Guiding Case No. 70:
Food and Chinese Medicine

Dr. Mei Gechlik
Zhaoyi (Troy) Song

The Takeaway

The blurred distinction between food and Chinese medicine may easily lead to food safety lawsuits. To avoid being entangled in the plethora of unclear standards as illustrated in Guiding Case No. 70, businesses would be wise to seek official approval for treating new edible substances with pharmacological potential as “new food raw materials”.

Yet China’s new law on Chinese medicine and related (2016–2030) strategic plan to promote Chinese medicine around the world, especially in countries participating in the Belt and Road Initiative, should make these businesses ponder whether identifying such new substances as “Chinese medicine” may be a better option.

The Rundown

Guiding Case No. 70 (“GC70”), released in December 2016, reveals the complexity of China’s food industry regulatory framework. In the adjudication of a food safety case, a court often has to go through multiple steps to determine whether a substance is prohibited from being included in the food at issue. The prohibition may be in the form of legal provisions or numerous lists prepared by various authorities. GC70 illustrates how the court went through these steps. The substance the defendants were jailed for adding into food was not specifically included in relevant regulations, official lists, standards, etc. It was, however, held to be toxic and harmful because experts’ tests and reports confirmed that it possessed the same attributes, and caused the same harm, as substances recorded on such official lists.

Facing such a complicated regulatory framework, food production businesses would be wise to make sure that anything added into food is explicitly allowed by Chinese law. For example, while drugs are generally prohibited by the Food Safety Law of the People’s Republic of China from being added into food, a certain type of Chinese medicine is allowed. Unfortunately, an official catalogue of these exempt Chinese medicinal materials remains to be issued, despite being years in the drafting.

The lack of a final version of this catalogue is undesirable, but innovative food production businesses can

Dr. Mei Gechlik

is Founder and Director of the China Guiding Cases Project (“CGCP”). She teaches the course “China Law and Business” at Stanford Law School. She is admitted as a barrister in England, Wales, and Hong Kong and is a member of the Bar in New York and the District of Columbia. She received her Doctor of Science of Law (JSD) from Stanford Law School and her MBA in Finance from the Wharton School at the University of Pennsylvania.
ensure that new edible substances with pharmacological potential are acceptable by seeking official identification of these substances as “new food raw materials”. With this approach, not only does the new edible substance have a more firm legal footing, helping to avoid food safety litigation, but the added novelty may open up more avenues, or create a new niche, in China’s enormous food market, leading to yet more business opportunities.

The release of the new *Law of the People’s Republic of China on Chinese Medicine*³ (the “Law on Chinese Medicine”), however, affords yet another approach. As a significant step taken by Chinese leaders to implement their long-term plan to promote Chinese medicine inside and outside the country, the new law calls on innovative food production businesses to think strategically: would identifying an edible substance with pharmacological potential as a type of Chinese medicine potentially yield more profits than identifying it as a “new food raw material”?

**THE BREAKDOWN**

*Guiding Case No. 70*

In GC70, the defendants were found guilty of the crime of producing and/or selling toxic and harmful food as provided for in Article 144 of the *Criminal Law of the People’s Republic of China*⁴ (the “Criminal Law”) because they added a “toxic and harmful non-food raw material” into food⁵ they produced and sold and/or knowingly sold food into which a “toxic and harmful non-food raw material” had been added.⁶

The substance added was buformin hydrochloride. In determining that the chemical was a “toxic and harmful non-food raw material”, the court relied on a judicial interpretation concerning the adjudication of food safety cases (the “Interpretation”).⁷ The court noted that buformin hydrochloride was neither “prohibited by laws and regulations from being added and used in food production and operation activities” nor recorded by the authorities on the *List of Non-Edible Substances That May Have Been Unlawfully Added to Food*⁸ or the *List of Substances That May Have Been Illegally Added to Health Food*⁹ (the “Lists”) (Article 20, Items 1–2 of the *Interpretation*). The court also found that buformin hydrochloride did not fall within the category “pesticides, veterinary drugs, and other toxic and harmful substances prohibited from being used as announced by the relevant department of the State Council” (Article 20, Item 3 of the *Interpretation*). The chemical was finally found to fall within the catchall provision of Article 20 of the *Interpretation*—“other substances that endanger human health”—because, according to Article 21 of the *Interpretation*, “inspection reports in combination with relevant materials, including expert opinions” bore out the finding.

To guide courts handling similar subsequent cases, the SPC distilled the above reasoning into the “Main Points of the Adjudication” section of GC70, which essentially provides that “although a substance added by an actor in food production and

**Zhaoyi (Troy) Song**

is an Assistant Managing Editor of the CGCP. He is an incoming trainee solicitor of an international law firm and qualified as an associate of the Charted Institute of Arbitrators. He is scheduled to graduate from the LL.B. program at Fudan University Law School in the summer of 2017.
operation [activities] is not on [the Lists]”, the substance should still be determined to be a “toxic and harmful non-food raw material” as provided for in Article 144 of the Criminal Law “if the substance possesses the same attributes as those substances recorded on the aforementioned lists and the substance can be determined, according to related materials, including inspection reports and expert opinions, [to cause] the same harm to human bodies”.

A Catalogue of Food–Chinese Medicinal Materials

The multiple steps taken by the court in GC70 provide a glimpse of the complexity of China’s food industry regulatory framework. To avoid being entangled in the web of legal rules and official lists, food production businesses naturally turn to what is explicitly allowed by law. An example concerns the use of drugs in food. While drugs are generally banned from being added into food, Article 38 of the Food Safety Law provides for an exception:

[...] but substances which are traditionally both food and Chinese medicinal materials may be added. The catalogue of substances which are traditionally both food and Chinese medicinal materials shall be formulated and published by the health administration department of the State Council in conjunction with the food and drug administration department of the State Council.

The above exception is consistent with Article 150 of the Food Safety Law, which defines “food” as follows:

All kinds of finished products and raw materials for people to eat or drink, as well as items which are traditionally both food and Chinese medicinal materials, excluding items used for the purpose of treatment. (emphasis added)

The recognition of substances which are traditionally both food and Chinese medicinal materials reflects the deeply ingrained view among Chinese that “the source of medicine and food is the same” (“药食同源”).

In 2014, the Catalogue of Substances Which Are Traditionally Both Food and Chinese Medicinal Materials (the “Catalogue”), together with related administrative measures, was released in draft form for comment. Once adopted, the administrative measures will replace the Administrative Measures on Health for Prohibiting Medicine from Being Added into Food. Similarly, the Catalogue, which includes just over 100 substances, is expected to replace the List of Varieties That Are Both Food and Medicine, which has 87 substances.

According to the draft administrative measures, “substances which are traditionally both food and Chinese medicinal materials” are “parts of animals and plants that can be used (including food raw materials, spices, and condiments)”, the oral consumption of which is part of “traditional eating habits”, and which have been listed in the “national standards for Chinese medicinal materials (including the Pharmacopeia of the People’s Republic of China and related standards for Chinese medicinal materials)” (Article 2). Further,
to be included in the Catalogue, a substance needs to meet a few other requirements, including “being recorded as edible in literature on Chinese medicine and not having been found to be toxic” (Article 6).

Unfortunately, both the Catalogue and the related administrative measures remain in draft form for comment.

“New Food Raw Material” vs. “Chinese Medicinal Material”

The lack of a final version of the Catalogue renders any attempt to build a legal argument upon the definition of the term “substances which are traditionally both food and Chinese medicinal materials” ineffective. For example, a party accused of adding a “toxic and harmful non-food raw material” into food may want to argue that the substance added is not “non-food” because it is a substance which is “traditionally both food and Chinese medicinal materials”—a type of food as provided for in Article 150 of the Food Safety Law. But the defense is weak, because the Catalogue, the only authoritative document that lists these substances, does not exist.

To avoid such pitfalls, it is wise for innovative food production businesses to take proactive steps by seeking official approval for identifying new edible substances with pharmacological potential as “new food raw materials”. According to the Administrative Measures for the Safety Review of New Food Raw Materials,15 “new food raw materials” are various items (e.g., “animals, plants, and microorganisms” and “ingredients extracted from animals, plants, and microorganisms”), the oral consumption of which is not part of the “traditional eating habits in China” (Article 2). In turn, “traditional eating habits [in China]” means that “a certain type of food has been produced or traded as standard or non-standard packaged food in a province for over 30 years and has not been listed in the Pharmacopeia of the People’s Republic of China” (Article 22). In addition to a few other requirements, “new food raw materials” cannot be “genetically engineered foods, health foods, or new varieties of food additives” (Article 23). As of 2016, more than 100 items, such as Panax Ginseng C.A. Meyer (人参(人工种植); Announcement No. 17 of 2012), have been approved as “new food raw materials”.16

Seeking to identify a new substance as a “new food raw material” also makes sense from a business perspective, as the added novelty may open up more avenues, or create a new niche, in China’s enormous food market. China’s food market is the largest in the world, with a valuation of over USD 1 trillion.17 Food exports and imports each have values in the tens of billions of dollars.18 With the population still steadily increasing (projected to reach approximately 1.4 billion by 2022) and incomes rising (from a gross national income per capita of USD 940 in 2000 to USD 7,900 in 2015),19 China’s demand for food will likely continue to be strong.

The promulgation of the new Law on Chinese Medicine and related (2016–2030) strategic plan demonstrate the Chinese leaders’ determination to promote Chinese medicine, an important heritage of humankind, on a large, global scale.
According to the *Strategic Plan*, in 2014, there were more than 3,000 enterprises producing Chinese medicine in China and the total output value of the Chinese medicine industry was RMB 730.2 billion. On this strong foundation, Chinese leaders plan to achieve various goals by 2020 (e.g., raising the total output value of the Chinese medicine industry to account for more than 30% of that of the pharmaceutical industry) and 2030 (e.g., consolidating China’s leading position in the development of traditional medicine in the world). Specifically, the *Strategic Plan* emphasizes the need to promote the “combination of Chinese and Western medicine”. It also states that there is an “urgent need to promote the innovative and overseas development of Chinese medicine” to further the development of the Belt and Road Initiative, China’s going-global plan that has expanded to embrace over 80 countries that together account for over 45% of the global economy by GDP.

In less than a year after the release of the *Strategic Plan*, the *Law on Chinese Medicine* was promulgated to, *inter alia*, require that the development of Chinese medicine be included in the national economic and social development plans prepared by people’s governments at or above the county level (Article 4). In addition, the law provides for the establishment of a system to evaluate “authentic regional Chinese medicinal materials” to ensure their good quality (Article 23) as well as a new regulatory framework for promoting compound Chinese medicine preparations originating from “famous ancient prescriptions” (Article 30).

In view of these opportunities and the fact that the number of officially-recognized Chinese medicinal materials recorded in the *Pharmacopeia of the People Republic of China* has increased from 65 in 1953 to 618 in 2015 and is still growing, innovative food production businesses must thoroughly consider whether identifying an edible substance with pharmacological potential as a type of Chinese medicine, rather than as a “new food raw material”, would be a better business move in the long run.

**The Conclusion**

Guiding Case No. 70 found a way to overcome hurdles in China’s unclear regulatory framework for the food industry. This approach is useful, but it should be regarded as an interim solution. China needs a clear legal framework for regulating food and Chinese medicine, especially because some Chinese medicinal materials are allowed as additions into food. A finalized, authoritative *Catalogue of Substances Which Are Traditionally Both Food and Chinese Medicinal Materials* should be issued without further delay.

The promulgation of the new *Law on Chinese Medicine* and related (2016–2030) strategic plan demonstrate the Chinese leaders’ determination to promote Chinese medicine, an important heritage of humankind, on a large, global scale. Businesses may seize the opportunity to develop more Chinese medicinal materials, but their enthusiasm will be curbed if the relevant regulatory framework is unclear. While they do not expect clear legal standards in this complicated area to be low-hanging fruit, such standards should not be as difficult to find as wild ginseng on tall mountains.
Endnotes

* The citation of this China Cases Insights™ is: Dr. Mei Gechlik & Zhaoyi (Troy) Song, Guiding Case No. 70: Food and Chinese Medicine, STANFORD LAW SCHOOL CHINA GUIDING CASES PROJECT, China Cases Insights™, Issue No. 2, June 26, 2017, http://cgc.law.stanford.edu/commentaries/2-insights-2017-gechlik-song. This piece was edited by Dimitri Phillips and Dr. Mei Gechlik; layout and design by Jacklyn Fang, Jennifer Ingram, and Dimitri Phillips. The information and views set out in this paper are the responsibility of the authors and do not necessarily reflect the work or views of the China Guiding Cases Project.


5. The “food” involved in Guiding Case No. 70 was “Sunshine100 Shanqishen Capsules”, which was specifically identified as “health food”.

6. The first-instance judgment is 《北京阳光一佰生物技术开发有限公司与尹立新、王海龙等生产、销售有毒、有害食品罪一审刑事判决书》 (Beijing Sunshine100 Biotechnology Development Co., Ltd., YIN Lixin, WANG Hailong, et al., The First-Instance Criminal Judgment of [a Case Involving] the Crime of Producing and Selling Toxic and Harmful Food) (2013) Yang Guang Xing Chu Zi No. 0330 Criminal Judgment), rendered by the Guangling District People’s Court of Yangzhou Municipality, Jiangsu Province, on Jan. 10, 2014, full text available on the Stanford Law School China Guiding Cases Project’s website, at http://cgc.law.stanford.edu/judgments/jiangsu-2013-yang-guang-xing-chu-zi-0330-criminal-judgment. The second-instance ruling (i.e., the (2014) Yang Xing Er Zhong Zi No. 0032 Criminal Ruling), which upheld the first-instance judgment, was rendered by the Intermediate People’s Court of Yangzhou Municipality, Jiangsu Province, on June 13, 2014. This ruling has not been found and may have been excluded from publication.

7. 《最高人民法院、最高人民检察院关于办理危害食品安全刑事案件适用法律若干问题的解释》 (Interpretation of the Supreme People’s Court and the Supreme People’s Procuratorate on Several Issues Concerning the Application of Law in the Handling of Criminal Cases on Endangering Food Safety), passed by the Adjudication Committee of the Supreme People’s Court and the Procuratorial Committee of the Supreme People’s Procuratorate on Apr. 28, 2013, issued on May 2, 2013, effective as of May 4, 2013, http://www.spp.gov.cn/zdgz/201305/t20130506_58566.shtml.

8. 《食品中可能违法添加的非食用物质名单（第1-5批汇总）》 (List of Non-Edible Substances That May Have Been Unlawfully Added to Food (Compilation of Batch Nos. 1–5)), issued by the Special Remediation Leading Group for the Nationwide Crackdown on the Unlawful Addition of Non-Edible Substances and Abuse of Food Additives on Apr. 19, 2011, http://www.moh.gov.cn/psp/201406/38e5c8a53615486888d93ed05ac9731.shtml.


国家食品药品监督管理局（China Food and Drug Administration),《既是食品又是药品的品种名单》(List of Varieties That Are Both Food and Medicine), http://www.sfda.gov.cn/WS01/CL1159.


上饶市食品药品监督管理局（Food and Drug Administration of Shangrao Municipality),《新食品原料名单和药食同源食品总览（更新日期：2016年10月）》(A List of New Food Raw Materials and an Overview of Foods and Medicines whose Sources are the Same (Updated in October 2016)), http://www.srfda.gov.cn/e/upload/s1/fck/file/2017/02/06/0908290781.pdf.


For more information about the initiative, see the Belt and Road Series section of the website of the Stanford Law School’s China Guiding Cases Project, at https://ege.law.stanford.edu/belt-and-road.
The CGCP thanks the following sponsors for their support:

Alston & Bird
Broad & Bright
Center for East Asian Studies, Stanford University
China Fund, Freeman Spogli Institute for International Studies, Stanford University
Fu Tak Iam Foundation Limited

Copyright 2017 by Stanford University