Chinese Law on Foods and Medicines

by

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I. Foundations of Chinese Food and Medicine Law

1.1 Global Agreements and Standards

China joined the WTO in 2001[1]. If we look at foodstuffs and medicines from a consumer viewpoint, the most important WTO agreements are the Technical Barriers to Trade Agreement (TBT Agreement) and the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement). The TBT Agreement covers all mandatory and voluntary technical regulations and standards, including testing and certification procedures. The aim of the agreement is that these technical measures do not create unnecessary obstacles to trade.[2] The SPS Agreement defines the rights and obligations of members with respect to application of sanitary and phytosanitary measures. This means laws and standards on food safety, animal health and plant health. Basically, the SPS agreement defines how food is to be regulated in order to maintain TBT agreement goals[3]. The TBT agreement also applies to medicines[4].

Disputes arise when trade restrictions are justified by somewhat ambiguous goals such as human health. The most famous food disputes resolved by the WTO Dispute Settlement Body are the 'hormones in beef case'[5] of 1998 and the 'sardine case'[6] of 2002. EC banning beef hormones was not justified according to the SPS agreement, because it was not based on Codex Alimentarius Standards. EC restricting the use of the term 'sardine' was not justified according to the TBT agreement, because the restrictions were not based on the Codex.[7]. Here we see the connection between Codex standards and WTO disputes: Codex rules are specifically referred to in the TBT Agreement[8] and the SPS Agreement[9], and are therefore used as a reference in

[1] This happened after lengthy discussions with the most important trading partners. As a non-member, China's exports were often the subject of discriminatory treatment in overseas markets. By adjoining, China gained new market access opportunities and new legal protections against discrimination. Gong 2005.

[2] Wanhua 2002, 316.

[3] Hollo 2008, 26.

[4] For example in the November 2007 meeting of the Technical Barriers to Trade Committee, Columbia raised a concern on Argentina's regulations for pharmaceuticals. These regulations involved for example application of tariffs or fees for undertaking verification visits to plants located in the countries of origin. World Trade Organisation. Committee on Technical Barriers to Trade. Specific Trade Concerns Relating to Access of Pharmaceuticals to the Argentine Market. Communication from Colombia. G/TBT/W/280. 30 October 2007.

[5] EC measures concerning meat and meat products (*Hormones*), WT/DS48/AB/R of 16 January 1998. (AB-1997-4).

[6] WT/DS231/R of 29 May 2002.

[7] Poli 2004, 615-616.

[8] The TBT Agreement covers all mandatory and voluntary technical regulations and standards, including testing and certification procedures. The aim of the agreement is that these technical measures do not create unnecessary obstacles to trade. Wanhua 2002, 316.

[9] The SPS Agreement defines the rights and obligations of members with respect to application of sanitary and phytosanitary measures. This means laws and standards on food safety, animal health and plant health.

trade disputes at the WTO.[10] Codex Alimentarius is an international organization governing foodstuffs and operating under United Nations organizations FAO[11] and WHO[12]. China is a member. Codex documents are global food law[13]: Codex Alimentarius pursues to protect the health of consumers and to promote fair international food trade.[14] The Codex Alimentarius Commission is the highest decision-making body, where the representatives of the approximately 180[15] member states meet every year. The Codex Alimentarius Commission is the most important global actor drafting food standards.

Codex documents are in the forms of standards, codes of practice, guidelines, principles, recommendations, etc. Standards often relate to product features and can be very precise, setting for example MRLs (maximum residue levels) for pesticides or medicinal substances in foods. There is for example a standard for canned baby food and a standard for frozen spinach. Codes of practice guide procedure as regards production, preparation, transport and storage, including HACCP[16] systems. Guidelines exist for example on nutrition and health claims[17]. Principles are more general and relate for example to import and export certificates. The division between different document types is not important as none of the Codex documents are directly binding on food industry operators. All of the above-mentioned document types are listed under 'standards' on the Codex web page[18]. It is important for China to defend their interests in Codex, particularly as a member of the WTO. The role of the Codex Commission is to provide a political forum to debate issues. The role of WTO Dispute Settlement Body is to ultimately resolve issues that cannot be agreed upon.

As regards to China, the absence of WTO disputes against China is seen as a sign of China's reasonably effective implementation of the WTO rules[19]. The worst possible scenario is that China would disrupt the whole WTO process that is based on consensus[20]. Trade partners expect China to comply with the spirit of the WTO agreements and to develop into a "more responsible member of the international community"[21]. Foreign businesses expected to benefit from a more

[10] World Health Organisation web page. Biotech: 20 questions. http://www.who.int/foodsafety/publications/biotech/20questions/en/.

[11] Food and Agriculture Organization.

[12] World Health Organization.

[13] Codex alimentarius means food law.

[14] www.codexalimentarius.net.

[15] Counted on Codex web page http://www.codexalimentarius.net/web/members_area.jsp?lang=EN, April 2007.

[16] Hazard Analysis and Critical Control Points.

[17] CAC/GL 23. 1997. Revised 2004, amended 2008.

[18] Codex Alimentarius web page at: http://www.codexalimentarius.net/web/standard_list.do?lang=en.

[19] Mertha 2008, 1.

[20] Qingjian 2002, vi.

[21] Kobayashi 2008, 1.

transparent and predictable business environment in China[22]. According to the US-China Business Council in 2008, China has gone a long way in fulfilling its WTO obligations, but there are still problems related to the principle of national treatment in particular. This means that foreign companies experience adverse treatment compared to Chinese companies. Discrimination comes in the form of stricter regulations and their enforcement. In addition, application procedures and license approval procedures are more stringent, time consuming or costly for foreign companies, foreigners are excluded from standards setting processes, and there is bias towards domestic goods in government procurement.[23] According to Peerenboom, some of the areas listed by foreign investors are actually required of China by the WTO, while others are just wishful thinking seeking to further foreign interests[24]. Besides factors related to the Chinese legal culture, employment and income levels of the Chinese people will determine whether China will fulfil its WTO obligations[25].

The TBT Agreement recommends the recourse to international standards wherever possible while drafting technical regulations. Besides Codex standards, ISO/IEC[26] standards are particularly referred to in the TBT Agreement[27]. ISO is the International Organisation for Standardisation, and has published several standards related to the food industry. ISO is a non-governmental organization "forming a bridge between the public and private sectors". ISO is a network of the national standards institutes of its 157 member countries. Many of the member institutes are part of the governmental structure of their countries, while others have been set up by national partnerships of industry associations.[28] Legal description of the ISO standards is difficult. They are not agreements between states as with Codex standards, and they are not self-regulation as governments are involved. They are followed voluntarily, although abiding by a standard might be required in practice. In any case, ISO standards can be defined as soft law.

On medicines, the WHO is involved in developing international medicinal products law. They develop international norms, standards and guidelines, and provide guidance, technical assistance and training to support countries in adopting these standards on medicinal products.[29] The WHO also organizes international conferences of drug regulatory authorities, where medicinal products law is discussed. The outcome of these meetings are "Recommendations", in which various areas of medicinal products law are discussed. They are

[22] Qingjiang 2002, v.

[23] US-China Business Council 2008, 10.

[24] Peerenboom 2008 b, 8.

[25] Qingjiang 2002, 308.

[26] "The International Electrotechnical Commission is the international standards and conformity assessment body for all fields of electrotechnology." http://www.iec.ch/.

[27] Annex 1 of the Agreement.

[28] ISO web page. http://www.iso.org/iso/about.htm.

[29] WHO web page. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/en/index.html.

in the form "member states should…"i.e. adoption is not mandatory. In 2006, it was agreed for example that member states should support clinical studies of herbal medicines[30], and seek efficient sanctions for false drug advertising, particularly internet advertising[31]. China is involved in the WHO discussions and drafting the recommendations on medicinal products law. China also works bilaterally on issues of medicine law. For example between China and the EU, the agreement on a "Consultation and Cooperation Mechanism" was signed in 2008. In 2009, the Chinese SFDA[32] met with the Director General Enterprise of the EC in the first annual high-level working conference under the "mechanism".[33]

1.2 From Rule of Man to Rule of Law

It has been said that the Chinese legal system cannot really be called 'legal' or 'system'. That is why investigating Chinese law is challenging for a European lawyer. Legal systems can be divided in Western and non-Western systems, where Western systems are individual-centered and non-Western systems are community-centered. Western systems can be further divided in common law and Romano-Germanic civil law. Non-Western legal systems can be divided in religious and non-religious systems. Non-religious systems include Asian law and traditional law. Asian law relies on the Confucian principle of mediation and avoiding disputes, which means courts and lawyers are not in a central role.[34] In this division, Chinese law is a member of the Asian family.

For the past 30 years, the Chinese have put focus on "socialist justice" and legality. A lot of legislative work has been done, particularly economic reforms including modern legislation.[35] Today, Chinese law shares many of the characteristics of the Romano-Germanic system. The legislation reflects a structural similarity to countries in the civil law family, and Chinese jurists value legal doctrines and hold written law in esteem. Concrete judicial decisions are not officially considered a source of law.[36] However, particularly the Supreme People's Court is influential in practice. Its decisions are in practice used as a guideline in the lower courts, when the provision of law is obscure.[37] According to Jones, China has succumbed to Western arguments and built a European-style legal system, but has never been entirely convinced[38]. The

[30] Icdra. 12th International Conference of Drug Regulatory Authorities. Recommendations. Page 5.

[31] Icdra. 12th International Conference of Drug Regulatory Authorities. Recommendations. Page 8.

[32] State Food and Drug Administration. China.

[33] SFDA web page at: http://former.sfda.gov.cn/cmsweb/webportal/W43879541/A64029996.html.

[34] Husa 2009, 126-127.

[35] Huotari – Seppälä 2005, 132-133.

[36] This can be attributed to the Europeanization in China in the end of the 19th century and the beginning of the 20th century, and is also based on Chinese tradition: statutes or codes were highly valued already by the Qin Dynasty in 221-207 BC. Liu 2000.

[37] Liu 2000.

[38] Jones 2003, 8.

Chinese legal system is closely linked to the economy: China is still balancing between market economy and socialism. The need to balance market efficiency and social stability has left administrators considerable discretion, which has resulted in legal and practical uncertainty as regards the roles of government vs. markets[39].

On the surface, Chinese statutes and institutions of food and medicine law are rather similar to the European ones. However, China is still heavily influenced by tradition. The most important trace of Chinese history is in the close connection between strong central government (previously headed by Emperor) and the administration[40]. In the history, the Emperor had all the power. Each dynasty had its own legal code. There could be no discussion on separation of powers: local officials carried out all government functions at the bottom level[41]. Separation between legislation, its execution, and adjudication still sounds strange to the Chinese.

When discussing Chinese law, we cannot presume that concepts such as state, law, or court mean the same as in Europe. The history and contemporary understanding of law in the Chinese society is different from ours. Donald C. Clarke has described methods for comparing Chinese law to Western, particularly American law. Firstly, the naive ignorance approach sees the two legal systems as similar and looks at legal texts only. This approach is to be avoided. We could also compare Chinese reality to an 'Ideal Western Legal Order'.[42] An alternative would be to see the 'errors' as normal features of the Chinese legal system[43]. A 'disciplinary model' might be fruitful in understanding the Chinese legal system. This model is based on the assumption of state as Emperor.[44]

An outright hostility towards law in a Western sense is inherent in Chinese history and culture. According to Confucius himself, the goal is a situation with no legal cases[45]. China started to create a legal system and law in a Western sense in the end of 1970's, in conjunction with its new open-door policy. In China, law was traditionally seen as an instrument of governance for the rulers, and 'rule of man' was applied instead of 'rule of law'[46]. There was law, but it was occupied with implementing the Emperor's orders, and did not have anything to do with

[39] Peerenboom 2008 a, 3.

[40] Jones 2003, 8-9. This system of government developed over 2000 years ago and remained similar until the 20th century.

[41] Jones 2000, 9.

[42] A sophisticated researcher with this approach will notice features of the Chinese legal system that do not fit the Western model, but still see them as errors. If we try to understand Chinese law and where it is going, we cannot simply presume it is going towards Ideal Western Legal Order. Clarke 2003, 99-100.

[43] Clarke 2003, 100.

[44] Clarke 2003, 102.

[45] Jones 2003, 7. Here Jones cites Bodde – Morris 1967.

[46] Kobayashi 2008, 3.

agreements or disagreements between citizens, or rights of citizens. There was in fact no such thing as citizen: people were subordinates.

As stated above, China has created large volumes of legislation in the past 30 years. However, laws are void without implementation. After writing the necessary legal texts, China has to create legal institutions to make law work in practice. The legal reform is closely connected to the economic transition. Government agencies are no longer primarily responsible for managing economic entities or planning their economic transactions. In the new economic order, it is enterprises and individuals and their relationships that are important. Private actors must believe that they will be held to their legal obligations, and that their legal rights will be protected. As the government can no longer command market actors to make economic decisions, it needs the ability to use administrative sanctions, and the ability to resort to courts.[47] Instead of command, the market now needs to be guided through law.

This leads us to the above-mentioned concept 'rule of law'. The discussion on modern Chinese law revolves around this concept. Several scholars are discussing the development, current level, and future direction of rule of law in China[48]. Building the rule of law has been on the Party agenda since mid-1990s, and the Constitution was amended in 1999 to include the concept[49]. It says in the Constitution that all organs, administrators and enterprises must abide by law, all acts in violation of the law must be investigated, and that no one is above the law[50]. These are rather familiar concepts to us Europeans, but novel to the Chinese.

There are narrow and wide concepts of rule of law. The narrow concept is rather formal and requires the very basic parts of the legal system to exist. This means meaningful restraints on the use of powers, supremacy of law, and equality of citizens before the law. In a society governed by rule of law, laws need to be general, public, prospective, clear, consistent, capable of being followed, stable, and enforced. Some insist the rule of law must include liberal democracy and human rights, and wider theories add political, social, and economic concepts. Some writers are of the view that China fulfils the narrow criteria. Some argue that China is a country of rule *by* law at best: law is used by the non-democratic state as an instrument for social control.[51]

[47] Lichtenstein 2003, 287.

[48] See for example the Rule of Law in China programme at the Foundation for Law, Justice and Society, a think-tank affiliated with Oxford University's Centre for Socio-Legal Studies. The scholars in this program have written several articles in English on rule of law in China, both generally and as regards certain legal areas such as employment or intellectual property. See Foundation for Law, Justice and Society at http://www.fljs.org. See rule of law in China publications at http://www.fljs.org/section.aspx?id=607.

[49] Wikipedia: http://en.wikipedia.org/wiki/Chinese_law.

[50] Article 5 of the Constitution.

[51] Qingjian 2002, 301, uses the words "rule through law". See also Wikipedia: http://en.wikipedia.org/wiki/Chinese_law. Wikipedia article sites Randall Peerenboom: China's Long March Toward Rule of Law, Cambridge University Press 2002, and Albert Huhg-yee Chen: An Introduction to the Legal System of the People's Republic of China, 1992.

Peerenboom sees China as following the 'East Asian model', where economic growth, legal reforms, democratization, and constitutionalism follow each other, in this order[52].

According to critics, China has a long way to go towards the rule of law. The Congress needs to be strengthened as legislator, the Constitution should be enforced, and the judiciary should be independent. Corruption is common among public officials: personal favours, bribery, and taking of public monies happen at all levels of government. The legal profession has also been inadequate and China is now putting effort in training competent judges and attorneys.[53] The legal reform revolves around taking some of the powers away from administrators, which up until now have been the legislators, the executors, and the judges.

According to Peerenboom, China's performance on rule of law might be best judged in relation to other countries in its income class[54], and China seems to be doing reasonably well by that measure[55]. There is also critique on the whole discussion on the rule of law in China. According to Jerome Cohen, the problem with Westerners is that we never go beyond that primitive stage we call the rule of law. According to him, China has always known that law is not enough to govern a society, and still knows it.[56] According to Qingjiang, *guanxi* (social connections) and *mianzi* (face) do still affect implementation of laws in China[57].

We are of the view that mere existence of laws, even laws of technically high quality, is not a goal in itself and guarantees nothing more than clarity on paper. The content, the substance of law, is what matters. Laws need to address the needs of companies and individuals. It is therefore integral that stakeholder voices are heard before making laws. It is also integral that laws are implemented in practice. Disputes need to be fairly resolved, whether by courts or by other means such as mediation[58].

[52] Peerenboom 2008, 6.

[53] Wikipedia: http://en.wikipedia.org/wiki/Chinese_law. Article sites Randall Peerenboom: China's Long March Toward Rule of Law, Cambridge Univeristy Press 2002, and Albert Huhg-yee Chen: An Introduction to the Legal System of the People's Republic of China, 1992.

[54] Wealth is highly correlated with good governance indicators, human rights, and other indicators of human weel-being.

[55] Peerenboom 2008 a, 5.

[56] Cohen according to Jones 2003.

[57] Guanxi can work both ways: it can either assist in enhancing law enforcement, or be used to avoid compliance of law. Similarly, law enforcement may also be related to the psychological assessment of saving face or losing face of the persons against whom law is enforced. Qingjiang 2002, 301.

[58] Lichtenstein 2003, 288.

1.3 National and Local Laws

We are now turning to the questions of *who* makes the law in China. The question of legislative competence of central government versus the competence of provinces and cities reminds us of the discussion of the competence of the EU vs. its member states.

In China, the Constitution is not a very important piece of law. According to Clarke, it does not constitute anything, and is perhaps the least important document in the entire legal system[59]. In reality, the government does not work in the way described in the Constitution. In theory, the Chinese central government is strong with powerful instruments at its disposal. All the powers of localities stem from the centre[60]. The central government decides who controls the provinces: It appoints the government top officials and the party top officials in the provinces. The central government also controls key economic resources like scarce raw materials, government investments, foreign loans and budgetary subsidies. Unity of the nation and thus strong central government is also culturally favoured: the Han majority of people want to see China as one.[61] In practice, Chinese localities have been given powers and resources to administer the state economy in the localities. Driven by local interests, local leaders have gradually become less obedient to the centre, and centrally promulgated laws are unevenly implemented at local level.[62]

Officially, the highest organ in China is the parliament, the National People's Congress (NPC). The amount of representatives has fluctuated between 2000 and 3500 members. Representatives are chosen by indirect election. Local congresses elect the members of provincial congresses, and provincial congresses elect the members of the national congress. The authorities of the Parliament are extensive. The Parliament enacts the national laws and appoints the prime minister, other ministers, and the president. The NPC also decides on the state economic plans and budgets.[63] The role of the parliament has increased in the recent years. The NPC chooses among itself a Standing Committee. The Standing Committee convenes the parliament, issues regulations, interprets laws, and oversees government activities. The chairman of the Standing Committee acts as the chairman of the parliament.[64] The National Congress appoints the members of the State Council, which is the highest executive organ in China, as well as the highest organ of State administration[65]. It is led by the prime

[59] Clarke 2003, 103.

[60] Qingjiang 2002, 305.

[61] Ren 2000, 102-103.

[62] Qingjiang 2002, 305.

[63] Huotari – Seppälä 1993, 128-129.

[64] Huotari – Seppälä 1993, 129.

[65] Official web page of the Central People's Government of the People's Republic of China. http://english.gov.cn/2008-03/16/content_921792.htm.

minister. The position of the Party has normally been decisive in choosing the members of the State Council[66].

According to the Constitution the government and the communist party work together to rule the country. Since the birth of the People's Republic in 1949, the Chinese communist party (*Zhongguo gongchandang*) has played a central role in state affairs.[67] Officially and formally, there are also other parties and citizen organizations in China, but their influence is not significant.[68] The real locus of central political power in China lies in the leadership of the Communist Party, which exercises power largely through the State Council. The party has inherent authority to make rules about anything, and now chooses to make certain rules through the National People's Congress.[69] The Party has a leading role in central and local government, army, and economy. Party organs make decisions and issue them to state organs for implementation. The same people work for the state and the party: party representatives have leading positions also in the government[70].

China's size and diversity have led the government to use a system of local autonomy. Below the central level, there are both geographically defined provincial authorities and sectorally defined ministries.[71] Because of the geographically and sectorally separated actors, legal and economic integration of China can not be realized at once. The Chinese have created Economic Zones as a type of regional economic experiments.[72] The establishment of these zones is to encourage economic cooperation by promoting division of labour and competition.[73] These are first steps towards integration of the Chinese economy. According to Weixin, the successful realization of regional integration in China requires institutional arrangements similar to those of the EU. Interests of the whole economy and the individual economies need to be coordinated.[74]

In environmental issues, the resistance of local and provincial governments is a serious obstacle to sustainable development policy. Similar problems relate to regulation of foodstuffs and medicines. The Chinese Food Hygiene Law of 1995 declared that precise food safety standards are to be decided locally. Standards vary, and national and local standards contradict one another. Implementation and control of the rules differs among provinces and cities. It is not possible for the central government to be aware of all the day-to-day decisions and actions of

[66] Huotari – Seppälä 1993, 130.

[67] Preamble of the Constitution, see also Amendment 2 of 1993 and Amendment 3 of 1999. Huotari – Seppälä, 124.

[68] Huotari – Seppälä 1993, 123.

[69] Clarke 2003, 111.

[70] Huotari – Seppälä 1993, 124.

[71] Weixin 1992, 48-49.

[72] Weixin 1992, 88.

[73] Weixin 1992, 91.

[74] Weixin 1992,86.

localities. Local officials might see national laws as obstacles to their cities' growth and personal promotion, and hence readily defy them. Promotions are often based on meeting economic targets, and cooperation with other provinces or cities is not rewarded. This enhances local protectionism.[75] Distrust in food and medicine markets describes consumer attitudes in China.

Geographically, China is divided into provinces[76], autonomous regions[77], special administrative regions[78], and municipalities directly under the central government[79]. Provinces and autonomous regions are further divided into autonomous prefectures, counties, autonomous counties and cities, and counties are divided into towns and townships.[80] Local and provincial legislation is given by local and provincial congresses. According to the Constitution and the 2000 Act of Legislation, the NPC Standing Committee oversees local regulations, and can annul any local regulations contravening the Constitution or national laws[81]. In practise, however, this responsibility is far from being realised, and a large number of local regulations contravene national laws[82].

The sectoral planning hierarchy also fragments the market. All sectors within the economy are organized vertically and headed by ministries under the State Council. Ministries include for example the Ministry of Health, the Ministry of Agriculture, and the Ministry of Science and Technology[83]. The Ministry of Health is the most relevant in regulating foodstuffs and medicines. Also the State Food and Drug Administration (SFDA)[84], founded in 2003, has its

[75] Lam 2006.

[76] Hebei, Shanxi, Liaoning, Jilin, Heilongjiang, Jiangsu, Zhejiang, Anhui, Fujian, Jiangxi, Shandong, Henan, Hubei, Hunan, Guangdong, Hainan, Sichuan, Guizhou, Yunnan, Shaanxi, Gansu, Qinghai, and Taiwan.

[77] Inner Mongolia Autonomous Region, Guangxi Zhuang Autonomous Region, Tibet Autonomous Region, Ningxia Hui Autonomous Region, and Xinjiang Uygur Autonomous Region .

[78] Hong Kong Special Administrative Region and Macao Special Administrative Region.

[79] Beijing, Tianjin, Shanghai, and Chongqing.

[80] Weixin 1992, 47.

[81] Jian 2003, 506-507.

[82] Jian 2003, 508.

[83] There are altogether 28 Ministries and Commissions under the State Council. In addition, there are at least 36 other organisations and institutions directly under the State Council. These include for example the Customs, the Bureau of Statistics, and the Intellectual Property Office. Governments official web portal: http://english.gov.cn/links.htm#1. See plans on restructuring the State Council at GOV.cn: Tuesday, March 11, 2008. http://english.gov.cn/2008-03/11/content_916738.htm.

[84] The State Food and Drug Administration was founded according to the restructuring plan of the State Council, approved by the First Plenary Session of the 10th National People's Congress, and "the State Council Notice on Government Structuring", No.8.2003. The new authority replaced the former State Drug Administration. http://www.sfda.gov.cn/cmsweb/webportal/W43879538/index.html.

role in drafting various guidelines related to safety and efficacy of foodstuffs and medicines[85]. The SFDA is at the moment directly under the State Council[86], but will be transferred under the Ministry of Health in the upcoming government restructuration, described in detail below. An important step towards centralisation is that currently all food and medicine pre-market authorisations are under the competence of the SFDA. This has eliminated the conflicting standards that previously prevailed among provincial government agencies.

Regulations that can be enacted by ministries are called *guizhang*. These regulations tend not to be results of comprehensive planning or strategy. They are rather reactions to problems arisen. Within the areas of food and medicines, several different government agencies have competence to regulate and supervise the entrepreneurs. When giving guizhang regulations, administrative organs do not necessarily check whether their guizhang is in agreement with laws or former regulations by the same administrative organ or another administrative organ. Thus, conflicts between *guizhang* provisions are not rare.[87] This is naturally confusing both to regulation targets and those that are supposed to supervise them.

1.4 Administrative Regulations and Court Interpretations

Today, the question of hard law vs. soft law is relevant also in China. First of all, there are laws enacted by the National People's Congress. Then there are regulations and directives given by the State Council, which is the highest administrative body in the nation. In reality, it is the State Council that decides on important law. In addition, there are regulations and directives given by various departments under the State Council. These departments include the Ministry of Health and the State Food and Drug Administration.[88] We stated above, that administrators previously had the imperial power and acted as legislators, executors, and judges. Administrative regulations were not seen as any kind 'soft law', as the simply were 'the law'.

According to Article 90 of the Chinese Constitution, "the ministries and commissions issue orders, directives and regulations within the jurisdiction of their respective departments and in accordance with the statutes and the administrative rules and regulations, decisions and orders issued by the State Council". The Ministry of Health has the official competence to legislate on the area of foodstuffs and medicines. The State Food and Drug Administration (SFDA), on the other hand, does not have hard-law legislative power. However, the SFDA's Department of Policy and Regulations, more precisely its Division of Regulations, has the following tasks:

[85] The SFDA has control over foods, medicines, and cosmetics. Its domain of is thus similar to that of the FDA in United States. In Europe, food and medicine administration is divided under two separate agencies at the EU level and also in most of EU Member States.

[86] http://www.sfda.gov.cn/cmsweb/webportal/W43879538/index.html.

[87] Bian 2004.

[88] Lists of Chinese food, drug and cosmetics laws in 2007 at: http://www.chinafdc-law.com/laws/index_1.html.

- 'studying and drafting legislation program and annual plan for food and drug administration;
- participating in, and/or organizing the drafting of Medicine Administration Laws and regulations;
- organizing relevant authorities to draft laws and regulations for safety management of food, health food and cosmetics
- organizing and carrying out review, coordination and issue of administrative provisions;
- interpretation of the related laws and regulations in accordance with law'.[89]

This means the SFDA is at the moment involved in both important stages of food and medicine law: preparing the laws and implementing the laws. The SFDA plans and drafts legislation, which is promulgated by the State Council of Ministeries. The Authority also gives its own administrative regulations, and interprets laws and regulations. The division of work between the Ministry of Health and the SFDA will be restructured in the future. According to information on the central government's website in March 2008, China is upgrading the Ministry of Health to better monitor the safety of foodstuffs and medicines. The SFDA will be transferred under the Ministry of Health (MOH). The "new MOH" will be authorized to coordinate food safety management, organize investigations into serious food safety incidents, and give "due punishment". The MOH is responsible for the constitution of the national food and medicine laws. The SFDA, after the reform, is responsible for food sanitation permits, monitoring food businesses, and monitoring the safety of medicines including their research, production, circulation, and use. [90] This means that in the future, the MOH will be giving all the laws on foodstuffs and medicines, not the SFDA. The task of the SFDA will be to more efficiently monitor the businesses.

In China, the court system has traditionally not been separated from administration. Cases have been handled as police or administrative issues.[91] This is still the case also with foodstuff and medicine administration. The Ministry of Health and the SFDA are entitled to carry out various executive punishments stipulated in the Food Safety Law and the Medicine Administration Law. In the new Food Safety Law, fines range from 2,000 yuan to ten times the value of the commodity in question. This means there are no maximum fine amounts for offences affecting large volumes of foods. The new law is similar the old one in stating that business licenses can be revoked in serious cases, and illegal gains shall be confiscated.

In addition to administrative penalties, violating the Food Safety Law may lead to civil responsibility. For causing a serious food poisoning accident or putting poisonous raw materials

[89] SFDA web page. http://www.sfda.gov.cn/cmsweb/webportal/W44993659/index.html.

[90] GOV.cn Tuesday, March 11, 2008 . http://english.gov.cn/2008-03/11/content_916856.htm.

[91] Huotari – Seppälä 2005, 131.

to foods, also criminal responsibility is possible.[92] With medicines, the pre-market and post-market control is under the competence of the SFDA. Administrative enforcement agencies are not willing to hand over their cases for criminal prosecution, because administrative penalties enhance their own operating budgets[93]. The autonomy of courts and the enforcement of judgments are by many scholars considered problematic in China[94]. The judicial system as a whole is weak and under the control of the Communist Party[95].

Finally, we have to note that courts in China often act like legislative bodies. They make law by issuing interpretations of laws that are binding on the courts. Every year the Supreme People's Court (SPC) issues interpretations, regulations, notices, replies, opinions, and policy statements. Most are binding on the courts, others are highly persuasive and likely to be followed. The 'interpretations' range from general statements to specific replies to inquiries from lower courts[96], and fill in the void left by inexistent or vague laws. The biggest problem with this distribution of work between the National People's Congress and the SPC is that the SPC is not adhering to recent process reforms to increase transparency and public participation. The SPC has started to respond to this criticism. The questions of legislative hierarchy still remain.[97]

1.5 NGO regulation and Self-Regulation

The Chinese government is calling for the participation of consumers, NGOs[98], and food companies in establishing food safety standards. In a document submitted to the World Health Organization in 2002, China called for increased participation on the part of "consumers, food industry and other stakeholders". China has stressed on increasing consumer awareness by hosting an annual "Food Hygiene Law Education Week" and implementing other educational programs on the importance of sanitary food handling.[99] This way some of responsibility can be shifted onto the shoulders of consumers themselves, and the large numbers of food poisoning incidents caused by Chinese consumers themselves can be lowered.

[92] For more information on pre-market, post-market control, and penalties as regards the law on foodstuffs and medicines, see our doctoral thesis.

[93] Mertha 2008, 2.

[94] See Seppänen 2005 on how empirical evidence is missing on these issues.

[95] Mertha 2008, 2.

[96] The latter means the Supreme People's Court acts similarly to the Europen Court of Justice, which can decide how law is to be interpreted in a case that is held by a member state court.

[97] Peerenboom 2008 c, 1.

[98] The term "NGO", non-governmental organization, means organizations outside of state systems, including advocacy organizations, non-profit service-providing institutions, religious groups, and social welfare organizations. Ma, 2002.

[99] Li 2005, 30.

The civilian consumer protection group system also plays an important role in Chinese food regulation. Consumer groups, such as the Chinese Consumer Association, obtain licenses from local government authorities to independently regulate and inspect food production facilities and plants. They also hear complaints and comments from consumers and report back to local government officials.[100] These groups are important in protecting people's rights. In addition, self-regulation by the industry itself exists: various chambers of commerce recommend their own voluntary standards to food producers. These standards cover many areas of food production. More and more food producers are adopting voluntary standards in order to achieve better market success.[101]

The new Food Safety Law urges both the industry organisations and social groups to be more involved. According to Article 7, food industry organisations shall tighten industry self-discipline, and guide producers and traders in complying with the law. In Article 8, the state encourages social and community groups to conduct educational activities as regards food safety laws. Article 8 also urges the media to publicise laws for free, and to provide oversight on acts that violate the law. It is interesting that also media is given responsibility on food safety. There seems to be a trend of shared responsibility that can be noted also for example in the European and American discussions on who is responsible for obesity.

Voluntary approaches have been criticized for not being sufficient, and greater government involvement has been demanded. China must build the capacity to oversee food production within its borders. Several severe food safety scandals have been the result of unsafe or inferior ingredients in processed foods, or chemical and pesticide residues.[102] These problems cannot be resolved through self-regulation or consumer awareness only. Food safety must also be a priority of the government, not just by consumers, their organisations, and the food industry.

II. Chinese Law on Foods and Medicines

2.1 Food or Medicine?

Functional foods often comprise of materials that are used in traditional Chinese medicine. The legal difference between health foods and medicines is that health foods have a special health function, but are not for curing a disease. The categorisation decision (medicine vs. non-medicine) is legally important. However, the Chinese classification rules are not clear and the

[100] Li 2005, 30-31.

[101] Bian 2004

[102] Li 2005, 30.

SFDA has not published any guidelines on the subject. Companies are consulting the SFDA on a case-by-case basis. [103]

In the Chinese Medicine Administration Law, pharmaceuticals are defined as articles intended for use in the prevention, treatment or diagnosis of human diseases, or intended to effect the purposive regulation of human physiological functions, for which indications or major functions, usage and dosage are prescribed. They include raw traditional Chinese medicinal materials, traditional medicines prepared in ready-to-use forms, and other prepared Chinese medicines, medicinal chemicals and their preparations, antibiotics, biochemical medicines, radioactive drugs, serums, vaccines, blood products, diagnostic aids, etc.[104] Traditional Chinese medicines are particularly mentioned in the definition. The Chinese want to emphasize the fact that modern and traditional medicine are treated as equal.

The new Food Safety Law makes a distinction between foodstuffs and medicines in Article 50: "Medicines can not be added to food, unless the added substance is traditionally considered both food and Chinese medicine." This means that foods must not contain medicinal substances, but can contain materials that have traditionally served as both food and medicaments. The same plant can be used as nutrition for healthy people and as medicine for sick people. The catalogue of substances that are traditionally considered both as food and as Chinese medicine will be published by the executive department of health under the State Council. This kind of catalogue will offer valuable guidance to producers and marketers.

The major implication of a product being classified as a medicine is that it imposes higher requirements for producers and sellers. For example, manufacturers of medicines must hold a GMP certificate, and wholesale and retail enterprises must hold a GSP certificate. The implications of the categorisation decision on marketing are also important. Only medicines can bear medicinal claims. This means claims of preventing, treating or curing a disease. Only health foods can bear health claims. Article 11 of the Health Food Regulation separates health foods and medicines from each other: "Any medicinal product approved by the government should not apply for the Certificate of Approval on Health Food". This way the health food category separates health foods from regular foods in the other end, and medicines in the other end. The function and the claim resolve the foodstuff vs. medicine -issue, not the raw material as such. Regular foods can bear nutrition claims, which means claims of the type "low-fat" or "high in fibre".

[103] Tsoi 2007.

[104] Article 102.

2.2 Structure of Food Law

In China, food law is given by the NPC, the State Council, or authorities under the State Council. Previously, Food Hygiene Law of 1995 was the basic piece of food law in China. Since June 2009, the basic piece of food law is the Food Safety Law. The Standing Committee of the National People's Congress passed the new Food Safety Law on February 28th 2009, and it went into effect in the beginning of June 2009. Based on the new law and its future implementing regulations, Chinese food law and particularly its implementation and control will be developed. The new law uses Western terminology in promoting safety "from farm to table". The new law is more comprehensive in spelling out who is responsible for what, focusing on the critical points where there have been problems in the past. The main structure and content of the two laws are similar, though. The new Food Safety law has ten Chapters[105].

The Food Hygiene Law of 1995 already was a modern food law similar to the Codex Alimentarius model. The Food Hygiene Law was enacted for the purpose of ensuring food hygiene, preventing food contamination and harmful substances from injuring human health, safeguarding the health of the people and improving their physical fitness.[106] Other national food laws were based on the Food Hygiene Law. Examples of Chinese food regulations based on the Food Hygiene Law are the Additive Regulation, the Novel Food Regulation, the GMO Food Regulation, and the Health Food Regulation[107]. For example on health foods, the national Health Food Regulation by the Ministry of Health is the basic law on health foods. In addition, health foods are governed by over 20 other rules or notifications by the Ministry of Health or the State Food and Drug Administration. These include for example the "Interim Regulations for the Registration of Health Foods", "Provisions for Health Food Labelling", "General Hygiene Requirements for Health Foods" and the "Notification on Preparing for Censoring Health Food Advertisements". [108] For clarity reasons, combining these in one piece of law might be considered in the future.

If the State has not formulated standards for a certain food, the people's governments of the provinces, autonomous regions, or municipalities directly under the Central Government may establish local standards for that food and report them to the administrative department of public health under the State Council and the competent standardization administration department under the State Council for the record.[109] Local standards are plentiful, and the

[105] Chapter One: General Provisions. Chapter Two: Surveillance and Assessment of Food Safety Risks. Chapter Three: Food Safety Standards. Chapter Four: Food Production and Trade. Chapter Five: Inspection and Testing of Food. Chapter Six: Food Import and Export. Chapter Seven: Response to Food Safety Incidents. Chapter Eight: Supervision and Administration. Chapter Nine: Legal Liabilities. Chapter Ten: Supplementary Provisions.

[106] Article 1.

[107] Kan and Zhang (2002) use the term 'management measures' of these pieces of law.

[108] List of Chinese food, drug and cosmetic laws at http://www.chinafdc-law.com/laws/list_1-27_5-118_1.html.

[109] Food Hygiene Law, Article 15.

delegation of more specific food hygiene legislation to local legislators has led to inconsistent standards and confusing licensing requirements[110]. For example in Hong Kong, there is a whole body of local food law. A general food and medicine code is complemented by legislation on specific matters[111]. Existing principles of legislative competence are upheld by the 2009 Food Safety Law[112].

When drafting new food regulations, central and regional government, businesses, associations, NGOs, and Internet are consulted[113]. According to Kan and Zhang, factors considered in formulating food standards are: feasibility of standards on the basis of research, current and future risk evaluation, international food law codes and standards of other countries, and industrial standards.[114] As means to better food legislation, Kan and Zhang urge that law shall be based on science, and regulators must look at the food chain from farm to table. Food law must emphasize the responsibility of food producers and sellers to guarantee food safety: food business operators must have effective in-house control, using HACCP[115] based systems. The businesses are responsible for taking dangerous products off the market. The government should do its share by reducing over-detailed regulation and emphasizing coordination.[116]

The Chinese views on how to develop food law sound similar to the European approach, where food law is legally based on scientific risk analysis, global harmonization is considered important from free trade perspectives, and industry is always consulted when drafting new legislation. In China, there is not a particular authority (like EFSA in Europe) responsible for scientific risk assessment as regards food law. Instead, risk assessment is performed by the Ministry of Health and the SFDA, which will in the near future be transferred under the Ministry.

2.3 Challenge of Food Safety

Food safety is today a top concern in China. It is important both for Chinese food export and for Chinese domestic markets[117]. This increased weight on food safety is due to several serious

[110] Li 2005, 29.

[111] Hong Kong government web page. http://www.fehd.gov.hk/safefood/foodlaw_list.html#part5.

[112] According to Article 24 of the new law, local food laws can be developed in the absence of national laws.

[113] Kan – Zhang 2002.

[114] Kan – Zhang 2002.

[115] Hazard Analysis and Critical Control Points.

[116] Kan – Zhang 2002.

[117] Since the 1990s, China has been an important exporter of food products such as vegetables, apples, shrimp, and poultry. However, China has recently had problems with food export because Chinese food has failed to meet stringent food safety standards in Japan, Europe, and other countries. Also Chinese consumers are more and more interested in food safety because of some domestic food contamination scandals.

food scandals where dozens of people have died. Food safety efforts are more advanced in the export sector[118], and more recent in the domestic sector. It is not rare that developing countries have, to promote their exports, stricter standards for exported food. According to Calvin et al., "China's efforts are an important case study of a country's striving to elevate standards in its food and agriculture sector to international food safety standards".[119] Export industry is has been regulated stricter because the export industry is easier to regulate because it is smaller than the general food industry, and because the export industry is a more motivating target as the exports generate considerable revenue, and China wants to keep up its international reputation.[120] The Chinese system was created as a response to bans of Chinese food in foreign countries. The Export-Oriented System monitors food products from exporting companies at every step, from the pesticides and chemicals used on farms to food processing facilities to packaging plants. Exporting food companies must obtain special licenses from the Export-Oriented System administration.[121] The approach taken resembles the European farm-to-table approach.

The new Food Safety Law covers food safety evaluation, monitoring, recall, and information release. In addition to the basic law, the government promised to stipulate or update more than 7,700 national standards for the safety of foodstuffs, medicines, and other consumer goods in 2008. The government states that after the current reform, all the requirements and testing methods should "comply with international standards". Legislators have promised to include the general public in the process law formulation, and to publicly post all the drafts.[122] Besides the central government, also local governments have been active in promoting safer food.[123] The general aim of food safety legislation is protecting consumers from unhealthy products, encompassing biological and chemical hazards.

According to Calvin et al, many of China's food safety problems can be traced back to the farm level. It is difficult to standardize and monitor production practices of the Chinese food production sector, which is composed of 200 million farm households. Important issues include both chemical and biological hazards. Chinese farmers must rely on heavy use of fertilizers to get production out of intensively cultivated soils. Chinese farmers also use many

[118] Chinese food must meet the international food safety standards, and the increased costs of achieving these standards might have an effect on growth of Chinese food exports. Chinese foods have been rejected because of excessive antiobiotic residues (EU rejected schrimp 2001,EU and Japan rejected poultry 2001, and EU rejected honey 2002), excessive pesticide residues (Japan rejected frozen spinach in 2002-2003, EU and Japan rejected tea 2002) and parasites (South Korea rejected fermented cabbage in 2005). Calvin et al. 2006, 18. News reports of product rejects compiled by USDA, Economic Research Service.

[119] Calvin et al. 2006, 17.

[120] Li 2005, 30.

[121] Li 2005, 30.

[122] GOV.cn Saturday, March 8, 2008. http://english.gov.cn/2008-03/08/content_914117.htm.

[123] Calvin et al. 2006, 20.

highly toxic pesticides. Some farmers have little understanding of correct chemical use. They may harvest right after applying a pesticide, which results in excessive residues in the harvested product. Antibiotics are widely used to control disease in livestock, poultry, and aquaculture products. Industrialization and lax environmental controls have also led to concern about heavy metals in food products. Untreated human and animal waste in fields and water raises the risk of microbial contamination.[124] Besides the farms, the Chinese system of food trade is a challenge to safety monitoring. Millions of Chinese small food businesses often keep no record of what they buy and sell. Ensuring traceability is difficult when there are millions of growers and buyers dealing with small volumes, like in China.[125] The Chinese food companies are now promoting approaches to gain greater vertical control over the food chain.[126]

Chinese food safety efforts at the farm level are primarily concerned with chemical residues in spite of the fact that food poisonings and deaths from microbial contamination exceed those from farm chemical exposure. China is developing good agricultural practice guidelines, ChinaGAPs, which will address minimizing the risk of microbial contamination.[127] The Ministry of Agriculture is the lead agency promoting food safety at the farm level. The ministry has created standards intended to guarantee that foods are free of contaminants. The "pollution-free program" and the "green food program" have standards specifying tolerances for harmful materials in soil, water, and air.[128] They also regulate the use of fertilisers and pesticides, and set maximum residue levels. The programs include certified production areas and trademarked symbols for use on consumer products. Packaged products carry information on the firm, which is a step towards a traceability system. Compliance is enforced by regular testing of soil, water, and air, and random testing of final products for residues.[129]

The above-mentioned programs are voluntary, and not yet commonly followed. In 2005, about 6 percent of the volume of agricultural production met the pollution free standard, and 1 percent the green standard, which is stricter.[130] The decision to produce green or pollution-free food is usually made by local officials or agribusiness enterprises, not the individual farmers[131].

[124] Calvin et al. 2006, 18.

[125] Calvin et al. 2006, 18.

[126]Firms have used a model in which the company leases land and controls production directly, and a model in which they use production contracts with growers that specify chemical use and production methods. Good agricultural practices (GAPs) and use of a type of Hazard Analysis and Critical Control Point (HACCP) are promoted. Calvin et al. 2006, 19.

[127] Calvin et al. 2006, 20-21.

[128] More specifically, the green food program defines two categories of green food. AA green food is equal to organic food, and A green food is between normal food and organic food. A green food is more realistic in China, as Chinese land is already heavily polluted. GMOs can be used in A but not AA green food.

[129] Calvin et al. 2006, 20.

[130] Calvin et al. 2006, 20.

[131] Calvin et al. 2006, 21.

The trend is inevitably towards green food, though. This is because exports require adherence to rather strict rules anyway, and because also Chinese consumers are becoming more aware and cautious. Bian sees green food as a suitable compromise between organic food and normal food, particularly for developing countries. Following the green food standard does not make food too expensive, but use of fertilisers and pesticides is still heavily restricted.

According to Huang, the measures taken have improved food safety in recent years. The general situation of food security concerning vegetables, meat, grains, fruits, dairy products, aquatic products and other food has turned better. However, supervision over food security is still weak in suburbs and rural areas, and about 8 percent of domestic food cannot reach the national food safety standards.[132] China will need equally strict food safety control for its domestic consumers than it already has in place for exports. The milk and dairy scandal discovered in September 2008 shows that China still has a long way to go.

In addition to food safety, food marketing is also now at focus in China. Until recently, nutrition claims have not been regulated in China. In November 2007, the Chinese Ministry of Health issued Administrative Measures on Food Nutrition Labelling[133]. The Measures are applicable from 1st May 2008. Nutrition labelling and nutrition claims are regulated by one single instrument. The new regulation stipulates the definition of food nutrition labelling and its scope, nutrition declaration and nutrition claim. The three technical annexes stipulate definition of nutrition ingredients, rounding rules, nutrients reference values, the conditions and terms of nutrition claims.[134] Guideline daily amounts (GDA) are used as a guide for consumer. Companies are not allowed to say their products are high in calcium, iron or low in fat unless they meet certain strict criteria. They must not make false claims nor exaggerate the nutritional benefits of the product. The prohibition of medicinal claims is also repeated: Labels must also not make direct or indirect claims of curing illness.[135]

2.4 Health Food Regulations

As stated above, additives, health foods, novel foods, and GMO foods are regulated separately in China. All have their separate pre-market authorisation procedures. The Chinese category for health foods covers a wide range of different products and includes the European categories

[132] Huang Hai, assistant minister of commerce. July 19 2005. Press conference reported by China Internet Information Center.

[133] 22 pages, in Chinese.

[134] WTO TBT/SPS notification.

http://www.tbt-sps.gov.cn/sites/English/News/Lists/news/DispForm.aspx?ID=60.

[135] Reuters Beijing January 11 2008.

of food supplements[136], fortified foods, and dietetic foods. Here we take a closer look at the regulations on health foods.[137] Health foods are foods which have a specific health function, are suitable for a certain group of people, and which are not for therapeutic purposes. Safety and efficacy of health foods are evaluated in a single procedure. We will not discuss the details of the application process here[138].

The new Food Safety Law states basic rules on health foods in its Article 51. It is first stated that "the state executes strict regulations on health foods". Health foods may not pose acute, sub-acute or chronic hazard to human body. Labels and instructions may not refer to disease treatment or prevention, all information and claims must be truthful, and the product must correspond to the information given. More precise rules on health foods are given by the Health Food Regulation of 1996[139] and its subsequent amendments. The Health Food Regulation was enacted to strengthen the administration and supervision of health foods, ensuring the quality of health foods[140]. The regulations focus on evaluation and approval of health foods, and are as such directed more at authorities than at entrepreneurs. However, there are also sections regulating production and marketing of health foods.

The regulations establish minimum safety and efficacy requirements for health foods as follows:

- raw materials and final products must comply with food hygiene requirements and shall not cause any acute, subchronic, or chronic harm to human body,
- necessary animal and/or human tests must have confirmed a clear and stable health effect,
- formulation and dosage must be based on scientific evidence (the functional ingredient should be identified but when that is impossible, at least the raw materials that cause the effect shall be listed),
- therapeutic effects shall not be claimed in labelling or advertising.[141]

Besides general hygiene rules, safety of health foods in controlled via controlling the choice of raw materials. A separate Notification from 2002[142] governs the raw materials of health foods.

[136] There is no specific legislation on food supplements in China and food supplements thus do not form a separate legal category. The pre-market authorisation requirements depend on whether the supplement contains vitamins, minerals, or something else, and whether or not health claims are presented on the product. As stated above, only health foods are allowed to bear health claims in China. This applies to foods in food form and food supplements.

[137] We will leave additives, novel foods, and GMO foods out of this article. Chinese regulations on these products have been discussed in our doctoral study.

[138] We have discussed the topic in our doctoral thesis.

[139] Ministry of Health: Administrative Regulations on Health Food, Order No. 46 (Promulgation Date: 1996-03-15; Effective Date: 1996-06-01.)

[140] Article 1.

[141] Health Food Regulation, Article 4. Huang – Lapsley 2005, 266.

First of all, the Notification aims to clear the situation of overlapping pieces of legislation. Novel foods are a separate issue from health foods. If a health food has novel ingredients, the Novel Food Regulation shall be followed. Further, if the health food uses food additives, additive law applies. There are also particular rules on fungal health foods[143], probiotic health foods[144], and nuclei acid type of health foods[145]. These products should follow these procedures respectively.[146]

If health foods involve protected wild animals or plants, they should be applied according to Notification of Restraining the Produce of Health Food using Wild Animal and Plants as Raw Materials of Ministry of Public Health of the Notification of 5th July 2001 restraining the use of certain single materials[147] that have anti-desert function in the wild.[148]

Other health food raw materials are regulated by three lists given by the Annexes of the Health Food Raw Material Regulation:

- List I includes materials that can be used either as foods or medicines.
- List II includes materials that can be used as health food materials.
- List III includes materials that are prohibited as health food materials.

The bit complicated rules are given by point 5 of the Raw Material Notification:

[142] Ministry of Health: Notification on Further Standardising the Management of Raw Materials for Health Food (Directive, Document No.:WeiFaJian[2002]51, Promulgation Date: 2002-02-28.

[143] Regulation on Evaluation and Examination of Fungal Health Foods, valid from March 23rd 2001. Fungal health food means food with specific health function, which uses edible macro-fungi and carpophores and filaments or filament macro-fungi. Fungal health food must be safe and dependable, i.e. safe for eating, non-toxic and not harmful. The strains used in production must have clear and stable characteristics of biology, genetics and functionality. Article 3. Only certain fungus species are permitted as health food ingredients. The permitted fungus species are the following: *Saccharomyces cerevisae, Candida atilis, Kluyveromyces lactis, Saccharomyces carlsbergensis, Paecilomyces hepiali Chen et Dai, sp. Nov, Hirsutella hepiali Chen et Shen, Ganoderma lucidum, Ganoderma sinensis, Ganoderma tsugae, Monacus anka, Monacus purpures*. Huang – Lapsley 2005, 266. If an entrepreneur wants a fungus to be added on the list, an application to the SFDA has to be made.

[144] Regulation on Evaluation and Examination of Probiotic Health Foods, valid from March 23rd 2001. Probiotic health food means preparation which promotes ecological balance of bacterial colony in intestine and is beneficial to human health. Article 2. The probiotic strains must belong one of normal bacterial colonies in human body. It is allowed to use live or dead bacteria and bacterial metabolites. The probiotic health food must be safe and dependable, i.e. safe for eating with no adverse reactions. The strains used in production must have clear and stable characteristics of biology, genetics and functionality. Only certain probiotic bacteria are allowed as health food raw materials. The permitted probiotics are the following: *Bifidobacterium bifidum, Bifidobacterium infantis, Bifidobacterium longum, Bifidobacterium breve, Bifidobacterium adolescentis, Lactobacillus bulgarius, Lactobacillus acidophilus, Lactobasillus casei subsp. Casei, Streptococcus thermophilus*. Huang – Lapsley 2005, 266. If an entrepreneur wants a probiotic to be added on the list, an application to the SFDA has to be made.

[145] This means health foods using DNA or RNA as raw material. The purity of DNA or RNA must be above 80 percent, and the recommended dosage for nuclei health foods should be 0,6g-1,2g per day. Huang – Lapsley 2005, 266.

[146] Points 1, 2, and 3 of the Notification.

[147] Wild licorice, saussurea involucrate, xxx and xxx. There is no English word for the latter two.

[148] Point 4 of the Notification.

- First of all, if health foods involve products (or materials) of animals or plants, the number of products (or materials) of animals or plants can not exceed 14.
- If health foods use products (or materials) that are not listed in the List of Materials which are used as either Foods or Medicines, the number of products or materials of animals or plants can not exceed 4.
- If health foods use products (or materials) of animals or plants not listed in the List of Materials which are used as either Foods or Medicines and neither in List of Materials which can be used in Health Foods, the number of products (or materials) of animals or plants can not exceed 1.

The other way round: If you want to use a material outside both lists, you can only use one. The one cannot be on the third list of forbidden materials. If you want to use materials on the first and the second list, or merely on the second list, you can use four materials altogether. If you can settle with the materials listed in the first list, then you can have 14 materials. Normal food materials are not included in this number: it only concerns materials with health effects.

Category I includes approximately 90 materials, for example Hawthorn fruit (*Fructus Crataegi*), Barbary wolfberry fruit (*Fructus Lycii*), Lotus leaf (*Folium Nelumbilis*), Lotus seed (*Semen Nelumbilis*), Hemp seed (*Fructus Cannabis*), Ginkgo seed (*Semen Ginkgo*), Oyster Shell (*Concha Ostreae*), Honey (*Apis Melifera*), Peppermint (*Herba Menthae*), Peach seed (*Semen Persicae*), and Tangerine peel (*Citrus Reticulata*).[149]

Some products made of these materials will be classified as traditional medicines. Whether a product is a health food or a traditional medicine will depend on functions and marketing claims of the product.

Category II includes approximately 110 materials, for example Ginseng root, leaf and fruit (*Radix Ginseng, Folium Ginseng, Fructus Ginseng*), Deer embryo (*Fetus Cervi*), Deer bone (*Fel Cervi*), White peony root (*Radix Paeoniae alba*), Red peony root (*Radix Paeoniae rubra*), Aloe vera (*Herba aloe*), Magnolia flower (*Flos magnoliae*), Tortoise shell (*Carapax et Plastrum testudinis*), and Ginkgo leaf (*Folium Ginkgo*).[150]

Category III includes approximately 60 materials, for example Poppy capsule (*Pericarpium Papaveris*), Quicksilver (Mercury), Chinese azalea flower (*Flos Rhododendri mollis)*, Lily of the valley grass (*Herba Convallariae majalis*), Mung bean blister beetle (*Lytta Caraganae pallas*), and Blowfish (Globefish, *Tetraodontiforms syn. Plectognathi*).[151]

[149] See complete list by Huang – Lapsley 2005, 267-269.

[150] See complete list by Huang – Lapsley 2005, 269-272.

[151] See complete list by Huang – Lapsley 2005, 272-274.

In addition to complying with the lists, the product must pass toxicological safety assessment. There is a Ministry of Health standard[152] establishing requirements for toxicological testing. Animal tests requirements vary from no need for toxicological testing to four tiers of tests (tier I: acute toxicity; tier II: genetic toxicity; tier III: sub-chronic toxicity; tier IV: chronic toxicity).[153] The test requirements depend on the categories of the raw materials. If the product is made of common foods and Category I ingredients, and processing and consumption of the food are traditional, no tests are required on raw material of finished products. However, if the product is processed and consumed so that dosage is greater than regular, tests are needed on final products. For foods made of category II ingredients, tests on the final product are always needed. For those other ingredients that are not common foods nor category I or II ingredients, tests are always needed both on the raw material and the finished product. The strictest requirements apply if the raw material has no historical human consumption data at all.[154]

For food supplements that contain authorised vitamins or minerals, there is a special procedure under the Health Food Regulation. They need to get an "Approval Certificate for Health Food" prior to production, but clinical tests on safety and efficacy of the vitamin or mineral are not required. The producer still needs to show hygiene, stability, etc. Other supplements such as those containing dietary fibres, proteins, or amino acids, are considered common foods where no pre-market control applies. For common foods, health claims are not allowed. If health claims are wanted, the supplement must undergo the whole health food process.[155]

Next, we turn to marketing of health foods. In Article 23 of the Food Hygiene Law, misleading advertising of health foods was prohibited. Article 51 of the new Food Safety Law states the same rules in new words. The content of the product description shall be accurate. The functions and ingredients of the product shall be identical with the information given in the product description and there shall be no false information. Claims that refer to prevention or treatment of disease (medicinal claims) are prohibited on health foods. Suitable and unsuitable user groups of the health food must be given, as also the functional ingredients and their content. There is certain mandatory information that must be given to consumers on health foods. According to the Health Food Regulation[156], the label and specification of health food must contain the following details: role of the product in health protection, suitable user groups, optimal dosage, storage method, name and quantity of effective components[157], order number of health food

[152] Ministry of Health: Technical Standards for Testing and Assessment of Health Food. Promulgation date 14 February 2003, effective 1 May 2003.

[153] Huang – Lapsley 2005, 274-275.

[154] Huang – Lapsley 2005, 275.

[155] Huang – Lapsley 2005, 266.

[156] Article 21.

[157] If components of effective function can not be determined under present conditions, names of major raw materials having a health protection function should be listed.

certificate, and the health food symbol. Names of health foods should be accurate, scientific, and should not use names of peoples, names of places, names that are misleading or exaggerating, or names of minor effective components[158]. There shall be no referrals to therapeutic effects. It is also forbidden to use superstition in health food advertisement.[159]

It is important to notice that in China, only health foods can bear health claims. Regular foods cannot bear health claims. On the other hand, health foods cannot bear medicinal claims. This way the health food regulation separates normal foods from health foods, foodstuffs from medicines, and food advertising from medicine advertising. To make the separate functions clear, health foods must bear the advice: 'this product cannot substitute any medicine'[160]. The verb "assist" is now used in 6 health claims. For example, one cannot say that a product lower hypertension; instead it is allowed to say that it assists in hypertension alleviation. This approach is similar to the European rules on health claims: one has to remind the consumer of the lifestyle factors.

There are currently 27 possible functions and claims for health foods, with other functions not accepted[161]. The Chinese health claim categories cover many of the important claims that are

[158] Health Food Regulation, Article 22.

[159] Health Food Regulation, Article 23.

[160] Functional Ingredients December 2005 China News. Available at www.functionalingredientsmag.com.

[161]
1. Enhancing immune function
2. Assisting in blood lipids reduction
3. Assisting on blood sugar reduction
4. Anti-oxidation (delay of aging)
5. Assisting in memory improvement
6. Reducing eye fatigue
7. Facilitating lead excretion
8. Thinning throat mucus (moistening of throat)
9. Assisting in hypertension (blood pressure) reduction
10. Enhancing sleep
11. Promoting lactation
12. Alleviating physical fatigue
13. Enhancing anoxia endurance
14. Assisting protection against irradiation hazard
15. Weight reduction
16. Enhancing child growth and development
17. Increasing bone density
18. Alleviating nutritional anemia
19. Assisting in protection against liver chemical injury
20. Alleviating acne
21. Eliminating skin pigmentation
22. Improving skin moisture
23. Improving skin oil content
24. Regulating gastrointestinal flora
25. Facilitating digestion
26. Alleviating constipation
27. Assisting in protection against gastric mucosa injury. Ministry of Health Notification 2003, point A.

interesting to functional food developers. The Ministry of Health revised the procedures for efficacy evaluation in 2003, when the current list of 27 functions/claims came into force. Cosmetic claims were separated into four different claims instead of just one. Similarly, gut health claims were separated into four different claims.[162] Two important claim types are prohibited: claims related to cancer, and claims related to sexual functions. It is not possible to market an all-purpose health food: a health food with same recipe is not allowed to apply for more than two functions.[163]

The list of allowed claims would not give much guidance without rules on scientific substantiation of the claims. According to the current rules on health food efficacy, animal trials are required for 22 of the 27 claims.[164] Human feeding trials are now required for 20 claim categories[165]. If both animal and human tests are required, human tests are done after getting a positive result with animal tests. Before a human feeding trial can be started, it must receive approval from an ethical committee. The regulations do not give precise requirements on how effective a product must be. Similarly to the European rules on claims, the regulations only give the scientific criteria that are used in the evaluation of the application. Whether the product is effective enough is a question that the SFDA will have to evaluate on a case by case basis.

In 2002, 60 percent of so far authorised health foods were focused on three functions: immune regulation, regulating blood pressure, and anti-fatigue. Health foods were not often in regular food form, instead they were primarily in the form of oral liquid, capsule, tablet, or powder. It is noteworthy, that in about 90 percent of health foods, the active ingredients of the products were related to Traditional Chinese Medicine.[166] Today, also other types of health foods are emerging, for example probiotic products are gaining interest. In 2002, 90 percent of health foods were marketed by Chinese companies, 10 percent were imported[167].

[162] Huang – Lapsley 2005, 264.

163 Ministry of Health Notification 2003, points B and C.

Animal trials are not required for claims on: alleviating eye fatigue, and cosmetic claims: alleviating acne, eliminating skin pigmentation, improving skin moisture, and improving skin oil content 164 Huang – Lapsley 2005, 277-281.

165 Human trials are not required for claims on: enhancing immune function, enhancing sleep, alleviating physical fatigue, enhancing anoxia endurance, assisting in protection against irradiative hazard, increasing bone density, and

assisting in protection against liver chemical injury. Huang – Lapsley 2005, 277-281.

166 Wang et al. 2003.

167 Huang – Lapsley 2005, 263.

2.5 Structure of Medicine Law

The basic Chinese law on medicines is the Medicine Administration law along with its Implementing Regulations. The law itself was enacted by the National People's Congress in 2001, and the implementing regulations were given by the State Council in 2002. More detailed information on what is required is to be found in the 'Registration Measures' given by the SFDA in 2007[168].

Similarly to the regulation of foodstuffs, the basic laws on medicines are complemented by several pieces of administrative regulations given by the SFDA. This material could be defined as soft law as it is given by the SFDA or its predecessor, the SDA. The SFDA has an important role as a formulator of laws and administrative regulations on medicines. The regulations include rules on manufacturing licences, certification for Good Manufacturing Practice, Good Clinical Practice, Good Supply Practice, distribution, labelling and packaging, advertising, pricing, import-export, etc. Medicine marketing was in 2007 regulated in a stricter and more detailed manner because of the problems and scandals related to false advertising. Medicine advertising is under pre-market control.

In China, there are basically two different kinds of medicinal products on the market: modern medicines and traditional Chinese medicines. As regards modern medicines, there are general standards, and specific standards for narcotics, psychotropic substances, toxic drugs for medicinal use, and radioactive medicines[169]. The specific standards shall not be discussed here. Traditional Chinese Medicine (TCM) remains a recognised and valued source of treatment[170]. A separate law on scientific evaluation of traditional medicines is also on the way, as the Chinese intend to be a global leader in bringing herbal medicine into the 21st century by establishing modern standards. The law has not been accepted yet, because it has caused controversy. Local government authorities have enacted their own medicine regulations which may supplement and modify some of the national regulations. Local rules exist particularly on labelling.

The Chinese rules on medicine marketing of 2007 aim to clean up medicine advertising mainly by two means: defining the prohibited marketing methods more precisely, and hardening punishments.

168 The SFDA promulgated the latest "Measures for the Administration of Drug Registration" on July 10 2007, and they entered into force in October 1, 2007.

169 Based on Medicine Administration Law, Article 35.

170 China-Britain Business Council. China-Britain Business Review Archive.

The 2007 rules on therapeutic claims are the same for modern and traditional medicines.[171] There are no special categories for medicines without proven therapeutic efficacy. However, the scientific criteria for efficacy of traditional medicines are not yet legally established.

2.6 Law on Modern Medicine

In the past few years, China has significantly modernized its legislation on medicines, in order to guarantee their safety, efficacy, and quality. China has simultaneously enhanced intellectual property protection, which is particularly important to the medicine industry.[172] The Chinese rules on medicines currently resembles for example the EU rules. Compared to food safety, medicine safety is more relative to the efficacy of the product, whereas food safety is more of an absolute requirement, The risk/benefit ratio is applied to medicines. All effective medicines have some side-effects and should only be used if needed. [173] Medicine safety is guaranteed by strict procedures on tests and trials, scientific risk assessment, pharmacovigilance, and by comprehensive user information. With herbal medicines, safety assessment is affected by nature: the plants vary as to where they grow.

The central government authority responsible for medicine control is the State Food and Drug Administration. A new medicine can be put into production only after the SFDA has approved it and issued a registered document of approval[174]. A new medicine which has completed its clinical tests and been approved after appraisal shall be issued a certificate of new medicine by the SFDA[175].

[171] According to the new Chinese Standards and Measures on medicine advertising (2007), claims on the curative effects of medicines in advertisements must be scientific and accurate and may not contain any of the following content:

- unscientific assertion or guarantee of efficacy;
- claims of curative rate or efficiency;
- comparison of effects and safety with other medicines;
- explicit or implicit suggestion that the drug can heal all diseases and is good for all symptoms in contravention of the rules of science;
- suggestion that the medicine is "safe with no toxic side-effect" or has "very little toxic side-effect";
- for proprietary Chinese medicine, explicit or implicit suggestion that it is "natural" and guaranteed safe;
- explicit or implicit suggestion that the medicine is essential for normal daily life and for the treatment of diseases;
- explicit or implicit suggestion that the medicine can help one cope with the tension of modern life, studies or examination, and can help boost academic performance, energy, competitiveness, height and intelligence;
- other unscientific terms or suggestions such as "the latest technology", "state-of-the-art science" and "the most advanced methods of preparation".

[172] Tsoi 2007.

[173] Kwak – Jukes 2000a, 105.

[174] Medicine Administration Law, Article 31.

[175] Medicine Administration Law, Article 29.

Production and sale of fake medicines is prohibited[176]. Production and sale of medicines of inferior quality is prohibited. This refers to medicines whose components do not conform to State pharmaceutical standards.[177] These standards are the "Pharmacopoeia of the People's Republic of China" and the pharmaceutical standards promulgated by the SFDA.[178] Import of medicines whose curative effects are uncertain or poor, or which produce adverse reactions or have other harmful effects on people's health is prohibited[179].

2.7 Law on Traditional Chinese Medicine

Traditional Chinese Medicine is an ancient Chinese system of medicine that includes meditation, herbal and nutritional therapy, restorative physical exercises and massage, and acupuncture[180]. Here we are mainly interested in herbal medicines[181]. Medicines of plant origin form the main part of traditional Chinese medicine. Their species, habitat, collection season, collection method, and storage are thus important factors determining their quality and efficacy. For example, some plants need to be collected when flowers are in full bloom, others when flowers are still in bud. Medicines from fruits are usually collected when the fruits are ripe, medicines from roots in late autumn or spring, and medicines from bark in early summer.[182]

Beginning in the 1920's, traditional Chinese medicines have been investigated in terms of modern medical science. Chemical ingredients and fractions have been isolated from herbs,

[176] A fake medicine has any one of the following characteristics: (1) Its components do not comply with State pharmaceutical standards. (2) A non-medical substance is passed off as a medicine, or one medicine is passed off as another. A medicine is legally a fake medicine in any of the following cases: (1) Where the use of the medicine has been prohibited by the SFDA; (2) Where the medicine is produced and imported without a legal approval or sold without being inspected according to the law; (3) Where the medicine has deteriorated; (4) Where the medicine has been contaminated; (5) Where the medicine has been produced of medicinal materials without obtaining a registration document of approval for the materials. (6) Where the indications or the functions marked on the label do not fall within the prescribed scope. Medicine Administration Law, Article 48.

[177] A medicine shall be handled as medicine of inferior quality also in any of the following cases: (1) An expiry date is not indicated or is altered; or (2) A registration number is not indicated or is altered; or (3) The medicine has passed its expiration date; or (4) The packages and containers which have direct contact with pharmaceuticals have not obtained approval; or (5) The medicine has been added presumptuously with colour or preservative additives, spice, disguising odour or supplementary materials; or (6) The medicine fails to meet the prescribed standards in other respects. Medicine Administration Law, Article 49.

[178] Medicine Administration Law, Article 32.

[179] Medicine Administration Law, Article 38.

[180] Spondylitis Association of America. Web page at: http://www.spondylitis.org/patient_resources/glossary.aspx.

[181] According to a survey from a few years ago, the number of traditional Chinese medicines is close to 13 000. Of these, over 11 000 are of plant origin; the rest are animal or mineral origin. This means traditional Chinese medicine often means herbal medicine. The Essentials of Traditional Chinese Herbal Medicine 2003, 1.

[182] The Essentials of Traditional Chinese Herbal Medicine 2003, 3.

and their actions studied. Since the 1950's, the Chinese government has paid a lot of attention to the development of traditional Chinese medicine. Colleges focused on the subject have been established in every province and autonomous region, hospitals and research institutes have been set up at national, provincial, municipal and even county level. New chemical ingredients are isolated. New forms of herbal remedies are instant powders, tablets, injections and capsules.[183] Herbal medicines are processed before being taken as medicines. Sometimes the purpose of processing is increasing potency, and hence effectiveness. Sometimes it is minimizing or eliminating side effects or toxicity. Sometimes processing makes drugs easier to prepare or store. Methods of processing can be divided into physical processing, liquid processing, fire processing and processing by both water and fire. Side effects are often reduced by boiling or steaming.[184]

Diseases are classified into two major categories: cold and hot. Medicines to counteract these diseases are either cool, cold, warm or hot. In terms of yin and yang, cool and cold belong to yin, and warm and hot belong to yang. Hot diseases are ones where body temperature, blood pressure, respiratory rate, and salive secretion are high. Cold diseases are the opposite. Hot diseases are treated with cold medicines and the other way around. Hot or warm medicines stimulate the central nervous system, promote the metabolid system and so on. Cold and cool medicines tranquilize, sedate, and have anti-microbial and anti-inflammatory actions.[185] The taste of a medicine is related to its therapeutic capability.[186]

In terms of safety or toxicity, traditional Chinese medicines can be classified as non-toxic, slightly toxic, moderately toxic and extremely toxic. Even some extremely toxic herbs thus have their medical uses. According to ancient literature, it is stated that no medicine is non-toxic if taken in excessive doses or for too long a period of time. When using traditional Chinese medicines, the properties, actions and toxicity are weighed against one another. Medicines are chosen according to the syndrome, and the doctor must look at the situation as a whole. [187] Dosage and method and time of administration are determined simultaneously[188]. For mild diseases and for children and other weak persons, dosage is smaller[189]. When discussing medicine safety, interactions of substances have to be taken into account. This includes medicine-medicine interactions and medicine-food interactions.

[183] The Essentials of Traditional Chinese Herbal Medicine 2003, 2.

[184] The Essentials of Traditional Chinese Herbal Medicine 2003, 4-5.

[185] The Essentials of Traditional Chinese Herbal Medicine 2003, 5-6.

[186] The Essentials of Traditional Chinese Herbal Medicine 2003, 6.

[187] The Essentials of Traditional Chinese Herbal Medicine 2003, 8.

[188] The Essentials of Traditional Chinese Herbal Medicine 2003, 10-11.

[189] The Essentials of Traditional Chinese Herbal Medicine 2003, 10.

In clinical practice, traditional Chinese medical doctors usually prescribe around ten or more herbs to make the best possible mixture in each individual case of symptoms. The medicines in a mixture can be classifed into four categories:

- the principal medicine(s) provides the principal curative action,
- the adjuvant medicine(s) strengthens this action and treats secondary symproms,
- the auxiliary or correctant medicine(s) relieves secondary symptoms or tempers the action of the principal medicine,
- the conductant medicine(s) directs the action to the right part in the body.[190]

Medicines in a prescription can either reinforce each other, weaken each other, neutralize side effects of each other, counteract each other (resulting in no therapeutic action), or are totally incompatible, where two medicines put together will result in enhanced side effects or toxicity.[191] There are lists of counteracting and incompatible medicines available to doctors. There are eighteen incompatible medicaments and nineteen medicaments of mutual restraint. For example, if Radix Veratri Nigri (lilu) is put together with Radix Ginseng, there will be serious side effects. If Radix Ginseng is put together with Faeces Trogopterorum (wulingzhi), Ginseng neutralizes the effect of Trogopterum. The mechanisms of these actions are not clear.[192] As there are 11 000 medicinal herbs in use, and only a couple of dozen are mentioned in the above mentioned incompatibility list, it is evident that a lot more research is needed on herbal interactions.

There is also a list of herbs that should not be used during pregnancy, as they might harm the fetus or cause abortion. Drugs that are prohibited or should be used with great caution during pregnancy are those that have a drastic action or are very toxic. These are for example Flos Genkwa and Radix Euphorbiae Pekinensis. Also drugs that are very warm or purgative should be avoided.[193] There are also guidelines on unwanted medicine-food interactions. Uncooked or cold food is not suitable for a person suffering a cold syndrome. Hot and greasy food is not suitable for persons with a hot syndrome: for example no chillies for insomniacs. Some medicaments do not work well together with for example Chinese green onion, garlic and radish. Peppermint counteracts turtle flesh, honey counteracts scallions, and so on.[194]

After discussing the tradition of traditional medicine, we will now turn to law on traditional medicine. In China, Traditional Chinese Medicine is under the administration of State Administration of Traditional Chinese Medicine and Pharmacology, which is under the Ministry of Health. National strategies, laws and regulations governing Traditional Chinese

[190] The Essentials of Traditional Chinese Herbal Medicine 2003, 8-9.

[191] The Essentials of Traditional Chinese Herbal Medicine 2003, 9.

[192] The Essentials of Traditional Chinese Herbal Medicine 2003, 9.

[193] The Essentials of Traditional Chinese Herbal Medicine 2003, 9.

[194] The Essentials of Traditional Chinese Herbal Medicine 2003, 9.

Medicine are in place to guide and promote the research and development in the industry.[195] Also the Ministry of Science and Technology has initiated a program that has ambitious goals related to Traditional Chinese Medicine. They have a program called "International Traditional Chinese Medicine Program for Cooperation in Science and Technology". The aim is to facilitate integration of traditional medicine with Western medicine all over the world.

According to of the Chinese Medicine Administration Law[196], "the State shall develop both modern and traditional medicines and encourage their role in the prevention and treatment of diseases and in health care". Further, "the State shall protect the resources of wild medicinal resources and encourage the domestic cultivation of Chinese traditional medicinal crops".[197] Traditional medicine is given clearly more weight compared to the European law on medicines.

The national Regulations on Traditional Chinese Medicine have been effective as of October 2003[198]. These Regulations do not specify rules on safety, efficacy and marketing of traditional medicines. Instead, the Regulations are focused more on attitudes towards and roles of traditional medicine. The objectives of the Regulations include:

- the development of the science of traditional Chinese medicine,
- the promotion of the development of undertakings engaged in traditional Chinese medicine, and
- the protection of public health.[199]

The Regulations apply to institutions and individuals engaged in healthcare involving traditional Chinese medicines, as well as to education, research and international cooperation related to the subject. The objectives of the State are to protect, support, and develop traditional Chinese medicine. The aim is to lay equal stress on traditional Chinese medicine and Western medicine and encourage development and integration of both schools.[200]

As stated above, the Regulations on Traditional Chinese Medicine do not include criteria on product safety, efficacy and marketing. Product development, production, marketing, use,

[195] Chinese Symbols web page. http://www.chinese-symbols.com/chinese-medicine/chinese-medicine.html.

[196] The Medicine Administration Law of the People's Republic of China, revised at the Twentieth Meeting of the Standing Committee of the Ninth National People's Congress on February 28, 2000. The revised law entered into force as of December 1, 2001.

[197] Article 3.

[198] Regulations of the People's Republic of China on traditional Chinese medicine. Adopted at the Third Executive Meeting of the State Council on 2 April 2003. Promulgated by Decree No. 374 of the State Council of the People's Republic of China on 7 April 2003. (Gazette of the State Council of the People's Republic of China, 30 May 2003, Issue No. 15, Serial No. 1086.)

[199] Summary of the Chinese Regulations on Traditional Chinese Medicines by WHO's "international digest of health legislation". Available on the WHO web page at: http://www.who.int/idhl-rils/frame.cfm?language=english.

[200] Summary of the Chinese Regulations on Traditional Chinese Medicines by WHO's "international digest of health legislation". Available on the WHO web page at: http://www.who.int/idhl-rils/frame.cfm?language=english.

supervision, and administration with respect to traditional Chinese medicines must comply with the Medicine Administration Law of the People's Republic of China. It is stated in Article 6, that the preparation of Chinese medicines shall be in accordance with the "Pharmacopoeia of the People's Republic of China", or in accordance with the "Preparation Standards" laid down by the department administering health in that province, autonomous region or municipality under the direct control of the Central Government.

Many of the safety problems with traditional Chinese medicines are due to poor quality. This means the plant itself might be safe, but due to heavy metal contamination or adulteration with prescription drugs, the product is dangerous. There may also be quantitative variations in constituents, which affects safe use of the product.[201] A regulation on Good Agricultural Practice of traditional Chinese medicines exists since 2002. This regulation is interim and given by the SDA, the predecessor of the SFDA.

As stated above, the law does not specify criteria on traditional medicines yet. The safety of traditional medicines is guaranteed by the traditional guidelines described above. In the beginning of 2007, the Chinese Ministry of Health completed the drafting of Law on Traditional Chinese Medicine, which was submitted to the State Council. The drafting of the law had drawn considerable attention from the National People's Congress (NPC) and government departments.[202] The goal of the Chinese government is to strengthen supervision on the sources of Chinese medicines, improve the administrative system for Good Chinese Medicine Production Practice (GCMP), push forward the implementation of GCMP and ensure the production quality of Chinese herbal medicines.[203]

Improving the legal framework on traditional medicine is among the important goals set by the Chinese government for the next few years. The goal is to establish and improve a system of Chinese traditional medicine standards. A comprehensive classification system of Chinese medicine is needed. Technical pre-market evaluation criteria shall be set, followed with post-market control criteria. To strengthen the knowledge base, research guiding principles of reference materials will be formulated, and a Chinese medicine library for standard materials will be established. China will actively advocate for the establishment of international standards for traditional medicines.[204]

[201] Barnes 2003.

[202] People's Daily Online. January 17 2007. Available at: http://english.people.com.cn/200701/14/eng20070114_341062.html

[203] Five-Year Plan for Food and Drug Safety. April 2007. Page 12.

[204] Five-Year Plan for Food and Drug Safety. April 2007. Pages 12-13.

III. Conclusions

China has in recent years created and considerably strengthened its food and medicine legislation. This process was related to China's entry to the WTO in 2001. The new Food Safety Law focuses on implementation and control, and the strict 2007 rules aim to clean up medicine advertising. As regards functional food products, the Health Food Regulation was important in setting common national rules. The proposed national law on traditional herbal medicines will strengthen patient confidence in China, and also promote acceptance of herbal medicine in foreign countries. The problem is not with legislation: China must now focus on the execution of laws, and particularly at the local level. Independent agencies such as the SFDA are valuable in resolving scientific issues based on science, not politics. Scientific risk assessments and issuance of scientific guidelines are the most suitable tasks for foodstuff and medicine agencies. If the SFDA is to perform impartial risk assessments based on science, its independence from political actors must be guaranteed.

The Chinese government has in food hygiene issues promoted self-regulation and regulation by consumer organisations. The Chinese are also campaigning to make consumers more responsible in food safety issues. Although important, these approaches will not suffice. Because it is an enormous task in China to officially control the whole food chain, the government wishes the food business operators and consumers could manage by themselves. In our opinion, foodstuffs and medicines are way too important for the government to step aside. Self-regulation has proven useful in certain minor questions where the industry as a whole is motivated in following common rules that often supplement hard-law norms.

Even though Chinese legal rules and institutions are more and more similar to the Western ones, legal culture will change slowly[205]. The Chinese tend to trust neither the law nor the companies. In China, the difference between legal system surface and legal reality is a wider cultural phenomenon. It is related to the notion of 'rule by man', the reliance to family and friends in the first place, and the Confusian principle of conflict avoidance. In the Chinese legal culture, the administrator long had all the (imperial) power. The 'rule by man' tradition runs counter to rule of law. The separation of powers is new to the Chinese. Reliance to social connections, *guanxi*, is deeply rooted and also runs counter to the establishment of rule of law[206].

Legal culture, including consumer trust in regulation, is not a stable phenomenon but changes through time. The roles of governments and other governance regimes are constantly in flux. Consumers will have to learn the most basic assumptions on a given legal culture:

[205] According to Jones, Chinese legal system may some day be what it now is on paper. He suspects this will not happen soon, if ever. He thinks the surface will be similar to Western legal systems, but the legal culture will continue to be influenced by history. Jones 2003, 40.

[206] Kubayashi 2008, 6.

- what can be expected of regulators,
- what can be expected of companies, and
- what is under their own responsibility.

From consumer viewpoint, there is not a big difference between who regulates the companies: whether it is governmental bodies or non-governmental bodies. From business viewpoint, there is a difference between law, co-regulation and self-regulation. As the scope of business law widens, the room for business ethics becomes narrower. And vice versa: if business ethics is highly developed, law is supposedly not needed.

Confucius relied on moral rather than legal rules; now rule of law is gaining importance in China. Reverting to legal proceedings is new in China and something that Confucius wanted to avoid. In China, legal institutions are needed because of the transition from planned economy to market ecocomy. This transition is not complete, which makes it difficult for the Chinese and others to know the roles of state vs. markets in China[207]. According to Qingjiang, there is no turning back China's progress into a market-oriented economy and rule-based society[208]. At the same time, rule of law is being discussed in Europe, as legislation is increasingly replaced by co-regulation, standards, and self-regulation. A new understanding of law is emerging. This means that when China accepts rule of law, rule of law might not be the same anymore.

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[207] See Lichtenstein 2003, 288, about corruption and the unclear role of the state.

[208] Qingjiang 2002, 62.

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