

# Food Safety Regulatory Frameworks: A Global Perspective

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## Abstract

The “flattening” of the world economy has produced many consequences. Over the past few decades, in fact, numerous technological developments have fundamentally contributed to a new pattern of food production, distribution, and consumption. As consequence, food products containing raw materials from multiple regions travel across many national borders for consumption or further processing. In response to ever-increasing multinational food safety incidents, many countries have been revising their food safety law systems and laid down various new regulatory measures. This paper covers the limitations of regulation by national food laws by analyzing the recent advances of the food safety regulatory framework of three major players in the global food trade: China, the United States, and the European Union. Contemporary food safety issues are of the same nature as the food production process: globalized. Consequently, the challenges that have to be faced, are beyond the competencies of individual nations. A comprehensive food safety regulatory strategy at both national and international levels is needed.

## Keywords

Food safety, legislation, globalization.

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## **MARCOS REGULADORES DE SEGURIDAD ALIMENTARIA: UNA PERSPECTIVA GLOBAL**

### **Resumen**

El "aplanamiento" de la economía mundial ha traído muchas consecuencias. De hecho, en las últimas décadas, numerosos avances tecnológicos han contribuido de manera fundamental a un nuevo modelo de producción, distribución y consumo de alimentos. Por consiguiente, los productos alimenticios que contienen materias primas provenientes de distintas regiones viajan a través de muchas fronteras nacionales para su consumo o procesamiento ulterior. Como respuesta al número cada vez mayor de incidentes multinacionales relacionados con la seguridad alimentaria, varios países han revisado sus sistemas legislativos en seguridad alimentaria y han establecido diversas y nuevas medidas formativas. Este artículo recoge las limitaciones de las regulaciones por las leyes nacionales de alimentos, analizando los avances recientes del marco formativo de seguridad alimentaria de tres de los principales actores en el comercio mundial de alimentos: China, Estados Unidos y la Unión Europea. Los problemas actuales de seguridad alimenticia son de igual naturaleza que el proceso de producción de alimentos: globalizados. Por tanto, los retos que se deben afrontar van más allá de las competencias de las naciones individuales. Es necesaria una estrategia integral que regule la seguridad alimenticia tanto en el ámbito nacional como en el internacional.

### **Palabras clave**

Inocuidad de los alimentos, legislación, globalización.

## **QUADRO REGULADOR DA SEGURANÇA ALIMENTAR: UMA PERSPECTIVA GLOBAL**

### **Resumo**

O "achatamento" da economia mundial trouxe muitas consequências. De fato, nas últimas décadas, numerosos avanços tecnológicos contribuíram de maneira fundamental a um novo modelo de produção, distribuição e consumo de alimentos. Por conseguinte, os produtos alimentícios que contêm matérias primas provenientes de diferentes regiões viajam através de muitas fronteiras nacionais para seu consumo ou processamento posterior. Como resposta ao número cada vez maior de incidentes multinacionais relacionados com a segurança alimentar, vários países reviram seus sistemas legislativos respeito à segurança alimentar e estabeleceram diversas e novas medidas formativas. Este artigo recolhe as limitações das regulamentações das

leis nacionais de alimentos, analisando os avanços recentes do quadro formativo de segurança alimentar de três dos principais atores do comércio mundial de alimentos: China, Estados Unidos e a União Europeia. Os problemas atuais de segurança alimentícia são de igual natureza que o processo de produção de alimentos: globalizados. Por tanto, os desafios que devem ser enfrentados, vão além das competências das nações de forma individual. É necessária uma estratégia integral que regule a segurança alimentar tanto no âmbito nacional como no internacional.

## Palavras chave

Inocuidade dos alimentos, legislação, globalização.

## Introduction

The “flattening” (Friedman, 2005) of the world economy has produced many consequences, not the least of which is the ability of consumers to obtain fresh foods from just about anywhere in the world. Over the past few decades, in fact, numerous technological developments have fundamentally contributed to a new pattern of food production, distribution, and consumption (Motarjemi et al., 2001). Advances in food science and agriculture-related technology have dramatically changed the production of food. Developments in transport technologies (Barry, 2006), food processing, packaging and preserving have facilitated the movement of foods. As consequence, food products contain raw materials from multiple regions and travel across many national borders for consumption or further processing (Singh, 2009). In response to ever-increasing multinational food safety incidents, many countries have been revising their food safety law systems and laid down various new regulatory measures. Such a wide range of food safety measures is based on a remarkable number of norms, including domestic legislation and regulation, international advisory health standards and guidelines, and binding international trade rules (Boisrobert et al., 2009).

Among these, domestic legislation and regulation are pivotal to ensuring food safety. However, national food law systems, especially those in developing countries, often suffer from numerous problems, such as overlapping competencies, ineffective law enforcement, regulatory fragmentation, and lack of capacity (Freckelton, 2010). In the globalized food trade of a “flattened world”, problems arisen in one

country and the consequences thereof inevitably pose significant health risks to many other countries. A failure of regulation to ensure food safety in one state can have worldwide implications. National food laws representing unilateral approaches to regulation could not possibly have the capacity to effectively address globalized food safety problems. This paper examines the limitations of regulation by national food laws by analyzing the laws of three major players in the global food trade: China, the United States, and the European Union.

## China's Food Safety System

The well-known melamine case in 2008 has set in motion the recent reform of food safety regulations in China. The basis of the legal framework for food safety was the Food Hygiene Law of 1995. This was aimed as much at companies as government agencies, and its objective was to regulate food hygiene. The law was mainly based on a non-exhaustive list of prohibited actions which left the industry unclear as to how to keep within its boundaries (Chaumet & Desevedavy, 2009). Furthermore, the law had limited reach: it only covered the processing or preparation of foodstuffs that were not their primary production. Farmers and breeders were therefore not covered by the law and food products for animal feed were equally excluded. The increase in the number of food safety scandals has forced the authorities to draft new laws that strengthen the consistency of the legal system regarding food safety issues, the standards required for companies and agency control mechanisms (Yongmin, 2004).

After several drafts, China's National People's Congress Standing Committee passed the Food Safety Law (FSL), a comprehensive effort to oversee food safety, on February 28, 2009. The FSL became effective on June 1, 2009. The major features of the new Chinese Food Safety Law include requirements on the application of risk assessment and scientific methods, the establishment of a national food safety committee, a mandatory product recall provision, and unification of food safety standards and standard-setting procedures (Anon, 2009).

First of all, notwithstanding the Chinese Food Safety Law's impressive effort in reforming the food safety system in place until then, some weakness of the previous regulatory framework have persisted.

One of the most complicated aspects of the FSL is identifying the “chain of command” to determine who has responsibility for implementing and controlling the implementation of the law. The Ministry of Health (MOH) plays a predominant role (Pei et al., 2011). The Rules state that the MOH shall work in collaboration with the Administration for Quality, Supervision, Inspection and Quarantine (AQSIQ), State Administration for Industry and Commerce (SAIC), State Food and Drug Organization (SFDA), Ministry of Commerce and Trade (MOFCOM), and other authorities under the State Council, to set up “the national food safety risk surveillance plan” (Pagnattaro & Peirce, 2010). This is a very ambitious and, quite possibly, difficult-to-implement task. All of the local and regional authorities are required to report to the MOH, which, in turn, must promptly communicate to departments under the State Council (Dellios, 2009).

The MOH also has the important responsibility of organizing the National Food Safety Standard Review Committee, which has the pivotal function of reviewing and approving national food safety standards. The range of discretion held by the MOH is imprecise. The FLS merely states that the Standard Review Committee should be formed by experts in medicine, agriculture, food, and nutrition, as well as representatives from “relevant” departments under the State Council (Pei et al., 2011).

The way the MOH should cooperate with other groups charged with responsibilities under the FSL is similarly imprecise. In other areas, the State Council seems to have a supervisory activity, as opposed to the MOH. The State Council’s Executive Department of Health and Agriculture, for instance, is responsible for pesticides, veterinary residues, and livestock and poultry slaughtering (Lin, 2011). These responsibilities clearly overlap with those of the MOH, and it is all but clear how the responsibilities should be divided. Further confusing factors in the responsibility flow are the role of local authorities and the requirement for industry self-regulation. The FSL requires local people’s governments to be actively involved in regulating food safety under their jurisdictions. In the absence of a national standard, local authorities may develop local food safety standards (Pagnattaro & Peirce, 2010). The risk is that issuing new local standards may be used to protect local industries. On the other side, local authorities might rely on the lacking of any national standards and simply pretend not to see the “need” to implement standards, which could negatively influence profits for local food producers and traders. Therefore, it seems possible that authorities at the local

level may not want to compel local producers to rigorous standards, which could slow production, increase inspections, or require expensive cleanup for premises.

The primary aim of the FSL is to “assure food safety and safeguard people’s health and life”. The law covers its scope comprehensively, including food producers, as well as food traders operating in China. The FSL also interprets “food” broadly, the definition being given as “any substance that has been processed or not processed that is suitable for eating and/or drinking, including substances used as food and medicine, excluding substances solely used as medicine”. Under the FSL, “food” therefore embraces food additives and food-related products. In addition, the FSL purposely states that it widens to “packing materials, vessels, detergents and disinfectants for food, as well as utensils and equipment used in food production and trading”. This represents a pivotal issue, as food contamination can occur at any stage before consumption.

It is worth noting, however, that the FSL seems to compel small food workshops to compliance, on one side, yet, on the other, it appears to set a positively vague goal for improved food safety management. More detailed prescriptions and mandatory requirements for small food workshops are a key issue to ensure food safety in China. By the end of 2008, nearly “70% of China’s 500,000 food processing firms [were] small-scale with fewer than ten employees” (Lafraniere, 2011) Stricter standards for such processors appear to be actually of most importance to ensure compliance with the FSL.

The ninth chapter of the FSL defines the legal liabilities for food producers and traders caught acting against the law. The law provides for civil penalties, damages for consumers and criminal prosecution for offenders.

Food producers and traders are not the only ones that can be considered liable according to the FSL. In fact, the law does state that food advertisements reporting “false publicity to cheat consumers,” will be punished under the Advertising Law of the People’s Republic; however, it goes even further, positively affirming that civil societies, organizations, and individuals “who recommend a food to consumers in untruthful advertisements” will be held liable together with the food producer or trader.

Interestingly, there is no provision related to the prohibition of exporting unsafe food products. In the “Import and Export of Food” section of the FSL, there are six articles related to the obligations of food importers, but merely one requiring sample inspectors and food exporters to “go through the record-filing formalities at the entry/exit inspection.” On the one hand, having such asymmetric regulations governing exports and imports, is deemed potentially dangerous by many observers, standing China’s status of great exporter of food products. On the other hand, however, a white paper recently published by the State Council showed that the quality control pass rates for food products from China exported to the US and the EU in 2010 reached 99.53 % and 99.78 % respectively (Anon, 2011a). The fact that, the very same day, Chinese media quoted Chen Junshi, researcher at the Chinese Center for Disease Control and Prevention, as saying that “it is of no practical use to set up a high national standard for food safety as domestic food companies would be incapable of meeting it” (Anon, 2011b) generated a national debate regarding the double standard over food safety existing in the country. Critical national media pointed out that “In terms of exported food, 99 percent can meet international standards. However, when it comes to food produced here for domestic consumption, we set far lower standards” (Anon, 2011b). Further critics argue that a lack of laws and regulations in China substantially contributed to the seriousness of the melamine case (Tang & Sphor, 2006). Yet, it is very clear that establishing new laws and regulations in itself can’t do the trick. The only way to properly address China’s food safety issues is to ensure the enforcement of adequate laws (Ni & Zeng, 2009). Such a task is daunting. In China, as anywhere in the world and even more, the problem of law enforcement is a crucial matter, and the gap between written and enforced laws has been widening (Lin, 2011). In addition, the recent reappearance of melamine-tainted milk in December 2009 gives the most disgraceful example of the serious problem of law enforcement in China (Pei et al., 2011). It must be mentioned that, in the area of food safety regulation, both the difficult and complex science of food safety itself and the ever increasing technical expertise required further aggravate the ineffectiveness of law enforcement, even more so at the level of local governments.

Apparently, the FSL seems to provide detailed information and prescriptions about monitoring and supervision of food safety, but it does leave a great load of doubt about how the law will be implemented and how it will work in practice. Even more so, because China has been blamed for having the “authority for food

safety enforcement ‘dispersed’ among too many agencies and different levels of government” (Fairclough, 2008). On its face, the FSL would rectify that problem.

## The U.S. Food Safety System and the Food Safety Modernization Act

The People’s Republic of China is not the only great food product exporter in the world revising his food safety system: ironically, the reasons driving the changes in the food regulatory system of U.S. are seemingly very close to those receiving an ever increasing blame in PRC, mainly from American observers: fragmented food safety responsibility and growing concern of American consumers towards the high-profile outbreaks related to various foods, from spinach and peanut products to eggs, that hit the country over the past few years (Negri, 2009).

In the United States, the primary responsibility for ensuring food safety is shared between the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA). Besides the USDA and FDA, The Government Accountability Office (GAO) has identified as many as fifteen federal agencies collectively administering at least thirty laws related to food safety (Johnson 2011a). This structure means a fragmented food safety system at the federal level, and even more so at the state level, where countless regulations are in place. As clearly highlighted by the Government Accountability Office (GAO), in its 2001 report on food safety and security, scattered structure of food safety systems reflects on limits to efficient coordination, difficulty in implementation, and ineffective enforcement in the United States (Hoffmann, 2010).

A previous bill in 2009 already changed the regulatory framework of the U.S: the Food Safety Enhancement Act (FSEA). Although it did not go so far as to reform the Department of Health and Human Services as the FSMA does, it nevertheless displayed important provisions for strengthening the regulation of drugs, devices, and cosmetics, and for enhancing the regulation of food, particularly food imported from other nations (Johnson, 2011b).

The Food Safety Modernization Act (FSMA), however, is the most significant change to food safety regulations since 1930, creating a new administrative agency entitled “Food Safety Administration”. This agency would aim to supervise food



safety, though without any authority over the drug approval program, which is currently overseen by the FDA together with food safety.

Overall, the FSMA aims to lead FDA's food safety practices to a core public health perspective, according to the Institute of Medicine recommendations, putting the accent on preventing food contamination rather than reacting after food safety incidents and developing a risk-based framework for inspections and regulation (Wallace & Oria, 2010).

The FSMA promotes primary prevention at the food processing stage, reducing food-borne illness at its source. The FSMA provides the implementation of preventive control plans and increased inspection frequency for premises. Most importantly, it provides risk-based standards for inspection frequency, aiming to an optimization of the FDA's resources (Johnson, 2011b).

One of the FSMA's most celebrated amendments is mandatory recall authority. Until the FSMA, the FDA did not have the authority to impose recalls for food apart from infant formula, and the system relied on producers to fulfil with voluntary recalls. Observance on a voluntary base proved to be scarcely efficient in response to serious outbreaks and, even more so, weakened public trust in the food safety system (Johnson, 2011b).

Improving the safety of imported food is the final major aim of the FSMA. The new regulation requires new inspections on imported food, including obligating importers to verify the food safety practices of their suppliers, leading to a new certification process for foods categorized as high-risk, and giving the FDA the possibility to inspect foreign premises. The FSMA also introduces the possibility for FDA to assist foreign regulatory bodies (Stewart & Gostin, 2011).

Notwithstanding the strengths of its reforms, the FSMA could not fill regulatory gaps and ensure the adequate funding and enforcement. Needless to say, the act does not cover USDA, leaving meat and poultry, and food safety practices thereof, untouched, with the consequence of a persisting structural and regulatory fragmentation. Even though the FSMA encourages FDA-USDA collaboration in the setting of safety standards, it does not operate in the direction of the consolidation of a single agency as the Government Accountability Office recommended (Stewart & Gostin, 2011).

Provided exemptions for small producers are another matter of discussion for the evaluation of the reformed food safety system. An amendment to the FSMA exempted small farms from requirements considered too burdensome for small activities. According to the FSMA, a small producer's exemption is lost in case of food safety incident, meaning that the producer was not able to comply with the act's prevention provisions. This reaction-based system of inspection is hardly in-line with the perspective introduced by the FSMA and, even though small producers can be deemed to represent a lower risk-profile activity than multinational conglomerates, a reliable food safety system requires regulation of all the actors to ensure both public health and public trust.

Implementation of the law may also turn out to be an important source of dismay. The act establishes new authorities and enforcement, but the FDA's ability to implement ambitious new programs will depend on adequate funding (Wallace & Oria, 2010).

## The EU General Food Law

Food regulation in Europe has a long history. Food safety laws within the EU were reviewed in 2002, following the infamous case of "mad cow disease" in Great Britain. This study had as outcome the "White Paper on Food Safety" (EU White Paper), that provided a number of recommendations for new proactive food legislation (Anon, 2000b).

The European Union adopted the General Food Law with the aim to provide a comprehensive framework of EU food safety rules overseeing to food and feed products.

A pivotal issue of the new approach to food safety regulation was the creation of a "framework regulation" (Anon, 2002), which lays down the general principles and requirements of EU food law, established the European Safety Food Authority, and defines procedures in matters of food safety. Most celebrated novelty of the EU's new approach was the "farm-to-fork" approach to food safety and inspection. This approach encompasses all sectors of the food and feed chain, stressing the critical importance of traceability. A second important issue was the establishment of an independent authority with the function of advisory board on scientific issues to the legislators. The final element of the new legislation called for the development of specific food and feed safety legislation, that amended the

former legislation and developed a framework for comprehensive food inspection. A rather essential concept, in the EU's food law that must be mentioned is the "Precautionary Principle" drafted in February 2000 (Anon 2000a). Theoretically, it aims at ensuring a higher level of environmental protection through preventative decision-taking in the case of risk. However, in practice, the scope of this principle is far wider and also covers consumer policy, European legislation concerning food and human, animal and plant health. According to the Commission, the precautionary principle may be invoked when a phenomenon, product or process may have a dangerous effect, identified by a scientific and objective evaluation, if this evaluation does not allow the risk to be determined with sufficient certainty (Anon, 2000a). The Precautionary Principle has been recognised by a number of international agreements. The Sanitary and Phytosanitary Agreement (SPS) stipulated in the framework of the World Trade Organisation (WTO) (Negri, 2009).

Overall, the General Food Law is comprehensive enough to be a model food law. It covers all stages of the food production chain, positively emphasizes citizens health protection and establishes a single body which serves as the scientific reference point for the regulators. Nevertheless, the General Food Law can be affected by two potential problems characterizing global food safety. First, similarly to the United States, a domestic comprehensive food safety system is unable to ensure the safety of imported food products. Since it is economically impossible for an importing state to perform complete border checking on all imported food products, potentially dangerous food products remain a threat for consumer health. The safety of imported goods depends extensively on the capacity of food law and the effectiveness of its enforcement in respective exporting countries. Furthermore, traceability information is subject to different considerations and the credibility of the exporting countries' authorities, even more so during food safety crises. Moreover, there are differences among EU member states in terms of their implementation and enforcement of the General Food Law (Weber, 2001). Even though such inconsistencies in implementation are all but unexpected under any multilateral legal framework, member states made "different legislative and institutional arrangements" (Houghton et al., 2008)

A further cause for inconsistent implementation by member states is the burdensome nature of the complying process by the new member states (Anon 2003). The presence of new member states means extended border lines and the need to train more personnel and develop a vast network of a number of increasingly skilled

laboratories for analytical testing. Nevertheless, according to the provisions of the General Food Law, neither member states nor the European Union as a whole are compelled to provide technical or financial assistance to new member states that obviously suffer from inadequate training in these areas. An EU-level comprehensive strategy for strengthening of the whole system as well as for providing financial and technical assistance is needed (Lin, 2011).

## Conclusions

Quite obviously, if every country had a comprehensive food law system, sufficient budget, adequate technical expertise, highly trained personnel, and effective law enforcement, food safety issues would be less challenging. Unfortunately, even developed states like the United States and European countries have numerous problems with their own food safety regulatory frameworks. In the United States, overlapping competencies among FDA, the USDA, and other federal agencies have undermined the efficiency of the government in handling routine food safety surveillance tasks and in responding to crises of foodborne hazards. Insufficient and ineffective border inspection of imported food remains a threat for both the United States and the EU. In the EU, inconsistencies among member states and new member states struggling to fill the technical and financial gaps, pose a problem to the effectiveness of the high-standard European General Food Law.

Problems of law enforcement and overlapping responsibilities among different regulatory bodies are similarly shared by China, which, in turn, suffers from a still underdeveloped regulatory framework. Despite the considerable progress in guarantying the safety and security of foodstuffs, as well as its demonstration of the political will to improve the current situation. Yet again, raising countries, like China, suffer largely from an inadequate capacity of basic infrastructure, of sufficiently trained personnel and of technical expertise. In light of the global nature of food-related hazards, even countries possessing vigorous food regulatory systems at the domestic level cannot ensure overall food safety. When addressing public health issues, collective action is necessary (Boisrobert et al., 2009). For example, sharing traceability information during international outbreaks, cooperation between laboratories and research institutions, and even a global tracking system of imported and exported food products could be deemed to be essential to ensure an optimal level of food safety. The safety of food, and public health more generally, is arguably a public good. Positively depending by the ever-increasing

international trade in food, food safety, like the free flow of food products, cannot be suitably addressed by national regulations. An effective and sufficient regulatory strategy must go beyond the discourse of national measures. While no global food control systems could ever ensure a zero-risk food supply (Singh, 2009), national measures alone are too obviously inadequate to address international food safety crises in an environment of global complexity. Contemporary food safety issues are of a globalized nature and pose global challenges beyond the authority and competencies of individual states. A comprehensive regulatory strategy at both national and international levels is urgently needed.

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