads/%7B184200AD-05DB-499B-925E-EF44095DAC7E%7D.pdf (last accessed July 2012)

—— (2001) *EUREPGAP Protocol for Fresh Fruit and Vegetables, Rev02*, Cologne: EUREPGAP

European Commission (2006) *Guidance Document: Key Questions Related to Import Requirements and the New Rules on Food Hygiene and Official Food Controls*, Brussels: European Commission, Health and Consumer Protection Directorate-General, available http://ec.europa.eu/food/international/trade/interpretation_imports.pdf (last accessed July 2012)

Falkenstein, D. (2010) 'Salinas Valley, Leafy Green Vegetables, and E. Coli', available http://www.foodpoisonjournal.com/2010/02/articles/food-poisoning-information/salinas-valley-leafy-green-vegetables-and-e-coli/ (last accessed July 2012)

Florida Department of Agriculture and Consumer Services: Division of Fruit and Vegetables (2011) *Food Safety Inspection – Tomato Good Agricultural Practices Open Field Production, Harvest and Field Packing Protocol*, Rule 5G-6.005, F.A.C., Winter Haven, FL: Florida Department of Agriculture and Consumer Services: Division of Fruit and Vegetables, available http://www.freshfromflorida.com/fruits/Tomatoes.html (last accessed July 2012)

FLSC (2007) *Food Safety Leadership Council: On-Farm Produce Standards*, Burbank: Food Safety Leadership Council, available http://www.nationalwatermelonassociation.com/FSLC%20On-Farm%20Standard.pdf (last accessed July 2012)

Fuchs, D. and Kalfagianni, A. (2010) 'The Causes and Consequences of Private Food Governance', *Business and Politics* 12.3: article 5

Fulponi, L. (2006) *Final Report on Private Standards and the Shaping of the Agro-Food System*, AGR/CA/APM(2006)9/FINAL, Paris: OECD, Directorate for Food, Agriculture and Fisheries, Committee for Agriculture, available

http://www.oecd.org/officialdocuments/displaydocumentpdf?cote=agr/ca/apm%282006%299/final&doclanguage=en (last accessed July 2012)

Gale, S.F. (2006) 'Case Studies in Food Protection: McDonald's USA: A Golden Arch of Supply Chain Food Safety', *Food Safety Magazine*, available http://www.foodsafetymagazine.com/articlePF.asp?id=491&sub=sub1 (last accessed July 2012)

—— (2004) 'Case Studies in Food Protection: Fresh Express: Cutting Edge Food Safety ', *Food Safety Magazine*, available http://www.foodsafetymagazine.com/articlePF.asp?id=1698&sub=sub1 (last accessed July 2012)

GLOBALG.A.P. (2012a) *Control Points and Compliance Criteria: Integrated Farm Assurance, Fruit and Vegetables*, English Version 4.0_ Edition 4.01-Fbe2012, Cologne: GLOBALG.A.P., available http://www.globalgap.org/cms/upload/The_Standard/IFA/Version_4.0-1_Feb2012/English/CPCC/120206_gg_ifa_cpcc_fv_eng_v4_0-1.pdf (last accessed July 2012)

—— (2012b) *Checklist: Integrated Farm Assurance, Fruit and Vegetables*, English Version4.0 Edition4.0-1_Feb2012, Cologne: GLOBALG.A.P., available http://www.globalgap.org/cms/front_content.php?idart=1440 (last accessed July 2012)

—— (2012c) *Control Points and Compliance Criteria: Integrated Farm Assurance, Crops Base*, English Version 4.0 Edition 400-1_Feb2012, Cologne: GLOBALG.A.P., available http://www.globalgap.org/cms/upload/The_Standard/IFA/Version_4.0-1_Feb2012/English/CPCC/120206_gg_ifa_cpcc_cb_eng_v4_0-1.pdf (last accessed July 2012)

—— (2010) *The GRASP Project Report: Towards Good Social Practice in Agriculture*, Cologne: GLOBALG.A.P., available http://www.globalgap.org/cms/upload/The_Standard/GRASP/100625_D-GRASP_Report_2010_small-doublepages.pdf (last accessed July 2012)

—— (2009) *Control Points and Compliance Criteria, Integrated Farm Assurance, Introduction*, English Version V3.0-3 April 2009, Cologne: GLOBALG.A.P., available http://www.globalgap.org/cms/upload/The_Standard/IFA/English/CPCC/GG_EG_IFA_CPCC_Intro-AF_ENG_V3_0_3_Apr09.pdf (last accessed July 2012)

Graffham, A. (2006a) *EU Legal Requirements for Imports of Fruit and Vegetables (a Supplier's Guide)*, Fresh Insights 1: DFID/IIED/NRI, available http://www.agrifoodstandards.net/resources/global/fresh_insights_1_eu_legal_requirements_for_imports_of_fruits_and_vegetables (last accessed July 2012)

—— (2006b) 'Overview of EU SPS Legislation (Imports from Third Countries)', presentation made at IDS workshop on Standards in Global Food Trade, Brighton, December

Graffham, A.; Karehu, E. and Macgregor, J. (2007) *Impact of EurepGAP on Smallscale Vegetable Growers in Kenya*, Fresh Insights 6, Greenwich: Natural Resources Institute, available http://www.dfid.gov.uk/r4d/PDF/Outputs/EcoDev/60506fresh_insights_6_EurepGapKenya.pdf (last accessed July 2012)

Graz, J.-C. and Nölke, A. (2008) 'Introduction', in J.-C. Graz and A. Nölke (eds), *Transnational Private Governance and Its Limits*, Abingdon and New York, Routledge: 1-26

Grocery Manufacturers Association (2007) *A Commitment to Consumers to Ensure the Safety of Imported Foods: Four Pillars of Public-Private Partnership: Executive Summary*, Washington DC: Grocery Manufacturers Association, available http://www.gmaonline.org/downloads/wygwam/FourPillarsSummary.pdf (last accessed July 2012)

Hatanaka, M.; Bain, C. and Busch, L. (2005) 'Third-Party Certification in the Global Agrifood System', *Food Policy* 30.3: 354-69

Heggum, C. (2010) 'Revolution in Food Safety Management: Practical Implementation by Industry', presentation made at 3rd Australian Food Safety Conference, Melbourne, 8-9 September

Henson, S. and Jaffee, S. (2008) 'Understanding Developing Country Strategic Responses to the Enhancement of Food Safety Standards', *The World Economy* 31.5: 548-568

Henson, S. and Reardon, T. (2005) 'Private Agri-Food Standards: Implications for Food Policy and the Agri-Food System', *Food Policy* 30.3: 241-53

Henson, S.J. and Humphrey, J. (2009) *The Impacts of Private Food Safety Standards on the Food Chain and on Public Standard-Setting Processes*, Paper prepared for 32nd session of Codex Alimentarius Commission ALINORM 09/32/9D-Part II, Rome/Geneva: FAO/WHO, available http://www.codexalimentarius.org (last accessed July 2012)

Hogan Lovells US LLP (2011) *FDA Food Safety Modernisation Act: Section-by-Section Analysis*, Washington DC: Hogan Lovells US LLP, available http://www.gmaonline.org/file-manager/Food_Safety/Summary_of_FDA_Food_Safety_Modernization_Act.pdf (last accessed July 2012)

Humber Authorities Food Liaison Group (n.d.) *Food Safety Act 1990: Guidelines on the Statutory Defence of Due Diligence*, Kingston on Hull: Humber Authorities Food Liaison Group

Humphrey, J. (2008) *Private Standards, Small Farmers and Donor Policy: EUREPGAP in Kenya*, IDS Working Paper 308, Brighton: Institute of Development Studies, available http://www.ids.ac.uk/files/Wp308.pdf (last accessed July 2012)

IFS (2010) 'History of the IFS', available http://www.ifs-certification.com/index.php/en/ifs-certified-companies-en/introduction-to-ifs/ifs-history (last accessed July 2012)

Interagency Working Group on Import Safety (2007a) *Action Plan for Import Safety: A Roadmap for Continual Improvement*, Washington DC, available http://archive.hhs.gov/importsafety/report/actionplan.pdf (last accessed July 2012)

—— (2007b) *Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety*, Washington DC, available http://archive.hhs.gov/importsafety/report/report.pdf (last accessed July 2012)

ISO (2010) *International Standards and 'Private Standards'*, ISO/TC 34 SC17, Geneva: International Organisation for Standardisation, available http://www.iso.org/iso/private_standards.pdf (last accessed July 2012)

Jaffee, S.; Henson, S. and Dias Rios, L. (2011) *Participation of Smallholder Farmers in Supply Chains to High-Value Markets: The Role of Exporters as Gatekeepers of Value Chain Participation*, Report 62324-AFR, Washington DC: World Bank, available

http://siteresources.worldbank.org/INTARD/Resources/Making_the_Grade_ePDF2.pdf (last accessed July 2012)

Jaffee, S. and Masakure, O. (2005) 'Strategic Use of Private Standards to Enhance International Competitiveness: Vegetable Exports from Kenya and Elsewhere', *Food Policy* 30.3: 316-33

Janning, F. (2008) 'Risk Regulation without Political Conflicts? Risk Structures in Food Safety Politics in Germany, Great Britain and the Netherlands', *German Policy Studies* 4.1: 67-106

Jim Prevor's Perishable Pundit (2006) 'Buyer-Led Food Safety Effort Leaves Open Question of Buyer Commitment', available http://www.perishablepundit.com/index.php?date=10/30/06&pundit=1 (last accessed July 2012)

Kirk-Wilson, R. (2008) *Review of Uptake of FSA Food Assurance Scheme Guidance by UK Scheme Operators* London: Food Standards Agency, available http://www.food.gov.uk/multimedia/pdfs/foodassurancereview.pdf (last accessed July 2012)

—— (2002) *Review of Food Assurance Schemes*, London: Food Standards Agency, available http://www.food.gov.uk/multimedia/pdfs/FAS_Report.PDF (last accessed July 2012)

Klaus, B. and Meyer, A.H. (2008) 'The Liability of the Distributors in the Event of Infringements of Food Law - Case Involving Lidl Italia: The Judgements of the European Court of Justice and the *Guidice De Pace* of Monselice, Italy', *European Food and Feed Law Review* 6. 407-12

Knowles, T.; Moody, R. and McEachern, M. (2007) 'European Food Scares and Their Impact on EU Food Policy', *British Food Journal* 109.1: 43-67

Knutson, R. and Ribeira, L. (2011) *Provisions and Economic Implications of FDA's Food Safety Modernization Act*, AFPC Issue Paper 11-1, College Station, TX: Texas A&M University, Agricultural and Food Policy Center, available http://www.afpc.tamu.edu/pubs/1/554/IP%2011-01.pdf (last accessed July 2012)

LGMA (2011) *Commodity Specific Food Guidelines for the Production and Harvest of Lettuce and Leafy Greens*, Sacramento: California Leafy Green Products Handler Marketing Agreement, available http://www.caleafygreens.ca.gov/sites/default/files/LGMA%20Accepted%20Food%20Safety%20Practices%207.22.11.pdf (last accessed July 2012)

—— (2010a) *Commodity Specific Food Guidelines for the Production and Harvest of Lettuce and Leafy Greens*, Sacramento: California Leafy Green Products Handler Marketing Agreement, available http://www.lgma.ca.gov (last accessed July 2012)

—— (2010b) *California Leafy Green Products Handler Marketing Agreement: Audit Checklist*, Sacramento: California Leafy Green Products Handler Marketing Agreement, available http://www.caleafygreens.ca.gov/sites/default/files/Audit%20Checklist%20California%207-23-10.pdf (last accessed July 2012)

Loader, R. and Hobbs, J. (1999) 'Strategic Responses to Food Safety Legislation', *Food Policy* 24.6: 685-706

Maertens, M. and Swinnen, J. (2009) 'Trade, Standards and Poverty: Evidence from Senegal', *World Development* 37.1: 161-78

Mayer, F. and Gereffi, G. (2010) 'Regulation and Economic Globalization: Prospects and Limits of Private Governance', *Business and Politics* 12.3: article 11

Mead, P.S.; Slutsker, L.; Dietz, V.; McCaig, L.F.; Bresee, J.S.; Shapiro, C.; Griffin, P.M. and Tauxe, R.V. (1999) 'Food-Related Illness and Death in the United States', *Emerging Infectious Diseases* 5.5: 607-25, available http://wwwnc.cdc.gov/eid/article/5/5/pdfs/99-0502.pdf (last accessed July 2012)

Mench, J. (2008) 'Farm Animal Welfare in the U.S.A.: Farming Practices, Research, Education, Regulation, and Assurance Programmes', *Applied Animal Behaviour Science* 113.4: 298-312

Mithöfer, D.; Asfaw, S.; Ehlert, C.; Mausch, K. and Waibel, H. (2007) 'Economic Impact of EUREPGAP Standard on Small to Large Scale Producers and Farm Worker Welfare in Kenya', Paper presented at FAO-UNCTAD Regional Workshop on Good Agricultural Practices in Eastern and Southern Africa: Practices and Policies, Nairobi, 6-9 March,

Murray, G. (2009) 'Produce Food Safety Standards Today: United Fresh Audits Benchmarking Matrix', background paper for Global Conference on Produce Food Safety Standards, Washington DC, April, United Fresh Produce Association, available http://www.unitedfresh.org/assets/files/2009GlobalConferenceFoodSafety/Cargill_Comparison_Food_Safety_Audits.xls (last accessed July 2012)

Nadvi, K. and Wältring, F. (2004) 'Making Sense of Global Standards', in H. Schmitz (ed.) *Local Enterprises in the Global Economy*, Cheltenham, Edward Elgar: 53-94

National Leafy Greens Marketing Agreement (2009) *Justification for Proposed Federal Marketing Agreement for Leafy Green Vegetables*, available http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5077207 (last accessed July 2012)

Odza, K. (2011) 'Preparing for FSMA Produce Safety Rules: What Ag-in-the Middle' Needs to Do', available http://www.foodliabilitylaw.com/2011/02/articles/general-information/preparing-for-fsma-produce-safety-rules-what-aginthe-middle-needs-to-do/ (last accessed July 2012)

Ollinger, M.; Moore, D. and Chandran, R. (2004) *Meat and Poultry Plants' Food Safety Investments: Survey Findings*, Technical Bulletin 1911, Washington DC: United States Department of Agriculture, Economic Research Service, available http://www.ers.usda.gov/publications/tb-technical-bulletin/tb1911.aspx (last accessed July 2012)

Paggi, M. (2008) 'An Assessment of Food Safety Policies and Programs for Fruits and Vegetables: Food-Borne Illness Prevention and Food Security', paper presented at North American Agrifood Market Integration Consortium Workshop, Austin, May 22, available http://naamic.tamu.edu/austin/paggi.pdf (last accessed July 2012)

Plunkett, D. and DeWaal, C.S. (2008) 'Who Is Responsible for the Safety of Food in a Global Market? Government Certification v. Importer Accountability as Models for Assuring the Safety of Internationally Traded Foods', *Food and Drug Law Journal* 63. 657-64

Prakash, A. and Potoski, M. (2010) 'Private Authority Certification Regimes: A Club Theory Perspective', in T. Porter and K. Ronit (eds), *The Challenges of Global Business Authority: Democratic Renewal, Stalemate or Decay?*, Albany, State University of New York Press: 39-64

Richards, T. and Patterson, P. (1999) 'The Economic Value of Public Relations Expenditures: Food Safety and the Strawberry Case', *Journal of Agricultural and Resource Economics* 24.2: 440-62

Rodman, N. (2008) 'Private Food Safety Standards and Value Chains: How Does GLOBALG.A.P. Change the Sourcing Strategies of German Supermarkets?', Diplomarbeit im Fach Wirtschafts- und Sozialgeographie Thesis, Cologne University

Shipman, D. (2009) *Statement before the Subcommittee on Horticulture and Organic Agriculture, House Committee on Agriculture* Washington DC: USDA, Agricultural Marketing Service, available http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5078608 (last accessed July 2012)

Suppan, S. (2008) *Import Food Safety in the Twilight of the Bush Administration*, Minneapolis: Institute for Agriculture and Trade Policy, available http://www.iatp.org/files/451_2_102786.pdf (last accessed July 2012)

Swoffer, K. (2005) 'EU Food Safety and the Increasing Role of Private Based Standards', Paper presented at ERS Conference, Washington DC, November 3, available http://www.farmfoundation.org/news/articlefiles/360-KSwoffer.pdf (last accessed July 2012)

Taylor, M. (2012) 'Ensuring Produce Safety in a Global Food System', Speech made at America Trades Produce meeting, Tubac, AZ, 22 March, available http://www.fda.gov/Food/FoodSafety/FSMA/ucm297839.htm (last accessed July 2012)

U.S. Food and Drug Administration (2012) 'FDA Food Safety Modernization Act (FSMA): Frequently Asked Questions (2012)', U.S. Food and Drug Administration, available http://www.fda.gov/Food/FoodSafety/FSMA/ucm247559.htm (last accessed July 2012)

—— (2011) *Safer Fruits and Vegetables: FDA Aims to Set Production Standards*, Washington DC: FDA Consumer Health Information, available http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM262154.pdf (last accessed July 2012)

—— (2010) 'FDA Food Safety Modernization Act (FSMA): Frequently Asked Questions', U.S. Food and Drug Administration, available http://www.fda.gov/Food/FoodSafety/FSMA/ucm247559.htm#scope1 (last accessed July 2012)

—— (2009) *Produce Safety Regulation*, Proposed Rule 0910-AG35 Washington DC: HHS/FDA, available http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=200910&RIN=0910-AG35 (last accessed July 2012)

—— (2008) 'Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables', U.S. Food and Drug Administration, available http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/produceandplanproducts/ucm064458.htm (last accessed July 2012)

—— (2007) *An Integrated Strategy for Protecting the Nation's Food Supply*, Washington DC: Department of Health and Human Services, Food and Drug Administration, available http://www.fda.gov/food/foodsafety/foodsafetyprograms/foodprotectionplan2007/ucm132565.htm (last accessed July 2012)

—— (2006) 'FDA Announces Findings from Investigation of Foodborne E. Coli O157:H7 Outbreak in Spinach', FDA News Release, U.S. Food and Drug Administration, available http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108748.htm (last accessed July 2012)

—— (2004) *Produce Safety from Production to Consumption: 2004 Action Plan to Minimize Foodborne Illness Associated with Fresh Produce Consumption*, Washington DC: Food and Drug Administration, available http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/FruitsVegetablesJuices/FDAProduceSafetyActivities/ProduceSafetyActionPlan/ucm129487.htm (last accessed July 2012)

—— (1998) *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, September, Washington DC: U.S. Food and Drug Administration, available http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/UCM169112.pdf (last accessed July 2012)

UK Government (1990) *Food Safety Act*, available http://www.legislation.gov.uk/ukpga/1990/16/enacted (last accessed July 2012)

United Fresh Produce Association (2009) *Food Safety Policy White Paper*, Washington DC: United Fresh Produce Association, available http://www.unitedfresh.org/assets/files/GR/United%20Fresh%20Food%20Safety%20White%20Paper%28final%20document%29.pdf (last accessed July 2012)

United States Congress (2010) *FDA Food Safety Modernization Act*, H.R. 2751, Washington DC: 111th Congress, available http://www.gpo.gov/fdsys/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf (last accessed July 2012)

—— (2009a) *Food and Drug Administration Globalization Act*, H.R. 759, Washington DC: 111th Congress, available http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h759ih.txt.pdf (last accessed July 2012)

—— (2009b) *Food Safety Enhancement Act*, H.R. 2749, Washington DC: 111th Congress, available http://www.gpo.gov/fdsys/pkg/CRPT-111hrpt234/pdf/CRPT-111hrpt234.pdf (last accessed July 2012)

United States Government Accountability Office (GAO) (2010) *FDA Could Strengthen Oversight of Imported Food by Improving Enforcement and Seeking Additional Authorities*, Washington DC: Government Accountability Office, available http://www.gao.gov/new.items/d10699t.pdf (last accessed July 2012)

Unnevehr, L. (2000) 'Food Safety Issues and Fresh Food Product Exports from LDCs', *Agricultural Economics* 23.3: 231-40

USDA (2009) *USDA Good Agricultural Practices & Good Handling Practices Audit Verification Checklist*, Washington DC: United States Department of Agriculture, available http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5091326 (last accessed July 2012)

van der Meulen, B. (2011) 'The Anatomy of Private Food Law', in B. van der Meulen (ed.) *Private Food Law*, Wageningen, Wageningen Academic Publishers: 75-111, available http://www.wageningenacademic.com/_clientFiles/download/EIFL-06-e.pdf (last accessed July 2012)

van der Valk, O. and van der Roest, J. (2008) *National Benchmarking against GLOBALGAP: Case Studies of Good Agricultural Practices in Kenya, Malaysia, Mexico and Chile*, Report 2008-079, The Hague: Wageningen, LEI, available http://edepot.wur.nl/11453 (last accessed July 2012)

Villegas, M. (2006) 'Mexico Calidad Suprema', presententation made to conference, Costa Rica, available http://www.aserca.gob.mx/artman/uploads/04-06--mexico-calidad-suprema.pdf (last accessed July 2012)

Vincent, K. (2004) '"Mad Cows" and Eurocrats – Community Responses to the BSE Crisis', *European Law Journal* 10.5: 499-517

Vogel, D. (2003) *The Politics of Risk Regulation in Europe and the United States*, Idées pour le Débat 01/2003, Paris: Institut du Développement Durable et des Relations Internationales, available http://www.iddri.org/Publications/Collections/Idees-pour-le-debat/id_0301_vogel.pdf (last accessed July 2012)

Will, M. (2011) 'GlobalGAP Smallholder Group Certification: Challenge and Opportunity for Smallholder Inclusion into Global Value Chains', in B. van der Meulen (ed.) *Private Food Law*, Wageningen, Wageningen Academic Publishers: 203-228, available http://www.wageningenacademic.com/_clientFiles/download/EIFL-06-e.pdf (last accessed July 2012)

Williams, R. (2010) *A New Role for the FDA in Food Safety*, Working Paper 10-69: George Washington University, Mercatus Centre, available http://mercatus.org/sites/default/files/publication/wp1069-a-new-role-for-the-fda.pdf (last accessed July 2012)

World Bank (2005) *Food Safety and Agricultural Health Standards: Challenges and Opportunities for Developing Country Exports* Report 31207, Washington D.C.: The World Bank, Poverty Reduction and Economic Management Trade Unit, available http://www-wds.worldbank.org/servlet/WDS_IBank_Servlet?pcont=details&eid=000160016_20050125093841 (last accessed July 2012)

WTO (2007a) *Private Voluntary Standards and Developing Country Market Access: Preliminary Results*, G/SPS/GEN/763, Geneva: WTO, Committee on Sanitary and Phytosanitary Measures, available http://www.wto.org/english/docs_e/docs_e.htm (last accessed July 2012)

—— (2007b) *Private Standards and the SPS Agreement, Note by the Secretariat*, G/SPS/GEN/746, Geneva: WTO, Committee on Sanitary and Phytosanitary Measures, available http://www.wto.org/english/docs_e/docs_e.htm (last accessed July 2012)