VIII. Comparing China's Food Surveillance System with Those in Other Countries:

The Case of Clenbuterol and Food Safety since late 1990s

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Preface

Whilst Asia is ranked as the most disaster prone region in the world in terms of both natural and manmade disasters, research and training in the Asia-Pacific region is limited. Better understanding of the
disaster epidemiological profile and human health impact will enhance response, preparedness and
mitigation of the adverse human impact of disaster. The concept of case-teaching method has been
used extensively in research and teaching of disasters and humanitarian studies at schools of public
health around the world, including Harvard School of Public Health, Johns Hopkins Bloomberg
School of Public Health and London School of Hygiene and Tropical Medicine. Through the existing
partners and networks of The Jockey Club School of Public Health and Primary Care, the Public
Health Humanitarian Initiatives of The Chinese University of Hong Kong, and the Collaborating
Centre for Oxford University and CUHK for Disaster and Medical Humanitarian Response, this
disaster and humanitarian relief monograph series composed of 8 case study reports have been
developed using a standardized analytical and reporting framework. Methods for case study including
literature review, stakeholder interviews and retrospective data analysis have been employed.

This case study series aims at highlighting the key lessons learnt in disaster medical and public health response in the Asia. The goal is to develop Asia-specific teaching materials for public health and medicine in disaster and humanitarian response.

The "Guidelines for Reports on Health Crises and Critical Health Events" framework has been adopted as a reference for the literature search and the identification of key areas for analysis (1). We acknowledge that disaster management is a multidisciplinary area and involves much more than health issues, but we believe that the public health impact of all interventions should be appreciated across all disciplines.

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Executive Summary

While food industry has grown to be the biggest business in China, more and more people are getting concerned about the emerging of food safety. The response of most countries undergoing these changes was to enact food laws and regulations, and to establish official organizations and institutions to administer food control activities. This case study mainly takes clenbuterol in China as an example. With this kind of chemical mixed to feeds, the pig grows with more lean meat. After the first regulation about banning implication of β-agonist including clenbuterol in livestock husbandry in 1997 by Department of Agriculture in China (2), the battle is almost over a decade. Yet, the clenbuterol still remains largely in the pork industry that causes a lot of toxin cases. This case study integrates information from literature review as well as a news database about food safety called "Zhichuchuangwai" ("Throw it out the Window": http://www.zccw.info/) to look at the reasons behind and compare China's food surveillance system with other countries addressing essential elements, namely food law, national food control strategy, food control functions, inspection services, analytical services and compliance functions. It found that producers tend to keep using clenbuterol as the profits can be as much as 275% and the better market of lean meat. Even though the food safety regulation in China are getting more and more specific, the overlapping responsibilities between eight sectors related to food safety restricted the efficiency of the surveillance system.

1. Introduction/Material/Methodology

1.1 Introduction

With increasing in globalization and trading, food safety issue is not only a concern in the local country but also an international concern. The United Nations Food and Agriculture Organization and the World Health Organization have produced the Codex Alimentarius – the International Food standards. In this case study, we will use the clenbuterol incident as an example for a comparative study of the food safety regulation system, using the Hazard Analysis & Critical Control Points from United States Food and Drug Administration to compare with the Chinese food safety regulation system.

With more and more exposure of food of poor quality, more and more people are getting concerned about food safety in China nowadays. One of the main concerns is the clenbuterol (CLB) as a feed additive in livestock breeding. The chemical remains in the livestock raised and enters people's body once eaten. There are still news about the people found poisoned after eating CLB contaminated meat even after CLB was banned in China and more than eight departments have taken the responsibilities to eliminate CLB. In attempt to obtain a better understanding of the situation and policy behind, this case study introduces the background of CLB in China, the effects of the outbreak cases and government's response. With this opportunity, the case study aims to look at the reasons behind and compare China's food safety system with US addressing essential elements, namely food law, national food control strategy, food control functions, inspection services, analytical services and compliance functions and to explore what improvement China needs to better control food safety.

1.2 Material

This case study integrates information from news and public health database. PubMed, Medline, Global health and Embase were searched for English language papers, and China Journal Net and Wanfang were searched for Chinese language papers. The keywords used were "clenbuterol", "shouroujing", "food safety", "food surveillance" combined with the term "China". News from governmental websites, Xinhua, Nanhai and Sohu were also used with the searching engine Baidu and Google.

1.3 Methodology and a theoretical framework for a food safety case study

To achieve a systematic examination of the case, major public health principles of disaster response and the disaster cycle model will form the theoretical framework for this analysis.

I. Public health principles of disaster response

According to the *Oxford Handbook of Public Health Practice*, the three main principles of public health response to disasters include securing basic human needs required to maintain health, determining the current and the likely health threats to the affected community, and acquiring and

providing the resources to address the two issues above (3). The discussion in this case study will focus on the five basic human health needs.

The five basic requirements for health include food, health services, information, clean water and sanitation, as well as shelter and clothing. Often after disasters, the access to these basic needs is affected. Securing the access to the basic needs is considered as the main goal of the emergency relief.

As a global effort in setting the standard for emergency relief, the international Sphere Project hosted by the International Council of Voluntary Agencies (ICVA) in Geneva is "a voluntary initiative that brings a wide range of humanitarian agencies together around a common aim - to improve the quality of humanitarian assistance and the accountability of humanitarian actors to their constituents, donors and affected populations." The Sphere Handbook, *Humanitarian Charter and Minimum Standards in Humanitarian Response*, provides a level of standard that has been agreed upon by a multitude of front line agencies (4). It contains the minimum standards for most aspects of the basic requirements for health, specifically water supply, sanitation and hygiene promotion; food security and nutrition; shelter, settlement and non-food items; and health action. For the specific sectors, they have distinct indicators to measure whether the minimum standards are being reached.

II. Definition of health

Health is a state of complete physical, mental and social well-being instead of the mere absence of disease or infirmity (5). Specifically, public health is defined as "[t]he science and art of preventing disease, prolonging life and promoting health through the organized efforts of society", according to Sir Donald Acheson (6).

III. The disaster cycle model

Apart from the general public health principles, it is important to recognize the different actions required during the various phases of disasters. The disaster cycle model helps to highlight the key

stages in post-disaster emergency response. It can serve as a useful reference for different parties to take actions during disaster management.

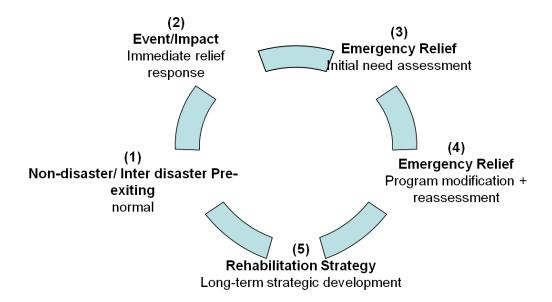


Figure 1 Disaster cycle

Source: Chan EYY, Sondorp E. Natural disaster medical intervention: missed opportunity to deal with chronic medical needs? An analytical framework. Asia Pacific Journal of Public Health. October 2007;19(Special Issue):45-51.

2. Pre-Event Status

2.1 Background

I. Clenbuterol (CLB)

Clenbuterol (CLB) is a sympathomimetic amine used by sufferers of breathing disorders as a decongestant and bronchodilator. CLB is usually used in dosages from 20-60 micrograms (mcg) a day when prescribed. As this chemical is relatively stable and the melting point is as high as 172~176°C, basic cooking can't destroy it and it then residues in organs. It is well absorbed by intestinal tract. Usually it takes 10~20 minutes to take effect and plasma drug level reaches the top within 1~2 hours.

Overdose in the body may cause nausea, headache, muscle tremors, palpitation, elevated blood pressure and even arrhythmia. Especially for patients with hypertension, heart disease, hyperthyreosis,

glaucoma etc., the chemical will aggravate the condition as it causes increase in aerobic capacity, central nervous system stimulation, blood pressure and oxygen transportation. Moreover, the long-term intake of CLB affects cardiovascular system and nervous system. There is also a study finding the accumulation in body induces chromosome aberrations which results in malignant tumours.

It was in the 1980s that the American scientist Ronald Dalrymple and Catherine Ricks accidently found that $\beta 2$ agonist including CLB can increase the lean rate by 9~16% and decrease the fat rate by 8~15% as it increases the body's basal metabolic rate. CLB was then used as feed addictive called "growth promoter" or "repartitioning agent" until it was found to have the side effects. The European Union banned CLB as a feed additive in 1988 and FDA banned CLB in 1991 while the positive side of CLB was first introduced to the Chinese community during that period without mentioning the side effects. When mixed into animal feed, a CLB-fed pig would not only have leaner meat, but also grow in half the time, reaching 75~80kg in 2-3 months, instead of 6, and enable Chinese producers to earn a net profit up to 275% greater than original. However, as CLB isn't destroyed by cooking, consumption of CLB-contaminated meat leads to acute poisoning and symptoms of nausea, headache, muscle tremors, palpitation, and arrhythmia (7). It was not until 1997 that the Department of Agriculture banned $\beta 2$ agonist including CLB as a feed additive in China (2). The Department of Agriculture organized an inspection campaign which targeted four cities including Beijing, Tianjin, Shanghai and Shenzhen from 2001 to 2003 that found the CLB rate in meat products reduced from 33.5% to 2.2%.

II. Animal husbandry industry in China

Food industry has grown to be the biggest in Chinese economy. The total value of food industry has grown from 343 billion to 600 billion from 1993 to 1998 with an average growth of 12%. The number is 1200 billion in 2003, far more than the total value of car industry which is 940 billion. In 2010, the value of animal husbandry industry is 2082.6 billion taking up 30% of the total value of agriculture, forestry, animal husbandry and fishery indices. Table 1 shows the animal husbandry industry rise from 18.4% to 30.0% during the past thirty years in China. Statistics from 2005 to 2010 showed

fluctuations that may due to the exposure of CLB cases. Animal husbandry industry remains to be one of the most important pillar industries in China, half of which is from pig husbandry. According to FAO, pork output in China has taken up about 46.1% of the world total in 2009. The pork consumption in the first months of 2003 is around the 62.23% of total poultry consumption.

Table 1 Value of animal husbandry industry and proportion from 1980 to 2010

Year	value of animal	take up the total value	Year	value of animal	take up the total value
	husbandry	of agriculture,		husbandry	of agriculture, forestry,
	industry	forestry, animal		industry (billion)	animal husbandry and
	(billion)	husbandry and			fishery indices
		fishery indices			
1980	35.4	18.4%	2006	1208.4	29.6%
1985	79.7	22.1%	2007	1612.5	33.0%
1990	196.7	25.7%	2008	2058.4	35.5%
1995	604.5	29.7%	2009	1946.8	32.3%
2000	739.3	29.7%	2010	2082.6	30.0%
2005	1331.1	33.7%			

2.2 Preparedness

The first food safety law in China— the Regulations on the Administration of Food Hygiene (Trial Implementation) was promulgated by The National People's Congress in 1965. It mainly focused on security of food supply because of the Great Chinese Famine in 1959-1961. However, the regulations failed due to the collapse of the legal system in China (8).

In 1979, the Regulations on the Administration of Food Hygiene was drafted, which was based on the one in 1965, and took into account the new economic situation (8). The regulations were then replaced by a trial of Food Hygiene Law on 1982 to accommodate the economic reforms and policy changes. The revised Food Hygiene Law was implemented in 1995 (8).

The 1995 Food Hygiene Law not only concerned food supply, but also food safety; it consisted of 57 articles to cover food hygiene, food additives, food packaging, food containers and hygiene standard of food (8). The law mainly focused on the safety of end products, but ignored the safety of raw materials and production; it did not take a from-land-to-table approach. Also, it did not establish a system to deal with major food incidents (8).

A current Food Safety Law has been implemented by The National People's Congress since 2009. The Law was set up including different areas: food safety assessment, food safety standard, food production, food checking, food imports and exports, food emergency management, surveillance and legal liability (9). To execute the law, Ministry of Health plays essential role. It sets up standards to regulate amounts of various harmful substances in food and food-related products; it takes regular checks on food and forbid sale of disqualified food (9). Also, it regulates food production, processing, packaging, labelling and storage. Ministry of Health even proposed food safety management system for food production enterprises to follow (9). To ensure efficiency of emergency response, a proposal of food related emergency issue was designed (9).

2.3 Hazard, vulnerability and risk

I. CLB contaminated meat in China

Statistics from the Ministry of Health find that the issues of food safety are increasing during the last years. Of the reported cases, animal-derived food is the main food poisoning cases, of which meat and related products take as much as 21.8%, followed by aquatic products by 10.1%.

Pigs are usually sold out at the weight of 75~80kg which takes 6 months. But CLB fed pigs can grow to that weight within two to three months. With the change of quantity, the demand of quality is also changing from fat to lean meat. In the market, CLB fed pigs are 0.1 to 0.4 yuan/kg higher than no fed ones which will be 20 to 50 yuan higher per head of pigs as CLB fed pigs have more lean meat that

sells better. For buying CLB for one pig, it needs 8 yuan, but the net profit can be as much as 22 yuan, which is 275% that of original.

II. Pork supply chain in China

Pig husbandry in other countries is usually controlled by big enterprises while in China there are mostly home based small pig farms. In 2009, the total number of pig farms in China is 940 that of US's. As listed in the table 2 below, farmers who sell 1~99 heads of pigs per year are taking up 98.68% in China while in US it's 70.5%. At the same time, the heads sold by pig farms who sell over ≥5000 heads per year take up 62.0% of the market in US while in China it only takes up 22%.

The scattered pig farms needs more quarantine officers and more testing equipment which most of the provinces do not have the equivalent budget to deal with. The US assurance system hires epidemiologists, microbiologists and food scientists into pig farms and food processing plants which supervises raw materials acquisition, production, distribution, sales, etc. Nevertheless, with the limit financial support, most of the pig farms are not equipped with enough quarantine officers and inspection equipment in China, let alone domestic raising farms with less than 10 pigs. Even though the pigs are raised by CLB added feeds, they can still meet the standard by stopping CLB feeding long enough to be detected.

Table 2 Pig farms comparison between US and China in 2009

Place	No. of Pig	1~99		100~4999		≥5000	
	farms	No. of pig	Percentage	No. of pig	Percentage	No. of pig	Percentage
		farms		farms		farms	
US	71,450	50,400	70.5	18,100	25.3	2,950	4.1
China	67,137,183	66,253,008	98.68	875,879	1.31	8,296	0.01

For transportation, the pigs need certification from the local animal quarantine station before it can be transferred to other provinces or enter the slaughterhouse. The reality is that three certifications

namely animal quarantine certification, vehicle disinfection certification, and non-infected areas certification can be bought without going through inspection with less than 2 yuan per head of pig. Even though there are checkpoints between adjacent provinces, they usually let the cars go without inspections as long as the certifications are complete as it takes time and huge financial input for a new round of inspections.

There are two kinds of meat processing plants. One is assigned slaughterhouse by the government which is usually near the local market. There are around 20,000 this kind of slaughterhouses that spread to different towns and even villages. The other is industrialised slaughterhouse by enterprises which is usually companied by meat processing equipment. Small slaughterhouses cannot afford inspection equipment or are not willing to pay millions to buy this equipment. It costs more if inspects more as it takes 30 minutes per pig with 20 yuan per testing paper.

According to regulations on pig slaughtering, the slaughterhouse must be equipped with quarantine officers and they have to monitor the slaughter procedure. All pigs are required be inspected before slaughtered. The reality is that the quarantine officers cannot regularly check with limited manpower and budget. The slaughterhouses can go on with procedures as long as the certificates are complete most of the time. The quarantine officers have to do inspections occasionally which are far more less than supposed to.

There are also competitions within the slaughterhouses as they have to keep running by making own profits. If one slaughterhouse is too strict with quality of pigs, the sellers would change to another slaughterhouse instead next time which affect the output of the slaughterhouse. Therefore, they usually still try to keep the business relationship.

3. Health Crisis and Critical Health Events

Since the first case of reported poisoning cases from CLB occurred in Spain in March 1990, there were 125 cases resulted from CLB till July 1990. Meanwhile, CLB was first introduced to China

during that period with only mentioning about its advantages. China banned CLB as a feed additive in 1997 while the first case about CLB poisoning cases in China was in 1998 that took place in Hong Kong. The special location and timing aroused a big reaction among the Chinese and CLB started to be a familiar and sick word to the population. Table 3 highlights further major exposed CLB cases from 1998 to 2012.

Table 3 Important CLB cases exposed from 1998 to 2012

Time	poisoning cases	Place	
1998.5	17	Hong Kong	CLB contaminated organs
1999	2	Shanghai	Athletes banned from competition
			because of CLB
2000.1	50+	Hangzhou, Zhejiang	CLB contaminated pork
2001.8	50+	Xinyi, Guangdong	CLB contaminated pork
2001.8	530	Xinyi, Guangdong	CLB contaminated pork
2001.11	484	Heyuan, Guangdong	CLB contaminated pork
2001.11	14	Beijing	CLB contaminated pork
2002.3	26	Suzhou, Jiangsu	CLB contaminated organs
2002.3	630	Heshan, Guangdong	CLB contaminated organs
2002.4	35	Zhanjiang, Guangdong	CLB contaminated organs and pork
2003.10	62	Liaoyang, Liaoning	CLB contaminated pork
2004.3	100+	Foshan, Guangdong	CLB contaminated pork
2005.1	42	Nanping, Fujian	CLB contaminated tofu
2006.9	330+	Shanghai	CLB contaminated pork
2008.11	75	Jiaxing, Zhejiang	CLB contaminated pork
2009.2	70+	Guangdong	CLB contaminated organs
2010.9	13	Shenzhen, Guangdong	CLB contaminated snake
2011.4	286	Changsha, Hunan	CLB contaminated pork

4. Damage & Consequences of Damage

4.1 Damage and disturbances (Human)

People poisoned from these cases usually felt nausea, headache, muscle tremors, palpitation and even arrhythmia after eating CLB contaminated pork or organs. Though the acute symptoms can be cured within one to two days, researchers have found long-term CLB intake also affects cardiovascular system and nervous system.

5. Responses

China banned CLB as a feed additive in 1997 while the first case about CLB poisoning cases in China was in 1998 that took place in Hong Kong. The special location and timing aroused a big reaction among the Chinese and CLB started to be the familiar and sick word to the population. After the initial CLB ban in 1997, multiple Chinese governmental departments strengthened the regulation with subsequent statements, regulations and inspection procedures between 1998 and 2003 (2) and found the CLB usage rate to have decreased. A year after the ban, however, the first poisoning outbreak occurred in Hong Kong among 17 people who ingested CLB-contaminated organs. In the subsequent decade, at least 17 CLB poisoning outbreaks occurred, in major cities of Beijing and Shanghai as well as provinces of Guangdong and Zhejiang (7). Each outbreak affected a range of 13 to over 500 people.

Items listed in Table 3 (see 3. Health Crisis and Critical Health Events) are exposed CLB cased that were largely reported and have urged the regulation response from the Chinese government. In March 2011, China's national TV channel exposed a subsidiary of Shuanghui Group, China's largest meat producer, using CLB-contaminated pork in its meat products. The Chinese government launched a one-year crackdown on illegal additives in pig feeds afterwards. A total of 72 people in central Henan Province, where Shuanghui is based, were taken into police custody for allegedly producing, selling or using CLB. Another big major case was in Hunan Province, where the CLB sales chain had spread to 16 provinces. Throughout the year, there were 125 crime cases cracked, 980 criminals caught, 12

production lines stopped and 19 illegal warehouses smashed. More than 30 enterprises were under investigation and 2.5 tons of CLB powder; but we still see CLB cases in 2012 showing that CLB is still existing though the spread has decreased drastically.

6. **Development**

China's food safety system underwent adjustments to face these modern challenges. Led by State Food and Drug Administration (SFDA), China's food safety system originally contained overlapping duties between eight departments, which was redefined in 2005 to divide responsibilities over the supply chain process, from Plant and Husbandry, to Processing, and Consumption (10). In 2009, the Food Safety Law was implemented, which comprises of areas such as food safety assessment, standardization, inspection, and emergency management (9). In March 2011, national media exposed China's largest meat producer to be using CLB-contaminated pork, ensuing in a major crackdown, with over 1,000 people taken into custody and 30 enterprises under investigation. Regardless, the usage of CLB still prevailed as there were CLB poisoning cases in 2012.

Table 4 displays the development of regulations throughout different sectors in China on the use of CLB.

Table 4 Regulations announced by different sectors regarding CLB in China

Time	Regulations released
1997.3	Development of Agriculture banned the implication of β-agonist in livestock
	husbandry.
1998	State Administration of Immigration Inspection and Quarantine Bureau set the rule
	that all doping urine sample of pigs exported to Hong Kong needed quarantine
	procedures.
1999	DA clearly stated that no produce and utilization of CLB combined feeds.
1999.5.29	Management Regulations for feed and feed additives from State Council stated that all
	feeds and feed additives should not include hormone drugs.
2000.4.3	SFDA had a joint statement to strengthen the investigation about CLB.
2001	DA issued two ways to detective CLB.
2003.8	Regulations on CLB residue in meat products was released as standardized lines.

Many circumstances in the pork industry complicate the practice of banning CLB use. Unlike other countries where the pork industry is controlled by large enterprises, pig husbandry in China is majorly reliant on small home-based farms (11). Inspections of these pig farms require lots of quarantine officers and testing equipment, which most provinces lack the financial capacity for. Additionally, CLB-fed pigs can still escape detection by suspending the CLB feeding several weeks before the inspection (11). Attempts at quality control at the slaughterhouses are easily thwarted since inspection-related certifications can be bought at ¥2 per pig. Competitions between slaughterhouses for business also limit the quality control since sellers would switch to another slaughterhouse if one was too strict on the quality.

The resources allocated to inspections in China are limited, while the inspections for CLB require a large financial and time commitment. The national inspection budget is around 0.1 billion per year which only allows unannounced spot-checks or intrusive inspections. In 2009, China inspected only 70,000 animal samples and 20,000 aquatic samples, compared to the 793,000 and 1,391,000 needed to match the EU sampling standard. The normal CLB test costs more than ¥2000 per box and ¥100-150 million for the inspection machine. This averages out to ¥100 per urine sample. It additionally takes 4-5 hours to inspect the urine, while one day is required to inspect pig organs.

7. <u>Discussion</u>

As Whitehead wrote in 1995, a well-structured, effective and efficiently administered national food control system provides the necessary assurances to consumers that health and safety risks from food are minimized or prevented.

7.1 Food law

"The foundation of a food control system is a comprehensive body of appropriate food law." China's food safety law consists of "Food Hygiene Law", "Food Safety Law", "Standardization Act", and "Law on Product Quality" which form the basic system, with the supplementary regulations including "Supervision and management measures of the quality and safety of food production and processing

enterprises", "Food Label Set", "Food Additive Regulations", etc. The "Food Hygiene Law" was first put into practice on a trial basis in 1982 and the "Food Safety Law" implemented in 2009. Though they form a generally standardized law system, there are still black holes which give chances for unqualified food. For example, the "Food Hygiene Law" has not included regulations on breeding process and the "Law on Product Quality" has not included primary agricultural products. Table 5 shows the comparison between China and US regarding the food law necessities mentioned by Whitehead.

Table 5 Comparison between China and US in terms of Food law necessities

Food Law Necessities	China	US
Clear definitions of the terms	Addressed	Addressed, with more
		detailed definitions for the
		related terms
2. Procedures to administer law	"Food Safety Law" only	"Food Safety Law"
	allocates responsibilities to	stipulates each step in
	different departments	administering
3. Authority to promulgate rules and	Addre	esad
regulations	Addie	sseu
4. Food quality standards, codes of	More than one law or	United standards for the
practice and procedures governing	regulation to address a product,	same product
food handling, processing, storage,	and thus sometimes two or	
shipping and sale	more sets of standards for the	
	same product	
5. Requirements and responsibilities	The recall process mostly replies	on food industry and the
of the food industry and the private		on rood industry and the
sector	private sector itself.	
6. Consumer redress procedures	Not stipulated in "Food Safety	Stipulated in "Food Safety

	Law"; handled by consumers'	Law"
	association	
7. Enforcement sanctions for non-	Stipulated, punishment for	Stipulated
compliance	non-compliance getting more	
	and more severe	

7.2 National food control strategy

There are about 1800 national standards regarding food safety and 2900 regarding food industry standards which aim to improve the level of food safety technology and food safety standardization, to better supervise food with a more clear work allocation between different sectors, to build a unified and efficient food safety inspection system, food certification and accreditation system, to refine an emergency response system and the harmonization of the laws and regulations. The number of standards China adopted is only 23% of the worldwide standard. There are 806 regulations about maximum residue limits till 2010 which is only 7.3% that of US. As shown in Table 4 (see Section 6 Development), despite regulations announced by different sectors regarding CLB, the normal practice emphasizes more on the small workshops at home which produce unqualified food with less concern to quality issues of regular manufacturers.

7.3 Food control functions

A national control system should include inspection, investigation, analytical and compliance (regulatory and voluntary) functions; provide technical, advisory, and educational services, and be oriented toward public service in terms of industry, media and public relations.

7.4 Inspection services

The inspection function should verify that food is handled, stored, manufactured or processed, shipped and marketed in accordance with the requirement of law and regulations. The US food safety departments are mainly divided by types of food that while for Chinese food safety departments always overlap with each other.

In China's safety system, there are eight departments involved which are led by State Food and Drug Administration (SFDA). In 2005, the State Council of China released a new document to further strengthen food safety and defined duties of each department related. The SFDA is responsible for general supervising, investigating and looking into serious food safety accidents. The duties of Department of agriculture (DA), Administration for Quality Supervision, Inspection and Quarantine (AQSIQ), Administration for Industry and Commerce (AIC) and Ministry of Health (MOH) are listed in Table 6. They lead each part with the assistance of Ministry of Public Security (MPS), Board of Trade (BOT), and Environment Protection Agency (EPA).

Table 6 Food safety regulation agencies and duties under State Council of China in 2005

Responsible department	Duties
DA	Plant and Husbandry
AQSIQ	Food processing and producing
AIC	Circulation
МОН	Consumption
SFDA	Supervision and Coordination

Food safety in US is mainly under the Department of Health and Human Service (DHHS), Food and Drug Administration (FDA), Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) and Animal and Plant Health Inspection Service (APHIS), Environmental Protection Agency (EPA) and Bureau of Customs and Border Protection (CBP). Hazard Analysis Critical Control Point (HACCP) which emphasis inspecting the whole process is applied to inspect food from the beginning to customers.

7.5 Analytical services

Sufficient analytical capability and capacity to determine and monitor the level of quality of the national food supply.

Though there are improvements in the inspection conditions in the inspection and quarantine agencies as MOH found the qualification rate for vegetables, meat products and aquatic products in 2009 was 96.4%, 99.5% and 97.2% respectively. There are gaps that are still not met between the needs and provision. One gap is the number of inspection equipment which is still far less than needed and unequally distributed between different sectors. The other gap is the low degree of standardization due to out-dated equipment and methods. Another gap is the quality of quarantine officers.

There are no CLB specialised agencies in China to inspect the additive. And there are no staff specially trained for CLB inspection. There are about four methods to detective CLB in China, gas chromatography—mass spectrometry (GC-MS), high-performance liquid chromatography (HPLC), enzyme-linked immunosorbent assay (ELISA) and capillary electrophoresis (CE). The previous two methods are adopted by the Chinese government while the normal practice is to use rapid colloidal golden testing paper and box. The cost of per testing box is above 2000 yuan and inspection machine is 100~150 million which mean per urine needs 100 yuan while the inspection budget is around 0.1 billion per year which only allows unannounced spot checks or intrusive inspections. It takes 4~5 hours to inspect pig urine while one day is needed to inspect pig organs. Some departments may use the limitation of budget, human resource and technology as excuses to lower the executive standards. In 2005, the EU managed to get 61 and 107 samples per 100,000 people accordingly for animal products and aquatic products. With this ratio and 1.328 billion people in China, the sample size should be 793,000 and 1,391,000 billion while only 70,000 and 20,000 were inspected in 2009.

7.6 Compliance functions

The official food control system should include mechanisms which develop and maintain the necessary compliance policy to assure fair and equal application of legal sanctions.

The US food recall system started from the 1960s which have developed over 50 years. The warning system is developed to better facilitate the recall system. Consumer's supervision and regular overall surveillance also enable the instant detection of unqualified food.

In China's food recall system, food safety law states that when food producers find unqualified products, they should stop producing and recall all food on sale, at the same time inform related food producers and consumers. It largely relies on the producers' own will whether to report or not. New acts about mandatory recall have been put into use to empower related department to recall unqualified food when the food producers refuse to do so. The "Food industry development planning" released in 2011 emphasized the implement of recall and traceability system of dairy products, meat products and wine industries.

8. Lessons Identified and Actions Recommended

Compared to regular manufacturers that are concerned with quality issues, the actual practice of pig husbandry in China comprises of small home-based farms. The food safety system must address this major detail to be effective.

Firstly, we should learn from the advanced food safety assurance system to form a more united and efficient food safety management agency, and to adjust the food safety system to better allocate jobs between different departments. Each procedure should be connected rather than overlapped, from plant and husbandry, food processing and producing, circulation to consumption, to assure the quality control and responsible lines. A unified inspection, certification and accreditation system needs to be constructed and implemented to reduce loopholes. Barriers to inspection, such as the financial limitations and time requirements, need to be reduced.

Secondly, the "Food Safety Law" has been put into act with spaces for improvement. The responsible departments should be clearly identified to avoid different departments not taking responsibilities. The

penalties can be more specific and increased to decrease the intension. A food recall system can be revised to be actually workable and implied.

Thirdly, more regulations and standards need to be published to better facilitate food safety control. Standards of qualifications and inspection methods between different departments should be revised and keep consensus with each other to avoid the confusion of enterprises, consumers and also law enforcement department.

9. Conclusions

This case study examined the possible reasons that CLB remains to be one food safety concern even after it was banned 16 years ago in China. The reasons about the advantages and limitations with three sectors including pig farms, pig transportation and meat processing plants were discussed. This case study also served to compare China's food safety system with US addressing essential elements, namely food law, national food control strategy, and food control functions including inspection services, analytical services, and compliance functions. It can be seen that food safety regulation in China are getting more and more comprehensive with lessons learnt from these unfortunate events, yet there are still places for improvement about China's food safety system.

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11. Appendices

Appendix I (Chinese only)

中华人民共和国食品安全法

(2009年2月28日第十一届全国人民代表大会常务委员会第七次会议通过)

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第一章 总 则

第一条 为保证食品安全,保障公众身体健康和生命安全,制定本法。

第二条 在中华人民共和国境内从事下列活动,应当遵守本法:

- (一)食品生产和加工(以下称食品生产),食品流通和餐饮服务(以下称食品经营);
- (二)食品添加剂的生产经营;
- (三)用于食品的包装材料、容器、洗涤剂、消毒剂和用于食品生产经营的工具、设备 (以下称食品相关产品)的生产经营;
 - (四)食品生产经营者使用食品添加剂、食品相关产品;

(五)对食品、食品添加剂和食品相关产品的安全管理。

供食用的源于农业的初级产品(以下称食用农产品)的质量安全管理,遵守《中华人民 共和国农产品质量安全法》的规定。但是,制定有关食用农产品的质量安全标准、公布食用 农产品安全有关信息,应当遵守本法的有关规定。

第三条 食品生产经营者应当依照法律、法规和食品安全标准从事生产经营活动,对社会和公众负责,保证食品安全,接受社会监督,承担社会责任。

第四条 国务院设立食品安全委员会,其工作职责由国务院规定。

国务院卫生行政部门承担食品安全综合协调职责,负责食品安全风险评估、食品安全标准制定、食品安全信息公布、食品检验机构的资质认定条件和检验规范的制定,组织查处食品安全重大事故。

国务院质量监督、工商行政管理和国家食品药品监督管理部门依照本法和国务院规定的 职责,分别对食品生产、食品流通、餐饮服务活动实施监督管理。

第五条 县级以上地方人民政府统一负责、领导、组织、协调本行政区域的食品安全监督管理工作,建立健全食品安全全程监督管理的工作机制;统一领导、指挥食品安全突发事件应对工作;完善、落实食品安全监督管理责任制,对食品安全监督管理部门进行评议、考核。

县级以上地方人民政府依照本法和国务院的规定确定本级卫生行政、农业行政、质量监督、工商行政管理、食品药品监督管理部门的食品安全监督管理职责。有关部门在各自职责范围内负责本行政区域的食品安全监督管理工作。

上级人民政府所属部门在下级行政区域设置的机构应当在所在地人民政府的统一组织、 协调下,依法做好食品安全监督管理工作。

第六条 县级以上卫生行政、农业行政、质量监督、工商行政管理、食品药品监督管理部门应当加强沟通、密切配合,按照各自职责分工,依法行使职权,承担责任。

第七条 食品行业协会应当加强行业自律,引导食品生产经营者依法生产经营,推动行业 诚信建设,宣传、普及食品安全知识。 第八条 国家鼓励社会团体、基层群众性自治组织开展食品安全法律、法规以及食品安全 标准和知识的普及工作,倡导健康的饮食方式,增强消费者食品安全意识和自我保护能力。

新闻媒体应当开展食品安全法律、法规以及食品安全标准和知识的公益宣传,并对违反 本法的行为进行舆论监督。

第九条 国家鼓励和支持开展与食品安全有关的基础研究和应用研究,鼓励和支持食品生产经营者为提高食品安全水平采用先进技术和先进管理规范。

第十条 任何组织或者个人有权举报食品生产经营中违反本法的行为,有权向有关部门了 解食品安全信息,对食品安全监督管理工作提出意见和建议。

第二章 食品安全风险监测和评估

第十一条 国家建立食品安全风险监测制度,对食源性疾病、食品污染以及食品中的有害因素进行监测。

国务院卫生行政部门会同国务院有关部门制定、实施国家食品安全风险监测计划。省、 自治区、直辖市人民政府卫生行政部门根据国家食品安全风险监测计划,结合本行政区域的 具体情况,组织制定、实施本行政区域的食品安全风险监测方案。

第十二条 国务院农业行政、质量监督、工商行政管理和国家食品药品监督管理等有关部门获知有关食品安全风险信息后,应当立即向国务院卫生行政部门通报。国务院卫生行政部门会同有关部门对信息核实后,应当及时调整食品安全风险监测计划。

第十三条 国家建立食品安全风险评估制度,对食品、食品添加剂中生物性、化学性和物理性危害进行风险评估。

国务院卫生行政部门负责组织食品安全风险评估工作,成立由医学、农业、食品、营养等方面的专家组成的食品安全风险评估专家委员会进行食品安全风险评估。

对农药、肥料、生长调节剂、兽药、饲料和饲料添加剂等的安全性评估,应当有食品安全风险评估专家委员会的专家参加。

食品安全风险评估应当运用科学方法,根据食品安全风险监测信息、科学数据以及其他 有关信息进行。

第十四条 国务院卫生行政部门通过食品安全风险监测或者接到举报发现食品可能存在安全隐患的,应当立即组织进行检验和食品安全风险评估。

第十五条 国务院农业行政、质量监督、工商行政管理和国家食品药品监督管理等有关部门应当向国务院卫生行政部门提出食品安全风险评估的建议,并提供有关信息和资料。

国务院卫生行政部门应当及时向国务院有关部门通报食品安全风险评估的结果。

第十六条 食品安全风险评估结果是制定、修订食品安全标准和对食品安全实施监督管理的科学依据。

食品安全风险评估结果得出食品不安全结论的,国务院质量监督、工商行政管理和国家食品药品监督管理部门应当依据各自职责立即采取相应措施,确保该食品停止生产经营,并告知消费者停止食用;需要制定、修订相关食品安全国家标准的,国务院卫生行政部门应当立即制定、修订。

第十七条 国务院卫生行政部门应当会同国务院有关部门,根据食品安全风险评估结果、食品安全监督管理信息,对食品安全状况进行综合分析。对经综合分析表明可能具有较高程度安全风险的食品,国务院卫生行政部门应当及时提出食品安全风险警示,并予以公布。

第三章 食品安全标准

第十八条 制定食品安全标准,应当以保障公众身体健康为宗旨,做到科学合理、安全可靠。

第十九条 食品安全标准是强制执行的标准。除食品安全标准外,不得制定其他的食品强制性标准。

第二十条 食品安全标准应当包括下列内容:

(一)食品、食品相关产品中的致病性微生物、农药残留、兽药残留、重金属、污染物质以及其他危害人体健康物质的限量规定;

- (二)食品添加剂的品种、使用范围、用量;
- (三) 专供婴幼儿和其他特定人群的主辅食品的营养成分要求;
- (四)对与食品安全、营养有关的标签、标识、说明书的要求;
- (五)食品生产经营过程的卫生要求;
- (六)与食品安全有关的质量要求;
- (七)食品检验方法与规程;
- (八)其他需要制定为食品安全标准的内容。

第二十一条 食品安全国家标准由国务院卫生行政部门负责制定、公布,国务院标准化行 政部门提供国家标准编号。

食品中农药残留、兽药残留的限量规定及其检验方法与规程由国务院卫生行政部门、国 务院农业行政部门制定。

屠宰畜、禽的检验规程由国务院有关主管部门会同国务院卫生行政部门制定。

有关产品国家标准涉及食品安全国家标准规定内容的,应当与食品安全国家标准相一致。

第二十二条 国务院卫生行政部门应当对现行的食用农产品质量安全标准、食品卫生标准、 食品质量标准和有关食品的行业标准中强制执行的标准予以整合,统一公布为食品安全国家 标准。

本法规定的食品安全国家标准公布前,食品生产经营者应当按照现行食用农产品质量安全标准、食品卫生标准、食品质量标准和有关食品的行业标准生产经营食品。

第二十三条 食品安全国家标准应当经食品安全国家标准审评委员会审查通过。食品安全国家标准审评委员会由医学、农业、食品、营养等方面的专家以及国务院有关部门的代表组成。

制定食品安全国家标准,应当依据食品安全风险评估结果并充分考虑食用农产品质量安全风险评估结果,参照相关的国际标准和国际食品安全风险评估结果,并广泛听取食品生产经营者和消费者的意见。

第二十四条 没有食品安全国家标准的,可以制定食品安全地方标准。

省、自治区、直辖市人民政府卫生行政部门组织制定食品安全地方标准,应当参照执行本法有关食品安全国家标准制定的规定,并报国务院卫生行政部门备案。

第二十五条企业生产的食品没有食品安全国家标准或者地方标准的,应当制定企业标准,作为组织生产的依据。国家鼓励食品生产企业制定严于食品安全国家标准或者地方标准的企业标准。企业标准应当报省级卫生行政部门备案,在本企业内部适用。

第二十六条 食品安全标准应当供公众免费查阅。

第四章 食品生产经营

第二十七条 食品生产经营应当符合食品安全标准,并符合下列要求:

- (一)具有与生产经营的食品品种、数量相适应的食品原料处理和食品加工、包装、贮存等场所,保持该场所环境整洁,并与有毒、有害场所以及其他污染源保持规定的距离;
- (二)具有与生产经营的食品品种、数量相适应的生产经营设备或者设施,有相应的消毒、更衣、盥洗、采光、照明、通风、防腐、防尘、防蝇、防鼠、防虫、洗涤以及处理废水、 存放垃圾和废弃物的设备或者设施;
 - (三)有食品安全专业技术人员、管理人员和保证食品安全的规章制度;
- (四)具有合理的设备布局和工艺流程,防止待加工食品与直接入口食品、原料与成品 交叉污染,避免食品接触有毒物、不洁物;
- (五)餐具、饮具和盛放直接入□食品的容器,使用前应当洗净、消毒,炊具、用具用 后应当洗净,保持清洁;
- (六)贮存、运输和装卸食品的容器、工具和设备应当安全、无害,保持清洁,防止食品污染,并符合保证食品安全所需的温度等特殊要求,不得将食品与有毒、有害物品一同运输;
 - (七)直接入口的食品应当有小包装或者使用无毒、清洁的包装材料、餐具;

- (八)食品生产经营人员应当保持个人卫生,生产经营食品时,应当将手洗净,穿戴 清洁的工作衣、帽;销售无包装的直接入口食品时,应当使用无毒、清洁的售货工具;
 - (九) 用水应当符合国家规定的生活饮用水卫生标准;
 - (十)使用的洗涤剂、消毒剂应当对人体安全、无害;
 - (十一) 法律、法规规定的其他要求。

第二十八条 禁止生产经营下列食品:

- (一)用非食品原料生产的食品或者添加食品添加剂以外的化学物质和其他可能危害人体健康物质的食品,或者用回收食品作为原料生产的食品;
- (二)致病性微生物、农药残留、兽药残留、重金属、污染物质以及其他危害人体健康 的物质含量超过食品安全标准限量的食品;
 - (三)营养成分不符合食品安全标准的专供婴幼儿和其他特定人群的主辅食品;
- (四)腐败变质、油脂酸败、霉变生虫、污秽不洁、混有异物、掺假掺杂或者感官性状 异常的食品;
 - (五)病死、毒死或者死因不明的禽、畜、兽、水产动物肉类及其制品;
- (六)未经动物卫生监督机构检疫或者检疫不合格的肉类,或者未经检验或者检验不合格的肉类制品;
 - (七)被包装材料、容器、运输工具等污染的食品;
 - (八)超过保质期的食品;
 - (九) 无标签的预包装食品;
 - (十)国家为防病等特殊需要明令禁止生产经营的食品;
 - (十一)其他不符合食品安全标准或者要求的食品。

第二十九条 国家对食品生产经营实行许可制度。从事食品生产、食品流通、餐饮服务, 应当依法取得食品生产许可、食品流通许可、餐饮服务许可。 取得食品生产许可的食品生产者在其生产场所销售其生产的食品,不需要取得食品流通的许可;取得餐饮服务许可的餐饮服务提供者在其餐饮服务场所出售其制作加工的食品,不需要取得食品生产和流通的许可;农民个人销售其自产的食用农产品,不需要取得食品流通的许可。

食品生产加工小作坊和食品摊贩从事食品生产经营活动,应当符合本法规定的与其生产经营规模、条件相适应的食品安全要求,保证所生产经营的食品卫生、无毒、无害,有关部门应当对其加强监督管理,具体管理办法由省、自治区、直辖市人民代表大会常务委员会依照本法制定。

第三十条 县级以上地方人民政府鼓励食品生产加工小作坊改进生产条件;鼓励食品摊贩进入集中交易市场、店铺等固定场所经营。

第三十一条 县级以上质量监督、工商行政管理、食品药品监督管理部门应当依照《中华人民共和国行政许可法》的规定,审核申请人提交的本法第二十七条第一项至第四项规定要求的相关资料,必要时对申请人的生产经营场所进行现场核查;对符合规定条件的,决定准予许可;对不符合规定条件的,决定不予许可并书面说明理由。

第三十二条 食品生产经营企业应当建立健全本单位的食品安全管理制度,加强对职工食品安全知识的培训,配备专职或者兼职食品安全管理人员,做好对所生产经营食品的检验工作,依法从事食品生产经营活动。

第三十三条 国家鼓励食品生产经营企业符合良好生产规范要求,实施危害分析与关键控制点体系,提高食品安全管理水平。

对通过良好生产规范、危害分析与关键控制点体系认证的食品生产经营企业,认证机构 应当依法实施跟踪调查;对不再符合认证要求的企业,应当依法撤销认证,及时向有关质量 监督、工商行政管理、食品药品监督管理部门通报,并向社会公布。认证机构实施跟踪调查 不收取任何费用。 第三十四条 食品生产经营者应当建立并执行从业人员健康管理制度。患有痢疾、伤寒、病毒性肝炎等消化道传染病的人员,以及患有活动性肺结核、化脓性或者渗出性皮肤病等有碍食品安全的疾病的人员,不得从事接触直接入口食品的工作。

食品生产经营人员每年应当进行健康检查,取得健康证明后方可参加工作。

第三十五条 食用农产品生产者应当依照食品安全标准和国家有关规定使用农药、肥料、 生长调节剂、兽药、饲料和饲料添加剂等农业投入品。食用农产品的生产企业和农民专业合 作经济组织应当建立食用农产品生产记录制度。

县级以上农业行政部门应当加强对农业投入品使用的管理和指导,建立健全农业投入品的安全使用制度。

第三十六条 食品生产者采购食品原料、食品添加剂、食品相关产品,应当查验供货者的许可证和产品合格证明文件;对无法提供合格证明文件的食品原料,应当依照食品安全标准进行检验;不得采购或者使用不符合食品安全标准的食品原料、食品添加剂、食品相关产品。

食品生产企业应当建立食品原料、食品添加剂、食品相关产品进货查验记录制度,如实记录食品原料、食品添加剂、食品相关产品的名称、规格、数量、供货者名称及联系方式、进货日期等内容。

食品原料、食品添加剂、食品相关产品进货查验记录应当真实,保存期限不得少于二年。 第三十七条 食品生产企业应当建立食品出厂检验记录制度,查验出厂食品的检验合格证和安全状况,并如实记录食品的名称、规格、数量、生产日期、生产批号、检验合格证号、购货者名称及联系方式、销售日期等内容。

食品出厂检验记录应当真实,保存期限不得少于二年。

第三十八条 食品、食品添加剂和食品相关产品的生产者,应当依照食品安全标准对所生产的食品、食品添加剂和食品相关产品进行检验,检验合格后方可出厂或者销售。

第三十九条 食品经营者采购食品,应当查验供货者的许可证和食品合格的证明文件。

食品经营企业应当建立食品进货查验记录制度,如实记录食品的名称、规格、数量、生产批号、保质期、供货者名称及联系方式、进货日期等内容。

食品进货查验记录应当真实,保存期限不得少于二年。

实行统一配送经营方式的食品经营企业,可以由企业总部统一查验供货者的许可证和食品合格的证明文件,进行食品进货查验记录。

第四十条 食品经营者应当按照保证食品安全的要求贮存食品,定期检查库存食品,及时 清理变质或者超过保质期的食品。

第四十一条 食品经营者贮存散装食品,应当在贮存位置标明食品的名称、生产日期、保质期、生产者名称及联系方式等内容。

食品经营者销售散装食品,应当在散装食品的容器、外包装上标明食品的名称、生产日期、保质期、生产经营者名称及联系方式等内容。

第四十二条 预包装食品的包装上应当有标签。标签应当标明下列事项:

- (一) 名称、规格、净含量、生产日期;
- (二)成分或者配料表;
- (三)生产者的名称、地址、联系方式;
- (四)保质期;
- (五)产品标准代号;
- (六)贮存条件;
- (七)所使用的食品添加剂在国家标准中的通用名称;
- (八)生产许可证编号;
- (九) 法律、法规或者食品安全标准规定必须标明的其他事项。

专供婴幼儿和其他特定人群的主辅食品,其标签还应当标明主要营养成分及其含量。

第四十三条 国家对食品添加剂的生产实行许可制度。申请食品添加剂生产许可的条件、程序,按照国家有关工业产品生产许可证管理的规定执行。

第四十四条 申请利用新的食品原料从事食品生产或者从事食品添加剂新品种、食品相关产品新品种生产活动的单位或者个人,应当向国务院卫生行政部门提交相关产品的安全性评估估材料。国务院卫生行政部门应当自收到申请之日起六十日内组织对相关产品的安全性评估材料进行审查;对符合食品安全要求的,依法决定准予许可并予以公布;对不符合食品安全要求的,决定不予许可并书面说明理由。

第四十五条 食品添加剂应当在技术上确有必要且经过风险评估证明安全可靠,方可列入 允许使用的范围。国务院卫生行政部门应当根据技术必要性和食品安全风险评估结果,及时 对食品添加剂的品种、使用范围、用量的标准进行修订。

第四十六条 食品生产者应当依照食品安全标准关于食品添加剂的品种、使用范围、用量的规定使用食品添加剂;不得在食品生产中使用食品添加剂以外的化学物质和其他可能危害人体健康的物质。

第四十七条 食品添加剂应当有标签、说明书和包装。标签、说明书应当载明本法第四十二条第一款第一项至第六项、第八项、第九项规定的事项,以及食品添加剂的使用范围、用量、使用方法,并在标签上载明"食品添加剂"字样。

第四十八条 食品和食品添加剂的标签、说明书,不得含有虚假、夸大的内容,不得涉及 疾病预防、治疗功能。生产者对标签、说明书上所载明的内容负责。

食品和食品添加剂的标签、说明书应当清楚、明显,容易辨识。

食品和食品添加剂与其标签、说明书所载明的内容不符的,不得上市销售。

第四十九条 食品经营者应当按照食品标签标示的警示标志、警示说明或者注意事项的要求,销售预包装食品。

第五十条 生产经营的食品中不得添加药品,但是可以添加按照传统既是食品又是中药材的物质。按照传统既是食品又是中药材的物质的目录由国务院卫生行政部门制定、公布。

第五十一条 国家对声称具有特定保健功能的食品实行严格监管。有关监督管理部门应当依法履职,承担责任。具体管理办法由国务院规定。

声称具有特定保健功能的食品不得对人体产生急性、亚急性或者慢性危害,其标签、说明书不得涉及疾病预防、治疗功能,内容必须真实,应当载明适宜人群、不适宜人群、功效成分或者标志性成分及其含量等;产品的功能和成分必须与标签、说明书相一致。

第五十二条 集中交易市场的开办者、柜台出租者和展销会举办者,应当审查入场食品经营者的许可证,明确入场食品经营者的食品安全管理责任,定期对入场食品经营者的经营环境和条件进行检查,发现食品经营者有违反本法规定的行为的,应当及时制止并立即报告所在地县级工商行政管理部门或者食品药品监督管理部门。

集中交易市场的开办者、柜台出租者和展销会举办者未履行前款规定义务,本市场发生食品安全事故的,应当承担连带责任。

第五十三条 国家建立食品召回制度。食品生产者发现其生产的食品不符合食品安全标准, 应当立即停止生产,召回已经上市销售的食品,通知相关生产经营者和消费者,并记录召回 和通知情况。

食品经营者发现其经营的食品不符合食品安全标准,应当立即停止经营,通知相关生产 经营者和消费者,并记录停止经营和通知情况。食品生产者认为应当召回的,应当立即召回。

食品生产者应当对召回的食品采取补救、无害化处理、销毁等措施,并将食品召回和处理情况向县级以上质量监督部门报告。

食品生产经营者未依照本条规定召回或者停止经营不符合食品安全标准的食品的,县级以上质量监督、工商行政管理、食品药品监督管理部门可以责令其召回或者停止经营。

第五十四条 食品广告的内容应当真实合法,不得含有虚假、夸大的内容,不得涉及疾病 预防、治疗功能。

食品安全监督管理部门或者承担食品检验职责的机构、食品行业协会、消费者协会不得 以广告或者其他形式向消费者推荐食品。

第五十五条 社会团体或者其他组织、个人在虚假广告中向消费者推荐食品,使消费者的 合法权益受到损害的,与食品生产经营者承担连带责任。 第五十六条 地方各级人民政府鼓励食品规模化生产和连锁经营、配送。

第五章 食品检验

第五十七条 食品检验机构按照国家有关认证认可的规定取得资质认定后,方可从事食品检验活动。但是,法律另有规定的除外。

食品检验机构的资质认定条件和检验规范,由国务院卫生行政部门规定。

本法施行前经国务院有关主管部门批准设立或者经依法认定的食品检验机构,可以依照本法继续从事食品检验活动。

第五十八条 食品检验由食品检验机构指定的检验人独立进行。

检验人应当依照有关法律、法规的规定,并依照食品安全标准和检验规范对食品进行检验,尊重科学,恪守职业道德,保证出具的检验数据和结论客观、公正,不得出具虚假的检验报告。

第五十九条 食品检验实行食品检验机构与检验人负责制。食品检验报告应当加盖食品 检验机构公章,并有检验人的签名或者盖章。食品检验机构和检验人对出具的食品检验报告 负责。

第六十条 食品安全监督管理部门对食品不得实施免检。

县级以上质量监督、工商行政管理、食品药品监督管理部门应当对食品进行定期或者不定期的抽样检验。进行抽样检验,应当购买抽取的样品,不收取检验费和其他任何费用。

县级以上质量监督、工商行政管理、食品药品监督管理部门在执法工作中需要对食品进行检验的,应当委托符合本法规定的食品检验机构进行,并支付相关费用。对检验结论有异议的,可以依法进行复检。

第六十一条 食品生产经营企业可以自行对所生产的食品进行检验,也可以委托符合本 法规定的食品检验机构进行检验。

食品行业协会等组织、消费者需要委托食品检验机构对食品进行检验的,应当委托符合本法规定的食品检验机构进行。

第六章 食品进出口

第六十二条 进口的食品、食品添加剂以及食品相关产品应当符合我国食品安全国家标准。

进口的食品应当经出入境检验检疫机构检验合格后,海关凭出入境检验检疫机构签发的通关证明放行。

第六十三条 进口尚无食品安全国家标准的食品,或者首次进口食品添加剂新品种、食品相关产品新品种,进口商应当向国务院卫生行政部门提出申请并提交相关的安全性评估材料。国务院卫生行政部门依照本法第四十四条的规定作出是否准予许可的决定,并及时制定相应的食品安全国家标准。

第六十四条 境外发生的食品安全事件可能对我国境内造成影响,或者在进口食品中发现严重食品安全问题的,国家出入境检验检疫部门应当及时采取风险预警或者控制措施,并向国务院卫生行政、农业行政、工商行政管理和国家食品药品监督管理部门通报。接到通报的部门应当及时采取相应措施。

第六十五条 向我国境内出口食品的出口商或者代理商应当向国家出入境检验检疫部门 备案。向我国境内出口食品的境外食品生产企业应当经国家出入境检验检疫部门注册。

国家出入境检验检疫部门应当定期公布已经备案的出口商、代理商和已经注册的境外食品生产企业名单。

第六十六条 进口的预包装食品应当有中文标签、中文说明书。标签、说明书应当符合本法以及我国其他有关法律、行政法规的规定和食品安全国家标准的要求,载明食品的原产地以及境内代理商的名称、地址、联系方式。预包装食品没有中文标签、中文说明书或者标签、说明书不符合本条规定的,不得进口。

第六十七条 进口商应当建立食品进口和销售记录制度,如实记录食品的名称、规格、数量、生产日期、生产或者进口批号、保质期、出口商和购货者名称及联系方式、交货日期等内容。

食品进口和销售记录应当真实,保存期限不得少于二年。

第六十八条 出口的食品由出入境检验检疫机构进行监督、抽检,海关凭出入境检验检 疫机构签发的通关证明放行。

出口食品生产企业和出口食品原料种植、养殖场应当向国家出入境检验检疫部门备案。

第六十九条 国家出入境检验检疫部门应当收集、汇总进出口食品安全信息,并及时通报相关部门、机构和企业。

国家出入境检验检疫部门应当建立进出口食品的进口商、出口商和出口食品生产企业的信誉记录,并予以公布。对有不良记录的进口商、出口商和出口食品生产企业,应当加强对其进出口食品的检验检疫。

第七章 食品安全事故处置

第七十条 国务院组织制定国家食品安全事故应急预案。

县级以上地方人民政府应当根据有关法律、法规的规定和上级人民政府的食品安全事故 应急预案以及本地区的实际情况,制定本行政区域的食品安全事故应急预案,并报上一级人 民政府备案。

食品生产经营企业应当制定食品安全事故处置方案,定期检查本企业各项食品安全防范 措施的落实情况,及时消除食品安全事故隐患。

第七十一条 发生食品安全事故的单位应当立即予以处置,防止事故扩大。事故发生单位和接收病人进行治疗的单位应当及时向事故发生地县级卫生行政部门报告。

农业行政、质量监督、工商行政管理、食品药品监督管理部门在日常监督管理中发现食品安全事故,或者接到有关食品安全事故的举报,应当立即向卫生行政部门通报。

发生重大食品安全事故的,接到报告的县级卫生行政部门应当按照规定向本级人民政府 和上级人民政府卫生行政部门报告。县级人民政府和上级人民政府卫生行政部门应当按照规 定上报。

任何单位或者个人不得对食品安全事故隐瞒、谎报、缓报,不得毁灭有关证据。

第七十二条 县级以上卫生行政部门接到食品安全事故的报告后,应当立即会同有关农业行政、质量监督、工商行政管理、食品药品监督管理部门进行调查处理,并采取下列措施,防止或者减轻社会危害:

- (一)开展应急救援工作,对因食品安全事故导致人身伤害的人员,卫生行政部门应当 立即组织救治;
- (二)封存可能导致食品安全事故的食品及其原料,并立即进行检验;对确认属于被污染的食品及其原料,责令食品生产经营者依照本法第五十三条的规定予以召回、停止经营并销毁;
 - (三) 封存被污染的食品用工具及用具,并责令进行清洗消毒;
- (四)做好信息发布工作,依法对食品安全事故及其处理情况进行发布,并对可能产生的危害加以解释、说明。

发生重大食品安全事故的,县级以上人民政府应当立即成立食品安全事故处置指挥机构, 启动应急预案,依照前款规定进行处置。

第七十三条 发生重大食品安全事故,设区的市级以上人民政府卫生行政部门应当立即 会同有关部门进行事故责任调查,督促有关部门履行职责,向本级人民政府提出事故责任调 查处理报告。

重大食品安全事故涉及两个以上省、自治区、直辖市的,由国务院卫生行政部门依照前款规定组织事故责任调查。

第七十四条 发生食品安全事故,县级以上疾病预防控制机构应当协助卫生行政部门和 有关部门对事故现场进行卫生处理,并对与食品安全事故有关的因素开展流行病学调查。

第七十五条 调查食品安全事故,除了查明事故单位的责任,还应当查明负有监督管理 和认证职责的监督管理部门、认证机构的工作人员失职、渎职情况。

第八章 监督管理

第七十六条 县级以上地方人民政府组织本级卫生行政、农业行政、质量监督、工商行政管理、食品药品监督管理部门制定本行政区域的食品安全年度监督管理计划,并按照年度计划组织开展工作。

第七十七条 县级以上质量监督、工商行政管理、食品药品监督管理部门履行各自食品 安全监督管理职责,有权采取下列措施:

- (一)进入生产经营场所实施现场检查;
- (二)对生产经营的食品进行抽样检验;
- (三)查阅、复制有关合同、票据、账簿以及其他有关资料;
- (四)查封、扣押有证据证明不符合食品安全标准的食品,违法使用的食品原料、食品添加剂、食品相关产品,以及用于违法生产经营或者被污染的工具、设备;
 - (五)查封违法从事食品生产经营活动的场所。

县级以上农业行政部门应当依照《中华人民共和国农产品质量安全法》规定的职责,对食用农产品进行监督管理。

第七十八条 县级以上质量监督、工商行政管理、食品药品监督管理部门对食品生产经营者进行监督检查,应当记录监督检查的情况和处理结果。监督检查记录经监督检查人员和食品生产经营者签字后归档。

第七十九条 县级以上质量监督、工商行政管理、食品药品监督管理部门应当建立食品 生产经营者食品安全信用档案,记录许可颁发、日常监督检查结果、违法行为查处等情况; 根据食品安全信用档案的记录,对有不良信用记录的食品生产经营者增加监督检查频次。

第八十条 县级以上卫生行政、质量监督、工商行政管理、食品药品监督管理部门接到 咨询、投诉、举报,对属于本部门职责的,应当受理,并及时进行答复、核实、处理;对不 属于本部门职责的,应当书面通知并移交有权处理的部门处理。有权处理的部门应当及时处 理,不得推诿;属于食品安全事故的,依照本法第七章有关规定进行处置。 第八十一条 县级以上卫生行政、质量监督、工商行政管理、食品药品监督管理部门应 当按照法定权限和程序履行食品安全监督管理职责;对生产经营者的同一违法行为,不得给 予二次以上罚款的行政处罚;涉嫌犯罪的,应当依法向公安机关移送。

第八十二条 国家建立食品安全信息统一公布制度。下列信息由国务院卫生行政部门统 一公布:

- (一)国家食品安全总体情况;
- (二)食品安全风险评估信息和食品安全风险警示信息;
- (三)重大食品安全事故及其处理信息;
- (四)其他重要的食品安全信息和国务院确定的需要统一公布的信息。

前款第二项、第三项规定的信息,其影响限于特定区域的,也可以由有关省、自治区、 直辖市人民政府卫生行政部门公布。县级以上农业行政、质量监督、工商行政管理、食品药 品监督管理部门依据各自职责公布食品安全日常监督管理信息。

食品安全监督管理部门公布信息,应当做到准确、及时、客观。

第八十三条 县级以上地方卫生行政、农业行政、质量监督、工商行政管理、食品药品监督管理部门获知本法第八十二条第一款规定的需要统一公布的信息,应当向上级主管部门报告,由上级主管部门立即报告国务院卫生行政部门;必要时,可以直接向国务院卫生行政部门报告。

县级以上卫生行政、农业行政、质量监督、工商行政管理、食品药品监督管理部门应当相互通报获知的食品安全信息。

第九章 法律责任

第八十四条 违反本法规定,未经许可从事食品生产经营活动,或者未经许可生产食品添加剂的,由有关主管部门按照各自职责分工,没收违法所得、违法生产经营的食品、食品添加剂和用于违法生产经营的工具、设备、原料等物品;违法生产经营的食品、食品添加剂

货值金额不足一万元的,并处二千元以上五万元以下罚款;货值金额一万元以上的,并处货 值金额五倍以上十倍以下罚款。

第八十五条 违反本法规定,有下列情形之一的,由有关主管部门按照各自职责分工, 没收违法所得、违法生产经营的食品和用于违法生产经营的工具、设备、原料等物品;违法 生产经营的食品货值金额不足一万元的,并处二千元以上五万元以下罚款;货值金额一万元 以上的,并处货值金额五倍以上十倍以下罚款;情节严重的,吊销许可证:

- (一)用非食品原料生产食品或者在食品中添加食品添加剂以外的化学物质和其他可能 危害人体健康的物质,或者用回收食品作为原料生产食品;
- (二)生产经营致病性微生物、农药残留、兽药残留、重金属、污染物质以及其他危害 人体健康的物质含量超过食品安全标准限量的食品;
 - (三) 生产经营营养成分不符合食品安全标准的专供婴幼儿和其他特定人群的主辅食品;
- (四)经营腐败变质、油脂酸败、霉变生虫、污秽不洁、混有异物、掺假掺杂或者感官 性状异常的食品;
- (五)经营病死、毒死或者死因不明的禽、畜、兽、水产动物肉类,或者生产经营病死、 毒死或者死因不明的禽、畜、兽、水产动物肉类的制品;
- (六)经营未经动物卫生监督机构检疫或者检疫不合格的肉类,或者生产经营未经检验 或者检验不合格的肉类制品;
 - (七)经营超过保质期的食品;
 - (八)生产经营国家为防病等特殊需要明令禁止生产经营的食品;
- (九)利用新的食品原料从事食品生产或者从事食品添加剂新品种、食品相关产品新品种生产,未经过安全性评估;
- (十)食品生产经营者在有关主管部门责令其召回或者停止经营不符合食品安全标准的 食品后,仍拒不召回或者停止经营的。

第八十六条 违反本法规定,有下列情形之一的,由有关主管部门按照各自职责分工, 没收违法所得、违法生产经营的食品和用于违法生产经营的工具、设备、原料等物品;违法 生产经营的食品货值金额不足一万元的,并处二千元以上五万元以下罚款;货值金额一万元 以上的,并处货值金额二倍以上五倍以下罚款;情节严重的,责令停产停业,直至吊销许可 证:

- (一)经营被包装材料、容器、运输工具等污染的食品;
- (二)生产经营无标签的预包装食品、食品添加剂或者标签、说明书不符合本法规定的 食品、食品添加剂;
- (三)食品生产者采购、使用不符合食品安全标准的食品原料、食品添加剂、食品相关 产品;
 - (四)食品生产经营者在食品中添加药品。

第八十七条 违反本法规定,有下列情形之一的,由有关主管部门按照各自职责分工, 责令改正,给予警告;拒不改正的,处二千元以上二万元以下罚款;情节严重的,责令停产 停业,直至吊销许可证:

- (一)未对采购的食品原料和生产的食品、食品添加剂、食品相关产品进行检验;
- (二)未建立并遵守查验记录制度、出厂检验记录制度;
- (三)制定食品安全企业标准未依照本法规定备案;
- (四)未按规定要求贮存、销售食品或者清理库存食品;
- (五)进货时未查验许可证和相关证明文件;
- (六)生产的食品、食品添加剂的标签、说明书涉及疾病预防、治疗功能;
- (七)安排患有本法第三十四条所列疾病的人员从事接触直接入口食品的工作。

第八十八条 违反本法规定,事故单位在发生食品安全事故后未进行处置、报告的,由 有关主管部门按照各自职责分工,责令改正,给予警告;毁灭有关证据的,责令停产停业, 并处二千元以上十万元以下罚款;造成严重后果的,由原发证部门吊销许可证。 第八十九条 违反本法规定,有下列情形之一的,依照本法第八十五条的规定给予处罚:

- (一)进口不符合我国食品安全国家标准的食品;
- (二)进口尚无食品安全国家标准的食品,或者首次进口食品添加剂新品种、食品相关 产品新品种,未经过安全性评估;
 - (三)出口商未遵守本法的规定出口食品。

违反本法规定,进口商未建立并遵守食品进口和销售记录制度的,依照本法第八十七条的规定给予处罚。

第九十条 违反本法规定,集中交易市场的开办者、柜台出租者、展销会的举办者允许 未取得许可的食品经营者进入市场销售食品,或者未履行检查、报告等义务的,由有关主管 部门按照各自职责分工,处二千元以上五万元以下罚款;造成严重后果的,责令停业,由原 发证部门吊销许可证。

第九十一条 违反本法规定,未按照要求进行食品运输的,由有关主管部门按照各自职责分工,责令改正,给予警告;拒不改正的,责令停产停业,并处二千元以上五万元以下罚款;情节严重的,由原发证部门吊销许可证。

第九十二条 被吊销食品生产、流通或者餐饮服务许可证的单位,其直接负责的主管人员自处罚决定作出之日起五年内不得从事食品生产经营管理工作。

食品生产经营者聘用不得从事食品生产经营管理工作的人员从事管理工作的,由原发证部门吊销许可证。

第九十三条 违反本法规定,食品检验机构、食品检验人员出具虚假检验报告的,由授 予其资质的主管部门或者机构撤销该检验机构的检验资格;依法对检验机构直接负责的主管 人员和食品检验人员给予撤职或者开除的处分。

违反本法规定,受到刑事处罚或者开除处分的食品检验机构人员,自刑罚执行完毕或者 处分决定作出之日起十年内不得从事食品检验工作。食品检验机构聘用不得从事食品检验工 作的人员的,由授予其资质的主管部门或者机构撤销该检验机构的检验资格。 第九十四条 违反本法规定,在广告中对食品质量作虚假宣传,欺骗消费者的,依照 《中华人民共和国广告法》的规定给予处罚。

违反本法规定,食品安全监督管理部门或者承担食品检验职责的机构、食品行业协会、 消费者协会以广告或者其他形式向消费者推荐食品的,由有关主管部门没收违法所得,依法 对直接负责的主管人员和其他直接责任人员给予记大过、降级或者撤职的处分。

第九十五条 违反本法规定,县级以上地方人民政府在食品安全监督管理中未履行职责, 本行政区域出现重大食品安全事故、造成严重社会影响的,依法对直接负责的主管人员和其 他直接责任人员给予记大过、降级、撤职或者开除的处分。

违反本法规定,县级以上卫生行政、农业行政、质量监督、工商行政管理、食品药品监督管理部门或者其他有关行政部门不履行本法规定的职责或者滥用职权、玩忽职守、徇私舞弊的,依法对直接负责的主管人员和其他直接责任人员给予记大过或者降级的处分;造成严重后果的,给予撤职或者开除的处分;其主要负责人应当引咎辞职。

第九十六条 违反本法规定,造成人身、财产或者其他损害的,依法承担赔偿责任。

生产不符合食品安全标准的食品或者销售明知是不符合食品安全标准的食品,消费者除要求赔偿损失外,还可以向生产者或者销售者要求支付价款十倍的赔偿金。

第九十七条 违反本法规定,应当承担民事赔偿责任和缴纳罚款、罚金,其财产不足以 同时支付时,先承担民事赔偿责任。

第九十八条 违反本法规定,构成犯罪的,依法追究刑事责任。

第十章 附 则

第九十九条 本法下列用语的含义:

食品,指各种供人食用或者饮用的成品和原料以及按照传统既是食品又是药品的物品,但是不包括以治疗为目的的物品。

食品安全,指食品无毒、无害,符合应当有的营养要求,对人体健康不造成任何急性、 亚急性或者慢性危害。 预包装食品,指预先定量包装或者制作在包装材料和容器中的食品。

食品添加剂,指为改善食品品质和色、香、味以及为防腐、保鲜和加工工艺的需要而加入食品中的人工合成或者天然物质。

用于食品的包装材料和容器,指包装、盛放食品或者食品添加剂用的纸、竹、木、金属、搪瓷、陶瓷、塑料、橡胶、天然纤维、化学纤维、玻璃等制品和直接接触食品或者食品添加剂的涂料。

用于食品生产经营的工具、设备,指在食品或者食品添加剂生产、流通、使用过程中直接接触食品或者食品添加剂的机械、管道、传送带、容器、用具、餐具等。

用于食品的洗涤剂、消毒剂,指直接用于洗涤或者消毒食品、餐饮具以及直接接触食品的工具、设备或者食品包装材料和容器的物质。

保质期,指预包装食品在标签指明的贮存条件下保持品质的期限。

食源性疾病,指食品中致病因素进入人体引起的感染性、中毒性等疾病。

食物中毒,指食用了被有毒有害物质污染的食品或者食用了含有毒有害物质的食品后出现的急性、亚急性疾病。

食品安全事故,指食物中毒、食源性疾病、食品污染等源于食品,对人体健康有危害或者可能有危害的事故。

第一百条 食品生产经营者在本法施行前已经取得相应许可证的,该许可证继续有效。

第一百零一条 乳品、转基因食品、生猪屠宰、酒类和食盐的食品安全管理,适用本法; 法律、行政法规另有规定的,依照其规定。

第一百零二条 铁路运营中食品安全的管理办法由国务院卫生行政部门会同国务院有关 部门依照本法制定。

军队专用食品和自供食品的食品安全管理办法由中央军事委员会依照本法制定。

第一百零三条 国务院根据实际需要,可以对食品安全监督管理体制作出调整。

第一百零四条 本法自2009年6月1日起施行。《中华人民共和国食品卫生法》同时废止。

12. Keywords

China; clenbuterol; crisis event management; crisis management; critical health event; disaster; Disaster Case Studies Series; emergency; emergency medical service(s); food safety; food surveillance system; health crisis

13. Abbreviations

APHIS Animal and Plant Health Inspection Service

AQSIQ Administration for Quality Supervision, Inspection and Quarantine

AIC Administration for Industry and Commerce

BOT Board of Trade

CBP Bureau of Customs and Border Protection

CE Capillary electrophoresis

CLB Clenbuterol

DA Department of Agriculture

DHHS Department of Health and Human Service

ELISA Enzyme-linked immunosorbent assay

EPA (China) Environment Protection Agency, China

EPA (US) Environmental Protection Agency, United States

FAO Food and Agriculture Organization of the United Nations

FDA United States Food and Drug Administration

GC-MS Gas chromatography—mass spectrometry

HACCP Hazard Analysis Critical Control Point

HPLC High-performance liquid chromatography

MOH Ministry of Health

MPS Ministry of Public Security

SFDA State Food and Drug Administration

US United States of America

USDA Department of Agriculture

WHO World Health Organization