An Insight into the Regulatory Framework of Food Safety Management

A comparative approach to food safety incident response in EU, US, China

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Abstract

Over the past decades the increased complexity of the food supply chain has contributed to global emergence of food safety incidents. As a result, reform of Food Safety Management regulation throughout the food supply chain has been gaining momentum in Legal systems worldwide. To this end, discrepancies in food safety incident response can be identified amongst Legal systems.

This research contributes a comparative study (structural- and functional method) to the regulatory framework of Food Safety Management focusing on discrepancies in food safety incident response. The study is accomplished through a so-called systemic approach to desk research. In addition, a case study is involved.

This study provides insights into the regulatory framework of Food Safety Management of some of the world’s largest economies: European Union, United States of America and the People’s Republic of China. In practice discrepancies can be identified in the way these Legal systems deal with food safety incidents. The results demonstrate the underlying causes can be found in both the legal culture in place, and (as a result) in the development, design and characteristics of the regulatory framework at stake. However, the comparative analysis demonstrates, irrespective of major discrepancies in the structure of the regulatory framework of Food Safety Management and the procedures the Legal systems implement in response to a certain food safety incident in practice, in general the approach of the Legal systems is broadly consistent with the assessed International (FAO/WHO) framework.

The results of this study emphasize the importance of taking the legal culture in place into account in comparing different Legal systems; therefore each Legal system is to be considered unique.

Keywords: discrepancies, food safety incident response, Legal systems, Food Safety Management, China, European Union, United States of America, legal culture.
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Glossary

General Food Law

PRC Food Safety Law
Food Safety Law of the People’s Republic of China. Adopted at the 7th Session of the 11th Standing Committee of the National People’s Congress of the People’s Republic of China on February 28, 2009 and revised at the 14th Session of the 12th Standing Committee of the National People’s Congress of the People’s Republic of China on April 24, 2015.

Food Safety and Modernization Act
An Act to amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply enacted by the Senate and House of Representatives of the United States of America in Congress assembled. Public Law 111-353, 111th Congress.

Legal Culture
For the purpose of this study, general overview of how the Legal systems are structured in terms of basic insights in 1) regulatory structure, 2) Legal system and institutions and 3) food culture.

Food culture
For the purpose of this study, national values towards food safety reflected in the food laws of the selected Legal systems.

Food and Agricultural Organization
An intergovernmental organization, consisting of 194 Member Nations, two associate members and one member organization, the European Union. Main goal: achieving food security and to make sure people have regular access to enough high-quality food to lead active, healthy lives.

Codex Alimentarius
The Codex Alimentarius, or the food code, is the global reference point for consumers, food producers and processors, national food control agencies and the international food trade. It is governed by the Codex Alimentarius Commission (Codex) which concerns the main global body that makes proposals to, and is consulted by, the Directors-General of the World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO) on all matters pertaining to the implementation of the Joint FAO/WHO Food Standards Program.
NIMS
A standardized approach to incident management developed by the Department of Homeland Security of the United States. The program was established in March of 2004, and is intended to facilitate coordination between all responders (including all levels of government with public, private, and nongovernmental organizations).

RASFF
A key tool of the European union to ensure the cross-border flow of information to swiftly react when risks to public health are detected in the food chain.

World Health Organization
A specialized agency of the United Nations that is concerned with international public health. Primary role is to direct and coordinate international health within the United Nations’ system.
### List of Abbreviations

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<thead>
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<th>Abbreviation</th>
<th>Full Form</th>
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<tr>
<td>AQSIQ</td>
<td>Administration of Quality Supervision, Inspection and Quarantine</td>
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<td>CAC</td>
<td>Codex Alimentarius Commission</td>
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<td>CDC</td>
<td>US Centre for Disease Control and Prevention</td>
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<td>CJEU</td>
<td>Court of Justice of the European Union</td>
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<td>CFSAN</td>
<td>Centre for Food Safety and Applied Nutrition</td>
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<td>CFDA</td>
<td>China Food and Drug Agency</td>
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<td>EC</td>
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<td>European Food Safety Authority</td>
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<td>EU</td>
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<td>FAO</td>
<td>Food and Agriculture Organization</td>
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<td>US Federal Food and Drug Agency</td>
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<td>FSC</td>
<td>Food Safety Commission</td>
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<td>FSMA</td>
<td>Food Safety and Modernization Act</td>
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<td>GFL</td>
<td>General Food Law</td>
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<td>MOA</td>
<td>Ministry of Agriculture</td>
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<td>MOFCOM</td>
<td>China Ministry of Commerce</td>
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<td>NHFPC</td>
<td>National Health and Family Planning Commission</td>
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<td>NIMS</td>
<td>National Incident Management System</td>
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<td>NPC</td>
<td>China National People’s Congress</td>
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<td>PRC</td>
<td>People’s Republic of China</td>
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<td>UN</td>
<td>United Nations</td>
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<td>US</td>
<td>United States of America</td>
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<td>USDA</td>
<td>US Department of Agriculture</td>
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<td>RASFF</td>
<td>Rapid Alert System for Food and Feed</td>
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<td>WHO</td>
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1. Introduction & Outline

Access to sufficient safe food is a basic requirement for human health; food security is a condition thereof. The World Food Summit of 1996 defined food security as existing when all people, at all times, have physical and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life. One of the essential dimensions of food security is food safety.

1.1 Introduction to the topic: discrepancies in Food Safety Incident Management

Modern food safety policy came into being mostly in response to food safety incidents such as food scandals and foodborne outbreaks. Behind these incidents lay dramatic changes in the economic structure of food production and distribution of states globally. Rapid technological change at the beginning of the 20th century was transforming life into something now recognizable as a modern urban industrial society. Back then food production shifted from home, local production and processing towards more industrial processing and regional, national or even cross-border marketing. This, considered the concept of globalization, resulted in a lengthening of the food chain, greatly increasing the complexity of the challenges for food safety. This phenomenon has inevitably lead to reduced insight into the origin and (pre-) treatments of raw materials and products.

As a consequence, in the past decades the increased complexity of the food supply chain has contributed to the global emergence of food safety incidents. These incidents have led to development and reform of food safety regulatory system of Legal systems worldwide. A great example thereof is the emergence of the bovine spongiform encephalopathy, BSE in the 1990’s in Europe, commonly known as the mad cow disease, which is considered a direct food- borne threat to human health and has contributed to European food law reform at the beginning of the 21st century. Another example is the occurrence of ‘China’s melamine scandal’, also known as the Tainted Infant Formula incidents in the period 2004–2008. This event demonstrated some of the shocking shortcomings of China’s food law system at that time and has hastened legal reform in terms of the

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2 The 1996 World Summit on Food Security convened by the Food and Agriculture Organization of the United Nations. The World Summit took place in Rome, Italy, between 16 and 18 November 2009. The decision to convene the summit was taken by the FAO Council, at the proposal of FAO Director-General Jacques Diouf. Sixty Heads of State and Government attended the summit. Countries unanimously adopted a declaration pledging renewed commitment to eradicate hunger from the earth at the earliest possible date.
4 Hoffmann et al. 2010, P. 1–2.
5 Ibid.
6 Bovine spongiform encephalopathy (BSE), commonly known as mad cow disease, is a fatal neurodegenerative disease (encephalopathy) in cattle that causes a spongy degeneration in the brain and spinal cord.
enactment of China’s 2009 Food Safety Law which concerns the basis of China’s contemporary Food Safety Law. Another, but far older, event is the Chicago Meat Packing scandal that occurred in the early part of the 20th century in the United States of America (US) which has led to major US food law reform under president Theodore Roosevelt, the law established at that time still forms the basis of current US Food and Drug law.

Consequently, over the past decades a series of food safety incidents have shown serious shortcomings in Legal systems worldwide (law enforcement, lack of appropriate response mechanisms, control systems etc.). Notwithstanding, the events are considered a lesson learned and have given opportunity to Legal systems to increasingly develop/modify their food law system as well. With this respect in the past decades the occurrence of food safety incidents (e.g. food adulteration, food borne risks, food fraud etc.) have drawn worldwide attention and as a result the effort to reform regulation of Food Safety Management throughout the food supply chain has been gaining momentum in Legal systems worldwide. To this end discrepancies in food safety incident response can be identified amongst Legal systems.

From a socio-legal angle, the safety of food can have enormous effects such could affect human health, economic benefits, consumer trust etc. The primary expectation of the general consumer today is that governments make sure proper measures are in place to ensure food sold is safe to eat. Hence, food is something we all consume, therefore the safety of food is an issue valued and widely drawn attention to. To this end, several factors influence how an event is approached including the number of people ill, the severity of the illness, the distribution and volumes of food, whether the contaminant is known or unknown, and the international and trade implications. In addition, the legal structure of a country (Food Safety Management regulatory framework) to respond to such event will play a critical role in the level of coordination and resources required.7

Moreover, how people react to risks is mediated by many factors, including how risk information is perceived, how we react to social and cultural influences and how choices are structured8, the latter influences the legal construction designed to manage risks.9 What might be handled as a routine incident in one country may be considered a crisis in another.10 To this end, it should be noted the socio-cultural environment (food culture, local traditions etc.) of where the occurrence of the event took place, co-influences the perception of the event. Consequently, in understanding the legal

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8 Ibid.
construction designed to manage risks—such as incident management, regulation of emerging incidents and measures taken in response to the event— one should take several aspects of the socio-legal environment (legal culture) of that particular Legal system into account as well.

Related research in this field is that of the seminal work of Ferrari a comparative law scholar who argues that the very notion of risks, as well as the understanding and evaluation of particular risks, reflect and shape the values, preferences and prejudices of society. In contrary to many legal scholars who have been interested in law and its social context, Ferrari took the challenge to use cultural values towards food safety in explaining governmental behavior towards food safety incident response from mainly a socio-legal angle. With this respect, he makes use of a comparative study involving the Mad Cow Crisis as a case study. He articulates a theory of legal change in the context of governmental behavior towards food safety incident management; takes into account the role of legal culture herein. Some applicable aspects of his theory will be applied in this study.

1.2 Research motive

The issue outlined in the introduction forms the starting point of this study (discrepancies in food safety incident response amongst Legal systems). This study is primarily a response to the scarce availability of scientific research in this field. In addition, not only can one identify scarce availability of scientific study providing insights into the regulatory framework of Food Safety Management in general, more importantly the implementation of a comparative approach in this field of study is even less available. As a consequence, from my point of view, currently insufficient scientific knowledge of the concerned area is to be identified. To this end, a comparative approach to the regulatory framework of Food Safety Management is an interesting field to explore. Given the dynamics and increased importance of Food Safety Management in the global arena, a study providing insights into the regulatory framework of Food Safety Management amongst major Legal systems will set to open new doors in the field of Food Safety Law. Subsequently, this research provides with a comparative study to the regulatory framework of Food Safety Management in the Legal system of Europe, United States of America and People’s Republic of China, not yet provided.

As a conclusive remark, apart from previous mentioned motive, this study is furthermore inspired by personal interests in the regulatory approach to food safety incidents from a comparative point of view.

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1.3 Research objective

The aim of this study is to provide a close look at the regulatory framework of Food Safety Management of the Legal system of the EU, US and China providing focus on the aspect of food safety incident response and to compare this from a legal angle focusing on mainly the system as established in the applicable law taking some influences of the legal culture in place into account as well.

1.1.1 Contribution of the research

This research will contribute to a comparative approach to the regulatory framework of Food Safety Management with a focus on food safety incident response. A comparative study to the regulatory framework of Food Safety Management focusing in specific on food safety incident response and in particular involving China’s Legal system, has been paid scarce attention to yet. Therefore, this research sets out to open a new door to this field of study by providing legal analysis applying a comparative approach to the EU, US and China Legal system.

1.4 Central question

This research is built around providing answers to the next question. “How can discrepancies in governmental response to food safety incidents be explained through the regulatory framework of Food Safety Management and what is the role of legal culture therein?”.

1.4.1. Sub-questions

In answering the central question, this study sheds some light on several relevant subjects. These subjects are translated into sub-questions. The next sub-questions are subject for research.

1. How have the Food Laws in the Legal systems developed over the years and what are they influenced by?
2. How is the Food Safety Law framework structured in the Legal systems and how is this in general enforced?
3. How is the applicable International framework of Food Safety Management designed and how have the Legal systems established the process of Food Safety Management in their regulatory framework?
4. To what extent do the Legal systems in general follow the applicable International framework in the process of food safety incident response in practice?
1.5 Methodology

This study concerns a so-called desk research study. Data/information is gathered from a wide variety of sources such as governmental websites, databases, newspapers, legal magazines, law books/collections, books etc. in both electronic and paper form; and integrated the retrieved information with existing knowledge. With this respect, the so-called systemic approach to desk-research is followed which is illustrated in the following.

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1.6 Research approach

Both a structural- and functional approach as parts of comparative law methods will be applied. With this respect it is not the purpose of this research to provide an understanding of the place these methods take within the common known area of comparative law. However, it is indeed of importance to provide brief explanation of the characteristics in the interest of understanding the role these methods play in this study. By structural approach in the context of this study, it is meant: analyzing the same set of variables in the three selected system and placing the results next to each other in an overview subject for comparison. This approach will be used for answering the sub-questions, the reader will be provided with a clear understanding of how the different Legal systems deal with the same set of selected variables. With this respect towards the aim of this study, the comparison contains only a marginal discussion of the overall subject of Food Safety Management regulation. The underlying reason for this is the fact that only the same set of variables (within the context of this research) will be subject for final comparative analysis that shall result in answering the central question. The latter will be based on a functional approach that needs to be understood in this context as: taking the results of the structural comparative analysis and placing them in their various cultural and political settings. For instance, explanation will be given why in US food law criminal law approaches are applicable and why for example in China the administrative oversight of Food Safety Law is not corresponding to its aim so far. In the context of this study the functional comparative analysis that will be provided (as a conclusive analysis) will be mainly based on the results of the structural comparison of the variables used taking some aspects of legal culture (further defined under ‘Scope’) that are specifically selected in the interest of the aim of this study, into account. Therefore the final analysis should be understood in its intended conceptual scope.

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12 Desk research consists of gathering and analyzing information, already available in print or published on the internet.

13 System retrieved from the library of the University of Amsterdam (UvA).

URL: <https://bib.hva.nl/nl/informatievindenverwerken/Deskresearchwatisdat/Paginas/default.aspx>.
1.7 Methodological accountability

As discussed before, in order to provide with an explanation of government behavior in terms of food safety response from different perspectives, a comparative approach will be applied. The analysis will deal with three specific Legal systems. In order to adequately provide a comparative explanation on how governments respond on a certain way taking into account the cultural background of the Legal system in place, it is imperative to make a comparison of different Legal systems with different legal cultures. Therefore, it is decided to compare three different Legal systems with different legal culture. Selection is made of the European Union, the United States of America and the People’s Republic of China (PRC). These systems do not only differ significantly with regard to their legal culture and legal historical background, likewise there is a strong variation of their socio-cultural background and traditions as well. In the following explanation will be provided of the selection of the Legal system subject to comparison.

The EU system was the first choice, the European food law system could be considered one of the largest integrated food law system in the world. Member States have surrendered most of their regulatory powers in the field of food safety to the European Union and this process has accelerated in the wake of probably Europe’s most famous food safety event, the BSE-crisis\(^{14}\). Furthermore, Europe’s food safety policy is characterized by its legal embedded preventive approach. Moreover, another interesting aspect that should be taken into account in the matter of legal culture in relation to Europe, is the concept of “cultural pluralism” and the characterizations thereof in the field of Food Safety Law.

The second selected Legal system is that of the United States of America (US). US food law system has a long-standing tradition in the regulation of foodstuff. The first US food law dates back to the 19th century initially being a response to cases of misbranding and food adulteration. Therefore the US have, in contrary to the EU, known a long tradition of food law development with mainly a responsive character. Another interesting aspect worth mentioning is the fact that US food law is a part of US federal regulation. Therefore, Food Safety Law gains an important position within US federal law as it is applicable on the highest government level. Moreover, US food law has recently known major legal reform with the enactment of the Food Safety and Modernization Act signed by president Barack Obama. Furthermore, the US’s leading role in the regulation and trade of foodstuffs ensures that its regulation of food safety incident response is interesting to explore.

The third selected system is that of People’s Republic of China. China has recently reformed its food safety framework as well. Originally China’s Legal system is influenced by teachings and ideas

\(^{14}\) Ferrari, M., 2009, P. 1.
mainly based on ethics and morals. However, after the taking over of the Communists and following the political crisis of the Communist regime (commonly known as the “Cultural Revolution”\(^{15}\)) which took place in the 1970’s, China has experienced major legal reform. This period of *modernization* was initially driven by economic interests. One of the focus areas was agriculture; in the field of foodstuff, the 1995 Food Hygiene law was established.\(^{16}\) However, the existing law soon appeared to be inefficient in ensuring food safety. Hence, China wanted to be an important trading player in the global arena. Driven by its ambitions, China became an important global partner in the specific area of food trade. Soon after, in the period of 1990–2008 a series of outbreaks occurred. The PRC Food Safety Law of 2009 came into being largely as a response to economic changes and shocking food safety incidents (foodborne outbreaks and adulteration). With respect to its history and (current) regulatory development in the field of food safety, the characterization of China’s food law system is particularly interesting to explore.

The three Legal systems considered are furthermore, as mentioned before, characterized by different legal-cultural environments. The analysis of such environments will permit some considerations to be drawn on the role legal-cultural variables play in the process of food safety incident management.

### 1.8 Scope

In this research the concept of *“Food Safety Management”* is limited to the concept laid down in the regulatory framework, primarily the Food Safety Laws, belonging to the selected Legal systems concerned. In general, related protocols/documents/action plans etc. that are applicable in the execution of Food Safety Management, are left outside the scope. In addition, preventive Food Safety Management measures in terms of controlling risks (e.g. HACCP, sampling, inspection methods etc.) fall outside the scope of this research as well. Rather, this study focuses primarily on governmental Food Safety Management (risk management measures) during and after the occurrence of a certain food safety incident.

Furthermore, the concept of *“legal culture”* in this research is based on the context of this study and is limited to a general overview of how the Legal systems are structured in terms of basic insights in 1) regulatory structure, 2) Legal system and institutions and 3) food culture. The latter shall be

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\(^{15}\) In 1966, China’s Communist leader Mao Zedong launched what became known as the Cultural Revolution in order to reassert his authority over the Chinese government. Believing that current Communist leaders were taking the party, and China itself, in the wrong direction. Mao called on the nation’s youth to purge the “impure” elements of Chinese society and revive the revolutionary spirit that had led to victory in the civil war 20 decades earlier and the formation of the People’s Republic of China. For more information see: “Mao’s Great Revolution” – 1971, XIV. Destroy The Old World By Robert Elegant.

\(^{16}\) Food Safety Law of the People’s Republic of China. Adopted at the 7th Session of the 11th Standing Committee of the National People’s Congress of the People’s Republic of China on February 28, 2009 and revised at the 14th Session of the 12th Standing Committee of the National People’s Congress of the People’s Republic of China on April 24, 2015.
understood as: national values towards food safety reflected in the food laws of the Legal systems. With this respect the concept of “food culture\textsuperscript{17}” falls under the umbrella of legal culture. The variables used in defining legal culture are selected towards relevance of the aim of this study. For further definitions, see the list of definitions.

Finally, it should be noted this research is limited to providing insights in the regulatory framework of Food Safety Management focusing on food safety incident response and aims to compare this from a legal angle focusing on mainly the system as established in the laws and the correlation thereof with some features of legal culture. It serves as an introduction to the regulatory framework of Food Safety Management from a comparatists angle providing opportunity for further research in this field.

1.9 Research Structure

This comparative study is content wise divided into five chapters.

**Chapter 1** serves as an introduction to the topic. It deals with an overview of the development of the food safety framework from a legal-historical context applicable to the selected systems. In addition, attention will be paid to the role of Food Safety Law in the global arena. Finally, a conclusive functional comparative analysis will be provided. With this respect, the structure of chapter 1 differs from the structure of the following chapters. The underlying reason for this is the fact that the results of chapter 1 form the foundation of this study. It is therefore of interest to provide a clear understanding of the foundations of the Food Safety Laws that will be discussed and compared throughout the study. **Chapter 2** deals with the Food Safety Law framework belonging to the three selected Legal systems at stake. Focus will be on several variables that indicate the characterization of contemporary Food Safety Law system in place. A structural comparative approach will be applied in this case. **Chapter 3** forms the core of this study, it focuses on the Food Safety Management process of the three selected systems as established in their regulatory framework. This chapter starts with an overview of the FAO/WHO risk management framework which will be the basis for final comparative analysis. With this respect, it should be noted all selected systems are a member of the Codex Alimentarius Commission (CAC). In addition, the Food Safety Management approach (establishment of the risk analysis concept, involved institutions, management tools and incident management) as established in the food safety framework of the concerned systems, will be analyzed. For this a structural comparative approach will be applied as well since variables will be selected and equally compared between the Legal systems. Furthermore, **chapter 4** deals with a case study demonstrating government response to emerging food safety incidents and their consistency with

\textsuperscript{17} In the context of this study: national values towards food safety
applicable international guidelines provided in chapter 3. In order to study and verify the consistency of the national framework with the relevant international framework of Food Safety Management a hypothesis will be drawn; in conclusion this hypothesis will be analyzed. Chapter 5 constitutes a functional comparative analysis. The analyzed results following from the sub-questions will be brought together. First, the chapter will deal with discrepancies in the Food Safety Management regulatory framework from a socio-legal angle. With this respect, the effect of the legal culture and national values towards food safety (food culture) on the contemporary food safety legal framework of the Legal systems will be provided. Hereinafter, a comparative analysis of the selected variables will be provided. The functional comparative analysis contributes to explanation of discrepancies in governmental response to food safety incidents\textsuperscript{16} taking into account the structure of the Legal system in place and the extent legal culture plays a role therein which results in answering the central question: “How can discrepancies in governmental response to food safety incidents be explained through the regulatory framework of Food Safety Management and what is the role of legal culture therein?”.

This study makes use of a comparative eye to the three Legal systems of the European Union, United States of America and People’s Republic of China respectively in answering the central question.

\textsuperscript{16}To the extent studied in this research and towards the aim set out in this study.
1.10 Introduction to the comparative study: legal culture in EU, US and China

Before starting with the comparative study, it is first imperative to provide a general understanding of the correlation of law and culture (often identified as legal culture) in the area of comparative law. Therefore, in providing such, this paragraph will serve as an introduction to this comparative study by providing a general overview of the role of law and culture in comparative law. The results of this paragraph will be subject for functional comparative analysis in chapter 5. Hereinafter, basal insights into the legal culture of the selected Legal systems will be provided.

Comparative Law studies: Law, Culture; Legal culture

Legal Methods regulate how the law evolves and is applied; legal methods are embedded in legal culture. For this study in order to give an adequate comparison and explain the differences in governmental response to emerging food safety incidents, it is not sufficient to merely use the law as a basis. Rather, the law needs to be understood from its cultural context. To understand the law is to understand the culture in which the law operates. Therefore, in comparing Legal systems the legal cultural background of the concerned state/ nation needs to be taken into account. The correlation between law and culture has been an intensively discussed topic amongst scholars (sociologists, lawyers, comparatists, anthropologists etc.). It is an extensive and difficult task to simply assume discrepancies in regulatory response based on the law merely as many factors involved must be taken into account. Hereinafter a general overview of the interrelationship of law and culture and the general understanding of legal culture in the field of comparative law will be provided.

The interrelationship between culture and law has long been postulated. Montesquieu\(^{20}\) postulated in his work "Esprit des Lois" (1748) the necessity for positive law to be adapted to the geographical features of the country and the cultural characteristics of its people\(^{21}\). Since the 19th century this idea of law as a cultural accomplishment of a particular people became popular. The key concept for a legal– sociological theory of integration is that of ‘legal– culture’. The concept of legal culture has been intensively discussed in legal discussions over the last twenty years or so. What is exactly meant by legal culture often remains unclear. legal culture is considered important, but an exact definition is not. The concept of legal culture however, is tackled from several disciplines, especially from those of law, anthropology and sociology. Sometimes, the term legal culture is used interchangeably with the term legal family or legal tradition. More specific concepts exist as well. Legal sociologists

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\(^{19}\) It should be noted the comparative overview of the legal culture in place is of importance in the interest of the central question.

\(^{20}\) Full name: Charles-Louis de Secondat, Baron de La Brède et de Montesquieu (18 January 1689 – 10 February 1755), generally referred to as simply Montesquieu, was a French lawyer, man of letters, and political philosopher who lived during the Age of Enlightenment. He is famous for his articulation of the theory of separation of powers or “trias politica” (legislative, executive, judicial), which is implemented in many constitutions throughout the world.

especially understand legal culture as the values, ideas and attitudes that a society has with respect to its law.\textsuperscript{22} It could be considered that legal culture stands between law and culture, with unclear borders in both directions. According to a widespread understanding, legal culture represents that cultural background of law which creates the law and which is necessary to give meaning to law. This encompasses the role of law in society, the role of different legal sources, the actual authority of different actors and institutions, etc.\textsuperscript{23} According to Volkmart Gesner\textsuperscript{24} it is no longer disputed that legal culture is both a cause and effect of law. He explains that on the one hand it shapes the essential basic ideas of national legal order, while on the other hand it is constantly exposed to legal influences. This implies in our case that understanding a certain behavior such as risk governance of a certain Legal system does not go without understanding the legal culture of that certain environment.

Furthermore, according to Nelken\textsuperscript{25} in employing the idea of legal culture in comparative exercises geared to exploring the similarities and differences amongst legal practices and legal worlds, the aim is to go beyond the tired categories so often relied on in comparative law such as ‘families of law’ and incorporate that attention to the ‘law in action’ and ‘living law’. Legal culture is a relatively new concept which, according to Nelken, can be traced to terms like legal tradition or legal style, which have a much longer history in comparative law or in early political science. It presupposes and invites us to explore the existence of systematic variations in patterns in “law in the books” and “law in action,” and, above all, in the relation between them.\textsuperscript{26}

Overview Legal Culture, EU, US and China

\textit{European Union}

When speaking of a legal culture in terms of EU law as a whole it is to be assumed this does not clearly exists. Despite the efforts of European harmonization efforts such as a European civil code (private law), European constitutional treaties, European principles, and European fundamental rights, in fact what we can find is European legal pluralism. Moreover, the efforts of creating or building a European legal culture are frequently criticized.\textsuperscript{27} An explanation for this could be found.

\textsuperscript{22} Michaels, R. 2011. P. 1 - 2.
\textsuperscript{23} Ibid. p. 2
\textsuperscript{24} Excerpt from Volkmart Gesnner (1993), pp. 5–18. Reproduced in Socio- legal contours of the project Europe: P. 518.
\textsuperscript{25} Nelken, D. (2004), P 1.
\textsuperscript{27} Helleringer & Parnhagen, 2014. P. 1
in the simple reason that EU Law in itself is initially not direct the product of a ‘European legal culture’. One could at best speak of a European legal culture in a very abstract sense. A closer look around Europe reveals a broad spectrum of valuations of and behaviors regarding the law. The widely differing attitudes towards e.g. sexual equality, tax obligation, abortion and environmental protection are some examples thereof. When comparing EU member states in terms of structure, legislative and judicial styles and legal–political discourse for example, what we can find is perhaps a higher degree of variety than can be found in any other single region of the world. EU law is created in relative isolation, considering hardly any legal–cultural expressions in the individual European societies are assessed upon its creation. However, over the past decades the trend of a more close orientation towards EU legal–cultural realities in norm setting EU institutions (e.g. EC Commission, European Courts of Justice) evolves. An example thereof is the establishment of the European Law Institute. The Institute aims to “help build a European legal culture. More consistency between Europe’s different Legal systems, will help strengthen mutual trust and our citizens’ confidence in the EU’s Legal system, strengthening confidence in the European rule of law, which is the cement binding the European Union together”. According to EU Justice Commissioner Viviane Reding the Institution “will make the European area of justice concrete and real so that people can exercise their rights and take advantage of the Single Market’s opportunities. The Institute will also bring added value to research on how EU law is implemented across the Union. It will engage in projects that will have concrete results for the daily lives of European citizens and legal practitioners.” An example of a sound EU understanding in the context of EU area of justice can be found back in the issues relating to the multilingual interpretation of EU legislation and case law by national courts and interpretative techniques of the CJEU, as well as the viability of the autonomy of EU legal concepts and the need for the professionalization of court interpreters Union-wide in response to Directive 2010/64/EU. This emphasizes the Commissions aim to further develop the concreteness of EU rule of law as this seems to be the foundation that binds the EU together. Furthermore, another interesting aspect worth noting is the fact that EU law itself provides space to variation. Hence, Article 5 of the Treaty imposes a wide variety of important duties on Member States. Assuming the implementation of EU law depends on orderly administrative enforcement and effective legal protection being assured at the national level, it makes a considerable difference whether in one country (Italy) knowledge of EU law remains very limited, administration is corrupt and inefficient, judicial procedure are long and slow, and the population is skeptical about government activity; while in another country (Denmark), the administration enjoys a high degree

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of confidence and complaints are almost never directed to the Courts but are regularly handled by the ombudsman; in a third country (Germany), administrative action is extensively juridified and conflicts – even those of political nature – quickly end up in the court room. Furthermore, that Swedish law is less systematic than German law is supposedly caused by the German preference for order. That English constitutional law prioritizes the businessman and French law prioritizes the consumer (Consumers and Consumer Protection Law) supposedly reflects the different attitudes of the respective countries toward the free market. These are just some examples of the large EU member states differences in institutions, legal rules, practices etc. To what concerns the explanation of EU legal culture in terms of Legal system, following an overview of the judicial and law-making system will be provided.

In EU judicial system, a certain case based on fundamental EU rights or EU law (e.g. Directives), must first be brought forward to the national competent Court. After the last resort on national level, the EU citizen is allowed to bring the case forward to the European court of Justice in case of criminal matters, or the European Court of Human Rights in case of fundamental rights. It must be noted that the competent Court is allowed to request a so-called preliminary ruling at the European Court of Justice on the interpretation of EU Law.

In addition, EU law knows three kinds of laws: Regulations, Directives and Decisions. The national laws of the Member States are harmonized in a great number of fields in the context of common policies. A special law is thus built to bring common policies into existence, a law that is superimposed and takes precedence over national law, even the constitutional law, of the Member States, whether national legislation predates or postdates European legislation. In fact, according to the Court of Justice, the Member States have definitively transferred sovereign rights to the Community (and now the Union) they created, and they cannot subsequently get back on that transfer through unilateral measures unless they decide to break away from the EU.

The legal instruments, which substantiate the common policies, have legal effect only if a treaty provision empowers the competent institutions – the European Parliament and/or the Council – to enact them (principle of conferral or of attribution of powers). Article 288 of the Treaty on the functioning of the EU (ex Article 249 TEC) provides for five forms of legal instruments, each with a different effect on the Member States' Legal systems. Some are directly applicable in place of national legislation, while others permit the progressive adjustment of that legislation to the European legislator. The main legal instruments are: Regulations (general scope and direct binding); Directives

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33 See Flaminio Costa v ENEL [1964] ECR 585 (6/64) of the European Court of Justice.
(up to the Member States to “implement” and choose the forms and instruments necessary for compliance); and Decisions (the decision is binding on the addressees it indicates).\textsuperscript{34}

Furthermore, with regards to its institutions the EU’s unique institutional set-up is as follows:

- The EU’s broad priorities are set by the European Council, which brings together national and EU-level leaders.
- Directly elected MEPs represent European citizens in the European Parliament. They represent the EU’s citizens and are directly elected by them.
- The interests of the EU as a whole are promoted by the European Commission, whose members are appointed by national governments.
- Governments defend their own country’s national interests in the Council of the European Union.

In addition, there are 3 main institutions involved in EU legislation:

- The European Parliament, represents the EU’s citizens and is directly elected by them;
- The Council of the European Union, represents the governments of the individual member countries. The Presidency of the Council is shared by the member states on a rotating basis.
- The European Commission, represents the interests of the Union as a whole.

Together, these three institutions produce through the ‘Ordinary Legislative Procedure’ (ex ‘co-decision’) the policies and laws that apply throughout the EU. In principle, the Commission proposes new laws, and the Parliament and Council adopt them. The Commission and the member countries then implement them, and the Commission ensures that the laws are properly applied and implemented.

Other important institutions are:

- the Court of Justice of the EU (upholds the rule of European law).
- the Court of Auditors (checks the financing of the EU’s activities).

The powers and responsibilities of all of these institutions are laid down in the Treaties, which are the foundation of everything the EU does. They also lay down the rules and procedures that the EU institutions must follow. The Treaties are agreed by the presidents and/or prime ministers of all the EU countries, and ratified by their parliaments.\textsuperscript{35}

Finally, it must be understood that the majority of EU member states national Legal system are based on the civil law family. This briefly means that the Legal system is derived from statutes. However, the United Kingdom – the founder of the common law family – has its Legal system based on the latter.


which constitutes that UK Legal system is mostly based on judicial decisions. Additional differences result from the dispersion of authority across the different levels of EU governance. Policymaking at the EU level does not follow the model of national decision structures. This is especially so because of lack of a formal authority hierarchy within the Union. The EU cannot compel national authorities to implement EU-wide measures unless national authorities have delegated the authority to do so to the EU. Consequently, in terms of EU legal culture one could speak of cultural pluralism, however with a sound aim (EU Commission) of building up more consistency of European Legal systems with the implementation of legal measures such as regulations and directives in the interest of common goals. This indicates the EU aim of coming closer together building a Union. In conclusion, with this regard it is worth noting that cultural pluralism might indeed be a distinctive feature of European legal culture. Diversity is not something that is in opposition to, but rather constitutes a new, different understanding of European legal culture.

United States of America

The United States of America constitute a federal system. This means that the 50 States are bound together by covenant (US constitution). Government in the United States is organized into three levels: Federal, State, and Local (e.g. County and Municipalities). Each level of government has its unique responsibilities. For example, the Federal government is responsible for national matters, such as international affairs and national safety and defense. State government is responsible for providing education and defining property rights. Local governments often address matters such as fire and police protection and land-use regulation. Even though these examples oversimplify the activities of government in the United States in the 21st century, they illustrate the relative roles of each level of government. The US constitution plays a significant role in the government structure. The Constitution was created by the people of the United States (as stated in the Preamble of the Constitution) in the late 1700’s through elected representatives or delegates. It must be understood that the Constitution is the document in which the powers/authorities of the government are defined. In the United States, the ultimate source of the law is the people; this is a critical point. Consequently, the law is not determined by a single authority. It is determined by elected officials, and if voters do not agree with the decisions made by elected officials, the voters can vote for other representatives at next elections. In the US there are three primary categories of law.

39 The text in the Preamble states: ‘We the people ... establish this Constitution for the United States of America.’
1) Constitution: The Constitution of the United States and the 50 state constitutions set out the structure and powers of government, protect individual liberties and govern a host of areas ranging from crime to social security benefit levels.

2) Statutes: the Statutes at large present a chronological arrangement of the laws in the exact order that they have been enacted. Public laws are incorporated into the United States Code, which is a codification of all general and permanent laws of the United States. The US Code is arranged by subject matter, and it shows the present status of laws (with amendments already incorporated in the text) that have been amended on one or more occasions.

3) Common law (case law)
The common law is the law judges make when they rule on cases. When a case is decided it becomes a precedent for future similar legal conflicts in the same jurisdiction.

An applicable constitutional provision Statute or Common law rule always governs the outcome of a legal problem. With this respect hierarchy is applicable. When there is no relevant constitutional provision or statute, as there often is not, the existing body of case law, called the common law, is the sole source of authority for evaluating and resolving a case.  

Furthermore, two Court systems operate simultaneously in the United States: the state court system and the Federal Court system. In both the state and federal court systems there are two types of courts: trial courts and appellate courts. Each State has its own jurisdiction (Court system). Although the structure of that system differs from state to state it is always hierarchical. There are trial Courts often an intermediate appellate Court and a Court of last resort, the tribunal at the top tier of the Court system. From the decision of a trial Court the losing party may appeal to the next level, the appellate Court. The appeal is heard by a panel of three to five judges of whom a majority must agree on a particular result. The result forms the basis of the court's opinion deciding the case. The appellate Court evaluates the lower court's decision and determines whether it committed any legal error that would warrant reversing or modifying the decision or ordering a new trial. The decision of the appellate Court may be appealed to the state's higher Court, which has the discretion to choose most cases it will hear. The decisions of the Courts of last resort are final and there is no further appeal of State Law issues. The Constitution and certain Federal Statutes establish the Federal Courts and empower them to hear certain kinds of cases. Federal courts hear all cases that arise under federal law, such as those involving the United States Constitution or federal statutes, disputes between two states or cases in which the United States is a party. In this case too there are three levels: trial Courts, appellate Courts and a Court of last resort. The highest Court is the Supreme Court.

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Court of the United States, consisting of the Chief Justice and eight Associate Justices, is the highest court in the Federal system. The Court hears a limited number of cases from the Courts of Appeals and on certain issues from the district courts and the highest state courts. The Court must accept review of certain types of cases but has the discretion to select others. Cases heard by the Supreme Court generally involve new or unresolved questions of federal law affecting people throughout the country and interpretation of federal statutes or the United States Constitution.

Furthermore, a hierarchical governance approach is applicable to the US Legal system. The highest law is the Federal law, all states and citizens shall abide by this constitutional law. Furthermore, State law applies. Every State has its own jurisdiction but State law shall not interfere with the Federal law. On the lowest level are local laws, like the previous mentioned local laws shall not interfere with Federal- and State law.

Following a brief overview of US legislative branch structure, established by Article I of the US Constitution, the Legislative Branch consists of the House of Representatives and the Senate, which together form the United States Congress. The Constitution grants Congress the sole authority to enact legislation and declare war, the right to confirm or reject many Presidential appointments, and substantial investigative powers. Next to the House of Representatives the legislative branch consists of the Senate. The Senate is composed of 100 Senators, 2 for each state. Until the ratification of the 17th Amendment in 1913, Senators were chosen by state legislatures, not by popular vote. Since then, they have been elected to six-year terms by the people of each state. The Vice President of the United States serves as President of the Senate and may cast the decisive vote in the event of a tie in the Senate. The Senate has the sole power to confirm those of the President's appointments that require consent, and to ratify treaties. There are, however, two exceptions to this rule. the House must also approve appointments to the Vice Presidency and any treaty that involves foreign trade.

Another important subject to note in the interest of US legal culture is that in the US there are differences in the enforcement of law between States. Some examples thereof are the application of Capital punishment (death penalty or execution), same-sex marriage, abortion etc. This is reflected in the norms and values applicable in that certain environment (State). Even though some of these aspects such as same-sex marriage are recognized by federal government, it has not been legalized in all US States until most recently Case law brought changes into this longstanding legal fact. However, the Legal system in the States is conform the Federal system. Therefore, on State level...

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41 White House Government website. ‘US Legislative Branch’ Online available at: <https://www.whitehouse.gov/1600/legislative-branch>.

42 Most recently the Supreme Court brought changes into this fact. On June, 26, 2015, the US Supreme Court ruled that the US Constitution guarantees the right for same-sex couples to marry in all 50 US States.
differences can appear on certain social matters but the States in general follow the same Legal system following from Federal Codes.

In addition, the constant battle between Democrats and the Republicans in US political arena is an commonly known characteristic of US Legal system as well. In relation to US legal history, another interesting aspect to note are the sensitivities going with the background of the US Constitution. With this respect Judith Resnik professor at Yale Law School in the US states. “I, a white law professor, have many times heard and told of the United States' legal structure as centrally about the domination of whites over blacks. I, a woman raised on the East Coast, see the impulse to frame the story of race as about black and white relations and specifically as about how African-Americans relate to whites”. Furthermore, in her work she describes the powers of the conservative (in the sense of preserving) powers of the law and economics movement, which is heavily financed by conservative (in the political arena) foundations and which dominates many scholarly fields, with tort law being a prime example. In addition, she mentions some aspects of the United States' Legal system – such as the conquest of Indian tribes and the current constitutional relationship between the United States government and the tribes. This relationship between US Federal law and the law of Indian Tribes is a unique one from a legal point of view. Nonetheless, this inevitably forms a part of the US history and consequently US legal culture.

People’s Republic of China

In understanding China’s legal culture and what it is influenced by, it is inevitable to gain at least a general brief understanding of the history of its legal cultural context. In contrary to Europe and the US which Legal system which have a relatively young history, China’s Legal system knows a long history which could be traced back to 563 BC. In this year during chunqiu (春秋), known as the "spring and autumn period", China had its first statutory law (xing ding (刑鼎)). It was written and published through casting on bronze vessels. At the same the the first state Xia (夏) Dynasty arose in China. The Chinese legal family which was mainly based on morality was further influenced by the colonial status through imperialist takeover after the Opium War between China and Britain in 1840. The traditional law began to water down through contract with Western powers and the last feudal Dynasty (Qing Dynasty) was forced to implement legal reform conform the Western model of law. This was mainly based on the civil law system in the late 19th century and the early 20th century.

Hereinafter, during the Republic of China (1911–1949) the Nationalist government continued legal reform on many areas of law. Next, the law was influenced by soviet thinking after the taking over of the Communists in 1949 when the People’s Republic of China was founded. Ever since, the Cultural

44 Feng, Y., 2009, P 2–3
45 Ibid.
Revolution in 1979 China’s Legal system has entered an era of legal reform being influenced by Western Legal systems both Common law and Civil law system, especially the Civil Law systems which is still the basis of today’s Legal system and is becoming increasingly modernized.\textsuperscript{46} Harmony is the highest value of Chinese culture. Through the thousands of years of Chinese history, Chinese society has held harmony as the highest ideal in dispute resolution. When adjudicating disputes, ancient officials focused on avoiding lawsuits and settling arguments through mediation. They strove to achieve the Confucian utopia of "a society without lawsuits". Some of the features of the Confusiasm philosophy has survived in the People’s Republic of China, although in very recent times some turn toward Western ideas of law can be observed.\textsuperscript{47} For instance, the preference of dispute resolution over litigation, the concept that there must be multiple reviews prior to the execution of the death penalty; and the distinction between formal and informal law has survived. With this respect it should be noted that in China legal culture the death penalty is largely applicable in case of serious crimes. Furthermore, in contemporary PRC law this distinction between formal and informal law is to be found back in different legal fields. In the field of lawmaking, the following categories can be found. The officially promulgated law, the official law as it is actually applied (the living law), the customary law of tradition, and usages that have been practically recognized and adopted. Furthermore, in the field of law enforcement there are the categories of adjudication through the Courts and mediation through neighborhood committees.\textsuperscript{48}

To understand food law of the People’s Republic of China, it is imperative to have at least some understanding of China’s State Organization Structure. I will attempt to provide such by first giving a simplified overview of the government structure and Legal system.

An important principle of PRC law is that no one is above the law. The constitution of China provides for three de jure levels of government. Currently, however, there are five practical (de facto) levels of local government: the province, prefecture, county, township, and village. The National People’s Congress (hereinafter: NPC) is defined in the 1982 Constitution as the “highest organ of state power”. The constitution states that “all power in the People’s Republic of China belongs to the people”. According to the constitution in principle the NPC is the supreme source of law in China and the basic laws and other laws adopted by the full NPC or its Standing Committee are the highest form of law after the Constitution. The NPC’s major functions are to amend the state constitution and enact laws; supervise the enforcement of the state constitution and the law; elect the president and the vice president of the republic etc.

The NPC consist of approximately 3,000 members which meet once a year and serve 5- years terms which is a reflection of the 5- year plans that are applied in China law development. Delegates of the NPC are elected by the people’s congresses at the provincial level as well as by the People’s Liberation Army. Because of the infrequent meetings, the NPC functions through a permanent body, the Standing Committee, whose members it elects. The Standing Committee’s powers were enhanced in 1987 when it was given the ability to “enact and amend laws with the exception of those which

\textsuperscript{46} Feng, Y., 2009, P 2.
\textsuperscript{47} Wieacker & Bodenheimer, 1990, P. 1- 29.
\textsuperscript{48} Feng, Y., 2009, P 8.
should be enacted by the NPC," thus giving this body legislative powers. The Standing Committee presides over sessions of the NPC and determines the agenda, the routing of legislation, and nominations for offices. The NPC also has six permanent committees: one each for minorities, law, finance, foreign affairs, and overseas Chinese and one for education, science, culture, and health.

In addition, another important organization is the State Council. The State Council executes laws and carries out the administrative functions of the Chinese government. The Premier heads the Council and is assisted by the Vice-Premiers and the ministers and chairmen of the commissions. Subordinate to the State Council are ministries, commissions, and direct offices, which constitute the State Council's principal policymaking and supervisory offices. The Chinese Constitution directs the State Council to assure that laws passed by the NPC are promptly and properly executed. Thus, it serves a primarily administrative function. The Constitution gives the State Council specific power to adopt administrative measures, enact administrative rules and regulations, and issue decisions and orders in accordance with the Constitution and statutes.49

The State Council maintains a large staff that enacts detailed regulations and instructions on how to execute the laws. Since the early 1980s, this staff has reflected an overall trend in Chinese government institutions toward greater professional competence and specialization. Improving the quality of its regulations and avoiding conflicts between law and administrative and local regulations on important issues have been high priorities. Through organizational changes, the State Council has sought to improve efficiency, combat corruption, and advance market-oriented economic reforms. In its March 2003 reform plan the NPC made several important changes to the State Council that reflect China's interest in developing a market economy with socialist characteristics. The merger of a number of government bodies that administer China's domestic and foreign trade regimes into a new Ministry of Commerce (MOFCOM) may prove to be the most significant of these changes. MOFCOM may simplify access to China's economy for foreign businesses and investors through greater centralization and coordination of regulatory activities.50

In terms of PRC judicial system, the following can be understood: the first instance Court is the Basic People's Courts, these courts handle every day first instance cases at local level. The second lowest Court is the Intermediate People’s Court which handles intermediate cases such as relevant important local cases in the first instance and hear appeal cases from the basic Court. Furthermore, a level above the intermediate Courts are the High People’s Courts. These High Courts are responsible for issues at the Provincial level. The highest Court is the Supreme Court, this Court is the highest judicial organ and handles national matters. It has four primary functions: interpretation of law, adjudication, legislation and administration of the judiciary. With this respect it should be noted that


within the PRC constitutional and legal interpretation is considered to be a legislative activity rather than a judicial one; the functions are split so that the NPC Standing Committee provides legal interpretations while the Supreme Court actually decides cases.

Another interesting point worth noting is that of China’s Standard setting. Chinese standards may be either mandatory or voluntary. Mandatory standards have the force of law as do other technical regulations in China. They are enforced by laws and administrative regulations and concern the protection of human health, personal property and safety such as food safety. There are 4 levels of standard levels (see illustration here below). These levels are hierarchical, so that Local Standards supersede Enterprise Standards, Professional Standards supersede Local Standards, etc. For any given product or service, only one type of Chinese standard will apply. National Standards are often referred to as “GB standards”. They are consistent across all of China and are developed for technical requirements. The Code of "GB" refers to mandatory standards.

A conclusive, but significant, aspect to mention in the context of China legal culture is that PRC law is based on a Socialist system. What this specifically constitutes has by many people long been perceived as a communist dictatorial system. This thought however is not consistent with current development in China’s Legal system. China recently made efforts to take away this perception trying and creating ‘demand’ for a more fair and less discriminatory Legal system by drawing a White paper (published by the government) about the development of China’s Legal system. The White paper is compiled extensively and sometimes it is hard to extrude the essence of its purpose. However, China’s government gives a clear understanding it attempts to steer in the direction of democracy. With this respect the government acknowledges the struggle of democracy, it states. “While struggling for the right to subsistence, the Chinese people have waged a heroic struggle for democratic rights”. China’s government further states the people have gained extensive political rights (compared to the situation up to the Cultural Revolution) and it attempts to head in a direction improving these rights even more. With respect to how the government identifies China’s Legal system in the White paper it states as follows.

“*The socialist system of laws with Chinese characteristics is a legal foundation for socialism with Chinese characteristics to retain its nature, a legal reflection of the innovative practice of socialism with Chinese characteristics, and a legal guarantee for the prosperity of socialism with Chinese characteristics. Its establishment is an important milestone in China's development of socialist democracy and the Legal system, and showcases the great achievements of reform, opening up and the socialist modernization drive. It is of great realistic and far-reaching historic significance*.”

Furthermore, China makes clear to the world its future plans for improvement.

“China will take active measures to strengthen legislation on socialist democracy. In order to meet the requirements of actively yet steadily advancing political reform, we will improve legal institutions concerning election, self-governance among people at the grassroots level and organization of state organs*.”
Legal Framework
Chapter 1 Introduction to Food Safety Law: History, Influences and Development

In order to develop an understanding of contemporary European, Chinese and US food law and practices, it is imperative to appreciate and understand the historical and political aspects of their Legal systems. This chapter is devoted to these aspects. First the role of food law in the global arena will be discussed. Following a brief overview will be provided of the history and influences of the Legal system at stake. In addition, the development of the food law system in the EU, US and China respectively will be dealt with; finally, a conclusion will be drawn. The question that will be answered in this chapter is, “How have the Food Safety Law system in the Legal systems developed over the years and what are they influenced by?”

1.1. The role of Food Law in the global arena

International Food Safety Law is considered to be a meta-framework which provides models and sets limits to the way states and other entities regulate the food sector. Nowadays the subject of food safety has been identified at domestic, regional and international levels as a public health priority, as unsafe food cause illness in millions of people every year with fatal consequences in many cases. According to the World Health Organization, serious outbreaks of foodborne disease have been documented on every continent in the past decade and in many countries rates of related illnesses are increasing significantly. Diarrheal diseases – both foodborne and waterborne – kill an estimated two million people annually, including many children in developing countries. Food contaminants, such as harmful parasites, bacteria, viruses, prions, chemical or radioactive substances, cause more than 200 diseases globally – ranging from infectious diseases to cancers. Given the risks involved, the concept of food safety has become an increasingly important subject in global political arena. Contemporary key global food safety concerns include the spread of microbiological hazards (including bacteria such as Salmonella or Escherichia coli, e. coli); chemical food contaminants; assessments of new food technologies (such as genetically modified food or “GMO”) and strong food safety systems in most countries to ensure a safe global food chain. The risks of unsafe food are substantial, but can be difficult to quantify. However, ensuring food safety in a highly globalized world presents increasingly difficult, and often under-appreciated challenges for governments, commercial organizations and individuals alike.


53 Ibid.

organizations play a role in the trade, safety management and policy-making of food. The United Nations (UN) lay emphasis on human rights such as the right to food and security. The Food and Agricultural Organization (FAO) and the World Health Organization (hereinafter referred to as WHO) have the lead in the core elements of normative work such as standard setting, risk assessment and risk management. The World Trade Organization (hereinafter referred to as WTO) plays a major role in application of food standards in the area of international trade and dispute resolution. The WHO operates risk communication structures, seminal in incident management. As a result of rapid globalization of food trade over the decades, since the 1960’s international standards concerning food trade are developing. International food law has taken up momentum after the entry into force of the WTO Agreement in 1995. As from the 1990s the private sector has taken the initiative in regulating (international) trade in food. With this respect in ensuring food safety through the food supply chain, collaboration of actors involved e.g. industry, consumer organizations, scientists etc., is vital to achieving safe food-chains on national level and cross national level as well. With regards to the latter, on international level, the World Health Organization plays an essential role. It has amongst other things, launched programs to raise awareness about the food safety agenda and galvanizes actions. Furthermore, in collaboration with the United Nations Food and Agriculture Organization, it has had a central international role in developing guidelines to strengthen and harmonize food systems, in particular through the jointly managed Codex Alimentarius Commission. Since most of its members are leading actors in global food trade, Codex standards have become the de facto international standards for food safety regulation worldwide.

1.2. History and Influences

In order to get a deeper understanding of the history of food law of the Legal systems at issue, it is of interest to gain some basic knowledge of the legal tradition/background where these systems are influenced by. Therefore, firstly, an introduction to the concept of legal families/tradition will be provided. In general most nations around the world today follow one of two major legal traditions/systems: common Law system or civil Law system. Next, these legal traditions will be each explained briefly.

**Common law system** is generally *uncodified* This means that there is no comprehensive compilation of legal rules and statutes. Common law is largely based on *precedent*, meaning the judicial decisions that have already been made in similar cases. The precedents are maintained over time through the

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56 Ibid.
records of the courts as well as historically documented in collections of case law known as yearbooks and reports. However, common law does also for a certain degree rely on some scattered statutes, which are legislative decisions. The precedents to be applied in the decision of each new case are determined by the presiding judge. As a result, judges have an enormous role in shaping the law of common law systems such as American and British law. Common law functions as an adversarial system, a contest between two opposing parties before a judge who moderates. The decision making is dependent of a so-called jury, a certain amount of ordinary people that ought to present general societal opinion, who decide on the facts of the case. The judge however, takes the verdict of the jury into account and determines the appropriate sentence.\(^{58}\)

Most countries of the former British empire belong to the common law family of law. In the area of food law these countries have been influenced by the concept of “adulteration” which takes a central position in their Food laws. This shows for example in the approach in the Adulteration of Food and Drink Act of 1860 and next in the Food and Drug Act of 1872.\(^{59}\) In the next paragraph food law in such system (former British colonies and the United States in particular) as a part of the common law family will be discussed further.

**Civil Law system** in contrast, is codified. The term “civil law” derives from the Latin *ius civile*, the law applicable to all Roman cives or citizens. Its origins and model are to be found in the monumental compilation of Roman law. Countries with civil law systems have comprehensive, continuously updated legal codes that specify all matters capable of being brought before a court, the applicable procedure, and the appropriate punishment for each offense.\(^{60}\) Such codes consist of two main different categories of law. *Substantive law* and *Procedural law*. Substantive law includes the statutory, or written law. It defines rights and duties and establishes which acts are subject to criminal or civil prosecution. It is codified in legislated statutes or can be enacted through the initiative process (a form of direct democracy such as a referendum). Substantive law stands in contrast to procedural law which could be considered the “machinery” for enforcing these rights and duties established by substantive law. Procedural law comprises the rules by which a court hears and determines what happens in civil or criminal proceedings, as well as the method and means by which substantive law is made administered.\(^{61}\) In a civil law system, the judge’s role is to establish the facts of the case, analyze the conditions to be met, and to apply the provisions of the applicable

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code. Though the judge often brings the formal charges, investigates the matter, and decides on the

case, the judge bases his/her decision on a framework established by a comprehensive, codified set of

laws and if applicable to the case, related case laws. The judge’s decision is consequently less crucial

in shaping civil law than the decisions of legislators and legal scholars who draft and interpret the

codes. However, legal doctrines are often a result of the case law (Court rulings) in civil law systems.

Continental European countries and a large part of their former colonies belong to the civil law

family of law. Its related approach to food is represented by the EU.

In conclusion to this subparagraph, the US Legal system could be considered largely influenced by

the common law family whilst the European Legal system (the United Kingdom excepted) is largely

influenced by the civil law family. China’s Legal system on the contrary, is influenced by various

aspects and not particularly by one or two Legal system/tradition(s). As previously mentioned in the

introduction, originally China’s Legal system is influenced by cultural deeply rooted philosophies of

classical China such as Confucianism, Daoism, Legalism. These teachings and ideas are mainly based

on ethics and morals. Development of contemporary Chinese Law however, is largely influenced by

external forces such as the Treaty System between China and the Western powers which forced

China to adopt Western legal principles such as the codes of continental European countries (civil

law system). After the Communist Party took control in 1949, Chinese law was influenced heavily by

the political philosophies of Marxism-Leninism and the Soviet Legal system. Currently one could

consider China’s Legal system as a mixture (a copy) of both Civil law and Common law system

trying to get the best out of each to be implemented in a Socialist system. In the next paragraph the

developments of the here above mentioned Legal systems will be further discussed.

1.3. Development of Food Law

In each of the Legal system Food Law has developed in several stages. As with any subject area,
current situations and reactions can best be understood if one understands how the situation has
developed. Therefore in the next subparagraph the developments of Food law in the US, EU and
China will be discussed respectively.

1.3.1. United States of America

The US food law system has been one of the first in the world. The main trigger for regulation of
Food Law in the US have been: crisis and consumer regulation (misbranding and adulteration). This
is reflected by history.

discusses the differences between China’s concepts of law and other legal systems; V. Li, (1977), Law Without Lawyers: A Comparative
View of Law in China and the United States 13–15, 25–26 (author discusses the “rule of law” under Confucian philosophy).
The development of US federal food law dates back to the late 19th century/ beginning of the 20th Century. In these early days food safety relied on a high level of trust. Food trade was mostly local and oriented; reputational mechanisms played a major role. The likelihood for food adulteration was therefore limited. However, as industrialization found its way up, food processing became widely used and consequently control weakened. For the consumer the situation changed from buying a ‘known’ product to acquiring a product from which its origin was not quite detectible. Substances that were poor quality, and often poisonous, were added to food and drinks for several reasons mainly for financial gain. Producers used chemicals to improve appearance, flavor and smell, while grocers mixed in all types of substances to give weight and bulk to products. Lack of analytical techniques limited the ability to detect adulteration. The more processing, the greater the opportunities of food adulteration. Therefore it is no coincidence that the earliest food laws covered the earliest processed foods: wine, beer and bread.64

In the colonial years British common law applied the earliest Food Safety Law. The essence of this law was plain but clear: 1) do not poison food, and 2) do not cheat.65 The years that followed food production began shifting from the homes to the manufacturers. As a result of the industrialization people moved to the cities and consequently bought more processed and manufactured foods. Reputation weakened as a means of control. There was wide spread complaint among merchants, they pushed for food inspection as they recognized inferior good circulated the market and wished for a level playing field.66 In the years that followed rapid development of analytical methods has contributed to identification of adulteration of shocking scope. Legislation up till then was largely focused on protecting commerce rather than food safety. The definitive turning point towards the era of US federal legislative reform in the field of food safety was the Chicago meat packaging scandal in 1905/1906 under president Theodore Roosevelt in where preliminary investigation showed shocking evidence of horrible meat handling and storage67. In 1906, after major public

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63 Passage from ‘Maud’ (1886), Poem of Alfred Lord Tennyson. See English Poetry III. From Tennyson to Whitman. The Harvard Classics No 649.
64 Meulen, Bernd M.J. van der, et al., 2009, P. 32
65 Ibid.
66 Ibid. P. 29.
support for a Federal Food and Drug Act, president Roosevelt signed both the Pure Food and Drug Act and the Meat inspection Act into law.\(^68\)

Subsequently, the law has been expanded and strengthened several times. The Elixir Sulfanilamide case (agonizing death of more than 100 people as a result of intoxication) in 1937 hastened the development of the Federal Food, Drug, and Cosmetic Act. This statute that today remains the basis for FDA regulation of these products was finally enacted in 1938. The Act was enforced by a federal single authority: the US Food and Drug Agency (hereinafter: FDA). The FDA was the first major agency at US federal level, from the beginning it was allowed to supervise the food market.

The pattern for major revision of US federal food law repeats itself; in 1962 in Europe and Canada the Thalidomide scandal took place. In this event a drug was provided (at the time sold under different brand names, for example in the Netherlands under the name ‘Softenon’) to pregnant women which initially should have served as a sleeping pill but unfortunately turned out to cause malfunctions to the fetus. The drug effected more than 10,000 babies. The reason thereof is to be found in the fact that in Europe and Canada drugs were freely accessible without premarket approval. The US regulatory system however, has intelligently responded to this tragedy that took place outside its borders by inserting legal instruments as a method of protectionism. The Federal Food, Drug, and Cosmetic Act was strengthened by the so-called US Kefauver Harris Amendment or “Drug Efficacy Amendment” of 1962. This amendment required a certain level of pre-market approval and at the same time strengthened the FDA’s powers. The Amendment introduced requirements for drug manufacturers to provide proof of the effectiveness and safety of their drugs before approval. The years that followed the Act was extended on various areas.

The latest development in US food legislation is the Food Safety and Modernization Act (FSMA), signed into law by President Barack Obama on January 4, 2011. The background for developing this law is to be found in the Congress’s need for enhancement of security after the events of September 11, 2001. Congress initially responded to this event by passing the Public Health Security and Bioterrorism Preparedness Response Act, or ‘the Bioterrorism Act’ which is signed by president Bush into law on June 12, 2002. The Bioterrorism Act of 2002 granted the FDA administrative detention authority over food items in case there is credible evidence or information that indicates the food presents a threat of serious adverse health consequences or death to humans or animals.\(^69\) However, due to development of international standards and a need for reform of the food safety approach (which was initially an exclusive task for the government), it appeared a new food law was strongly

\(^{68}\) Meulen, Bernd M.J. van der, et al., 2009, P. 35

desirable and subsequently these features were incorporated in the FSMA. The FSMA aims to ensure the US food supply is safe by shifting the focus from mainly response to prevention. The law is said to be the most sweeping reform of the US Food Safety Laws in 70 years, by the FDA herself. 70

1.3.2. European Union

European Law itself is not a national law system as Chinese Law is. Neither does it relate to a common federal law system such as in the US. In Europe each country has its own national Legal system. However, on many areas which effect the “common interest” of the European Union nations have transferred their sovereignty to a higher power: the European Community. Therefore European Law is also known as “supranational law”, the law in which the rights of sovereign nations are limited in relation to one another.

European legislation on food is in contrast to US food law quite young it only dates back to the beginning of the European Economic Community in 1958. As a result of the agreements made in the Treaty of Rome in 1957, the six original members (Netherlands, Belgium, France, Italy, Luxembourg and West- Germany) of what is today the European Union, created a community with an economic character. This was not only reflected in its original name (European Economic Community) 71, but also in its original goal to create a Common Market as an occasion of the poor economic situation after WO II. European legislation on food therefore was mainly market- oriented. It was based on the treaty provision on harmonization for the internal market 72.

Development of contemporary European food law system can be divided in three phases. 1) the market oriented phase I, 2) market- oriented phase II, 3) reform of food law (e.g. introduction of the General Food Law) after the emerging of the BSE crisis. The market- oriented phase can be divided in two categories of legislation: vertical legislation and horizontal legislation; will be discussed in the following.

Although after WO II Member States agreed generally upon the desirability of trade without frontiers, in practice it appeared that countries developed national laws/regulations to protect own economies. During the first years of implementation of the ambitious idea of trade without frontiers, Community legislation aimed primarily at facilitating the internal market through the harmonization of national standards. To reach this goal directives were issued on the composition of certain specific food products: vertical legislation. However, this type of legislation soon appeared unrealistic as there appeared to be simply too much food products circulating the Union to deal

The European law-maker soon realized it would have to deal with an overload of law-making which would not make any sense. The European Commission sought for alternatives to this problem. However, it was case law that largely advanced European Food law from then on. A ruling of the Court of Justice triggered European co-operation in the area of food law.

The Court of Justice gave a quite broad interpretation of the concept of ‘measures with equivalent effect’. This must be understood in relation to Article 36 TFEU which provides possible exemptions to this prohibition laid down in Article 34 TFEU. This rule of reason derives from another Court ruling that has had major effects on the development of European Food law and today is still referred to in Courts: the Cassis de Dijon case.

Consequently, case law brought the development of European Food law to fruition. The principle of mutual recognition signaled a giant leap forwards in European law; Cassis de Dijon became a symbol at this stage of the development of the European understanding of free movements of goods. With its ruling the European Court of Justice laid down the legal foundation for a well-functioning common market. Food products that comply with the statutory (safety) requirements of the member state where they are brought on the market must, in principle be admitted to the markets of all other member states. This concept, as a result of mutual recognition, is called harmonization. However, it soon appeared reform of European food law as a result of the rulings by the Court could not stand on case law alone. In this respect the limitations of the principle of mutual recognition highlighted the need for further harmonization of product requirements at European level. Consequently, targets shifted to the need to alleviate the consequences of the common internal market; emphasis shifted from product-specific (vertical) legislation, to general rules addressing common aspects for all foodstuffs, or at least for as many as possible (horizontal legislation).

Nowadays some vertical legislation is still in force. Within European food law wine legislation is even a body of law in itself. Consequently, for a couple of specific products vertical legislation appeared from a legal point of view in need of specific technical legislation. Next to the mentioned

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73 Van der Meulen & Van der Velde, (2011). P. 231–232
74 In 1974 the Court interpreted in the so-called “Dassonville-case” Article 34 TFEU “Prohibition of quantitative restrictions on imports”, quite broadly. This provision forms the key for the current concept of free movement of goods in the common market.
75 Article 36 TFEU (ex. Art 30 TFEU).
76 EC Court of Justice 20 February 1979, Case 120/78 (Cassis de Dijon), ECR 1979, page 649.
77 The ruling comes down to the fact that the Court in this case found that Article 36 TFEU (the exemptions to the broad defined prohibition in Article 34) has a limited character. It found that the grounds laid down in Article 36 TFEU were insufficient to meet the public interests of the Member States.
78 Exceptions can be based only on Article 34 TFEU or on the ‘rule of reason’.
79 Van der Meulen & Van der Velde, (2011). P. 235
80 Ibid.
81 E.g. sugar, honey, fruit juices, milk, spreadable fats, jams, jellies, marmalade, chestnut puree, coffee, chocolate, natural mineral waters, minced meat, eggs, fish. Wine legislation is a body of law in itself. For Fresh Fruits and Vegetables specifically international marketing and quality standards apply.
case law, there are a number of other cases which have contributed to European law reform on various areas also crossing the line of European food law specifically. However, these cases are not further discussed here towards relevance.

The fundamental reform of food law in the European Union has reached its optimum right after the eruption of the bovine spongiform encephalopathy\textsuperscript{82} (BSE) crisis in the 90’s. The food and agricultural sectors in the European Union emerged deeply traumatized. A series of crisis resulted in the breakdown of consumer confidence in public authorities, industry and science. This stage forms the third phase of the development of EU food law. Although, the BSE-crisis was not the first and not the worst food safety crisis in the EU, it caused major awareness in the legal and regulatory landscape of Europe. It formed a major challenge to European co-operation in the area of food safety. Above all, it was the lack of risk communication and risk management (comprehensive/integrated approach) that brought the weaknesses of the, at that moment, legal food system into light. The shortcomings in the handling of the crisis clearly revealed a need for a new, integrated approach to food safety.

After a period of opinions and discussions in the political arena, on January 12, 2000 the European Commission launched its so-called White Paper on Food Safety\textsuperscript{83} which encompasses the Commission’s vision on the future shape of EU food law. Plans for new food safety legislation were presented in where it was called for a corpus of legislation covering all aspects of food products from ‘farm to fork’. Furthermore, plans for a European Food Safety Authority were presented. To sum up further events, the General Food Law\textsuperscript{84} was created and the European Food Safety Authority (EFSA) was established. Today the EU food safety system is based on a farm to fork approach and could be considered one of the most integrated food systems globally. However, it still does cope with certain criticism and urgent matters such as the approach of food fraud and the continuation of nutritional safety problems. Nevertheless, EU Food Safety Law is quite young; future developments are to be expected and remain of great public interest.

\textsuperscript{82} See footnote in Introduction for further information on BSE.

\textsuperscript{83} Its objective: ‘Outlining a comprehensive range of actions needed to complement and modernize existing EU food legislation, to make it more coherent, understandable and flexible, to promote better enforcement of that legislation, and to provide greater transparency to consumers; in addition, to guarantee a high level of food safety’. For further information see: White paper on food safety of 12 January 2000 [COM/99/0719 final - Not published in the Official Journal]. Online available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:l32041>.

1.3.3. China

As previously mentioned, Chinese contemporary law has been influenced by both internal and external factors. From the beginning it has mainly been influenced by internal factors such as culture and deeply rooted philosophies and morals of classical China such as Confucianism, Daoism, and Legalism. Moreover, Chinese Law has been influenced by external forces such as the Treaty System between China and the Western powers which have led to the adoption of Western legal principles such as the codes of continental European countries. In 1949 China has been taken in control by the Communist Party. Consequently, Chinese law was influenced considerably by political ideologies such as Marxism–Leninism (the official ideology of the Communist Party of the Soviet Union) and Mao Zedong (Chinese Communist revolutionary and the founding father of the People's Republic of China). These political philosophies are based on the Soviet Legal system Chinese Law in the second half of the 21st century was strongly influenced by.\(^\text{85}\)

At its arrival the Chinese Communist Party (hereinafter: CCP) issued a directive abolishing the six codes all modeled after European legal codes, including the Constitution, Commercial Law, Civil Law, Civil Code of Procedure, and Criminal Code.\(^\text{86}\) In September of 1949, the CCP issued the Common Program of the Chinese People’s Consultative Conference, which became the temporary basic law of China until 1954. After this event, the People’s Republic of China (hereinafter: PRC) was proclaimed on 1 October 1949. The CCP pursued a program based upon the concept of historical determinism, which provides that the party is the primary means of transforming China from a feudalistic society into a Communist utopian society.\(^\text{87}\) In the context of food legislation, in 1965 China promulgated its first Food Safety Law: the Regulations on the Administration of Food Hygiene (trial implementation). These regulations mainly referred to state-owned food producers. The main concern at this time was the security of the food supply rather than the safety of the food itself. These first regulations failed however, due to the collapse of the Legal system in China in the decade following.\(^\text{88}\)

After stagnation of environmental development for the legal profession during the late 1960s, and the failure of the Great Leap Forward (1958–62), the Cultural Revolution (1966–1976) took place. The Cultural Revolution began as a political struggle between Mao Zedong and other CCP leaders in the interest of dominance of the party. Mao’s thoughts for a Great Revolution for short failed and


\(^{86}\) The CCP order is referred to as the Directive Regarding the Abolition of the Guomindang’s Complete Book of Six Codes and the Affirmation of the Legal Principles in the Liberated Areas. See also Li, Philosophical Influences on Contemporary Chinese Law, 6 Ind. Int’l & Comp. L. Rev. 327 (1996).


The Cultural Revolution led to the abandonment of China’s fledgling Legal system. The excesses of the Cultural Revolution prohibited the development of either a Western- or Soviet-styled Legal system. During the Cultural Revolution the legal profession strongly weakened; law schools were closed, almost no laws were enacted and no law books published. During this period civil disputes were resolved mainly by local mediators and criminal law cases were handled in the political arena by the Ministry of Public Security, party committee structure, or the State Courts that remained open. The Cultural Revolution ended in 1976 with the death of Mao and the arrest of his most influential adherents. As previously mentioned, prior to the end of the 1970s, China’s economy was strictly planned and controlled by the State. All food production factories were owned and controlled by the state, and observed some simple food standards. There were few food safety problems because most food was produced using traditional methods without heavy use of chemical fertilizers, pesticides and additives. Profits were not the aim of food producers because the entire food production chain, from the materials, equipment and technologies, to distribution and sale, were centrally planned and controlled by the State. Food safety incidents were occasional, but did not damage the overall image of food safety.

After the Cultural Revolution the Chinese government took steps towards opening the door to the world. The period of 1976-1989 was dominated by “restructuring”. As a follow up on the developments of China’s food law, in 1979 the Regulations on the Administration of Food Hygiene were drafted. They were based on the 1965 Regulations and took into account the new economic situation. Three years later, the new regulations were replaced by a new version in 1982. This constituted the Food Hygiene Law. This was also a trial implementation to accommodate the situation of continuing economic reforms and frequent policy changes. A few years prior, in 1978, government instituted the Four Modernizations, a program designed to develop and modernize China’s politics and economy: agriculture, industry, national defense; and science and technology. A significant aspect in this plan was the initiative of a modern Legal system as a key element to ensure the institutionalization of economic reform and to gain the confidence of the global community. This is consistent with the goals set out in the *White paper* as mentioned before in the Introduction under *Legal culture*. Having learned from its past and to guard China from returning to a similar

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situation, the National People’s Congress\textsuperscript{92} (NPC) stressed the need to develop a Legal system to ensure the stability and continuity of the laws; guarantee the equality of all people before the laws and to deny anyone the privilege of being above the law.\textsuperscript{93}

A few years after, the 1982 amended Food Hygiene Law was amended by the Food Hygiene Law of 1995 and was passed by the NPC. This version regulates most aspects of food safety. However, after a rise of industrialization at the beginning of this millennium, a series of food crises became to appear. One of these major crises was the infant formula tainted powder in the period of 2004–2008. Taking into account its rapid economic growth and the complex control on the food supply chain as a result of international trade and the repeated food scandals, the Chinese government soon realized a comprehensive Food Safety Law needed to be created as soon as possible. After a relative short period of time of law development, the PRC Food Safety Law came into being in 2009. After its enactment it appeared to contain major gaps in the interest of transparency, absence of ministerial–level oversight and overlapping and redundant, missing food safety standards etc. As a response thereof the government made same changes in the amendment of 2011 and after the government developed some more changes necessary in the revised amendment of 2014 ( into law October 1\textsuperscript{st} 2015). In a State Council meeting Chinese Vice Premier Li Keqiang said, "Food is essential, and safety should be a top priority. Food safety is closely related to people's lives and health and economic development and social harmony," at a State Council meeting in Beijing.\textsuperscript{94}

At the behest of the international community, China has been quick to tap into the legal standards of its trading partners to hasten its development efforts, to build the confidence of foreign investors. Chinese food law system has followed the development of China’s agricultural policy and over the past 20–30 years China went through a period of mainly restoring economic ability and growth. Corresponding to its realistic market- driven vision to strengthen its economy and becoming an important trade partner in the global arena, it has adopted a number of laws and regulations from various international sources. In terms of food law, China has shifted from passive food law regulation to a strong State controlling Food Safety Law system with some characteristics of both EU- and US food law placing these features in its (developing) Socialist Legal system.

\textsuperscript{92}The National People's Congress (usually abbreviated NPC) is the national legislature of the People's Republic of China. With 2,987 members in 2013, it is the largest parliamentary body in the world.

\textsuperscript{93}Zimmerman, J.M., 2010, P. 54.

1.4 Conclusion: Comparative analysis

In conclusion to the provided analysis one could state US food safety policy came into being at the turn of the twentieth century in response to scandals in the meat- packing and food- processing industries. This emerged when at the beginning of the 20th century food processing shifted from home and local production and processing toward more industrial processing and regional or even national marketing. In this century several food scares occurred in the food supply chain mainly linked to food adulteration and misbranding. The first US food laws were therefore established based on these features. Institutions that had emerged to manage risks in an economy of local production and distribution were incapable of providing socially acceptable protection in this more nationally integrated economy, with this respect institutional innovation was needed to manage the resulting changes in health risks; consequently the FDA was established in 1906. With this respect it should be understood contemporary US food policy is built around the concept of prohibiting the placing on the market of adulterated and misbranded foods. The underlying reason for this was not only to be found in enhancing food safety, rather the first US food laws were established as a result of economic incentives. There was widespread complaint among merchants, they pushed for food inspection as they recognized inferior good circulated the market and wished for a level playing field. Subsequently, a closer look to US Food Safety Law provides us with the understanding that the latter is initially based on criminal law approaches and designed around the aspects of response to food adulteration and misbranding. This proclaims the fact that, prior to the FSMA, US Food Safety Law was strongly top- down structured. An event that triggered legal reform in the field of food safety was that of September 11, 2001. US congress felt the need for enhancing protection of the United States such as in the food supply chain against terrorism attacks and consequently the Bioterrorism Act was enacted in 2002 which provides the FDA with administrative detention authority over food items if there is credible evidence or information that indicates the food presents a threat of serious adverse health consequences or death to humans or animals. The FSMA could be considered an enlargement thereof, this is reflected in the fact that it broadens the before mentioned authority, allowing for administrative detention based on ‘reason to believe’ that the food item has been misbranded or adulterated and thus violates a legal standard for the product. Another factor that has influenced the enactment of the FSMA, is that after the millennium international standards strongly developed the thinking of a self- regulatory system of the food industry. US government realized that its food law system was a long way behind this international development and at the same time its system was not working sufficiently (expensive, government capacity, complexity in control food

95 For a historical perspective on economic and social situations leading to food safety legislation in the United States in 1906, see generally Upton Sinclair, The Jungle (Doubleday, Jabber & Company 1906). 
supply chain etc.). Consequently, US government was determined it had to change its food safety policy corresponding to international developed policy and economic and technological transformations in both food and food supply system. As a response US government developed a new approach equal to EU food law and sound with the developments of international (FAO/WHO) food safety standards and guidelines; covering a stricter protection against terrorism attack on the food supply chain as well. Since 2011 with the enactment of the Food Safety and Modernization Act, the US shifted its food safety policy from a main responsive approach to a preventive approach giving reference to international standards. Notwithstanding, it should be understood the FSMA is an enlargement of the initial food law and therefore its structure is still built around the aspects of food adulteration and misbranding. This fact implies US food law system is twofold, at one hand it provides preventive approach by establishing a self- regulatory food safety system for food industry and at the other hand it strongly strengthens the powers of the FDA to enforce the law and prevent adulterated and misbranded foods (which are criminal law aspects) circulating the market. This implies that contemporary US food law is indeed about do’s (in terms of food industry) but certainly still about don’ts (role FDA enforcement) as well.

In the EU on the other hand, an integrated approach to food safety was only applicable after the establishment of the European Union. Before its existence, food safety relied on national food safety policy. After WO II continental countries gathered aiming to form a Common Market; the European Community was formed consisting of three international organizations that were governed by the same set of institutions. In the field of food law, at the beginning of its establishment and aiming at developing a Common Market, the Community established vertical legislation which was mainly market- oriented. The legislation was mainly developed for products of animal origin within the Common Agriculture Policy in a set of ‘vertical’ directives, each covering a restricted range of foodstuffs, usually in considerable detail and including some non- sanitary measures. They contained a number of inconsistencies often for no obvious technical reasons. After some years, case law brought changes in this method of legislation and in the interest of the concept of free movement of goods, horizontal legislation was applicable to foods. In the interest of enhancing a common market it was now for Member States no longer allowed to prohibit products from other member states based on protectionist measures (e.g. discrimination of origin). In this period, in the field of food law, majority of policies were directives which were product based. However, in the 90’s as foods circulating the Common Market without frontiers strongly increased, a series of food scares revealed. One of Europe’s most shocking food scare was the BSE crisis that emerged mid 90’s –

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97 These institutions consisted of: European Coal and Steel Community (ECSC); the European Atomic Energy Community (Euratom) and the European Economic Community (EEC). The latter was renamed the European Community (EC) in 1993 by the Treaty of Maastricht.

the beginning of the 21st century. Europe soon realized it was coping with the fact that it has reached a functional single market in which foods were circulating from both cross-border continent as between Member States themselves, but was lacking an integrated approach to food safety.

Consequently, the European law-maker realized the Common Agricultural Policy was not sufficient in achieving safe foods circulating the market in the interest of guaranteeing high degree of consumer protection/public health as it has established in its treaties. Rather, Europe had to develop an integrated approach in the field of food safety policy. Short after the emerging of the BSE-crisis which in Europe resulted in public lack of confidence in science and EU government, as a response the EU commission rapidly developed an integrated approach to food safety: the establishment of the General Food Law and the European Food Safety Authority. After the creation of the General Food Law, whole packages of new legislation followed. EU food law is mainly established in the form of regulations which means that the law is directly binding to all of its Member States.

Figure 1.1 Highlights in the overhaul of EU food law.\footnote{Meulen, Bernd M.J. van der. 2013. P. 78.}

<table>
<thead>
<tr>
<th>Year</th>
<th>Regulation</th>
</tr>
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<tbody>
<tr>
<td>2002</td>
<td>Regulation 178/2002 (General Food Law)</td>
</tr>
</tbody>
</table>
Regulation 882/2004 Official controls  
Regulation 1935/2004 Food contact materials |
| 2005 | Allergen labelling requirements included in Directive 2000/13 |
| 2006 | Regulation 1924/2006 Nutrition and health claims |
| 2007 | White Paper A Strategy for Europe on Nutrition, Overweight and Obesity related health issues |
| 2008 | Regulations 1331–1334/2008: Food Improvement Agents Package (FIAP); additives, flavorings and enzymes |
| 2009 | Regulation 1169/2011 Food information to consumers |

This fits the idea of establishing a law that shall ensure food safety in the interest of public health and consumer protection on EU level. With its farm to fork approach Europe aims to ensuring safe foods on the shelves. From its establishment European food law is designed with a strong preventive approach (food shall not be placed on the market if it is unsafe) involving the food industry as the main responsible actor for ensuring food safety in all steps of the food supply chain by requiring an in place system built around prevention (e.g. sampling, traceability, HACCP system, industry safety management system etc.). EU law therefore strongly applies a bottom-up approach giving space for
the emergence of a so-called self-regulatory system to the food industry. Member States gained the responsibilities of enforcement, monitoring and verification of the in place system of the food business operators.

Regarding the correlation of the responsibilities laid down in the general Food Law, one could speak of an EU approach that is mainly based on do’s. Furthermore, the EU has specifically incorporated the precautionary principle in its food law. This is consistent with the aim of regaining consumer trust in science and EU politics after the emergence of the BSE-crisis. Involving the precautionary principle in the risk analysis framework in EU food law strongly implies that risk management is a process separated from risk assessment in which there is margin provided to the risk managers (law-maker) to impose this principle in case of scientific uncertainty. This strongly underpins the importance of the concept of food risk prevention in EU food safety policy. These features will be subject for further comparison in chapter 2 and 3.

In case of China one could speak of a relatively young food safety system. Emerging economies, such as China’s, are moving through periods of rapid industrialization and urbanization similar to those that Europe and North America experienced in the nineteenth century. In case of China food safety issues aroused only after it has opened her doors to the world since the 80’s. Before this period one could speak of little food safety concern since the food industry was state owned. The existent legislation with regards to food that fell under Agricultural Policy was that of hygiene legislation, which consisted of certain quality standards/requirements the food industry was required to comply with. However, after the period of economic reform China’s food industry was subject to foreign investment and private ownership. The economic reform was also targeted on agriculture which was in service of market driven incentives.

As a consequence, with rapid industrialization, increasing complexity of the food supply chain, its demographic situation and its leading role in global trade, China slowly came to experience the emergence of food scares it faced. At the beginning of the 21st century a series of food scares emerged, these were mostly food scandals linked to food fraud (e.g. adulteration and counterfeiting). These events have hit the headlines worldwide. Chinese government soon realized the hygiene legislation in place was not sufficient in ensuring food safety. After the emergence of the tainted infant formula (Melamine Scandal) in the period of 2004–2008, Chinese government felt global pressure in developing a Food Safety Law. As a response, in relatively short period of time, China managed to develop a Food Safety Law which was enacted in 2009: the 2009 PRC Food Safety Law. This law was the first law dealing with specific food safety issues in terms of preventing unsafe foods on the market. Regarding its incentive and its role within the Codex Alimentarius, China’s PRC Food Safety Law is based on prevention and strong science (risk assessment).
needs to find its place in the hundreds of year-old legal culture (institutions, Legal system, regulatory structure etc.). China is at its very heart of food safety policy reform as the US and EU have dealt with in the past centuries. It is therefore not surprising that the 2009 PRC Food Safety Law is already amended twice. The latest revised amendment (in force as per October 1st 2015) is stricter with features mainly based on restructuring of institutions taking away overlap of regulatory tasks and food law enforcement with linkage to criminal law. These features will be further analyzed in their legal cultural context in chapter 6.

In conclusion, one could speak of the US applying a twofold system of do’s and don’ts, at one hand providing for a self-regulatory system of food industry and at the other hand still applying criminal law approaches in the interest of a high level of protection (e.g. against terrorism) of the food supply chain and therefore providing far reaching tools to the FDA in terms of enforcement. The underlying reason for this is the origin of US food law that is based on criminal law approaches and the fact that these laws are still the basis for contemporary US food law; the fact that US food law with the involvement of the FSMA provides for a preventive approach as well. In terms of the EU the General Food Law was the first integrated food safety policy. The triggers (food scares) for its realization and Europe’s aim for strengthening public confidence in politics and science reflect in the law which is science-based, consumer-oriented and provides for a strong preventive approach. In case of China the PRC Food Safety Law is a first comprehensive Food Safety Law as well. Its underlying triggers are to be found in the new economic strategy of China after the Cultural Revolution; as a result the continuous food scares it deals with up until this day. The relatively fast development of the PRC food law, Amendment and Revised Amendment, are a reflection of the current food safety issues China deals with and the learnings thereof.

On the next page an overview of the development of the food laws in the Legal systems is provided.
The discussed features in this chapter provide us with some understanding of the characteristics of the food law systems involving legal institutions, regulatory structure and legal system. These aspects are all considered parts of the overall concept of legal culture in the context of this study. The results of this analysis demonstrate in order to explore a certain system’s legal culture subject for comparative analysis, it is inevitable to dive into its context by understanding the history and development. Therefore, this chapter must be considered a starting point and foundation at the same time of this study shedding some light on the features that have formed the system’s legal culture in the context of Food Safety Law. The result will be subject for further elaboration in the functional comparison in Chapter 5.

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100 E.g. Cassis de Dijon, Dassonville (see paragraph 1.2 development EU law)
101 See figure 1.1: Highlights in the overhaul of EU food law.
Chapter 2 The Food Safety Legal Framework: A comparative structural approach

In this Chapter the Food Safety Legal Framework takes a central role. The legal rules concerning food safety are countless. Therefore the variables selected are limited towards the aim of this research. An overview of the food safety framework in place of the EU, US and China respectively will be provided. Furthermore, a basic understanding of how the Legal systems at stake have designed their enforcement strategies with regards to Food Safety Law will be dealt with. Finally, in conclusion a structural comparison will be provided. The central question that will be answered in this chapter is: “How is the Food Safety Law framework structured in the Legal systems and how is this in general enforced?”

2.1 National Food Safety Framework

Over the past decades Food Safety Law has taken a prominent role in the legal framework of Legal system worldwide. Different Legal systems have established and developed their own food safety frameworks. Next the food safety framework designed in the three Legal system concerned, will be discussed.

2.1.1 European Union

In Europe Regulation (EC)178/2002102, also known as “the General Food Law”, is the main legal framework of foodstuff that are placed on the market. This Regulation, adopted on the 28th of January 2002, lays down the general principles and requirements of Food Law, established the European Food Safety Authority (EFSA) and lays down the procedures in matters of food safety. Although all Member States have established overarching principles of food safety and consumer protection in their national legislation, at EU level food legislation has evolved without some of these basic principles having been established in an overarching legal instrument. In October 2010, the European Commission initiated the ‘fitness check’ exercise, it was aimed to review an entire body of legislation in a certain policy area with the purpose of identifying excessive burdens, overlaps, inconsistencies, gaps and/or obsolete measures.103 The food chain was one of the four pilot projects. It was identified an extensive legislative EU framework and was found to be one of the most EU-level harmonized sectors. Furthermore, the socio-economic importance of the food sector in Europe

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103 This fitness check provided the groundwork for the Regulatory Fitness and Performance Program (REFIT) which was introduced at the end of 2012.
} This determines the importance food law takes within EU legal framework.

### 2.1.1.1 Aim & Scope

Article 1 (1) establishes the aim of the General Food Law: "This Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market. It establishes common principles and responsibilities, the means to provide a strong science base, efficient organizational arrangements and procedures to underpin decision-making in matters of food and feed safety".\footnote{105 Article 1 (1) General Food Law}

One could simply state the General Food Law aims to provide a framework to ensure a coherent approach in the development of food legislation. Moreover, it provides the general framework for those areas not covered by specific harmonized rules but where the functioning of the Internal Market is ensured by mutual recognition. It lays down definitions, principles and obligations covering all stages of food/feed production and distribution.\footnote{106 European Commission Website, ‘General Food Law’ (Last update March 2015). [Data file]. Retrieved from <http://ec.europa.eu/food/food/foodlaw/index_en.htm>.
} The Regulation does however not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption.\footnote{107 Article 1 (3) General Food Law
}

### 2.1.1.2 Definition of ‘Food’

The General Food Law gives an extensive elaboration concerning the definition of ‘Food’. It lists both aspects are not considered falling under the definition and those which should not be understood as falling under the scope of the definition. The next conditions should be met to identify a certain product or substance as a ‘Food’ (or ‘foodstuff’) falling under the Regulation: 1) any substance or product 2) whether processed or unprocessed 3) that is intended to be or reasonably expected to be ingested by humans.\footnote{108 Article 2 (1) General Food Law
} It further includes drink, chewing gum and any substance including water which is intentionally incorporated into the food during its manufacture, preparation or treatment.\footnote{109 For a list of exemptions to this definition see Article 2.1 (a/h) General Food Law.
}
2.1.1.3. **Perception of ‘Food Safety’ established in Law**

The main food safety requirement within the General Food Law is: “Food shall not be placed on the market if it is unsafe”.\(^{110}\) No food stuff dangerous to health and/or unfit for consumption may be placed on the market. To determine whether a foodstuff is dangerous, the following is considered.

- the normal conditions of use;
- the information provided to the consumer;
- the probable immediate or delayed effect on health;
- the cumulative toxic effects;
- the specific sensitivity of certain consumers.

Where any food which is unsafe is part of a batch, lot or consignment, it is assumed that the whole batch, lot or consignment is unsafe.

2.1.1.4. **Principles of Food Law**

The General Principles of Food Law are included in Chapter I of the General Food Law. These principles must be followed when measures are taken. The three main principles established in the law are.

1) **General objectives**

This principle, established in article 5 of the GFL, designates to a threefold fundamentals. First of all the food law aims at ensuring a high level of protection of human life and health, taking into account the protection of animal health and welfare, plant health and the environment. This integrated approach stand for the so-called "farm to fork" approach and has become a general principle for EU food safety policy.\(^{111}\)

Secondly, another objective is that of ensuring the free movement of food and feed in the EU which is another important objective of the General Food Law.\(^{112}\) In order to ensure this objective EU food law aims to harmonise existing national requirements.

Thirdly, the food law recognises the EU’s commitment to its international obligations and the need to take international standards in consideration when developing and adapting the law. However, except where this might undermine the high level of consumer protection pursued by the EU.\(^{113}\)

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\(^{110}\) Article 14(1) General Food Law

\(^{111}\) Art. 5(1) General Food Law

\(^{112}\) Art. 5(2) General Food Law

\(^{113}\) Art. 5(5) General Food Law
2) Risk regulation (the concept of risk analysis)

The second main principle of the General Food Law is the concept of risk analysis as included in article 6 of the General Food Law. Article 6 (1) states: “In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure”. Based on this paragraph one could state EU food safety risk regulation is science based. Hence, depending on the nature of the measure, food law, and in particular measures relating to food safety must be underpinned by strong science.

The Regulation establishes the structures and mechanisms for the scientific and technical evaluations which are undertaken by the European Food Safety Authority (EFSA). The EU has been at the forefront of the development of the risk analysis principles and their subsequent international acceptance. The risk analysis principle consists of the three inter-related components 1) risk assessment (science based), 2) risk management and 3) risk communication.114 These components provide the basis for food law as appropriate to the measure under consideration. The aspect ‘risk’ is defined by the Regulation as: “a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard”.115 To what concerns the first component, risk assessment, the Regulation states: “Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner”.116 Consequently, scientific assessment of risk must be undertaken in an independent, objective and transparent manner based on the best available science. Risk assessment is furthermore defined and explained as: “risk assessment means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation”.

The second component risk management is explained as: the process of weighing policy alternatives in the light of results of a risk assessment and, if required, selecting the appropriate actions necessary to prevent, reduce or eliminate the risk to ensure the EU objective of high level of health protection.117 In this second phase of the risk analysis, the decision makers need to consider a range of information in addition to the scientific risk assessment. These include, for example, the feasibility of controlling a risk, the most effective risk reduction actions, taking into account the socio-

114 Article 3(10) General Food Law
115 Article 3 (9) General Food Law
116 Article 6 (2) General Food Law
117 Article 3 (12) General Food Law
economic effects and the environmental impact.\textsuperscript{118} This phase could therefore also be considered as the phase of political decision making.

The last phase is the phase of risk communication. In this phase the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions, takes place.

3) Precautionary principle

The practice of the precautionary principle in EU Food Law is a widely discussed topic among scholars. The Regulation formally establishes the Precautionary Principle as an option open to risk managers when decisions have to be made to protect health but scientific information concerning the risk is inconclusive or incomplete in some way: scientific uncertainty. The precautionary principle is relevant in those circumstances where risk managers have identified that there are 1) reasonable grounds for concern that 2) an unacceptable level of risk to health exists  3) but the supporting information and data may not be sufficiently complete to enable a comprehensive risk assessment to be made.\textsuperscript{119} When faced with these specific circumstances, decision makers or risk managers, may take measures or other actions to protect health based on the precautionary principle while seeking more complete scientific and other data. Such measures have to comply with the normal principles of non-discrimination and proportionality and should be considered as provisional until such time that more comprehensive information concerning the risk can be gathered and analysed.\textsuperscript{120}

4) The principle of transparency

This aspect may not be one of the principles as stated under Section I of the general food law, indeed it plays an essential role in the overarching Food Safety framework. It is therefore considered to be included in Section II of the General Food Law.\textsuperscript{121} Food Law both at national and EU level, establishes the rights of all EU consumers to obtain safe food and accurate and honest information. It is therefore expected that public consultation and information are being shared in a transparent

\textsuperscript{119} Article 7 General Food Law
\textsuperscript{121} Section II ‘Principles of Transparency’ Regulation 178/2002 the General Food Law
manner to the extent possible and reasonable without prejudice to the provisions in the General Food Law and national food law.122

2.1.1.5. Responsibilities & obligations

The Regulation establishes the basic principle that the primary responsibility for ensuring compliance with food law, and in particular the safety of food, rests with the food business. To complement and support this principle, there must be adequate and effective controls organised by the competent authorities of the Member States. The responsibilities of the business operators and authorities respectively are incorporated in Article 17 of the Regulation. The primary responsibility for ensuring foods satisfy the requirements of food law at all stages of production, processing and distribution under the control of the business is entitled to the food business operator. Furthermore, the Regulation requires the food business operators to verify that such requirements are met.123 In other words, food business operators must apply the food legislation at all stages of the food chain, from the production, processing, transport and distribution stages through to the supply of food.

In addition, operators are responsible for ensuring the traceability of products at all stages of the production, processing and distribution, including with regard to substances incorporated into the foodstuffs. Furthermore, if an operator considers that a food is harmful to human or animal health, they immediately initiate the procedures to withdraw the product from the market and inform the competent authorities. Where the product may have reached the consumer, the operator informs the consumers and recalls the products already supplied.

At the other hand the Regulation expects and requires the Member States to enforce food law and monitor and verify that the relevant requirements of food law are fully met by the food business. For that purpose the Member States need to maintain a system of official controls and other activities including public communication on food risks, food safety surveillance and other monitoring activities covering all stages of production, processing and distribution.124 Consequently, European food law is designed with a ‘laissez faire’ character. The Member States have gained mainly a complementary task in enforcing food safety in where it basically comes down to providing a legal framework for the business operators and to enforce those rules.

122 Article 9, 10 General Food Law
123 Article 17 (1) General Food Law
124 Article 17 (2) General Food Law
The main obligations for the food business operators that derive from the General Food Law are:

- **Safety**
  Operators shall not place on the market unsafe food or feed\(^\text{125}\)

- **Responsibility**
  Operators are responsible for the safety of the food and feed which they produce, transport, store or sell produce, transport, store or sell produce, transport, store or sell.\(^\text{126}\)

- **Traceability**
  Operators shall be able to rapidly identify any supplier or consignee.

- **Transparency**
  Operators shall immediately inform the competent authorities if they have a reason to believe that their food or feed is not safe.

- **Emergency**
  Operators shall immediately withdraw food or feed from the market if they have a reason to believe that it is not safe.

- **Prevention**
  Operators shall identify and regularly review the critical points processes and ensure that controls are applied at these points.

- **Co-operation**
  Operators shall co-operate with the competent authorities in actions taken to reduce risks.

The responsibilities are further detailed in the guidance document on the implementation of the main General Food Law requirements. This comprises guidance documents which have been developed by a working group of Member State experts. These requirements are traceability of food and feed products, responsibility of operators, withdrawal of unsafe food or feed from the market and notification to the competent Authorities. Their implementation, from 1st January 2005, has given rise to numerous questions in particular from E.U. food chain operators and third country trading partners. The guidance document aims to assist all players in the food chain to better understand and to apply the Regulation correctly and in a uniform way. Over the years this document has been reviewed and complemented. A new section has been developed on food safety requirements, and the sections on traceability, withdrawal/recall and export of food and feed, have been redrafted with a view to simplifying, clarifying and completing them. The Standing Committee on the Food Chain and Animal Health has approved the last revised version of the guidance document at its meeting of 26 January 2010.

\(^{125}\) Article 14 General Food Law

\(^{126}\) Article 17 General Food Law
2.1.1.6. Traceability

Within the General Food Law, traceability comprises one of the general requirements of food law.\textsuperscript{127} The facilitation of the ability to trace a certain product is of essence in all stages of the food chain. The General Food Law defines traceability as: "the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution."\textsuperscript{128} Moreover, Article 18 of the General Food Law is devoted to this subject. It establishes responsibilities towards food business operators\textsuperscript{129} to account for the ability to identify any person from whom they have been supplied with a food or any substance intended to be, or reasonably may be expected to be, incorporated into a food. To this end, the food business operators need to have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.\textsuperscript{130}

\begin{flushleft}
\textsuperscript{127} Section 4 General Food Law "General Requirements of Food Law"
\textsuperscript{128} Article 3 (15) General Food Law
\textsuperscript{129} Food Business operators should be in this context according to Article 3 (3) GFL understood as "the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control".
\textsuperscript{130} Article 18 (1) General Food Law
\end{flushleft}
2.1.2. United States of America

To understand US Food Law, it is imperative to have at least a basic understanding of the applicable law. In this chapter it will be attempted to provide such by first giving a simplified overview of the US government structure and Legal system. Hereinafter the US Food Safety Framework, which consist of the Food Safety and Modernization Act under the Federal Food, Drug and Cosmetic Act, will be discussed in details.

In terms of food legislation, the US have established a legal framework on Federal level. In the US different food laws have been enacted over the decades. US food Law system could perhaps be considered the most progressive food law system in global arena. It has shifted from a strong rooted system of response to a reformed system of prevention. As described in previous chapter, after the Elixir Sulfanilamide disaster\textsuperscript{131}, the US Federal, Food, Drug and Cosmetic Act (hereinafter the FD&C Act) was passed by Congress in 1938 giving the authority to the US Food and Drug Administration (FDA) to oversee the safety of food, drugs and cosmetics. The FD&C Act which encompasses a set of laws replaced the earlier Pure Food and Drug Act of 1906. The Act has been amended many times over the past decades. The most recent, and perhaps the most important amendment in the interest of our subject, is the FDA Food Safety Modernization Act. The FDA Food Safety Modernization Act (Hereinafter: “FSMA”). It aims to ensure the US food supply is safe by shifting the focus of federal regulators from response to prevention. The FSMA has been called “historic” because it puts the focus of the FDA on prevention, working to ensure that unsafe foods are not distributed in the first place\textsuperscript{132}. Moreover, the FSMA is considered the most sweeping reform of the US Food Safety Laws in more than 70 years by the FDA itself\textsuperscript{133}. Furthermore, the Washington Post considered the Act to be the first major piece of federal legislation addressing food safety since 1938.\textsuperscript{134} The FSMA enables the FDA to better protect public health by strengthening the food safety system. The law enables the FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides the FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to problems when they do occur. The law also provides the FDA with important new tools to hold imported foods to the same standards as domestic foods and directs the FDA to build an integrated national food safety system in partnership with state and local authorities.

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In the interest of remaining within the scope of our subject, the comparison will be applied to the FD&C Act which for that purpose will be mostly highlighting aspects of its food law division: the FSMA.

2.1.2.1 Aim & Scope

The FD&C Act in general aims to establish a set of laws giving authority to the US FDA to oversee the safety of food, drugs and cosmetics.

In terms of food safety the FSMA, as a part of set of laws under the FD&C Act, could be considered the US Food Safety Law system. The FSMA technically aims to improve capacity to prevent food safety problems\textsuperscript{135} and to improve the safety of food.\textsuperscript{136} However, the underlying thought of these improvements is the awareness of legal reform of the US Food safety framework. With this respect the general assumption is that foodborne illness is largely preventable if everyone in today’s global food chain could be held responsible and accountable at each step for controlling hazards that can cause illness. Under the FSMA the FDA will now have new prevention-focused tools and a clear regulatory framework to help make substantial improvements in the approach to food safety. For example, for the first time, FDA has a legislative mandate to require comprehensive, preventive-based controls across the food supply chain. Preventive controls include steps that a food facility would take to prevent or significantly minimize the likelihood of problems occurring. The FSMA also significantly enhances FDA’s ability to achieve greater oversight of the millions of food products coming into the United States from other countries each year.\textsuperscript{137}

2.1.2.2 Definition of ‘Food’

The FD&C Act defines the term “food” relatively concisely. It defines as follows. “food” means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.\textsuperscript{138}

2.1.2.3 Perception of ‘Food Safety’ established in Law

In US food law food shall be deemed unsafe when it is adulterated\textsuperscript{139} or misbranded.\textsuperscript{140} These acts and the cause thereof are prohibited by law and is established by the US code which states as follows.

\textsuperscript{135} 21 USC. 321. under section 201. Title I. FD&C Act
\textsuperscript{136} Ibid. Title III
\textsuperscript{138} 21 USC. 321. under section 201 { CHAPTER II—DEFINITIONS} FD&C Act
\textsuperscript{139} 21 USC. 321. under section 342 of the FD&C Act
\textsuperscript{140} 21 USC. 321. under section 343 of the FD&C Act
21 US Code Sec 331. “The following acts and the causing thereof are prohibited.

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.”

When a food is found to be adulterated or misbranded, it shall be deemed to be unsafe. Consequently, in general terms, adulterated or misbranded food are not allowed be sold since it is considered to be unsafe.

- Adulterated food in general means any food that 1) contains any substance, food additive, or pesticide chemical residue which may render it injurious to health or unsafe; 2) consists of any filthy, putrid, or decomposed substance; 3) is unfit for food; 4) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated; 5) is the product of a diseased animal or an animal that died other than by slaughter; 6) its container is composed of any substance which may render the contents injurious to health; or 7) has been intentionally irradiated.\(^\text{141}\)

- Misbranded food means any food that 1) its labeling or advertising is false or misleading; 2) is offered for sale under the name of another food; 3) is an imitation of another food but the label does not bear the word “imitation”; 4) its container is made or filled to be misleading; or 5) its label does not provide i) the name and place of the manufacturer, and ii) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.\(^\text{142}\)

Moreover, with regards to the jurisdiction, the prohibition is applicable to food in interstate commerce. The broad definition of interstate commerce and the extensive movement of commodities, food ingredients, and food products leaves very little food outside the definition of interstate commerce. Consequently, very little food in the United States fall outside the jurisdiction of US Federal law.\(^\text{143}\)

2.1.2.4. Principles of US Food Law

In US food law the main key principle is that food shall not be misbranded or adulterated, in that case it is deemed to be unsafe and is prohibited to be sold. Contemporary US food safety framework is built around this principle. However, along with the amendment of the FSMA, the principle of

\(^{141}\) 21 USC. 342. under section 402 of the FD&C Act

\(^{142}\) 21 USC. 343. under section 403 of the FD&C Act

Prevention gained an essential place in US food safety system as well. In this regard it is worth to note that US Congress has made prevention the foundational principle of the FSMA. The 5 key principles/elements in this new preventive approach are.\textsuperscript{\ref{144}}

\textit{Preventive controls}\nFor the first time, the FDA has a legislative mandate to require comprehensive, prevention-based controls across the food supply.

\textit{Inspection and Compliance}\nThe legislation recognizes that inspection is an important means of holding industry accountable for its responsibility to produce safe food; thus, the law specifies how often the FDA should inspect food producers. The FDA is committed to applying its inspection resources in a risk-based manner and adopting innovative inspection approaches.

\textit{Imported Food Safety}\nFDA has new tools to ensure that imported foods meet US standards and are safe for consumers. For example, for the first time, importers must verify that their foreign suppliers have adequate preventive controls in place to ensure safety, and the FDA will be able to accredit qualified third party auditors to certify that foreign food facilities are complying with US food safety standards.

\textit{Response}\nFor the first time, the FDA will have mandatory recall authority for all food products. The FDA expects that it will only need to invoke this authority infrequently since the food industry largely honors their requests for voluntary recalls.

\textit{Enhanced Partnerships}\nThe legislation recognizes the importance of strengthening existing collaboration among all food safety agencies—US federal, state, local, territorial, tribal and foreign—to achieve public health goals. For example, it directs the FDA to improve training of state, local, territorial and tribal food safety officials.

\textit{Precautionary principle}\nIn the FSMA the precautionary principle is not clearly mentioned, nor is it quite clear to what extent it is even applicable to foodstuff particularly since in the US the precautionary principle is mainly regulated under environmental law.\textsuperscript{\ref{145}}

\begin{itemize}
\item \textsuperscript{145} Bedansky et al.,1994, P. 203.
\end{itemize}
Risk regulation (the concept of risk analysis)

US Food Safety Law is intended to reduce the risk of unsafe food. To reduce the risk of unsafe food, food businesses are urged to pursue the practice of risk analysis and its three components as it relates to food safety: 1) risk assessment, 2) risk management and 3) risk communication. In the US definitions of risk assessment, risk management and risk communication are similar to the EU, based on the international framework (Codex).

2.1.2.5. Responsibilities & obligations

With the introduction of the FSMA food safety responsibilities have shifted from government (top down regulation) to industry (bottom up regulation). The FSMA introduces a preventive approach to food safety. Consequently, the FSMA shifts food safety focus from reaction and response to prevention, from catching food safety problems after the fact to systematically building in prudent preventive measures across the food system.

The law also codifies the principle that the primary responsibility for prevention rests with the food and feed industries. Within the preventive controls framework, the FDA plays its role most effectively by setting science-based, prevention-oriented standards and working to ensure high rates of industry compliance with the new standards.146

2.1.2.6. Traceability

“Product tracing doesn’t prevent an outbreak, as it’s more about response”, says Bill Correll at FDA’s Center for Food Safety and Applied Nutrition. He further states, “However, it can prevent further illnesses during an outbreak when FDA can determine the source, contain further exposure and get the product recalled and out of distribution and consumer households”.147 FDA is directed by the FSMA to upgrade its ability to track both domestic and imported foods. To do this, the FDA established pilot projects to test how to rapidly identify recipients of food, this is critical information the FDA needs to rapidly find the source of a foodborne outbreak and to understand its scope.

In US Food law system traceability is regulated under Sec. 204148 of the FSMA. The law establishes a pilot program to be conducted by the Secretary of Health and Human services starting within the first year after the enactment of the FSMA. The Secretary of Health and Human services needs to take

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147 Ibid.

148 21 USC. 321. under section 204: 'Enhancing tracking and tracing of food and recordkeeping ' FD&C Act
into account recommendations from the Secretary of Agriculture and representatives of State departments of health and agriculture. The Secretary is required to establish pilot projects in coordination with the food industry to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death to humans or animals health. The Secretary of Health and Human Services is required to accomplish different pilots in coordination with processors and distributors and take into account various sectors that ought to represent the overall food sector. With this respect the next requirements apply: data gathering, additional recordkeeping and requirements for high risk foods and establishing record product tracing system.\textsuperscript{149}

\textit{Pilot Projects for Improving Product Tracing along the Food Supply System Final Report}

Since the new food safety approach to foodstuff is quite new with regards to the implementation of the FSMA, pilot projects are created in order to develop the tracing system. One of these seminal projects was the \textit{“Pilot Projects for Improving Product Tracing along the Food Supply System Final Report”}. The objectives of the pilot projects were 1) to identify and gather information on methods to improve product tracing of foods in the supply chain, and 2) to explore and evaluate methods to rapidly and effectively identify the recipient of food to prevent or mitigate a foodborne illness outbreak 3) and to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated or misbranded. Another important objective was to involve numerous stakeholders throughout the process including the food industry, USDA, multiple state public health agencies, consumer groups, and other governmental agency partners.\textsuperscript{150}

\textsuperscript{149} 21 USC 321. under section 204 of the FD&C Act

2.1.3. China

China’s contemporary food safety framework is based on the People’s Republic of China Food Safety Law (hereinafter referred to as, PRC Food Safety Law). The Law formally came into effect on June 1, 2009 superseding the 1995 Food Hygiene Law. It has been amended two times since its enactment in 2009. Its first amendment was submitted to the State Council for comment in late 2013. The State Council received numerous comments and proposals and subsequently made further modifications to the Amendment. Hereinafter, in June 2014 the Revised Amendment of the PRC Food Safety Law was submitted for public comment via the National People’s Congress’ official website. Compared with the Amendment, the content of the Revised Amendment to the PRC Food Safety Law is much more comprehensive, it further increases fines for food safety violations, regulates health food advertising and record management, clarifies food safety training requirements, and specifically addresses infant formula production safety, all of which reflect the growing attention paid by the state to food safety issues. This Revised Amendment is subject for comparison in this research.

Prior to the enactment of the 2009 PRC Food Safety Law, regulation concerning foodstuff was mainly based on Food Hygiene Law which consisted of several hundreds of disparate regulations and standards. PRC Food Safety Law consolidated these regulations and standards, that prior to its enactment governed the Chinese food industry, into one unified, published, national food safety standard. PRC Food Safety Law brought sweeping changes to China’s Food industry.

2.1.3.1 Aim & Scope

Article 1 of PRC Food Safety Law provides with the aim of the law which states, “the law is formulated to assure food safety and safeguard people’s health and life”. Furthermore, the Law covers the following business activities carried out within the territory of the People’s Republic of China:

1) Food production and processing (“Food Production”); food sales and catering service (“Food Trading”);
2) Production and trading of food additives;

151 Food Safety Law of the People’s Republic of China. Adopted at the 7th Session of the 11th Standing Committee of the National People’s Congress of the People’s Republic of China on February 28, 2009 and revised at the 14th Session of the 12th Standing Committee of the National People’s Congress of the People’s Republic of China on April 24, 2015.


154 Article 1 PRC Food Safety Law revised Amendment.
3) Production and trading of packing materials, containers, detergents and disinfectants for foods, as well as tools and equipment used in food production and trading (hereafter referred to as “Food-related Products”);
4) Food additives and food-related products used by food producers and traders;
5) Food storage and transportation;
6) Safety management of food, food additives and food-related products.

The quality and safety management of primary agricultural products for consumption (hereinafter referred to as “Edible Agricultural Products”) fall under the Law of the People’s Republic of China on Quality and Safety of Agricultural Products. However, the marketing and sales of edible agricultural products, development of relevant quality safety standards and publishing of relevant safety information as well as the quality and safety management of agricultural input is covered by the PRC Food Safety Law.

2.1.3.2. Definition of ‘Food’

According to PRC Food Safety Law “Food” is defined as: any substance that has been processed or not processed that is suitable for eating including substances traditionally used as food and Chinese herb medicine, excluding substances solely used for disease treatment.\footnote{155} 

2.1.3.3. Perception of ‘Food Safety’ established in Law

The law clearly expresses its interpretation of the concept of food safety. It states as follows: “Food Safety means the assurance that the food is nontoxic, harmless, and compliant with reasonable nutritional requirement, and will not cause any acute, chronic and potential hazards to human health”.\footnote{156}

2.1.3.4. Principles of China Food Law

According to the Law, Food safety work shall abide by the principles of: “putting prevention first, risk management, wholeprocess control, and making efforts by the whole society”, aiming to establish a science– based and strict– oversight system.\footnote{157}

Risk assessment

China establishes the food safety risk assessment mechanism to assess the risks on biological, chemical and physical hazardous factors in foods, food additives, and food related products.\footnote{158}
food safety risk assessment shall use science-based methods, and shall be conducted based on food safety risk surveillance information, scientific data, and other relevant information. Article 18 of the PRC Food Safety Law establishes food safety risk assessment and requires that it shall be conducted when the following situations occur\(^{159}\):

1. Food safety risk surveillance or report reveal possible safety problem for food, food additives, and food related products;
2. Need to provide science basis for developing or revising national food safety standards;
3. Risk assessment is necessary to identify prioritized area or (food) variety in regulatory work;
4. Discovered factors that may cause harm to food safety;
5. Need to judge whether a factor constitutes food safety risk;
6. Other situations the NHFPC deems necessary to conduct risk assessment.

**Precautionary principle**

Chinese government formulates the sustainable development strategy and clearly objects to using the precautionary principle everywhere. The evolution of environmental laws in China showed that the precautionary principle had not been explicitly applied in Chinese environmental policies. In China, the government insists on the principle of sustainable development which emphasizes the balance between development and environment but opposes using the precautionary principle in general especially in world trade.\(^{160,161}\)

### 2.1.3.5. Responsibilities & obligations

The basic assumption of the PRC law is that it is mainly a responsibility for producers and traders to assure food safety.\(^{162}\) The Law requires food producers and traders to follow laws, regulations and food safety standards in their production and trading activities. They are required to ensure food safety, be honest and self-disciplined, be responsible for the society and the public, be supervised by the public, and bear the social responsibilities. Furthermore, producers and traders are required to management responsibilities of their production and trading activities and take safety responsibility of their produced and traded foods. Moreover, the law provides consumer protection in case of suffered damages. Consequently, the law requires food producers and traders to take compensation responsibility to the health, assets, or other damages caused by their produced or traded foods; they shall take other legal responsibilities for their activities that cause serious harm to the society.

\(^{159}\) Article 19 PRC Food Safety Law revised Amendment


\(^{162}\) Article 4 PRC Food Safety Law revised Amendment
addition, the law establishes responsibility onto the China Food and Drug regulatory department under the State Council (hereinafter: CFDA), which is responsible for regulating food production and trading activities, and undertakes the daily work of the Food Safety Committee.163 Governments on County level are held responsible for defining the responsibilities of the CFDA, the Health department and relevant departments at their own levels. Furthermore, relevant departments are responsible for food safety regulatory work within their respective jurisdiction.164 Furthermore in terms of risk assessment, the National Health and Family Planning Commission (hereinafter referred to as: NHFPC) is responsible for organizing food safety risk assessments. An expert committee on food safety risk assessment which is composed of experts on medical science, agriculture, food, and nutrition, is to be established to conduct the food safety risk assessment.165

2.1.3.6. Traceability

PRC Food Safety Law establishes food traceability systems that cover the whole process. CFDA will work with Ministry of Agriculture (hereinafter: MOA) and relevant departments to establish the coordinated traceability system for the whole process of food and edible agriculture products.

Food producers and traders are bound to establish the food traceability system as well pursuant to provisions of the law to guarantee traceability of foods. They are encouraged to adopt information technology measures in establishing the food traceability system.166

163 Article 5 PRC Food Safety Law revised Amendment
164 Article 6 PRC Food Safety Law revised Amendment
165 Article 17 PRC Food Safety Law revised Amendment
166 Article 42 PRC Food Safety Law revised Amendment
2.2. Enforcement

Generally speaking enforcement encompasses both verification of compliance with legal obligations and application of sanctions in case of infringements. This paragraph aims to shed some light on the way compliance of food law is regulated and which sanctions are generally applied in the three Legal system at stake.

2.2.1. Food Safety Law enforcement in the European Union

As previously discussed, the General Food Law holds the Member States responsible for the enforcement of food law. As discussed in previous paragraph, Article 17(2) of the General Food Law establishes the Members States’ responsibility to enforce food law. Consequently, EU food law increasingly sets standards for national enforcement and provides for supervision. Regulation EC 882/2004 is a leading example of this thought, it is recited as: Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.\footnote{Reg. EC 882/2004 published on 30 April 2004 in the Official Journal of the European Union.}

This Regulation includes obligations for verification by the Member States, measures to be taken in case of infringements, a framework for co-operation between national authorities and the Commission, and for the Commission to monitor the performance of national authorities in the Member States and in third countries.

In case of non-compliance enforcement authorities can do two things: 1) they can take measures to remedy the problem and to ensure future compliance, 2) or they can take measures to punish the perpetrator to induce from future infringements. Deciding what action to take the competent authority needs to take into account the nature of the non-compliance and the operator’s past record with regard to non-compliance.\footnote{Article 54 Regulation EC 882/2004.}

When a Member State establishes non-compliance of a food business operator it is primary expected to ensure the operator remedies the situation. Such action can include the imposition of sanitation procedures or recall of the product, restriction or prohibition of placing foods on the market or a closure of all or a part of the business concerned. Furthermore, in case of imported products measures that may include are: destruction, special treatment to solve the irregularity or dis-patch of the product to the state of origin. For the latter action a timeframe of no more than 60 days applies.\footnote{Van der Meulen & Van der Velde, 2011, P. 408.}
In case of measures to punish non-compliance the Regulation states as follows:

Member States shall also lay down the rules on measures and penalties applicable to infringements of food and feed law. The measures and penalties provided for shall be effective, proportionate and dissuasive.\textsuperscript{170}

As a conclusive statement the nature of the sanctions, whether it would be administrative or criminal, is left entirely to the Member States. The Commission in its first draft\textsuperscript{171} intended to impose the use of criminal law on the Member States, but this intention did not survive the legislative process. Therefore, the nature of the sanctions is up to decide by the competent authorities of the Member States. Due to the place food law takes within the field of law, administrative sanctions are widely applied by Member States.

\textbf{2.2.2. United States of America}

FDA Commissioner Margaret A. Hamburg says the law (FSMA) directs the agency to oversee food safety in a way that applies “the best available science and good common sense to prevent the problems that can make people sick.”\textsuperscript{172} Michael R. Taylor, FDA’s deputy commissioner for foods adds. “These new authorities are critical for the law’s success, they give the food companies strong additional incentives for keeping their products safe, and that helps us achieve the new law’s goal, which is to protect consumers from unsafe food”. In the first place the US approach to food safety is to prevent that unsafe foods (when they are qualified as to be misbranded or adulterated) are placed by applying preventive control measures. However, in the event that potentially unsafe food has already entered the marketplace, the FSMA has strengthened the FDA’s enforcement tools inter alia: \textit{Suspension of registration}\textsuperscript{173}. The law authorizes the FDA to suspend the registration of a facility under certain circumstances if the food it manufactured, processed, packed, received or held presents a serious health hazard. A facility with a suspended registration will not be able to legally offer food for sale in the United States until the FDA lifts the suspension.

The sanctions in case of non-compliance with US Food Law are regulated in chapter III of the FD&C Act.\textsuperscript{174} The sanctions/penalties contain both criminal law and civil law clauses. Most violations under the act are civil, though repeated, intentional, and fraudulent violations are covered as criminal law. When it is established that a food is considered falling under the prohibited acts under US Law\textsuperscript{175}.

\textsuperscript{170} Article 55 Regulation 882/2004
\textsuperscript{173} 21 USC. 321. under section 102(b), FD&C Act
\textsuperscript{174} 21 USC. 321. Chapter III. Prohibited Acts and Penalties. FD&C Act
\textsuperscript{175} 21 USC. 321. under section 331, FD&C Act
imprisonment and/or imposing of fines are consequences. The general rule is, any person who violates any of the prohibited acts as established by Section 331 could be imprisoned. The specific sanctions of conviction and fines are to be determined depending on the character of the prohibited act. Furthermore, a case-by-case study is applicable. In certain cases imprisonment can reach 10 years and fines can even reach thousands of dollars. All violations of the FD&C Act require interstate commerce because of the commerce clause, but this is often interpreted broadly and few products other than raw produce are considered outside of the scope of the act.

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176 21 USC 321, under section 333, 1(a), FD&C Act

177 Penalty and sanction regulation in case of other prohibited acts are further to be found in Section 331 a/g of the Act

178 The Commerce Clause gives Congress the power “to regulate commerce with foreign nations, and among the several states, and with the Indian tribes.”
2.2.3. China

PRC food law states the administrative departments for health, quality supervision, industry and commerce and CFDA at the county level or above may take actions in the course of performing their respective duties of supervising and administrating food safety, such as: 179
1) Entering production and trading sites for field inspection;
2) Conducting sample testing on food/food additives produced or traded;
3) Reviewing and copying relevant contracts, documents and notebooks and other information;
4) Seal up and detain food proven to violate food safety standards or proven by evidence to have hidden safety hazards, illegally used food raw material, food additives and food-related products;
5) Closing down places of illegal production and trading of food.

In case of violation with the law, PRC Food Safety Law provides for legal liabilities with linkage to both civil law as criminal law. Illegally gained- benefits of produced or traded foods and food additives are subject to a fine in the range of RMB 50,000 – 100,000. 180 Furthermore the law provides the authorities to order the concerned entity/ person that is in violation with the law, to terminate the law violation activity, confiscate its illegal gain of benefits, and impose a fine between RMB 50,000 to RMB 100,000. In case consumer’s lawful rights are harmed, the entity/ person shall take joint liability with the food/food additive producers/ traders. In case of illegal use of extreme poisonous pesticides and highly toxic pesticides, (the responsible person) shall be detained by the public security agencies in addition to the penalties imposed by relevant laws and regulations. Consequently, linkage to criminal law is made as an aim to strict the law and punish Food Safety Law offenders. 181

When false information (which constitutes behavior disrupting public order), is spread either by media, trader or food producer, civil law will be applicable. In this case China liability law will be applicable. With this respect the law states: “If the case of severe false food publicity, the provincial food and drug regulatory department shall suspend sale of the food, and make public announcement to the public; if the food is still sold in market, the provincial food and drug regulatory department shall confiscate the illegally gained benefits and the illegally traded food; the trader is also subject to a fine of RMB 20,000 and 50,000*. 182

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179 Article 110 PRC Food Safety Law revised Amendment
180 Article 122 PRC Food Safety Law revised Amendment
181 Ibid.
182 Article 140 PRC Food Safety Law revised Amendment
2.3 Conclusions: A structural Comparison

In this paragraph the results of the variables will be compared (structural comparison).

**Variable A** (Applicable law). The Legal systems have developed own Food Safety Laws in their regulatory framework. In the EU the General Food Law is a regulation and therefore is directly binding in all Member States. In the US the FSMA is a Federal law (Act) and therefore is directly applicable in all States. In China the PRC Food Safety Law is part of State law and therefore is applicable throughout the territory of the People’s Republic of China.

**Variable B** (Context). EU food law is designed with mainly a preventive approach, it establishes primarily responsibilities for the food business operators to ensure safe foods throughout the food supply chain. Therefore the General Food Law can be considered largely based on “do’s”. In the US, with the enactment of the FSMA food law has been shifted from a responsive approach to a preventive approach. The FSMA puts emphasis on FDA’s powers and introduces enhanced enforcement powers for the FDA. PRC Food Safety Law is, similar to the EU and US, designed with a preventive approach. However, PRC Food Safety Law involves the aspect of State control through its multi-leveled governance structure.

**Variable C** (Aim and Scope). the General Food Law is applicable within the boundaries of the European Union with the aim to prevent the placing of unsafe foods on the market. US food law is applicable to interstate commerce with the aim to enhance capacity and powers of FDA to oversee food safety and carry out preventive control. With this respect US food law is designed with the prohibition of food adulteration and misbranding and hence the food need to be safe. PRC Food Safety Law is applicable in the territory of the People’s republic of China and aims to the assurance of food safety and safeguard people’s health and life.

**Variable D** (Perception of “Safe Food”). EU food law establishes the concept of: “food may not be placed on the market when it is unsafe”, with this respect it applies a science-based approach. US food law on the other hand, considers food to be unsafe when proven adulterated or misbranded. With this respect, laying down these prohibitions US food law is next to its preventive approach towards food safety, also about don’ts. PRC Food Safety Law considers food to be safe based on the assurance that the food is: nontoxic, harmless, compliant with reasonable nutritional requirements, and will not cause any acute, chronic and a potential hazards to human health.

**Variable E** (Principles of food law). EU food law establishes several principles inter alia the precautionary principle, farm to fork approach and risk analysis. US food law establishes its principles based on tools and powers to FDA. PRC Food Safety Law establishes the principles of prevention, shared responsibilities, risk management and strict oversight system: active government.
Variable F (Responsibilities and Obligations). The General Food Law establishes the main responsibility for the food business operators to ensure food is safe across the food supply chain. In addition, it establishes the responsibility for the Member States to enforce food law and establish a monitoring and verification system. US food law on the other hand, establishes the responsibility for the food industry to establish an in place safety management system (preventive control measures). In addition, US food law establishes responsibilities for the FDA to carry out preventive control (inspection), oversight and enforcement. PRC Food Safety Law establishes the concept of shared responsibility involving, next to government and industry, other actors such as health care providers, consumers etc. The main responsibilities are for the food producers and food traders, from these actors PRC Food Safety Law requires a Food Safety Management system (preventive measures), the State Council is responsible for oversight and preventive control through its risk surveillance system.

Variable G (Food Traceability System). The General Food Law requires food business operators the ability to identify any person from whom they have been supplied with a food, for this the food business operators need to have a in place system. With this respect the General Food Law requires Member States to have a verification mechanism in place. US food law on the other hand, establishes a food traceability system with the aim to rapidly and effectively identify harmful recipients, the FDA has a leading task with this respect. The food industry is required to maintain record keeping. The US consider the traceability system as a strong tool for response. PRC Food Safety Law establishes a traceability system that covers the whole process, traders and producers are expected to facilitate such and are encouraged by government to use information technology.

Variable H (Measures in case of non-compliance). The General Food Law establishes a first choice remedy (recall, withdrawal, prohibition placing on the market etc.). With this respect the first responsibility lays at the food business operators. US food law establishes a first remedy as well, providing opportunity to the food industry (operator) to voluntary recall its product when revealed non-compliant. If not, or not adequately executed by the food industry (operator), than FDA directly intervenes and applies its management tools (mandatory recall, suspension of registration etc.). PRC Food Safety Law establishes a first remedy as well for the food traders and producers to act upon (recall, removal, destruction etc.). If not adequately executed, the government directly intervenes on local or higher level government.

Variable I (Measures to punish non-compliance). The General Food Law leaves enforcement measures up to the Member States(sanctions should be proportionate, effective and dissuasive). US food law establishes the possibility of imposing fines and imprisonment (dependent on the case) when adulteration and misbranding are proven. PRC Food Safety Law establishes criminal law approaches such as imprisonment and fines (linkage with criminal law) when adulteration is discovered. When false information sharing is revealed, civil law liability is applicable.

Variable J (Nature of Sanctions). The General Food Law leaves the nature of the sanctions (criminal or administrative) up to the Member States to decide. US food law provides sanctions to be based on
civil law and in some cases criminal law (dependent on the case). PRC Food Safety Law goes a step further, it establishes mostly linkage to criminal law features in its sanctions, another possible nature of sanction mentioned in the law is that of civil liability law.

Following, on the next page, an overview of conclusions of the structural comparison is provided in a table sheet.
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<td>Based mostly on civil law and criminal law features.</td>
<td>Based on criminal law features mostly and Civil liability law</td>
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Chapter 3. Legal Framework of Food Safety Management: A structural comparison

This chapter focuses on Food Safety Management specifically as established in the legal framework of the selected systems. The concept of risk management as a part of risk analysis is a key concept with this respect. Risk management is a consultative and decision-making process. The risk management process begins before risk assessment, runs concurrently with it and continues beyond it. Risk managers work in expert teams along with experts in the area of risk assessment, risk communication, food technology, public health nutrition, economics, food regulation etc. It should be noted that both the EU, US and China are members of the Codex Alimentarius. Therefore, this concept established on international level, will be subject for analyzing food safety incident response in the next chapter and shall consequently serve as a basis for functional comparison in the final analysis in Chapter 6.

The aim of this chapter is to provide a structural comparison of the way the selected Legal systems have laid down the concept of risk management regulation in their food law framework in order to give a general understanding of how the selected systems have established their approach to food safety risks from a legal point of view. In other words, the way their laws have established the way food safety incidents should be assessed and how the results thereof should be managed. The key question with this respect is: “How is the applicable International Framework of Food Safety Management designed and how have the Legal systems established the Food Safety Management process in their regulatory framework?”. Therefore firstly, the general approach to risks in the risk management process will be discussed including the International legal framework of food risk management (FAO/WHO). Hereinafter, for the purpose of this study, several selected variables regards the risk management process (involved institutions, management tools and incident management) and the assessment thereof will be analyzed and compared between the food law system of Europe, the U.S and China respectively. In conclusion, a comparative overview of the topics dealt with in this chapter will be provided.


185 The US member since 1963, China member since 1984, the European Union member since 2003. For more information see Codex Alimentarius Website. Online available at: https://www.codexalimentarius.org/members-observers/members/en/?no_cache=-1>.
3.1. General approach to risk management from an International perspective

Much of the conceptual thinking on risk management systems has been taking place at the international level through intergovernmental organizations such as the Codex Alimentarius Commission (CAC). This is not surprising since these organizations are involved in setting standards for foods in international trade. With the diversity of approaches to food production and manufacturing worldwide, it was critical for the Commission to establish general principles and concepts related to food safety risk management decision-making that could lead to harmonized international standards for the wide range of foods and potential hazards.\(^{186}\)

In the year of 1997 the concept of risk management was discussed in a second Joint WHO/FAO Consultation.\(^{187}\) This consultation reviewed risk management practices in the framework of Codex and the expert committees. Furthermore, elements and general principles of risk management of foods were defined. Risk management was considered a major element in the risk analysis process and was defined as: “the process, distinct from risk assessment, of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures”. Risk managers, in developing approaches to managing risk, utilize the risk characterization that results from the risk assessment process. With this respect an important principle that was recognized by the 1995 consultation was the functional separation of risk assessment from risk management. The consultation identified four major elements of the concept of risk management as follows.\(^{188}\)

1. **Risk evaluation** (Preliminary risk management activities)

   The risk evaluation process consists of the identification of the food safety problem, and the establishment of a risk profile. This involves describing a food safety problem and its context in order to identify those elements of the hazard or risk relevant to the various risk management decisions. In addition, this step also includes ranking of the hazard for risk assessment and risk management priority and the establishment of risk assessment policy for the conduct of risk assessment. Risk assessment policy would include such activities as establishing the populations that may be at risk in relation to specific hazards in food, establishing the criteria for ranking of hazards, and preparing guidelines for the application of safety factors.

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\(^{188}\) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and Agreement on Technical Barriers to Trade (TBT), Module 10 risk analysis and Codex, Section 10.4: Risk management. Online available at: <http://www.fao.org/docrep/003/x7354e/x7354e10.htm>.
Moreover, risk evaluation also includes commissioning of a risk assessment and the consideration of risk assessment results.

2. **Risk management option assessment**

This step includes the identification of the available management options, selection of preferred management options, including consideration of an appropriate safety standard (acceptable level of risk) and the final management decision.

3. **Implementation of management decision**

This step includes the implementation of the in the previous step selected preferred management options.

4. **Monitoring and review**

This is the process of monitoring and reviewing to assess the effectiveness of the measures taken, and a review of the risk management and/or assessment as necessary.

Next to the establishment of these four elements of risk management, the Consultation also identified eight basic principles that are to be taken into account during the food safety risk management process. These are as follows.

- Principle 1. Risk management should follow a structured approach.
- Principle 2. Protection of human health should be the primary consideration in risk management decisions.
- Principle 3. Risk management decisions and practices should be transparent.
- Principle 4. Determination of risk assessment policy should be included as a specific component of risk management.
- Principle 5. Risk management should ensure the scientific integrity of the risk assessment process by maintaining the functional separation of risk management and risk assessment.
- Principle 6. Risk management decisions should take into account the uncertainty in the output of the risk assessment.
- Principle 7. Risk management should include clear, interactive communication with consumers and other interested parties in all aspects of the process.
- Principle 8. Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions.
3.2 Comparison. Risk Management Process

Next to these 4 elements which serve as international standards/ guidelines during the food risk management process, it is particularly of interest to study how the three selected system have perceived these international standards/ guidelines and how they have established specific procedures in the context of risk management procedure in their own food safety framework. The system selected have established specific laws regarding the institutions involved in the risk management process and the same accounts to the management tools that are available to insert when a certain food risk incident arises. These aspects will be dealt with in this paragraph. In addition, the procedure to be followed in case of incident management as established in the Legal systems concerned will be dealt with.

3.2.1. European Union

According to the GFL, assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner. Hereto related it should be noted that in the European food safety system, risk assessment is done separately from risk management. However, the institution(s) involved in the risk assessment process work closely with risk managers throughout the European Union. According to the EU system the importance of the separation of responsibilities and functions between assessors and managers is generally recognized. Science should not be influenced by values and political issues; and management decisions almost always involve more than the science–based conclusions, even in those circumstances where the scientific conclusions can be expressed with some certainty. The EU system considers management goals to be more precise in terms of particular policy and legal contexts. The needs of risk management should therefore inform the way that the risk assessment is carried out. On the other hand, the needs of risk management will not always be compatible with what can be achieved through science. Therefore, it is strongly recognized that these differences in perceptions and responsibilities argue for close collaboration and the need of dialogue between assessors and managers.189

3.2.1.1. Involved Institutions

According to the General Food Law190 the European Commission, European Parliament and EU Member States are the key risk managers in the EU system. They are responsible for making European policies and taking decisions to manage risks associated with the food chain. For instance, this can involve adopting or revising European legislation on food safety, initiate emergency

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190 Article 53 et seq. General Food Law.
measures etc. In terms of risk assessment the European Food Safety Authority (EFSA) situated in Palermo (Italy) is the risk assessor. EFSA is established by the GFL,\(^{191}\) the authority is independent and deals with scientific advice, identifying emerging food safety risks, scientific opinion and technical support.\(^{192}\) EFSA works closely with risk managers throughout the European Union. EFSA’s main client is the European Commission, which has a key role in risk management at EU-level and frequently requests scientific advice from EFSA.\(^{193}\) The EFSA has four primary components\(^ {194}\): 1) Management Board (14 members + Commission); 2) Executive Director including staff; 3) Advisory Forum; 4) Scientific Committee including Panels. In case of emerging risks, the EMRISK unit of EFSA is responsible for establishing procedures to systematically collect up-to-date information and data in order to identify and analyze emerging risks in the field of food safety. This includes:

- coordinating risk assessments and identifying emerging risks;
- providing scientific and technical advice to the Commission, including in connection with crisis management;
- collecting and publishing scientific and technical data in areas relating to food safety;
- establishing European networks of organizations operating in the field of food safety.

Furthermore, the Directorate-General for Health and Consumer Protection (DG Sanco) which is a Directorate of the European Commission and aims to make Europe a healthier, safer place, where citizens can be confident that their interests are protected by reducing and managing risks, is responsible for Food Safety Risk Management.\(^ {195}\) With this respect the Directorate has the following tasks:

- Regulations and Directives in hygiene and food safety
- Food Control Harmonization
  - Rapid Alert System (RASFF)
  - Reference Laboratory network (CRLs & NRLs)

In conclusion, in the European Union involved institutions and the division of their tasks are established as follows. Risk assessment is carried out by EFSA and risk management by the applicable European Legislative bodies. The institutions work closely together which results in a close dialogue between the risk assessors and risk managers. The General Food Law clearly establishes that risk management shall take into account the results of risk assessment (based on scientific evidence) as

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\(^{191}\) Article 22 section 1 General Food Law

\(^{192}\) Article 22 section 2 et seq. General Food Law


\(^{194}\) Articles, 23, 24, 25, 26 General Food Law

conducted by EFSA. Furthermore, the law establishes the requirement for risk managers to take into account the scientific opinion of the authority concerned in particular.\footnote{Article 6 (1,2,3) General Food Law} Risk management in the European Union is therefore strongly based on risk assessment conducted, which also associates with the science-based approach to Food Safety Law.

3.2.1.2. Management tools

Article 17 of the General Food Law regulates the responsibilities of the Member States to enforce food law, and to monitor and verify that the relevant requirements of food law are fulfilled by food business operators. The General Food Law gives several possibilities to initiate measures aiming at reducing or eliminating the risk due to the placing on the market of unsafe foodstuffs and at preventing, reducing or eliminating the risk due to the placing of the market of food that may be injurious to health.\footnote{GUIDANCE ON THE IMPLEMENTATION OF ARTICLES 11, 12, 16, 17, 18, 19 AND 20 OF REGULATION (EC) N° 178/2002 ON GENERAL FOOD LAW Rationale Article 19, 20 Dec. 2014.} The General Food Law regulates, that for determining the proportionality of the actions taken to reduce or eliminate a risk, reference to the criteria for applying the concept of unsafe food\footnote{As laid down in Article 14 General Food Law} needs to be made. With this respect it should be noted that the measures available when an immediate action is necessary to eliminate a risk, are mainly withdrawal and recall. The General Food Law refers to withdrawal as the process of taking the product that is reasonably believed to be non-compliant with the food safety requirements, from the market where the product concerned has left immediate control of the food business operator. In this case it should be noted that the General Food Law is designed with the conception that the assurance of placement of safe foods on the market that comply with the food safety requirements, is primarily a responsibility of the food business operators.\footnote{Article 17 section 1 General Food Law}

Therefore, food business operators are expected to, if despite all science-based preventive measures that need to be taken, select a circulation of food that does not comply with the food safety requirements, take immediate action. Furthermore, if the food business operator considers that the food it has placed on the market is injurious to human health\footnote{Article 19 (3) General Food Law. In this case it suffices when the food business operator has "reasonable believe that the food is injurious to human health"} it immediately should notify the competent authorities thereof. In addition, where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal.\footnote{Article 19 (1) General Food Law} Another management tool is that of product recall. This applies when the product that is believed to be non-compliant with the requirements of Food Safety Law has been supplied to the consumer.

\footnotetext[196]{Article 6 (1,2,3) General Food Law}
\footnotetext[197]{GUIDANCE ON THE IMPLEMENTATION OF ARTICLES 11, 12, 16, 17, 18, 19 AND 20 OF REGULATION (EC) N° 178/2002 ON GENERAL FOOD LAW Rationale Article 19, 20 Dec. 2014.}
\footnotetext[198]{As laid down in Article 14 General Food Law}
\footnotetext[199]{Article 17 section 1 General Food Law}
\footnotetext[200]{Article 19 (3) General Food Law. In this case it suffices when the food business operator has "reasonable believe that the food is injurious to human health"}
\footnotetext[201]{Article 19 (1) General Food Law}
This management tool shall only be implemented as a last resort when other measures are not sufficient to achieve a high level of health protection. Consequently, with regards to the application of management tools the general Food Law provides the applicability of sequence, recall shall only follow when the measures of withdrawal are not sufficient enough.

3.2.1.3. Incident management

Notwithstanding the primary responsibilities of the food business operators to insert management tools and closely collaborate with the competent authorities in case of food incidents, in some cases when an incident turns into an emerging event, intervention of competent authorities on European level is necessary. The General Food Law provides emergency procedures in the interest of management of such incidents. The General Food Law provides with two procedures to be followed depending on the gravity of the incident. It distinguishes incidents that should be identified as emergencies, where emergency procedures need to be followed and emerging incidents that even require crisis management.

Emergencies

The General Food Law confers special powers to the European Commission for taking emergency (protective) measures. According to the General Food Law an emergency is applicable when it is evident that a food originating in the EU, or imported from a third country, is likely to constitute a serious risk to human health, animal health or the environment, and that such a risk cannot be contained satisfactorily by means of measures taken by the Member States. When an emergency is identified, action can be initiated by the Commission itself, or be requested by a Member State. Depending on the gravity of the situation, emergency measures can take the form of:

- a suspension of the marketing or use of the feed or food in question (suspends the placing on the market or use of products originating from the EU; suspends imports of products originating from third countries);
- subjecting the use and marketing of the food to special conditions; or
- any other appropriate interim measure.

In case following information from a Member State on the need to take emergency measures, the Commission does not initiate the procedure for the adoption of emergency measures at Community level, the Member State in question may adopt interim protective measures. The Member State may

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202 Article 19 (1) General Food Law
203 Article 2 General Food Law
204 Article 3 General Food Law
205 Article 53 (1) General Food Law
206 Article 53 (1,b,c) General Food Law
maintain its national interim protective measures until a Community decision has been adopted concerning the extension, amendment or abrogation of the said measures.207

Crisis management
The General Food Law provides for the establishment of a general plan for food/feed crisis management and the creation of a Crisis Unit. This Crisis Unit will be set up by the Commission in cases where the Commission identifies a serious direct or indirect risk to human health deriving from food and feed and the risk cannot be managed adequately by application of existing provisions, in particular the emergency procedures. The European Food Safety Authority (EFSA) will participate in the crisis unit and provide scientific and technical assistance. The Crisis Unit will be responsible for collecting and evaluating all relevant information and identifying the options available to prevent, eliminate or reduce the risk at stake. The Crisis Unit will keep the public informed of the risks involved and the measures taken.

Crisis-management plan
In case of situations entailing direct or indirect risks to human health which are not likely to be prevented, eliminated or reduced to an acceptable level by the management tools in place or cannot adequately be managed solely by way of application of the emergency procedures as mentioned before, EFSA and the Member States may establish a general crisis-management plan.208 Similarly, in the case of a serious risk, which cannot be dealt with under the existing provisions, the Commission must immediately set up a Crisis Unit, in which EFSA participates by providing scientific and technical support. The crisis unit is responsible for collecting and evaluating all relevant information and identifying the options available for preventing, eliminating or reducing the risk to human health.209

Finally, it should be noted that although Article 17 of the General Food Law holds the Member States responsible for the enforcement of food law. European food law increasingly sets standards for national enforcement and provides supervision. Consequently, European food law does not provide a comprehensive approach of punishment in terms of non-compliance. Therefore the nature of the sanctions, administrative or criminal, is left entirely to the discretion of the member states. The commission in its draft intended to impose the use of criminal on the Member States, but this intention did not survive the legislative process.210

207 Article 54 General Food Law
208 Article 53 (2) General Food Law
209 Article 56 General Food Law
210 Van der Meulen & Van der Velde, 2011, P. 409.
3.2.2. United States of America

First, it should be noted that the US similarly to the EU, follow the risk analysis concept of the Codex Alimentarius, which is the functional separation of risk assessment from risk management. Consequently, the US system considers the concept that policy decisions about food depend on a continuous dialogue between policy makers (“risk managers”) and scientists who produce data that inform those decisions (“risk assessors”) as built into the risk analysis framework. According to the US system this not only helps ensure that policy decisions are relevant, but also the decisions are objective; and are based on science.211

3.2.2.1. Involved Institutions

In the specific area of food safety, the US Food and Drug Administration (FDA)212 is the leading organization concerned with the overall concept of risk analysis in the context of food safety in the US. The FDA uses risk analysis, which as previously mentioned, is a framework fostered by the World Health Organization, to ensure that regulatory decisions about foods are science-based and transparent.213

The FDA is a federal agency of the United States Department of Health and Human Services (Health Department) which is a cabinet level executive department of the US federal government. The Health Department aims to protect the health of all Americans and to provide essential human services. As a part of the Health Department, the FDA is responsible for protecting and promoting public health through regulation and supervision of several areas ranging from food safety, drugs (medications) to tobacco products etc.. The FDA is empowered by the US Congress to enforce the FD&C Act (Federal Food, Drug and Cosmetic Act), which serves as the primary focus of the Agency.214 Within the FDA the responsible institution for promoting and protecting public health by ensuring the US food supply is safe, is the Center for Food Safety and Applied Nutrition (CFSAN) in conjunction with FDA field staff. Furthermore, in ensuring the Nation’s commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged, the Food Safety and Inspection Service (FSIS) is the responsible public health agency. FSIS is a part of the United States Department of Agriculture (USDA).215 Hence, in the US Legal system the management of food safety is divided in two areas: 1) the overall safety of the food supply and; 2) the safety of commercial supply and labeling of meat, poultry and egg products in specific. In the following this should be taken into

212 The Agency is led by the Commissioner of Food and Drugs, currently Stephen Ostroff who is (as from January 2015) appointed by president Barack Obama.
214 The FDA also enforces other laws, notably Section 361 of the Public Health Service Act and associated regulations, many of which are not directly related to food or drugs. These include regulating lasers, cellular phones, condoms and control of disease on products ranging from certain household pets to sperm donation for assisted reproduction.
account, hence the USDA is responsible for emergency response in case of meat, poultry and egg products (commercial supply). The FSIS accomplishes risk assessment, inspection of interstate commerce and imported products, based on the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA) and Egg Products Inspection Act (EPIA). The inspection, control and response of the FSIS is based on US Food Safety Law as established in the Food Safety and Modernization Act. Therefore, the analysis in the following subparagraph applies to specific agricultural products as well. However, the differences in oversight of certain products and responsible institutions thereof should be taken into account.216

What concerns the execution of assessing risks of foodstuff in general, the FDA’s Center for Food Safety and Applied Nutrition (CFSAN) is involved in both assessing and in managing risks, even though in all cases, the two activities are functionally separated.217 Built into the CFSAN risk analysis framework is the concept that policy decisions about food depend on a continuous dialogue between policy makers (“risk managers”) and scientists who produce data that inform those decisions (“risk assessors”).218 Notwithstanding the fact risk assessment and risk management are considered functionally separated, in the US system a single institution (FDA- CFSAN) is concerned with the execution and management of all elements of risk analysis which involves the integration and coordination of activities associated with risk assessment as well as risk management and risk communication. To what concerns the way the different steps of risk assessment and risk management are dealt with, a working group is organized by CFSAN that is to evaluate and improve the quality and consistency of major risk assessments conducted by the Center. As a result of risk analysis experiences, CFSAN developed a practical framework for initiating and managing risk assessments, including addressing issues related to (1) commissioning a risk assessment, (2) interactions between risk managers and risk assessors, and (3) peer review. Furthermore, the importance of public input is also built into the framework, according to the FDA to help ensure the real world relevance and feasibility of CFSAN’s policy decisions, as well as transparency.219 For example, when CFSAN undertakes a project that will inform a policy decision, the Agency posts Federal Register notices to request input from the public, including the food industry and consumer groups, and may also hold public meetings.

The fact is, in the US regulators have a mandatory duty to respond in writing to comments by stakeholders regarding risk assessments.220 It could be considered the US system regards risk management as a process separate from risk assessment. However, it adopts a decision-based approach to identify and select risk assessments particularly those considered major (complex and

216 USDA (FSIS) specific control plans will be left out in this study. Focus will be mainly on federal FDA intervention.
219 Ibid.
impacting or involving multiple offices). This indicated that risk assessment and risk management are very closely related. However, risk management is to be considered the overarching process involving transparency by inviting the public to the decision-making and considering all stakeholders involved.

3.2.2.2 Management tools

The Food Safety and Modernization Act provides science-based preventive management tools to food business operators such as mandatory preventive controls for food facilities; mandatory produce safety standards; authority to prevent intentional contamination. Therefore, the US government expects the food business operators shall abide their responsibilities to ensure food safety in all steps of the food supply chain. However, the FSMA recognizes that the FDA must have tools to respond effectively when problems emerge despite the attempts of science-based preventive controls across the food supply. Firstly, mandatory recall could be issued when a company fails to voluntarily recall unsafe food after being asked to by the FDA. Before the FSMA, the FDA had to rely on a firm’s voluntary decision to remove food from the marketplace that could be hazardous to humans or animals. Under the FSMA, the agency can order a recall if the company does not cease distribution itself and recall its product. Mandatory recall is applicable when there is a reasonable probability that an article of food is adulterated under section 402 or misbranded under section 403(w) and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals. The FDA in that case provides the responsible party with an opportunity to cease distribution and recall such article. If the responsible party delays in recalling, the FDA can recall it and the responsible party shall pay for the fees for this service. Next to the mandatory recall, the FDA has powers to impose administrative detention and expand this if necessary. The FSMA provides the FDA with a more flexible standard for administratively detaining products that are potentially in violation of the law (administrative detention is the procedure the FDA uses to keep suspected food from being moved). Another, but more far-reaching measure is the suspension of registration. The FDA can suspend registration of a facility if it determines that the food poses a reasonable probability of serious adverse health consequences or death. A facility that is under suspension is prohibited from distributing food. There are several other tools the FDA has powers to use, however are left out towards relevance.

3.2.2.3 Incident Management

The US system provides emergency procedures in case of food safety emergency that arise on State/Federal level. The US system establishes the so-called public health emergency procedures to be

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222 21 USC. 321. under section 206 of the FD&C Act

223 As defined in 21 USC. 321. under section 417 of the FD&C Act

224 21 USC. 321. under section 207 of the FD&C Act

225 21 USC. 321. under section 102 (b) of the FD&C Act
followed on federal level, these emergencies differ from nature disasters such as earthquakes; terrorism, to food safety issues. Consequently, food safety emergencies that require rapid intervention are primarily dealt with on FDA (federal) level. Focusing on food safety incidents, the FSMA refers to national emergency framework in case of emergency procedures to be followed. It should be noted that with this respect the FDA has established the Regulatory Procedures Manual which constitutes a reference manual for FDA personnel. The manual provides information on internal procedures to be followed in case of Inspections, Compliance, Enforcement, and Criminal Investigations to be used in processing domestic and import regulatory and enforcement matters. Chapter 8 of this procedural manual establishes procedures to be followed in case of emergency matters. Its purpose is to set forth emergency management procedures for the Food and Drug Administration's headquarters and field personnel resulting from various Presidential Decision Documents, the Stafford Disaster Relief and Emergency Assistance Act, and the National Response Framework.

To come back to food safety incident management that require intervention beyond the food safety tools imposed by the FDA as provided by the FSMA, Section 108 of the Food Safety and Modernization Act concerning the National Agriculture and food defense strategy is applicable. It refers it shall be consistent with (A) the National Incident Management System; (B) the National Response Framework. The National Incident Management System (NIMS) provides a systematic, proactive approach to guide departments and agencies at all levels of government, nongovernmental organizations, and the private sector to work seamlessly to prevent, protect against, respond to, recover from, and mitigate the effects of incidents, regardless of cause, size, location, or complexity, in order to reduce the loss of life and property and harm to the environment. NIMS works hand in hand with the National Response Framework (NRF). NIMS provides the template for the management of incidents, whilst the NRF provides the structure and mechanisms for national-level policy for incident management. In General the FSMA establishes that the strategy needs to include a description of the process to be used by the Department of Health and Human Services, the Department of Agriculture, and the Department of Homeland Security in order to achieve the goals

226 21 USC. 321. under section 108 of the FD&C Act concerning the National Agriculture and food defense strategy
set out in the implementation plan.\textsuperscript{229} This plan\textsuperscript{230} needs to consist of different goals: 1) preparedness goal; 2) detection goal; 3) emergency response goal and 4) recovery goal.\textsuperscript{231}

Briefly explained, the preparedness goal aims to enhance the preparedness of the agriculture and food system by:

1. conducting vulnerability assessments of the agriculture and food system;
2. mitigating vulnerabilities of the system;
3. improving communication and training relating to the system;
4. developing and conducting exercises to test decontamination and disposal plans;
5. developing modeling tools to improve event consequence assessment and decision support;
6. preparing risk communication tools and enhancing public awareness through outreach.

The second goal that needs to be incorporated in the plan, the detection goal, aims to improve agriculture and food system detection capabilities by:

1. identifying contamination in food products at the earliest possible time;
2. conducting surveillance to prevent the spread of diseases.

The third goal, emergency response goal, is to ensure an efficient response to agriculture and food emergencies by:

1. immediately investigating animal disease outbreaks and suspected food contamination;
2. preventing additional human illnesses;
3. organizing, training, and equipping animal, plant, and food emergency response teams of— (I) the Federal Government; and (II) State, local, and tribal governments;
4. designing, developing, and evaluating training and exercises carried out under agriculture and food defense plans;
5. ensuring consistent and organized risk communication to the public by— (I) the Federal Government; (II) State, local, and tribal governments; and (III) the private sector.

The fourth goal, the recovery goal, is to secure agriculture and food production after an agriculture or food emergency by:

1. working with the private sector to develop business recovery plans to rapidly resume agriculture, food production, and international trade;
2. conducting exercises of the plans described in the emergency response goal subparagraph with the goal of long-term recovery results;

\textsuperscript{229} 21 USC. 321. under section 108 under 1 (b) of the FD&C Act
\textsuperscript{230} 21 USC. 321. under section 108 under 2 of the FD&C Act
\textsuperscript{231} 21 USC. 321. under section 108 under 2 (a) et seq. of the FD&C Act
3. rapidly removing, and effectively disposing of— (I) contaminated agriculture and food products; and (II) infected plants and animals;
4. decontaminating and restoring areas affected by an agriculture or food emergency.

In conclusion to these goals, it should be noted evaluation finally takes place in coordination with the Secretary of Agriculture and the Secretary of Homeland Security. In this evaluation metrics to measure progress for the evaluation shall be developed and report on the progress shall be measured. Consequently, the US system provides far reaching management tools to the FDA in order to manage food safety through the food supply chain. The FSMA firstly establishes food safety requirements and responsibilities to the food business operators to apply science- based preventive measures. In case of non-compliance with these requirements, the FDA is authorized to impose the different management tools as discussed previously. In case of an emerging food safety incident such as a crises arises that requires far reaching intervention, national federal emergency procedures apply. In this case the FDA is provided with internal emergency procedures and a national agriculture and food defense strategy shall be compiled and executed in compliance with national response framework.

232 21 USC. 321. under section 108 under 3 of the FD&C Act
3.2.3. China

In China’s food law system the concept of risk management is a main principle. The Law states: "Food safety work shall abide by the principles of putting prevention first, risk management, whole process control, and making efforts by the whole society", according to the law, aiming to establish the strictest regulatory system. This implies that the concept of risk management plays a significant role in the food safety framework. The concepts of risk assessment and risk management are both incorporated in China’s Food Safety Law. The law is clear about the characterization of risk assessment which is science-based. China establishes the food safety risk assessment mechanism to assess the risks on biological, chemical and physical hazardous factors in foods, food additives, and food related products. The law however, does not clearly define the concept of risk analysis and its elements. However, the structure of the law shows us that food safety risk assessment is closely related to international standards and international food safety risk assessment (Codex). In its food law development, Codex provides China with valuable guidance through the reform of its national food safety control system and development of new food safety legislation and national food standards, serving as an important international reference point in the development of Chinese domestic food regulations. In fact it is established that the formulation of national food safety standards needs to refer to the result of food safety risk assessment. In addition, food safety risk assessment results are the scientific basis for developing and modifying food safety standards, as well as food safety regulatory work (risk management). Furthermore, according to the law, the risk management process shall consider opinions from food producers, traders and consumers. In conclusion it could be considered that in China’s food safety framework risk analysis is applied, with risk assessment as a basic tool for risk management (decision- and law making).

3.2.3.1 Involved Institutions

In China’s food law framework several institutions are involved. There is no unified administrative organ/authority to deal with all the issues relating to food safety. However, short after the enactment of PRC Food Safety Law in 2009 it soon appeared that from the regulatory perspective a key component of strengthening Food Safety Management, was improving ministerial coordination. Therefore the State Council created a central governing body, the Food Safety Commission (FSC)

233 Article 3 PRC Food Safety Law revised Amendment
234 Article 17 PRC Food Safety Law revised Amendment
235 Article 28 PRC Food Safety Law revised Amendment
237 Article 28 PRC Food Safety Law revised Amendment
238 Ibid.
established in 2010 to supervise and coordinate food safety matters. With this, the State Council created a central governing body, to manage all government food safety work.

The National Food Safety Commission is established by the State Council as laid down in article 5 of the PRC Food Safety Law. From 2010 China has been reforming its supervision mechanism mainly to integrate overlapping institutions and tasks and increase centralization of supervision on ministerial level. Currently the division of food safety supervision mechanism is regulated as follows:

- China Food and Drug Administration (CFDA);

The China food and drug regulatory department under the State Council, in accordance with this law and the responsibilities identified by the State Council, is responsible for regulating food production and trading activities, and undertakes the daily work of the Food Safety Commission.

In 2013 this regulatory body was rebranded and restructured elevated to a ministerial- level agency. It replaced a large group of overlapping regulators with an entity streamlining regulation processes for food and drug safety. The CFDA is directly under the PRC State Council and is in charge of comprehensive supervision on the safety management of food, health and cosmetics and is the competent authority of drug regulation.

- The National Health and Family Planning Commission (NHFPC)

The ministry is created from the former Ministry of Health (MOH) and National Population and Family Planning Commission. In the reforms of 2013 the Ministry of Health has been dissolved and its functions have been integrated into the new agency, the NHFPC. This was announced at the 2013 National People's Congress. The NHFPC conducts food safety risk surveillance, risk assessment, develops and publishes national food safety standards.

- General Administration of Quality Supervision Inspection and Quarantine (AQSIQ);

The AQSIQ is a ministerial- level department under the State Council as well. It regulates safety of food imports and exports. It is in charge of national quality, metrology and entry-exit commodity

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241 It should be noted that only the main institutions in the interest of the subject will be highlighted.

242 Article 5 PRC Food Safety Law revised Amendment


244 Article 91 PRC Food Safety Law revised Amendment

inspection amongst other in the interest of food safety. In addition, it is in charge of certification and accreditation, standardization, as well as administrative law enforcement.\textsuperscript{247}

- Ministry of Agriculture (MOA)

MOA is an executive state agency within the government of the People's Republic of China. Areas of responsibility include agriculture and environmental issues relating to agriculture, fishery, consumer affairs, animal husbandry, higher education and research in the field of agricultural sciences etc. The Ministry is officially formed in 1954.\textsuperscript{248} In the interest of food safety, MOA is involved in the safety of edible agricultural products. Hereafter it should be noted that next to foods\textsuperscript{249} PRC Food Safety Law covers also primary agricultural products for consumption (edible agricultural products). However, only the development of quality and safety standards of relevant edible agricultural products and the publication of information of the safety thereof falls under the scope of PRC Food Safety Law. Other responsibilities applicable to edible agricultural foods fall under the Law of the People’s Republic of China on Quality and Safety of Agricultural Products.\textsuperscript{250}

According to the law the NHFPC is responsible for organizing food safety risk assessments. An expert committee on food safety risk assessment which is composed of experts on medical science, agriculture, food and nutrition is established to conduct the food safety risk assessment. As mentioned before, for risk assessment science based methods shall be used. The assessment needs to be conducted based on food safety risk surveillance information, scientific data and other relevant information.\textsuperscript{251} If the CFDA, AQSIQ and/or MOA, find it is necessary to conduct food safety risk assessment in their regulatory work, they shall propose to NHFPC to conduct food safety risk assessment and provide the following information and materials needed.\textsuperscript{252} Furthermore, food safety risk assessment shall be conducted when the following situation occur:

1. Food safety risk surveillance or report reveal possible safety problem for food, food additives, and food related products;
2. Need to provide science basis for developing or revising national food safety standards;
3. Risk assessment is necessary to identify prioritized area or (food) variety in regulatory work;
4. Discovered factors that may cause harm to food safety;
5. Need to judge whether a factor constitutes food safety risk;

\textsuperscript{247} China gov. Website: AQSIQ. ‘Who we are’. Retrieved from: <http://www.aqsiq.net/>.
\textsuperscript{249} Definition of food in article 154 PRC Food Safety Law: 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.
\textsuperscript{250} Article 2 PRC Food Safety Law Revised Amendment
\textsuperscript{251} Article 17 PRC Food Safety Law Revised Amendment
\textsuperscript{252} Article 19 PRC Food Safety Law Revised Amendment
6. Other situations the NHFPC deems necessary to conduct risk assessment.

In case of food safety risk assessment and quality safety risk assessment of edible agricultural products MOA and NHFPC keep close collaboration.

3.2.3.2. Management tools

Similar to the EU and US food law system, China’s food law system emphasizes the responsibility of the food industry, in this case, food producers and traders as to be the first persons responsible for food safety. According to China’s Food Safety Law they need to take management responsibilities of their production and trading activities. PRC Food Safety Law provides the opportunity for food business operators to establish self-examination system; regularly examine their own food safety situation. However, if despite the preventive control measures of the food business operators products are believed to be unsafe, CFDA (in case of foodstuff circulating the market) and AQSIQ (in case of (boarder) import-export products) shall immediately take actions. In first instance if the food producer/trader notices that the production and trading condition changes and do not comply with food production and trading requirements, they shall immediately take rectification measures, if potential food safety incident risk exists, the producer/trader shall immediately terminate production and trade, and report to the county level food and drug regulatory department where it locates.

Furthermore, the law established a food recall system. In case a food producer finds that the food being produced is non-compliant with food safety standards or has evidence the food may harm human health, the food producer shall immediately stop production in first instance. In addition, the food producer is responsible to recall the food product released to the market and notify relevant producers, traders and consumers. Moreover, it shall create a record of recalls and notifications. In case of food traders the same applies, however it shall, other than in case of the producer, notify relevant producers, traders and consumers, and create a record of the trading suspension and notifications. Other actions that are expected to be taken by the producers and traders in case of preventing already entered food to re-enter into the market, are, remedy, removal of harm, or destruction. However, products recalled due to incompliant label, mark or instructions could be sold after the producers take remedy measures and guarantee safety of the food; such remedy measures

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253 Article 18 PRC Food Safety Law revised Amendment
254 Article 20 PRC Food Safety Law revised Amendment
255 Article 4 PRC Food Safety Law revised Amendment
256 Article 21 PRC Food Safety Law revised Amendment
257 Article 47 PRC Food Safety Law revised Amendment
258 Article 63 PRC Food Safety Law revised Amendment
259 Ibid.
shall be informed to consumers while the product is sold. In the event that a food producer or trader fails to recall or stop trading of the food, the county and above level food and drug regulatory departments could order it to recall or stop trading of the food.\textsuperscript{260}

China established the food safety risk surveillance system, which monitors food-borne diseases, food contamination and other food-related hazards.\textsuperscript{261} This happens in collaboration with CFDA, AQSIQ and NHFPC. The CFDA and other departments verify the food safety risk information they receive, and immediately report the information to the NHFPC.\textsuperscript{262} In case if food safety risk surveillance analysis result reveals hidden food safety risk, the county and above level health department shall notify relevant information to the food and drug regulatory department and the government of the same level, and to the health department of the higher level. The food and drug regulatory department shall conduct further investigation into the hidden food safety risks detected in the risk surveillance process.\textsuperscript{263} If the investigation reveals possible safety problems, food safety risk assessment shall be carried out by the NHFPC. If then the authorities after a risk assessment conclude that a food is unsafe, the CFDA and AQSIQ shall immediately take actions. They shall make sure production and trading activity of the food are terminated; they shall inform consumers to stop consumption or usage of the product; if necessary, the NHFPC shall immediately formulate or modify the relevant food safety national standards.\textsuperscript{264}

3.2.3.3 Incident management

Chapter 7 of PRC Food Safety Law deals specifically with handling of food safety incidents. The law strongly involves the food producers and food traders into the incident management process. It states that food producers and traders are responsible to develop a response plan for food safety incidents, regularly inspect the implementation of preventative measures related to food safety, and eliminate potential food safety risks in a timely manner.\textsuperscript{265} Thus, the law clearly applies a preventive approach to food safety risks establishing responsibilities thereof to the food producers and traders in the first place. Furthermore, it is established that the State Council is the party that organizes the formulation of national emergency plans for food safety incidents. Based on relevant laws, regulations, and the emergency plan of the higher level government, as well as considering the local situation, county and above level governments shall formulate emergency plans for food safety incidents in the prefecture; the plan shall be filed to the higher level government for record. Consequently, on lower

\textsuperscript{260} Article 63 PRC Food Safety Law revised Amendment  
\textsuperscript{261} Article 14 PRC Food Safety Law revised Amendment  
\textsuperscript{262} Ibid.  
\textsuperscript{263} Article 16 PRC Food Safety Law revised Amendment  
\textsuperscript{264} Ibid.  
\textsuperscript{265} Article 102 PRC Food Safety Law revised Amendment
level government the emergency plan is primarily based on higher level plans but taking the local conditions into account as well. The content of the emergency plan needs to have provisions for:

1. grading of incidents;
2. commanding system for incident handling and its responsibilities;
3. prevention and early warning system;
4. incident handling procedure and measures guarantee enabling the emergency incident handling.

Furthermore, in the event that a food safety incident occurs overseas and may impact China, or a major food safety problem is detected in imported food, food additive or food related products, AQSIQ shall issue a risk alert or take control measures in a timely manner and notify the CFDA, NHFPC, and MOA.

Next to the responsibilities of the governments and food industry, the law also mentions other entities in case of the management process of food safety incidents. It regulates that entity having a food safety incident shall take immediate actions to prevent spreading of the incident. The entity and medical institutes receiving/treating patients shall immediately report to the county level food and drug regulatory department and health department where the incident takes place. An important aspect with this respect is that the law regulates that any entity or individual is forbidden to conceal, lie about, or delay the reporting of the food safety accident, or hide, forge or destroy relevant evidence.

The law pays close attention to medical institutes as to be an important role player within the food safety incident management procedure. It establishes the responsibility for the medical institute to timely report to the county-level health department of discoveries of patients to be sick caused by food-borne disease, food poisoning, or possible food-borne disease and food poisoning. In this case the county level health department shall immediately inform the food and drug regulatory department of the same regulatory level when it is believed the disease is related to food safety. In this case when the health department discovers in its investigation that it concerns an infectious disease or other public health incident outbreak, it shall inform the food and drug regulatory department immediately. Upon receiving the food safety incident report, the county and above level food and drug regulatory department shall immediately conduct investigations into the incident, jointly with the health department, the agriculture department and the quality supervisory

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266 Article 102 PRC Food Safety Law revised Amendment
267 Article 95 PRC Food Safety Law revised Amendment
268 Article 103 PRC Food Safety Law revised Amendment
269 Article 104 PRC Food Safety Law revised Amendment
department of the same level; they shall take the following measures to prevent or diminish the harm to the public:\textsuperscript{270}

1. Deploy emergency rescue, arrange first aid and treatment to the persons injured in the food safety accident;
2. Seal up the food and raw materials likely causing the food safety accident and conduct immediate testing; for the food and raw material that are confirmed to be contaminated, order the food producer and trader to recall, suspend operation, and destroy the product according to previous mentioned management tools;
3. Seal up the contaminated tools and devices, issue order to have the tools and devices cleaned and sterilized;
4. Properly handle news release; disclose information of food safety accidents and the treatment thereof in accordance with laws, provide explanations and clarifications possible harms.

In the event of an outbreak of a food safety incident, sanitary treatment shall be implemented at the site and epidemiology investigation shall be deployed into relevant factors of the incident, which shall be assisted by relevant departments. An epidemiology investigation report shall be submitted to the food and drug regulatory department and health department of the same level. In the event of a food safety incident that activates the emergency plan, above level government shall handle the food safety incident according to the emergency plan concerned. The city and above level government shall immediately work with relevant departments and carry out investigations to determine responsible party of the incident; they shall urge relevant departments to perform their duties, and submit an investigation report identifying responsibilities to the government of the same level. Furthermore, in case a major food safety accident which involves more than two provinces, the CFDA shall organize the investigation into responsibility of incident according to national regulation:\textsuperscript{271}

In conclusion, the law clearly emphasizes the urge of an integer science–based investigation in case of food safety incidents. It regulates that it is required to timely and accurately determine the nature and reason of the incident, identify responsible party of the incident, and propose improvement measures. In addition, it calls upon a certain transparency. It regulates that in identifying the responsible party for the food safety incident, the investigation shall also identify any negligence or misconduct by regulatory and licensing/certification departments, as well as the responsible staff within the licensing/certification institutions.\textsuperscript{272}

\textsuperscript{270} Article 105 PRC Food Safety Law revised Amendment
\textsuperscript{271} Article 105 PRC Food Safety Law revised Amendment
\textsuperscript{272} Article 107 PRC Food Safety Law revised Amendment
3.3 Conclusions: A Structural Comparison

In this paragraph the results of the variables will be compared (structural comparison).

Variable K (The basics of risk analysis). EU food law establishes the Codex risk analysis concept and as a consequence considers the distinction between risk assessment and risk management. US Food Law, similarly to the EU, establishes the Codex risk analysis concept as well and as a consequence the distinction between risk assessment and risk management. PRC Food Safety Law however, does not follow the Codex risk analysis concept and therefore the distinction between risk assessment and risk management is unclear. Risk management could be considered the main principle in PRC Food Safety Law and risk assessment is the scientific basis. However, the law does not establish the risk communication concept, rather it involves certain aspects of transparency and government risk communication in its legal framework. Notwithstanding, the results demonstrate all three Legal systems establish a science-based approach to Food Safety Law.

Variable L (Involved Institutions). In EU food law the Member States and the European Commission (DG Sanco) are risk managers in the food risk management process. The General Food Law establishes the European Food Safety Authority (EFSA) and identifies this authority as a neutral organization. In EU food law EFSA is the risk assessor. US food law provides for a distinction in oversight: the FDA is the responsible organization with regard to foods in general, the USDA is responsible in case of agricultural food products: poultry, meats and eggs. Therefore, in case of foods in general the FDA is risk manager and the USDA is risk manager in case of poultry, meats and eggs. Consequently, US food law, unlike EU food law, does not provide in a neutral distinct organization for the execution of risk assessment. With this respect risk assessment is carried out by a certain department belonging to the risk manager. In case of foods in general CFSAN (under the FDA) and in case of poultry, meats and eggs FSIS (under the USDA). PRC Food Safety Law, similarly to the US, provides for a distinction in oversight. In case of foodstuff in general the CFDA is the main risk assessor. However, if the situation concerns quality standards or an imported-exported food product, the AQSIQ is the risk manager. If the situation concerns an edible agricultural product as defined by the law, the Food Safety Management process falls under the supervision of agricultural policy and MOA is the risk manager. Risk assessment is in all cases carried out by the Ministry of Health (NHFPC).

Variable M (Management Tools). The General Food Law provides for a first responsibility for the food business operators to voluntarily take measures and cooperate with the Member State concerned. With this respect the General Food Law provides for sequence in inserting management tools. 1) withdrawal and 2) recall. The measures are based on the concept of "a reason to believe the food is unsafe". This is considered to be the first responsibility of the food business operator.
concerned to signalize and further cooperate with the applicable authorities of the Member State concerned. Further measures are not provided by the law and are up to the Member States to decide upon. Unlike EU food law, US food law emphasizes FDA’s powers and leading role in assuring food safety (prevention, response, inspection and compliance). The FSMA provides for far reaching tools to be inserted by the government (FDA). The FDA is authorized to insert the next enforcement tools (in the context of response), mandatory recall, expanded administrative detention, suspension of registration and enhanced product tracing abilities. With this respect the FSMA recognizes that FDA must have the tools to respond effectively when problems emerge despite preventive controls. PRC Food Safety Law at the other hand, establishes a twofold Food Safety Management system. First it establishes the Food Producer and Food Trader food safety self-examination system. This management system constitutes a preventive response mechanism. The food producers and food traders are required to regularly examine their own food safety situation. If the production and trading condition changes and does no longer comply with food safety requirements, the producer and trader shall immediately take rectification measures; if potential food safety incident risk exists, the producer/trader shall immediately terminate production and trade, and report to the county level food and drug regulatory department where it locates. Second, parallel to the industry Food Safety Management system, PRC Food Safety Law establishes the Food Safety Risk surveillance system, which is carried out by the authorized government institutions and monitors food-borne diseases, food contamination and other food-related hazards. NHFPC, CFDA and AQSIQ jointly develop and enforce the national food safety risk surveillance plan.

Variable N (Incident Management System).

The General Food Law provides for an emergency procedure and, when the emergency procedure does not suffice for the situation occurred, the law provides with a crisis management procedure (Crisis Management Plan and Crisis Unit). However, first the law considers cooperation of the food business operator with the Member State concerned in case of a certain food safety incident. US food law on the other hand, when the management instruments of the FDA do not suffice, refers to national emergency framework (e.g. National Response Framework) in case of emerging incidents. With this respect, intervention on Federal level will be applicable. PRC Food Safety Law establishes a response plan for Food Producers and Food Traders in case of food safety incidents. However, when this appears not sufficient in ensuring food safety throughout the food supply chain, the applicable government level food and drug regulatory department will intervene. Dependent on the situation, the county level department will draw a food safety incident emergency plan in accordance with the State Council Emergency Plan and file at the higher level government for record.

Following an overview of the conclusions of the structural comparison is provided in a table sheet.
<table>
<thead>
<tr>
<th>Legal system</th>
<th>EU</th>
<th>US</th>
<th>China</th>
</tr>
</thead>
</table>
| **K** The Basics of Risk analysis | - Science- based approach  
- Distinction between risk assessment and risk management  
- Risk communication concept  
* Risk analysis conform Codex | - Science- based approach  
- Distinction between risk assessment and risk management  
- Risk communication concept  
* Risk analysis conform Codex | - Science- based approach  
- Risk management main principle  
- No clear Risk analysis concept  
- Risk assessment scientific basis  
- No risk communication concept  
* Partial Codex risk analysis |
| **L** Food Safety Management: Involved Institutions | - EU Commission (DG Sanco)- (risk manager)  
- Member States (risk manager)  
- EFSA (risk assessor & neutral)  
- Cooperation of members  
* Preliminary responsibility FBO’s (self-regulatory system) | - Distinction in oversight: 2 areas  
- FDA (overall oversight)  
- USDA - poultry, egg, meats  
- FDA/ CFSAN (risk manager and risk assessor)  
- USDA/FSIS (risk manager and risk assessor)  
* Preliminary responsibility food industry (emphasis food supply chain) | - No unified administrative organ  
- Risk management Ministerial level (CFDA, AOSIQ, MOA)  
- Distinction in oversight: 2 areas (foods & edible agricultural products)  
- CFDA (foodstuff general)  
- AOSIQ (quality and import/ export)  
- MOA (quality and safety standards of edible agricultural products)  
- NHFPC (risk assessor)  
* Preliminary responsibility food traders (FT) and producers (FP) (ensure safety). |
| **M** Management tools | - Proportionality based on “unsafe foods” concept  
- Either voluntarily by FBO in cooperation with MS  
- When FBO fails by MS  
- Sequence: Withdrawal and Recall  
- Measures up to Member States | - Based on adulteration and misbranding concept  
- FDA takes action  
- First: Voluntary recall food business  
- Mandatory recall  
- Administrative detention  
- Suspension of registration  
- Enhanced product tracing abilities  
- Additional recordkeeping for high risk foods (issue proposed rulemaking to establish recordkeeping requirements designates as high-risk foods). | - Based on 1) Food Safety Risk Surveillance & 2) FP/FT food safety self-examination system  
- 1. CFDA and AOSIQ take action:  
- Recall and stop trading when failed by FP/ FT  
- terminating production and trade activity  
- Inform consumer stop to consume/ usage  
- Formulate/ Modify food safety national standards.  
- 2. FP and FT take action:  
- Conditions not in compliance: rectification measures.  
- Potential food safety incident risk exists: termination production and trade and report county level CFDA. |
| **N** Incident Management System | - FBO in cooperation with Member State concerned.  
- Emergency procedure.  
- Crisis management → Crisis Unit and  
- Crisis management Plan (EFSA and Member States). | - When FDA– tools do not suffice, intervention on FDA/ federal level.  
- Emerging incidents such as crises intervention of national emergency framework.  
- National Agriculture and food defense strategy.  
- the National Incident Management System; the National Response Framework. | - FP and FT response plan.  
- When not efficient, governmental intervention.  
- Multi-leveled approach governmental intervention  
- Government level concerned files at higher level government for record. |

* "FP" stands for Food producer and "FT" stands for Food trader
Case study
Chapter 4  Case study: A comparative analysis based on FAO/WHO Food Risk Management Framework

In previous chapters focus was mainly on food safety incident management as established in the books (e.g. laws, guidelines, regulations etc.). This chapter however, will be devoted to the practical features of Food Safety Management (in practice) in the field of food safety incident response. The question that will be answered in this chapter is: "To what extent do the Legal systems follow the applicable international framework in the process of food safety incident response in practice?"

With this respect the hypothesis that takes a central role in this chapter and will be subject for analysis is: "Since the Legal systems are a member of the Codex Alimentarius Commission, it is expected their food safety incident response is broadly consistent with the international guidelines". First of all, the concept of a food safety incident for the purpose of this study will be established. In its report of 2010\textsuperscript{274} the WHO in cooperation with FAO has classified responses to a food safety incident in 4 categories, different terms may be used to describe the severity of an event. The first category requires minimum intervention. The second category requires mainly industry and local government intervention. Emerging food safety incidents such as incidents that constitute emergencies and crisis, require efficient preparedness and government intervention which in many cases lead to international cooperation as well. These so-called emerging food safety incidents\textsuperscript{275} are subject for case study in this chapter. In addition, the results of each case study will be assessed against the Codex/WHO food safety risk framework as well. Finally, a conclusion of the results will be drawn which will result in verification of the hypothesis.

\textsuperscript{274} FAO/WHO framework for developing national food safety emergency response plans. Rome 2010. P.10

\textsuperscript{275} It must be noted that an incident dependent on the increasing severity, can escalate into an emerging incident (emergency/crisis).
Food safety emergency is identified by Codex as: “A situation whether accidental or intentional, that is identified, by a competent Authority as constituting a serious and as yet uncontrolled foodborne risk to public health that requires urgent (governmental) action”.276 A situation can change quickly or evolve over time to require varying amounts of resources, coordination and management in the response.

Several factors influence how an event is approached, including the number of people ill, the severity of the illness, the distribution and volumes of food, whether the contaminant is known or unknown, and the international and trade implications. In addition, the structures in place in a country (see chapter 2, 3) to respond to such an event will play a critical role in the level of coordination, management and resources required. What might be handled as a routine incident in one country may be considered a crisis in another. These variations can lead to difficulties in determining what constitutes a food safety emergency.277 With this respect countries describe an emergency in terms of their own control system as discussed before in chapter 3. As a result, the definition of an emergency may vary from country to country, and the threshold of response will differ. While different terms may be used to describe the severity of an event. Nevertheless, in this chapter the Codex definition for a food safety emergency as an overarching concept will be applied. Hence, the definition provides a general description of a food safety emergency that will apply to a broad range of situations as well (e.g. microbiological risks, contaminants, epidemics etc.).

4.1. Research method: selection

In order to provide an objective comparison with regards to how the Legal systems respond to a certain food incident in practice, it is of interest to firstly use the same set of variables subject to analysis. With this respect both the background of the scare as the severity thereof need to be on the same line. We have already established that a food safety incident referred to in this case study is consistent with WHO guidelines and is to be understood as. “A situation whether accidental or intentional, that is identified, by a Competent authority as constituting a serious and as yet uncontrolled foodborne risk to public health that requires urgent action”. The selected cases are therefore based on this definition. Furthermore, it is imperative to make use of incidents that have recently occurred in order to determine the response based on valid legislation. The reason for this is that we are dealing here with dynamic food laws. PRC Food Safety Law for example is amended in 2011 and revised in 2014. Therefore, the incidents subject for analysis is only useful when at least falling under the amended law as used throughout this study. Furthermore, the same type of


incidents will be used. microbiological outbreaks in specific a microbe under the family of the microbe Salmonella. In conclusion, as EU provides for a bottom-up approach as discussed before it is of interest to use an incident occurred in a Member State. For the case study and in the interest of access to information, the Netherlands is selected.

It must be noted the case study is based on information provided by government and is strictly limited to the risk management procedure as communicated by government (government risk communication) during the food safety incident.  

4.2 Case study Europe

In Europe a series of food scares have occurred over the past 30 years or so. Table 4.2 illustrates a chronological timeline of some of the main “food scares” that have occurred over the period 1986–2006 throughout Europe.

<table>
<thead>
<tr>
<th>Year</th>
<th>Place</th>
<th>Microbiological</th>
<th>Place</th>
<th>Contaminants</th>
<th>Zoonotic/Epizootic</th>
</tr>
</thead>
<tbody>
<tr>
<td>1988</td>
<td>UK</td>
<td>Salmonella</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1989</td>
<td>UK</td>
<td>Listeria, Salmonella Enteritidis, Botulism in Hazelnut Puree</td>
<td>EU, FR</td>
<td>Alar pesticide, Sewage contamination of fresh meat</td>
<td>BSE (UK)</td>
</tr>
<tr>
<td>1990</td>
<td></td>
<td></td>
<td>EU</td>
<td>Benzene in Perrier bottled water</td>
<td></td>
</tr>
<tr>
<td>1992</td>
<td>FR</td>
<td>Listeria</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1995</td>
<td>UK</td>
<td>Campylobacter</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1996</td>
<td>UK/SW</td>
<td>E. coli</td>
<td></td>
<td></td>
<td>CJD deaths (BSE-aftermath) in UK</td>
</tr>
<tr>
<td>1998</td>
<td>IT</td>
<td>Salmonella Enteritidis</td>
<td>EU, FR</td>
<td>Dioxins animal feed, Carbon Dioxide in cola</td>
<td>CJD alert in red wine (FR)</td>
</tr>
<tr>
<td>1999</td>
<td>FR</td>
<td>Salmonella Typhimurium</td>
<td>EU, EU</td>
<td>Dioxins animal feed, Carbon Dioxide in cola</td>
<td>CJD alert in red wine (FR)</td>
</tr>
<tr>
<td>2000</td>
<td>NL</td>
<td>Salmonella Enteritidis</td>
<td>EU</td>
<td></td>
<td>BSE (FR, GR, SP)</td>
</tr>
<tr>
<td>2001</td>
<td>BE</td>
<td>Listeriosis</td>
<td>SP/UK</td>
<td>Olive oil contamination</td>
<td>BSE (IT) FMD (NL, UK, FR, IR)</td>
</tr>
<tr>
<td>2002</td>
<td></td>
<td></td>
<td>EU</td>
<td>Acrylamide</td>
<td></td>
</tr>
<tr>
<td>2003</td>
<td>UK/SP</td>
<td>Campylobacter</td>
<td>UK</td>
<td>Mercury poisoning fish</td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td>DK</td>
<td>E. Coli</td>
<td>UK</td>
<td>Lasalocid in eggs</td>
<td>Avian flu (EU)</td>
</tr>
<tr>
<td>2005</td>
<td>NE</td>
<td>Listeria</td>
<td>EU</td>
<td>Sudan I</td>
<td>Avian flu (EU)</td>
</tr>
<tr>
<td>2006</td>
<td>UK</td>
<td>Salmonella Montevideo</td>
<td>BE/NE</td>
<td>Dioxins in animal feed</td>
<td>Avian flu (EU)</td>
</tr>
</tbody>
</table>

278 The following information used in the case studies is retrieved from governmental information in the context of the concept of food risk communication. Only governmental information/sources as communicated during the Food Safety Management process is used.

279 Adapted from Knowles et al, European food scares and their impact on EU food policy, British Food Journal Vol.109 No.1, 2007 pp. 43

280 Epizootic: a disease event in an animal population. Zoonotic: infectious diseases of animals (usually vertebrates), that can naturally be transmitted to humans.
A food safety emergency that requires intervention on European level are a few in number. As we have discussed in chapter 3, in the EU crisis situations are those where critical factors are involved at such a level that the Commission considers that the management of the risk in question deriving from food will be of such complexity that it cannot be managed adequately by existing provisions or solely by way of application of Articles 53 and 54 General Food Law. This implies that crisis management only applies when neither measures on Member State level nor emergency procedures in cooperation with the Commission suffice. According to EU decision on the General Plan for food/feed management, experience has shown that situations involving risks are normally managed appropriately using existing procedures. This implies that the situations which should be considered to be crisis situations will be very few in number, not to say exceptional. These critical factors are, in particular, the following: the situation involves a serious direct or indirect risk to human health and/or is perceived or publicized as such or can be perceived and/or publicized as such and the risk is spread or could be spread by a large part of the food chain and it is highly likely that the risk will spread to several Member States and/or non-Community countries. It is therefore recognized that in general in case of emerging food safety incidents the Member States are the key food safety managers and in case of emergencies conform the General Food Law, coordinate with the European Commission. Therefore, in conducting the case study with respect to the EU Legal system, examples should be given on Member State level since the structure of the GFL provides food risk emergency management on Member State level in the first place.

4.2.1 Case study “Salmonella Thompson related to Salmon in the Netherlands, 2012”.

Facts.

On 15 August 2012, an increase in the number of Salmonella Thompson cases was noticed by the Salmonella surveillance in the Netherlands. A case–control study was performed, followed by food investigation. In total 1,149 cases were laboratory-confirmed between August and December 2012 of which four elderly (76–91 years) were reported to have died due to the infection. It is reported to be the largest outbreak of salmonellosis ever recorded in the Netherlands. The temporary closure of the processing site and recall of the smoked salmon stopped the outbreak. The cause of the outbreak was smoked salmon processed at a single site. The smoked salmon had been continuously contaminated in the processing lines through reusable dishes, which turned out to be porous and had become loaded with bacteria. An estimated four to six million Dutch residents were possibly exposed to the contaminated smoked salmon and an estimated 23,000 persons would have had acute gastroenteritis with Salmonella Thompson during this outbreak.


Involved institutions.
- Epidemiology and Surveillance Unit, Centre for Infectious Disease Control, National Institute for Public Health and the Environment (RIVM).
- Dutch Food and Consumer Product Safety Authority (NVWA).
- Laboratory for Infectious Diseases and Perinatal Screening, Centre for Infectious Disease Control
- Preparedness and Response Unit, Centre for Infectious Disease Control, RIVM.
- Centre for Zoonosis and Environmental Microbiology, Centre for Infectious Disease Control, RIVM.

Risk assessment methods.
- Laboratory surveillance network
The Dutch laboratory surveillance network is based on 16 regional public health laboratories, which send Salmonella isolates from patients to the National Institute for Public Health. Each isolate is accompanied by a standardized completed request form with information about the submitting laboratory, basic demographics of the patient and the isolate. At the RIVM, the isolates are serotyped and the results and background information are filed in the laboratory registry system. Additionally, during this outbreak, Dutch diagnostic laboratories outside the surveillance network, were encouraged to submit Salmonella group C isolates, to which Salmonella Thompson belongs, in order to get a more complete picture of the outbreak.

- Epidemiological investigation
Cases were defined as residents of the Netherlands with an Salmonella Thompson isolate cultured from any sample type, confirmed at the RIVM. Between 16 August (week 33) and 28 September (week 39) when the source was identified, the regional public health services were requested once a week to contact the new cases of that week within their region after obtaining consent from the doctor in attendance, to administer an extensive questionnaire. On 28 September (week 39) the source was found, namely smoked salmon, and a product recall of government was started to remove the product from the market. As the number of submitted isolates kept rising after the recall, a supplemental study was performed between 19 October and 22 November (week 42–47), in order to monitor the course of the outbreak and to check whether smoked salmon was still the cause. Cases with a first date of illness after 5 October 2012 (more than one week after the start of the recall) or unknown onset of illness were contacted with a short questionnaire. The cases were asked when they fell ill, whether they had eaten fish or seafood and if so, where they had bought or eaten it, when, and what type of fish or seafood. Cases were also requested to indicate whether they had been in contact with another patient with similar symptoms in the week before falling ill.

Surveillance and outbreak reports. Online available at:
Microbiological investigation
Salmonella isolates submitted to the RIVM were serotyped based on O- and H-group antigens according to the World Health Organization (WHO) Collaborating Centre for Reference and Research on Salmonella. A subset of isolates of Salmonella enterica subsp. enterica Thompson from patients and food samples were subjected to molecular typing according to the PulseNet International protocol. The banding patterns, i.e. DNA fingerprints, strains were sent to Centers for Disease Control and Prevention (CDC) in Atlanta for DNA fingerprinting.

International inquiry
An urgent inquiry was sent out by the RIVM on 23 August 2012 to European Union (EU) Member States via the Epidemic Intelligence Information System (EPIS), managed by the European Centre for Disease Prevention and Control (ECDC). Member States were asked to report any increase in the number of cases of S. Thompson in their countries. On 1 October a notice was sent to all National Focal Points in Europe via the Early Warning and Response System (EWRS).

Statistical analyses
All statistical analyses were performed using SAS 9.2 (SAS institute Inc., USA). In the case–control analysis, variables with a p-value of less than 0.20 in the univariate logistic regression were entered into the multivariate analysis. Day of onset was mainly available for the cases completing the extensive questionnaire or the supplemental questionnaire, and only rarely for the other cases via the form accompanying the Salmonella isolate presented for serotyping. The epidemic curve of the frequencies of cases by dates of onset was biased, as the questionnaires were completed at the beginning of the outbreak (extensive questionnaire) or at the end of the outbreak (supplemental questionnaire). Therefore, for cases without known day of onset but with a date of sampling, an estimated day of onset was calculated based on the median number of days between date of onset and sampling for the cases in the same period (whereby the time of the outbreak was divided in three periods: beginning, middle and end). This time span between onset and sampling was estimated using data from cases with both dates available. See following illustration for an overview of the process

Figure
Number of Salmonella Thompson outbreak cases according to reported and estimated day of disease onset, the Netherlands, 18 June–30 December (n=1,077)

Despite a total of 1,077 laboratory-confirmed cases were part of the outbreak, only 122 are depicted in this Figure because for 955 cases the date of disease onset could not be determined due to missing information.

Figure 4.3: Number of Salmonella Thompson outbreak according to reported and estimated day of disease.
Implemented tools by government (risk management).

Food and trace-back investigations, Recall and Closure

The NVWA (Dutch food and product safety authority) followed up the results of the case-control studies, supermarkets and patients were contacted and food samples were taken. Ready-to-eat vegetables were quickly ruled out, as they included a large variety of vegetables from many different sources and producers. When the case-control analysis pointed toward smoked fish consumption, particularly smoked salmon, the purchasing organization indicated that all smoked salmon originated from one Dutch producer. The day after this finding the NVWA visited the Dutch fish producer and collected samples from different batches of smoked salmon products, as did the fish producer. Salmonella Thompson was detected by the NVWA in four of nine sampled batches. Subsequently, all smoked salmon from this producer was recalled, starting two days after and a public warning was published.

A trace-back analysis by the fish producer showed that the positive batches were produced on certain production lines in the Greek processing plant of this company. There, the fish is processed before being transported to the Netherlands for further distribution. After two weeks other products containing possibly contaminated smoked salmon, such as ready-to-eat salads, were also recalled. Information given by the producer also indicated that smoked salmon was exported to countries in Europe, North America and Central America. As a response an alert was sent out via the Rapid Alert System for Food and Feed\textsuperscript{283} to inform these countries of the recall and the ongoing outbreak. This notification did not lead to reports of cases.

Furthermore, the Greek authorities were informed about the problem in the Greek production facility of the Dutch fish producer. Based on this alert notification and additional information, the authority temporarily closed the Greek production site of the Dutch fish producer. After analysis of the production process in Greece, the Dutch producer concluded, that the continuing contamination of smoked salmon must have been caused by cross contamination from dishes on which the salmon was transported within the processing lines. These reusable dishes were the most recent main adaptation in the production process and where known to be porous. Indeed, research conducted by the fish producer showed that the inner layer of the dishes appeared to be filthy and was contaminated with bacteria, including Salmonella. Additional research conducted by the Netherlands Organization for Applied Scientific Research (TNO) showed that the inner layer of the dishes was highly porous and absorbing the Salmonella. How the dishes initially got contaminated remains unknown. Furthermore, as a result of the risk assessment conducted temporary closure of the processing site and recall of the smoked salmon were imposed and resulted in a halt of the outbreak.

\textsuperscript{283} RASFF; 2012.1382
4.3. Case study United States of America

In the US, similar to the EU, a series of food scares have occurred over the past decades as well. As we have discussed in chapter 3, in the US food safety emergencies are dealt with by FDA (in case of poultry, eggs, and meats by the USDA). This implies that the competent authority for food risk management in case of an emerging food safety risk, is the FDA taking into account the hierarchical legal approach (Local, State, Federal). 284

4.3.1. Case study: Salmonella Bareilly; Salmonella Nchanga outbreak in Tuna in the US, 2012

Facts.
In early March 2012, Federal officials learned of infections from Salmonella Bareilly, bacteria that can cause diarrhea, fever and abdominal cramps if eaten in contaminated food. Left untreated, the illness can lead to death in high-risk populations, such as infants, older adults, and pregnant women. Since then, about 250 people have been infected in 24 states and the District of Columbia, according to the Centers for Disease Control and Prevention (CDC). In the end, the prime suspect was a frozen raw yellowfin tuna product, called Nakaochi Scrape, imported from India. This tuna is used to make sushi, and many of the people who became ill reported eating sushi, with spicy tuna a common ingredient. This outbreak is linked to a frozen raw yellowfin tuna product, known as Nakaochi Scrape, from Moon Marine USA Corporation.

Involved institutions.
- FDA
- Centers for Disease Control and Prevention (CDC)
- CORE (FDA’s Coordinated Outbreak Response and Evaluation Network. Created to manage not just outbreak response, but surveillance and post-response activities related to incidents involving multiple illnesses linked to FDA-regulated human and animal food and cosmetic products).
- EOC (FDA’s Emergency Operation Centre)
Collaborative investigation efforts of state, local, and federal public health agencies.

Methods. risk assessment method

Trackback and assessment
In the tuna case for the FDA it was first utmost important to trace the source causing the illnesses that were reported from several states. A traceability research was conducted to get to the source in order to manage the risk. Therefore an “Outbreak Identification and Source Implication” research was conducted first.

284 This case study is based on governmental information sharing such as reports and other data from the next competent authorities: Federal Food and Drug Agency (FDA Website) and Centre for Control Disease and prevention (CDC Website).
Following an overview of the timeline of this research:

On March 1 New York State Department of Health notified CDC’s Outbreak Response Team (ORT) of a cluster of 4 ill persons infected with Salmonella Bareilly with the same unusual pulsed-field gel electrophoresis pattern. On March 2 PulseNet shows 11 persons in 7 states with the same pattern. CDC began coordinating a multistate investigation and held first multistate conference call. A few days after exposure information from 8 ill persons revealed that 7 reported eating seafood and 5 ate sushi in the week before becoming ill. The Department of State Health Services reported first cluster of 2 unrelated ill persons who ate at the same Japanese steakhouse which serves sushi. Wisconsin Department of Health Services (WDHS) reported a second cluster of unrelated ill persons eating at the same Japanese restaurant. A few days after, preliminary information from 22 ill persons revealed that in the week before the illness 80% of the respondents confirmed eating seafood and 55% reported eating sushi. Among 8 ill persons who reported the type of sushi, all reported eating tuna. WDHS reported a third cluster of unrelated ill persons who ate sushi purchased from the same grocery store. Among 19 ill persons who were asked detailed questions about eating sushi, 18 reported eating sushi in the week before illness and 80% of sushi eaters reported eating spicy tuna. The Department of Public Health reported a fourth cluster of unrelated ill persons who ate sushi at the same restaurant. Hereinafter the Department of Health and Mental Hygiene reported a fifth cluster of unrelated ill persons who ate sushi at the same restaurant. Furthermore, among 29 ill persons who were asked detailed questions about eating sushi, 90% reported eating sushi and 81% of sushi eaters reported eating spicy tuna. As a response to these result, in tracing the link to the source, a Restaurant sushi order comparison study was launched. In the meantime the CDC posted initial web announcement about the investigation. Short after, Preliminary results of restaurant comparison study from 4 restaurants show that the proportion of comparison sushi orders containing spicy tuna as an ingredient averaged 37% (ranging from 29% to 53%). WDHS notified CDC’s ORT about 5 recent *Salmonella* Nchanga infections occurring in the same states as the *Salmonella* Bareilly cases. One ill person in Wisconsin had reported eating tuna sushi.

After keeping narrowing down and analyzing reams of data, the IMG selected and mapped four of the clusters of illnesses in Connecticut, Rhode Island, Texas, and Wisconsin as the investigation’s focus. Further analysis verified that all four had received the same imported, frozen raw Nakauchi Scrape tuna product from a single tuna processing facility in India. Now that the source was detected, it was up to the competent authorities to manage the food safety risk event.

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FDA Laboratory Results

Short after the outbreak was revealed and the source was traced, FDA laboratories have identified Salmonella in a sample of Nakaochi scrape yellowfin tuna with a Pulsed-Field Gel Electrophoresis (PFGE) pattern indistinguishable from the outbreak-associated strain of Salmonella Bareilly strain involving 190 cases in 21 states and the District of Columbia. This sample also yielded another type of Salmonella with a PFGE pattern indistinguishable from an additional cluster of 10 cases of Salmonella Nchanga infections in 5 States associated with this outbreak. The sample was collected from a distributor of such tuna. The Nakaochi scrape yellowfin tuna associated with this outbreak is being voluntarily recalled by Moon Marine USA Corporation, based in Cupertino, California. Another sample of Nakaochi scrape yellowfin tuna, collected from a different distributor, identified Salmonella with a PFGE pattern indistinguishable from the outbreak strain of Salmonella Bareilly.

Short after, yellowfin tuna samples (17 were nakaochi scrape and 1 was saku all sourced from Moon Fishery [India] Pvt. Ltd.) collected as part of the traceback investigations, 4 were negative for Salmonella (including the saku); 5 yielded Salmonella with a pulsed-field gel electrophoresis (PFGE) pattern indistinguishable from the outbreak strain of Salmonella Bareilly (including the tuna strips); 2 yielded Salmonella with a PFGE pattern indistinguishable from the outbreak strain of Salmonella Nchanga; and 7 yielded Salmonella with PFGE patterns indistinguishable from the outbreak strains ...
of both Salmonella Bareilly and Salmonella Nchanga. Increased surveillance efforts resulted in the collection of 13 additional samples of tuna sourced from Moon Fishery (India) Pvt Ltd.

Persons infected with the outbreak strains of *Salmonella* Bareilly and *Salmonella* Nchanga, by date of illness onset*

### Implemented tools by government: risk management

*Trace-back and risk analysis*

FDA began receiving supplier and invoice data collected by state and local departments of health and agriculture. The FDA actually started with FDA’s Coordinated Outbreak Response and Evaluation Network (CORE). In addition, the FDA activated an Incident Management Group and transferred *Salmonella* Bareilly response activities within the FDA Emergency Operations Center. CDC staff member joined FDA Team in Washington, DC. This branch of FDA—on the frontlines of response to outbreaks of foodborne illness—evaluated and monitored the initial reports. With the source identified, FDA quickly alerted consumers and health agencies to the potential dangers of eating the recalled product. In addition, FDA conducted a seafood Hazard Analysis and Critical Control Point inspection at Moon Fishery Pvt Ltd. in India. FDA announced finding the outbreak strains of *Salmonella* Bareilly and *Salmonella* Nchanga in unopened packages of yellowfin tuna product imported from Moon Marine USA Corporation. The findings demonstrated the outbreak strains of *Salmonella* Bareilly and *Salmonella* Nchanga in unopened packages of yellowfin tuna product imported from Moon Marine USA Corporation. FDA provided information on symptoms of illness, at-risk populations, and precautions consumers can take in the future. With this regard it must be noted, as soon as the source was traced, the company that imported the tuna from India—Moon Marine USA Corporation of Cupertino, California—voluntarily recalled the product. It recalled 3 production dates of frozen raw yellow tuna fish. WDHS announced that the Department

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288 *n=425 for whom information was reported as of July 25, 2012*
of Agriculture Trade and Consumer Protection laboratory had found *Salmonella* Bareilly contamination in recalled yellowfin tuna and in a spicy tuna roll made with the recalled fin tuna product, labeled as Nакaochi Scrape AA or AAA from a single tuna processing facility in India.

As a response CDC and FDA warned public not to eat the recalled product. Furthermore, the FDA issued two Import Alerts for fresh and frozen tuna from Moon Fishery India Pvt Ltd. In the meantime, similar to the EU case, the public was constantly updated about the case. In the tuna case the CDC posted initial web announcement about the investigation. For a detailed overview of the timeline of both the trackback and regulatory activities and outbreak identification and source implication, please see Annex 1.
4.4. Case study China

In China a remarkable amount of food scares have occurred recent years. At present, China's food safety is a serious issue and major fatal food safety incidents occur occasionally. The great majority of the reported food scares in China are linked to counterfeit in the food supply chain. In addition, the numbers repeat each year and the repeated incidents cause major decrease of public confidence in China’s food supply chain. There are hardly government reported data of food safety incidents managed by government (risk management process). This emphasizes lack of an integrated concept of risk communication in current PRC Food Safety Law framework. However, it should be noted that China faces an era of Food Safety Law establishment and reform; its situation bears some resemblance to what the US went through early in the last century, when shockingly unsanitary conditions in the meatpacking industry became a target of the progressive movement. Attempts to include an emerging food safety incident dealt with by government conform PRC Food Safety Law fails, for this sufficient data simply lack. According to the observations in this study, this has twofold reason.

First, Risk communication is not a common aspect in China regulatory system. For instance, in 2003 the occurrence of SARS indicated the problems of China’s government dealing with a traditional strong and centralized information control system. The way the government dealt with the SARS epidemic indicated a typical example of failure in risk communication. China’s government soon realized adopting changes became inevitable, the event is considered the beginning of risk communication in China. The period 2004-2008 was marked by building up the system of information disclosure, and emphasizing the importance of risk communication in public health risks; mainly transparent, timely and accurate information disclosure. With this respect, it must be noted China has incorporated in its Revised Amendment the establishment of a unified food safety information release platform and implements the unified food safety information publication mechanism in order to increase information sharing between government level departments. However, the revised amendment will be in force as per October 2015 and therefore the risk communication mechanism is not clearly acted upon yet as it is currently in its developing stage.


290 Severe acute respiratory syndrome (SARS) is a serious form of pneumonia. It is caused by a virus that was first identified in 2003 in China. Infection with the SARS virus causes acute respiratory distress (severe breathing difficulty) and sometimes death adapted from the US national library of medicine. Retrieved from: <http://www.nlm.nih.gov/medlineplus/ency/article/007192.htm>.


292 Article 18, 23, 118 and 119 PRC Food Safety Law revised Amendment
Second, and related to the previous mentioned, China’s Food Safety Law is at it behest of its existence; it has been continuously developing after its enactment in 2009 trying to fill in the legal gaps it faces. The most recent progress in this field is the Revised Amendment. The Amendment has involved the aspect of risk communication to a certain degree\textsuperscript{293}, however up till now it seems this has not been applied in practice yet which is a logical occurrence since the revised law is not in force yet. Notwithstanding, in order to give an insight in how recent food scandals are dealt with, following an analysis of a food safety scare based on media reports is provided.


\textbf{Facts.} \textit{This case study is based on media reports.}

CNN reported that a food processing plant of Shanghai Husi Food, a subsidiary of US-based food supply giant OSI Group applied malpractices to meat handling\textsuperscript{294}. The food scare broke when a secret filmed video surfaced in Chinese media showing appalling practices in a Shanghai food-processing factory that supplies ingredients to many international restaurant. Husi had been supplying chicken and beef products to branches of McDonald’s, Papa John’s, Burger King, Starbucks, KFC, and Pizza Hut in several cities in China. Several scenes showed the employers picking up meat that had fallen on the floor and returning it directly into the processing machine. The tainted meat supply has been found to reach across China, all the way to Hong Kong, and even to Japan.

\textbf{Approach government.} \textit{Food Safety Management}

\textit{Investigation Traceability}

Shanghai Municipal Food and Drug Administration (CFDA) subsequently investigated the factory and found that expired beef and chicken products were processed and repackaged with new expiration dates. Amongst the tainted products, they were able to trace forged production dates on more than 4,300 cases of smoked beef patties, with more than 3,000 cases already sold.

\textit{Management tools. Closure, detaining and sales ban}

Although no one has fallen sick as a direct result of the tainted meat supply, Shanghai's FDA has closed the Husi plant at the center of the scandal, and detained five employees for questioning. Furthermore, the government issued an import and sales ban. Meanwhile, Shanghai's top official has pledged to mete out "severe punishment" for anyone involved in the incident, China Daily reported\textsuperscript{295}.

\textsuperscript{293} The law merely provides in transparency in case of risk assessment and food safety regulation see article 8 and 23 PRC Food Safety Law revised Amendment.
4.4 Conclusions: assessment of national framework against international standards

Now that we have carried out the case studies and thus have gained overall knowledge of how the selected systems respond to a certain food safety incident (emerging food safety incident that requires governmental intervention), in the following the results of the case studies will be assessed against the Codex/WHO food risk management framework.

**Case study 1. Salmonella Thompson related to Salmon in the Netherlands, 2012**

Transparency (accessible information) on the Eurosurveillance website of the process followed during the case study provides us with a clear understanding of the procedure followed by the Dutch competent authorities. We will focus merely on the presence of the four steps of risk management. The results of the risk management process indicate that in general all 4 steps of the Codex framework are taken into account.

<table>
<thead>
<tr>
<th>Codex/WHO Food Safety Management risk framework</th>
<th>Risk Evaluation</th>
<th>Risk management option assessment</th>
<th>Implementation of management decision</th>
<th>Monitoring and Review</th>
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<td><em>Salmonella Thompson related to Salmon in the Netherlands, 2012</em></td>
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**Case study 2. Salmonella Bareilly; Salmonella Nchanga outbreak in Tuna in the US, 2012**

Transparency (accessible information) on the website of the FDA and CDC of the process followed during the case study provides us with a clear understanding of the procedure followed by the US competent authorities. We will focus merely on the presence of the four steps of risk management. Similar to the EU case, the results of the risk management process indicate that in general all 4 steps of the Codex framework are taken into account.

<table>
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**Case study 3. Tainted meat scandal China, 2014**

As mentioned before, it has been attempted to include an emerging food safety incident dealt with by government conform the PRC Food Safety Law Revised Amendment, however sufficient data lack. Therefore PRC Food Safety Law will not be subject to assessment against the codex framework.
To come back to the hypothesis. It has been assumed that since all three selected systems are members of the Codex Alimentarius Commission (CAC), one may expect their Food Safety Management framework and response to food safety incidents are broadly consistent. However, this research has shown this assumption is not correct. In case of the EU and US this assumption was correct in case of both their regulatory Framework of Food Safety Management and their approach to food safety incident response. However, the assumption was wrong in case of China.
Comparative analysis: Functional comparison
Chapter 5  Food Safety Incident Response: A functional comparative analysis

This chapter provides with a functional comparison. The subject that will be compared is the Food Safety Management Regulatory Framework of the selected systems at stake. Previous chapters have dealt with this subject from different perspectives. In this chapter all features dealt will be brought together involving the features of legal culture and will be analyzed with a functional approach towards the central question: "How can discrepancies in governmental response to food safety incidents be explained through the regulatory framework of Food Safety Management and what is the role of legal culture therein?".

Previous chapters have shed some light on the selected features of the regulatory framework of Food Safety Management in the three Legal systems at stake considering possible explanation of discrepancies in food safety incident response. For this, the sources used are mainly based on the law (the regulatory framework of Food Safety Management). However, in order to give a more in-depth approach in comparing food incident management dealt with by the three selected systems, the features of the legal culture concept as defined in the context of this study (such as legal institutions, national values towards food safety (food culture)) will be involved in this functional comparison and further explained.

The aim of this chapter is to give an understanding of the regulatory framework of Food Safety Management in the three different Legal systems with a focus on providing some explanations for discrepancies in response to food safety incidents. This study, in its introduction, started with an overview of the role of legal culture in each Legal system. Hereinafter, in chapter1, a general understanding of the characteristics of contemporary food laws of the selected systems is provided by dealing with the roots of the food law systems and the factors the systems are influenced by. In addition, we have dealt with the contemporary structure of the Food Safety Law system in the three systems concerned. Furthermore, a close look at the Food Safety Management framework as established in the laws belonging to the three selected systems is provided as well in order to provide an understanding of the foundations and regulation of the systems’ approach to food safety incidents. A more practical approach is provided in chapter 4 in where the execution of the Food Safety Management framework is demonstrated in practice by the use of case studies and the analysis of the hypothesis that has taken a central role in the case study. Next to the regulatory structure, Legal system and involved legal institutions which have been extensively dealt with in previous chapters through a structural comparison, first the remaining aspect of what constitutes Legal system, which is food culture, will be involved as well in the analysis. The analysis will provide with a functional approach to the results of the structural comparison in this study. With this respect, a more in-depth approach from a socio-legal angle will be used in order to give an understanding of how legal culture has contributed to contemporary management framework of food incident response (reflections in the law).

296 See legal culture in the list of definitions.
5.1. Comparative Analysis: Food culture and Legal culture

In his work Ferrari argues that some dangers, which are objective and real, are elected as risks by societies according to the values and interests of that society that are threatened by the dangers concerned. The more the threat is perceived as endangering values and interests which are considered fundamental for the survival of the society's cultural identity, the more that threat will be construed as a 'risk'. This paragraph will shed some light on the national values towards food safety (food culture) and at the same time provides a functional comparison including the role of legal culture.

5.1.1 National values towards food safety (food culture)

Firstly, it should be noted that some societies accept certain risks whilst another finds it too burdensome to be tolerated. The line dividing risks into acceptable and unacceptable is traced according to cultural evaluations. This concept of risk acceptability is an important variable in determining the differences in the food safety legal culture. Another important aspect that needs to be taken into consideration is that of risks and emotions. Direct reactions based on emotions deeply influence the way we perceive the risk. The concept of experience is the main catalyst with this respect. When strong emotions are triggered by a given risk, we tend to focus on worst case scenario (the realization of the risk), regardless the probability that such will occur. An example thereof is that of when people tend to ask for stricter regulation when neglecting the objective matter (probability that the risk occurs) and taking away resources of more efficient use. The way societies relate to food consumption and food safety varies greatly mirroring the existence of a plurality of food cultures, each one with its own preferences in terms of taste and safety. This multi-ethnicity of food cultures within society demonstrates us that one cannot just speak of a food culture especially in case of the US and Europe. The reason for this is that both within Europe and the US food cultures vary significantly, it is therefore hard to imagine a monolithic food culture. Such a high degree of homogeneity is unthinkable in large societies. Furthermore, the US and EU are large multiethnic societies with different historical backgrounds, it is possible to imagine the coexistence of a number of food cultures. China at the other hand, can be considered more homogeneous. However, in these societies sub-cultures also compete with one another. With this respect Ferrari argues one can speak of a European food culture or US food culture, since the competition between

298 Ibid. P. 17
299 In the context of this study food culture needs to be understood as: “national values towards food safety”. See list of definitions.
300 Ferrari, M., 2009, P. 18–19
301 Ferrari, M., 2009, P. 19–20
various sub-cultures leads, in fact, of the predominance of one these sub-cultures. With regard to the EU for example, the predominant culture is connected to the preservation of local traditions. This is in particular applicable to the Mediterranean countries (e.g. Italy\textsuperscript{302} and France) while it is more nuanced in the case of the UK. Another aspect worth noting is the importance of the use of local ingredients in predominance food culture in Europe. This fact is reflected in the important role of legal protection of the place of origin and geographical indication of many regional ingredients and foods in EU law. This can be seen not only as a tool to protect the economic interests of the local producers, but also as a way of strengthening the traditional food culture.\textsuperscript{303} As a result, based on the reflections in the law, one could consider in general for Europeans food must preferably be the product of a natural process. *natural foods*.\textsuperscript{304} This has important consequences with regards to food safety. Since the (predominant) culture of Europe favors “natural” foods, consequently there will be a higher tolerance towards defects following from these ingredients such as risks coming from the consumption of cheese made with raw milk.\textsuperscript{305} Consumers will tend to downplay the risks that come from the naturalness of the food.\textsuperscript{306} However, on the contrary, Europeans tend to have a negative perception of the use of technology in food production. This is reflected in the adoption of the precautionary principle in the food safety context. The adoption itself thereof can be seen as a cultural emblem of European sensibility of regarding the protection of the food chain from the assault of technology.\textsuperscript{307,308} Finally in terms of EU food culture, it could be considered that if the cultural predisposition is to favor food which is perceived, marketed or in any event labeled as “natural”, products which, on the contrary, are clearly the result of an industrial process will be seen as threatening the traditional cultural values characterizing the society.

On the other hand, in the US for example, the food culture is not based on traditional food culture like in the EU. In the US there is lack of a common culinary tradition. This has inter alia to do with the large differences in multi-ethnicity, such as the large variety of immigrants with different cultural backgrounds. Consequently, instead of a food culture mainly shaped by tradition such as the case in the EU, US food culture has been more shaped by economic interests. Food production has long been characterized by heavy industrialization, especially after WO II. As industrialization rapidly developed, the market focused on providing convenience to the consumer. As too was the

\textsuperscript{302} In Italy, the Minister of Agriculture and the Minister of Culture have issued a Ministerial Decree providing that Italian traditional foodstuffs are considered part of the national cultural heritage. see Ministerial Decree, May 29, 2008.

\textsuperscript{303} Ferrari, M. 2009. P. 28


\textsuperscript{305} Echols, M. 2001. P. 8

\textsuperscript{306} Ferrari, M. 2009. P. 29

\textsuperscript{307} See art. 7 General Food Law for further information on the Precautionary Principle.

\textsuperscript{308} Ferrari, M. 2009. P. 29–30
In case of Chinese food culture one could speak of a rich food tradition\(^{309}\); Chinese food is nowadays one of the leading cuisines globally. China is a country with a long history of ritual and etiquette, and eating is a highly important feature of China’s culture. Still today’s Chinese cuisine is a strong essence of China’s traditional food culture. Before and short after the Cultural revolution in the late 70’s, the food industry was State owned, therefore there was no strong economic interest and thus commercial competition was not common. In addition, local foods were used in food preparation since China was relative isolated from the Western world. There was hardly any import/ export in terms of food trade. Therefore China’s national cuisine largely relied on traditional food, even though specific aspects of the food tradition differ amongst regions. Because of the low food safety risks (e.g. state owned, natural foods etc.) only limited food related laws under which the hygiene law, were applicable. After the ending of the cultural revolution in 1978/1979 China opened her doors to the world. China shifted from a relative isolated economy to ambitions to be a world economy in the global arena. High increase of international trade became an important aspect thereof. This has had consequences on the national food culture. China’s consumers were exposed to foreign food cultures as a result of increasing foreign investments (largely US companies). Foreign food cultures such as fast food culture were introduced to the Chinese consumer. Furthermore, as the market grew increasingly, market competition was largely present. A result thereof are the repeated cases of food adulteration in recent and past food safety incidents. This has largely affected trust of the Chinese consumer and resulted in major public outcry. As a result thereof it appeared of great essence to introduce a Food Safety Law and as a result the PRC Food Safety Law of 2009 and its later Amendments were enacted. Although, the influences of international food culture, China’s food culture is still predominant in china and forms a strong essence of China’s national culture. An example of a typical characterization of the Chinese food culture are the large amount of street food vendors. Natural foods are directly heated/ cooked/  


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prepared and provided to the consumer. In this case the consumer has insight into the food provided. Hence, it should be noted that is mainly the case in the food supply chain of processed foods where the series of food incidents take place. However, apart from these traditional cultural aspects, consumer research has shown\textsuperscript{310} that the Chinese consumer supports technology in terms of foods. Now, with a highly desired and incredibly rapid transition to a large open economy, the Chinese are forward looking. Technological novelties from the rest of the world are often considered much-needed improvements, rather than reasons for concern. In China, a lot of researchers found that a positive predisposition towards scientific innovation was demonstrated by a strong agreement among a majority of respondents that science improves the quality of life.

5.1.2 Conclusions

Following, an overview of some of the identified features of legal culture and food culture (in the context of this study) will be provided.

We have discussed the characterization of legal culture and food culture (in the context of this study) in all three selected systems. The concepts of legal culture and food culture are complex to analyze from a comparative point of view. Unlike previous chapters, in this paragraph a same set of variables is not used. The underlying reason for this is the fact that the legal culture of the system concerned are that different that it is impossible to apply an analysis on conceptual terms such as legal culture and food culture. Therefore each system has been analyzed based on the definitions of legal culture and food culture as defined in this study, consisting of 1) regulatory system, 2) Legal system and legal institutions and 3) food culture.

With regards to the results of our research to the cultural values towards food safety, we can assume the coupling of industrialization and food is more embedded in American culture than in European\textsuperscript{311} and original China food culture, although the impact of globalization strongly evolves and particularly in China. In the US the lower degree of cultural resistance to the industrialization of the food sector is due to lack of homogeneous culinary traditions, which on the contrary, are present in Europe and China. While in the EU consumers need to be reassured that the food they consume is not the result of an industrial process, even if this is not true, American and Chinese consumers seem to pay only spasmodic attention to this aspect. They are not overly concerned about the industrial versus natural character of the food they purchase as they generally do support the use of science to their foods to a higher degree than the average EU consumer.\textsuperscript{312} Therefore, in the


\textsuperscript{311} Ferrari, M. 2009. P. 33

\textsuperscript{312} Ibid.
US risks that technology may pose in food production are perceived as less alarming than in countries such as in Europe where the cultural background is hostile to the employment of food production technologies. Rather, in the US but also in China tin general here is support of using technology to control risks which is of a lesser degree the case in the EU. As a matter of fact the general US and Chinese consumer supports the use of biotechnology in agriculture such as the use of GMO which is a common aspect in the daily foods of Chinese and US consumer. This attitude towards technology in foods is reflected in the US and China’s approach thereof (more open towards GMO use in foods). The resistance towards GMO’s in EU food safety politics however, demonstrates that the EU consumer is relatively skeptical about this. Furthermore, this feature can be found in European law as well (e.g. precautionary principle and premarket approval GMO). However, at the other hand in the US, because of negative experiences, there is more concern about risks of food contamination in the food supply chain as a result of terrorist attack and the dietary aspects of the consumption of certain foods. This is in contrary to the European and Chinese consumer while statistically they are exposed to the same risks of terrorist attacks of the food supply chain. If we are looking to this example, it is to be considered what matters is the perception of such risks more than their statistical likelihood or extent; an interesting aspect in this regard are some reflections in the Food Safety Laws. This provides us with the understanding that in comparing the aspect of legal culture embedded in the system concerned is essential to be taken into account. One cannot judge a certain system without understanding– and taking into account the context it functions.

Consequently, with respect to food culture (national values towards food safety) and the correlation thereof with Food Safety Law, this research demonstrates that for understanding the law one should understand the cultural values towards foods of the place where the law is designed. The research has shown, the food law culture of a certain place largely reflects in the food law system concerned.

Our research to the legal culture demonstrates legal culture plays a major role in understanding the structure and functioning of contemporary Legal system. The way laws are established, their characteristics, the Legal system as well as how and by whom (institutions) the laws are enforced provides understanding of contemporary legal structure of the food law system. The EU should be seen as an overarching Legal system. It governs every day politics by means laws such as Regulations and Directives through its structure of EU institutions. One cannot speak of a legal culture but more of a pluralistic culture since each Member State is to hold its own legal culture. Amongst EU Member States legal cultures differ significantly. This is reflected in the fact that the General Food

313 Ferrari, M., 2009, P. 33
315 Ferrari, M., 2009, P. 34
Law leaves enforcement measures (sanctions) up to the Member States to decide based on their own legal framework. The US on the other hand, is to be seen as a typical Federal Legal system providing law on Federal level (laws that are broadly applicable to each US citizen), leaving more specific laws up to the States to govern. With this respect it should be noted among States there are differences in Legal system (e.g. legalization of same-sex marriage\textsuperscript{316} and capital punishment). However, on Federal level one could speak of legal culture with regards to its Legal system (US Code, Acts, Constitution, judicial system etc.). China on the other hand, is a classic example of a Socialist system. China concerns a Republic with influences of the Communist Party that took the country over in 1949. However, contemporary PRC law indicates it is shifting to a strong market economy and therefore it has been quick to tap into foreign and international policies on mostly economic policies.

Similarly to the US, China has a long standing embedded legal culture with regards to its Legal system, institutions, and regulatory structure. The embedded legal culture perhaps forms, at least in the field of food safety policy, an obstacle as well. China is willing to come along with the developments of international food safety standards and therefore made efforts for change in the field of food safety regulation by enacting Food Safety Laws. However, the execution thereof in practice is another challenge China faces. China’s PRC Food Safety Law is ambitious and complex formulated, in an ideal environment it would reach high level of food safety assurance. However, in practice aspects of its Legal system, institutions, and regulatory structure\textsuperscript{317}, form a major obstacle in adequate execution of the ambitious PRC Food Safety Law.

Hence, China’s monitoring system can be unresponsive and the government departments that oversee and enforce policies have overlapping and often ambiguous duties\textsuperscript{318}. Notwithstanding, China has made efforts to improve its regulatory shortcomings in the field of Food Safety Law by for example taking away major overlap and improvement of communication exchange, this is reflected in the PRC Food Safety Law Revised Amendment. Furthermore, in its White paper it has acknowledged changes need to be made in the field of its Legal system. The characterization of China’s Legal system has been widely perceived as a communist system, dictatorship, something between democratic system and dictatorship etc.. However, in 2011 China’s government published a White paper in where it makes clear to the world it is reforming its Legal system’s identification ideally improving- and strictly enforce a Socialist democratic legal- and political system with

\textsuperscript{316} Most recently harmonized in all 50 States through Case law of the Supreme Court. See Introduction under Legal Culture for further details.

\textsuperscript{317} In specific the structure of oversight multi-leveled governance approach and the amount of governmental agencies involved in the responsibility to ensure food safety.

“Chinese characteristics”. The aim of this incentive is to ensure that the people can fully enjoy their civic rights and better exercise their political right of running the country. However, despite these efforts our analysis has shown there is still room for further improvement of ensuring food safety which is a major challenge for a country having one of the world’s largest population.

5.2. **Comparative Analysis, history, development and influences**

This feature has been extensively analyzed in chapter 1 and, a part from the other chapters a functional comparison is already provided in chapter 1 as well. Therefore, the following analysis will be brief.

One could speak of US Food Law that is mainly based on criminal law approaches. EU food law however, is half a century younger. The EU does not have its own system of criminal law. For both reasons EU food law is mainly based on administrative law approaches. The US apply a twofold system of do’s and don’ts, at one hand providing for a self- regulatory system of food industry and at the other hand applying criminal law approaches in the interest of a high level of protection of the food supply chain and therefore providing far reaching tools to the FDA in terms of enforcement and oversight. The underlying reason for this is the origin of US food law that is based on criminal law approaches and the fact that these laws are still the basis for contemporary US food law; the fact that US food law with the involvement of the FSMA provides for a preventive approach in terms of industry obligations as well. In terms of the EU, the General Food Law was the first integrated food safety policy. The triggers (food scares) for its realization and Europe’s aim for strengthening public confidence in politics and science, reflect in the law which is science- based and provides for a strong preventive approach. In case of China similar to the EU, PRC Food Safety Law is China’s first comprehensive Food Safety Law. Its underlying triggers are to be found in the new economic strategy of China after the Cultural Revolution; as a result the continuous food scares it deals with up until this day. China is currently experiencing problems with food safety control in terms of execution of the law. The latter is a result of continuous emergence of food scandals which are mainly linked to food fraud in the food supply chain and have drawn worldwide attention. The stricter features of the Revised Amendment (e.g. linkage to criminal law) is a clear example of using the law as a tool for solving major social issues by correcting/ deter criminal behavior. The relatively fast development of PRC food law (Amendment and Revised Amendment) are a reflection of the current food safety issues China deals with and the learnings thereof.

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320 Ibid.
5.2.1 Conclusions

Research carried out in this study in the context of history and development of the Legal systems demonstrates the three selected systems have completely different roots and their Food Safety Laws have undergone development in different context. To this end it is not only referred to the events the development of the laws are triggered by, but also globalization, economic reform and some aspects of legal culture (Legal system, legal institutions and food culture) certainly have plaid major role in the design and structure of current Food Safety Laws of the selected systems.

5.3. Comparative Analysis. Food Safety Regulatory Framework

In the interest of what constitutes a ‘Food Safety Framework’ subject for functional comparison, we will limit ourselves here to highlighting some of the variables used in chapter 2 that are interesting to further explore in the context of this study from a functional comparative perspective. In this comparison we will deal with some features of the main food laws belonging to the selected system: General Food Law, FSMA and PRC Food Safety Law used in the structural comparison in Chapter 2.

Variables B & C. (Context & Aim and Scope)

The EU in its aim provides for a twofold function. It regards the General Food Law as the basis for assurance of a high level of protection of human health and consumer protection at one hand and at the other hand it regards the law as to be an instrument for further development- and assurance of- the functioning of the internal market. The latter is reflected in the aim. “… establishment of the common principles and responsibilities, the means to provide a strong science base, efficient organizational arrangements and procedures to underpin decision-making in matters of food and feed safety"321 The US on the other hand, as a result of the FSMA being a part of the FD&C Act, does not provide in a single aim. The FD&C Act in general aims to establish a set of laws giving authority to the US FDA to oversee the safety of food, drugs and cosmetics. The FSMA however, does not clearly state its aim, however a more closer look provides us with the understanding the FSMA technically aims to improve capacity to prevent food safety problems322 (reflects the organizational reform and restructure of execution e.g. shifting to bottom up approach) in order to improve the safety of the foods.323 China’s PRC Food Safety Law at the other hand, is quite brief in its formulation to what concerns the aim of the law. It formulates the law is to assure food safety and safeguard people’s health and life. With this respect providing a central role to safeguard public health. The comparison provides us with interesting perceptions. The different goals of the laws reflect the development and background of the Legal system in place. The fact that EU food law aims to assure a high level of public health is in accordance to the Union’s aim as incorporated in its Treaties (TFEU). Furthermore, the fact that the General Food Law shall serve as a tool to enhance the functioning of the internal market (e.g. efficient organizational arrangements) is in accordance to

321 Article 1(1) General Food Law  
322 21 USC. 321 under section 201 of the FD&C Act  
323 Ibid.
one of Europe’s main aim since its foundation: creating a functioning internal market. In case of the US, its aim is in accordance with the capacity problems the government dealt with in ensuring food safety across the food supply chain prior to the enactment of the FSMA. Providing capacity in this case meant shifting from response to prevention by extending capacity from government to food industry. In case of China an explanation could be given as well. The law in itself is built around safeguarding people’s health, a logical explanation for this is the fact that the law in itself is established due to continuous occurrence of food scares that have affected public health (e.g. consequences Melamine scandal are reported: 300,000 babies ill hospitalized and 11 possible deaths324) and caused major public outcry.

**Variable D.** Perception of ‘Food Safety’ established in law

In EU food law the concept of food safety is incorporated in maybe its main principle: food shall not be placed on the market if it is unsafe.325 The law gives an extensive elaboration to what constitutes a food to be unsafe (toxic effects, information and labeling etc.) with the underlying thought that no food stuff dangerous to health and/or unfit for consumption may be placed on the market. This implies that EU food law is about ‘Do’s’, since food business operators are expected to maintain and act upon own food safety system to ensure the foods placed on the market are safe. In case of the US, food law is built around the aspects of adulteration and misbranding, these aspects are prohibitions laid down in the law.326 This is a clear explanation of the statement that US food law is about ‘don’ts’. Hence, the law states that acts leading to food adulteration and misbranding are prohibited and thus one is prohibited to commit such crimes. Consequently, US food law when proven adulterated or misbranded considers the food to be unsafe. It is clear that EU and US at this point (approach to what constitutes food safety) differ significantly; that is reflected in the structure of the laws as well. EU food law is built around- and focused on responsibilities of the food industry and US food law is mainly focused on FDA powers to monitor, enforce and prevent the prohibited crimes to occur in the food supply chain. In case of PRC Food Safety Law, to what constitutes food safety is mainly human health targeted. The law clearly expresses its interpretation of the concept of food safety. It states as follows: “Food Safety means the assurance that the food is nontoxic, harmless, and compliant with reasonable nutritional requirement, and will not cause any acute, chronic and potential hazards to human health”.327 With this respect China shows some similarities to the EU which also involves mainly human health aspects. However, the difference here is that EU food law is quite extensive in elaborating the issues that constitute the safety of the food and thus narrows the topic down whilst PRC Food Safety Law is quite brief with this respect and applies a general definition. An explanation for this can be found in the fact that in EU food law the aspect of what constitutes food safety is a main principle whilst in PRC Food Safety Law what constitutes food safety is mentioned in the list of definitions. Another similarity between EU food law and PRC food law is

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325 Article 14(1) General Food Law
326 21 USC. 321. under section 351 of the FD&C Act
327 Article 150 PRC Food Safety Law revised Amendment
that of not involving fraudulent/ criminal acts with respect to food safety in the definition of food safety itself. However, a difference is to be found in the fact that PRC Food Safety Law clearly prohibits fraudulent acts and what this constitutes regards to food safety and also provides penalties with linkage to criminal law with this respect. EU food law on the other hand, does not provide in a definition of what constitutes food fraud and does not further mention this in the law. US food law on the other hand, is quite clear with this respect as the law itself is built around the features of food fraud/ counterfeit. PRC Food Safety Law however, only mentions health consequences in the context of food safety response in the interest of Food Safety Management. With this respect we can say the laws need to be viewed with the knowledge of differences in structure. This implies the different perceptions of what constitutes ‘food safety’. In next paragraph more details with this respect will be provided incorporating these differences/ similarities in the Food Safety Management framework specifically.

Variable E. Principles of food law

EU food law is clear about the principles of food law, as a matter of fact the General Food Law provides sections concerning the Food Law principles. Section 1 of the General Food Law provides general principles of food law; section 2 provides the principles of transparency. EU food law is well-known for its integrated farm to fork approach. Furthermore, EU food law as one of its principles (obligations) emphasizes and recognizes the Union’s commitment to its international obligations and taking international standards in consideration when developing and adapting the law. Except where this might undermine the high level of consumer protection pursued by the EU. Another principle of EU food law is that of risk regulation, more specific: risk analysis. According to the General Food Law depending on the nature of the measure, food law, and in particular measures relating to food safety must be underpinned by strong science. With this respect it should be noted EU food law follows the Codex framework of risk analysis. Next paragraph will provide more details on the feature of risk analysis. In addition, the General Food Law establishes the concept of transparency as one of its main principles, this principle plays an essential role in the overarching food safety framework and is reflected in the way the EU deals with food safety issues and consequently food safety incidents. Furthermore, EU food law is well-known for the precautionary principle. When scientific risk assessment is inconclusive (scientific uncertainty) the precautionary principle justifies temporary measures to be taken to protect from possible risks, which constitute justification to risk managers to work from a worst case scenario when scientific risk assessment indicates that health risks may exist but causality remains uncertain (suspicion but not proof). Previous mentioned features are all principles as laid down in the General Food Law. This implies the General Food Law is founded on these principles. US food law, the FSMA, on the other hand is more concisely and specific towards its principles. In general US food law main key

328 Article 149 PRC Food Safety Law revised Amendment
329 Art. 5 (3) General Food Law
330 Art. 6 General Food Law
331 Art. 7 General Food Law
principle is that misbranding and food adulteration are prohibited acts, as mentioned before since its existence US food law is built around this principle. However, along with the amendment of the FSMA, the principle of prevention gained an essential place in US food safety system as well. In this regard it is worth noting US Congress has made prevention the foundational principle of the FSMA. The 5 key principles/elements (mandatory recall, suspension of registration etc.) in this new preventive approach are all based on tools that strengthen the FDA’s powers. This is an interesting aspect, considering the main principles the FSMA is founded on, one could state US food law has shifted to a preventive approach as a direct result of the need for improving capacity to prevent food safety problems. It appeared to be an effective solution for government control on the food supply chain. At one hand responsibilities have shifted to the food industry whilst at the other hand FDA’s enforcement powers are strengthened significantly. This implies with the enactment of the FSMA government has given away tasks and duties concerning industry safety management (HACCP etc.) to the industry to be able to focus more on other features such as enforcement and oversight. In order to adequately intervene when necessary it has provided itself with strong enforcement mechanisms. Unlike the EU the US food law system does not provide for a precautionary principle. Neither does the law incorporate risk analysis and transparency as main food law principles. These aspects are indeed incorporated in the law, however they have not gained a central role such as in EU food law. Similar to the US, the PRC food law system does not provide for the so-called precautionary principle. However other than the US food law system, the concept of risk assessment and risk management are incorporated separately. The next paragraph will deal further with the comparison of the risk analysis concept.

PRC Food Safety Law is founded on the principles of “putting prevention first, risk management, wholeprocess control, and making efforts by the whole society”, aiming to establish the strictest regulatory system.333 PRC Food Safety Law similarly to US food law highlights the aspects of prevention by food industry and governmental risk management in its food law principles. However, PRC Food Safety Law distinguishes itself with the principle of ‘effort by the whole society’. With this respect it goes a step further than the EU and US who already establish a shared responsibility of government and food industry. PRC Food Safety Law particularly involves other actors such as for example health care providers in the process of food safety incident management. Hereto related, the main principle of PRC Food Safety Law is that of Food Safety Management (execution by government). The feature that strikes the most from this comparison is that EU food law is based on a wide range of principles and these principles are reflected in the characterization of the law itself as well as the way EU law in general is governed (extensive regulation). It is interesting to notice that all principles of the selected Legal systems are somehow to be traced back in each other’s system. However, in one Legal system a certain aspect has been given an essential role as to be a principle while in another system this aspect is not a main principle but just a requirement or rule. What makes a certain aspect to be qualified as to be a principle (fundamental

333 Article 3 PRC Food Safety Law revised Amendment
truth or proposition that serves as the foundation for a system\textsuperscript{334} is dependent on the background of the law itself (see functional comparison 6.1).

**Variable F.** Obligations and Responsibilities

EU food Law establishes the basic principle that the primary responsibility for ensuring compliance with food law, and in particular the safety of food, rests with the food business. To complement and support this principle, there must be adequate and effective controls organized by the competent authorities of the Member States. Consequently, following EU food law the primary responsibility for ensuring foods satisfy the requirements of food law at all stages of production, processing and distribution under the control of the business is entitled to the food business operators. Similarly to the EU, US food law codifies the principle that the primary responsibility for prevention rests with the food and feed industries. Within the preventive controls framework, FDA plays its role most effectively by setting science-based, prevention-oriented standards and working to ensure high rates of industry compliance with the new standards. With this respect, the role of the government is more specified and emphasized in US law than in EU food law. PRC Food Safety Law, as previously mentioned, takes for granted a shared responsibility of the whole society. Similar to US and EU food law, food traders and producers are responsible for food safety across the food supply chain (mentioned as whole process).

However in contrary to EU food law, PRC food law pays close attention to the role of government. The law is mainly based on Food Safety Management principles (governmental food safety surveillance etc.). China’s government has an active role in PRC Food Safety Law in the field of enforcement and oversight. Consequently, European Food Law is designed with a ‘laissez faire’ character. Member States have gained only a complementary role in the General Food Law that is enforcing food safety in where it basically comes down to providing a legal framework for business operators to verify and enforce these rules. The main obligations for ensuring food safety is left to the food business operators who are provided with a self-regulatory system whilst PRC Food Safety Law and US food law provide a central role of government in Food Safety Management.

5.4 Comparative analysis. Food Safety Risk Management Process & the International framework

In the interest of what constitutes ‘Food Safety Risk Management Process’ subject to functional comparison, we will limit ourselves here to highlighting some of the variables compared in chapter 3 interesting to further explore in the interest of functional comparison.

In this comparison we will deal with some features of the food safety risk management process in the food laws belonging to the selected systems. General Food Law, FSMA and PRC Food Safety Law as well as international WHO/ Codex standards and guidelines as dealt with in the structural comparison in Chapter 3. First of all, it must be noted that all three selected Legal systems make reference to international standards in their Food Safety Laws; all three system are members of the Codex Alimentarius Commission and therefore it is previously mentioned that their risk management approach may be expected to be broadly consistent with Codex, FAO/WHO standards, guidelines and recommendations. To the extent this assumption is to be considered correctly is already dealt with in the conclusion of chapter 4. However, at the end of this paragraph the results will be further discussed from a functional approach involving applicable features of legal culture as to be understood in this study.

Next to assessing the way the governments respond to food safety incidents, it is of interest to assess the entire regulatory framework of Food Safety Management as analyzed in chapter 2 and 3 against applicable international standards/ guidelines as well. Therefore, in this subparagraph a functional comparative analysis of the risk management process as established in the Food Safety Management framework of the selected Legal systems at issue will be provided. In addition, the results will be assessed against the 8 principles of food safety risk management as discussed in chapter 3.

Variable K. The basics of risk analysis

Both the EU and US follow the Codex risk analysis framework (consisting of the concept of risk assessment, risk management and risk communication) and apply a functional separation of risk assessment and risk management. The latter is an important principle that was recognized by the 1995 consultation.\(^{335}\) For example, in case of the EU the functional separation of risk assessment and risk management has given space for inserting the precautionary principle in the General Food Law. PRC Food Safety Law on the other hand, does not clearly provide in a risk analysis concept. However, the concepts of risk assessment and risk management are both incorporated in China’s Food Safety Law. The law is clear about the characterization of risk assessment that has gained an essential role in the law which is science based. China establishes the food safety risk assessment mechanism to assess the risks on biological, chemical and physical hazardous factors in foods, food additives, and food related products. The structure of PRC Food Safety Law demonstrates that food safety risk assessment is closely related to international standards and international food safety risk assessment (Codex). As too is risk management an aspect that plays a significant role (we have discussed before

\(^ {335}\) See chapter 3.1 for further information on this issue.
that this is a main principle) in PRC Food Safety Law. The concept of risk communication however, is not clearly to be found. However, there are some aspects of transparency included in the revised amendment (articles 8, 23, 115). This is to be found for instance, in Article 8 of PRC Food Safety Law in the following sentence: The county and above level food and drug regulatory department and relevant departments shall strengthen communication and coordination, exercise the rights and bear the responsibilities. Furthermore Article 23 states: The county and above level health department, along with other government agencies, the food safety risk assessment expert committee and its technical institutes, shall carry out exchanges with food producers/ traders, food testing institutions, certification organizations, food industry associations, consumer associations and media on food safety risk assessment information and food safety regulatory information. The exchange and communication shall be science based, objective, timely and open. Article 115 of PRC Food Safety Law, focuses on some features of risk communication establishing an information release platform and implements the unified food safety information publication mechanism to enhance government risk communication. However, in contrary to US and EU Food Safety Law, PRC Food Safety Law does not follow the overall Codex concept of risk analysis, it has chosen to use the elements of risk management and risk assessment of which the latter is science based. The concept of risk communication is not incorporated although the Revised Amendment attempts to create more transparency and enhance government risk communication through different legal instruments. This is consistent with current development in the field of risk communication in PRC Law in general.

**Variable L**: Involved Institutions

In EU food law in general three institutions are involved in governmental Food Safety Management, these are: European Commission (DG Sanco), the Member States and the European Food Safety Authority (EFSA). On European level the risk assessor is EFSA which is according to its establishment in the General Food Law, a neutral organization. The European Commission and the Member States are risk managers. EFSA and the European Commission work closely together: According to the GFL initially on Member State level the Food business operators work closely together with the competent authorities of the Member States. The General Food Law states EFSA, the European Commission and Member States shall cooperate to promote the effective coherence between risk assessment, risk management and risk communication functions. In US food law distinction in oversight is applicable; this is determined by the characterization of the food. If it concerns poultry, egg products or meats the USDA is the risk manager and FSIS the risk assessor. FSIS is part of the USDA and is thus, unlike EFSA, not a neutral organization. If the food concerns other than the three categories mentioned, the FDA is risk manager and CFSAN is the risk assessor. With this respect CFSAN is a part of the FDA and consequently risk assessment is not accomplished by a neutral

336 Article 8 PRC Food Safety Law revised Amendment
337 Article 23 PRC Food Safety Law revised Amendment
338 Article 22 (8) General Food Law
institution as the case in Europe. Even though the US applies a functional separation of risk management and risk assessment, a single institution is responsible for both risk processes.

In China a part from the EU and US, several governmental agencies are involved. Firstly, it should be noted that similar to the US, PRC Food Safety Law provides in distinction in oversight. If the food concerns an edible agricultural product, the Ministry of Agriculture is responsible for the risk management tasks. If it concerns a food other than the previous mentioned category, it depends on the field of food safety which institution is involved. Foodstuff in general is governed by the CFDA who is considered to be the risk manager. If it concerns the quality of the food (e.g. certification) and/or an imported or exported products the AQSIQ is the risk manager. Consequently on State Council Level (Ministerial level) there are three risk managers: CFDA, AQSIQ and MOA. Which institution is applicable, is dependent on the characteristics of the food and the destination thereof. Furthermore, the NHFPC is the risk assessor in all cases. All risk managers need to inquire the NHFPC for food risk assessment. The NHFPC is the government of health which falls directly under the State Council on Ministerial Level as well.

In China there is no unified administrative organ in case of food safety administrative oversight. Several governmental institutions on Ministerial and State Council level are involved as a result there is a risk of overlap of governmental tasks. Furthermore, it should be noted that in China a multi-leveled governance approach is applicable. The before mentioned institutions have establishments on each government level (multi-leveled approach e.g. local, county, province, state etc.). Therefore, governmental oversight is made even more complex to adequately guarantee. Although in the US too there is a certain level of hierarchy in government oversight such as Local, State and Federal level. However, other than in China it is a single institution that is dealing with oversight: FDA (or USDA in case of meats, egg products and poultry). In Europe on the other hand, a clear separation of tasks is established. However, this has to be viewed from the angle that EU law in itself is created with the idea of leaving enforcement measures and execution up to the competent authorities of the Member States. The EU Member States have explicitly chosen for this structure maintaining enforcement of measures and penalties within own Legal system.

**Variable M. Management tools**

In EU food law the tools implemented in case of a food safety incident is dependent on the concept of ‘Unsafe food’. As discussed before, the General Food Law establishes preliminary responsibilities to food business operators. Therefore it is a preliminary responsibility for the food business operator to take responsibility and act upon a certain food safety incident. The tools that can be used are mainly withdrawal and/or recall. When the food business operator has reason to believe a food it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements it shall primarily withdraw the food in question from the market. The General Food Law refers to withdrawal as the process of taking the product that is reasonably believed to be non-compliant with the food safety requirements, from the market where the product concerned

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339 As laid down in Article 14 General Food Law
has left immediate control of the food business operator. Therefore, food business operators are expected to, if despite all science-based preventive measures that need to be taken, select a circulation of food that does not comply with the food safety requirements, take immediate action. Furthermore, if the food business operator considers that the food it has placed on the market is injurious to human health, it immediately should notify the competent authorities thereof. In addition, where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal. Another management tool is the concept of product recall. This applies when the product that is believed to be non-compliant with the requirements of Food Safety Law has been supplied to the consumer. This management tool shall only be taken as a last resort when other measures are not sufficient to achieve a high level of health protection. Consequently, with regards to the application of management tools the general Food Law provides the applicability of sequence, recall shall only follow when the measures of withdrawal are not sufficient enough. Other measures to be taken when the food business operator does not comply with its obligations are not further specified in the General Food Law, rather this is left entirely to the Member States. However, with this respect the General Food Law has given some directions: the measures and penalties provided need to be effective, proportionate and dissuasive.

In US food law on the other hand, the management tools implemented are dependent on the concept of food adulteration and misbranding (unsafe food concept). As we have discussed before dependent on the characteristics of the food the USDA or FDA takes action. The Food Safety and Modernization Act, when despite preventive measures a food safety incident occurs, provides in a first remedy by requesting/expecting a voluntary recall from the food industry when a food is found to be unsafe. When this is not followed by the food business than the FDA takes immediate action. Dependent on the situation it can insert several tools ranging from mandatory recall to suspension of registration (the latter implies the food business is no longer allowed to operate). The far reaching tools fit the aim and principles of the Food and Modernization Act as previously discussed under paragraph 6.2.

In case of PRC Food Safety Law the tools that can be implemented are dependent on the applicable Food Safety Management procedure. If it concerns a food safety incident selected as a result of the Food producer and/ or Food Trader Food Safety Management system, the law expects the food producer to, dependent on the situation, insert rectification measures and immediately notify the local food and drug department. If a food incident is not selected or reported by the food trader or a food producer but by the governmental Food Risk Surveillance System, dependent on the situation the CFDA or AQSIQ shall intervene. In these cases the concerned governmental organization may insert the termination of production and trade activities; inform the consumer to stop consume/use and if necessary formulate/Modify food safety national standards. In this case different procedures and institutions are applicable dependent on the situation and on the characteristics of the food at

340 Article 19 (3) General Food Law. In this case it suffices when the food business operator has “reasonable believe that the food is injurious to human health”.

341 Article 19 (1) General Food Law

342 Article 17 (2) General Food Law
issue. PRC Food Safety Law similarly to US Food Safety Law provides far reaching tools for government to insert. However, similarly to the EU and US it provides a first remedy to be solved by the food trader or producer itself.

**Variable N. Incident Management System**

EU food law provides for a management system consisting of 3 procedures. When it concerns a food safety incident firstly it is required to be solved on Member State level between the food business operator(s) and the competent authorities of the Member State. When it concerns an emerging food safety incident that requires intervention of the Commission (e.g. significant amount of sick people or deaths), the European Commission shall intervene and work closely together with EFSA, the Member State(s) and the food business operator(s) at issue. In case of a food crisis (e.g. several member states affected and severe consequences to human health) that requires strategic crisis approaches and emergency procedure do not suffice, the European Commission in collaboration with the Member States will come up with a Crisis Plan and set up a Crisis Management team. Consequently, EU food law provides a sequence approach to food safety incident management varying from national level approach to EU- level crisis management approach dependent on the situation.

US food law on the other hand, strongly beliefs in the far reaching management tools provided to the FDA to intervene. In this case it should be mentioned that the FDA operates on both local, State and Federal level. However, when emerging food safety incidents occur (e.g. terrorism attack food supply chain or risk of national level epidemic) and such FDA- tools do not suffice, intervention on federal governmental level supporting the FDA will be applicable. In this case emergency procedures on federal level will be followed. National emergency framework such as the National Incident Management System and the National Response Framework will be involved. Furthermore, the FSMA requires for a national Agriculture and food defense strategy that needs to be drawn and followed in response to the emerging food safety incident at issue. Consequently, the US provides for a hierarchical governance approach of the FDA, reaching to FDA national (Federal) level government in case of emergencies requiring Congress level intervention. In this case national response framework are applicable. However, the latter is an ultimate last resort remedy. In practice the chance of occurrence of such level emergencies in the food supply chain is relatively low.

PRC Food Safety Law requires on the other hand food traders and food producers to draw food safety incident response plans. It assumes that when response on food industry level is not sufficient, government will directly intervene. PRC Food Safety Law adopts a multi- leveled approach to food safety incident response. Response of any government level needs to be in compliance with the State Council National Emergency Plan. The concerned governmental level involved, is dependent on the situation. The system works as follows: an incident is selected on local level, the local lower government level will inform the direct higher government level and draw up an emergency plan based on the situation and files this at the higher government level for record. In case of an emerging food safety incident requiring high level of incident management, State level Food and
Drug Agency (CFDA) will act as the risk manager. Hence, in China the way a certain food safety incident is responded to is dependent on inter alia the severity of the event, capacity level of oversight, transparency, communication and accuracy of the government level concerned.

5.5. Conclusions Comparative Analysis

So far we have extensively discussed several subjects under the umbrella of the aim of this study. To this end, features are analyzed in the interest of providing answers to the selected sub-questions from both a structural and functional comparative point of view. In the introduction of this research the aim is defined as follows: “The aim of this research is to provide insights into the regulatory framework of Food Safety Management of different Legal systems providing focus on food safety incident response and to compare this from a legal angle focusing on mainly the system as established in the laws taking some influences of the legal culture in place into account as well”. Looking back to this study so far with a focus on all chapters, this aim could be considered achieved. Nonetheless, in conclusion to this study, it is imperative to provide a balanced answer to the central question. In finalizing this study the central question will be answered providing conclusions of each sub-questions answering the central question: “How can discrepancies in governmental response to food safety incidents be explained from the regulatory framework of Food Safety Management and what is the role of the legal culture therein?”.

Discrepancies in Regulatory Framework of Food Safety Management

To come back to the features of legal culture selected for the purpose of this study, Legal culture constitutes a general overview of how the Legal systems are structured in terms of basic insights in: 1) regulatory structure, 2) Legal system and institutions and 3) food culture. The latter needs to be understood as national values towards food safety reflected in the food laws of the Legal systems. The term of Legal culture further used in this conclusive paragraph needs to be perceived based on the three selected aspects.

First of all, the basis for discrepancies in regulatory framework of Food Safety Management between the systems selected is to be found in the legal culture, background and history (that determine the Legal system concerned) of the selected Legal systems. This has constituted in differences in the variables selected in chapter 2 (food safety framework). We have determined each analyzed variable is established differently between the Legal systems. With this respect, few similarities are to be identified. To this end, a certain causal relationship could be noticed between the history and development of the Food Safety Laws and the current regulatory framework of Food Safety Management. Results of this study demonstrate the selected Legal systems have completely different roots and their Food Safety Laws have undergone (and undergo) development in different context. As a result, the Legal systems have designed their own regulatory system and established legal institutions in compliance with their own Legal system.
For instance, the fact that the first US food laws are triggered by food scandals such as adulteration and misbranding, explains contemporary US food law is built around the aspects of food adulteration and misbranding and consequently applies criminal law approaches. It has always been the task of the FDA to provide for administrative oversight and enforcement of US food law. However, these tasks have long been a major challenge for the FDA to act upon since prior to the FSMA, US food law applied a strong top-down approach. FDA was responsible for significant amount of food safety management tasks even on industry level. Not only was this system too expensive to maintain, the FDA struggled with capacity problems as well. With the enactment of the FSMA the FDA has shifted these preventive measures obligations to the industry with the aim to focus more on administrative oversight and enforcement achieving the new law’s goal, which is to protect consumers from unsafe food. Therefore, the FSMA provides the FDA with a high level of protection of the food supply chain and provides the FDA with far reaching tools in terms of enforcement at the same time. This example of the history and development of US food law provides us with some understanding of contemporary US food law system and at the same time provides insights into the way the framework of Food Safety Management is designed. Based on the research conducted, we now can understand why the main principles of US food law are mainly based on enhancing FDA’s powers and why the FDA takes a central role in food risk assessment and food risk management. The latter is to be explained by the history of the establishment of the institution itself. The first US food law (Pure Food and Drug Act 1906) was enacted along the establishment of the FDA that was responsible for administrative oversight and enforcement of the Act. It was chosen for an agency on federal level to make sure the law is enforced. This aspect is part of US legal culture as well. The fact that the FDA is the institution that mainly deals with risk assessment and risk management of foods, is thus dependent on the design of legal institutions regulated in the US. As discussed before, throughout the decades and until the day of today, this Agency on federal level has always been the main institution dealing with all aspects of US food law on all government levels (local, State and Federal). Therefore, it is no surprise it is primarily responsible for the risk analysis procedure by carrying out both risk assessment and risk management at the same time. Moreover, with regards to the distinction of food safety management oversight, in the US meet, eggs and poultry fall under Agricultural policy and therefore currently in case of risk management and risk assessment, these food product fall under the authorization of the USDA.

In terms of the EU, explanations of contemporary Food Safety Management framework based on some features of the history, development of EU food law and EU legal culture, can be given as well. The General Food Law was the first integrated food safety policy. The triggers (food scares and enhancing functioning of the internal market) for its realization and Europe’s aim for strengthening public confidence in politics and science, reflect in the Law which is science-based, consumer-oriented and provides for a strong preventive approach. Furthermore, similar to the US the legal culture reflects the food safety management approach as well. In Europe legislation that fall under the Common goal are largely regulated on EU level through e.g. Directives and Regulations. EU food law is mainly regulated through Regulations; the General Food Law itself concerns a Regulation. This implies the Law is direct binding to all Member States. However, as a result of Europe applying
a preventive approach to Food Safety Law and involving the food industry as an important stakeholder in risk management procedures, the preliminary responsibility for assuring food safety across the food supply chain lays with the food business operators. An important aspect worth noting is that enforcement is left to the Member States. As a result, the responsibility to verify and monitor lays at Member State level. This is an important indication of EU legal culture, or better defined: EU pluralistic culture. Member States have each a different legal culture. Therefore, during the development of the General Food Law it has been clear Member States did not agree on an EU level enforcement mechanism. As a result of the process of law-making established in the EU treaties, Member States have the right to reject a certain proposal. This has been resulted in EU food law leaving enforcement measures up to the Member States to deal with since Member States have rejected the proposal.

In terms of Food Safety Management, these before mentioned features are to be identified as well. A certain incident must be first dealt with on Member State level in corporation with the food business operator(s). If it concerns an emergency or crisis as defined in the General Food Law the Commission will play the role of risk manager. However, there will be always corporation with the Member State(s) concerned. This system of governance is general consistent with EU Legal system. Which is generally characterized by the fact when measures on Member State level are not sufficient enough, intervention on EU level is applicable.

In case of China, PRC Food Safety Law is the first comprehensive Food Safety Law. Its underlying triggers are to be found in the new economic strategy of China after the Cultural Revolution; as a result the continuous food scares it deals with up until this day. The relatively fast development of PRC food law (Amendment and revised Amendment) is a reflection of the current food safety issues China deals with and the learnings thereof. On account of the ongoing revealed food scares after the enactment of the 2009 PRC Food Law, China found it was necessary to strengthen the law by inserting an amendment only to revise the Amendment three years later. Furthermore, the way the Food Safety Management system is designed in China’s food safety regulatory system corresponds to its Legal culture. Originally, prior to the enactment of the Law, several State level institutions were engaged in different aspects of food safety governance (e.g. quality, import/ export, safety in terms of health, commerce etc.). In addition, different laws/ standards were applicable. With the enactment of the Law in 2009, all aspects were integrated in one law but the institutions remained the same.

As a result, China dealt with a large amount of involved institutions dealing with a single law. Soon after, it appeared this created system was not working and with inserting the Amendment China attempted to take away major overlap of duties and tasks by integrating institutions. However, despite its efforts for improvement, China still deals with an inefficient large amount of involved institutions. Another aspect that makes the situation even more complicated, is that of an important feature of China’s legal culture: China’s multi-leveled governance approach. The before mentioned institutions are established on different State government level (e.g. County, Province, State etc.). Therefore, governmental oversight has become even more complex to adequately guarantee. With this respect, there is potential information sharing of sufficient data of a certain food safety risk will
be omitted even though the government level agencies are required to share information in the revised Amendment. Furthermore, the previous mentioned features are reflected in the Food Safety Management framework as well. In case of risk management, several institutions are risk managers; this is consistent with the amount of institutions involved. Consequently, one could consider in China’s Legal system the way a certain food safety incident is responded to is dependent on inter alia the extent of publicity of the event; capacity level of oversight; transparency; and communication and accuracy of the government level concerned.

Furthermore, with respect to food culture and the correlation thereof with Food Safety Law, this research demonstrates that for understanding the law one should understand the cultural values towards food safety of the place where the law is designed. To this end this research demonstrates the food law culture of a certain place largely reflects in the food law system concerned. For example, the US has experienced several terrorism attacks, especially in the past 10–15 years or so. These attacks, especially that of 09/11, have had enormous social impact (emotional impact such as fears for another attack to emerge) on the general US citizen. Such fears appeared applicable to the food supply chain as well. It is therefore to be noticed government’s response to this event, the development of the Bioterrorism Act, is consistent with the national values towards food safety and is thus a reflection thereof to be found in the law.

Another example, is the reflection of national values towards food safety in China’s relatively strict food law. China has experienced a series of food scares over the past 15–20 years or so. These incidents, mostly linked to food adulteration/ misbranding for financial gain, have had enormous socio-economic impact; e.g. people hospitalized ill, large brands such as Mc Donald’s and KFC had to abstain from selling meats/poultry because of the unsafety thereof (unsafe handling as a result of criminal incentives by the producer,). The famous Melamine scandal has even resulted in a large amount of sick people and reported deaths (mostly infants). These events have, as reasonably to be expected, led to major public outcry. The strict features of the revised Amendment (e.g. linkage to criminal law) are a clear example of China using the law as a tool for solving major social issues by intending to correct/deter criminal behavior. The relatively fast development of PRC food law in short period of time (Amendment and revised Amendment) is a reflection of the current national values towards food safety as a result of the impact of the food safety issues China deals with and the learnings thereof.

In the EU a reflection of the food law culture (predominant values towards food safety) in its law can be identified as well. The predominant food culture is mainly to be retraced in the importance of the preservation of local traditions. This is in particular applicable to the Mediterranean countries (e.g. Italy and France). With this respect, the importance of the use of local ingredients in
predominance food culture in Europe is highly valued. These facts are reflected in the important role of legal protection of the Place of Origin and Geographical Indications of many regional ingredients and foods in EU law. This can be seen not only as a tool to protect the economic interests of the local producers, but also as a way of strengthening the traditional food culture.

In conclusion, discrepancies in Food Safety Management framework are not only to be found in the events the development of the laws are triggered by, but also globalization, predominant food culture in place, economic reform and legal culture are all aspects that certainly have played major role in the design and structure of current Food Safety Laws of the systems concerned. In addition, this study demonstrates the food law culture of a certain place largely reflects in the food law system concerned.

Discrepancies in Food Safety Incident Response

The structure of a Legal system’s regulatory framework of Food Safety Management has direct impact on how governments deal with a certain food safety incident in practice. Hence, food safety incident response is a direct effect of the food law structure that establishes the legal basis for execution (response) in practice. The results of this study demonstrate the Legal systems have established their regulatory framework in completely different ways. As a result, the management tools; involved legal institutions; and incident management system are consistent with the legal culture in place and follow the regulatory framework these analyzed variables are established in.

In all selected and analyzed variables of the Food Safety Management system discrepancies can be identified. For instance, the involved institutions are not only different in terms of government level institutions, but more important are the discrepancies in risk managers and risk assessors between the Legal systems. Whilst in Europe the risk assessor (EFSA) is neutral, in the US the FDA as a Federal State agency is both risk assessor and risk manager and in China the risk assessor is even the Ministry of Health (NHFPC). These differences are inherent to the legal culture in place as previously discussed. The same accounts to the tools implemented and the approach to food safety incidents. These features are dependent on the legal structure itself and the involved institutions that apply these instruments.

In addition, with regards to the selected and analyzed variables, few similarities are to be identified. One of the few similarities identified are the preventive approach to Food Safety Law and the adoption of variable K (basics of risk analysis). With respect to the latter, both EU and US food law follow the Codex concept of risk analysis. China however, follows some parts of this concept and thus does not incorporate the Codex concept to the extent the EU and US do. Another similarity noticed is that in all Legal systems a system of lower level government and higher government of food safety response is applicable to some extent. For instance, in the US response is dependent on the situation intervention can occur on local, State or Federal level. In the EU, also dependent on the situation, intervention can occur on Member State or European level; in China the same accounts
but then on local (such as province, prefecture, county, township, and village) or State level. However, one needs to take into account that we are dealing here with differences in involved legal institutions (variable L), different management tools (variable M) and completely different incident management system (variable N). The underlying reason for these differences are, again, simply the features of Legal culture (differences in the design of the regulatory system, Legal system and Legal institutions).

Now that we have analyzed and compared the variables selected within the context of food safety risk management in the interest of food safety incident response, next these systems established in the laws will be in general assessed against the 8 principles of the food risk management process provided by the applicable International framework (FAO/WHO Food Risk Management Process). The assessment will be based on the general impression gained based on research so far conducted in this study to the Food Safety Management framework of the three selected systems at stake.

### Figure 6.3 Assessment Food risk management process

<table>
<thead>
<tr>
<th>Legal system</th>
<th>EU</th>
<th>US</th>
<th>China</th>
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<tbody>
<tr>
<td><strong>Codex principles of food risk management process</strong></td>
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<tr>
<td>Principle 1: Risk management should follow a structured approach.</td>
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<td>V</td>
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<td>Principle 2: Protection of human health should be the primary consideration in risk management decisions.</td>
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<td>V</td>
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<td>Principle 3: Risk management decisions and practices should be transparent.</td>
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<td>Principle 4: Determination of risk assessment policy should be included as a specific component of risk management.</td>
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<tr>
<td>Principle 5: Risk management should ensure the scientific integrity of the risk assessment process by maintaining the functional separation of risk management and risk assessment.</td>
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<td>V</td>
<td>• 344</td>
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<tr>
<td>Principle 6: Risk management decisions should take into account the uncertainty in the output of the risk assessment.</td>
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<td>V</td>
<td>• 345</td>
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<tr>
<td>Principle 7: Risk management should include clear, interactive communication with consumers and other interested parties in all aspects of the process.</td>
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<td>V</td>
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<tr>
<td>Principle 8: Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions.</td>
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</table>

In general the Food Safety Management framework of the selected system as established in the legal framework is broadly consistent with the Codex principles. However, in case of China, some principles are not clearly identifiable. Some uncertainties (principle 5 & 6) are present regards to risk communication. This is consistent with the results of the analysis in chapter 3 and chapter 4 where it is established China does not apply the Codex risk communication concept; it appeared to be reflected in its approach to food safety incidents as well although it cannot be concluded these

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344 Since the functional separation of risk assessment and risk management is not clearly mentioned in the law and risk assessment seems the basis for food safety reform and decision-making, this feature cannot be answered with certainty.

345 Ibid.
principles are not present in PRC Food Safety Law at all. PRC Food Safety Law simply does not provide in clarification with this respect.

In the following the results of the case study and the absence of China therein will be briefly explained from a socio-legal context. With regards to the execution of food safety incident response in practice, the US and EU follow the Codex concept of risk analysis, with this respect these Legal systems show similarities. Furthermore, the case study demonstrates the EU and US in general follow their regulatory Food Safety Management framework in dealing with food safety incidents in practice which is broadly consistent with the four key elements of the International FAO/WHO Framework of Food Risk Management.

However, the results of the case study demonstrate the situation is different in case of China. China’s regulatory framework of Food Safety Management is not quite clear with respect to the concept of risk communication (see assessment with Codex principles). Chapter 4 already shaded some light on possible explanation thereof. It comes down to the fact China originally can be considered to be a highly centralized political system. Furthermore, its multi-leveled government system (hierarchical approach) contributes to potential that information sharing of sufficient data of a certain food safety risk will be omitted. Hence, for a certain event to reach higher level government, several formalities need to be met. Furthermore, chances are local government restrain from information sharing. This is reflected in case of the Melamine scandal for example. In this case it has been reported that during the event various local government and industry tried to hide information, and even deleted messages from the internet. Only in September that year (6 months after) State level government finally gained information and as a response directly initiated the Major Food Safety Incident Class I Response Mechanism. It is believed that the local government was so deeply involved in the interest that they did not have enough incentive to communicate with the public.  

Previous mentioned justifies the situation China currently faces: ongoing occurrence of food scares. The occurrence of food scares seems to proceed despite government’s efforts to stricter the law and deter fraudsters to commit food adulteration/counterfeit. Hence, underlying reasons for this are not only to be found in the Countries’ size, number of people and complex food supply chain which makes traceability a challenge to control, its legal structure is another obstacle as well. In conclusion, it is a fact that the feature of risk communication is not an embedded concept within PRC law in itself. The absence of accessibility to risk communication and thus not being able to provide a case study on China’s food incident response, is an entourage thereof.

China has experienced difficulties in the past as a result of its weak system of risk communication (e.g. consequences of Melamine crisis, SARS etc.). As a result it has acknowledged the gaps in PRC food law with regards to risk communication and in particular in its health policies (food safety policy fall under this area). China in the revised Amendment of its Food Law has clearly shown

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346 Results of Yandong & Zhang (2013), source used in case study. In March, 2008, some children were found to have stone in kidney, which was soon related to the infant formula they ate. A harmful additive, melamine, was found in the infant formula and related milk products.
efforts for major change in the field of risk communication. Establishing communication platform exchange in the interest of strengthen government risk communication mechanism and establishing the principle of transparency in risk management processes, are major steps towards opening up to the public. Since currently the revised Amendment is not in force yet, it is a logical outcome access to information on risk management processes with regards to food safety incident response is scarce.

Consequently, in the revised Amendment certain features with regards to government risk communication exchange and transparency are incorporated even though these features are not fully consistent with the risk communication concept as defined by the International standards/guidelines. With this regard, it should be noted it is not correct in the interest of the comparative approach method to use the Codex concept of risk communication as an ideal end– point for comparing different Legal systems. This would be considered wrong as each Legal system is to be considered unique from its legal– cultural context.

Therefore, it is not justified to simply state it is mainly the law in itself that is lacking the concept of risk communication which results in lack of governmental information on food safety incidents. Rather, with this respect one should take into account the context the law is placed: involving its Legal culture and current developments in the field of Food Safety Law. Only future development of China’s establishment of risk communication can justify and judge China’s approach to food safety incidents.

In conclusion to this analysis and as an answer to the central question, “How can discrepancies in governmental response to food safety incidents be explained from the regulatory framework of Food Safety Management and what is the role of the legal culture therein?”, the following can be stated: the food laws of all selected system have different roots, are influenced by different factors and as a consequent have undergone developments in different context and, particularly in case of China, currently undergo developments as well. These features result in major discrepancies in the design of the Food Safety Law system of the Legal systems concerned.

Furthermore, the comparative analysis demonstrates that in explaining discrepancies in Food Safety Management system and as a result discrepancies in food safety response, it is inevitable to incorporate the legal culture of the context in where the law is established. Hence, Legal culture intertwines with the Legal system’s laws and the same applies to, in the interest of this study, the regulatory framework of Food Safety Management.

As a conclusive remark on this comparative analysis, the food laws have been designed in different context (roots, influences, development) and at the same time function in different conceptual framework as well (legal culture and reflection of national values towards food safety in Food Safety Law), this determines heterogeneity in the food laws themselves and as a result, discrepancies in the management framework and food safety incident response.
Conclusion & Discussion

This study provides insights into the regulatory framework of Food Safety Management of some of the world’s largest economies: European Union, United States of America and China. The study has provided interesting results towards understanding discrepancies in food safety incident response from mainly a legal angle including some socio-legal aspects. The results have provided answers on how discrepancies in food safety incident response amongst different legal systems can be identified, sustained by an in-depth analysis of the applicable regulatory framework. For determining discrepancies between the selected Legal systems, selected variables are compared and analyzed. The comparative analysis of the selected variables has contributed to answering the central question. To this end, the results of this study demonstrate legal culture (as defined for the purpose of this study) plays a crucial role in the structure and development of the Food Safety Laws belonging to the Legal systems. Therefore, for understanding the discrepancies identified in the comparison of the variables, one should take the legal culture in place into account. The results of this study emphasize the importance of taking the legal culture in place into account in comparing different Legal systems; therefore each Legal system is to be considered unique.

Furthermore, the comparative analysis of the case study has shown that, irrespective of major discrepancies in the structure of the regulatory framework of Food Safety Management and the procedure the Legal systems implement in response to a certain food safety incident in practice, in general these features are broadly consistent with the applicable International (FAO/WHO) framework. This in particularly accounts for the EU and US. In general these analyzed Legal systems fully comply with the assessed framework. However, in case of China, the results emphasize the complexity of comparing completely different Legal systems.

In assessing China’s framework with the applicable International framework, it appeared some principles were not clearly identifiable. With this regard the results show some uncertainties regards to the concept of risk communication. This feature influences China’s approach to food safety incident response and determines the results of the case study. In the comparative analysis this feature has already been extensively discussed. It comes down to the fact that the feature of risk communication is not an embedded concept within PRC Law in itself. The absence of accessibility to risk communication and thus not being able to provide a case study on China’s response to food safety incidents, is an entourage thereof. However, China in the revised Amendment of its 2009 PRC Food Safety Law, has clearly shown efforts for major change in the field of government risk communication. For China to establish a communication platform exchange in the interest of strengthen its government risk communication mechanism and to establish the principle of transparency in risk management processes, are major steps towards opening up to the public. Since currently the revised Amendment is not in force yet, it is a logical outcome access to information on risk management processes with regards to food safety incident response is scarce. Only future developments in China’s government risk communication mechanism will justify China’s establishment of risk communication in its approach to food safety incidents.
Moreover, with regards to the development of PRC Food Safety Law in general, China is willing to come along with the developments of International Food Safety policies and therefore made changes in the field of food safety regulation. With this respect, it should be noted China faces an era of Food Safety Law establishment and reform; its situation bears some resemblance to what the US went through early in the last century, when shockingly unsanitary conditions in the meatpacking industry became a target of the progressive movement. To this end, China’s Food Safety Law is still in its infancy.

From the outcomes of this study it can be considered the major challenge China currently faces, is the execution of its fledging Food Safety Law in practice. China’s PRC Food Safety Law is ambitious and complex formulated; and in an ideal environment it would reach high level of food safety assurance. However, its legal culture (e.g. Legal system, legal institutions etc.) and in specific its oversight multi- leveled governance approach and as a consequence lack of unified administrative oversight, forms a major obstacle in adequate execution of the ambitious 2009 PRC Food Safety Law. To this end, future development of China’s Food Safety Law is interesting to follow. It’s revised Food Safety Law (revised Amendment) in force per October 1st 2015, is promising. However it is China’s future approach to the execution thereof that shall define.

This study could be considered a starting point providing opportunity and, hopefully, reason for further research in the interesting and dynamic field of Food Safety Law from a comparative point of view; and in particular that of China’s Food Safety Law, which from my point of view is paid little attention to yet.
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Appendix I

Timeline of Events: Multistate Outbreak of *Salmonella* Bareilly and *Salmonella* Nchanga Infections Associated with a Raw Scraped Ground Tuna Product -- United States, 2012

**Outbreak Identification and Source Implication**

- **March 1**: NY State Department of Health notified CDC's Outbreak Response Team (ORT) of a cluster of 48 persons infected with *Salmonella* Bareilly with the same unusual pulsed-field gel electrophoresis pattern.
- **March 2**: PulseNet showed 13 persons in 7 states with the same pattern. CDC began coordinating a multistate investigation and held first multistate conference call.
- **March 8**: Exposure information from 8 ill persons revealed that 7 reported eating seafood and 5 ate sushi in the week before becoming ill. TX Department of State Health Services reported first cluster of 2 unrelated ill persons who ate at the same Japanese steakhouse which serves sushi.
- **March 13**: WIC Department of Health Services (WICDS) reported a second cluster of unrelated ill persons eating at the same Japanese restaurant.
- **March 16**: Preliminary information from 22 ill persons revealed that in the week before illness 80% reported eating seafood and 55% reported eating sushi. Among 8 ill persons who reported the type of sushi, all reported eating tuna. WICDS reported a third cluster of unrelated ill persons who ate sushi purchased from the same grocery store.
- **March 17**: Among 19 ill persons who were asked detailed questions about eating sushi, 18 reported eating sushi in the week before illness and 80% of sushi eaters reported eating spicy tuna. CDC Department of Public Health reported a fourth cluster of unrelated ill persons who ate sushi at the same restaurant. MD Department of Health and Mental Hygiene reported a fifth cluster of unrelated ill persons who ate sushi at the same restaurant.
- **March 29**: Restaurant sushi order comparison study launched.
- **April 4**: CDC posted initial web announcement about investigation.
- **April 9**: Preliminary results of restaurant comparison study from 4 restaurants show that the proportion of comparison sushi orders containing spicy tuna as an ingredient averaged 19% (ranging from 29% to 53%).
- **April 10**: WICDS notified CDC's ORT about 5 recent *Salmonella* Nchanga infections occurring in the same states as the *Salmonella* Bareilly cases. One ill person in WI had reported eating tuna sushi.

**Number of persons by week of upload to PulseNet**

**Number of persons by week of illness onset**

**Trackback and Regulatory Activities, and Results of Product Testing**

For more information, visit CDC's *Salmonella* website: [http://www.cdc.gov/salmonella/](http://www.cdc.gov/salmonella/)

- **March 15**: FDA began receiving supplier and invoice data collected by state and local departments of health and agriculture.
- **March 20**: FDA activated an Incident Management Group and transferred *Salmonella* Bareilly response activities within the FDA Emergency Operations Center. CDC staff member joined FDA Team in Washington, DC.
- **April 2**: FDA conducted an Incident Management Group and transferred *Salmonella* Bareilly response activities within the FDA Emergency Operations Center.
- **April 3**: FDA conducted a seafood Hazard Analysis and Critical Control Point inspection at Moon Fishery Pvt. Ltd.
- **April 13**: FDA issued two Import Alert for fresh and frozen tuna from Moon Fishery India Pvt. Ltd.
- **April 19 - 24**: FDA conducted a seafood Hazard Analysis and Critical Control Point inspection at Moon Fishery India Pvt. Ltd.
- **April 20**: FDA announced finding the outbreak strains of *Salmonella* Bareilly and *Salmonella* Nchanga in unopened packages of yellowfin tuna product imported from Moon Marine USA Corporation.
- **April 26**: FDA announced finding the outbreak strains of *Salmonella* Bareilly and *Salmonella* Nchanga in unopened packages of yellowfin tuna product imported from Moon Marine USA Corporation.