

Chinese Approach To Regulating Health Foods



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List of Abbreviations

AQSIQ: Administration of Quality Supervision, Inspection and Quarantine

AHT: Animal & human test

AT: Animal test

CA: Competent Authority

CFDA: China Food and Drug Administration

CFSA: China National Centre For Food Safety Risk Assessment

Chin: Chinese

China CDC: Chinese Centre for Disease Control and Prevention

CIQ: China Inspection and Quarantine Services

CNCA: Certification and Accreditation Administration

CGMPs: current Good Manufacturing Practices (implemented by the U.S. dietary supplement industry)

DHA: Docosahexaenoic Acid

DSHEA: Dietary Supplement Health and Education Act 1994

EFSA: European Food Safety Authority

ENG: English

EC: European Commission

EU: European Union

GMO: Genetically Modified Organism

GMP: Good Manufacture Practice

HPA: U.S.–China Health Products Association

HT: Human test

IADSA: International Alliance of Dietary /Food Supplement Associations

IEC: International Electrotechnical Commission

ISO: International Standardization Organization

MIIT: Ministry of Industry and Information Technology

MoA: Ministry of Agriculture

MOFCOM: Ministry of Commerce

MoH: Ministry of Health of the People's Republic of China (post-October 2013: NHFPC)

MPS: Ministry of Public Security

NHFPC: National Health and Family Planning Commission of the People's Republic of China

NLEA: Nutrition Labelling and Education Act 1990

NPC: National People's Congress

NPCSC: National People's Congress and its Standing Committee

PCSC: People's Congress and its Standing Committee of the provinces, municipalities directly under the Central Government and autonomous regions

RIAHF: Regulation on Inspection and Administration of Health Foods

SAC: Standardization Administration of China

SAIC: State Administration for Industry and Commerce

SFDA: State Food and Drug Administration (post-October 2013: CFDA)

TCM: Traditional Chinese Medicine

USDA GRIN Report: USDA Global Agriculture Information Network Report

U.S. FDA: U.S. Food and Drug Administration

WHO: World Health Organization

Abstract

Chinese health foods refer to vitamin and mineral supplements and functional health foods that have certain health functions and claim these as such. The aim of this research is to make suggestions to improve the Chinese regulatory framework for health foods by means of a comparative study of the approach to regulating food supplements in the EU and dietary supplements in the US. The motivation for this study is vested in the fact that the Chinese approach to regulating health food appears lengthy and costly.

The methods to conduct research combine a review of the regulatory instruments, journal articles and working documents published by the CFDA, EC and FDA as well as telephone interview and case study.

This research suggests that the heavy registration burdens placed on both authorities and producers could be partly lightened by implementing a notification scheme that might require a simplified premarket test to double-check the safety of final products to certain health foods. First, vitamin and mineral supplements could be subject to the notification scheme given the verified safety of these substances. Second, the same notification scheme might be applicable to functional health foods when the functional health foods in question conform to the existing positive lists of health foods substances and comply with the conditions of use of the health claims on positive list. The conditions to use health claims need to be specified by the CFDA.

The major limitation in this study is the lack of insight in the study on the regulatory approach in the Asian countries. The functional foods and / or health supplements in the Asian countries may be more comparable to Chinese health foods and therefore provide a better basis for comparison than food supplements in the EU or dietary supplement in the USA.

Summary

Problem statement

Recently, the China Food and Drug Administration (CFDA) has been considering reforming its current approach to regulating health foods as this approach placed heavy burdens on both authorities and producers. Specifically, health foods that is foods that have certain health functions and make a claim on it, as well as vitamin and mineral supplements, need to register with the CFDA and follow three separate registration assessments on a case-by-case basis. Suffering from the heavy registration burdens, the health food producers proposed a notification system to replace the existing registration scheme. They suggested that under this notification system, health foods in question only need to be reported to the Chinese food authority prior to entering market instead of being authorized through the three separate assessments. This notification system has been discussed by the CFDA since 2009 but is still on hold pattern primarily due to the low trust in health foods producers' self-regulation.

Research objectives

The objectives of this research are twofold. The first objective is to analyse the Chinese regulatory framework for health foods and then investigate the challenges that authorities and producers have been experiencing. The second objective is to make suggestions to improve the current regulatory framework by consulting the EU and U.S. legal system.

Research questions

This research is built on 3 research questions:

- Central question 1: What is the regulatory framework for health foods in China?
- Central question 2: What are the possible challenges to authority and producers under the current framework?
- Central question 3: What can be learnt from the EU and U.S. approaches to improve Chinese framework?

Methodology

Aligned with the research questions, this study focuses on the analysis of the Chinese regulatory framework for health foods, the investigation of challenges to authorities and procurers, and a comparative study of the regulatory approach in China, the EU and US.

The analysis of the Chinese regulatory framework for foods and health foods employs a review of the Chinese regulatory instruments, including food law, rules, regulations, normative documents, and national standards. Besides, reported food accidents that occurred between 2013 and 2014 in China, the CFDA's public presentation materials and the webinar provided by international organizations are referred to help understand how the regulatory instruments are implemented in practice.

Next, the investigation of challenges consists of the collection of data from the CFDA's Chinese health foods database, from a telephone interview with the CFDA and from the Chinese registration consultancies. The challenges are also recognized through case study and journal articles.

Finally, the discussion of the EU and U.S. system of regulation mainly adopts a review of relevant regulatory instruments, journal articles and working documents published by the EC and FDA.

Conclusions

The major challenge is the lengthy and costly registration. This registration in nature is an authorization process that includes three separate health foods assessments. The heavy authorization burdens could perhaps be lightened by exempting one subcategory of health foods, namely vitamin and mineral supplements from registration given the verified safety of these substances. Alternatively, vitamin and mineral supplements exempted from the authorization should be subject to a notification that might require a simplified product premarket test to double-check the safety of final products.

The same notification scheme might be applicable to the other subcategory of health foods, namely the foods that have certain health functions and must carry at least one health claim from the positive list to demonstrate the health functions. Specially, this notification is applicable only when the health foods in question conform to the existing positive lists of health foods substances and comply with the conditions of use of the health claims on positive list—the conditions to use health claims haven't been specified by the CFDA. In other words, the CFDA has substantiated the 27 health claims exclusively used for health foods without providing the explanations for application, therefore the check on the correct use of health claims takes place during the health foods authorization. This research suggests that the CFDA should strive to verify and establish the conditions of use of the 27 health claims, which will enable producers self-determine the correct use of health claims and thus liberate them from the costly and lengthy registration. Likewise, health foods falling into this subcategory which are free from registration should have the CFDA notified and probably go through fast notification tests for safety purposes.

Limitations

Three limitations remain in this research. First, this research discusses the similarity between health foods, food supplements and dietary supplements without analysing the difference between the three food categories.

Second, this study only focuses on the health claims that occur on functional health foods without examining the nutritional claims that vitamin and mineral supplements may carry.

Last but not least, food supplements in the EU and dietary supplements in the U.S. may not be the most comparable food categories to Chinese health foods considering the geographical location and food tradition. Instead, the concept of functional foods and / or health supplements in the other Asian countries, such as Korea, Singapore as well as Indonesia, may be equivalent to the Chinese health foods.

Advice

Future study on how to improve the Chinese regulatory framework for health foods could consult the regulatory approach to functional foods in the Asian countries, as the content of these functional foods and the health foods may be similar. Therefore, the investigation of other Asian approach may make the better suggestions to reform the Chinese approach than that of the EU and US approach.

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1 Introduction

This research is the final thesis that is a compulsory part of the master study on food safety law at Wageningen University. The aim of this research is twofold: to understand the Chinese premarket approval framework for health foods and then make suggestions for improvements by referring to foreign approaches to the similar food category.

Two issues are clarified in this Chapter: research background and research design. Research background is discussed in section 1.1. Research design consists of conceptual design and technical design, which are addressed in section 1.2 and section 1.3 respectively.

1.1. Research Background

Chinese health foods, a food category that has certain health functions or aims at supplementing vitamins and minerals, need to be authorized by Chinese food authority before being marketed¹. However, over times this authorization system has been facing challenges provoked from industry due to costly and lengthy authorization procedures. Consequently, the health food industry proposed a notification system to replace that authorization system, wishing under this notification system the burden on marketing a health food could be greatly relieved². Will industry succeed in influencing the Chinese food authority to adopt notification system? The answer is still ambiguous. Based on a recent telephone interview with the Chinese Food and Drug Administration (CFDA), the authority has oversight of food safety regulation and health foods authorization, after rounds of discussion among China Central Government, CFDA and industry the final decision will be made and publicized within year.

This thesis aims to analyse the Chinese regulatory framework for health foods and investigate the challenges under this framework. It also aims to make suggestions to improve the current approach to health foods by consulting the EU and US legal systems.

1.1.1. Motives for the Research

I want to deepen the understanding of the Chinese approach to a food category that is regulated in a different way in the EU and U.S., and then develop the analytical ability to evaluate the Chinese approach using a comparative study. The EU and U.S. regulatory approaches are referred to mainly because their approaches to law have influenced many other countries in the world³.

Comparable food categories in the above three areas are chosen, namely health foods in China, food supplements in the EU and dietary supplements in the U.S.. The

¹ Jinjing Zhang. (August, 2011). A comparative research on the regulation of health foods in China and other countries. *Shanghai Drug and Food Information Research Vol. 111*, pp.24-30.

² For example, the International Alliance of Dietary/Food Supplement Associations (IADSA) discussed with what is now Chinese Food and Drug Administration about introducing a more accessible system to replace the existing registration, available at: <http://newhope360.com/international/iadsa-china-talk-health-food-regulations>, accessed on July 12, 2014.

³ This opinion was addressed in the course "International and American Food Law", provided by Law and Governance Group, Wageningen University.

similarities of health foods, food supplements and dietary supplements are described in Chapter 5. In brief, these three food categories are similar in terms of scope, functions and general labelling requirement. This complies with the opinion held by the International Alliance of Dietary/Food Supplement Associations (IADSA)⁴, an international platform for the development of the food supplements sector worldwide, that there is no globally accepted term for dietary/food supplements and both terms are similar to some extent. In the US, dietary supplements is a legal term. In the Europe, food supplements is more widely used. In Asia, health foods and health supplements are adopted.

⁴ www.iadsa.org. Accessed 5 March 2014.

1.2. Research Design – Conceptual Design

The function of a research design is to ensure that the information obtained enables the research to fulfil the objective as unambiguously as possible⁵. It can be comprised of the conceptual design and technical design.

The conceptual design aims to formulate an effective research objective, design an efficient research questions, outline a clear research framework and clarify relevant research issues. These issues are clarified between subsection 1.2.1 and 1.2.4.

The technical design concerns the different ways of collecting information required, the selection of an adequate research strategy, and making of a research plan⁶. The elements included in technical design are specified between subsection 1.3.1 and 1.3.3.

1.2.1 Research Objective

The aim of this research is twofold: to understand the Chinese premarket approval framework for health foods and then make suggestions for improvements by consulting the EU and U.S. legal system where food supplement and dietary supplement were regulated.

1.2.2 Research Questions

Research questions break down the overall research objective into several more specific central questions and sub questions. After answering these questions, the research objective is expected to be achieved.

This research involves 3 central questions:

Central question 1: What is the regulatory framework for health foods in China?

- Sub question 1.1: Since health foods are under the umbrella of food, so what is the Chinese food legal system like, specifically, who (authorities) are involved in the food regulation, and what are the legal instruments composed of?

⁵ David de Vaus. (2001). Research Design in Social Research. <http://www.sagepub.com/books/Book205847/toc>.

⁶ Piet Verschuren and Hans Doorewaard. (2010). Designing a Research Project.

<http://www.boomlemma.nl/methodologie-vaardigheden/catalogus/designing-a-research-project-2#>

- Sub question 1.2: What is the regulatory framework for health foods in China?

Central question 2: What are the possible challenges to authority and producers under current framework?

- Sub question 2.1: What are the possible challenges to authority and producers under current framework?
- Sub question 2.2: What are the hurdles for implementing premarket notification system for health foods?

Central question 3: What can be learnt from the EU and U.S. approaches to improve Chinese framework?

- Sub question 3.1: What is the regulatory framework for food supplement in the EU?
- Sub question 3.2: What is the regulatory framework for dietary supplement in the U.S.?
- Sub question 3.2: What can be learnt from the EU and U.S. approaches to improve Chinese framework?

1.2.3 Research Framework

The research framework illustrates how this research is structured. It is divided into 3 parts, namely theoretical framework, diagnose and final results.

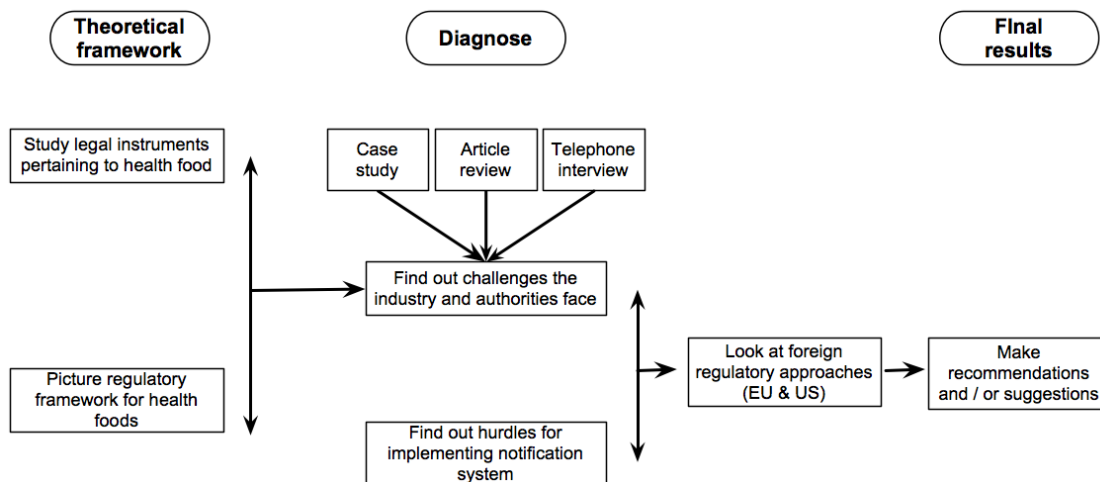


Figure 1-1 Research framework

Theoretical framework focuses on the analysis of legislation pertaining to health food. The intended purpose is to develop a comprehensive understanding of regulatory framework for health food.

Diagnose involves article review, case study and interview. The purpose of this part is to find out the challenges this framework is facing and determine whether notification system would be a success in China at present.

Finally, the result part seeks to make suggestions to improve the Chinese approach to health foods, combining the results obtained at the first two stages and the analysis of the EU and U.S. approaches.

1.2.4 Definition of Concepts

China's health food

Health food, as defined in the Article (2) of Administrative Measures on Health Foods Registration (Interim) 2005 (Measures 2005)⁷, the fundamental instrument to regulate health foods, refers to those foods

which claim to have certain health functions or aim at supplementing vitamins and minerals, namely, the foods that are used for certain groups of people with the aim to adjust organic function instead of curing diseases and will not cause any acute, sub-acute or chronic damages to human body.

Health Food must register with CFDA so that they can bear the “Health food (Mandarin Chinese Pinyin name: Bao Jian Shi Pin)” on its label, together with the functional claims⁸.



Figure 1-2 Health food label

EU food supplements

Food supplements, as defined in the Article 2 of Directive 2002/46/EC⁹ means

⁷ Available at:

[http://www.aunew.org/Rules%20&%20Regulation/Provisions%20for%20Health%20Food%20Registration%20\(int%20interim\).pdf](http://www.aunew.org/Rules%20&%20Regulation/Provisions%20for%20Health%20Food%20Registration%20(int%20interim).pdf) . Accessed 5 March 2014.

⁸ According to Measures 2005, health foods that supplements vitamins and minerals do not bear claim.

⁹ Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0046:EN:NOT>. Accessed 5 March 2014.

foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities; 'nutrients' means the following substances: (i) vitamins, (ii) minerals.

US dietary supplements

The definition of dietary supplement is given by Dietary Supplement Health and Education Act of 1994 (DSHEA). The definition of dietary supplement can be found in 21 U.S. Code § 321 (ff)¹⁰ but it is hard to follow¹¹. According to FDA's explanation, a dietary supplement "is a product taken by mouth that contains a 'dietary ingredient' intended to supplement the diet. The 'dietary ingredient' in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids, or powders"¹².

¹⁰ <http://www.law.cornell.edu/uscode/text/21/321#ff> .

¹¹ Fortin ND. 2009. Food Regulation. Hoboken, New Jersey, USA: John Wiley & Sons, Inc. P.326

¹² Available at: http://www.fda.gov/Food/DietarySupplements/QADietarySupplements/default.htm#what_is.

1.3. Research Design – Technical Design

The technical design is addressed in this part, consisting of the different ways of collecting information required (section 1.3.1) and the selection of an adequate research strategy (section 1.3.2).

1.3.1. Research Material

Research material is gathered to obtain the knowledge required and to answer research questions as unambiguously as possible. What material needs to be collected is detailed around the three central research questions. Basically, two types of material are needed: legal instruments and literatures.

Central Q1: What is the regulatory framework for health food in China?	
Methods: legal instruments collection and study	
Material: Books	<ul style="list-style-type: none"> China Legal Publishing House. 2011. Handbook of Food Safety Law of P.R.China (Chinese title: Shi Pin An Quan Fa Yi Ben Tong) China Legal Publishing House. 2012. Food Safety Codex of P.R.China (Chinese title: Shi Pin An Quan Fa Dian)
Material: Chinese legal instruments	<ul style="list-style-type: none"> Food Hygiene Law 1995 Food Safety Law 2009 Provisions for Health Foods 1996 Administrative Measures on Health Foods Registration (Interim) 2005 Other relevant legal instruments
Central Q2: What are the possible challenges to authority and producers under current framework? And what are the hurdles for implementing premarket notification system for health foods?	
Methods: article review, case study, and telephone interview.	
Material: Articles	<ul style="list-style-type: none"> Reports from the international consultant firm Reports from the USDA Foreign Agricultural Service Reports from the China Food and Drug Administration and its branch offices Telephone interviews with official(s) from the CFDA
Central Q3: What can be learnt from the EU and U.S. approaches to improve Chinese framework?	
Methods: article review and legislation study.	
Material: Books	<ul style="list-style-type: none"> Fortin ND. 2009. Food Regulation. Hoboken, New Jersey, USA: John Wiley & Sons, Inc.
Material: Legal instruments	<p>The European regulations and directives pertaining to food supplement</p> <ul style="list-style-type: none"> Directive 2002/46/EC on Food Supplements Regulation (EU) No 1924/2006 on Nutrition and Health Claims

	<ul style="list-style-type: none"> • Regulation (EU) No 1169/2011 on Food Information • EU legal requirements on food hygiene, such as Regulation (EC) 852/2004 on the Hygiene of Foodstuffs • Other relevant regulations, directives and guidance <p>The U.S. legislation pertaining to dietary supplement</p> <ul style="list-style-type: none"> • Dietary Supplement Health and Education Act of 1994 • Nutrition Labeling and Education Act (NLEA) 1990 • Current Good Manufacturing Practices (established by the FDA) • Other relevant legislations and guidance
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1.3.2. Research Strategy

Breadth versus depth

This thesis will examine the Chinese legislation pertaining to health foods in depth.

Qualitative versus quantitative research

This thesis adopts qualitative research. Qualitative research “refers to the meanings, concepts, definitions, characteristics, metaphors, symbols, and descriptions of things¹³”. Since the motive for this study is to enhance the understanding of how comparable food categories are regulated under different legal systems, therefore qualitative research can better meet the objective. This is because qualitative methods provide a depth of understanding of the operation and processing of legal system and the knowledge gained through qualitative investigations is more informative¹⁴.

Empirical versus non-empirical research

This thesis will be conducted both empirically and non-empirically, with non-empirical being primary. Legislation study and article review will be the main tools. To verify the essential results of the research, telephone interview with official(s) from the China Food and Drug Administration will be conducted.

¹³ Richard Tewksbury. (2009). Qualitative versus Quantitative Methods: Understanding Why Qualitative Methods are Superior for Criminology and Criminal Justice. *Journal of Theoretical and Philosophical Criminology*, Vol 1 (1), pp.38-58. Available at: http://jtpcrim.org/January_Articles/Qualitative_Vs_Quantitative_Richard_Tewksbury.pdf.

¹⁴ *Ibid.*

2 Introduction to Food Regulation in China

This chapter elucidates the Chinese legal system, with a focus on the food regulatory framework. The purpose of this chapter is to pave the way for the analysis of the Chinese approach to health foods in Chapter 3.

Section 2.1 provides a general explanation of the Chinese legal system, which consists of the Constitution, laws, regulations and rules, as well as national standard system.

Section 2.2 presents an overview of food regulatory instruments, consisting of food laws, regulations, rules, normative documents and standards.

Section 2.3 introduces government authorities involved in national food safety supervision and their respective functions, employing five case studies to explain how the regulatory functions are exercised in reality.

Section 2.4 summarizes the key points.

2.1. China's Legal System and Legal Instruments

This section gives a brief introduction to the Chinese legislative hierarchy, which consists of the Constitution, laws, regulations and rules (section 2.1.1). Furthermore, an important legal instrument—normative documents (section 2.1.2)—and the national standard system (section 2.1.3) are described.

2.1.1. Constitution, Laws, Regulations and Rules

According to Article 2 of *Legislation Law of the People's Republic of China*¹⁵, the Chinese legal system is based on 4 levels, with the Constitution outranking the other levels and each descending level outranking the lower level:

- Constitution
- Other Laws other than the Constitution
- Regulations (Mandarin Chinese Pinyin name: Fa Gui or Tiao Li)
- Rules (Mandarin Chinese Pinyin name: Gui Zhang)

The functions of which are as follows:

Firstly, the *Constitution of the People's Republic of China*¹⁶ has the highest legal effect of all the types of legislation. "No laws or regulations may contravene the Constitution"¹⁷. The *Constitution* was adopted on December 4, 1982¹⁸ by the National People's Congress (NPC), the supreme organ of state power. The *Constitution* stipulates the fundamental rights and duties of citizens and the structure of the State.

Below the *Constitution* are laws. China governs the country according to the *Constitution* and laws¹⁹. "Basic laws" such as criminal law are enacted by NPC. Laws other than "basic laws" are enacted by NPC Standing Committee (NPCSC) that is composed of Chairman, Vice Chairmen, the Secretary-General and other members. Currently in China, the most important legislation in food safety is the *Food Safety Law 2009 (2009: the year of implementation, hereinafter)*.

¹⁵ ENG: http://english.gov.cn/laws/2005-08/20/content_29724.htm. Chin: http://www.gov.cn/test/2005-08/13/content_22423.htm. Accessed on 12 March 2014.

¹⁶ Available at: http://www.npc.gov.cn/englishnpc/Constitution/node_2825.htm.

¹⁷ Article 5, *Constitution*.

¹⁸ Since the foundation of People's Republic of China, four Constitutions have been enacted: in 1954, 1975, 1978 and 1982. The 1982 Constitution was amended in 1988, 1993, 1999 and 2000.

¹⁹ Article 5, *Constitution*.

The third type of legal instruments is regulations, which were introduced to implement the provisions of laws. There are 4 types of regulations, among which administrative regulations have higher legal effects than the others as they are enacted by the State Council (the Central People's Government and also the supreme organ of State administration), while the other three regulations are local regulations, autonomous regulations and special decree, which were enacted by the NPCSC of provinces, autonomous regions and municipalities respectively. One important food regulation that was promulgated most recently was the *Regulation on the Implementation of the FSL 2009*.

Lastly, at the lowest legislative level are rules. Rules are classified into department rules and local government rules based on the promulgators. First, department rules are enacted by the ministries and commissions of the State Council in order to implement the laws or the administrative regulations and orders of the State Council²⁰. For example, one of the ministries under the State Council is the Ministry of Health (MoH) and it issued the rules for health foods regulation, known as *Administrative Provisions for Health Foods 1996*. Second, local government rules are granted by the people's governments of the provinces, autonomous regions and municipalities.

In short, the *Constitution* is above all legislation. China governs the country according to the *Constitution* and other various laws. Regulations are introduced to implement laws. Rules enforce laws and orders of governments at all administrative levels (provincial and municipality).

2.1.2. Normative Documents

There is no legal definition of normative documents in the *Legislation Law*. However, normative documents are regarded as one of the most common and important types of working document issued by the administrative organs at all levels in accordance with their respective statutory functions and powers, and have general binding force on citizens, legal entities and other organizations²¹.

²⁰ Article 71, *Legislation Law*.

²¹ Article 2, *Provisions of Guangdong Province on Administration of Normative Documents of Administrative Organs*. See at <http://www.lawinfochina.com/display.aspx?lib=law&id=11729&CGid=>.

The function of the normative documents is to implement the provisions of rules or regulations. For example, to clarify the specific regulatory matters and to answer questions that have arisen from the administrative organs at lower levels. One example concerning clarifying the specific regulatory matters is that to prohibit the use of Sudan dyes as food additives in China, a normative document entitled Notice of the MoH on the Prohibition of the Use of Sudan Dyes as Food Additives 2005 was published by the Ministry of Health (MoH) in 2005.

In summary, the legislative hierarchy discussed in section 2.1.1 and 2.1.2 comprises five levels: Constitution, laws, regulations, rules and normative documents as Figure 2-1 presents.

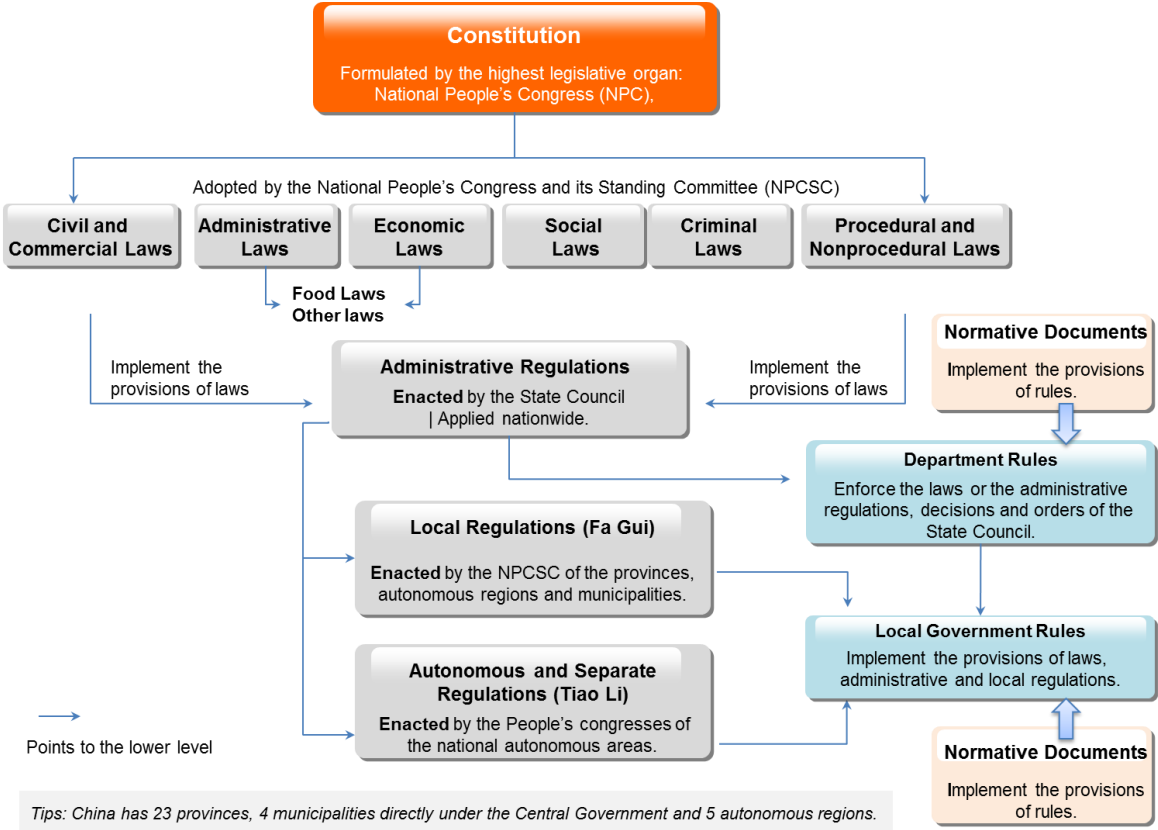


Figure 2-1 Hierarchy of the Legal System in China

Source: Based on Legislation Law of the People's Republic of China

Note: China Legislative Information Database²² shows that legislation related to foods falls into administrative laws and economic laws and their corresponding regulations and rules.

²² Eng: <http://www.npc.gov.cn/englishnpc/Law/Frameset-index.html>. Chin: <http://law.npc.gov.cn:87/home/begin1.cbs>.

2.1.3. National Standard System

National standards are not included in the Chinese legal system. However, in practice standards may be even more important than legal instruments since legal instruments only provide general provisions. Standards, on the other hand, stipulate the specific requirements that should be met when dealing with certain issues.

Regulatory Authority

In China, the Standardization Administration of China (SAC)²³ is authorized by the State Council to carry out centralized administration for standardization. Standardization is comprised of the creation of standards, the implementation of standards and the supervision of the implementation of standards²⁴. Other functions of SAC include representing China in the international or regional standardization organizations, such as International Standardization Organization (ISO) and International Electrotechnical Commission (IEC). When it comes to food, the Agriculture and Food Standards Department²⁵ of the SAC takes responsibility for the planning of and the implementation of national standards of foodstuff, food safety, food related products.

SAC is under the control of the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ).

Regulatory Instrument

The creation and implementation of standards are based on the *Standardization Law of the People's Republic of China 1989*²⁶. The aim of this law is to improve standardization work so that it can meet the needs of socialist modernization and of the development of economic relations with foreign countries²⁷.

System of Standards

According to Article 6 of the *Standardization Law*, the Chinese standard system is composed of 4 levels, flowing from national, technical, local and enterprise

²³ http://www.sac.gov.cn/sac_en/.

²⁴ Art. 3, *Standardization Law*.

²⁵ http://www.sac.gov.cn/sac_en/Departments/201011/t20101123_4172.htm

²⁶ Eng: <http://www.lehmanlaw.com/resource-centre/laws-and-regulations/consumer-protection/standardization-law-of-the-peoples-republic-of-china-1989.html>. Chin: <http://www.cws.net.cn/guifan/bzhf.htm>.

²⁷ Art. 1, *Standardization Law*.

standards²⁸. The standards at the lower levels were formulated in case those at the upper levels are provisionally lacking. Standards were classified into compulsory standards and voluntary standards²⁹.

²⁸ Art. 6, Standardization Law.

²⁹ Art. 7, Standardization Law.

2.2. Food Legislation

This section presents an overview of the Chinese food regulatory instruments, including laws, regulations, rules and normative documents (section 2.2.1). Furthermore, this section classifies these regulatory instruments into three sectors: product, process and communication (section 2.2.2).

2.2.1. Food Laws, Regulations, Rules and Normative Documents

In accordance with the Chinese legal system (Figure 2-1), foods in China are regulated by the food laws, regulations (consist of administrative regulations, local regulations, autonomous regulations and separate regulations), rules (consist of department rules and local government rules) and normative documents. Due to large amounts, only the most important legislation, namely laws (passed by the NPCSC), administrative regulations (enacted by the State Council), department rules (issued by the Ministries or Commissions under the State Council) and essential normative documents are discussed.

Food Laws

In China, Three food laws were proposed and / or implemented since the first food law in 1965³⁰. Specifically, the Regulations on the Administration of Food Hygiene (Trial Implementation) was the first law pertaining to food³¹. Food Hygiene Law 1995 (FHL) was the second food law and superseded by the Food Safety Law 2009 (FSL) on 1 June 2009. Currently, FSL 2009 plays a central role in the overall regulation of food. Just like European Commission Regulation 178/2002 on Food Law³², the principal aim of this law is to ensure food safety and protect human health in relation to food. It lays down the general principles and requirements of food legislation. However, as China restructured its food regulatory regime at the annual National People's Congress (NPC) in 2013, food regulatory functions assigned to different authorities under the FSL 2009 have undergone a significant transformation and thus

³⁰ Regulations on the Administration of Food Hygiene (Trial Implementation).

³¹ According to Bian Yongmin, "these regulations mainly referred to state-owned food producers. The main concern at this time was the security of the food supply rather than the safety of the food itself, and came shortly after the terrible Three-Year Famine. These first regulations failed however, due to the collapse of the legal system in China in the decade following". Bian Yongmin. The Challenges for Food Safety in China, China Perspectives [Online], 53 | May- June 2004, Online since 19 April 2007, available at <http://chinaperspectives.revues.org/819> (23 July 2014).

³² Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002R0178:EN:NOT>. Accessed on 11 March 2014.

were out-dated. In response to the changes, the *Draft of Revised FSL 2009*³³ was proposed by the China Food and Drug Administration (CFDA) and submitted to the State Council for the approval in October 2013³⁴. One of the key provisions is to write the role of the China Food and Drug Administration (CFDA) in the overall supervision of food into law.

Food Regulations

Food regulations enforce food laws. 13³⁵ regulations (or entitled implementing measures) have been promulgated following the passage of the *FHL 1995* and *FSL 2009*. For example, there are regulations dealing with the slaughter of hogs, dairy products, genetically modified foods, alcohol, and salt. A newly established regulation is the *Regulation on the implementation of FSL 2009*, implementing the *FSL 2009*.

Food Department Rules

Food department rules implement laws and regulations, which are issued by several food authorities. Specifically, these food authorities include two ministries and three organizations directly under the State Council, namely the Ministry of Health (MoH), Ministry of Commerce (MOFCOM), General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), State Administration for Industry and Commerce (SAIC) and State Food and Drug Administration (SFDA). It should be noted that a few of the above authorities underwent the integration after the twelfth NPC, held on March 2013, and a new regulatory regime is formed accordingly. The new regime is discussed in section 2.3.

Food department rules cover rules throughout the whole food supply chain, including food production, food circulation, food catering and food import and export.

For example, the SAIC once formulated two rules regarding food circulation, namely *Measure for the Supervision and Administration of Food Safety in the Circulation Links 2009* and *Measures for the Administration of Food Circulation Permits 2009*. This is because the State Council once charged the SAIC with implementing the

³³ Available at:

<http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Food%20Safety%20Law%20Draft%20for%20Comment%20Beijing%20-%20Peoples%20Republic%20of%2011-8-2013.pdf>. Accessed on 11 March 2014.

³⁴ By far (July 2014), the Draft of Revised FSL has been approved by State Council (May 2014) and is under the first review by NCPSC (June 2014).

³⁵ See at http://www.chinafdc-law.com/laws/list_1-0_5-116_1.html

supervision on food circulation till 2013. In the new regulatory regime, the supervisory functions of the SAIC on food circulation were transferred to the CFDA. The AQSIQ, in charge of food production, established Measures for Supervising and Administrating the Production of Food Additives 2010.

Food Normative Documents

Normative documents implement the provisions of rules or regulations. They are publicized less formally and sometimes only circulated between governments, so it is not feasible and necessary to list all of them. However, two normative documents are worth stating, which are related to the monitoring and assessment of food safety risks—Interim Measures on Food Safety Risk Monitoring 2010 and Interim Measures on Food Safety Risk Assessment 2010. These two documents indicate the state’s willingness to establish the national food safety risk assessment system. One of the achievements so far is the creation of the China National Centre For Food Safety Risk Assessment (CFSA) in 2011³⁶, which contributes to provide scientific advice on the existing and emerging risks.

2.2.2. Structure of the Chinese Food Legislation

To better understand the effective Chinese food legal system, Table 2-1 provides a structure of the Chinese food legislation based on three sectors: product, process and communication.

Sectors		Corresponding legal instruments
Product	Health foods	Administrative Measures on Health Foods Registration
	Food additives	Administrative Measures for Food Additives Hygiene
	New food materials	Administrative Measures for Safety Evaluation of New Food Materials
	GMOs	Administration Regulations on Biosafety of GMOs
	Green foods	Administrative Measures for Green Foods
	Organic foods	Certification Regulations on Domestic Organic Foods
	Conventional foods, such as dairy, fruits and vegetables.	Corresponding regulations and/or rules
Process	Production	Measures for the Administration of Food Production Licenses
		Implementing Rules for the Administration of Quality and Safety of Food Manufacturers and Processors

³⁶ <http://www.cfsa.net.cn/>

	Food safety standards	National Food Safety Standards System (More than 4,000 standards covering the production chain, such as veterinary drugs, pesticide residues, microbial, HACCP, meat products)
	Circulation	Measures for the Supervision and Administration of Food Safety in the Circulation Measures for the Administration of Food Circulation Permits
	Catering	Measures for the Supervision and Administration of Food Safety in the Catering Services Administrative Measures for the Licensing of Catering Services
	Recall	Administrative Provisions on the Recall of Foods
Communication	Labelling	Administrative Provisions on Food Labelling Administrative Provisions for Import/Export Food Labelling
	Advertising	Provisions for the Administration of Food Advertisement
	Risk management	Interim Measures on Food Safety Risk Monitoring
		Interim Measures on Food Safety Risk Assessment

Table 2-1 structure of the Chinese food legislation

Source: Zhe Jiang Provincial CFDA³⁷.

Table 2-1 is adapted from the table in which a provincial CFDA summarizes regulations and directives on food, drug and cosmetics. This table tends to present the Chinese food legislation in an organised way. First, in product sector this table distinguishes between conventional foods and other food categories that either need pre-market authorization, for example, health foods, new food material and food additives or need certain certification, such as organic foods and green foods, or are distinct from traditional food, such as Genetically Modified Organisms (GMOs).

Second, in process sector, this table features the Chinese approach to the regulation of food over years till 2013, that is, for years the Chinese food supply chain was divided into three segments: production, circulation and catering till 2013. AQSIQ, SAIC and SFDA took charge of each segment. After 2013, CFDA has taken over of functions of AQSIQ, SAIC and SFDA and has been in the overall supervision of the food regulation. Besides, food safety standards and recall are added into this sector as well.

Finally, in communication sector, labelling, advertising and risk management stand together.

³⁷ Available at: http://www.chinafdc-law.com/laws/index_b.html.

2.2.3. Food Standards

Existing Chinese food standards, covering compulsory and voluntary standards on the quality and safety of edible agricultural products, on food hygiene and food quality, and on food-related products, are being unified³⁸. This means over 2,000 national standards, more than 2,900 industrial standards and over 1,200 local standards pertaining to food, food additives and food-related products are being harmonized and incorporated into the Chinese National Food Safety Standards System³⁹. Based on the “Twelfth Five-Year” Plan⁴⁰, by the end of 2015, the integration of food standards should be completed and the construction of the National Food Safety Standard System should be finalized. NHFPC is taking charge of the construction of the National Food Safety Standard System⁴¹.

National Food Safety Standard System

During the International Symposium on Food Safety Risk Assessment 2012, the MoH (has been integrated into NHFPC) Director General detailed the structure of the future National Food Safety Standard System whereby food safety standards will be classified according to the various factors that influence the safety and quality of a food product throughout the production chain. See Figure 2-2:

³⁸ Art. 22, *FSL 2009*.

³⁹ Art. 19, *FSL 2009*.

⁴⁰

http://gain.fas.usda.gov/Recent%20GAIN%20Publications/12th%20Five%20Year%20Plan%20for%20National%20Food%20Safety%20Standard-final_Beijing_China%20-%20Peoples%20Republic%20of_6-28-2012.pdf

⁴¹ Retrieved from <http://www.nhfpc.gov.cn/sps/pzyzz/lm.shtml>.

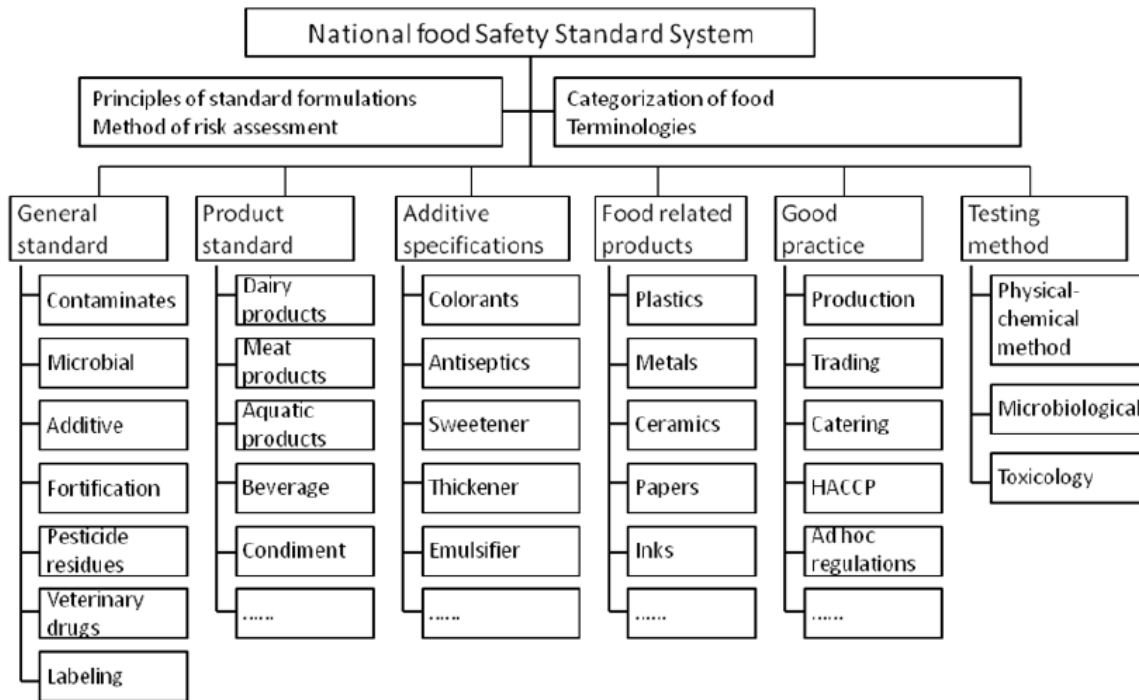


Figure 2-2 National Food Safety Standard System;

Source: USDA report⁴²

⁴² See at : <http://gain.fas.usda.gov/Recent%20GAIN%20Publications/The%20Food%20Safety%20Management%20System%20in%20Beijing%20China%20-%20Peoples%20Republic%20of%204-26-2013.pdf>. Accessed 7 March 2014.

2.3. Restructured Food Regulatory Authorities

In 2013 at the twelfth National People's Congress, China restructured its food regulatory regime, which was regarded as the most significant change in recent history in relation to food.

Some highlights of this restructuring were the establishment of the CFDA and the full integration of the SFDA into the CFDA. After this restructuring, the CFDA takes over production supervision from AQSIQ, distribution supervision from SAIC and catering supervision from SFDA⁴³.

Section 2.3.1 presents the new food regulatory regime and emphasises functions of relevant regulatory authorities.

Section 2.3.2 adopts a case study— “Export meat product to China”—to illustrate how the export/import foods were regulated under the new regulatory regime.

Section 2.3.3 introduces four more cases studies concerning domestic food regulation, with a focus on product, process and communication.

2.3.1. The Respective Regulatory Functions

Under the new food regulatory regime, the CFDA is directly in charge of the administration of food safety. Other important food regulatory functions have been retained by the Ministry of Agriculture (MoA), NHFPC and AQSIQ⁴⁴. Besides, SAC, SAIC, Certification and Accreditation Administration (CNCA), Ministry of Public Security (MPS), Ministry of Industry and Information Technology (MIIT) and Ministry of Commerce (MOFCOM) are not directly tasked with ensuring food safety, but are involved in the administration of the food industry.

The respective responsibilities of the afore mentioned authorities that are directly and indirectly connected with food safety regulation can be summarized as follows:

⁴³Section 1 (3), *Rules for the Main Functions, Internal Departments and Staffing of CFDA (Chin)*. See at http://www.gov.cn/zwqk/2013-05/15/content_2403661.htm. Article 3, *Decision of the First Session of the Twelfth National People's Congress on the Plan for Restructuring the State Council and Transforming Functions* (Chin), see at <http://www.miit.gov.cn/n11293472/n11293832/n13095885/15284650.html>.

⁴⁴ <http://www.chinafdc-law.com/glossary.html#46>. Accessed on 25 Feb. 2014

Authorities	Food Chain	Functions
Most Relevant Authorities		
MoA	Feed & Grower	Supervision and management of <ul style="list-style-type: none"> • Farm produce; • Agricultural food products before placed on the market; • Veterinary drugs, feed, feed additives, pesticides, fertilizers and the like.
CFDA	Process, Retail, Consumption	<ul style="list-style-type: none"> • Overall control of food production, distribution and consumption. • Draft food safety regulations and rules. • Grant food approval (such as additives and health foods) • Provoke food recall
NHFPC	Consumer protection	<ul style="list-style-type: none"> • Assess food safety risks; • Establish food safety standards.
AQSIQ	Food imports & exports	<ul style="list-style-type: none"> • Supervision and management of food packaging materials, containers and tools for food production and trading. • Inspection and quarantine of import/export food products.
Other Related Authorities		
SAC	Carry out centralized administration of standardization work nationwide.	
CNCA	Responsible for Export/Import businesses registration.	
SAIC	Responsible for local business registration and approval.	
MIIT	Administer food industry; Monitor food industry performance.	
MOFCOM	Oversee the development of commercial circulation network. Certifies whether a company qualifies as an import/export business.	
MPS	Response to food safety related criminal conduct.	

Source: Official websites of authorities: MoA (moa.gov.cn). CFDA (sda.gov.cn). NHFPC (nhfpc.gov.cn). AQSIQ (aqsiq.gov.cn). SAC (sac.gov.cn). CNCA (cnca.gov.cn). MIIT (miit.gov.cn). MOFCOM (mofcom.gov.cn). MPS (mps.gov.cn).

2.3.2. Exercise of Regulatory Functions (1)—Export Meat Products to China

The aim of this case is to develop a general understanding on how the import/export regulations on food were executed under the new regulatory regime.

Briefly, businesses wishing to export meat products to China are required to meet the provisions of the *FSL 2009, Administrative Measures for Inspection, Quarantine and Supervision of Inbound and Outbound Meat Products 2011 (Measures 2011)* and the protocols signed between China and the exporting countries⁴⁵.

Before Customs releases meat products, importing businesses must approach the AQSIQ and its branch organization because AQSIQ is responsible for the safety, testing and management of food imports and exports. The Chinese local consignees

⁴⁵ EU SME Centre Webinar—How To Export Meat Products To China

are required to go through a series of administrative registration: register at the SAIC for businesses license, AQSIQ for inbound meat products, and MOFCOM as a foreign trade operator. Once meat products are on the market, the supervision will be administered by the CFDA as it takes overall control of food production, distribution and consumption.

The regulatory instruments sourced, regulatory authority involved, and the detailed import procedures are detailed in Table 2-2.

Regulatory Instruments	Provisions	Procedures	Regulatory Authorities
Exporting Side			
Measures 2011	Art.3: AQSIQ is the competent authority for nationwide inspection, quarantine and supervision of inbound and outbound Meat Products.	1. Exporting country submits export request to AQSIQ	AQSIQ; CA* of exporting countries
FSL 2009	Art.65: Overseas enterprises shall register with CNCA		
Measures 2011	Art.7 Inbound meat products shall comply with national food safety standards and inspection and quarantine requirements set out in agreements or protocols made between China and the countries of origin.	2. Bilateral protocol negotiation;	AQSIQ; CA of exporting countries
Measures 2011	Art.8 Meat products shall be in accordance with the laws, regulations and national food safety standards of China. National meat product standards (examples): Poultry National Standard GB 16869-2005; Hygienic Practice For Meat Processing Establishments GB/T 20094-2006;	3. Bilateral protocol negotiation	SAC (develop standards) CNCA (inspect foreign establishments)
Regulations 2012**	Art.5: Overseas producers of food on the List may only export their product(s) to China upon being registered. (List refers to the List of Implementation of Registration of Overseas Producers of Imported Food)	4. Exporter registration	CNCA***
Measures 2011	Art.13: Inbound meat products shall be stored in the points authorized by CIQ office and recorded by AQSIQ.	5. Meat products enter into China	CIQ AQSIQ
Measures 2011	Art.4: Local office of AQSIQ shall take charge of inspection, quarantine and supervision of inbound and outbound Meat Products under their respective purview.	6. Inspection and quarantine on meat products	Local offices of AQSIQ
FSL 2009	Art.62: Customs office shall release the imported food on the basis of a customs clearance certificate issued by the Local Offices.	7. Customs release meat products	Customs offices
Importing Side			
FSL 2009	Art.29: The state adopts a licensing system for food production and trading.	1. Obtain businesses license	SAIC
Measures	Art.10: Local Offices shall maintain a registry of	2. Consignees	Local office

2011	consignees of inbound Meat Products.	registration	of AQSIQ
Measures 2004 ****	Art. 2: Foreign trade operators that engage in the import and export of goods or technology shall handle record filing and registration with the MOFCOM.	3. Register as a foreign trade operator	MOFCOM
Measures 2011	Art.67: The importer shall establish a food import and sale record system.	4. Meat products enter market	Enterprise self-regulation
Draft of Revised FSL 2009	Art. 5: CFDA takes control of food safety matters relevant to the production, distribution and consumption of foods.	5. Post market surveillance	CFDA

*CA: Competent Authorities

** Regulations 2012: Regulation on Registration and Management of Overseas Producers of Imported Food 2012⁴⁶

*** For example, CNCA publicizes the “List of French Registered Meat Enterprises Export Products to China”⁴⁷

****Measures 2004: *Record Filing and Registration of Foreign Trade Operators Procedures*⁴⁸

Source: EU SME Centre Webinar—How To Export Meat Products To China

Table 2-2 Regulatory Instruments and Authorities Involved in the Meat Export

2.3.3. Exercise of Regulatory Functions (2)—Chinese Beef Meat Scandal 2013

Cases introduced in section 2.3.3–2.3.5 help understand domestic food safety management. Again, it should be kept in mind that the regulatory responsibilities of food production, distribution and consumption are all in the hands of the CFDA after October 2013.

Retrospective of beef meat scandal. Beef meat scandal was regarded a top five-food safety incident in China last year⁴⁹. In short, in September 2013, six workshops near Xi'an and Shanxi province were shut down after they were found to have produced fake beef meat using pork meat and mixed it with industrial salts⁵⁰. The provisions sourced and actions taken by the authorities are presented in Table 2-3:

⁴⁶

<http://www.google.com.hk/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=4&cad=rja&uact=8&ved=0CDkQFjAD&url=http%3A%2F%2Fwww.seafood.no%2Fcontent%2Fdownload%2F70240%2F874261%2Ffile%2FAQSIQ%2520%2520notifikasjon%2520nr%2520%2520145.doc&ei=J4pFU8aqKsa50QXLtIGIDw&usg=AFQjCNGDXt20C432KMY-PVqMSaTBsm7gvQ&bvm=bv.64507335.d.bGQ>

⁴⁷ <http://en.ciqcid.com/Registered/Registered1/Food/44714.htm>

⁴⁸ Available at: <http://www.trade.cn/article/reference/50.html>.

Chin: <http://www.mofcom.gov.cn/article/swfg/swfgbf/201101/20110107351053.shtml>.

⁴⁹ Available at: http://en.wikipedia.org/wiki/Food_safety_incidents_in_China#Beef_Meat_Scandal

⁵⁰ Available at: http://shanghaiist.com/2013/09/14/20000_kilos_of_fake_beef_seized_in_xian.php.

Regulatory Instruments	Provisions	Actions	Regulatory Authorities
FSL 2009	Art.80: CFDA, upon receipt of public report, shall conduct timely response and verification. Art.82: Major food safety accidents shall be announced by the food safety supervision and administration department.	<ul style="list-style-type: none"> • Timely responded to the public report • Announced this incident 	CFDA
FSL 2009	Art.82: If suspected of a crime, the case shall be transferred to the public security organs according to the law.	<ul style="list-style-type: none"> • Seized fake beef meat • Shut down processing site • Arrested 28 people engaged in the production 	MPS
FSL 2009	Art.77 Food safety supervision and administration have authority to take the following measures: 2) Conduct sample inspection...5) Close down places where illegal food production or trading activities are conducted.	<ul style="list-style-type: none"> • Conducted testing on fake beef 	AQSIQ

Table 2-3 Regulatory Instruments and Action Taken by Authorities in Beef Meat Scandal

MPS intervened because the producers were suspected to be criminal and AQSIQ conducted sample tests to prove the beef meat in question was adulterate. However, according to an official of CFDA, this incident hasn't received a final judgement yet owing to the lack of provisions on food related criminal conduct in criminal law.

2.3.4. Exercise of Regulatory Functions (3)—Coca-Cola chlorine contamination and tainted products withdrawal

Retrospective of Coca-Cola contamination⁵¹. In 2012, Coca-Cola Shanxi Beverages Co Ltd admitted that some of its products were contaminated by chlorine on 3 February due to small amounts of chlorine flowing into the water used for producing drinks. The Shanxi provincial AQSIQ tested final products produced between 4 and 8 February and ordered the company to cease production for rectification on 28 April. At the same time, the SAIC ordered supermarkets and retail stores to withdraw some brands, such as Cola, Sprite and Fanta till 19 April. President of Coca-Cola Greater China and Korea apologized for the public. The

⁵¹ Mark Astley. (May 2, 2012). China halts production at chlorine contamination Coca-Cola bottling plant. *Foodproductiondaily.com*. Retrieved on June 22, 2014 from <http://www.foodproductiondaily.com/Safety-Regulation/China-halts-production-at-chlorine-contamination-Coca-Cola-bottling-plant>.

company insisted that all products were safe, however, in order to save images in China, the chlorine-tainted products were recalled.

The followings are the provisions sourced and actions taken by the AQSIQ and SAIC.

Regulatory Instruments	Provisions	Actions	Regulatory Authorities
FSL 2009	Art.77 Food safety supervision and administration have authority to take the following measures: 2) Conduct sample inspection...5)	<ul style="list-style-type: none"> Conducted testing on chlorine-tainted products produced between 4 and 8 Feb. Testing showed that the content of chlorine was below 0.005mg/L. 	AQSIQ
National standards for drinking water quality	The maximum contaminant level of chlorine is 0.005mg/L	This standard was promulgated by the SAC.	SAC
Although the products in question were up to standard, this event revealed the quality and production problem at the plant.			
FSL 2009	Art.4 AQSIQ, ASIC... implement the supervision and administration respectively on food production, food circulation...	<ul style="list-style-type: none"> Ordered supermarkets and retail stores to withdraw several involving brands. Ordered the company to suspend the production. 	AQSIQ & SAIC

Since this cases happened before the restructuring of the old food regulatory regime, therefore SAIC still was in charge of food circulation so that’s why the SAIC was vested with power to execute withdraw and recall. The SFDA (now CFDA) at that time was responsible for food catering and didn’t get involved in.

2.3.5. Exercise of Regulatory Functions (4)—Risk Management on Phthalates Containing Foods

Retrospective of risk management on phthalates containing foods. Under the *FSL 2009*, the State Council charged MoH with conducting food risk assessment⁵². Therefore, MoH is responsible for monitoring the safe use of substances added in foods and food additives, such as authorizing substances that can be used in foods and forbidding the use of articles that are deemed unsafe. In 2011, MoH formulated a notice about the health risks posed by phthalates to alert manufacturers that adding

⁵² Art. 11 & 13, *FSL 2009*.

phthalates in food is illegal. At that time and also to date, the SFDA (now CFDA) managed health foods safety. In response to the notice, the SFDA together with provincial SFDA reviewed health foods database and then withdrew two specific health foods containing phthalates from market, and halted production in question. The co-regulation of MoH and SFDA in this case is detailed below:

Regulatory Authorities	Actions	Regulatory Instruments formulated in this case
MoH (to date NHFPC)	On 1 June 2011, MoH published a notice that phthalates and other chemical forms of it will pose health risk and may have been illegally added into foods/food additives.	MoH, Normative document No. 16, 2011 ⁵³ .
SFDA (to date CFDA)	On 3 June 2011, SFDA informed the provincial SFDA to withdraw two specific health foods containing phthalates from market, and suspend the production that used phthalates as food ingredient.	SFDA, Normative document No. 82, 2011 ⁵⁴ .
SFDA	On 8 June 2011, SFDA published an urgent notice that a Taiwan producer added phthalates in its food additives products and sold the additives to other Taiwan health foods manufacturers. SFDA ordered the provincial SFDA to tested health foods originated from Tanwai. Meanwhile, the tainted health foods must be traced, withdrawn and recalled by the manufacturers in question.	SFDA, Normative document No. 83, 2011 ⁵⁵ .
SFDA	On 25 July 2011, SFDA issued a normative document to the provincial SFDA and Testing Laboratory, which stipulated the substitutes of phthalates and other chemical forms of it. The alternatives shall be applied to the production within 3 months.	SFDA, Normative document No. 337, 2011 ⁵⁶ .

2.3.6. Exercise of Regulatory Functions (5) — CFDA Banned Deceptive Advertising

Retrospective of false advertising. In the routine inspection in 2013, the CFDA found 7 false advertisements in relation to health foods, among which some used misleading statements on health foods while others adopted health claims on conventional foods that were not allowed to carry health claims unless being authorized as health foods. For example, one health food was authorized to use the claim of improving immunity, its advertisement, on the other hand, used exaggerated

⁵³ Available at: http://www.gov.cn/zwgk/2011-06/02/content_1875356.htm

⁵⁴ Available at: http://law.pharmnet.com.cn/laws/detail_2246.html

⁵⁵ Available at: http://law.pharmnet.com.cn/laws/detail_2253.html

⁵⁶ Available at: http://law.pharmnet.com.cn/laws/detail_2275.html

claims and implied the product could cure disease by stating that “high blood sugar and high blood pressure were under control”⁵⁷. The CFDA banned and transferred the deceptive advertisements to the SAIC. SAIC punished the illegal companies by a fine.

The followings are some details about provisions sourced and actions taken by the CFDA and SAIC.

Regulatory Instruments	Provisions	Actions	Regulatory Authorities
Requirements on the Approval of Health Foods Advertisements	Art.11: Advertisements should not contain the false statements, including that health foods could prevent, treating or curing a human disease or imply such properties by means of pictograms, symbols or any other forms.	<ul style="list-style-type: none"> The advertisements in question were determined misleading and false. CFDA ordered companies in question to correct statements. CFDA transferred the illegal businesses to the SAIC 	CFDA
Advertisement Law of the People’s Republic of China	Art.18 CFDA is authorized to inspect the companies that use exaggerated or false statements in advertisements to correct the false advertisements.	<ul style="list-style-type: none"> SAIC Imposes penalty on the illegal food businesses. Available data show that one company got fine of €1,250. 	SAIC

2.3.7 Conclusion

To conclude, case 1—export meat products to China—basically serves as a guidance for exporters wishing exporting meat products to China, which details the exporting procedures and the authorities in charge.

Case 2, 3 4 and 5 present “small” food incidents in terms of societal impact: fraud beef meat scandal, food contamination incident, food risk management and false advertising on food. The idea is to demonstrate the Chinese approach to food regulation under new regulatory regime, therefore, food scandals, such as melamine

⁵⁷ <http://www.sfda.gov.cn/WS01/CL0606/92454.html>.

formula happened before 2013 were not considered. The major limitation on these cases is that they were all not fully reported, so that the discussions are kind of incomplete.

2.4. Summary

This Chapter aims to picture China's legal system and legal instruments pertaining to food. Having this picture beforehand will facilitate the analysis of the regulatory framework for health foods.

The key information is that foods in China are regulated by the laws, regulations, rules, normative documents and standards. Specifically, the only effective law pertaining to foods is Food Safety Law 2009, but due to the restructuring of the food regulatory regime in 2013, a new revision to Food Safety Law 2009 is reported to be released within this year.

Under the new food regulatory framework established in 2013, the most relevant regulatory authorities of food are the CFDA, MoA, NHFPC and AQSIQ. CFDA takes overall responsibility for food safety supervision and coordination. MOA is responsible for monitoring the quality and safety of farm produce and various other agricultural products. NHFPC deals with food safety risk assessment and develops food safety standards. AQSIQ mainly manages imported and exported food products, as well as food packaging materials, containers, and tools for food production and trading.

3 The Regulation of Health foods

Chapter 2 examines the Chinese food legal system. This chapter concerns the regulation of health foods, the core of which is premarket registration.

This chapter begins with an overview of the legislation pertaining to health foods (section 3.1), and then figures out what exactly health foods are, its categories and differences to conventional foods and drugs (section 3.2). Lastly, it focuses on the detailed registration procedures and requirements on health food claims, raw materials, production, labels, advertising and imported health foods (section 3.3).

Several case studies are provided to help better understand the execution of the legal requirements, such as the time frame and costs associated with registration, the Amway™ sample label and the paths to sell import (health) foods in China.

The purpose of this chapter is to answer Central Question 1: What is the regulatory framework for health foods in China? The answer forms a basis for the diagnosis and discussion of the challenges and hurdles for implementing the notification system for health foods in Chapter 4.

3.1 Scattered Health Foods Legislative System

This section reveals the legal instruments pertaining to health foods, which are composed of laws, regulations and rules (section 3.1.1), normative documents and standards (section 3.1.2).

Firstly, Chinese legislative hierarchy is refreshed and visualized in Figure 3-1. The point is laws outrank regulations and rules. Another thing is normative documents and standards are introduced to implement the provisions of laws, regulations and rules, although not being included in the Chinese legal system according to the Legislation Law.

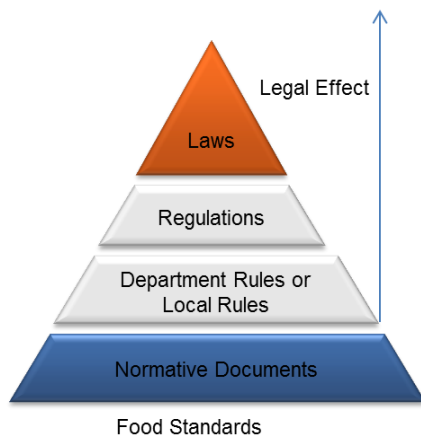


Figure 3-1 A review of Chinese Legislative System

3.1.1. Laws, Regulations and Department Rules

The important legal instruments on health foods for now are FSL 2009, Regulation on the Implementation of FSL 2009, and the rule entitled Measures on Health Foods Registration 2005.

However, before the establishment of current legal framework, the regulation of health food has experienced four stages. First, when health food industry started to boom in 1980s, the relevant legislation was absent, therefore, the concept of health food had no legal status⁵⁸. Second, in 1995 the MoH (now NHFPC) established the

⁵⁸ Li Jiang-hua and LI Dan. (2011). Current Status of Chinese Legal System and Standard System for Health Food. *Food Science*, Vol. 32 (21): 318-323.

first rule for regulating health foods—Provisions for Health Food 1996. Third, in 2005 the SFDA (now CFDA) completely took over MoH’s tasks for the regulation of health foods, and established the fundamental rule—Measures on Health Foods Registration 2005. Fourth, in 2009 FSL 2009 —currently the only law pertaining to food replaced Food Hygiene Law 1995 and went effective. At the same year, Regulation on the Implementation of FSL 2009 was enacted immediately, which stated CFDA shall strictly regulate production and sale of health foods. Furthermore, in accordance with this regulation, CFDA has drafted the first regulation on health foods. Table 3-1 presents such progress and the regulatory reform at each stage.

Development of the Legal System On Health Food (1)			
Period	Laws, Regulations & Rules	Definition of Health Foods	Regulatory Reform
Before Oct. 1995	<ul style="list-style-type: none"> No legislation 	Health food were either classified as <i>health Chinese traditional medicine</i> or treated as <i>new food materials</i> .	The health food industry was booming by the 1980s, but the legal instruments for health foods were absent till 1995.
Oct. 1995- June 2005	<ul style="list-style-type: none"> Rules—Provisions for Health Food 1996 <p>Based on Food Hygiene Law 1995</p>	Only referred to food that claimed to provide particular health care functions. (Art.2 Provision 1996)	<ul style="list-style-type: none"> Established the first legislation for health foods. Annulled <i>health Chinese traditional medicines</i>. Assigned oversight responsibility from MoH to SFDA after April, 2003. Initiated registration scheme as of June 2004.
July 2005 - May 2009	<ul style="list-style-type: none"> Rules—Measures on Health Foods Registration 2005 <p>Based on FHL 1995 and Provisions 1996</p>	Extended to include vitamins/ minerals supplements. (Art.2 Measures 2005)	<ul style="list-style-type: none"> Created a relative comprehensive rules. Imposed registration on all health foods, including vitamins/minerals supplements.
June 2009 to date	<ul style="list-style-type: none"> Measures 2005 <p>Mainly based on Food Safety Law 2009</p>	Excluded vitamins/ minerals supplements from health foods. (Art.51 FSL 2009).	<ul style="list-style-type: none"> Lack of corresponding legislation to implement health foods related provisions under FSL.
Future	<ul style="list-style-type: none"> Regulation on Health Food (not effective yet) <p>Based on the Revised FSL 2009 (not effective yet)</p>	Probably will only refer to foods providing health care functions. Probably will apply premarket Notification to vitamins / minerals supplements (Art.129 draft of Revised FSL)	<ul style="list-style-type: none"> To set out a systematic regulatory framework. To develop Notification system To lighten safety assessment burden on CFDA by adopting premarket registration & notification.

Table 3-1 Development of the Regulatory System On Health Food (1)

Note: This table is adapted from the GAIN Report (2012) that the regulatory system on health food reportedly has experienced three periods since 1996⁵⁹.

The scope of health foods also varied over the years. The key point is whether vitamins and minerals should be given another name, such as supplements, instead of health foods. Probably this will be the case in future, since the effective FSL 2009 no longer attributes to health foods the functions of supplementing minerals and vitamins⁶⁰.

This study further investigates the essential provisions stipulated in the aforementioned and other relevant legal instruments, although only 4 of 10 are effective (see Table 3-2).

⁵⁹

<http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Health%20and%20Nutritional%20Food%20in%20China%20-%20Shanghai%20ATO%20China%20-%20Peoples%20Republic%20of%2010-26-2012.pdf>, accessed on 6 July, 2014.

⁶⁰ Art.51 FSL 2009.

Law, Regulations and Rules Pertaining to Health Foods			
Legislation	Status	Provisions	Impact/Disadvantage
Laws			
FHL 1995 (Invalid as of June 2009)	nullified	Article 22, 23, 45. Stipulations: Foods claimed to have specific health care functions must be approved by the MoH.	<ul style="list-style-type: none"> Established the concept of 'food claimed to ...' for the first time under FHL. However, the definition of 'health food' was absent in these two laws.
FSL (Effective as of 1 June 2009)	Effective	Article 51. Stipulations: The state implements strict regulation of 'food claimed to ...'	<ul style="list-style-type: none"> Supervisory and regulatory measures mentioned in FSL still in a holding pattern.
Revised FSL	not passed	Article 56, 129. Stipulations: Premarket Registration and notification apply to health foods. Health food is defined as the food "that claims to ..., to be suitable for specific groups, and to be consumed at a specified quantity."	<ul style="list-style-type: none"> Probably will establish the definition of 'health food' by means of law. Probably will set up Notification programme to relieve both authorities and producers from administrative burdens. Not promulgated yet.
Regulations			
Regulation on the Implementation of FSL (Effective as of 20 July 2009)	effective	Article 63 Stipulations: CFDA shall strictly regulate production and sale of foods borne health claims. The specific measures shall be prepared by the State Council.	<ul style="list-style-type: none"> Specifies CFDA's oversight responsibility. Regulatory measures still under discussion since FSL went into force 4 years ago.
Regulation on Health Foods	not passed	(This regulation has been revised at least 5 times by the CFDA. The final version is currently not available online.)	<ul style="list-style-type: none"> Aims to set out specific supervisory measures and create notification system.
Department Rules			
Provisions for Health Foods 15 Mar. 1996	effective (to be nullified)	Work together, covers: <ul style="list-style-type: none"> Definition of health food and regulatory authority. Approval procedures. 	<ul style="list-style-type: none"> Implemented and supplemented by a number of normative documents; Out-dated due to no amendments made after FSL entering into force.
Measures on Health Foods Registration (Effective as of 1 July 2005)	Effective	<ul style="list-style-type: none"> Regulations on raw materials, production, distribution, inspection, labels, package insert and advertisement. Liability of producers and authorities. 	

Table 3-2 Law, Regulations and Rules Pertaining to Health Foods

Source: FHL 1995; FSL 2009; Draft of Revised FSL; Regulation on the Implementation of FSL; Draft of Regulation on Health Foods; Provisions for Health Foods 1996; Measures on Health Foods Registration 2005.

As can be seen from Table 3-2, the existing legal system for health foods is perceived fragmented mainly for three reasons:

First, the revision to the FSL 2009—the only law pertaining to food—needs to be enacted due to changes brought forth by the newly established food regulatory regime in 2013;

Second, some provisions of Measures 2005—the major legislation for health foods—are still based on the invalid FHL 1995;

Third, newly proposed Regulation on Health Foods—to implement specific supervisory measures stated in FSL 2009—is still under the discussion since 2009.

3.1.2. Normative Documents and Standards

This section looks at other regulatory instruments for health foods, namely the normative documents and standards, which address specific matters relevant to health food regulation, such as labels and Good Manufacture Practice (GMP).

The progress in the formulation of normative documents and standards can be divided into two stages based on the time when the two rules for health food—Provisions 1996 and Measures 2005—were promulgated.

An overview of the evolving development is presented in Table 3-3:

Development of the Regulatory System On Health Foods (2)		
Period	Regulatory Emphasis	
Provisions 1996	1	Enact Document No.38 pertaining to Health Foods hygiene requirements along with Provisions 1996.
	2	Enact Document No.38 pertaining to Health Foods Labels along with Provisions 1996.
	3	Enact Document No.38 pertaining to Technical Standards For Health Foods Approval along with Provisions 1996.
	4	Establish National Standards (GB16740) pertaining to health foods, combining manufacturing, labelling and hygiene requirements in 1997.
	5	Establish National Standards (GB17405) pertaining to GMP for Health Foods in 1998.
	6	Establish lists of authorized and unauthorized raw materials in 2002 and 2005.
	7	Revise technical standards for health foods approval in 2003.
	8	Establish Document No.77 pertaining to Inspection and Evaluation of the Implementation of GMP in 2003
Measures 2005	9	Establish Document No.261 pertaining to SFDA Inspection of Production Sites along with Measures 2005.
	10	Establish Document No.203 pertaining to the Requirements on Registration Dossiers along with Measures 2005.
	11	Establish Document No.211 pertaining to Health Foods Advertisement in 2005.
		Establish Document No.304 pertaining to Health Foods Name in 2007.
	12	Establish lists of accredited Testing Laboratories that carry out safety assessment on health foods and create the management measures between 2010 to date.

Table 3-3 Development of the Regulatory System On Health Food (2)

Source: Zhe Jiang provincial CFDA⁶¹.

Table 3-3 indicates that various normative documents and standards were formulated, covering different aspect relevant to health food regulation, which includes the production, authorization and communication (labels and advertisement). It seems that every aspects have been considered, but the biggest problem is the lack of a consistent and systemic framework or guidance for industry to implement. For example, if a producer wished to build a plant to develop health foods, he would get confused and frustrated to get started because he may know that Measures 2005 should be referred to in the first place, however, only referring to Measures 2005, he does not get a picture of the whole regulatory instruments involved due to the lack of the connection between Measures 2005 and individual national standards and normative documents.

3.1.3. Conclusion

The rule—Measures 2005—is the foundation of regulating health foods. Measures 2005 implements FSL 2009 and is supported by a national standard on health food and various normative documents. The biggest problem at present is twofold. First, FSL 2009 stipulates that other specific measures to regulate health foods should be formulated but what those measures refer to still remain unclear. Second, within the current legal instruments (Measures 2005, national standards and normative documents), there is an absence of close connection between these legal documents. In other words, the predominant rule Measures 2005 is more like an independent rule rather than accommodating other legal instruments as the standards and normative documents related to health foods are rarely reflected in it.

⁶¹ http://www.chinafdc-law.com/laws/list_1-27_5-119_1.html, accessed on 6 July, 2014.

3.2. What Is a “Health Food”?

The concept of health food can be traced back to ancient China. There is an ancient saying in China that is still widely acknowledged by Chinese nowadays that food is better than tonics and food treatment is superior to all kinds of medicine. Food treatment is encompassed in the theory of the Traditional Chinese Medical System, which maintained and promoted health by using the natural sources of plants, animals and minerals. The therapeutic effects of these Chinese medicinal herbs and natural sources of animals and minerals, such as ginseng and Sanchi, are known as Traditional Chinese Medicine (TCM) and the foundation of health foods today.

This section deals with the statutory definition of food and health food, its categories and relationship to foods, drugs and foods for special dietary uses, as well as authorities responsible for regulating health foods.

3.2.1. The Definition of Food

Food, as defined in Article 99 of FSL 2009 means that any processed or raw substance for people to eat or drink, as well as substances which are both food and drug according to the tradition, excluding substances for the purpose of treatment.

The definition of food demonstrates that food in China is only for human consumption.

3.2.2. The Definition of Health Foods

Both invalid FHL1995 and effective FSL 2009 did not defines health foods, instead, health foods were described as “food claimed to have specific health care functions” and “shall be no acute, sub-acute or chronic harm to the human body. Their labels and instructions shall not contain disease prevention or treatment functions”⁶².

Measures 2005, the foremost legislation for health foods, defined health foods as “foods that claim to have certain health functions or aim at supplementing vitamins and minerals. Those foods are used for certain groups of people with the aim to

⁶² Art. 51, FSL 2009.

modify a physiological function instead of curing diseases and will not cause any acute, sub-acute or chronic damages to human body”⁶³.

Obviously, Measures 2005 extended the scope of health food to include vitamins/minerals supplements. In either case, the fundamental requirements on health foods were not changed, that is, health foods cannot be claimed to cure diseases and cause any harms to the human body.

3.2.3. Categories

Health foods were divided into two categories under Measures 2005: foods having health functions and vitamins/minerals supplements. Examples are fish oil, fruit and vegetable fibre, carotene, garlic, ginkgo, fish oil, vitamin supplements, mineral supplements and botanical supplements.

3.2.4. Difference to Conventional Foods, Drugs and Foods for Special Dietary Uses

Health Foods vs. Conventional Foods

Health food is one category of food⁶⁴. However, health foods have its unique features. The biggest uniqueness is health foods need to be approved by authority. It also includes that in health foods, specific ingredients are accumulated to certain degree to modify physiological functions or provide health benefits while that of conventional foods are at low content to give additional benefits.

Health Foods vs. Drugs

Health foods are food and thus they are totally different from drug. Specifically, health foods can give health benefits but absolutely cannot be claimed to cure disease while drugs can.

Health Foods vs. Foods for Special Dietary Uses

Another food category that is likely to be confused with health foods by consumers is *foods for special dietary uses*. Indeed, these two categories share some similar

⁶³ Art. 2, Measures 2005.

⁶⁴ Art. 3 (1) of National Standard GB16740—General Standard for Health Foods.

features but are different from each other. The similarity between the two groups is they both contain certain amount of functional components and are suitable for certain groups of people. The difference mainly lies in the amount of functional components in *foods for special dietary uses* is not sufficient to give health benefits while health foods does. For example, infant formula is a kind of *foods for special dietary uses* but not a health food.

3.2.5. Responsibility of Manufacturers and Regulatory Authorities

Manufacturers' responsibility

Under FSL 2009, food producers and traders take the primary responsibility for ensuring the safety of health foods. They should engage in production and distribution activities in accordance with legislation and food safety standards.

Authorities' functions

CFDA. Under the new food regulatory regime, the oversight responsibility for health food rests with CFDA, including approving sample products, health claims, labels and advertisement. This also involves the obligation of post-market surveillance, such as to withdraw and/or recall the unsafe products. Furthermore, CFDA stays involved in drafting health foods-related regulations and rules.

AQSIQ. AQSIQ is mainly responsible for the inspection and quarantine of imported and exported food products. For example, AQSIQ is authorized to evaluate whether an import health food complies with the Chinese safety requirements to enter the Chinese market.

SACI. Any firms in China are required to register with the SACI to obtain Business License prior to starting business.

MPS. MPS assists the CFDA in post-market surveillance, especially when a production and/or distribution activity was suspected to be criminal. In such a context, MPS has authority to penalize the illegal conduct, including detaining and destroying

foods deemed to be unsafe and shutting down the places where the illegal food production and/or trading activities are conducted⁶⁵.

NHFPC. NHFPC is in charge of the development of and revision to health foods standards.

⁶⁵ Art. 77, *FSL 2009*.

3.3. Premarket Approval Scheme–Registration

Registration, as specified in Article 4 of *Measures 2005*, refers to the products application and CFDA’s approval procedures. The process of approval includes assessing whether the sample product complies with requirements on safety, quality, labels and claims.

Registration is the core of the regulation of health foods. According to Article 5 and Article 14 of *Provisions 1996*, only when manufacturers successfully registered their sample products with the MoH (taken over by the CFDA now), and passed through MoH’s hygiene inspection (replaced by CFDA’s GMP certification now), were they granted Production Permit and allowed to start production.

Subsection 3.3.1 to 3.3.6 analyse 6 interrelated aspects: registration procedures, health claims, raw materials, manufacture, labelling and advertising, as well as import health foods. The analysis is based on *Measures 2005*, the foremost legislation on health foods at present, together with the most relevant and recently issued normative documents and standards.

Referred relevant regulatory tools are listed as follows:

	General provisions	Registration procedures	Claims	Raw materials	Production	Labelling	Advertising
Measures 2005	Yes	Yes	Yes	Yes	Yes	Yes	
Doc. No.4266		Yes	Yes	Yes			
Doc. No.51 ⁶⁷				Yes			
Doc. No.202 ⁶⁸				Yes			
Doc. No.38 (1) ⁶⁹				Yes			
Doc. No.38 (2) ⁷⁰						Yes	
Doc. No.211 ⁷¹							Yes
National Standard GB 17405 ⁷²					Yes		
Doc. No.77 ⁷³					Yes		
National Standard GB 16740 ⁷⁴						Yes	

Note: Hyperlinks that direct to the original version of the above regulatory tools are provided on page of “List of Abbreviations” following the cover page. Currently, only a few are available in English.

⁶⁶ [*Technical Standards for Testing & Assessment of Health Foods 2003*](#)

⁶⁷ [*Notice on the Regulation of Raw Material as Health Food Ingredient 2002*](#)

⁶⁸ [*Provisions on Vitamins/Minerals Supplements 2005*](#)

⁶⁹ [*Hygiene Requirements on Health Foods*](#)

⁷⁰ [*Requirements on Health Foods Labels 1996*](#)

⁷¹ [*Requirements on the Approval of Health Foods Advertisements 2005*](#)

⁷² [*Good Manufacture Practice on Health Foods GB 17405*](#)

⁷³ [*Provisions on Inspection and Evaluation of the Implementation of GMP 2003*](#)

⁷⁴ [*General Standards for Health Foods*](#)

3.3.1. Registration Procedures and Assessment

The procedures of and assessment on the registration of sample health foods are regulated under two instruments respectively:

- Chapter II of Measures 2005
- Doc. No.42—Technical Standards for Testing & Assessment of Health Foods

First of all, Chapter II “Application and Approval” of *Measures 2005*, covering Article 7 to 58, specifies that health foods, whatever it is imported or domestic, must be registered with the CFDA, together with adequate scientific report to substantiate that the product in question is safe. The burden of carrying out the scientific experiments falls on national Testing Laboratories accredited by the CFDA. Chapter II of Measures 2005 also outlines the registration procedures (see Figure 3-2).

Second, another fundamental instrument for the authorization is a normative document entitled *Technical Standards for Testing & Assessment of Health Foods 2003 (Doc. No.42)*, a revision to the former version granted in 1998. It is a rationale for health foods authorization as it sets standards on performing experimental assessment on sample product and evaluating the qualification of sample product.

The registration process is composed of 5 steps based on the Chapter II of *Measures 2005*:

- First, applicants approach a Testing Laboratory who carries out initial assessment and presents results of the assessment in report. This report will then be forwarded to CFDA or provincial FDA.
- CFDA or provincial FDA conducts the first review of the application dossiers and the assessment report produced by the Testing Laboratory. If no safety concerns raised,
- CFDA or provincial FDA delegates a different Testing Laboratory to carry out the second safety assessment. If no safety concerns raised,
- CFDA requests its Evaluation Committee of Health Foods to organise the final evaluation. If no safety concerns raised,
- CFDA progresses to the administrative approval.

These five steps are visualized in Figure 3-2:

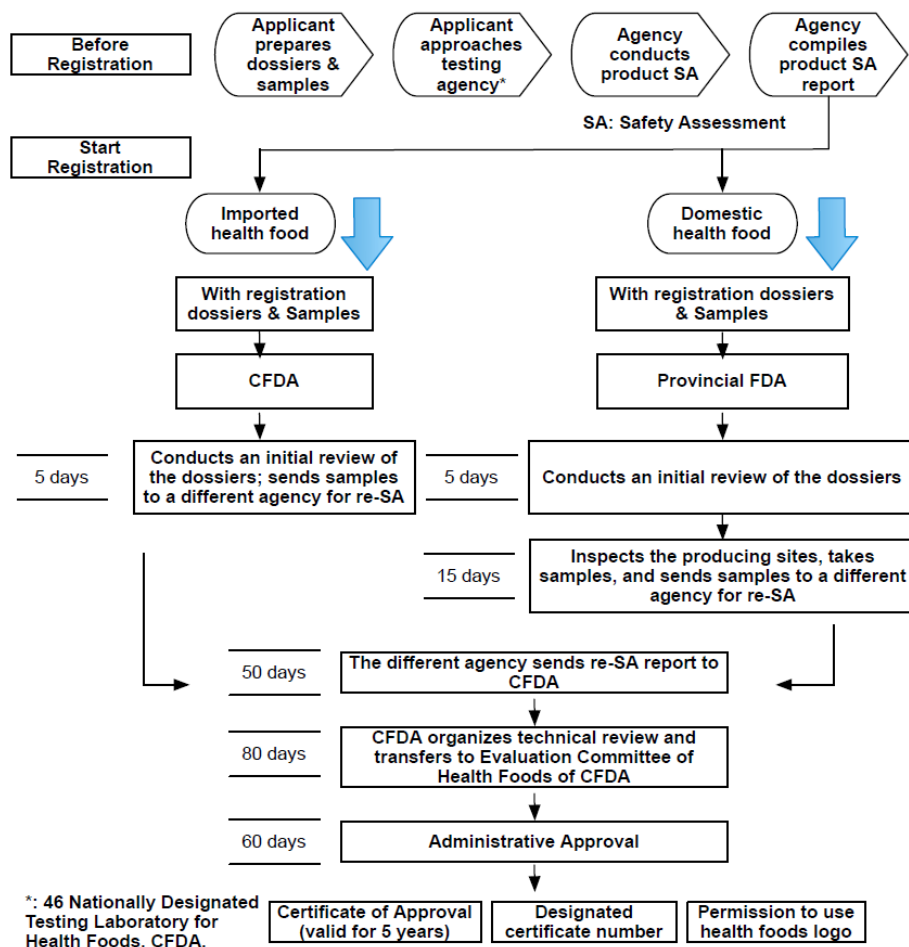


Figure 3-2 Registration Procedure of Health Foods under *Measures 2005*

Source: *Measures 2005*

Under this registration system, products in question will be evaluated three times. Specifically, the initial assessment is carried out by one of 46 Nationally Designated Testing Laboratories (the number keeps changing). In process of registration, re-evaluation conducted by a different Testing Laboratory and final (third) assessment by the CFDA Evaluation Committee are compulsory.

The three evaluations intend to maximize the safety of health foods. However, one concern may be arisen regarding the capacities of authorities to conduct assessment for a fast-growing industry. Specifically, a limited number of qualified Testing Laboratory, 46 so far (by February 2014), undertake the health claim evaluation, toxicology assessment and other obligatory testing for the whole industry, which

include 2000 manufacturers in 2010, as reported by the CFDA⁷⁵. As a result, the current premarket registration may have posed hurdles for an efficient CFDA authorization and thus the idea of premarket notification sounds plausible. The problem regarding the CFDA not capable of granting authorization timely will be further discussed in Chapter 4.

During the CFDA authorization, the results of the three assessments decide whether a health food can be approved. Assessment items specified in Article 21 of Measures 2005 include the followings:

Sample Assessment Items	Application	Instruments of Assessment
Hygiene Testing	To all health foods	Doc. No.42
Stability Testing		
Testing on substances that characterise product		
Toxicology Testing	Not required for vitamins/minerals supplements	
Correct use of health claims on positive lists		
Additional Testing, such as hormones and dopes	Depends on specific substances	

To interpret the consequence of abstract assessment items into figures that producers could easily understand, the data of registration costs and time were collected from two Chinese registration agents Miracle Consulting (miracleconsulting.com.cn) and Tianjianhuacheng Consulting (zhuceabc.cn):

CFDA/ Testing Laboratory (TL)	Testing items	Time Scale	Costs
TL	Hygiene Testing	120 days	€2,500~3,800
TL	Stability Testing		
TL	Testing on substances that characterise product		
TL	Toxicology Testing	150 ~ 330 days (not required for vitamins/minerals supplements)	€5,000~7,500
TL	Claims Testing		€10,000~35,000
Above only concerns the 1st assessment			
CFDA	Review dossiers	5 days	Free of charge
CFDA	Take samples for 2 nd	15 days	Free of charge

⁷⁵ Jinjing Zhang. 2011. Regulation on Health Food in China. US-China Food and Drug Law Conference. Available at <http://www.fdi.org/docs/default-document-library/jinjing-zhang---regulation-on-food---translated.pdf?sfvrsn=0>.

	assessment		
TL	2 nd assessment	50 days	€1,300~2,500
CFDA	Organize final evaluation	85 days	Free of charge
CFDA	Final evaluation	150 days	Free of charge
CFDA	Administrative approval	60 days	Free of charge
A rough estimate			
Health foods other than vitamins/minerals supplements		635 ~ 815 days	€18,800 ~ 48,800
Vitamins/minerals supplements		485 days	€3,800 ~ 6,300

Source: Miracle Consulting (miracleconsulting.com.cn); Tianjianhuacheng Consulting (zhuceabc.cn/)

3.3.2. Claims Authorization

Before any discussions, understanding what a claim means is necessary. The major legislative instruments pertaining to health foods covered in Section 3.1 did not provide any explanations. International reference standards, namely Codex Alimentarius Guidelines on Claims⁷⁶, defines claim as “any representation which states, suggests or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality”.

In China, two instruments were adopted by the CFDA as main tools to authorize health foods claims: Measures 2005 and Doc. No.42–Technical Standards for Testing & Assessment of Health Foods. The former one provides general requirements on claims. The latter one establishes a positive list of 27 permitted claims (see Figure 3-3).

As regards general requirements, firstly, the authorization of claims follows the same five steps as that of sample products (see Figure 3-2). Secondly, according to Article 20 of Measures 2005, producers seeking the authorization of claim(s) should only use the 27 allowable claims, otherwise, additional requirements are required. Specifically, applicants shall carry out additional animal test and human trial before approaching Testing Laboratory and fulfil concrete material requirements listed in Appendix 1 of Measures 2005. Although as of July 2005, the application of new claims is allowed, a published article from a CFDA official⁷⁷ in 2011 indicates that the

⁷⁶ Available at: <http://www.codexalimentarius.org/standards/list-of-standards/>.

⁷⁷ Jinjing Zhang. 2011. A comparative research on the regulation of health foods in China and other countries. *Shanghai Drug and Food Information Research*. 111. (Translated).

CFDA has not received any such applications by 2011. Seemingly, requesting other claims beyond the positive list is not wise at present since the CFDA lacks experience in approving new claims and more importantly, new evaluation criteria on the approval of new claims are still prepared: after the final criteria are established, a normative document will be promulgated for this purpose, whose provisional name is “Provisions on the Evaluation of New Claims Made on Health Foods”⁷⁸.

The 27 permitted claims are detailed in Figure 3-3:

Claims	
Function	
1) Enhance immunity	13) Increase bone density
2) Antioxidative	14) Improve nutritional anemia
3) Assist in memory improvement	15) Assist in protecting against chemical injury to the liver
4) Alleviate eye fatigue	16) Eliminate acne
5) Facilitate lead excretion	17) Eliminate skin chloasma
6) Moisten and clean throat	18) Improve skin water content
7) Improve sleep	19) Improve skin oil content
8) Facilitate milk secretion	20) Regulate gastrointestinal tract flora
9) Alleviate physical fatigue	21) Facilitate digestion
10) Enhance anoxia endurance	22) Facilitate feces excretion
11) Assist in irradiation hazard protection	23) Assist in protecting against gastric mucosa damage
12) Improve child growth and development	
Reduction of disease risk	
24) Weight loss	26) Assist in blood sugar reduction
25) Assist in blood lipids reduction	27) Assist in blood pressure reduction

Figure 3-3 27 Permitted Health Claims in China

Source: Yuexin Yang. Scientific Substantiation of Functional Food Health Claims in China.⁷⁹

It should be mentioned that this list was modified based on the previous 12 claims introduced in 1996 and 1997 respectively, 24 claims in total. Doc. No.42 established the final list. Doc. No.42 also serves to judge whether a health food is properly claimed as Chapter III of it provides a step-by-step instruction for Testing Laboratory to ensure that only appropriate claims were applied. Examples of approved health foods suggest that more than one claim are allowed to use on a specific health food⁸⁰.

⁷⁸ Available at: (Chin) <http://www.sda.gov.cn/WS01/CL0780/75896.html>

⁷⁹ Yang Y (2008) Scientific substantiation of functional food health claims in China. *Journal of Nutrition* 138, 1199S–1205S. Chinese content are available at <http://www.sda.gov.cn/WS01/CL1163/>.

⁸⁰ Approved health foods are stored in the CFDA database.

However, based on the registration timescale created in section 3.3.1, the more claims were applied, the more time was needed to assess.

Since getting claims approved is costly, properly selecting claims becomes important. To give practical suggestions to applicants, relevant articles are reviewed and five suggestions are formed:

- Firstly, different functional component contributes to different claim(s). The application of a claim is based on the function on functional component, which is, as defined in Health Food Standard (GB 16740)⁸¹, the component that could regulate human body functions by initiating enzyme activities or by other means. For example, CFDA health foods database shows that Docosahexaenoic Acid, known as DHA, can bear a claim of “improve memory”. Radix Astragali, the article also used in Chinese traditional medicine, has been substantiated to assist in blood lipid reduction.
- Secondly, according to Doc. No.42, specific claims require either animal testing (AT) or human testing (HT) or the combination of the two (animal & human testing, AHT). A detailed requirements are summarized:



AT 7	HT 5	AHT Other 15
Protect liver against chemical damage	Improve oil content of the skin	
Enhance immunity	Relieve eye fatigue	
Improve sleep	Eliminate acne	
Relieve physical fatigue	Eliminate chloasma	
Enhance oxygen deficient endurance	Improve moisture of the skin	
Help protect against radioactive matters		
Increase bone density		

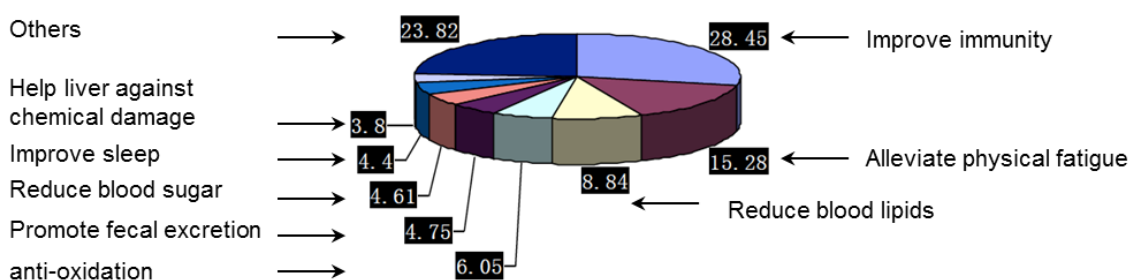
Source: Doc. No.42

- Thirdly, time frame and cost varies by different testing. Miracle Consulting provides the following data on its website:

⁸¹ Available at: <http://apps.fas.usda.gov/gainfiles/200111/130682581.pdf>.

AT	HT	AHT
5 ~ 6 months	8 months	10 months
10,000~ 20,000€	25,000~ 27,000€	25,000~ 35,000€

- Fourthly, since the application cost in terms of both time and money are huge, taking into account how frequently a health claim was used would be helpful to decrease the investment failures. Researcher Mei He, from the Chinese Centre for Disease Control and Prevention, in her study “Status of health foods industry in mainland China”⁸² (literally translated), pointed out that among the 27 allowable claims, 4 claims, namely the claim of improve immunity, assist in blood lipids reduction, anti-oxidation and alleviate physical fatigue are most commonly used by manufacturers, amounting to 60% of the overall approved products. A detailed claims usage distribution was provided in the same study (see below).



Source: Mei He. Status of health foods industry in mainland China.

Note: The content of this study is only presented in slides, not in the article⁸³.

- Last but not least, in June 2012, the CFDA issued a notice codified No.268⁸⁴ on the amendment of the effective 27 claims and sought public comments. According to this notice, 5 claims are likely to be eliminated in future, i.e. the claim of help protect against radioactive matters, improve moisture of the skin, improve oil content of the skin, improve growth and development and lastly,

⁸² Mei He. Status of health foods industry in mainland China. The content of this study is only presented in slides, not in the article. Available at:

http://www.google.com.hk/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=1&ved=0CCcQFjAA&url=http%3A%2F%2Fwww.fda.gov.tw%2Fupload%2F133%2FContent%2F991201-%25E5%2585%25A9%25E5%25B2%25B8%25E5%2581%25A5%25E5%25BA%25B7%25E9%25A3%259F%25E5%2593%2581-1%25E4%25BD%2595%25E6%25A2%2585_%25E5%25A4%25A7%25E9%2599%25B8%25E4%25BF%259D%25E5%2581%25A5%25E9%25A3%259F%25E5%2593%2581%25E7%2594%25A2.pps&ei=l_xPU9unOMfX0QWj54HYBg&usq=AFQjCNFmhNTKDmXYPMJ5I3ocFEyBJYCyJg

⁸³ *Ibid.*

⁸⁴ Available at: (Chin) <http://www.sda.gov.cn/WS01/CL0780/72295.html>

help in lowering blood pressure. When selecting claims, manufacturers are strongly advised to avoid using these 5 claims.

3.3.3. Regulation of Raw Materials

Likewise, understanding what raw materials refer to is essential to start the following discussion. As defined in Article 59 of Measures 2005, raw materials used in health food refer to the original materials related to the functions of health foods, in other words, the substances that characterise the products.

The safety of raw materials as well as vitamins and minerals, can decisively impact the approval of final product. As significantly important as it is, raw materials are regulated under five regulatory instruments:

- Measures 2005, Chapter III
- Doc. No.38 (1)–Hygiene Requirements on Health Foods
- Doc. No.42– Technical Standards for Testing & Assessment of Health Foods
- Doc. No.202– Provisions on Vitamins/Minerals Supplements
- Doc. No.51– Notice on the Regulation of Raw Material as Health Foods Ingredient

To begin with, Measures 2005 provides general provisions on the regulation of raw materials in Chapter III, ranging from Article 59 to 66. The key provisions are Article 61 that raw materials should not have any form of harm to the human body and Article 63 that the raw materials published by the SFDA and used in the production of conventional food, can be used in health food, except that producers could provide a report of additional self–conducted toxicology tests and submit published scientific evidence regarding the safety of new substances.

Article 61 highlights the safety of raw materials. A set of safety standards was set out in Doc. No.38 (1), including standards on physical, chemical and microbiological agents. Examples of microbiological criteria are translated and provided as follows:

Liquid Products				
Aerobic plate count (cf/g/ml)	Coliform bacteria (100g/ml)	Mold (cfu/g/ml)	Yeast (cfu/g/ml)	Pathogen
≤1000	≤40	≤10	≤10	Absent

Source: Doc. No.38 (1)

In addition, according to Doc. No.38 (1), the manufacturer could follow national standards GB 5009 on testing physical and chemical agents and GB 4789 on testing microbiological agents to self-assess whether safety requirements are met.

Article 63 emphasises the use of approved ingredients, which were laid down in Doc. No.51 and Doc. No.202. The major contributions of these documents are the lists of authorized and unauthorized raw materials used in health foods developed by the CFDA and MoH for manufacturers to consult. Three major lists are explained as follows:

- when developing vitamins/minerals supplements, Doc. No.202 should be referred to as it listed 14 vitamins and 10 minerals as well as minerals substances that may be used for manufacturing vitamins/minerals supplements.

14 permitted vitamins:

Vitamin A, Vitamin C, Vitamin D, Vitamin B1, Vitamin B2, Vitamin B6, Vitamin B12, Vitamin E, Vitamin K, Niacin, Folic Acid, Biotin, Choline and Pantothenic Acid.

10 allowable minerals:

Calcium, Magnesium, Potassium, Manganese, Molybdenum, Iron, Zinc, Selenium, Chromium and Copper.

Source: Doc. No.202

- when producing functional foods, Doc. No.51 is of fundamental importance because it formed “Three Lists” of authorized and unauthorized materials for the use in health foods. The “Three Lists” are the A “List of Substances that Can Be Used in Food and Drug”, B “List of Substances that Can Only Be Used in Health Food”, and C “List of Substance that Cannot Be Used in Health Food”. List A includes 84 substances that are the important sources for developing conventional foods and health foods. List B contains 114 substances that are authorized to add only in health foods, not in conventional foods. Lastly, 59 unauthorized materials are given in List C. In the same study researcher Mei He⁸⁵ found that in addition to the 198 (84

⁸⁵ Mei He. Status of health foods industry in mainland China. The content of this study is only presented in slides, not in the article. Available at: <http://www.google.com.hk/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=1&ved=0CCcQFJAA&url=http%3A%2F%2Fwww.fda.gov.tw%2Fupload%2F133%2FContent%2F991201->

plus 114) approved substances that contain functional components (such as protein and fibre), conventional food, including vegetable, fruit, grain and much more are generally regarded the source of functional components as well. It was further concluded by Mei He that between 1996 and 2008, the most frequently used functional components were saponins, carbohydrate and flavonoid, accounting for 26%, 17% and 13% respectively of all materials selected by manufacturers. Saponins, attracting the most attention, can be found in around 100 different plant families, including food sources such as beans and legumes. CFDA database containing all approved health foods shows that health benefits of saponins include improving immunity and reducing risk of heart disease. Examples of other authorized and unauthorized substances are as follows:

PinYin name	Pharmaceutical name	English name
<u>Authorized herbs in functional foods</u>		
Renshen	<i>Radix ginseng</i>	Ginseng
Renshenye	<i>Folium ginseng</i>	Ginseng leaf
Renshenguo	<i>Potentilla anserina L.</i>	Silverweed cinquefoil
Sanqi	<i>Radix notoginseng</i>	Sanchi
Tufuling	<i>Rhizoma smilacis glabrae</i>	Glabrous greenbrier rhizome
Daji	<i>Herba seu radix Cirsii japonici</i>	Japanese thistle herb or root
Nuzhenzi	<i>Fructus ligustri lucidi</i>	Glossy privet fruit
Shanzhuyu	<i>Fructus corni</i>	Common macrocarpium fruit
Chuanniuxi	<i>Radix cyathulae</i>	Medicinal cyathula root
Chuanbeimu	<i>Bulbus fritillariae unibracteatae</i>	Unibract fritillary bulb
<u>Unauthorized herbs in functional food</u>		
Bajiaolian	<i>Rhizoma et radix dysosmatis</i>	Common dysosmatis rhizome and root/sixangular dysosmatis rhizome and root
Shanlangdang	<i>Radix anisodi tangutici</i>	Tangut anisodus radix
Ma sang ye	<i>Coriariae sinicae folium</i>	Tutu leaf
Maqianzi	<i>Semen strychni</i>	<i>Nux vomica</i>
Tianxianzi	<i>Semen hyoscyami</i>	Henbane seed
Badou	<i>Semen crotonis</i>	Croton seed

Figure 3-4 Examples of Authorized & Unauthorized Substances for Use in Health Foods

%25E5%2585%25A9%25E5%25B2%25B8%25E5%2581%25A5%25E5%25BA%25B7%25E9%25A3%259F%25E5%2593%2581-1%25E4%25BD%2595%25E6%25A2%2585_%25E5%25A4%25A7%25E9%2599%25B8%25E4%25BF%259D%25E5%2581%25A5%25E9%25A3%259F%25E5%2593%2581%25E7%2594%25A2.pps&ei=l_xPU9unOMfX0QWj54HYBg&usg=AFQjCNFmhNTKDmXYPMJ5I3ocFEyBJYCyJg.

Source: Yuexin Yang. Scientific Substantiation of Functional Food Health Claims in China⁸⁶.

- when developing other specific types of functional foods, for example, probiotics, normative document No.202 granted in 2005 by the SFDA was in place. This document set out 11 fungi and 10 probiotics to be used in health foods. 10 probiotics are detailed below:

Approved 10 Probiotics Used in Health Foods under Document No.202:

Bifidobacterium bifidum

Bifidobacterium infantis

Bifidobacterium longum

Bifidobacterium breve

Bifidobacterium adolescentis

Lactobacillus delbrueckii subsp. Bulgaricus

Lactobacillus acidophilus

Lactobacillus casei subsp. Casei

Lactobacillus reuteri

Streptococcus thermophilus

Contents above elaborate on what substances were allowed and what were prohibited. In the practical assessment, Testing Laboratories will follow protocol specified in Doc. No.42 to carry out Testing on raw materials.

Two suggestions so far for producers are that since the regulatory framework for health foods is changing and the list of permitted claims as explained in section 3.3.2 is also undergoing modification, materials as well as claims that were frequently used should be the first consideration. In addition, manufacturers attempting to enter the health foods business should keep a close eye on any potential regulatory changes.

⁸⁶ Yang Y. (2008). Scientific substantiation of functional food health claims in China. Journal of Nutrition 138, 1199S–1205S. Chinese content are available at <http://www.sda.gov.cn/WS01/CL1163/>.

Newly granted documents will be available at CFDA's website allocated to health foods: <http://www.sfda.gov.cn/WS01/CL1027/>.

3.3.4. Regulation of Manufacture

The first time that the regulation of health foods production was addressed was in 1996 when the *Provisions 1996* was promulgated. *Provisions 1996* was the first legislation pertaining to health foods. Article 14 of it specified that only manufacturers who passed through MoH's hygiene inspection would be granted Production Permit and allowed to start production.

In 1998 the MoH formulated a national standards GB 17405–1998 on GMP for health foods to incorporate the concept of Hazard Analysis and Critical Control Points (HACCP) with reference to GMP for drug⁸⁷. This standard covered 7 chapters, being 1) production operator' practical skills and educational qualifications, 2) design of plant, 3) safety control of raw materials in the plant, 4) production process, 5) product storage and transportation, as well as 7) product quality and safety management. However, there was no supervisor tool in place at that time for the MoH to judge whether manufacturers complied with GMP requirements. Given this fact, it can be reasonably concluded that hardly did any health foods manufacturers strictly adopt GMP throughout the first few years, partly because of no regulatory measures available and mainly owing to the fact that the permission of production still depended on hygiene inspection instead of GMP assessment.

In response to the regulatory need for GMP assessment, normative document entitled *Provisions on Inspection and Evaluation of the Implementation of GMP 2003* was granted in 2003, which classified the 7 Chapters of GB 17405 into 140 assessment items. Among which there were 18 most important items, 32 important items and 90 general items. Whether or not a plant could be certified as GMP depends on the number and ratio of items that failed to meet requirements. The criteria translated from the original content are detailed as follows:

Results	Ratio / number of items that below standards		
	Most important items	Important items	General items
GMP Certified	0	< 3	< 20%

⁸⁷ GB 17405–1998 On GMP For Health Foods.

Close to GMP Certified (Re-assessment required)	0	< 3	20% ~ 30%
	0	3 ~ 5	≤20 %

Source: Provisions on Inspection and Evaluation of the Implementation of GMP 2003

Two years after the announcement of the implementation of GMP, Measures 2005 was published for the purpose of systematically regulating premarket registration that was already initiated as of June 2004. However, Measures 2005 did not place as much emphasis on GMP as on raw material, provided that only one provision was made concerning GMP. Specifically, Article 26 stipulates that the production of health foods shall be in accordance with national standards of GMP, namely, GMP on Health Foods GB 17405. However, Article 26 did not explicitly connect GMP assessment with production permit approval. In other words, it is not clear whether GMP assessment was compulsory. It was also quite vague whether GMP audit was the prerequisite for obtaining production permit.

To make clear how this matter was dealt with in the real situation, an internal training material provided by the CFDA was found⁸⁸. According to it, two permissions are required in advance of organizing the production lawfully. Firstly, a manufacturer should have the Certificate of Approval granted by the CFDA, which means product in question has been already authorized as health food. Secondly, a manufacturer should be certified as GMP manufacturer by the provincial CFDA and thus obtain Production Permit accordingly. (Of course, it doesn't necessarily mean that the manufacturers should be the applicants for registration, because holders of Certificate of Approval can sell their Certificate of Approval to a company that has production ability). However, GMP was not fully adopted among health foods manufacturers as it should be. In their empirical study conducted by Zhuge and Liu in 2012⁸⁹, 6 out of 29 health foods plants in a city named Shenzhen were not certified as GMP manufacturer but still engaged in the production of health foods. This may imply that although the CFDA aimed at pushing manufacturers to adopt GMP, in reality there is still a long way to go before all adaptation.

⁸⁸ Available at:

http://www.google.nl/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=1&cad=rja&uact=8&ved=0CCkQFjAA&url=http%3A%2F%2Fwww.jlida.gov.cn%2Fztlm%2Fshipinxuke%2Fbaojianshipingaikuang.ppt&ei=UQBvU93qLMnpPKX1gNAM&usq=AFQjCNGbAARwBlq4M1R_QuirtsfRq3cyA&bvm=bv.65058239.d.ZWU. Accessed on 21 April 2014.

⁸⁹ Zhuge Li-ying and Liu Hao. 2012. GMP Implementation Analysis of Dietary Supplements. *Journal of Asian Drugs*: 7(1) pp. 45-47. Available: <http://www.asianjsp.com/qikan/manage/wenzhang/AJSP2011-0060.pdf>.

To conclude, the production of health foods is regulated under three instruments:

- Measures 2005
- GMP on Health Foods GB 17405–1998
- Doc. No.77–Provisions on Inspection and Evaluation of the Implementation of GMP

The regulatory model of “GMP certified first, production next” is not fully implemented nationwide at present, but adopting GMP has greatly improved compared with years ago and is getting closer to the all implementation.

Under this model, steps manufacturers should take from registering health food(s) till getting Production Permit are summarized as follows:

- Register health food(s) with CFDA and obtain the Certificate of Approval;
- Set up a wholesome GMP plant in accordance with national standards—GMP on Health Foods GB 17405;
- Prepare certification dossiers in accordance with Doc. No.77, i.e. Provisions on Inspection and Evaluation of the Implementation of GMP 2003, the provincial CFDA depends on which to conduct GMP evaluation.
- Request GMP audit from the local provincial CFDA;
- Provincial CFDA conducts onsite inspection of the GMP plant in question;
- Provincial CFDA grants Production Permit to qualified GMP plant in 10 days, or gives comments to those fail to pass audit.

As regards manufacture, two points should be aware of. First, a manufacture should develop a general appreciation of the costs to build a GMP plant. In the same empirical study conducted by Zhuge and Liu⁹⁰ in 2012, it was estimated that at least €40,000 are needed. The costs may go much higher depending on specific health foods to be produced.

Second, for new manufacturers lacking experience and skills to design and construct plant as well as to prepare qualified GMP audit dossiers, the professional help offered by registration consulting agencies is recommended. One example is Canny Consulting (www.china-canny.com), focusing on pharmaceutical and foods regulatory compliance for 15 years.

⁹⁰ Zhuge Li-ying and Liu Hao. 2012. GMP Implementation Analysis of Dietary Supplements. *Journal of Asian Drugs: 7(1)*, pp. 45-47. Available: <http://www.asianjsp.com/qikan/manage/wenzhang/AJSP2011-0060.pdf>.

3.3.5. Regulation of Labels and Advertisement

Health food label, as defined in Article 3 of Doc. No.38 (2)—Requirements on Health Foods Labels—means any words, pictorial matter and other means placed on food packaging to present and express the specification, functions, storage conditions and ‘use by’ date, intended consumers, instructions for use and other relevant information relating to the product it attached to.

In terms of advertisement, according to Article 34 of Advertisement Law of P.R.C⁹¹, commodities, include pharmaceuticals and veterinary drugs, shall be subject to the examination prior to being released. After the examination, they can be published by means of radio, cinema pictures, television, newspaper, magazine, periodical and other media. Health foods are one of such commodities, as Article 2 of Doc. No.211—Requirements on the Approval of Health Foods Advertisements—specifies that any advertisements regarding health foods must be approved by the (provincial) CFDA prior to being published.

Five regulatory instruments work together to enable that products are properly labelled and advertised:

- Measures 2005, Chapter IV (Label)
- Doc. No.38 (2)—Requirements on Health Foods Labels
- GB16740—General Standards for Health Foods (Label)
- Doc. No.304—Requirements on the Naming of Health Foods and Guide to the Naming of Health Food 2012
- Doc. No.211—Requirements on the Approval of Health Foods Advertisements

First of all, Chapter IV of Measures 2005, containing article 67 to 71, stipulated that sample label and package insert are on the list of application documents that must be approved by the (provincial) CFDA together with sample products. Specially, the requirements on the name of health foods are highlighted in Article 69 and 70, which stated that a health food name consist of brand name, generic name and the name reflecting product properties. These names should not cause any confusion to general consumers. CFDA published Doc. No.304 as a guide for industry to name their products appropriately. However, even authorities made an effort to have health food named correctly, names that misled consumers still got approved. A well-known

⁹¹ Available at: http://www.saic.gov.cn/english/lawsregulations/Laws/200602/t20060227_55252.html

Chinese brand “Nao Bai Jin” (literally “Brain Platinum”) representing such discrepancy is discussed in Chapter 4.

Doc. No.38 (2) and GB16740 clarify the essentials of a health foods label, i.e. mandatory particulars and prohibited information.

First and foremost, labels as well as advertisement, must not attribute to health foods the property of preventing, treating or curing a human disease, or imply such properties by means of pictograms, symbols or any other forms. This was always emphasised wherever the concept of health food was mentioned in the legislative instruments.

Secondly, a label should contain the following mandatory particulars:

-
- name of health food;
 - health food logo and certificate number;
 - list of ingredients;
 - nutritional ingredients that characterise function(s) of product and its determination;
 - net quality;
 - claim(s);
 - name and address of the manufacturer;
 - suitable and unsuitable group;
 - recommended consumption dosage and instruction for use;
 - manufacturing date, date of minimum durability and/or the expiration date;
 - storage conditions;
 - product standard code and certificate number;
 - precautions;

Note: Regarding the claims on the label of vitamin and mineral supplements, the statement that this product supplements, for example vitamin C was made instead of health claims.

Last but not least, authorized health foods must bear a logo of so called “blue cap” and the certificate number on its label to differentiate itself from other food products and enable consumers to make informed choices. The “blue cap” is designed as the followings: under the “blue cap”, there are three statements indicating the Mandarin Chinese Pinyin name of health foods, namely “Bao Jian Shi Pin”, certificate number and a sentence of “Approved by CFDA” respectively.



To better understand what a qualified label looks like, a sample label is provided. This sample label is taken from an approved health food with brand name being Nutrilite and generic name being "All Plant Protein". It was produced by Amway Corporation, a USA based enterprise and a leading health foods business in China.



Art.2 Logo & certificate No.

Art.1 product name indicates the functional components or relates to health claim

Art.3 Net quality

Art.1 Brand name



Art.5 Nutritional ingredients that characterise function(s) of product and its determination

Art.6 Two health claims

- Improve immunity
- Relieve physical fatigue



Art.4 List of ingredients

Art.7 Suitable group:
People with low immune systems or chronic fatigue syndrome
Unsuitable group:
Adolescent & Children

Art.8 Instruction for use & recommend daily dosage

Art.12 Name & address of manufacturer



Art.9 Manufacturing date & date of minimum durability (24 months)
Art.10 Storage conditions
Art.11 Product standard code and certificate number

A statement that this product cannot be used as a substitute for a drug.

Regarding advertising health foods, the process of pre-examination is not complicated. Special attention should be paid to three key articles under Doc. No.211: Article 10 states that information shown in an advertisement should conform to what was shown on labels approved by the CFDA; Article 11 specified that the following items should be highlighted: the name of health food, product certificate number and advertisement certificate number, “blue cap”, unsuitable group and the statement that this health food should not be used as a substitute for a drug; and Article 8 detailed the prohibited information. Several pieces of prohibited information are excerpted:

-
- 1. A statement that health could be sustained by consuming the product;
 - 2. A statement implies or indicates that the product is suitable to all groups;
 - 3. Any words or descriptions that are not commonly used and cannot be understood by general consumers;
 - 4. A statement that make reference to recommendations of individual doctors or health professionals and other associations;
 - ...
 - 17. Directly or indirectly abet consumers over consumption of product.
-

Although detailed provisions were made to prevent consumers being misled, in circulation sector, the cases that the legislation was deliberately violated are not rare. The case study discussed in section 2.3.6 of Chapter 2—CFDA banned false advertisement—implies that illegal business operators often use misleading statements on health foods and attach health claims to conventional foods to deceive consumers for the sake of money.

3.3.6. Regulation of Import Health Foods

The regulation of import health foods has been partly revealed in Figure 3-2 of section 3.3.1. Imported products are required to go through nearly the same registration procedures as domestic products do prior to being sold. The slight differences lie in that exporting manufacturers should submit their registration application directly to the CFDA rather than the provincial CFDA, and that on-site inspections are only conducted on an ad hoc basis in comparison it is compulsory for domestic health foods.

Regulatory instruments for domestic health foods are all applicable to import health foods. Besides, import health foods are placed more requirements. Key points and additional requirements pertaining to import health foods under Measures 2005 are summarized in Table 3-4, which details answers to practical questions, such as who can register, what products can be registered, and what are the additional documents required?

Provisions on Import Health Foods	
Legislation?	<u>Measures 2005</u> applies to import health foods registration (Article 3);
Who can register?	Registration should be applied by the foreign representative offices located in China or other commission agency registered in China (Article 6);
Registration qualification?	Only the products that have been sold at least one year in other countries/areas outside China and attempt to enter the Chinese market are eligible for registration (Article 19);
Registration procedures?	Pursuant to Chapter II of <u>Measures 2005</u> , visualized in Figure 3-2;
Registration Requirements?	Raw material added in import health foods should meet the requirements that were imposed on domestic products (Article 66)—explained in section 3.3.3.
Registration documents?	<ul style="list-style-type: none"> • Quality Assurance Certificate: granted by exporting country to ensure that production conforms to local quality standards; • Marketing Status Certificate: notarized by exporting country of at least one year of foreign selling experience when products were allowed to enter China. • Lists of relevant food standards adopted by the exporting producers; • A copy of Registration Certificate of Foreign Representative Offices or a copy of the business license of commission agency entrusted; • The original packaging, label and package insert of import products; • Three consecutive batches of samples; Appendix 1 of <u>Measures 2005</u> .

Table 3-4 Additional Provisions on Import Health Foods

Source: Measures 2005

Before initiating discussions as to how import operates in the real trade, it is necessary to clarify what kind of foods outside China are eligible to be registered as Chinese health foods. This thesis provides a focus on the EU and U.S. markets.

As far as American origin products concerned, U.S.–China Health Products Association (HPA) (www.uschinahpa.org), an association commits to increase the trade between its member’s products and services and China’s dietary supplement and overall natural health product industry, suggests that vitamins and dietary

supplements can be registered as Chinese health foods based on their experience. Dietary supplements include the followings:

Dietary Supplements:

- Herbal or traditional supplements: ginseng, garlic, etc.
- Non-herbal supplements: minerals, probiotics, fish oils, etc.
- Combination: Herbal or traditional + non-herbal supplements.

Source: HPA webinar: Selling nutritional supplements in China⁹².

When it comes to food supplements in the EU, it is hardly found any associations, like HPA, facilitating the trade between China's health foods and the European food supplements. However, the CFDA's database listing all import health foods shows that some leading providers of food supplements based in the Europe have successfully registered their products as health foods. Examples are the French company Forte Pharma and the company Seven Seas Ltd in the UK. Food supplements can be grouped into seven main categories based on a European Commission working document prepared in 2008⁹³:

Food Supplements:

- Vitamins and minerals
- Amino-acids
- Enzymes
- Prebiotics and probiotics
- Essential fatty acids
- Botanicals and botanical extracts
- Other substances: Soy isoflavone, Spirulina, etc.

Source: European Commission (2008).

Based on HPA's survey, in reality there are two pathes to sell nutritional supplements in China:

Path 1. Exporting manufacturers follow the CFDA's registration procedures. Under this path, the manufacturers should conform to the provisions listed in Table 3-5. When the Certificate of Approval is granted by the CFDA and shipment arrives in China, local offices of AQSIQ will conduct the inspection and quarantine on the inbound products. If being approved, the products will be released by Customs and enter the Chinese market.

⁹² Available at: [http://www.oceac.com/China Nutritional Supplements 06-12-2012_PW5389461.wmv](http://www.oceac.com/China%20Nutritional%20Supplements%2006-12-2012_PW5389461.wmv).

⁹³ Commission staff working document. 2008. Characteristics and perspectives of the market for food supplements containing substances other than vitamins and minerals, available at: http://ec.europa.eu/food/food/labellingnutrition/supplements/documents/2008_2976_F_WD1_en.pdf.

Path 2. Path 1, however, from HPA’s observation, was not the best solution for exporting producers. In practice, most foreign producers bypassed the registration and exported vitamins and food/dietary supplements as conventional foods via AQSIQ inspection and quarantine. This is because, from HPA analysis, AQSIQ food import approval is must faster, easier and more economical. A detailed comparison in terms of money and time invested for both paths is made in Chapter 4. In brief, only \$400 to \$500 are charged and up to 4 weeks are taken through AQSIQ approval as compare to € 10,000 to € 48,800 are needed and up to 3 years are required to complete the CFDA’s authorization. Therefore, Path 2, as a business strategy, implies that the Chinese regulatory environment presents trade barriers for international nutritional supplements businesses. The following is a simplified AQSIQ approval flowchart:

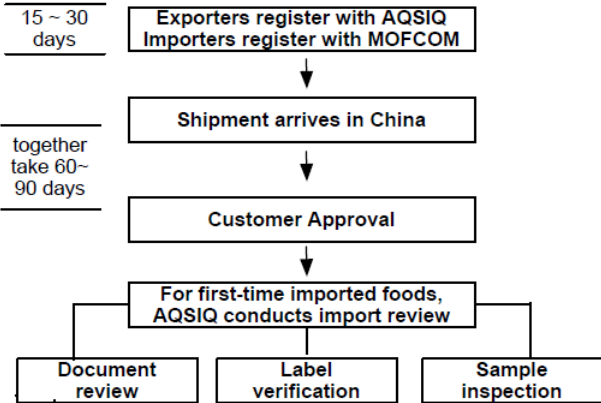


Figure 3-5 AQSIQ Food Import Approval Procedures

Source: adapted from China Solutions Inc. (2012)⁹⁴.

⁹⁴ <http://www.chinasolutionsllc.com/2012/12/importing-food-into-china/>. Accessed on June 29, 2014.

3.4. Summary

This Chapter aims to answer Central Question 1: what is the regulatory framework for health foods.

At the heart of this regulatory framework is the registration—a premarket approval scheme and GMP certification. To be successfully registered, sample health foods, sample labels, sample advertisement when there was, and the claims made on labels need to go through scores of tests (biological, physical, chemical, animal and clinical) to ensure the safety of products, the appropriateness of claims and the accuracy of labels. The CFDA and the National Testing Laboratory commissioned by the CFDA are in charge of conducting the tests, with the CFDA being responsible for reaching the final decision on approval. To produce lawfully, manufactures should request GMP audit from the provincial CFDA first and then apply for production permit when passing through audit. Besides, this framework is known by its positive list of raw material added in health foods and the 27 permitted health claims that appear on the labels.

Challenges that both industry and the CFDA experience are also partly revealed along with the whole discussion, including false advertising, the poor implementation of GMP and the costly registration. A deep understanding on these challenges will be developed in Chapter 4. In additional, a noticeable challenge is specific supervisory and regulatory measures mentioned in *FSL 2009* are still in a holding pattern.

Figure 3-6 captures the essence of health food regulation, the essential legal requirements and apparent challenges discussed in this Chapter:

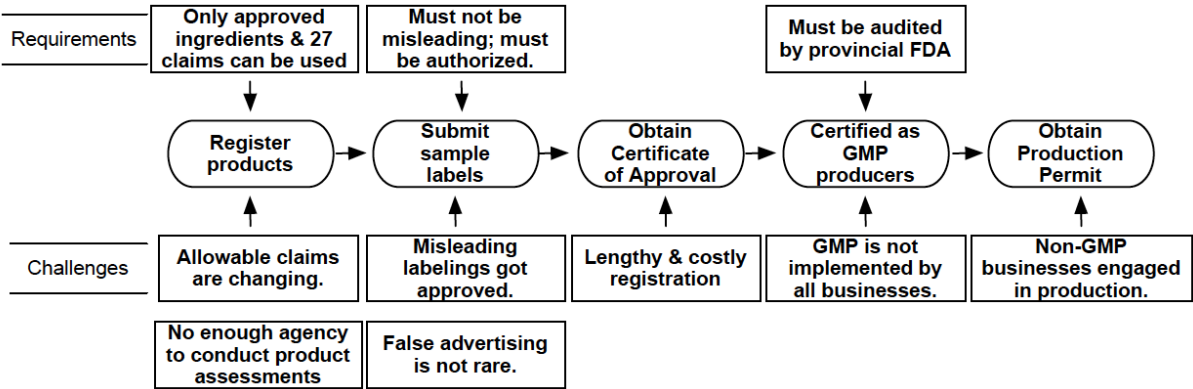


Figure 3-7 Current Regulatory Route for Health Foods and Some Challenges

4 Challenges Analysis

Chapter 3 mainly examines six sectors included in the regulation of health foods and also mentions challenges associated with these sectors that authorities and producers experience. The six sectors refer to raw materials, health claims, premarket registration, production, labelling and advertising, and import health foods.

This chapter further investigates the challenges that Chapter 3 already mentions and suggests other challenges to have health food industry well regulated. Being well regulated in this context refers to that the safety of health foods and industrial growth can be ensured. Finally, these challenges are verified by the CFDA's official through telephone interview.

After the analysis of challenges, hurdles for implementing premarket notification—the alternative scheme to the current registration—are briefly discussed.

The content below is structured in the following ways. In section 4.1, each subsection (4.1.1 ~ 4.1.6) hypothesizes and analyses one challenge, either to authority or producer; based on the analysis, section 4.2 designs interview questions and conducts interview to verify the hypothetical challenges; section 4.3 discusses hurdles for the adoption of notification scheme in health food industry; summary of Chapter 4 is made in section 4.4.

The purpose of this chapter is to answer Central Question 2: What are the possible challenges to authority and producers under the existing regulatory framework?

4.1. Challenges Analysis Based on Survey

Each subsection below suggests and analyses one challenge, either to authority or producer. Six challenges are identified.

4.1.1. Hypothetical Challenge 1: Costly Market Entry—The Analysis of Registration Cost and Business Capital Investment

This case delivers author's concern that the costly and lengthy premarket registration hampers market access to new entry by domestic and foreign firms.

Specifically, the CFDA authorization of a health food other than vitamins/minerals supplements requires € 18,800 to € 48,800 (see Table 4-1). The discrepancy in cost mainly lies in the testing on toxicology and claims, which jointly take more than 75 per cent of total cost and thus constitute the biggest expenses. Vitamins/minerals supplements, on the other hand, not required for toxicology and claims testing, are charged with a significantly smaller registration fee, being € 3,800 to € 6,300. As regards the length of registration, vitamins/minerals supplements take 485 days at maximum, while the health foods that claim to have certain health functions may require between 635 and 815 days.

A detailed analysis on registration fee and waiting period is made as follows:

Health Foods Registration Cost			
CFDA/ Testing Laboratory (TL)	Testing items	Time Scale	Costs
TL	Hygiene Testing	120 days	€2,500~3,800
TL	Stability Testing		
TL	Testing on substances that characterise product		
TL	Toxicology Testing	150 ~ 330 days (not required for vitamins/minerals supplements)	€5,000~7,500
TL	Claims Testing		€10,000~35,000
Above only concerns the 1st assessment			
CFDA	Review dossiers	5 days	Free of charge
CFDA	Take samples for 2 nd assessment	15 days	Free of charge
TL	2 nd assessment	50 days	€1,300~2,500
CFDA	Organize final evaluation	85 days	Free of charge
CFDA	Final evaluation	150 days	Free of charge

CFDA	Administrative approval	60 days	Free of charge
Rough estimate			
Health foods other than vitamins/minerals supplements		635 ~ 815 days	€18,800 ~ 48,800
Vitamins/minerals supplements		485 days	€3,800 ~ 6,300

Table 4-1 Health Foods Registration Cost

Note: Data are adapted from Miracle Consulting (miracleconsulting.com.cn), Tianjianhuacheng Consulting (zhuceabc.cn/) and U.S.–China Health Products Association (HPA) (www.uschinahpa.org).

Extra fees are required for the imported health foods in addition to the same range of cost used for the CFDA registration, which are generated in various ways, such as hiring a registration consultant⁹⁵ and preparing supplementary certificates in accordance with *Measures 2005*, including Quality Assurance Certificate and Marketing Status Certificate (a list of certificates are provided in section 3.3.6 of Chapter 3). HPA in its webinar—Selling Nutritional Supplements to China—indicated that an average cost of registering dietary supplements as health foods exceeds \$50,000.

Therefore, registration turns out a heavy burden, especially the registration of health foods other than vitamins/mineral supplements. This is approved by a study reported by the Chinese Centre for Disease Control and Prevention (China CDC) and HPA’s experience in importing the U.S. dietary supplements to China. The China CDC’s report investigated the ability of health food businesses to make capital investment and concluded that small and medium enterprises are the major drivers of the industrial growth (see Figure 4-1). It further calculated that the investment on manufacturing equipment averaged by 453 domestic manufacturers (incorporating small, medium and large-scaled enterprises) and covering 12 provinces was only ¥2.4 million (roughly €0.3 million). It found that small companies only have production equipment that is worth ¥10,000 (roughly €1,250). However, € 18,800 ~ 48,800 were needed for the CFDA approval, and obviously unaffordable for those small and medium enterprises.

⁹⁵ As stipulated in Article 6 of *Measures 2005*, the registration of imported health food should be applied by the foreign representative offices located in China or other commission agency registered in China. Therefore, foreign producers have to hire a registration consultant (normally from professional commission agency) to assist application if they do not have representative offices in China.

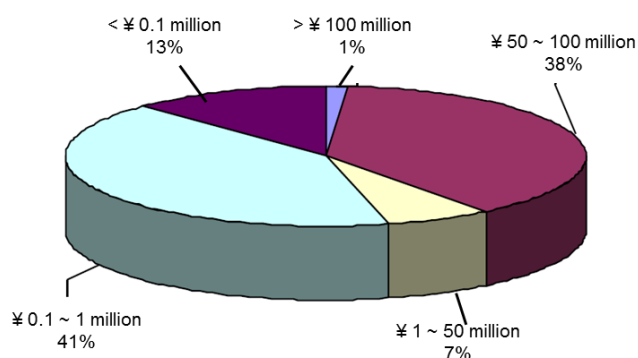


Figure 4-1 Capital Investment of Health Food Businesses

Source: Chinese Centre for Disease Control and Prevention (2009)⁹⁶.

Registration costs were also deemed exorbitant for foreign producers. Based on its experience, HPA pointed out that most of the international companies were intended to import dietary supplements as conventional foods because this path is much more economical and convenient, given that only \$400 to \$500 are needed and used in the approval of labelling when pre-packaged conventional foods were exported to China⁹⁷. By contrast, the CFDA registration charges 100 times of labelling authorization fee. Furthermore, getting labelling approval only takes up to 4 weeks. However, this solution is not perfect. The drawback is that not all dietary supplements can be imported as conventional foods. If a food fell into the following three categories, it must be registered as health food: foods that carry claim(s), foods containing ingredients that were not permitted in the use of conventional foods, and foods that were marketed in other forms rather than common forms of conventional foods⁹⁸.

In short, the current costly and lengthy premarket registration for products could hinder industrial growth and limit business opportunities for both domestic and foreign producers.

⁹⁶ Chinese Centre for Disease Control. Status of health foods industry in mainland China.

⁹⁷ HPA. (June, 2012). Selling nutritional supplements in China, available at: [http://www.oceac.com/China Nutritional Supplements 06-12-2012_PW5389461.wmv](http://www.oceac.com/China%20Nutritional%20Supplements%2006-12-2012_PW5389461.wmv).

⁹⁸ Tianjianhuacheng Consulting. (2013). Protocol for Foreign Countries to Register Health Foods (literately translated), available at: <http://www.51mokao.com/Careers/TestTipDetails.aspx?id=1909>.

Hypothetical trigger for costly market entry

Current three-round testing procedures and complex testing items (including animal test, clinical test and toxicology text) on a case-by-case basis makes it financially unaffordable for the small and medium sized businesses that have limited capital investment.

4.1.2. Hypothetical Challenge 2: Inefficient Authorization Process

Since health foods registration is found costly and tedious, diagnosing the whole process might be helpful to suggest an efficient framework. Based on the estimated timescale detailed in Table 4-2, time taken to complete the first and second assessments conducted by the Testing Laboratory exceeds half the registration span. Specifically, authorizing health foods other than vitamins/mineral supplements takes 635 ~ 815 days while the first and second assessments account for 320 ~ 500 days. Therefore, it is essential to evaluate whether the existing 46 Testing Laboratories (by April 2014) are sufficient in terms of amount and proficiency. This evaluation process is designed through comparing the real demand of health foods certificates with already issued certificates. If the real demand of industry was far greater than the CFDA outputs, then a great number of Testing Laboratories may be needed.

Firstly, the key figures used for the evaluation are 9664 Certificate of Approval were granted to the health food industry by 2009⁹⁹, and 2000 manufacturers involved in the industry at the same year¹⁰⁰. The judgement is made through two steps, together with other data:

Secondly, the demand for certificate from large enterprises is calculated:

- According to the analysis made by Guangfa Security Co.,Ltd, a Chinese stock company (commits to providing international institutional investors various industry analysis), the average number of certificates that were granted to large companies amounted to 37 (see Figure 4-2)¹⁰¹;

⁹⁹ Mei He. Status of health foods industry in mainland China. The content of this study is only presented in slides, not in the article. Available at <http://www.google.nl/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=1&ved=0CCkQFjAA&url=http%3A%2F%2Fwww.fda.gov.tw%2Fupload%2F133%2FContent%2F991201-%25E5%2585%25A9%25E5%25B2%25B8%25E5%2581%25A5%25E5%25BA%25B7%25E9%25A3%259F%25E5%2593%2581->

¹⁰⁰ Jinjing Zhang. 2011. Regulation on Health Food in China. US-China Food and Drug Law Conference.

¹⁰¹ This report was entitled An analysis report on health food industry, available at: http://pg.rj.com.cn/acc/Res/CN_RES/INDUS/2014/5/9/afdad2d6-0940-4f91-a4ff-5cf42c8de1f6.pdf.

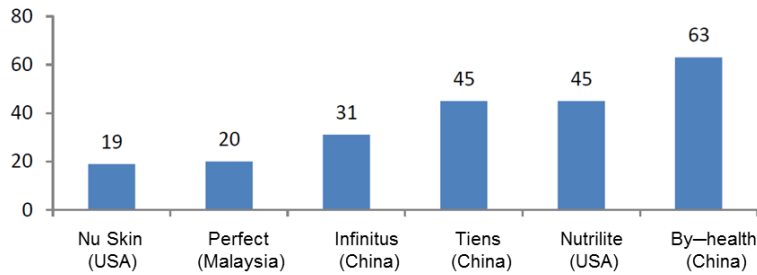


Figure 4-2 Distribution of Health Foods Certificates

Source: adapted from Research Centre of Guangfa Security Co.,Ltd (2013)¹⁰².

- As indicated in Figure 4-1 Capital Investment of Health Food Businesses, 1% health food business were large-scaled in terms of capital invested, therefore in 2009 the number of large companies were $2000 * 1\% = 200$;
- Multiply 37 and 200, nearly 7400 certificates were granted to large enterprises.

Thirdly, the demand for certificate from small and medium enterprises is estimated:

- First of all, the total number of small and medium sized companies reached 1800 (subtract 200 from 2000) in 2009;
- Based on the figures calculated in step 1, the rest 2260 (subtract 7400 from 9664) certificates were distributed to the 1800 small and medium companies, suggesting averagely, each of these companies could only be granted 1 or 2 certificates so that the Testing Laboratory could deal with all of authorization requests.

Owning 1 or 2 certificates means businesses can only develop 1 or 2 types of health foods, which seriously limits the product variety. Product packaged in different forms, for example capsule and tablet, are two types according to the requirements on application dossiers stipulated in *Measures 2005*. From industry perspective, the permission of developing 1 or 2 types of products would jeopardize the product differentiation and therefore create barriers to gain a competitive advantage.

Therefore, in reality, firms must strive for obtaining more certificates and thus place the CFDA under huge pressure due to insufficient evaluation agency in place to process requests.

¹⁰² *Ibid.*

As regards assessment proficiency, each laboratory differs greatly. This is supported by a document that lists the qualification of each authorized Testing Laboratory¹⁰³. In this document, only a few laboratories conduct a relative wider range of claim testing. In addition, it is a little surprising that there is no Testing Laboratory capable of testing all of 27 permitted claims. Only several laboratories were able to assess around 20 claims at most.

Based on the analysis above, one conclusion can be drawn that although Testing Laboratories play a significant role in the registration, they did not work effectively and have been overloading due to extensive assessment demand.

From author's viewpoint, rather than the authority cannot meet industrial demand, it is industry that adds heavy pressure on the authority. After all, health foods regulation is a relative new project for the CFDA (from 2003 to date) and major attention should be placed on improving food safety and quality as China still faces greater international pressure to effectively and transparently address concerns over domestic food quality, especially when it comes to food exports¹⁰⁴.

Although there are some voices that the economic growth can increase the food safety because the laws to regulate food safety become more detailed and complete as the economy grows¹⁰⁵, it would be running the risk of weakening regulatory control before such detailed and complete regulations were in place.

Hypothetical trigger for the inefficient authorization process

Rapidly growing but not well-regulated industry puts extensive workload on an immature regulatory framework.

4.1.3. Hypothetical Challenge 3: The Poor Implementation of GMP

Good Manufacture Practice (GMP) for health foods in China was developed in this way: it was established as national standard in 1998 by MoH, namely GB 17405

¹⁰³ China CFDA. Lists of authorized Testing Laboratory. Available at: <http://www.sfda.gov.cn/WS01/CL1158/>

¹⁰⁴ Drew Thompson and Hu Ying. (2007). Food Safety in China: New Strategies, Global Health Governance, Volume I, No. 2, available at: http://www.google.nl/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=6&cad=rja&uact=8&ved=0CEgQFjAF&url=http%3A%2F%2Fwww.ghgj.org%2FThompson_Food%2520Safety%2520in%2520China.doc&ei=ciufU4u_Nln_QZSngYAH&usq=AFQjCNHhkIjpr0ghBbEVr7LEMzna710oLQ&bvm=bv.68911936.d.ZWU.

¹⁰⁵ Zhe Feng. (May, 2013). Chinese Food Safety: What Can We Eat in China?, available at: <http://polisci.indiana.edu/undergraduate/theses/Feng.pdf>.

1998; then Measures 2005 specifies that the production of health foods shall meet GMP standards; in 2009 the CFDA emphasised that a manufacturer should be audited as qualified GMP manufacturer by the provincial CFDA and thus obtain Production Permit accordingly. Therefore, GMP audit forms a precondition for the production. Meanwhile, it is CFDA's responsibility to push health food businesses to carry out GMP in the production.

A provincial CFDA inspection conducted in the year between 2004 and 2006 once reported that 96.6 per cent of 86 health food businesses involved in the investigation passed through GMP audit at the first check¹⁰⁶.

However, another survey carried out by a university researcher shows far less positive results. Specifically, Zhuge and Liu conducted an empirical survey on the implementation of GMP in health food industry in the same province in 2012, and found that GMP certification was not strictly audited in plants¹⁰⁷. Two major problems were reported. Firstly, nearly 20 per cent of 29 businesses involved in the survey were not certified as GMP manufacturer but still engaged in the production. Secondly, those GMP manufacturers generally failed to follow GMP standards in the daily operation. For instance, some companies used raw materials that lacked safety certificate, and some others were incapable of conducting mandatory testing of raw materials as required¹⁰⁸.

Unlike that it should not be held liable for the lengthy authorization, the CFDA is largely responsible for manufacturers' negative attitude towards adopting GMP. This is because auditing process is also an on-site education and training process, which helps producers realize that GMP ensures quality and food safety. Auditors work in an unprofessional manner adversely influences producers and discourages them to strictly adopt GMP.

Besides the unprofessional audit, two other reasons may also account for the difficulty in implementing GMP thoroughly. Firstly, the major one is the absence of

¹⁰⁶ Guang Dong FDA Centre for Evaluation & Certification. (Oct., 2007). An Analysis on GMP Inspection in Health Foods Industry In Guang Dong Province between 2004 and 2006 (literally translated), *Journal of Guangdong College of Pharmacy*, Vol. 23 (5), available at:

http://www.google.nl/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=6&ved=0CEUQFjAF&url=http%3A%2F%2Fzhgysh.yywkt.cn%2FMagazine%2FPDFShow.aspx%3FID%3D134974&ei=KzKfU_qHllaLOPjglAB&usg=AFQjCNEdC_XsySEV6ia1_ViNlr5WKoz9_w.

¹⁰⁷ Zhuge Li-ying and Liu Hao. (2012). GMP Implementation Analysis of Dietary Supplements. *Journal of Asian Drugs*, Vol.7(1), pp.45-47. Available at: <http://www.asianjsp.com/qikan/epaper/zhaiyao.asp?bsid=14685>.

¹⁰⁸ *Ibid*.

powerful legislative instruments to penalize illegal business, which also leads to other various problems, such as deceptive labelling and advertising represented by Nao Bai Jin case. Secondly, small and medium enterprises—the major pillars of industry—are not well developed, and lack technical training and specially, adequate investment to carry out GMP completely.

Hypothetical triggers for the poor implementation of GMP	
Trigger 1	Overall unprofessional audit leads to GMP being poorly implemented.
Trigger 2	Illegal businesses were not penalized sufficiently.
Trigger 3	Businesses lack sufficient experience and adequate investment.

4.1.4. Hypothetical Challenge 4: Lack of A Trusting Business Environment—Nao Bai Jin Case

Nao Bai Jin case represents a wide-spread curse in Chinese health foods industry that most brands would die within five years¹⁰⁹. This curse was uttered based on the fact that some brands became nationally well-known overnight through big marketing investment, sometimes even with deceptive advertising, but could only be sustained several years. A Chinese stock company, Guangfa Security Co.,Ltd, investigated the most famous brands emerged in China since 1984, and found most of which adopted the business model of cumulating abnormal returns in short-term, but had to exit health foods market due to tarnished business image (see Figure 4-3)¹¹⁰. Consequently, consumer trust and a positive business environment were significantly destroyed after a series of such scandals.

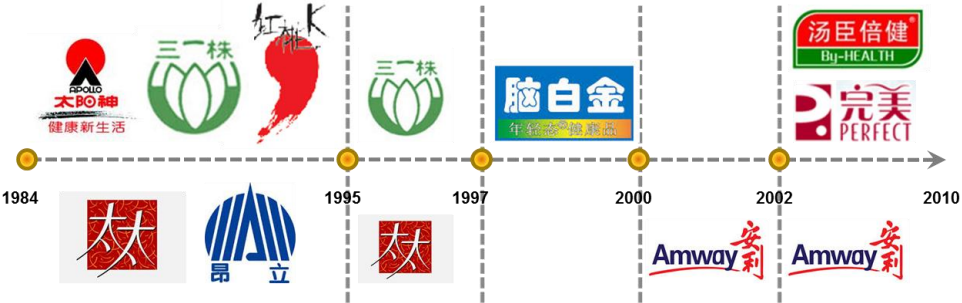


Figure 4-3 Most Famous brands and Their Development from 1984 till 2010

¹⁰⁹ News Evening. (November, 2013). The Bottleneck in the Industrial Growth on Health Foods. *People.cn*. Retrieved on June 19, 2014 from <http://shipin.people.com.cn/n/2013/1128/c85914-23685187.html>.

¹¹⁰ This report is available at: http://pg.jrj.com.cn/acc/Res/CN_RES/INDUS/2014/5/9/afdad2d6-0940-4f91-a4ff-5cf42c8de1f6.pdf.

Source: Guangfa Security Co.,Ltd. An analysis report on health food industry (the title was literally translated)¹¹¹.

The major product information of Nao Bai Jin (literally “Brain Platinum”) include that it was authorized health food in December 1997 and approved to use two health claims, namely to improve sleep and promote fecal excretion¹¹². The major functional component said on the package inset was melatonin, a hormone found in animals, plants, and microbes. The package inset stated that the suitable group were middle-aged consumers and the elderly. The final products were packaged in glass bottles and capsules as shown in Figure 4-4.



Figure 4-4 Package of Nao Bai Jin

Nao Bai Jin became well known and then notorious in China due to its relentless TV commercials in nearly every channel owned by the provincial and city TV stations and owing to advertorials flooding everywhere all across the country, including convenience stores, supermarkets and drug stores¹¹³. As such, Chinese people, as long as he/she watched TV and went shopping, couldn't be invisible to its infamous advertising slogan—“This Chinese New Year/public holiday gifts received are only Nao! Bai! Jin!”.

The powerful but nauseating marketing strategy successfully trapped consumers and made Nao Bai Jin a huge success in terms of monetary returns. In their research,

¹¹¹ *Ibid.*

¹¹² The information is based on the CFDA health foods database, available at: <http://app1.sfda.gov.cn/datasearch/face3/base.jsp?tableId=30&tableName=TABLE30&title=国产保健食品&bclid=118103385532690845640177699192>.

¹¹³ Chen Junsong and J.Price. (2005). Nao Bai Jin Case. Available at: <http://www.ceibsonline.com/case/en/show/index/id/193>.

Chen Junsong and J.Price estimated that sales of Nao Bai Jin between 1997 and 2000 hit 1.2 billion RMB (about 0.15 billion euro)¹¹⁴. Nao Bai Jin definitely beat other health foods brands in the same period.

However, from the year of 2000 alleged health benefits of Nao Bai Jin were strongly questioned by domestic experts, consumers and people paying attention to Nao Bai Jin phenomenon. In addition, fierce criticisms from public on its misbranding, as well as exaggerated and misleading advertising were provoked. Evidences of deceptive behavior include the name of “Nao Bai Jin” (literally “Brain Platinum”) misled consumers to believe its mental improving functions, such as increasing memory or intelligence. This obviously breached the fundamental rule under Requirements on the Naming of Health Foods and Guide to the Naming of Health Food that product name should indicate real property of product (Article 3)¹¹⁵. Astoundingly, Nao Bai Jin was an legal name from MoH’s perspective and got approved as such.

In addition, Chen Junsong and J. Price stated that various versions of deceptive stories appeared on the advertorials. Examples include that there were more than 7,000 articles providing scientific evidence on the two claims carried by Nao Bai Jin, and that Nao Bai Jin had been made popular in developed regions like North America and Western Europe. As can be seen from the package of Nao Bai Jin in Figure 4-2, a figure of a senior male was printed on the blue outer package with an intention to convey this false information to consumers.

Furthermore, Nao Bai Jin illegally carried claims that were unauthorized for it. Through googling searching, many consumers complained that in the flyers spread in supermarkets, Nao Bai Jin were claimed to have additional functions that were not approved to use on it. One consumer even filed a lawsuit against the manufacturer of Nao Bai Jin because of being deceived in this way.

Nao Bai Jin was penalized from 2000. From 2000, provincial FDA, such as Shanghai FDA and Zhejiang FDA banned Nao Bai Jin’s TV advertisement. A news report from Xinhua News Agency stated that Zhejiang and other provincial SAIC fined the local

¹¹⁴ *Ibid.*

¹¹⁵ Requirements on the Naming of Health Foods and Guide to the Naming of Health Food. Available at: <http://www.sfda.gov.cn/WS01/CL0847/69935.html>

TV stations 5,000 RMB (around 600 euros) for the illegal publishing¹¹⁶. However, Nao Bai Jin was still allowed on market.

However, such so called penalties raised doubts on whether the authorities were meant to strictly supervise Nao Bai Jin or just did superficial work at the expense of consumer health and a positive regulatory environment. To some extent it is the governmental loose supervision that led to the prosperity of Nao Bai Jin.

Chinese health foods industry was deemed a huge potential due to consume demand¹¹⁷. However, the success of health foods industry cannot be achieved without the safe food products, strict regulation and moral responsibility of businesses to provide safe food. Nao Bai Jin case implies that a trustworthy and well-regulated market is still years away. The corresponding triggers, as analyzed above, probably consist of the followings:

Hypothetical triggers for a low-trust business environment	
Trigger 1	In some cases, authorities did not follow a strict authorization process from the very beginning and take control afterwards.
Trigger 2	Authorities' performance was not closely monitored.
Trigger 3	Illegal businesses were not penalized sufficiently.

4.1.5. Hypothetical Challenge 5: Direct Selling Model Leads to Irrational Purchase Behaviour—Amway Nutrilite® Case

Amway Nutrilite case expresses author’s deep concern as to whether there is a risk of excessive consuming if sales of certain health food continuously break record. More importantly, whether it can be regarded misleading consumers if buying a certain product makes purchasers believe they can earn profits in future from this buying or obtain other things even more attractive, such as a chance of becoming a millionaire. In other words, if a business scheme potentially results in an over purchased behaviour, should it be called misleading and therefore, be reformed? This doubt was raised from a prevailing view among Chinese consumers that Amway

¹¹⁶ SAIC banned Nao Bai Jin’s illegal TV advertisement again (literally translated). *Xinhuanet.com*. Retrieved April 2014 from http://news.xinhuanet.com/fortune/2006-01/20/content_4075453.htm.
¹¹⁷ Jennifer Grebow. (June, 2014). China Should Be the Largest Market for Dietary Supplements. *nutritionaloutlook.com*. Retrieved June 2014 from <http://www.nutritionaloutlook.com/140606/China>.

Nutrilite® health foods, primarily were not health foods, but a way to make quick money.

Amway Corporation was already mentioned in section 3.3.5 of Chapter 3 where a label of its health food product—All Plant Protein Powder—was exemplified. Being a general Chinese consumer, author regards Amway as famous as Nao Bai Jin in terms of brand recognition and sales records they made. Sales of Nao Bai Jin hit 0.15 billion euros between 1997 and 2000 (mentioned in Section 4.1.1) while that of Amway Corporation have increased consistently since 2006, see Figure 4-5:



Figure 4-5 Amway China Sales Review

Source: Harvard Business Review Chinese Version (2013)¹¹⁸

On the other hand, the difference between Amway and Nao Bai Jin lies in that some people take selling Amway a way to start one's own business and achieve their millionaire dreams. Its well-known slogan in China is "Running business with Amway, I will be retired in 2 to 5 years". The other half, oppositely, perceive Amway as fraud as Nao Bai Jin because of its overpriced products and a promised chance of being millionaire that was finally approved to hardly come true for a majority of those involved. These two radically different perceptions resulted from Amway's direct selling model, or pyramid scheme defined by its opponents.

Direct selling, according to Xardel Dominique, is defined as the direct personal presentation, demonstration, and sale of products and services to consumers, usually

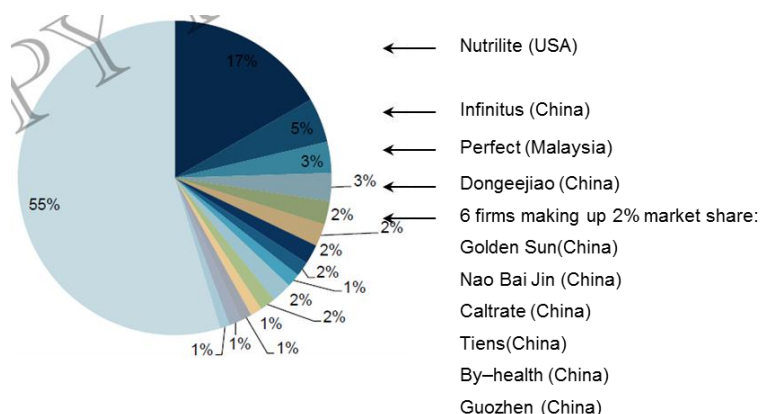
¹¹⁸ Doug DeVos. (2013). Reinventing the Business to Succeed in China. *Harvard Business Review*, available at: <http://web.resource.amchamchina.org/cmsfile/2013/06/18/a63304e8291fe7679adad38986f8e40c.pdf>.

in their homes or at their jobs¹¹⁹. Those direct sales people get certain percent of commission on everything they sell.

Pyramid scheme, explained by USA *Federal Bureau of Investigation*, “referred to as franchise fraud or chain referral schemes—are marketing and investment frauds in which an individual is offered a distributorship or franchise to market a particular product. The real profit is earned, not by the sale of the product, but by the sale of new distributorships.”¹²⁰.

Whatever it is termed, this marketing model totally fits in Chinese market, given that President DeVos of Amway Inc., reported that China has been Amway’s biggest market, accounting for more than a third of Amway's sales¹²¹. Particularly, Nutrilite® health foods made the largest contribution steadily compared with China Amway’s other products, which reportedly made up 60% annually by *China Information Times*¹²².

Not only do Nutrilite® health foods play a significant role among all Amway’s products, but since 2001, it also has become a major player (see Figure 4-3) and has created a competitive advantage over its international rivals in Chinese market. An analysis regarding Chinese health foods market share in 2013 made by Industrial Economics & Knowledge Centre of Taiwan illustrates how Amway outperformed its competitors in Chinese market¹²³.



¹¹⁹ Xardel Dominique. (1993). *The Direct Selling Revolution. Understanding the Growth of the Amway Corporation*. Blackwell Publishing. pp. 3–4. ISBN 978-0-631-19229-9.

¹²⁰ USA Federal Bureau of Investigation. *Pyramid Schemes*. Retrieved April 2014, from <http://www.fbi.gov/scams-safety/fraud/fraud>.

¹²¹ Doug DeVos. (2013). *Reinventing the Business to Succeed in China*. Harvard Business Review.

¹²² Xuelin Deng. (2009). *Amway Nutrilite: Huge Potential of Chinese Market*. Retrieved April 2014, from http://informationtimes.dayoo.com/html/2009-10/14/content_730344.htm.

¹²³ Industrial Economics & Knowledge Centre of Taiwan. (2013). *New Demands For Health Foods Market and the Market Expansion*.

Figure 4-6 Chinese Health Foods Market Share Analysis 2013

Source: Industrial Economics & Knowledge Centre of Taiwan (2013).

Since Nutrilite® health foods were so popular in China, it becomes interesting to check its registration status with the CFDA. The CFDA health foods database shows that Amway successfully got authorization for 7 different products since 1997 under one brand Nutrilite, including 4 vitamin supplements (Vitamin C Complex, Natural Vitamin B, Vitamin E and Beta-carotene), 1 mineral supplement (Calcium-Magnesium Supplements) and 2 healthcare foods (Protein Powder And Fibre). On China Amway website (*amway.com.cn*), three products were displayed with information of detailed product descriptions and costs. Key information is briefed as follows, together with the packaging figures:

Product Name	All plant protein powder	DouBLE (vitamins and herbal extracts)	Memory builder with ginkgo
Claims	<ul style="list-style-type: none"> Improve immunity Relieve physical fatigue 	<ul style="list-style-type: none"> Improve immunity Increase bone density 	Improve memory
Net weigh & Cost	770 (g) ¥560 €70	105 (g) ¥460 €55	28 (g) ¥402 €50



Source: China Amway Corporation (*amway.com.cn*).

As mentioned at the beginning of this section, for most Chinese consumers the first thing that came to mind about Amway is its commission structure that is said to accumulate person fortune wisely and steadily. So when a sales representative made a certain amount of net sales, he/she could earn commissions that were calculated on a percentage basis. It is believed that commissions under this condition were generated from the high selling price, so that is why Amway blamed on its overpriced products. Because part of money paid by consumers actually went to commissions. To check whether this opinion is true, a common health food product—protein

powder—is taken to make price comparison between Amway and other international producers. Other producers are those included in the CFDA health foods database, 6 producers in total. Besides, a Chinese manufactures, By-health Corp., which was considered the best-selling brand in domestic industry, was taken as an example as well.

The claims, net weight, suppliers and country of origin are supplementary information to selling price. Producers are ranked from the highest market price to the lowest, except for the last two whose selling price is not available on line.

Producers	Claims	Net weight	Price	Suppliers	Country of Origin
BiProUSA	Improve immunity	40 (g)	¥226 €28	800pharm.com	USA
Glanbia Foods	Improve immunity	380 (g)	¥380 €48	Jd.com	USA
Amway Corp.	Improve immunity Relieve physical fatigue	770 (g)	¥560 €70	Amway.com.cn	USA
By-health Corp.	Improve immunity	455 (g)	¥348 €43	by-health.com	China
Hill View Pharmaceuticals Inc.	Improve immunity	455 (g)	¥298 €37	800pharm.com	USA
Haleko Hanseatisches Lebensmittelkontor GmbH & Co.OHG	Improve immunity Protect liver against	750 (g)	¥238 €30	Jd.com	Germany
DuPont-Protein Technologies International	Assist in blood lipids reduction	420 (g)	Unknown		USA
Bott Laboratories	Improve immunity	275 (g)	Unknown		USA

Table 4-2 Price Comparison between Amway and Other Producers

As Table 4-2 indicates, Amway Nutrilite® protein powder ranks the third most expensive among the six brands. Although it is not convincing that Amway’s products were overpriced as far as the price comparison above concerned, it is the truth that the consumption of Amway Nutrilite® became greater and greater each year. Another fact is that Amway adopts the multi-level business model so that the more products the lower-level employees sell, the more senior workers can relax and profit. As such, workers at the lower-level make every effort to recruit new direct sellers to

transform themselves into the level higher than before and earn commission on new recruits. Attracted by the slogan that “I’ll be retired in 2 to 5 years” and confident of so-called innovative way to make money, hundreds of thousands consumers (this number was revealed by the President of China Amway Corp.) became direct sellers (according to Amway’s regulation, only its consumers are given eligibility as sales representatives) and then jointly made Amway Nutrilite® the only one leading health foods brand in China in less than ten years.

As can be reasonably assumed, behind building this business empire was the potential risk of over consumption and the ambition of nutritionally supplementing every Chinese, although only certain groups are suitable for health foods whatever their functions are. Unfortunately, the proper consumer education to avoid such risk was neglected under the current regulatory framework.

Hypothetical triggers for irrational purchase behaviour	
Trigger 1	Direct selling structure may lead to over consumption.
Trigger 2	Consumer education to avoid risk above is neglected.

4.1.6. Hypothetical Challenge 6: Technical Barriers to the International Trade— An Example of Conflict Concerning Health Claims

International trade attracted author’s attention mainly because when the regulation of health claims was examined in Chapter 3, a big conflict was found between the Chinese approach and the EU approach. This conflict concerns the use of probiotics and the corresponding health claims.

Chinese approach is discussed at first. As stipulated in Document No.202— Provisions on Vitamins/Minerals Supplements, 10 probiotics (see Table 4-3) are permitted in the use of health foods and therefore can bear health claims. The CFDA databases shows that these 10 probiotics can carry claims, such as improving immunity and facilitating digestion.

Unlike the Chinese approach, in the EU, live yoghurt cultures that contain *Lactobacillus delbrueckii subsp. bulgaricus* and *Streptococcus thermophiles* were

substantiated to have relationship to health¹²⁴. This was set out in Regulation (EU) 432/2012. The approved health claim was that live cultures in yoghurt or fermented milk improve lactose digestion of the product in individuals who have difficulty digesting lactose. The conditions of use were that yoghurt or fermented milk should contain at least 108 Colony Forming Units live starter microorganisms (*Lactobacillus delbrueckii subsp. bulgaricus* and *Streptococcus thermophilus*) per gram. By contrast, individual probiotic was prohibited to claim any health effect due to the lack of scientific evidence.

Approved 10 Probiotics Used in Health Foods under Document No.202:

Bifidobacterium bifidum

Bifidobacterium infantis

Bifidobacterium longum

Bifidobacterium breve

Bifidobacterium adolescentis

Lactobacillus delbrueckii subsp. Bulgaricus

Lactobacillus acidophilus

Lactobacillus casei subsp. Casei

Lactobacillus reuteri

Streptococcus thermophilus

Table 4-3 Allowable Probiotics in the China

Furthermore, market status of probiotics containing health foods was checked through CFDA database. When ‘probiotic’ was inputted as a keyword of product name, only one international business (French company) was found, who used *Lactobacillus acidophilus* and *Bifidobacterium longum* to produce probiotic particle. In contrast, 41 Chinese firms develop probiotic-containing foods with various forms,

¹²⁴ This is based on EU-wide positive lists of nutrition and health claims—EU Register on Nutrition and Health Claims (ec.europa.eu/nuhclaims).

including powder, capsules, tablets and yogurt. Apparently, Chinese producers have more options when developing probiotic foods. However, these foods are not eligible for export to the EU.

The US approach is also checked regarding this conflict. Same as the EU, FDA approved health claims do not include probiotic.

Specially, health claims that can be made for dietary supplements consist of 1) health claims that were authorized by the Nutrition Labelling and Education Act (NLEA) and 2) qualified health claims that describe a possible relationship between an ingredient and a health-related condition¹²⁵.

Firstly, NLEA authorized health claims did not include any probiotics (see Table 4-4). One example of NLEA authorized health claim was *“food containing 0.7 g or more of Plant Stanol Esters per serving eaten two to three times a day with meals may reduce the risk of heart disease as part of a diet low in saturated fat and cholesterol. A serving of BENECOL® Spread contains 1.7 g of Plant Stanol Esters.”*

Secondly, qualified health claims were unrelated to probiotics based on the USA FDA database¹²⁶. One example of qualified health claims was *“very limited and preliminary scientific research suggests that eating one-half to one cup of tomatoes and/or tomato sauce a week may reduce the risk of prostate cancer. FDA concludes that there is little scientific evidence supporting this claim.”*

Health claims meeting the standard of significant scientific agreement authorized by the NLEA of 1990
Dietary saturated fat and cholesterol and risk of CHD
Fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of CHD
Sodium and hypertension
Dietary lipids (fat) and cancer
Fiber-containing grain products, fruits, and vegetables and cancer
Fruits and vegetables and cancer
Calcium and osteoporosis
Folate and neural tube defects

Table 4-4 NLEA Authorized Health Claims

¹²⁵ Fortin ND. (2009). Food Regulation. Hoboken, New Jersey, USA: John Wiley & Sons, Inc., p.363.

¹²⁶ USA FDA. Summary of Qualified Health Claims Subject to Enforcement Discretion. Available at: <http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm073992.htm>.

Source: American Society for Nutrition (2008)¹²⁷.

Besides, in the U.S., other categories of health claims include health claims based on authoritative statements from the U.S. government or the National Academy of Sciences and structure/function claims that link an ingredient in a food or supplement to a specific effect on the body. However, the former one can only be made for conventional food¹²⁸; the latter one were not approved by the FDA and producers can attribute their products certain effects as long as a disclaimer was accompanied that *“This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.”*

International guidance was also referred to. World Health Organization (WHO) and the World Cancer Research Fund (WCRF) did not involve any probiotics in their investigation as to the strength of evidence on foods and food components that give a health benefit. The results of this investigation can be found on page 44~45 of the report formulated by IADSA¹²⁹.

In conclusion, unlike the EU and US approaches and WTO study, health benefits of 10 probiotics were substantiated in China. These benefits include improving immunity and facilitating digestion. As such, Chinese enterprises develop probiotics containing health foods and link those products to specific health claims. However, those food products are likely to be rejected to export to the EU, US and other foreign areas.

Hypothetical trigger for international trade

Conflict with the EU and US approaches to substantiating health claims.

4.1.7. Conclusion

Subsection 4.1.1 ~ 4.1.6 hypothesize six challenges the authority and producers faced currently (see Table 4-5).

Two of six relate to health foods safety: that GMP is not strictly implemented and that false claims and advertisement made on health foods is everywhere.

¹²⁷ American Society for Nutrition. (2008). Health Claims in the United States: An Aid to the Public or a Source of Confusion? Available at: <http://jn.nutrition.org/content/138/6/1216S.long>.

¹²⁸ Fortin ND. (2009). Food Regulation. Hoboken, New Jersey, USA: John Wiley & Sons, Inc., p.366.

¹²⁹ IADSA. (2010). Scientific substantiation of health claims: A global analysis.

Another two concern market entry: whether the registration scheme encourages or discourages producers with access to health food business.

The other two deal with potential problem of over consumption and the barrier in the international trade.

In section 4.2, an interview is conducted with the CFDA officials, with aims to recognise the regulatory challenges from CFDA’s perspective and verify the six proposed challenges.

Six Challenges			
No.	Challenges	No.	Hypothetical triggers
1	Health foods industry has very high entry barrier.	1.1	Current three-round testing procedures and complex testing items on a case-by-case basis make it financially unaffordable for both domestic and foreign producers.
2	The industry faces an inefficient authorization process.	2.1	Existing 46 Testing Laboratory cannot meet the excessive request of health food registration.
3	GMP is not implemented firmly by domestic health foods businesses.	3.1	Overall unprofessional audit
		3.2	Businesses lack sufficient experience and adequate investment.
		3.3	Illegal businesses were not penalized sufficiently.
4	Most health foods businesses make false claims and advertisements, which results in low consumer trust.	4.1	Authorities did not follow a strict authorization process.
		4.2	Authorities' performance was not closely monitored.
		4.3	Illegal businesses were not penalized sufficiently.
5	Over consumption probably is arisen in health food industry.	5.1	Direct selling structure leads to over consumption.
		5.2	Consumer education to avoid over consumption is neglected.
6	International trade faces technical barriers.	6.1	Conflict with the EU, US and international approaches to substantiating health claims.

Table 4-5 Six Challenges

4.2. Challenges Analysis Based on Interview

This interview with the CFDA's official aims to verify the six challenges suggested in section 4.1, and also aims to recognise other challenges from CFDA's perspective.

4.2.1. Interview Questions and Results

Questions 1-3 focus on Challenge 1: *The health foods industry has very high entry barrier.*

- Question 1: does the annual growth rate on new application for health foods increase, or decrease from recent years?
Answer: *New application for health foods registration was increasing since 2012, mainly because being approved by the CFDA and having health foods logo on the label help producers sell more products.*
- Question 2: does the annual growth rate on new health foods companies increase, or decrease?
Answer: *there is very slight variation in the number of manufacture over past years. The amount of manufacturers keeps stable around 2300.*
- Question 3: what is the average per cent of rejected product in total application submitted?
Answer: *Besides the products withdrawn at the first and second assessment, approximately 30% products that pass the first two assessments were rejected by CFDA's evaluation.*

Questions 4-5 focus on Challenge 2: *Health food industry faces an inefficient authorization process*

- Question 4: is it right to say that limited amount of Testing Laboratory stops the assessment being efficient and financially affordable?
Answer: *In fact, it is a new policy that has the great impact on the time line of assessment rather than the amount of Testing Laboratory. This policy cuts off the benefit the Testing Laboratory gained through conducting assessment, which leads to Testing Laboratory's motivation to progress the assessment becoming weak.*

- Question 5: what suggestions can be made to optimize current registration procedure based on available resources?
Answer: The best solution for now is to exempt certain type of health foods from registration by specifying the conditions of use of claims. Health foods that are exempted should be presumably safe based on sufficient scientific evidence, including minerals and vitamins.

Question 6 focuses on Challenge 3: *GMP is not implemented firmly by domestic health foods businesses.*

- Question 6: what major challenges do producers face when implementing GMP?
Answer: Capital investment. GMP certification actually serves to remove incompetent manufacturers.

Question 7 focuses on Challenge 4: *Most health foods businesses make false advertisements.*

- Question 7: some producers purposely make false advertisements and claims, is it true that over 50% producers are inclined to behave like that?
Answer: Even greater than 50%. A study conducted by the Chinese Health Product Association recently found that nearly 94% of the health foods on market bear false or misleading claims.

Questions 8-9 focus on Challenge 5: *The issue about over consumption probably is arisen in health food industry.*

- Question 8: is there concern that certain brands of health foods are being over consumed?
Answer: Some consumer group may have high expectation on certain health foods, but the over-consumption is rare on the whole.
- Question 9: is there any communication channel to provide consumer education on health foods?
Answer: Consumer education on health foods mainly relies on the mandatory statement that “This product is not the substitute for drug” on the TV commercials and labels.

Question 10 focuses on Challenge 6: *The international trade in health foods faces technical barriers.*

- Question 10: what hampers the international trade in health foods or food supplements most?

Answer: *First, the international standards, such as Codex guidelines on food supplements are far less than we assumed harmonized. Besides, the national or regional dietary choice and the minimal and maximum levels of ingredients allowed in food supplements, especially that of vitamins and minerals are different.*

Questions 11-13 aims to find other key issues about health foods regulation.

- Question 11: were there any cases of food safety accident concerning health foods happening over past years since Registration system went effective?

Answer: *There is no adverse case reported so far.*

- Question 12: after Food Safety Law 2009 becoming effective and CFDA becoming more experienced in the regulation of health foods, what problems have been solved or what improvement has been made?

Answer: *The achievements include the procedures of registration system becoming more fluent, organized, and transparent. Additionally, relevant requirements on health foods, such as GMP requirements have been well developed.*

- Question 13: the regulation of health foods is not an easy work, which part is much harder than others?

Answer: *The major concern is still about the manufacturer self-regulation. In other words, manufacturers didn't follow GMP rules, adulterate products and claim products have some effects that they actually don't.*

4.2.2. Conclusion

This interview affirms three proposed challenges and more importantly, corrects other three hypothetical challenges.

Factual answers to the three misperceptions are the followings. First, the amount of health food manufacturers is not on a significant increase but fairly stable around 2300, therefore the 46 Testing Laboratories basically could satisfy the need of

assessment. Second, the lengthy registration was not resulted from the lack of enough Testing Laboratories but from the absence of a reward system to motivate Testing Laboratories to work more efficiently. Third, over-consumption of health foods is not often heard, but consumers tend to imagine additional benefits on health foods.

Three hypotheses that are confirmed by the CFDA's official include that most manufacturers are perceived dishonest due to the deceptive claims made, that small and medium sized manufacturers often cannot meet GMP requirements due to financial problem and that the international trade in health foods and food supplements is very complex because the national and regional standards diverge greatly on this issue.

This interview also provides two pieces of important information. One is that registration system is probably not going to be replaced by notification system as registration scheme protects public health the best; however, some changes will be made, probably including establishing an "exemption list of registration".

The other one is that *Health Food Regulation* perhaps will not be established and enacted as expected, therefore, *Measures 2005* still acts as the foundation of the regulation of health foods. However, amendments to *Measures 2005* will be included in the *Revision of Food Safety Law 2009*.

4.3 Hurdles for the Application of Premarket Notification

This section introduces the proposal of health foods notification program made by the CFDA, and points out why notification may not be a success in China at present.

Notification of health foods was proposed in the following way: it was suggested by the CFDA in 2009 at least when the *Draft of Health Foods Regulation* that aimed to establish notification system was publicized for the first time¹³⁰. In the same year, *FSL 2009*, the most important law pertaining to food in China entered into force but did not state any provisions concerning notification system. Four years later in October 2013, the *Draft of Revised FSL 2009* began to seek public comments and till then this notification system was known by public in an official way¹³¹.

The conditions to apply notification were laid down in Article 56 in *Draft of Revised FSL 2009* that notification system applies except for three situations. The three situations are: health foods used new substances that were not derived from approved materials and conventional food; health foods were developed in new forms; health foods were imported for the first time. Only in these three situations, registration with the CFDA is needed¹³².

Accordingly, premarket notification was applicable to health foods that are equivalent to already existing products. If established as such, notification system would be widely welcomed by the most companies engaged in the health food industry because the vast majority of health foods enterprises are small and medium sized, who have limited capital investment and are likely to copy the existing products rather than developing innovative products. Therefore, notification totally fits their situation and will greatly relieve them from administrative burdens. Consequently, the industrial growth seems to increase dramatically.

However, after a long period of formulation, this notification system perhaps will no longer be adopted¹³³ given the already existed problems, including dishonest production, claiming and advertising. Furthermore, the CFDA's official indicates that

¹³⁰ The Central People's Government of the People's Republic of China. Health Foods Regulation (Draft for Comment), *gov.cn*. Retrieved June 19, 2014 from http://www.gov.cn/qzdt/2009-05/31/content_1328230.htm.

¹³¹ USDA Foreign Agricultural Service. (November 2013). Food Safety Law (Draft for Comment) of the People's Republic of China.

<http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Food%20Safety%20Law%20Draft%20for%20Comment%20Beijing%20China%20-%20Peoples%20Republic%20of%2011-8-2013.pdf>. Accessed June 19, 2014.

¹³² *Ibid.*

¹³³ This news was obtained through the interview conducted with an official from the CFDA on 19 June 2014.

existing 2300 manufacturers are able to supply the sufficient health foods to meet the consumer demand and that health food products on market have been in surplus. The major attention was paid to tighten market entry and prevent fraud business practice.

4.4 Summary

This Chapter aims to answer Central Question 2: What are the possible challenges to authority and producers under the current regulatory framework? And what are the hurdles for implementing premarket notification system?

Three challenges hypothesized through article review and case study are affirmed by the CFDA's official. First, the number of deceptive labels and claims is startling, amounting to 94%; second, GMP production is hardly followed in small and medium sized enterprises; finally, diverging national standards on the safety level of substances have a great impact on the international trade in health foods and food supplements.

Besides, practical problems that were rarely mentioned in the publications are found. One example is that the way of allocating the registration fee paid by applicants between Testing Laboratory and the CFDA damages Testing Laboratory's incentive to response applications timely and actively. In short, too many practical things appear when the regulations were put into action. The conflict of interests between parties involved in the regulatory framework sometimes makes the health foods industry victim.

It is the combination of the apparent challenges as well as other practical problems that makes notification an unfeasible plan in China.

5 A Possible Solution to Improve the Chinese Approach Based on the Chinese, EU and U.S. Approach

Chapter 3 reviews regulatory framework for Chinese health foods, the core of which is the registration system on a case-by-case basis and GMP certification on manufacturers.

Chapter 4 analyses the challenges under this regulatory framework and summarizes hurdles for implementing premarket notification system in health food industry.

This chapter attempts to reveal how food categories that are similar to health foods were regulated in the EU and U.S., and give answers to Central question 3: what can be learnt from the EU and U.S. approaches to improve the Chinese approach.

EU and U.S. regulatory approaches were referred to mainly because their approaches to law have influenced many other countries in the world¹³⁴.

The structure of Chapter 5 is as follows.

Section 5.1 identifies that dietary supplements in the U.S. and food supplements in the EU are comparable to health foods in terms of functions and scope.

Section 5.2 briefly reviews the European regulatory framework for food supplements, focusing on the regulation on nutrients, labelling, claiming and production.

Section 5.3 briefly reviews the U.S. regulatory framework for dietary supplements, focusing on the regulation on nutrients, labelling, claiming and production.

Section 5.4 combines the suitable principles of the Chinese, EU and U.S. approaches into a possible solution to improve the Chinese approach.

As usual, the summary of this Chapter is made at the end.

¹³⁴ This opinion was addressed in the course “International and American Food Law”, provided by Law and Governance Group, Wageningen University.

5.1 What Are the Comparable Food Products to Health Foods?

Like the saying that no two leaves are ever exactly alike, a same food term that was coined under separate regulatory frameworks may have its unique scope and concepts. This can be exemplified by the term “food additives”¹³⁵. In contrast, certain food categories with different names in the different countries and/or areas may play the similar role in promoting public health. This section aims to recognise the comparable food categories in the EU and U.S. to health foods with regard to the health benefits they bring to consumers. Only after achieving this recognition, the studying of the related regulatory system is possible.

The similar food categories to health foods are identified under three ways: review amongst legally established food categories, compare the functions and scope, and look at the international trade cases.

5.1.1. Review the Food Categories Legally Defined and their Specific Functions

Identifying the target food categories should base on the food categories that were established by legislation and regulated under given regime. There is no doubt that new terms, such as nutraceutical and functional food that are seemingly similar to health foods had emerged¹³⁶. However, many of these terms lack legal definitions in the EU and U.S.¹³⁷.

Food categories in the US were reviewed first. In the U.S., only food categories that were identified in 21 CFR 170.3¹³⁸ or additional food categories that were determined appropriate by the FDA can be consumed by humans and registered with the FDA¹³⁹. Specifically, 21 CFR 170.3 establishes 43 categories and the FDA affirmed 11 categories¹⁴⁰. These 54 legal categories are summarized in Table 5-1.

¹³⁵ eg. Dominique A. Sinopoli (PhD student at Wageningen University) conducted a comparative study to clarify the differences between food additives in the EU and U.S. on the concepts and functions, available at: <http://edepot.wur.nl/265305>.

¹³⁶ Fortin ND. 2009. Food Regulation. Hoboken, New Jersey, USA: John Wiley & Sons, Inc., p.323.

¹³⁷ *Ibid.*

¹³⁸ 21 CFR 170.3 is available at: <http://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol3/pdf/CFR-2012-title21-vol3-sec170-3.pdf>.

¹³⁹ This is stipulated in the Food Safety Modernization Act, Relevant provisions are available at: <http://edis.ifas.ufl.edu/pdffiles/FS/FS23100.pdf>.

¹⁴⁰ *Ibid.*

Food categories in the EU were set out in Annex II to Regulation (EC) No 1333/2008 on Food Additives¹⁴¹, which aggregates individual food items into a number of food groups and 18 broader food categories¹⁴² (see Table 5-2). Furthermore, the EU food experts and European Food Safety Authority (EFSA) staff once developed a system to standardise food classification in the EU-wide¹⁴³. This system entitled *Food Classification And Description System FoodEx 2* puts individual foods under 117 groups outranked by 20 categories. For example, category “fruit and fruit products” consists of 7 groups, including pome fruit and stone fruit. Another example is category “additives, flavours, baking and processing aids” that is composed of food flavours, food additives and the other 5 groups¹⁴⁴. Both Regulation 1333/2008 and *System FoodEx 2* are the authoritative sources to use, and the analysis presented in Table 5-2 relays on Regulation 1333/2008.

Following the discussion concerning food category above, a summary of food categories legally established in the U.S. and EU can be made accordingly:

¹⁴¹ This Directive is available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0016:0033:en:PDF>.

¹⁴² Regulation (EC) No 1333/2008 on food additives, available at http://www.fsai.ie/uploadedFiles/Consol_Reg1333_2008.pdf.

¹⁴³ More information about this System is available at <http://www.efsa.europa.eu/en/datex/datexfoodclass.htm>.

¹⁴⁴ EFSA. Food Classification and Description System, available at <http://www.efsa.europa.eu/en/supporting/doc/215e.pdf>.

U.S. Food Categories based on 21 CFR 170.3 and additional food categories determined by FDA			
Source	Categories	Groups	Descriptions
21 CFR 170.3	General food categories	Baked goods and baking mixes, beverages, alcoholic, chewing gum, meat products, etc.	These 43 categories were formulated based on the detailed food classifications lists developed by the National Academy of Sciences/National Research Council ¹⁴⁵ .
Additional food product categories ¹⁴⁶	Dietary supplement categories	Vitamins	These types of supplements include vitamin supplements, mineral supplements and their combination.
		Minerals	
		Miscellaneous supplements	These types of supplements consist of proteins, amino acids, fats and lipid substances, animal by-products and extracts, herbals and botanicals.
	other additional food product categories	Acidified food, baby food products, cheese and cheese product categories, etc.	

Table 5-1 The U.S. Food Categories

Source: 21 CFR 170.3; Institute of Food and Agricultural Sciences at the University of Florida (2013)¹⁴⁷;

¹⁴⁵ 21 CFR 170.3.

¹⁴⁶ Additional food product categories can be found in the report formulated by the Institute of Food and Agricultural Sciences at the University of Florida (2013), available at: <http://edis.ifas.ufl.edu/pdf/files/FS/FS23100.pdf>.

¹⁴⁷ *Ibid.*

European Food Categories based on Part D of Annex II to Regulation (EC) No 1333/2008				
No.	Categories	No.	Groups	Descriptions
1-12 & 14-16	General food categories		Dairy products, fruit and vegetables, meat, etc.	These 15 categories can be regarded traditional because they constitute normal diet of an adult.
13	Foods intended for particular nutritional uses as defined by Directive 2009/39/EC.	13.1	Foods for infants and young children defined in Directive 2006/141/EC and Directive 2006/125/EC.	Refer to foods for infant under the age of 12 months and young children aged between one and three years.
		13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC.	Refer to foods specially processed or formulated intended for the dietary management of patients and to be used under medical supervision.
		13.3	Dietary foods for weight control diets intended to replace total daily food intake or an individual meal.	Refer to foods presented as replacements for all or part of the total daily diet.
		13.4	Foods suitable for people intolerant to gluten as defined by Commission Regulation (EC) No 41/2009.	Refer to foods produced, prepared and/or processed to meet the special dietary needs of people intolerant to gluten.
17	Food supplements as defined in Directive 2002/46/EC	17.1	Vitamin and mineral supplements	Cover vitamin only supplements, mineral only supplements and their combinations.
		17.2	Miscellaneous supplements	Cover bee-produced supplements, fibre supplements, herbal formulations and plant extracts, algae based supplements and other common supplements.

Table 5-2 The European Food Categories

Source: Regulation (EC) No 1333/2008;

Note: 1. the Arabic numerals are in accordance with Part D of Annex II to Regulation (EC) No 1333/2008; 2. some of the "Descriptions" are cited from EFSA document (2013)¹⁴⁸.

So, as Table 5-1 and Table 5-2 indicate, among various established food categories, only dietary supplements and food supplements seem comparable to health foods and vice versa in terms of the scope and functions (detailed discussion made in section 5.1.2). On the other hand, these two supplements are equivalent in many ways. First, both of them tend to cover very broad territories. For example, the list of eligible ingredients for dietary supplements is nearly all-encompassing as almost any ingredient could be considered "a dietary substance for use by man to supplement

¹⁴⁸ This EFSA document is entitled Guidance document describing the food categories in Part E of Annex II to Regulation (EC) No 1333/2008 on Food Additives, available at: http://ec.europa.eu/food/food/FAEF/additives/docs/guidance_1333-2008_descriptors_annex2_20131218_en.pdf.

the diet by increasing the total dietary intake”¹⁴⁹. For food supplement, European Commission estimated that the number of substances other than vitamins and minerals used on the European market is over 400¹⁵⁰. Second, the similarity is also highlighted by the common nutrients encompassed by the two supplements. For instance, both food supplements and dietary supplements include the most widespread supplements, such as vitamins, minerals, probiotics, botanicals and botanical extracts, fatty acids and proteins products. Last but not least, these two supplements categories play a similar role in promoting individual health by being additionally added to the diet to reach nutritional balance. For example, dietary supplements aim to supplement the diet and not intend to be a drug or a conventional food¹⁵¹, similarly, food supplements also help supplement the normal diet¹⁵².

It needs to realize that even with the aforementioned likenesses, European food supplements and U.S. dietary supplements are more likely to vary greatly when it comes to, for example, the recommended daily usage, permitted and prohibited ingredients for a specific supplement product, given that many determinants could affect population dietary choice, include geographical location¹⁵³. Therefore, just as stated at the beginning, a similar or even a same food term coined under separate regulatory framework may have its unique scope and functions. However, the similarities between dietary supplements and food supplements found above make the comparison of their legal systems possible and reasonable.

5.1.2. Similarity of Health Foods, Dietary Supplements and Food Supplements

When compared to dietary/food supplements, similar function of health foods is of the first importance. This means health foods are also perceived being food sources of nutrients and therefore can supplement the diet, given the definition of health food in Article 2 of Measures 2005 that health foods are foods that claim to have certain

¹⁴⁹ Fortin ND. 2009. Food Regulation. Hoboken, New Jersey, USA: John Wiley & Sons, Inc., p.329.

¹⁵⁰ Commission staff working document. (May, 2008). Characteristics and perspectives of the market for food supplements containing substances other than vitamins and minerals, Retrieved June 2014 from http://ec.europa.eu/food/food/labellingnutrition/supplements/documents/2008_2976_F_WD1_en.pdf.

¹⁵¹ Fortin ND. 2009. Food Regulation. Hoboken, New Jersey, USA: John Wiley & Sons, Inc., p.329.

¹⁵² Article 2 (a), Directive 2002/46/EC on Food Supplements, available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:183:0051:0057:EN:PDF>.

¹⁵³ European Food Information Council. (April, 2005). The Determinants of Food Choice. Retrieved June 2014 from <http://www.eufic.org/article/en/page/RARCHIVE/expid/review-food-choice/>.

health functions or aim at supplementing vitamins and minerals, and that those foods are used for certain groups of people with the aim to modify a physiological function instead of curing diseases.

Besides, health foods are comparable to food/dietary supplements owing to that the typical nutrients used are also widely used in and characterise the latter two. Specifically, these common nutrients, which are also referred to functional components in health foods, include vitamins, minerals, proteins, fibre, amino acid, carbohydrate, lipids and more¹⁵⁴. Of course, due to the diverse food tradition and dietary intake, the dietary need and preference to the nutrients are dissimilar. Table 5-3 can help better understand the Chinese preference to the multiple nutrients.

Nutrients	Saponins	Carbohydrate	Flavonoid	Fatty acid	Anima / Plant extracts	Amino acid	Protein
Used in health	26%	17%	14%	13%	11%	8%	7%
	Others	Organic acid	Oils / Fats	Fungus			
	4%	3%	3%	3%			

Table 5-3 The Frequency That Nutrients Were Used in Health Foods

Source: Mei He¹⁵⁵.

Note: 1. the data above were collected from health food industry between 1996 and 2008, which didn't include vitamins and minerals. 2. original data contain overlaps among different nutrient groups, so the aggregate of each part exceeds 100%.

In addition to functions and scope, both health foods in China and supplements in the EU and U.S. are under the umbrella of food, not drug. Furthermore, the forms of health foods, the method used to separate health foods from conventional food, and the rule that "cannot claim to treat, cure or prevent and disease" are made closely in line with food/dietary supplements. Table 5-4 presents these similar aspects among health foods and dietary/food supplements.

¹⁵⁴ Mei He. Status of health foods industry in mainland China (literally translated). The content of this study is only presented in slides, not in the article. available at

<http://www.google.nl/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=1&ved=0CCkQFjAA&url=http%3A%2F%2Fwww.fda.gov.tw%2Fupload%2F133%2FContent%2F991201-%25E5%2585%25A9%25E5%25B2%25B8%25E5%2581%25A5%25E5%25BA%25B7%25E9%25A3%259F%25E5%2593%2581->

¹⁵⁵ *Ibid.*

Comparison of Health Foods, Dietary/Food Supplements On Functions, Forms and Scope			
	Health Foods in China	Dietary Supplements in the U.S.	Food supplements in the EU
Classification	Food	Food	Food
Functions do's	have certain health functions or aim at supplementing vitamins and minerals ¹⁵⁶	supplement the diet and not intended to be a drug or a conventional food ¹⁵⁷	supplement the normal diet ¹⁵⁸ and cannot be used for preventing, curing and treating a human disease. ¹⁵⁹
Functions don'ts	cannot claim to cure diseases ¹⁶⁰	may not claim to treat, cure or prevent and disease ¹⁶¹	must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties ¹⁶² .
Forms	similar to the latter two; package in capsules, tablets, particle, powder, liquid, pills, pastilles or conventional food forms ¹⁶³ .	packaged in certain forms, such as capsules, tablets, liquids, pills, pastilles, powders, softgels, or gelpcaps formor in conventional food form ¹⁶⁴ .	packaged in certain forms, such as pills, capsules, pastilles, tablets, sachets of powder, ampoules of liquids and other forms ¹⁶⁵ .
Separate from conventional food	must bear health food logo ¹⁶⁶	labelled as a dietary supplement ¹⁶⁷ , e.g. garlic supplement and vitamin c supplement ¹⁶⁸ .	food supplements are only allowed to be sold in pre-packaged forms under the name 'food supplement' ¹⁶⁹ .
Scope (including, but not limited to)	vitamins	vitamins	vitamins
	minerals	minerals	minerals
	probiotics	probiotics	prebiotics and probiotics
	fatty acids	fats and lipid substances	essential fatty acids
	botanicals	herbals and botanicals	botanicals and botanical extracts
	animal by-products and extracts	animal by-products and extracts	other substances: soy isoflavone, spirulina
	other nutrients	other nutrients	other nutrients

Table 5-4 Comparison of Health Foods, Dietary Supplements and Food Supplements on Functions, Forms and Scope

¹⁵⁶ Art. 2, *Measures 2005*.

¹⁵⁷ Fortin ND. 2009. Food Regulation. Hoboken, New Jersey, USA: John Wiley & Sons, Inc., p.329.

¹⁵⁸ Art. 2 (a), Directive 2002/46/EC on Food Supplements, available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:183:0051:0057:EN:PDF>.

¹⁵⁹ Art. 6 (2), Directive 2002/46/EC on Food Supplements.

¹⁶⁰ *Ibid*.

¹⁶¹ The DSHEA provides for the use of various types of statements on the label of dietary supplements, although claims may not be made about the use of a dietary supplement to diagnose, prevent, mitigate, treat, or cure a specific disease (unless approved under the new drug provisions of the FD&C Act).

¹⁶² Art. 6 (2), Directive 2002/46/EC, available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:183:0051:0057:EN:PDF>

¹⁶³ *Id*. He. Status of health foods industry in mainland China.

¹⁶⁴ 21 U.S.C. § 321 (ff) (2), available at <http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdact/fdactchaptersiandiishortitleanddefinitions/ucm086297.htm>.

¹⁶⁵ Art. 6 (2), Directive 2002/46/EC.

¹⁶⁶ This is stipulated in the Normative Document entitled Requirements on Health Foods Labels, established by CFDA.

¹⁶⁷ 21 U.S.C. § 321 (ff) (2).

¹⁶⁸ Council for Responsible Nutrition. Before and After DSHEA. *Crnusa.org*, retrieved June 2014 from http://www.crnusa.org/leg_DSHEApub.html.

¹⁶⁹ Art. 6 (1), Directive 2002/46/EC.

In short, with regard to regulatory classification, functions (both do's and don'ts), forms of final product, general labelling requirements and scope, dietary and food supplements are comparable to health foods.

5.1.3. Trade in Health Foods and Supplements Between China and EU/U.S.

The international trade cases point out that Chinese health foods, including vitamins, minerals and herbal products, are generally regulated and sold as conventional foods and supplements in Europe and the United States¹⁷⁰. Especially, in the U.S. some Chinese herbal medicine were also marketed and grouped into dietary supplements, which leads to the U.S. being the third largest market for Chinese herbal medicine¹⁷¹. However, a trade barrier that is hard to remove concerns the various safety levels of specific nutrients that are established by national and regional risk assessment bodies. Therefore exporting manufacturers are required to check and comply with the maximum and minimum levels set by importing country.

As stated in section 3.3.6 of Chapter 3 that U.S. vitamins and dietary supplements as well as EU food supplements have been successfully registered as Chinese health foods. These supplements include herbal or traditional supplements, such as ginseng and garlic, non-herbal supplements, such as minerals, probiotics and fish oils and the combination of herbal and non-herbal supplements. For example, Forte Pharma, a leading brand of food supplement in France and well known by its fat burner and detox drinks products, sells fatigue relief health foods in China. Seven Seas Ltd, a major supplier of branded vitamins, minerals and supplements in the UK has introduced its cod liver oil to the Chinese health foods market¹⁷².

5.1.4. Conclusion

Based on the comparison of health foods, dietary supplements and food supplements, it can be seen that health food, dietary supplements and food supplements are similar in their forms of final product, general labelling requirements,

¹⁷⁰ The Ministry of Commerce and China Chamber of Commerce for Import & Export of Medicines & Health Products. 2013. Guide of Quality & Safety Control to Export-oriented Health Products. Pp. 13-19, available at <http://www.cccmhpie.org.cn/Pub/6281/71741.shtml>.

¹⁷¹ *Ibid.*

¹⁷² Information on the company profiles is collected from company's website. Information on their health food products is based on the CFDA's health foods database.

functions and scope. The international trade also affirmed that the European and USA producers of supplements sometimes choose to register their products as health foods. However, a limitation in this study is that it does not provide an in-depth investigation concerning the similarities, therefore, major differences between these three food categories are not found.

5.2. European Approach to Food Supplements

This section analyses the European approach to food supplements with an aim to see if its principle can be adopted to improve the Chinese approach.

This section includes two parts. Section 5.2.1 provides a brief introduction to Directive 2002/46/EC, which is the foundation for food supplements regulation; section 5.2.2 presents an overview of other relevant regulatory instruments pertaining to food supplements.

5.2.1 Directive 2002/46/EC & A Brief Summary

The adoption of Directive 2002/46/EC on Food Supplements in June 2012 was marked a milestone towards the harmonization of the legal framework on food supplements¹⁷³. This is because this directive established harmonised rules for the labelling of food supplements and introduces specific rules on **vitamins** and **minerals** in food supplements¹⁷⁴. One important rule in this Directive is Article 15 (b) that the trade of products containing vitamins and minerals not listed in Annex II (entitled Vitamin and mineral substances which may be used in the manufacture of food supplements) has been prohibited from the 1st of August 2005.

Food supplements, as defined in the Directive are concentrated sources of **nutrients** or **other substances** with a nutritional or physiological effect whose purpose is to supplement the normal diet, marketed in dose form, including capsules, pastilles, tablets, pills and other similar forms. **Nutrients** in the context of the Directive only refer to vitamins and minerals. At the time of this writing, 136 minerals and 45 sources of vitamins were included in the Annexes to the Directive, which collectively formed a so-called “positive list”. The Annexes have been amended and consolidated by Regulation (EC) 1170/2009 by expanding the permitted minerals and vitamins as the historic “positive list” only included a total of 80 minerals and 32 sources of vitamins¹⁷⁵. **Other substances** in the context of the Directive refer to those with nutritional or physiological properties other than minerals and vitamins, which are estimated over 400 and dominated by 6 categories: amino acids, enzymes, prebiotics

¹⁷³ EFSA. 2009. EFSA completes first EU-wide assessment of vitamin and mineral sources used in food supplements, available at: <http://www.efsa.europa.eu/en/press/news/ans090728.htm>.

¹⁷⁴ European Commission. Food Supplements, available at: http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm.

¹⁷⁵ *Ibid.*

and probiotics, essential fatty acids, botanicals and botanical extracts, and lastly, miscellaneous bioactive substances. Currently, specific rules on these substances are not harmonized at the European level; instead, they are governed by individual EU Member States¹⁷⁶.

In short, *Directive 2002/46/EC* establishes a definition for food supplements, makes a positive list of permitted vitamins and minerals and sets labelling requirements. A wide range of other substances that may be present in food supplements, such as amino acids and herbal extracts, are regulated by legislations under the Member States.

5.2.2 An overview of Relevant Regulatory Instruments

This section provides an overview of the various pieces of legislation concerning food supplements along with explanations of the legislation.

The following legal instruments cover nutrients used in food supplements, the addition of new nutrients, claims, labelling and production (see Table 5-6).

Aspects	Regulatory Instruments
Vitamins and minerals	<i>Directive 2002/46/EC on Food Supplements (hereinafter: Directive)</i>
Adding new vitamins and minerals	EFSA's Guidance for the addition of new substances ¹⁷⁷
Substances other than vitamins and minerals	Member State national legislation
Health claims	<i>Regulation (EU) No 1924/2006 on Nutrition and Health Claims</i>
Labelling	<i>Directive 2002/46/EC on Food Supplements</i>
	<i>Regulation (EU) No 1169/2011 on Food Information</i>
Production	EU legal requirements on food hygiene, such as <i>Regulation (EC) 852/2004 on the Hygiene of Foodstuffs</i>
	Member State national legislation

¹⁷⁶ Commission staff working document. 2008. Food supplements containing substances other than vitamins and minerals.

¹⁷⁷ Health and Consumers Directorate-General. 2012. Administrative Guidance on Submissions for Safety Evaluation of Substances Added for Specific Nutritional Purposes in the Manufacture of Foods, available at: http://ec.europa.eu/food/food/labellingnutrition/nutritional/adm_guidance_safety_substances_en.pdf.

Table 5-5 Regulatory Instruments Concerning Food Supplements

Source: EFSA

Note: adapted from U.S. Commercial Service (2011)¹⁷⁸.

The aforementioned pieces of legislation are briefly discussed below.

First is the regulation of permitted vitamins and minerals as well as new vitamins and minerals. As discussed in section 5.2.1, “positive list” established by the Directive had been amended through legislative procedure. “System of positive lists set by statutory law is still the core mechanism of premarket approval schemes in the EU”¹⁷⁹. European Food Safety Authority has taken charge of evaluating safety and bioavailability of the individual mineral and / or vitamin. The time scale of the inclusion of new vitamin and mineral substances is estimated between two and three years, which generates \$119,000 to \$372,000 to finalize the whole authorization procedure¹⁸⁰.

Second is the regulation of other substances. Other substances are subject to Member State national legislation. However, a problem under Member States legislation is that the regulatory status on the use of certain substances varies significantly across the Member States. For example, supplements containing garlic needs to go through pre-market approval authorization in France, but is permitted for use in Germany and Italy without authorization. Another controversial case is the regulatory status of certain herbal ingredients: Gingko is permitted for use in food supplements in 7 Member States, such as Denmark and Poland, but regarded as medicinal in other Member States including Greece, Germany and Sweden. In other words, the European food supplements market is less united in a way that it is up to the individual Member States to take the regulatory or non-regulatory approaches to certain substances that are intended to be added in food supplements¹⁸¹.

¹⁷⁸ U.S. Commercial Service. 2011. EU Regulations on Food Supplements, Health foods, herbal medicines, available at: http://export.gov/europeanunion/static/MR162-%20FoodSuppsMIupdate2011_Latest_eg_eu_032796.pdf.

¹⁷⁹ Bernd M.J. van der Meulen, Harry J. Bremmers, Jo H.M. Wijnands and Krijn J. Poppe. (2012). Structural Precaution: The Application of Premarket Approval Schemes in EU Food Legislation. *Food and Drug Journal*, 67, 454-473, p.458.

¹⁸⁰ Sara Atherton Mason. (2010). Dietary supplement regulation: a comparative study of Transnational Law & Policy, 2010-2011, pp. 105-127.

¹⁸¹ European Advisory Services. (March, 2007). The Use Of Substances With Nutritional Or Physiological Effect Other Than Vitamins And Minerals In Food Supplements, (to next page)

In order to facilitate free movement of food supplement between Member States, the “principle of mutual recognition” set out in the Treaty on the Functioning of the European Union applies. Briefly, mutual recognition stipulates that Member States cannot prohibit the sale of a product that is lawfully manufactured or marketed in the exporting Member State on their territory. Mutual recognition also stipulates that the importing Member States are allowed to call for the prior authorization procedure on the basis that authorization must be readily accessible and would be completed within a reasonable time¹⁸².

In the trade in food supplements (include minerals, vitamins and other nutritional supplements) between Member States, the *Directive* allows Member States to require manufacturers’ notification if they wish, which means whether or not a notification is mandatory depending on the individual Member States¹⁸³. For example, in Germany, a compulsory notification scheme for food supplements is adopted, meaning manufacturers wishing to market a food supplement on the German market must notify the German competent authority. By contrast, the UK has decided not to make such requirement, reducing the burden on UK businesses¹⁸⁴.

Third is the regulation of labelling. Food supplements have their own labelling requirements as laid down in the *Directive*. The fundamental rule is that the labelling of food supplements must not contain any statement attributing to the product properties of preventing, treating or curing a human disease and any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general¹⁸⁵. This rule grouped food supplement into food, not drug. However, the *Directive* didn’t establish specific values for maximum and minimum levels for vitamins and minerals present in food supplements, therefore “member States may establish national rules in compliance with Articles 34 and 36 of the Treaty on the Functioning of the European Union”¹⁸⁶. This implies that manufacturers

http://ec.europa.eu/food/food/labellingnutrition/supplements/documents/2007_A540169_study_other_substances.pdf. Accessed on June 18, 2014.

¹⁸² *Ibid*, pp. 58-59.

¹⁸³ Art.10 of Directive 2002/46/EC Relating To Food Supplements.

¹⁸⁴ UK Department of Health. (Sep., 2011). Food supplements: Guidance notes on legislation implementing Directive 2002/46/EC on food supplements, p.21.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/204324/Supplements_SI_guidance_Jan_2012_DH_FINAL.pdf. Accessed on June 18, 2014.

¹⁸⁵ Art. 6 (2), Directive 2002/46/EC.

¹⁸⁶ European Commission. (2012). Guidance document for competent authorities for the control of compliance with EU legislation on Directive 2002/46/EC. P9.

wishing to export food supplements to individual Member States should look at and comply with specific national legislation of importing Member States.

In addition to Directive 2002/46/EC, Regulation (EU) No 1169/2011 on Food labelling is applicable to food supplements as well. An exception is that the nutrition declaration included in this regulation doesn't apply to food supplement¹⁸⁷.

Forth concerns the regulation of health claims. Only health claims established by Regulation (EC) No 1924/2006 on Nutrition and Health Claims (NHCR) can be selected to use. Specially, all the necessary conditions for the use of health claims must be met. All of the authorized and rejected health claims, together with specific conditions of uses and other detailed information, such as Commission regulation referred to, can be found in an EU Register¹⁸⁸, which is accessible to the public.

Under Article 13 & 14 of Regulation (EC) No 1924/2006, there are 3 types of health claims:

- General "health claim" suggests a relationship between food and health;
- "Reduction of disease risk claim" suggests a relationship between food and the reduction of a risk factor in the development of a human disease;
- Claims referring to children's development and health.

For health claims, so far, most health claims for vitamins, some minerals, omega-3s and sterols/stanols are substantiated by the EFSA, but hundreds of claims especially for pre- and probiotics are rejected because related scientific assessment cannot validate claimed effects¹⁸⁹. Health claims regarding botanicals will be considered after 2011¹⁹⁰.

For disease risk reduction claims and claims referring to the health and development of children, by January 2014, 75 scientific opinions have been adopted¹⁹¹. As a result, 20 health claims referring to risk reduction and to children's have been established¹⁹².

¹⁸⁷ Art. 29. 1 (a), Regulation (EU) No 1169/2011.

¹⁸⁸ http://ec.europa.eu/food/food/labellingnutrition/claims/community_register/authorised_health_claims_en.htm

¹⁸⁹ U.S. Commercial Service. 2011. EU Regulations on Food Supplements, Health foods, herbal medicines, available at: http://export.gov/europeanunion/static/MR162-%20FoodSuppsIMIupdate2011_Latest_eg_eu_032796.pdf.

¹⁹⁰ *Ibid*.

¹⁹¹ EFSA. (Jan., 2014). Claims on disease risk reduction and child development or health under Article 14. <http://www.efsa.europa.eu/en/topics/topic/article14.htm>. Accessed on June 18, 2014.

¹⁹² Available at: <http://ec.europa.eu/nuhclaims/?event=search&CFID=1136928&CFTOKEN=8c591f1e2f62c96f-6417E72E-CC87-156A-7A22F6B4A8E0708A&jsessionid=93124ab5fbecb80e403e27f1f55048314d64TR>.

All applications in relation to these two types of claims submitted to EFSA are included in the Register of Questions¹⁹³.

Finally, legislation on the production of food supplement that aims to ensure the safety and quality of final product are discussed. The production of food supplements should comply with the EU legal requirements on food hygiene and specific national legislation in their home country¹⁹⁴. Across the EU, a key act addressing hygiene rules is Regulation (EC) 852/2004 on the hygiene of foodstuffs¹⁹⁵. This Regulation makes Hazard Analysis Critical Control Point (HACCP) within the food industry legal requirements since 1st January 2006¹⁹⁶. Furthermore, food supplements must be manufactured in accordance with the national requirements. For example, in Ireland the national requirements were established under the European Communities (Food Supplements) Regulations¹⁹⁷.

5.2.3 Conclusion

The European approach to food supplements seems to perfectly guarantee the safety and quality of products, as hardly, any adverse report resulted from consuming food supplements can be found. It appears few cases of recall or withdraw in relation to food supplements either. However, enacting the Directive 2002/46/EC came at a price. The strong opposition to the Directive was expressed by the industry and consumer as the Directive threatened a large number of products that contain hundreds of nutrients out of the “positive list” and restricted the consumer choice¹⁹⁸. However, in terms of human health and consumer protection, the Directive 2002/46/EC is successful.

¹⁹³ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=NDA&foodsectorarea=27>.

¹⁹⁴ Food Supplement Europe. (March, 2014). Food Supplements Europe Guide to Good Manufacturing Practice for Manufacturers of Food Supplements, available at: <http://www.foodsupplementseurope.org/sites/0023/uploads/content/publications/good-manufacturing-practice-for-manufacturers-of-food-supplements.pdf?1397143544>.

¹⁹⁵ EFSA. Food Hygiene - Basic Legislation, available at: http://ec.europa.eu/food/food/biosafety/hygienelegislation/comm_rules_en.htm.

¹⁹⁶ European Federation of Associations of Health Product Manufacturers. (November, 2007). Quality guide for food supplements: Guidance for the manufacture of safe and consistent supplements across the EU. <http://www.ehpm.org/attachments/article/11/04%20EHPM%20Quality%20Guide.pdf>. Accessed on June 18, 2014.

¹⁹⁷ This Regulation is available at: [http://www.fsai.ie/uploadedFiles/SI_506_2007\(1\).pdf](http://www.fsai.ie/uploadedFiles/SI_506_2007(1).pdf).

¹⁹⁸ Roberto Giunta, Giovanni Basile and Arianna Tibuzzi. (2011). Legislation on Nutraceuticals and Food Supplements: A Comparison between Regulations in USA and EU, p.5. https://www.landesbioscience.com/pdf/24Giardi_Tibuzzi_Giunta.pdf.

5.3. U.S. Approach to Dietary Supplements

This section analyses the U.S. approach to dietary supplements with an aim to find out if its principle can be used to improve the Chinese approach.

This section includes two parts. Section 5.3.1 provides a brief introduction to DSHEA 1994, which is the prevailing regulation governing dietary supplements; section 5.3.2 presents an overview of other relevant regulatory instruments pertaining to dietary supplements.

5.3.1 DSHEA 1994 & A Brief Summary

Dietary Supplement Health and Education Act 1994 (DSHEA 1994)¹⁹⁹ reaffirmed dietary supplements as food not drug and established a new regulatory framework for dietary supplements²⁰⁰.

Under the DSHEA 1994 and Federal law, a dietary supplement is any food product taken by mouth that contains one or more dietary ingredients such as vitamins, minerals, herbs or other botanicals, amino acids or other ingredients used to supplement the diet²⁰¹. The list of eligible ingredients is nearly all-encompassing because almost any ingredients could be used to supplement the diet²⁰². For instance, even a substance that has been approved as a drug or is under a new drug application is dietary ingredients as long as long it was first marketed as supplement or food before the passage of DSHEA 1994²⁰³.

More importantly, DSHEA 1994 established a new regulatory framework for dietary supplements. One important provision is that ingredients of dietary supplements could not be regulated as food additives²⁰⁴, which was a direct victory for industry because before DSHEA, the FDA attempted to classify non-vitamin/mineral ingredients of dietary supplements as unapproved food additives.

¹⁹⁹ Dietary Supplement Health and Education Act of 1994, Public Law 103-417.

<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticA>. Accessed June 18, 2014.

²⁰⁰ Council for Responsible Nutrition. DSHEA Summary & Analysis. *Crnusa.org*, Retrieved June 2014 from <http://www.crnusa.org/leg.html#dshea>.

²⁰¹ *Ibid*.

²⁰² Fortin ND. 2009. Food Regulation. Hoboken, New Jersey, USA: John Wiley & Sons, Inc., p.329.

²⁰³ Steve Myers. (April, 2014). The Importance of DSHEA: Past, Present, and Future. Retrieved June 2014 from <http://www.naturalproductsinsider.com/articles/2014/04/the-importance-of-dshea-past-present-and-future.asp>.

²⁰⁴ Council for Responsible Nutrition. Before and After DSHEA. *Crnusa.org*, Retrieved June 2014 from http://www.crnusa.org/leg_DSHEApub.html.

Another major principle set forth in DSHEA 1994 is that the dietary supplement manufacturers are responsible for ensuring the safety of a dietary supplement and not required to demonstrate safety by notifying the FDA before marketing a dietary supplement, provided the ingredients were marketed in the U.S. before October 15, 1994^{205 206}. This decision was made mainly because the USA Congress held that safety problems with dietary supplements were relatively rare and thus these supplements could be provided a presumption of safety²⁰⁷. Consequently, the FDA bears the burden of proof to show that a dietary supplement is unsafe and if this is the case, FDA can remove a dietary supplement from the market. A supplement was deemed unsafe if it presents “a significant or unreasonable risk of illness or injury” or that it contains “a poisonous or deleterious substance which may render it injurious to health”²⁰⁸. An example of FDA taking action against unsafe dietary supplement is “OxyElite Pro” case arose in October 2013. In this case, FDA suspected a possible link between OxyElite Pro products and cases of liver failure and non-viral hepatitis in Hawaii. Then FDA warned the public and immediately launched an investigation with state officials and the Centres for Disease Control and Prevention (CDC). Finally, the producer agreed to recall and destroy the OxyElite Pro supplements²⁰⁹.

5.3.2 An Overview of Relevant Regulatory Instruments

This section provides an overview of the various pieces of legislation pertaining to dietary supplements along with explanations of each legislation.

The legal instruments concerns dietary ingredients, claims, labelling, and manufacturing (see Table 5-7).

²⁰⁵ Fortin ND. 2009. Food Regulation. Hoboken, New Jersey, USA: John Wiley & Sons, Inc., p.352.

²⁰⁶ Dietary supplement ingredient that were not marketed in the United States before October 15, 1994 are referred to “new dietary ingredients”. New dietary ingredients need a mandatory 75-day premarket notification to the FDA before entering into market. *Source*: 21U.S.C.350b and 21 C.F.R. 190.6 on requirement for premarket notification.

²⁰⁷ Fortin ND. 2009. Food Regulation. Hoboken, New Jersey, USA: John Wiley & Sons, Inc., p.352.

²⁰⁸ Council for Responsible Nutrition. DSHEA Summary & Analysis. *Crnusa.org*, Retrieved June 2014 from <http://www.crnusa.org/leg.html#dshea>.

²⁰⁹ This case is available on FDA website at: <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm374742.htm> (accessed June 13, 2014).

Aspects	Legislation
Old Dietary Supplement Ingredients	<i>DSHEA 1994</i>
New Dietary Supplement Ingredients	<i>Food Drug and Cosmetic Act 21 U.S.C. § 350b²¹⁰</i> (provision governing new dietary ingredients)
Health Claims on Dietary Supplement	<i>Nutrition Labelling and Education Act (NLEA) 1990</i>
	<i>FDA's guidance (entitled Interim Procedures for Qualified Health Claims in the Labelling of Conventional Human Food and Human Dietary Supplements)²¹¹</i>
Labelling	DSHEA 1994
Manufacture	Current Good Manufacturing Practices (established by the FDA)

Table 5-6 Regulatory Instruments Concerning Dietary Supplements

Source: U.S. FDA Website

Note: Adapted from Natural Products Association (2011)²¹².

The content below starts with the regulation of dietary ingredients. Dietary ingredients were marketed either without any evidence of efficacy or safety or just with too less regulatory oversight²¹³. Specifically, ingredients that were sold in the United States before 1994 can be used directly without having the FDA notified (i.e. old dietary ingredients or pre-DSHEA dietary ingredients). For ingredients that were introduced since 1994, it is required to notify the FDA with a dossier showing safety and other required data (i.e. new dietary ingredients NDI)²¹⁴. However, the provision regarding NDI has by far not been enforced²¹⁵, mainly because there is no authoritative list of old dietary ingredients and therefore manufacturers and distributors are responsible for determining if an ingredient is an NDI²¹⁶. This leads to the fact that the purity and quality of the ingredients (both old and new) sometimes cannot be guaranteed on the evidence that dietary supplements accounted for more than half of the Class 1 drugs

²¹⁰ The provision includes general information of NDI, covering definition and notification, available at: <http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap9-subchapIV-sec350b.pdf>, access on 13 June, 2014.

²¹¹ U.S. FDA. Summary of Qualified Health Claims Subject to Enforcement Discretion, available at: <http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm073992.htm>.

²¹² Natural Products Association. (2011). *Regulation on Dietary Supplements*, available at: http://www.npainfo.org/NPA/About_NPA/NPA/AboutNPA/AbouttheNaturalProductsAssociation.aspx?hkey=8d3a15ab-f44f-4473-aa6e-ba27ccebcb8.

²¹³ Pieter A. Cohen, M.D. (2012, Feb.2). Assessing Supplement Safety — The FDA's Controversial Proposal. *The New England Journal of Medicine*. Retrieved June, 2014 from <http://www.nejm.org/doi/full/10.1056/NEJMp1113325#t=article>.

²¹⁴ *Ibid.*

²¹⁵ *Ibid.*

²¹⁶ U.S. FDA. New Dietary Ingredients in Dietary Supplements - Background for Industry. <http://www.fda.gov/food/dietarysupplements/ucm109764.htm>. Accessed June 18, 2014.

recalled by the U.S.²¹⁷. The majority of those recalled supplements contained unapproved medicinal ingredients²¹⁸.

Second, all health claims on dietary supplement need to be preapproved by the FDA as regulated under the NLEA 1990 and FDA's guidance concerning Qualified Health Claims. The NLEA 1990 established NLEA Authorized Health Claims and the FDA's guidance proposed Qualified Health Claims. Both of them describe a relationship (NLEA claims) or possible but not well-established relationship (Qualified claims) between an ingredient and reduced risk of a disease or health-related condition²¹⁹. A list of NLEA claims and Qualified claims in the labelling of dietary supplements can be found on the FDA website^{220 221}.

However, there is another type of claims that demonstrates certain effects without the FDA's preapproval, known as Structure/Function Claims. Structure/Function Claims must be accompanied with a disclaimer that *"This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease."* The main problems with this is that currently on the U.S. market, the great majority of supplement claims are Structure/Function Claims²²², however those claims will be notified to the FDA only after the product is on the market as "manufacturers must notify the FDA of the health claims they are making within 30 days of marketing a given dietary supplement."²²³, which means before the claims were found inappropriate, the products may have reached consumer who probably was misled by that inappropriate claims. Additionally, some structure or function claims are so confusing that may be regarded as having the same function as drugs. For example, claim that "reduces irritability, bloating, and cramping associated with

²¹⁷ St. Michael's Hospital. (2013, April 18). More efforts needed to regulate dietary supplements, experts urge. *ScienceDaily*. Retrieved June, 2014 from www.sciencedaily.com/releases/2013/04/130418124907.htm.

²¹⁸ *Ibid*.

²¹⁹ U.S. FDA. (December, 2013). Label Claims for Conventional Foods and Dietary Supplements, available at: <http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm111447.htm>.

²²⁰ NLEA claims: U.S.FDA. (January, 2013). Guidance for Industry: A Food Labeling Guide (11. Appendix C: Health Claims), available at: <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064919.htm>.

²²¹ Qualified claims: U.S. FDA. (July, 2013). Guidance for Industry: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements, available at: <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm053832.htm>.

²²² Natural Products Association. (2011). Regulation on Dietary Supplements.

²²³ 21 C.F.R. § 101.93.

premenstrual syndrome” is confusing enough to make consumer believe its disease reduction function. However, this claim was OK after the FDA’s review²²⁴.

Third, after the passage of DSHEA 1994, the accuracy of labels for dietary supplements has arisen scientists’ concerns due to serious health issues. Although DSHEA 1994 stipulated that all dietary supplement ingredients must be listed on the label, and the product must meet the strength, quality, and purity levels the supplement is represented to have²²⁵, this stipulation, regulated by manufacture itself, is hardly satisfactorily fulfilled. For example, problems with the labels of dietary supplement found by the FDA and some independent researchers include the followings: supplements contained none of what was listed on the label; supplements contained more or less than the amount listed on the label; extra ingredients were added in supplements. In the last situation, public health would be greatly threatened if man-made drugs were deliberately added and the person doesn’t know he or she is taking a drug²²⁶, which has happened before and led to human death and life-threatening side effects²²⁷. Worse, even those adverse events happens, dietary supplement manufacturers are not legally required to report to the FDA, including injuries or illnesses²²⁸.

Last but not least, the quality and purity of final dietary supplement are largely ensured by implementing current Good Manufacturing Practices (cGMPs) that were established by the FDA exclusively for dietary supplement industry and went effective in 2007. Under this GMP, dietary supplement manufacturers must adhere to Good Manufacturing Practices as of June 2010, the time FDA started conducting GMP Audits²²⁹. By adopting this cGMPs, it is believed that dietary supplements meet quality standards and are manufactured consistently as to their identity, purity,

²²⁴ American Cancer Society. (June, 2014). Dietary Supplements: What Is Safe?, p.10.

²²⁵ Natural Products Association. (2011). Regulation on Dietary Supplements.

²²⁶ American Cancer Society. (June, 2014). Dietary Supplements: What Is Safe? pp.7-8, available at: <http://www.cancer.org/acs/groups/cid/documents/webcontent/002385-pdf.pdf>.

²²⁷ One example is OxyElite Pro supplements case that causes one death and illnesses so severe that several patients required liver transplants, available at: <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm374742.htm>.

²²⁸ U.S. Pharmacopeia. The Regulation of Dietary Supplements. Retrieved June 14, 2014 from http://www.usp.org/sites/default/files/usp_pdf/EN/USPVerified/dietarySupplementRegulation.pdf.

²²⁹ U.S. FDA. (October 2007). Overview of the Implementation of the Current Good Manufacturing Practices for Dietary Supplements Guidance for Industry, available at: <http://www.fda.gov/Food/GuidanceRegulation/CGMP/ucm173996.htm>.

strength, and composition²³⁰. However, as with Chinese manufacturers, not all U.S. manufacturers follow the rules²³¹.

5.3.3 Conclusion

Different than the way of reviewing the European approach to food supplements, the U.S. approach is accompanied with a series of negative consequences, such as human death, adverse side effects and false labels. That's why some researchers even argued that keeping the status quo might taint the dietary supplement industry as a whole²³². However, on the other hand, under DSHEA 1994 the industry was given the greatest possible support and consumers get the fullest access to their favourite supplements.

²³⁰ *Ibid.*

²³¹ American Cancer Society. (June, 2014). Dietary Supplements: What Is Safe?, p.8.

²³² St. Michael's Hospital. (2013, April 18). More efforts needed to regulate dietary supplements, experts urge. ScienceDaily. Retrieved June 14, 2014 from www.sciencedaily.com/releases/2013/04/130418124907.htm

5.4. A Possible Solution to Improve the Chinese Approach Based on the Chinese, EU and U.S. Approach

Based on all of the discussions made in this and other Chapters, this section aims to answer Central Question 3: what can be learnt from the EU and U.S. approaches to improve the Chinese approach.

Indeed, there are some principles that are well worth considering and also some lessons that can be learnt. First, the Chinese, EU and U.S. principles diverge greatly from each other as Table 5-7 presents.

	Chinese approach	EU approach	U.S. approach
Major principles	Health foods are considered unsafe until proven safe.	Food supplements are considered unsafe unless “positive lists” were complied with.	Dietary supplements are considered safe until proven unsafe.

Table 5-7 Principles of the Chinese, EU and U.S. Approach

However, the Chinese and EU approach are a bit closer as both consider products unsafe first, while the U.S. adopts an opposite attitudes that firstly deem products safe until proven unsafe. One major consequence of the U.S. approach is the increase in life-threatening illnesses, deaths and other serious adverse events that food supplements involve for six consecutive years²³³. As Figure 5-1 tells from 2008 through 2013, 10,585 mandatory has been reported. Therefore, the U.S. principle that dietary supplements are safe until proven unsafe is not recommended. However, the CFDA should continue conducting GMP audits on manufacturers as the FDA does.

.....
Mandatory adverse event reports (supplements) submitted to FDA

2013: 3,289
2012: 2,844
2011: 2,037
2010: 1,014
2009: 714
2008: 687

Source: FDA

..... **Figure 5-1**

²³³ Josh Long. (April, 2014). Dietary Supplement Adverse Event Reports Increase. Retrieved on June 19, 2014 from <http://www.naturalproductsinsider.com/news/2014/04/dietary-supplement-adverse-event-reports-increase.aspx>.

Source: Nutritional Products²³⁴

Part of the EU approach, mainly defining the conditions of the use for health claims is currently considered by the CFDA, with an intention to both relieve burdens on manufactures and ensure that final products are properly showing claims²³⁵. The present reality in the Chinese approach to health foods is that the CFDA established the 27 claims for health foods, but in which condition these claims could be made was not summarized yet. Consequently, all new products need to be authorized on a case-by-case basis. In future after the conditions of the use of (some) health claims are substantiated, if the products meet the conditions of using certain health claims, those products no longer need to go through registration, instead, they are merely required to be notified to the CFDA before or after being marketed. At the first phrase of initiating this notification scheme, the CFDA is advised to review the European Health Claim Register that defines the conditions of using health claims and then establish its own health claim system.

Notification may suit the health foods that contain a single nutrient or simple combinations of nutrients, such as mineral and multi mineral supplements, vitamin and multi vitamin supplements, and the combination of one or two herbal preparations because the efficacy of these nutrients has long been acknowledge worldwide and probably it's less harder for the CFDA to define the conditions of claiming effects. For example, the CFDA could establish a positive list of health claims that are related to Vitamin D (or other Vitamins) and define use conditions as EFSA has affirmed that Vitamin D contributes to normal absorption and utilisation of calcium and phosphorus. This claim can be used for food which at least contains 0.75 µg Vitamin D²³⁶; in addition, the WHO also has convincing evidence that Vitamin D is good for bone health²³⁷. Accordingly, health foods containing at least 0.75 µg Vitamin D and with a claim, for example, "maintenance of normal blood calcium

²³⁴ *Ibid.*

²³⁵ This information was indicated by the CFDA's officials on the interview conducted on June 19, 2014. Whole list of interview questions are presented in section 4.2.1& 4.2.2 of Chapter 4.

²³⁶ This health claim is retrieved from the EU Register on nutrition and health claims, available at: <http://ec.europa.eu/nuhclaims/>. The original condition is defined as "The claim may be used only for food which is at least a source of vitamin D as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.". According to Regulation (EC) No 1924/2006, A claim that a food is a source of vitamins and/or minerals may only be made where the product contains at least a significant amount as defined in the Annex to Directive 90/496/EEC where "Source of" Vitamin D is 0.75µg.

²³⁷ IADSA. (2010). Scientific substantiation of health claims: A global analysis, p.45, available at: http://www.iadsa.org/publications/1285935246_The_scientific_Substantiation.pdf. Accessed on June 19, 2014.

concentrations”²³⁸, only need to submit notification to the CFDA and need not to go through registration. An important rule is that the regulation of nutrients should be in accordance with the current normative documents, the core of which is nutrients must be derived from the approved materials or conventional foods²³⁹.

A case-by-case registration framework has its advantages and thus should be retained. Specifically, given the Chinese dietary tradition, most of the modern health foods are herbal and botanical supplements that Chinese consumers give the greatest preference, so that they dominate the health foods market, accounting for 41.5% health foods²⁴⁰. A single herbal supplements may contain 14 preparations at the most²⁴¹ out of 198 approved botanicals and animal products (198 refers to the three positive list of approved raw materials and does not take into account other positive lists on, for example probiotics and enzymes). Therefore, various combinations makes it hard for the CFDA to acknowledge the benefits of individual combination²⁴² and this is why each combination undergoes registration currently. Likewise, registration should be still retained for the health food if it remains unclear whether the health food in question is eligible to bear one or more of the 27 permitted claims. In addition, a big advantage of this case-by-case registration is that it helps manufacturers reduce the potential product risk.

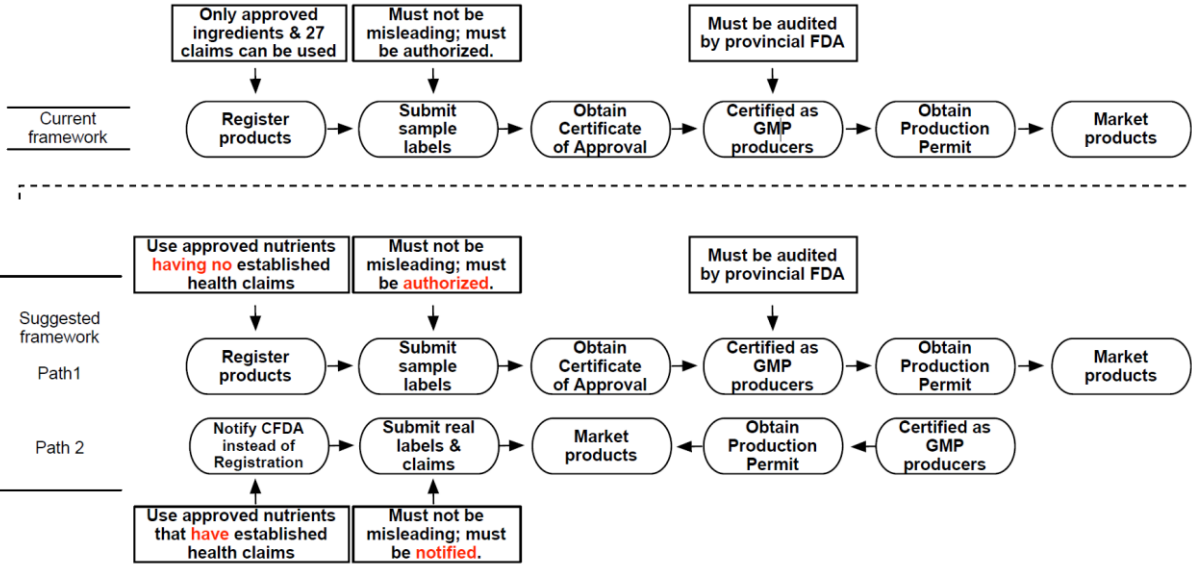
²³⁸ This health claim is retrieved from the EU Register on nutrition and health claims, available at: <http://ec.europa.eu/nuhclaims/>.

²³⁹ Art. 63, *Measures 2005*.

²⁴¹ Art. 5, *Doc. No.5*: If a health food to be registered contains substances of plant or animal original, the totality of the substances should not exceed 14.

²⁴² When registering their health foods, applicants are free to choose from the 27 health claims to use on their products based on the scientific evidence. However, the CFDA and its testing laboratory will determine the correct use of health claims.

Finally, taking into account all positive benefits and negative consequences above, a new solution for the Chinese approach is pictured as follows:



The current framework refers to the case-by-case registration framework that the CFDA implements at present. The essences include that sample health foods, sample labels, proposed claims and sample advertisement (when there is) must be registered (or authorized) altogether with the CFDA, that raw materials used in health foods must be on the approved list or derived from conventional foods, that proposed claims must be from the 27 ones, and that only GMP certified companies could produce health foods.

Suggested framework, on the other hand, is based on the former case-by-case registration and on the notification scheme that certain health foods may involve.

Specifically, notification scheme could be applied to the health foods whose compositions comply with the conditions to use one or more of the 27 claims, such as mineral supplements, vitamin supplements and some herbal supplements. Accordingly, real health foods, real labels, claims and real advertisement should be notified to the CFDA.

Registration is needed for other health foods when the compositions of which are not in accordance with the established conditions of use of the (27) claims and therefore need to be evaluated. In these cases, producers are required follow the same registration as it is today.

Finally, whether notification could go effective and how many products could be exempted from registration totally depends on the CFDA's achievement to clarify the conditions of use of the claims.

5.5. Summary

This Chapter aims to answer Central Question 3: what can be learnt from the EU and U.S. approaches to improve the Chinese approach. This question is answered in section 5.4 after the EU and U.S. approaches to supplements are reviewed.

Briefly, part of the U.S. approach is highly recommended, including the concept of notification and GMP audits conducted by the FDA to ensure supplements quality and safety. Although applying notification to all health foods in China and invalidating registration system will probably trigger off the huge risk of unsafe health foods being marketed, implementing the notification of vitamin and mineral supplements and other common health foods, such as protein powder and fish oil, seems plausible.

Some of the European approach is also a good fit in China, especially defining the conditions of use of the claims. By doing so, a food supplement meeting the claim conditions is free to bear the specific claims. The CFDA also considers defining the claim usage conditions for its 27 claims that health foods can bear. Likewise, a health food satisfying the claim conditions is exempted from registration.

The Chinese registration scheme is retained for the health foods when the compositions of which are not in accordance with the established conditions of use of the (27) claims and therefore need to be evaluated.

Finally, a new solution for Chinese approach is based on two paths: notification system for vitamin and mineral supplements, as well as the health foods that conform to the existing positive lists of health foods substances and comply with the conditions of use of the health claims on positive list—the conditions to use health claims haven't been specified by the CFDA at present. The registration system for the other health foods.

The main advantage of this framework is to reform the current lengthy and costly registration by pushing the CFDA to focus on substantiating health claims made on complex health food mixtures. The limitation of this framework is that it doesn't directly deal with false labels and advertisement, which may still lean heavily on the CFDA's inspection in short term.

6 Conclusion

This Chapter reviews the research goals first and then concludes this study by restating what answers I have found to the three Central questions.

Two goals are defined. First, I want to deepen the understanding of the Chinese approach to a food category that is regulated in a different way in the EU and U.S., and then develop the analytical ability to make suggestions to improve the Chinese approach through the comparative study.

Three food categories are involved: Chinese health foods, the European food supplements and the U.S. dietary supplements.

Three Central questions are organized around the two goals.

- Central question 1: What is the regulatory framework for health foods in China?
- Central question 2: What are the possible challenges to authority and producers under current framework? And what are the hurdles for implementing premarket notification system for health foods?
- Central question 3: What can be learnt from the EU and U.S. approaches to improve the Chinese framework?

Central question 1 seeks to develop a comprehensive understanding of the regulatory framework for health food. Central question 2 aims to find out the challenges this framework is facing and determine whether notification system would be a success in China at this moment. Central question 3 makes suggestions to overcome challenges and then reform the framework, taking into account the answers to Central question 1 and 2 and the analysis of the EU and U.S. approaches.

The answers to the three Central questions are detailed as follows:

- Central question 1: What is the regulatory framework for health foods in China?

First, Chinese health foods are regulated by a set of legal instruments, primarily by *Food Safety Law 2009 of People's Republic of China* and a rule entitled *Administrative Measures on Health Foods Registration (Interim) 2005 (Measures 2005)*. Other legal instruments include two national standards on health foods and a great number of normative documents to clarify specific issues, such as to establish

positive lists of substances added in health foods, and to provide guidance for the industry to properly name a health food.

Second, the CFDA has oversight of the regulation of health foods. This means the CFDA supervises health foods production, on-site inspection, GMP audit, product authorization, labels and advertisement preapproval, as well as post market surveillance. NHFPC takes charge of when national standards on health foods are updated, modified, and need to be developed.

Lastly, at the core of the regulatory framework is product registration on a case-by-case basis and GMP certification on manufacturers. Only after passing the strict registering process, a health food is granted the Certificate of Approval and after certified as GMP plant, manufacturers are allowed to produce specific health foods. The registration involves the test on the functional components that characterize the sample product, the test on the hygiene and stability of the sample product, the test on the health claims to see if the product in question does have the claimed health effect, the preapproval of sample labels and advertisement. One of the most important rules is that only the substances that are derived from conventional foods and approved materials can be used in health foods. Hundreds of approved substances have been established by the CFDA, including 198 botanicals and animal products, 14 minerals, 10 vitamins, 11 fungi, 10 probiotics, enzymes and some plants under national protection. There are 59 substances forbidden in the use for health food. Another important rule is the CFDA validated 27 health claims for industry to use on health foods. New health claims are required for additional authorization.

- Central question 2: What are the possible challenges to authority and producers under current framework? And what are the hurdles for implementing premarket notification system for health foods?

For the producers, three visible barriers remain. First and foremost, producers bear heavy burden on product registration that is seen as costly and lengthy. Part of being lengthy includes a conflict of interest between the parties involved in authorizing products. Second, high investment in building a GMP certified plant encourages capable companies while discourages some small and medium sized entrepreneurs with access to the qualified production activities; however, those entrepreneurs still

engage in the production but without product permit. Lastly, an all-inclusion and straightforward regulation or rule is absent; instead, numerous rules, normative documents and standards jointly comprise a set of legal instruments, which inevitably makes new producers floundering to fully appreciate how to get started and then progress. In response to the fragmented legal instruments, the revision to FSL 2009 reportedly to be released this year may hopefully tackle this concern.

For the CFDA, the biggest regulatory challenges remain the manufacturers' poor self-regulation. This involves that the number of deceptive labels and advertisements of health foods on market is startling, amounting to 94%. The CFDA's official also expressed the deep concerns about the companies' trustworthiness in the production. In other words, it's one thing to have the sample product approved, but it's another to ensure the real product has the same attributes, such as stability and composition. Likewise, being certified as GMP manufacturers doesn't necessarily mean the real production without on-site inspection follows the strict GMP procedures.

Consequently, the costly and lengthy premarket registration will still dominate the regulation of health foods due to the low trust in producers' self-regulation and the authorities commitments to guarding food safety.

- Central question 3: What can be learnt from the EU and U.S. approaches to improve Chinese framework?

The EU and U.S. approaches are investigated to answer this question. In brief, the principle of the EU approach is that food supplements are considered unsafe unless "positive lists" were complied with. In other words, food supplements only containing the nutrients on the positive lists are free to be marketed. By contrast, the U.S. approach adopts the principle that dietary supplements are deemed safe unless proven unsafe. Therefore, dietary ingredients were marketed either without any evidence of efficacy or safety or just with too less regulatory oversight when a dietary supplement contains new dietary ingredients.

Part of the U.S. approach is worth well considering, although the entire U.S. approach is not highly recommended due to the fact that thousands of cases of life-threatening illness have happened from the recent years and 5 death reports on

average each year. First, the FDA established the GMP guidance that exclusively focuses on dietary supplements industry and then conducts strict GMP audits on dietary supplement manufactures. This is absent in the European approach; instead, the EU places great emphasis on Hazard Analysis Critical Control Point. The positive benefits of reinforcing GMP certification in China involve the already certified manufactures being more alter to regular inspections and non-certified manufactures being forced to prepare for the certification.

Besides, the concept of notification is highly recommended and should be adapted in China. Specifically, the notification applies under the U.S. framework only when a dietary supplement contains articles that were not marketed in the U.S. before October 1994, if this is the case, manufacturers must notify the FDA at least 75 days ahead of marketing that dietary supplement, and when a dietary supplement is made with Structure/Function Claims, if this is the case, manufacturers must notify the FDA of the health claims they are making within 30 days of marketing that dietary supplement. In Europe, notification of a food supplement is voluntarily implemented by Member State. An adapted solution that suits China is that health food products that are exempted from registration must be notified to the CFDA before or after entering the market. An advantage of having these health foods notified is that it prompts manufacturers to think twice before conducting dishonest production and labelling activities.

Some of the European approach is also a good fit for China. Specifically, the EU greatly relieves the administrative burdens on producers while deeply ensures the safety use of nutrients and health claims by establishing positives list of vitamins and minerals and defining the conditions to use health claims. Using this principle to China's advantage, the CFDA could maintain the established positive list of nutrients and the 27 claims, but needs to specify the conditions to use these claims.

Finally, the core of the Chinese approach—a case-by-case registration framework—should be retained, given that there were no reported adverse illness and death cases related to health foods since this framework was effective. More importantly, a great number of health foods perhaps could not be simply notified because their compositions are so complex that probably do not conform to the established

conditions of use of claims. In these cases, health foods need to be evaluated to bear any claims.

In brief, based on the above discussion, this study proposes a new regulatory framework, primarily aiming to reform the lengthy and costly registration scheme, the biggest challenge for producers. This new framework consists of two parts: notification and registration.

At the first stage, notification could be open to the health foods that are only made of, for example, vitamins, minerals and other common substances. The health benefits of these products are well substantiated worldwide and generally regarded as safe under the recommended daily intake. Therefore, the CFDA doesn't need to conduct hygiene and stability tests on them. Instead, manufactures are required to send real product and labels before or after the products enter the market. At the later stage, notification could also apply to the health foods that have a long history of consumption in China, such as soybean, Chinese dates, radix astragali, coixseed, fungi and some Chinese herbals and plants, when the CFDA could scientifically clarify the conditions to claim the benefits.

Registration applies to health foods that have complex compositions, for example, four, five, six or even more Chinese herbals go together. In other words, the efficacy of a single herbal preparation and a compound of two or three may have long been identified in China, but that of the more complex mixtures are not well established yet by the CFDA. Once the safety and functions of a specific mixture are validated, then its equivalences will be subject to notification. Similar to the current framework, the product labels must be preapproved.

In either case, GMP certification must be strictly implemented. The health foods ingredients must be derived from the conventional foods and approved raw materials.

The main advantage of this framework is to push the CFDA to focus on substantiating health claims made on complex health food mixtures, so that more and more manufacturers will probably be relieved from registration. The limitation of this framework is that it doesn't directly deal with false labels and advertisement, which may still lean heavily on the CFDA's inspection in short term.

7 Limitations & Advice

7.1. Limitations

Three limitations remain in this research. First, the research compares health foods and food supplements and dietary supplements, reaching the conclusion that the three food categories are comparable in many aspects: food categorization, role in supplementing normal diet, claim of health functions as well as the wide range of content. However the major differences between health foods, food supplements and dietary supplements were not discussed due to the absence of an in-depth comparison, as a result of time constraints to this study.

Second, this study only focuses on the health claims that occur on functional health foods without examining the nutritional claims that vitamin and mineral supplements may carry.

Last but not least, food supplements in the EU and dietary supplements in the U.S. may not be the most comparable food categories to Chinese health foods considering the geographical location and food tradition. Alternatively, similar food category in the Asian countries, such as health functional foods in Korea, and health supplements in the southeast Asian nations, namely Indonesia, Malaysia, the Philippines, Singapore, and Thailand are likely to use the Chinese traditional herbal as ingredients. Therefore investigating the regulatory system of functional foods and / or health supplements in other Asian countries may facilitate making suggestions to improve the Chinese approach to health foods.

7.2. Advice

Future study on how to improve the Chinese regulatory framework for health foods could consult the regulatory approach to regulating functional foods in the Asian countries as the content of these functional foods and of health foods may be similar. Therefore, the investigation of other Asian approach may make the better suggestions to reform the Chinese approach than that of the EU and US approach.

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FDA Federal Food, Drug, and Cosmetic Act (FD&C Act) <<http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdact/fdactchaptersiandiishorttitleanddefinitions/ucm086297.htm>>

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