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Building Food Safety Governance in China

Edited by Jérôme Lepeintre and Juanjuan Sun

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2018

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"Compiled by a number of international experts, this book provides a comprehensive picture of the food safety system in China. It will be of great use to those who want to understand better the Chinese regulatory environment in the field".

– Vytenis Andriukaitis, *European Commissioner for Health and Food Safety.*

"I have been truly impressed by the increasing effective engagement and participation of China in the work of the FAO/WHO Codex Alimentarius Commission, which is the internationally recognised food safety and quality standards-setting organisation. China is a very complex and unique country whose intricacies are difficult to understand for those who are not well versed in its system. This comprehensive book not only gives readers an in-depth presentation of the provisions of the Chinese food safety legislative framework but it also presents the keys to understanding its rationale and objectives. I highly recommend this book to all those involved in the food regulatory field".

– Awilo Ochieng Pernet, *Senior Food Safety Expert (Switzerland), Vice-Chairperson and Chairperson of the FAO/WHO Codex Alimentarius Commission from 2011 to 2017.*

"The right to the safety of food is a fundamental human right, a right of human dignity, and an essential value shared by all humankind. Safeguarding the right to food safety and promoting food safety governance is, therefore, a common challenge and mission of every country across the globe. Based on this shared consensus, food safety has already become an international topic. For this reason, China's efforts are not only oriented to safeguarding the right to food safety for both national and international citizens; China is also strongly devoted to continuous exchange and cooperation with other countries and regions in the field of food safety. We have to draw from the experiences in food safety governance of the European Union and its Member States, shape food justice, and create shared food safety cooperation mechanisms. At the same time, China's own experiences in food safety governance will also enrich other countries' food safety culture and systems. I believe that this book provides an excellent opportunity to understand China's experiences and peculiarites".

– Han Dayuan, *Professor, Law School of Renmin University of China; Executive Director, Renmin University of China's Center for Coordination and Innovation of Food Safety Governance.*

"This book contains a comprehensive review and analysis of the current Chinese food safety regulatory framework. China is a country of paradoxes, relying on its age-old history on one hand, and able to quickly implement considerable changes on the other hand. I contributed to training courses on food safety organised in the context of the Shanghai 2010 Expo and could already feel there the resolute determination to progress of the Chinese authorities. I strongly recommend this book to anyone interested in food safety in China".

– Eric Poudelet, *former Director responsible for Food Safety in the European Commission Directorate General for Health & Consumers.*

Contents

List of abbreviations

AQSIQ: General Administration of Quality Supervision, Inspection and Quarantine

CAC: Codex Alimentarius Commission

CFDA: China Food and Drug Administration

CIQ: Entry-Exit Inspection and Quarantine Bureaus

CNCA: Certification and Accreditation Administration

FAO: Food and Agriculture Organisation of the United Nations

GACC: General Administration of China Customs

IPPC: International Plant Protection Convention

MoA: Ministry of Agriculture

MARA: Ministry of Agriculture and Rural Affairs

MoH: Ministry of Health

NHC: National Health Commission

NHFPC: National Health and Family Planning Commission

NPC: National People's Congress

NPCSC: National People's Congress' Standing Committee

OIE: World Organisation for Animal Health

QTS: Bureau of Quality and Technical Supervision

SAC: Standardisation Administration of China

SAIC: State Administration for Industry and Commerce

SAMR: State Administration for Market Regulation

SDA: State Drug Administration

SFDA: State Food and Drug Administration

WHO: World Health Organization

WTO: World Trade Organization

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I am extremely grateful to all the authors as well as my co-editor Sun Juanjuan for accepting to share their experiences and knowledge on their respective field of expertise. It was essential for this project to get contributions from people who are really involved in the daily management and research of food safety in China and not pure theoreticians.

I also want to address a special thanks to Alessio Petino and Lu Yixin from Development Solutions Europe Ltd., who did not count their hours to deliver under the pressure of a very tight calendar and who were always constructive and innovative to find practicable solutions when needed. The project could not have been finalised without their dedication.

I am also very appreciative of the support received from the European Union Delegation to China, the Ambassador of the European Union to China, Hans Dietmar Schweisgut, my direct colleagues and friends from the Agri-Sante section, Nicolas Dandois, Markus Klinger and Wang Huan, the hierarchy and colleagues in Brussels Headquarters of the European Commission, particularly Sandra Gallina, Michael Scannell, John A. Clarke, Koen van Dyck, Andrea Dionisi, Cécile Billaux and Wolf Maier.

There is also one person I wish to thank specifically, not only in the context of this book, but also more generally for her irreplaceable cooperation, support and help in everything in relation to food safety in China. This person is Zhang Ziting from the European Union Chamber of Commerce in China.

Last but certainly not least, I would like to thank my wife Mercedes Révy for constantly encouraging me from the first day. She has always been my inspiration, motivation and an invaluable adviser in all dimensions of this project.

My sincere hope is that this book could help, in one way or another, people having to deal with food safety regulations in China, officials, government representatives of exporting countries, lawyers, regulatory affairs managers, lobbyists, journalists, academics, consumers and their representatives, etc. This book is dedicated to them.

Jérôme Lepeintre
Beijing, May 2018

Foreword

Food security has always been a major concern for Chinese leaders. Being the country with the largest population in the world – currently 1.4 billion – China is facing an equation that is well known but not easy to solve: how to feed 21% of the world's population with only 12% of the available land and 9% of the water? Urbanisation introduces additional challenges. In 1950, only 13% of the population lived in cities, today this figure is largely over 50%, leaving the land unattended. The shifting dietary preferences of China's more affluent population raises even more difficulties. In short, the quantity, range and quality of China's food supply are among of the country's most pressing challenges.

Trade can provide an answer: China is one of the biggest markets for food exporting countries worldwide. The increasing demand for food not only creates opportunities for farmers and producers all over the world but also puts a floor under the global prices for agricultural products. Matching supply and demand through trade, China and the European Union progressively became very close trade partners. China, including Hong Kong, is now the second export market for European food and drinks with a total value of €16 billion in 2017 representing 12% of total EU food exports.

But food security cannot be achieved without food safety. From "gutter oil" to melamine-tainted milk, and fake meat to contaminated strawberries, there is a long list of food safety incidents in China. These scandals caused great anxiety among domestic consumers who are requesting the government to find solutions.

One characteristic of China is the very fragmented nature of its food chain with numerous intermediaries multiplying the probability of non-compliances. The country has a huge network of small food production and processing companies, 98% of them with less than 10 employees, which makes it extraordinarily difficult for the authorities to carry out their duties of supervision and control.

In 2008, after the scandal of milk tainted with melamine, the situation became unsustainable and the authorities quickly understood that it was time to "take the bull by the horns".

The rhythm of reforms and new laws accelerated: new *Food Safety Law* in 2009, then considerably revised in 2015, creation of the risk assessment authority in 2011, creation of the China Food and Drug Administration in March 2013, then dismantled and reincorporated in the State Administration for Market Regulation, while the Food Safety Bureau of the General Administration of Quality Supervision, Inspection and Quarantine was moved into the Customs administration in March 2018.

From the beginning the EU closely followed this reform process and supported China by sharing its experience and best practices through various cooperation instruments, EU-China Trade Project, Partnership Instrument, Better Training for Safer Food to name a few of them.

Now, 10 years later, and just after the massive restructuring of the government during the spring of 2018, it may be a good moment to look back, review all what has been done and analyse the current food safety legislative framework of China to identify its strengths, but also its weaknesses on which we may focus our bilateral cooperation in the coming years. This is precisely the purpose of this book: compiling a series of chapters, covering all aspects of food safety, from standards to penalties, written by the most qualified experts, mostly Chinese, in which the entire food safety system is described and analysed with the objective to better understand the background and the rationale of its evolution. The reader will discover many parallels with the European Union which also went through the rebuilding of its food safety legislative framework 20 years ago. Food safety is a continuous task for China, the EU and globally. New challenges and new hazards appear and require a constant adaptation of the control system to protect our consumers' health while setting the conditions for a wide choice.

Today in our globalised world with a liberalised trade regime, cross-national and cross-continental production and with the exponential development of e-commerce, food and associated safety hazards are crossing borders like never before. Food safety can only be achieved and efficiently dealt with through international cooperation. The Food and Agriculture Organization, Codex Alimentarius, World Health Organization and World Trade Organization are the places where we must invest our energy, time, creativity and sufficient resources to create a framework that allows us to feed future generations in a sustainable manner.

We sincerely wish that this book, freely available for electronic download to anyone both in English and Chinese languages, could contribute to an even better understanding, a closer cooperation between European and Chinese actors involved in food safety, at regulatory and industry levels, with a dual objective in mind: supporting our bilateral trade and hence our economies while protecting consumers' health in a sustainable and responsible manner.

John A. CLARKE
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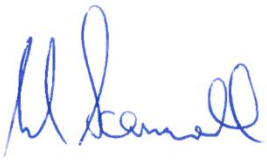

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Chapter One

Introduction

Sun Juanjuan [*]

The Chinese saying firewood, rice, cooking oil, salt, sauce, vinegar and tea are the seven necessities to begin a day" shows the great significance that Chinese people attach to food. The saying that "the country is based on the people and the people regard food as heaven" not only further remarks the importance of food as a basic need for people's livelihood, but at the same time emphasises that the state must pay attention to food issues from all the economic, political, legal and cultural perspectives in the process of governance. Moreover, owing to the prominence of food safety issues, the addition to the above saying of the remark that "safety comes first when it comes to food" also shows that safety and security have become the bottom line of food-related regulations. Undoubtedly, all countries face various food-related regulatory challenges, including those covering food supply, food safety, and food quality, but due to differences in economic and social development contexts as well as in political and legal systems, both similarities and diachronic and consensual differences emerge when tackling such challenges. In this regard, China attaches great importance to food safety and emphasises the shift from regulation to governance. This shift not only serves as a gateway for understanding the evolution and improvement of food safety policies, laws and systems, but also provides rich materials for analysis and case studies to any reader who is engaged in the fields of law, food, and Chinese research, or who is simply interested in these topics.

1.1. Food safety and rights

Food embeds the power of life and death.[1] Ensuring the safety of food determines whether this power benefits rather than endangers mankind. In this vein, what is food safety? Although the answer may differ depending on one's specific field, profession or experience,

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[*] *Dr. Sun Juanjuan is a researcher at the Centre for Coordination and Innovation of Food Safety Governance of the Renmin University of China, and lecturer for publicity campaigns on the Food Safety Law organised by the China Food and Drug Administration. Dr. Sun has participated in the European Food Law Programme Lascaux under the EU 7th Framework Research Programme, as well as in legislative activities in China for the* Food Safety Law. *Her achievements include a book on a comparative study of food safety regulation in light of the European, American and Chinese law, and Chinese translations of European food laws.*

[1] Wilson, B. (2010), *"Swindled: from poison sweets to counterfeit coffee: the dark history of the food cheats"*, translated by Zhou Jilan, Sanlian Bookstore, p.11.

one broad consensus is that food safety relates to the health and life safety of humankind, and therefore it has important historical, political, and economic implications. For this reason, food safety and how to safeguard it can constitute a macro issue relating to a country's food policy and legal system, as well as to international coordination and domestic participation of various stakeholders.[2] However, it needs to be stressed that food-related issues are problem-oriented, and are normally polycentric.

On one hand, in addition to food safety, there are a wide variety of other topics directly relating to food supply, including food security, food safety, food nutrition, food quality, and food fraud. Food security emphasises, from a quantitative perspective, the elimination of hunger and addresses malnutrition through the provision of adequate staple food and a variety of non-staple food supplies. Following the changes in dining habits, malnutrition is no longer a mere health problem originating from inadequate nutrition, but also embraces chronic food-borne diseases caused by over-nutrition. In addition, following the overall raising levels and upgrade of consumption, consumers' demands for food are no longer limited to meet basic subsistence needs such as food sufficiency and safety, but are increasingly becoming differentiated and based on individual preferences. It is true that fraud involving food safety and food quality are not a novel topic, but with the extension as well as the increasing complexity of the food supply chain, food fraud – in particular economically motivated adulteration – has become a new global issue.[3] Within this process of dietary changes and cross-cutting issues, multiple safety issues from the 1980s have successively highlighted the importance of safety in food, making into an independent regulatory issue.[4] Yet, as part of the entire food system, food safety closely links to other food issues such as food security, food quality, and food nutrition. The solution to food safety is constrained by both other separate food issues and the food system as a whole, and in return can affect both solutions to other food issues and the overall functioning of the food system.

On the other hand, when the changes within the food supply chain constitute the micro background of food safety governance, the solution to food-related problems cannot be separated from their socio-economic, environmental and cultural macro context, because only with such a comprehensive macro analysis can the roots of the problem be eradicated completely. The formulation of food-related policies and laws will also need to take into account such factors. For example, while the role of science may contribute in converging food regulations in various countries, cultural factors have represented an obstacle for the United States and the European Union to reach a consensus on the implementation of

[2] F.Yiannas, "Food safety=behavior", translated by Sun Juanjuan, *Science Press*, 2018.

[3] Jeffrey C. Moore, John Spink and Markus Lipp, "Development and application of a database of food ingredient fraud and economically motivated adulteration from 1980 to 2010", *Journal of Food Science*, 2012, 77(4), pp. 118-126.

[4] Sun Juanjuan, "The evolving appreciation of food safety", *European Food and Feed Law Review*, 2012, Volume 7, Number 2, pp.84-90.

pasteurised milk, the use of hormones in cattle breeding, and the development of genetically-modified (GM) foods. As if it was not enough, the interaction of the socio-economic, environmental and cultural macro background with the micro context of the food supply chain itself will also generate new food or cross-cutting issues, which in turn will require systematic thinking and overall analysis. For example, when it comes to food safety and health safety, it is also necessary to consider the concept of "One Health" – a new concept proposed against the background of zoonosis outbreaks at the beginning of the 21st century. In view of the relationship between animal health and human health, and of the need for interdisciplinary cooperation in preventing such health problems, the concept of One Health emphasises the correlation of humans, animals, environment, and health, and thus provides a cooperative governance approach for various disciplines and international organisations in their joint commitment to solving problems such as food safety and climate change.[5]

In this context, the proposal of "right to food" has not only ensured the realisation of basic subsistence needs through the establishment of human rights, but has also provided evidence for the state to get involved in the supervision and management (监管, *jianguan*) of the food sector, also preventing regulatory agencies from implementing policies that go against this right. The right to food is not only a right eliminating hunger, but also a right ensuring access to adequate food which integrates the above-mentioned different demands on the quantity and quality of foods. As a basic right, the "right to adequate food" means that everyone has access to sufficient, safe, and nutritious food so that they can live with dignity. In summary, "adequate food" is a right that emphasises three key factors: adequacy, availability, and accessibility. "Adequacy" requires that food can solve the problem of hunger and malnutrition in a quantitave measure, and also that it can guarantee the quality of food so that people's health will not be threatened by any kind of harmful substance. "Availability" requires that food can be obtained from agricultural production or from food supply chain purchase. "Accessibility" emphasises that individual needs for food should not impair other rights such as access to housing and education, and it also emphasises that everyone, including in particular special groups such as children and the elderly, can get access to food, even under special circumstances like natural disasters. However, difficulties emerge today in the exercise of rights due to problems such as unfairness and non-transparency in the modern system of food production and distribution system.[6] Consequently, various issues concerning food security, food nutrition, food safety, and food quality also arise. At the same time, the state has the obligation to respect, safeguard and help the fulfilment of these rights. Thus, it is necessary that policies, laws and other tools are employed to deal with different types of food-related issues.

[5] Sun Juanjuan (2016), "Legislative development of food safety: basic needs, safety priorities and One Health", in *Human Rights* (5), p.71.

[6] Sun Juanjuan, Yangjiao, "Legalised Development of Right to Adequate Food and Relevant Conceptions", *Human Rights*, 2017(3), 88-104.

As mentioned above, food safety problems are not novel ones; but given the prominence of food safety issues, particular attention has increasingly been put on its legislation, regulation and governance. The initial goals of food-related regulation tended to focus on ensuring sufficient supply. Though supervision and management of sanitary conditions were also enforced to ensure the safety of food, these remained a secondary regulatory goal as considerations were primarily given to economic factors. Only after the constant emergence of food safety issues did food safety start to receive the required attention, and consequently became a risk regulatory area independent from food quantity and food quality. The limited professional knowledge and lack of food information affecting the majority of consumers make them unable to effectively manage the risks caused by unsafe food. These risks are even further exarcebated by the shift towards centralised, technological and scale production of food due to broader scale and potential scientific defects in new technologies. It becomes therefore necessary that such public risks – which are not well-understood and controlled by individuals – are maintained to an acceptable level through government regulations, so as to ensure that individuals are exempted from consequent health threats. In this view, states are taking increasingly active efforts in the regulation and governance of risks as a means to ensure food safety. In this regard, it has already become a common practice to adopt a basic food safety law to establish a legal system of risk management and a corresponding system of supervision and management.

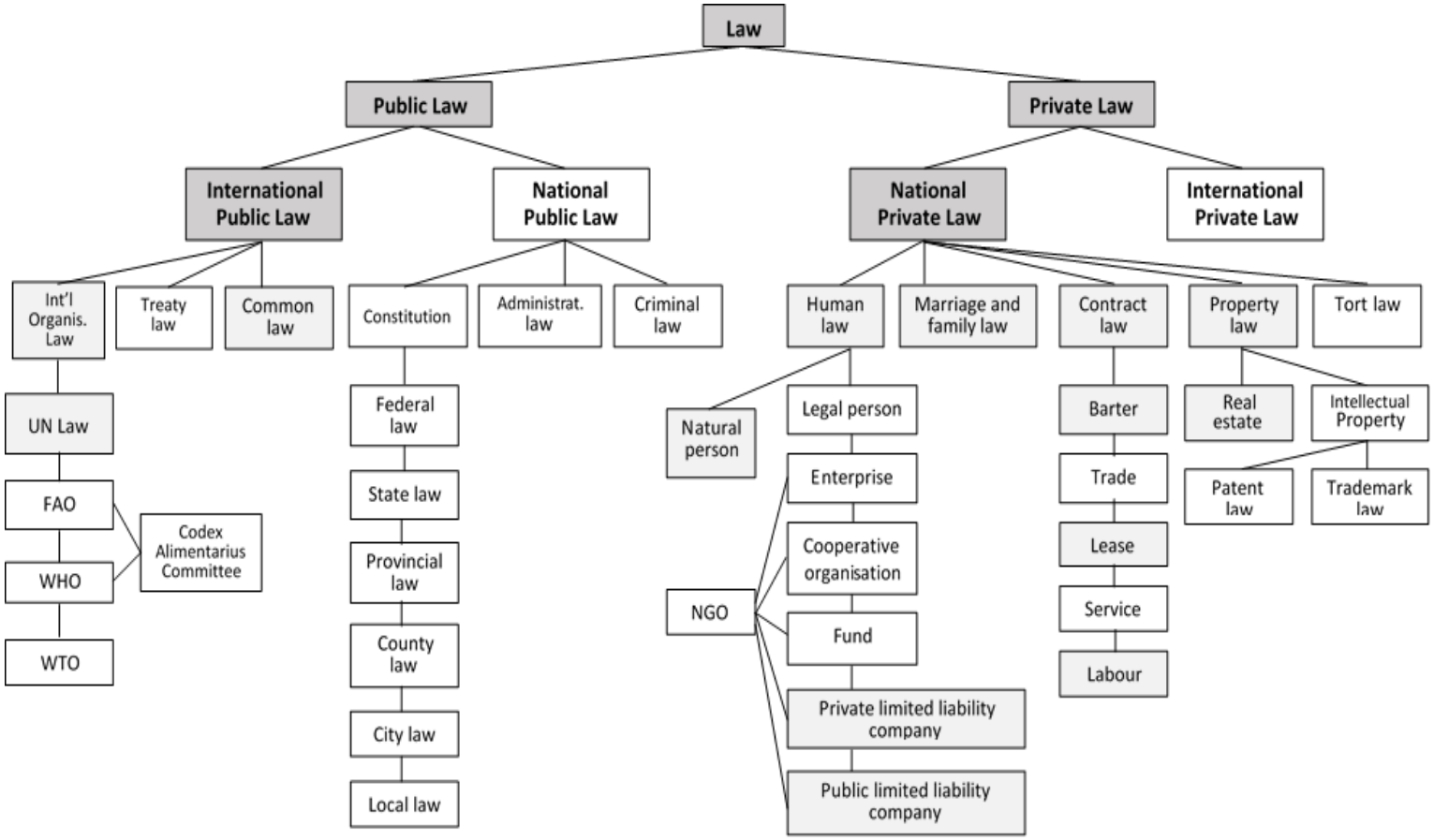
1.2. Laws and food safety

As a kind of social control, law is a portrait of the society, and its functions lie in maintaining social order. The primary function of law is therefore to regulate and limit the behaviour of individuals in their interactions with others, and the law itself reflects the current intellectual, socio-economic and political conditions. On this account, in order to address constantly emerging challenges within the food supply chain, food safety regulations must in first place ensure that relevant laws are updated and in line with the times.

As a code of conduct, law is a rule that sets limits on different human behaviors so as to manage how people should behave.[7] Rules preventing unsafe foods to be sold on the market do not guarantee that this phenomenon will not happen; rather, they require that this phenomenon should not happen. This means that it is the obligation of the main actors who circulate foods in the market to ensure safety. This also means that although there exist rules that prevent unsafe foods to be sold on the market, there should also be rules to deal with the consequences if unsafe food products have entered the market. In this sense, the function of law is to prevent and resolve disputes by establishing rights and obligations in our society. In general, laws can be understood through the dichotomy between private laws and public

[7] Bernd van der Meulen (eds), "European Food Law Handbook", *Wageningen Academic Publishers*, 2014, p.54. The picture of the law framework at p. 7 is also retrieved from this book.

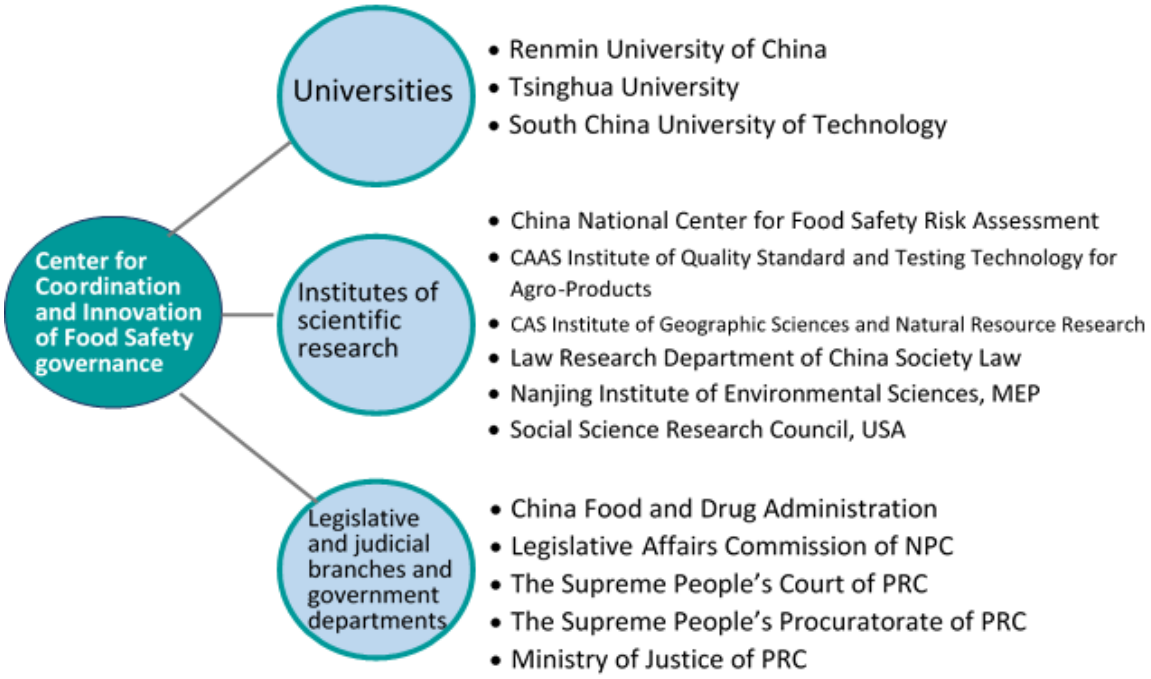
laws. Private laws refer to those affecting the relationship between parties that neither have public power nor perform public power. Distinctions can further be made between property law, contract law and tort law. Public law, on the other hand, deals with the relationship between public agencies with public power, and it can further be divided into the Constitution, administrative law, and criminal law. Laws are based on national laws and are usually divided into two main systems, namely common law and civil law systems. In addition to mutual exchanges between legal systems, however, following the spreading of globalisation legal coordination at the international level is also increasingly being promoted. A typical example is the development of international economic laws concerning the World Trade Organization, which also involved the integration of international food trade-related rules, among which the "*Agreement on the Application of Sanitary and Phytosanitary Measures*" and the Codex Alimentarius are particularly noteworthy.



Regarding laws on food safety as well as their development, the legislative model adopted throughout a relatively long period has been problem-oriented, that is, relevant legal provisions have been formulated or modified in accordance with the occurrence of food safety issues. Experience shows, however, that this kind of reactive stopgap legislative approach is not sufficient to safeguard public health due to the high recurrence of food safety problems. It is precisely for this reason that China, after the 2008 milk scandal, decided to

thoroughly reform its food safety legislation, by means of introducing a basic law integrating all existing food safety-related rules. The function of the basic law is to provide a basis to the legal framework which is constituted by legislations at different levels, such as administrative regulations, local regulations, and departmental rules. Moreover, the significance of a basic law such as the "*Food Safety Law of the People's Republic of China*" (hereinafter referred to as the "*Food Safety Law*"), lies in the fact that it clearly indicates public health as the first objective to achieve, and also emphasises the perspective of risk management in safeguarding food safety. Risk management is a scientific means applied to the regulatory field, which as such shall firstly be based on science. Through risk assessments, the nature, degree and scope of risks are identified and confirmed, and on this basis corresponding risk management measures are taken. Throughout this process, it is necessary to establish participation channels for experts in the field to provide scientific opinions, as well as to other relevant stakeholders and the general public to express their demands and perceptions, while constantly keeping them informed. Because of this, risk management, risk assessment and risk communication together form a structural decision-making system, that is, risk analysis. Within the field of food safety, risk analysis has already become a fundamental principle which ensures the scientific and democratic character of regulation. Correspondigly, risk assessment and communication mechanisms have already been introduced within China's legislation, thus recognising risk management as a legal principle. Chinese food safety legislation has successively introduced systems of risk assessment and risk communication, and has defined risk management as a legal principle.

In addition, food safety has also drawn attention from law circles, with several case studies on food safety-related laws conducted on the basis of traditional sectorial laws, which have in turn gradually contributed to adding an "interdisciplinary" characteristic to the development of food safety. Being interdisciplinary does not only refer to an "intra-crossing" among various disciplines of law, such as administrative law, economic law and criminal law; it also refers to reaching the fields of law and economics, sociology and management, as well as other social studies, until such development will finally also embrace the coordination role of natural sciences. It is noteworthy that "food law" has already risen in numerous countries as an independent law field. In China, existing academic research on food safety law does not only already reflect a problem-oriented approach, but also shows that it advances with the times and keeps up with world trends. For instance, in line with the emergence and development of food law, the Center for Coordination and Innovation of Food Safety Governance of the Renmin University of China – with which the author of this chapter is affiliated – has been very active in promoting the development of food law in China through establishing new disciplines and coordinating relevant research activities, as well as through cooperation with other research fields to provide intellectual support and experience-sharing.

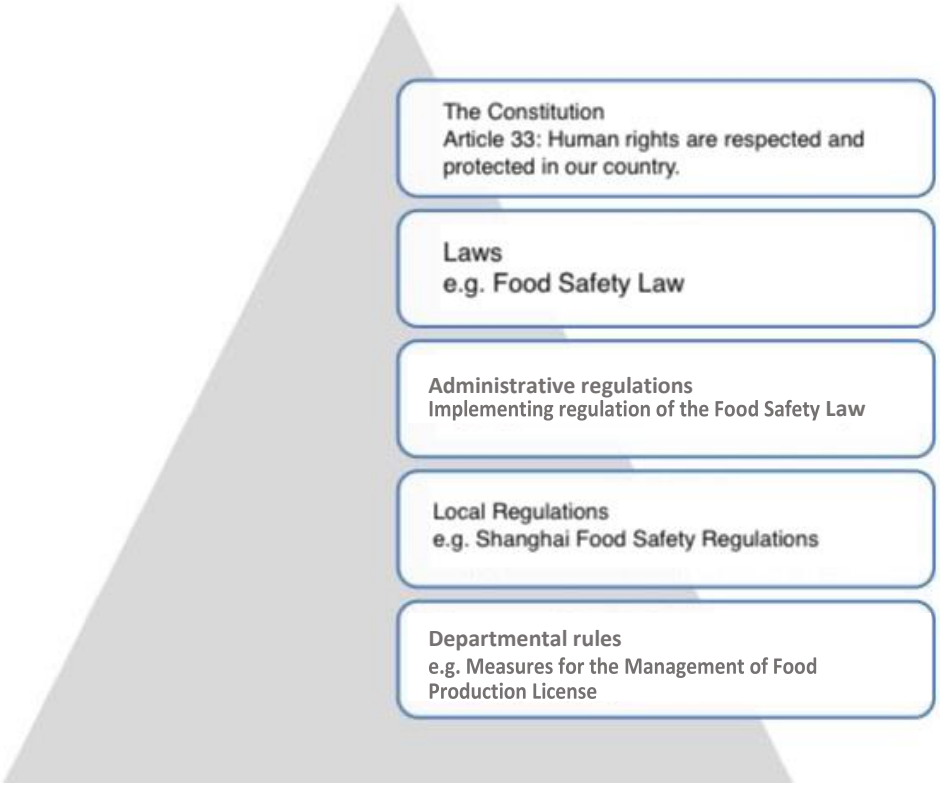


1.3. China's concerns and progress

As far as food is concerned, food security, food safety, food quality, food nutrition as well as food fraud are what China has always been highly concerned about and what it has constantly been trying to improve. Among these, given its large population, China has always been granting special attention to food security. The topics of food safety covered by this book outline an important lesson to learn: if the state intervention fails in solving problems that threaten the safety or health of the public or consumers, the consumers will lose their faith in both the food industry and in the country's capability to conduct public governance. It not only includes native Chinese consumers, but also involves international consumers brought by the globalisation of food trade. That is also the reason China has paid unprecedented attention to food safety governance and put into place laws and regulations that are "the most stringent in history".

The focus of this book – China's food safety governance in a legislative perspective – lies against the backdrop of China's construction of its legal system as a whole. China is now pursuing the objective of the modernisation of governance, a necessary condition of which is the implementation of the rule of law: the rule of law therefore should be regarded as the basic method of country governance. In this regard, the report of the 19th National Congress of the Communist Party of China puts forward that China should unswervingly remain committed to the path of socialist rule of law with Chinese characteristics, by perfecting the socialist law system with Chinese characteristics centered on the country's Constitution, establishing a system of socialist rule of law with Chinese characteristics, and building a country with socialist rule of law. China's legal system forms a top-down hierarchical ladder which consists of the Constitution, laws, administrative regulations, local regulations, and

administrative rules.[8] These legal documents are different in terms of legislating bodies, legislating procedures, and legislated subjects, etc. Moreover, this ladder of legal effectiveness highlights the principle that priority should be given to higher-level laws instead of lower-level ones in case conflicts between the two arise. That is to say, the supreme law of the Constitution is above all regulations, and administrative laws and regulations from higher-level departments outweigh counterparts from lower-levels. Besides, people's congresses and their standing committees of provinces, autonomous regions and direct-controlled municipalities can formulate their own local regulations in order to address the specific conditions and practical needs of local administrations; yet, such regulations cannot conflict with the Constitution, nor with laws or administrative regulations. It is also noteworthy that following the delegation of legislative competence to lower-level administrations, cities with districts also became able to formulate local regulations on issues such as urban development and management, environmental protection, and historical and cultural protection.



Against this background, it is particularly important to stress thinking guided by law as an important part of China's food safety governance. In fact, China also attaches large

[8] Administrative rules can be further divided into department rules and local rules. Local rules are formulated by local State authority organs and can only be applied to areas under the same territorial administration. Department rules are formulated by the department of the State Council and are effective nation-wide. Within the applicable geographical area, department rules outweigh local rules. Yet local rules can reduce or increase the rights and obligations of citizens, legal persons or organisations, while department rules do not involve the creation of rights and obligations. See Guogang Chen, "Municipal Legislative Competence in Cities Which Are Divided into Districts: Analysis of Legislation Law", *Study & Exploration*. 2016 (7). p.81-86.

importance to applying thinking guided by law as well as methods of rule of law to the governance of specific fields such as food safety. For instance, President Xi Jinping has remarked that the country should set the most stringent standards, the most rigorous supervision, the most severe punishment and the most serious accountability (commonly referred to "Four Strictest") to promote the unity, professionalism, level and effectiveness of food safety supervision and management. In this regard, supervision and management activities should be carried by laws, regulations and rules, and take institutional form. Correspondingly, the Standing Committee of NPC, the State Council and the China Food and Drug Administration (CFDA) [9] have also exerted tremendous efforts in amending the *Food Safety Law* and the *Regulations for the Implementation of the Food Safety Law*. With the implementation of *Food Safety Law*, CFDA – the then responsible agency – further formulated and amended additional rules in order to implement the *Food Safety Law*, and improved related systems and working norms to form a legal system that can ensure food safety. These measures showcase the principle of applying the rule of law into the governance of food safety.[10]

Among these measures, the formulation and revision of the *Food Safety Law* provides a legal foundation for food safety supervision and management, at the same time underlining the principles of prevention as main priority, risk management, whole-process control, and social co-governance. Furthermore, numerous institutional requirements are outlined for the subjects, content and tools of governance in order to further refine these principles. For example, food producers and distributors are required to assume primary responsibility, while systems are established for risk communication, complaints and reports, ten-times compensations, linking civil and criminal law enforcement, and credit management. In addition, all the rules formulated by CFDA, together with the coordinated action of all other relevant departments – exemplified by the streamlining and improvement of standards by health departments, or by the formulation of the *Law of the People's Republic of China on Quality and Safety of Agricultural Products* (*Law on Quality and Safety of Agricultural Products*) by agricultural departments – constitute a close-knit network of laws for food safety supervision and management in China, contribution to the achievement of the requirements set out by the "four strictest".

In addition, the emphasis put on social co-governance has also become an important feature of China's response to food safety. The command-and-control type of regulation previously adopted translated into government's intervention in the private market so as to protect public health and public interests. The advancement and evolution of regulatory reforms in various countries, however, shows that the continuous strengthening of government regulations might hinder the role of market mechanisms in resource allocation,

[9] CFDA was reorganised in the institutional reform in 2018. For more details, see Chapter 4 of this book.

[10] Hu Jinguang, "Governance of Food Safety through the Thinking Guided by Law", *China Food Safety News*, available at: http://www.cfsn.cn/2013-11/13/content_160887.htm.

and that the strict control of social organisations is not conducive to the development of social self-governance. On the other hand, as a continuous process of interaction and management, governance is characterised by the fact that public institutions and private institutions, besides governments, can also become important power centres at different levels thanks to the public's recognition of their power exercises, thereby coordinating collective actions and sharing their interests and responsibilities. For this reason, social co-governance has been proposed in the area of food safety in the hope that all subjects from society can actively participate in food safety governance. The emphasis of social co-governance of food safety is also related to its very characteristics: in fact, food supply as well as food supervision and management involve multiple and diverse stakeholders such as producers, processers and retailers, as well as official supervision under the multisector model. In other words, the lack or perhaps overlapping of duties caused by division of labour creates a situation where everyone is responsible, but no one has responsibility. Frequently, food practitioners would shift the responsibility to others, and authorities would evade or abuse their responsibilities. On this view, a whole-control process covering the entire from-farm-to-fork stage, and emphasising food safety as a shared responsibility, have been considered as important principles for further enhancing food safety work. Accordingly, the aim of social co-governance is social sharing.[11] If all social subjects in the food field can take up their social responsibilities, they actually become responsible for themselves. For any producers and sellers that are involved in any segment of the entire industry chain, producing and selling safe food equals to responsibility for their own businesses. Only responsible enterprises can have a future with room to grow. If the government food supervision and management bodies can earnestly perform their own assigned functions, then they are fulfilling their own social responsibility, which equals to being in control of their credibility. If any consumer is able to truly monitor the safety level of the production and manufacturing of their daily food, then we can say they are truly responsible for their health and lives. More importantly, with regards to the approaches to shared responsibility and co-governance, China in its food safety-related laws has already established a system of responsibility from liability to accountability, including administrative and criminal punishment, and civil compensations. On this basis, institutional arrangements such as complaints, reports, risk communication, and media supervision also provide channels and benefits for all society subjects to participate in the governance of food safety.

1.4. Structure of the book and acknowledgements

This book is divided into eight chapters. This introductory Chapter 1 briefly introduced the theoretical developments, legislative improvements, institutional support, and China's

[11] Hu Jinguang, "*Only Social Goverance Can Secure Food Safety*", April.1.2017, available at: http://www.chinafoodsecurity.com/article/?id=828.

concerns related to food safety from a legal perspective. On this basis, Chapter 2 will focus on the core content of China's food legislative framework improvements and the advancement of the rule of law, illustrating innovation and Chinese experience around the concept of "governance"; Chapter 3 will continue introducing food safety standards from the perspective of the legal system, as in China they are a mandatory national standard and directly affect food safety law enforcement and justice in the country. Chapter 4 discusses China's organisational arrangements for food safety supervision and management, including historical evolutions and current structures, from the perspective of regulatory systems. Chapter 5 to Chapter 7 introduce "selective topics" of China's food safety governance by providing examples of official regulatory regimes, co-governance participation systems, and specific types of food. Examples are abstracted from relevant institutional arrangements and Chinese experiences. Chapter 8 introduces, from an extra-territorial perspective, the similar experiences of China and the European Union in food safety supervision and management, particularly with respect to the deep legislative, institutional and regulatory reforms triggered by food safety issues, as well as to bilateral cooperation and interactions throughout the process.

The speciality of this book is reflected on the choice of topics and its authors. The co-editor has been directly involved in the study of the rule of law in food safety for more than ten years, and translated the official report "50 Years of Food Safety in the European Union" – sponsored by the European Union in 2008 – an important publication offering the EU's experience to China's food safety supervision and management reforms. In 2018, the two editors further compiled, again under the support of the EU, *Building Food Safety Governance in China*, which introduces and shares China's food safety experience with European countries and a broader audience of readers from other countries. Thanks to the experience of revision of and assessment of the *Food Safety Law*, the co-editor is very familiar with the developments and path of food safety legislation in China, especially with the ways China food safety governance has kept pace with times under the pressure and challenges posed by domestic affairs, foreign experiences and international demands, by reforming and innovating in aspects such as concepts, legislation, and legal system. Therefore, the framework and topics of this book not only represent key issues in China's food safety governance, but also serve to inspire other countries.

At the same time, in order to ensure professional writing, every chapter of this book is assigned to a specific author according to his or her background. Among them, there are scholars specialised in theoretical research and pragmatic research, officials who directly took part in legislation processes, as well as professionals from media, enterprises and foreign countries. I express my sincere gratitude to everyone who contributed to this book regardless of their tight schedule, and cooperated with us to arrange and adjust the contents and to improve the structure of the book. I give special thanks to Jérôme Lepeintre, Minister Counsellor of the Agriculture, Health and Food Safety Section at the Delegation of the

European Union to China. In fact, this book on China's food safety governance would have not become reality without the preliminary research results as well as the support received under this EU-funded project. And because of the participation of such a wide range of scholars, officials and professionals, the formulation of the book itself embodies the social appeal of co-governance – that is, research on food safety governance presents interdisciplinary, cross-profession and cross-domain characteristics, and at the same time, relevant discussions and practice promotions also require the participation of and cooperation among different actors. Of course, research on food safety is a long-term process. Due to limits of length, some issues such as a traceability system and organic foods may have not been fully covered or need further study; in the future, we will continue to study and to find opportunities to introduce to interested readers additional institutional arrangements and innovation practices from China on these issues.

Chapter Two

Law: transformation of ideas and innovation of the legislative system

Xu Jinghe [*]

Food safety has a direct impact on the health and safety of the public, as well as on the country's economic development, social harmony and national image. In recent years, experts and scholars have conducted a series of studies and made reflections on food safety in China, particularly around how to improve the food safety regulatory system and on how to comprehensively raise the food safety safeguarding level. These studies have contributed to the public's gradual understanding that the shift from food hygiene and food quality to food safety and from specific management to comprehensive supervision is not simply an adjustment of vocabulary, denotations and connotations. Rather, the changes constitute a profound transformation of food safety governance ideas. This marks the beginning of a new era for food safety governance.

2.1. Analysis of the ideas of food safety governance

Ideas usually refer to those guiding ideologies, fundamental objectives, and core values which have been shaped by human rational thinking and practices and reflect the laws of nature. Ideas, in general, are fundamental. Since the launch of its economic reforms in 1978, China has made remarkable achievements transitioning from a closed, traditional, agrarian society to a modern, industrial one. In order to fully complete this transition process and realise an historical leap-forward development, it is necessary to be open-minded and keep in line with the new thoughts. The forces of globalisation and trade liberalisation have helped food safety to become a major social issue that both China and the international community must address. To confront the contemporary challenges that human survival and development face, the international community is working on a reform and innovation in the legislative framework, governance system and mechanisms, as well as the *ideas* of governance themselves. These issues are addressed in China's *Food Safety Law*, which represents its

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macro strategy for its food safety governance.

2.1.1. Consensus on and approaches for whole-process control

The whole-process control of the food supply chain can serve as a starting point for understanding this new era for food safety governance. Food production and distribution are divided into farming, breeding, production, processing, storage, transportation, sales, consumption, as well as other segments. Traditionally, the focus of food safety has been on food processing, in line with the fundamental belief that food safety can be effectively be guaranteed as long as adequate attention is paid to the processing stage. In recent years, however, this assumption has been disproven by a series of outbreaks of foodborne diseases that were linked to problems originating in other segments of the food chain, particular at the origin. The outbreak of bovine spongiform encephalopathy (BSE), for instance, is connected to feed contamination. Frequent outbreaks of foodborne diseases have increased concerns amongst consumers around whether farming, breeding, production, processing, storage, transportation, sales and other activities can effectively guarantee public health. In addition to knowing what they are eating, consumers increasingly want to know details of the origin and about the production methods of the food.

Consumers, therefore, have become aware that defects in segments of the food production and distribution chain could result in the collapse of the entire system that is intended to guarantee food safety. It has become impossible to provide consumers with sufficient and effective levels of food safety only through enforcing inspection and rejection methods at the final stage of the production line – measures which can also run counter to the principles of a free market economy. On this basis, the international community has identified a food chain approach for guaranteeing food safety, namely extending control and governance over the two poles of the food chain. At the origin, governance should be extended to the farming and breeding of agricultural, animal and aquatic products, and even to the production and use of agricultural inputs; at the back end, governance should be extended to the point of consumption. By improving connections across all segments of the food production and distribution chain prior to consumption, a comprehensive prevention of foodborne diseases and the whole-process control of risks can be achieved.

2.1.2. Upgrade and coordination of government governance

As food safety is a social issue on a global scale, governments face heavy pressure and huge responsibilities to meet the expectations of society. This is even more of a pressing issue for developing countries, especially in this age of globalisation and digitalisation, where there are major challenges to matching food safety capabilities to the desires and needs of consumers.

Firstly, food safety is now an important part of a country’s public safety and national

security as well as an important measure of government administration capacity. The integration of food safety into the broader sphere of public safety and national security highlights food safety's strategic value. To improve the level of food safety, governance in this area involves: advocating scientific concepts, determining development strategies, improving safeguarding measures and the safeguarding system, integrating supervision and management (监管, *jianguan*) resources, enhancing basic investments, strengthening supervision of operations, and optimising the social environment.

Secondly, in recent years government management of food safety has attracted widespread attention in international public policy debates. In 2003, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) jointly published "Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems", an important document which articulated the positioning, basic rules, strategies and measures for government and its governance of food safety. The publication of these guidelines urges the competent authorities of individual countries, particularly developing countries, to complete the establishment of food control systems, and to select the best legislative, structural and implementation solutions for food control systems. The objectives of national food control systems involve: protecting public health by reducing the risks of foodborne diseases; protecting consumers from foods that are unhygienic, harmful to health, misbranded or adulterated; maintaining consumers' confidence in the food production and distribution system, and providing a rational legal basis for domestic and international food trade to facilitate economic development.

Thirdly, food safety issues have already crossed national borders and become a common issue faced by governments across the world. Chemical and biological contamination has spread with extraordinary width around the globe and countries can itself from. For this reason, ensuring food safety has become a responsibility that governments not only have to their own citizens, but also to the wider international community. In other words, each country should, on the one hand, integrate the resources for food safety supervision and gradually establish a uniform, efficient, authoritative and convenient food safety governance system, resulting in improved food safety capacities for the benefits of their own citizens; on the other hand, they should work together in order to address challenges brought by food safety. From the perspective of the international community, each country should gradually align their food safety laws, standards, information, testing and other rules and contents so as to establish a unified and harmonious voice on food safety issues.

2.1.3. Science-based and democratic risk governance

In a market economy, both government governance and enterprise governance must be based on scientific principles and rules, focusing on scientific approaches and methodologies to prioritise efficiency. The value of scientific and technological support in food safety

governance is reflected in the extensive application of technologies for food safety monitoring, detection, assessment, evaluation, alert, tracing, etc. As the main goals and tasks of food safety governance are to prevent and reduce food-related risks, the core mission of the scientific governance of food safety is, therefore, risk governance.

In recent years, the international community has reached a broad consensus over the framework for food safety risk analysis, namely based on risk assessment, risk management, and risk communication. Among these, risk assessment is a scientific process aimed at the determination and assessment of the level of food-related risks and at answering the following three questions: what may happen (situation)? How may this problem arise (possibility)? If the problem arises, what may it lead to (severity)? Risk assessment is divided into four steps: hazard identification; hazard characterisation; exposure assessment; and risk characterisation. With respect to risk management, its purpose is to determine the supervision and management measures required to minimise food safety risks to levels that are acceptable by the society. When addressing food safety-related risks, risk management plans should be formulated; at the same time, their effectiveness should be assessed, and consideration should be given to their impact on relevant stakeholders and industry development. In comparison, risk communication primarily intends to cope with food safety risks from the perspective of society. It consists of an interactive exchange of information and opinions among risk assessors, risk managers, consumers, industry players, academia, and other relevant stakeholders, on issues relating to hazards and risks, risk-related factors and concepts within the process of risk analysis. Risk communication contain explanations of risk assessment results and risk management decisions.

2.1.4. Experiments and innovation of social governance

During the Third Plenary Session of the 18th CPC Central Committee (November 2013), it was remarked that the general objectives for comprehensively deepening Chinese reforms are to complete and develop a socialist system with Chinese characteristics and to advance the modernisation of the national governance system and capacities. Although 'social management' and 'social governance' might appear similar at least in terms of wording, the latter marks a significant turn in China's approach to social development. Embodying the same logic, momentum and vigour implied by social governance, food safety governance has since become the entry point and test field for innovating Chinese social governance.

Firstly, food safety governance recognises the existence of diversified stakeholders. Food is one of the most fundamental materials for human survival and development; it is an important product consumed by every person in their whole life. For this reason, food safety touches upon the widest variety of stakeholders, from enterprises to industry associations, local government agencies, supervision and management authorities, testing agencies, certification agencies, media, and consumers. Among these, the government plays a critical or a leading role, but it does not undertake every action. Although in food safety governance

every relevant stakeholder has its own interests, either public or private, this does not prevent them from identifying their responsibilities, contributing with efforts and realising their goals: rights and obligations, benefits and risk accompanying each other. Diverse stakeholders therefore imply diversified governance and responsibilities, and guaranteeing their participation becomes an important prerequisite to advance social governance. In short, the fundamental pattern of social co-governance of food safety is shaped by enterprise primary responsibility, industry self-discipline, government supervision and management, coordination among different authorities, social participation, and media supervision.

Secondly, food safety governance seeks to maximise common interests. Promoting the pursuit of common interests is an important goal for achieving social governance. Food safety governance advocates that different stakeholders, although each with its own interests, should seek to maximise common or social interests; in other words, food safety governance strives to achieve the greatest common indicator of group or social interests whilst recognising the variant interests of different stakeholders. Whilst the interests of stakeholders vary, however, food safety is the common ground through which such interests can be catered for and without which such interests would no longer exist. The wine glass can contain “fragrant wine” (i.e. common interest) desired by all relevant stakeholders; the glass’ “stem” corresponds to “safety”: if the “stem” is broken, the “fragrant wine” will be poured on the ground. Common interests therefore can only be achieved by establishing a community of common destiny jointly caring about the “stem”.

Thirdly, food safety governance determines the network structure of governance relationships. Promoting new governance relationships becomes an important means to achieve successful social governance. As current food safety risks faced by society are complex and volatile, food safety governance does not simply revolve around a linear relationship of hierarchy and subordination between government and enterprises, but rather a complex networking relationship where governments, enterprises and civil society constantly interact. Such a networking structure models a new form of partnership among different stakeholders, characterised by equality, exchange, cooperation, negotiation, coordination and collaboration, in turn modelling a new pattern of governance characterised by interaction, mutual assistance, mutual benefits, shared governance, and win-win outcomes. Taking food safety risk communication as an example, it consists of an exchange process of relevant risk assessment, regulation and supervision information among industry actors, industry associations, technical agencies, consumer associations and media, organised by food safety competent authorities and risk assessment agencies, and based on scientific, objective, punctuality and transparent principles. This process shall end by publicly informing society according to the law and providing scientific, objective, comprehensive and correct information to respect the legitimate rights of consumers and food enterprises.

In sum, the transition from food safety management to food safety governance indicates

a transition from monism to pluralism, from partial to comprehensive, from linearity to ramification, and to a new realm of governance with broader horizons, expanded patterns, and greater momentum.

2.2. Progress for building the food safety legislative system

The directions and trajectory of food safety governance will be decided by putting into practice the ideas of governance and by innovating the legislative system for governance. The establishment of a legislative system for governance also laid the foundation for ensuring food safety in China.

2.2.1. History: evolution of the legislative system

Since the economic reforms and opening-up initiated in 1978, the National People's Congress of the People's Republic of China has promulgated nearly twenty food safety-related laws to safeguard the health and longevity of its people, including for the *Product Quality Law* and the *Food Hygiene Law*. The State Council has formulated nearly forty relevant administrative regulations, including the *Regulation on Pesticide Administration*, the *Regulations on Veterinary Drug Administration*, and the *Regulations on Administration of Hog Slaughter*. Relevant ministries or agencies of agriculture, health, quality inspection, and industry & commerce under the State Council have issued nearly 150 department-level regulations, such as the *Administrative Measures for the Safety Assessment of Agricultural Genetically Modified Organisms*. These laws, administrative rules and department-level rules established the basic legislative framework and basic legislative system of food safety in China, playing a crucial role in increasing the country's capacity to guarantee food safety.

Nonetheless, during the early stages of the establishment of the legislative system, a series of problems were encountered relating to "food hygiene" and "food quality":

The system was incomplete. The *Food Hygiene Law* regulated activities only in the segments of food production (except for farming and breeding), collection, acquisition, processing, storage, transportation, display, supply and sales. The *Product Quality Law* regulated the production and sale of commercial processed food. The legislative system, however, did not cover the whole process from farm to fork.

The content of the system was incomplete. Some important legislative systems widely adopted at the international level, such as the food safety risk assessment system, were not incorporated within the scope of law adjustment and revision, resulting in inconsistencies within the food safety legislative system.

The elements of the system were highly overlapping. For instance, food production was regulated based on two elements, i.e. food hygiene and food quality. However, both elements in turn included results safety and process safety.

The division of responsibilities among different actors remained not well-defined. The *Food Hygiene Law* appointed the State Council's health administrative authority as the body in charge for nation-wide food hygiene supervision and management, while other relevant authorities under the State Council would be responsible for the administration of food hygiene within the scope of their jurisdictions. Although the 1998 institutional reform of state administrations led to the establishment of a multi-sectoral food safety supervision and management system, the *Food Hygiene Law* still granted no room for action to relevant authorities under the State Council.

The reforms within the system were disconnected. After China completed a major reform of the food safety supervision and management system, which created a complementary mechanism integrating general supervision and specific management, there remains a law regulating and safeguarding the responsibilities and duties of the generally supervisory authority in terms of comprehensive supervision, coordination, and legal investigations and handling of major food safety incidents.

Legal liability was not adequate. The *Food Hygiene Law*, the *Product Quality Law* and other related laws did not present adequate punishment for illegal and criminal behaviours jeopardising food safety, thus could not match the requirements for cracking down existing food safety crimes.

As a response, on 1 September 2004 the State Council issued the *Decision of the State Council about Further Strengthening Food Safety* (*Guo Fa [2004] No. 23)*, raising the issue of improving relevant food safety laws and regulations, and urging its Legal office to amend the *Food Hygiene Law*. There were, however, different views on what channels were to be adopted to quickly improve China's food safety legislative system. In particular, one of them advocated to change the *Food Hygiene Law* into *Food Safety Law*: the rationale behind this was based on the perceived necessity to recognise a legal position for "food safety" as it was already a global concern. On the broader idea of "food safety" which includes both food hygiene and food quality, as well as other relevant ideas; and on the fact that a *Food Safety Law* could not coexist with a *Food Hygiene Law*.

Finally, China chose the *Food Safety Law* as the basis for food governance legislation. On 28 February 2009, the *Food Safety Law* was passed at the 7th Meeting of the Standing Committee of the 11th National People's Congress. The *Food Safety Law* embodied guidelines for food safety work, including prioritising prevention, scientific management, clarification of responsibilities, and comprehensive governance; it clarified the food safety supervision and management mechanism, combining division of responsibilities with uniform coordination; it provided a legal safeguarding basis for strengthening food safety and for accomplishing whole-process, scientific and effective supervision and management. The 2009 *Food Safety Law* was a milestone in the history of food safety development in China. Shifting from food hygiene to food safety is not a mere adjustment of vocabulary denotations and connotations, but rather

a profound transformation of the ideas and the mode of food safety governance. This marked the beginning of a new era for food safety governance.

In 2013, China's food safety regulatory system went through significant institutional reforms. Furthermore, following the rapid development of the food industry and the increasing demand for food safety, as well as the strengthening of government supervision and management, parts of the 2009 *Food Safety Law* failed to fully adapt to socio-economic development needs, highlighting the need for prompt modifications and improvements. Accordingly, on 24 April 2015, the 14th Meeting of the Standing Committee of the 12th National People's Congress deliberated and adopted the newly amended *Food Safety Law*. This new revision of the *Food Safety Law* fully reflects the new ideas, conclusions and requirements for strengthening food safety work provided by the CPC Central Committee and the State Council in the new era; it innovates the ideas, institutional layout, governing system, mechanisms and methods of supervision and management; and it solves the outstanding problems and further facilitates food safety work in a science-based, effective manner. The revision of the *Food Safety Law* is problem and practice-oriented. It not only embodies an international vision but also considers China's national conditions and actively responds to social concerns.

2.2.2. Concept: food safety

The creation of the legal concept of "food safety" to incorporate such concepts as "food hygiene" and "food quality", together with the replacement of the *Food Hygiene Law* with the *Food Safety Law*, suggests the following:

Firstly, this change shows a comprehensive point of view. Food safety covers all segments of the food production and distribution chain as well as all relevant stakeholders such as enterprises, supervision and management authorities, and intermediary agencies. The gaps of the then department-oriented or phase-oriented legislative system were filled by establishing a comprehensive food safety safeguarding system that brought each segment and element of the food production and distribution chain close together.

Secondly, this change is science-based. From a global perspective, the *Food Hygiene Law* belongs to the first generation of food protection laws, which embodied traditional social governance methods featuring government approval and penalty. The *Food Safety Law*, however, belongs to the second generation of food protection laws, which reflect modern social governance methods based on scientific risk assessment, incorporating both administrative approval and guidance, and balancing macro government supervision and micro enterprise safeguarding.

Thirdly, the change highlights uniformity. China has established a "segmented regulation" system in which government supervision and management are oriented on specific segments of the food production and distribution chain, supplemented by the administration on specific food varieties (see chapter 4 for more details). Food safety may be used to unify the entry

conditions and standards of each segment and institution, to avoid overlaps or multiple enforcement of hygiene and quality on the same enterprise in the same segment of production and distribution.

2.2.3. Objective: safeguarding livelihoods

The *Food Safety Law* defines its legislative objective as "to ensure food safety and protect the health and safety of the public". During the revision process of the *Food Safety Law*, some advocated the addition of the sentence "to promote the healthy development of the food industry" as a legislative objective, leading to intense discussions among experts and scholars. Most agreed that the objective of legislation should be around fundamental and direct issues but not instrumental in their effects. Indeed, the government administration of food is closely linked to that of the food industry, but the starting points and the focuses of the two are not exactly the same: they can be connected at the macro level, but cannot be confused or crossed. That is to say, although the promotion of industrial development is closely linked to the protection of food safety, the basic positioning of the *Food Safety Law* as a "livelihood safeguarding law" determines that "promoting the healthy development of the food industry" cannot be a legislative objective of the *Food Safety Law*.

2.2.4. Principle: risk governance

The newly revised *Food Safety Law* defines an important principle in the General Provisions, that is, the efforts to ensure food safety should mainly be based on "prevention as main priority, risk management, whole-process control, and social co-governance", so as to establish a scientific and stringent supervision and management system. The essence of this principle is to strengthen the comprehensive management of food safety risks. The newly revised *Food Safety Law* contains plenty of important contents in this respect.

Firstly, within the idea of food safety governance, risk governance reflects the methodological aspect of governance. In general, risk refers to the objective uncertainty of the final loss caused by an event under specific situations at a specific time. Over the past two decades, the biggest change in food safety was the emergence of the idea of risk governance, which shadows a fundamental, overall, and directional impact on food safety governance. The emergence of the idea of risk governance represents the significant shift of food safety governance from experience-based governance to science-based governance, from result governance to process governance, from crisis governance to problem governance, from response governance to prevention governance, from passive governance to proactive governance, and from traditional governance to modern governance. However, in order to face current challenges such as improving risk assessment, risk management and risk communication systems, as well as to coordinate comprehensive governance and focus-oriented governance, it is necessary to determine the basic strategy of food safety governance – namely, category-by-category governance and step-by-step implementation. For instance,

through risk assessment, the risk status of specific products, phases, times and locations can be analysed scientifically, and the focus, methods and frequencies of governance can be determined. Correspondingly, based on this idea, Article 109 of the newly revised *Food Safety Law* implements risk ranking. In other words, the implementation of focused governance based on comprehensive governance helps to optimise the allocation of resources, to highlight governance objectives, to clarify governance orientation, and to raise governance efficiency.

Secondly, within the idea of food safety governance, whole-process control reflects the spatial and procedural aspects of governance. Whole-process control closely concerns the supervision and management system. Within contemporary society, factors of risk exist throughout the entire chain, from research & development, to production and distribution. A whole-process control "from farm to fork" is therefore required to effectively ensure food safety. At the same time, the connotations of whole-process control are continuously evolving with rapid social development: food safety governance should cover the full life-cycle of foods to avoid the collapse of the entire system resulting from defects of a certain segment in the production or distribution process; in terms of comprehensive prevention, active and effective risk prevention and control measures must be implemented during the entire production and distribution process to maximise the safeguarding of public interests; with respect to focusing on the source, although food production and distribution can be divided into several phases, each phase has its own source: only by examining the source can food safety be ensured; with respect to coordination, close connections shall be maintained among all segments of the food production and distribution chain, to prevent supervision and management blind spots and dead zones due to miscoordination; to ensure uniformity, emphasis should be put on subordinating all cross-phase factors to a uniformed management; lastly, to ensure responsibilities are kept, enterprises and supervisory authorities shall pay full attention to every phase in the food's life cycle, to effectively identify and control safety risks.

Thirdly, within the idea of food safety governance, social governance reflects the vision and pattern of governance. Safeguarding food safety is a common responsibility across society; therefore, social participation and mobilisation in food safety governance shall be encouraged. Food safety attracts the widest range of stakeholders, but the quest of how to form a close community of common destiny still requires further research and investigation. Although the idea of food safety social co-governance has already taken shape, establishing an effective institutional mechanism to implement the idea remains a more arduous task. To safeguard food safety in the era of globalisation and digitalisation, a wider vision on health, safety, risk, society and governance must be applied; the coordination among various government stakeholders, institutions, enterprises, industries, the public, and the media, shall be arranged through scientific institutional mechanisms, and an interlaced and interconnected food safety governance network with clearly defined responsibilities shall be formed.

2.2.5. Core: responsibility system

Although there is consensus that everyone is responsible for food safety, the realisation of the social co-governance mentioned in the previous paragraph still depends on the safeguarding of the responsibility system. In fact, the core of the legal relationship of food safety lies in the relationship between rights and obligations, or, in other words, in the relationship of responsibilities. The design of the food safety responsibility system aims to be "clearly divided, appropriately matched, effectively implemented, and scientifically traced". The newly revised *Food Safety Law* emphasises the scientific allocation of rights, obligations and responsibilities among food safety stakeholders such as food producers and distributors, local governments, supervision and management authorities, food industry associations, consumers' associations, media, inspection agencies, certification agencies and consumers. It guarantees and promotes the effective exercise of rights, the effective performance of obligations and the effective implementation of responsibilities. Moreover, in order to strengthen the full implementation of food safety responsibilities, the revised *Food Safety Law* promotes a food safety governance mechanism that combines incentives with restraints, rewards with punishments, impetus with pressure, and self-discipline with heteronomy, so that food safety stakeholders become more proactive and more responsible in all aspects, the food safety supervision and management results enhanced, and the level of food safety governance is constantly increased.

Primary responsibility

In the popular saying that "food safety must be the result of 'production' and 'governance'", 'production' requires food producers to be primarily responsible for food safety. With the development of science and technology, food production and distribution activities from farm to fork are becoming increasingly sophisticated. Only food producers can fully know their production and distribution activities, and thus they are well-placed to take more effective measures addressing food safety risks. Therefore, to improve food safety, the central task is to strengthen corporate responsibility. Correspondingly, the newly revised *Food Safety Law* further strengthened the responsibilities of food safety stakeholders, and food producers. Distributors were made the first party responsible for food safety. They are responsible for the safety of the food they produce and distribute and are expected to follow laws and regulations, as well as food safety standards when engaged in production and distribution. They should ensure food safety, be self-disciplined, be responsible for society and the public, accept social supervision, and assume social responsibility.

In summary, according to the newly revised *Food Safety Law*, food producers and distributors should assume the following chief obligations: to obtain food production and distribution license; register for special food products or formulas; file a record for enterprise standards; file a record for products; establish an internal food safety management system; be equipped with food safety management personnel; establish a health management system

for employees; formulate requirements for production and distribution control; establish food safety traceability system; establish food safety self-examination system; establish inspection and record systems for materials purchase and products delivery; formulate a scheme for recalling problem foods; implement management systems for food labels, instructions, and advertisements; formulate a scheme for food safety incident handling, and fulfil obligations when such food safety incidents take place; accept food safety liability appointment talks and administrative penalties for illegal behaviour; bear liabilities for damages.

Regulatory responsibilities

In the same popular saying that "food safety must be the result of 'production' and 'governance'", 'governance' focuses on the government governance of food safety. Apart from exploring and establishing a scientific, unified, authoritative and efficient food safety supervision and management system, it is also important to properly handle the relationship between central and local governance.[12] China is a unitary state. According to the provisions of its Constitution, the division of functions and powers between the central and local governments shall obey the principle of allowing full play to the local initiative and proactivity under the unified leadership of the central government. Correspondingly, at the central level, according to the *Plan for the Institutional Restructuring and Transformation of Functions of the State Council* promulgated in March 2013, the State Council established the China Food and Drug Administration (CFDA) to take charge of the unified supervision and management of food safety in the production, circulation and consumption stages.

At the local level, Article 6 of the revised *Food Safety Law* stipulates that local people's governments at or above the county level shall be responsible for the supervision and management of food safety in their respective administrative jurisdictions, uniformly leading, organising, and coordinating food safety supervision and management work, dealing with food safety incidents within their respective areas, and establishing and improving whole-process food safety supervision and management mechanism and information sharing mechanism. In comparison, the requirement that local governments shall bear overall responsibility for food safety is a contested issue. Since 2000, a series of investigations have been carried out on the responsibility of local governments for food safety, which evolved from an original policy concept to a legal one with continuously enriched and developed connotations and denotations. However, it must be clarified that local governments shall bear "overall responsibility" and not "full responsibility": the complete food safety responsibility system includes corporate responsibility, central government responsibility and local government responsibility, etc.

[12] A more specific introduction of China's food safety supervision and management system and the relationship between the central and the localities is included in the fourth chapter of this book.

Multiple accountability

Besides the clear division and effective implementation of responsibilities, the accountability tracing for food safety should also be rational and strict. In the new era, the central government puts forward the "Four Strictest" requirements for food safety (i.e. strictest standards; strictest supervision; strictest punishment; and strictest accountability). The new *Food Safety Law* further improves the political, social and legal responsibility systems of food safety.

Political responsibility generally refers to the negative legal consequences such as resignation, dismissal, and displacement that should be assumed by senior decision-making and management officials whose decisions or behaviour has led to significant loss of human lives, state properties, or public interests. The sentence "the person chiefly in charge shall take the blame and resign" stipulated in the new *Food Safety Law* refers to this political responsibility for food safety. From a global perspective, the political responsibility is theoretical and abstract, without clear and specific imputation elements. Therefore, the tracing of political responsibility should be especially prudent and rational, to ensure that the uniformity of both legal effects and social effects is reached.

Social responsibility generally refers to the responsibilities that an enterprise shall bear for the society, other than those for the interests of its shareholders. The social responsibility of food producers and distributors mainly consists of meeting the needs of social development, and to produce and circulate products that are of higher-quality, economical and healthier. To fully promote enterprises' social responsibility, further institutional arrangements are needed because food safety is also in urgent need of structural reforms on the supply-side.

Third, the investigation of legal responsibility should distinguish between the different responsibilities undertaken by various agencies to avoid "collective punishment" of agencies. The relationship among civil liability, administrative liability and criminal liability needs to be precisely gauged. Responsibility is a "double-edged sword" that needs to be allocated scientifically, systematically, coordinatingly and legally.

Civil means should be fully applied. Compared with administrative and criminal means, civil means are low-cost, flexible and effective, but historically have not been given sufficient attention because they were perceived to be soft, weak and ineffective. At present, China is still in a period of high recurrence of food safety risks: solely relying on government supervision and management is far from enough to govern Chinese food producers and distributors that are currently various, small, scattered and low-end. The activation of civil means can effectively compensate for insufficient government supervision and management resources, reduce the cost of food safety governance, and explore a broader path for co-governance. For instance, in online food transactions, if damages of the legitimate rights and interests of consumers are caused due to the failure of the third-party platform to carry out real-name registration and license examination, or to perform the obligations for reporting or

halting online transaction platform services, the third-party platform should bear joint liability with the food distributors. Such institutional arrangement can urge the third-party platform to exercise their management obligations. Similarly, if damages of the legitimate rights and interests of consumers are caused by illegal activities of the food producers or distributors, the providers of production and distribution spaces or of other conditions shall also assume joint liability if aware of the violation. Such institutional arrangement can urge the providers of the production and distribution spaces or other conditions to prudently choose business transactions. In addition, when implementing corporate responsibility, strengthening interests synergy, and extending social co-governance, the primary responsibility system, the liability insurance system, and the punitive damages system also play crucial roles that cannot be ignored.

Administrative means should also be actively innovated. Compared with civil and criminal means, administrative means are large-scale, adaptable and powerful. Administrative means have generally been used in the means of property penalties and qualification penalties. With the deepening of social governance, some new administrative means can be explored, such as detention, public security punishment, and blacklisting. For instance, the revised *Food Safety Law* stipulates that public security authorities shall, according to the law, impose public security law to those fabricating or disseminating false food safety information that violate rules. Food producers and distributors whose licenses have been revoked, their legal representatives, as well as directly responsible supervisors and other directly responsible personnel shall not apply for relevant food production and distribution licenses, nor to engage in food production, distribution and management activities, or to hold food safety management posts food enterprises within five years from the date of the punishment decision. Those who have been sentenced to prison sentences due to food safety-related crimes will be banned for life from any food production, distribution and management activities, or from holding relevant posts in food enterprises.

Criminal behaviour should be cracked down on with force. At present, Chinese criminal laws define food safety-related crimes mainly as: production and sale of foods that do not meet the food safety standards; production and sale of toxic and harmful foods; and the misconduct of food supervision and management. On 2 May 2013, the Supreme People's Court and the Supreme People's Procuratorate jointly issued the *Interpretation on Several Issues concerning the Application of Law in the Handling of Criminal Cases of Jeopardising Food Safety*. In judicial practices, food safety-related crimes also include the production and sale of fake and sub-quality products and illegal distribution. Generally, however, food safety crimes are still limited to crimes that disrupt market order and that produce concrete hazards; punishments are still insufficient for some behaviour that severely harms society. It is necessary to intensify the criminal crackdown on illegal and criminal behaviours to meet the current food safety needs.

2.2.6. System: governance mechanism

To initiate the governance of food safety, there is an urgent need for innovating governance mechanisms. But what is it referred to by "mechanisms"? Generally speaking, mechanisms can be understood from two perspectives: on the one hand, superficially, they are carriers or platforms for work whose main function is to integrate governance resources and enhance governance cooperation. Examples in this sense include: comprehensive coordination mechanism, whole-process supervision and management mechanism, emergency response mechanism, case-transfer mechanism and interest maintenance mechanism. On the other hand, more deeply, mechanisms can be understood as impetus for growth and development, and whose main function is to implement governance responsibilities and stimulate governance dynamics. Examples of mechanisms in this sense include: accountability mechanism, performance assessment mechanism, credit rewarding and punishment mechanism, and social participation mechanism. Both types of mechanisms play important roles in improving governance effectiveness.

Compared with legislative systems, mechanisms have five main characteristics. They have strong adaptability: mechanisms are mostly institutional arrangements, but in some cases, mechanisms can also be non-institutional arrangements, for instance during social transition periods mechanisms might have a large operating space before relevant institutional systems are established.

Mechanisms have strong flexibility: ensuring food safety involves a large number of stakeholders; however, each stakeholder's conditions and expectations are different, thus resulting in different incentives and constraints that can be adopted. Local governments and relevant regulatory authorities can therefore use a variety of flexible means to address different stakeholders.

Mechanisms have a strong guiding role: every mechanism is established to fulfil a specific purpose, such as the integration of governance resources, enhancement of governance synergy, implementation of governance responsibilities, stimulation of governance dynamism, and promotion of governance effectiveness, etc. The policy and directions reflected by the specific mechanism design will move the relevant target toward achieving the desired goal.

Mechanisms have strong operability: currently, food safety issues are growing in several countries whilst the forms of effective mechanisms to solve these problems varies. All specific mechanisms are designed for solving particular problems. Problems will always be present and so will innovative practices: different problems therefore can be solved with different governance mechanisms.

Mechanisms have strong complementarity: institutional or legislative systems often has the advantage of uniformity and stability, but sometimes also present the cons of rigidity and inflexibility. Thanks to their flexibility and adaptability, mechanisms can, to some extent, fill

the shortcomings of legislative systems. In addition, the results and effects of mechanisms can also, to a certain degree, serve as a test if the legislative system is science-based and rational. In this sense, mechanisms may also lead to corrections of the legislative system. In recent years, relevant authorities in various regions have conducted a series of bold investigations into the means of implementing governance responsibilities, enhancing governance synergy and improving governance efficiency, all leading to positive results, for instance:

Categorised regulatory mechanism: The development of the food industry in China is rapid yet unbalanced. Food enterprises of different types and in different regions vary greatly. Therefore, based on the concrete conditions of the country, grade- and category-based supervision and management strategy must be implemented. The quantitative classification management system for food hygiene executed in the past by health administrative authorities, as well as the food safety credit rating management implemented by food and drug regulatory authorities, represent positive practices. On the basis of these practices, the combination of the credit system with categorised and graded supervision and management system must actively be explored in order to urge food producers and distributors to strengthen self-restraint, self-motivation, and self-improvement.

Credit reward and punishment mechanism: The modern society is a credit-based society. In recent years, relevant authorities have cooperated closely to actively promote the establishment of a credit system, and have achieved certain results, although still far from giving full play to the credit system's value. There is an urgent need to speed up the establishment of a sound scientific credit evaluation mechanism for food enterprises, bringing all types of food enterprises into credit investigation, evaluation and disclosure network, through which the credit status of food companies can be disclosed comprehensively, objectively, and timely. This shall contribute to consumers when making purchase decisions; to relevant supervision and management authorities to implement categorised supervision and management; as well as to food enterprises to strengthen self-discipline management.

Case-transfer mechanism: In recent years, food crimes have been rampant. One of the major reasons is the substitution of criminal punishment and administration with fines. Although this should be partly attributable to legislative issues (e.g. absence of relevant laws to comply with, or difficulty in complying with existing laws), most of it relates to law enforcement issues. It is necessary to establish a mechanism for timely transferring criminal cases, intensifying criminal penalties, and increasing the deterrence and impact of law. In recent years, the state has issued relevant systems and mechanisms for the timely transfer of food-related crimes and cases, but these still need to be put into full practice.

Inspection and supervision mechanism: In recent years, governments at all levels have generally conducted food safety inspection and monitoring to ensure effective implementation at the grassroots level of central government policies and major initiatives relating to food safety governance. To ensure all governance tasks can be fulfilled in an

effective and timely fashion, supervision and management authorities at higher levels need to maintain process control, and promptly inspect the work of lower-level authorities to identify any problems and make the necessary adjustments. To strengthen the authority and effectiveness of inspection and monitoring activities, it is necessary to combine inspection and supervision mechanisms with performance appraisal mechanisms in an organic way.

Performance appraisal mechanism: The *Food Safety Law* defines the responsibilities of local governments at or above the county level for reviewing and evaluating the performance of food safety supervision and management authorities. For many years, by targeting local governments, the food and drug supervision and management authority has established a comprehensive food safety evaluation mechanism, which reflects the responsibilities and work performance of local governments and those of the supervision and management authority through management indicators, variety detection indicators, and public satisfaction indicators. This mechanism was established to achieve the purposes of inspiring and encouraging people, and of all-round promotion and common improvement.

Communication and collaboration mechanism: China's food safety supervision and management system previously focused on a segmented regulation of all segments of the food production and distribution chain, supplemented by the administration of specific food varieties. To reduce and avoid supervision and management gaps resulting from segmented regulation, the *Food Safety Law* clearly stipulates that local people's governments at or above the county level should establish a sound food safety supervision and management mechanism, and that the national administrations for health, agriculture, quality supervision, industry and commerce, and food and drug supervision, should enhance communication and cooperate closely. In recent years, based on actual conditions, different regions and authorities have established food safety communication and collaboration mechanisms that are multi-level, multi-sector, and multi-field. For instance, food safety committees and food safety leadership groups have been established to ensure there are no blind spots or supervision gaps in the management process.

Social participation mechanism: Experience shows that supervision and management will be constrained and affected, in their width or depth, when relying solely on the limited capabilities of the authorities. Social participation can represent an effective remedy to the serious shortage of current supervision and management resources. At present, many places have set up a reward-for-reporting mechanism where informants can be rewarded appropriately if the reporting is verified to stimulate the public fight against the violation of the law.[13] In addition, the public interest litigation mechanism and the group litigation mechanism are also effective means to mobilise society to participate in food safety monitoring and effectively deter illegal activities.

[2] More detailed information on of the award-winning reporting system is also included in the sixth chapter of this book "*Reporting system in the social co-governance system*".

Innovation of mechanisms acts as the inexhaustible motive force for promoting the progress of social governance. Principles of innovation of food safety governance mechanisms include the affinity to the people, the reflection of the époque, the grasp of the law of nature, and the advocation of creativity. Based on ideological emancipation, brainstorming and brave experimentation, China may gradually establish a food safety governance mechanism that is more consistent with its national conditions, promote food safety to achieve continued progress, and quickly enter the stage of scientific development.

2.3. Adhering to governance by rule of law

So far, China has realised remarkable achievements in building up the food safety legislative system. The basic legislative system for food safety has been established; the awareness on the rule of law of food safety has been significantly enhanced; and the legal order for food safety governance has been preliminary established. It should be noted that the *Food Safety Law* is a basic law that merely defines the fundamental framework of various systems; each concrete system contains very rich contents which need to be further elaborated and enforced by administrative regulations, rules, and normative documents. For example, CFDA, the competent authority at central level, in order to implement the system stipulated by the *Food Safety Law*, has formulated or revised several administrative regulations including the *Administrative Measures for Food Recalls*, the *Measures for the Supervision and Administration of Quality and Safety Marketing of Edible Agricultural Products*, the *Measures for the Administration of the Routine Supervision and Inspection of Food Production and Distribution*, and the *Measures for the Illegal Activities Investigation and Treatment of Internet Food Safety*.

In addition, it should be emphasised that the vitality and authority of the law relies on its effective implementation. The central government has repeatedly stressed that public food safety must be guaranteed by adhering to the most stringent standards, the most rigorous supervision, the most severe punishment and the most serious accountability (i.e. the “Four Strictest”). The law can be effectively enforced only by executing it in a strict, standardised, fair and civilised manner. Strictness is the basic requirement of law enforcement, standardisation is the code of conduct, justice is the value orientation, and civilisation is the professional characteristic of enforcement. Facts are the basis, the law is the criterion, the spirit of law must be adhered, and the law must be enforced strictly to uphold the authority and dignity of law. All people are equal under the law, and discretionary power must be standardised to prevent “selective law enforcement”, “preferential law enforcement”, different liabilities and punishments for similar cases, excessively heavy or light punishment or unfairness. Law enforcement must be people-oriented, and the legitimate rights and interests of the people involved must be respected. The idea of law enforcement must be correct, the division of responsibilities must be clear, the procedure must be complete,

information must be disclosed, and the enforcement must be efficient and convenient to parties who are involved.

Moreover, it is also important to note that enforcement is just as important as the written articulation of the law. Since the beginning of the new millennium, food supervision and management authorities have explored and established comprehensive evaluation mechanisms, performance appraisal mechanisms, contribution rewarding mechanisms, model demonstration mechanisms, quantitative classification management mechanisms, accountability appointment talk mechanisms, and joint responsibility mechanisms, and have achieved remarkable results. At present, governance mechanisms should be further improved to encourage all stakeholders to be willing to take initiative, bear responsibility, and fulfil obligations, as well as to maintain a good environment that combines incentives and constraints. To face such broad, complex and concealed food safety risks in the new era, active governance requires food safety stakeholders to be problem-oriented, respond positively to social concerns, carefully investigate safety risks, and strive to eliminate safety hazards in the cradle.

Finally, when consensus is reached on the fact that “food safety is a major issue, an eternal issue and everyone’s issue”, a new era of food safety governance naturally begins. As long as we take a long-term perspective, grasp laws, control and guide the overall situation, follow the trend, and take advantage of the situation, the future of China’s food safety governance will definitely reflect the times, grasp the regularity and be creative, and we will certainly be able to create a more splendid achievement in a harmonious socialist society, ultimately making greater contributions to the healthy development of economy and all-round social progress.

2.4. Conclusions

Food is a special product that affects human health and life, therefore the strictest regulatory system must be implemented to ensure food safety. The newly revised *Food Safety Law* incorporates more than 50 new articles, revises substantively 70% of existing articles and identifies an important principle in particular, namely that the work to protect food safety should be based on “prevention as main priority, risk management, whole-process control, and social co-governance”, in order to establish a scientific and strict supervision and management system. Correspondingly, many systems are original: believing in the innovation of these important systems will be beneficial in achieving the comprehensive prevention and control of risks, the comprehensive implementation of responsibilities, the comprehensive advancement of the institutional system, and the comprehensive promotion of capacity. Ultimately, the innovation of systems will be helpful for ensuring the comprehensive promotion of public food safety and overall well-being.

Chapter Three

Standards: system building and institutional arrangements

Fan Yongxiang;[*] *Xing Hang* [**]

Admittedly, standards do not have a clear status as a type of technical regulation within the Chinese legal system. However, in the field of food safety supervision, the *Food Safety Law of the People's Republic of China* clearly stipulates that food safety standards are compulsory. Besides food safety standards, no other compulsory food-related standards may be established. It is precisely for this reason that food safety standards have become the basis and reference for law enforcement and judicial practices. In this regard, the provisions for food safety standards are indispensable. As food safety issues are diverse and involve many stakeholders, the bodies responsible for the formulation of standards, the scope of their application as well as the areas of concern also differ accordingly.

3.1. Roles and classification of standards in the food industry

According to the *Standardisation Law of the People's Republic of China*, standards refer to unified technical requirements needed in fields such as agriculture, industry, service sector, and other social undertakings. As an industrial product, food should have corresponding standards of quality, specifications and grades to guide producers; moreover, safety and hygiene requirements should also be in place to protect the health of consumers. Food standards embody two factors, namely food safety and food quality. Food safety standards are compulsory, while all other standards are recommendatory and are governed by different government authorities. Food standards can be divided into national standards, industry standards, local standards, association standards and enterprise standards. All together, these different levels of standards form the Chinese food standard system.

Food safety standards are technical regulations for various factors in food that affect consumers' health. As mentioned above, the *Food Safety Law* defines the scope of food safety standards, categorising them as the only food-related "compulsory standards". In terms of classification, food safety standards include national food safety standards and local food safety standards. At the same time, the government encourages food producers to formulate

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enterprise standards that are stricter than national or local food safety standards. These standards are applicable to enterprises themselves and record-filing (备案 *bei'an*) shall be done with provincial-level health administrative authorities.

Due to historical reasons, in the food industry there are both quality standards and compulsory food hygiene or food safety standards. The food hygiene standards developed by the former health authority, and the food safety standards promulgated after the implementation of the *Food Safety Law*, are aimed at protecting consumers' health; another category of standards does not relate directly to consumers' health but involves food quality, grades and specifications, and as such is oriented towards producers. Food safety standards are the minimum requirements that food producers and distributors must follow, and are thresholds that food products must meet in order to be qualified to enter the market. Non-food safety standards are voluntarily adopted by food producers and distributors, and can be used to produce and improve products to increase competitiveness.

After the *Food Safety Law* was enacted, the National Health and Family Planning Commission [14] (hereinafter referred to as "NHFPC") started a campaign involving experts and relevant authorities to streamline quality and safety standards for edible agricultural products, food hygiene standards, and food quality and industry standards, with a focus on repetitive, overlapping, and contradictory standards. After the campaign, which led to the publication of the *Notification on publishing Food Safety National Standards catalogue, and the clearing and integration of food-related standards* (*Guo Wei Ban Shi Pin Han [2017] No. 697*), 1,082 pesticide and veterinary drug residue-related standards were transferred to the Ministry of Agriculture (hereinafter referred to as "MOA") for further clearing and integration. The following conclusions were made on another 3,310 food standards:

Firstly, after a process of extension, transformation, revision and merging, some standards should be incorporated into the national standards currently in force;

Secondly, some standards should be promptly abolished;

Thirdly, some standards should be removed from the national food safety standards system.

The food safety standards system emerged after the unification campaign, which now includes generic standards, product standards, process-based standards, and inspection and testing standards, representing a more systemic, scientific, and pragmatic standards system. By the end of 2017, a total of 1,224 national food safety standards had been issued, involving more than 20,000 food safety indicators and covering all types of food products that are consumed daily by the public. As a result, a relatively sound national food safety standards

[14] Following the 2018 institutional reform approved by the National People's Congress, NHFPC has changed its name into National Health Commission.

system was put in place.

3.2. Formulation and revision of national food safety standards

According to Article 27 of the *Food Safety Law*, the responsibilities of relevant government authorities in formulating national food safety standards are divided as follow:

- The State Council's health administrative authority, in collaboration with the food and drug administrative authority, develop national food safety standards;
- The State Council's standardisation administrative authority assigns national standard numbers;
- The State Council's health administrative authority, food and drug administrative authority, and agriculture authority together formulate the provisions on the pesticide and veterinary drug limits in food, their inspection and testing methods and procedures;
- The State Council's agriculture authority in collaboration with the health administrative authority formulate the inspection procedures for the slaughter of livestock and poultry.

According to the *Administrative Measures on National Food Safety Standards* released in 2010, the formulation and revision of national food safety standards follow eight steps: blueprint planning, specific project planning, project initiation, drafting, examination, approval, issuance, amendment, and review. It usually takes one to three years for a standard to pass through project initiation phase to the issuance phase.

Calling for comments on the draft standards blueprint and formulation (revision) plans: The State Council's health administrative authority together with other relevant authorities, formulate the overall blueprint for national food safety standards, as well as annual standards formulation or revision plans. Before annual standards formulation and revision plans are drafted, all other relevant authorities shall submit proposals to the State Council's health administrative authority. Any citizen, legal person or organisation may also submit proposals for initiating the formulation or revision process of national food safety standards.

Determining the plan for the formulation and revision of standards: The National Food Safety Standards Evaluation Committee (hereinafter referred to as the "Evaluation Committee") conducts research on the proposals received by relevant authorities for formulating or revising national food safety standards. It then submits its recommendations to the State Council's health administrative authority, which, in turn, shall also solicit opinions from the public on the draft of the food safety standards blueprint and formulation (revision) plan. Based on the recommendations of the Evaluation Committee and opinions and suggestions collected from the public, the State Council's health and administrative authority officially releases the national food safety standards blueprint and the annual standards

formulation and revision plan.

Drafting the standards: The State Council's health administrative authority selects appropriate organisations with the necessary capabilities to draft national food safety standards. Based on the results of food safety risk assessment, and those of edible agricultural products quality and safety risk assessment, and with reference to relevant international standards and international food safety risk assessment results, the drafting organisation shall conduct in-depth research and take into full consideration the social and economic development and the pragmatic needs of China.

Soliciting public opinions: Upon completion of the draft standards, the drafting organisation solicits opinions in written form from all relevant stakeholders, including scientific research institutions, industry associations and enterprises, consumers, experts, and supervisory authorities. After a preliminary screening of the draft standards, the State Council's health administrative authority solicits a second round of public opinions on its website, with the solicitation period generally lasting two months. The health administrative authority's Secretariat will collect feedbacks and report them back to the drafting organisation, which in turn revises and incorporates the opinions received into the draft standards, and providing clear explanations in case certain feedback and suggestions are not finally adopted.

Examining standards: The Standards Examination Sub-Committee of the National Food Safety Standards Evaluation Committee assesses whether the draft standards are science-based and pragmatic. The draft standards are approved by the sub-committee if over three-fourths of its members agree. If the majority is not reached, the sub-committee shall issue a written notification to the drafting organisation specifying the reasons for rejection and outlining recommendations for revision. After further revision, the draft standards will be re-submitted to the Examination Sub-Committee. Approved draft standards will be signed off by the sub-committee's director before being submitted to the Directors' Meeting of the National Food Safety Standards Evaluation Committee for final deliberation.

Approving and promulgating the standards: Upon approval by the Directors' Meeting of the National Food Safety Standards Evaluation Committee, the State Council's health administrative authority officially promulgates the standards in a written announcement, which shall be published on the website of the health administrative authority for public consultation within 20 working days from the date of promulgation.

Following-up and evaluation: The State Council's health administrative authority appoints the National Food Safety Standards Evaluation Committee, provincial health administrative authorities and other relevant organisations to follow-up and evaluate the implementation of standards. Any citizen, legal person or organisation may also submit opinions and suggestions concerning any problems encountered during the implementation of standards.

Revising and reviewing the standards: When specific parts of national food safety

standards need to be adjusted after their promulgation, the State Council's health administrative authority shall issue an announcement indicating a list of standards to be revised. After the promulgation of national food safety standards, the Evaluation Committee shall conduct periodical reviews and formulate recommendations for the standards' continuation, revision or repeal. The standards that need to be revised shall be incorporated into the annual national food safety revision plan (points 1 and 2 above) in a timely manner.

According to the *13th Five-Year Plan on Food Safety Standard, Monitoring and Assessment (2016-2020),* the focus during the five-year period lies on improving the food safety standards system and to make the standards more pragmatic.

Firstly, 300 national food safety standards will be formulated and revised in order to address regulatory needs as well as the current situation and development trends of the industry. These will include generic standards, hygienic standards for production and distribution, inspection and testing methods, and pesticide and veterinary drug residue standards. Greater efforts will be made on the formulation of nutritional food standards for special groups such as infant formulas and foods for special medical purposes (FSMP), as well as distribution standards for food safety and nutrition in schools, hospitals, and nursing centres. These efforts will make standards more pragmatic and easy to apply and monitor.

Secondly, the standard management system will be improved. Management measures for food safety standards will be issued, ensuring that food safety standards are in line with the "Three Novel Foods" (i.e. novel food raw materials, novel food additives, and novel food-related products), that national standards are in line with local standards, and that food safety standards formulation is in line with the formulation of designated standards for imported food without a comparable Chinese national food safety standard.

Thirdly, the service capabilities of standards will be enhanced. Service and work platforms for food safety standards relating to health authorities at any jurisdictional levels will be established and improved. Local standards will also be improved so to effectively complement national standards. Trainings, consultation sessions, and follow-up evaluations will be organised to evaluate the effectiveness of standards. These efforts will better serve industry regulators and enterprises.

Lastly, basic research on the formulation of food safety standards will be strengthened. The application of data collected from monitoring and sampling tests of foodborne diseases, food contaminants and other harmful factors will be increased during the standards formulation process. Basic data concerning technical regulations and standards at the national level will be organised and improved so to provide a solid technical basis for the formulation and revision of standards, administrative supervision, industry development, and risk communication. Standards will be improved and revised based on the results of monitoring and evaluation activities. Greater efforts will be made on promoting standards-related basic research so that more relevant scientific and technological achievements will be translated

into standards.

3.3. National food safety standards: content and implementation

According to Article 26 of the *Food Safety Law,* food safety standards should include:

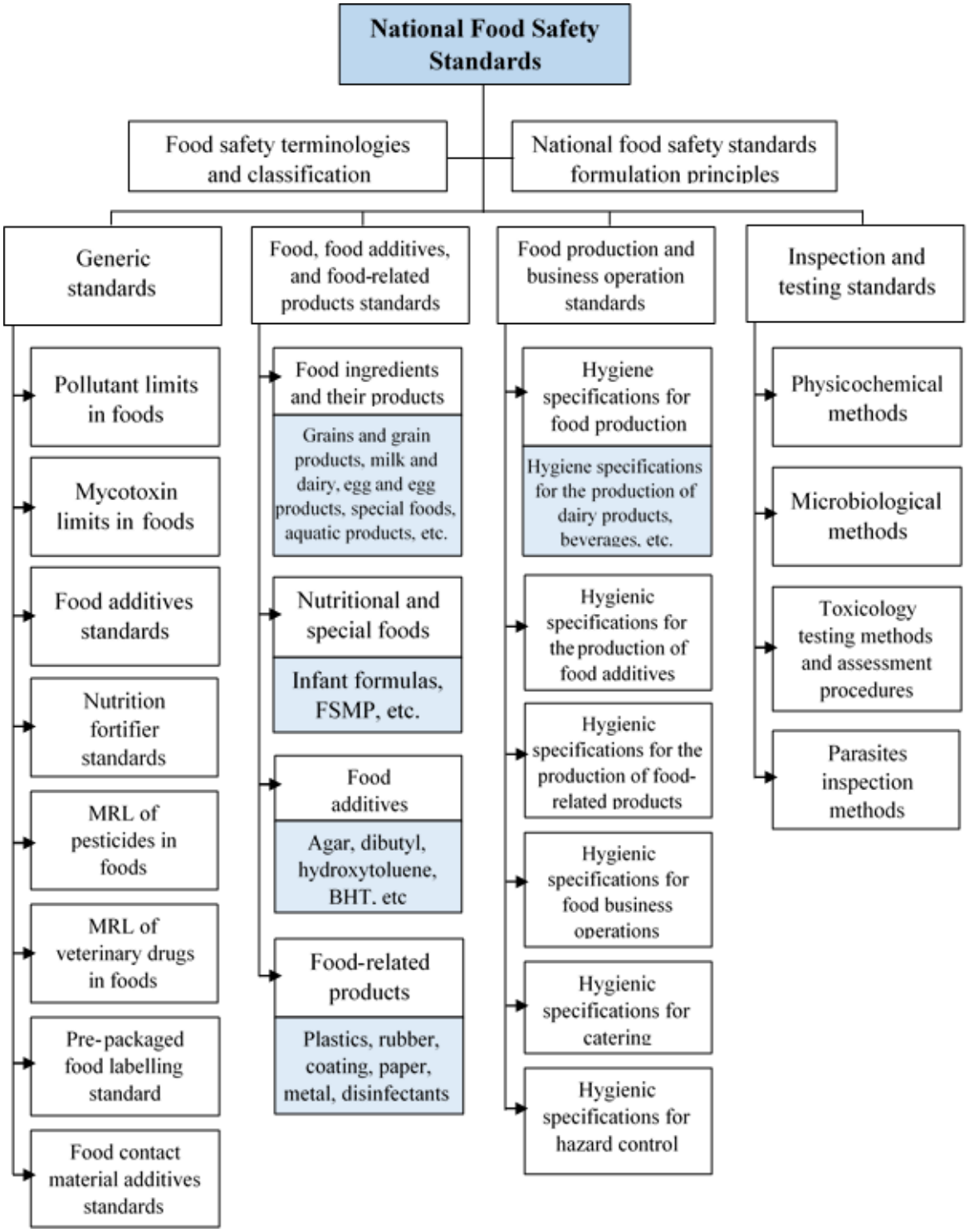
1) Provisions for pathogenic microorganisms, pesticide residues, veterinary drug residues, biological toxins, heavy metals, pollutants and other substances hazardous to human health contained in foods, food additives, and food products;
2) Variety, scope of use and dosage of food additives;
3) Nutrition content requirements for staple and supplementary foods for infants and other special groups;
4) Food safety-related hygienic and nutrition requirements for labels, signs, and instructions;
5) Hygienic requirements for food production and distribution;
6) Food safety-related quality requirements;
7) Food safety-related inspection and testing methods and procedures;
8) Other content that is necessary for the formulation of food safety standards.

Based on these eight requirements, national food safety standards can be divided into four categories, as depicted in the next page: Generic Standards, Product Standards, Process-based Standards, and Inspection and Testing Standards.

By 2017, NHFPC, together with MOA and the China Food and Drug Administration (CFDA), had formulated and issued 1,224 national food safety standards, which together form China's food safety standards system. Within this system, generic standards are parallel with specific standards, testing methods are complementary to the maximum residue limit (MRL) standards, and product standards are complementary to regulatory standards. More specifically, there are 11 generic standards, 64 food product standards, 9 special food standards, 586 food additive quality-related standards, 29 food nutrition fortifier quality standards, 15 food product standards, 25 production and distribution regulatory standards, 227 physicochemical testing method standards, 30 microbial testing method standards, 26 toxicological testing method and procedural standards, 29 veterinary drug residue testing method standards, and 106 pesticide residue testing method standards. More information is available at http://bz.cfsa.net.cn/db.

3.3.1. Generic standards

Generic standards include the maximum limit in foods of microorganisms, pesticide residues, veterinary drug residues, heavy metals, pollutants, mycotoxins, etc., as well as standards for the use of food additives and food product additives, and labelling specifications. Generic standards define general and universal food safety hazards and measures. These standards cover and apply to a wide range of foods. For instance, the *National Food Safety*



Standard for Food Additives (GB2760-2014) establishes regulations for the use of nearly one thousand types of additives in over ten categories of foods. Another example is the *National Food Safety Standard for Mycotoxin Limits in Foods (GB2761-2017)*, which sets limits for six mycotoxins in ten categories of foods. There are also standards that closely concern consumers, such as the *National Food Safety Standard – General Rules for Pre-packaged Food Labelling (GB7781-2011)*, and the *National Food Safety Standard – General Rules for Nutrition Labelling of Pre-packaged Food Nutrition Labelling (GB28050-2011)*.

Regarding the management of pollutants and mycotoxins, a campaign was launched in 2010 to streamline the standards on pollutants and mycotoxin limits that existed in the then valid edible agricultural products quality and safety standards, food hygiene standards, food quality standards, and relevant industry standards. After the campaign, a pollutant standard framework was established based on two national standards, namely the *National Food Safety Standard for Mycotoxin Limits in Foods (GB2761)*, which regulates the limit of mycotoxins; and the *National Food Safety Standard for Pollutant Limits in Foods (GB2762)*, which regulates the limit of chemical pollutants other than biotoxins and radioactive substances.

Limits for pathogenic bacteria are set in generic standards and in some product standards. In accordance with the requirements of the *Food Safety Law*, the *National Food Safety Standard for Pathogenic Bacteria Limits in Foods (GB29921-2013)* was formulated: targeting pre-packaged foods, this standard sets out requirements for pathogenic bacteria in eleven major categories of foods. In addition, pathogenic bacteria limits were specified in eleven milk and dairy products standards issued in 2010, seven for infant formula and special food standards issued from 2010 to 2014, as well as in the *National Food Safety Standard for Packaged Drinking Water (GB19298-2014)*, which sets the maximum limit for seven pathogenic bacteria such as *Salmonella*, listeria monocytogenes, and staphylococcus aureus. There are 57 "food-pathogen" limiting indicators such as "*Salmonella* in meat products" and "listeria monocytogenes in cheese".

The development of pesticide residue standards can be roughly divided into three phases:

- In the first phase, the pesticide residue work mainly focused on the residue detection and testing of high-toxicity organic phosphorus pesticides. A series of national standards for the appropriate use of pesticides was formulated;
- In the second phase, the *National Food Safety Standard for Maximum Residue Limits of Pesticides in Foods (GB2763-2005)* was issued in 2005, involving 478 limits for 136 pesticides. GB2763-2005 replaced former GB2763-1981 and other 34 standards;
- In the third phase, the *National Food Safety Standard for Maximum Residue Limits of Pesticides in Foods (GB2763-2016)* was revised and re-issued on 18 December 2016. This new national standard covers almost all commonly-used pesticides and main agricultural products in China, and recommends standards on detection methods. It thus contributed to major breakthroughs in the number, coverage, and feasibility of standards, and solved the problem of standards inconsistency and inadequacy. It was designated to be mandatory, systematic and pragmatic.

Regarding MRL standards of veterinary drugs, according to Notice No. 235 of MOA issued in 2002, the MRL requirements for veterinary drugs in foods of animal origin are divided into four categories: veterinary drugs without MRL requirements (88 types); veterinary drugs with MRL requirements (94 types); drugs being used in food animals for therapeutic purposes but not be detected in foods (9 types); and drugs prohibited for use in food animals. The MRL

standards of veterinary drugs only apply to original primary products of animal origin, and do not apply to processed products such as table foods, food produced by food processing plants, or dairy products. Complementing this, a total of 500 veterinary drug residue testing and inspection methodological standards have been issued (*MOA's Compilation of Testing and Inspection Methodological Standards for Veterinary Drug Residue in Foods of Animal Origin*); MOA and NHFPC's Notice No. 1927 in 2013 further released additional 29 standards. 344 types of compounds can be detected through the above-mentioned standards, covering foods of animal origin that are commonly consumed by Chinese nationals and common in imports and exports. Currently-existing standards are basically able to meet the needs for the supervision and management (监管, *jianguan*) of the safety of foods of animal origin.

The *National Food Safety Standard – General Rules for Pre-packaged Food Labelling (GB7781-2011)* streamlines regulations and standards governing the management of food labels. It stipulates that the label of the pre-packaged food directly provided to consumers must indicate the name of the food, table of ingredients, net content and specifications, name and address of the producer and/or distributor, contact information, production date, shelf life, storage conditions, food production license number, product standard code, and other contents that need to be marked. The label of pre-packaged food not directly provided to consumers must indicate the name of the food, specification, net content, production date, shelf life, and storage conditions in accordance with the corresponding requirements included in Article 4.1 of the Standard. Other contents, if not displayed on the label, should be specified in the instructions or in the contract. At the same time, the GB7781-2011 recommends that the product lot number, instructions for consumption, and allergens are also displayed on the label.

The *National Food Safety Standard – General Rules for Pre-packaged Food Nutrition Labelling (GB28050-2011)* is a very important generic standard as it represents China's first compulsory standard for nutrition labelling. Its implementation will help promote food nutrition knowledge, will guide the public to scientifically select foods, and will promote a reasonable balance between diets and physical health. It will also contribute to regulate the correct food nutrition labelling among food enterprises, and the sound development of food industry. GB28050-2011 includes one main text and four appendices. The main text is further divided into seven parts, i.e. scope, terminologies and definitions, basic requirements, mandatory contents on the label, optional contents on the label, how to display nutrients, and pre-packaged foods that are exempted for compulsory nutrition labelling. The four appendices are further divided into four parts, i.e. nutrient reference values (NRV), format of nutrient labels, standard terms for energy and nutrient content claims and comparative claims, and standard terms for nutrient function claims.

3.3.2. Products standards

Product standards include standards for food products, food additives, and food products.

Examples include standards for dairy products, meat products, aquatic products, and beverages; standards for the quality and specifications of food additives; and standards for food packaging materials, detergents, and disinfectants. In case these standards overlap with the contents already specified in generic standards, then generic standards shall apply. Due to the specificity and possible risks of certain products, special indicators, limits (or measures) and other necessary technical requirements must be specified in corresponding product standards.

Before the *Food Safety Law* came into force, there were more than 1,000 product standards in China. 64 national food safety standards then emerged from the campaign for streamlining and integrating national standards, including the *National Food Safety Standard for Cheese (GB5420-2010)*, the *National Food Safety Standard for Bean Products (GB2712-2014)*, the *National Food Safety Standard for Instant Noodles (GB17400-2015)*, etc. In the near future, there will be approximately 80 food product safety standards covering 21 categories: grain and grain products; milk and dairy products; eggs and egg products; meat and meat products; aquatic products; vegetables and vegetable products; edible oils; oil and fat and their products; beverages; alcohols; beans and bean products; edible starch and its products; condiments and spices; nuts and seeds; canned foods; baked foods; sweets and chocolates; bee products; tea; irradiated foods; health foods and other foods.

Besides citing relevant generic standards, product standards generally include: scope of application, terms and definitions, raw material requirements, sensory requirements, safety standards that are not covered by generic standards (such as cyanide), quality indicators concerning food safety, indicator bacteria, inspection and testing methods, and other necessary requirements. Food safety-related quality indicators generally include: indicators that may indirectly cause food safety risks (such as moisture in some foods); indicators for the distinctiveness of products (except for indicators reflecting quality level, special colour or fragrance); indicators for production processes that may cause nutrient malfunctions and safety risks in the final product; and special requirements in the production, processing, storage and transportation of special products.

Before the *Food Safety Law* was enacted, China did not have a clear definition or framework system for special foods. Some special food standards existed in the form of ordinary product standards. With the implementation of the *Food Safety Law* and the continuous improvement of national food safety standards, and based on international and laws and regulations from other countries, the definition and standards system of China's special foods have gradually become clear and systematic. China's national standards define special foods as foods specifically processed or formulated to satisfy special dietary requirements of specific physical or physiological conditions, and/or to satisfy the needs for treating diseases, disorders, and other conditions. Currently, there are four categories of special foods in China, namely infant formulas, supplementary foods for infants and young

children, foods for special medical purposes (FSMP), and other special dietary foods. By the end of 2017, nine product standards for special foods had been released, leading to a better standard system and an increasing variety of products that satisfy different consumer demands. Examples include, respectively: the *National Food Safety Standard for Infant Formula (GB10765-2010)*; the *National Food Safety Standard for Cereal Supplementary Foods for Infants and Children (GB10769-2010)*; the *National Food Safety Standard Food – Generic Rules for Foods for Special Medical Purposes (GB29922-2013)*; and the *National Food Safety Standards – Generic Rules for Nutrition Foods for Sports (GB24154-2015)*.

Quality specification standards for food additives are the quality requirements that must be met by food additives which are allowed to be used in China. Before the *Food Safety Law*, food additives quality specification standards were mainly governed by national standards, industry standards and enterprise standards. After the *Food Safety Law* came into force, food additives quality standards were incorporated into the scope of national food safety standards. Such quality specification standards stipulate the technical requirements that must be met by those food additives that are allowed to be used in China, including the description of the production process; basic information of the food additive such as molecular structure, molecular formula and molecular weight; sensory, physicochemical, and microbiological indicators that food additives are supposed to meet; as well as inspection and testing methods and identification methods of food additives.

Required by the *Food Safety Law* and its *Regulations for the Implementation*, the then Ministry of Health drafted, based on the old version of *the Hygienic Standards for Food Nutrition Fortifiers (GB14880-1994)*, the new *National Food Safety Standard for Food Nutrition Fortifiers (GB14880-2012)*. The formulation of this new standard, which officially took effect on 1 January 2013, draws nutrition fortifier management experiences from the Codex Alimentarius Commission (CAC) and other countries, takes into consideration the nutritional conditions of Chinese people, and refers to risk assessment results. Nutrition fortifiers included in the GB14880-2012 must adopt quality specification standards as the basis for food production and distribution. However, under the old regulations, nutrition fortifiers fell under the category of food additives. The result is that most of the quality specifications of nutrition fortifiers are currently managed as those of food additives, while some others are managed by specified standards (or pharmacopoeia standards). Meanwhile, the application of new varieties, as well as the extension of the scope and amount of usage of nutritional fortifiers, shall follow relevant provisions of food additives, and shall be approved through administrative licensing.

The *Food Safety Law* stipulates that food products include food packaging materials, containers, detergents, disinfectants, and tools and equipment used for food production and distribution, providing clear definitions for each category. Food packaging materials and containers refer to the paper, bamboo, wood, metal, enamel, ceramics, plastics, rubber, natural fibres, chemical fibres, and glass that are used to pack, display food and food additives

as well as coatings that are in direct contact with food or food additives. Food detergents and disinfectants refer to substances that are directly used for washing or disinfecting foods, tableware, as well as tools, equipment, food packaging materials and containers that are in direct contact with food. Tools and equipment used for food production and distribution refer to the machinery, pipes, conveyors, containers, utensils, and tableware that are in direct contact with food or food additives during production and circulation.

At present, China mainly manages the safety of food-related products through food-related product safety standards. Food-related product standards consist of four parts: basic standards, product standards, inspection and testing standards, and regulations. A combination of positive lists in basic standards and product standards governs product safety. Inspection and testing method standards specify the supporting methods for inspecting safety-related indicators. Regulations focus on monitoring the production processes of food product manufacturers. New varieties of food-related products are approved through administrative licensing. The approved substances are included in the relevant food-related product safety standards.

3.3.3. Process-based standards

The *Food Safety Law* clearly stipulates the requirements that food production and distribution should meet. In particular, the fourth chapter "Food Production and Distribution" specifies the detailed requirements for plant layout, equipment and facilities, and personnel hygiene, for instance prohibiting "foods using non-food raw materials, adding chemical substances other than food additives, or adding other substances hazardous to human health", as well as foods that are "mixed with foreign substances, or fraud".

Since 2010, China has issued a total of 25 national standards concerning food production and distribution, including hygienic regulations for food production, such as the *National Food Safety Standard for Hygienic Specifications of Beer Production (GB8952-2016)*; hygienic regulations for the production of food-related products, such as the *National Food Safety Standard – Generic Hygienic Specifications for the Production of Food Contact Materials and Relevant Products (GB31603-2015)*; hygienic regulations for the production of special foods, such as the *National Food Safety Standard for Good Manufacturing Practices of Food for Special Medical Purposes (GB29923-2013)*; and the *National Food Safety Standards – Generic Hygienic Regulations for Food Production (GB14881-2013)* and the *National Food Safety Standard – Hygienic Specifications of Food Distribution (GB31621-2014)*. GB14881-2013, in particular, thanks to its wide application and usage, forms the basis of the national standards system for food production and distribution, and for the formulation of any future regulations governing production hygiene.

3.3.4. Inspection and testing standards

Food inspection and testing standards are an important part of China's food standard

system. They involve a wide range of food industries, covering product categories, testing principles, and testing indicators. Due to the large number of authorities and industry organisations involved in the work of food standards in China, the volume of food testing and inspection standards in the country is also high; multiple inspection and testing standards may apply to the same object of the testing. Inspection and testing standards can be divided into: basic method standards; and inspection method standards. Basic method standards refer to a series of normative method standards such as food analytical terminology, inspection sampling, and generic methodology; inspection method standards refer to the detection of one or more components and different types of products, and can be further divided into three categories: physicochemical methods, microbial methods and toxicological methods. Physicochemical testing methods and microbiological testing methods are aligned with the indicators in generic standards and product standards. They are in place to meet the needs of food safety supervision and self-management of food producers and distributors. Inspection and testing methods and procedures standards generally specify the methods, principles, instruments and equipment used for the inspection of maximum limit indicators, and their corresponding specifications, operation procedures, results determination and reporting.

Under the *Food Safety Law*, inspection and testing standards have become compulsory in China. At present, China has basically put in place a food safety inspection and testing system based on the *Physicochemical Food Hygiene Inspection Methods (GB5009)*, *Food Hygiene Microbiology Inspection (GB4789)* and *Food Safety Toxicology Assessment Procedures (GB15193)*. GB5009 series standards and other series standards currently consist of 227 analytical testing items, covering the analytical methods for the generic components, metal contaminants and trace elements, pesticide residues, veterinary drug residues, food additives, mycotoxins, vitamins, food packaging materials, health food ingredients, and organic contaminants in all types of foods in the product standards system. The 30 standards in the GB4789 series include inspection methods for indicator bacteria and pathogenic bacteria in foods. As foodborne diseases caused by microorganisms have become the primary food safety concern, the food hygiene microbiological inspection becomes an important means for the prompt determination of the cause of disease. The 26 standards in the GB15193 series cover toxicological assessment procedures and test methods. These three major sets of standards do not only satisfy national inspection requirements, but also are easy to apply at the grass-root level. They play an important role in ensuring China's food safety by improving food safety inspection and detection capabilities.

3.4. International coordination of Chinese food standards

China is the only developing country that serves as host government of both the Codex Committee on Food Additives and the Codex Committee on Pesticide Residues. It has successfully held the annual Codex Alimentarius Commission (hereinafter referred to as "CAC") meetings for eleven consecutive years, leading the formulation and revision of international

standards in these two fields. China is committed to strengthening international exchanges, fostering talent, and enhancing technical capabilities, so as to ensure that its standardisation system is in line with international developments. At the same time, China has taken the lead in formulating ten international standards including those for non-fermented soybean products and for arsenic limits in rice.

Following several years of development, China's food safety standards have become basically consistent with international standards systems and principles. Both aim to ensure people's health and to guarantee safe food production, abiding by the principles of food safety risk management. China's national food safety standards system, procedures for standard formulation, and their scientific basis are in line with those of CAC and of major developed countries, as illustrated in the two tables in the next page.

3.5. Conclusions

After the recent campaigns for standards streamlining and integration, China put in place a system of food safety standards which is in line with its national conditions and the needs of relevant stakeholders. During the 13th Five-Year Plan period (2016-2020), China's food safety standardisation work will closely follow the principles outlined by the *Food Safety Law*. Additionally, in accordance with *Healthy China 2030 Plan* and the current level of standardisation, the standardisation work will further apply food safety risk analytics, establish a system that is more science-based and feasible, engage in the formulation of international food standards, enhance international exchanges, facilitate the absorption of international standards into China, and introduce Chinese standards to the world.

Table 1: Comparison between CAC Standards and China's National Food Safety Standards (in terms of principles)

	Codex Alimentarius Commission	**China**
Objective	To protect health and facilitate trade	To ensure safety by establishing a scientific protection standard
Standard System	Basics + Products (Food) + Regulations	Basics + Products (Food, food additives, and food-related products) + Regulations + Methodology
Nature of Standard	Recommendatory, whose adoption is up to member countries	Compulsory
Formulation Procedures	Open, transparent, strict, compromising	Open, transparent, strict
Basis of Formulation	Science-based; Risk Assessment (JECFA/JEMRA/JMPR)	Science-based; Risk Assessment (Food Safety Risk Assessment Commission)

Table 2: Comparison between CAC Standards and China's National Food Safety Standards (in terms of standards)

		Codex Alimentarius Commission	China
Generic standards		Pollutants, additives, microorganisms, labels, special foods, analytical and sampling methods, import and export inspection and certification, pesticides, veterinary drugs, and genetically modified foods	Pollutants, additives, microorganisms, labels, special foods, pesticides, veterinary drugs, and food-related products
Product standards	**Food ingredients and product standards**	Including quality and safety indicators. Cover food categories such as meat and meat products, fish and fish products, milk and dairy products, grains and beans, cocoa products, chocolate, vegetables, oil, bottled water, special foods, irradiated foods, etc.	Only including safety indicators and quality indicators that are safety-related. Cover meat and meat products, fish and fish products, milk and dairy products, grains and grain products, eggs and egg products, special foods, irradiated foods, nuts and seeds, beverages, honey products, etc.
	Food additives quality specification	Only listing food additives and spices. Specific standards shall refer to JECFA	Food additive quality specifications are in place
	Food-related standards	N/A	Food related standards are in place
Regulatory standards		Divided into general standards, specific standards, and hazardous factors control guide.	Divided into general standards, specific standards and hazardous factors control guide.
Inspection and testing standards		Only general standards exist. Specific inspection methods shall refer to ISO, etc.	Including physicochemical, microbiological and toxicological methods

Chapter Four

Regulation: institutional arrangements and organisational evolution

Hu Yinglian[*]

Food safety has become a major issue affecting basic livelihoods in China as well as its economy and politics.[15] The issue of food safety in China remains severe and ensuring food safety is a great challenge. A close review of the institutional and organisational evolution of the food safety system since the foundation of the People's Republic of China will contribute to a better understanding of the governance methods for food safety in a country as large as China.

4.1. Food hygiene management prior to the economic reforms and opening-up (1949 – 1978)

The Chinese government began administrating food safety regulations since the foundation of the People's Republic of China. On 1 November 1949, the central government established the Ministry of Health (MOH); in the same year, the Changchun Railway Bureau set up the first health and anti-epidemic station in China. In January 1953, the Government Administration Council decided to expand health and anti-epidemic stations nation-wide, at the same time requiring local health authorities at all levels to set up food safety offices (or teams) inside them to undertake food hygiene supervision and management. The central health administrative authority issued hygienic standards that covered, amongst other items, grains, oil, meat, eggs, alcohol, and dairy products, and began the implementation of hygiene supervision measures that aimed to prevent problems such as food poisoning and infectious intestinal diseases. For example, the *Interim Administrative Measures for Cool Drinks and Foods* issued by the MOH in 1953 represents the first food hygiene-related legislation of the People's Republic of China, directly addressing the issue of unsanitary cool drinks leading to food poisoning and infectious intestinal diseases. In 1957, the MOH circulated a piece of legislation nationwide that was originally formulated by the Tianjin Municipal Bureau of Health, stipulating a maximum amount of 1 mg/kg of arsenic content in soy sauce. Similarly, in 1960, the State Council circulated nationwide the *Administrative Measures for Synthetic*

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[15] Wang Yang, "Supervision and Management is the Key to Food and Drug Safety", *Qiushi*, 2013, No.16, pp. 3-6.

Food Pigments. Originally issued jointly by the State Scientific and Technological Commission, MOH, and the Ministry of Light Industry (MOLI), the document determined five synthetic food pigments that were permitted for usage in China together with their usage limits. Meanwhile, the Ministry of Chemical Industry (MOCI) appointed a series of manufacturers specifically dedicated to the production of synthetic food pigments in an effort to halt the abuse of poisonous, cancer-causing pigments. Despite this, the primary concern of the food-related administration at that time was focused on ensuring people's daily subsistence needs as food was in short supply and provided through a ration coupon system; in other words, during this time, quantity was more important than quality. By exerting firm control on the food industry, governments at all levels considered the safeguarding of food supply as an important political task. The creation and daily operations of food enterprises fell under direct government control.[16]

From 1953 to 1978, the total output of China's food industry grew at an average annual rate of 6.8%.[17] At the same time, the government's role in food administration was gradually expanded and refined. Food hygiene issues fell under the management of the Ministry of Health as well as other authorities in relevant sectors; a joint management model between food industry and health authorities was thus established. After the second Chinese institutional reform was initiated in 1956, all relevant authorities in light industry, commerce, domestic trade, and the chemical industry set up food hygiene inspection and management agencies to safeguard the quality and eligibility of products for commercialisation. In August 1965, the State Council approved and circulated the *Trial Administrative Provisions for Food Hygiene* jointly issued by five ministries, including the MOH and the Ministry of Commerce, which required authorities in each relevant sector to be responsible for the enforcement of food safety standards and for the hygiene administration of food enterprises. More specifically, relevant authorities should discipline business activities by adopting internal management processes of "command and control", such as ideological education, quality competition, mobilisation of masses, and administrative disciplinary procedures. The health authority played a subordinate role within this institutional arrangement, *de facto* limited to providing solely technical guidance, with no capacity to deal with non-compliant enterprises. Fortunately, as enterprises during the era of the planned economy had few economic needs or demands. A limited number committed fraud or used inferior materials in pursuit of profit and counterfeiting was also very rare. During this period, food hygiene problems mostly originated from factors associated with the "pre-market" risks due to underdeveloped productivity, such as low levels of techniques and equipment or internal management deficiencies.

[16] Hu Yinglian, "The Institutional Logic in the 'Overhaul' for Food Safety", *China Reform*, 2013, No.3, pp. 29-32.

[17] Lyu Lyuping, "An Introduction to Chinese and Foreign Food Industry", *The Economic Daily Press*, 1987.

4.2. Mixed and transitional system (1979 – 1993)

4.2.1. Development of the food industry and food hygiene problems at the beginning of the economic reform period

The Third Plenary Session of the 11th CPC Central Committee (December 1978) put forward the issue that the main priority of both the Party and the State should shift to promoting economic development. As the food production, distribution and catering industry were characterised by low access restrictions and small investments (whilst facing large demand with potentially of quick returns) attracted a large amount of workers. Although State-owned enterprises maintained their dominant role, a wider range of players with different types of ownership started to emerge in the market including private businesses, joint ventures, sole proprietorship, and self-employed entrepreneurs. Consequentially, profound changes also took place in the behaviour of market players. While during the era of planned economy the government managed to control the quality of food additives and food packaging materials by appointing specific manufacturers, with the gradual phasing out of planned procurement and distribution, any products which met national hygiene standards could be sold under the free market system. Exposure to competition stimulated market players, a basic balance between supply and demand was achieved, and consumer demand started to diversify. From 1979 to 1984, the total output of China's food industry enjoyed a spectacular 9.3% annual growth rate.[18]

Such changes at the very foundations of the economy sent an urgent call for reforming the regulatory model and system. In 1978, following the State Council' approval, the Ministry of Health coordinated the establishment of the National Steering Group for Food Hygiene, together with other relevant ministries. The Steering Group began to address and control food contamination in areas such as agricultural planting and breeding, food production and distribution, as well as imports and exports, particularly targeting pesticides, diseased livestock meat, industrial wastewater, waste gases and residues, and mildew. Admittedly, China made remarkable progress in food hygiene supervision at the beginning of the economic reform period. In 1982, the overall compliance rate of food hygiene inspections reached 61.5%, while that of cold drinks and soy sauce increased to over 90% and 80% - respectively from 40% and 20% under the planned economy.

Nonetheless, the 1965 *Trial Administrative Provisions for Food Hygiene* already mentioned in the previous section, as well as the 1979 *Administrative Provisions for Food Hygiene*, only specified collectively-owned enterprises or "enterprises owned by the whole people" (i.e. State-owned enterprises) as targets for food hygiene supervision and management. As a result, a large number of enterprises in the food industry remained unregulated. In this regard, the food hygiene supervision system failed to keep pace with the

[18] Yang Like, Xu Guangtao, "China's Food Industry Develops Rapidly", *People's Daily*, 29 November 1988.

economic environment, restricting the development of the food industry. Meanwhile, the deepening of economic reforms alongside the expansion of the market, size, technological approaches, production and marketing meant that the food industry was quickly diversifying.

Government policies aimed at invigorating the economy enabled an overall favourable environment for prosperity. Enterprises of various ownership structures were increasingly motivated to pursue business profits, generating opportunistic behaviours such as evasion and resistance to law enforcement, or using illegal methods to pursue exorbitant profits. The pressure generated by rapid market expansion and inadequate management meant this period continued to present traditional risks associated with a "pre-market" status but also new human-made challenges caused by market competition and the drive for profits. Reports of severe food poisoning incidents were not rare.

4.2.2. Initial legislation of food hygiene management

Based on its experience accumulated over more than three decades of food hygiene management, on 19 November 1982 the 25th session of the 5th National People's Congress' (NPC) Standing Committee deliberated and approved the *Food Hygiene Law of the People's Republic of China (for trial implementation)* (hereinafter referred to as the *Trial Law*) – the first food hygiene law in China. Based on its sound structure and systematic structure, the *Trial Law* outlined detailed provisions on the hygiene requirements for food, food additives, containers, packaging materials, utensils and equipment used for food. It also formulated food hygiene standards as well as regulations for food hygiene management, licenses, supervision, medical inspections and clarified the legal responsibilities of relevant personnel working within the food industry. The *Trial Law* represents the first initial step towards the establishment of the basic framework of modern food hygiene.

The *Trial Law* stipulated that China implements a food hygiene supervision system, thus re-shaping the existing layout where the responsibilities of carrying food hygiene supervision and management laid within "food hygiene steering groups" established at various government levels. In this way, it made clear that the health administrative authorities at various levels led the food hygiene work and acted as law-enforcement bodies. As the planned economy continued to be in place, the *Trial Law* did not change the joint management model of health and industry authorities. Within this model, health authorities were responsible for supervising and enforcing food hygiene, while industry authorities were responsible for administering food production and distribution standards within enterprises. Such models had, in particular, the following features: firstly, health and anti-epidemic stations or food hygiene supervision and inspection offices at county-level or above should be responsible for food hygiene supervision within the scope of their jurisdiction. Secondly, in those sectors featuring an evident combination of government functions with enterprise management such as railway, transportation, factories and mining, health and anti-epidemic stations should, within the scope of their jurisdiction, function as the responsible agencies for

food hygiene supervision; in this case, local food hygiene supervision agencies would be responsible for providing professional guidance. Thirdly, relevant industry and commerce administrative authorities – which were restored in 1978 – should be responsible for food hygiene administration and general inspection work in urban and rural markets, while food hygiene supervision agencies should be responsible for hygiene supervision; agriculture, animal husbandry and fishery administrative authorities would be responsible for food hygiene and veterinary inspections of livestock and poultry. Moreover, food hygiene supervision and inspection frontier agencies (then under the jurisdiction of health authorities) should be responsible for supervising and inspecting imported foods, while exports should be the responsibility of relevant national inspection agencies. Lastly, authorities in charge of enterprises engaged in food production or distribution should be responsible for conducting food hygiene work within their respective administrative systems; together with the enterprises themselves, they should build and improve food hygiene management and inspection bodies within their own administrative systems or should appoint full-time or part-time personnel to manage food hygiene.

4.2.3. Integrating traditional and modern food hygiene management approaches

Following the profound changes that took place at the foundation of the industry and within the institutional system, the effectiveness of traditional administrative interventions such as executive instructions declined significantly, highlighting the urgency of making policy tools available. To address this need, the government gradually introduced a number of new measures such as regulatory standards, market rewards and punishments, as well as judicial verdicts. In 1981, MOH set up the Sub-committee for Standard Techniques in Food Hygiene, and entrusted the Hygiene Institute at the Chinese Academy of Medical Sciences (later renamed as China National Centre for Food Safety Risk Assessment) with the formulation of a five-year plan for the development of food hygiene standards, and with the release of over 80 standards – including product standards, limit standards, and microbiological and physicochemical inspection and testing standards – in various areas ranging from condiments to food additives and packaging materials. In 1984, China became a member of the Codex Alimentarius Commission (CAC), and took an increasingly active role in formulating international food standards. Meanwhile, health authorities began to encourage enterprises to focus on food hygiene by fully leveraging market mechanisms. Another major change was brought by the joint publication of the *Interim Measures for Charging Standards of Health and Epidemiological Agencies* by MOH, the then State Administration for Commodity Prices, and the Ministry of Finance: these *Measures* resulted in a decrease of government subsidies and in the establishment of paid services as important source of income for food hygiene supervisory agencies. From this period onwards, food hygiene supervision and monitoring gradually became a joint responsibility of both consumer and the State. It was no longer

offered as a public and not-for-profit service - instead supervisory and regulatory powers were clearly defined at all levels.

The commodity economy injected new impetus to the supervision and management of food hygiene in China. The *Trial Law* played a significant role in improving the country's food hygiene level and in facilitating the development of the food industry. Public awareness of legal aspects of food hygiene was significantly enhanced, knowledge of food hygiene gradually diffused among a wider pool of people and the overall food compliance rate with required standards increased from 61.5% in 1982 to 82.3% in 1994. In 1990, there were 75,362 operating enterprises employing 4.85 million people in the food industry with a total output of 144.78 billion RMB. Tax revenue from food enterprises amounted to 40.7 billion RMB, ranking third among all sectors.[19] In view of the economic and social conditions, management systems, and policy tools, food hygiene work in China was in a transitional phase of uneven change. It hovered between basic subsistence needs and fine dining demand, between a planned economy and a commodity economy, between areas where government functions and enterprise operations were combined and those where they were separated, between industrial management and external supervision, and between traditional and modern forms of regulation.

4.3. Comprehensive external supervision system (1994 – 2002)

4.3.1. New characteristics of the food industry pattern and of regulatory ideas under the market economy

In October 1992, the 14th CPC National Congress announced the establishment of a socialist market economy in China, putting forward the "separation of government functions from enterprise management, so as to gradually grant autonomy to enterprises in their production and distribution". Following this milestone, the 1993 institutional reform of the State Council abolished the Ministry of Light Industry, replacing it with the China Light Industry Association. Food enterprises were thus officially separated from relevant light industry departments, putting an end to the combination of government functions and enterprise management that had dominated them for over the past 40 years. This further contributed to stimulate and motivate various market actors to enter the food industry, which consequentially started to witness an unprecedented level development. In 2000, fixed asset investments of food enterprises "above designated size" [20] accounted to 510.37 billion RMB, over 30 times higher than that registered in 1980. As the industry expanded, the food market became geared towards buyers, resulting in fiercer competition and wider choices for

[19] Fu Wenli, Tao Wanting, Li Ning, "Innovations of Food Safety Regulation Mechanisms", *Journal of Chinese Institute of Food Science and Technology*, 2015, No.5, pp. 261-266.

[20] A statistical term used in China to indicate all State-owned enterprises as well as non-State-owned enterprise with then an annual sales revenue of over 5 million RMB (increased to 20 million RMB in 2011).

consumers. Similarly, production and distribution models also started to witness large changes, with the number of State-owned enterprises dropping whilst other forms of ownership grew significantly. Novel food and healthy food became more popular and widely produced. The broader trends in the reform and opening-up process, more foreign trade and economic and social development brought food hygiene closer together with core policy issues. The need for food hygiene to keep up with improving living standards became urgent.

As market competition became more intense, relevant authorities in charge of the food industry started to abandon old models of planned food procurement and level-by-level distribution; instead, they started to delegate administration authority to lower levels. On the one hand, this had the potential to give more autonomy and flexibility to food enterprises in their production and distribution, whilst loosening food hygiene management requirements for enterprises. Motivated by their own interests, some administrative authorities only failed to abide by the food hygiene management obligations set out in the *Trial Law* and went further to obstruct law enforcement by food hygiene supervisory bodies. Similarly, driven by "developmental localism", some areas rushed to establish food production enterprises and wholesale markets, which contributed to shaping a small but complete regional food industry pattern in the early 1990s. This disrupted the order of the market. Protectionism rose as some authorities and local governments fell into a trade-off between achieving the policy goal of economic development or that of food hygiene. During this period, major risks for food safety in China had fully completed their transition from "pre-market" risks to manmade food safety and quality risks driven by economic profits.

Faced with the grim reality, China took a series of measures to crack down on local protectionism, correct market failure, and encourage competition.[21] In 1994, the Third Plenary Session of the 14th CPC Central Committee for the first time urged to "improve and strengthen market management and supervision, establish normal market entry, competition and transaction order, ensure fair trade and equal competition, and protect the lawful rights and interests of businesses and consumers". As reflected in key documents and reports that followed, national leaders started to pay stronger attention to food hygiene. In March 1995, the then Premier Li Peng included in the annual government work report the need to "enhance supervision and management of drugs, food, and social public health"; in 1997, the government work report emphasised that "supervision and management of food and social public health will be tightened", which followed the joint release earlier in January that year of the *Decisions on Health Reform and Development* by the CPC Central Committee and the State Council. The *Decisions* ranked food hygiene at the top of five "public health issues", requiring "efforts to be taken to address food hygiene, environmental health, occupational health, radiological health, and school health".

[21] Mertha, Andrew, "China's "soft" Centralization: Shifting Tiao/Kuai Authority Relations since 1998", *China Quarterly*, 2005, No. 184, pp. 791–810.

4.3.2. Contents and significance of the Food Hygiene Law

These significant changes in the macroenvironment paved the way for the official implementation of the *Trial Law*, which by then had been in force for over a decade. Under an initiative led by former State Council's Legislative Affairs Bureau and MOH, the *Food Hygiene Law* was officially approved on 30 October 1995 during the 16th session of the 8th NPC Standing Committee, marking the beginning of the legislation phase of food hygiene management in China. The overall framework, major systems and clauses of the original *Trial Law* were retained in the new *Food Hygiene Law*, while other relevant regulations on health food were added, administrative penalty clauses clarified, and administration on street food and imported food enhanced.

The *Food Hygiene Law* reiterates that China implements a food hygiene supervision system, ends the responsibility of various industry authorities which was the result of a former structure combining government functions with enterprise management and confirms that health administrative authorities are the main party responsible for food hygiene law enforcement. Specifically, the *Food Hygiene Law* specifies ten functions for the Ministry of Health: develop food hygiene supervisory and administrative rules and regulations; develop hygiene standards and inspection procedures; examine and approve health foods; supervise, inspect, and approve hygiene standards of food imports, utensils and equipment; approve and issue hygiene licenses; approve new products such as Novel resource food and food additives; examines and approves relevant design and delivery of construction, renovation and expansion projects of food enterprises; carry out daily food hygiene supervisory examinations and inspections; adopt temporary control measures on food enterprises which have caused food poisoning incidents; implement administrative penalties.

Other departments under the State Council are also responsible for conducting food hygiene management within the scope of their jurisdiction. For instance, agricultural authorities are responsible for the supervision of planting and breeding; food hygiene supervisory bodies under railway and traffic authorities and within the military system are in charge of food hygiene management of their own industry. The *Food Hygiene Law* also established authoritative external food hygiene law enforcement and supervisory bodies, which replaced internal food hygiene authorities that had been established in most areas. This meant that both the supervisor and the supervised are included into the legal framework. Despite differences still exist in the specific institutional setup and division of responsibilities, under this market economy independent third-party supervisory bodies have now taken over the main supervisory. An overall external supervisory system was therefore put in place.

The new management system helped improve the four-level (county, prefecture/municipal, provincial, national) food hygiene law enforcement and supervision system, as well as the supporting technical system. Approximately 100,000 hygiene supervisors and 200,000 hygienic technicians were employed nation-wide for food hygiene

licensing, supervision, inspection, monitoring, food poisoning incidents handling, and food-derived diseases prevention and control.[22] In March 1997, MOH released a more detailed *Food Hygiene Supervision Procedures* to further strengthen food hygiene supervision and law enforcement. The Procedures further tightened food hygiene-related market access requirements for enterprises operating in food production and distribution, as well as standardised administrative licensing for food additives, novel resource foods, and health foods. A series of sampling tests and ad hoc rectifications were conducted all across the country. Several food hygiene-related cases that aroused strong public response were investigated and properly handled.

4.3.3. Emergence of new policy tools and the idea of 'food safety'

In order to cope with the socialist market economic system, traditional administrative intervention practices started to be gradually abandoned. Health authorities continued to strengthen national legislation, technical standards, and administrative law enforcement. At the same time, new regulatory tools such as quality certification, risk monitoring, and scientific awareness-raising started to be introduced. Firstly, over 90 supplementary rules and regulations for the *Food Hygiene Law* were developed, covering food, food additives, food packaging materials, containers, and food hygiene supervision and penalty. Similar rules and regulations were also developed and put into effect by different local administrations: a well-structured legal system for food hygiene with Chinese characteristics was thus basically established. Secondly, the standardisation system was also incorporated into the legislation. By the end of 1998, 236 national food hygiene standards, 227 standard inspection methods, and 18 industrial standards were formulated, granting shape to a national food hygiene standards system comprising basic standards, product standards, conduct standards and inspection methods.[23] Thirdly, a "Food Safety Action Plan" was developed and implemented in 2003 based on advanced foreign expertise, adapting them to China's specific circumstances. The Plan mainly included the promotion of a quantitative classification management system in food hygiene supervision, promoting Good Manufacturing Practice (GMP) and Hazard Analysis and Critical Control Point (HACCP) management systems, establishing a monitoring network for food contaminants and food-derived diseases, and conducting risk assessment. Fourth, several food hygiene-related awareness-raising and education activities were carried out, including eleven annual editions of the "National Food Hygiene Law Week" starting from 1996. Information relating to food hygiene and food poisoning incidents were also regularly

[22] Chen Xiaohong, "*Development and Current Status of China's Food Safety Regulatory System*", during the "Provincial and Ministerial Leadership Seminar on Enhancing Food Safety Regulation" organised by the Organisational Department of the CPC Central Committee, FSCO, and the Chinese Academy of Governance, 9 May 2011.

[23] Ni Nan, Xu Demin, "Historical Revolution of the Legal Construction of Food Hygiene in the new China and Its Implications", *Journal of Socialist Theory Guide*, No.11 2012, pp. 103-105.

announced and reported to the public, encouraging the latter to actively participate in public food hygiene supervision.

Food hygiene means that foods should be non-poisonous, harmless, and meet certain nutrition requirements. The goal is to prevent any negative impacts on human bodies from food contamination and hazardous factors. The planting and breeding stages do not fall under this scope. As China's food industry grows and market expands, food hygiene management focusing only on consumption stages can no longer be a sufficient target for supervision; an ideal supervisory chain covers all segments starting from the beginning and ending at the very end. In 2000, the World Health Assembly (WHA) approved the *Food Safety Resolution,* developed a global food safety strategy, listed food safety as a priority area in public health and required member states to develop their own action plans to minimise the threat of food-derived diseases on public health. Many countries including China responded to this action to further enhance food safety-related work.[24] Food safety involves food surface hygiene, quality, properties and nutrition of foods, covering the entire industry chain, from planting and breeding of agricultural products, processing of agricultural side-line products, food circulation and distribution, to catering services. The shift from food hygiene to food safety is an inevitable result of socio-economic development.

This conceptual change was reflected in the 1998 reform of the supervisory system. Although the State Council restructuring that took place in that year was aimed at streamlining government agencies and personnel, the central government still managed to enhance relevant departments' functions of food safety supervision. The State Bureau of Technical Supervision was renamed State Bureau of Quality Technical Supervision, and was assigned the responsibility of approving and releasing national food hygiene standards – originally under the functions of MOH; it also become responsible for developing quality standards, detection system and methodologies for grains and oil – which formerly were under the responsibilities of the State Grain Administration. In the same year, the former State Administration for the Inspection of Import and Export Commodities, Plants and Animals Quarantine Bureau of the Ministry of Agriculture (MOA), and the Health Quarantine Bureau of MOH, were integrated to form the State Administration for Entry-Exit Inspection and Quarantine, a new body responsible for the administration of food imports and exports nation-wide. In April 2001, the State Administration for Industry and Commerce was upgraded to ministerial level. It continued to be responsible for food hygiene management on urban and rural free markets; it also began to undertake the food quality supervision and management within the distribution segment of the food chain – an area which was formerly the responsibility of quality and technical supervision authorities. In 2001, the recently-established State Bureau of Technical Supervision and the State Administration for Entry-Exit

[24] The Ministry of Health, Notice on Issuing the Food Safety Action Plan (*Wei Fa Jian Fa [2003] No.219*), Website of the Central People's Government of the PRC, available at: http://www.gov.cn/gongbao/content/2004/content_62680.htm, 2016-06-07.

Inspection and Quarantine were further integrated into the ministerial-level General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ). Furthermore, in order to break the long-standing local protectionism, vertical administration (a model through which central and provincial governments are directly responsible for supervising their counterparts at lower administrative levels, in contrast to "level-to-level administration") was adopted at below the provincial level in industry and commerce, quality supervision, and later food and drug regulation, which differ from regular government agencies particularly in the area of institutional setup and management, financial and funds management, staff and leaders management. The MOA is still responsible for the quality and safety regulation of primary agricultural products in the planting and breeding stage. By restructuring and merging various food safety regulatory based on their functions, China laid the foundation for its "phase-oriented segmented regulation and management system" which would be adopted in the following years.

The implementation of the *Food Hygiene Law* and the emergence of new regulatory concepts and institutions have boosted the sustained, rapid, and sound growth of China's food industry. Food hygiene, quality and safety largely improved. Food-derived contagious diseases threatening human health such as cholera, dysentery and typhoid fever were kept under control. Statistics from the *China Health Yearbook* and the *China Health Statistical Yearbook* show that in 2004 90.13% of food in the country met the hygienic standards, seven percentage points higher than that registered in 1995 (83.1%), and 29 percentage points higher than 1982 (61.5%). Also, the number of food poisoning incidents in China dropped from 1,405 in 1992 to 522 in 1997 and 379 in 2003, with the number of food poisoning victims decreasing from 47,367 in 1990 to 13,567 in 1997. All indicators showed a trend towards better food safety.

4.4. Scientific regulation system (2003 – 2011)

4.4.1. Impact of the WTO membership on the food industry

On 10 November 2001, the fourth Ministerial Conference of the World Trade Organization (WTO) held in Doha unanimously approved China's entry into the organisation. The WTO membership brought two significant changes to China's food safety. First, a large number of imported food products started to enter the Chinese market, bringing about risks associated with intellectual property rights as well as trade barriers whilst enhancing consumer awareness of food safety. Second, China began exporting more food products overseas, further adding a political significance to the issue of food safety, which was implicated in cross-border trade and diplomatic relations.

After years of development, China's food industry witnessed significant changes: productivity was largely unleashed and expanded and an industrial chain and production

system with full categories was established. China shifted from a nation suffering from food shortage to a major global food producer, from a semi-closed country to one fully open to international trade. China's competitiveness and comprehensive strengths registered remarkable growth: in 2007, the total output of China's food industry accounted to 3.27 trillion RMB; profits and tax revenue generated accounted to 548.2 billion RMB, of which net profit was 235.5 billion RMB. The figures posted an increase of 34 and 45 times respectively compared with those in 1983, which yet was still a productive year at that time. China was already the world's largest, or one of the largest producer of rice, wheat flour, edible vegetable oil, fresh chilled and frozen meat, biscuits, juice and fruit drinks, beer and instant noodles.[25]

With rapid socio-economic development, people's demands were constantly growing. The provision of goods and services evolved into a qualitative issue from a quantitative one. In the food sector, consumers not only expected to reach satiety but also quality, safe and nutritious foodto improve the quality of their lives. Sadly, however, food safety incidents were reported frequently during this period and this encouraged political leaders to pay more attention to the industry. Market order was no longer their only concern; comprehensive issues like industry foundations, public health and social stability became new priorities. The shift was also evident in the wording relating to food safety in several government work reports formulated over this period. In 2001 it aimed to "establish a food safety and quality standard and testing system" butin the following year former Premier Zhu Rongji highlighted the importance of "cracking down on counterfeiting in the food sector which severely jeopardise people's life and health". In 2004 the key task however was to "carry out more special programs to address food and drug issues which directly affect people's health and safety". Compared with government work reports in the 1990s, the focus in this period changed fundamentally, paving the way to the adoption of a "segmented regulation and management system" for food safety.

4.4.2. The model of "comprehensive coordination and segmented regulation", and its challenges

In order to improve inter-department coordination on food safety, during the 2003 institutional reform of the State Council the former State Drug Administration was upgraded to the State Food and Drug Administration (SFDA), assuming the responsibility to conduct comprehensive supervision of food safety, coordinating, investigating and dealing with major incidents, and at the same time reviewing and approving health foods. In September 2004, the State Council issued the *Decision on Further Strengthening Food Safety Work* (*Guo Fa [2004] No.23*), which introduced a model of "segmented regulation" in which each relevant

[25] Xinhua News Agency, "*China, a Major Global Food Producer 30 Years into Reform and Opening-up Drive*", official website of the Central People's Government of the PRC, http://www.gov.cn/jrzg/2008-12/13/content1177387.htm, 2016-06-07.

food safety regulatory department would be responsible for supervising a particular segment of the food chain, clarifying the functions and responsibilities of each department in charge of food safety supervision. Under this model, agricultural authorities were responsible for supervising the production stage of primary agricultural products; quality inspection authorities would be responsible for supervising food production and processing; industry and commerce authorities would be responsible for supervising food distribution; health authorities would be in charge of supervision food consumption stages, including the catering industry and canteens; while food and drugs regulators assumed the role of overall food safety supervision. The State Council's *Decision* therefore established a system of "comprehensive coordination and segmented regulation". It clarified that local government should take responsibility for food safety within the scope of their jurisdiction by guiding and coordinating food safety regulation and remediation work and by establishing and improving organisation and coordination mechanisms for food safety.

In terms of specific and concrete work, quality inspection authorities would take the lead and coordinate with other relevant authorities to establish and improve food safety standards and testing and inspection systems, at the same time strengthening grassroots law enforcement squads. Food and drug regulators would take the lead in speeding up the establishment of a food safety credit system and the application of information technologies.

Three months later, in December 2004, the State Commission Office for Public Sector Reform (SCOPSR) issued the *Notice on Further Clarifying the Division of Duties of Food Safety Authorities* (*Zhong Yang Bian Ban Fa [2004] No.35)*. The *Notice* further refined the division of responsibilities among relevant authorities in food production and processing, distribution, and consumption. Quality inspection authorities would be responsible for the daily supervision and management of food quality in both the production and processing stages. On the one hand, by enforcing a food quality and safety market access system based, on production permits as well as mandatory inspections to identify non-compliant or illegal behaviours in production and manufacturing processes. They would also timely report any case of permit issuance, withdrawal or revoking to food hygiene and industry & commerce authorities. Industry and commerce authorities would be responsible for quality supervision and management throughout the food distribution segment, and for the registering enterprises and individual industrial and commercial households engaged in food production and distribution. They would also outlaw unlicensed food enterprises, enhance quality supervision and inspection on foods sold on the market, investigate into and deal with the sale of substandard foods and other illegal activities impacting food quality, crack down on false food advertising and trademark infringements, and report any case of business license issuance, withdrawal or revoking to quality inspection and hygiene authorities. Hygiene authorities would be responsible for hygiene supervision and management throughout the distribution and consumption segments. They would also be in charge of granting hygiene permits at the food production and processing segments, a process involving assessment and

review of the sanitary and prevention conditions, as well as the health and hygiene conditions of relevant personnel. They would also investigate and deal with any illegal activities falling within the scope of the above activities, reporting any case of hygiene permit issuance, withdrawal or revoking to quality inspection and industry & commerce authorities.

With the newly assumed responsibility of conducting overall coordination, the SFDA in 2004 led an investigation in Fuyang, Anhui province, into a fake milk powder incident. It also organised the 11th Five-year Plan for Food and Drug Safety (2006-2010), initiated the "Food Safety Project (2005-2007)", launched relevant food safety evaluations in provincial capitals, initiated the establishment of food safety demonstration counties and districts, promoted the establishment of a food credit system, drafted food safety status reports, and established a mechanism for information disclosure and communication. Food safety coordination mechanisms were also gradually established at the local level, led by local government leadership and participated by responsible cadres from relevant departments, with a coordination office established within local-level food and drug administrations (with the only exceptions being Beijing and Fujian Province, for which the food safety coordination office was established respectively within the industry and commerce authority, and the economy and trade authority). This represents a comprehensive and interconnected mechanism among different government levels.

Although all relevant agriculture, quality inspection, industry and commerce, and health authorities put forth a lot of efforts in supervising and managing their respective areas and segments, under such segmented regulation model with sometimes overlapping functions or multiple enforcement, ineffective measures or conflicts of interests among different departments soon started to appear. As food production and distribution was a continuous process, contradicting policies and rules of various authorities could be confusing for both the supervisor and the supervised, resulting in low efficiency in law enforcement and compliance. Therefore, food safety incidents constantly occurred.

These major problems with food and drug regulators were directly listed and addressed by Vice Premier Wu Yi during a February 2007 national teleconference on enhancing food and drug control, supervision and management. She explicitly mentioned that biased thinking occasionally affected supervision and management; that relevant government departments did not have a clear understanding of their responsibilities; that the relationship between the government and enterprises, between supervision and service, and that between commercial interests and public interests needed to be improved; and that the vision of "helping businesses to promote economic growth" had been over-emphasised. [26]

[26] Wu Yi, "*Address on the 2007 National Work Conference on Enhancing Food and Drug Administration*", official website of the Central People's Government of the PRC, http://www.gov.cn/wszb/zhibo9/content_521888.htm, 2016-06-07.

Following this conference, and in line with the Scientific Outlook on Development (a guiding socio-economic principle outlined by former President Hu Jintao in 2003), a new concept of "scientific management" gradually started to replace the old methodology as the main guiding principle for supervisors and regulators.[27] A new food safety responsibility system was also put forward by the conference, where "local governments take total responsibility, supervision and management departments take their own responsibilities, and enterprises are the prime responsible actors".

4.4.3. Promulgation of the Food Safety Law, and establishment of the State Council's Food Safety Committee

Against this background, it had become clear that a neutral and independent was necessary to further push forward the reforms, particularly to sort out the relationship between regulators and the industry, and to safeguard public interests. After the 2008 State Council restructuring reform, which followed the principle of establishing larger government departments, the SFDA – formerly directly under the State Council – was transformed into a state bureau under the MOH, and the administrative functions of MOH and SFDA were swapped: MOH became responsible for the comprehensive and overall coordination of food safety work, as well as for leading investigations into major food safety incidents, for developing food safety standards, conducting risk monitoring, assessment and alert, for developing qualification criteria and testing rules for relevant food safety inspection agencies, and ultimately for releasing food safety-related information; SFDA became responsible for food safety supervision at the consumption stage of the food chain, including the catering industry and canteens, as well as for supervising health foods. The functions and responsibilities of the agricultural authorities, quality inspection authorities and industry and commerce authorities remained unchanged. Furthermore, in order to enhance the role of local governments, on 10 November 2008, the State Council replaced the former model of vertical administration in food and drug regulation at below the provincial with a hierarchical level-to-level administration model, in which local authorities would be directly guided and supervised by both their corresponding counterpart at one administrative level higher and by hygiene departments at the same administrative level. By the end of 2011, the General Office of the State Council released the *Notice on Issues Concerning the Adjustment of Administrative Control System below Provincial-level for Industry and Commerce and Quality Supervision to Enhance Food Safety Regulation* (*Guo Ban Fa [2011] No.48*), which extended the adoption of such level-to-level administration in the areas of industry and commerce, and quality supervision (by then both areas were also implementing a vertical administration

[27] Shao Mingli, "Establish and Practise Philosophies of Scientific Regulation", *Management World*, 2006, No. 11, pp. 1-5, 58.

model), with the purpose of strengthening the responsibilities of local governments in food safety. Unfortunately, these reform attempts were not successful for several reasons.

After the adoption of segmented regulation for food safety, as early as September 2004 relevant central authorities already put on the agenda a revision of the *Food Hygiene Law*, a process which was led by the State Council's Legislative Affairs Office, and participated by relevant departments, experts, industry associations, enterprises, and even foreign institutions so as to avoid conflicts of interest among different departments. Almost simultaneously, relevant authorities started the drafting of the *Law on Quality and Safety of Agricultural Products* – which was ultimately approved at the 21st session of the 10th NPC Standing Committee held in April 2006, before entering into force on 1 November of the same year. The Political Bureau of the CPC Central Committee in its 41st Group Study session in April 2007 emphasised the need for relevant authorities to assume a deep sense of responsibility to the people when conducting agricultural standardisation and food safety work.

The *Food Hygiene Law*, however, focused mainly on food hygiene management throughout the entire industry chain. Areas under the regulation of primary agricultural product at the production segment, such as planting and breeding, were not included in the *Law.* The same applied to food safety risk monitoring and assessment, removal of foods from shelves and food recall systems, health food and food additives regulation, food advertising regulation, civil liability for compensation, administrative law enforcement, and criminal justice and other modern measures which fit more easily into a market economy. Hence during the revision of the *Food Hygiene Law*, voices for bringing it to a higher level of *Food Safety Law* started to emerge, becoming stronger day by day. A first draft of such higher level of *Food Safety Law* was submitted for the State Council's approval in 2006, and to the NPC Standing Committee in 2007. The Sanlu outbreak infant formula scandal in 2008 further intensified public disputes on food safety regulation. At the end, after nearly two years of deliberation, the 7th Session of the 11th NPC Standing Committee on 28 February 2009 officially approved the *Food Safety Law of the People's Republic of China*, and immediately repealing the previous *Food Hygiene Law*.

On the basis of the provisions stipulated in the *Food Safety Law*, on 6 February 2010 the State Council issued the *Notice on Establishing the Food Safety Commission Office of the State Council* (*Guo Fa [2010] No.6*), establishing a Food Safety Committee composed by representatives from 15 government departments, including health, development and reform, industry and information, finance, agriculture, industry and commerce, quality inspection, and food and drug administration, and led by State Council personnel. As a high-level consultation and coordination body of the State Council on food safety issues, the Committee assumed the responsibility of continuously examining the status quo of food safety in China, studying, implementing and guiding food safety work, proposing major policy measures, and ultimately ensuring the fulfilment of food safety supervision and management responsibilities.

The Committee's daily work then took over by the Committee Office established in December 2010 with the *Notice on the Institutional Setup of the State Council's Food Safety Committee Office* (*Zhong Yang Bian Ban Fa [2010] No. 202*), issued by the State Commission Office for Public Sector Reform (SCOPSR), thus replacing the MOH as the highest level of overall coordination body for food safety. The newly established Office contributed to enhanced supervision of food safety, coordinating the proper handling of major food safety-related issues, consulting with the Central Political and Legal Affairs Commission to research and improve policy measures to fight against food safety-related illegal criminal activities, adopting concrete control measures for dairy product quality and safety and to crack down on illegally recycled waste cooking oil, and developing the Plan for the National Food Safety Regulatory System during the 12th Five-year period.

4.4.4. Inner logic of the evolution of the food safety system

Looking back at the evolution of China's food safety until 2011, we realise that its concepts and evolution are in line with the institutional logic of the time. At the early stage of the reform and opening-up drive, the national economy was in a precarious state. In the new era, the main contradiction in the food sector was ensuring the daily food subsistence of the people, with the main food hygiene problems in this period being associated with the "pre-market" risks of an underdeveloped economy. Encouraging industry administration authorities and local governments to assume an active role in expanding the food industry therefore became a reasonable choice for decision-makers. As a result, laws and regulations, the regulatory system as well as relevant policy measures featured a distinctive mix of features of both a planned and commodity economy. Starting from this moment, however, the development of China's food industry was disordered, market order was disrupted, and institutional barriers emerged. Against the backdrop of the market economy guided by socialist principles, a second reform was destined to take place. The central government initiated a battle against local protectionism and departmental interests by enhancing overall external supervision, by institutionalising food hygiene management, and by putting forth a new concept of food safety that should meet the needs and requirements for the development of the industry chain. Although economic development was still the "biggest political priority", food hygiene and safety in this period clearly gained more attention from policy-makers.

The constantly improving market economic system together with China's entry into the WTO accelerated the development of food industry. The extended food industry chain and the emergence of new risks required changes in the institutional design. The political leadership came to realise that the safeguarding of consumers' public interests was far more important than the commercial interests of the food industry.

The adoption of a model of "comprehensive coordination and segmented regulation", together with the clarification of the responsibilities of local governments, must therefore be

seen as a useful attempt to achieve this goal. Facing frequent food safety incidents, the institutional structure underwent constant adjustments, and modern regulatory and management tools were introduced one after another. Such new regulatory concepts and practices were eventually defined and clarified in the *Food Safety Law* promulgated in 2009. The establishment of the State Council's Food Safety Committee Office further contributed to the achievement of food safety policy goals from a top-down institutional design. This evolution of China's food safety (hygiene) system from 1979 to 2011 is summarised in Table 3.

Table 3: Evolution of Chinese Food Safety (Hygiene) System (1979-2011)

Duration / Variable	1979-1993	1994-2002	2003-2011
Foundations of industry	Food industry was generally underdeveloped	Food market was disordered	food enterprises were "numerous, small, and scattered"
Main risks	"Pre-market" risks coexisted with conscious malicious behaviours	Profit-driven man-made problems	Modern risks
Policy goals	Ensure food and basic subsistence; boost production growth	Break local protectionism, separate government and enterprise functions, maintain market order	Ensure food safety and promote healthy industrial development
Administr. system	Industry administration and government supervision coexisted	Mainly independent external supervision	Comprehensive coordination and phase-oriented segmented regulation
Landmark event	*Food Hygiene Law (for trial implementation)* was promulgated and implemented	The 3rd Plenary Session of the 14th CPCCC (1994) urged for the first time to "improve and strengthen market management and supervision"	The State Council issued the *Decision on Further Strengthening Food Safety Work*
Policy instruments	Administrative instructions, pedagogic persuasions, regulations and standards, rewards and punishments, judicial adjudication	Traditional administrative intervention measures became outdated; new regulatory tools emerged	Modern, market- and information-based regulatory measures

Source: collected by the author

In conclusion, foundational issues within the industry determine the main conflicts and risks associated with the food sector in each historical period. The concerns for food safety issues of the political leaders, therefore, vary accordingly. Policy goals are usually solidified

and magnified amidst market disorder and public incidents; relevant laws and regulations, the regulatory system, as well as the policy measures, therefore, change therewith. In other words, food safety regulations, laws, institutions and policy tools are a reflection of the food industry foundations as well as social demands; the top-level institutional design of food safety supervision and management therefore must follow and adjust to changes in the socio-economic foundations, regardless of whether such institutional adjustments are mandatory and pushed by external forces, or induced by endogenous and spontaneous factors. The independent variable of China's food safety institutional transition, is the food industry and social demand embedded by regulatory agencies; while the dependent variable is the specific institution at different stages, with policy goal of regulatory agency as intermediate variable. Throughout all three historical stages of evolution of Chinese food safety concepts and practices, what has been changing are the specific circumstances that occurred within the food sector, while the inner institutional logic has remained unvaried.

4.5. Modernisation of governance: China's food safety in the new era (2012 – present)

China's food safety entered into a new phase with the 18th CPC National Congress, which stressed the need to modernise national governance. As it was seen in the previous sections of this chapter, food safety regulation in China features both lessons and experiences learned in the past, as well as new concepts and practices. Therefore, by summarising the internal logic implied in the institutional evolution of Chinese food safety after the 1978 economic reforms and by analysing the paradigm shift from regulation of food safety, to governance of food safety, we can better grasp and understand the unique path of a "Chinese-style" regulatory State.

4.5.1. Multiple factors influencing food safety

In the past, people used to consider food safety as a technical matter of food hygiene and product quality. The 2008 Sanlu infant formula scandal, which harmed hundreds of thousands of consumers nationwide, had a profound impact on China's domestic dairy industry and the consequences are still visible today. In annual surveys conducted by the magazine *Insight China* to identify the "top ten concerns of Chinese people within the course of building an all-round moderately prosperous society", food safety has ranked top for several consecutive years. Having witnessed several incidents and scandals, people have become increasingly aware that government regulations alone cannot ensure food safety. This can only be ensured and safeguarded by improving awareness amongst relevant market players and by encouraging full public participation. These shall also contribute to the development of the food industry.

General Secretary Xi Jinping has remarked that food safety is in first stance the result of both “sound regulation” and “safe production”. This highlights how food safety is influenced by multiple factors but particularly from three issues. The first is “production”: individuals and enterprises engaged in food production and distribution are the prime responsible persons for food safety. Currently, there are more than 200 million farmers engaged in farming and animal husbandry in China. For them, however, the costs for violating relevant laws and regulations still remain relatively low, resulting in difficulty in controlling their behaviours. The second factor is “regulation”: a strong industry and powerful regulations can mutually support each other. In practice, however, there are approximately 100,000 certified long-term food and drug regulatory staff in China, while the total number of certified food enterprises accounts to several millions – hence there is a huge gap between the number of regulatory staff and the targets to be regulated. The third factor is “background”, that is the impact that the overall environment and background have on food safety. Furthermore, according to the present institutional layout, soil remediation, environmental protection and food safety are separately administered by land resources departments, environmental protection departments, and food and drug departments, respectively. This means that each relevant department sets policy agendas based on their own functions and responsibilities, resulting in a lack of complementarity and consistency of policies.

4.5.2. Paradigm shift from regulation to governance

Theoretically, regulation refers to the practises of government either guiding or restricting the activities of market players, while governance emphasises more the activities and processes in which government, market, and society actors adopt flexible approaches realise public benefits, contributing to improving institutional performance by building a comprehensive network. National governance involves governance system and capabilities, with the former focusing on the rationality of the institution and the latter on the effectiveness of institutional implementation.

In the modern world with its inherent risks, no actor can handle the increasingly complicated safety problems alone. The complexity of the causes of food safety issues require an integrated coping approach. In addition to government regulation, the self-governance of enterprises, the self-discipline of the industry, media supervision, consumers’ participation and judicial adjudications are all indispensable approaches to correct market failures and to ensure food safety. The modernisation of food safety governance therefore requires a change in approach and a redefinition of the role of regulators, enterprises, industry associations, media, consumers and all other relevant stakeholders, as well as a redefinition of the relationship between their rights and obligations. When such a relationship is institutionalised through written laws or regulations, the food safety governance system can be established. The institutional implementation, e.g. guiding or restricting relevant behaviours within the food industry, will reflect a country’s governance capabilities.

At the beginning of 2011, the central government, for the first time, urged the development of a food and drug safety regulatory system as a major task for enhancing public safety systems and for achieving innovations in social management. This *de facto* repositioned the responsibilities for market regulation. In this context, the 18th CPC National Congress, as well as the Third and Fourth Plenary Sessions of the 18th CPC Central Committee (November 2013, October 2014, respectively) further raised the task of institutional reform and institutionalisation of the food and drug safety system. In 2013, the then Vice Premier Wang Yang, who was in charge of food safety work, remarked that the country should establish a food safety co-governance system embracing the whole society, whose main features should be self-discipline of enterprises, government supervision and management, social coordination, public participation, and legal protection. Afterwards, relevant authorities put forward the new concept of modernisation of food safety governance, with the aim of breaking away from the traditional approaches of hierarchical regulation. The main themes of the 2014 and 2015 editions of the National Food Safety Promotion Week were, respectively, "Uphold Moral Values, Observe the Laws, and Comprehensively Improve Food Safety Governance Capabilities", and "Uphold Moral Values, Observe the Laws, and Comprehensively Improve Food Safety under the Rule of Law". The 2015 National Work Conference on Food and Drug Administration and on Improving Party Conduct and Promoting Integrity was themed "Deepen Reforms, Enhance Rule of Law, and Work to Improve Governance Capabilities in Food and Drug Safety"; while in 2016 it was themed "Accelerate the Establishment of Food and Drug Safety Governance System at the Beginning of the 13th Five-Year Plan".

Incorporating food safety supervision and management into the broader strategies of economic restructuring, transformation of government functions and innovation of social governance requires the establishment of a high-level and comprehensive regulatory body which can arrange food-related regulatory and other relevant socio-economic policies, and can act as a coordinator of goals such as food industry development, food quality and safety, and food accessibility. During the 23rd Group Study Session of the CPC Central Committee Political Bureau, General Secretary Xi Jinping stressed the need to establish an all-round public safety network, of accelerating the establishment of a scientific and sound food and drug safety governance system, and of ensuring that both the Party and the government are equally accountable for food safety. In another move aimed at innovation, the Fifth Plenary Session of the 18th CPC Central Committee (October 2015) upgraded food safety as part of a shared development path (Table 4), remarking the efforts to build an healthy China, to implement food safety strategies, establish a stringent and effective food safety governance system co-governed by the society, ultimately ensuring that people have confidence in the food they eat.

4.5.3. Enhancing the unification and authority of the regulatory system, and the introduction of the new Food Safety Law

The *Food Safety Law* formulated in 2009 specified that government at the county level or above shall be responsible for leading, organising and coordinating local food safety supervision and administration. However, the main issue that emerged concerned relevant administrative authorities for industry and commerce, quality inspection, and former food and drug regulation, had long implemented a model of vertical administration below the provincial level, which mismatched with the general responsibilities local governments held. Additionally, given the increased severity assumed recently by food safety issues, the existing institutional design brought considerable administrative accountability risks to local governments. Voices for institutional reform were becoming louder.[28]

Table 4: Positioning of food safety within the layout of national economic and social development since the 11th Five-Year Plan (2006 – 2010)

Document	Date of approval	Policy orientation	Goal	Area
Recommendations for the 11th Five-Year Plan of the CPC Central Committee	11 October 2005	Protect the lives and properties of the people	Ensure safety	Boost the building of a harmonious socialist society (9/10)
Recommendations for the 12th Five-Year Plan of the CPC Central Committee	18 October 2010	Strengthen and make innovations in social management	Reduce risks	Strengthen social development, and establish and improve the basic public service system (8/12)
Recommendations for the 13th Five-Year Plan of the CPC Central Committee	29 October 2015	Make progress in building a Healthy China	Improve benefits	Pursue shared development and improve people's wellbeing (7/8)

Source: materials collected by the author

In March 2013, the First Plenary Session of the 12th National People's Congress adopted the *Plan for the Institutional Restructuring and Transformation of Functions of the State Council*, a major reform plan aimed at integrating relevant functions, increase the availability of resources at lower levels, strengthening regulations, and enhancing the unification and authority of food and drug regulatory system in governments at all levels. The integration of food safety regulatory functions of various authorities was hence institutionalised in written

[28] Hu Yinglian, "Unified Market Regulation and Food Safety Guarantees: A Category-Oriented Study Based on the 'Coordination-Professionalisation' Framework", *Journal of Central China Normal University (Humanities and Social Sciences)*, 2016, No.2, pp. 8-15.

form at this point, and the reform of the administrative system of industry and commerce, and quality inspection bodies at below the provincial level was initiated. The *Plan* also upgraded the State Food and Drug Administration to the ministerial level (and renamed it into China Food and Drug Administration, CFDA) to grant it stronger authority and allow it to conduct a unified and comprehensive supervision and management over the safety of foods at the development, production, distribution and consumption stages. The *Plan* also emphasised that, after the reform, relevant food and drug safety authorities should transform their management concepts, innovate their management methods, fully leverage on market mechanisms, self-discipline of the industry and social supervision, establishing an effective mechanism in which food producers and distributors are the prime responsible actors for food safety.[29] Afterwards, local food and drug administrations were elevated to independent government agencies, while Beijing municipality and Hainan province continued to implement a model vertical administration for lower level administrations. Local governments also set up food and drug supervisory agencies at the village, town, or district levels and installed necessary technologies and equipment, filling the gap in law enforcement at the grassroots level.

Later that year, the Third Plenary Session of the 18th CPC Central Committee proposed the reform of the market supervision system to implement a unified supervision mechanism; it also sought to enhance the unification and authority of the food and drug regulatory system. In July 2014, the State Council released the *Opinions on Promoting Fair Market Competition and Maintaining Market Order* (*Guo Fa [2014] No. 20*), pointing to the integration and optimisation of resources for market supervision enforcement, to the reduction of hierarchy in law enforcement, to the improvement of coordination mechanisms, and to the enhancement of regulatory effectiveness. Already starting from the end of the previous year, some local governments had started to integrate, at different levels, the structure and functions of relevant departments of industry and commerce, quality supervision, food and drug, and in some cases even of commodity prices, intellectual property, and urban administration; that is, a reform of the law enforcement system based on the "merging of many into one". Market regulations bureaus or commissions were also established.

Despite such attempts, the central government continued to emphasise that food and drug regulatory capacities should be strengthened during the integration and optimisation of resources for supervision, as some grassroots areas at the community, village and town level were still vulnerable to food safety risks. According to the State Council's requirements in the *Guidelines on Reforming and Improving Food and Drug Regulation Systems at Local Levels* (*Guo Fa [2013] No. 18*), food safety supervision squads as well as testing and inspection agencies within departments of industry and commerce and quality supervision, were

[29] Ma Kai, "Explanations for the Program for Institutional Reform and Functional Transformation of State Council", *people.cn*, http://cpc.people.com.cn/n/2013/0311/c64094-20741513-2.html, 2016-06-08.

transferred to food and drug administration authorities; food and drug supervisory and regulatory agencies were also established at the administrative level of villages, towns, or districts, installed necessary technologies and equipment, and thus filled the gap in law enforcement at the grassroots level.

With socio-economic development, however, new food safety-related risk continued to emerge constantly. In order to address these issues, as well as to better adapt to the new food safety regulatory system, the 14th Meeting of the Standing Committee of the 12th National People's Congress, held on 24 April 2015, approved the revision of the *Food Safety Law*. The new revised version specified that the main line of food safety-related work lies on "prevention as main priority, risk management, whole-process control, and social co-governance", so as to establish a set of scientific and stringent supervision and management system. The main highlights of the revised *Food Safety Law* lie on the: innovation of supervisory tools, including information disclosure, connection of administrative with criminal liabilities, risk communication, and punitive damages; refinement of social co-governance and market mechanisms; and on the establishment of social supervision tools such as model demonstration, contribution-based awards, and awareness-raising activities. Lastly, the revised *Food Safety Law* also laid a foundation for the future directions of institutional reform, such as regulatory team-building, regional layout of regulatory resources, and scientific division of supervisory authority.

4.5.4. Achievements and challenges in the new era

After the 2013 institutional reform introduced in the previous section, food and drug regulatory functions were strengthened, and regulatory capabilities and guarantees were steadily enhanced to unprecedent levels. Among the several indicators that can be used to assess the overall level of food and drug safety in a country or region, the compliance rate of product samples under inspection is often a very used one. In 2016, competent authorities conducted nation-wide sampling tests on 257,000 food samples, 96.8% of which met the standards, an increase of 2.1 percentage points compared to 2014. From a statistical perspective, this represented significant progress. The compliance rate of drug samples has too remained above 98% for years.

During the 12th Five-Year Plan period (2011 – 2015), competent authorities investigated 958,000 food safety civil cases, as well as over 80,000 food safety criminal cases – highlighting the efforts and intensity of the "Four Strictest" requirements (i.e. strictest standards; strictest supervision; strictest punishment; and strictest accountability). For instance, according to relevant statistics, the number of nation-wide regulatory staff for food, drug, cosmetics, and medical devices increased from 103,600 in 2012 to 180,000 in 2017. In spite of slowing fiscal revenue growth, the central government still launched several programmes for building food safety monitoring capabilities, and earmarked 18.45 billion RMB for investments in infrastructures. The scope of food monitoring also continuously expanded: at the end of the

12th Five-year Plan, there were a total of 3,883 sentinel hospitals in the monitoring network of food-derived diseases, and 2,656 monitoring sites for food contaminants and hazards.

In addition to increased regulatory capabilities, the food industry also developed steadily. According to figures released by the National Bureau of Statistics, in 2016 food enterprises "above designated size" (see footnote n. 20) realised nearly 12 trillion RMB of income from core business, accounting to over 10% of the total national industrial output. By then, the food industry had become the largest industrial sector and a pillar industry of the national economy, registering significant achievements.

Nevertheless, food safety regulation still faces challenges. The goal of the system reform is to establish a unified, authoritative and professional food and drug regulatory system. The key lies in understanding what "unified" refers to. Some argue that it refers to consistency of the institutional layout, which includes horizontal consistency – i.e. the consistency of the institutional layout among local governments – as well as vertical consistency – i.e. provincial-level agencies to follow the scheme of the State Council, and municipal/county-level agencies following that of provincial-level agencies. In reality, however, we should not limit our understanding of this term to its literal meaning. In fact, it is neither possible nor necessary to achieve consistency in the institutional layout of the national food and drug regulatory system. The key is to further mobilise, efficiently motivate, and scientifically allocate regulatory resources.

4.5.5. The 2018 institutional reform

The *State Council Institutional Reform Plan*, approved by the 13th National People's Congress in March 2018, put forward a new institutional layout where the functions of the State Administration for Industry and Commerce (SAIC), the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), the China Food and Drug Administration (CFDA), as well as the price supervision and anti-monopoly law enforcement function of the National Development and Reform Commission, the anti-monopoly law enforcement function of the Ministry of Commerce, and the function of the Anti-Monopoly Committee of the State Council are integrated into the newly-established State Administration for Market Regulation (SAMR), which operates directly under the State Council. Its major functions include: comprehensive market supervision and management; establishment of uniform registration procedures for market players and of an information disclosure and sharing mechanism; comprehensive law enforcement in market regulation; unification of anti-monopoly law enforcement works; standardisation and maintenance of market order; implementation of the strategy to raise China's strengths in product quality; regulation and management of the quality and safety of industrial products, foods, and special equipment; uniformed management of measurement standards, inspection and testing, and certification and accreditation.

Due to the particularities of drug regulation, the State Drug Administration (SDA) was established directly under SAMR. SAMR applies level-to-level administration, with the lowest administrative level of drug regulation being set at the provincial level. The regulation of drug distribution and sales is undertaken by market regulatory authorities at the municipal/country level.

The staff and their functions of managing entry-exit inspection and quarantine in AQSIQ were transferred to the General Administration of Customs. The Food Safety Commission and the Anti-Monopoly Committee of the State Council were retained, but their tasks transferred to under SAMR. The functions of the Certification and Accreditation Administration (CNCA) and Standardisation Administration of China (SAC) were transferred to SAMR, but their names were retained. SAIC, AQSIQ, and CFDA ceased to exist.

The latest round of institutional reform for food and drug regulation shows a top-down design in which reforms are carried out beyond the segmentation of authorities and the safeguarding of food and drug safety transcends traditional regulatory measures. Certainly, any reform scheme features advantages and challenges. However, the administrative model of “Macro Market and Specialised Drug” addresses two key issues in the current governance of food and drug safety: the coordination and comprehensiveness of food safety regulation, and the particularity and specialisation of drug regulation. Overall, the reform is based on the currently unified market regulation exercised at municipal- and county-level, and is a scheme that gains significant benefits from merely modest changes. The reform is conducive to the unification of market regulation to a certain extent. However, the biggest challenge remains over how to ensure specialised regulation of food and drug safety; this is also the most important question left unanswered by past reforms at the grassroots level.

The reform adjusts the regulatory system both horizontally and vertically. On the one hand, by specifying institutional arrangements and functions, the reform ensures specialised staff to be in charge of specialised tasks while strengthening unified enforcement – this is why an independent SDA was established, On the other, by properly defining the functions and obligations of central and local authorities, the reform tackled overlaps in the distribution of competence at different administrative levels – this is why the lowest level of drug administrative authorities was set at the provincial level, demonstrating certain features of a vertical administration that differs from the level-to-level administration of market regulation. It should be noted that “Macro Market” is not the equivalent of “Macro Industry and Commerce”, and drug regulation did not return to the model prior to 2013. The understanding of the reform should not be limited to the split, merge, or restructuring of authorities, and it does not matter whether one authority was incorporated into another. The institutional reform should be seen as a paradigm innovation of institutions against the background of national governance modernisation.

During the implementation of subsequent policies, three issues ought to be given special attention. First, regulatory powers shall be properly distributed. Based on the differences between food and drug in their industrial foundations and associated risks, the regulatory powers of drugs shall be centralised prior to market entrance, while the daily regulatory powers of food production and distribution as well as drug operations and sales shall be properly delegated to lower levels. Second, the regionalisation of reform shall be considered. Provincial governments can be granted with more powers to conduct individual reforms. Independent bureaus of food and drug administration can still be established in regions with a high concentration of food and drug industries. Third, the enthusiasm of administrative staff shall be maintained. Local reforms shall take the needs and interests of grassroots civil servants into full consideration. This is particularly important for the food and drug administrative staff who have experienced several rounds of reforms.

4.6. Conclusions

The "Chinese story" of food safety is a microcosm of the market regulation history over forty years of economic reform and opening-up. Meanwhile, it also vividly depicts the image of a "Chinese-style" regulatory state, demonstrating profound theoretical and historical implications. The unique path of development of a "Chinese-style" regulatory state mainly results from two factors. First, China stands in a transitional period where it faces multiple challenges (China currently has to simultaneously deal with the slowdown in economic growth, make difficult structural adjustments, and absorb the effects of previous economic stimulus policies). Food safety belongs to the public security system, which has its intrinsic characteristics and patterns. International experiences show that the relationship between a country's socio-economic development with its public security evolves in an inverted U pattern (also known as the Kuznets Curve). Environmental protection [30] and workplace safety[31], which also belong to the sphere of public security, evolve in a similar way. Public security may manifest itself in the form of different problems at different stages of development. China's food safety environment and the current socio-economic transition mean that various food safety problems may be pervasive. Second, China reversed its path of institutional evolution. The concept of "regulatory State" has been discussed by the Western political scientists over the past twenty years. It summarises the relationship between state, market, and society after passing the stages of welfare state and free market state. Notably, it was after hundreds of years of development of market economy and civil society that Western countries were able to establish a modern food safety regulatory system featured by prevention and process control with mutually complementing approaches and measures. In contrast, China started its regulatory institutional reform when its market economy and

[30] Theordore Panayotou, "Economic Growth and Environment", *CID Working Paper*, No.56, July, 2000.

[31] Li Yizhong, "China's Safe Production Situation and Tasks", *People's Daily*, 29 June2007.

society was still immature. Therefore, during certain stages of socio-economic development, the government must cultivate market players while regulating their behaviour at the same time.

In all, the past forty years of reform and opening-up in China have seen socio-economic development and upheavals in public consumption patterns. Throughout this period, China's food industry has expanded and has continuously sought to satisfy public demands for quality food after meeting their daily subsistence needs. However, under the restrictions of the ecological environment, industrial foundation, and regulatory capacity, China is witnessing high risks regarding modern food safety, and frequent food safety incidents outbreaks. Meanwhile, due to structural factors such as the superimposing stages of socio-economic development and the reverse path of institutional evolution, China's food safety is currently faced with grim challenges which are incomparable to those in Western countries. To enhance the level of safeguarding for food safety, the Chinese government has exerted great efforts in laws and regulations, regulatory systems, and policy measures, and has made certain progress after several trials. In the new era, China's political leaders have proposed to establish a stringent and effective food safety governance system which features society-wide co-governance, and decided to elevate the political statue of food safety to that of public security and national strategy, aiming to ensure that every bite of food people eat meets the "Four Strictest". Predictably, China will work hard to press ahead in the area of food safety in the future, thus laying a material foundation for the Chinese dream of national rejuvenation.

Chapter Five

Examples of food safety regulatory systems

Long Lu[*]

In this peculiar period of social transition, China's food safety is not only facing the difficulties affecting developed countries, but also the plight of developing countries. Therefore, it is necessary to ensure the food safety bottom line with the "strictest" mindsets and methods. This "strictest" guiding ideology is accordingly embodied by the amendment of China's *Food Safety Law*, which not only introduced major changes to the original food safety system, but it also incorporates new and necessary institutional arrangements. For instance, it stipulates that competent authorities shall establish a scientific and strict supervision and management (监管 *jianguan*) system complying with the legal principle of "prevention as main priority, risk management, whole-process control, and social co-governance". The regulatory arrangements in the *Food Safety Law* can be summarised under multiple perspectives, such as regulatory arrangements targeting food varieties, or targeting different production and business entities. In view of the analytical framework of previous chapters, this chapter adopts a "ex-ante, during-, and ex-post" [32] analytical perspective, focusing on the licensing system for market entry, the risk rating and sampling testing systems for daily supervision, as well as the link between administrative and criminal penalties for illegal activities.

5.1. License examination

Administrative licensing, as a kind of ex-ante regulation, is designed to prevent behaviours that are not in the interest of the public. According to the *Administrative License Law of the People's Republic of China*, administrative licenses can be established for specific activities directly involving public safety and health.

Accordingly, licensing is an important regulatory tool for ensuring food safety, public health and life safety. In practice, there are not only licenses for food production and

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[32] "Ex-ante, during-, and ex-post" refers to a comprehensive approach focusing on all phases of the regulatory process, from market access licenses (ex-ante) to control and monitoring of operations (during) to handling of results such as in the case of administrative or criminal punishments (ex-post).

distribution, but also registration requirements for special foods such as health food. In addition, under the broader context of government reforms for streamlining administration and delegating powers, in the field of food safety "ex-ante regulation" generally appears simplified, while regulation is strengthened in the "during-" and "ex-post" phases, especially when small-scale food producers and distributors are concerned. This section of license examination will mainly focus on three main aspects: food production licensing, food distribution licensing, and licensing reform.

5.1.1. Food production license examination system

Food production license examination refers to the examination that food and drug administrative authorities must conduct for granting production licenses for food and food additives, as well as for altering or renewing already issued licenses.

Legal basis

In order to effectively implement relevant provisions of the *Food Safety Law* and the *Administrative Measures for Food Production Licensing*, to strengthen the supervision and management of food production, and to regulate food production license examination, on 9 August 2016 the China Food and Drug Administration (CFDA) [33] issued the *General Provisions for Food Production License Examination (Shi Yao Jian Shi Jian Yi [2016] No. 103)*, which came into effect on 1 October 2016. The *General Provisions* are used in conjunction with corresponding detailed rules for food production license examination such as: *Detailed Rules for Health Food Production License Examination*, *Detailed Rules for Complementary foods for Infants and Young Children Production License Examination (2017 Edition)*, *Detailed Rules for Infant Formula Milk Powder Production License Examination (2013 Edition)*, *AQSIQ Notice on Releasing Detailed Rules for Production License Examination of Seven Types of Foods Including Pastry* (*Guo Zhi Jian Shi Jian [2006] No.365*), *Notice on Releasing Detailed Rules for Food Production License Examination of 26 Types of Foods Including Edible Vegetable Oil* (*Guo Zhi Jian Shi Jian [2006] No. 646*), *Detailed Rules for Food Production License Examination of Thirteen Types of Foods Including Confectionery Products* (*Guo Zhi Jian Jian [2004] No. 557*), and *Notice on Releasing Detailed Rules (Revision) for Food Production License Examination of Fifteen types of Foods Including Wheat Flour* (*Guo Zhi Jian Jian [2005] No. 15*).

Examination methods

The examination methods for food production license mainly include a review of application materials, and an on-site verification. The review of application materials is a necessary procedure, and mainly relates to verifying that the application materials are

[33] The China Food and Drug Administration (CFDA) was reorganised during the 2018 institutional reform of the State Council, and incorporated into the newly-emerged State Administration for Market Regulation (SAMR). See chapter 4 of this book for more details.

complete, standardised and compliant. It is the only step required for the examination of applications for license renewal, food variety change and legal personality change. The on-site verification mainly involves checking the compliance of the actual conditions of the applicant as well as their consistency with the corresponding items declared in the application materials. According to Article 19 of the *General Provisions for Food Production License Examination*, on-site verification is required under seven circumstances, including:

- When the applicant applies for the first time for the food production license;
- When there are changes in the applicant's production site, technological equipment and production processes, main production facilities, food variety, and other production conditions that may affect food safety. In such case, the focus of the on-site inspection will be on verifying these changes;
- When the applicant applies for license renewal and declares that there are changes in the production conditions that may affect food safety. In such case, the focus of the on-site inspection will be on verifying these changes;
- When the application for license alteration or renewal requires a new verification of the compliance of the written application materials and food variety with relevant implementation rules and standards;
- When the applicant reapplies for food production license due to relocating the production site out of the territorial jurisdiction of the original license issuing authority;
- When a license application or an application for license alteration or renewal is submitted by an applicant whose food safety credit shows records of unqualified inspections, non-compliant supervisory reviews, food safety incidents, or other food safety-related hazards;
- In other circumstances specified in laws, regulations and rules that require on-site verification, such as the four ones specified in Article 3.1.3.5 of the *Detailed Rules for Health Food Production License Examination* issued by CFDA in 2016.

At the same time, on-site verifications can also be suspended in two special circumstances: one is because of *force majeure* or objective reasons such as obstacles in power and water supply, in which case the suspension period shall not exceed ten working days; the other is in case the applicant is suspected of illegal activities concerning food safety and is already under investigation of the food and drug administrative authorities. In the latter case there is no specific indication of the duration of the suspension period, although in principle on-site verifications shall be carried out as soon as the illegal activities are investigated and punished accordingly (except when the investigation leads to the suspension of production and distribution, or the revocation of license, in which case no on-site verification will be needed), or as soon as the case is withdrawn if such illegal activities are confirmed to be non-existing.

Procedural requirements of the examination

Time requirements prior to the examination: While the application for new food production licenses does not feature specific time requirements for the applicants, license alteration or renewal must meet the following time requirements:

- The application for license alternation shall be submitted to the original license issuing food and drug administrative authority within 10 working days after the changes occur, except for the following three conditions: when the production site is relocated out of the territorial jurisdiction of the original license issuing authority; when changes occur within the same food variety specified in the copy of the food production license; and when the peripheral warehouse address is relocated.
- The application for license renewal shall be submitted to the original license issuing food and drug administrative authority 30 working days prior to the expiration of the food production license.

Time requirements for on-site verification: After the on-site verification procedure begins, the examining authority shall organise a verification team within three working days after receiving the application materials. The verification team shall complete the on-site verification and submit relevant materials to the reviewing authority within ten working days from the beginning of the on-site verification mission.

Overall time requirements for license examination: The licensing authority is responsible for collecting and summarising relevant materials, and for making a final decision within 20 working days from the day the application was received. The decision period may be extended by an additional 10 working days for special reasons and with the approval of the director of the licensing authority, in which case the applicant shall be informed accordingly on the reasons for the extension.

Special requirements

License examination for special foods: Special foods, such as health food, food for special medical purposes (FSMP) and infant formulas, are designed for special groups. Therefore, they are subject not only to the national-level product or formula registration and record-filing (备案 *bei'an*) system, but also to the production licensing system at the provincial level. There are three particular requirements for special foods production license applications:

- First, application materials shall also include the documents supporting the compatibility of the product with the production quality management system, as well as relevant documents of product or formula registration or record-filing;
- Second, if changes occur to the product or formula registration or record-filing, the application materials for license alteration or renewal shall also include relevant registration and record-filing supporting documents in line with the content of the alteration;

- Third, the application materials for license alteration shall include the documents supporting the compatibility of the product with the production quality management system; the application materials for license renewal shall include a self-examination report on the operation status of the production quality management system relevant to the food produced.

Entrusted production of health food: The *Administrative Measures for Food Production Licensing* revoked the provision requiring food producers to record their entrusted processing with the regulatory authorities. The *Measures*, however, also stipulate that food producers entrusted with producing health food shall include, on the copy of their food production license, relevant information about the entrusting enterprise, such as company name and location. The entrusted production of health food therefore falls within the scope of the production license examination. Combined with the relevant provisions stipulated by the *Detailed Rules for Health Food Production License Examination*, the license examination of entrusted production of health food shall include the examination of the entrusted production agreement, label instructions, and the entrusting enterprise's health food registration documents. Since the license examination of entrusted production of health foods is mainly an examination of the entrusted party (especially for on-site verification), any changes in the name or location of the entrusting enterprise may be subject to paper examination only.

Verification and rectification mechanism: In case there exist management flaws, even if the on-site verification led to a positive outcome, the applicant shall be granted the food production license but at the same time is required to remedy to such flaws within one month. The relevant food and drug administrative authority or its dispatched agency responsible for the day-to-day food safety supervision and management of the applicant, shall then conduct another inspection of the enterprise within three months, focusing in particular on assessing whether relevant management flaws have been addressed.

5.1.2. Food distribution license examination system

The food and drug administrative authorities shall conduct a category-based food distribution license examination based on the applicant's main business type, distribution scope, all the while considering relevant risks. In principle, on-site verification shall be carried out on all occasions except when the application relates to sales of pre-packaged foods (excluding cold and frozen foods), or when applying for food distribution license alterations without changing the facilities and factory layout.

Legal basis

In order to implement the relevant provisions stipulated by the *Food Safety Law* and the *Administrative Measures for Food Distribution Licensing*, to strengthen the supervision and management of food distribution, and to regulate food distribution license examination, on

30 September 2015 CFDA released the *General Provisions for Food Distribution License Examination (Trial)* (*Shi Yao Jian Shi Jian Er [2015] No. 228*), which officially came into effect on 1 October 2015.

Mechanisms for category-based examination

Relevant time requirements for food distribution license examination are roughly the same as those for the food production license, and therefore will not be repeated in this section. Instead, the section will focus on the category-based examination system.

Detailed contents: The category-based system of food distribution license examination demonstrates that the examination is becoming increasingly scientific and precise. The examination in fact applies a new model combining main business type and distribution scope, rather than merely focusing on one single category.

The *Detailed Rules for Food Distribution License Examination (Trial)* (hereinafter referred to as "*Detailed Rules*") stipulates a "two-track" requirement for license examination. Article 4 of the *Detailed Rules* defines three main business categories: food vendors, catering service providers, and canteens. Article 5 defines ten distribution categories: sales of pre-packaged food, bulk food, special food, and other foods; and the preparation and sales of hot food, cold food, raw food, pastry, homemade beverage, and other foods. The relationship between the main business categories and the distribution categories is, in general, defined as follows: food vendors correspond to the first four sales categories of distribution; catering service providers and canteens correspond to the latter six preparation and sales categories of distribution. Nonetheless, it should be noted that, in principle, canteens at vocational schools, general secondary schools, primary schools, schools for special education and kindergartens are not allowed to apply for the distribution category relating to the preparation and sales of raw food. At the same time, online food distributors without physical stores are not allowed to apply for any distribution category relating to preparation and sales of food, or to the distribution category relating to the sales of bulk cooked food.

Flexible application of the category-based examination: In order to avoid rigidity and improve administrative efficiency, the category-based examination grants flexibility to exempt from further examinations the food safety management personnel of a food distribution enterprise which has already obtained relevant qualifications prescribed by the State or the industry. It may also exempt applicants applying to multiple distribution categories from multiple examinations of the basic and general requirements as specified in the *Detailed Rules*.

5.1.3. Licensing reform

According to the reality of China's food safety regulation as well as to traditional dietary habits, two special practices are adopted on top of the food production and distribution licensing:

- First, the market entry threshold for edible agricultural products sales is eliminated. The first clause of Article 35 of the *Food Safety Law* stipulates that "China adopts a licensing system for food production and distribution. Enterprises engaged in food production, food sales and catering services shall obtain licenses according to the law. However, no license is required for selling edible agricultural products". Instead, centralised market distributors are obliged to conduct admission inspection on both products and vendors, focusing in particular on product quality and traceability.
- Second, small-scale food producers, processors and street vendors are subject to separate supervision. The first clause of Article 36 of the *Food Safety Law* stipulates that "small-scale food producers, processors and street vendors shall comply with the food safety requirements corresponding to their scale and conditions, as stipulated in this *Law*. They shall ensure that the food they produce and sell is hygienic, non-toxic and harmless. The food and drug administrative authorities shall strengthen the regulation over them". In addition, the *Food Safety Law* also stipulates that specific management regulations for small-scale food producers, processors and street vendors must be formulated by provinces, autonomous regions and direct-controlled municipalities, which shall reflect their unique local conditions.

There are different practices in terms of the scope of application: some regions such as Tianjin, Shanghai and Henan province regulate merely small-scale food producers, processors and street vendors; other regions such as Shandong, Guangdong, Sichuan and Hebei provinces regulate small-scale food producers and processors, restaurants/small shops, and street vendors; other areas such as Beijing and Zhejiang province regulate small-scale food producers and processors, restaurants, shops, and street vendors.

The market access systems in different regions also reflect different supervision and management concepts, particularly in terms of regulation of small-scale food producers: some regions such as Liaoning, Hunan and Hubei provinces adopt food production licensing mechanisms while simplifying the requirements for license examination; some other regions such as Chongqing, Shandong and Guangdong provinces, adopt a registration and record-filing mechanisms to regulate and encourage small-scale mills to undergo and upgrading.

The management approaches are "bipolarised": some regions formulate catalogues of foods allowed to be produced and sold (such as regular pre-packaged foods and local foods) in order to achieve strict regulation and strengthen risk control; while other regions formulate catalogues of high-risk foods prohibited to be produced and sold (such as dairy products, infant formulas and health food) based on the risk ranking mechanism.

Taking unlicensed catering services (which have existed for a long time) as an example, according to the *Food Safety Law*, they are required to obtain the relevant license. Licensing conditions and requirements are further clarified in the *Administrative Measures for the Food Distribution Licensing*. This translates into potential of closedown and suspension for

unlicensed catering. The government's reforms to "simplify procedures, decentralise powers, enhance supervision, and optimise public services" provided a "cure" for unlicensed catering. In this regard, the *Food Safety Law* requires that the management system – including licensing – for small and micro catering services shall be further developed by provincial-level governments. Subsequently, while optimising market access mechanisms for small catering services by means of registration and record-filing, local governments also outlined the main regulatory rule as "current management" and "afterwards punishment". Nonetheless, the question of how to ensure the food safety of unlicensed and "newly licensed" catering services still poses a challenge that local food and drug administrative authorities need to face.

Another example can be taken from pharmacies that sell drugs and foods at the same time. In China, since drugs and foods are regulated differently for every process, from market access to distribution inspection, such pharmacies need to apply for multiple licenses and go through multiple inspections. To solve this problem, pilot mechanisms integrating multiple licenses into a single one (*duo zheng he yi*) have been introduced by many local food and drug administrative authorities, such as the "five licenses into one" adopted by Hubei province's capital Wuhan, or the "nine licenses into one" model in the Putian municipality of Fujian province, or the "fifteen licenses into one" model in the Jiangmen municipality of Guangdong province. Therefore, agencies issuing licenses may, on the basis of the *Administrative License Law of the People's Republic of China*, centralise license examination procedures which were originally handled by multiple agencies, in the same way that the food and drug administrative authority centralises the license examination of drugs and foods within its jurisdiction. As a specific measure for streamlining administration, the mechanism of integrating "multiple licenses in one" not only enhances the efficiency of the government administrative service by simplifying and shortening the approval process, but also facilitates market access and benefits business innovations by reducing institutional costs. The extension of the "multiple licenses in one" pilot scheme from the municipal-level to the provincial-level, currently taking place, demonstrates a system innovation that not only follows the trend of streamlining administration and decentralising powers, but also seeks to realise a win-win management model to safeguard people's livelihood, optimise business environment, and support business innovation. Therefore, when simplifying the market access regulation by means of "multiple licenses in one", there is the need to not only enhance the "during-" and "ex-post" regulation to ensure food safety, but also to explore a top-down design to overcome the existing systematic obstacles and to ensure the necessary standardisation and organisation for the advancement of the pilot project.

5.2. Risk ranking

Article 109 of the *Food Safety Law* stipulates that food and drug administrative authorities and quality supervision authorities of the local governments at or above county level shall, based on food safety risk monitoring and assessment results and the real food

safety conditions, determine the focus, methods and frequency of the supervision and management activities, and implement risk ranking management.

Subsequently, on 5 September 2016, China Food and Drug Administration (CFDA) officially released the *Administrative Measures for the Risk Ranking of Food Production and Distribution (Trial),* establishing the concept of risk ranking management and clarifying its mechanisms. Risk ranking management refers to the different levels and degrees of supervision and management exercised by food and drug administrative authorities on food producers and distributors. It is based on a risk analysis and is in line with risk assessment indicators reflecting the food category, business type, scale or production and distribution, food safety management capacities, and credit records of food producers and distributors all the while considering the resources and supervisory capacities of local-level authorities. The production of food additives is also incorporated into the risk ranking management system. The operational model of the risk ranking management consists of a dynamic adjustment between static risk factors (40% of the total) and dynamic risk factors (60%) of food producers and distributors, before these are ultimately rated according to four risk levels (A, B, C, D from low to high).

5.2.1. Main structure

Static risk factors

Static risk factors include the food category, business scale, target consumer, etc., and are divided into grade I, grade II, grade III and grade IV as the risk factor ascends from low to high. Different static risk factors are adopted in different phases of the food production and distribution process, namely production, sales and catering phases. It is noteworthy that, in order to comply with the "four strictest" principles, the static risk grade of the food producers and distributors who handle multiple types of foods is determined by the food with the highest risk grade rather than the average value of all types of foods.

Food production phase: According to the food production license catalogue, CFDA formulated the *Quantitative Score Table of Static Risk Factors for Producers of Food and Food Additives*. The score table includes 31 main classes and 89 subclasses of food and food additives, with corresponding risk levels and scores. For example, all special foods are grade IV, namely high-risk; most common foods such as processed grain products, condiments, table sugar are grade I, namely low-risk.

In cases relevant adjustments need to be made by provincial food and drug administrative authorities to reflect the peculiar local conditions within their jurisdictions, their supervisory personnel and technical specialists can conduct a static risk assessment on 31 classes of food based on the following 8 factors (with 5 score points for each factor): food category, property of main food ingredients, complexity of food formula, dosage of food additives, complexity of production process, food storage conditions and shelf life, problems

discovered in sampling tests, target consumer group and degree of social attention. The average score for each type of food is then calculated to determine the food risk level.

Food sales phase: The static risk factors of food sellers include the extension of their business premises, number of stock keeping units of pre-packaged foods or bulk foods (commonly referred to as "finished products"), food storage requirements (room temperature, refrigeration, freezing), as well as the number of suppliers. In other words, the scale of operations, food type, food storage requirements and the complexity of restocking channels are proportional to static risks. For example, the static risk grade of chilled and frozen food sellers is usually grade III, while the static risk grade of common pre-packaged food is usually grade I.

Catering service phase: The static risk factors of catering service providers include the business type and scale, and the food type and quantity. It should be noted that, on one hand, business type should be evaluated in combination with the scale: for example, catering service providers are evaluated according to the extension of their premises; canteens and food delivery companies for schools and kindergartens are evaluated according to the number of their consumers; while central kitchen systems are evaluated according to the number of stores they deliver to. On the other hand, food type should be evaluated in combination with the quantity of food: for example, the production and sale of cold food, pastry (including decorative cakes), and hot food are evaluated according to their stock keeping unit quantity; the production and sale of raw food, homemade beverages, and other food types are evaluated according to their stock keeping unit quantity as well as the quantity of the perishable ingredients.

Dynamic risk factors

Dynamic risk factors mainly include the maintenance the conditions for production and distribution, the control of the production and distribution process, and the establishment and implementation of management mechanisms. It is important to note that new food producers and distributors may be exempted from the dynamic risk assessment, and their risk level may be determined only by static risk scores.

Evaluation criteria: The evaluation of the dynamic risk factors of food producers should take into account conditions such as enterprise qualification, purchase check and inspection, production process control, and pre-delivery inspection. For special food producers, conditions such as product formula registration and implementation of quality management systems shall also be considered. For health food producers, the condition of entrusted processing shall also be taken into account. For food additive producers, the conditions of the raw materials and the conformity of the production process with the product standards shall be considered as well.

The evaluation of the dynamic risk factors of food sellers should take into account conditions such as business qualification, management process control, and food storage.

The evaluation of the dynamic risk factors of catering service providers should take into account conditions such as business qualification, employee management, ingredients control, and production process control.

Method of evaluation: Dynamic risk factors can be evaluated through two main approaches: the first is to determine the risk level based on the results of routine supervision and inspections; the other is to conduct an on-site assessment based on the dynamic risk evaluation table (included as annex to the 2016 *Administrative Measures for the Risk Ranking of Food Production and Distribution (Trial))*.

For the former method, complete results of routine supervision and inspections of both the current and previous year shall be considered. Scores are accumulated item-by-item according to the dynamic risk evaluation table. An advantage of this method is the optimisation of the allocation of administrative and human resources, saving time and costs for law enforcement. The drawback is that it requires a wide coverage for routine supervision and inspections, and inspectors who must possess strong relevant capacities.

For the latter method, the evaluation can be carried out in accordance with the *Administrative Measures for the Routine Supervision and Inspection on Food Production and Distribution* released by CFDA in 2016. If necessary, professional technicians may be hired to participate during the on-site evaluation process. This method is more targeted and specific, but, as a one-time evaluation, it may fail to comprehensively identify potential risk points in the dynamic and continuous food production and distribution process.

Dynamic adjustments

Based on the results and records obtained in one year following routine supervision and inspections, sample testing, investigations of illegal behaviours, handling of food safety incidents, and recall of unsafe foods, relevant food and drug administrative authorities shall dynamically adjust the following year's risk level of food producers and distributors within their administrative areas. There are three scenarios of dynamic adjustment, for which the risk level may be raised, unchanged, or lowered.

On one hand, the *Administrative Measures for the Risk Ranking of Food Production and Distribution (Trial)* issued by CFDA in 2016 outlines seven situations in which the risk level can be raised, mostly related to the extent of social impact, harmful consequences, the severity of the nature of the offence, and the subjectivity of the perpetrator of the illegal behaviour. On the other hand, similarly to the red list and credit restoration mechanisms within China's credit system, the risk level can be lowered for food producers and distributors who have not had any negative food safety records for three consecutive years, who have obtained HACCP

certification (except for FSMP and infant formula producers and distributors), or who have won quality awards from people's governments above the municipal level.

5.2.2. Effective utilisation of risk ranking results

The basic purpose of risk ranking is to implement effective scientific supervision and management, to implement food safety regulatory responsibilities, and to ensure food safety. In order to translate the risk ranking results into concrete practice and to avoid the embarrassing position of leaving it as a mere armchair strategy, the key lies in how to effectively use the results of risk ranking to realise risk ranking supervision and management. In this regard, the *Administrative Measures for the Risk Ranking of Food Production and Distribution (Trial)* effectively connect credit management, routine supervision and management, and the quantitative classification of catering safety.

Relationship with the credit management mechanism

Article 113 of the *Food Safety Law* stipulates a food safety credit record system for food producers and distributors, which records situations such as license issuance, routine supervision and inspection results, and investigation and punishment of illegal behaviours. The food safety credit record system and the risk ranking management system are mutually complementary and form a two-way interactive mechanism. On one hand, incorporating risk evaluation results into the food safety credit records not only urges relevant regulators to increase the frequency of supervision and inspection on food producers and distributors with bad credit records, but also enhances the public credibility of the risk ranking management system through information disclosure. On the other hand, the food safety credit records can in turn be an important factor to be considered in risk ranking, directly affecting the dynamic adjustment of the risk level in the following year. Risk ranking can urge food producers and distributors to pay attention to and maintain their own credit, thus further fulfilling their food safety responsibilities.

Relationship with the routine supervision and inspection management system

Risk ranking results are mainly used in the following aspects of the routine supervision and inspection:

- As the basis for the formulation of annual supervision and inspection plans. In combination with local regulatory resources and capacities, it is possible to reasonably determine the frequency, contents, methods and other regulatory measures of the supervision and inspection; and
- As the premise for implementing a scientific allocation and effective use of supervision and management resources. The results not only afford priority to the supervision and management of high-risk producers and distributors over lower-risk

ones, but also help identifying key areas, industries and enterprises for targeted supervision and management.

Furthermore, the results of routine supervision and inspections can in turn affect the dynamic adjustment of the risk level of food producers and distributors. Risk ranking management and routine supervision and inspections mutually affect each other, promote each other, and play an important role in enhancing food safety supervision and management.

Relationship with the catering safety quantitative classification management system

The *Administrative Measures for the Risk Ranking of Food Production and Distribution (Trial)* stipulate that the risk evaluation results of the catering service providers can be used as the basis for quantitative classification adjustments.[34] The two conclusions are as follows. First, if there is a significant difference between the risk ranking results and catering safety quantitative classification results, and in particular if high-risk catering service providers obtain a good quantitative classification result, then the latter result shall be timely adjusted by taking the former result as reference, in order to ensure the consistency and uniformity between the two classification systems. For example, the quantitative classification result of catering service providers that are classified as risk level D may not have an "excellent" quantitative classification result. Second, in practical operations, the catering safety quantitative classification management system corresponds to the dynamic risk factors within the risk ranking management system. In fact, the evaluation content of the former is roughly the same as that of the latter and therefore can be converted.

5.3. Sampling testing

Sampling testing is a statistical method and theory applied to assess the conformity of a certain lot of products by testing a small quantity (samples) from the lot. Article 87 of the *Food Safety Law* clarifies the necessity of sampling testss in the field of food safety supervision and management, by stipulating that "food and drug administrative authorities of governments above the county level shall conduct periodic or aperiodic sampling tests on foods, and publish the testing results in accordance with relevant regulations. No foods can be exempted from testing".

In order to further standardise food safety sampling testing work, at the end of 2014 and 2016, CFDA formulated, respectively, the *Administrative Measures for the Food Safety*

[34] The food safety supervision quantitative cassification for catering service is divided into a dynamic grade and an annual grade. The dynamic grade refers to the evaluation of the food safety management situation of the catering service provider as a result of single inspections made by regulatory authorities. As such, three types of grades can be assigned, i.e. optimal, good, and poor, to each of which an expressive laughing, smiley or frawning face is associated. The annual grade refers to the evaluation of the food safety management situation of the catering service provider based on the results of all inspections made by regulatory authorities in the past 12 months; three types of grades can be assigned, i.e. optimal, good, and poor, to each of which an alphabet letter from A to C is associated.

Sampling Testing (CFDA Decree No. 11) and the *Food Inspection Specifications*. Additionally, food safety sampling testing plans and requirements, as well as national food safety supervision and sampling testing implementation rules, have been formulated by CFDA on an annual basis in order to guide the nation-wide implementation of food safety sampling testing.

5.3.1. Sampling testing procedure

In general, the sampling testing procedure is divided into five main steps.

Formulation of the sampling testing plan

First, in order to achieve legal, scientific, and standardised food safety sampling testing, a plan that covers the full process of food production and distribution shall be formulated. CFDA has been responsible for the formulation of the national food safety sampling testing annual plan. Local food and drug administrative authorities above the county level are responsible for formulating annual plans or schemes for sampling testing work within their respective jurisdictions, which are then reported to food and drug administrative authorities at the superior level.

The food safety sampling testing plan is crucial as it directly determines the direction and development of sampling testing activities each year. It also adjusts relevant policies and priorities in a timely fashion according to most recent food safety regulatory developments. For example, the *2018 Food Safety Sampling Testing Plan and Requirements* included a total of six principles guiding the specific work content and requirements of testing, up from the four principles of the previous year, with the two newly-added principles being: scientific standardisation, and four-level coordination (which requires close cooperation among the governments at the national, provincial, municipal, and county levels).

Sampling

Sampling can be conducted by the authority itself, or by the entrusted food testing agencies with legal qualification. In case the sampling conducted by the entrusted food testing agencies is needed for a case or incident investigation, relevant food safety administration and law enforcement officers should also be present.

Food sampling should follow two requirements:

- Adhere to the principle of compensated sampling, namely that samples should be compensated at market price or sale price;
- In principle, the subject tested shall be a food producer and distributor with legal qualifications (i.e. possessing all relevant licenses and certificates). Exceptions are allowed only in certain circumstances, such as for risk monitoring, case investigation, incident investigation, and emergency handling.

Testing

Testing actors: Tests shall be carried out by testing agencies complying with the *Qualification Accreditation Requirements for Food Testing Institutions* released by CFDA and China's Certification and Accreditation Administration in 2016. These agencies have obtained qualification accreditation in accordance with relevant regulations, and are equipped with authorised testing capabilities, unless otherwise stipulated in other relevant laws and regulations. Testing agencies usually are exclusively selected by food and drug administrative authorities by means of open bidding or selection. Therefore, testing tasks cannot be subcontracted to other actors unless previously agreed to by relevant authorities.

Testing phase: In general, the testing phase is divided into three parts: sample examination, sample testing, and testing results.

Sample examination is the premise of conducting testing. Given the precise, rigorous and scientific requirements of food sampling testing, the condition of the samples directly affects the objectivity, fairness and accuracy of the results. In practice, the improper preservation of the samples can result in false testing conclusions.

The basic requirements for sample tasting are not limited to those stipulated in food safety standards. Contents and methods excluded from the food safety standards may also be adopted for circumstances such as risk monitoring, case investigation, incident investigation, and emergency treatment. The adoption of such irregular contents and methods shall be subject to the consent of the national or provincial food and drug administrative authorities.

The testing agency shall submit a test result report within 20 working days from the date in which the sample was received, unless otherwise agreed with the food and drug administrative authority. The testing agencies and the testers shall be responsible for the data and conclusions of the result report, as well as for the overall testing work.

Communication of testing results and re-testing

This step is peculiar and will be elaborated on in section "food safety supervision sampling testing" below.

Handling of results

The handling of sampling testing results differs widely in form compared to sampling and testing procedures. These differences will be introduced later in combination with specific forms of sampling testing.

5.3.2. Main forms of sampling testing

Food safety sampling testing is divided into two main forms: food safety supervision sampling testing, and food safety risk monitoring. Both forms have their own characteristics

in terms of content, methods and handling, and each has its own peculiar role in the area of food safety supervision and administration.

Food safety supervision sampling testing

Food safety supervision sampling testing refers to the sampling, testing, re-testing and handling of food (including food additives and health food) activities organised by the food and drug administrative authorities in accordance with the law, and as part of their daily work of routine supervision and inspection, overhaul campaigns, case investigation, incident investigation and emergency treatment.

The food safety supervision sampling testing is unique in procedural aspects of sampling, testing, re-testing, and handling of results.

Firstly, in the sampling phase, the samples are divided into testing samples and backup re-testing samples, which are sealed separately. No less than two testers are required to record the sampling information in detail by using standardised templates after revealing their identity and purpose of sampling.

Secondly, testing agencies have up to two working days to file a report for unqualified samples, with the exception for case investigations, incident investigations and emergency treatment.

Thirdly, food safety supervision sampling testing also features a re-testing and dissenting system, with clearly-defined obligations and time limits for re-testing. The tested food producer and distributor or the nominal food producer may, within seven working days from the date of receiving the negative testing results, submit a written application request for re-testing. The nominal food producer also may, in case of dissents over the authenticity of the samples examined, submit a written application request for a dissenting review within five working days from the date of receiving the negative testing results. There are however four circumstances in which re-testing is not allowed:

- The testing results indicate that the microbiological indicator exceeded the quota;
- The backup sample for re-testing exceeded its expiration date;
- The request for re-testing is not submitted on time; and
- Other reasons which make the backup samples unable to serve the purpose of the re-testing.

Fourthly, both food producers and distributors as well as food and drug administrative authorities have the following handling obligations after being notified that the tested samples are not qualified. On one hand, food producers and distributors should immediately take measures to control food safety risks, such as sealing up the unqualified food in the inventory; suspending the production, sale and use of the unqualified food; and recalling relevant unqualified food lots. They should make corrections voluntarily and at the same time

report to competent local food and drug administrative authority. On the other hand, the local food and drug administrative authority should handle the unqualified food and investigate its producer and distributor in a timely manner, urging the latter to fulfil their legal obligations, and filing relevant information in the food safety credit record. In addition, food and drug administrative authority should also disclose relevant information of unqualified foods on either a periodic or an irregular basis.

Food safety risk monitoring

Food safety risk monitoring refers to those activities by which relevant food and drug administrative authorities systematically and continuously collect monitored data or other information relating to harmful factors in food, and conduct analysis and treatment.

The sampling phase and result handling phase of food safety risk monitoring have the following features. Firstly, the food safety risk monitoring staff are entitled to enter the sites where relevant edible agricultural products were grown or where foods were produced and sold, in order to collect samples and relevant data. Moreover, the staff often purchase samples randomly as normal consumers, meaning that there are no restrictions or limits on the number of samples, sampling location or enterprise to be sampled, thus contributing to a scientific and objective risk monitoring.

Secondly, the result handling phase follows four chronological steps if potential food safety hazards are identified by risk monitoring results. National and provincial food and drug administrative authorities organise experts in reverent fields to analyse and evaluate the monitoring results. If potential safety hazards are indeed confirmed by the experts' analysis and evaluation, food and drug administrative authorities should notify relevant food producers and distributors to adopt control measures. After receiving the notice, food producers and distributors should immediately take measures to control food safety risks, such as sealing up the unqualified food in the inventory; suspending the production, sale and use of the unqualified food; and recalling relevant unqualified food lots. They should then take the initiative to make relevant corrections and to report to relevant local food and drug administrative authority.

5.3.3. Special practices - sampling tests on internet foods

With the rapid development of China's e-commerce economy, online shopping has become a trend. Due to its close tie to people's daily life, food sold online is increasingly becoming the focus of food safety supervision and management. Food sold online is virtual, invisible, cross-regional, widely distributed, and uncertain, piling on its safety hazard. Incorporating food distributed online into the scope of sampling testing is both inevitable and effective. For this reason, on 13 July 2016 CFDA issued the *Measures for the Illegal Activities Investigation and Treatment of Internet Food Safety*, which officially came into effect on 1 October 2016, creating a new testing mode of purchasing samples from the internet.

Procedures for sampling testing of internet-sold food are roughly the same as those for regular sampling testing, but also present peculiarities in aspects such as sampling, communication of testing results, and subsequent handling.

Sampling phase

In the cases of testing samples being purchased from the internet, food sampling should take into account these three particular issues:

- Information relating to internet food is mainly obtained from the product's label as well as from public information on the producer's website, rather than from checking receipts or inquiring directly the tested enterprises during regular on-site sampling tests. In addition to file records of the sample's name, category and quantity, the staff who purchases the sample should also record their own name, account used to conclude the transaction, the user account number, the receiver's address and relevant contact details. Relevant receipts should also be kept;
- Staff purchasing the samples from the internet shall test the sample package, seal up samples and backup samples separately, and take photos or videos to record the unpacking process;
- Taking into account potential damages caused by the sample delivery process, samples should be purchased in suitably large quantities. The testers should ensure by means of communication that the samples purchased belong to the same product batch with the same production date.

Communication of testing results

The communication of testing results contemplates rights and obligations for third-party internet food platforms. If the testing result, for instance, shows that the samples purchased through the third-party platform do not comply with relevant food safety standards, this platform shall be notified. If the sampled food producer or distributor is unreachable by the testing agencies, the third-party platform is obliged to assist in transmitting the notification.

Handling of results

In principle, the investigation and prosecution of the illegal activity of unqualified online food producers and distributors should be handled by the local food and drug administrative authority above the county level under whose jurisdiction the food producer or distributor is located, or under whose jurisdiction the food production or distribution is conducted. It therefore should not be handled by the food and drug administrative authority that organises or entrusts the sampling testing. Additionally, in order to strengthen the control, investigation and prosecution of unqualified internet food, the third-party internet food platform should also be responsible for: suspending the sales of unqualified products once being notified the

negative results of the testing; and for suspending the unreachable producer or distributor from operating on the platform.

5.4. Case investigations

Case investigation is a crucial step in food safety supervision and management. It is a powerful tool for regulating the activities of food producers and distributors, and for inspecting and prosecuting illegal activities.

5.4.1. Main competent authorities for enforcement and investigation [35]

The main case investigations enforcement actors are professional and authoritative inspection agencies established by food and drug administrative authorities. Despite regional differences, inspection agencies share two main characteristics and functions, i.e. responsibility for inspecting and prosecuting safety violation cases for trans-regional foods and major foods (including food additives and health food); and responsibility for coordinating administrative law enforcement and criminal jurisdiction.

5.4.2. Main forms of case investigation

Inspection and prosecution of major food safety cases

Major food safety violation cases refer to serious violations of laws and regulations concerning food (including food additives) and health food, which have led to the production, sale or use of products which can cause, or have already caused, serious harm. The key difference between case investigations and general inspections lies with the inspection and prosecution of major food safety violation cases, and where case investigations manifest their role.

There is no clear definition of the scope and category of major food safety violation cases. These are normally determined by the food and drug administrative authorities at various levels according to the food safety regulation realities in their respective jurisdictions. However, after the release on 10 July 2014 of the *Measures for the Supervision of Major Food and Drug Safety Cases* by CFDA, major food safety violation cases are related to – although not limited to: food and drug quality safety cases which cause human death or serious health harm; violations that are serious enough to lead to suspension or revocation of relevant approval certificates; cases in which fake or shoddy products are sold at a price of over 10 million RMB; or other cases of significant relevance.

[35] This section has to be read in conjunction with the sections of this book describing the administrative reform of March 2018, particularly section 4.5.5. The names have evolved but the mechanisms and procedures remain unchanged.

The inspection and prosecution of major food safety violation cases must be carried out in accordance with the *Regulations on Administrative Punishment Procedures for Food and Drug* (CFDA Decree No. 3) and other relevant regulations and be subject to a specific supervision procedure where inspecting authorities are coordinated, guided, and supervised by higher-level food and drug administrative authorities throughout all the phases of the inspection and prosecution work. This also includes during the determination of illegal behaviour, law enforcement, case handling process, punishment, and case transfer. Such a supervision procedure is put into motion by the inspection agency of the higher-level food and drug administrative authority based on the complexity of the case or other needs. It may also be initiated by the lower-level food and drug administrative authorities themselves in case they have difficulties in dealing with complex multi-regional cases. Once activated, the enforcement authority shall accept the guidance, coordination and supervision from the supervising authority, and report to the latter any progress in the inspection every 30 working days until the case is closed, and notify the final result of the inspection within 10 working days from the closure of inspection.

Coordination of administrative law enforcement and criminal jurisdiction

On 22 December 2015, CFDA, the Ministry of Public Security (MPS), the Supreme People's Court, the Supreme People's Procuratorate and the Office of Food Safety Committee of the State Council jointly released the *Measures for Coordinating Administrative Law Enforcement and Criminal Jurisdiction* (*Shi Yao Jian Ji [2015] No. 271*), launching a new chapter of coordination between administrative law enforcement and criminal jurisdiction. These were completed on 24 January 2018 by the *Regulations on Strengthening the Enforcement of Food and Drug Safety Laws and Strictly Penalizing Individuals for Illegal Conducts* (*Shi Yao Jian Fa [2018] No.12*), jointly released by CFDA and MPS to further improve the mechanism of administrative law enforcement and criminal jurisdiction coordination, to make clear provisions on the scope of application and procedures, and to provide guidance for food safety case investigation.

Scope of application: There are mainly three circumstances in which such coordination is applied. The first relates to the transfer, from the food and drug administrative authority to the public security authority (also notifying the people's procuratorate at the same level), of cases which are suspected to belong to the criminal sphere. In the *Regulations on Strengthening the Enforcement of Food and Drug Safety Laws and Strictly Punishing Individuals for Illegal Conducts*, the scope of suspected criminal cases is listed as: crime of endangering public safety by dangerous methods (Article 114 and 115 of the *Criminal Law*); crime of producing or selling fake and shoddy products (Article 140 of the *Criminal Law*); crime of producing or selling food that is not in conformity with safety standards (Article 143 of the *Criminal Law*); crime of producing or selling toxic or harmful foods (Article 144 of the *Criminal*

Law); crime of illegal distribution (Article 225 of the *Criminal Law*); and crime of providing false documentation (Article 229 of the *Criminal Law*).

The second circumstance relates to the conversion of criminal cases into administrative cases. If illegal food safety cases are determined by the public security authority to be either not criminal or too minor to be penalised as such, they should be timely transferred to the food and drug administrative authority and be subject to administrative punishment.

The third circumstance involves coordination for administrative detention. This is a very special case targeting only the six "grave scenarios" of food safety violations stipulated in Article 123 of the *Food Safety Law*. Once the case is determined to belong to one of these six scenarios, it is immediately transferred by the food and drug administrative authority to the public security authority.

Procedures: The following procedures shall be flexibly adopted for case investigations involving the coordination of administrative law enforcement and criminal jurisdiction.

Firstly, in order to ensure the feasibility and promptness of the administrative and criminal coordination mechanism, the 2015 *Measures for Coordinating Administrative Law Enforcement and Criminal Jurisdiction* outline a clear time limit for transferring suspected criminal cases. Furthermore, the Measures also break the deadlock of one-way communication from the food and drug administration. On one hand, the public security authority is required to notify the food and drug administration of their decisions (whether to file, reject, or withdraw the case) within three days after the decision has been made and on the other hand, the food and drug administration can require the public security authority to re-investigate the case if they believe the case has been improperly rejected. This is conducive to intensifying the crackdown on criminal conducts in the field of food and drug safety and safeguarding people's health and lives.

Second, food and drug administrative authorities are required, upon request, to assist public security authorities such as the People's Procuratorates or the People's Courts, in a timely manner in the course of handling food safety crimes, for instance by providing investigation conclusions and opinions. Food and drug administration authorities may also directly communicate their opinions and reasons for the identification of criminal responsibility in cases involving food products specified in the second clause (meat and meat products originated from livestock, poultry, wild animals, and aquatic animals died of illness or unclear reasons) and third clauses of Article 1 of the *Interpretation of the Supreme People's Court and the Supreme People's Procuratorate on Several Issues Concerning Applicable Laws for Handling Criminal Cases Against Food Safety* (*Fa Shi [2013] No.12*).

Lastly, investigative leads and information exchange systems shall be implemented. Any evident crime leads or important information concerning food safety violations prescribed in the *Food Safety Law* should be reported to the public security authorities in a timely manner.

Institutional explorations – building a general framework for food case investigations

Within the process of case investigations, problems often emerge as a result of different institutional settings, different law enforcement concepts, and ineffective regional and departmental coordination. In order to solve these problems, CFDA proposed to build a genereal institutional layout for food case investigations to further improve investigation coordination mechanisms and to unify nation-wide case investigations into a "single chessboard". Such investigative efforts include the following aspects.

Achieve seamless coordination of case investigations with routine and sampling tests: The close coordination between case investigation agencies on one hand, and routine regulatory and food inspection authorities on the other, should be strengthened; mutual assistance between case investigation results and routine and sampling test results should be promoted. In fact, problems identified during routine and sampling tests can serve as potential sources and leads for case investigations. Similarly, problems identified during case investigations can help assess the weaknesses in routine regulatory and sampling tests, thus ensuring that both the effects and the root of the problems encountered in the crackdown on food safety illegal conducts are addressed.

Improve departmental and regional coordination mechanisms: In order to strengthen the crackdown on illegal conducts against food safety and to trace and investigate the source of the problematic food, it is necessary to strengthen the departmental and regional coordination between different levels of food and drug administrative authorities.

For instance, in terms of departmental coordination, CFDA and the State Administration of Industry and Commerce jointly executed a special action on internet market supervision and management; CFDA and the National Health and Family Planning Commission jointly executed a special action to crack down illegal medical care and cosmetology; CFDA and other nine ministries, including MIIT, also jointly carried out a campaign to overhaul food and health food fraud and false advertising.

As an example of regional coordination, the food and drug administrative authorities of Beijing, Tianjin and Hebei jointly established the "Beijing-Tianjin-Hebei Food Case Investigation Coordination Committee" and signed the *Work Agreement on Beijing-Tianjin-Hebei Food Case Investigation Coordination*. At the 2017 joint "10+3" meeting on food and drug inspection and anti-fraud regional coordination, ten cities from Guangdong, Guangxi, and Hainan provinces signed the *Agreement on Food and Drug Inspection Collaboration between Ten cities from Guangdong-Guangxi-Hainan*. Member authorities from the Shanghai-Jiangsu-Zhejiang-Anhui-Fujian-Jiangxi-Shandong-Henan "7+1" food and drug inspection collaboration zone in 2017 signed the *10th "7+1" Food and Drug Supervision and Inspection Collaboration Zone Memorandum*.

Information-sharing and formulation of case studies: In order to solve the problem of "different punishments for the same type of cases" encountered in the processes of case investigation and given the impossibility to operate a nation-wide administrative penalty case system, CFDA advocated for the promotion of an information-sharing and case study-based practice to stimulate inspection and enforcement exchanges and upgrade. In this regard, on 20 December 2017 it issued the *Detailed Rules for the Disclosure of Information on Administrative Penalties of Food and Drug*, requiring food and drug administrative authorities at all levels to publish the administrative penalty decisions for all cases further investigated and prosecuted following regular procedures. This requirement serves as the foundation for case investigation and enforcement standardisation. In addition, each year, "Excellent National Food and Drug Inspection and Law Enforcement Cases" are selected and distributed to food and drug administrative authorities at all levels as references for future cases.

5.5. Conclusions

Since the entry into force of the revised *Food Safety Law* on 1 October 2015, food safety supervision and management in China has entered a new "big era" in which the focus has gradually shifted from market access and ex-post investigation, to a "ex-ante, during- and ex-post" whole-process and comprehensive model. This shift shows that China's food safety supervision and management is becoming increasingly scientific and precise, in an attempt to realise strict source prevention, process regulation and risk control, ultimately ensuring people's physical safety. This chapter endeavoured to demonstrate the basic framework and model of China's food safety supervision and management. It did so by selecting particular angles such as license examination, risk rankings, sampling tests, and case investigations. The purpose was to deepen the reader's understanding of China's current regulatory situation, and to highlight the necessity and feasibility to explore new modes of regulation, in the hope of benefiting the further improvement and promotion of food safety regulation institutional reform.

Chapter Six

Examples of food safety social co-governance systems

The establishment of the concept of food safety social co-governance and the provisions of relevant laws guarantee institutional protection for the exchange, engagement, cooperation and coordination between multiple stakeholders and the public in relation to food safety. The current institutional design established, above all, the primary responsibility of food producers and distributors. This has led to self-regulation derived from mechanisms such as the Good Manufacturing Practice (GMP), becoming the first threshhold in safeguarding food safety, that is, safe food is in first and foremost the result of production.

Secondly, it introduced the punitive damage system for which the purpose is to solve the lack of protection of individual consumers' rights. However, the resulting phenomenon of "professional anti-counterfeiters" (i.e. individuals deliberately buying expired or counterfeit goods and then demanding compensation from sellers for economic gain, sometimes with success and sometimes not), not only caused the abuse of administrative and judicial resources, but also put the rationality of the current institutional arrangements into question.

Thirdly, the role of media supervision lies not only in overseeing food safety administration and uncovering food safety problems, urging producers and distributors to follow food safety regulations; it also lies in reaching out to a large audience to promote and popularise food safety knowledge and to raise legal awareness. In particular, the advantages of new media in terms of promptness and coverage as a result of internet development should be fully leveraged.

Fourthly, the reporting system provides institutional support to enable and guide the consumers and the public to engage in social supervision and governance, such as filing complaints and reports to expose food safety hazards and to provide leads on cases involving food safety violations. The consolidation of reporting incentivises and safeguards the legitimate rights and interests of the reporters.

Fifthly, the risk communication system, introduced after the 2015 revision of the *Food Safety Law*, will further promote the implementation and optimisation of risk analysis as a structural decision-making system within China's food safety supervision and management (监管, *jianguan*). Consequently, the risk communication system will make the decision-making process more democratic through the participation and engagement of the wider

public and relevant stakeholders, also providing risk management decision-making with other reasonable food safety-related demands.

Sixthly, in view of the age of digitalisation and the popularisation of the Internet, the introduction of a credit management system can strengthen food producers and distributors' awareness about the fact that "those who honour their obligations will benefit in all aspects, and the discredited will face challenges everywhere". This is achieved first by aggregating government information with the market, and second by the public's attention to reputation and to "voting with feet". Therefore, food safety can be achieved through the dual-restriction of compliance and self-discipline.

6.1. Primary responsibility and self-regulation of food producers and distributors

Wang Xu[*]

In the realm of food safety laws, self-regulation plays an important role in making up for the ineffiency and lack of professionalism that is often found in government supervision and management. Meanwhile, different forms of self-regulation have been developed, including: standards and certification, process supervision and management, and third-party agreements. The recently revised *Food Safety Law* clearly sets the tone for self-regulation, and identifies three speficic types of self-regulation, incorporating the distinct features of food safety governance in China. Self-regulation in food safety governance may also address potential risks such as government inaction and lack of democratic legitimacy, which need to be effectively warded off when the *Food Safety Law* is implemented.

As China's food safety governance progresses, its underlying philosophy has led to a transformation from government-led supervision and management into "corporates taking the primary responbility" and "social co-governance". The new *Food Safety Law* – which went into effect on 1 October 2015 – develops a large number of self-regulation measures with Chinese characteristics. This section will carry out an in-depth analysis on the rationale, categories and regulatory framework of these self-regulation measures.

6.1.1. Rationale

The articles in the *Food Safety Law* laying down the legal basis for self-regulation are:

- Article 4: "*Food producers and distributors shall be liable for the safety of food they produced or distributed. Food producers and distributors shall produce and distribute*

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food in accordance with relevant laws, regulations, and food safety standards. They shall ensure food safety, be creditable and self-disciplined, and be accountable to society and the public. They shall be subject to social supervision and they shall take their social responsibilities"; and

- Article 9: "*Food industry associations shall strengthen industry self-discipline, establish and improve industry standards and award and punishment mechanisms pursuant to their articles of association, and provide services such as information and technology relating to food safety. They shall direct and supervise food producers and distributors to produce and distribute food according to the law, drive the development of industry integrity, and promote and popularize knowledge on food safety*".

The reasons for the *Food Safety Law* to stipulate the primary liability of food producers and distributors and the self-regulation of food industry associations can be summarised as follows:

First, there is a gap between the size of the food market and the capacity of government supervision and management. Before the 2013 institutional reform, supervision and management over the food industry in China was a responsibility shared by several departments, including agriculture, health, food administration, quality inspection, industry and commerce, etc.; this resulted in insufficient capacities to focus on pure food supervision and management. Even after the integration among different agencies and functions as a result of the reform, the performance of relevant personnel remained less than ideal. Therefore, food supervision and administration authorities are faced with a major practical challenge – a significant lack of law enforcement capacity (including shortages in inspection personnel). This is in spite of the contituous enlargement of Chinese food market since the economic reforms and opening-up in the late 1970s. The massive gap between the size of the food market and the government's capacity to supervise and manage this sector requires the enterprises' self-discipline and self-regulation to fill the gap, as opposed to solely relying on government measures such as increasing public expenditure, employing more personnel, and introducing new technologies. It is safe to say that this was the most important policy consideration when the legislation set up the principle of self-regulation.

Second, the effectiveness of the rigid government supervision and management falls short of expectations in face of the huge differences in management capabilities among Chinese food market players. The food market in China is characterised not only by its magnificent size, but also by the huge differences among enterprises in terms of structural design, level of technological development, and transparency. In China, there is a large number of small businesses and vendors – the exact number of which cannot be defined – using low-end food processing technologies; there are many centralised and large-scale modern food manufacturing and processing factories; and there are also modern food

corporates equipped with top-notch technologies. The government cannot regulate these diverse enterprises with the same force, approach, or procedure. For instance, when it comes to medium and low-end food enterprises, the more effective supervision and management methods would be administrative licensing and sampling testing. At the same time, high-end food enterprises are generally already equipped with technologies and internal quality control systems that are so complex that even the government cannot compare with their expertise and technical equipment. Therefore, if quality and safety problems occur within such high-end food enteprises, the government can then only take responsive measures after the emergence of problems, in which case it may already be too late as losses and damages will have already been caused. Therefore, a stricter regulatory system can only be formed when complex and diverse food enterprises in China can clearly identify their own obligations and responsibilities according to the law, attaching strict legal restrictions to their internal quality control systems, adapting supervision and management measures traditionally undertaken by the government into their internal management systems, and fulfilling their own obligations – while at the same time relevant public departments exercise an effective supervision.

Third, China's recent policy adjustments, particularly focusing on the reform of the administrative licensing system, will certainly further promote self-regulation. The 3rd Plenary Session of 18th CPC Central Committee (held in November 2013) identified the general objectives of the economic reforms to be "allowing the market to play a decisive role in the allocation of resources and enabling the government to better serve its functions". The new central government leadership also set "streamlining administration and delegating power" as the core philosophy for adjusting its relationship with the market. Against this general policy background, the role of the government changes significantly: in the past, it controlled the power of issuing licenses and permits, its law enforcement approaches were characterised by ex-ante supervision and compulsory orders. Now, it encourages market players to exercise self-regulation, while it moves torwards the indirect supervision role of "supervision over the supervisors". In other words, the role of the government is shifting from one that "rows the boat" to one that "takes the helm".[36] Therefore, it is natural that the law put primary responsibility on enterprises and the food industry, as it further underlines that they should bear more responsibilities as they are given more freedom and independence.

6.1.2. Categories

A distinctive feature of the new *Food Safety Law* is that it has established a comprehensive self-regulation system, which not only incorporates different types of regulations in accordance with international standard practices, but also includes terms which

[36] R. Baldwin, M. Cave, M. Lodge, Understanding Regulation, Oxford University2011, p. 142.

are reflective of China's supervision and administration contexts. Self-regulation can be divided into three categories based on the market players concerned.

Self-regulation of enterprises

Similarly to most other countries, the new *Food Safety Law* clarifies that "enterprises shall bear the primary responsibility". A large number of self-regulation measures directly target the most important food enterprises.

Establishment of standards: Establishing enterprise standards which are more stringent than the national and local standards is a typical measure of self-regulation. Through the establishment of stricter and more sophisticated requirements, enterprises can be subject to a clearer and more effective supervision by the State and by the market (*Article 30: The State encourages food production enterprises to formulate their enterprise standards much more stringently than national or local standards for food safety to be applied within the enterprises and to file with the health administrations of the people's governments of provinces, autonomous regions, and municipalities directly under the Central Government, to be recorded*);

Monitoring of the environment: The environment is the foundation and prerequisite for self-regulation. Every phase in the production and distribution must be equipped with the right external conditions and elements to ensure food safety. The new *Food Safety Law* specifically outlines the establishment and implementation of the following systems: hygienic environment of the production and distribution premises; facilities and equipment; food safety professionals, food safety managers and administrative rules; reasonable equipment layout and process control; training, assessment, and health management (*Articles 44, 45 and 46*);

Self-tracing: Essentially speaking, the establishment of a traceability system does not fall within the government's obligations, but is rather a requirement for enterprises to control risk factors and to clarify accountabilities.[37] The *Food Safety Law* stipulates that: "*Food producers and distributors shall establish a food traceability system in accordance with this Law so as to ensure that the food is traceable. The State shall encourage food producers and distributors to establish the traceability system by means of information technology*";

Safety self-inspection: The *Food Safety Law* stipulates that food enterprises shall inspect and assess food safety on a regular basis. In the case that food safety requirements are no longer up-to-standard due to changes of production or distributionn conditions, food producers or distributors shall take rectification measures; in the case where potential food safety risks are exposed, the producers or distributors shall forthwith cease the production or

[37] S. Hence, J. Caswell, "Food Safety Regulation: An Overview of Contemporary Issues", *Food Policy* (1999), 589-603.

distribution and report to the food and drug administration of the people's governments in the location where they produce or distribute such food. The most significant progress is the stress on the “potential risk report” system, which reinforces the coordination between risk assessment and risk information exchange systems;

Hazard analysis and critical control point system: The *Food Safety Law* encourages food producers and distributors to comply with good manufacturing practices (GMP) and to implement the Hazard Analysis and Critical Control Point (HACCP) system. Certifications will be granted to enterprises complying with this system. This is also an important demonstration that self-regulation is in line with international norms, as it uses rational risk control on a specific food production chain along with problem-oriented supervision and administration to disperse the overall risks (*Article 48*);

Whole-process checking and verification system: Because food safety involves enterprises engaging in different phases of food production and distribution, it is inevitable that food safety in general requires concerted efforts from all players – all involved actors should oversee each other’s conducts and jointly safeguard food safety. For this reason, the new *Food Safety Law* for the first time clearly instructed that enterprises engaging in food production, processing, transportation and storage, distribution and catering shall check and verify the food safety licenses and certificates of their suppliers. For instance, food producers shall check the license of the supplier and compliance certificate of the product when purchasing food ingredients, food additives, and food products; food producers shall establish a record-keeping mechanism for verifying incoming food ingredients, food additives, and food-related products and shall keep relevant credentials; food distributors shall store food in accordance with food safety assurance requirements, and regularly check the food in storage and remove spoiled or outdated items in a timely manner. Food producers shall establish and maintain an inspection record for outgoing food that verifies the inspection certificates and safety status of the outgoing food, containing correctly such information as name, specification, quantity, production date or lot number, shelf life, inspection certificate number, sales date, name, address and contact information of the purchaser, and also relevant credentials;

Food recall system: The food recall system is also regarded as a type of self-regulation measure that food enterprises should adopt in line to their obligations. In the event that a food producer finds that the food being produced does not comply with food safety standards or is proven to likely endanger human health, the food producer shall immediately stop production of the food, recall the food product released to the market, notify relevant producers, distributors and consumers, and create a record on recalls and notifications.

Co-regulation of industry associations and enterprises

Co-regulation is a special type of self-regulation that can refer to both the co-governance by the government and the enterprises in jointly developing and implementing standards,[38] and to the co-governance by industry associations and the enterprises within the industry. The *Food Safety Law* designs relevant systems of co-regulation, such as: food industry associations shall strengthen industry self-discipline, establish and improve industry norms, establish and improve reward and punishment mechanisms, and provide food safety information and technology services; food producers may examine the food produced by themselves, or entrust examination agencies compliant with the requirements of the *Food Safety Law* to examine.

Self-regulation via contracts

It can be said that self-regulation is a type of "governance through private law means". In other words, by means of contracting, it legally binds equal entities to agree on special obligations and liability terms regarding food safety, thus achieving self-regulation among the enterprises through the implementation of contracts and the punishment of defaulters.[39] This kind of self-regulation should be highly valued by contemporary society, as it features the following advantages: first, it reduces governance costs for the government, and can effectively avoid the government's direct intervention in the market; second, it formulates a kind of "aggregated liability"[40]: from the enter parties' entering into a contract to their fulfilling or breaching of the terms set out in the contract, different liabilities are established throughout this entire process; instead of simply focusing on the consequences of breaching a contract, this measure combines prevention of risks and penalties.

The *Food Safety Law* also outlines three typical ways of self-regulation via contracts.

Regulations on distributors of centralised trading market: Centralised trading market distributors, stall leasers, and trade fair organisers shall review the license of the admitted food distributors, specify their food safety management responsibilities, and regularly inspect their operation environment and conditions. Upon finding of any activity in breach of the *Food Safety Law*, the market distributors shall immediately cease the activity and report to the food and drug administrative authority at the county level.

If centralised trading market distributors, stall leasers and trade fair organisers fail to fulfill these obligations, thus leading to the occurrence of food safety incidents in the market, they shall be held jointly and severally liable with the food producers and distributors.

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[38] R. Baldwin, M. Cave, M. Lodge, "Understanding Regulation", *Oxford University,* 2011, p.373.

[39] Van der Meulen, B. (ed), "Private Food Law: governing food chains through contract law, self-regulation, private standards, audits and certification schemes", *Wageningen Academic Publishers*, 2011.

[40] Gao Qinwei, "Administrative Law Obligations of Private Entities", *China Legal Science*, No.1, 2011.

Regulations on third-party platform providers for online food trade: Third-party platform providers have three contractual obligations. The first is registration for which they shall implement real-name registration of admitted food distributors, specify their food safety management responsibilities, and inspect their licenses if such is required by law. The second is inspection for which upon finding any activity in breach of the *Food Safety Law*, they shall immediately stop the activity and report to the food and drug administrative authority at the county level. In case of a serious breach, they shall immediately stop providing online trading platform services. The third is indemnification liabilities meaning they should be held jointly and severally liable with the food producers and distributors, or that they should be held liable independently. Any consumer whose lawful rights and interests are damaged due to the purchase of food via any third-party platform of online food trade may claim indemnification against the admitted food producer or distributor. If the third-party platform provider of online food trading fails to provide the real name, address, and valid contact of the admitted food producer or distributor, such provider shall be liable for indemnification.

Regulations on food advertising agencies: Food advertisements shall be truthful and lawful, may not include any false information or claim any disease prevention or treatment functions. Food producers or distributors shall be liable for the authenticity and legality of food advertisements. Any advertiser or publisher who designs, produces, or publishes false food advertisements that cause damage to the lawful rights and interests of the customers shall be held jointly and severally liable along with the food producer and distributor.

6.1.3. Characteristics

By comprehensively examining the three categories of self-regulation established by the new *Food Safety Law*, three main distinctive characteristics can be identified.

Combination of substantive regulations and procedural regulations

The philosophy of self-regulation embedded in the new *Food Safety Law* emphasises not only the approach of substantive regulations, but also the supervision over processes and the control over procedures. The establishment of standards, environmental monitoring and so on can be all considered as self-regulation via the establishment of substantive regulations. In view of the whole-process and multi-stage characteristics of food safety governance, the *Food Safety Law* also designs measures focusing on processes and procedures in order to build a most comprehensive self-regulation system, such as whole-process self-check, hazard analysis and risk point control, and traceability and recall system. Enterprises should not only establish their own substantive standards and implemented them spontaneously, but should also have specific obligations of self-discipline to fulfil in every procedure of the food industry. This system is more comprehensive compared with mere static standards.

Combination of direct regulation and indirect regulation

The *Food Safety Law*'s interpretation of self-regulation also includes the direct regulation of measures voluntarily taken by the enterprises and the indirect regulation of measures imposed by the industry and by contracts. One of the biggest drawbacks of direct regulation is the lack of adequate and effective supervision. Therefore, if self-regulation were only to rely on direct regulation, it may be transformed into "violations of regulations under internal supervision". In this sense, supervision from the industry and inter-regulation formed via contracts between enterprises can put all market players in a state where they would oversee and inquire each other's activities, which is more conducive to the thoroughness and effectiveness of regulation.

Establishment of different sets of liability systems

The new *Food Safety Law* also introduces a self-regulatory system composed of multiple liability systems. Certain systems target the completely independent liabilities of enterprises, such as the whole-process traceability system; some are based on the legal concept of "several liability", and enterprises are liable only for the consequences caused by their own illegal activities or mistakes; while some stringly target joint liabilities. This is particularly the case of the regulation via contracts, where both parties must be held completely liable for the losses caused to the consumers under certain circumstances, and the consumers can plead any party to be independently, completely or fully liable.

6.1.4. Conclusions

Although great significance is attached to self-regulation both worldwide and within the revised version of China's *Food Safety Law*, this does not mean that such regulatory measure does not have limits. For instance, how to effectively tackle cases in which a "coalition for interests" emerges from rules and norms jointly formulated by enterprises and the industry, preventing self-regulation and causing harm to consumers, remains critical. In addition, another limit of self-regulation, resulted from China's overall food governance capacities, is how to prevent government inactions in the disguise of self-regulation of enterprises. The *Food Safety Law* stipulates that "enterprises take the primary responsibility for food safety". It also stipulates that "local governments shall bear the overall responsibility for food safety". How can one accurately interpret the relationship between these two terms? While enterprises are exercising self-regulation, the question of how to ensure that relevant government authorities fully and effectively perform their regulatory duties currently remains a major issue to reflect on.

To solve the above-mentioned issues, on the one hand, the most important thing is to ramp up efforts to establish a fairer procedure and to thoroughly implement the principle of transparency. The establishment of such a fairer procedure means that social actors including media, consumers, neutral third-party supervisory organisations (such as the Consumer Protection Association), and in particular directly-concerned stakeholders, must engage in

relevant procedures when enterprises set up standards, establish hazard and quality control systems, and exercise whole-process self-regulation. Since self-regulation features the sharing of public rights, it is necessary to ensure procedural supervision over sharing process.

On the other hand, the key to warding off the risk of government inaction lies in clarifying the relationship between self-regulation and government responsibilities. Self-regulation is still a kind of regulation in nature, rather than *laissez-faire*, so self-regulation does not equal to a complete retreat of the government or the abandonment of government duties; rather, it simply indicates a change from a direct, upfront government supervision to an indirect, backstage one – "the supervision over the supervisors". The government should employ measures such as record-filing (备案 *bei'an*), enquiries, spot checking, notifications and interviews on a regular basis to check the enterprises' self-built standards, operational environments, and self-regulatory obligations. In the meantime, the government should also remind enterprises of the risks involved in their self-regulation in a proper and timely manner. According to the traditional "subsidiarity principle" of the civil law systems, when the social mechanism of self-regulation misfunctions, the government must play the role of being the final thread that holds things together; in other words, the government should curb the regulatory risks and negative consequences which have already taken place.

Therefore, in this sense, the rules of self-regulation stipulated by the *Food Safety Law* do not merely target enterprises. They are not only the "code of conducts" for enterprise self-discipline, but are also the "code of judgement" and "code of law enforcement" for the government to determine the compliance of the enterprises' conducts with the requirements of the system. For the government's dereliction of duty, stakeholders shall effectively exercise supervision through the systems of administrative reconsideration and administrative litigation. The existing law still needs to clarify the aforementioned governmental liability clauses in enterprises' self-regulation, so to be prepared for future judicial needs.

6.2. Punitive damages as a tool of food safety governance: institutional arrangements and practical challenges

*Xiong Bingwan**

Throughout China's rapid urbanisation process, how to ensure the food safety of a large number of non-agricultural population has been plaguing Chinese society for more than twenty years. From the perspective of social public governance, the type of legal system that

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can ensure food producers and distributors provide consumers with safe food is a major subject of study for legal professionals and political decision-makers.[41] After more than twenty years of institutional practice and experimenting, China is moving towards a path of social co-governance, for instance emphasising the synergic impact of public supervision implemented by government agencies with private supervision derived from consumers. In tort liability law, consumers have the right to claim punitive compensations from producers and distributors, which is a typical institutional arrangement of private supervision. This section introduces the punitive damages system in China as well as the major challenges that the system encounters in practice. It is hoped that this introduction will provide relevant experience or lessons for other jurisdictions with circumstances similar to China's.

6.2.1. History and framework of the consumer punitive damages system

Tort liability law has been traditionally regarded as private law, with its core institutional function being the compensation and relief given to individual victims. However, punive damages feature the evident functions of punishment and deterrence, and therefore are incompatible with the private law attribute of tort liability law. Comparatively speaking, there are obvious differences in jurisprudence, institutional arrangements and practices between Europe (especially the European Civil Law) and the United States. Europe tends to stick to the traditional theory of private law,[42] while American law has the inclination to break the tradition and to widely employ the system of punitive damages.[43]

The development of contemporary private law in China has been deeply influenced by the European civil law system. In terms of form, China is a typical statutory law country. However, when it comes to contents, China has been affected by both the civil law system and the common law system (especially the American law system), embarking upon the path of pragmagtism and forming a hybrid legal system. This is reflected by the introduction and strengthening of punitive damages in private law since 1993. This is also why experts in Chinese law based abroad remarked on China's tort liability law as a "common law-like civil law and a public face for private law".[44]

First introduction in the Law on Protection of Consumer Rights and Interests

As early as 31 October 1993, the *Law of the People's Republic of China on the Protection of Consumer Rights and Interests* (hereinafter referred to as "*Consumer Protection Law*"),

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[41] Wang Xu, "Governance Logic and Basic Systems of the New Food Safety Law of the People's Republic of China: a Focus on Social Co-Governance", *Journal of Resources and Ecology*, 2018 9(1) 92-ten5.

[42] See Helmut Koziol, "Chinese Punitive Damages Seen in a Comparative Perspective", *Frontiers of Law in China*, Vol. 9, No.3, 2014, pp. 308-320.

[43] See Vincent R. Johnson, "Punitive Damages, Chinese Tort Law, and the American Experience", *Frontiers of Law in China,* Vol. 9, No.3, 2014, pp. 321-358.

[44] Jacque deLisle, *"A Common Law-like Civil Law and a Public Face for Private Law: China's Tort Law in Comparative Perspective"*, in "Towards a Chinese civil code: comparative and historical perspectives", 353, 353 (Martinus Nijhoff 2012).

promulgated by the National People's Congress Standing Committee, introduced for the first time the punitive damages system. In particular, Article 49 of the law stipulated that "*distributors engaged in fraudulent activities in supplying commodities or services shall, on the demand of the consumers, increase the compensations for victims' losses; the increased amount of the compensations shall be two times the costs that the consumers paid for the commodities purchased or services received*". The background for this institutional arrangement is that business ethics had not been effectively established in China's rapidly expanding urban consumer market. On the contrary, counterfeit goods fraudulent activities, including incidents involving fake and shoddy food products, frequently took place, but obtaining and collecting information on illegal activities remained challenging due to the constraints of regulatory agencies' capacities and resources. Even if all regulators worked relentlessly, it was unlikely that they would be able to complete the task of effective law enforcement on a large quantity of fake goods all by themselves. Therefore, legislators hoped that by increasing the amount of compensations, consumers would be encouraged to actively follow after and plead liable those businesses violating the law. This institutional arrangement sought to enhance the exercise of consumers' private power to law enforcement, to increase the likelihood of punishment of illegal conducts, thus increasing the economic cost for illegal business activities and encouraging businesses to operate in accordance with the law.[45] A large number of professionals welcomed the establishment of this system, believing that China would usher in a new era of rights protection.

This institutional arrangement was based on the presumption that consumers would be given effective incentives to initiate punitive damages lawsuits. However, the reality was very different. It was very rare to see real cases where a consumer would go to court to claim punitive compensations as stipulated in Article 49 of the *Consumer Protection Law*.[46] On the contrary, in 1995, the second year of implementation of Article 49, an individual named Wang Hai consciously bought fake goods and brought a punitive damages lawsuit to court. Since then, the number of such cases increased, until gradually forming a social phenomenon commonly known as the "Wang Hai Phenomenon". At first, "Wang Hai cases" were positively received by society, and the act of claiming indemnities was considered an act of righteousness. The court also supported Wang Hai's request for punitive indemnities.

However, later on, Wang Hai and other people gradually turned "extorting indemnities" into a profession, with the obtainment of compensantions as a means of economic benefit becoming the main drive for initiating lawsuits. This group of individuals became widely known as "professional anti-counterfeiters". Such behaviour of consciously purchasing fake

[45] An early introduction to private law enforcement, see Mark A. Cohen & Paul H. Rubin, "Private Enforcement of Public Policy", *Yale Journal on Regulation*, Vol. 3, No. 1, 1985, pp. 167-194.

[46] Empirical research and cause analysis on obstacles of consumer rights protection in China. See Ying Feihu, "Thinking into applying punitive indemnification to knowingly purchase fake products; from the perspectives of legal economics and legal sociology", *China Legal Science*, No. 6, 2004, pp. 115-118.

goods, however, began to face mounting controversy in both theory and court decision. Although many jurists and courts continued to support "Wang Hai cases", many courts had since dismissed the claims of punitive indemnities from such people.[47] Initially, the reasons for rejecting the punitive damages claims of "professional anti-counterfeiters" were mainly because of two aspects.[48] One is of moral considerations, that is, consciously buying fake products is not only a dishonest behaviour, but also an act of getting something for nothing. The court's support to such claims would encourage immoral behaviours.

The other reason comes from the interpretation of legal texts. For example, Article 2 of the *Consumer Protection Law* stipulated that "*the rights and interests of consumers in purchasing and using commodities or receiving services for daily consumption shall be under the protection of the present Law*". The judges who opposed the act of consciously purchasing fake goods believed that this article signifies that "Wang Hais" did not belong to the category of "consumers", as their purchases of goods were not for the purpose of "daily consumption", rather for profit, so their rights and interests were not under the protection of the punitive damages system as stipulated in Article 49 of the *Consumer Protection Law*. Another example is the publication, in 1988 and by the Supreme People's Court, of the *Opinions on the General Principles of the Civil Law*, namely a judicial interpretation on the applicability of the *General Principles of Civil Law of the People's Republic of China* promulgated by the NPC in 1986. Article 68 of these Opinions stipulated that "*in case any party purposely conveys any false information to the other party, or purposely disguises any fact so as to induce the other party into making any false declaration of will, such act shall be determined to be a fraudulent act*". The judge who, on this basis, objected to the claims of "Wang Hais", believed that their purchase decision was not tricked by "fraudulent behaviour" of the producer, but rather by the consciousness of potentially obtaining punitive damages.

Although the system of punitive damages has been controversial from the beginning, Chinese legislators still continued to enthusiastically uphold it. In fact, in subsequent legislations, punitive damages played an increasingly important role in the legal framework of consumer protection. The following is an overview of relevant major legislative developments.

Amount of punitive damages raised by the Food Safety Law

The doubled punitive compensation stipulated in Article 49 of the 1994 *Consumer Protection Law* applied to all types of goods and did not differentiate food from other commodities. But on 28 February 2009, the Standing Committee of the National People's Congress officially promulgated the *Food Safety Law*, which set out specific provisions for the

[47] Courts that rejected Wang Hai's claims did not state that they had no right to legal reliefs, but only that they should ask for a refund in line with the terms of the business contracts law.

[48] New reasons for objection will be dealt with in detail later in the article.

consumers' right to punitive damages in the food sector. The second clause of Article 96 stipulated that "*besides claiming damages, a consumer may require the producer, who produces food which does not conform to the food safety standards, or the seller who consciously sells food which does not conform to the food safety standards, to pay ten times the price*".

This provision introduced three major changes to the previous punitive damages system. First of all, it increased the amount of punitive compensations. The initial double compensation of goods which applied to all types of products was raised to ten times for the costs incurred for food products. Second, producers were included as tortfeasors alongside distributors. Third, the subjects of liability changed: Article 49 of the *Consumer Protection Law* defined the subjects of liability from the subjective perspective of "distributors engaged in fraudulent activities", whereas the new provision did so from an objective perspective, namely the production and distribution of "food not conforming to food safety standards".

China's strengthening of the punitive damages system in the 2009 *Food Safety Law* resulted from the overflow of fake and shoddy food present in the market during that period. In particular, the outbreak of the "Sanlu milk powder scandal" in 2008 – toxic baby formula contaminated by melamine – generated panic throughout the entire society about food safety, and drew widespread criticism towards the government. The ten-time punitive compensation as stipulated in the *Food Safety Law* was therefore a legislative response from the Chinese government to this food safety issue. In fact, in the same year, on 26 December 2009, the *Tort Law* promulgated by the National People's Congress Standing Committee once again reaffirmed the commodity punitive indemnification system from the perspective of civil basic law. In particular, Chapter Five of the *Tort Law* included provisions on "product liability", with Article 47 stipulating that "*where a producer or distributor, when knowing any defect of a product, still produce or sell the product and the defect causes the death or any serious damage to the health of another person, the victim shall be entitled to require the corresponding punitive compensation*". Specific provisions regarding punitive damages in these two legislations show that the Chinese legislators attributed high expectations to the "consumer" to act as a private force for law enforcement, and to play the role of food safety social governance outside of government regulation.[49]

Further strengthening of the punitive damages system in the new Consumer Protection Law and the new Food Safety Law

In law practice, the controversy over whether those "professional anti-counterfeiters" constitute "consumers" has never lost momentum among academics and judiciaries. Despite

[49] In 2008, Sanlu Milk Powder, a domestic baby formula brand which had a large market share was found to have contaminated their products with melamine. A large number of infants were diagnosed with diseases like renal calculus as a result. For more analysis on the social context of the punitive indemnification system in China's *Tort Law*, see deLisle, supra note 4, at 367-369.

this, in subsequent legislative revisions, Chinese legislators kept strengthening, rather than weakening, the consumers' role in punitive damages. This is especially evident in the following two recent legislative amendments.

On 25 October 2013, the Standing Committee of the National People's Congress amended the *Consumer Protection Law*. The first clause of Article 55 stipulates that "*distributors that fraudulently provide commodities or services shall, as required by consumers, increase the compensation for consumers' losses; the increase in compensation shall be three times the payment made by the consumer for the commodity purchased or the service received, or shall equal to 500 RMB if the increase as calculated before is less than 500 RMB...*". Compared with the previous version, the revised *Consumer Protection Law* not only raises the amount of punitive compensation from two times to three times – so as to boost the incentive impact of punitive damages; it also grants low-price quality purchasers the right to directly request for 500 RMB compensation, so that even victims that suffered from small losses would be motivated to initiate lawsuits.

The *Food Safety Law* amended by the Standing Committee of the National People's Congress on 24 April 2014 also employs similar institutional arrangements. In particular, the second clause of Article 148 instructs that "*in the event that any manufacturer produces food that does not conform to food safety standards or distributes food while being aware of its nonconformity with food safety standards, the customer can demand the producer or distributor to pay a penalty of ten times the paid amount or three times the amount of the loss, in addition to the compensation for the loss thereof. If the additional compensation is less than 1,000 RMB, such additional compensation shall be increased to 1,000 RMB; unless the defects are contained in labels and instructions of food that will neither affect food safety nor mislead consumers*". Compared with the previous 2009 version, the amended *Food Safety Law* introduces the extra option of "three times the amount of loss" apart from the ten times the amount of price, and offers individual victims suffering from small losses a compensation of up to 1,000 RMB.

Reviews and comments

In the entire field of consumer protection – including the food sector – China's punitive damages system was adopted and expanded in constant controversy. This controversy mainly centred around the phenomenon of "professional anti-counterfeiters". During the first twenty years after the enactment of the *Consumer Protection Law*, criticisms from the academia and the judiciary were mainly based on academic theories and moral arguments. In spite of such criticisms, the Chinese legislature adopted a pragmatic legal approach to constantly develop and expand the role of punitive damages, hoping to compensate for the deficiency of public supervision by continuously strengthening the incentives for "consumers" – a private force for law enforcement. In reality, though, it was the group of "professional anti-counterfeiters" that got incentivised, rather than the real consumers.

Once the incentives were raised to a certain level, "Wang Hai cases" began to differentiate. Some of the legal actions of the punitive damages system not only failed to regulate food safety, but also brought unnecessary burden to regular food producers and distributors, deviating from the expectations that legislators had for their role and functions. The differentiation of "Wang Hai cases" has pushed China's punitive damages system to a crossroad, and until now no clear direction has been thought of for moving forward.

6.2.2. Punitive damages system at the "crossroad"

After the enactment of the 1993 *Consumer Protection Law*, although courts and academia were divided on the issue of "professional anti-counterfeiters", legislative bodies and the Supreme People's Court – i.e. the highest level of judiciary – did not take a stance on this issue, but rather left it as an experiment for local courts. Of course, many believed that the silence of legislative bodies and the Supreme People's Court was in fact a disguised form of support to "professional anti-counterfeiters". Though the claims of such group of individuals were occasionally rejected by some courts, they still continued receiving support from a large number of courts. As a result, this group of individuals witnessed large expansion during the first twenty years after the enactment of the *Consumer Protection Law*, although the overall size still remained limited.

Judicial interpretations and guiding cases regarded as turning points

It was not until the end of 2013 that the situation began to change significantly. A new judicial interpretation, namely the *Provisions of the Supreme People's Court on Several Issues concerning the Application of Law in the Trial of Cases Involving Food and Drug Disputes* (hereinafter referred to as *Judicial Interpretation of Food and Drugs*), and in particular Article 3, stipulated that "*where, in a dispute arising out of quality problems with food or a drug, the buyer files a claim against the manufacturer or the seller, and the manufacturer or the seller argues that the buyer purchased the food or the drug while knowing that it had quality problems, the people's court shall not support the manufacturer or the seller's argument*". For the first time, this interpretation explicitly acknowleged the right to claim punitive compensations in the food and drugs sectors for those who consciously purchase fake products on the national judicial level.

An additional guiding case issued by the Supreme People's Court in 2014 further reinforced the aforementioned judicial interpretation. According the Guiding Case No. 23 – namely the Sun Yinshan vs Nanjing Auchan Supermarket Co., Ltd. Jiangning store contract dispute case – on 1 May 2012 the plaintiff Sun Yinshan purchased fifteen packets of Yutu sausages from Nanjing Auchan Supermarket Co., Ltd. Jiangning store (hereinafter referred to as Auchan Supermarket Jiangning store). Fourteen of these packets worth a total 558.6 RMB were however expired. After paying for all the goods at the cashier, Sun Yinshan directly went to the service desk and asked for indemnities. Since the two parties failed to reach an

agreement in the consultation, the case was brought to court. Sun asked for a compensation of 5,586 RMB to be paid by Auchan Supermarket Jiangning store, which was ten times the original price. The People's Court of Nanjing Jiangning District, Jiangsu Province made a verdict on ten September 2012, and supported the plaintiff's claims. Neither side appealed.

In the ruling, on the issue of whether the plaintiff Sun Yinshan was to be considered a consumer or not, on the basis of Article 2 of the *Consumer Protection Law* the court explained that *consumer* is a concept opposite to *seller* and *producer*: as long as the purchase and use of goods or services in the market is for personal or domestic needs, not for the purpose of production and business activities, or for the purpose of professional activities, the buyer should then be identified as a consumer making purchases "for daily consumption needs", and the consumer's rights and interests are under the protection of *Consumer Protection Law*. According to the court, in this case the plaintiff did not purchase the sausages for the purpose of re-selling, therefore the consumer's claim for indemnities was an exercise of his legitimate rights. Moreover, the court also stated that Article 96 of the (pre-amendment) *Food Safety Law* did not stipulate restrictions on the consumer's subjective motives for purchasing goods, but only that "consumers are entitled to compensation of ten times the price", and therefore the defendant's claims could not be supported.

This judicial interpretation and guiding case have been widely interpreted by the academic community as the Supreme People's Court taking the stance of supporting "professional anti-counterfeiters", at least in the food sector. This not only directly caused an exponential increase in the number of punitive damages cases in the food and drugs sectors, but also largely impacted trials and academic observations in other sectors. It also triggered a new round of academic debates over the issue. Consequently, "professional anti-counterfeiters" (or to put it in a more neutral way, "people who consciously purchase fake goods") saw a massive increase in number afterwards, as testified by an overflow in the number of punitive damages being brought to court. Some courts even established ad hoc teams to deal with consumer contract dispute trials. Another important piece of evidence could be found in the increased number of "consumer" complaints received by local industry and commerce bureaus and food and drugs administrations. A large number of claimants later adopted a specific work-flow, in which they would in first place identify goods with defects, before filing complaints to supervision and management authorities. Obliged to investigate, the latter would provide administrative penalty rulings to claimants, which would in turn use these rulings as an evidence of "unsafe food" in court to claim for compensation.

The alienation of "professional anti-counterfeiters"

The claims made by professional anti-counterfeiters led to increased theoretical criticism and controversy in actual trials. New empirical evidence from critics was also added to the

controversy.[50] Some of them in fact began to alienate themselves from the original path and began to engage in opportunistic acts not even remotely linked to consumers right protection and in some cases even harming them just for the sake of getting punitive damages.

For example, in real trials, there have often been cases of punitive damages lawsuits against minor labelling issues which do not have substantial safety risks and do not have a misleading impact on consumers' decision-making process. Common cases alike include: no Chinese labels for products purchased overseas (especially food products); size of a monitor labelled as 21 Chinese inches (*cun*) actually being 21 British inches large;[51] clothing whose label reads pure cotton actually consists of 96% of cotton;[52] information about materials on the Chinese label is inconsistent with that on the English label for imported clothes,[53] and so on. While this kind of lawsuit certainly contributed to more standardised labelling by producers and distributors, it also had the potential to lead to a chilling effect – more producers and distributors increasing the costs for standardising labelling for no concrete reasons other than dodging the risks of being "cracked down for frauds".

In addition, anti-counterfeiting actions taken after the publishing of a product recall notice by a producer or distributor could also hinder the latter from recalling defective products in a timely manner, thus ultimately damaging the interests of consumers. In other cases, activities such as deliberately creating defective products and then consciously

[50] For specialised research into this controversy, see Xiong Bingwan, "Formalism and Functionalism in Legal Reasoning: An Exemplary Study of Punitive Damages for Intentional Purchasers of Defective Products", *Peking University Law Journal*, No.2 2017, pp. 300, 327-334.

[51] "Yang Lianzhi v. Juli Technology & T-mall, false advertisements" (product in dispute: personal computer, the labelled screen size is 21.5 *cun*, while the actual screen size is 21.5 inches), Weifang High-technology Development Zone Court (2015) Kai Min Chu Zi No. 833 Civil Case Decree (Reasons for rejecting the plaintiff's claims: "this does not constitute fraud", "the plaintiff knowingly made the purchase").

[52] Some courts identified overseas *"daigou"* (shoppers purchasing food products on behalf of consumers and directly shipping them from bonded zones or overseas in the name of consumers) as "civil agents" and regarded the "missing of Chinese labels" as a result of the principal's voluntary choice, thus rejected the plaintiff's appeals. For example, in "Xiong Xueping v. Yu'ou Cross-border E-Commerce Company, dispute over product liability" (product in dispute: imported milk powder with no Chinese labels), Chongqing Shapingba District People's Court (2015) Sha Fa Min Chu Zi No. 06058 Civil Case Decree. However, a number of courts supported these types of claims. For example, in "Zheng Zhiju v. Dayi Internet Company, consumer rights and interests protection dispute", the plaintiff Mr. Zhang showed two unopened packages and opened them in court, all the food products purchased overseas including rice powder, meat mince, cream puff and fish liver oil had no Chinese labels. The decree from Suzhou Wuzhong District People's Court did not mention the controversy over "consciously purchasing fake goods" and backed the plaintiff's compensation requests. See (2015) Wu Min Chu Zi No. ten2, No. ten3 Civil Case Decrees. In "Zheng Jianfang v. Zhizao Kongjian Company, contract of sale dispute", Beijing Dongcheng District People's Court adopted similar practice (product in dispute: imported confectionery without Chinese labels), see (2015) Er Zhong Min (Shang) Zhong Zi No. 02340 Civil Case Decree.

[53] See "Lu Guangning v. Wangfu Hotels Co. Ltd., contract of sales dispute" (product in dispute: Armani Shirt, information about materials indicated on the Chinese label inconsistent with that found on the English label), Beijing Dongcheng District People's Court (2008) Dong Min Chu Zi No. 05234 Civil Case Decree (the ruling considered that the inconsistency between Chinese label and English label was caused by oversight in the import labelling process, but that the materials listed on the English label were indeed consistent with the actual materials used, so there was no intention to deceive).

purchase them (a typical behaviour relates to hiding food products in places difficult to be seen by shelf stockers, and then buying them after their expiration) pushed many supermarkets into resorting to preventative business activities such as installing monitoring system, increasing the cost of shelf stocking, and stamping "the products have not expired" on the receipts, all of which unnecessarily increased the costs of operations, which would then reflect in higher prices for consumers.

In more extreme cases, the "professional anti-counterfeiters" would ask for large compensations from the producers and distributors in addition to the punitive damages stipulated in the law, by way of claiming to report to law enforcement authorities or disclosing information to media. As rational business actors, producers and distributors would usually evaluate and compare the consequences of directly facing legal penalties, and then decide the appropriateness of reporting such extortions to public security authorities and accept the consequences imposed by law. But there have also been cases in which insufficiently informed producers and distributors would overestimate the severity of legal penalties and pay sums of "ransom money" far exceeding the legal amount of the compensation.

Change of stance of the Supreme People's Court

The substantial evidence brought up on the recent alienation of "professional anti-counterfeiters" kick-started a new wave of heated debates. The stance of supporters of "professional anti-counterfeiters" remained strong in academia and in the judicial system, but criticism and opposition started to grow louder and louder. A large number of scholars began to write feature articles, criticising the behaviour of consciously purchasing defective products. In particular, some articles advocated for a complete denial of the identity of "professional anti-counterfeiters" as "consumers". Other articles however still maintained their support to this behehaviour. Enterprises (especially Walmart, Nestlé and other foreign-invested enterprises) also took active part in the public debate, supporting academic discussions in the area, and lobbying scholars, courts, legislators and media in various ways to influence their stances. The European Union Chamber of Commerce in China, the American Chamber of Commerce in China as well as local Chinese Chambers of Commerce, legal officers from foreign embassies and consulates in China, also actively supported the lobbying actions of these companies, which were frequent targets of "professional anti-counterfeiters".

Against this background, the attitude of the courts and industy and commerce authorities began to change.[54] Evident signs can be found in two main aspects.

First, the State Administration for Industry and Commerce issued the *Regulations for the Implementation of the Law of the People's Republic of China on the Protection of Consumer*

[54] For the author's comments on this matter, see Xiong Bingwan, "How should the law treat anti-counterfeit professionals", *Caijing*, No. 15 2017, pp. 142 – 144, available at http://yuanchuang.caijing.com.cn/2017/0616/4286426.shtml (last visited: 21 Feb, 2018).

Rights and Interests (Consultation Paper) on 5 August 2016, explicitly stipulating in Article 2 that "*this Regulation does not apply to the purchase and use of goods or services for the purpose of profit*".[55] This was widely understood as an intention to completely strip "Wang Hais" of their rights to claim punitive damages. This piece of legislation however sparked criticism from China Consumers' Association and academia, and is yet to be implemented.

Second, on 19 May 2017 the General Office of the Supreme People's Court sent the *Reply to Proposal No. 5990 from the 5th Session of the 12th National People's Congress (Fa Ban Han [2017] No. 181)* to the General Office of the State Administration of Industry and Commerce. In reponse to the suggestions put forward by National People's Congress representatives, the document stressed that "*at present, we can look into gradually introducing restrictions on the profit-making behaviours of professional anti-counterfeiters, with exceptions being made to the purchase of food and drugs. At the appropriate timing, we can rely on judicial interpretations and guiding cases to gradually curb the profit-making behaviours of professional anti-counterfeiters*". Before this, some local courts, such as the Chongqing Higher People's Court, clearly issued trial directions to the lower-level courts, asking them not to support such cases of punitive damages claims. However, this statement by the Supreme People's Court failed to effectively convince those who are supportive of professional anti-counterfeiters, and controversy still remains.

Reviews and comments

The issue of consciously purchasing defective products accompanying the punitive damages system is nowadays more controversial than ever in Chinese society. The institutional arrangements in this regard have come to a crossroad. Judicial and legislative authorities in China need to evaluate punitive damages from a more systematic perspective, especially concerning the "professional anti-counterfeiters" phenomen, so as to make a more rational choice for institutional design. Due to limits in length, the last section will only introduce factual observations and policy recommendations that the author made in previous studies, in the hope that these can offer inspiration to other jurisdictions facing similar situations.

6.2.3. Conclusions

The author believes that the Chinese legal community should deepen its systematic understanding of the background, practical impact and institutional solution behind the "professional anti-counterfeiters" phenomenon, through engaging in a more practical debate, so as to avoid the awkward situation of fragmentation and inconsistency law enforcement.

[55] Available at http://www.gov.cn/xinwen/2016-08/05/content_5097833.htm (last visited: Feb 21, 2018).

The author has made an empirical analysis of all the lawsuits filed at Beijing local courts in the past two decades.[56] Findings show that on the one hand, there indeed is evidence of "malicious anti-counterfeiting" among these professional anti-counterfeiters, which definitely requires proactive countermeasures from the government. On the other hand, however, "Wang Hais" have also contributed to file lawsuits against a large number of business frauds and unsafe foods, including, for instance, moldy beef jerky; expired sausages, shrimp and sauces; tea leaves with over-limit heavy metals or unclear production dates; counterfeit Daoxiangcun mooncakes and Maotai liquor; counterfeit weight loss capsules and anti-hairloss drugs; compound Chinese caterpillar fungus capsules with no production certifications; health food that falsely advertised its efficacy; "pure cotton" clothing containing less than 50% cotton; artificial Italian "natural leather" jackets; "natural crystal" replicas; fake walkie-talkie; and so on.[57] The author calls this latter kind of behaviour as "benevolent anti-counterfeiting".

In general, Beijing municipal courts adopted a case-by-case principle, supporting "benevolent" compensation claims while dismissing "malicious" ones. Courts, however, have adopted different responses to the enterprises' defense against the act of "consciously purchasing defective goods". For example, although many decrees clearly document the defendant's plea of "consciously purchasing defective goods" in their defense statements, such behaviour is not mentioned in the explanation of the final sentence, or it is simply referred to as "lack of factual and legal basis". Some other decrees directly tried to respond to this issue, but the defendant was in these cases required to meet very high standards of proof to prove that the buyer had effectively made an informed decision when buying the defective good, which in practice made it almost impossible (unless the buyers would admit by themselves to have consciously purchased defective goods). Paradoxically, however, few courts have invoked the exception to minor labelling flaws as stipulated in second clause of Article 148 of the *Food Safety Law*.[58] But in any case, the methods employed by Beijing courts do not constitute a "clean-cut" institutional choice, and cannot be seen as a complete denial or rejection of all behaviours of "professional anti-counterfeiters". If the experiences of Beijing courts can be better promoted and applied, then, the judiciary authorities can send a clear signal to "Wang Hais" consciously purchasing defective goods, thus effectively trying to encourage "benevolent" anti-counterfeiting purchases while suppressing "malicious" ones.

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[56] See Xiong Bingwan, "Formalism and Functionalism in Legal Reasoning: An Exemplary Study of Punitive Damages for Intentional Purchasers of Defective Products", *Peking University Law Journal*, No.2 2017, pp. 323-334.

[57] See Xiong Bingwan, "Formalism and Functionalism in Legal Reasoning: An Exemplary Study of Punitive Damages for Intentional Purchasers of Defective Products", *Peking University Law Journal*, No.2 2017, pp. 325-326.

[58] "Unless the defects are contained in labels and instructions of food that will neither affect food safety nor mislead consumers". For more information, see the provisions included in the first part of this article.

In summary, the author believes that "professional anti-counterfeiters" are neither angels nor demons. They may become either one or the other. The key point is whether the legal system and the judges making the verdicts can carry forward the general experience of Beijing courts, and adopt the "case-by-case" principle trying to distinguish different kinds of anti-counterfeit behaviours, ultimately ensuring that virtue is rewarded and vice punished. For other jurisdictions facing similar situations, it is necessary to seriously consider the lessons China has provided over the past two decades if a punitive damages system is to be introduced as a social co-governance tool in food safety or in the consumer market in general.

6.3. Media supervision

*Jiang Hongyu**

Chen Junshi, a researcher at the National Food Safety Risk Assessment Centre, during an April 2012 conference entitled "*'Face-to-face with the media': food safety from a global perspective*" said that "some food safety information that consumers get is unscientific, inaccurate and highly misleading". "Lack of information" and "mismatch of information" can worsen the food safety problem. And, for the public, media is one of the important sources of information.[59]

Nowadays, the information media is highly developed. According to the State Administration of Press, Publication, Radio, Film and Television,[60] there were 1,911 different kinds of newspapers (excluding university school newspapers and local radio and television newspapers) published by Chinese provinces, municipalities and the People's Liberation Army in 2017. There were also 10,093 periodicals. Meanwhile, the 41st China Internet Development Statistical Report issued by the China Internet Network Information Centre (CNNIC) showed that the number of internet users in China in December 2017 had reached 772 million. In such an era where "everyone has a microphone" and "everyone is a propagator", the media has penetrated into all aspects of our lives. If we lok at major international and domestic food safety incidents which have happened in recent years, both traditional and new media have played a pivotal and irreplaceable role in the exposure and handling of such incidents. This

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[59] Media, as referred here, includes news media, generally speaking, new media include print media (newspapers and magazines) as well as electronic media (radio, television). Internet has gradually become a new type of media with the development of the Internet. The news media dealt with in this article cover both newspapers, magazines, radios and new media as well as we-media.

[60] In the 2018 institutional reform, the State Administration of Press, Publication, Radio, Film and Television was split into three separate agencies directly affiliated with the State Council, and ceased to exist. The new agencies include the State Administration of Radio and Television; the State Film Administration; and the State Administration of Press and Publication – which doubles with the National Copyright Administration.

was the case for the Fuxi incident in 2014. News and media have become an important force in food safety supervision and management, as well as social governance.

6.3.1. Provisions regarding media supervision in China's laws and regulations

Provisions and incentives about the media exerting social supervision have been in China's laws and regulations for a long time.

The *Food Hygiene Law* promulgated in 1995 outlined that the State shall encourage and protect the social supervision of food hygiene by social organisations and individuals. Any person shall have the right to inform the authorities or lodge a complaint about violations of the *Food Hygiene Law*.

On 28 February 2009, the first *Food Safety Law* was officially promulgated. It stipulated that the State shall encourage social groups and autonomous grassroot organisations to carry out the popularisation of food safety-related laws, regulations, standards and knowledge, to advocate healthy diets, and to enhance consumers' food safety awareness and self-protection capabilities. It also stipulated that media shall promote food safety laws, regulations, standards and knowledge *pro bono* and conduct public supervision over violations of the *Food Safety Law*.

On 4 March 2010, the *Measures for the Supervision and Management of Food Safety in Catering Services* were issued by the former Ministry of Health. They stipulate that catering service providers shall engage in catering service activities in accordance with the laws, regulations, food safety standards and other relevant requirements, be responsible to the society and the general public, guarantee food safety, receive the supervision from the public, and bear the responsibilities for food safety in catering services. Any organisation or individual shall be entitled to conduct social supervision over food safety in catering services, report the activities of any catering service provider in violation of these Measures, obtain relevant information and put forward opinions and suggestions on food safety work in catering services.

The 2015 amended version of *Food Safety Law* made minor adjustments to the provisions regarding media's social supervision responsibility. It stipulates that people's governments at all levels shall strengthen the promotion and education on food safety, popularise knowledge on food safety, and encourage social groups and autonomous grassroot organisations to carry out the popularisation of food safety-related laws, regulations, standards and knowledge, to advocate healthy diets, and to enhance consumers' food safety awareness and self-protection capability. The media shall promote food safety laws, regulations, standards and knowledge *pro bono*, and at the same time conduct public supervision over food safety-related violations, but are required to provide authentic and impartial information and reports. Meanwhile, entities and/or individuals who made outstanding contributions to the work of food safety shall be honoured and rewarded in accordance with relevant national provisions.

The media is the main carrier of public supervision, and they are often on the frontline of information. The above-mentioned laws and regulations guarantee the media's right of discourse in reporting food safety incidents, and provide strong support to them to fulfil their purposes. Traditional media and new media have the functions of overseeing the government's inaction and the business' illegal production activities, and of helping consumers to get timely informed about food safety related problems and information. The exposure of food safety incidents by various media platforms has brought about unprecedented attention to food safety. Strong pressure from public opinion has played a role in promoting government regulatory reform and the implementation of corporate responsibilities.

For consumers, media coverage is an important channel through which they can obtain information on food safety, and thus through which their purchasing choices are affected. Media's guidance can help consumers to pay more attention to the food production process, and nutrition and health properties, prompting them to obtain relevant knowledge, and raising their awareness on healthy consumption.

6.3.2. Media supervision role and effectiveness in practice

In a developing country currently undergoing economic and social transition, and at the same time being a large country in terms of food production and consumption, the issue of food safety cannot be neglected. With the protection of laws and regulations, the media casted off restrictions and overcame many challenges in the process of uncovering food safety incidents, educating the public, and dismissing rumors. The media has contributed to remarkable accomplishments, for instance in the past ten years, melamine, Sudan red, gutter oil, clenbuterol, gelatin jelly and other food safety incidents quickly came to the attention of regulatory authorities and the public after being exposed by them.

In these food safety incident reports, the media served as an optimal agent for information dissemination rather than as a source of breaking news. The public did not place any expectations on the media's capabilities in such cases. The media reported the actual situation in a truthful, rational and constructive manner – which satisfied the public's right to access information. It also supervised public opinion, and protected the public's lawful rights and interests. The media's safeguarding of the food safety order by means of exposure and divulgation is not only an obligation stipulated by the law, but also a professional quality as a medium for disseminating facts and truth.

In practice, the media's supervisory functions can be reflected, above all, in the number of food safety incidents exposed. Statistics show that in 2012, the number of food safety incidents exposed by the media mounted to 1,942.[61]

[61] Suggestions from this article come from *News Report Service Handbook for Food and Drugs Safety*, 2016.

On 11 September 2008, *Oriental Morning Post* reporter Jian Guangzhou paved the way for the outbreak of the Sanlu milk powder scandal that caused widespread concern after the publishing of an article entitled "*Fourteen infants in Gansu diagnosed with kidney diseases, suspectedly caused by drinking Sanlu milk powder*". The following day, the Ministry of Health preliminary confirmed the factual findings on the contaminated Sanlu infant formula causing urinary calculus among infants. Another example is the airing by CCTV on 15 March 2011 – the Consumer Rights Day – of a special report entitled *"The truth of 'bodybuilding pigs'"*, which revealed the fact that the Henan province-based Shuanghui enterprise used clenbuterol (also known as "lean meat powder" in Chinese), and questioned the use of this substance in the enterprise's meat products. After this report was aired, the Henan Provincial Party Committee and the provincial government took emergency response measures: all the sixteen pig farms involved in the news report were shut down, and all the live pigs and 134 tons of pork products suspected to contain clenbuterol sealed up. Relevant authorities even sent out working groups to carry out in-depth investigations in many regions.

In recent years, as the government continuously strengthened its supervision and management over food safety, there have been fewer cases of large-scale food safety incidents. As a result, the media's focus on food safety-related information shifted towards the popularisation of scientific knowledge and the dismissal of ungrounded rumours.

In September 2013, in Guangxi province's Longshen, rumours of hookworms grown out of pork, which cannot be killed by boiling, frying and high temperature, went viral on the Internet. In the following years, many similar rumours also emerged across many provinces, including Guangdong, Jiangsu, Liaoning, and Sichuan. For example, on 23 October 2014 WeChat subscription account "Shun Si Network" published an article titled "*Hookworms found in pork products from many different regions! Eating pork has already been banned in many regions!*"; on 28 September 2016, another WeChat subscription account "Stuffs about Shanwei" published an article titled "*A woman from Shanwei bought a slice of pork, only to find* that thing *in it after cutting it up*". The first response to these rumours came in the same year from local media in Guangxi province, which revealed that "pork hookworm" was in fact a false message, with *Guangxi Daily* posting such information on its official Weibo account to dispel this rumour. At the beginning of June 2016, the former China Food and Drug Administration (CFDA) also responded to this rumour; *People's Daily*, Xinhua News Agency and many other media outlets also diffused relevant information to dispel this rumour. At the 2016 China Food Rumour Refutal Forum, held on 27 June that year, the Chinese Food Rumor Alliance revealed three big rumours related to food – among which the so-called "pork hookworm" was proved to be non-existent.

At the beginning of March 2018, an article entitled *"CCTV exposed that what you have been drinking is not tea, but poison!"* was widely circulated on WeChat, attracting a lot of attention from the tea and beverage industry as well as consumers. It also had a negative

impact on production and sales of the upcoming spring tea. Soon thereafter on 6 March, the WeChat subscription account "Food and drug news in China" – run by the CFDA – as well as the *China Pharmaceutical News* timely published special coverage to refute the rumour.

The media is an important force in food safety related work. At present, food safety has become a hot topic of discussion and concern to the whole society. By actively responding to social concerns, by reporting achievements and challenges faced in food safety enforcement, and by exerting public opinion supervision, media have effectively raised the public's self-protection awareness and capabilities. It has also promoted the establishment of a social credibility system. Ultimately, the media has played an important role in facilitating the work of the government, safeguarding the public's right to access information and protecting the fundamental interests of the public.

6.3.4. Media reports: problems and solutions

The media plays an irreplaceable role in promoting the government's supervision and management reform and the implementation of corporate responsibilities. However, some media outlets are over-obssessed with sensational impact and are blindly following the trend to create frenzy. At present, five different forms of inappropriate sensationalised reporting on food safety incidents can be found within media, namely: reporting inaccurate information; confusing key concepts; exaggerating the extent of the problem; not providing sufficient explanations; and spreading false information.[62] Beginning in 2008, rumours about KFC's "six-winged chicken" and "spider chicken" have been wildly circulated throughout the country. Many people have even made the connection between "six-winged chicken" and genetically modified foods, for fear that eating six-winged chicken may lead to genetic mutation in their own bodies. By the end of April 2015, there were more than 4,000 relevant entries relating to "six-winged chicken" and "spider chicken" on WeChat subscription accounts, over 130 of which featuring more than 100,000 hits, and in particular ten of which being particularly popular among netizens. Inaccurate information quoted in these articles had been identified as one of the "eight outrageous events" in media as early as 2008. *Xinmin.cn*, *People.cn*, *Sina.com*, *Sohu.com* and other media all tried to dispel the KFC rumour, although with little impact. On 26 May 2015, KFC sued ten WeChat subscription accounts. In early February 2016, the first-instance verdict ruled that the three defendants involved with the ten WeChat subscriptive accounts shall issue apologies on first page columns of major websites' news sections and pay 600,000 RMB of economic compensations and other reasonable fees to the plaintiff.

The newly revised *Food Safety Law* outlines strict requirements for food safety related news reporting. In particular, any media outlet which produces or disseminates false food

[62] See Gao Yue: Problems of media reports on food safety and cause analysis, *Science & Technology Information*, No.4 2011.

safety information shall be punished by the relevant competent authority, together with its direct principle as well as other directly responsible personnel. If the lawful rights and interests of any citizen, legal entity, or other organisations are damaged, such media outlet shall be liable under civil law for eliminating influence, restoring reputation, indemnifying loss, and extending apologies. In order to avoid the issue of spreading false information in news reporting, the media shall regulate their news reporting activities. Some precautions and suggestions are as follows: [63]

1) The media shall cite authoritative and professional sources of information, and clearly identify the sources in the reports. Among all the official channels of information from government agencies, the most authoritative ones are the various information platforms set up by CFDA, such as the official Weibo account "@China Food and Drug Administration", and the official WeChat account "China food and drug news";
2) The media shall make sure reports on major controversial issues are carefully verified. It shall verify, as much as possible, the information with experts from various sectors in order to form a multi-source verification, so as to avoid the negative social impact caused as a result of inaccurate descriptions in some of the reports. For food and drug safety news which have already been covered by other media outlets, media agencies shall still carefully verify whether the source is authoritative and professional, whether the content is true, rather than simply following the trend and reposting such articles;
3) News reports on food and drug safety in the nature of popularising scientific knowledge shall adopt the peer review system. Most journalists are not experts in the field of food safety. In order to avoid reports containing errors going against the scientific nature of the issue covered, to prevent themselves from becoming creators and disseminators of food and drug safety rumours, and to avoid social panic caused by false reports, it is recommended that media shall employ the peer review system and contact experts in the field to ensure the accuracy of the information reported;
4) The media shall ensure that the information conveyed by the title is accurate, clear and impartial. Titles of the reports on food and drug safety shall not be taken out of context for the purpose of creating sensational effects;
5) The media shall pay attention to the logic of news reporting and shall not make any presumptions about causes and effects or draw false deductions based on false conclusions. Professionals in the media industry shall read and be trained on logics, should grasp the basic principles behind each kind of logical reasoning, and should think more and ask more questions;
6) The media shall differentiate advertising from news, clearly labelling the former,

[63] Suggestions from this article come from *News Report Service Handbook for Food and Drugs Safety*, 2016.

especially when relating to food. Article 14 of China's *Advertising Law* stipulates that an advertisement shall be identifiable so that consumers could identify it as such. Advertisements shall not be published in disguised of news reports on mass media. Any advertisement published on mass media shall be conspicuously indicated as an "advertisement" to distinguish it from other non-advertisement information in order to avoid misleading consumers;

7) The media shall be innovative in reporting methods and formats, and serve the users in the age of new media. Big data mining technology can be used to carry out in-depth data analysis in the field of food safety. Use data visualisation to present reports and introduce a new energy into food safety reporting. Attract public participation and create a platform for the public to discuss food safety issues;
8) Finally, the media shall clarify the complexity of food safety issues and maintain positive interactions with the government. The media shall not only enable people to behold the various problems emerged in the field of food safety, but also follow up on new policies and measures on food and drug regulations, and monitor the implementation of these policies. Of course, this also requires government agencies to perform well in information disclosure and to work and communicate with media in a more open-minded manner.

6.3.4. Conclusions

In summary, the media has the sacred duty of respecting facts and upholding justice. It has breathed new life into the supervision and management of food safety in China. While executing their supervisory role, media should bear in mind not to have any presumptions and not to exaggerate facts for the sake of attracting attention, so to avoid posing negative impacts on the social co-governance of food safety.

6.4. Complaints and whistleblowing

*Zhao Zhongxue**

In March 2016, the China Food and Drug Administration (CFDA) issued the *Measures for the Administration of Food and Drug Complaints and Reports*. These Measures are considered to be China's first uniform departmental provisions[64] on complaints and whistleblowing.[65]

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[64] See Jiang Peng, "China's complaint and report system: hidden perils, causes and solutions – from the perspective of tackling the issue of anti-counterfeit professionals", *Hebei Youth College of Management Paper*, 2017, No.29 (5):67.

[65] Generally speaking, complaint and report are two different concepts. Complaints refer to the situation where a citizen or an entity considers its legitimate rights and interests to have been violated, thus requesting relevant

Their legal basis can be found in Article 12 and Article 115 of the *Food Safety Law*, and they abide by the same principle of social co-governance.[66] Although the Measures are meant to regulate complaints and whistleblowing related to both food and drugs, in reality, around 80% or even more of the total complaints filed concern food exclusively. A total of 1.11 million food-related complaints were filed in 2017, up from only 190,000 cases in 2013. This, however, does not mean that there was an increase in the number of problems; rather, it demonstrates that the complaint and whistle-blowing system gradually acquired stronger recognition and more frequent utilisation by the public, which came from the value of participation also thanks to government responses. Evidently, as an institutional framework, complaints and whistle-blowing on food products integrate the different interests of producers and distributors, regulators and consumers, and have become a part of China's food safety social co-governance system and capability. This section is grounded on reflections on the formation and development of this system – especially on its path of evolution from a food legislation perspective – as well as on the challenges that such a system faces in practice. It will contribute to a better understanding for the reader of the food complaint and whistleblowing system in China.

6.4.1. The institutional evolution of the complaint and whistleblowing system from the perspective of food legislations

From a legal perspective, although the purpose of complaints and whistleblowing is to protect the interests of consumers or of the public, their starting point lies in the logic that the public has the power of supervision, and they are deduced from the political rights of appeal, indictment and prosecution that the Constitution endows to citizens. Ancient Chinese laws starting from the Zhou Dynasty (1046-256 BC) until the Qing Dynasty (1644-1912) all included provisions and records of reporting traiters and crimes. Various forms of reporting

departments to deal with the situation according to law. Reports refer to reporting the perpetrators and wrongdoing to relevant departments. The former has a direct link or correlation with the complainants' own interests, while in the latter the reporters do not generally become involved in the cases. The Measures combine these two concepts: food and drug complaints and reports refer to the reporting, by citizens, legal persons or other organisations to food and drug authorities at all levels, of suspected violations of relevant laws committed by producers, distributors and other entities during the production or distribution of food (including food additives), drugs, medical devices and cosmetics.

[66] *Food Safety Law of the People's Republic of China (2015)* Article 12: Any organisation or individual may report illegal acts relating to food safety, obtain information on food safety from relevant departments, and have opinions and/or make suggestions about the supervision and administration of food safety. Article 115: The food and drug administrations and quality supervision administrations of the people's government at the county level or above shall publicise their emails or telephone number to accept consultancy, complaints, and reports. Consultancy, complaints, and reports that fall within its duties shall be replied to, verified, and managed within the statutory time limit; if not, such consultancy, complaints, and reports shall be referred to competent authorities and the consulting person, complaint filer, and reporter shall be notified in writing. The competent authorities shall manage such consultancy, complaints, and reports within the statutory time limit. In the event that the report is verified as true, the reporter shall be awarded. Related departments shall keep the information of such reports confidential so as to protect the reporter's lawful rights and interests. The employer of such reporter may not retaliate such reporter by rescinding or changing their employment contract or by other means.

crimes throughout these eras include *Feibang Mu* (ornamental column on which people can write their complaints), *Fei Shi* (red stone in the shape of a lung on which people can write down their complaints), *Tong Gui* (copper box into which people can insert anonymous complaints or suggestions), *Deng Wen Gu* (a drum placed outside of the local government, people who want to make complaints or file lawsuits can beat this drum to signal their intentions).[67]

After the founding of the People's Republic of China in 1949, and especially since the economic reforms initiated in 1978, China witnessed rapid economic development. In order to curb corruption among officials, in 1988 China first introduced a whistleblowing system within the supervision and procuratorial agencies.[68] It also set up a whistleblowing agency and published a telephone number for exposing information, which played an important role in gathering accusations.[69] Since then, a nationwide whistleblowing network has been established in the departments of public security, industry and commerce, taxation, customs, as well as food and drug. Specific legislations and departmental rules also include several stipulations on complaints and whistleblowing. The application, as a legal system, of the complaint and whistleblowing system in the area of food supervision and management, was formed after the 1978 economic reforms, and it underwent through four main stages.

Infancy stage (1979 – 1983)

During this stage, China was still in the phase of planned economy, in which the government had full power and authority to plan and control the entire food industry chain, from production to sales. All food producers in this stage used traditional methods to produce food. Accidental food hygiene incidents were unlikely to spread to large scales, and such incidents would not generally damage the overall image of the government. The responsibility for food hygiene supervision lied with health and anti-epidemic stations at all levels, while light industry, commercial and other food production and distribution departments and entities also established inspection and management agencies to safeguard food hygiene.

Article 17 of the *Regulations on the Administration of Food Hygiene*, issued in August 1979 by the State Council, clarified the right of food hygiene management and inspection personnel to report the status of food hygiene in food production and distribution to superior authorities. Although the individuals who file the content of their complaints and the receivers of the complaints were all limited to internal personnel of the organisation, and although whistleblowing channels were unclear, granting the right to "report" already demonstrates the awakening of participation awareness. Some scholars believe that in this

[67] See Feng Tiejin, "Forms of reporting in the ancient times", *Supervision in China*, 2001, No.22, p56.

[68] See Pan Qingbin, Zhang Qilin, Zhang Jishan, "On the people report system", *Social Sciences in Xinjiang*, 1989, No. 4, p. 83.

[69] See Lv Heyun, Shen Deli, "A comprehensive review on the implementation of people report system, *Law Review*, 1991, No.4, pp. 74-79.

stage, "food hygiene management started to shift from purely administrative management towards legal management".[70]

Development stage (1983 – 2009)

This stage matches with the period in which the economic reform and opening-up were at their most rapid development, and in which China's society was was undergoing profound transformations. The introduction of market mechanisms provided an economic condition for the government to shift towards a role with more limited functions. As chapter 4 of this book highlighted, the food industry with its 13% average annual growth gradually became the pillar industry of national economic development, at the same time leading to an improvement in food consumption patterns.[71] The public's focus on food was slowly moving from quantity to hygiene and safety. The legislation was accordingly updated, for instance with the introduction in July 1983 of the *Food Hygiene Law (for trial implementation)*, which ended with the final promulgation of the *Food Hygiene Law* in October 1995. Although the main purpose of this piece of legislation was to ensure food hygiene, it also granted the public the right to actively engage on a legal level. For example, Article 3 of the 1983 *Food Hygiene Law (for trial implementation)* stipulated that "*any person shall have the right to report and accuse any behaviours violating this Law*", to which a key sentence was added by Article 5 of the final 1995 *Food Hygiene Law*, namely that "*the State encourages and protects social groups and individuals to exert social supervision over food hygiene*". Evidently, this was a response to the supervisory right stipulated by Article 41 of the 1982 Constitution. But as it was the case in the previous stage, the legislation failed to clarify the actors, channels and safeguarding measures for complainants and whistleblowing: these remained vague and generalised.

According to Article 3 of the *Food Hygiene Law*, the health administrative authorities of the State Council shall be responsible for the nationwide supervision and management of food hygiene. Other relevant authorities of the State Council shall be responsible for the administration of food hygiene within their relevant scope of duties. Duties and responsibilities were further clarified in 2004: authorities with competence in food supervision and management granted, in their respective legislative areas, the right for the public to complain, prosecute and report in food – although this was not limited to food only. Complaint and whistleblowing channels were set up accordingly. For example, the State Administration for Industry and Commerce launched the 12315 Complaints and Reports Hotline on 15 March 1999; the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) launched the 12365 Complaints Hotline on 13 March 2001; the Ministry of Health unveiled the 12320 Government Public Service Hotline on 9 December 2005; the

[70] See Ma Zhaohui, "Review and outlook on food hygiene in China", *Capital Medicine*, 2003, No.15, p. 17.

[71] Li Bai, Chenglin Ma, Shunlong Gong, Yinsheng Yang, "Food safety assurance systems in China", *Food Control*, 2007, 18 (5), pp. 480–484.

Ministry of Commerce introduced the 12312 Complaints Hotline in 2006, a service which in 2008 was extended to cover hog slaughter and alcohol circulation.

However, the most effective channels were the several consumer associations and the 12315 hotlines run by industry and commerce administrations at all levels of jurisdiction.[72] Thanks also to the protection guaranteed by the *Consumer Protection Law*, the number of complaints and reports filed surged. By contrast, the quality inspection, health, commerce and agriculture authorities received fewer complaints and reports – not because there were no issues; rather that information mismatch and the highly specialised nature of such bodies de facto hindered public participation. The "12345" Mayor's Line first created in Hangzhou in 1999 – whose functions also include that of receiving complaints and reports – was also recognised by the public and promoted across the country.

The empowerment of rights and the establishment of whistleblowing channels gradually boosted the public's enthusiasm in safeguarding their lawful rights and interests. Some scholars have pointed out that a major change occurred during this period was the awakening of civic consciousness and the rise of civil society.[73] They specifically emphasised that the 2007 marked China's "year of public expression" and "year of public participation".

Strengthening stage (2009 – 2015)

This stage matches with the rapid development of China's food industry. During the 12th Five-Year Plan period (2011-2015), the number of entities subject to food supervision reached 11.8 million across the country, the business revenue of enterprises "above designated size" [74] in the food industry reached 11.35 trillion RMB and registered a 12.5% average annual growth, and the value of food imports and exports grew by 23.9%.[75] The contradiction between low level industry development and public's high demand for food, however, led to the intensive outbreak of food safety issues. Among all of these, the "Sanlu milk powder incident" that happened between September 2008 and March 2009 is widely perceived as having epochal significance to China's food safety supervision and management, even forcing the by then finalised and ready-to-be-enacted *Food Safety Law* to be revised and postponed to June 2009. The supervision and management system shifted its approach from segmented co-administration by different bodies towards a coordinated and unificated one (see chapter 4 of this book for more details on the evolution of China's supervision and management

[72] The China Consumers' Association was established in December 1984 with approval by the State Council. It is a nationwide social organisation and one of its duties for the public interest is to accept consumer complaints, and to investigate and mediate complaints.

[73] Yu Keping, "Several issues on the study of China's civil society", *Journal of the Party School of the Central Committee of the Communist Party of China*, 2007, 11 (6), pp. 17 – 18.

[74] A statistical term used in China to refer to enterprises with an annual revenue of and above 20 million RMB from their main businesses.

[75] See *13th Five-year Plan for National Food Safety*.

approach in food safety); it also shifted its purpose of legislation from ensuring food hygiene to ensuring food safety.

Recognising the seriousness of the food safety situation and the limitations of its own supervision and management, and at the same time pressured by public fear and anger, in the *Food Safety Law* the government put more emphasis on the role of industry associations, consumer organisations, media and autonomous organisations. In the case of complaints and reports, Article 10 of the new legislation instructed that "*any entity or individual shall be entitled to report any violation of this Law committed during the food production and distribution process, get food safety information from relevant departments and put forward opinions and suggestions on the food safety supervision and management work*"; it also specified Article 80 to regulate complaints and whistleblowing.[76] Article 53 of the subsequently released *Regulations for the Implementation of the Food Safety Law* further identified the channels for filing complaints and reports.[77] Compared with the 1995 *Food Hygiene Law*, the new *Food Safety Law* expanded the scope of the participation, defined the roles and responsibilities of various authorities, identified the channels for filing complaints and reports, and changed "prosecution and accusation" into "complaints and whistleblowing". However, it still failed to provide any stipulations on safeguarding the implementation of the system. It is also noteworthy that Article 96 included provisions on punitive damages, reflecting the specific application in the food sector of the "punish damages system" orginated from the British and American legal systems and first adopted in the 1994 *Consumer Protection Law* – which aimed at encouraging consumers to protect their legitimate rights and interests.

Another feature which suggests the strengthening of the system during this stage can be found in the introduction of the rewarded whistleblowing system. This system was formulated in 2011 by the State Council's Food Safety Committee (responsible for the comprehensive supervision of food safety in China) with the issuance of the *Guiding Opinions on the Establishment of Food Safety Rewarded Reporting System*. The Guiding Opinions – which at the same time also represented the first piece of administrative regulation on

[76] 2009 *Food Safety Law*, Article 80: Where a health administrative department, quality supervision department, industry and commerce administrative department or food and drug supervision and administration department at or above the county level receives a consultation request, complaint or tip-off, it shall accept it if it falls within the scope of its functions, and shall timely make a reply, verify and deal with it. If it does not fall within the scope of its functions, it shall give the party concerned a written notice and transfer the case to the competent department. The competent department shall timely deal with it and shall not decline it. If it is a food safety accident, it shall be handled under the relevant provisions of Chapter VII of this Law.

[77] *Regulations for the Implementation of the Food Safety Law of the People's Republic of China*, Article 53: The health administrative departments, agriculture administrative departments, quality supervision departments, industry and commerce administrative departments, food and drug supervision and administration departments and other departments shall publish their e-mail addresses or telephone numbers to receive consultation requests, complaints or tip-offs; and in accordance with Article 80 of the *Food Safety Law*, make replies to, verify and handle the consultation requests, complaints or tip-offs received, and maintain a record of information on such consultation requests, complaints and tip-offs as well as replies, verifications and handling.

rewarded whistleblowing in the food sector – provided brief provisions on the scope of application, the acceptance of information, the verification of information and the rewards. They also requested government at all levels to develop more specific measures to implement the incentives. It should be noted that the rewarded whistleblowing system in the Guiding Opinions covered edible agricultural products, food and food-related products, involving the whole process "from farm to fork", and stressed that the information on informants should remain confidential; it also increased the amount of rewards for internal reporting. The same year in April, the State Council circulated to lower-level authorities a notice on a special overhaul campaign, although its content and effectiveness were limited. [78] Subsequently, the food safety rewarded whistleblowing system began to be implemented nation-wide. Public data shows that by March 2014, 31 provinces (regions, municipalities) launched food safety rewarded whistleblowing systems, with Shaanxi and Jilin setting aside 5 million RMB dedicated rewards; Hunan setting aside 3 million RMB as special incentives; while Guangzhou and Shijiazhuang respectively put 6 million and 3 million RMB into the reward pool. In 2011, a total of 3,189 food complaints were received in Liaoning province, 927 cases of which were filed, with cash rewards granted in 146 cases. In 2012, Jilin Province verified a total number of 163 whistleblowing rewards, and granted 1.57 million RMB of rewards – a figure that increased to 2.21 million RMB two years later. In early 2015, the same province also raised the incentive standard for a single case, from 200,000 to 300,000 RMB.

Compenent authorities actively followed up. For example, in December 2011 the State Food and Drug Administration (SFDA, i.e. the predecessor of CFDA) issued the *Measures for the Administration of Food and Drug Complaints and Reports (trial)*, and required local authorities to launch the 12331 complaints and whistleblowing hotline. In January 2013, SFDA along with the Ministry of Finance (MOF) jointly issued *Measures for Rewarding the Reporting of Violations of Law in Food and Drug Products* – although only targeting catering services. After the 2013 institutional reform, CFDA (emerged from SFDA) integrated complaining and reporting duties in the food production and distribution process; it also set up the Administrative Service and Complaints Centre in June 2014, with the duty of collecting information, coordinating and tracking the progress of food and drug complaints from across the country.[79] Between 2013 and 2015, the number of food complaints received across the country reached 190,000, 410,000, and 600,000, respectively. The significant downward trend registered over the same period in terms of volume of food-related complaints handled by the 12315 - 21,664 in 2015, down from 42,973 in 2013 – reflects the transition in the role played by the Hotline.

[78] *State Council General Office Notice: crack down on illegally adding food additives in order to strengthen the supervision over food additives* (Guo Ban Fa [2011] No. 20).

[79] For more information on the Administrative Service and Complaints Center: http://www.sfdaccr.org.cn/.

In addition, increased promotion is another feature that has grown during this period of system strengthening. For example, the "3.15 Gala" held by China Central Television on 15 March every year, began not only to expose issues but also to support the public to defend their rights, winning wide recognition. The National Food Safety Promotion Week started to be organised since 2011 by the Office of the State Council's Food Safety Committee, and is currently held in June every year covering a population of more than 700 million people.[80] From 2014 onwards, 31 March has been identified as the Food and Drug Complaint Reporting Day, during which the concept of social co-governance is publicly promoted. The system of complaints and whistleblowing and the system of rewarded whistleblowing have been increasingly known and used by the public, and each publicity campaign brings about increases in the number of complaints and changes in governance impact.

Standardisation stage (2015 – present)

During this stage, food safety governance was incorporated into the national governance system and was elevated to the position of national strategy; [81] the entire society's understanding of food safety reached a high level as it integrated social, economic, livelihood and political issues.[82] Officials believe that since the 1978 economic reforms, it took over 30 years for China to go through a food supervision and management process which, in comparison, took the United States more than a hundred years to complete. However, the food safety situation remains grim. It is at a special stage where several issues co-exist, including food adulteration, technical risks, the menace of sudden incidents and new risks brought about by technological changes. In this context, the most stringent *Food Safety Law* in history was revised and officially enacted on 1 October 2015, introducing a brand-new concept of food safety governance of "prevention as main priority, risk management, whole-process control, and social co-governance", and stipulating that the supervision "from farm to fork" should be the shared responsibility of the agriculture, food and drug administration, and health authorities. The revised *Food Safety Law* also made great improvements compared to its previous 2009 version in terms of provisions on complaints and whistleblowing. For example, Article 115 not only confirms the provisions on informants' rewards, confidentiality of informants' information, and protection of internal informants from a legislative perspective; it also emphasises the statutory time requirement on "reply, verification, and handling". In addition, provisions on punitive damages in Article 148 of the revised *Food Safety Law* are more specific and feasible. In March 2016, CFDA began to implement the

[80] See *Thirteenth Five-year Plan for Food Safety*.

[81] On 29 October 2015, the Fifth Plenary Session of the 18th Central Committee of the Communist Party of China approved *Suggestions for the 13th Five-Year Plan for the Economic and Social Development of the People's Republic of China*, which clearly stated: "implement food safety strategy, form a sophisticated, efficient food safety governance system with the feature of social co-governance, ensure people's access to safe food".

[82] Xu Jinghe, "A few thoughts on the improvement in unified authoritative food and drug supervision system", *China Food Drug Administration*, 2016 No.4, p. 18.

Measures for the Administration of Food and Drug Complaints and Reports, which specify the agencies responsible for taking in complaints, as well as channels, procedures, methods and protection measures for making complaints. In August 2017, CFDA and MOF modified the *Measures for Rewarding the Reporting of Violations of Law in Food and Drug Products (2013)* and expanded their application to include food production and distribution. They also established an internal reporting incentive mechanism, and raised the incentives for a single case from 300,000 to 500,000 RMB. Finally, it also clarified the circumstances and standards rewarding important cases, improving and further clarifying the methods and procedures for anonymous whistleblowing rewards. The main highlight, however, remains the establishment of an error correction mechanism, according to which the whistleblower may appeal for a re-examination of the report in case disputes arise.

By the beginning of 2017, throughout the country, 28 provinces, more than 300 prefecture-level cities, and nearly 1,500 counties and districts had set up food and drug complaint and whistleblowing agencies. Provincial-level "12331" hotline centres had been set up in 16 provinces (regions, municipalities), and complaint and whistleblowing websites had been launched in 30 provinces. Relevant measures for the administration of complaints and whistleblowing had been introduced in 27 provinces (regions, municipalities) on the local level.[83] At present, food and drug administrations or the market regulation administrations at all levels of jurisdiction are the main competent authorities for reviewing complaints regarding food production and distribution; the 12331 hotline is the main channel, while online platforms, letters, and site visits are supplementary channels. In 2016 and 2017, the number of food complaints received across the country was about 820,000 and 1.11 million respectively, which represents four and five times the number of complaints received in 2013, when CFDA was first set up.[84] The 12315 hotline and the 12345 hotline timely channel and transfer complaints received but which go beyond their scope of competences, for instance in cases involving civil liabilities which need to be regulated by the *Consumer Protection Law*. In order to be more standardised and more effective, some local jurisdictions integrated the 12315, 12331 and/or 12345 hotlines, with the aim of preventing the public from confusing the agencies. One example is Beijing which merged the 12331 hotline into the 12345 in December 2015; and Jinzhou in Shanxi province, which merged all the three outlines in September 2016.

The number of complaints and reports vary from place to place. In 2016, Beijing, Shanghai, Shandong, and Guangdong received more than 100,000 complaints and reports. In 2017, Shanghai, Beijing, and Shandong, Guangdong, and Jiangsu provinces alone received 46.4% of the total number of complaints received nation-wide. Over the same period, Hunan,

[83] Pang Cun, "The establishment of complaint and report system to guard food and drug safety complaints and reports has been included in the thirteenth five-year plan for food and drug", *China Food and Drug Administration*, 2017 No.4, p. 9.

[84] Source of statistics: CFDA website.

Hubei, and Hebei provinces received about 40,000 to 50,000 complaints and reports, while Jilin, Inner Mongolia, Gansu, and Ningxia received about 10,000.[85] The content of complaints and whistleblowing however is generally the same, regardless of when and where they are filed. These mainly cover uncertified production and distribution, food adulteration, strange odours or tastes, exceeded expiration date, labelling inconsistent with regulations, and food fraud, etc. The main feature of this stage of standardisation is that, with the development of "Internet+" businesses, complaints and whistleblowing targeting food and meals sold online gradually became a trend. This prompted the release of the *Measures for the Investigation and Punishment of Unlawful Acts concerning Online Food Safety* and *Measures for the Supervision and Administration of Food Safety in Online Catering Services* by CFDA. It is generally believed that there is a negative correlation between the number of complaints and the effectiveness of food safety governance, but it is clear that these differences are related to the level of regional economic development, the level of food industry development, the density of population, food consumption patterns, as well as the level of public awareness.

6.4.2. Predicaments and challenges in reality

Overall, the complaint and whislteblowing system on food is consistent with the requirements and changes of China's food safety governance. Although there has been "tinkering" here and there regarding the supporting regulations, the legislative evolution of the complaint and whistleblowing system remained consistent, and its framework grew clearer. Measures such as the unified authority for taking in complaints, the varied smooth channels established for making complaints, standardised procedures for taking in complaints, the gradually improving efficiency and relatively sound relief measures ensured the public's active participation and supervision implementation. The development of the complaint and whistleblowing system gradually grew consistent with that of Europe and of the United States in the area of information collection, divided and leveled handling process, follow-up actions, analysis and evaluation.[86] But in a global context where food safety issues are complex, China's "unified and authoritative" food and drug regulatory mechanism has yet to take full shape. The weak industrial foundation led to insufficient implementation of corporate responsibility and public participation in food safety governance is still limited to the surface level due to restrictions in capabilities and lack of awareness. The impact of these factors brings challenges to the complaint and whistleblowing system in practice – these are China's characteristics.

As far as the complaint and whistleblowing system is concerned, first of all, there is an unbalanced participation from principal parties. In the perspective of the initial legislation purpose, individual consumers or social organisations are both the principal parties for filing

[85] Sources of statistics: CFDA website and other public reports.

[86] Mao Zhenbin, Sun Jing, "The development trend of food and drug complaint and report system in China and abroad (one)", *China Food and Drug Administration*, 2012 No.1, p.40.

complaints and reports. The intention of the legislation is to encourage the latter to play a more important role for the sake of safeguarding the public interest. But the current situation is that participation mainly comes from individual consumers and such participation is usually for the sake of their own interests. Voices from industry associations, *pro bono* organisations, and expert committees are rarely heard. It was not until November 2016 that the first "civil public interest litigation case"[87] appeared in the field of food and drug safety in China.

Second, is internal reporting suitable for China? Although Article 17 of the *Measures for Rewarding the Reporting of Violations of Law in Food and Drug Products* provided the path for anonymous informants to claim rewards, in reality the decision on its actual implementation depends on the local food and drug administrative authorities, thus hindering the provision's effectiveness and authority. [88] The incentive scheme also encourages internal reporting by doubling the amount of incentive payments. However, there is no specific safeguard measure for the informant other than that "such a whistleblower cannot be retaliated by their employer by means of rescinding or changing their employment contract or by other means", thus questioning the effectiveness of this provision. Another point to be highlighted is that, Chinese food producers are generally family businesses, scattered and small-sized, which, combined with a high staff turnover rate, make internal reporting difficult.

Third, reward and protection: decoration or rhetoric? Governments at all levels and sectoral authorities have issued provisions on whistleblowing rewards and have gradually increased the amount of incentives each year. But in reality, most reports made on food only relate to general food safety problems, which usually do not involve a high amount of rewards. A simple 200 RMB or 1%-2% reward is not attractive enough for the public, also considering the fact that the process for claiming rewards is rather complicated. At the same time, although there are stipulations on the confidentiality of informants' information in relevant legislations, in practice, their information is often shared, uploaded and summarised by the State, province, city, and county (district) authorities. In the era of big data, confidentiality is also very challenging.

In addition, the implementation of the complaint and report system may also be influenced by several factors already introduced throughout this book, such as the

[87] On 1 November 2016, Changchun Intermediate People's Court held a public trial: Jilin Province Consumers' Association v. Han Xlong and Wang Xli, Guangfu Lu Longchang Sources Store, this was the first civil public interest litigation in the field of food and drug safety supported by the procuratorate department in China.

[88] Artile 17: anonymous informants who hope to claim rewards shall provide information which can be used to identify themselves as identity codes, and coordinate with a designated person from the food and drug administration agencies to agree on the notification methods of report code, report processing results, and rewards. Upon receiving notification that they can receive a reward, and the informants decide to take the reward, they shall provide information on their identity code and report code, so that the food and drug administration agencies can verify their identies. Food and drug administration agencies can set specific procedural regulations on giving out rewards for anonymous reporting based on actual circumstances.

institutional reform, the integration of duties, the punitive damages system and "professional anti-counterfeiters" (see previous sections in this chapter), as well as the differentiated treatment of edible agricultural product due to the parallel implementation of the *Food Safety Law* and the *Law on Quality and Safety of Agricultural Products*.

6.4.3. Conclusions

The open global food market has increased the likelihood of risks, and "shared responsibility" has become a consensus. In fact, China often searches for answers from western successes and experiences in order to improve and to ensure consistency with international rules and actions. For example, China has taken from EU's *General Food Law* such as "from farm to fork", "prevention as main priority", "risk management", and "social co-governance", and has also committed itself to realising the goal of "establishing a high level of protection of human life and consumers' interests in relation to food".[89] However, it is not advisable to simply copy the models and mechanisms of other countries: for instance, applying the protection of informants as stipulated in the United States *Whistleblower Protection Act* [90] (the informants usually refer to internal employees) does not fit the current situation in China, especially given the fact that there currently is no "informant protection law". This may be the "naturally accessible" option, but not the first or best option – we cannot look at the predicaments and challenges of the complaint and report system merely with the will to improve it. The key to realise breakthroughs is to build a complete and mature food safety governance system, enrich and improve the governance toolbox, so that there will be more options available in the face of risks. This might be a complex and difficult task, also a task which may never be completed in a perfect way. Still, it is gratifying to observe that China is moving towards that goal as a major food supply and consumption country and as an advocate of the "community of shared destiny for all humankind".

6.5. Risk communication

*Ding Ning**

The purpose of introducing a food safety risk communication system was to improve food safety social co-governance, as pointed out in the revision explanations of the *Food Safety*

[89] Luigi Costato, Ferdinando Albisinni, "*European Food Law*", translated by Sun Juanjuan, etc.; Beijing: Intellectual Property Publishing House, 2016: 44.

[90] The safety of the whistleblower is protected by Marshal Office, Department of Justice Executive Office, Federal Prison and Office of the Attorney-General, protective measures include granting new identities, change of addresses, plastic surgery and emigration. If the whistleblowers were subject to unexpected deaths, under-age offspring will be raised up by relevant agencies.

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Law (revised draft for reading). The explanations highlight that food safety supervision and management authorities and food safety risk assessment agencies shall, through national institutional design, execute food safety-targeted risk communication in a scientific, objective, timely and open manner. Among these, risk communication activities carried out by county-level or higher-level food and drug administration departments aim to promote food safety social co-governance through standardising exchange of information on food safety supervision and administration. As a way of implementing social co-governance, risk communication was taken on by the government to guarantee food safety. Its fulfilment, however, does not only require the government to actively provide or request information; it also involves encouraging other social entities to participate in the information exchange process, including food producers and distributors, food inspection agencies, food industry associations, consumer associations, certification bodies, media and other interested parties.

6.5.1. Brief introduction of food safety risk communication

Definition of risk communication

In 1989, the United States Committee on Risk Perception and Communication defined risk communication as an "interactive process during which individuals, groups and organisations exchange information and views, and which involves the characteristics of risk as well as other relevant information. It not only directly shares information regarding risk, but also delivers concerns, opinions and reactions regarding risk events, or publishes risk management regulations and measures for the State or organisations".[91] This definition clearly defines the importance of information exchange at all levels of risk communication, rather than being a mere unidirectional propaganda or inculcation tool. In 2014, China's National Health and Family Planning Commission released the *Food Safety Risk Communication Technical Guide*, putting forward that "food safety risk communication refers to the process of exchanging information and views among interested parties regarding food safety risks, factors involved in the risk, and risk perceptions".[92]

Risk communication is different from food safety education and popularisation, as it runs through the whole process of risk analysis. A wide range of parties are involved in the task of risk communication, including food safety scientists, government regulators, food producers and distributors, consumers, as well as other interest groups. Food safety risk communication is an important content and objective of modern food safety governance.

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[91] National Research Council, "Improving risk communication [M]", Washington D.C., *National Academy Press*, 1989: pp. 21-24.

[92] National Health and Family Planning Commission of the People's Republic of China, "*Food Safety Risk Communication Technical Guide [EB/OL]*", 2014-11-24. http://www.nhfpc.gov.cn/sps/s7885/201402/c73f0cf331234ef285c010fd1df5b915.shtml

Principles of risk communication

Food safety risk communication is of great significance to food safety supervision and management. It requires adherence to the principles of scientific objectivity, openness and transparency, promptness and effectiveness, and multi-party participation.

The principle of scientific objectivity involves two main aspects. First, risk communication must be based on science: the information provided by the interlocutors on risk hazard, risk level, risk related factors and consumer response measures must have scientific and accurate information sources. Second, the methods and techniques of risk communication should too be based on science:[93] interluctors must possess knowledge of psychology, communication, decision-making and behavioural science, and carry out scientific and systematic risk communication based on the cognitive level of the audience.

The principle of openness and transparency requires the food safety administration and risk analysis process to be open, allowing all stakeholders involved in the food industry chain to actively participate in the process and to make recommendations, thus increasing the enthusiasm of all parties involved in the food safety administration system.[94]

The principle of promptness and effectiveness is very important in handling food safety incidents. Food safety incidents generally consist of sudden events which attract a high level of attention from consumers and media in a short period of time. Timely risk communication can avoid the spreading of rumours and groundless allegations which would impact the divulgation of authoritative information; it can also prevent a food security incident from escalating into a food safety crisis. Even if, in some cases, information first released may contain certain errors or imprecisions, the timing of communication must not be delayed for this reason. Allowing consumers and other stakeholders to be aware of the situation and to take countermeasures in a timely manner could minimise the impact and harm on society brought about by the risk.

The principle of multi-party participation requires food safety adminsitrators, evaluators and stakeholders to exchange views and suggestions on major food safety issues, social concerns and management decision-making. Food safety administration agencies are required to strengthen the monitoring of public opinion, so to understand social reactions and the public's expectations; they should involve all parties from the onset or even before the risk emerges, in order to guide the audience to avoiding a panic situation.

Significance of carrying out risk communication in China

China is still in a stage where certain food safety risks remain outstanding. Food safety incidents break out in a concentrated manner, and in locations where the overall food safety

[93] FDA.FDA's strategic plan for risk communication. 2009:10-19.

[94] Wei Yimin, Wei Shuai, Guo Boli, "Mainstream views and methods regarding food safety risk communication", *Journal of Chinese Institute of Food Science and Technology*, 2014 No.14(12), pp. 1-4.

situation is still severe. Risk communication is effective for changing the model of food safety supervision and management, which can make the supervision "yield twice the result with half the effort". Although in recent years China's food safety supervision and management has achieved remarkable results, with the qualification rate of food safety sampling tests increasing year after year, public concerns and misconceptions about food safety still persist, and the public's immediate feelings are highly inconsistent with the overall food safety situation in today's China.[95]

At the same time, Chinese government agencies have been constantly making efforts towards strengthened and improved supervision and management. While carrying out the principles of risk management, they have also been stressing the need to accelerate the establishment of food safety social co-governance, which includes enterprise self-discipline, government supervision, social coordination and public participation. This further requires national food safety regulatory authorities to carry out timely and effective risk communication, and to establish a food safety risk communication system at the national level. Food safety supervision and management agencies, together with food safety risk assessment agencies, must organise food safety risk communication by adhering to the principles of science, objectivity, promptness and openness, and guide all relevant stakeholders to participate in this process so as to concretely increase the effectiveness.

6.5.2. Status quo of food safety risk communication in China

Interpretations of relevant laws, regulations and policies

In the *Food Safety Law (revised draft for reading)* submitted by the China Food and Drug Administration (CFDA) to the State Council in 2013, defined risk communication as "exchanges of food safety risk assessment information and food safety supervision and management information among food producers and distributors, industry associations, technical agencies, media and consumer associations, organised by food safety supervision and management authorities and food safety risk assessment agencies on the basis of the principles of science, objectivity, promptness and openness".

Regrettably, such provision was eliminated from the *Food Safety Law (revised draft)* released for public consultation on 30 June 2014 after the first reading at the Ninth Meeting of the 12th NPC Standing Committee, nor was there any mention of risk communication in other sections.

Despite this, it is reassuring to see that China's food and drug regulatory authorities have indeed realised the importance of food safety risk communication in food safety administration. Risk communication, in fact, has been granted increasing attention. Article 23

[95] Wang Weiguo, "It is preferable to include risk communication system into the law", *China Food Safety Newspaper*, 11 April 2015, p. A2.

of Chapter II of the *Food Safety Law* formally promulgated by the State Council in 2015 stipulates that "food and drug administrations and other relevant departments of local governments at county level and above, together with food safety risk assessment expert commissions and their technical institutions, shall organise exchanges of information on food safety risk assessment and administration among food producers and distributors, food inspection institutions, certification institutions, food industry associations, consumers associations, and media, based on the principles of science, objectivity, promptness and openness". This article made it clear that food and drug regulatory authorities must undertake and implement food safety risk communication.

In the same year, CFDA drafted the *Regulations for the Implementation of the Food Safety Law (revised draft)*, further specifying, supplementing and improving its previous version, on the basis of the *Food Safety Law*'s requirement to establish a scientific and stringent supervision and management system. In the revised draft for reading of the Regulations, released in August 2015, Article 15, Article 16, Article 20 and Article 21 of Chapter II set out relevant rules on the organisers, participants and contents of food safety risk communication. Particularly, Article 20 stated that "food and drug supervison and management departments of the State Council shall set up food safery risk communication systems with other relevant departments, to encourage and to support food producers and distributors, food safety technical institutions, scientific and research institutions, food industry associations, consumers associations, lawyers associations, and media, to engage in food safety risk communication". Article 21 stated that "food and drug supervison and management departments of the State Council shall work with other relevant departments to establish food safety risk communication consulting committee, formed by experts in food, public health, clinical medicine, environment and ecology, quarantine and epidemic prevention, nutrition, news and communication, and law, and which shall provide insights and suggestions on food safety risk communication". This revised draft remarked the important role of risk communication in food safety supervision and management, which not only requires relevant working groups and mechanisms to be set up by the government, but also relies on the role of a committee made up of experts from several fields. It demonstrated the scientific nature of risk communication, while also stressing the participation of third-party social forces, in order to establish food safety social co-governance.

In the *13th Five-Year Plan for National Food Safety (2016-2020)* released by the State Council in 2017, the section "improving technical support capabilities" requires national food safety supervision and management authorities to "improve the risk communication system, and to regularly organise, in accordance with the principles of science, objectivity, promptness and openness, information exchanges on food safety risk assessment and food safety supervision and administration among food producers and distributors, food inspection agencies, certification bodies, food industry associations, consumers' associations, and media". This section also required national food safety supervision and management

authorities to “standardise food safety information disclosure mechanisms and system”, to “establish a four-level public food safety risk perception survey system at the national, provincial, municipal and county-level, and a three-level risk communication expert support system at the national, provincial and municipal-level”, and to “encourage large-scale food production and distribution enterprises to actively participate in risk communication”. Furthermore, the section entitled “accelerate the establishment of social co-governance” requests national food safety supervisory and management authorities to “carry forward the organisation of the ‘National Food Safety Promotion Week’, to include food safety education in the national educational system and to treat it as an important component of civil legal education, scientific education and vocational training”. It also requests national food safety supervisory and management authorities to “enhance the popularisation of science, promoting food safety in rural areas, enterprises, communities and shopping malls, and encourage the active participation of research institutions, universities and associations, in order to improve all citizens’ understanding of food safety”. In accordance with the requirements of this 13th Five-year Plan, government departments should establish a risk communication system embracing all regulatory bodies at all the administrative levels, carrying out regular multi-level risk communication exchanges, at the same time including public food safety education into the broad risk communication framework, ultimately boosting food safety social co-governance.

From the above, it is clear that in recent years, thanks to the attention from government and academic circles, food safety risk communication in China has begun to move towards a gradual institutionalisation, legalisation, and to become disciplined. Henceforth, a large extent of intensive risk communication work will be executed. China’s food safety risk communication system will play a far-reaching and positive role in increasing public awareness and understanding of food safety risk information, in pushing for the effective implementation of regulatory measures, in improving social food safety, and ultimately in promoting the healthy development of food industry.

Current situation of China’s food safety risk communication

1) National level

Food safety risk communication had a late start within China’s food safety supervision and management, and it currently remains a challenging task with high requirements. At present, it is mainly led by the government. From CFDA’s official website it can be seen that Division III of Food Supervision and Management is the body specifically responsible for the food safety rapid risk alert system, and for food safety risk communication.[96] As a national-level authority, its specific responsibilities include enhancing the guidance and coordination

[96] CFDA’s official website was changed and adjusted after the 2018 institutional reform. The information included here refers to the pre-reform website of CFDA.

of food safety risk communication, promoting the establishment of risk communication mechanisms, building the risk communication working system, setting up a food safety risk communication expert group, achieving innovation in risk communication channels, strengthening personnel training and capacity-building, and expanding international cooperation and exchange. This role of CFDA began from scratch, and so far has led to the gradual improvement of communication, coordination and joint-action mechanisms, to the formation of a working mechanism for risk communication, and to the establishment of an official food safety publicity website and mobile app, on which food safety consumption tips and risk analyses are frequently published by CFDA. These are in turn widely reposted on local government department websites. CFDA also carries out food safety publicity and education campaigns every year, and organises food and drug supervision agencies of all levels to exchange emergency information with one another after the breakout of food safety incidents.

So far, CFDA has published 32 risk notifications or consumption tips, of which five were in the form of animated videos, covering more than 30 types of key edible species, seasonal food, wild vegetables, and wild poisonous mushrooms. Five issues of food safety risk analysis were curated on topics such as “norovirus infection”, “chloropropanol and glycidyl methacrylate”, and “sulfur fumigation rose”, directly as a response to hot topics discussed in the media, social concerns, outstanding issues and news events from overseas. During the Food Safety Publicity Week, several handbooks or information materials were distributed to the audience, such as the *Food Safety Risk Analysis Collection (2014-2017)*, *How to Eat Safer - Food Safety Consumption Tips (2015-2016)*, and *How to Eat Safer - Food Safety Consumption Tips (2016 - 2017)*, all of which received a lot of attention and unanimous positive feedback.

In September 2017, CFDA’s Division III of Food Supervision and Management released the *Guiding Opinions on Properly Carrying out the Work of Food Safety Risk Warning*. This document called for food and drug regulatory departments at all levels to prioritise the work of food safety risk warning, to extensively collect food safety risk information, to scientifically organise food safety risk assessment, to timely adopt risk warning measures, to effectively safeguard the implementation of risk warning, and to effectively push forward the work of food safety risk warning and communication. In the same year, it also launched a work mechanism according to which CFDA can warn all provincial governments about potential risks. For instance, on behalf of the State Council Food Safety Office, it notified Jiangsu provincial government about the vomiting toxin found in wheat powder; along with the Ministry of Agriculture and on behalf of the State Council Food Safety Office, it notified the monitoring progress on fipronil in eggs.

CFDA has also been expanding the forms of communication and risk alert, exploring the possibility of engaging large food enterprises in risk communication, and guiding third-party platforms to play an active role in this and in risk alert. For example, it worked with the China

Food Information Center (an independent non-profit scientific organisation engaged in communicating science-based information on food safety, and nutrition and health) to implement a regular third-party risk communication programme. It also ramped up its efforts in international cooperation and exchanges, for instance it worked with the United States, France, New Zealand, Germany and other countries and organised exchange training courses on food safety risk alerts for five consecutive years. It also deepened its cooperation with universities and research institutions, including working with Peking University to promote the application of risk communication outcomes; with Tsinghua University to assess the effectiveness of information disclosure; and with Renmin University to study the risk alert model. It also worked with the China Center for Disease Control and Prevention and with the Chinese Nutrition Society to carry out scientific researches into analysing sample inspection results, and the relationship between food and health.

2) Local level:

Although at the moment a risk communication system fully covering regulatory agencies at all government levels (national, provincial, municipal, county, and township) has not been completely established, resulting in some weaknesses in risk communication, many local governments are constantly updating and developing their concept of food safety supervision and management, and increasingly deepening their attention to risk communication dissemination.

For example, the Food Safety Committee of the Hebei grovincial government formed a food safety expert committee and established a work mechanism engaging experts in risk alert communication work; it also promulgated the *Hebei Food Safety Risk Joint Meeting System*, a system integrating the strengths of experts and the joint efforts of multiple departments to guarantee the promptness and accuracy of risk study and assessment. The Food and Drug Administration of Hebei province also holds on a quarterly basis a provincial-level joint meeting on food safety risk prevention and control, during which the member organisations of the provincial Food Safety Committee jointly analyse and evaluate the food safety situation within the province, with the objective of formulating main risk control measures. Special consultation meetings on food safety risks have also been held on an irregular basis, to discuss, study, assess, and deal with sectoral and regional food safety risks emerged from daily supervision, sampling testing and monitoring, public reporting, and media reporting. From 2015 to 2017, Hebei held a total of 12 risk prevention and control joint meetings, studied and assessed 57 risks, recognised 36 risks, deployed 15 special overhaul campaigns, arranged 12 special sampling tests, and released 12 pieces of risk alert information. Study and assessment of risk effectively played the role of a “lightning rod” in eliminating hidden food safety risks.

The Food and Drug Administration of Guizhou province experimented with a comprehensive food communication exchange centred on a big data platform – “Food Safety

Cloud". By doing so, it not only enhanced the application of big data results, but also ensured the smooth implementation of food safety alert and communication. Starting from 2017, the Food Safety Committee of the Guizhou provincial government has listed food safety eary warning and communication as a top priority in the overall food safety work. For instance, it set up a leading group on food safety risk alert and communication, comprised of 14 member organisations. It also set up a leading group on food safety statistics and alert communication, providing a solution to cross-department data exchange: food safety-related statistics collected from different government departments would be aggregated into the Food Safety Cloud, thus providing a vast amount of data for the study and assessment of risk information. The platform has a sophisticated statistical index system which facilitates the display of risk information. The establishment of this platform has strongly supported the disclosure of information to the public, particularly regarding the overall situation, affected area, and potential health hazards of food safety risks; it has also provided clear targets for the special overhaul campaigns organised by the provincial Food Safety Committee together with participation of the provincial Agricultural Committee and the provincial Administration of Grain.

6.5.3. Conclusions

At present, China is still in a stage where food safety risks are inclined to break out frequently. There is still a long and winding road ahead for the prevention of and response to food safety emergency incidents, and food safety risk communication still faces many challenges. For instance, the current risk communication system has a relatively weak foundation. Many difficulties must be overcome in order to fully execute risk communication work. The development of risk communication in China still presents a large gap with international practices and with its actual internal demand. This is mainly due to relatively underdeveloped systems and institutions, a serious shortage of professional talent, and a lack of funds. The situation is worsened by the rapid development of new media, which have frequently misled the public. Establishing an effective risk communication mechanism and setting up standards have therefore become even more pressing. As if it was not enough, the rapid advancement of science and technology, with the emergence of a large quantity of new products and new technologies in the food industry, have not only added new challenges to supervision and management work, but also made risk communication all the more difficult. Food safety incidents can easily trigger strong public reactions: once problems occur, the public and the media often show "zero tolerance" on food and drug safety issues, and government supervision will be placed under "full accountability". The requirements for risk communication have become increasingly higher.

Overall, while food safety risk communication has been gradually implemented in China, it is still not systematic enough for there to be a need to form a top-down communication mechanism to further strengthen risk communication. Moreover, after the latest round of

institutional reforms among food and drug agencies (see chapters 4 and 8 of this book), food safety risk communication is still in a severe situation and faces many challenges. There is an urgent need to vigorously promote the establishment of the food safety risk communication system, to lay a solid foundation for carrying out risk communication work, to improve its capabilities, and to effectively prevent and respond to unexpected events. At present, although domestically there is a certain level of theoretical foundation, most current research refers to theories established in other countries. These tend to be too scholarly and academic, and thus not fully understandable and recognisable by food supervision and management personnel. The public's understanding and acceptance of such theories also remains limited. Future research will therefore need to widely use social resources to study risk communication theories in the new era, factoring in the current main contradictions and the present situations. They will need to carefully choose to work with experts from scientific research institutes who have a certain level of knowledge in food and drug supervision and who have enthusiasm and expertise in the study of risk communication, and to form a set of systematic risk communication theories which caters to our development needs through.

In practice, in order to guide the risk communication work at the grassroot level, it is necessary to have a deep understanding of its situation and demands. At present, although grassoroot food supervision and management personnel have a preliminary understanding of food safety risk communication, they still hold different degrees of doubts over its role and effectiveness. They would only realise the importance of risk communication once they have to engage in emergency public relations or respond to public opinion, but do not have a sufficient understanding of the necessity of day-to-day risk communication. Staff of senior supervison and management agencies should delve deeply into the grassroot level, understand and analyse the supervision and management situation at all administrative levels under different regional regularoty models, and finally overcome problems and difficulties.

In light of the development of the domestic food and drug supervision and management system in the new era, and of the public's awareness of food safety, there is a need to absorb a positive experience from newly acquired communication theories, and to actively establish cooperative links with international organisations like the World Health Organisation and International Food Safety Association. It is also important to work together with food safety regulatory bodies in the European Union, the United States and other countries and regions. This basis should lead to the formulation by experts of risk communication guidelines suiting China's current food safety situation and identifying the overall framework for a new stage of risk communication, including principles, main actors, basic procedures, choice and effectiveness of channels, etc, thus providing an important reference to all social stakeholders in launching risk communication.

6.6. Credit management

Sun Juanjuan

The credit system originated from the "society of strangers" and market transactions, where information asymmetry complicated the attempts of both parties in a transaction to obtain mutual trust, especially in financial deals. Therefore, there is a need to rely on mutual trust to maintain the relationship the two parties, that is, to fulfil the commitments towards each other and to accumulate personal integrity and credibility over a long period of time to reduce transaction costs. Credit devices have become popular thanks to the increased diffusion of third-party and even public organisations' credit reports and credit rating systems. From the realm of ethics through to economic behaviour and legal systems, the role of credit has not only been to prioritise society over the individual but to facilitate the financing, investment and consumption behaviours of individuals and organisations. In this sense, the establishment of the online platform "Credit China" can be seen as a response to contemporary trends and the demands of the general public. That is to say, after the society of acquaintances deconstructed into the society of strangers due to the advent of the market economy, the collection, evaluation and disclosure of credit information can provide the basis for evaluation and judging the credibility and compliance abilities of a partner. Building on these foundations, rewards and punishments given to compliant and non-compliant behaviour can help to enhance the binding force of credit, thus realising a market supervision mechanism with credit at its core. Since the credit system contributes to reconstruct trust, the establishment of such a system has been regarded as a fundamentally effective solution to the existing trust crisis.

Against this background, the credit system for food safety keeps pace with contemporary currents through its usage of information tools and internet technology to tamp down credit as a cornerstone of the market economy, to achieve the free circulation of food, and to protect consumer interests. Furthermore, the disclosure of credit information has also provided a channel for the participation of consumers and the public as well as social co-governance, that is, to restrict or stimulate the behaviours of food producers and distributors by relying on responses from consumers and the public. Examining the progress made by the Chinese food safety credit system, this section will introduce three issues: the sectoral characteristics of establishing a food safety credit system; the progress made in establishing the food safety credit system with the active participation of multiple parties; and finally the synergic effect of other related systems in promoting food safety credit management, as there are important overlaps between different systems.

6.6.1. Characteristics of the food safety credit system

In addition to the above-mentioned macro level environment, there are three pressing considerations when promoting the food safety credit system. Firstly, food is a kind of good

which itself requires trust. Nowadays, food consumption mainly involves purchasing products which have entered into the food supply chain; the increasing complexity of food processing (such as the use of various food additives) as well as the continuos extension of the supply chain (especially cross-border trade), mean that poorly informed consumers would find it difficult to determine the safety and quality of food, even after eating it. Therefore, mandatory information disclosure is needed to balance the information discrepancy between producers, distributors and consumers. The disclosure of credit information can benefit consumers in their selection of food producers and distrubutors, enabling them to penalise dishonest food producers and distributors through their purchasing power. [97, 98]

Secondly, food safety in China is suffering from a crisis of trust. This was illustrated by a 2013 survey which showed that 96.22% of respondents had this belief. [99] Even though institutional reforms and amendments to legislation have enhanced supervision and management efforts since 2013, it is extremely challenging to amend the lack of trust in food safety. The establishment of a food safety credit system is one step towards healing the deficit, addressing some of the root causes. [100]

Thirdly, within food safety governance there are many laws and mechanisms employing information-based tools. However, in order to reduce the safety risk in food production and consumption, it is not only necessary to reveal the producers' qualifications and relevant safety information but to also use the information for market regulation. For example, by making decisions based on the information revealed, users of such information can urge other actors to comply with existing regulations.

Furthermore, it is noteworthy that in the *Communist Party of China Central Committee's Suggestions on Making the Outline of the 13th Five-Year Plan for the National Economic and Social Development of the People's Republic of China* (submitted in late 2015), "Internet+", "food safety" and "credit system" are three prominent topics. Among these, "Internet+" will will play a constructive role in improving the food safety governance system and the social credit system. For example, the record-filing, collection, evaluation and disclosure of credit information can benefit from information technology, which can increase the efficiency of credit management. In this regard, the integration of features in "Internet+" into the traditional credit industry offers new potential to expand the scope of credit data, reducing the cost of data collection and improving information processing.

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[97] Shi Xinzhong, "On the historical evolution of the idea of credit", *Journal of Peking University (Humanities and Social Sciences)*, 2007 No.6, p. 125.

[98] Zhang Weiying, "Social Credit system: the cornerstone for entering into modernisation", *China Reform*, 2001 No.9, p.16.

[99] Lian Yingting, "96.22% of the surveyed believed there is a trust crisis in food safety", *Legal Daily*, 13 May 2013.

[100] Department of Food Safety Supervision, State Food and Drug Safety Administration, "Food safety credit system is a measure that addresses the root cause", *Jiangxi Food Industry*, 2005 No.1, pp. 4-6.

6.6.2. Progress made in establishing the food safety credit system with the active participation of multiple parties

Administrative authorities are responsible for actively facilitating the establishment of the social credit system within their own supervision areas.[101] These include the establishment of a credit system for agricultural product quality and safety by the Ministry of Agriculture [102] and the establishment of the food and drug safety credit system by the China Food and Drug Administration (CFDA).[103] Second, local governments and relevant competent authorities have implemented specific food safety credit systems, such as those pioneered by the *Beijing Administrative Measures on the Establishment of Food and Drug Safety Supervision Credit System (trial)*, and the *Shanghai Food and Drug Administration Regulations on the Strengthening the Administration of Credit Information of Food and Drug Producers and Distributors*. Third, industry associations, third-party credit agencies and other social entities are also actively exploring approaches for establishing relevant food safety credit systems. For example, the *Guangdong Food Industry Association Implementation Measures on Credit Rating of Food Companies (trial)* recommended voluntary credit evaluation within the industry association, which will help to improve the credibility of the whole sector as well as individual enterprises.

National requirements for the establishment of the food safety credit system

In November 2015, the CFDA issued the *Guiding Opinions on Promoting the Establishment of the Food and Drug Safety Credit System*, to accelerate the establishment of a credit system for food and drug safety and to safeguard food and drug safety. According to the document, the establishment of the food and drug safety credit system is divided into three stages: during the first stage running until the end of 2016, the top-level institutional design of the food and drug safety credit system should be completed; relevant systems perfected; files on the credit information of enterprises and relevant personnel established; steps should be made to establish a credit information database; and methods explored for setting up credit rating and categorisation management standards for food and drug producers and distributors based on the characteristics of product categorisation. In short, credit rating mechanisms should be preliminary set up. The second stage, between 2017 and 2018, covers the establishment of a food and drug safety credit information database; the

[101] *Notice of the State Council on Issuing the Outline of Plan for Building the Social Credit System (2014–2020)*, (Guo Fa Announcement [2014] No. 21), State Council, 14 June 2014.

[102] *Ministry of Agriculture Guiding Opinions on Accelerating the Establishment of Credit System for Quality and Safety of Agricultural Products* (Nong Zhi Fa Announcement [2014] No.16).

[103] *China Food and Drug Administration Guiding Opinions on Promoting the Establishment of Credit System for Food and Drug Safety*, Shi Yao Jian Ji Announcement No.258 [2015], 19 November 2015. It should be noted that the China Food and Drug Administration was reorganised during the 2018 institutional reform of the State Council, and incorporated into the newly-emerged State Administration for Market Regulation (SAMR). See section 4.5 of this book for more details.

improvement of credit rating and categorisation management standards for food and drug producers and distributors; and comprehensive promotion of the new system. The third stage, from 2019 to 2020, involves the establishment of an interconnected food and drug safety credit information database among national, provincial, municipal and county-level food and drug authorities, putting into initial operation the management of food and drug production and distribution enterprises and related personnel based on credit rating and categorisation, thereby shaping a social co-governance pattern.

To further contribute towards these objectives (particularly the institulisation of credit information collection, disclosure and rating), in 2016 the CFDA issued the *Measures for the Administration of Food Safety Credit Information*. As the CFDA was also the body that rolled out the top-level institutional design for the formation, disclosure and use of credit information, it also highlighted that the food and drug administration in provinces, autonomous regions, and direct-controlled municipalities can, according to their local circumstances, formulate detailed food safety credit information administrative measures to be applied within their jurisdictions.

Local experiences in establishing the food safety credit system

The framework of the credit system in food safety supervision and management can further be refined according to local experience, at least in terms of the general content of the above-mentioned practical tasks, such as the collection of credit information, rating, disclosure and rewards and punishments. Using the *Beijing Administrative Measures on the Establishment of Food and Drug Safety Supervision Credit System (trial)* as an example, information collection can be further divided by categories of information and the establishment of a credit platform. The credit details of the principal actors involved in production and distribution can be categorised into basic information, access information, good information and bad information. As well as this, new or updated information or evaluation can be released through the food and drug safety credit information platform.

Secondly, in the assessment of credit information, in addition to the national standards which classify food production and distribution entities into trustworthy (A), basically trustworthy (B), non-compliance (C) and serious non-compliance (D),[104] it is possible to add or deduct credit, which means ratings can be constantly updated.

Thirdly, a blacklist system can be helpful to create an incentive and punishment system and allow actors to be managed according to their category. Finally, it is also noteworthy that the above-mentioned Admnistrative Measures in Beijing include provisions regarding the utilisation and credit restoration of bad information in regions other than Beijing.

[104] *China Food and Drug Administration Guiding Opinions on Promoting the Establishment of Credit System for Food and Drug Safety*, Shi Yao Jian Ji Announcement No.258 [2015], 19 November 2015.

By comparison, the application of enforcement measures in cases of non-compliance helps to highlight the role the system has in deterring undesirable behaviour. For this reason, some regions further enhanced punishment measures. For example, in the *Jiangxi Province Food and Drug Safety Credit Information and 'Blacklist' Management Measures (trial)*, blacklisted entities became the focus of greater supervision and were subject to measures such as more frequent verifications, sampling tests, and heavier penalties if further violations are identified. Moreover, it is notable that the 2016 *Guiding Opinions of the State Council on Establishing and Improving the System of Joint Incentive for Keeping Faith and Joint Punishment for Losing Faith and Accelerating the Advancement of the Development of Social Honesty* clearly outlines that the food industry will feature a joint punishment system. With the development of this, dishonest agents will not only be subject to intensive sampling testing and a higher licensing threshold in the food and drug administration system but will also face administrative restraints and penalties in cross-region, cross-sector and cross-field procedures.

Establishment and development of the "agricultural safety credit"

As far as practical implementation is concerned, in addition to strengthened inspections and verifications on non-compliance entites through the use of the blacklist or of the list of key supervisees, the credit system in the food sector is also still being refined, namely through specifically targeting particular segments or individual products. For instance, the establishment of a "credit system for agricultural product quality and safety" specifically targeting agricultural inputs and products, also in progress at the time of writing, refines the agricultural products credit system. The inclusion of the safety of edible agricultural products not only reflects the application of the credit system to the primary production segment, but also incorporates two special issues relevant to edible agricultural products.

First, although the advancement of modern agriculture has changed the nature of large-scale models of production and distribution, enabling the safety management of raw materials and of the production process through modelled management systems, small-scale decentralised farming is still the main form of agricultural production.

Even in the long term, this is unlikely to change radically. Because of this, it remains a formidable challenge to establish a credit system in edible agricultural products, particularly over the regulation of scattered individual farmers and of a large number of small and medium-sized rural enterprises.

In fact, producers and distributors differ in size as well as in capacity, resources and compliance willingness. By contrast, credit or reputation is an important economic and social capital for large enterprises, and the disclosure of credit and blacklist information can therefore represent an effective way of regulating these. As for small or individual investors, information constraints may be rendered ineffective due to the low market awareness of

these entities and the small penalities of violating the law. But as the role of the credit system extends beyond the punishment of non-compliance behaviours to include rewards for trustworthiness, it is possible to incentivise small-scale farmers to recognise the value of credit and to improve their production – especially the safety of edible agricultural products through easily accessible financial loans or agricultural subsidies.

Second, because edible agricultural products are not only used directly for consumption, but also as important raw materials for many processed food products, food safety often emphasises the safety of the source – namely in primary agricultural production.

However, this means that the agricultural environment and agricultural inputs used in the farming process are the real source of the food supply chain. Historical accidents have also shown that the abuse of pesticides and feed not only affect the health of animals and plants, but also have an impact on human health and safety from animal and plant consumption. Hence the establishment of an "agricultural safety credit" should also take into account the safe use of such agricultural inputs, and should make full use of producers and distributors' credit and blacklist information disclosure to ensure the safety of edible agricultural products from the source. This is reflected in the *Ministry of Agriculture Guiding Opinions on Accelerating the Establishment of Credit System for Quality and Safety of Agricultural Products* released in 2014 (see footnote n. 102), which clearly stipulates that the focus of establishing agricultural product quality and a safety credit system should not be limited to agricultural products, but should also include agricultural inputs, in which manufacturers and distributors of seeds, pesticides, fertilisers, veterinary drugs, and feed are central.

As far as practical progress is concerned, under the existing institutional framework there is no clear certificate for the geographical indication of general edible agro-products other than the quality certification system of "three products, one indication" (i.e. pollution-free agro-products, green food products and organic agro-products; agro-product geographical indication). In this respect, to further enhance the link between, on one hand, place-of-origin management with quality conformance of agro-products at its core, and market entry management on the other, in July 2016 the Ministry of Agriculture decided to pilot a quality certificate management system for major edible agro-products in selected provinces including Hebei, Heilongjiang, Zhejiang, Shandong, Hunan, Shaanxi. On this basis, Zhejiang became the first province in China to fully activate the quality certification scheme of edible agro-products, after the provincial agriculture, forestry and fishery departments published the *Zhejiang Province Measures on the Administration of Quality Certificates for Edible Agro-products*. After the measures came into force in May 2017, large-scale agricultural producers in Zhejiang province were required to spontaneously issue quality and safety certification marks for their edible agricultural products. At an experience-sharing meeting in August 2017, the Ministry of Agriculture remarked that the certification of edible agricultural products is

an important vehicle for achieving quality-driven prosperity in agriculture, and therefore top-level institutional design should be strengthened, and relevant laws and regulations formulated to achieve a unified nation-wide management system. Accordingly, the "certificates" of the pilot programme indicate the qualification of edible agro-products in the form of self-declarations. Furthermore, by being included into the credit system, the measures provoke food producers and distributors to take control measures to ensure the safety of the agricultural products they sell by enforcing thresholds for market access.[105]

6.6.3. The synergic effect of other relevant systems

To promote a credit system on the basis of the existing institutional framework, the overlaps between different systems should also be taken into account. That is to say, when there are many different systems to guarantee food safety, these systems should be organically combined together, through mutual coordination and cooperation, so that a broad church of views has influenced their behaviour. In other words, in the absence of a complete information-related supporting system, the credit system cannot play an effective role by itself, and therefore it should be combined with the institutional requirements that already exist for producers and distributors such as the food safety traceability system. The *Food Safety Law* does not require producers and distributors to use information technology to collect and retain production and distribution information; however, in the process of promoting digitalised supervision, local governments would ensure food traceability through government-led traceability platforms, and build credit profiles of relevant producers and distributors by using the certificates and inspection results uploaded to such platform, such as the Shenzhen food safety traceability credit management system. It is noteworthy that the electronic traceability system can be used as an internal management system for large-scale food producers and distributors, thus achieving multiple goals including legal compliance, public-private partnership and the fulfilment of the safety demands of the public. For small and medium-sized food producers and distributors, the morphing of this technology into internal management processes still presents a cost issue. Moreover, compared with large food producers and oeprators, the binding force of the credit system on small-scale producers and distributors is relatively weak. Therefore, the question of how to regulate the safety obligations of small-scale food producers and distributors through "elastic rules" remains a tricky issue in the establishment of a credit system.

On the other hand, establishing a government-led credit system requires that the record-filing, collection and disclosure of credit information are digitally based. Above all, in the fulfilment of its duties the government will record a large amount of information related to the credit status of relevant actors, such as the results of sampling tests or administrative

[105] Ministry of Agriculture, "Agro-products sold on market, from quality conformance by default to quality conformance by indication [N]", *Xinhua Net*, 27 July 2016 (updated 23 December 2016): http://news.xinhuanet.com/food/2016-07/27/c_129183038.htm.

punishment data. Although relevant information may be stored within different organisations or institutions as a result of the division of responsibilities, digitalised management can overcome issues such as fragmentation in record-filing and isolated information-sharing. Compared to technology requirements, there is an even stronger need to enhance the obligation requirements for the digitisation of government affairs, especially in response to the modern trend of data disclosure. Finally, increased digitalisation will also contribute to the openness of government data and information, promoting social co-governance of food safety through government transparency, external participation and social cooperation.

Although the food safety credit system has been regarded as the fundamental solution to the crisis of trust in food safety, the establishment and improvement of "institutional trust" not only lies in the government's ability to commit to corresponding institutional arrangements, but also in whether the public truly believe that enforcement authorities can fulfill their commitments.[106] For this reason, institutional trust itself is intimately linked to broad societal trust in the government. Internet-based online governance has provided a new opportunity to improve the trust in government: differing from the regulatory model set up by the market and by different levels of bureaucracy, the diversity, value convergence, and action dependence that characterise the internet requires assistance from coordination, information disclosure, guidance and mobilisation to build diversified forms of governance. Through the benign interaction of cooperation and mutual benefit, existing problems will be solved and trust promoted.[107] In this regard, the principle of social co-governance, the requirements for information disclosure and risk communication, the assessment on performance and accountability stipulated in the *Food Safety Law*, can all help to improve the performance of government agencies in implementing food safety related systems, thus improving the public's satisfaction and ultimately their trust in the efforts made to ensure food safety.

6.6.4. Conclusions

In China, the food safety credit system has become an important instrument to ensure food safety. However, to improve the role of such tool – no matter if through top-down institutional refinement, cooperation among different entities, or synergy between different systems – requires the joint efforts of information-sharing, mutual recognition of ratings, and joint punishment. Still, facing the existing differences in the institutional building among different local governments and departments, as well as a new reform of the food supervision and administration system, the question of how to integrate existing food safety credit systems will continue to be the focus and a challenge in the future.

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[106] Zou Yuchun, "Improving institutional trust: an important direction to ensure the positive functioning of government", *China Development Report*, 2014 No.8, p. 40.

[107] Yin Yifen, "Online governance: the new framework for public management", *Journal of Public Management*, 2007 No.1, pp. 89-96.

Chapter Seven

Examples of specific safety supervision and management mechanisms for certain food types

The *Food Safety Law of the People's Republic of China* and other relevant laws and regulations provide basic legal principles and institutional requirements for the supervision and management of foods. On this basis, because of reasons such as segmented regulation, scientific relevance or epochal challenges, the supervision and management of particular food types present specific characteristics.

The first section of this chapter introduces edible agricultural products as they are primary products which are supervised on the basis of different segments along the production and distribution chain, and at the same time have become a point of focus due to the "governance of the origin of the supply chain" concept stipulated in the *Law on Quality and Safety of Agricultural Products*. The second section is related to dairy products, which is a key regulatory subject not only because of the strict supervision to which it has been subject after the 2008 crisis, but also because it is a topic of great concern both in China and overseas. The supervision of dairy products helps to promotes the healthy development of the industry. The third section of this chapter focuses on special food, which in China refers to health food, food for special medical purposes (FSMP), and infant formulas (including infant formula milk powder). The supervision and management of special food as a whole – thus including all three categories of special food [108] – emerged after the revision of the *Food Safety Law*, which set new requirements for systems and mechanisms development. The fourth section covers imported and exported food, which will contribute to a better understanding from the European Union's and other countries' perspective of China's specific requirements in this area, so as to better promote food circulation and safety within international trade. The fifth section introduces the supervision and management of novel food raw material: it will not only help overseas countries to better understand of the institutional requirements for the entry of novel food ingredients into China, but also to understand how food regulation integrates scientific assessment and cultural factors. The final section of this chapter focuses on food sold online, especially on online catering business, reflecting the advanced supervision and management experiences of Chinese authorities in the Internet era. As the

[108] Infant formula, foods for special medical purposes and health foods (food supplements in Europe).

first country in the world to formulate regulations for food sold online, China's experience and challenges in this area can serve as a model to be applied in other countries.

7.1. Edible agricultural products

*Tian Feng**

The quality and safety of agricultural products directly affect food safety and people's health. The "Sanlu milk powder" incident of 2008, the "lean meat" incident of 2011, and the later "toxic cowpea" and "toxic ginger" incidents drew great attention from the public and the government to the quality and safety of agricultural products. The government has adopted a series of measures, launched campaigns, and strengthened supervision and management to ensure the quality and safety of agricultural products to re-boost consumers' confidence. Thanks to these efforts, the overall qualification rate of China's agricultural product has now reached about 97%, and public satisfaction is also on the rise each year.

7.1.1. China's legal system for the quality and safety of agricultural products

Legislation of agricultural products quality and safety

China's agricultural product quality and safety legislation consists of three levels: laws, administrative regulations, and departmental rules.

Regarding the first level – laws, the *Law on Quality and Safety of Agricultural Products* enacted in 2006 is the fundamental law governing the quality and safety of agricultural products. It covers the entire process of agricultural products, from the place of production to the market. Before the entry into force of this law, the concept of food safety in China was still limited to food hygiene, and laws and regulations such as the *Food Hygiene Law* and *Product Quality Law* failed to cover the cultivation stage of agricultural products. Nonetheless, government authorities still exercised supervision and management of agricultural products. For instance, in 2001 and in 2002 the Ministry of Agriculture (MOA) promulgated the *Harmless Food Action Plan* and the *Administrative Measures for Harmless Agricultural Products*, respectively, in order to meet the needs of agricultural development and improve the quality, safety and market competitiveness of China's agricultural products. In addition to the *Law on Quality and Safety of Agricultural Products*, the *Food Safety Law* is another major piece of legislation, first promulgated in 2009 and then revised in 2015, and it

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is commonly referred to as "the strictest law in history". In terms of agricultural products, the *Food Safety Law* mainly covers agricultural input products, the sales of edible agricultural products, the formulation of safety standards, and the publication of relevant safety information. Furthermore, in response to the rising number of food safety cases, in 2013 the Supreme People's Court and the Supreme People's Procuratorate jointly issued judicial interpretations for handling food safety crimes, whose strictness in terms of punishment show the authority's strong determination to tackle the grim situation of food safety. For instance, individuals who misuse or overuse additives, pesticides and veterinary drugs in the growing, breeding, selling, transporting, and storing of edible agricultural products, in amounts that can potentially cause serious food poisoning accidents or other serious food-borne diseases, as well as individuals who use prohibited substances such as banned pesticides, veterinary drugs, or other toxic and hazardous substances, shall be convicted of crimes of producing and selling substandard, toxic and harmful foods.

Regarding the second level – administrative regulations, in 2007 the State Council issued the *Special Provisions of the State Council on Strengthening Supervision and Administration of the Safety of Food and Other Products* (hereinafter referred to as the "Special Provisions"), aiming at strengthening safety supervision and management of food products (including edible agricultural products), defining the responsibilities of producers, supervision and management authorities and local people's governments, and strengthening the coordination and cooperation among various supervision and management authorities in order to ensure public health. The scope of application of the Special Provisions is very broad: they apply to situations not covered by relevant laws, or where the provisions of laws are not clear. Therefore, it is fair to describe them as the bottom-line regulation governing agriculture quality and safety supervision and management. At the same time, administrative regulations also contain rules governing agricultural input products such as pesticides, veterinary drugs, feeds and feed additives. They serve as effective supplements to the supervision and management of agricultural product quality safety.

Departmental rules mainly involve supporting measures related to the supervision and management of the quality and safety of agricultural products, such as the *Administrative Measures on Quality and Safety Monitoring of Agricultural Products*, the *Administrative Measures for the Safety of Places of Origin of Agricultural Products*, the *Administrative Measures on Agricultural Product Packaging and Labelling*, the *Administrative Measures on Harmless Agricultural Products,* and the *Agricultural Products Geographical Indications*.

At the same time, some local authorities have also formulated local administrative regulations according to local conditions, which are relatively more targeted and operational.

Implementation of the Law on Quality and Safety of Agricultural Products in China

The author of this section in the past conducted a survey among provincial agricultural legislation authorities and some grassroot law enforcement agencies in 31 provinces,

municipalities and autonomous regions across the country. 71% responded that they were familiar with relevant provisions of the *Law on Quality and Safety of Agricultural Products*, but 29% were not. Moreover, 60% of survey respondents stated that there were many challenges in implementing the law, the top three of which being institutional flaws, lack of funding, and unsound team. Moreover, the *Law on Quality and Safety of Agricultural Products* itself is also not very operational. For example, it requires the government to designate the areas regarded unsuitable for the production of specific agricultural products as prohibited production areas. However, the provisions fail to define corresponding legal responsibilities, thus such requirements were seldomly applied in practice. It is precisely because of the above reason that the number of investigations involving the quality and safety of agricultural products is far lower than that of agricultural input products. In recent years, problems concerning the most commonly consumed agricultural products such as leek, bean sprouts, Chinese cabbage, ginger, and garlic were exposed. Public concerns over the safety of agricultural products have been on the rise, prompting local governments to pay more attention to law enforcement. But despite this, even in those provinces with excellent law enforcement performance, the annual number of cases involving agricultural products quality and safety was limited to around 30; for some provinces, the number was zero. For this reason, in 2017 the General Office of MOA issued the *Opinions of MOA on Strengthening the Law Enforcement of Quality and Safety of Agricultural Products*. The Opinions guide local agricultural authorities to clearly define law enforcement responsibilities, strengthen law enforcement, improve mechanisms, and enhance capabilities so as to improve quality and safety of agricultural products. At the same time, quality assessment, food safety assessment, and performance extension assessment shall be utilised at local levels for law enforcement, routine inspections, and supervision of production and distribution actors. In 2017, MOA announced for the first time nine typical cases of quality and safety of agricultural products nationwide.

The vagueness of legal concepts also leads to certain confusion in the application of laws. The *Food Safety Law* and the *Law on Quality and Safety of Agricultural Products* both define the concepts of agricultural products and food respectively. The revised *Food Safety Law* defines “food” as a variety of finished product and raw material for human consumption or drinking; it also includes the objects that are both Chinese herbal medicines and food by tradition, but do not include objects for the purpose of treatment. At the same time, Article 2 of the *Food Safety Law* stipulates that edible agricultural products are primary products for consumption derived from agriculture, a definition that originates from that of agricultural products contained in the *Law on Quality and Safety of Agricultural Products*, which is, primary products derived from agriculture. However, these two laws do not further define “derived from agriculture” and “primary products”, making it difficult to distinguish the nature of some products. For example, the debate over whether bean sprouts belong to food or agricultural products has never ceased. In China, the concepts of “food” and “edible

agricultural products" are not strictly differentiated. Food is generally a broader concept that includes edible agricultural products unless "edible agricultural products" are specifically mentioned. The reason why the concepts of food and edible agricultural products need to be distinguished is because China implements a model of segmented regulation over food safety. For example, if a bean sprout product is defined as a processed product (so as food), the supervision and management over its production process will fall under the responsibility of food and drug authorities; but if the production of bean sprouts is defined as agricultural production (so as agricultural product), agricultural authorities will be responsible supervision and management. The same problem also exists in some simple dried and peeled products as it is difficult to distinguish their nature, often generating confusion in terms of which grassroot regulatory agency should be responsible. Such confusing concepts have also led to many embarrassments where different judgments are made for the same kind of cases.

In addition, the *Law on Quality and Safety of Agricultural Products* stipulates that local agricultural administrative authorities at or above county level are the responsible bodies for the supervision and management of agricultural product quality and safety. In 2013, the General Office of the State Council issued the *Notice of the General Office of the State Council on Strengthening the Supervision over the Quality and Safety of Agricultural Products*, reserving special emphasis on integrating the supervision and law enforcement of agricultural products quality and safety into the scope of comprehensive agricultural law enforcement. Therefore, at present, most of the agricultural product quality and safety law enforcement is undertaken by local comprehensive agricultural law enforcement agencies. But in these agencies there still are challenges in keeping up with the requirements for the supervision and enforcement, both in terms of number and quality of personnel.

7.1.2. China's supervision and management system for the quality and safety of agricultural products

China's food safety supervision and management models, and duties of supervisors

Since 1949, China has carried out many reforms and adjustments at the central level to the supervision and management of food (including edible agricultural products). The supervision and management system has consequently undergone three shifts, from the initial planned supervision and management system where the health authority played a supporting role, to one of segmented regulation by different authorities, to one which is relatively unified. The number of China's food regulatory authorities is declining, moving toward a more unified and authoritative direction. As far as the safety supervision of edible agricultural products is concerned, the 2013 State Council's *Institutional Reform and Function Transformation Plan* stipulated that before edible agricultural products can enter the wholesale market, retail market, and production and processing enterprises (hereinafter referred to as the "three befores"), they shall first be supervised by the agricultural authority.

After entering the wholesale market, the retail market, and production and processing enterprises (hereinafter referred to as the "three afters"), they shall be supervised by the food and drug authority. At the same time, the Plan also transferred supervision authority for hog slaughter from the Ministry of Commerce to MOA. The reform and the new *Food Safety Law* gave the overall coordination power of food safety to CFDA, forming a centralised supervisory system. The ping-pong of responsibilities among different authorities has, as a result, diminished in line with the decrease of the number of responsible authorities; however, it has not been completely eliminated. For example, at present, the division of responsibility between the food and drug and the agricultural authorities in "three befores and three afters" of agricultural products is relatively clear. But neither the supervisory bodies nor the supervisory approaches are specified for many other segments of the from farm to market chain, such as the purchase, storage and transportation: in these processes, there are certain overlaps of functions between the food and drug and the agricultural authorities, together with regulatory vacuums. In 2017, the "goats killed by poisonous onion" incident exposed the lack of supervision over purchase, storage, and transportation.[109]

In contrast to the central level, in 2013 the State Council released the *Guiding Opinions of the State Council on Local Reforms to Improve the Food and Drug Supervision and Management System*, emphasising that local governments at all levels should, in principle, refer to the State Council's integration model for food and drug regulatory agencies; integrate within the food and drug administrative authority all the supervisory functions of the Food Safety Commission Office, the industry and commerce authority, and the quality supervision authorities; while the agricultural authority was still responsible for the supervision of quality and safety of agricultural products. It is worth mentioning that when it comes to the supervision and management of bean sprouts products, the decision over which body should assume competence was left to local governments, while at the central level the supervision remained the joint responsibility of the agricultural authority and the food and drug authority.

Supervision and management system for the quality and safety of agricultural products

The supervision and management system for the quality and safety of agricultural products is an important institutional guarantee for agricultural authorities at all levels to perform their supervisory duties. Following the promulgation and implementation of the *Law on Quality and Safety of Agricultural Products* in 2006, China has gradually established a top-down quality and safety supervision and management system for agricultural products. In 2008, MOA established the Agricultural Product Quality and Safety Supervision Bureau, responsible for organising and conducting agricultural product quality and safety risk assessments, supervision and sampling tests, and law enforcement supervision. After ten years of efforts, 97% of the townships, 80% of the cities and counties, and all provincial-level

[109] Further analysis on the institutional reform can be found in chapter 4 of this book.

agricultural authorities had set up agricultural product quality and safety supervision agencies. From then on, agencies, personnel, funds, and regulatory means were put in place at all levels in order to regulate agricultural products. At the same time, in some areas, agricultural product quality and safety supervisors are hired at village-level, making the supervision and management of agricultural product quality safety dive further into the grassroots community. Nevertheless, the current agricultural product quality and safety supervision and management system still remains incomplete; the capacity of townships agencies is still relatively weak; the regulatory targets are complex; and it is still difficult for the government to undertake such a large volume of regulatory tasks.

Standardisation system for the quality and safety of agricultural products

Quality and safety standards of agricultural products are not only a crucial basis for government law enforcement; they also represent an important technical guarantee supporting and normalising production and distribution. Quality and safety standards of agricultural products include two major aspects: one is the maximum residue limits, and the other is production technical standards, and inspection and testing method standards. During the 12th Five-Year Plan period (2011-2015), China formulated 4,140 pesticide residue limit standards and 1,584 veterinary drug residue limit standards, basically covering all of China's main edible agricultural products and commonly used pesticides and veterinary drugs. China also formulated and issued 5,121 agricultural industry standards and 18,000 technical standards for agricultural production, covering production environment, agricultural input products, production specifications, product quality, safety limits, testing methods, packaging and labelling, and storage and transportation. At present, productions in agricultural cooperatives and family farms can basically meet the standards. It is worth mentioning that after the revision of the *Food Safety Law* in 2015, pesticide and veterinary drug residues as well as food-related testing methods and procedures were incorporated into the food safety standards system; the responsible authorities for the formulation of standards were designated to be the health, agricultural, and food and drug administrative authorities within the State Council.

Testing system for the quality and safety of agricultural products

Monitoring of the quality and safety of agricultural products in China began in the 1980s, although the targets and types monitored were on a relatively small-scale. After the implementation of the *Harmless Food Action Plan* in 2001, pilot programmes for the routine monitoring of agricultural products were carried out in some provinces and municipalities. In 2004 and 2005, monitoring of pesticides and veterinary drugs, lean meat, and aquatic products was comprehensively launched. From 2006 to 2015, China carried out two phases of system-building for the quality and safety testing of agricultural products; 2,770 quality inspection agencies within ministries, provinces, prefectures, and counties were also

established, employing a total of 35,000 inspection personnel. So far, China has put in place a quality and safety monitoring system for key agricultural products and for agricultural input products, comprised of routine monitoring, supervision and sampling tests in production sites, wholesale markets, supermarkets and other stages. The monitoring covers 109 products of five major categories of over 150 large and medium-sized cities in 31 provinces (regions, and municipalities), including vegetables, fruits, tea, livestock and poultry products, and aquatic products; for each of these more than 90 indicators are examined. In 2017, the overall nation-wide qualification rate of agricultural products reached 97.8%; among these, the qualification rate for vegetables, livestock and poultry products, and aquatic products was 97%, 99.5% and 96.3%, respectively.

7.1.3. China's supervision and management mechanisms for the quality and safety of agricultural products

Quality and safety information disclosure mechanisms for agricultural products

Consumer' confidence towards the quality and safety of agricultural products is based on information disclosure. Food safety supervision and management must, therefore, be transparent to the public.[110] In 2006, the *Law on Agricultural Products Quality and Safety* established a system for information disclosure. In 2010, the *Measures for the Administration of Agricultural Products Quality and Safety Information Disclosure* issued by MOA stipulated detailed provisions regarding the main body responsible for information disclosure, as well as regarding the contents and procedures of disclosure. The disclosure of information currently follows the requirements of the new *Food Safety Law*, which implements a unified system for food safety-related information disclosure consisting of the publication, by the State Council's food and drug authority, of information relating to the overall food safety situation in China, food safety risk warnings, major food safety incidents, investigation and prosecution information, as well as other information that the State Council deems necessary to be disclosed. Local food and drug, quality supervision, and agricultural administrative authorities at or above county level shall publish daily supervision and management information in accordance with their respective responsibilities.

Market access mechanism

Agricultural product market access means that only agricultural products that meet the relevant quality and safety standards can be sold on the market. Market access is a key segment along the "from farm to fork" chain, as it controls, through obligation, the quality and safety of agricultural products entering the market. The *Food Safety Law* does not require a permit for the sale of edible agricultural products in China; but it does require food producers to check the supplier's license and product quality certification during procurement,

[110] Huang Yali, "*American Food Safety Supervision System and its Enlightenment to China*", Shaanxi Normal University, Master's Degree Thesis, 2014.

and that food ingredients without certification must be examined according food safety standards. Therefore, this can be considered as another form of market access threshold. In particular, after CFDA issued, at the end of 2015, the *Measures for the Administration of Quality and Safety of Edible Agricultural Products in the Market,* agricultural authorities actively increased their efforts to implement the certification for edible agricultural products. In 2016, the Ministry of Agriculture issued the *Measures for the Administration of Certification of Edible Agricultural Products*, and pilot programmes on food and agricultural product certification were launched in six provinces including Zhejiang and Shandong. Under these programmes, producers and distributors of edible agricultural products may, by means of self-inspection, entrusted inspection, internal quality control, and self-commitment statement, issue quality and safety certification labels for their own products. At the same time, these programmes also allow the following items to be regarded as self-issued quality and safety certification labels: valid certificates or registration copies of harmless agricultural products, green food, organic agricultural products, and agricultural products with geographical indication; valid quality and safety traceability labels for edible agricultural products; and meat qualification stamps. These pilot programmes exemplify how the certification system requires joint efforts from both the food and drug authorities, on one hand, and agricultural authorities on the other.

Traceability management mechanism

The requirements of the traceability system are clearly outlined in the revised *Food Safety Law*. The food and drug administrative authority of the State council, together with relevant authorities such as the agricultural authority, must establish a whole-process traceability coordination mechanism for food safety; while food producers and distributors are the main implementers of the traceability system, and thus must ensure that food is traceable.

In terms of the specific approaches, methods and legal liabilities for traceability management, the *Food Safety Law* does not impose mandatory requirements. At present, at the national level, MOA has established a national agricultural product traceability platform, and trial-runs were carried out in 2017 in Sichuan, Guangdong and Shandong provinces. In the same year, MOA also formulated the *Measures for Traceability Management of Agricultural Products* and relevant technical standards and norms. Many regions have also set up the platforms for tracing agricultural products. However, since the law does not impose mandatory requirements, food producers and distributors have not been particularly enthusiastic towards the platform; moreover, data across different platforms is not interconnected. As a result, the efficacy of the traceability system is not satisfactory.

Quality marks on environment and geographic indications

MOA began certificating Green Food in the early 1990s. After the implementation of the *Harmless Food Action Plan* in 2001, the certification for harmless agricultural products and

organic food also began. In 2005, China also started to label specialty agricultural products produced in specific areas with their geographic indications. At present, the total number of valid harmless agricultural products, green foods, organic foods and products of geographical indication has reached 107,000, accounting to 40% of the total number of agricultural products. These have better met the needs of urban and rural consumers. At the same time, branded agricultural products have already become the main components of agricultural exports, playing a leading and model role.[111]

7.1.4. Conclusions

In recent years, the Chinese government has devoted great efforts to food safety governance. The regulatory system has been streamlined, the supervisory responsibilities among different authorities have been clarified, supervision personnel has been reinforced, and supervisory capabilities have been improved. In particular, China started a campaign to develop the National Agricultural Quality and Safety Counties in 2014. Such counties play a leading role in the institutional development, standardised production, whole-process monitoring, whole-process traceability, and credit system development of agricultural product quality and safety supervision and management. Two batches of counties have been certified or developed so far. At the same time, the interpretation and implementation of the system must be safeguarded by the law. In particular, after the State Council's institutional reform in 2013, the adjustment of responsibilities of the agricultural and the food and drug authorities, as well as the existing laws and provisions for agricultural product quality and safety, remained disconnected or in conflict, generating troubles in law enforcement at the local level. Therefore, MOA began the revision of the *Law on Agricultural Product Quality and Safety* in 2014 and carried out extensive research. The revision adheres to the principles of "governance of the source, risk prevention and control, and social co-governance", and special attention is paid to the whole-process supervision and control covering agricultural input products, source environment, production processes, and storage and transportation. The revision not only intensifies the degree of punishment, but also takes into consideration the matching between violation and penalty, ensuring the full application of legal liabilities stipulated in the law. Currently, after the latest 2018 round of institutional reform of the State Council, supervision and management responsibilities for the quality and safety of agricultural products have been further clarified, and the trend and requirements for comprehensive law enforcement in agriculture sector further developed, making it more urgent and necessary to revise the relevant agricultural product laws.

[111] Ministry of Agriculture, "Press Conference to Promote the Quality of Agriculture and Ensure the Safety of Agricultural Products" (2017-8-17). http://www.moa.gov.cn/hdllm/zbft/ncpxfygqk/.

7.2. Quality and safety of dairy products

*Guo Liya**

The quality and safety of dairy products affects nutritional safety and consumer health. The Chinese government has always attached great importance to this issue and has introduced a series of policies to strengthen supervision and management of the quality and safety of dairy products to protect consumers. In recent years, China's continuous socio-economic development has led to positive changes in the supervision and management of dairy products and in the development of the dairy industry. The year 2008 was a turning point in this regard: it marked the shift of the conventional approach of "segmented regulation" targeting different segments of the production and distribution chain into a new form of high-pressure and specialised supervision and management. This shift, which was triggered by the "infant milk powder" incident that year, significantly influenced national food safety supervision and management. The Chinese government has since issued major new laws and regulations such as the *Food Safety Law*, the *Regulations on the Supervision and Management of Dairy Quality and Safety,* and the *Interpretations on Several Issues concerning the Application of Law in the Handling of Criminal Cases of Jeopardising Food Safety*; it also published the *Outlines of the Programme on Rectification and Revitalisation of the Dairy Industry*, and promulgated 66 compulsory standards for dairy safety such as the *National Food Safety Standard – Raw Milk*. These initiatives clarified the supervision and management responsibilities of government authorities. The National Centre for Food Safety Risk Assessment was also established and reforms on food (including dairy products) safety research, analysis, risk alert and technological innovation were launched.

7.2.1. Institutional and functional changes in the supervision and management of dairy products quality and safety

Following the 2008 milk powder scandal, China further intensified and increased the level of regulation of dairy products safety. In October that year, China's first specialised dairy regulation – the *Regulations on the Supervision and Management of the Quality and Safety of Dairy Products* (hereinafter refers to the "Dairy Regulations") were implemented, marking the beginning of dedicated and specialised supervision and management of dairy products. The Dairy Regulations not only bridged the gap in China's regulatory system for dairy products, but also reformed the country's food safety regulatory system in general, by providing a legal basis for the rectification, rejuvenation, and healthy development of China's dairy industry.

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According to the Dairy Regulations, local governments at and above county level shall be responsible for the overall supervision and management over the quality and safety of the dairy products within their respective jurisdictions. Their stockbreeding and veterinary administrative departments were made responsible for the supervision and management of dairy animals and the production and purchase of fresh milk. Their quality supervision, inspection and quarantine administrative departments were made responsible for the supervision and management over the production, import and export of dairy products. Their industry and commerce administrative departments became responsible for the supervision and management over the sale of dairy products; their food and drug administrative departments were made responsible for the supervision and management over the catering services relating to dairy products. Within their respective functions, other relevant departments were made responsible for other tasks relevant to the supervision and management of the quality and safety of dairy products. National standards for dairy quality and safety were now formulated by the health administrative authorities of the State Council and shall be promptly revised based on risk monitoring and assessment results.

After the 2013 institutional reform, the newly-formed China Food and Drug Administration (CFDA) took responsibility for exercising unified safety supervision and management in the production, circulation, and consumption of dairy products. The also newly-formed National Health and Family Planning Commission (NHFPC) became responsible for conducting dairy safety risk assessments, and for developing food safety standards. The Ministry of Agriculture (MOA) became responsible for quality and safety supervision and management over cow breeding, raw milk procurement stations, and raw milk production and transportation. This major institutional reform enabled the Chinese government to centralise administrative functions and to reduce regulatory procedures, ensuring the effectiveness and systematisation of the supervision and management of food, especially concerning dairy products. This was further achieved with the latest round of institutional reform in 2018, with the establishment of the State Administration for Market Regulation (SAMR), which aims to solve repetitive enforcement by different government agencies at different levels, to reform the market regulation system, and to unify market regulation. The new institutional layout centralises the management of food production, operation, circulation, consumption, quality supervision, price supervision, and anti-monopoly; supervision and management responsibilities are integrated and further simplified to achieve greater efficiency. With the new round of institutional reform, China's dairy quality and safety supervision and management enters a new phase of adjustment and gradual optimisation.

7.2.2. Current status and changes of supervision and management of dairy products quality and safety

Under the leadership of the State Council, China's dairy quality and safety supervision and management work has been solidly implemented and advanced. Since 2008,

responsibilities have been further clarified, measures haven been further strengthened, and penalties have been further intensified. New works, new arrangements and new reforms have continued to develop, providing a strong guarantee for the quality and safety of dairy products.

State Council's "six key works" for dairy products: performing the leading role in supervision and management

In 2010, the General Office of the State Council issued the *Notice on Further Strengthening the Quality and Safety Work of Dairy Products*, to stress the quality and safety supervision and management of dairy products. Specifically, the Notice outlined 22 tasks to undertake in six key areas:

- In terms of distribution, the Notice requires strict control of production and distribution licensing, and strengthened dairy products industry management. Raw milk purchase, transportation licensing and dairy product circulation licensing should be strictly managed;
- In terms of inspection and testing, the Notice requires the strengthening of the examination of raw milk, raw milk powder, and feed for dairy animals; the enhancement of the inspection of dairy products upon exiting the factory and during the circulation; and the effective monitoring and assessment of risks to raise the overall level of inspection efficiency;
- In terms of system development, the Notice requires the improvement of the traceability system for dairy products, the establishment and improvement of the certification and ticket verification system, the improvement of the purchase inspection system, and the establishment of the electronic information tracing system;
- In terms of milk powder regulation, the Notice requires the strengthening of the supervision and management of infant formulas. Hazard Analysis and Critical Control Point (HACCP) system review shall be enhanced, the factory-stationed inspector mechanism shall be strictly implemented, and the supervision and management during circulation shall be strengthened;
- In terms of law enforcement, the Notice requires strengthened efforts to crack down and punish the illegal production and distribution of dairy products. The "criminal retreat" for illegal activities shall be eliminated, investigation shall be reinforced, and punishment shall be intensified, and social supervision shall be encouraged;
- In terms of the supervision of responsibilities, the Notice requires the strict fulfilment of the responsibilities of all parties involved in dairy quality and safety. Enterprises should earnestly fulfil their primary responsibility for food safety. Local governments have overall responsibility for the quality and safety of dairy products in their respective jurisdictions. Relevant authorities must fulfil their own responsibility and

cooperate closely.

New deployment of dairy products' supervision and management work: responding to the new needs of development

In 2012, the State further enhanced the food (including dairy products) safety regulatory framework and issued the *Decision of the State Council on Strengthening Food Safety.* The Decision outlined dairy safety work as a priority, reinforcing the imperative to improve the safety supervision and management system, enhancing regulation, and implementing the primary responsibility of producers and distributors. The *12th Five-Year Plan for the Food Safety Supervision and Management System* issued around the same time highlighted the achievement of all-angle supervision and management and comprehensive food industry safety protection. These shall be done from the aspects of laws and regulations, standards, monitoring and assessment, inspection and testing, whole-process control, import and export food safety regulation, emergency management, comprehensive coordination, science and technology support, food safety credibility, and education and training.

Key areas of dairy products regulation: safeguarding the health of infants and children

The work around the quality and safety of infant formulas is a top priority within the supervision and management of dairy products. The Chinese government focuses on strengthening supervision and management to improve the quality of milk powder and to ensure the health of infants and young children. In 2013, the State Council issued the *Notice on Opinions for Further Improving the Quality and Safety of Infant Formula Milk Powder,* which elevated the quality and safety of infant formulas to the highest level of concern in relation to livelihoods and socio-economic development, assigned infant formula quality and safety as a key breakthrough point for achieving overall food safety, and aimed to recapture consumer confidence towards domestically produced milk powder.

In terms of administration of infant formulas production, the *Detailed Rules on Production License Examination for Infant-formula Milk Powder Producers (2013 Version)* and *Good Manufacturing Practice of Powdered Infant and Young Children Formula Food (GB 23790-2010*) were issued, taking reference from relevant administrative measures for drugs. These made licensing requirements for infant formula producers considerably stricter. First, production equipment and facilities, raw and auxiliary materials, production process control, inspection and testing capabilities, personnel competency, environmental condition control, and independent R&D capabilities are required to be enhanced in order to improve production conditions. Second, infant formula producers must strictly implement systems and mechanisms in aspects of raw milk powder and whey powder batch-by-batch pre-delivery inspection, raw and auxiliary materials purchase check, production process control, sales records and defected products recall, as well as internal food safety

management divisions, full-time food safety management personnel, and new employee training and regular training.

In the meantime, the Ministry of Industry and Information Technology took the lead to formulate and publish the *Action Plan for Improving the Quality of Milk Powder to Boost Consumer Confidence*, and the *Working Plan to Accelerate Mergers and Reorganisations of Infant and Young Children Formula Milk Powder Enterprises*. It also introduced preferential policies that covered the entire industry chain (such as those for safe production and high quality dairy sources), to accelerate the healthy development of the infant formula industry. MOA formulated the *Notice on Strengthening the Supervision of Quality and Safety of Milk Sources and Milk Stations for Infant Formula*, and the *Six Measures to Ensure the Safety of Infant Formula Milk Powder and Milk Sources*; it also proposed other measures such as special overhaul campaigns targeting ill practices, increased testing and inspections, thorough examination and record-filing (备案 *bei'an*) to further support the establishment and enhancement of the supervision and management of infant formula milk.

New changes in the supervision and management of dairy products: underscoring the strategic position of the dairy industry

Two issues demonstrate the importance given by the government to the supervision and management of dairy products and to the development of the dairy industry.

Firstly, a new plan for the dairy industry was promulgated. In January 2017, MOA issued the *National Dairy Industry Development Plan (2016-2020)*, marking the beginning of the development and regulation of China's dairy industry in the 13th Five-year Plan period. Compared with previous plans for the dairy industry, the dairy industry 13th Five-year Plan made several breakthroughs:

- It set the dairy industry as a strategic industry with clear positioning in the wider economy. The dairy industry is an indispensable for strengthening the country and its people, and an essential prerequisite and symbol for a Healthy China. The dairy industry is also a representative for general food safety: the quality and safety of the industry reflects the overall food quality and safety, and it is a barometer of consumer confidence. The dairy industry is also a landmark for agricultural modernisation, and it is expected to assume the lead in modernisation. Finally, the dairy industry is a strategic industry that coordinates the development of the primary, secondary, and tertiary industries. The plan highlights the dairy industry's characteristics of integrated cross-industry development;
- The Plan explicitly stipulates that a percentage higher than 70% of the milk source must be domestically produced over the 2016-2020 period. Data shows that after the "infants milk powder incident" in 2008, imports increased substantially, whereas the percentage of domestically-produced milk decreased year by year from 95% to

78%.[112] This reflects the government's concern over the scandal as well as the importance it places on the dairy industry;

- The Plan also breaks new ground through its revision of dairy standards. It outlines that raw milk national standards should be revised and a raw milk grading standard system should be established to ensure quality products and affordable prices. Production standards for liquid milk such as sterilised milk shall be revised, and stricter rules shall be imposed on the use of raw materials. National food safety standards for reconstituted milk detection methods shall be formulated to provide the basis for reconstituted milk regulation. Liquid milk processing technology standards shall be formulated to improve the quality and safety of dairy products. Formulated in 2010, some provisions of the existing dairy quality and safety standards are no longer suitable for the needs of current and future industrial development. For example, the indicators of the national standard for "raw milk" are rather low; raw milk powder is allowed in liquid milk; reconstituted milk testing and inspection only have industry standards but no national standards; dairy processing technology standards are incomplete. All of these areas have been included in the new Plan and are expected to be revised;
- Finally, more than ten major tasks are set for the dairy industry to promote the industry's revitalisation, including: the development of standardised cattle breeding of scale, the promotion of the dairy processing industry, the supervision of dairy product quality and safety, the promotion of industrial integration, the building of domestic dairy brands, the comprehensive utilisation of cow manure, etc.

On the other hand, the registration system for infant formula started to be implemented. On 1 October 2016, the *Administrative Measures on Product Formula Registration of Infant Formula Milk Powder* entered into force, marking the beginning of the reform of milk powder supervision and management. There are four major highlights regarding the new rule. First, formula management is changed from a "record-filing system" to a "registration system", similar to that of the drug management. Second, limits are imposed on the number of formula that can be registered, and producers must mark their labels carefully. In principle, each enterprise must not have more than three formula series or nine product formulas. Third, labelling became under regulation and unclear and exaggerated advertising was prohibited. For example, the source of raw materials must be clearly indicated; vague information such as "produced from imported milk", "origin of foreign ranch", or "imported materials" are not allowed; labels are not allowed to express or imply functional benefits, such as "good for intelligence development", "increases immunity/resistance to diseases", or "protect the intestinal tract". Fourth, supervision requirements and the applicant's legal liabilities are

[112] Yang Zhenhai, Wang Yuting, "Status Quo and Thoughts on the Development of Dairy Industry", *Journal of Animal Husbandry in China*, No. 16, 2014, 3-5.

more clearly defined. These rules fundamentally regulate the market order and promote industrial reform for higher quality products.

At the same time, CFDA strengthened the supervision and management of milk powder production by issuing the *Notice on Further Strengthening the Supervision of Infant Formula Milk Powder,* which specifies relevant requirements for the transitional period of formula registration system reform, in order to ensure a smooth transition in market order. The *Notice on the Regulation and Inspection of Infant Formula Labelling* was also issued, stipulating routine supervision and management of infant formula labelling, regulating infant formula labelling and function claims, addressing violations and mislabelling of product names, contents, and function claims, and safeguarding the legitimate rights and interests of the consumers. Statistics show that by February 2018, CFDA had approved a total of 1,138 infant formula of 148 factories at home and abroad. Compared with the previous number of formulas on the market which was more than 2,700, the number of formulas after the implementation of registration system was reduced by over a half. [113]

7.2.3. Monitoring and information sharing and exchange of dairy quality and safety

China's relevant regulations stipulate that sampling testing of dairy quality and safety must be carried out, and relevant information published. For instance, the 2008 *Regulations on the Supervision and Management of the Quality and Safety of Dairy Products* outline that dairy producers must implement whole-process quality control, from raw materials supplied to the factory, to finished products ready to be distributed; an inspection system over raw milk supplies must be established: every lot of purchased raw milk supplies must be examined, together with every lot of products leaving the factory for distribution. The Regulations also stipulated that animal husbandry and veterinary authorities, shall, together with quality supervision authorities, conduct sampling tests on dairy products and implement dairy product quality safety monitoring and risk warning. The *China Dairy Industry Policy (2009 revision)* also announced stricter sampling requirements for dairy products in terms of production chain and types of products. Each batch of dairy products exiting the factory for distribution is subject to examination, and key products shall be examined monthly. Raw milk, auxiliary materials and additives used in the production must comply with the laws and administrative regulations as well as with national standards for the quality and safety of dairy products.

In terms of food monitoring and regulation, the *12th Five-Year Plan of the National Food Safety Supervision System (2011-2015)* increased the attention towards the distribution and coverage of product sampling tests. Taking raw milk as an example, it is clearly required that

[113] "The Number of Registered Formulas for Infant Formula in China Reduced – CDFA's responsible officer interpreting of 'the Strictest Milk Powder Policy in History'", *Xinhua*, available at: http://www.xinhuanet.com/2018-03/17/c_1122552088.htm.

in the key areas and regions where the dairy industry is more developed, the number of raw milk samples inspected should be three per 10,000 tons. At the same time, the 2010 *Notice of the General Office of the State Council on Further Strengthening the Quality and Safety Work of Dairy Products* also required that food processing enterprises must conduct melamine tests in each purchased lot of raw milk and raw material powder, and that the proportion of samples tested shall not be less than 15% of all purchased lots; manufacturers of dairy products must also carry out melamine and other inspections on each lot of products ready to be distributed; quality supervision authorities shall also conduct sampling tests on the manufacturer's product every week. In 2012, the *Decision of the State Council on Strengthening Food Quality and Safety* emphasised that food production and distribution businesses must ensure necessary food safety investments, strictly implement various inspection systems such as for purchased supplies and for products ready to be put distributed the market, and constantly improve food safety conditions.

The quality and safety of dairy products must be supported by scientific and detailed data. According to relevant data, starting from 2016, Chinese dairy industry associations began to share data and information on Chinese dairy product quality and safety across-the-board to consumers all over the world.

For instance, China released its first *China Dairy Quality Report* in 2016. This was the first time that China's national dairy authority released large-scale and detailed information on the quality of the dairy industry. The report answered questions of China dairy quality situation in a comprehensive and authoritative manner, meticulously and scientifically collected through daily monitoring, sampling tests, risk assessments, and domestic and international comparisons. The report showed that after more than 60 years of reform and development, and especially after 2008, China's dairy industry changed dramatically and achieved impressive achievements. For example, the reports showed that in 2015, the qualification rate of dairy sampling tests nationwide reached 99.5% - the highest among all types of foods; the average amount of milk protein and milk fat in fresh milk had exceeded the national standard, while the average number of somatic cells in fresh milk from large-scale farms was lower than EU limits. The quality and safety of Chinese dairy products had risen significantly.

In 2017, the China Dairy Association released the second edition of the *China Dairy Quality Report*. The report shows that the level of quality and safety of Chinese dairy products has increased substantially, the competitiveness of dairy products companies had increased steadily, and the dairy industry had taken new steps in its overall revitalisation. According to the report, China's dairy production, quality and safety presented "five major characteristics" in 2016.

First, dairy production remained stable. China's milk production amounted to 37.12 million tons, and dairy product output was 29.93 million tons. The production scale ranked third in the world, after the United States and India;

Second, dairy quality kept improving. In 2016, the qualification rate of fresh milk sampling tests reached 99.8%, while dairy products accounted for 99.5%, higher than other food varieties. The qualification rate of infant formula sampling was 98.7% - 1.5% higher than the 2015 figure;

Third, the modern dairy industry was steadily advancing. The average yield of Friesians cows nationwide was 6.4 tons, a year-on-year increase of 6.7%. Large-scale farms with more than 100 cows took up 53% of the total number of cow farms, an increase of 4.7% year-on-year. 100% mechanised milking was achieved in scale ranches, and more than 80% of them were equipped with total mixed ration (TMR) mixer trucks;

Fourth, quality and safety supervision and management remained strict. For the eighth year in a row, a special overhaul and safety monitoring campaign was carried out on fresh milk quality. A total of 26,000 lots of fresh milk samples were tested throughout the year; 11,000 milking stations and 8,200 transport vehicles were examined on site. 3,318 lots of dairy products and 2,532 lots of infant formula milk powder were tested throughout the year. Efforts were also made to conduct on the spot supervision and inspection of reconstituted milk labels and logos;

Fifth, leading companies scored remarkable achievements. In 2016, the top 20 dairy companies (D20) had self-built pastures with 1.68 million Friesians dairy cows, which accounted for 24% of the total number of Friesian cows in China; dairy product sales amounted to 193 billion RMB, accounting for approximately 55% of the country's total dairy product sales.

At the same time, the report shows that in 2016, a total of 154 batches of imported milk products across ten categories from 19 countries did not meet China's current national standards and were returned or destroyed. The report's comparative study found that the sample of imported normal-temperature milk is not as nutritious as domestically produced liquid milk. Compared with domestic milk products, the amount of the heat-sensitive indicator – proline – in imported milk products was significantly higher, and the amount of active protein such as β-lactoglobulin was significantly lower than that of domestic milk products, indicating risks of overheating in UHT sterilised milk products; another problem of imported milk products identified was the long transportation distance and long storage time.

China has entered a new era of socio-economic development, reforms have been deepened, and efforts to further open up continue to intensify. China is confronted with many major tasks in adjusting its economic structures and modes. The dairy industry also faces increasing competition and serious challenges at home and abroad. Particularly, in the past

ten years, the rapid growth of imported dairy products in China has had a large impact on the development of the domestic dairy industry.

Statistics show that before 1999, the volume of China's dairy imports remained under 100,000 tons. [114] Over the period 2000-2008, dairy imports increased to 351,000 tons, amounting to average annual increase of 8%". From 2008 to 2014, dairy imports continued to increase rapidly, at an average annual rate of 30%. In terms of types of milk imports, milk powder imports grew at the fastest rate – at an annual average rate of 40% from 2008 to 2014; other dairy products in 2014 increased at an average of 13% year-on-year, equivalent to more than 12 million tons of raw milk, which account for 32% of the country's total milk production. New Zealand was the largest exporter, accounting for 80%; imports from the American continent and Australia accounted for about 10% of the total, while those from the European Union to 8%. The advantages of these countries lie in developed dairy industries and low breeding costs – the average milk price being 2 RMB per kilogram, whereas in China the price ranges between 3.50 and 4.05 RMB per kilogram. The international price of milk powder fell sharply after 2014, and the auction price of whole milk powder dropped from a maximum of over 5,000 USD per ton in 2013 to around 2,000 USD per ton in 2015. It is estimated that the cost of imported milk powder per ton in China is 10,000 to 20,000 RMB lower than domestically-produced products. Price competitiveness therefore is one of the main reasons behind the continuous growth of imports of foreign dairy products. In terms of market responses, from 2008 to 2017, the volume of raw milk powder imports in China increased from 101,000 tons to 717,400 tons. Public data shows that since 2008, the share of imported products of the total dairy consumption growth in China accounts to 80%.[115] New figures also show that, in 2017, the output of Chinese dairy products was 89.35 million tons, 62.1% higher than that of 2008. The raw milk production accounted to 35.45 million tons – 0.3% lower than that of 2008. [116] These rises and drops highlight the profound impact that dairy imports have had for several consecutive years on China's raw milk production, dairy market and the whole industry.

7.2.4. Conclusions

Since 2008, the supervision and management responsibilities on dairy products have become clearer, objectives have become more specific, the system has become more robust, and safeguarding measures strengthened. Laws and regulations, regulatory agencies, inspection and testing, qualification certification and licensing, emergency response, and risk

[114] Guo Li, Wang Yuting, Zhang Yangdong, "The Status Quo of China's Dairy Industry Development and Countermeasures Analysis of Major Problems", *Chinese Animal Husbandry Magazine*, 2015 No. 20, pp. 20-24.

[115] Ministry of Agriculture, National Development and Reform Commission, Ministry of Industry and Information Technology, etc.: National Dairy Industry Development Plan (2016-2020) (Agriculture and Animal Husbandry [2016] No. 14).

[116] National Bureau of Statistics: Statistical Communique of the National Bureau of Statistics on National Economic and Social Development in 2017, 2018.

prevention and control of dairy quality and safety work have constantly improved, together with the supervision and management system. Nevertheless, to achieve sustainable development, China's dairy industry still faces challenges and uncertainties in domestic and foreign markets. This will require tremendous courage as well as capability. Renewed efforts must be made to improve the dairy quality and safety supervision and management system, to ensure the safety of dairy products, to ensure the sustainable development of green and healthy dairy products, and to realise the revitalisation of the Chinese dairy industry.

7.3. Special foods: an example of the registration and record-filing management system

*Zhang Shouwen**

According to the relevant provisions of the *Food Safety Law,* starting from 2016 the China Food and Drug Administration (CFDA) formulated and issued, among others, the *Administrative Measures for the Registration and Record-Filing of Health Food,* the *Administrative Measures for the Registration of Infant Formula Milk Powder Product Formulas*, and the *Administrative Measures for the Registration of Formula Foods for Special Medical Purposes.* In April 2017, CFDA established the Special Food Registration Management Department to comprehensively promote the reform of the review and approval system to strengthen registration and supervision of special foods. China's special food registration management formally entered the "fast track" and the special food industry entered a new era.

7.3.1. Overview of the implementation of China's special food registration management system

CFDA continued to deepen the reform of "streamlining administration and delegating power" to improve the business environment. Starting from August 2017, each Friday morning, the Special Food Registration Department conducts a weekly on-site consultation service on special food registration regulations in the reception service hall, where staff members professionally answer questions raised by the applicants regarding the registration process. At the same time, registration is conducted by strictly following the law, license approval procedures were simplified, the time required for the examination and approval was shortened, and online application services have been made available. All these efforts have simplified the procedure for producers.

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Orderly promotion of registration and approval work

Registration of infant formula milk powder product formulas: Review and approval criteria for product formula have been set. Approval procedures were optimised, both domestic and foreign enterprises are now examined in parallel and enterprises that have already obtained production licenses are no longer subject to on-site inspections to ensure higher quality and faster approval process. By 31 December 2017, 34 lots of formula registration lists were announced, covering 130 factories, 323 series of products, and 952 formulas, which guaranteed the sufficient supply of infant formula milk powder on the market.

Steady progression of registration, examination and approval of FSMP: Through measures such as the proper adjustment to the transitional registration period, the further clarification of product application materials and requirements, and the addition of stability testing requirements, by the end of December 2017 there were three formula products from two producers that have passed registration.[117] In order to further standardise the clinical trials of Food for Special Medical Purposes (FSMP), opinion soliciting on the guiding principles for clinical trials of FSMPs such as inflammatory bowel disease formula and diabetes formula have been completed.

"Dual Track System" for health food registration and record-filing: In 2017, CFDA issued *The Health Food Raw Materials Directory and the Directory of Health Function Available to Claim for Health Food*, and reviewed the first lot of products involved in both directories. At the same time, an in-depth study of the raw material directory and the functional claims management system was conducted, and revisions of the research and evaluation methods of 26 types of raw materials and 16 health functions were made. Several research works were also completed, such as the research on the relationship between health food and Chinese medicines, health food positioning, raw material evaluation, functional claims evaluation, and on the formulation and revision of raw materials and functional directories. These efforts aimed to make examination and approval processes more rule-based. By the end of December 2017, 2,506 health food registrations have been approved and 262 have been filed.

Directions of the reform of the registration of special food

Health food management: Studies on health food function assessment methods will be conducted, functional claims shall be more science-based and standardised, and some health function evaluations will need to be supported by human trial test data. As raw materials and functional directories are core factors and major foundations for registration and record-filing, the availability list and the prohibition list of raw materials must be revised as quickly as possible. Studies will also be carried out on how to use raw materials, while the scope of the raw materials directory will be expanded, in order to promote a new pattern of "more record-

[117] "New chapter in the management of registration of special food", *China Pharmaceutical News*, 8 February 2018: http://epaper.cnpharm.com/zgyyb/html/2018-02/08/content_574791.htm?div=-1.

filing and less registration". Priority should be given to the registration of products for special groups of people and urgently-needed products, especially formula products for infants under the age of one.

Verification and evaluation: In 2017, on the basis of the "institutions do record-filing voluntarily, enterprises choose independently, and the government supervises by law" principle, private technical institutions were encouraged to participate in verification and evaluation. At the same time, through the implementation of a record-filing system for technical verification and evaluation institutions, and the formulation of work and technology rules, the management of such institutions was strengthened so to ensure a better level of service to enterprises. In 2018, the management of technical verification and evaluation agencies will be further strengthened, especially clinical trial agencies and technical functional evaluation institutions. On-site sampling tests and verifications will also be conducted on record-filed agencies.

Digitalisation and smart examination and approval: In 2017, online application, examination, approval, and inquiries services became available for special foods registration management online. On this basis, in 2018 a "blind review" approach will be adopted, which will contribute to the improvement of the electronic certificate management system. Full traceability of information, data, examination and approval process will be promoted; data across different systems will be integrated, and the ad hoc analysis of key issues emerged during the examination and approval of registration information data will be enhanced in order to optimise the system.

7.3.2. Categories, definitions and classifications of special food

Categories of special food

On 1 October 2015, the newly revised *Food Safety Law of the People's Republic of China* officially came into effect. Section IV "Special Food", Chapter Four of "Food Production and Distribution" defines three categories of special foods: health food, food for special medical purposes, and infant formula food (including infant formula milk powder); Chapter Nine "Legal Liability" entails punishments for illegal conducts on special food.

Definition and classification of health food

Health food refers to foods that claim to have specific health functions or that aim to supplement vitamins and minerals. That is to say, health food targets specific groups of people to improve health conditions, but does not aim to treat diseases or produce any acute, sub-acute or chronic harm to the human body. Functions of special foods are shown in the table in the next page.

Table 5: Functions of health food	
Enhance immunity	Weight loss
Help decrease hypolidemia	Improve physical growth
Help decrease hypoglycemia	Increase bone density
Antioxidant	Improve nutritional anaemia
Help improve memory	Protect liver from chemical induced damage
Relieve visual fatigue	Eliminate acne
Facilitate lead discharge	Eliminate chloasma
Clear throat	Improve skin moisture
Help lower blood pressure	Improve skin oil balance
Improve sleep quality	Improve intestinal flora balance
Facilitate lactation	Improve digestion
Ease physical fatigue	Improve bowel movements
Improve tolerance for hypoxia	Protect stomach from gastric mucosal damage
Help protect from radiation	

Definition and classifications of FSMP

Food for special medical purposes refers to food specifically processed and prepared to target the special needs of nutrients or diets of certain groups of people with eating, digestive and metabolic disorders, or with special diseases. Such food includes infant formula for special medical purposes for infant at the age of 0 to 12 months, and formula foods for special medical purposes for people over 1 year-old.

The former further includes: lactose-free formula food or low-lactose formula food, formula food with partial hydrolysis of lactoprotein, formula food with deep hydrolysis of lactoprotein or amino acid formula food, formula food for infants of premature birth/with low birth weight, formula food for amino acid metabolic disorder and breast milk nutrition supplement.

The latter further includes: formula foods with complete nutrition, formula foods with special complete nutrition and formula foods with non-complete nutrition. Among these, formula foods with complete nutrition refer to formula foods for special medical purposes that could function as the sole source of nutrition of the target group; formula foods with special complete nutrition refer to formula foods for special medical purposes capable of serving as the sole nutrition source of the target group with specific diseases or under specific medical conditions. Common formula foods with special complete nutrition target: diabetes; respiratory system diseases; kidney diseases; tumours; liver diseases; sarcopenia; trauma, infection, operation and other stress states; inflammatory bowel disease; food protein allergy; intractable epilepsy; gastrointestinal absorption disorder and pancreatitis; obesity and fat loss surgery.

Formula foods with non-complete nutrition refer to formula foods for special medical purposes only partially meeting the nutritional needs of the target group and thus not applicable as the sole nutrition source. Common formula foods with non-complete nutrition include: nutrient components (protein component, fat component, and carbohydrate component), electrolyte formula, thickening component, liquid formula and amino acid metabolic disorder formula.

Definition and classification of infant formula milk powder

In terms of infant formula foods, milk-based baby foods refer to liquid or powder foods that use milk and milk protein products as the main raw material, supplemented with the appropriate amount of vitamins, minerals and/or other ingredients, processed only by physical methods, and suitable for healthy babies. Other energy and nutrient ingredients can meet the normal nutritional needs of infants aged 0 to 6 months. The same applies to bean-based baby foods that use soybean and soy protein products as the main raw material.

In addition, formulas for older infants and young children refer to liquid or powder foods that use milk and milk protein products and/or soy beans and soy protein products as the main raw materials, supplemented with appropriate amount of vitamins, minerals and/or other excipients. Only physical methods are used for processing and the foods are suitable for older infants and young children. Their ingredients can meet the nutritional needs of normal older infants and young children – i.e. aged 6 to 12 months or 12 to 36 months.

7.3.3. Purpose of Chinese government's implementation of the special food registration system

The special foods registration system is completely different from the previous food safety supervision and management systems. From the perspective of food safety laws and food safety standards, special foods mainly include infant formulas, formulas for older infants and young children, infant formulas for special medical purposes, slimming and weight-loss formulas. Target groups are individuals with high health awareness, sub-health groups, the elderly, infants and young children. Therefore, compared with other ordinary foods, China imposed special requirements for applicable groups, nutrients and/or nutrient amount, and special requirements for labels. Generally, requirements are higher and supervision stricter for special foods than that of ordinary foods; the implementation of a registration system therefore becomes necessary.

Article 77 of the revised *Food Safety Law* stipulates that "*in the case of health food that must be registered according to the law, such materials as research and development reports, product formula, production processes, assessments on safety and health-care functions, labels, instructions and relevant samples, as well as relevant certificates, shall be furnished upon registration*". Article 80 stipulates that "*Foods for special medical purposes shall be registered with the food and drug administration under the State Council. Product formulas,*

production processes, labels and instructions, as well as materials proving product safety, adequate nutrition, and clinical effects of special medical purposes shall be provided upon such registration". While Article 81 stipulates that "*Enterprises that produce infant formula shall implement full-process quality control from incoming materials to outgoing finished products and inspect the outgoing infant formula food lot by lot, so as to ensure food safety*".

The quality and safety of infant formula milk powder concerns the health and life of infants and young children, and even the future of the Chinese nation. However, the current situation in the Chinese market is that there are too many brands of formulas for infant formula powder products, each with vastly different qualities. The effectiveness of some formulas is not scientifically verified. Some commercial advertisements tend to exaggerate their functions, confusing consumers and some formulas are frequently changed during the production process, resulting in quality and safety hazards. In order to address these problems and ensure infant formula milk powder meets the nutritional needs of normal infants, formula for infant formula milk powder shall be registered at CFDA in line with the provisions of the *"Food Safety Law"*. China's infant formula milk powder market is different from that of foreign countries. On one hand, infant formula milk powder has a large market demand, and the industry is developing rapidly; on the other, there are still some ill practices in the market that need to be addressed for the sound development of the industry. Registration of product formulas will further regulate the production and sales of infant formula milk powder and promote the sustained and healthy development of the industry.

7.3.4. Regulations on special food registration and record-filing management

Health food

Currently, Chinese laws, regulations and regulatory documents for the management of health food have already become a system, which has constantly improved as it has been coupled with a growing number of additional supporting regulations and regulatory documents. From a legal perspective, the *Food Safety Law* is the basic law governing health food products. In this piece of legislation, there are eight provisions concerning health food products, namely Article 74, Article 75, Article 76, Article 77, Article 78, Article 79, Article 82, and Article 83. They cover areas of health food supervision, registration approval, function claims, raw material management, and production quality management system.

Regulations and other regulatory documents concerning the registration of health food include the *Administrative Measures on the Registration and Record-Filing of Health Food, Requirements for Registration Materials of Health Food*, the *Notice on the Implementation of Administrative Measures on the Registration and Record-Filing of Health Food, (CFDA, [2016] No. 81)*, the *Circular on the Implementation of Relevant Matters Concerning the Implementation of Registration and Record-Filing Management of Health Food (CFDA [2016] No. 103)*, the *Guidelines for the Registration of Health Food Registration Applications (2016*

Edition), the *Rules on Health Food Registration Review and Approval (2016 Edition)*, the *Health Food Ingredient Catalogue (1)*, the *Directory on the Allowed Health Care Function Claims for Health Food (1)*, the *Requirements for the use of Catalogue on Raw Material for Nutritional Supplements in Health Food*, the *Guidelines for Technical Requirements for Registration of Raw and Supporting Materials for Health Food* (First batch), the *List of Supplementary Materials that Need Further Research for Health Food Registration* (*Draft for Soliciting Opinions)*", the *Administrative Measures for Health Functions in Health Foods Catalogue and Raw Materials Catalogue (Draft for Soliciting Opinions),* and the *Opinions on Management of Health Food Function Claims.*

Regulations and other regulatory documents concerning record-filing of health food include the *Administrative Measures for the Registration and Record-Filing of Health Food*, the *Guide on the Registration of Health Food (Trial)*, the *Regulations on Permitted Supplementary Materials and their Usage in Record-filed Health Food (Trial)*, the *Main Production Techniques of Record-filed Health Food (Trial)*, the *Notice of CFDA on the Launch of Health Food Record-Filing Information System ([2017] No. 68)*, the *Notice of CFDA on matters relating to the Record-Filing of Health Food ([2017] No. 2017),* and the CFDA's *Notice on Implementing the Relevant Matters Concerning the Management of Registration and Record-Filing of Health Food ([2016] No. 103)*.

Regulatory documents concerning techical examination include the *Rules on the Examination and Approval of Health Food Registrations (2016 Edition)*, the *Rules on Review Techniques of Health Food Registration* the *Guidelines on Stability Testing of Health Food, and Notice on Transitional Matters on Health Food Registration Review and Approval (2016) No. 172)*, and the *Notice on Issues Concerning Naming of Health Foods ([2016] No. 43)*.

Food for special medical purposes

From a legal perspective, the *Food Safety Law* is the basic law governing FSMP. In this piece of legislation there are four provisions concerning FSMP, namely Article 74, Article 80, and Article 82, Article 83. They cover supervision, registration, approval, and production quality management system.

Regulations and other regulatory documents concerning the registration of FSMP include the *Administrative Measures for Registration of Formula Food for Special Medical Purposes*, the *Application Materials and Requirements for Registration of Formula Food for Special Medical Purposes (Trial)*, the *Application Materials and Requirements for Registration of Formula Food for Special Medical Purposes (Trial) (2017 Revised Edition)*, the *Requirements for Labels and Instructions Sample of Formula foods for special medical purposes (Trial)*, the *Food Stability Requirements for Special Medical Formula (Trial)*, the *Testing Stability Requirements for Formula foods for special medical purposes (Trial)*, the *Testing Stability Requirements for Formula foods for special medical purposes (Trial) (2017) (Revised)*, the *On*

Spot Check Points and Evaluation Principles of Production Enterprises of Formula Foods for Special Medical Purposes (Trial), the *Notice of on Clinical Trial Quality Management for formulas for FSMP (for trial implementation) (No. 162 of 2016)*, the *Administrative Measures on Experts for Registration Review of Formula Foods for Special Medical Purposes (Trial)*, the *Notice of Offering the Transition Period for Registration of Formula Foods for Special Medical Purposes (No. 119 of 2016)*, and the *Bulletin on the adjustment of Transition Period for Registration of Formula Foods for Special Medical Purposes by CFDA and AQSIQ (2017, No. 139)*.

Infant formula milk powder

From a legal perspective, the *Food Safety Law* is the basic law governing infant formula milk powder. In this piece of legislation, there are four provisions concerning FSMP, namely Article 74, Article 81, and Article 82, Article 83. They cover areas including infant milk formula supervision, registration and approval, raw materials, production quality management system, etc.

Regulations and other regulatory documents concerning registration of infant formula milk powder include the *Administrative Measures for the Registration of Infant Formula Milk Powder Product Formulas (CFDA Order No. 26)*, the *Application Materials and Requirements for Infant Formula Milk Powder Product (Trial)*, the *Application Materials and Requirements for Infant Formula Milk Powder Product (Trial) (2017 Revised Edition) ([2017] No. 65)*, the *Technical Guidelines for Labels of Registered Infant Formula Milk Powder Products (Trial) (No. 66 of 2017)*, the *Matters Concerning Changes to the Registration Labelling of Infant Formula Milk Powder product formulas ([2017] No. 150), On the Spot Check Points and Evaluation Principles of Production Enterprises of Infant Formula Milk*, and the *Notice on Regulating the Use of Registered Infant Formula Milk Formulations of a Wholly-Owned Subsidiary of the Same Group Company ([2017] No. 154)*.

7.3.5. Procedures and time limits for special food registration

The procedures for applying for the registration of health food, FSMP, and infant formula milk powder are basically the same. There are only minor differences in terms of certain time limits, which will be introduced below.

Procedures for special food registration

Administrative acceptance of applications: Registration application materials are accepted by the CFDA's Administrative Affairs Acceptance Service and Complaints, Reports Centre. It shall make a decision on whether to process the application according to relevant regulations;

Technical examination: The Health Food Evaluation Centre of the CDFA reviews the application materials and conducts on-site verifications, sampling tests, and expert discussions according to the actual needs of the technical examination, on the basis of which final examination conclusions will be made;

On-site verifications: The Food and Drugs Testing and Inspection Centre of the CDFA conducts on-site inspection on production enterprises, as well as on-site verification of clinical trials, on the basis of which a final report is issued;

Sampling testing: Competent inspection agencies conduct testing and inspection of the testing samples, on the basis of which an inspection report is issued;

Administrative approval: Based on the review results of the Health Food Evaluation Centre, CFDA will make a final decision on the administrative approval of the application;

Certification: A registration certificate will be issued to those entities which have passed the registration procedure;

The validity of registration certificates for health food, FSMP and infant formula milk powder will last for five years.

Time limits for special food registration

Time limit for the administrative acceptance of applications: The application centre shall complete the examination of the application materials within five working days after receiving the application for FSMP, and within three working days after receiving the application materials for health food and infant formula milk powder, and make a decision on whether to process the application materials or not. In case the application materials for health food, FSMP and infant formula milk powder are incomplete or do not fulfil relevant requirements, the Centre shall, on the spot or within five working days, notify the applicant regarding the additional materials to be submitted or to be revised. If no notifications are provided within the time limit, the application will be considered as complete and eligible to be processed;

Time limit for the technical examination: The examination agency shall complete the technical examination within 60 working days from the date of receiving the application materials, and formulate examination conclusions. In special cases and under the approval of the responsible officer of the examination agency, the examination time could be extended for 30 additional working days. If additional materials, on-site verifications, and sample inspections are required, the time required for submitting new materials or for conducting on-site verification and sampling testing is not counted within the time limit for the technical examination;

Time limit for supplementing or correcting application materials: In case the applicant needs to add or correct the application materials during the examination process, the examination agency shall inform the applicant of the specific content required. Applicants for

FSMP shall, within six months, resubmit application materials at once; while applicants for health food and infant formula milk powder shall do it within three months. The applicants who failed to submit supplementary materials within the specified time limit will be treated as first-timer applicants. After the examination agency receives the supplementary materials, the time limit for the technical examination is restarted, with the time spent for submitting supplementary materials not counted within the examination time limit;

Time limit for on-site verification: The examination agency shall, within 20 working days from the date of receiving the notification, complete the on-site verification of FSMP or infant formula milk powder producer, and issue a verification report. It shall complete the clinical trial within 40 working days from the date of receiving the notification, and issue a verification report. In the case of health food producers, the on-site verification shall be completed within 30 working days from the date of receiving the notification; the verification report shall be sent to the examination agency;

Time limit for sampling tests: The food inspection agency shall complete sampling tests of FSMP and infant formula milk powder within 30 working days after receipt, or within 60 working days in the case of health food;

Time limit for the administrative examination and approval: CFDA shall make a decision on whether to approve the registration within 20 working days from the date of accepting the application. The time required for on-site verification, sampling testing, and technical examination is however not counted;

Time limit for issuing certification: if the application is approved, the application centre shall issue a registration certification within 10 working days from the date of CFDA's decision. The same time limit applies to the notification to rejected applicants;

Time limit for the registration of foreign enterprises: the time limit for overseas on-site verification and sampling testing for overseas applicant of FSMP formulas shall be determined according to the latter's actual situation.

7.3.6. Health food registration and record-filing

Definition of health food registration

The registration of health food refers to the process by which food and drug supervision and management authorities carry out, on the basis of legal procedures, conditions and requirements, a systematic evaluation of safety, health functions and quality controllability of health food included in the application, and decide whether to approve the registration. Registration is also an administrative license and is a prerequisite for obtaining a health food production license.

Definition of health food record-filing

The record-filing of health food refers to the process by which health foods producers

submit, on the basis of legal procedures, conditions and requirements and to food and drug supervision and management authorities, materials that indicate the safety, health functions, and quality controllability of their products for archiving, disclosure, and checking. Record-filing is not administrative licensing or approval, but rather an informative filing.

The "two directories" of health food

The *Health Food Raw Materials Directory* and the *Directory of Health Function Available to Claim for Health Food* serve as important basis and prerequisites for the registration and record-filing management of health food.

The *Health Food Raw Materials Directory* refers in particular to the list of substances and their corresponding information that, following safety tests and functions verifications, can be used in health food. It includes raw materials' names, compatibility, dosage, permitted health function claims, quality standards, efficiency components and testing methods, as well as related instructions. The *Raw Materials Directory* is divided into a list of raw materials for supplementing nutrients such as vitamins and minerals, and a list of raw materials for other health functions. At present, CFDA has only issued *Health Food Raw Materials Directory (first batch)-Nutrition Supplement Raw Materials Directory*. Other lists have not yet been published but are currently being created. In the future, any health food developed by producers using only raw materials included in the *Raw Materials Directory* will not need to undergo national registration and approval, but will only be required to do record-filing with provincial-level food and drug supervision and management authorities.

The *Directory of Health Function Available to Claim for Health Food* refers to the list of permitted health food function claims that have been rigorously evaluated and verified with clear evaluation methods and criteria. It includes the name and description of the health functions. At present, CFDA has only issued *Directory of Health Functions Claimed by Health Food (first batch)-Health Functions Directory of Nutrition Supplements*, which only covers one health function, namely the "supplement of vitamins and minerals". Other health functions directories are currently being created.

Qualification requirements for health food registration applicants and records filers

The registration applicants of health food must meet the following qualifaction requirements: registration applicants for domestic health food should be legal persons or other organisations registered within China; while registration applicants for imported health food should be a foreign producer of marketed health food. Applications for imported health foods shall be handled by its representative office in China or by its agency in China.

The records filers of health food must meet the following qualifaction requirements: the filer of domestically-produced health foods should be the health food producer or the original

registration applicant; while the filer of imported health food should be the foreign producer of marketed health food.

Health food registered by CFDA

This category includes health food that uses raw ingredients not included in the *Health Food Raw Materials Directory*; as well as health food imported for the first time (excluding nutrition supplement such as vitamins and minerals). The latter category refers to health food products that apply for the right to be sold in China, and that are not produced in the same country, by the same company, or with the same formula. The validity of the health food registration certificate obtained in this way is five years.

Health food record-filing done by CFDA

This category refers to health food imported for the first time as nutrition supplement such as vitamins, minerals, and other nutrients. Their nutritional substances should be listed in the *Health Food Raw Materials Directory*.

Health food record-filed and managed by provincial food and drug supervision authorities

According to the *Food Safety Law*, domestic producers doing record-filing for health food only need to do it at the provincial food and drug supervision authorities, provided that the raw materials used in the products are listed in the *Health Food Raw Materials Directory*.

Health food record-filing procedures

The procedures for record-filing of produced and imported health food whose raw materials have been included in the *Health Food Raw Materials Directory* are as follows:

- The record filer for domestic health food shall be a health food producer or the original registration applicant;
- Provincial-level food and drug authorities handle, in accordance with the law, relevant record-filing materials;
- The format of the record-filing number for domestic health food is: *ShiJianBei G +* 4 digits of the year code + 2 digits of the provincial administrative region code + 6 digits sequence code.

The procedures for record-filing of health food imported for the first time as nutrition supplement, such as vitamins and minerals, are:

- The record filer for imported health food shall be an overseas producer with marketed products;
- The nutritional substances of the health food imported for the first time as a nutrition supplement shall be listed in the *Health Food Raw Materials Directory*;

- CFDA's Administrative Affairs Acceptance Service and Complaints, Reports Centre is responsible for receiving record-filing materials for imported health food.

7.3.7. Registration of food for special and medical purposes

Registration of FSMP refers to the process by which CFDA, on the basis of the procedures and requirements stipulated by relevant regulations, review the product formula, production processes, labels and instructions, as well as documentation proving product safety, adequate nutrition, and clinical effects of special medical purposes, and makes a decision on whether to approve the registration.

Qualifications of the applicants

Applicants for the registration of FSMP must meet the following qualifaction requirements:

- Be the producer of FSMP that are intended to be produced or sold in China, or the overseas producer that intend to export to China;
- Have sufficient research and development (R&D) capacities; and set up R&D facilities for the FSMP which shall employ full-time researchers and staff that hold senior professional titles or related competence in food safety-related subjects;
- Have sufficient production capacities with staff and technicians employed in food safety management; the facility shall follow good manufacturing practices and shall implement food safety management systems for FSMP;
- Be capable of testing all requirements for every single product lot as required by FSMP national food safety standards;
- Other documents evidencing the product safety, nutritional sufficiency and clinical effect of the FSMP.

Documents for the registration application

The applicant shall submit the following documents to CFDA for registration of FSMP:

- Application form for registration of FSMP;
- Product R&D report as well as the product formula design and its basis;
- Production technique materials;
- Requirements provided in relevant standards concerning product quality;
- Samples of product labels and descriptions;
- Testing report of the samples;
- Documents evidencing capacities for R&D, production and testing;
- Other documents proving the safety, nutritional sufficiency and clinical effects of the FSMP.

Varieties of FSMP requiring clinical testing

According to the *National Food Safety Standard – General Provisions of FSMP* (*GB29922-2013) Appendix A*, a total of 13 varieties of special complete nutrition and formula foods are required to undertake clinical testing, i.e. those targeting: diabetes; respiratory system diseases; kidney diseases; tumours; liver diseases; sarcopenia; trauma, infection and operation and other stress states; inflammatory bowel disease; food protein allergy; intractable epilepsy; gastrointestinal absorption disorder and pancreatitis; fatty acid metabolic disorder; and obesity and fat loss surgery.

7.3.8. Product formula registration for infant formula milk powder

Definition of infant formula milk powder registration

The registration of infant formula milk powder products refers to the process by which CFDA, in accordance with the procedures and requirements stipulated in the *Administrative Measures for the Registration of Infant Formula Milk Powder Product Formulas*, examines the application for the registration of infant formula milk powder, and decides whether to approve the registration.

Definition of infant formula milk powder

Under relevant laws and regulations and national food safety standards, infant formula milk powder products refer to milk powder food products that use milk and milk proteins as main raw materials, that are supplemented with an appropriate amount of vitamins, minerals and/or other ingredients, and that are produced only by physical methods and are suitable for healthy babies.

Definition of the product formula of infant formula milk powder

Infant formula milk powder product formula refers to food ingredients and food additives – and their dosage – used in the production of formula powder for infants and young children, as well as to the product's nutrient contents.

Scope of application of the product formula

The product formulas of infant formula milk powder produced, distributed or imported into China, are all subject to approval of CFDA.

Qualifications requirements for registration applicants of product formula

The Applicant should have "three capacities", namely, R&D, production, and testing capacities matching the production of infant formula. This also applies to producers that intend to produce or sell infant formula milk powder in China, and to foreign producers that intend to export such products to China.

In addition, the applicant should also follow good manufacturing practices and the Hazard Analysis and Critical Point (HACCP) system, and should be capable of testing pre-delivery products for any items required by national infant formula food safety standards.

Application materials and requirements for the registration of product formula

The applicant should:

- Ensure that the product formula for which registration application is submitted complies with the provisions stipulated by relevant laws, regulations and national food safety standard, and that it can meet the nutritional needs of infants for growth development;
- Submit the application form for the registration of product formula; the applicant's credential documents; quality and safety standards for raw materials and auxiliary materials; formula R&D report; description of the production process; testing report of the product; documents evidencing capacities for R&D, production and testing; and other documents evidencing the scientific basis and safety of the product formula;
- In theory, the infant formula milk powder product formula should be as close as possible to breast milk. The number of formulas registered must, in principle, not exceed three formula series and nine product formulas. In order to register for more than two product formulas, one business entity must demonstrate, with scientific evidence, distinct differences between the formulas.

Sharing of the product formula within the same group company

One infant formula milk powder product formula registered by a wholly-owned subsidiary within one group company can be also used by other wholly-owned subsidiaries of the group, as long as the latter also register the product formula and obtains production license. In addition, before starting production, the group company shall submit a written report to CFDA, which will then release the information to the public.

Regulations for labelling and description

The applicant who applies for the registration of infant formula milk powder product formula shall submit samples of the labels and descriptions, and provide explanations and supporting materials for any claims therein contained. Claims about the product formula must meet the following strict criteria:

- The content of the label and description should be consistent with the product formula registered, and include the registration number;
- Labels should include the product's ingredient table, nutrition fact table, origin of materials, and applicable age for use;
- The product labels and descriptions should not contain any claims that:

- Involve disease prevention and treatment;
- Express or imply health functions;
- Express or imply functional benefits, such as benefits for the development of intelligence, for the building up of immunity and resistance to diseases, or the protection of the intestinal tract, etc;
- Use the expressions “not adding”, “not containing”, or “zero adding” to emphasise the unused or non-existing substances that are prohibited by food safety standards in food recipes or foods;
- Contain information that is false, exaggerated, against scientific principles, or that outline absolute statements; and
- Any other claims inconsistent with the registered formula.

7.3.9. Link between the registration of special food and the food production license

Article 35 of the *Food Safety Law* stipulates those intending to engage in the production or sale of food, or in the catering services, shall legally obtain a license.

Therefore, obtaining product registration certificates and food production licenses are necessary conditions for enterprises in China to produce special food. Regarding the specific procedures, producers that intend to produce or sell special food in China shall, in the first place and according to the law, obtain business licenses for the corresponding scope of their business; afterwards, they shall apply, according to relevant rules and regulations, for registration of health food, FSMP, and infant formula.

Once the product registration certificate is obtained, enterprises shall apply for the relevant production licenses according to the provisions stipulated by the *Administrative Measures for Food Production Licensing*, the *Detailed Rules for Health Food Production License Examination*, the *Detailed Rules for Infant Formula Milk Powder Production License Examination*, and the *Detailed Rules for FSMP Production License Examination (Draft for Soliciting Opinions)*. Only after the production license is obtained may the production of special food start.

7.3.10. Conclusions

On 17 March 2018, the *Plan for Institutional Reform of the State Council* was passed in the first meeting of the 13th National People’s Congress of the People’s Republic of China. As a result, the State Administration for Market Regulation (SAMR) was established, and the China Food and Drug Administration (CFDA) abolished. This means that the registration, record-filing, and supervision responsibilities that once belonged to CFDA will be transferred under the responsibility of the newly-established SAMR and its departments at local levels.

From a macro perspective, this institutional reform has improved the market supervision system, and promoted the strategy for building a strong nation with quality products, an

honest market environment and fair competition. It has also strengthened the supervision and law enforcement for product quality and safety so that the population will be able to purchase, use and eat worry-free products. How to maintain professionalism throughout the supervision process of special food safety will be one of the new market regulator's focuses in future work.

7.4. Imported and exported food

*Jiao Yang**

Finding its foundations in the *Food Safety Law*, the supervision of imported and exported foods in China features a multipronged approach in regulatory concepts, regulatory frameworks, governance systems, and relevant supporting systems. Cumulatively, the aim is to achieve a regulatory system based on risk management and to protect the safety and enhance the quality of imported and exported foods.

Rule of law is a necessary condition for implementing food safety governance; establishing a comprehensive legislative framework is a basic premise for achieving this objective. In recent years, China's food safety laws and regulations for imported and exported food products have developed rapidly. On the basis of the legislative framework set forth by the new *Food Safety Law*, a legal framework for importing and exporting foods has been established that is consistent with international standards and modern food supervision concepts.

Basic thoughts for the establishment of the legal system for import and export food safety in China

First, the principles of "prevention first, risk management, whole-process control, and social co-governance" must be embodied. This is not only a requirement outlined by the new *Food Safety Law*, but also a practice commonly used by trading partners and advocated by the Codex Alimentarius Commission (CAC). These basic concepts shall be fully understood and implemented throughout the design, formulation and execution of the food safety regulations for imported and exported food.

Second, the relationship among constitutional order, efficiency and safety must be well-balanced. Order and efficiency are the fundamental values of law. In terms of food trade, relevant food safety laws and regulations not only need to maintain the order of food imports and exports, but must also facilitate trade with greater efficiency. Thus, the aim should be to

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ensure an appropriate level of risk protection but without enacting unnecessary barriers to trade in food products.

Third, the roles of government, the market and society must be well-balanced. The main role of government should be in correcting "market failures" in food safety. This is not only the economic basis for a government to obtain legitimacy, but also the grounds for evaluating the effectiveness of the food safety governance system. However, government supervision and management also has limitations. Therefore, during the development of the legal system, it is necessary to allow market forces to promote and ensure food safety. The key is to rationally define the boundaries between the government and the market, and clearly define the responsibilities of all relevant parties.

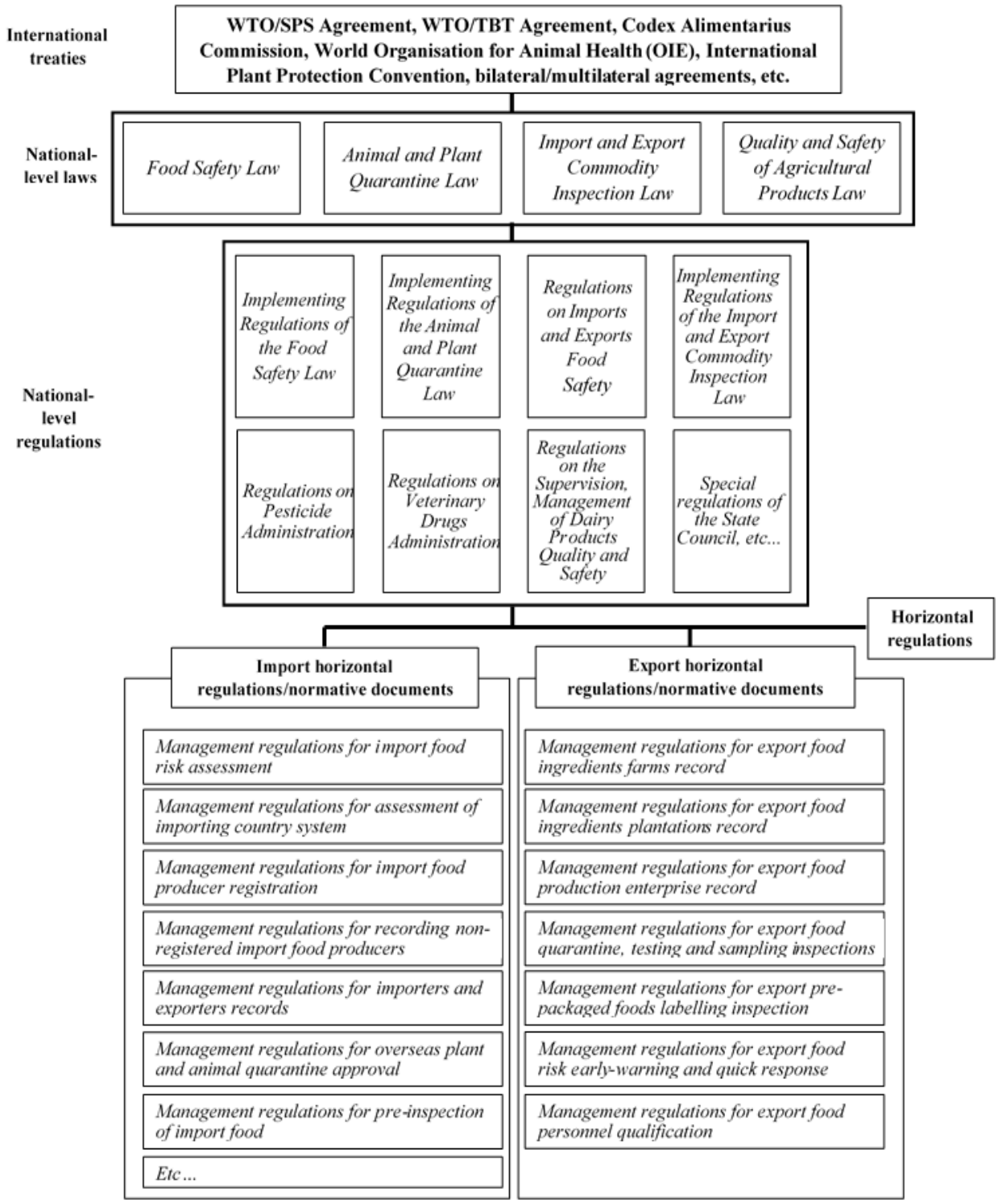
Fourth, the relationship between international rules and rules with special Chinese characteristics must be balanced. The food safety governance of imported and exported foods needs to abide by international rules and carry out international joint governance, while also factoring in China's specific conditions, as well as the historical process and development stage of the country's food safety governance of food imports and exports (in particular for food exports).

China's legal system for import and export food safety

The basic framework of China's legal system for import and export food safety: The framework of China's legal system for food imports and exports is based on laws and regulations, departmental rules, and rules for implementation. Horizontal regulations shall prevail within departmental rules/normative documents. General rules for each specific link of the chain shall be formulated individually in line with the flow of food imports or exports. If certain products or matters require special provisions, an appendix is to be added in the horizontal regulations/normative documents, so as to reduce the number of vertical regulations. The basic framework of the legal system for import and export food safety is depicted in the table in the next page.

Laws and regulations at the national level: In terms of laws, it is recommended that the relevant provisions regarding safety for food imports and exports in the *Food Safety Law* be further revised as follows. First, the fundamental principle of "risk ranking management" for food imports and exports should be adopted. Second, the current "testing qualification" approach should be changed and based on "supervised sampling testing based on risk assessment results". Third, the market entry assessment requirements and origin inspections for food imports should be strengthened. Fourth, additional provisions should be added with respect to sampling and testing of food exports. Finally, the "*Law of the People's Republic of China on the Entry and Exit Animal and Plant Quarantine"* (hereinafter referred to as "*Animal and Plant Quarantine Law*") should be amended to include risk analysis-related provisions.

The basic framework of China's legal system for import and export food safety



In terms of regulations, formulating a set of *Regulations on the Food Safety of Imports and Exports* shall be taken into consideration, while relevant mechanisms and measures for import and export food safety shall be further improved.

Departmental rules and regulatory documents: In accordance with the basic framework of China's legal system for import and export food safety, efforts in reforming relevant

departmental rules and regulatory documents should be accelerated. Many blanks that currently exist in regulation should be filled, while existing regulations should be revised. Old and outdated regulations should be abolished based on new regulatory concepts and requirements outlined under new *Food Safety Law*.

7.4.2. Governance system for import food safety

China's governance system for imported food safety is based on the *Food Safety Law*. Its core principles rest on the four pillars of "prevention, risk management, comprehensive control, and international joint governance"; ensuring the food safety of imports is the ultimate goal.

Pre-import stage

Under the *Food Safety Law*, China adopts a food safety management system and examination mechanism for exporting countries/regions, according to which food safety responsibilities are transmitted to the government of the country/region exporting food products to China. For foods exported to China for the first time – or for those which have recently had a ban lifted – the competent authority of the exporting country/region is required to submit a written application as well as information for risk assessment to the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ).[118] Experts for conducting assessments and review of the food safety management system and the food safety situation of the exporting country/region are then appointed in order to determine (i) whether the safety of exported foods is guaranteed; and (ii) whether the requirements stipulated by relevant Chinese laws, regulations and standards are met. If the risk assessment results indicate that the grade of risk is controllable, consultations shall be conducted with the competent authority of the exporting country/region to determine the inspection and quarantine requirements for the exported food. Following this, a bilateral inspection and quarantine protocol is then signed to define the responsibilities of the government and enterprises of food exporting countries/regions. The inspection and quarantine requirements for foods exported to China are published on the official website of AQSIQ, together with administrative orders lifting bans on certain exports. This mechanism is currently applied to some high-risk products.

According to the *Food Safety Law*, overseas food producers that export foods to China shall register with AQSIQ. This is the basic system for transmitting food safety responsibilities to the governments of food exporting countries/region in order to ensure food safety in China. The competent authority of the exporting country/region submits to the Certification and

[118] Following the 2018 institutional reform of the State Council, the quarantine functions of AQSIQ have been taken over by the General Administration of Customs (GAC), while all the others have been taken over by the newly-created State Administration of Market Regulation (SAMR). Agencies which were under AQSIQ will maintain their name and responsibilities after the reform.

Accredition Administration (CNCA) under AQSIQ a list of recommended food producers for registration, together with relevant documentation. The CNCA then organises experts to examine whether the food exporters meet the registration requirements and may conduct on-site inspections as required. Producers that meet the registration requirements are allowed to register and will be published on the CNCA website. The rules for implementing this mechanism apply to meat products, aquatic products, dairy products and edible bird's nests.

As stipulated under the *Food Safety Law,* a record-filing management system for overseas food exporters has been established, which is a basic system for transmitting food safety responsibilities to overseas exporters or agents that export foods to China. Record-filing is to be done online with AQSIQ, and must include the name of the exporter or agent, country/region of origin, address, name of the contact person, telephone number, exported food type, as well as the name and telephone number of the person who fills in the form. The list of the names of overseas exporters or agents is then published online.

The *Food Safety Law* also established a record-filing management system for importers of food from overseas. Record-filing is to be done online with the respective local quarantine and inspection authority, and must include the name of the importer or agent, address, name of the contact person, telephone number, food types, name and telephone number of the person who fills in the form and commitment statement. The list of the names of overseas importers or agent is published online.

An official inspection certificate system for food exported to China was also established by the *Animal and Plant Quarantine Law*. This system consists of an endorsement to the food exporting country/region to prove that it has fulfilled its duties in ensuring the safety of food exports, and that the exported lot is under the effective supervision of its official regulatory system and complies with China's requirements. The format, content, and comments of the official certification documentation (such as animal health, plant health, and food hygiene certificates) is determined through negotiations between AQSIQ and the government authorities of the exporting country/region. When the food is exported to China, the competent authorities of the exporting country/region issues an official inspection certificate for each lot exported; the registered overseas exporter or agent will issue a verification of the compliance materials and attach it to the shipments. This mechanism is currently being applied to all food exports other than deep processing pre-packaged foods.

According to the *Food Safety Law,* there is also a system for allowing food importers to review and examine overseas producers, according to which food importers or agents shall review overseas exporters or producers from which products are supplied. The content of the review and examination covers the overseas exporters and producers' implementation of food safety risk prevention/control plans and of food protection measures; as well as the compliance of the Chinese label and explanations of imported pre-packaged foods with

relevant Chinese laws, regulations and national food safety standards. Importers must report the results of the review to inspection and quarantine authorities; non-qualified products shall not be imported.

According to *Animal and Plant Quarantine Law*, there is also a system for the quarantine and approval of animal- or plant-derived foods. According to this system, which is thought to ensure that each lot of imported food meets the requirements for animal and plant quarantine, food importers or agents in China must apply for quarantine approval from the inspection and quarantine authorities before signing a trade contract. The latter will then conduct a preliminary examination of the submitted application materials, before a final review is conducted by AQSIQ. A quarantine permit for the entry of animal and plants is issued to products meeting the requirements. This system is currently applied to imports of meat products, eggs, casings, aquatic products, dairy products, rice, mixed grains and beans.

Under the *Animal and Plant Quarantine Law* and the *Law of the People's Republic of China on Import and Export Commodity Inspection* (hereafter "*Import and Export Commodity Inspection Law*"), a pre-inspection and quarantine system for food exports has been established with the aim to facilitate trade globalisation. According to this system, the competent authority of the exporting country/region must submit an application to AQSIQ, which will then make arrangements for pre-inspecting the foods exported to China. A protocol is signed upon agreement on the arrangements, with the responsibilities of the competent authority of the exporting country/region subsequently defined. Before the food is exported to China, the importer or its agent must submit to the inspection and quarantine authorities an application for pre-inspecting the exported food; pre-inspection and quarantine could be conducted by the inspection and quarantine authorities or qualified third-party inspection institutions. Those exports which pass the pre-inspection and quarantine shall be granted facilitated customs clearance.

Finally, a "good importer accreditation system" is a voluntary measure that encourages food importers to strengthen self-inspection, self-control and fulfil food safety responsibilities. The requirements for being accredited as a "good importer" are developed by AQSIQ and cover the situation of the regulatory agency of the place of production, the safety control measures adopted by the producer, the review and examination of the importer over the exporter, import history records, the importer's guarantee measures, etc. Those importers which obtain "good importer" accreditation shall be granted facilitated customs clearance.

Import stage

The *Animal and Plant Quarantine Law* and the *Import and Export Commodity and Inspection Law* have established an inspection and quarantine declaration system for foods imported into China. The importers or their agents must apply for inspection at the place of declaration and submit relevant documentation in line with existing regulations – consisting

mainly of contracts, invoices, packing lists, bills of lading, and certifications such as health certificates, entry permits for animal and plant quarantine, self-declaration of conformity, etc. The inspection and quarantine authorities at the place of declaration will review the materials provided, and issue a customs clearance certificate if the import food is qualified.

The *Food Safety Law* also establishes a system according to which importers or agents of the imported food must verify compliance materials of the shipment. Importers and agents therefore take primary responsibility for ensuring food safety. AQSIQ formulates relevant requirements for the submission of self-compliance statements by importers of food featuring higher risks or other special conditions. When the goods arrive at the port for inspection, the importer or agent submits the compliance materials attached to the shipments to the inspection and quarantine authorities at the place of declaration – such as a self-inspection report, self-compliance statements, and so on. At present, this system is mainly implemented for dairy products and edible vegetable oils.

Under the *Food Safety Law* and the *Import and Export Commodity Inspection Law*, a port inspection and quarantine supervision system for food imports has also been established. According to this system – which is essential for the supervision of food imports and for holding enterprises accountable for food safety – AQSIQ conducts unified risk assessments on food imports, on the basis of which annual sampling quarantine and inspection plans are formulated for entry ports; which in turn are based on compliance assessments of the risk grade and ranking. For low-risk products, invoices and relevant certificates are examined, while on-site inspections and sampling tests are conducted at a low ratio (the ratio of sampling tests and on-site inspections increases for medium-risk and high-risk products, with self-qualification inspections statements by importers required to be submitted for the latter). The annual sampling and inspection plan is executed by local inspection and quarantine agencies at each port of entry through a compliance assessment of the imported food. If the imported food meets relevant requirements, it shall be cleared. Enhanced supervision may be implemented in the case of non-qualified products – namely, an increase in the sampling testing ratio for the same category of imports from the same exporter and the same country. If the imported food still fails to qualify during the enhanced supervision period, it will be retained for further inspection and the imported shall be required to provide a self-qualification inspection report, while the local inspection and quarantine agency will undertake a compliance assessment. Relevant custom agencies shall not clear the imported food before the results of the compliance assessment are completed.

The *Food Safety Law* also establishes a risk surveillance system, which is of significant importance for monitoring and detecting potential safety risks of non-national standards foods imported into China. Under this system – which has been implemented for many years – experts are appointed by AQSIQ to formulate an annual safety risk monitoring plan for imported foods not falling under national standards. Inspection and quarantine agencies shall

examine products and samples in a laboratory. Relevant departments of the State Council or local governments must be notified in a timely manner in instances where potential issues are identified.

The *Food Safety Law* also establishes a rapid risk alert system. According to this system – which embodies the internationally-accepted principle of "prevention, intervention, and response" during the supervision of food imports and exports – experts are appointed by AQSIQ to collect information and conduct inspection and quarantine risk assessments. If any potential risk is detected, risk warning notifications or public notices shall be released in a timely manner, and rapid response measures shall be adopted to notify the competent authorities of the exporting country/region.

A designated port entry system has been established according to the *Animal and Plant Quarantine Law* in order to guarantee animal and plant quarantine and food safety, and to eliminate or reduce animal and plant quarantine and food safety risks. According to this system, certain types of high-risk food imports may only be imported through specifically designated ports. An application for being recognised as such must be submitted by local governments to AQSIQ in line with the supervision and management requirements stipulated by the latter.

Finally, a third-party inspection certification system has also been established in line with the *Import and Export Commodity Inspection Law* and Article 87 of the *Food Safety Law*. This system aims to engage non-governmental stakeholders in an attempt to realise co-governance. Third-party inspection certification agencies may conduct inspections of the imported food's production site, facility, as well as pre-inspection and quarantine and port inspections. This system allows for a reduction in inspection costs, as well as enhancement of monitoring, and therefore represents a market-based mechanism making full use of social resources.

Post-import supervision and management

The *Food Safety Law* has established a post hoc inspection system for exporting countries/regions and producers. It consists of a basic oversight system for ensuring that food exports into China comply with relevant Chinese food safety regulations and standards. Experts are appointed by AQSIQ to conduct, on a periodic or irregular basis, post hoc inspections on the food safety management system of a country/region that export foods to China, as well as on the food safety control mechanisms adopted by already-registered producers to assess: (i) whether they still continue to meet relevant requirements and regulations; (ii) the effectiveness with which they implement Chinese food safety-related laws, regulations and standards; and (iii) the accuracy of the review and examination conducted by their corresponding importer or agents in China. Corrective measures will be required by AQSIQ for those food exporting countries/regions or producers that no longer meet such

requirements – if the result of these corrections remain non-compliant, AQSIQ will cancel their access or registration qualifications, resulting in a ban on further imports of their products in China.

At the same time, the *Food Safety Law* also establishes a credit management system for food importers, exporters and producers. This system urges enterprises to abide by laws during production and distribution processes, and gives full rein to the role of public supervision. Inspection and quarantine authorities adopt credit management for producers and distributors of imported and exported foods and establish credit records, which are disclosed to the public. Punitive measures will be imposed on subjects with negative records, while incentives such as facilitated customs clearance will be rewarded to subjects with positive records.

The *Food Safety Law* also outlines a system for allowing direct inquiries and interviews with importers and agents. AQSIQ or inspection and quarantine agencies are permitted to summon the legal representatives or relevant responsible persons of the food importer for talks or clarifications, particularly in cases where they are responsible for major food safety incidents, illegal conduct or import of food with potential risks. During the inquiry, inspection and quarantine agents indicate the list of issues and corresponding requirements that the importers must correct and the deadlines by which these must be addressed. A correction report shall then be submitted by the importer. This system is currently being implemented mainly for imported dairy products and edible food oils.

A record-filing system of imports and sales is also in place to handle risk control in a rapid, accurate and effective manner in instances where food safety issues occur. As stipulated by the *Food Safety Law*, after importers or agents obtain the "inspection and quarantine certificate for entry goods", they must conduct record-filing related to the importation and sale of each lot of imported food. Failure to do so will result in penalties in accordance with the relevant provisions of the *Food Safety Law*. Specific regulations for the implementation of this system have already been formulated and put into force.

Finally, the *Food Safety Law* also outlines a system for the recall of imported foods. According to the system, if a problem emerges after the entry of the imported food into China, its corresponding importer or agent shall voluntarily recall all the affected products or lots according to the level of risk. Relevant reports shall also be submitted to inspection and quarantine agencies. If the importer or agent fails to initiate a recall, a mandatory recall notice will be issued by AQSIQ or the inspection and quarantine authorities.

7.4.3. Governance system for export food safety

Based on the current situation and development of China's food export industry, and in order to improve the quality and efficiency of food exports, a food export quality and safety

management system has been established that promotes the participation in the governance of food safety and quality among non-government actors.

Corporate Accountability

Corporate accountability is the core of the quality and safety management system for food exports. It is also an important means for achieving the transformation of the government's role and functions, conforming to industry development, and encouraging enterprises to enhance the quality of food.

Planting and breeding: Crops and livestock farms exporting raw materials are subject to a record-filing system. The purpose is to standardise the practices of farms exporting plant a food raw materials so as to encourage relevant enterprises to undertake food safety and quality management during the planting or breeding stages, and ensure high quality directly at the source, while facilitating monitoring of these raw materials by entry and exit inspection and quarantine departments. Organisations with legal personality, such as export food production and processing enterprises, farms, and professional agricultural cooperatives, are responsible for undertaking record-filing with the local inspection and quarantine authority, and also for assuming primary responsibility for the quality and safety of exported food raw materials. The contents required to be submitted in record-filing include basic information on the filer as well as the quality and safety management measures it adopted, including for instance commitments taken on soil, irrigation water, relevant quality and safety control mechanisms, and lists of commonly used agricultural inputs. Local inspection and quarantine authorities are responsible for the supervision and management of record-filed planting and breeding farms within their jurisdictions; the quality and safety of their products, in accordance with relevant laws, regulations; and directory management. The directory of planting and breeding farms exporting food has been adopted and implemented since 2005. Currently, this record-filing management system is implemented for aquatic products, meat products, egg and egg products, bee products, vegetables (including edible fungi), rice, tea, and raw milk.

Production and processing stage: A record-filing system has also been established for producers of exported foods. Enterprises applying for record-filing shall establish a food safety and health control system based on hazard analysis and prevention and control measures, in order to ensure that the production, processing and storage of the exported food meet the quality and safety requirements stipulated by the laws, regulations, standards and other regulatory documents of both China and the destination country/region. As part of the application, the producer of the exported food must submit an application form together with relevant certification materials to entry-exit inspection and quarantine departments. Their information will be filed only if the subsequent review and on-site examination by authorities are approved.

Finally, the producers of exported food are also subject to a quality and safety personnel system, according to which they must follow the same practice as domestic food production enterprises in opening specialised food safety management positions for food safety personnel familiar with relevant laws, regulations, national standards, and processing techniques.

Follow-up management stage: The producers and distributors of exported food shall establish a food safety traceability system to record and preserve the quality and safety information of exported foods in an objective, effective and truthful manner. The objective here is to trace the quality and safety of food in order to control potential risks. In cases where quality and safety problems emerge, this system allows the affected products to be recalled; the causes of the problems to be investigated; and relevant enterprises to be held accountable. The record-filed information required includes raw materials; food additives; source information of food packaging materials; stock inspection/acceptance information; production; process quality and safety control information, such as raw and auxiliary materials storage, storage, and delivery; production and use information; production-related information; production inspection related information; factory inspection information; product flow information, etc.

The producers and distributors of exported food are also expected to take the initiative to rapidly, efficiently and scientifically reduce and eliminate food safety-related issues for exports, so to avoid potential disruptions of the export market. They are required to adopt emergency responses immediately after the occurrence of food quality and safety incidents. Such responses may include, e.g., investigations, assessments, and controls, and can be terminated only after the hidden danger or risk has been eliminated. The entry-exit inspection and quarantine authority shall also adopt emergency responses in accordance with relevant provisions of AQISQ.

Finally, a business integrity system has been established for food exporters, urging them to abide by ethical conduct and integrity throughout food production, and to contribute to the principal of social co-governance. Food exporters must follow the quality and safety requirements of both China and the destination country or region;must voluntarily fulfil the responsibilities and procedures regarding quality and safety management; and must provide information regarding their production and distribution status to relevant supervisory authorities in an accurate, objective and timely manner. Inspection and quarantine authorities will establish for food exporters record-filing mechanisms focusing specifically on integrity, in line with the principle of “rewarding enterprises with integrity, and punishing those without integrity”, with the purpose of guiding enterprises to conduct business in good faith and in accordance with existing laws and regulations.

Improvement of supervision and management effectiveness

The government shall engage in the role of supervision. In particular, export food quality

and safety management authorities, in accordance with relevant quality and safety requirements and enterprise quality management measures, are tasked with: carrying out process supervision; testing samples, and undertaking risk management in order to hold production enterprises accountable.

The export food safety risk monitoring system is an important system for monitoring quality and safety risks and for obtaining information on the quality and safety of exported food. Experts are appointed by AQSIQ to research, formulate and implement the export food risk monitoring plan based on risk assessments. In case potential food safety hazards are identified, AQSIQ or entry-exit inspeciton and quarantine authorities shall immediately adopt countermeasures; relevant departments of the State Council or local governments shall also be notified.

The export food safety sampling testing system is an important system for ensuring quality and safety of exported foods. It consists of sampling, inspection, processing, and reporting of exported foods by the entry-exit inspection and quarantine authorities, based on the sampling testing plan of exported foods. It also represents an important means for assessing the compliance of exported foods. Each year, experts are appointed by AQSIQ to determine the ratio and key focus of sampling tests based on risk assessments. Local sampling testing plans may also be formulated by local branches of AQSIQ according to the needs of their jurisdictions. Prompt measures shall be adopted by AQSIQ and entry-exit inspection and quarantine authorities in case problems are identified during sampling tests; relevant departments of the State Council or local governments shall also be notified.

The rapid risk alert system for the quality and safety of exported food can be seen as the application of the “prevention, intervention, and response” principle of food safety risk prevention. The system consists of five main parts.

Information collection: AQSIQ establishes a nation-wide unified food safety information collection network system to collect risk information related to the inspection and quarantine of exported food;

Risk analysis: AQSIQ sets up a risk analysis expert committee for conducting risk analysis, formulating risk assessment conclusions, and outlining recommendations on countermeasures;

Rapid risk alert: AQSIQ publishes food safety-related rapid risk alert notifications in cases of potential safety hazards; relevant measures are also adopted, including conditional restrictions or a ban of exports, and initiation of

the safety emergency response;

Rapid risk alert implementation: Entry and exit inspection and quarantine departments implement control measures for relevant exported foods in accordance with the risk warning requirements issued by AQSIQ;

Lift of risk alert: When food safety-related risks of exported food cease to exist or are reduced within acceptable levels, rapid risk alert and control measures shall be lifted by AQSIQ. Entry-exit inspection and quarantine authorities shall, on the basis of a risk warning-removal notice issued by AQSIQ, lower the level of risk control measures or restore routine supervision.

Establishment of export food quality and safety demonstration zones

The establishment of a comprehensive, regionalised management platform for ensuring the quality of exported food that mobilises relevant stakeholders and focuses on all segments of production, processing and exports provides a number of potential benefits. Most notably, it promotes agricultural investment and trade while simultanerously enhancing the quality and safety of food exports.

In order to realise these benefits, the regional management system for the quality and safety of exported food has focused on establishing demonstration areas for export food quality and safety. Its objectives include promoting increases in regional quality and safety levels, upgrading the industry, and supporting supply-side structural reforms in agriculture. Export food quality and safety demonstration zones at the national-level have been established under the responsibility of local governments. Applications for establishing such zones are collected by line inspection and quarantine agencies, which are also responsible for screening, recommending and supervising applications. AQSIQ is responsible for the assessment, approval, publication and selective inspection of approved demonstration zones. Within demonstration zones, model companies for food exports are selected to drive domestic sales of food, based primarily on five selection criteria, including: quality, innovation capabilities, strictness of standards, brand effect, and social reputation.

7.4.4. Conclusions

China has already entered its 13th Five-year period. The 13th Five-year Plan particularly puts forward the implementation of the food safety strategy and the enhancement of supervision and management over imported food. Under the guidance of the Plan, China has already gradually formulated a risk assessment-based food safety regulatory system governing the import and export food, in line with the international practices. In addition, following the deepening of the institutional reforms, the food safety regulatory system regulating imported and exported food will continue to be improved and upgraded. As the system becomes increasingly integrated into the economy, it will promote the development of international trade while ensuring that people can safely purchase and consume food.

7.5. Novel food raw materials

Sun Juanjuan

In terms of legislation, the concept of "novel food" has witnessed a transition from "novel food resources" and "novel resource foods", to "novel food raw material". Generally, the regulatory system begins first with a safety assessment, followed by administrative approval, only after which production and use can take place. [119]

7.5.1. Legislative evolution from "novel resources" to "novel foods", and to "novel raw materials"

China ranks among the first group of countries that first began to crate and implement this type of regulation. It originated from the *Food Hygiene Law of the People's Republic of China (for trial implementation)*, which was enacted in 1983. In particular, according to Article 22, before producing new types of food and food additives using new resources, or food containers, packaging materials, tools and equipment that are produced using new raw materials, producers and distributors first needed to submit a hygiene evaluation, together with relevant nutritional information in the former case. Furthermore, samples of the above new varieties also had to be submitted for approval according to the food hygiene standard approval procedures, before production could start. [120] In this regard, it is noteworthy that the products involved in these "new resources" and "new materials" not only involved the food itself, but also food additives and related products that enter into physical contact with the food.

On 18 August 1987, in order to specifically implement the provisisions of the *Food Hygiene Law* trial, the former Ministry of Health – as the competent authority in charge of public health – issued the *Measures for the Hygiene Management of Novel food resources*. The Measures stipulated that "novel food resources" refer to objects that are traditionally not or rarely used in the production of food, or that are only used in a few areas; to objects that are intended to be used for producing food (including food raw materials) and food additives; as well as new raw materials used to produce food containers, packaging materials, food tools, and equipment. This definition suggests that, the "new" factor taken into account by legislation at that time mainly focused on eating habits; after all, China's research on new food technologies was still relatively limited at that time. Moreover, given the limited volume of international food trade, the consideration of eating habits was also based on the internal

[119] Wang Yongfang, "The Status Quo and Analysis of China's Novel resource foods Management", *Chinese Journal of Health Supervision*, No. 1, 2011, p. 21.

[120] Sun Chunwei, Zhao Guihua, "The Institutional Changes and Responses from Novel resource foods to Novel food raw materials", *Science and Technology of Food Industry*, No. 1, 2014, p. 17.

circulation of food which brought to nationwide scale food resources typical to certain localities.

The Ministry of Health, however, in 1990 replaced the above Measures with other regulations specifically targeting novel resource foods. This shift from "novel food resources" to "novel resource foods", on one hand, contributed to a better clarification of the concept to include "newly-developed", "newly-discovered", or "newly-introduced" objects, as well as regional foods and ethnic foods consumed only in circumscribed areas. The inclusion of words such as "newly-developed" and "newly-introduced" suggests that legislation on novel foods at that time had also incorporated foods produced by new technologies and introduced by importers – meaning in both cases they were not previously available in China. On the other hand, the new definition of "novel resource foods" includes two categories: food raw materials and finished products. In addition, the new regulations further stipulated labelling requirements for novel resource foods, which were now added to the provisions relating to the approval and supervision of novel resource foods stipulated by the *Food Hygiene Law*. Novel resource foods under pilot production were required to highlight the word "novel resource food" and its approval number in prominent positions in advertising and packaging, and were also forbidden to advertise or imply effects for medical treatment in any form. Furthermore, in the same year the Ministry of Health also formulated the "*Procedures for the Examination and Approval of Novel resource foods*", indicating the documentation and corresponding procedures for the preliminary examination, pilot product, and full-scale production of novel resource foods.

On 1 July 2002, the Ministry of Health further implemented the *Administrative Measures of Genetically Modified Foods*, which regarded genetically-modified (GM) foods as "novel resource food". The Measures also stipulated that GM foods require examination and approval by the Ministry of Health before being produced or imported as either food or food raw materials. GM foods refer to foods and food additives produced by animals, plants, and microorganisms whose genetic structure was changed with genetic engineering tehnologies, including in particular: (1) Transgenic plants and animals, and microbiological products; (2) Transgenic plants and microorganisms; and (3) Foods and food additives produced by using transgenic plants, animals, microorganisms or their directly processed products as raw materials. The introduction of the Measures signifies the involvement of the Ministry of Health in the management of GM foods, especially regarding overseas products and imports. This means that, imports of GM foods into China, such as genetically modified soybeans, require not only the safety evaluation of the Ministry of Agriculture, but also the approval from the Ministry of Health in order to be listed as an approved food item. For this reason, this piece of regulation is considered to reflect the efforts of the Chinese government to

strengthen the management of imported GM foods.[121] Nonetheless, the Measures were repealed in 2007.

In 2007, the Ministry of Health reformulated the *Measures for the Management of Novel resource foods*, in accordance with the *Food Hygiene Law* which was officially enforced in 1995. Their main features are as follows:

- Redefinition of "novel resource foods", to exclude GM foods and food additives. It was specified that GM foods shall follow a series of relevant national laws and regulations on GM foods, including the *Regulations on the Safety Management of Agricultural Genetically-Modified Organisms*, formulated by the State Council; and the *Administrative Measures on the Safety Evaluation of Agricultural Genetically-Modified Organisms*, the *Regulations on the Administration of Labelling of Agricultural Genetically-Modified Organisms*, and the *Administrative Measures for the Safety of Imported Agricultural Genetically-Modified Organisms*, formulated by the Ministry of Agriculture;
- People's safety is included as main focus, in addition to health management. This means that novel resource foods shall not present any acute, sub-acute, chronic or other potential health hazards for the human body. The Measures also introduced the establishment of a safety evaluation system with risk assessment and substantive equivalence principles for novel resource food, to be adopted during the review and examination of novel resource foods;
- Obligation for producers and distributors to ensure the safety of novel resource foods produced or sold, that is, they must not use novel resource foods that have not been approved and published by MOH as foods or foods raw materials for production;
- Requirement for producers of novel resource foods or of food which contains novel resource foods, to establish a safety information collection and reporting system, and to report on an annual basis relevant information to local health administrative authorities. This requirement is added to the common obligation for producers and distributors to ensure the compliance of labelling with relevant laws and regulations. In case safety-related problems are identified, they should be reported to the local health administrative authority in a timely manner. Correspondingly, supervisory authorities have the right to inspect the above-mentioned information collection reports. Those who conceal or fail to report relevant food safety information may be condemned and criticised;
- Introduction of a new approval model for novel resource foods, from one based on single product approval and certification, to a list-based one shared with the public.[122] They also recognise the principle of substantial equivalence, namely that

[121] "Approval of Importation of Genetically Modified Foods by the Ministry of Public Health", "*Feeds Angle*", No. 10, 2002, p. 5.

[122] Wang Yongfang, "The Status Quo and Analysis of China's Novel resource foods Management", *Chinese Journal*

novel resource foods that can prove substantial equivalence with other food or with other novel food raw material that have already been included in the public approved list, do not need to apply again for approval.[123] The substantial equivalence should be in terms of species, source, biological characteristics, main ingredients, edible parts, dosage level, scope of application and target group of consumers, while the processing techniques and quality standards adopted should be basically identical. However, at present, there are still difficulties in putting this principle into practice. For instance, the information in the announcements for novel food raw material are often not very detailed, therefore, it is difficult to make a final assessment on the substantial equivalence. The approach used in practice is that enterprises submit applications for substantial equivalence based on a self-assessment of the substantial equivalence with products already on the list. When applicants find it difficult to complete the self-assessment, or have safety-related questions, they can apply to the competent authorities for assistance.[124]

As a relatively mature piece of legislation, the 2007 *Measures for the Management of Novel resource foods* have replaced the original pilot production system with a legislative framework covering safety assessment, licensing, production and distribution obligations, supervision and management, and punishments of illegal behaviours. As a supplement, the Ministry of Health also formulated the *Procedures for the Safety Evaluation of Novel resource foods* and the *Regulations on Health License Application and Acceptance for Novel resource foods*.

7.5.2. Existing regulations targeting "Novel food raw material"

The *Food Safety Law* first introduced in 2009 replaced the *Food Hygiene Law* to become the fundamental law in food safety regulation. According to Article 44 of the law, an entity or individual that applies for the utilisation of novel food raw material for the production of food, or for the production of new varieties of food additives or other food-releated products shall submit the safety assessment documents of the relevant product to the health administrative authority of the State Council. The latter shall, in turn, within 60 days from the date of receipt of the application, conduct an examination of the safety assessment documents of the relevant product and, if requirements are met, grant a permit and announce it publicly. In case the requirements were not met, the permit shall not be granted and a written explanation of the reasons of the decision should be provided. On this basis, on 5 February 2013 MOH released the *Measures for the Management of the Safety Examination of Novel*

of Health Supervision, No. 1, 2011, pp. 20-21.

[123] Wang Yongfang, "The Status Quo and Analysis of China's Novel resource foods Management", *Chinese Journal of Health Supervision*, No. 1, 2011, p. 21.

[124] Yang Yuexin, "Judgement and Basis for De Facto Equivalence of Novel resource foods at Home and Abroad", *Chinese Journal of Hygiene Supervision*, No. 1, 2011, pp. 18-19.

food raw material, which entered into force in October the same year repealing the 2007 *Measures for the Management of Novel resource foods.* The newly-issued Measures update the definition of "novel food raw material" in the following areas:

First, the original concept of "novel resource foods" is changed to "novel food raw material". It refers to the following objects or materials that are not traditionally consumed in China: animals, plants and microorganisms; substances derived from animals, plants and microorganisms; food substances whose chemical structure has been changed; and other newly-developed raw materials for food. In comparison, the concept of into "novel food raw material" incorporates the former "novel resource foods", thus including both food raw materials and finished food products. The concept is also made more general to include newly-developed raw materials.[125] The scope of "food traditionally consumed" is clarified for the first time, to include a type of food that has been produced or traded on a provincial scale as either packaged or unpackaged food for over 30 years, and that is included in the *Pharmacopoeia of the People's Republic of China*. It is worth mentioning that novel food "non traditionally consumed in China" includes not only exotic foods, but also local traditional foods which are not consumed on a provincial scale. The extended definition of the latter became conducive to the development of local food and ethnic food in China. Finally, the Measures specified that the scope of "novel food raw material" in the Measures does not cover GM foods, health food, or new varieties of food additives.

Second, in addition to maintaining the provisions of the previous original safety assessment system relating to the examination of application materials and to the follow-up evaluation of already licensed novel resource foods, the newly-issued Measures further add two additional examination parts:

- The need for the National Health and Family Planning Commission (which in 2013 substituted the Ministry of Health), as the relevant authority, to not only appoint experts to review the documentation for the safety assessment of novel food raw material, but also to openly solicit comments and opinions from the public after accepting the application. Thanks to deeper understanding of the subject of food safety, regulators had become increasingly aware that the primary responsibility of ensuring food safety rests not only with food producers and distributors, but also with the engagement of society, including self-governance of industry associations, media supervision, stakeholders, and the general public. Therefore, more and more systems for ensuring public engagement were introduced into food safety supervision, including the calls for comments in the 2013 *Measures for the Management of the Safety Examination of Novel food raw material*. It is also worth mentioning that the revised *Food Safety Law* provides a legal basis for public

[125] Sun Chunwei, Zhao Guihua, "The Institutional Changes and Responses from Novel resource foods to New Food Materials", *Food Industry Technology*, Vol. 1, No. 1, 2014, p. 17.

engagement through the principles of social co-governance and risk communication;

- The requirement for conducting on-site inspections. That is, if an on-site inspection of the production process is required during the examination of the application documentation, experts can be appointed to conduct on-site inspections to verify the production of the novel food raw material, on the basis of which an inspection report is drafted. Experts conducting the on-site inspection, however, must not take part in the review of the product safety assessment documentation.

Third, the Measures introduce, for the first time, a distinction in the product safety assessment between domestic applications and import application. Any entity or individual planning to engage in the production, use or import of novel food raw material, shall submit the following materials:

- Application form;
- Development report of the novel food raw material;
- Safety assessment report;
- Production techniques;
- Relevant standards enforced (including safety, quality, specifications, and testing methods standards);
- Labels and instructions;
- An analysis of the status of research and utilisation both in China and abroad, together with safety-related documents;
- Other materials facilitating the review process;
- One sealed product sample, or 30-gram of raw materials (packed) shall be submitted.

In addition, applicants applying for imported novel food raw material shall also submit the following materials:

- Certificates issued by the competent authority or agency in the exporting country (region) proving that the relevant product is permitted to be produced or sold in the country;
- Examination or verification certificates issued by the competent authority or organisation in the exporting country (region) to the applicant producer.

In view of the fact that the Measures introduced the requirement for publishing a call for comments from the public on the application materials and in order to protect the rights of confidentiality, applicants can remarks as to which content from among the application materials are non-confidential and thus can be released to the public.

The procedures of the safety examination mainly refer to the application and acceptance of the application of novel food raw material. Based on the 2013 *Measures for the Management of the Safety Examination of Novel food raw material*, MOH further formulated the *Regulations for the Application and Acceptance of Novel food raw material* with the

objective of further clarifying the requirements on the documentation to be submitted for the safety assessment of the novel food raw material, as well as the requirements for the administrative procedures for examination and acceptance of application. With respect to the examination, according to the *Procedures for the Safety Examination of Novel food raw material*, it is devided into a technical examination and an administrative examination. The former refers to the assessment of hygiene, toxicology and other aspects of the novel food raw material, conducted by an expert committee comprised of experts in food, nutrition, medicine and pharmacy. On-site inspections may eventually be conducted. On the basis of the technical exaimation, NHFPC makes an administrative examination to decide whether the administrative license can be granted. In addition to the specific requirements outlined by the *Procedures for the Safety Examination of Novel food raw material*, the administrative examination is also conducted according to the procedures stipulated by the *Administrative License Law of the People's Republic of China*. Administrative agencies and relevant personnel who violate the *Administrative License Law* are held accountable in case administrative license is not granted to applications satisfying all the requirements, or in case legal duties and obligations have not been fully performed during the acceptance and examination procedures.

7.5.3. Conclusions: similarities and differences between novel foods and ordinary foods

The main reason for distinguishing novel foods from ordinary foods is that the latter have been proven to be safe by the historical experience of eating or scientific assessments. To ensure the safety of newly-discovered, newly-developed or newly-imported food without previous consumption habits, new measures and regulations are formulated. Through the review and analysis of China's current supervision and management of "novel foods", it is not difficult to recognise its increasing improvement, in particular regarding the definition and scope of core concepts, on one hand, and oversight regulation on the other.

In terms of core concepts, the definition of "novel foods" evolved from "resources", to "food", and finally to "raw materials". As an example of practical experience, the products that were initially approved under the 1987 *Measures for the Hygiene Management of Novel food resource* consisted mainly of final products. Following the rise of health food as well as regulatory standardisation, the approval of novel resource foods has gradually shifted from the approval of the finished product, to that of the raw material. Announcements regarding the lists of approved products have avoided repetitiveness in product-based approval.[126] The 2013 *Measures for the Management of the Safety Examination of Novel food raw material* further outlined a clear definition of "raw materials" and provided a legal basis for the

[126] Wang Yongfang, "The Status Quo and Analysis of China's Novel resource foods Management", *Chinese Journal of Health Supervision*, No. 1, 2011, p. 20-21.

adoption of raw materials for new research and development through general provisions. In other words, as long as the new raw material has been approved, foods made by such raw materials no longer need to undergo an examination. Nonetheless, it should be noted that compared with the approval of novel foods, the approval of new raw materials imposes more stringent requirements for dosage level, thus calling for further supervision to ensure the safe use of novel food raw material. In comparison, the scope of "novel foods" has become narrower. Initially, under the 1987 *Measures for the Hygiene Management of Novel food resource*, "novel food resources and new materials" was included within the supervision and management of food-related contact materials other than food; the 2007 *Measures for the Management of Novel resource foods* transferred "genetically-modified foods" outside of the scope of supervision and management of novel foods; while the 2013 *Measures for the Management of the Safety Examination of Novel food raw material* extended this exclusion from supervision and management also to health food and new varieties of food additives. Although the European Union has also adopted a legislation to exclude "genetically-modified foods" from its "novel food" supervision and management scope, the main rationale was to regulate their licensing, labelling and traceability through more specific regulations. [127, 128] In China, however, after the abolition of the 2002 *Administrative Measures of Genetically Modified Foods*, unfortunately there have no longer been dedicated legislations on GM foods. It was only with the revised *Food Safety Law* in 2015 that the labelling and marks requirement of GM foods are once again emphasised. In contrast, health foods and new varieties of food additives both have their dedicated measures and regulations.

Second, whether it is for novel food resources, novel resource foods, or novel food raw material, the safety inspection and licensing system has a "dynamic" feature. Specifically, after the license for novel food raw material is granted and announced to the public, an explanation limiting the scope of its use is also provided. Production shall be carried out in accordance with the requirements of the announcement to ensure the safety of novel food raw material. In addition, after these approved new resources/foods/raw materials have been used for a certain period of time, they can be converted by the health authority to ordinary foods through public announcements, meaning that any further safety review is no longer necessary for them. One example is provided by the *Circular on the Rectification of the Health Food Market (Wei Jian Fa Fa [1998] No. 9)* issued in 1998 by the Ministry of Health, which, in accordance with the *Food Hygiene Law* and the 1987 *Measures for the Hygiene Management of Novel food resources*, converted into ordinary foods several categories of food previously recognised as "novel food resources", such as rapeseed pollen, corn pollen,

[127] Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed.

[128] Regulation (EC) No 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

pine pollen, sunflower pollen, milk vetch pollen, buckwheat pollen, sesame pollen, sorghum pollen, konjac, spirulina platensis, spirulina maxima, Robinia, and roselle silkworm cocoons. Furthermore, there are two types of approval after the application of novel resource foods has been reviewed: the first one relates to the announcement of novel resource foods by public announcement; the second relates to foods that will be managed as ordinary foods after they have been consumed in China for a certain period of time.[129] Finally, unlike the general foods that are no longer subject to safety review, MOH has the responsibility to review the novel food raw material again when their safety is questioned due to new scientific discoveries or evidence indicating potential safety hazards.

Finally, lists of approved novel food raw material are published by the relevant health authority through public announcements, approvals, or letters of reply. For instance, in order to implement the 2013 *Measures for the Management of the Safety Examination of Novel food raw material*, MOH published a list summarising and gathering together all the lists of of food raw materials approved through various means. In addition, the same means will also be used by the same relevant health authority to address issues relating to scope, usage or labelling of novel food raw material, meaning that producers should follow relevant requirements when engaging in the production of novel food raw material.

7.6. Internet food: the example of online food catering services

*Ding Dong**

The platform economy has become the core feature of the Internet economy. From the development path of emerging businesses across industries, it can be observed that the speed of new business development is much faster than legislation that covers it. From Internet finance and travel to online catering services, the "innovation of business models precedes, and rules and regulations follow". In the food sector, the legislation covering online food safety generally evolved from vague to clear, which corresponded to greater understanding of business models and the logic of the online food industry. Moreover, the focus on third-party platforms and online food distributors shows that legislation is based on the principle of pragmatism. The virtuality of cyberspace and transforming consumption settings have indeed put forward new requirements for online food distributors and platforms in different aspects of food safety and protection of consumer rights to information. Objectively speaking, in terms of food safety, the rise of China's online food industry has not changed the essential

[129] Zhang Xiaoxia, "Analysis and Thinking on the Status Quo of Novel food resources in China", *Chinese Journal of Hygiene Supervision*, No. 4, 2012, p. 317.

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characteristics of food operations. The food safety requirements of online and offline food operations are not fundamentally different due to different consumption patterns. The solution to food safety problems or risks not only hinges on online regulation, but on the collaborative management from both online and offline. On that basis, this section uses the legislation of food safety as a starting point and focuses on the development of the online catering service market, the legislative status quo and the developmental trend, offering an overview of online food safety legislation in China.

7.6.1. Progress in the legislation of online food supervision and management

Overview of food safety legislation and online food supervision

China's current food safety supervision and management system is centred on the *Food Safety Law*. This can be observed from a comparison between the 2009 and 2015 editions of the *Food Safety Law*: the former, which came into effect on 1 June 2009, did not contain any provisions on the Internet food industry. In 2013, CFDA was established, and China's food safety supervision and management system changed from a segmented approach to greater centralisation. To adapt to the new reform, the revision of the *Food Safety Law* included online food businesses and regulation of third-party platforms and online distributors.

At the national level, on 1 October 2015, the newly revised *Food Safety Law* was officially implemented with food safety obligations and legal liability clauses for third-party platforms. One year later, on 1 October 2016, the *Measures for the Investigation and Punishment of Unlawful Acts concerning Online Food Safety* were implemented, and so were on 1 January 2018 the *Measures for the Supervision and Administration of Food Safety in Online Catering Services*. At the local level, the online food industry is mostly regulated by local legislation and regulatory documents formulated by local food safety administrative authorities. For example, the Zhejiang provincial food and drug administration issued the *Regulations on the Supervision and Administration of Third-Party Platform Internet Orders in Zhejiang Province* in 2015. Shanghai, Jiangsu, Guangdong, Henan, Hubei, Shaanxi, and other provinces have also adopted regulatory documents for online catering services and online food sales. As a result, a food safety legal system for online catering services has taken shape, centred around the *Food Safety Law* and supported by several departmental and local regulations.

The core content of online food regulation

Current regulations stipulate legal obligations and liabilities for third-party platforms and the online food distributors.

1) Third-party platforms:

Third-party platforms feature the typical traits of the "two-sided market" described by Jean Tirole, the 2014 Nobel Prize Laureate in Economic Sciences. According to Tirole, platforms have a similar nature to the traditional trading market, which is "getting the two

sides on board"; however, the key reason for platforms to become a two-sided market is that they can affect the volume of transactions through their structure rather than simply charging fees. At the same time, the two-sided market has the positive cross-side network effect: the more buyers, the more the platform attracts the sellers, and vice versa, thus with the potential of forming a positive cycle in which the more users there are, the greater the value of the platform is.[130] When the first draft of the revised *Food Safety Law* was published for public comments in 2013, the first clause of Article 59 stipulated that the third-party platform of an online food business should obtain food distribution licenses, suggesting that third-party platforms were regarded as food distributors. This reflected the overall perception of the emerging platform economy at that time. However, this clause was deleted from the final version of the *Food Safety Law* published in 2015. The deletion is in line with the basic model and business logic of the Internet food business, as the new *Food Safety Law* defines the legal nature of the third-party platform as a service provider for intermediary information services rather than the food distributors. This view on third-party platforms is shared by other governments such as the Food Safety and Standards Authority of India, which in 2017 issued the *Guidelines for Operations of E-Commerce Food Business Distributors* stipulating that e-commerce entities providing listing/directory services may not be required to obtain license/registration as they are not engaged in food production or operation.[131]

The *Food Safety Law*, however, does not clearly define third-party platforms. Simply put, the trading of internet foods on online platforms (including online catering services) is a process of shifting food consumption from offline to online. An accurate definition of third-party platforms is provided by the *Shanghai Municipal Measures for the Supervision and Administration of Food Safety in Online Catering Services*: "*[the third-party platform] refers to the providers of information network systems that offer web space, virtual business sites, trading rules, transaction facilitation, and information publication services to online food traders in order to facilitate independent transactions between two or more parties*". This definition clarifies the role of the third-party platform as information service agent in online food businesses.

Concerning legal obligations and liabilities, Article 62 of the 2015 *Food Safety Law* stipulates four primary obligations for third-party platforms, namely the need to register the legal names of food traders admitted to the platform, check their licenses, halt illegal activities and file a report with the government, and suspend online trading platform services when a serious illegal act is discovered. Article 131 specifies the administrative and civil liabilities in case these guidelines are violated:

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[130] See JC Rochet, J. Tirole, "Two-sided markets: a progress report", *Rand Journal of Economics,* 2006, 37(3):645-667.

[131] *Guidelines for Operations of E-Commerce Food Business*: http://www.fssai.gov.in/dam/jcr:3d0b2d13-c4b9-46ae-a96f-d2787b3bede8/Order_Guidelines_FBOs_03_02_2017.pdf

- Administrative liabilities mainly refer to the confiscation of illegal income and administrative fines (50,000 – 200,000 RMB); if there are any serious consequences, operations shall cease and the license shall be revoked by the original license issuing authority (which here mainly refers to the value-added telecommunication business license issued by the telecommunications authorities);
- Civil liabilities consist, in turn, of two aspects: first, if any damage is caused to the lawful rights and interests of consumers, the third-party platform shall assume joint and limited liability with the food trader. Second, in case of damages claimed by a consumer against the food trader admitted to the platform, the third-party platform shall compensate only if it is unable to provide the legal name, address and valid contact information of the food trader. But of course, if the ultimate liability lies with the food trader/producer, after making compensation the platform shall be entitled to recover it from the food trader/producer.

Based on the *Food Safety Law*, CFDA further formulated the *Measures for the Investigation and Punishment of Unlawful Acts concerning Online Food Safety* (October 2016), and the *Measures for the Supervision and Administration of Food Safety in Online Catering Services* (January 2018) to further specify the food safety management responsibilities of third-party platforms. In addition to the four obligations stipulated in the *Food Safety Law,* the platforms are required to register with the food supervision and management authorities after obtaining the "value-added telecommunication business license", to establish a consumer complaint reporting system and a dedicated department for food safety management. They are also required to assign dedicated personnel to food safety management, and to conduct sampling tests and monitoring on the admitted catering service providers. This demonstrates the future direction of legislation towards placing stronger obligations on third-party platforms.

2) Legal obligations and liabilities of food distributors

The 2009 version of the *Food Safety Law* divided food operations into food distribution and catering services, requiring each distributor to obtain food distribution licenses and catering service licenses. The 2015 version of the *Food Safety Law* combines food distribution and catering services into food operations and unifies the two corresponding licenses into a single food operation license. The law also has systematic and detailed provisions for the food distributors' responsibilities, with key points mainly including: obtainment of the food operation license before starting business activities such as food sales and catering services; the inspection on the purchased food and food raw materials as well as their purchase receipts; and process control and standardisation of food business activities.

When food operations move from offline to online, only the trading space and the payment method change. Taking catering services as an example, the scenarios that do not change are: food production is completed by offline physical locations, and the consumers'

dining process is completed offline as well. The scenarios that change are: consumers' decision-making, payment methods and delivery order – that is, consumers do not need to visit the physical store, but food will be delivered to designated locations by the platform or the business distributor. Similarly, both these similarities and differences between offline and online food operations also affect the design of relevant laws and regulations. The *Measures for the Investigation and Punishment of Unlawful Acts concerning Online Food Safety* and the *Measures for the Supervision and Administration of Food Safety in Online Catering Services* stipulate that the supervision and management of online food businesses (such as online catering services) shall be consistent with offline businesses, and that the shift of food businesses from offline to online essentially does not change the fundamental logics of food distribution. Therefore, in terms of food safety, online food distributors must fulfil the same obligations as their offline counterparts: for example, licenses must be obtained, operations must not extend beyond the designated scope, and food and food ingredients must be purchased under inspection and with receipts; unsafe food and food ingredients are prohibited for purchase or use; food distributors who engage in work involving contact with ready-to-eat food must hold a health certificate.

The difference lies on the fact that consumers do not necessarily need to go to the physical store and food is delivered. Consumers' consumption decisions also mainly depend on information displayed online. Therefore, the regulations of online food operation are special to some extent, as it can be observed from the two food safety's dimensions of "safety" and "confidence". On one hand, the delivery of food must be standardised to prevent food poison and other potential hazards to health. For example, Article 20 of the *Measures for the Investigation and Punishment of Unlawful Acts concerning Online Food Safety* stipulates that if foods that are traded online require special storage conditions, such as freshness preservation, heat preservation, cold storage, and freezing, the online food producers and distributors shall adopt storage and transportation measures that can ensure food safety or entrust competent companies to store and deliver. The *Measures for the Supervision and Administration of Food Safety in Online Catering Services* also require strengthening the management and training of food delivery personnel, using non-toxic and clean containers for food delivery, and that food delivery personnel maintain personal hygiene and avoid contact with food. Shanghai, Zhejiang and other local regulatory authorities require that food delivery personnel must also obtain health certificates. At the same time, it is required that online catering service providers must not entrust other entities to process food to ensure food safety.

On the other hand, the regulations concern the consumer's right to information, and "confidence". The rationale of the system design is that the comprehensive knowledge of true information about goods and services is a prerequisite for consumers to make correct consumption decisions, and it is also a basis for consumers to have confidence in food safety. Therefore, the entire system design focuses on the listed information of admitted food

distributors. For example, food distributors on the platform should publicise their food business licenses. Catering service providers need to publicise information on their food safety grade, the names of the dishes and their main ingredients. Other measures in Shanghai and other provinces also require the publication of the catering provider's employee health certificates.

Distributors in violation of the regulations are subject to administrative and civil legal liabilities. Administrative liabilities refer to the violation of relevant provisions of the *Food Safety Law.* For food distributors, fines shall be imposed, business activities suspended, illegal income confiscated, and the distribution license revoked. Civil liabilities relate to compensations provided to consumers in case of damages or losses, such as punitive damages that must be assumed when food distributors are not compliant with food safety standards (as extensively illustrated in chapter 6 of this book). In addition to the illegal behaviours and legal liabilities stipulated in the *Food Safety Law*, based on two departmental rules of CFDA, food supervision administrative authorities shall order the distributors that fail to fulfil their obligations of information disclosure to correct their behaviour; only those who fail to proceed accordingly will be subject to punishment. This serves the purpose of the *Chinese Administrative Punishment Law* of combining education with punishment for administrative violations.

7.6.2. Specific analysis of supervision and management of online catering services

Overview of the market development of internet catering services

The online catering service market in China started to develop relatively early. In 1999, Sherpa's, a food delivery company founded in Shanghai by an American citizen, Mark Secchia, can be regarded as the first food delivery platform in China. At that time, Secchia, who was studying at the China-Europe International Business School, realised that foreigners in Shanghai used to encounter several language obstacles when dining outside, prompting him to set up a take-out company. Sherpa's targeted high-end market and served foreigners living and working in China. All delivery staff were directly employed and trained by Sherpa's. [132] From orders submitted first by telephone and then through website and App (O2O model), after more than a decade Sherpa's still has a sizeable share in the Chinese online catering market.

After this period, China's online food industry entered the era of group buying. With large inflow of capital, a number of group buying websites emerged since 2010. There was intense competition for market share, while the online catering service market was relatively undeveloped. In 2009, *Ele.me* was launched; *daojiameishi.com* and *linghaoxian.com* followed

[132] Li Bing, "From the Trail Blazers to the Leaders of the Food Market, the Invisible Champion "Sherpa's", *China Ethnic Magazine*, July 18, 2017, 9th edition.

in 2010; in 2013, Meituan Group officially started to offer online food delivery services, and in the same year Alibaba Group formed *taodiandian.com*; in 2014, Baidu Food Delivery was launched. Following the involvement of an increasing number of players in this market, since 2015 China's online catering service have entered a relatively stable stage of development. The overall competition features the typical characteristics of the Internet economy, namely: the emergence of industry opportunities; capital and players from different sectors pour in; fierce competition knocks some players out of the market and mergers & acquisitions start; business model and industry development patterns tend to stabilise; fierce competition among multiple scattered players transforms into competition between a few key players". In 2017, Baidu Food Delivery merged with *Ele.me*, leaving Meituan and *Ele.me* as the two major competitors. According to the *2017 China Mobile Internet Industry Development Analysis Report* released by Trustdata, the market size of online catering service industry continued to grow in 2017, with the value of total transactions completed reaching nearly 200 billion RMB. [133]

Positive effects and challenges in the market development of online catering services

The rapid development of China's online catering service market has brought tangible impact on market actors. Profound changes have taken place in consumer lifestyles and consumption patterns, and people lives have become more focused on services that prioritise convenience. Secondly, the industry also addresses the dining difficulties of special groups such as doctors, nurses, patients, unattended children and the elderly. Thirdly, the capacity, scale and quality of catering service providers has increased as platforms enable them to have longer business hours, a larger service radius and higher service efficiency. Finally, delivery jobs have contributed to an increase in the employment rate and income levels.[134]

However, as online catering service space is virtual, transactions are not made face-to-face thus it is vital to ensure consumers' right to information and privacy. Another challenge is to ensure the safety of foods sold online.

Evolution of food safety supervision and management regulations for online catering services

The effective implementation of any kind of law and regulation must be based on the specific development of its target industry. Otherwise, the law runs counter to reality of the market. China's online food catering market has developed in parallel with general trends in offline catering services. Data from some provinces and municipalities show that small and micro-sized restaurants dominate China's catering service industry. For example, in Jiangsu province, more than 70% of the 330,000 catering service businesses are small and micro

[133] Trustdata, "*2017 China Mobile Internet Industry Development Analysis Report",* January 2018. Although different research reports have different conclusions on the market size and transaction volume of online catering services in 2017, 200 billion RMB is a generally accepted data.

[134] Meituan Research Institute, "2017 Delivery Research Report", January 2018.

entities. There are more than 40,000 so-called "small food businesses" with small business premises, a low number of employees, simple conditions, and a lack of variety in foods. [135] According to statistics released in June 2017, in Chengdu there are more than 1,300 small food production workshops, over 50,000 small food stores, and more than 5,000 food street vendors. [136] The large number of small and micro food businesses reflects the fragmented nature of China's catering service industry. The analysis report of the China Cuisine Association shows there are still problems such as unbalanced development in the catering market in terms of business types, quality, region, urban and rural areas.[137]

Given the status of China's catering industry, the problem for food safety is that small catering businesses find it difficult to meet the requirements necessary to obtain food licenses as stipulated in the *Food Safety Law*. The review and license approval process also involve indicators unrelated to food safety, such as the nature of the property (which must be commercial housing) and the environmental impact assessment. Notwithstanding, small catering businesses play a positive role in creating jobs and providing convenient services for people, which means shutting them down is not always a straightforward option. Online food catering services face the same challenges.

From the perspective of food safety risk control, licensing – as a prerequisite for food distribution – does not necessarily ensure food safety. Licensing is just a proof of qualification; even if a license is granted, food safety issues will arise if relevant food safety procedures and operating practices are not strictly respected. Acknowledging this problem, food safety regulatory authorities across China began to explore alternative non-licensing management methods such as registration, record-filing, and approval of small restaurants to meet basic food safety and hygiene requirements. It reflects a positive shift in the management approach of relevant authorities, from one that places excessive emphasis on "ex-ante regulation", to one adapting management practices based on the actual conditions of the catering industry.

7.6.3. Platforms' responses

The 2015 version of the *Food Safety Law* identifies social co-governance as one of its basic principles. The implementation of the *Food Safety Law* relies on the participation of all parties in society, and third-party platforms are an important link in the food safety management chain. Taking Meituan-Dianping Group as an example, its vision is to be a "socially responsible company", and it endeavours the principle of "eat better, live better".

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[135] "Qin Qinhu, Deputy Director of the provincial CPPCC and Provincial Food and Drug Administration, "*Good Food safety Takes Care of the Public's Stomach*", http://k.sina.com.cn/article_2188202475_826d51eb020003319.html, accessed on March 24, 2018.

[136] "*Interpretation of Implementation Rules (Trial) for Chengdu Food Workshops, Small Business Stores, and Street Vendors*", http://www.cdfda.gov.cn/zwgk/zcfg/zcjd/8710.html, accessed on March 24, 2018.

[137] "*Chinese Cuisine Association Interpretation of 2017 Catering Market Forecast 2018 Market Outlook*", http://www.ccas.com.cn/Article/HTML/108620.html, accessed on March 24, 2018.

The Group takes full advantage of Internet technologies such as big data to fulfil food safety management responsibilities and participate in the food safety social co-governance.

Food operation license review and verification system

In accordance with the newly revised *Food Safety Law*, the *Measures for the Investigation and Punishment of Unlawful Acts concerning Online Food Safety*, and the *Measures for the Supervision and Administration of Food Safety in Online Catering Services*, *Meituan.com* developed an "electronic record-filing system for online merchants" through which food distributors are reviewed before being admitted to the platform, are filed when operating on the platform, and are traced after leaving the platform, thus covering the entire business lifecycle.

The basic logic of the system is as follows. Food distributors upload photos of their food distribution licenses on the platform. A self-developed optical character recognition (OCR) image recognition system automatically identifies and files records of key information contained in the photos, including the name of the distributor, persons responsible, business address, license number, business scope, and validity. The photo-uploading process prevents the manual entry of information. After the preliminary review of the license is completed, the authenticity of the license is verified and classified by a system that connects to government data. After the review approval, food distributors are subject to supervision and management on a regular basis; risk alerts will also be issued to food distributors when their licenses expire or when their activities exceed the scope of their business license. At the same time, the authenticity of the restaurant address is checked by delivery personnel to prevent ghost restaurants. Negative comments and complaints are filed in the system. The system shares data with the food and drug administrative authorities of Beijing, Shanghai, Xiamen, Shenzhen, Jinhua, Ningbo, etc., so that "registration" and "verification" of merchant information are completed simultaneously.

Food safety system during the food delivery process

Ensuring that food is not contaminated during delivery is a new requirement for online catering services. To ensure "food temperature, delivery time limit, and delivery personnel's health", Meituan group developed the "Real-Time Delivery Intelligent Dispatch System" to shorten delivery time through big data estimation, real-time distribution simulation, and super machine learning. The average delivery time of a single order is 28 minutes, with a delivery punctuality rate of 98%. Consumers can therefore enjoy their food in the shortest time possible. At the same time, new double-layer cold and heat insulation boxes are used to ensure food temperature. Strict cleaning and disinfection rules are implemented to ensure the cleanliness of the delivery boxes and the hands of the deliverymen. To ensure that delivery personnel have no direct contact with food, the Meituan group also designed a unified take-away seal: once it is torn open, it cannot be restored again.

Public evaluation big data system for restaurants food safety

The world's earliest independent third-party consumer review website, *dianping.com*, which is owned by the Meituan-Dianping Group, has accumulated hundreds of millions of consumers' evaluations through big data. By restructuring and visualising the evaluations, the Meituan-Dianping Group developed the "Tianyan System" versions 1.0 and 2.0 in collaboration with the Shanghai Food and Drug Administration, followed by a nation-wide version 3.0 which objectively reflects the evaluation of the quality and safety of restaurants by consumers across the country, and provides reference for the regulatory authorities to understand the overall industry situation and conduct offline supervision and management.

Compliance education of catering business

Food producers and distributors take primary responsibility for food safety. Both offline and online businesses must strictly follow the requirements of the *Food Safety Law*. As online food distributors admitted to platforms are the first purchasers and producers of food and raw materials, it is crucial they have a strong awareness of food safety. The Meituan-Dianping Group adopts a training system to let food distributors better understand the regulatory and licensing management requirements concerning food safety.

7.6.4. Conclusions

The platform economy is the core feature of the Internet economy era. China's current legal system for Internet food safety is pragmatism-oriented. It defines the obligations of online distributors and recognises greater management responsibilities for third-party platforms. Objectively speaking, the virtual Internet sets new requirements for food distributors regarding food safety and consumer rights to information (such as food safety requirements in the delivery process and information disclosure requirements), as well as higher requirements for the platform to provide better after-sales services. This is where the difference between online and offline food business lies and it has also become an important focus of current food safety regulation.

At the same time, in terms of food safety, the rise of China's online food industry has not changed the essential attributes of food business. From the perspective of civil law, both online and offline businesses involve a contractual relationship of goods or services. The obligations of food distributors, regardless of whether they are online or offline, have not fundamentally changed due to deviations in consumption habits. The so-called online food safety problem is often a manifestation of offline issues. Therefore, food safety problems or risks cannot be solved by simply regulating the online side; synergy between online and offline management is required. The regulation of offline food distribution is in fact more important and should be given more weight in changes made to China's online food safety regulations.

Chapter Eight

International cooperation on food safety: A special relationship between China and the European Union

*Jérôme Lepeintre**

"Improving food safety concerns the health and life of more than 1.3 billion people in China, and we can never be too strict on the issue".

Xi Jinping, President of the People's Republic of China*

Access to sufficient safe food [138] is an essential requirement for human health. Yet, according to the World Health Organisation (WTO), deaths of an estimated 2 million people annually are linked to unsafe food. Food containing harmful bacteria, parasites, viruses and chemicals, is also responsible for more than 200 diseases, ranging from infectious diseases to cancer.[139]

Although food has never been safer than it is today, food safety remains a global concern that has been among the top priorities of governments around the world, including China [140] and the European Union. The reasons for this are numerous. More than ever, there is strong consumer awareness of food quality and safety, and this continues to increase with better education and information for consumers. As a result of changes in the methods of food production at the farm and processing stages, new risks and challenges have emerged. Further challenges arise from food-borne pathogens, which can be related to climate change.[141] Moreover, globalisation and changes in consumer habits have triggered consumer demand for a wider variety of foods. Consumption patterns and consumer preferences for

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* *Speech on 30 December 2016.*

[138] Food refers to the definition of the Codex Alimentarius Commission, i.e. "any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing-gum and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances used only as drugs" Procedural Manual of the Codex Alimentarius Commission, 2017, 26th ed., p.23

[139] http://www.who.int/foodsafety/publications/foodborne_disease/fergreport/en/

[140] In all this chapter, China refers to the People's Republic of China.

[141] Gunderson L, Holling CS. Panarchy, "*Understanding transformations in systems of humans and nature*", Washington, DC: Island Press; 2001.

the variety and shelf-life of foods, as well as preservation techniques, are changing rapidly. Since the creation of the WTO in 1995, the international food trade system has exponentially developed, and this increases the risk of infectious agents being disseminated from the original point of production to other countries. All this leads to an increasingly complex global food chain with more intermediaries, thus multiplying the hazards and risks for foods to become contaminated and harmful to human health.[142]

More concretely, if consumers trace back the origin of the food they had for breakfast, lunch or dinner today, it is very likely that several countries and possibly even continents would be involved. Food safety cannot be successfully managed by a single country, there is an absolute need for international cooperation to address these overarching and global challenges.

This chapter, focussed on international cooperation on food safety, attempts to give an overview on the special relationship which exists between China and the European Union and analyses the circumstances and events under which this special relationship was built and evolved during the last 10 years, i.e. from 2008 to 2018.

8.1. A big crisis gives way for a radical reform

8.1.1. The 2008 milk scandal in China: a starting point for food safety reconstruction

The 2008 Olympic games were the first held in China and the country aimed to use the event to project its best image to the rest of the world, speeding up its integration with the global community. It was also the year of the milk scandal: melamine, an industrial chemical used in plastics, was discovered in milk and it was found to have caused kidney stones and illness for nearly 300,000 infants whilst killing six babies.[143] Melamine was added to water-diluted milk to fool quality inspectors with artificially high protein levels. Melamine is a nitrogen-rich compound and as protein levels are estimated by measuring Kjeldahl nitrogen content,[144] adding melamine increases the calculated level of proteins based on the nitrogen content. It is now suspected that the use of melamine could have been much more widespread than initially thought as a common way to manipulate protein levels. While Chinese authorities initially announced that the contaminated products were only sold domestically, evidence was soon that some batches had been marked for export. As a result of this, several countries, including the entire EU block, banned Chinese dairy and dairy-

[142] Ercsey-Ravasz M, Toroczkai Z, Lakner Z, Baranyi J., "Complexity of the International Agro-Food Trade Network and Its Impact on Food Safety". *PLoS ONE*. 2012;7(5):e37810.

[143] Guixia Qian, Xiaochuan Guo, Jianjun Guo & Jianguo Wu (2011), "China's dairy crisis: impacts, causes and policy implications for a sustainable dairy industry", *International Journal of Sustainable Development & World Ecology*, 18:5, p.434-441.

[144] Nitrogen Determination by Kjeldahl Method https://www.itwreagents.com/uploads/20180114/A173_EN.pdf.

containing products such as yogurt, cookies, and candy. China's milk exports had immediately dropped by 92% in September 2008,[145] when the scandal became public.

Facing blame for the addition of the illicit and toxic substance, farmers complained that the drastic price controls imposed on food by the government were pushing them to dilute milk to survive. Pressure on farmers had come from dairy companies responding to price controls aimed at combating inflation. SANLU and other dairy companies had lowered their prices earlier in 2008 but transferred the burden of cutting costs to farmers, who had weak bargaining power against the big dairy companies.[146]

These events took place in the context of increasing consumer demand. Over the last two decades, demand for and production of liquid milk had dramatically risen in China, despite a high proportion of Asians being lactose-intolerant or lactase-deficient. Since the late 1990s, liquid milk consumption in urban areas has grown annually at double-digit rates. The average urban resident in 1996 consumed just 5 kg of fresh dairy products per year, while in 2016 consumption more than quadrupled to 21 kg. Rising household incomes, new perceptions that milk products are healthy food items (for example, milk making people tall and strong), increased advertising and marketing, and the adoption of school milk campaigns are clearly contributing factors. Former Chinese premier Wen Jiabao declared in 2007: "*I have the dream to provide every Chinese, especially children, sufficient milk each day*". China now produces 35.7 million tons of cow milk per year, making it the third largest producer in the world. China consumes most of this domestically, exporting milk to a handful of Asian countries as well as Russia.

The rapid expansion of milk production and consumption has transformed the structure of the value chain. The traditional system in which small local producers deliver milk directly to consumers has been wiped out by large national producers and increased sales through supermarkets and, more recently, e-commerce. The increased focus on milk processing and retailing, however, has not been accompanied by changes in milk production. China's big dairy companies still mostly rely on small farms supplying raw milk. Much of these supplies come from independent and unregulated brokers who collect raw milk from farmers who have three or four cows each, on average. But the situation is rapidly changing. In 2015, the world's biggest dairy farm, with around 100,000 cows, was created in Heilongjiang province to export milk to Russia,[147] where new market opportunities arose after the ban of imports from the European Union to Russia.

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[145] Yang, R., Huang, W., Zhang, L., Thomas, M. and Pei, X. (2009), "Milk adulteration with melamine in China: crisis and response", *Quality Assurance and Safety of Crops & Foods*, 1: p.111-116.

[146] Lu Xiaojing (2011), "The Cause and Effect Analysis of the Melamine Incident in China", *Asian Journal of Agricultural Research*, 5: p.176-185.

[147] 100,000-cow-power dairy farm in China to feed Russian market, 2015-07-09 By William Hennelly (China Daily USA).

The Chinese milk scandal perfectly illustrates the cross-border nature of food safety issues. Importing countries cannot alone fully address the safety risks attached to food products without proper measures and cooperation with the exporting country authorities and suppliers.

8.1.2. The parallel between EU and China in building their new food safety control system

The BSE crisis in Europe

In addition to their strong food cultures,[148] the EU and China share, to a certain extent, comparable experiences in ensuring food safety and fighting hazards. In the mid-1990s the first BSE (Bovine Spongiform Encephalopathy – mad cow disease) crisis occurred in Europe. BSE had already been identified in Great Britain in 1986 by Dr. Colin Whitaker, a veterinarian, but it remained an obscure issue until 20 March 1996, when the United Kingdom's chief medical officer Sir Kenneth Caiman held a press conference and declared there was likely a link between the BSE and the human Creutzfeldt-Jakob Disease (CJD). The official acknowledgement that eating British beef might cause CJD became the crisis event as it was widely disseminated by the media, all over the world. This was nearly 6 years after the (in)famous photo [149] of the United Kingdom Minister for Agriculture's 4-year-old daughter eating a beef burger, an attempt to rescue the beef sector from further danger.

This marked the starting point of a major European crisis: beef consumption collapsed, the United Kingdom could not export its beef to other EU Member States, EU beef was banned in many markets across the world. The confidence European consumers had in food had been destroyed for a long time. The main cause of the disease was meat and bone meal (MBM) that had been fed to cattle. In the rendering process, animal parts and carcasses were boiled and cooked to produce MBM, which is fed to animals as a food supplement. Deregulation during the Margaret Thatcher years appears to have encouraged the industry to become careless. The temperatures reached during the rendering process to prepare MBM had been reduced, meaning that the infectious agent, not a conventional bacteria or virus but a misfolded protein called prion, remained active and could spread more rapidly.[150]

The dioxin crisis in Belgium and Europe

Other food crises punctuated the end of the 20th century in Europe. During the BSE episode, another major food scare struck in Belgium in the spring of 1999, when huge

[148] Femandez Armesto, F., "*Food: a history*", Pan Macmillan Ltd, 2002, p.13.

[149] http://home.bt.com/news/on-this-day/may-16-1990-minister-john-gummer-enlists-daughters-help-in-fight-against-mad-cow-disease-11363981336399

[150] Taylor D.M., Woodgate S.L. (2003), "Rendering practices and inactivation of transmissible spongiform encephalopathy agents", *Rev. sci. tech. Off. int. Epiz*., 2003, 22 (1), p.297-310.

quantities of dioxins entered the food chain through the contamination of animal feed with industrial oil (cooling oil used in electric transformers) due to feed manufacturer's negligence and profit motivation. Dioxins are produced in small concentrations when organic material is burned in the presence of chlorine. In higher amounts they become carcinogenic and cause developmental and reproductive problems. Hens, pigs, and cattle consumed the contaminated feed and high levels of dioxin were consequently found in meat products as well as eggs. This was the beginning of another European food safety scandal characterised by dramatic revelations and public outcry. The scandal, which led to the slaughter and disposal of 7 million chickens and 60,000 pigs, was followed by the resignation of two ministers and contributed to a landslide vote that removed the incumbent Belgian government at elections held one month later.[151] The government's major error was that it did not promptly communicate its knowledge of the crisis, which led to accusations of a self-serving cover-up. Two weeks after the first announcement of contamination, at least 30 countries, including Canada, Australia, Russia, Egypt, Algeria, South Africa, Poland, Switzerland, as well as most EU countries, banned imports of Belgian agriculture products and removed Belgian products from stores. As the crisis developed, more products were added to the lists of banned imports such as chocolates and other processed foods containing chicken or eggs. Some countries also banned imports from France, the Netherlands, and Germany, who had been affected by the Belgian crisis. The United States and Singapore went one step further and banned all European poultry and pork.

Learning the lessons

1) In Europe

A crisis is often an opportunity to bring radical change. The EU was able to review its entire system of food safety governance and began this with the publication of a White Paper on Food Safety in January 2000, which paved the way for a new era of reconstruction. [152]

The series of food and feed crises revealed major weaknesses in the design and application of food legislation within the EU. As EU Commissioner David Byrne said on 25 June 2002 "*Our food law was like an old car, heavily modified and customised over the years to try and keep abreast of the times and of new developments… A new model was needed. Modern, streamlined, efficient, well-engineered, with a synergy of components geared towards optimum performance. And that is what we are building in the field of food safety. A new vehicle fit for the demands of the new millennium*".[153] The European Commission therefore

[151] Lok C., Powell D., (2000), "*The Belgian Dioxin Crisis of the Summer of 1999: a case study in crisis communications and management*", Technical Report #13, Department of Food Science, University of Guelph Guelph, Ontario, N1G 2W1.

[152] White Paper on Food Safety, 12 January 2000, COM (1999) 719 final.

[153] Byrne D., SPEECH/02/301, European Food Safety and Legislation: Challenges and Future Policy, European Food Law Conference, Brussels, 25 June 2002.

decided to prioritise a high level of food safety with the primary objective of protecting consumers' health. Unlike before, this move was not primarily motivated by trade concerns. It proposed 84 legislative measures, enabling food safety to be organised in a more coordinated and integrated manner based on risk. This included the establishment of the independent European Food Safety Authority (EFSA), which was responsible for scientific advice and risk communication, a rapid alert system, an improved legal framework covering all aspects of food products "from farm to fork", greater harmonisation of national control systems, and reinforced dialogue with consumers and stakeholders. The initial BSE crisis also pushed the European Commission to separate the services in charge of food safety legislation and inspection from the production-oriented Directorate General in charge of agriculture (DG VI) and move them to a new consumer-oriented entity (DG XXIV), which would soon become the Health and Consumers Directorate General (DG SANCO) refocused on Health and Food Safety in 2014 (DG SANTE). This was accompanied by the creation of a unique organisational structure, the Food and Veterinary Office (FVO), which was decentralised in Ireland and subsequently moved to County Meath in Ireland. Staffed with around 150 inspectors the FVO became responsible for all inspection services in the field of food safety, animal health, and plant health. Through its audits, inspections, and related activities, its mission is to monitor compliance with EU food safety and quality, veterinary, and plant health legislation within the European Union; with EU import requirements for non-EU countries exporting to the EU; and to contribute the development of effective control systems in the food safety, animal health and welfare, and plant health sectors. One unique characteristic of FVO is its transparency. All data from audits and inspections, including findings, conclusions, and recommendations are publicly available. This inspection and audit workforce at the European Commission quickly acquired international recognition as the best and most qualified in the world, admired and envied by many countries including China. It is still in operation today, with enlarged responsibilities including medical devices and organic food. Its world-famous name of "*Food and Veterinary Office*" was changed to "*Health and food audits and analysis Directorate*" in 2015.

Following its comprehensive reform, the entire EU food safety legal framework was rebuilt from scratch. The general food law was adopted in 2002, the comprehensive hygiene package and the official food and feed control regulation in 2004. These cornerstone laws were complemented by specific regulations that covered all aspects of the food chain, making the EU food safety system one of the best in the world.

2) In China

If we replace 1996 with 2008 and BSE with melamine, we see how comparable China's food safety crisis was to the EU's. In China, the crisis opened the door to a series of major reforms of the food safety control system: landmark initiatives such as the establishment of the China Food and Drug Administration in March 2013, the publication of the *Food Safety*

Law in 2009 and its revision in 2015, the creation of the State Administration for Market Regulation (March 2018) and the transfer of import export food safety control to the powerful General Administration of China Customs.

Other frequent food safety incidents in China – either intentional adulteration, contamination, or toxic contaminants in food – destroyed consumer confidence and resulted in strong criticism of the authorities' inability to ensure food safety and protect consumers' health. Confidence levels were at the lowest in 2008 during the melamine milk contamination crisis, as explored earlier in this chapter. This major food safety incident was a clear signal that a total revamp of the system was needed, mirroring, to a certain extent, what Europe experienced in the 1990's during the mad cow and dioxin crises. The political and economic backlash drove authorities to reconsider China's food management system, streamline government supervision, unify food safety standards, and reinforce penalties for non-compliance. More recent refinements accentuated the shift toward a more vertical, product-oriented structure for China's food safety management system.

In 2013, China established the China Food and Drug Administration (CFDA) to integrate and streamline the domestic food safety regulatory and enforcement regime. After this, the food safety enforcement system is still in the process of restructuring into a top- to-bottom management approach.

During the period of reform, China completed the review and consolidation of over 5,000 food safety and hygiene standards. This laid out the blueprint for a compulsory national food safety standard system.[154]

To reflect these changes to China's regulatory system and cope with shifting food safety priorities, in April 2015 China further amended the 2009 *Food Safety Law* that took effect from 1 October 2015. In addition to the *Regulations for the Implementation of the Food Safety Law*, a series regulations, rules and measures were issued to carry out the provisions of the Law. The Chinese authorities had even proceeded to go 'too far' by deciding on counterproductive measures like the "certification of all foods", which would waste precious certification and control resources on non-risky products like coffee, biscuits, or sweets, which could be better targeted on risky products. Fortunately, this measure, initially planned to enter into force on 1 October 2017, was delayed by two years following massive and coordinated lobbying. Some hope it will be withdrawn altogether.

[154] Kevin Chen, Wang Xin-xin, Song Hai-ying, "Food safety regulatory systems in Europe and China: A study of how co-regulation can improve regulatory effectiveness", *Journal of Integrative Agriculture*, Elsevier, November 2015.

The legislative framework needs continuous adaptation

1) In Europe

All these events show that ensuring food safety in a highly globalised world is much more complicated than expected, with new challenges constantly arising. Changes in food production, distribution and consumption, climate change as well as new pathogens and the development of antimicrobial resistance, all pose challenges to national food safety systems. The exponential development of travel and globalised trade have also multiplied the probability of contamination internationally.

The legislative framework on food safety is constantly evolving and has adapted to address new challenges and issues. In line with the political agenda defined by the European Commission President Mr. Jean-Claude Juncker that gives priority to modernisation and simplification of existing legislation, the EU general food law was subject to a comprehensive policy evaluation sixteen years after it was first adopted. This assessed whether the legislative framework introduced by the General Food Law Regulation of 2002 for the entire food and feed sector was still '*fit for purpose*' and whether it captured and reflected policy trends of today.

This evaluation concluded that the General Food Law Regulation had kept up with the current trends of growth, competitiveness and globalisation. Overall, the General Food Law Regulation has achieved its core objectives, namely through its high-level protection of human health and consumer interests and the smooth functioning of the internal market. Current food safety levels are more favourable than before the adoption of the General Food Law Regulation, food in Europe is now largely free of pesticide residues and of veterinary medicinal product residues. The systematic implementation of the risk analysis principles in EU food law has overall raised the level of protection of public health. The creation of EFSA has dramatically improved the scientific basis of EU measures. Major improvements have been made in EFSA's scientific capacity of expertise, its quality of its scientific outputs, its collection of scientific data, and in its development and harmonisation of risk assessment methodologies. EU emergency measures and existing crisis management arrangements have overall achieved consumer health protection, efficient management, and the containment of food safety incidents.

The General Food Law Regulation has contributed to the effective functioning of the internal market by creating a level playing field for all feed and food business operators in the EU market and reducing trade disruptions. The value of EU internal trade in the food and drink sector has increased by 72% over the past decade. It has also contributed to worldwide recognition of EU food safety standards and more positive perceptions of EU food products in non-EU markets. The EU food and drink industry is now in a much more competitive position since 2003 vis-à-vis its main trading partners.

However, shortcomings have been identified. The General Food Law fell short of addressing new challenges such as general food sustainability, and more specifically, food waste. The 2011 *Escherichia coli* outbreak in German sprouts has, in addition, stressed the need to continuously re-evaluate the management of food crises. There are still national differences in the implementation and enforcement of the EU legislative framework keeping the concept of 'EU single entity' theoretical and, at times, far from the reality. Despite considerable progress overall, transparency of risk analysis remains an important issue affecting perceptions. Civil society does not view EFSA as transparent or independent, which in turn has a negative impact on its reputation for science amongst the public. Communicating risks has not always effectively shaped consumer trust, such as the acceptability of risk management decisions on glyphosate or endocrine disrupters. A number of negative signals have been identified on the capacity of EFSA to maintain a high level of scientific expertise and to fully engage all Member States in scientific cooperation. In addition, lengthy authorisation procedures in some sectors (e.g. feed additives, plant protection products, food improvement agents, novel foods, health claims) slow down the market entry process. As a result to this evaluation, a European Commission proposal to modernise the General Food Law has been prepared and will go through the legislative process of adoption in 2018-19.

2) The 2018 massive overhaul of the Chinese administrative structure involved in food safety

In March 2018, at the end of the *Liang Hui*, the State Council announced the reorganisation of several ministries and commissions under its supervision, in line with "*the spirit of the party's Nineteenth Congress and [to] adhere to Marxism-Leninism, Mao Zedong Thought, Deng Xiaoping Theory, and the "Three Represents"*.

The 13th National People's Congress approved the Institutional Reform Plan of the State Council a few days after on 17 March 2018. Among the reforms under the Plan, the primary agency in charge of food, drugs, medical devices, and cosmetics regulation, the CFDA and, the chief healthcare regulator, the National Health and Family Planning Commission (NHFPC) were dismantled and integrated into other agencies. This change undoubtedly has significant implications for the future development of China's food, drug and healthcare regulatory regime and policies.

State Administration for Market Regulation integrating AQSIQ, CFDA and SAIC: The current CFDA, the product and import quality regulator (General Administration of Quality Supervision, Inspection and Quarantine - AQSIQ) with the exception of the food safety import export bureau and quarantine services, the business, consumer protection, advertisement regulator (State Administration for Industry and Commerce - SAIC), and certain subdivisions of other agencies have been merged into a new authority called the State Administration for Market Regulation (SAMR), established as a "*directly subordinate agency*" under the State

Council. This means in practice that this new Administration will handle food, health food, infant formula, medical food, cosmetics, and medical devices regulations and policies.

SAMR now has the food and drug regulatory responsibilities of other commissions or subdivisions. In particular, the authority is responsible for the Food Safety Commission of the State Council, the Certification and Accreditation Administration, and the Standardisation Administration (CNCA). This new administration has considerable powers over food safety policy, powers to enact national standards in each of these areas, powers to accredit laboratories and register certain food establishments abroad (e.g., dairy and meat products).

Unlike CFDA, SAMR also has a variety of other responsibilities that are not related to science-based decisions about product safety and effectiveness. For example, it has the company registration, consumer protection, advertising, and anticorruption enforcement powers previously held by SAIC and the price regulation and antimonopoly enforcement powers of NDRC. SAMR is aimed at building a 'unified, open and orderly market system' as declared by its top leader in early May 2018. Its responsibilities will include market supervision and management, registration of market entities, information disclosure and sharing mechanisms, unified anti-monopoly enforcement, unified quality and safety standard management regime covering food, equipment, measurement, inspection and testing certification and accreditation, oversight of the China National Drug Administration and State Intellectual Property Office.

The week following the announcement of the reform, the former commissioner of CFDA, Bi Jingquan was appointed Party Secretary[155] for SAMR, and the most recent Commissioner of SAIC, Zhang Mao became Commissioner of SAMR and deputy Party Secretary.

This new structure is a major change in terms of market supervision, in particular for food safety and quality. It should be seen as a positive change facilitating a comprehensive supervision and implementation of food safety regulations in China, while in the previous structure, responsible agencies often held diverging views about quality and safety standards. Having one single interlocutor will likely facilitate EU cooperation activities on food safety and IPR enforcement. A new structure (sub-bureau) called State Drug Administration (SDA) was (former function from CFDA).

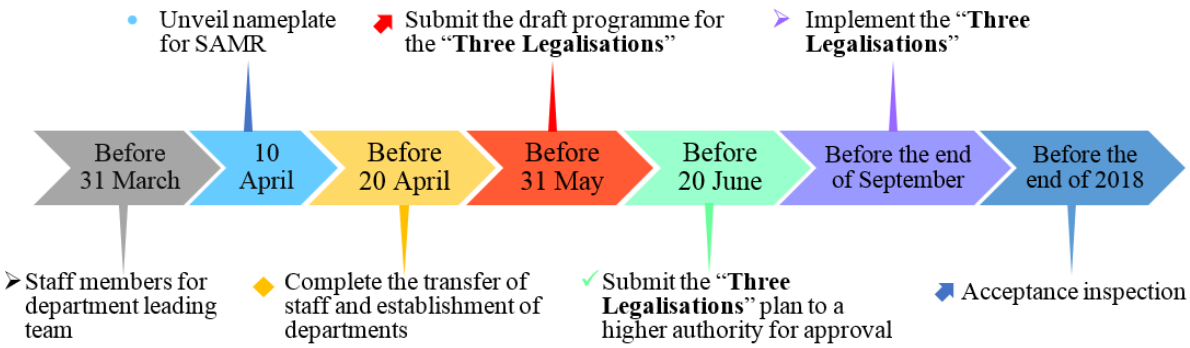
On 10 April 2018, SAMR issued a Notice on the Supervision of Food and Drugs during the transition period. This notice confirmed the changes announced by the Decision of the Central Committee of the Communist Party of China about Deepening the Institutional Reform of the Party and State Institutions and the Decision of the First Session of the 13th National People's Congress, i.e. the SAMR is established as a department directly under the State Council; SDA is established and administered by SAMR; and CFDA is abolished. The notice further explains

[155] A party secretary is not the minister of an agency but exercises important influence over the direction of the agency.

that before the "Three Legalisations" plan of SAMR and SDA are issued, the matters undertaken by the former CFDA are still handled according to the original regulations, including the review, approval, supervision, inspection, law enforcement, complaints report, and information disclosure for food, health food, infant formula milk powder, foods for special medical purpose (FSMP), medicines, medical devices, and cosmetics.

Minister Zhang Mao gave details on the main steps and the schedule of the 2018 institutional reform as detailed in the following chart. This means, in practice, that SAMR will only be fully operational from the end of 2018.

Timeline for SAMR's institutional reform [156]



Integration of border inspection (ex-CIQ) and quarantine functions of former AQSIQ into the General Administration of China Customs (GACC): There was apparently some internal debate on where to put the Food Safety Import-Export Bureau from the former AQSIQ. Two options were considered: either include the bureau in SAMR to create a single structure in charge of food safety risk management (risk assessment is kept separated as prescribed by the principles of risk analysis), or include the bureau in the General Administration of China customs. The second option was ultimately chosen and therefore sanitary and phytosanitary and market access issues are now under the responsibility of the Customs Administration. The rationale was that this would create synergies between SPS control services and customs: in particular, simplify, rationalise, and shorten the procedure of customs clearance when goods enter Chinese territory.

Ministry of Agriculture and Rural Affairs (MARA): Mirroring the title of the European Commission's DG AGRI, the Ministry of Agriculture and Rural Affairs has clearly been reinforced with new functions related to long-term investment projects and as such confirms its major role in the rejuvenation of rural areas, as already detailed in the State Council Number One Document released in early February 2018.

[156] Source: website of the State Administration for industry and Commerce http://samr.saic.gov.cn/xw/yw/zj/201804/t20180410_273684.html

The change of the name, which adds adding 'rural affairs' is also significant. Minister Han Changfu was confirmed in his position with enlarged powers. It should be noted that functions related to grasslands management and pollution will be transferred to other ministries. While keeping the responsibility over the fisheries policy, the transfer of responsibility for fishing boats inspection to the Ministry of Transport could affect the on-going cooperation on Illegal Unregulated and Unreported (IUU) fishing and, indirectly, concerning the on-going negotiations of the Ocean (Blue) Partnership.

National Health Commission to replace NHFPC: China's previous NHFPC regulated family planning, food standards and the healthcare system, including doctors, hospitals, and the Center for Disease Control. Following the reform, the family planning part of the agency was dropped and NHFPC and the Office of the Leadership Group for Deepening the Medical and Health System Reform was merged into the National Health Commission (NHC).

NHC was established as a constituent department of the State Council, taking over all or some of the responsibilities of the current authorities including NHFPC, the Reform Office, the National Working Commission on Ageing, the Ministry of Industry and Information Technology, and the State Administration of Work Safety Supervision.

The State Administration for Traditional Chinese Medicine also falls under the New Commission. NHC's main responsibilities include developing healthcare policies, coordinating and expanding healthcare reform, organizing the national essential drug system, regulating public health, food standards, medical services and health emergencies.

New State Intellectual Property Office, integrating functions from SIPO, SAIC (trademarks) and AQSIQ (geographical indications): With this reform, like most counties around the world, China has one single office to deal with intellectual property rights promotion and protection (registration and invalidation). It is regarded as a good move in the long term but may have short-term consequences on the current negotiations for the agreement on Geographical Indications. The overall leading role of the Ministry of Commerce (MOFCOM) in the GI negotiations is expected to remain, and with a single IP office dealing with trademarks and GIs, one could think that it could facilitate the process of negotiations … if the implementation of the reform is rapidly completed. The new SIPO operates under the supervision of the New State Administration of Market Regulation.

8.2. Bilateral cooperation between the EU and China

The EU is firmly committed to international cooperation, with China and other trade partners to assess the current and future challenges faced and to share best practice and initiatives.

Authorities cannot make food safe alone, responsibility for food safety rests first and foremost with food business operators. Ensuring food safety requires team work, but the

game is no longer at the national level - it is at world level. To play this game successfully, countries must work hand in hand and build a common culture of real collaboration and partnership. All countries share the same goals: food has to be safe, consumers need to have confidence, and international food trade should not be jeopardised by food safety problems.

The bilateral cooperation between EU and China has been formalised in a series of agreements detailed below.

8.2.1. Chinese authorities involved in food safety

The General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ) [157]

A Memorandum of Understanding (MoU) was first signed in 2006 between European Commission DG Health and Consumers and Chinese AQSIQ. It was renewed and extended in 2008 and 2012, with the latter including cooperation on audits and inspections with the EU Food and Veterinary Office. This MoU was aimed at mutual understanding, trust and trade in agricultural, fishery products and processed food and at establishing channels of consultation and communication. It established a cooperation arrangement on joint prevention of illegal import and export of food and granted China the access to the Rapid Alert System for Feed and Food (RASFF) notifications. The MoU also sets an annual frequency for a high level meeting at ministerial level and a SPS technical working group, which will alternate between being hosted in China and the EU. Although this frequency is not strictly respected, the technical and political dialogues have been maintained and allowed many bilateral issues to be solved. In 2014, AQSIQ and DG SANCO agreed to limit the FVO routine audits in China to 4 audits per year in exchange for clearing the backlog that existed at the time. This is still respected today, with 3 audits planned in 2018.

The China Food and Drug Administration (CFDA) [158]

A Consultation and Cooperation Mechanism between the Directorate-General for Health and Consumers of the European Commission and the China Food and Drug Administration (CFDA) was agreed on 26 October 2010 and subsequently amended on 7 June 2013. This "mechanism" aims at promoting information exchange, mutual understanding and co-operation between the EU and China on pharmaceuticals, medical devices, cosmetics,[159] food safety and related administrative, regulatory or scientific matters. It also aims to provide trust

[157] In March 2018 the AQSIQ Import Export Food Safety Bureau was transferred to the General Administration of China Customs. The remaining part of AQSIQ was included in the State Administration for Market Regulation.

[158] The Food part of CFDA was transferred in March 2018 to the State Administration for Market Regulation (SAMR). The competencies for drugs were given to the State Drug Administration (SDA) under supervision from SAMR.

[159] In 2014, at the appointment of the new European Commission, the responsibility for medical devices and cosmetics was transferred to Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs.

and help enhance mutual understanding and co-operation in the pharmaceutical, medical devices cosmetics and food safety areas.

On this basis, the two sides have since engaged in a constructive dialogue on legislation, regulations and related Issues dealing with pharmaceuticals, medical devices cosmetics and food safety. Four working groups have been established: “Pharmaceuticals”, “Medical devices”, “Cosmetics” and “Food safety”. A specific cooperation framework has been set up with the European Medicines Agency on pharmaceuticals. There is also the explicit desire to promote bilateral trade. There is also the explicit desire to promote bilateral trade. CFDA quickly became the Chinese administration that had the best relationship with the EU Delegation, firstly because of a close proximity of the portfolios of CFDA and DG SANTE, and secondly thanks to the openness and professionalism of the CFDA Department for International Cooperation.

Annual meetings are being held alternatively in Europe and in China to discuss major issues related to the protection of consumer safety and health and related legislation or regulations, to compare and assess differences in regulatory or legislative approaches and to explore possibilities for co-operation in the field of harmonisation and standards

The Ministry of Agriculture (MoA) [160]

In 2007, another MoU was signed between European Commission DG Health and Consumers and the Chinese Ministry of Agriculture. Its objectives are to establish a timely exchange of information on the occurrence of certain infectious diseases (including avian influenza, foot-and-mouth disease, classical swine fever) via specific contact points. Practical cooperation foresees temporary reciprocal exchange of technical staff and sharing of biological materials (e.g. isolates of disease agents) between designated reference laboratories. More generally, both parties agreed to improve international cooperation and expertise (e.g. on OIE positions).

The National Health and Family Planning Commission (NHFPC) [161]

Terms of Reference (ToR) for a dialogue on Health between European Commission DG Health and Consumers and the Chinese Ministry of Health were agreed in 2009. They provide a general and flexible framework for developing and implementing a health policy dialogue between both parties. Contact points were nominated on each side and working groups were established. In particular, food safety was identified as a priority area for this cooperation.

[160] Renamed Ministry of Agriculture and Rural Affairs (MARA) in March 2018.

[161] Renamed the National Health Commission (NHC) in March 2018.

8.2.2. Cooperation instruments

Better Training for Safer Food (BTSF)

"Better Training for Safer Food" (BTSF) [162] is a Commission initiative aimed at organising a Community (EU) training strategy in the areas of food law, feed law, animal health and animal welfare rules, as well as plant health rules.

While the European Commission sets policy and general strategy for Better Training for Safer Food, an Executive Agency (CHAFEA) puts this initiative into practice by managing all phases of projects, from launch of calls for tender to evaluations of offers, award of contracts, and supervision of implementation.

Article 51 of Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, provides the legal instrument for this initiative.

Originally designed for competent authorities of Member States involved in official control activities to keep them up-to-date with all aspects of Community law and ensure that controls are carried out in a uniform, objective and adequate manner, this training programme was progressively opened to non-EU countries and particularly aimed at developing countries to ensure they are familiar with EU import requirements and, where it exists, the possibility of EU support. For this purpose, training courses organised for Member States in the EU are open to a limited number of participants from non-EU countries and specific training courses are also organised exclusively for non-EU country participants outside of the EU.

The main objective of the "Better Training for Safer Food" initiative is the organisation and development of a Community training strategy with a view to:

- Ensuring and maintaining a high level of consumer protection and of animal health, animal welfare and plant health;
- Promoting a harmonised approach to the operation of Community and national control systems;
- Creating a level playing field for all food businesses;
- Enhancing trade of safe food;
- Ensuring fair trade with third countries and particularly developing countries.

China is regularly invited by the European Commission to send Officials to participate in training courses taking place in the Member States or even in other non-EU countries, with all expenses covered by the European Commission. In addition, several sessions were specifically designed to take place in China, such as a course on risk analysis principles applied to food safety in May 2014 and a session on Official Controls in November 2018. All these

[162] http://ec.europa.eu/chafea/food/

training courses are designed in close cooperation with the relevant Chinese ministries to ensure they address the needs of the participants.

EU-China Trade Project (EUCTP)

The EU-China Trade Project (EUCTP) was launched in June 2004 and lasted more than 10 years until early 2016. [163] It was the largest trade and investment cooperation programme ever implemented with China and it covered a very wide variety of sectors including food safety, plant health and animal health areas. It was entirely funded by the European Union and had a value of more than 19 million EUR.

The activities supported the modernisation of China's agriculture and agro-food sector, food safety strategy and administrative capacity to improve food and feed safety, animal health and welfare and plant health. This was done in line with the principles and values of WHO, FAO, OIE, Codex Alimentarius and the EU food safety framework and took international standards and international best practice in standards development into consideration. Numerous activities such as seminars, conferences, study tours, traineeships, covered relevant issues such as traceability management and pesticide control; food contact materials requirements; scientific risk assessment; shared responsibility among government, the food industry and consumers on food safety control. Two practical courses on Codex Alimentarius were organised in 2012 and 2014. A general conference of the then newly adopted food safety law was jointly organised with the United States Embassy in Beijing on 1 September 2015 to address the new provisions and answer the questions of government and industry representatives.

The activities also aimed to strengthen and streamline inter-ministerial cooperation at the central level and between the central and local authorities on food safety and SPS issues. In addition to helping deliver safer, more trustworthy food to consumers, enhanced compliance with international standards has the potential to improve the economy in agricultural areas, contributing to rural development and equality, and higher living standards in some of China's poorest areas.

One of the most appreciated characteristics of this programme was its flexibility. It was always possible to fine-tune or re-orientate planned activities to address new emerging issues. One of the best examples is the series of activities carried out to address Chinese measures on the presence of phthalates (plasticizers) in imported wines and spirits, which were suddenly put in place at the end of January 2013. Perseverance and repetition finally led to the alignment of the Chinese rules with European legislation and a complete lifting of these unjustified trade obstacles.

[163] http://www.euctp.org/index.php/en/press-and-news.html

All good things come to an end and EUCTP was terminated in early 2016. Other instruments were still available, but they were less flexible and reactive, leaving the EU much less equipped than before to deal with unforeseen issues.

Partnership Instrument (PI)

The Partnership Instrument (PI) is the main instrument in the EU external action package with a worldwide global budget of 954,765,000 EUR for the period 2014-2020.[164] It supports measures that respond in an effective and flexible manner to objectives arising from the Union's bilateral, regional or multilateral relationships with non-EU countries and address global challenges whilst ensuring an adequate follow-up to decisions taken at the multilateral level.

The overall objective of the PI is to advance and promote EU interests by supporting the external dimension of EU internal policies and by addressing major global challenges such as climate change and food safety.

The PI also addresses specific aspects of the EU's economic diplomacy with a view to improving access to non-EU country markets by boosting trade, investment and business opportunities for European companies. It supports public diplomacy, people to people contacts, academic cooperation and outreach activities to promote the Union's values and interests.

With a different approach compared to established models of development co-operation to promote policy co-operation, the PI focusses on countries with which the EU has a strategic interest in promoting links with. This includes countries which play an increasingly prominent role in global affairs, international economy and trade, multilateral fora and global governance or where the Union has other significant interests. China is obviously one of the main targets of the PI.

The PI allows the EU to develop and engage in an overarching political dialogue with China. Its global reach and flexibility are essential elements to enable the Union to respond to the fast-changing nature of partner countries and to key global policy challenges. Several projects are specifically targeted on food safety. A series of seminars was organised in 2017: food official certification on 6 April, special foods on 20 July and animal health on 12 October. These events allowed experts to exchange views and were an excellent opportunity to promote the EU regulatory framework.

Partnership with the European Union Chamber of Commerce in China (EUCCC)

A very special partner has to be mentioned: The European Union Chamber of Commerce in China (European Chamber) which was founded in 2000 by 51 member companies that

[164] https://ec.europa.eu/europeaid/funding/funding-instruments-programming/funding-instruments/partnership-instrument_en.

shared a goal of establishing a common voice for the various business sectors of the European Union and European business operating in China. It is a members-driven, non-profit, fee-based organisation and with a core structure of 45 working group, it represents European business in China. The European Chamber now has nearly 1,800 members in seven chapters across nine cities.

The level of expertise in EUCCC is very high and cooperation with the EUCCC staff is always fruitful. For example, the cooperation on infant formula between the EUCCC and the EU Delegation allowed great achievements and successes.

8.2.3. Specific fora of exchange and cooperation

Political and trade sectors

There is a long list of dialogues and partnerships made at the political and general trade levels where sanitary and phytosanitary issues, including food safety, can be addressed, particularly when the economic and trade consequences are important (for example, the BSE/beef ban). Whilst it is not the purpose of this chapter to enter in the details of these mechanisms, it is necessary to mention the most important of them.

China and the EU established the "Comprehensive Strategic Partnership in 2003" opening a new era of fruitful and intense relations.[165] However, between 2006 and 2009, the relationship experienced a difficult period until Premier Wen Jiabao made his "Journey of Confidence" in Europe. 2010 was a positive year, with the China-EU high-level strategic dialogue officially launched in August 2010.

China-EU political dialogue is conducted at the following levels: annual EU-China Summit meetings; high-level strategic dialogues; ministerial meetings; annual meetings; dialogues on special topics; and regular expert-level dialogues.

The EU and China jointly adopted the EU-China 2020 Strategic Agenda for Cooperation in 2013. The two sides committed to fully implement the Strategic Agenda for Cooperation through their annual Summit, which provides strategic guidance to their relationship; through the three pillars directly underpinning the Summit (the annual High Level Strategic Dialogue, the annual High Level Economic and Trade Dialogue, and the bi-annual People-to-People Dialogue); through their regular meetings of counterparts and through their broad range of sectoral dialogues.

[165] Jingkun Li, Chen Zhao, Lei Zhang, Hui Cao and Haiyang Zhang, "China-EU Political Relations", pp. 35-67, in Zhou, H. (ed), "China-EU Relations: Reassessing the China-Eu Comprehensive Strategic Partnership", *Springer*, 2017.

In 2016 the EU adopted a new strategy on China mapping out the European Union's relationship with China for the next five years. The Strategy promotes reciprocity, a level playing field and fair competition across all areas of co-operation.

The EU and China discuss policies and issues regarding trade in a range of dialogues. In particular, the EU-China High Level Economic and Trade Dialogue where the EU vice-president and Chinese Vice Premier meet to discuss issues, accompanied by EU Commissioners and Chinese Ministers; there is also the Joint Committee on Trade, which is an annual ministerial-level meeting, the Trade and Investment Policy Dialogue at Director-General level, and the Economic and Trade Working Group at expert level.

Dialogues on SPS issues

As mentioned earlier in the section dealing with memoranda of understanding and other informal agreements, there is a series of regular (annual in principle) high level meetings at ministerial level between European Commission Directorate General for Health and Food Safety (DG SANTE) and ex-AQSIQ SPS services now relocated in the General Administration of China Customs (GACC), ex-CFDA now included in the State Administration for Market Regulation (SAMR), the Ministry of Agriculture and Rural Affairs (MARA) and the National Health Commission (NHC).

The European Commission Directorate General for Agriculture and Rural Affairs (DG AGRI) also managed a series of dialogues at various levels, where SPS and food safety issues can be touched upon taking into account the proximity of the topics. In addition, the European Commission being "one and indivisible", all three Commissioners for Agriculture, Health and Trade take every possible occasion to raise SPS issues in a coordinated and cooperative manner.

Asia-Europe Meeting (ASEM)

The Asia-Europe Meeting (ASEM) is an intergovernmental forum for dialogue and cooperation which fosters political dialogue, reinforces economic cooperation and promotes collaboration in other areas of mutual interest. [166] It involves the 28 EU member states, the European Commission, 20 Asian countries and the secretariat of the Association of Southeast Asian nations (ASEAN). Its objective is to strengthen the relationship between the two regions in a spirit of mutual respect and equal partnership.

ASEM Summits have been held every two years since 1996. The most recent took place in Ulaanbaatar, Mongolia on 15-16 July 2016. Regular meetings of senior officials complement ASEM ministerial meetings, covering areas of mutual and global concern. On top of official meetings, many initiatives have been implemented including numerous gatherings at expert-level, thematic working meetings and symposia gathering business communities and civil

[166] http://www.aseminfoboard.org/about.

society groups from the two regions. For example, the 2nd ASEM Conference on Sanitary and Phytosanitary (SPS) - Food Safety: new policies, new challenges, new cooperation and technical aspects took place in Brussels on 5-6 December 2017; it was an excellent opportunity to share experience and best practices on food safety. A high-level delegation from the China Food and Drug Administration actively participated in this meeting.

China International Food Safety & Quality (CIFSQ) Conference

The China International Food Safety & Quality Conference takes place alternatively in Beijing and Shanghai each year in early November. [167] Although it is a private event, it quickly became one of the top worldwide events on food safety that brings together officials and professionals across China and from around the world for two intensive days of learning and networking. This conference represents an excellent opportunity to interact with the top food safety leaders of the world. EU Commissioner Andriukaitis, in charge of Health and Food Safety, made a keynote speech in 2015 and is planning to come back in 2018 for the 12th edition. The European Food Safety Authority (EFSA) send representatives every year and its Executive Director Mr. Bernhard Url was a keynote speaker there in 2016 and 2017; he also took the opportunity to meet the key officials present.

8.2.4. Cooperation between EU Member States and China

The EU Member States have cooperation activities with China in place; some of them are very active, obviously the biggest, but small Member States also put in place cooperation programmes focused on their main interests. Of course, most of the time, these cooperation activities, e.g. seminars, study tours, secondment of experts, etc, have the main objective of accessing the lucrative Chinese market for their national exports and businesses. As China does not recognise the EU as a single entity, and despite the fact that the trade policy is exclusive characteristic of the EU, the real practical negotiations for market access have to take place country by country following lengthy bureaucratic and cumbersome procedures. EU Member States compete between themselves for market access and the first to succeed often gains market shares that are difficult for the others to challenge subsequently. The economic importance of the Chinese market is such that political leaders are queuing to visit China with agendas heavily loaded with trade issues. Experience has proved that this is the most effective approach to get their country file back on the top of the pile. The stereotypical image of how EU Member States cooperate and act as a team is far removed from the reality. However, following the successful results of collective actions, transparency and information sharing have improved in recent years.

[167] http://www.chinafoodsafety.com.

8.2.5. Specific trade and cooperation agreements

Geographical Indications (GIs) Agreement [168]

After years of negotiations, a bilateral agreement between the EU and China promising mutual recognition and protection of geographical indications (GI) is expected to be finalised in 2018. This agreement, likely to be the first trade agreement between the EU and China, can be regarded as a milestone in the economic relationship between the two trade partners.

According to the World Intellectual Property Organisation (WIPO), a GI is defined as "*a sign used on products that have a specific geographical origin and possess qualities or a reputation that are due to that origin*". To be protected as such, a product must therefore be labelled as produced in a given area and must exhibit certain qualities and characteristics, which are dependent on the environmental or cultural conditions of the place.

In 2017, the European Commission and China's Ministry of Commerce decided to publish a list of 100 geographical indications from each side, which was an essential step paving the way for the conclusion of the agreement. While there is a long history of recognizing GIs in the EU, the law in China is more recent and can also be applied to non-food products.

The first discussions, which began ten years ago, led to the "*10 + 10*" pilot project protecting 10 GIs from each side. The EU and China GI systems were similar, but, there were "*significant differences in procedures and linguistic problems had to be overcome*" according to the European Commission press release. The knowledge acquired during this process was an invaluable learning curve for subsequent negotiations.

As China is one of the largest importers and consumers of food in the world, the protection of GIs is of increasing importance for foreign companies. There is a growing taste for European food and drink products in China and the Chinese agricultural sector wants to make its products more widely available in Europe. China is rather late in protecting GIs. However, there is a wide range of local products suitable for the application of GIs and they can now be protected globally. The same applies for producers in Europe. By securing intellectual property rights in an attractive and ever-growing market such as China, they hope to reduce the risk of counterfeiting, build the reputation of their products and increase profit margins. China ranks among the five most important export markets for European GI products. This is a meaningful fact for the European agricultural sector as its GI market makes up 15% of all food and drink exports.

This agreement, when concluded, will be the result of the wider success story of GIs. As well as protecting consumers and local farmers, it enables relevant companies to export their products to promising markets such as China. Conversely, the agreement offers the same chance for the Chinese agricultural sector with its own GIs registered under the EU law. This

[168] Source: European Commission documents.

agreement can be seen as a major milestone in economic relations between China and the EU, and even in the global field of IP rights.

EU-China organic food equivalency

The EU and China are respectively the second and fourth largest markets for organic products in the world. In recent years, trade in organic products between the EU and China has continuously increased, but it still has a great potential for development.

China's green food industry is growing fast and gradually expanding its overall market share. According to the latest figures, China has more than 10,000 accredited green food companies producing more than 26,000 types of products.[169] In 2005, China applied to be included in the list of non-EU countries recognised by the EU as equivalent for production and certification of organic food. Currently, China can export organic products to the EU only through recognised control bodies operating in China and recognised by the EU. However, a reciprocal mechanism for EU organic exports does not yet exist. The system of EU Member States authorisation for single consignments, which ran in parallel, was phased out in 2015 and can no longer be used.

Obtaining equivalency status would make China's access to the EU market simpler and easier. All listed Chinese organic products could enter the EU accompanied by certificates of inspection issued by the Chinese control authority or control bodies, and possibly bearing the EU organic farming logo on their packaging, without additional checks.

In June 2012, the Memorandum of Understanding on mutual recognition in organic agriculture was signed between EU and China. The first meeting to discuss how to reach a mutually beneficial and balanced equivalence was held on 9 April 2013.

Progress on the file since then has been very slow and this is largely due to Chinese insistence that the EU should first accelerate the procedure for the Chinese initial application. The EU has emphasised reciprocity, in particular as regards to the recognition of control bodies.

Following audits by the European Commission Food and Veterinary Office, systemic weaknesses were found in the Chinese organic system. The EU is especially concerned about China's control system for organic products, particularly the detection rates of pesticides in imported products.

Audits confirmed that the results of the sampling and testing for pesticide residues indicate a very high level of irregularity. In 2012, Greenpeace carried out a survey on Chinese teas imported into the EU, which revealed that all samples contained pesticides residues frequently above the internationally recognised maximum residue levels and, even more

[169] http://www.china.org.cn/business/2017-08/18/content_41438773.htm

worryingly, sometimes for substances prohibited in the EU due to their high toxicity. In addition, audits also demonstrated that farmers and processors had a very basic knowledge of organic production.

Moreover, sustainable agricultural practices are not a tradition in most parts of China. Farmers have easy access to plant protection products and organic production sites are often located in intensive production areas with a high prevalence of plant pests. It should also be noted that labour costs have significantly increased in China, which has made manual weeding expensive and brought an increased risk that operators will use herbicides in organic production to reduce production costs.

At this stage, both sides must find solutions that are reciprocal and mutually acceptable.

Trilateral cooperation

China, the European Union and the United States have a long history of partnering to help making sure that the food traded between them meets robust food safety standards. To further strengthen food safety cooperation and to promote global governance on food safety, the Chinese AQSIQ, together with the United States Food and Drug Administration (FDA) and Directorate- General of Health and Food Safety of European Commission (DG SANTE) upgraded this level of cooperation within our more globalised food safety system and agreed on a new trilateral cooperation mechanism on 2 November 2015 in Beijing. Taking into account that these three partners together provide nearly half of the world's foods, this is a significant move.

With an open attitude aimed at building mutual understanding and confidence, the three partners held thorough discussions on conducting information, scientific and technical exchanges, regulatory cooperation and trilateral cooperation mechanism on food safety thus forging the path toward global food safety governance.

This trilateral cooperation comes in addition to regular bilateral meetings on important issues affecting the safe production of food and cooperation in multilateral fora such as the Codex Alimentarius Commission and the World Trade Organization (WTO).

Three subsequent meetings were organised. The second technical meeting in Beijing (2016) focused on sharing information about the food safety laws and regulations as a basis for future cooperation. In the 2017 exchange in Washington DC, technical regulatory operations including risk assessment, certification, and e-commerce oversight were discussed in detail. In 2018 in Parma, Italy, debates were centred on trends and developments in risk assessment, including the application of whole genome sequencing, on e-commerce and the future on development of food safety under regulatory point of view. Through these exchanges, the three parties have gained deeper knowledge about each other's approaches to food safety regulation. It was further agreed to continue benefitting from this trilateral cooperation mechanism by using every possible occasion and venue, such as in the margins

of international meetings (e.g. Codex Alimentarius sessions) to have exchange of views and coordination of positions.

8.3. Multilateral cooperation

Multilateral cooperation takes place in many international organisations and structures. This section focuses on the most relevant in the food safety field: Codex Alimentarius Commission, World Health Organisation, Food and Agriculture Organisation, World Organisation for Animal Health, and World Trade Organization.

8.3.1. The Codex Alimentarius Commission

In 1962, the United Nations Food and Agriculture Organization (FAO) and the World Health Organization (WHO) acknowledged the need for a set of international standards to provide guidance to the food industry and protection to consumer health and, consequently, developed the Codex Alimentarius Commission (CAC) which administers the Joint FAO/WHO Food Standards Programme.[170] The core objectives of Codex are to protect consumer health and ensure fair trade practices involving food.

The Codex Alimentarius Commission (CAC) has risen from a rather obscure "*Gentlemen Club*" responsible for setting food standards during more than 30 years to an international organisation with heated debates, which has direct impact on decisions taken at the World Trade Organization (WTO). Codex effectively plays an important role in agri-food trade since 1995 because its standards, guidelines, and recommendations are acknowledged in the Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Agreements of the WTO Agreement. Under the WTO Agreement, non-conforming measures that restrict trade must be repealed as a basic principle, however, a number of exceptions are foreseen for measures and regulations which, for example, are necessary to protect human, animal, or plant life and health. This protection was originally exclusively contained in Article XX of the General Agreement on Tariffs and Trade (GATT, 1947) but has now been incorporated into the WTO Agreement as Article XX of the GATT. In effect, it is Article XX(b) of GATT which enables member states to define legislation creating barriers to trade to ensure food safety.

The SPS Agreement makes reference to the importance of "*relevant international organisations*" in setting "*international standards, guidelines or recommendations*" while the TBT Agreement makes reference to "*international standards*" and "*conformity assessment systems*". In the SPS Agreement, Codex is specifically mentioned as one of these bodies and, while not specifically mentioned in the TBT Agreement, its reference can be inferred; particularly, since the TBT Agreement deals with issues of labelling as technical barriers. Both

[170] Lupien, J.R. (2000). The Codex Alimentarius Commission: International science-based standards, guidelines, and recommendations. AgBioForum, 3(4), 192-196. Available on the World Wide Web: http://www.agbioforum.org.

the SPS and TBT Agreements encourage all parties to harmonise their domestic standards with international standards, guidelines, and recommendations, where such standards exist. In the case of trade disputes, standards, guidelines, and recommendations—like those created by the Codex Alimentarius Commission, the World Organisation for Animal Health (OIE), and the International Plant Protection Convention (IPPC), often nicknamed the "Three Sisters"—enjoy a preferred and protected status under the WTO dispute resolution process. While the provisions determining the existence of non-conforming measures are different under the two agreements, an important similarity exists between them in that any internationally adopted standard by the "Three Sisters" is protected from challenge as being an obstacle to international trade. Thus, once international standards are adopted, their transposition into national legislation is very difficult to challenge under the WTO dispute resolution mechanism. Such legislation then becomes a legitimate exception to WTO rules set up to facilitate free trade.

Codex and the WTO are partners, with Codex standards forming a clear and recognizable part of what the WTO accepts as limitations to free trade.

The European Union allocates important resources to contribute to the work of international organisations dealing with food safety and is pleased to see the growing involvement of China in the work of Codex. China now hosts two very important Codex committees: Food Additives and Pesticides Residues and is delivering more and more in Codex work. China and the EU now increasingly cooperate in Codex work when they both have converging interests. This was obviously the case during the discussions on maximum residue levels for ractopamine, a growth promoting substance added to feed. China and the EU allied in this debate against the use of ractopamine represented 70% of the world's production and consumption of pork.

8.3.2. World Health Organisation cooperation on food safety in China [171]

WHO is the directing and coordinating authority for health within the United Nations galaxy. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends. China has been a member of WHO for more than 60 years - since the organisation's inception on April 7, 1948. WHO has since then been working closely with the Government of China to improve the health and well-being of the people of China. WHO has a representative office in China since 1981.

First steps on food safety

WHO World Health Assembly adopted in 2000 a resolution to recognise food safety as an

[171] This section on WHO was drafted by Mercedes Revy, Food Safety Policy Officer during the year 2015 at the WHO China Office with the help of Zhang Pingping, Food Safety Officer at the WHO China Office.

essential public health function. In 2010 the World Health Assembly went a step further by adopting a new resolution on food safety titled "*Advancing food safety initiatives*". This resolution urges Member States to:

- Further develop surveillance for foodborne diseases and food contamination; including strengthened laboratory capacity; risk assessment and risk management, including the Hazard Analysis and Critical Control Points system, and risk communication; food safety emergency response; product tracing and recall;
- Participate fully in the **International Food Safety Authorities Network** (INFOSAN) which is a global network of national food safety authorities, activities, launched in 2004 in collaboration with FAO and aiming to prevent international spread of contaminated food and foodborne diseases and strengthen food safety system, communication and coordination system in food safety and zoonotic emergencies. China is actively participating in INFOSAN system's work. The Ministry of Health (NHC) hosts INFOSAN emergency contact points.
- Enhance the integration of food-safety in food aid, food security and nutrition;
- Continue to develop and maintain a sustainable systems approach to food safety encompassing the complete food-production chain from farm to consumption, including education;
- Promote dialogue and collaboration among human health, veterinary and food-related disciplines for foodborne risk reduction along the whole food-production chain and adopt Codex Alimentarius standards whenever appropriate.

In the 2011 Regional Committee Meeting, health representatives from countries in the Western Pacific Region (including China) endorsed the Western Pacific Regional Food Safety Strategy. Member States and countries were urged to use the strategy as a framework for strengthening the national food control systems to effectively protect public health, prevent fraud, avoid food adulteration and facilitate safe and healthy food.

For more than a decade, the WHO China Office has worked with key Chinese partners to provide technical support on a wide range of food safety activities and actively supported China's food safety legislative and institutional reforms.

World Health Day

On 7 April each year, the World Health Organisation (WHO) marks the World Health Day. The theme for World Health Day 2015 was food safety. This was an excellent opportunity to alert people dealing with food, working in governmental agencies, farmers, manufacturers, shopkeepers and consumers about the importance of this issue. The World Health Day on Food Safety represented a milestone in cooperation between WHO and China Food and Drug Administration (CFDA). The day featured many events aimed at providing better information to the Chinese population through simple messages, using the WHO "*Five keys for safer food*"

concept. WHO has developed this concept of "*Five keys for safer food*", summarising the basic principles to be respected during food handling and preparation that each individual across the world should know in order to prevent foodborne diseases. WHO's "*Five keys to safer food*" offer simple practical and efficient guidance to vendors and consumers for handling and preparing food to prevent food contamination by following good practices:

- Keep clean;
- Separate raw and cooked food;
- Cook food thoroughly;
- Keep food at safe temperatures;
- Use safe water and raw materials.

In the framework of the cooperation between CFDA and WHO, a campaign on the "*Five keys for safer food*" concept to educate Chinese population was launched. This campaign was based on short video clips and electronic posters posted across different types of media. It proved to be a very successful operation implemented in schools, supermarkets, broadcasted on television and public transport and further relayed across traditional and social media.

Cooperation on the Food Safety Law revision

In July 2014, WHO Director-General Margaret Chan and the CFDA Minister Zhang Yong jointly signed a "*Declaration of Intent*" to support an increase of CFDA's regulatory and managerial capacity in food safety management. The Declaration of Intent highlighted the intention of CFDA to further build up its regulatory and managerial capacity on food safety and the intention of WHO and CFDA to cooperate in areas of mutual interest.

In order to better implement this Declaration of Intent, Director General of CFDA International Cooperation Mr Yuan Lin and WHO Representative in China Dr Bernhard Schwartländer signed a "*Joint Cooperation Plan on Food Safety between the Chinese Food and Drug Administration and the World Health Organisation*" on 18 September 2015 in Geneva at WHO Headquarters. The *Regulations for the Implementation of the Food Safety Law* was a priority area.

WHO contributed to further strengthen CFDA's role as a main player of food safety management. Cooperation took the form of project implementation aimed at sharing experiences and contributing to improve food safety at the regional level in the Western Pacific region. Projects built on previous work with CFDA. The consultancy, seminars and trainings on food safety management formed the basis of the WHO-CFDA food safety projects. The output formed the basis for high-level policy dialogue and cooperation in the area of food safety. Strengthening communication as well as capacity building and learning from other countries' experiences were part of the cooperation in food safety management.

WHO also supported NHFPC to implement a project titled "*Study on Trend and Control Strategy for Antimicrobial Resistance of China Foodborne Pathogens*".

Codex Alimentarius

As one of the two parent organisations of the Codex Alimentarius Commission, WHO actively promotes the use and implementation of Codex Alimentarius standards and related texts to strengthen food safety. As detailed above, taking responsibility for two Codex subsidiary bodies is a very challenging task and is clear evidence of the Chinese Government's commitment to international collaboration on food safety issues. This illustrates the importance given to international food safety collaboration, particularly following the accession of China to the World Trade Organization in 2001. Professor CHEN Junshi from the Food Safety Commission was the key mentor and architect of this successful involvement.

WHO and CFSA cooperation

WHO China also closely worked with the China National Centre for Food Safety Risk Assessment (CFSA) on different projects including risk communication. The main project took place during autumn 2015. The objectives of the project were to conduct food safety standards' impact evaluation - regulation impact evaluation and assessment or cost-benefit analysis. This cooperation provided CFSA with a platform for exchange of experience and best practice. CFSA's role was to provide support in implementing the projects, provide access to documents and organise collaboration of the relevant units of CFSA and related agencies including logistical details for the study tour.

With the cooperation of WHO, a risk communication seminar was also organised. It focused on hands-on exercises and case studies, emphasising the basic principles of risk communication such as openness, transparency, responsiveness, and timeliness.

Particularly during 2015, synergy between WHO and the various actors involved in food safety in China proved to be extremely successful and has been frequently quoted by Chinese Officials as one of the best examples of international cooperation in that field. In a world dominated by economic interests, the aura of WHO and the absence of underlying trade and mercantile interests are clearly winning cards which could be exploited even more in a spirit of fair, open, transparent and balanced cooperation.

8.3.3 The Food and Agriculture Organisation in China

The Food and Agriculture Organisation of the United Nations (FAO) is a specialised agency of the United Nations galaxy that leads international efforts to defeat hunger. Serving both developed and developing countries, FAO acts as a neutral forum where all nations meet as equals to negotiate arguments and debate policy.

FAO is also a source of knowledge and information. One of its main tasks is to help developing countries to modernise and improve agriculture, forestry and fisheries practices, ensuring good nutrition and food security and safety for all. FAO has 197 Member States, along with the European Union as a "Member Organization".

FAO leads international efforts to build a world free of hunger and malnutrition where food and agriculture contribute to improving the living standards for all, especially the poorest, in an economically, socially and environmentally sustainable way.[172]

As a (still) developing country with 1.4 billion population, China always attaches high importance to food and agriculture development. [173] After resuming its membership in 1973, China has maintained close cooperation with FAO. In 1982, FAO announced the establishment of a Representation Office in China, shortly before entering an important era of "*Reform and Opening-up*".

In the 21st century, FAO's cooperation with China has entered a new era. China become one of the major supporters of the FAO in its fight against hunger and food insecurity through its experience in the rest of the developing world.

China is now in its 13th Five-Year Development Period (2016-2020), and FAO, together with multiple stakeholders in the country, has developed a new Country Programming Framework (CPF) for 2016-2020. It sets out four priority areas:

- Fostering sustainable and climate-resilient agriculture development;
- Reducing rural poverty, food insecurity and malnutrition;
- Promoting one-health approach for sustainable agricultural trade and improved public health;
- Fostering regional and international agriculture cooperation.

Food safety is at the core of most activities of FAO. It is useless and even counterproductive if the food distributed is unsafe, particularly with populations experiencing difficult living conditions as it may lead to higher receptivity to diseases and decreased immunity.

Despite its rapid economic rise, China is still striving for a balanced and low carbon development pathway that is equitable as well as environmentally sustainable and climate friendly. China has acknowledged this is essential both for its own environmental sustainability and to contain climate change globally.

FAO supports the **"One Health" approach** for sustainable agriculture and trade and improved public health. The objective is to reduce the impact of animal and plant diseases and other public health global threats, e.g. Antimicrobial Resistance (AMR), improving food safety and human health and nutrition while enhancing trade flows that in return support the development of the economy. FAO and its partners, including the EU, have been successfully

[172] Anríquez, G. & Stamoulis, K. 2007, "*Rural development and poverty reduction: is agriculture still the key?*", ESA Working Paper No. 07-02. FAO, Rome.

[173] Despite the exponential development of the economy in the last 25 years, China remains a developing country because its per capita income is still a fraction of that in advanced countries and its market reforms are incomplete. According to China's current poverty standard (per capita rural net income of 2,300 RMB per year in 2010 constant prices), there were 55 million poor in rural areas in 2015.

conducting the China Field Epidemiology Training Programme for Veterinarians (CFETPV) through the "One Health" approach since October 2010.

8.3.4. World Organisation for Animal Health (OIE)

The World Organisation for Animal Health (OIE) is an intergovernmental organisation created in 1924 with the mandate of coordinating, supporting and promoting animal disease control. [174]

The main objective of the OIE is to control epizootic diseases and thus prevent, or at least limit, their spread. Other objectives consist of transparency, scientific information, food safety and animal welfare, international solidarity, sanitary safety, and the promotion of Veterinary Services. It is recognised as a reference organisation by the World Trade Organization (WTO) and it has a total of 181 Member States. China joined OIE in 1992 but became a full member only in May 2007.

The General Session of the World Assembly of Delegates takes place every year in May in Paris. During this 5-day-meeting, delegates adopt and approve international standards in the field of animal health, especially for international trade. They also adopt resolutions on the control of the major animal diseases. In addition, they appoint the Director General of the OIE and Members who are elected for the governing bodies of the OIE. They examine and approve the annual report of activities and the financial report of the Director General and they agree and approve the annual budget of the OIE. Delegates also meet their respective Regional Commissions to discuss problems of common interest. At Chief Veterinary Officer level, an annual coordination meeting is organised between the EU and the Chinese delegations to exchange positions and support each other as often as possible.

8.3.5. World Trade Organization

The World Trade Organization (WTO) is an intergovernmental organisation which regulates international trade. [175] Signed by 123 nations on 15 April 1994, the WTO officially started on 1 January 1995 under the Marrakesh Agreement and replaced the General Agreement on Tariffs and Trade (GATT), which started in 1948. It is the largest international economic organisation in the world. The WTO deals with regulation of trade in goods, services and intellectual property between participating countries by providing a legal framework for negotiating trade agreements and a dispute resolution process aimed at enforcing participants' adherence to WTO agreements.

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[174] Brückner G.K. (2009), "The role of the World Organisation for Animal Health (OIE) to facilitate the international trade in animals and animal products", *The Onderstepoort Journal of Veterinary Research*, 76, 141–146.

[175] Ferdi De Ville (2012), "European Union regulatory politics in the shadow of the WTO: WTO rules as frame of reference and rhetorical device", *Journal of European Public Policy*, 19:5, 700-718, DOI: 10.1080/13501763.2011.646781.

Two WTO agreements[176] are particularly important in the context of the international food trade:

- **The Agreement on the Application of Sanitary and Phytosanitary Measures** – SPS Agreement – was negotiated during the Uruguay Round and entered into force with the establishment of the WTO at the beginning of 1995. Under the SPS agreement, the WTO sets constraints on members' policies relating to food safety (bacterial contaminants, pesticides, inspection and labelling) as well as animal and plant health (imported pests and diseases);
- The **Agreement on Technical Barriers to Trade** is an international treaty of the World Trade Organization. It was also negotiated during the Uruguay Round and entered into force with the establishment of the WTO at the beginning of 1995. This agreement ensures that technical negotiations and standards, as well as testing and certification procedures, do not create unnecessary obstacles to trade.

China became a member of the WTO on 11 December 2001. The admission of China to the WTO was preceded by a lengthy process of negotiations and required significant changes to the Chinese economy.

China gained observer status with GATT and from 1986, started the full accession process.[177] China wanted to be included as a WTO founding member (which would validate it as a world economic power) but this was opposed by United States, European countries, and Japan which requested that China first reform various tariff policies, including tariff reductions, open markets and industrial policies.

Exactly 15 years after its accession, China requested the implementation of an agreement by the WTO's other members, made when China joined and according to which it should by now be regarded as a "market economy" and consequently benefit from the simplification granted to this status and the abolition of provisional measures designed to compensate the lack of full compliance with WTO requirements. The United States and the European Union opposed this "upgrade" and claimed that China was not a free market by any reasonable definition. Indeed, cheap Chinese exports from heavily subsidised industries, notably steel, created unfair competition. Granting a trading partner with "market economy status" (MES) implies acceptance that its domestic prices are largely set by open competition rather than the government.

China's request was based on a clause included in the accession agreement (dating from 2001) that appeared to grant automatic MES after a 15-year period. According to the US and

[176] See section on Codex Alimentarius Commission for more details.

[177] Bransetter, Lee (2008), "China's embrace of globalization", in Brandt, Loren; Rawski, G. Thomas, "China's Great Transformation", Cambridge, UK: *Cambridge University Press*, p. 655.

EU, in reality the clause continued to allow China's trading partners the right to grant MES and not according to their own laws and assessment.

To avoid any attempt to challenge its law, the EU removed the distinction between market and non-market economies in its trade legislative corpus. As is usual in the international trade environment, this case will not be solved overnight. Far from it, as the completion of the mechanism to deal with the Chinese complaint is expected to last around 2 years.

In case of a trade dispute between Members, WTO has specific mechanisms to reach a conclusion. A good example is the **WTO dispute between EU and China on Poultry Meat Products**. On 8 April 2015, China launched a case against the European Union regarding measures to modify the European Union tariff concessions on certain poultry meat products. China claimed the preference given to Brazil and Thailand as the attribution of quotas was not compliant with WTO rules. On 8 June 2015, China requested the establishment of a panel. Nearly two years later, on 28 March 2017, the panel report was circulated to Members.

As a result of several SPS measures, imports of poultry products from China into the European Union were prohibited between January 2002 and July 2008. Following a relaxation of the SPS measures in July 2008, imports of poultry products from China under two of the seven tariff lines increased significantly over the period 2009-2011. In late 2011, China accounted for more than 50% of imports into the European Union under two tariff lines.

Before the Panel, China claimed that the European Union acted inconsistently with various provisions of the GATT 1994.

With respect to two of the ten TRQs at issue in this dispute, the Panel found that the European Union's allocation of TRQ shares among supplying countries was inconsistent with the requirements of Article XIII:2. Specifically, the Panel upheld China's claim that its increased ability to export poultry products to the European Union following the relaxation of the SPS measures in July 2008 was a "special factor" that had to be taken into account by the European Union when determining which countries had a "substantial interest" in supplying the products concerned, or when determining the TRQ shares to be allocated to the category of "all other" countries that were not recognised as substantial suppliers (including China) pursuant to Article XIII.

The Panel rejected China's other claims in this dispute.

On 21 June 2017, the European Union and China informed the DSB they were seeking to mutually agree on a period under Article 21.3(b), even if such agreement is reached beyond the time provided for in Article 21.3(b). In addition, the European Union and China informed the DSB of their common understanding on the applicable deadlines if the matter were referred to arbitration under Article 21.3(c) of the DSU.

8.4. EU-China agri-food trade

8.4.1. Performance of EU-China agri-food trade in 2017

As mentioned, the core objective of bilateral cooperation between exporting countries and China is to develop exports and benefit from the gigantic Chinese market which has acted as a real life-saver for many sectors of the European economy, despite complicated, bureaucratic and burdensome authorisation procedures that, in many cases, have constituted trade obstacles. As detailed above, China is not a market economy and still wants to keep tools that artificially regulate the market to protect the national production which is far from being competitive in many sectors.

Before deciding to conquer the Chinese Eldorado, every exporter should be clear about the following facts: the game is not fair, the rules are rigged, but the potential gain is still very attractive.

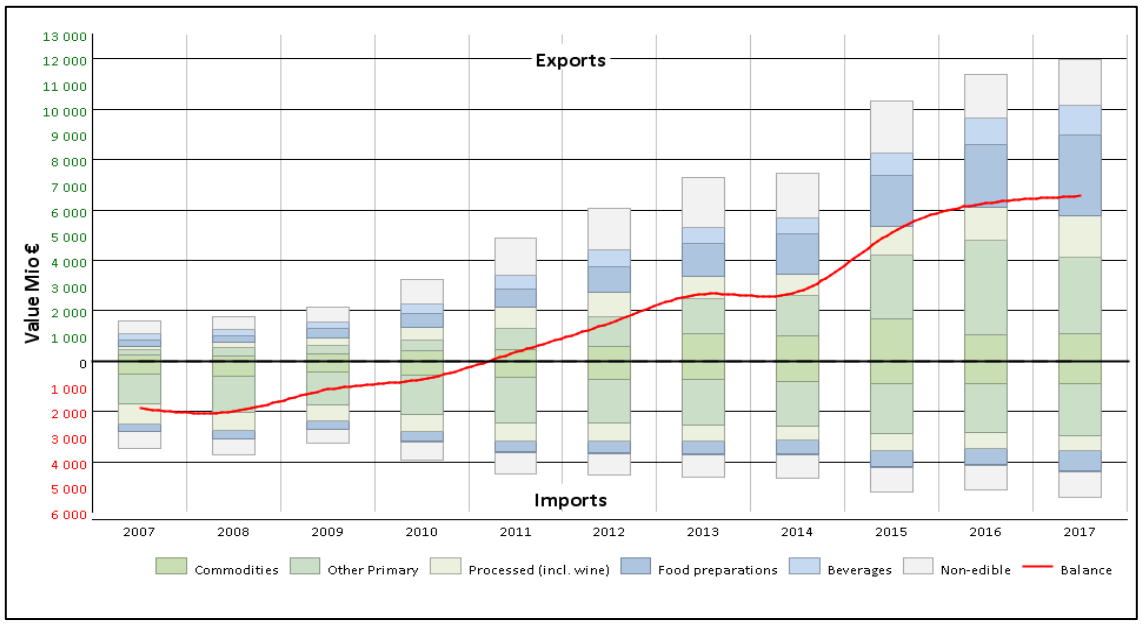
As regard EU agri-food exports to China, 2017 was globally a very good year which saw a complete restoration of the losses of 2016 when imports had dropped significantly. China's demand for foreign agri-food increased of EUR 10 billion (+10,3%) to reach EUR 103 billion.

The EU remains in third place of all suppliers of China (12.5% of imports) behind Brazil (20.7%) and the US (19.7%).

With total agri-food exports valued at EUR 12 billion and imports valued at EUR 5.4 billion, China is the second most important destination for EU agri-food exports (8.7 % of all EU agri-exports) and the fifth most important origin (4.6 %) for EU agri-food imports.

As shown in table 6, the EU has been a net exporter of agri-food products to China since 2011 and the trade balance is increasingly in favour of the EU. In 2017, it reached the record level of EUR 6.6 billion.

Table 6: Structure of EU28 agri-food trade with China 2007-2017

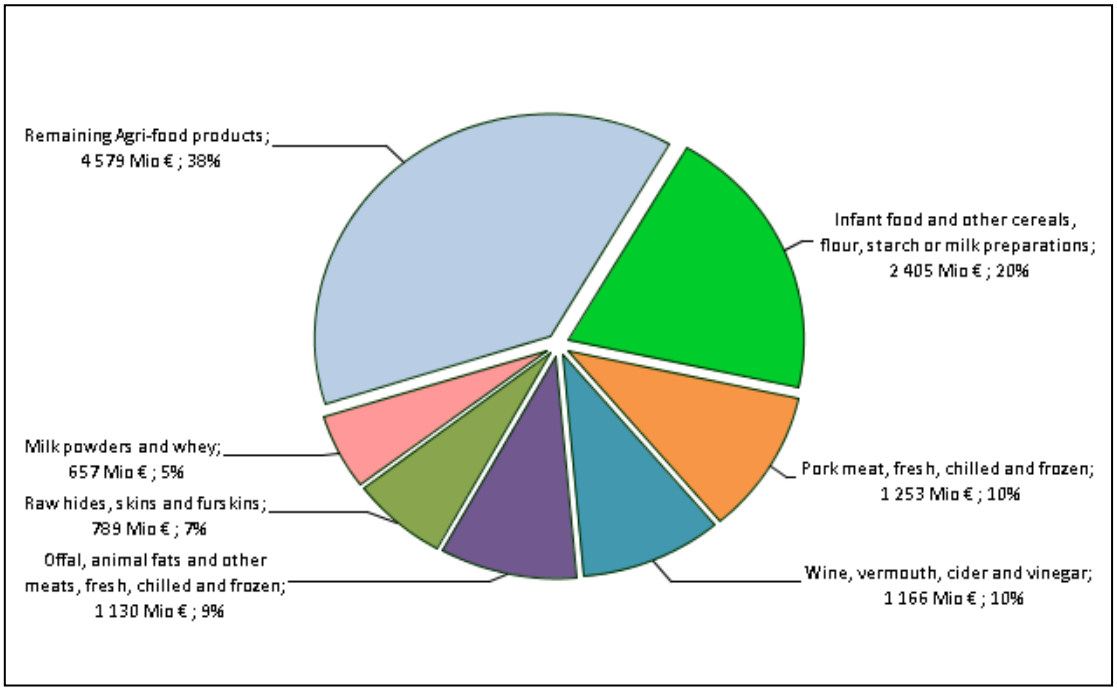


Notably, the trade balance shows that higher exports in 2017 were driven by a strong increase in exports from processed agricultural food including wine (+24%) and particularly from food preparations and beverages (+24%).

China is mainly demanding a selected range of products from the EU. Infant food and other cereals clearly remain the most important export category increasing the share up to 20%, meaning +30% in value compared to 2016. A similar increase can be seen in the wine, vermouth, cider and vinegar category +25%, which hold a share of 10% and rank third.

On the other hand, pork meat decreased significantly in export value and its share is back to more normal levels, which is still the second highest it has ever been, after the enormous boom in 2016. A similar pattern can be seen for offal (-18%). Pork and offals account together for almost a fifth of EU exports to China in 2017, demonstrating the importance of pig meat for this destination.[178] Raw hides and skins (share of 7%) and milk powders and whey (share of 5%) complete the top-six.

Composition of EU agri-food exports to China in 2017

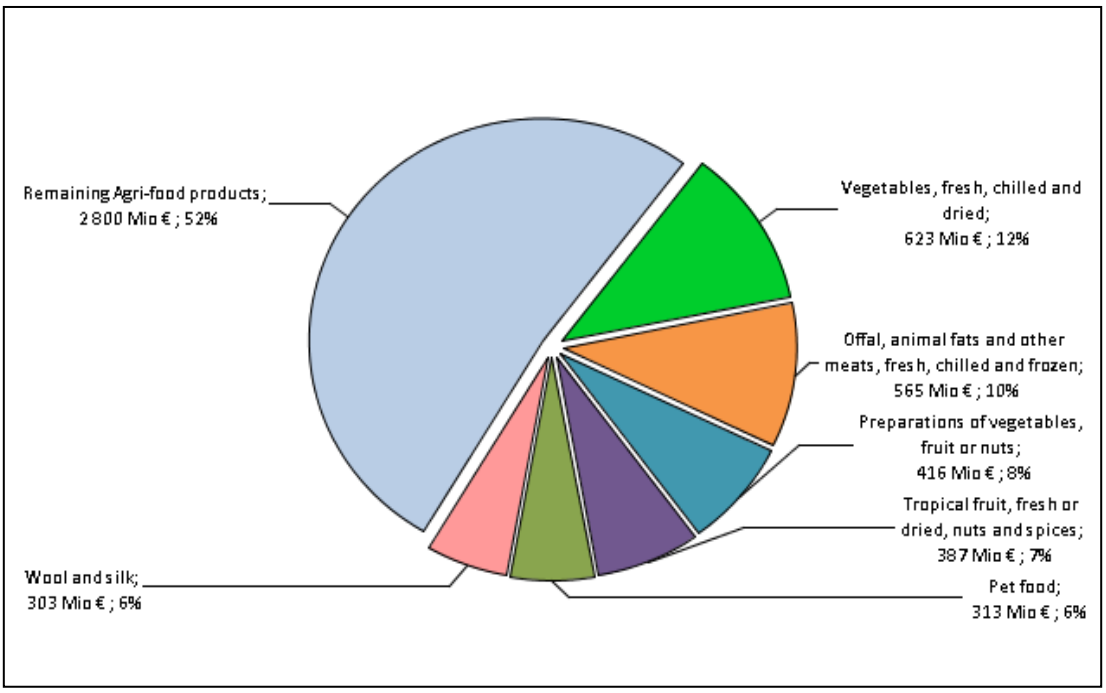


China is the number one destination for EU offal (38%) or pork meat (25%), but also for many dairy products (milk powders, whey, butter, fresh dairy products and infant food).

Regarding imports from China to the EU, vegetables dominate whether fresh and dried (12 %) or prepared (8 %, together with fruit preparations), followed by offal (9 %), tropical fruit (7 %), pet food (6%), wool and silk (6%). Striking is the increase of pet food imports (+84% compared to 2016).

[178] 66% of the meat consumed in China is pork.

Composition of EU agri-food exports to China in 2017



8.4.2. Main SPS barriers on imports from the EU into China [179]

China is an important market for EU exporters of agri-food with important ongoing trade. The EU has previously never exported more food than it does now, however, SPS barriers imposed by China unnecessarily hamper further market access of EU agri-food products. Most of the barriers China keeps in place relate to non-respect of international standards and lengthy, burdensome, complex and non-transparent application procedures. EU MS are obliged to undergo a country-by-country approval as China does not recognise the EU as a single entity. China does not have a single set of import conditions and carries out a risk assessment for each of the EUMS applications which is then followed by tailor made and unnecessary stringent import conditions, which could be different per EU Member State. The WTO SPS Agreement clearly identifies that every WTO Member has the right to set its appropriate level of protection but this should be based on international standards, science and not discrimination between its domestic market or between Members, in particular between Members where similar or identical conditions are present (such as between EU Member States). It should be noted that an application submitted by China for exports to the EU is valid for access to the whole EU, i.e. 28 countries in one application.

It is also noteworthy that communications between the different Chinese ministries and departments involved in applications from the EU (and other trading partners) are rather limited. In addition, the rules are not always clear and often overlap.

[179] Source: European Commission documents.

Beef exports to China

Due to Bovine Spongiform Encephalopathy (BSE), China has banned imports of all EU beef and bovine products in for more than 20 years. The safety of European beef has been internationally recognised. In addition, the use of hormonal growth promoters has been banned in the EU since the 1980s. Antibiotics can only be used for therapeutic purpose (and animal products are then subject to a withdrawal time) and all use for prevention or growth promotion has been banned since 2004. Moreover, all bovine animals are individually identified with double ear tags, which ensure full traceability and control of the movements. For the quality of the meat, Europe has a diversity of breeds linked to their terroir, some of them being worldwide famous for the quality of their meat (e.g. Charolais, Limousine). Since 2005, the European Commission has asked China to start procedures that would allow the resumption of beef exports from EU Member States and provided all necessary details that would allow lifting the ban. China has never provided any science-based justification for this ban. Moreover, China allows imports of beef from other trading partners which have the same BSE risk status as most of the EUMS, namely negligible country risk status.

Recent progress has nevertheless taken place. The state of play for the main EU Member States in April 2018 is illustrated in the following table. [180]

MS	Status	MS	Status
Belgium	Questionnaire sent back. BE authorities invited the Chinese authorities for a first inspection; developments expected in May 2018 with the visit of Commissioner Hogan in China; Recent scandal in Belgium could affect this process	**Italy**	In December 2017, China recognised Italy's status of country with negligible BSE-risk status; It was expected, but not yet planned, to have an inspection visit to slaughterhouses and cutting plants in the course of 2018; After that, it was expected to have a protocol and the draft of a certificate; Due to the re-organisation of the Chinese agencies, the negotiations are at a standstill
Denmark	Absolutely nothing since May 2017, when a reply was given to the questionnaire from AQSIQ	**Netherlands**	The protocol for exporting veal (up to 12 months) to China almost finalised; Protocol was enlarged to include not only frozen meat but also chilled meat; It was due to be signed on 12th April, but because of the re-organisation of the Chinese agencies the signature was cancelled; The next step should be the inspection of the Dutch beef/veal establishments but no timeline, the veterinary protocol might be agreed before Summer 2018

[180] Source: Document Union Européenne du Commerce du Bétail et de la Viande (UECBV) Ref: 13309 dated 19 April 2018.

MS	Status	MS	Status
France	BSE ban lifted; AH and veterinary services assessment done; The veterinary protocol has been drafted; The French beef establishments inspected in May 2018; veterinary protocol and the veterinary certificate should be agreed in June; The first beef shipment is expected on 14th July (Chinese commitment during President Macron's visit in January 2018)	**Romania**	Previously approved for cattle export to China but lost the approval because of a BSE case
Germany	Three questionnaires were sent to the Chinese authorities at the beginning of 2018. No response has been received from China	**Spain**	In September 2017, the questionnaire was sent by the Spanish authorities to the Chinese authorities; A non-official visit by AQSIQ is expected in the near future to compare what was answered in the questionnaire with what can be seen in the field (a couple of plants and farms will be visited). Spain expects to have its BSE status of negligible risk by the end of 2018, have the protocol finalised in 2019, have visits to approve plants at the end of 2019 or beginning of 2020 and have the first consignments at the end of 2020
Hungary	Approved for beef export to China	**United Kingdom**	An agreement to progress lifting the BSE ban on British beef exports to China was announced on 1st February 2018 during PM Theresa May's trip to China. The ban could be lifted within 6 months but it will be subject to a visit from Chinese inspectors
Ireland	BSE ban lifted; AH and veterinary services assessment done; Veterinary protocol agreed; Irish beef establishments inspection done; Three Irish beef establishments are approved; Certificate agreed with China for beef and beef offal; First Irish beef shipments expected in May 2018		

EU's exports of pork blocked due to African swine fever

Poland, in particular, has been severely hit due to the agri-food export ban imposed by Russia in 2014. The pork sector is one of the most affected ones. In addition, on 24 January 2014, China initiated a total and country-wide ban of Polish pork due to outbreaks of African swine fever (ASF) that were initially detected in cadavers of wild boar close to the Belarus border. The EU took immediate measures to restrict movements out of the well-defined infected areas. The EU considers such country-wide bans unjustified and disproportionate as

these are not in line with the WTO SPS Agreement or the international standards of the World Organisation for Animal Health (OIE) which advocate for the least trade disruptive measure which means in this case to only put trade restrictive measures in place on the well-defined and controlled affected zone and not a whole country.

Poultry ban due to highly pathogenic avian influenza (HPAI)

China immediately implements a country-wide ban when an outbreak of HPAI is notified. In the EU, when an HPAI outbreak occurs, stringent control measures are immediately implemented in a well-defined zone which guarantees that safe trade can continue to take place from non-affected areas and from non-affected products. This international recognised principle is called regionalisation and the EU follows here strictly the rules established by the World Organisation for Animal Health (OIE).

Ignoring these principles, China imposed a country-wide ban and does not recognise the regionalisation measures put in place in the EU. The procedure for lifting of the ban (and recognition of regionalisation measures) is not clear and not predictable.

EU's pending applications for meat and dairy

China maintains a country-by-country assessment on applications made for meat and dairy products. This process is lengthy, burdensome and non-transparent. China is not always timely responding to applications made and does not provide any justification based on science for keeping its market closed or for any delays seen in the process. When market access is granted, it is only valid for a limited number of meat/dairy products. If a country wants additional products to be authorised for imports into China, a new application needs to be submitted and this can take several years. Once market access is granted, it is only valid for a number of authorised establishments. Adding establishments to the approved list requires an audit on-the-spot by China. This process is overly burdensome, lengthy, disproportionate and overly trade restrictive. The EU applies the principle of pre-listing, meaning the management of the list of establishments authorised to export is managed directly by the competent authority of the exporting country. China is now considering reciprocating this approach, at least for certain sectors.

The situation is more positive for dairy products than for the meat sector. Since 1 May 2014, China has strengthened its import conditions for dairy and milk products requiring both a country approval and approval of individual foreign establishments. The majority of EU Member States have lodged applications to export dairy/milk products to China. Most of them have been rapidly approved (less than a year). Several EU MS still have pending applications. For some EUMS, China does not always respond to the applications made and does not provide any justification. 11 EU MS out of 28 are authorised for exporting infant formula. 18 EU MS out of 28 are authorised for exporting dairy/milk products.

Most applications for poultry of EUMS are blocked due to a country-wide ban in place due to HPAI (see above). At present, only Poland is allowed to export poultry meat.

8.5. Conclusions

During the last decade, between 2008 to 2018, the evolution of the legal framework for food safety has considerably evolved. Food safety and quality standards have transformed significantly as agri-food production became more industrialised and globalised. In 2008, China faced a major food incident and reacted by trying to hide the crisis and avoid information spreading. Most of the time, this behaviour has dramatic consequences as when it is discovered, the population loses its confidence in the authorities. This situation has happened both in China and in Europe. When there are not several solutions, the only way forward is to totally reconstruct the system from scratch brick by brick starting with the foundations based on principles. Europeans and Chinese share a common objective: the consolidation and development of their mutual trade relations and the rebuilding of their consumers' trust have been the driving forces of the EU-China cooperation in food safety policies.

However, China has had a big advantage: it could benefit and take inspiration from the European experience. In addition, Europe, like all major exporting countries, is willing to cooperate, because this allows wider access to the lucrative Chinese market of 1.4 billion consumers: first by a better compatibility between the two systems and second by establishing closer links between authorities, which leads to better trust.

International cooperation is the only way forward. Since 1995 and the creation of the World Trade Organization, the development of international food trade went beyond the wildest predictions. Food and beverages travel all over the world for economic reasons but also because consumers, themselves travelling a lot, request a wider choice of products and do not accept seasonal or geographical limitations. In addition, the development of e-Commerce, particularly in China, introduces multiplication factors. Chinese authorities understood early the need to invest on the international scene, starting with the World Trade Organization and continuing with the Codex Alimentarius Commission. The EU is China's biggest trading partner and China is now the EU's second trading partner. China's share of total EU trade in goods with the EU has almost tripled since 2000.

Looking to the future, China and the EU should continue to get closer and closer. China and the EU share a very rich food culture which should encourage cooperation. A bifurcation between export markets and domestic markets should be avoided. Of course, the temptation of protectionism regularly reappears on both sides – but hopefully this will become inconceivable, unrealistic and outdated in our globalised world.

ANNEX – An Industry Perspective on Food Safety in China: An Overview [181]

*Abigail Stevenson**

Global food safety: current challenges and trends

Food safety is one of the fundamentals of food security, defined by the Food and Agriculture Organization as existing when "…all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food which meets their dietary needs and food preferences for an active and healthy life".[182] Food safety is an area of public health both relevant to everybody on the planet and an outcome of many complex processes such as regulatory, educational, agricultural, environmental and investment to name but a few.

New food safety risks are emerging constantly and some of the food safety challenges that those involved in the global food supply chain face today are becoming ever more complex. King et al (2017) describes an 'urgent' need to ensure improvements in the efficiency and effectiveness of supply chains, stating that: "the global population is expected to reach at least 9 billion by the year 2050, requiring up to 70% more food, and demanding food production systems and the food chain to become fully sustainable. This challenge is complicated by a number of overarching issues, including increasing complexity of food supply chains, environmental constraints, a growing aging population and changing patterns of consumer choice and food consumption. Within this context, food safety must be an enabler and not inhibitor of global food security". King et al (2017) also cites 'harmonisation of regulation and equivalence of standards' as a key challenge suggesting the need to find mechanisms that manage and nurture the food supply as a single system rather than as a series of disparate geographic entities. [183]

Addressing these challenges requires food safety science to better manage both known food safety threats as well as those that are emerging, and the as yet unknown challenges

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[181] The objective of this Annex is to give one significant example on how a private company can efficiently contribute in helping public authorities achieving their duties on food safety. This cooperation public-private, when correctly managed and supervised could certainly become a model for the future.

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[182] FAO. 1996. Rome Declaration on World Food Security and World Food Summit Plan of Action. World Food Summit 13-17 November 1996. Rome.

[183] King T., Cole M., Farber J. M., Eisenbrand G., Dimitrios Z., Fox M. J., Hill J. P. (2017), "Food safety for food security: relationship between global megatrends and developments in food safety", *Trends in Food Science and Technology*, 68, 160-175.

that may be faced in the future. It also requires a focus on technology and science to enable the identification and isolation of potential and developing issues faster and more effectively than ever before. This will be required to deliver absolute transparency in supply chains and to verify sourcing, in addition to a global approach to food safety governance in the form of effective and enforced regulation.

A governance-driven approach

Food safety is a challenge that is common to both the developed and developing world. Indeed, due to the increasingly global nature of the food supply chain the goal of safer food for all is unlikely to be achieved without global focus. Currently governance tends to be developed at a country level leading to a global picture of varying food safety regulations and standards [184] and while there are good examples of policies that are based on a rigorous, scientifically-based approach, this is not always the case. Globally, more collaborative work will be required, in addition to the open sharing of information and governance relating to the safety of global food supply chain. There is a need to consider systems that monitor risk for all stakeholders in the food supply in real time. Current legal frameworks do not encourage open and transparent dialogue or the free sharing of information. The challenge here is that consumers need to be protected, and there must be consequences where breaches of regulation take place. However, arguably the more collaborative and integrated industry and regulatory bodies can be, the more effective the defence of consumers.

Positive steps are being taken towards creation of a global governance approach. Organisations such as Codex (currently 189 members including China) are focused on setting global scientific standards, and the Global Food Safety Partnership (GFSP) was established in 2012 as a public-private partnership dedicated to supporting and promoting global cooperation for food safety capacity building. The GFSP aims to give visibility to food safety initiatives and identify potential efficiencies and capability gaps, such as variations in standards. [185] Typically, the role of business has been to comply with regulations. Many businesses have contributed to standards and the training of regulators and health inspectors, and government industry groups have focused on developing meaningful and implementable standards. Today a new phase is emerging through open sharing of data. The notion of open data sharing changes the dynamics between government and industry groups and may lead to broader findings outside the scope of current regulation.

There are significant pockets of collaboration among industry representatives, regulators and academia in areas such as industry working groups and industry associations. That said,

[184] Stacey P., Fons G. and Bernardo T.M. (2015), "An open ecosystem engagement strategy through the lens of global food safety", *F1000 Research*, Volume 4, May 27, Article number 129

[185] King T., Cole M., Farber J. M., Eisenbrand G., Dimitrios Z., Fox M. J., Hill J. P. (2017), "Food safety for food security: relationship between global megatrends and developments in food safety", *Trends in Food Science and Technology*, 68, 160-175.

fundamentally there is an opportunity to go further through shared research projects of common interest and collaboration with data sharing in real time. Through collaboration we are working together to define the future of food safety which is a step removed from operational food safety today. In the future could industry and regulators establish a joint mission for example aimed at addressing the pervasive nature of *Salmonella* through the food supply so uniting consumers, regulators, academics and businesses in a common transparent objective? Or perhaps in understanding the relevance and importance of the spread of antimicrobial resistance via foodborne vectors? This would allow us to go from research and understanding to impact and outcomes.

In China there have been a number of examples of developments designed to further increase efficiency and effectiveness of as part of food safety governance aims.

As cited by Rongduo et al (2014),[186] food safety issues in China have led to reduced consumer confidence. Significant work has been undertaken since the launch of the China *Food Safety Law* in 2009 and its first revision in 2015 to understand the implications for compliance, auditing and how it relates to other regulations around the world such as the United States' Food Safety Modernization Act (FSMA). Ensuring clarity of the requirements across, and the precise implications for, local supply chains is important, as is the need to ensure focus on critical requirements and to verify compliance with other global food safety standards. The China *Food Safety Law* is extensive and there are some challenges regarding interpretation and implementation of the law, and how it relates to other standards such as the FSMA requirements.[187] The Chinese government has called upon industry peers to collaborate openly on food production standards, supply chain management, agriculture and logistics management. To further increase the efficiency and effectiveness of regulation, structural changes were applied by the Chinese government in early 2018 with the consolidation of food safety, market operations and competition organisations into a single, newly-established State Administration for Market Regulation (SAMR).[188] Changes to import inspection functions are expected to further streamline import procedures, with the planned consolidation of market supervision functions aimed at enhancing effective enforcement.

Mars global food safety management perspective, methods and collaborations

At Mars, quality and food safety are business fundamentals. Quality – one of the Mars Five Principles – is always the starting point when it comes to our products. We make products

[186] Rongduo Liu, Zuzanna Pieniak, Wim Verbeke (2014), "Food-Related Hazards in China: Consumers' Perceptions of Risk and Trust in Information Sources", *Food Control*, 46 291 -298.

[187] Geng S., Liu X., Beachy R. (2015), "New Food Safety Law of China and the special issue on food safety", *China Journal of Integrative Agriculture*, 14(11): 2136–2141.

[188] Lau N. (2018), "China's massive government restructure explained", [online] Available at:https://www.lexology.com/library/detail.aspx?g=0f929294-e5f4-4bad-b60e-3c2310c15082 [Accessed 03 May 2018].

we are proud of, that we are confident in, and that we know are safe for the people and pets in our families and beyond to consume. We are dedicated to improving food safety across our supply chain – whether partnering with suppliers to ensure safe ingredients, or collaborating with the wider food industry to research new solutions. If it is not safe, it is not food. For us, food safety is not just about guaranteeing the best for our own products, it is also about ensuring that the work we do increases global access to sufficient, safe, nutritious food.

The Mars approach to quality and food safety starts with the Mars Quality Management Program (QMP) which is a mandated internal process comprised of consistent standards across the globe, anchored around a risk-management-based approach to food safety management. The QMP involves rigorous risk assessment, governance, listening to consumers and an ongoing, audited program of continuous improvement. Mars actively partners with universities to ensure the right scientific insights are used to inform standards. Close collaboration is also fostered with non-governmental organisations (NGOs), intergovernmental organisations (IGOs), and regulators to share food safety intelligence on a global basis.

Case study: How Mars works as a role model for transnational companies contributing to Chinese food safety governance through global collaboration

Introduction to the Mars GFSC

As a company, we believe industry has a crucial role to play in helping all stakeholders in the food supply chain identify risks and solutions, however, no entity can do this alone. That is why we are advocating for a new approach to food safety, rooted in knowledge sharing and collaboration and why Mars launched the Mars Global Food Safety Center (GFSC) in 2015. The Mars GFSC, centered in Beijing, China is a visible demonstration of our commitment to open collaboration through research, training and convening the very best experts to focus on food safety challenges. We believe that by taking this open approach, both society and business benefit.

The Mars GFSC, situated within the Huairou Science and Technology Park, is a pre-competitive facility meaning that it is truly dedicated to openly sharing research and insights to help raise standards of food safety across the global food supply chain. The center conducts original research in a number of critical food safety areas: mycotoxin management, pathogen management, raw material and product authenticity, operational food safety optimisation and transforming food safety through data integration. Since the center opened more than 500 people from organisations ranging from academics to government officials have visited. As well as conducting research and sharing knowledge with our many global partners and through collaboration the Mars GFSC also shares food safety science and risk management knowledge at scientific fora and through scientific publications. This ensures that we foster quality discussions with key experts in the field and evolve our research areas to remain

contemporary with current and future risks, continuously improving the strength of the research the center delivers.

Through our work we are investing in science and technology that aims to drive a new approach to food safety management. Our vision is an integrated, systematic approach with the codification of the factory environment in order to predict potential food safety issues based on environmental changes beyond the norm. The IBM-Mars Consortium for Sequencing the Food Supply Chain is one such example and early signs are encouraging.

About the Mars Global Food Safety Center

Mars began building the Mars Global Food Safety Center in the spring of 2014, with the official opening in September 2015. The center contains a 100-person capacity amphitheater, and 1,300 square meters of dedicated research facilities with microbiology and analytical laboratories.

The key goals of the Mars Global Food Safety Center are to:

- Accelerate discovery and adoption of new techniques and methods that will enhance food safety globally both within our own food supply chain and across the food industry;
- Enable networking and collaboration in support of the development of food safety standards, contributing where appropriate to government food safety knowledge and understanding;
- Leverage the skills and knowledge of a global network of universities and research institutions to improve our ability to respond to new challenges in food safety, and support learning across the globe.

Image (above): The Mars Global Food Safety Center in Huairou, Beijing

Sharing insights in China

The Mars GFSC aims to increase scientific understanding and capability in order to help ensure safe food for all.

1) Training

Based on input from a range of stakeholders including regulators, non-governmental organisations and industry, an initial training portfolio has been developed with a range of courses including: the full Best Process Control School course, the internationally-recognised Good Manufacturing Practices (GMP) and Good Hygiene Practices (GHP) courses, laboratory-based methods training for subject matter experts, advanced technical training in quantitative risk assessment, mycotoxin control and management training, and training on the U.S. Food Safety Modernization Act (FSMA) and other regulatory changes. These courses have been delivered to a number of local regulators and food safety practitioners looking to increase their knowledge and understanding.

2) Knowledge sharing

As well as being a physical entity, the center operates as a global virtual knowledge sharing hub.

Research findings generated through the work of the Mars GFSC are openly shared through scientific journals and at world leading symposia in order to ensure access to the latest advances in the food safety field. Mars has actively published food safety research for many years, even before the creation of the center, including peer reviewed articles on topics ranging from managing mycotoxin risk to rapid detection methods. A full list of our publications is available on our website (www.marsgfsc.com).

Mars has been collaborating with the Chinese government for some years in the area of food safety.

In 2007, Mars China worked with industrial partners to initiate the Food Safety Standard and Regulation Committee within the framework of the China National Food Industry Association. Since its formation this forum has been working closely with legislators sharing knowledge and insights to support the development of the China *Food Safety Law* and the food safety standard system which is based on product testing to production process management. Mars China has chaired the forum since it was founded in 2007, whose members include multinational, state-owned and privately-held food and beverage companies in China.

During the China formula milk powder contamination crisis of 2008, Mars shared knowledge and analytical methodologies with the China Center for Disease Control and Prevention (CDC) to assist with the investigation.

The Mars GFSC has also actively participated in the China Food Safety Week primarily to share insights and best practice.

Following the official opening of the center in September 2015, Mars signed a memorandum of understanding (MOU) with the China Centre for Food and Drug International Exchange (CCFDIE) to help build the capabilities of local food safety inspectors within the China Food and Drug Administration (CFDA) system.

The Mars GFSC has also been working with the Chinese Academy of Inspection and Quarantine (CAIQ) to highlight opportunities for building food safety capability.

As yet China does not have a standard for aflatoxin although China regulators are taking a proactive approach and are focused on developing a national standard. Mars has provided expert advice concerning the aflatoxin contamination of grains and peanuts and will continue to provide insight and perspective as regulators develop standards for a number of other substances in food stuffs. The Mars GFSC provides informal input into the China Food Safety Initiative (CFSI) through information relationships and capability building. The China National Center for Food Safety Risk Assessment (CFSA) is another such initiative supported by the Mars GFSC, along with the China Association of Official Analytical Chemists (AOAC) and the China Food Industry Association (CFIA). We actively seek future opportunities to strengthen our collaborations and local networks.

The Mars GFSC projects and collaborations

The Mars GFSC focuses on both global collaborations and targeted, local collaborations.

Through the Mars GFSC Mars conducts original science and partners with international academic partners and others to help move the needle on critical long-term food safety challenges including mycotoxins and pathogens. Initiatives include:

- The IBM-Mars Consortium for Sequencing the Food Supply Chain which is exploring the potential for sequencing factory and material microbiomes in order to observe and predict changes in an environment which could signal outbreaks before they happen which could change the face of pathogen management.
- In 2016 the Mars GFSC hosted its first global food safety science symposium “Uncommon Collaborations and the Future of Food Safety Science”. The three-day event brought together more than 60 global food safety experts from industry, NGOs, regulators and academia to discuss the future of food safety science and the critical role of collaboration in the drive towards safer food for the world.
- To mark World Food Day 2017, Mars, together with global partners, launched an initiative to help eradicate aflatoxin, a cancer-causing poison, from the food supply chain. Using the computer game Foldit, gamers from around the world are competing to redesign enzymes that could have the potential to degrade aflatoxin. At the time of writing, gamers have generated over 400,000 designs that are currently being

tested by the Siegel Lab at the University of California, Davis. The hope is that one of these designs will create an enzyme that can degrade aflatoxin helping to eradicate this poison from the food supply chain.

- To address the growing issue of food fraud, the Mars GFSC, together with Danone, the University of Laval, Quebec, and Queens University, Belfast hosted a global workshop in October 2017: Global Understanding of Food Fraud - Towards Global Action for Prevention and Mitigation of Food Fraud. The two-day event focused on collaborative action through knowledge sharing and the development of key principles for a universal food fraud prevention framework that can be leveraged by Codex Alimentarius Commission (CAC). Experts from more than 100 non-governmental organisations, regulators and retailers attended the event. The Mars GFSC continues to work with partners to develop actionable steps and insights.

The Mars GFSC in China: environment, opportunity, Mars and China

China is very important to Mars. We have been investing in China and developing mutual relationships for decades with Chinese universities, regulators and through our dedicated Mars Associates.

We are proud to have made Huairou the home of the Mars Global Food Safety Center. We recognise that China is a global center of scientific excellence and through this location we will be able to contribute to global standards for food safety.

Our decision to base the center in China was influenced by a number of factors: there was recognition at the highest level in the Chinese government that this was an appropriate move. The purpose and goals of the Mars GFSC are very closely aligned with the vision and strategy China has developed for science and technology. When considering the global food supply chain, we believe that China already plays a significant role in this that is only set to grow in the future. We also believe that the knowledge and skill base is yet to reach its full potential within China and there is an opportunity to help build talent and capabilities. Lastly, through being located within close proximity to existing Mars operating sites in the area, we are able to work directly with our China business to leverage our best practice approach in support of China's aspiration to be a world leader in science and technology. We are very excited to be part of a future focused and inspirational science and technology plan for both China and the Huairou area more specifically.

To better protect our consumers the food industry and the food supply chain we are taking a future focused, collaborative approach to food safety. This enables us to help with the development of industry standards and the creation and implementation of related regulation, and in return we gain early alerts of new food safety threats that help us to better prepare our supply chains globally. We also feel it is very important to establish networks of experts so we can help improve our own food safety organisation and approach, assist the Chinese food industry with increasing its reputation more broadly, and contribute to a quality

and food safety talent pipeline that is currently very challenging to fill within the region. Through a deep understanding of the interdependencies and structure of global supply chains, and through leveraging the scale of China's food manufacturing systems, we will expand our food safety and surveillance capability.

How the GFSC contributes to foods safety in China: project examples

As a foreign multinational in China Mars aims to be a role model manufacturer. A best practice approach will help to raise food safety standards for the entire industry. Across our businesses both in China and globally, we have openly shared our approach to quality and food safety management, demonstrating how we operate within our factories and facilitating dialogue to help shape food safety standards of the future. We also contribute through providing a global and national perspective and by sharing input and expertise to support continuous improvement efforts relating to existing regulation and the development of new standards. For example, the development of the China *Food Safety Law*, aflatoxins standards, and pet food safety standards.

In China specifically, the Mars GFSC provides insights on food safety and in specific areas of expertise such as mycotoxins and pathogen management, as well as piloting food safety education programs in order to help develop a 'food safety' mind-set. For example, in 2017 Mars and the China Development Research Foundation (CDRF) provided support for the "School Meal Project" designed to support 9-15-year-old children's food safety education in China's rural, poverty-stricken areas. In June 2017, the Mars GFSC joined with China Children and Teenagers' Fund (CCTF) to launch a children's drawing competition about food safety, as part of continued joint working on the National Children's Food Safety Guard Campaign children's education program. The children were invited to draw in order to share their understanding of food safety, and the aim is to further educate children about food safety habits to help protect their healthy development.

Initiatives that aim to facilitate Chinese food safety governance

As Mars, we welcome food safety legislation that is effective and appropriately enforced. We also believe that the food industry has to take responsibility for self-governance while also taking a mutual approach with government. The ideal model would involve government oversight in the form of compliance auditing and testing, combined with appropriate self-governance by food manufacturers. Industry has a role to play in helping to co-create food safety standards grounded in scientific fact that enable fit for purpose self-governance.

The Mars GFSC plays a critical role in sharing knowledge through a pre-competitive and collaborative approach based on scientific truth and technical impact relating to food safety. We are committed to seeking alignment around the highest priority food safety topics, insight sharing and capability building both within China, and around the world in order to create a food supply chain that enables access to safe food for all.

About DEVELOPMENT Solutions

DEVELOPMENT Solutions (DS) is a European consultancy with its primary focus on supporting EU external policies and cooperation strategies towards third countries, in particular strategic partner countries. DS designs and delivers projects in the areas of economic and trade policy and business internationalisation in support of sustainable development and sustainable investment objectives, world-wide. Our expertise is built on our strong grounding in project design and management, research, policy and regulatory analysis, and the management of capacity strengthening programmes.

"… Really a must-read for anybody who wishes to understand the rationale, the objectives, the architecture and the functioning of the Chinese food safety system…."

Europe and China share a lot of similarities regarding food, which has always been at the centre of their respective cultures. The European Union totally reshaped its food safety regulatory framework at the beginning of this century following a series of food crises, which were the clear sign that the law was not anymore matching the reality. China is experiencing the same phenomenon today and is methodically rebuilding brick by brick its entire food safety control system since 2008, year of the melamine milk scandal.

This book provides a very comprehensive overview of the Chinese Food Safety Law and analyses the rationale and background which guided the Chinese authorities to build a unique food safety regulatory system, learning lessons from crises and taking inspiration in particular from the European model. This is really a must-read for anybody who wishes to understand the rationale, the objectives, the architecture and the functioning of the Chinese food safety system, including the latest reform of March 2018.

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to the People's Republic of China

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