

GOVERNING A GLOBAL FOOD SUPPLY: HOW THE 2010 FDA FOOD SAFETY MODERNIZATION ACT PROMISES TO STRENGTHEN IMPORT SAFETY IN THE US

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Abstract

Food systems worldwide have experienced a significant level of integration in recent decades, creating a global and dynamic food supply. In the US, imports amount to 15% of the American diet and nearly doubled in value during the last decade, reaching \$90 billion in 2008. If food imports satisfy a growing domestic demand, they also pose formidable regulatory challenges when it comes to safety. A global food supply may introduce in domestic systems new, non-endemic risks, re-introduce risks that were controlled and rapidly spread contamination across borders. Recent food scares caused by imported foods have highlighted the vulnerabilities of the US food safety system in addressing the risks posed by a global food supply and increased public and private demands for food safety. In January 2011, President Obama signed into law the FDA Food Safety Modernization Act, a comprehensive reform bill promising to significantly improve the US food safety system and introduce new instruments to minimise risks at home and abroad. The objective of this article is to understand how a major world economy is responding to the import safety challenge and what institutions and regulations are emerging to ensure the safety of a global food chain. We do so by analysing the new legislation to identify the policy approaches chosen and evaluate their promise and pitfalls. In the absence of a general theoretical model defining an optimal regulatory mix to promote food import safety, our analysis was informed by recent studies on the challenges of import safety as well as research on specific aspects of food safety regulatory policy that we encountered in the reform bill. The results of our analysis highlight a four-pronged approach in the reform bill based on (1) risk-based interventions and prevention; (2) information management and record keeping; (3) third-party certification; and (4) international activities. Several provisions extend the US authority to carry out enforcement and other activities in exporting countries, raising concerns about extraterritorial jurisdiction. Additionally, the reform institutionalises a growing trend where food safety governance derives from public and private regulations. Although reliance on private regulation may be desirable given the advances in safety controls in the private sector, regulators should exercise caution and set up adequate incentives and checks to avoid problems of conflicts of interest and capture.

1 Introduction: Eat at Your Own Risk

Dan Glickman, US Secretary of Agriculture from 1995 to 2001, used to repeat that the United States has the safest food supply in the world.¹ In March 2009, President Barack Obama echoed that the United States is one of the safest places in the world when it comes to food.² In spite of these assurances, frequent reports of food scares may indicate just the opposite. Hundreds of foods are recalled every year because they are contaminated or otherwise not in compliance with the law, including recent egregious cases involving half a billion eggs carrying Salmonella and lettuce and beef contaminated with *E. coli*.³ The Centers for Disease Control and Prevention estimate that in the US there are approximately 48 million cases of foodborne illnesses every

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¹ See, for example, Don Glickman's interview for the PBS Frontline documentary 'Modern Meat', available at: <http://www.pbs.org/wgbh/pages/frontline/shows/meat/interviews/glickman.html>.

² President Barack Obama's Weekly Address: Reversing a Troubling Trend in Food Safety, 14 March 2009.

³ See: <http://cdc.gov/salmonella/typhimurium/update.html> (last accessed 28 April 2010); <http://www.cdc.gov/ecoli/2009/index.html> (last accessed 28 April 2010).

year, 128,000 hospitalisations and 3,000 deaths,⁴ resulting in significant costs for consumers, healthcare and the private sector. A recent report estimated the overall costs of foodborne illnesses in the US at \$152 billion a year, of which almost \$39 billion are attributable to produce vehicles.⁵

One of the most urgent challenges facing the US food safety system is ensuring the safety of imported foods, which constitute a large share of US foods. In recent years, a string of food scares originating from imported foods raised public awareness on the global nature of the food supply, renewing pressures on policymakers to address the threats associated with import safety. Food imports may originate from countries that have inadequate food controls and spread threats rapidly across borders. Food import safety problems are likely to increase due to the steady growth of food products coming from abroad, coupled with a system of domestic rules that have not always adjusted to the globalisation of the supply chain. Therefore, unless carefully regulated, food imports may further compound the vulnerabilities of the already fragile US food safety system.

The purpose of this article is to define the challenges to the US food safety system deriving from a global food supply, in light of a recent legislative reform that promises to strengthen the Food and Drug Administration (FDA) and tighten controls on imports. The FDA Food Safety Modernization Act, passed by Congress in December 2010, introduced the most comprehensive reform to the US food safety system in decades.⁶ This article analyses in detail how the legislative reform promises to improve import safety, discusses the strengths and weaknesses of the measures targeted to imports and identifies some novel regulatory trends present in the law.

The article is organised as follows. Section 2 describes the safety threats introduced with imports and globalisation. Section 3 provides an overview of the food safety administration in the US and discusses the complexities of food imports governance. Section 4 illustrates changes in the political climate in recent years and how they led to the current reform. Section 5 analyses the import safety provisions of the new law and identifies their strengths and aspects that warrant concern, as well as the broader regulatory philosophy that informs the law. Section 6 offers some concluding remarks on the lessons that can be drawn from the import safety debate in the US, as well as the regulatory challenges posed by globalisation.

2 The Threats of a Global Food Supply

According to the US Department of Agriculture (USDA) Economic Research Service, approximately 15% of the US food supply by volume is imported and the total value of food imports doubled in the last decade, nearing \$90 billion in 2008. What has driven this sharp increase in imports? Not only is the US population more diverse and inclined towards exotic foods, but consumption behaviours have also changed. If in the past the availability of fruits and vegetables was seasonal, consumers now expect to find fully stocked supermarkets where products are available year-round. Consumption of fresh fruit and vegetables has increased 36% from 1981 to 2000,⁷ a trend that has boosted demand for produce from foreign countries. Innovations in transportation and communication have enabled retailers to satisfy this growing demand by sourcing their products globally. The share of imports is particularly high for fresh foods. According to USDA data, imports of fresh fruits as a share of domestic consumption grew from

⁴ See: <<http://cdc.gov/foodborneburden/2011-foodborne-estimates.html>> (last accessed 26 December 2010).

⁵ Robert L. Scharff, 'Health-related Costs from Foodborne Illnesses in the United States', Produce Safety Project at Georgetown University, 3 March 2010.

⁶ H.R. 2751, 111th Congress, Public Law 111-353.

⁷ FDA Food Protection Plan 2007.

35% in 1990 to approximately 50% in the mid- to late-2000s.⁸ In the period 2000-2008, imported vegetables accounted for 15% of US vegetable consumption,⁹ while as much as 80% of seafood in the US is imported.¹⁰

A global food supply may be convenient for consumers, but it presents specific challenges when it comes to food safety. This is because it could not only introduce new risks but also reintroduce risks that were previously controlled and expand the boundaries of contamination across countries.¹¹ Recently, food scares originating abroad received intense press coverage, raising concerns about the safety of imported foods and the adequacy of public controls. In 2008, infamous Jalapeño peppers from Mexico caused 1,442 cases of salmonellosis, 286 hospitalisations and possibly two deaths.¹² In 2007, 4,000 animals died after eating pet food containing melamine, a chemical that can increase the protein content of foods. The pet food was imported from China and ended up in farm animal and fish feed, and some animals that had eaten the contaminated feed ended up being slaughtered for human consumption.¹³ The FDA also issued import alerts for several other products originating from China, including farm-raised fish and shrimp¹⁴ and, more recently, honey. The most egregious scandal that heightened attention to food safety standards in China, and possible spill-overs in countries receiving Chinese products, was the incident of melamine-contaminated milk that sickened 300,000 Chinese children and killed at least six.

Some regulatory responses were introduced to reduce informational asymmetries between markets and consumers. Mandatory country of origin labels (COOLs), for example, provide ‘ultimate purchasers’ with information on the origin of meats, wild and farm-raised fish, fresh and frozen fruits and vegetables and nuts.¹⁵ However, if an imported food is used by a US food processor and undergoes ‘significant transformation’ in the US (for example if it is cooked or cured), consumers need not be notified of the foreign origin of the food.¹⁶ Therefore, when consumers eat processed foods, they are not aware that, although the package may indicate the food was produced in the US, the ingredients may come from countries that have weak food safety standards, inadequate regulatory infrastructures or tolerance for a higher risk level.

Information on the origins of certain fresh foods alone does not suffice to quell the fears of consumers, who appear to be increasingly concerned about import safety. According to a recent poll, 64% of voters think the federal government is not doing enough to ensure the safety of imports.¹⁷ As many as 89% of voters, across political orientations, support government efforts to pass more stringent food safety rules, and 72% of voters would be willing to pay 3% to 5% more for their groceries to cover the

⁸ See: <<http://www.ers.usda.gov/briefing/fruitandtreenuits/trade.htm#frut>> (last accessed 27 April 2010).

⁹ See: <<http://www.ers.usda.gov/Briefing/Vegetables/trade.htm>> (last accessed 27 April 2010).

¹⁰ GAO-09-873, Report to Congressional Committees, *Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food*, September 2009.

¹¹ Jean C. Buzby (ed.), ‘International Trade and Food Safety: Economic Theory and Case Studies’, USDA Agricultural Economic Report No. 828, November 2003, at 1.

¹² *Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report*, Outbreak of *Salmonella* Serotype Saintpaul Infections Associated with Multiple Raw Produce Items – United States, 29 August 2008 / 57(34); 929-934.

¹³ See: <<http://www.fda.gov/animalveterinary/safetyhealth/recallswithdrawals/ucm129575.htm>> (last accessed 3 May 2010).

¹⁴ Fred Gale and Jean C. Buzby, ‘Imports from China and Food Safety Issues’, USDA Economic Information Bulletin 52 (July 2009).

¹⁵ The country of origin labelling (COOL) requirements were introduced in the Farm Security and Rural Investment Act of 2002 (Public Law 107-171) and later expanded by the Food, Conservation, and Energy Act of 2008 (Public Law 110-234), which extended requirements to new foods. It should be noted that Canada and Mexico challenged the COOL requirements before the World Trade Organization for being in violation of trade agreements. DS/384 “United States of America – Certain Country of Origin Labelling (Cool) Requirements” (Complainant: Canada) and DS/386 “United States of America – Certain Country of Origin Labelling Requirements” (Complainant: Mexico).

¹⁶ Geoffrey S. Becker, *Country-of-Origin Labeling for Foods*, Congressional Research Service Report for Congress, 13 May 2008, at 2.

¹⁷ *Americans’ Attitudes on Food Safety*, conducted 29 June-3 July 2009, by Hart Research Associates and Public Opinion Strategies on behalf of the Pew Charitable Trusts and the Produce Safety Project.

costs of enhanced food safety measures.¹⁸ This is in line with research showing that, as a general trend, as consumers become more affluent and aware of the connections between diet and health, their demand for safe foods tends to increase.¹⁹

The private sector is also demanding more stringent food safety standards to protect itself from the losses deriving from food scares and recalls caused by unsafe products (be they domestic or imported). Because traceability mechanisms are still limited, when food scares erupt it is difficult to immediately pinpoint the culprit and losses may extend to sectors only indirectly involved in the contamination. The salmonella outbreak of 2008, initially blamed on tomatoes, cost the US tomato industry an estimated \$200 million, while the real origin of the contamination were Mexican Jalapeño and Serrano peppers that are usually consumed with tomatoes.²⁰

Policymakers, the public and the industry appear to have reached consensus on the need to overhaul food safety governance in the US. Any attempt to update US food safety policies will also need to tackle the challenges presented by a food supply that has gone global. Therefore, ensuring the safety of foods at home entails engaging with foreign governments, solving questions of enforcement and extraterritorial jurisdiction and aligning food production standards. Paradoxically, one of the biggest obstacles to effectively regulating food import safety in the US is the very organisation of the food safety administration, with its complex structure and overlapping responsibilities, as explained in the section that follows.

3 The Limitations of the US Food Import Safety System

The shortcomings of the regulatory system addressing food import safety can be attributed to: (1) a confusing governance architecture where responsibilities are shared among a plethora of federal, state and local agencies; and (2) the FDA's antiquated approach based on (insufficient) inspections of final food products rather than prevention and risk analysis. As we shall discuss in more detail in section 5, the 2010 FDA Food Safety Modernization Act will modernise the FDA's approach through a strong emphasis on risk analysis and prevention. However, the new law does not tackle the coordination problems because food safety responsibilities remain split among multiple agencies. Let us analyse the weaknesses of the regulatory system, some of which will be corrected under the new law, in order.

3.1 A Chaotic Governance Architecture

The US food safety system is extremely complex because responsibilities are split along food categories between the US Department of Agriculture and the Food and Drug Administration. This distribution of jurisdiction emanates from the history of the two agencies. The FDA was initially part of the USDA, where it investigated food adulteration, and it was not until 1940 that it became a separate agency under the Department of Health and Human Services.²¹ Under this arrangement, the USDA would maintain responsibility for meat and poultry inspection, and the FDA would oversee all remaining food products. This separation of jurisdictions still stands today, although USDA's responsibilities were later expanded to include egg products.²²

¹⁸ Id.

¹⁹ Laurian J. Unnevehr and Helen H. Jensen, 'The economic implications of using HACCP as a food safety regulatory standard' (1999) 24(6) *Food Policy* 625-635.

²⁰ D.G. Maki, 'Coming to Grips with Foodborne Infection – Peanut Butter, Peppers, and Nationwide Salmonella Outbreaks' (2009) 360(10) *New England Journal of Medicine* 949-953.

²¹ Richard A. Merrill and Jeffrey K. Francer, 'Organizing Federal Food Safety Regulation' (2000) 31 *Seton Hall L. Rev.* 61.

²² USDA inspection authorities were expanded in 1957 with the Poultry Products Inspection Act (Public Law 85-172) and in 1970 with the Egg Products Inspection Act (Public Law 91-597).

Today, the governance of food safety in the US remains extremely fragmented, so much so that some commentators define it as a ‘balkanised structure’.²³ Responsibilities are shared not only between the FDA and the USDA, but also among the federal, state and local levels. At the federal level alone, 15 agencies administer some 30 laws related to food safety.²⁴ Approximately 80% of foods fall under FDA jurisdiction, a market worth more than \$450 billion every year.²⁵ The only food categories that are not regulated by the FDA are meat, poultry and processed eggs products, for which the USDA is responsible. The FDA has oversight over more than 136,000 registered domestic food facilities, regulates more than 2 million farms, over 900,000 restaurants and 114,000 supermarkets and other food outlets.²⁶ The FDA carries out a limited number of food safety inspections and has been blamed for merely reacting to food scares, rather than adopting policies that would prevent them. The USDA’s Food Safety and Inspection Service (FSIS), on the other hand, relies heavily on inspections of products *before* they reach consumers and oversees some 7,600 inspectors based in 6,000 establishments.

Other federal agencies involved in food safety governance are the Centers for Diseases Control and Prevention, which are in charge of preventing illnesses due to foodborne diseases, the Environmental Protection Agency, which regulates pesticides and tolerated thresholds in food, the Department of Commerce’s National Marine Fisheries Service, which regulates seafood, the Federal Trade Commission, which is in charge of preventing false advertising in food, and the Department of Homeland Security, which is responsible for food security. At the state and local level, some 3,000 health and agriculture agencies are responsible for retail food establishments.²⁷ Although the jurisdiction is split among agencies according to food category, there are many crossover products, for example processed foods that contain a certain percentage of meat, where regulatory oversight is shared between FDA and USDA, generating confusion when attributing responsibilities, especially in the case of foodborne outbreaks.²⁸

This chaotic regulatory system is also reflected in food imports oversight. Besides the FDA and the USDA, Customs and Border Protection (CBP) is also responsible for import safety. Specifically, the CBP enforces import regulations for 46 agencies, including the FDA and the USDA.²⁹ The CBP receives importers’ advance information on imports and communicates it to the FDA. The CBP also requires importers to post a monetary bond to be forfeited in case they fail to comply with obligations established by law or regulation. However, the bond’s entity is not large enough to suffice as an incentive for compliance, as many importers appear to include it in ‘the cost of doing business’ and may introduce violative food products into US commerce in spite of the bond.³⁰

The fragmentation of responsibilities among agencies has negative repercussions also in terms of records management and information sharing. For example, although importing firms should be assigned a unique number to facilitate their identification, especially in case of outbreaks or violations, a recent Government Accountability Office (GAO) report found that the FDA and the CBP use different unique identification numbers for importers, making it difficult to cross-reference data. The paradox is that a single firm can have multiple ‘unique’ identifiers, on average three identifiers per firm, with one firm having as many as 75, creating confusion for detecting violators and an opportunity to evade the FDA’s control.³¹ Additionally, communication among agencies

²³ ‘Reforming the Food Safety System: What If Consolidation Isn’t Enough’ (2007) 120 *Harv. L. Rev.* 1345.

²⁴ GAO-07-310, *High-Risk Series: An Update*, January 2007.

²⁵ Institute of Medicine, *Enhancing Food Safety: The Role of the Food and Drug Administration* (Washington, DC: The National Academies Press 2010).

²⁶ FDA Food Protection Plan 2007.

²⁷ Institute of Medicine, Committee to Ensure Safe Food from Production to Consumption, National Research Council, *Ensuring Safe Food: From Production to Consumption* (Washington, D.C.: The National Academies Press 1998).

²⁸ ‘Reforming the Food Safety System’, above n. 23, at 1361.

²⁹ GAO-09-873, above n. 10.

³⁰ *Id.*, at 21.

³¹ *Id.*, at 21.

appears inadequate. For example, the CBP does not notify the FDA or the FSIS when imports arrive at a port, especially truck ports, and this poses a risk because the FDA may only learn about a tainted product *after* it has been introduced into commerce by an importer. In addition, some importers engage in ‘port shopping’ and try to access the US from a new port of entry after having failed to pass inspections in another port.³² Clearly, the current import safety architecture is too convoluted and allows ample margins to circumvent FDA requirements.

3.2 A Reactive System

The second shortcoming of the import safety system is constituted by the FDA’s outdated and largely reactive methods. The FDA’s approach to import safety does not generally rely on preventive requirements but on inspections at the border. Under the Federal Food, Drug, and Cosmetic Act, the FDA has the authority to refuse admission of foods that, upon examination, appear to be adulterated, misbranded or in violation of the law.³³ What is disconcerting is that, in spite of an increasingly global food supply, the FDA is examining only a minimal fraction of imports: only about 1% of imports undergo physical inspection.³⁴ In 2008, out of an estimated 189,000 registered foreign food facilities, the FDA inspected a mere 153.³⁵ From 2001 to 2008, the FDA conducted only 1,186 inspections in 56 countries.³⁶

The Bioterrorism Act of 2002 strengthened requirements for food imports, focusing also on improving the FDA’s ability to manage information about foreign facilities.³⁷ The law established a requirement of prior notice, under which importers need to file information such as their name and address, a description of the food and the anticipated port of entry. Although filed information is screened electronically, record keeping is largely inadequate, as the FDA lacks the capacity to verify how accurate and updated the information provided by importers is.³⁸ The Bioterrorism Act also added provisions for ‘one-up/one-down’ traceability, which require food manufacturers, processors and receivers to maintain records of the immediate previous sources of foods and the immediate receivers.³⁹

As we shall discuss in more detail in section 5, before the introduction of the 2010 FDA Food Safety Modernization Act, the FDA did not require process management standards that could facilitate the early detection of risks, save for a restricted number of foods. Neither did the agency adopt a life-cycle approach to identify steps in the life of an import where safety risks are higher in order to adopt preventive measures. In spite of several attempts at modernisation, for decades the FDA’s approach to food safety has been largely reactive and inspection-based, rather than preventive and risk-based. In recent years, the deficits in the regulatory system have become evident, prompting an intensification of legislative activity to reform this area.

4 Changes in the Political Climate and the Current Reform

In Washington D.C. there is a long-standing, albeit inconclusive, debate about consolidating all food safety jurisdiction under a single agency. Some advocates and

³² Interagency Working Group on Import Safety, *Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety*, 10 September 2007.

³³ Federal Food, Drug, and Cosmetic Act, SEC. 801. (21 U.S.C. § 381) Imports and Exports.

³⁴ GAO-09-873, above n. 10, at 13.

³⁵ GAO-10-699T, Testimony Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives, *Food Safety: FDA Could Strengthen Oversight of Imported Food by Improving Enforcement and Seeking Additional Authorities*, Statement of Lisa Shames, Director Natural Resources and Environment, 6 May 2010, at 4.

³⁶ *Id.*

³⁷ Public Law 107-188.

³⁸ Shannon G. May, ‘Importing a Change in Diet: The Proposed Food Safety Law of 2010 and the Possible Impact on Importers and International Trade’ (2010) 65 *Food Drug L.J.* 1.

³⁹ *Id.*

policymakers emphasise the advantages of streamlining responsibilities into one agency.⁴⁰ Despite numerous bills calling for a merger, political consensus has never coalesced around such proposals. Major advocates for food safety reform have hence shifted their efforts from consolidation to modernisation, starting with the FDA, the agency that presents the most serious vulnerabilities in the US food safety system.

Several recent initiatives at the government and congressional level demonstrate that there is a sense of mounting urgency to ensure food (including imports) safety. In 2007, the GAO listed food safety as a high-risk area.⁴¹ Several important initiatives were launched under the presidency of George W. Bush. In 2007, the Interagency Working Group on Import Safety issued 'Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety', recommending a risk-based preventive approach.⁴² Also in 2007, the FDA issued its 'Food Protection Plan', calling for a stronger focus on prevention, evaluation of risks in a product's life cycle and the use of science for food safety.⁴³ In 2008, then Senator Barack Obama introduced the Improving Foodborne Illness Surveillance and Response Act, showing his commitment to this policy area. Between 2007 and 2009, over two dozen congressional hearings analysed food safety needs.⁴⁴

In the 111th Congress alone, nearly 20 bills were introduced to improve food safety. In March 2009, President Obama declared in his weekly address that outbreaks from contaminated food are on the rise and that 'no parent should have to worry that their child is going to get sick from their lunch'. He announced the creation of a food safety working group formed by experts from all federal agencies in charge of food safety to identify the necessary upgrades to the legislation.⁴⁵

In 2009, two similar bills promised to improve food safety through a comprehensive reform of the FDA, attributing new authority and resources to the agency. The Food Safety Enhancement Act of 2009 (H.R. 2749), introduced by Rep. Dingell, was approved in the House of Representatives with a bipartisan vote of 283 to 142 on 30 July 2009. In the Senate, the FDA Food Safety Modernization Act (S. 510), introduced by Illinois Senator Richard Durbin, was approved and reported to the full Senate by the Senate Health, Education, Labor and Pensions Committee on 18 December 2009. The two bills shaped the reform that was passed by both Houses in December 2010 and signed into law by President Obama in January 2011, the FDA Food Safety Modernization Act (hereinafter FSMA), arguably the most significant initiative to revamp the US food safety system in decades.

5 Food Import Safety under the FDA Food Safety Modernization Act

The FSMA includes numerous provisions focusing on import safety, signalling the growing concern for this policy area. Some new requirements apply to domestic and foreign facilities, while others are specifically targeted to imports.

Unfortunately, there is no consolidated literature on the optimal regulatory approaches to ensure food import safety. Research on this relatively new phenomenon is recent and tends to concentrate on the redistributive effects of safety requirements for developing countries.⁴⁶ A comparative framework analysing how the major importing countries are responding to the regulatory challenge of providing food import safety is still

⁴⁰ For a complete description of the consolidation debate and related literature, see 'Reforming the Food Safety System', above n. 23.

⁴¹ Geoffrey S. Becker, *Food Safety: Selected Issues and Bills in the 111th Congress*, Congressional Research Service Report for Congress, 21 April 2010.

⁴² Interagency Working Group on Import Safety, above n. 32.

⁴³ FDA Food Protection Plan 2007.

⁴⁴ Becker, above n. 41.

⁴⁵ President Barack Obama's Weekly Address: Reversing a Troubling Trend in Food Safety, 14 March 2009.

⁴⁶ See, for example, Chunlai Chen, Jun Yang and Christopher Findlay, 'Measuring the Effect of Food Safety Standards on China's Agricultural Exports' (2008) 144(1) *Review of World Economics* 83-106; Tsunehiro Otsuki, John S. Wilson and Mirvat Sewadeh, 'Saving Two in a Billion: Quantifying the Trade Effect on European Food Safety Standards on African Exports' (2001) 26 *Food Policy* 495-514.

lacking. Similarly, there is no empirical research measuring the effectiveness of specific regulatory approaches to import safety that we could use as a benchmark to evaluate the US food safety reform. Absent such a framework, we have based our analysis on the regulatory trends identified in recent research projects on import safety.⁴⁷ Such research points to the prominent role played by private food safety regulation and highlights that food safety governance in global markets depends on a close collaboration between public and private regulations. Our analysis is also grounded on the more general literature laying out the rationale for food safety regulation and the actors at play in food safety governance.⁴⁸

Government intervention to provide food safety is justified by the fact that markets alone do not provide optimal protection against foodborne illnesses for several reasons. First, when consumers purchase a food, they are often unable to judge if it is perfectly safe, hence there exists an information asymmetry between producers and consumers. Second, it is extremely complicated for consumers to pinpoint precisely the food that made them sick, especially in the case of late onset diseases, limiting the effectiveness of liability protection. Third, for milder cases of food poisoning, consumers may choose not to pursue costly legal battles. Finally, consumers are not the only ones bearing the costs of food illnesses, as costs fall also on healthcare systems, companies that suffer from work time lost and families that need to care for the sick, creating diffuse negative externalities.⁴⁹ Such reasons provide a robust rationale for government intervention, but different countries choose different regulatory approaches based on their political environment, societal values and risk tolerance levels. In general, food safety regulation is the result of a mix of approaches ranging from stringent product standards to process standards and disclosure-based approaches to educate consumers.

Building on this body of literature, this article aims to identify what regulatory approaches were chosen for food import safety in the US legislative reform and highlight regulatory trends and general lessons that could be of interest not only to scholars but also to policy-makers dealing with import safety regulation. Our analysis shows that the new legislation adopts a four-pronged approach to ensure import safety based on: (1) risk-based approaches and prevention; (2) information management and record keeping; (3) third-party certification; and (4) international activities. We shall discuss these approaches and the most significant import safety provisions of the bill in which they are reflected in detail below.

Perhaps the most interesting feature of the import safety provisions, and one that cuts across the four approaches that we shall analyse, is their reliance on new governance mechanisms that enlist non-government actors, from importers to producers and certification bodies, to ensure food safety. The relationship between public and private food safety systems is highly dynamic. Although traditionally it has been the role of governments to set standards, performance objectives and liability incentives for compliance, in recent years numerous private regulatory systems have emerged, sometimes complementing public ones, blurring the boundaries between private and public regulation and creating new governance opportunities in what is believed to be the 'most dynamic field in international product safety regulation'.⁵⁰ In a food chain that is increasingly global and consolidated, large supermarkets with established brands have much to lose in the case of an outbreak and have even greater incentives to engage in self-regulation.⁵¹ In order to increase or protect their market share, companies have

⁴⁷ Cary Coglianese, Adam M. Finkel and David Zaring (eds.), *Import Safety: Regulatory Governance in the Global Economy* (2009); Buzby, above n. 11.

⁴⁸ See also Spencer Henson and Julie Caswell, 'Food Safety Regulation: An Overview of Contemporary Issues' (1999) 24 *Food Policy* 589-603; John M. Antle, 'Benefits and Costs of Food Safety Regulation', (1999) 24 *Food Policy* 605-623; Jean C. Buzby and Paul D. Frenzen, 'Food Safety and Product Liability', (1999) 24 *Food Policy* 637-651.

⁴⁹ David A. Hennessy, Jutta Rosen and Helen H. Jensen, 'Systemic Failure in the Provision of Safe Food' (2003) 28 *Food Policy* 77-96.

⁵⁰ Errol Meidinger, 'Private Import Safety Regulation and Transnational New Governance' in: Coglianese, Finkel and Zaring, above n. 47 at 235.

⁵¹ Marian Garcia Martinez and Nigel Poole, 'The Development of Private Fresh Product Safety Standards: Implications for Developing Mediterranean Exporting Countries' (2004) 29 *Food Policy* 229-255.

adopted mechanisms of self-regulation or third-party certification to improve the quality and consistency of their products.⁵² Scholars agree that the new global governance of food safety results from national public regulations but also international standards set by the Codex Alimentarius Commission and private standards that are so common as to have become *de facto* mandatory.⁵³

The new legislation incorporates and institutionalises some regulatory strategies developed in the private sector, such as HACCP and third-party certification, and enlists private actors to achieve public goals, for example mandating that importers carry out detailed audits on the foods they introduce into domestic commerce. Legislators do not attempt to strengthen import safety solely through expanding the FDA's authority, because such an approach would prove anachronistic and impractical, if not ineffective, in tackling challenges of a global nature. Their choice is rather to use a combination of traditional top-down public regulation and voluntary regulatory mechanisms that are already in place in the private sector, a trend that has also been observed in European food safety regulation, especially in response to the bovine spongiform encephalitis (BSE) crisis.⁵⁴

Some scholars suggest that global consumer safety can be better achieved through a 'delegated governance' model relying on a coordinated approach involving public and private actors and a variety of regulatory arrangements.⁵⁵ The proposed legislation appears to follow this novel regulatory trend, especially when it comes to import safety, as we shall detail below in describing its four principal features.

It should be recalled that, although the FSMA will significantly modernise the FDA by focusing on risk analysis and enlisting public and private regulation for food safety governance, the reform does not address the problem of the parcelling of jurisdiction among agencies. The salmonella outbreak of August 2010, which led to the recall of half a billion eggs and sickened nearly 1,500 people, is a glaring example of the inefficiencies of the current system. The food crisis highlighted how egg safety responsibilities are shared among the FDA, which regulates shell eggs, the USDA, which is in charge of egg products, and state health departments, which are responsible for the disposal of chicken litter. In such a fragmented system, agencies may wrongly expect other actors in the regulatory chain to carry out critical responsibilities, creating serious gaps in food safety oversight. This balkanised food safety system hampers response to emergencies because identifying the competent agency can be extremely complex, which in turn limits the mechanisms that are used to hold administrators accountable. Strengthening the FDA is part of an incremental approach to improve the US food safety system. However, until responsibilities are rationalised and assigned to a single regulatory entity, the system will remain vulnerable.

5.1 Risk-based Approaches and Prevention

The FSMA includes several provisions that would shift the FDA's approach from reaction to risk-based prevention, signifying a dramatic shift from the agency's traditional methods. It should be noted that such provisions are not specific to imports but would also apply to domestic foods. Nevertheless, since risk-based policies and prevention are likely to significantly strengthen import safety, we have chosen to emphasise this aspect in our treatment of the reform. The two most significant policy changes in this area are the introduction of *hazard analysis and risk-based preventive controls* and *inspection frequency* based on the risk profile of foods.

⁵² Henson and Caswell, above n. 48.

⁵³ Spencer Henson, 'The Role of Public and Private Standards in Regulating International Food Markets' (2007) 4(1) *Journal of International Agricultural Trade and Development* 63-81. See also Spencer Henson and Thomas Reardon, 'Private Agri-food Standards: Implications for Food Policy and the Agri-food System' (2005) 30 *Food Policy* 241-253.

⁵⁴ Terry Marsden, Robert Lee, Andrew Flynn and Samarthia Thankappan, *The New Governance of Food: Beyond the Food Crisis?* (2010).

⁵⁵ David Zaring and Cary Coglianese, 'Delegated Governance' in Coglianese, Finkel and Zaring, above n. 47..

A *sine qua non* for a strong and effective food safety system is the use of a risk-based methodology to design policies and target resources. Risk analysis, articulated in three steps – risk assessment, risk management and risk communication – is a consolidated discipline informing the food safety architecture of numerous countries.⁵⁶ The FDA has lagged behind in fully adopting risk analysis and is often criticised for an antiquated approach to food safety that focuses on reacting to foodborne outbreaks rather than preventing them with risk-based methods.⁵⁷ Although there have been some modest improvements in recent years, the adoption of a coherent risk-based approach remains a long-term challenge of the FDA.⁵⁸ Currently, the agency does not sufficiently emphasise prevention, and its scarce resources are not targeted to the areas that pose the highest threats. This results in a long list of food scares involving both domestic and imported food products and diminishing public trust in the US food safety system. A risk-based approach, on the other hand, would enable the agency to identify and rank risk areas and plan preventive interventions accordingly, thus controlling risks and reducing the need for responsive reactions.⁵⁹

An important step in the direction of enhancing prevention of foodborne illnesses is the introduction of mandatory Hazard Analysis and Critical Control Points (HACCP) for all domestic and international facilities under section 103 of the new law.⁶⁰ HACCP are a preventive process management instrument through which companies conduct risk analyses to identify the critical points in which risks may enter the food chain, formulate strategies to minimise risks, monitor and document the process and take corrective actions if needed. Using HACCP, companies can take control of risks before they occur, thus focusing on preventive strategies rather than reactive ones. An adaptable risk management tool, HACCP can be used by any segment of the food industry and at every step of the supply chain.⁶¹ Although the private sector has been using HACCP on a voluntary basis for decades, in the US system HACCP are mandatory for certain food categories, such as meat and poultry (regulated by the USDA) and juice and seafood (regulated by the FDA). The FSMA will considerably expand the use of HACCP to encompass *all* food facilities that fall under FDA jurisdiction, although the FDA may establish exemptions for certain kinds of facilities (for example those solely engaged in producing animal feed or certain storage facilities). The law requires the owner, operator or agent of a facility to (1) conduct a hazard analysis; (2) identify and implement effective preventive controls; (3) monitor preventive controls; (4) institute corrective actions; (5) conduct verification activities; (6) maintain records of monitoring, corrective action and verification; and (7) reanalyse for hazards.⁶²

The Secretary of the Department of Health and Human Services (hereinafter, the Secretary) has the authority to identify hazards and establish controls for specific food types and shall issue guidance on science-based standards to conduct hazard analysis. Facilities are required to revise their hazard analysis if there is a significant change in their activities and in any other case with at least a three-year frequency.⁶³

The second provision is the introduction of inspections with frequency adjusted to the risk level of food facilities. The FDA is recurrently criticised because the number of inspections it carries out is grossly inadequate. From 2004 to 2008, the FDA inspected on average only 24% of facilities every year. In addition, the number of inspections has been declining, even while the number of facilities has increased. During this time period, of roughly 51,000 facilities under FDA authority, as much as 56% were never

⁵⁶ WHO and FAO, 'Food Safety Risk Analysis: A Guide for National Food Safety Authorities', FAO Food and Nutrition Paper 97 (Rome 2006).

⁵⁷ Caroline Smith DeWaal, 'Food Safety and Security: What Tragedy Teaches Us About Our 100-Year-Old Food Laws' (2007) 40 *Vanderbilt Journal of Transnational Law* 921.

⁵⁸ Joseph A. Levitt, 'FDA's Food Program' (2001) 56 *Food and Drug Law Journal* 255.

⁵⁹ Institute of Medicine. above n. 25.

⁶⁰ H.R. 2751 § 103, 111th Congress.

⁶¹ M.D. Pierson and D.A. Corlett, Jr. (eds.), *HACCP: Principles and Applications* (1992).

⁶² H.R. 2751 § 103, 111th Congress.

⁶³ Id.

inspected.⁶⁴ It should be noted that the number of inspections for high-risk facilities declined and that, save some cases, there are no guidelines determining inspection frequency. The FSMA would redress this by intensifying the number of inspections for domestic and foreign facilities and making their frequency risk-based. Inspection frequency shall be commensurate with the risk presented by the food, the facility compliance history and the rigor of the facility's preventive controls.⁶⁵ Domestic high-risk facilities shall be inspected at least once in the five years after the enactment of the FSMA, and at least every three years thereafter. Domestic non-high-risk facilities shall be inspected at least once within seven years of enactment of the law and at least once every five years thereafter.⁶⁶

The FSMA includes a specific section devoted to the inspection of foreign facilities and imported foods at the port of entry, signalling the high level of urgency attributed to ensuring the safety of foreign aliments entering the US food chain. The FSMA prescribes that the Secretary shall inspect at least 600 facilities the first year after enactment, and that in the five subsequent years the number of inspections should be doubled every year respect the amount conducted the previous year. Inspections at the port of entry shall be based on the risk profile of imported foods, which in turn depends on the safety risks of the import, the known safety risk of the countries of origin and transport, the compliance history of the importer, the rigour of the foreign supplier verification programme covering the food, participation in the voluntary qualified importer programme, and whether the food meets certification requirements.⁶⁷ These provisions raise concerns of potential limitations to free trade, as attributing a high risk profile to a country may serve to *de facto* limit access to US markets. An appeal mechanism for exporting countries wishing to object to the risk profiles that they were assigned may redress this imbalance.

Mandatory HACCP and risk-based inspections constitute very significant steps towards strengthening the US food system. Initially introduced in the private sector, HACCP have also become a prominent instrument in public regulation because they constitute an alternative to end-point testing and allow firms some margin of flexibility in adapting the instrument to their characteristics.⁶⁸ HACCP are a consolidated process control measure widely recognised as effective and economically efficient in mitigating risks.⁶⁹ The FSMA describes the steps of such preventive analyses, but at the same time leaves companies a margin of flexibility by requiring them to carry out their own planning and implementation, falling under the category of process-based or management-based regulation⁷⁰ – a growing regulatory trend and a shift from more traditional command and control approaches.⁷¹

As regards risk-based inspection frequency, focusing resources on steps in the supply chain that present higher risk levels as well as targeting high-risk foods are steps in the right direction to complement preventive measures such as HACCP controls. Even though the new law shifts the FDA's approach from reaction to prevention, inspections are still needed to monitor compliance and create sufficient enforcement mechanisms.

Under the new legislation, the FDA will not only intensify inspections – a much needed change given the agency's abysmal inspections record – but shall also focus on high-risk areas, thus ensuring higher protection levels and a more effective use of resources.⁷² Although targeting inspections according to the risk profile of imported foods is a promising policy development, much of its effectiveness will hinge on

⁶⁴ Department of Health and Human Services, Office of Inspector General, *FDA Inspections of Domestic Food Facilities*, OEI-02-08-00080, April 2010, at 2.

⁶⁵ H.R. 2751 § 201, 111th Congress.

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ Karl Ropkins and Angus J. Beck, 'Evaluation of Worldwide Approaches to the Use of HACCP to Control Food Safety' (2001) 11 *Trends in Food Science and Technology* 10-21.

⁶⁹ Unnevehr and Jensen, above n. 19.

⁷⁰ Cary Coglianese and David Lazer, 'Management Based Regulation: Prescribing Private Management to Achieve Public Goals' (2003) 37 *Law and Society Review* 691.

⁷¹ Henson and Caswell, above n. 48.

⁷² Caroline Smith DeWaal, 'Food Safety Inspections: A Call for Rational Reorganization' (1999) 54 *Food and Drug Law Journal* 453-458.

improved record keeping, a very vulnerable area in the current food safety system that the legislative reform aims to correct. Similarly, the effectiveness of foreign inspections would be contingent on the FDA's ability to enter into agreements with foreign countries and to hire and train personnel capable of carrying out inspections in different cultural and regulatory environments.⁷³

5.2 Information Management and Record Keeping

Effectively managing information on companies involved in the food supply chain is a key element of a robust food safety system. Requiring companies to provide accurate and updated information is essential for tracking every step in the supply chain and for setting up traceability systems. In the case of an emergency, it is also especially critical to identify the point of entry of contaminants and their subsequent distribution. The FDA has not been very effective at maintaining useful records, due in part to the complex governance structure of food safety, with a multitude of actors involved at the federal, state and local levels. As highlighted earlier in this article, poor information management and limited communication among agencies is to blame for a very ineffective record keeping when it comes to importers.⁷⁴ To address this issue, the FSMA requires all facilities (domestic and foreign) to register with the FDA. The new legislation also increases responsibilities for importers in order to verify compliance with previous steps in the supply chain.

At present, the legislation requires all domestic and foreign facilities to register with the FDA.⁷⁵ The term facility is to be interpreted in a very comprehensive fashion, intending 'any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food.'⁷⁶ However, facilities are not required to periodically update their filings, and critics suggest that the company information that is currently held is largely outdated and not usable.⁷⁷ The FSMA requires facilities to renew their registration every two years, and gives the Secretary authority to cancel or suspend registrations that violate the law. The original House bill assessed an annual registration fee of \$500 to defray the costs of food safety activities.⁷⁸ However, this requirement was criticised by the industry because of the financial burden it would impose and because of the one-size-fits-all amount that might penalise smaller facilities. The final FSMA legislation was influenced by the Senate bill, which was friendlier to the industry as it did not include a registration fee.⁷⁹ The reform is a promising step, because it will provide the FDA with updated and more comprehensive company information, which should improve compliance monitoring and facilitate response to emergencies. The absence of the registration fee, however, risks to limit the agency's availability of resources necessary to revamp its food safety activities and hire new employees for domestic and international inspections.

Since record keeping is particularly deficient in the area of food imports, the new legislation lists specific requirements for importers, who are asked to verify that their foreign suppliers are in compliance with US law and adopt risk-based processes to ensure product safety. The FSMA introduces a Foreign Supplier Verification Program that mandates importers to perform a risk-based verification of their suppliers' compliance with the law. Importers are responsible for verifying that food imports are not adulterated or misbranded and that their suppliers follow risk-based preventive controls such as hazard analysis. To carry out verification activities, importers can monitor suppliers' records and conduct annual on-site inspections and product tests, as well as check their HACCP. Finally, importers are required to maintain records of their verification

⁷³ For a description of challenges facing inspectors abroad, see Kenneth A. Bamberger and Andrew T. Guzman, 'Importers as Regulators' in Coglianesi, Finkel and Zaring, above n. 47.

⁷⁴ GAO-09-873, above n. 10.

⁷⁵ 21 U.S.C. 350d.

⁷⁶ Id.

⁷⁷ Becker, above n. 41, at 8.

⁷⁸ H.R. 2749 § 743, 111th Congress.

⁷⁹ S. 510 § 102, 111th Congress.

activities for a period of two years.⁸⁰ The approach of risk-based prevention, which underlies the food safety reform, therefore applies not only to domestic producers, but also to foreign ones, and importers share the key responsibility of verifying compliance. The FSMA also establishes a voluntary fast-track programme for importers, called 'Voluntary Qualified Importer Program.' This programme will provide for an expedited review process for foods originating from eligible certified facilities and the Secretary shall decide on eligibility depending on the compliance history of foreign facilities, the known risks of the food, and the adequacy of the regulatory system of the country of origin.⁸¹

The requirement to register all facilities and provide updated company information to the FDA is uncontroversial from the standpoint of enabling the agency to provide protection and intervene in a timely fashion in case of an emergency. As a corollary to improved information management and record keeping, the new legislation expands the Secretary's authority to access all records related to foods that could be adulterated or otherwise pose serious health consequences.⁸² The most remarkable feature of this body of provisions, however, is the reliance on importers to verify compliance with the law for previous steps in the supply chain of an import. This is another example of a regulatory approach where authority is delegated to private actors. Although the Foreign Supplier Verification Program would allow importers to access suppliers' records, conduct inspections and control their HACCP plans, it is unclear how importers should conduct themselves if they are denied access to records or facilities. On the one hand, one could hypothesise that they would refuse to import foods that have an unclear record. On the other hand, unless importers face serious enforcement and liability penalties, they may not have sufficient incentives to comply. Some research argues that until importers face the threat of strict liability, they will hardly act as *de facto* regulators of food imports.⁸³ For this approach to be effective, the government should therefore set penalties for importers at a level where they would constitute a credible compliance incentive, without being incorporated into 'the cost of doing business'. In parallel, since importers are assigned such a crucial role in verifying their suppliers' compliance, the government should also conduct inspections to ensure that importers carry out all the requirements listed in the bill.

5.3 Third-party Certification

Third-party certification plays a crucial role in ensuring import safety. Since the FDA cannot deploy an army of inspectors to verify the increasing number of food imports entering into US commerce, the legislators' choice was once again to rely on a private regulatory strategy and to institutionalise it by making it a formal requirement for imports. Like inspection frequency, this provision is informed by risk-analysis principles, as it does not apply to all imports, or to all countries, but is targeted to countries and food items that pose higher threats to food safety. The Secretary may require certification of compliance with the Federal Food, Drug and Cosmetic Act provisions (1) for foods originating from countries with inadequate safety protection; (2) for high-risk foods; and (3) for countries where there is a known food safety risk.⁸⁴ Failure to comply results in a product being denied admission into US commerce. The range of actors that can provide the certification is quite ample. A qualified certifying entity can be an agency or a representative of the government of the country from which the food originates. Alternatively, it can be an individual, an entity or an accredited body as long as they are *recognised by the Secretary*.

The FSMA also lays down comprehensive provisions to ensure the integrity of the certifying entities and to minimise conflicts of interest. To guarantee integrity, the Secretary shall establish criteria for the recognition of accreditation bodies and standards

⁸⁰ H.R. 2751 § 301, 111th Congress.

⁸¹ H.R. 2751 § 302, 111th Congress.

⁸² H.R. 2751 § 101, 111th Congress.

⁸³ Bamberger and Guzman, above n. 73.

⁸⁴ H.R. 2751 § 303, 111th Congress.

for regulatory audit reports to be carried out by third-party certifiers. Additionally, certifying agencies cannot be owned by companies whose products they certify, nor should they have any financial interest in or any kind of ownership of the products they certify. The Secretary retains authority to revoke accreditation in case the certified food is linked to an outbreak, or if the third-party auditor no longer meets accreditation requirements.⁸⁵

More than any other provision in the bill, third-party certification embodies the new trend of delegated governance. Certification in the food sector was introduced as an initiative of large retailers to protect their brands by complementing their private quality standards with independent audits.⁸⁶ Because the safety or other intrinsic qualities of a food may not be evident to consumers, companies have relied on certification to bring their investments aimed at enhancing food safety or quality to the attention of consumers, who are generally willing to pay a premium for certified products. Third-party certifiers should validate the safety or quality of food products and mitigate the information asymmetry between producers and consumers.⁸⁷ Compliance with certification is often signalled on food packaging in the form of a label bearing information on compliance with a particular standard (for example the humane treatment of animals or fair trade). Certification also allows companies to verify that their suppliers (both domestic and international) meet specific standards, be they publicly mandated or privately adopted.⁸⁸

From an agency theory perspective, the problem with third-party certifiers is that they appear to serve as agents for three principals: retailers who want to maximise profits, consumers who demand safe foods, and finally governments who rely on third-party certifiers to verify regulatory compliance. Such an arrangement generates conflicts because the principals' interests are not aligned, as well as problems in the accountability mechanisms to oversee how certifiers (the agents) operate. In theory, the third-party nature of certifiers should provide a sufficient guarantee of independence and reliability,⁸⁹ as opposed to first-party audits (internal audits performed by firms upon their own products or procedures) or second-party audits (performed by companies upon their suppliers). However, lack of independence is often the Achilles' heel of third-party certification, because of possible conflicts of interest and capture by the entities that are being certified. Research shows that oligopolist retailers may have 'encapsulated' third-party certification to legitimise and promote their standards of production.⁹⁰

Additionally, if certifiers are the expression of a trade association or have too cosy a relationship with the industry they certify, their independence may be compromised, together with the credibility of their certification. A recent news report, for example, exposed how the integrity of a third-party organisation certifying organic crops from China was tainted by a serious conflict of interest.⁹¹ The fact that companies that undergo the regulatory audit have to pay for certification may further distort incentives for third-party certifiers, who may opt for more leniency to maintain profits.

Finally, a recent study has highlighted that audits are often reduced to mere checklists and demonstrated that the impact of certifications is highly dependent on the quality of the auditors.⁹² Given the influence that concentrated and highly organised private interests could exercise on third-party certifiers, the diffuse interests of unorganised

⁸⁵ H.R. 2751 § 307, 111th Congress.

⁸⁶ Maki Hatanaka, Carmen Bain and Lawrence Busch, 'Third-party Certification in the Global Agrifood System' (2005) 30 *Food Policy* 354-369.

⁸⁷ Felipe Almeida, Huascar F. Pessali and Nilson Maciel de Paula, 'Third-party Certification in Food Market Chains: Are You Being Served?' (2010) 44(2) *Journal of Economic Issues* 479-485.

⁸⁸ Martinez and Poole, above n. 51.

⁸⁹ B. Tanner, 'Independent Assessment by Third-party Certification Bodies' (2000) 11 *Food Control* 415-417.

⁹⁰ Almeida, Pessali and Maciel de Paula, above n. 87, at 485.

⁹¹ William Neuman and David Barboza, 'U.S. Drop Inspector of Food in China', *The New York Times*, 13 June 2010.

⁹² Friederike Albersmeier et al., 'The Reliability of Third-party Certification in the Food Chain: From Checklists to Risk-oriented Auditing' (2009) 20 *Food Control* 927-935.

consumers may end up at a disadvantage under this type of regulatory approach, unless there is serious public scrutiny of certifiers (whether by the government, the media or civil society).

5.4 International Activities: Food Safety Beyond Borders

Besides relying on third-party certification, the new legislation would significantly strengthen the FDA's international enforcement capabilities by granting the agency authority to inspect foreign facilities and suppliers, targeting resources specifically to high-risk foods facilities.⁹³ Food from facilities or countries that refuse US inspection will be denied admission to the US. As in the case of the country risk profiles discussed earlier in this article, this provision may be used opportunistically as a non-tariff barrier to limit the market access of certain foreign countries. The FSMA also establishes the creation of foreign offices with the purpose of providing assistance to foreign food safety authorities to build their capacities and conduct inspections of products for import into the US. Given the increasing volume of imports, the new law gives the Secretary authority to expand the number of foreign offices in the future, signalling a long-term plan to engage foreign governments and emphasise international cooperation.⁹⁴ The new legislation specifies that the Secretary may enter into agreements with foreign countries to facilitate the inspection of facilities abroad.⁹⁵ Clearly, although the law extends the agency's authority to also inspect foreign facilities, this expanded jurisdiction is conditional on acceptance by foreign firms and countries.

Research argues that the clash between the globalisation of the food supply and the territorial boundaries of jurisdiction is being addressed by gradually shifting from vertical and purely domestic approaches to open, horizontal approaches that encourage exporting countries to harmonise regulatory responses and build capacity in emerging countries.⁹⁶ The food safety reform in the US offers some evidence to this effect. Under the 'Beyond Our Borders' initiative, the FDA has already entered into agreements with foreign countries to increase collaboration, share knowledge and inspectional resources and promote responsible international standards.⁹⁷ Currently, the FDA has over 100 agreements with 29 countries, eighteen agreements with its European Union counterparts and two agreements with the World Health Organization. As of November 2008, the FDA has opened a number of overseas offices to work with local food safety counterparts and collect information on food safety practices.⁹⁸ The FDA is also developing a Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting system (PREDICT), a risk-based screening instrument to target high-risk shipments. The system, initially launched as a pilot for seafood imports, significantly improved the detection of violations. However, its full implementation has been delayed because of difficulties in integrating it into the FDA's outdated information system.⁹⁹ The new law appears to follow and institutionalise the path traced by these earlier initiatives.

Although the reform strengthens collaboration with exporting countries, it falls short of establishing an equivalency standard for trading partners. A regulatory option for ensuring the safety of imports is to require that the controls applied by foreign countries

⁹³ H.R. 2751 § 306, 111th Congress.

⁹⁴ H.R. 2751 § 308, 111th Congress.

⁹⁵ H.R. 2751 § 306, 111th Congress.

⁹⁶ Christine Boisrobert et al. (eds.), *Ensuring Global Food Safety: Exploring Global Harmonization* (2010).

⁹⁷ FDA Consumer Health Information, *FDA Beyond Our Borders*, 9 December 2008, available at: <<http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/ucm103044.pdf>> (last accessed 18 May 2010).

⁹⁸ The FDA has offices in Asia (Beijing, Guangzhou, Shanghai, New Delhi and Mumbai), in Europe (Brussels, London and soon Parma, Italy) and in the Americas (San Jose, Costa Rica; Santiago, Chile; and Mexico City). For security reasons, the FDA Middle East Office is operating from the US. GAO-10-699T, above n. 35.

⁹⁹ Testimony of Michael R. Taylor, Deputy Commissioner for Foods, Food and Drug Administration, Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, 6 May 2010.

meet domestic standards. The USDA applies an equivalency standard under which countries that wish to export meat, poultry or eggs into the US are required to seek USDA certification that their domestic food safety requirements meet US standards.¹⁰⁰ The certification decision depends on the outcome of extensive USDA audits in the foreign country to determine if its safety system attains the same level of protection achieved under US standards.¹⁰¹ Inspections are carried out periodically to ensure that certified countries maintain their eligibility requirements over time. Currently, only 35 countries are certified to export USDA-regulated food into the US.¹⁰² Additionally, all imports undergo reinspection at 150 FSIS facilities located in the proximity of about 30 ports.¹⁰³ Equivalency, a principle also adopted by the European Union for products of animal origin, represents an intermediate level of rapprochement among trading parties, on a spectrum that sees full harmonisation of food safety regulations as the strongest strategy and simple coordination as the least invasive.¹⁰⁴

The approach chosen to reform the FDA is to strengthen coordination, presumably because applying an equivalency system to approximately 150 countries (this is the number of countries that currently export FDA-regulated products to the US) would be extremely resource-intensive and because of the risk profile of the products it regulates. The new legislation includes specific provisions to facilitate collaboration with other countries and build their capacities to ensure adequate levels of food safety protection.¹⁰⁵ The FSMA also requires the Secretary to devise a plan that would improve '*the technical, scientific, and regulatory food safety capacity*' not only of foreign governments, but also of their food industries.¹⁰⁶ The plan shall include important provisions to facilitate food safety governance beyond borders through bilateral and multilateral agreements, electronic data sharing, mutual recognition of inspection reports, training of personnel and harmonisation, including for lab testing.¹⁰⁷

Without the cooperation of foreign governments, FDA international food safety activities and inspections are unlikely to be very successful, therefore focusing on capacity building appears to be an adequate approach to strengthen prevention and minimise the need for ex-post inspections. A potential drawback of this approach is that it may impose a certain regulatory model (in this case the US model) on foreign countries, especially smaller trading partners, with consequences in terms of equity and legitimacy. This trait is also common to private regulations, where quality standards imposed by large supermarket conglomerates may become a burdensome benchmark, especially for small and medium-sized suppliers in the developing world.¹⁰⁸ The debate on standards and their impact on developing economies remains open, with some scholars arguing that, although adjusting to foreign standards may impose high initial costs, it also provides access to large and stable markets and a competitive advantage for producers in developing countries.¹⁰⁹

Finally, although building capacity among foreign administrations and firms is a valuable strategy to put in place preventive controls in the country of origin of a food, it is also time-consuming task that will yield results only in the long run. Considering that US imports originate from over 150 countries, building capacity even in a fraction of these would be very resource-intensive. Unless capacity building is backed by a significant FDA investment in terms of resources and dedicated personnel, it is unlikely to reach the goals of enhancing safety protection abroad.

¹⁰⁰ 21 U.S.C. § 620.

¹⁰¹ See: <http://www.fsis.usda.gov/regulations_&_policies/Equivalence_Process_Overview/index.asp> (last accessed 4 May 2010).

¹⁰² See: <http://www.fsis.usda.gov/regulations_&_policies/Eligible_Foreign_Establishments/index.asp> (last accessed 4 May 2010).

¹⁰³ GAO-09-873, above n. 10.

¹⁰⁴ Neal H. Hooker, 'Food Safety Regulation and Trade in Food Products' (1999) 24 *Food Policy* 653-668. H.R. 2751 § 305, 111th Congress.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ Hatanaka, Bain and Busch, above n. 86.

¹⁰⁹ For a discussion of this debate, see Spencer Henson and John Humphrey, 'The Impact of Private Food Safety Standards', paper prepared for FAO/WHO (2009).

6 Conclusion

Food trade has expanded significantly across borders, creating a global and dynamic food market. In the United States, food imports have intensified in recent years, allowing consumers to access a wider and cheaper selection of foods. Unless carefully regulated, food imports may also bring into domestic markets harmful foodborne contamination. Recent food scares, including several originating from imported foods, have significantly eroded consumers' trust and intensified public demand for improved food safety.

Legislators have recently passed a comprehensive overhaul of the US food safety system that would expand the FDA's authority and resources. The reform includes several measures aimed at improving the safety of imported foods by focusing on prevention and risk-based strategies, improved information management, third-party certification and international activities (from enforcement to capacity building). The reform is a significant effort to shift from reaction to prevention and to target resources according to risk levels. Its vulnerability, however, lies in its reliance on enforcement activities to be carried out abroad, raising concerns of extraterritorial jurisdiction. Several provisions would depend on agreements with foreign countries and their willingness to accept US regulatory intervention to build their capacities. Unless addressed by regulators, these aspects may undermine the implementation and the impact of the reform.

A further concern is that the reform fails to address the parcelling of food safety responsibilities among different agencies – perhaps the most serious deficiency in the US food system. Additionally, the bill relies on a mix of public and private regulation by institutionalising some safety measures introduced by the industry and delegating significant power to non-government actors, such as third-party certifiers and importers. Collaborative governance is a growing trend and may be particularly valuable in dynamic sectors where regulators have lagged behind the industry in terms of regulatory innovation. However, unless coupled with controls and incentive systems, the interests of private actors may not be aligned with those of the general public and excessive reliance on non-government entities may lead to capture and conflicts of interest. Regulators should be mindful of these aspects and closely monitor the non-government partners they choose to enlist to ensure that the intended public policy objectives are met.

