CRITICAL THINKING ABOUT THE PRECAUTIONARY PRINCIPLE IN CHINA’S FOOD SAFETY LAW

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Abstract We are living in a risk society where people devised the Precautionary Principle in order to minimize the harm caused by risk ex ante. Compared to the previous Food Hygiene Law (FHL) and the 2009 Food Safety Law, the 2015 revised Chinese Food Safety Law (FSL) made a real breakthrough in the sense that it legitimates an important principle in food safety governance. Apart from laying down the fundamental importance of this principle in food safety regulations, the FSL 2015 also invented arrangements from different aspects in order to implement this principle. In other words, the FSL 2015’s incorporation of the Precautionary Principle in a very real sense marked a transition from a demonstrative preventive food safety management regime to a more effective precautionary regime. However, the Precautionary Principle needs to be adopted in a “precautionary” way since this principle has its own limitations and defects. Incautious application of the principle may create new risks. This article compares the European approach in implementing the Precautionary Principle, and examines China’s legal arrangements against negative impacts brought by the Precautionary Principle. Three perspectives are discussed: independence of scientific institutes; proportionality in risk management measures, and the shift of burden of proof for market authorization.

Keywords the Precautionary Principle, food safety law, institutional independence, proportionality, burden of proof

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INTRODUCTION

We are living in a risk society.\(^1\) Introduced by modernization and industrialization, research and investigative journalism have documented multiple hazards and insecurities facing human beings, many of which were unknown in the past. In particular, food safety hazards are one of the fundamental risks to public health that have grown into a top concern in both domestic and global food markets. The past two decades witnessed food safety crises in different corners of the world. Foodborne diseases spread, casualties resulted, food trade was affected, and consumers’ confidence in the government was shattered. Against this backdrop, prevention of risks to human health is pressing. In this risk society, the government is empowered to take preventive measures in the public health field, in which the core notion is the Precautionary Principle. This article endeavors to take stock of the Precautionary Principle practices during the evolution of China’s food safety laws and explores experiences that we can learn from in the European Union (EU) Food Law.

I. THE PRECAUTIONARY PRINCIPLE

Originating from German environmental law since 1970,2 the Precautionary Principle has eventually become a “universal custom”3 in international environmental law. The Rio Declaration on Environment and Development did not first develop the Precautionary Principle until 1992.4 Although there is no unified definition thus far, it is often5 defined as precautionary measures which should be taken when an activity raises threats of harm to human health or the environment, even if some cause and effect relationships are not fully established scientifically.6 This principle relates to an approach to risk management whereby, if there is the possibility that a given policy or action might cause harm to the public or the environment, and if there is still no scientific consensus on the issue, the policy or action in question should not be pursued.7 In other words, unless scientific studies indicate a certain level of safety to human health, the proposed policy should not be implemented. Although this principle is simple enough in words, carrying it out in legal practice is not an easy task.

When we focus on environmental law, a value inherent in the Precautionary Principle is that if further environmental damage is to be minimized, eliminated, and ultimately reversed, precaution and prevention must be the overriding principles of policy. This is also called the “Better Safe than Sorry Principle” or the “No Regrets Policy.”8 The Precautionary Principle requires that if we err, we err on the side of caution and put health first.9 As an important field in public health, food safety faces a certain level of scientific uncertainty similar to environmental protection. Therefore, this principle has gradually been introduced into the field of food safety law. Back in 1983, an European Court of Justice (ECJ) case exemplified this line of value judgment in its ruling. When faced with the question of how much daily vitamin intake raise safety concerns to human health, the court held that since scientific evidence neither present exact critical quantities of vitamins as a safe level nor the specific effects stemming from its consumption, the

3 Id. at 284.
8 See Trouwborst, fn. 2 at 8.
relevant prohibition of vitamins was justified. After two decades of judicial practices, in 2002 the EU White Paper on Food Safety and General Food Law (Regulation (EC) No 178/2002) finally incorporated the Precautionary Principle as a baseline in EU food safety law. The EU legislative and judicial experiences on the Precautionary Principle, especially in the field of food safety regulation, have great impacts on the probe of this principle in other jurisdictions. As such, this article chose the EU as a comparison with China.

With regard to risks against the backdrop of globalization, scholars conceived that increasing interconnectedness of risk had at least three implications: First, risks may spread more quickly across borders and populations, thus challenging us to develop earlier warning signals and more coordinated responses. Second, in an interwoven web of increasingly interconnected risks, each intervention to reduce one risk may yield more trade-offs with other risk and social impacts, near and far, current and future. These side effects challenge us to think more comprehensively about systemic interactions, to make difficult choices among conflicting objectives, and to innovate better policies and to reduce overall risks. Third, potential solutions and accumulated experience can spread more readily in an increasingly interconnected marketplace of ideas, facilitating learning and borrowing of innovations in risk management, public policy, and law.

The application of the Precautionary Principle involves deliberation on a range of normative dimensions, which need to be taken into account while making the principle operational in the public policy context. There are two particular circumstances where the precautionary principle might be invoked:

1. The principle is to be applied in cases of potential adverse impacts on the environment or human health with serious consequences;
2. Governmental action should be taken even though “complete” scientific evidence is not available, there is on-going scientific controversy, and/or there are disagreements about the lack of scientific knowledge. These circumstances are referred to as instances of scientific uncertainty. Scientific uncertainties arise because of controversies over the

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14 Id. at 3–4.
possibility of adverse effects to the environment or human health, their scope or their
degree of seriousness.  

The concepts of precaution and prevention have always been at the heart of public
health practice. Public health is inherently about identifying and avoiding risks to the
health of populations, as well as identifying and implementing protective measures. In the
past, public health interventions focused on removing hazards that had already been
identified and “proven.” As “modern” potential risk factors become more complex and
far-reaching, the Precautionary Principle addresses uncertain risks and seeks to shift the
ways in which science informs policy from a strategy of “reaction” to a strategy of
“precaution.” Furthermore, countries whose economies are in transition, such as China,
have special environmental and health problems. The consequences of poor or even
deteriorating public health and the demands of rapid political, social, and economic
changes pose additional problems for decision-makers. In such countries the need to
balance economic development and health protection is no less pressing than in
industrialized countries. The Precautionary Principle is significant since it serves as a
decision-making tool to shape polices where great scientific uncertainties exist, builds up
public confidence, improves research and innovation capacities, and helps shift burdens
from the public institutions to those creating the risks.

II. STRUCTURE OF THIS ARTICLE

While admitting that the Precautionary Principle is fundamental to public health
protection, especially food safety governance, one should also keep in mind the debates
over negative impacts brought by this principle. Several commonly occurring themes can
be abstracted from the complex, and at times confusing, debate on the meaning and
applicability of the Precautionary Principle. Such debates include: a willingness to take
action in advance of formal justification of proof; proportionality of response so that
actions taken are cost-effective; a preparedness to provide ecological space and margins
for error, given the great uncertainties surrounding many environmental risks; a
recognition of the well-being interests of non-human entities; a shift in the burden of
proof to those who propose potentially harmful activities, and a greater concern for
intergenerational effects on future generations, etc.

In order to reduce doubts concerning these themes, the EU has provided abundant

16 René von Schomberg, The Precautionary Principle, in William Sims Bainbridge eds. Leadership in
17 Marco Martuzzi & Joel A. Tickner eds. The Precautionary Principle: Protecting Public Health, the
18 Id. at 4.
19 Andrew Jordan & Timothy O’Riordan, The Precautionary Principle: A Legal and Policy History, in
Marco Martuzzi & Joel A. Tickner eds. The Precautionary Principle: Protecting Public Health, the
experiences as reference. This article takes China’s recently revised Food Safety Law20 as a case study to examine the Chinese way of combating these negative dangers. The EU experience is used as a comparison. Considering that the 2015 revised FSL is the first time when the Precautionary Principle was explicitly laid down by the law, a thorough, critical study is necessary to further improve the application of this principle in China. Therefore, this article seeks to answer the overall question of whether China is prepared to adopt the Precautionary Principle. By “being prepared” the author assumes, while the Precautionary Principle is reflected in the legal texts, multiple legal arrangements should also be set down in order to limit abuse of the principle. Otherwise, simply introducing the principle without effective restrictions will invite more harmful results in food safety governance.

This article is organized into four parts. The first part introduces evolution of the Precautionary Principle in China’s food safety regulations. It aims to illustrate how China has been dealing with food safety risks and why it finally decided to legitimize the Precautionary Principle in the FSL 2015. Although the Precautionary Principle is an invention of the late 20th century, the idea that a certain amount of cautiousness should be adopted in food safety governance is not new. It is interesting to note how Chinese legislators eventually concretize the idea of precaution and incorporate it into the law.

The second to fourth parts of the article compare the European and Chinese approaches in implementing the Precautionary Principle. In the second part, this article examines the independence of scientific institutes. It explores the following questions: Are the scientific institutes independent in both jurisdictions? What does independence mean? What kinds of influence might there be if independence is not well preserved?

The next part looks into the proportionality test in managing risk. The questions to be answered are: What is the proportionality test? How can risk managers make sure proportionality is evaluated? Is there a side effect of this test, such as abuse of discretion by the risk managers? If so, what should be curbed and how?

Finally, in the fourth part, the article uses the example of genetically modified organism (“GMOs”) to discuss the shift of burden of proof. It answers the following questions: Before the safety of GMO-related food products is manifested by science, how do food authorities regulate marketing of GMOs in both jurisdictions? What attitude do they adopt: conservative or aggressive? Accordingly, what legal arrangements do they prescribe to balance the marketing of GMOs and food safety protection?

### III. Evolution of the Precautionary Principle in China’s Food Safety Regulations

China’s legal regulation of food has gone through a long journey from a focus on ex

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post inspection to a focus on ex ante precaution. This journey witnessed the eventual introduction of the Precautionary Principle. There are three laws that related to food governance during this process. The first law was the Food Hygiene Law21 (“FHL”), issued in 1995. The aim of the FHL was to protect “food hygiene” instead of “food safety,” which is a more comprehensive concept than “food hygiene.” As discussed below, the notion of “food safety” was not prevalent in China in 1990’s. The subsequent food safety law (“FSL 2009”)22 in 2009 abolished the FHL. The FSL 2009 was the first “Food Safety Law” in China’s regulatory history in the real sense. Since 2013, China has been undergoing massive legal reform under the XI Jinping administration. Following this trend the legislature promulgated the FSL 2015 on October 1, 2015.

A. Superficial Practice of the Precautionary Principle in the FHL

During the first era in the 1990’s, “food safety” was not a prevalent notion in China. Instead of regulating food safety, which seeks to avoid foodborne diseases,23 the FHL only regulated food hygiene. “Food hygiene” emphasizes the physical properties of food. Specifically, it refers to a situation where the food is “nontoxic and harmless, conforms to proper nutritive requirements and has appropriate sensory properties such as color, fragrance and taste.”24

The FHL set up hygiene requirements on food production, food additives, containers, equipment, etc. These measures mostly target foreseeable hazards, such as hygiene requirements on personnel and food processing instruments. The FHL used two chapters to formulate such hygiene requirements.25 This part does not involve the issue of scientific uncertainty. The physical requirements on hygiene conditions were formulated from previous laboratory tests and practices. Since one of the fundamental conditions, i.e. scientific uncertainty, is lacking, although hazards led by violation of these rules would probably be rather serious, such measures cannot be regarded as practicing the Precautionary Principle. Take, for example, food poisoning caused by food that contains pathogenic parasites or microorganisms,26 scientific evidence of which the pathogenicity is solid. In these aspects the FHL was aimed at prevention of foreseeable hazards instead of uncertain risks.

Now is the perfect time to clarify the author’s definitions of four words: hazard, risk,

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24 See fn. 21, Art. 6.
25 E.g. in FHL, Chapter II is about “Food Hygiene” and Chapter IV is about “Hygiene of Containers, Packagings, Utensils and Equipment Used for Food.”
26 See fn. 21, Art. 9(3).
precaution, and prevention. Hazard means the food condition that will incur negative impact on human health, due to chemical, physical, or biological reasons.\textsuperscript{27} Risk means the possibilities that a hazard may harm human health and the seriousness of such harm.\textsuperscript{28} In this sense, hazard refers to the problems that will occur based on scientific evidence while risk refers to the problems that might exist and engender people’s caution based on scientific uncertainty. Furthermore, by prevention, the author means a decision to take cautious actions after people are aware that a certain hazard will occur. Such awareness is based on scientific certainty that this hazard exists, while the question rests on whether it will happen in a certain process. In contrast, precaution, as indicated in the rest of this article, means a decision to take careful actions when people are facing risks. It might not be certain whether the risks exist or not, or one can say, that the probability of risks are much lower than that of the hazards.

For example, when a car owner knows that the car will suffer a breakdown due to damage in one wheel, scientific evidence allows him to reasonably foresee that the car will get stuck on the road. What is uncertain is just the level of probability that the breakdown will happen on that day’s trip. So the car owner may “plan and act” to this problem by taking the car in for repair. This potential “getting stuck” problem is a hazard, and the behavior of taking the car for repair is a prevention. In contrast, a product developer usually hypothesizes possible benefits of a new product first and then puts it into simulative market tests to verify the possibilities of such benefits. In this scenario, scientific uncertainty exists so the developer could only hypothesize potential problems and needs market tests to identify them. These potential problems are risks which are not based on sound scientific evidence. The action of putting the new productions into market tests in order to find out solutions is prevention.

Apart from the preventive measures, there was a small portion of requirements in the FHL that were actually practicing the Precautionary Principle. For example, Article 20 is about production of new varieties of food or food additives with new resources. It requires that “before starting production of new varieties of food or food additives with new resources, the enterprises engaged in their production or marketing should submit the data required for evaluation of the hygiene and nutrition of such products; before starting production of new varieties of containers, packaging, utensils, or equipment used for foods, with new, raw, or processed materials, the enterprises engaged in production or marketing should submit the data required for evaluation of the hygiene of such products. Before the new varieties mentioned above are put into production, it shall also be necessary to provide samples of the varieties and the matter shall be reported for examination and approval in accordance with the specified procedures for examining and

\textsuperscript{27} The General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) \& Standardization Administration of the People’s Republic of China (SAC), \textit{Working Rules on Food Safety Risk Analysis}, GB/T 23811-2009.

\textsuperscript{28} Id.
approving food hygiene standards.\textsuperscript{29} This is to say, before a new variety of food or food related products are put into production, the FHL requires evaluation and approval to make sure that sufficient scientific evidence allows further production.

According to the official publication of the National People’s Congress, the Precautionary Principle is not included in the FHL.\textsuperscript{30} Instead, it only adopted the “hygiene supervision mechanism,” which was an inflexible administrative mechanism, emphasizing following established standards instead of taking potential risks into consideration. The author partially agrees with this viewpoint. Admittedly this critique is reasonable considering the undeveloped legal techniques and rigid legal system in China in the 1990’s. However, it might be too blunt to conclude that there is no Precautionary Principle included in the FHL.

The author submits that we can find a primitive version of the Precautionary Principle reflected in the FHL, although the legislators back then did not know about the exact expression of the principle. The FHL did take unknown risks into consideration and set forth certain procedures to identify them. Article 20 on the production of new varieties of food or food additives with new resources is an example. Basically, the legislators of FHL did not intentionally incorporate the Precautionary Principle. However, they remained slightly conscientious of potential problems brought by new materials in food production and put forward correspondent measures. This was compatible with the Precautionary Principle. Thus, the FHL also reflected the Precautionary Principle, but only at a superficial level.

\textit{B. Implied Precautionary Principle in the FSL 2009}

Heading into the 21st century, a series of food safety scandals erupted in China. There was a growing consensus that more caution and more aggressive measures should be implemented in the food safety field. As the first food safety law in China, the FSL 2009 introduced a new era of food safety regulation into Chinese legal history. For the first time, it regulated food safety instead of food hygiene. Furthermore, according to a few Chinese scholars,\textsuperscript{31} the Precautionary Principle is arguably implied in this law. Some argue that the FSL 2009 served a goal, which was to establish a risk analysis system centered on precaution.\textsuperscript{32} For instance, the FSL 2009 added a chapter on food safety risk monitoring and assessment.

\textsuperscript{29} See fn. 21, Art. 20.
\textsuperscript{32} Id. at 30.
This argument pointed out the important relationship between the Precautionary Principle and Risk Analysis. Risk Analysis follows a structured approach comprised of the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the Codex Alimentarius Commission (Codex), each component being integral to the overall risk analysis. The Precautionary Principle is a decision-making approach to facilitate risk management. As Food and Agriculture Organization of the United Nations (FAO) points out, there are several approaches under risk management, including: Zero risk; Weight-of-Evidence; Sound Science; Precautionary Principle; As Low As Reasonably Achievable (ALARA) Principle; Reasonable Relationship; Balancing Standards Risk-Benefit; Comparative Risk, and the Cost-Benefit Analysis.

Incorporating Risk Analysis in the FSL 2009 did not necessarily mean it adopted the Precautionary Principle, because this principle is subject to the legislators’ choice in different jurisdictions. However, the conclusion made by the above scholars claiming that the Precautionary Principle is implied in the FSL 2009 was correct to some extent. Although no explicit provision lays down this principle, there were a few arrangements, which reflected the legislators’ intention to take precautionary measures. For instance, Articles 16 and 17 provided the measures to take after risk assessments indicate food safety concerns:

Article 16 The results of food-safety risk assessments provide a scientific ground for formulation and revision of food-safety standards and food-safety supervision and administration.

In the case of food products which have been classified as “unsafe” through food-safety risk assessments, quality supervision and industry and commerce administration authorities under the State Council and the national food and drug administration should according to their respective duties, take necessary measures to ensure that these products are suspended from production, and notify the consumers to

33 Codex, 13th Procedural Manual (2003), at 52. According to the Codex, Risk Assessment refers to “a scientifically based process consisting of the following steps: (i) hazard identification; (ii) hazard characterization; (iii) exposure assessment; and (iv) risk characterization.”

34 Id. According to the Codex, Risk Communication refers to “the interactive exchange of information and opinions throughout the risk analysis process concerning risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.”

35 Id. According to the Codex, Risk Management refers to “the process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.”


38 Id.
stop eating these products. The public health authority under the State Council should immediately formulate or revise relevant national food-safety standards as and when necessary.

Article 17 The public health authority under the State Council shall, jointly with other departments under the State Council, carry out comprehensive analysis of relevant food-safety operations on the basis of the results of food-safety risk assessments and monitoring outcomes. The public health authority under the State Council shall issue public warning about food products of which a high level of food-safety risk has been detected.

The Precautionary Principle is implied in the FSL 2009. On the one hand, the FSL 2009 did not explicitly put forth the Precautionary Principle. On the other hand, it was the first time Risk Analysis was incorporated in the food law and under the risk management scheme, traces of the Precautionary Principle showed in several arrangements. However, the principle was still not reflected throughout the entire FSL 2009. This is to say, in order to fully enforce the Precautionary Principle, the whole piece of law should provide a set of arrangements in various perspectives. Compared to the FSL 2015, as discussed below, we can only conclude that the FSL 2009 was not prepared to fully incorporate the Precautionary Principle.

C. Explicit Precautionary Principle in the FSL 2015

The FSL 2015 made a real breakthrough by expressly adding the Precautionary Principle as one of its overall principles. Article 3 of FSL 2015 states that:

The work in connection with food safety shall follow the principles of prevention first, risk management, whole-process control, and joint public oversight and a scientific and strict supervision and administration system shall be established.

The new law also adds specific provisions in order to carry out this principle. These arrangements include risk classification and management by food agencies, risk communication among all food industry participants, a food safety self-inspection system established by food producers and business operators, regulatory talks conducted by food agency officers, a system for whole-process traceability of food established by the State Council, and a recall system including both food producers and business operators.

39 See fn. 20, Art. 109.
40 Id. Art. 23.
41 Id. Art. 47.
42 Id. Arts. 104 & 107.
43 Id. Art. 42.
44 Id. Art. 63.
According to the National People’s Congress Magazine, laying down all principles followed in the General Principle Chapter conveys an important message that these principles are followed throughout the law.\(^{45}\) Furthermore, from its appearance, the FSL 2015 has prepared a whole set of arrangements to facilitate the application of the Precautionary Principle. In spite of this, is the FSL 2015 fully prepared to adopt this principle? Are the facilitating arrangements sufficient to implement it? The following parts will examine whether the new law effectively confronts the negative impacts of the Precautionary Principle.

**IV. PROBLEM #1: INDEPENDENCE OF SCIENTIFIC EVALUATION INSTITUTIONS**

The Precautionary Principle requires that a decision be made on the basis of scientific evidence, be the concern a “risk,” which is a future harm with uncertainty, or a “hazard,” which is harm with a certain level of certainty. Although the Precautionary Principle is different from the Risk Analysis Principle, since it is closely related to risk management, it is unavoidable to start studies of this principle based on risk assessment.

*A. Plausible Independent Risk Assessment in the EU*

The EU divides risk assessment into four steps: hazard identification; hazard description; exposure evaluation, and risk description.\(^{46}\) When it comes to a comprehensive scientific activity, the independency of the scientific body is an important issue. Here, independence refers to independence both from political control by the government and commercial control by the industry.

The European Food Safety Authority (EFSA) was established in 2002 as the EU’s independent risk assessment body for food and feed safety, which places independence as the top working value.\(^{47}\) The Policy on Independence and Scientific Decision-Making Process describes all the steps taken by EFSA to ensure the implementation of its core values in its scientific outputs and decision-making processes. The goal of this policy is to assure high-quality scientific outputs based on transparent, open, and unbiased scientific decision-making processes.\(^{48}\)

However, although independence is the overarching goal of EFSA, it is not easy to maintain it. In the past years, a few conflicts of interest (“COI”) scandals arose with

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\(^{45}\) See China National People’s Congress 2014, fn. 34.


EFSA scientists.\textsuperscript{49} All of these scandals happened between EFSA experts and the industry. It is dangerous for a scientific institute to be captured by the industry. There is a consensus that mingling with the industry ruins the reputation of EFSA as a public agency which is meant to work in the public interest and whose workload consists of at least 60\%\textsuperscript{50} of assessing industry products. In response, EFSA issued its declarations of interest (“DOI”) policy, which requires all EFSA experts to declare any specific interests which might be considered prejudicial in relation to items on the agenda of the meetings they attend.\textsuperscript{51} Nevertheless, critics remain doubtful of the efficacy of this policy. One recommendation proposed a change of aim within the EFSA: instead of managing the COIs, it should aim at banning COIs.\textsuperscript{52} This sounds plausible because this change removes the fundamental basis for scientific bias as COIs exist. However, it is still a challenging task for EFSA in regard to how to make such a change to ensure absolute independency.

\textbf{B. Lack of Independence of the Scientific Body in China}

The Chinese equivalent institution — China National Center for Food Safety Risk Assessment (CFSA) and its local branches — has been a government-designated system from its inception. Under the FHL regime, the food safety scientific institution was the Nutrition and Health Bureau under the Chinese Center for Disease Control and Prevention (CDC). It was replaced by the CFSA in 2013 and ungraded to the same level as the CDC. In both periods, the scientific body was under the supervision of the National Health and Family Planning Commission (NHFPC, formerly Ministry of Health (MOH)). In a notification issued from the NHFPC to CFSA and its provincial branches, it emphasized that food safety risk assessment should be subject to the comprehensive

\textsuperscript{49} E.g. Sep. 29, 2010: EFSA’s Management Board’s chair (Banati) found by MEP Bové to have a COI with industry (ILSI Europe); Feb. 23, 2011: four members of the Management Board (Kovac, Horst, Ruprich, Vanthemsche) are found to have links with industry by CEO; Apr. 7, 2011: 3 members of the PPR panel (Moretto, Boobis, Brock) are found to have COIs with the pesticide industry by Earth Open Source; Jun. 15, 2011: 11 out of the 20 members of the ANS panel have COIs with industry, report by CEO. Four also did not declare links with ILSI Europe; Oct. 17, 2011: NDA panel chair (Flynn) has COI with industry, report by Süddeutsche Zeitung; Nov. 2011: 12 out of 21 members of the GMO panel have COIs with industry, notably the panel’s chair (Kuiper) — CEO report; December 2011: 10 out of 13 members of EFSA’s working group on TTC have COIs with industry, report by PAN Europe. See Martin Pigeon, Independence at the European Food Safety Authority: What Is The Problem?, available at http://corporateeurope.org/sites/default/files/attachments/presentation_to_efsa_june_5_2013_0.pdf (last visited Jan. 14, 2016).
\textsuperscript{50} Id.
\textsuperscript{52} See Martin Pigeon, fn. 53.
control of the governments at the corresponding level as well as their overall planning.\textsuperscript{53} It is, however, questionable whose interests that CFSA was serving: the government’s or science?

The FSL 2015 does not touch upon this issue. Since the nature of government guidance remains the same, one can evaluate the effectiveness of this arrangement from previous incidents. Reflecting on the 2008 Melamine Scandal, all poisonous milk underwent scientific inspection and evaluation, but no problem was disclosed until real injuries and deaths were reported. Several factors contributed to this tragedy.

First, all food safety risk assessment institutes are part of the government from central to local levels. One criticism of governmental organs’ involvement in scientific evaluation is the rigidity of following administrative instructions and thus a lack of creativity. For example, this problem led to the lack of scientific capability to test melamine amounts in baby formula in the 2008 Melamine Scandal. As background information, melamine is an industrial material which is not expected to be found in food or to be tested against a certain food safety standard. Although it is hard to assume that an independent food safety risk assessment institution would discover the adulteration of milk with an industrial material, it is plausible that bureaucrats are more likely to follow the established evaluation methods while lacking flexibility in scientific innovation.

Moreover, the management structure of the CFSA operates like other government organs. Within CFSA, the Steering Council is the policy-and decision-making body. It is responsible for reviewing the development strategy, financial budget, the handling of major affairs, and the preparation and revision of the regulations. It also undertakes various management duties, such as personnel management and the supervision of CFSA’s operations. The NHFPC acts both as the CFSA’s host organization and undertakes the Center’s routine functions, \textit{i.e.} Party affairs, administration and logistics, etc.\textsuperscript{54} The scientists in the CFSA serve as civil servants and are ranked according to administrative titles, such as directors, deputy directors, and assistant directors. In this sort of administrative organization, which is under double supervision from the government and the party authority, scientists have to undertake administrative responsibilities apart from scientific work. Their promotion is closely linked to administrative rankings. As such, this system leads to insufficient scientific human resources and lack of enthusiasm for scientific innovation.

In addition, it is not easy to avoid corruption at the local governmental level. The major baby formula producer in the 2008 scandal, Sanlu Group, had a close connection with the local government. Sanlu was listed as a national inspection exemption label, \textit{i.e.}

\textsuperscript{53} 国家卫生计生委关于进一步加强食品安全风险监测工作的通知 (\textit{Notification of NHFPC on Furthering Food Safety Risk Assessment Performance}), Jul. 24, 2013, NHFPC Order No. 6 (2013).

its previous good record exempted it from food safety inspection. After tens of thousands of injured babies were reported in the widespread media coverage, Sanlu bribed the local food safety inspection institution and forged a report indicating no safety concerns with its products.\textsuperscript{55} The local risk assessment institute not only failed to inspect potential risks in the baby formula before it was put on the market, but also failed to produce an objective scientific conclusion.

Furthermore, the CFSA suffers from short-handedness and lack of responsiveness in reporting procedures. As a part of the government, the CFSA and its local branches are subject to strict headcount control. The vice director of CFSA disclosed, in an interview, that currently there are only 200 headcounts allocated to the CFSA by the central government.\textsuperscript{56} In Germany, where the population is 80 million, the headcount for the national food safety risk assessment institution is 700. In contrast, China only has 200 people in the national risk assessment institute while there is a population of 1.4 billion.\textsuperscript{57} What is more, a lack of human recourses also decelerates the assessment and reporting process.

In this sense, a lack of independence of the risk assessment system impedes healthy exercise of the Precautionary Principle. The Precautionary Principle is a science-based principle. Therefore, scientific resources in risk assessment of food technology should be well equipped. Being “well-equipped,” means having enough scientists, updated laboratory equipment, an encouraging environment to boost innovation free from administrative intrusion, etc. “Lack of independence,” means that administrative and partisan control in the CFSA and its local branches exert heavy political influence. This reduces the capability and vitality of efficient scientific evaluation and scientific innovation.

There might be two solutions. One would be to completely move the CFSA out of the governmental structure, as the EFSA is. However, this is not feasible in current China, due to the extreme importance of food safety to society. The government is not willing to set aside this task to an independent party. Alternatively, the CFSA could be relieved from political constraints to some extent. For example, by reducing certain administrative work assigned to scientists, cooperating with independent research institutes or college


\textsuperscript{57} Id.
laboratories, etc.

C. Comparison

In truth, neither the EFSA nor CFSA is purely independent. Although the EFSA prioritizes independence as its top policy, and is separate from governmental influence, it did not manage to ensure its independence from commercial interests in the food industry. When it comes to China, it seems that the CFSA suffers from a lack of independence both from the government (together with the party) and industry. On the one hand, the CFSA is within the governmental structure and subject to political and partisan planning. On the other hand, corruption of the CFSA and its local experts could not be effectively curbed. Despite the different types of lack of independence, both institutes need to work on enhancement in the future. Only when scientists conduct research independently, can food safety policies be set down without bias. Food safety governance’s cause is protecting the public good, which cannot yield to any interest groups.

V. PROBLEM #2: PROPORTIONALITY IN RISK MANAGEMENT

After dealing with science, the Precautionary Principle requires proper measures to reduce the problems caused by scientific uncertainty. The ambiguity of the Precautionary Principle demands a high level of cautiousness in implementing precautionary measures. This is where the Proportionality Principle and Cost-Benefit Analysis come into play. On the one hand, the precautionary measures may create new risks while they aim to remove existing risks. On the other hand, implementation of any kind of precautionary measures may incur social costs. The concerns between these two aspects need to go through a proportionality test. Proportionality examines whether the means are “proportionate” to the ends: whether the costs are excessive in relation to the benefits.

A. Implied Application of Cost-Benefit Analysis in Proportionality Test in the EU

It seems that in the area of risk regulations, the European courts take a relatively modest approach. Generally speaking, the courts are restricted to analyzing whether one EU measure is manifestly inappropriate to achieve the desired objective.

It is noteworthy that the European official views, scholarly views, and judicial practices all combine the Proportionality test and the Cost-Benefit Analysis in food risk management. For example, the EFSA directs that when calculating the human health risks and human health benefits, there are several factors to consider: importance of specification of nutrient form; information on dose response; need for good data on dose (intake) and response; quantification of benefit at a range of fortification levels of folate


59 Id.
and in eliminating folate deficiency in the elderly; estimation of risks of masking of B12 deficiency; identification of population at risk or likely to benefit (numbers or proportion), etc. It also prohibits risk managers from comparing risks with benefits directly. Moreover, the EFSA differentiates three types of risk-benefit analysis (systematic qualitative assessment, semi-quantitative assessment, fully quantitative assessment) and sets forth guidance on what type to adopt. It mandates that it depend upon the needs of the risk manager, availability of data, and that it should be decided on a case-by-case basis. If qualitative analysis indicates risk clearly outweighs benefit or vice versa, continuing the analysis may be unnecessary.

Professor Wiener points out that European law applies the principle of proportionality, which implies balancing benefits and costs. Professor Trachtman observes that proportionality, stricto sensu, is in fact a cost-benefit analysis with a certain margin of appreciation, as it does not require that the costs be less than the benefits. He maintains that both the proportionality test and cost-benefit analysis may be either static or comparative. A comparative approach to proportionality testing would include in its calculus the costs and benefits of alternative rules. This argument points out that in risk management, the decision-making process should not merely weigh the costs and benefits of different options. Therefore, a combination of the Proportionality test and Cost-Benefit test would serve as a useful tool. In any case, this observation provides guidance for risk managers on how to make choices when managing risks.

In a 2002 case, which addressed the issue of the authority of European Community institutions in regulating the marketing of antibiotics for use as an additive in “feeding stuffs,” the Court famously held that application of the Proportionality test includes a cost-benefit analysis:

The Court considers that a cost/benefit analysis is a particular expression of the principle of proportionality in cases involving risk management...the principle of proportionality, which is one of the general principles of Community law, requires that measures adopted by Community institutions should not exceed the limits of what is appropriate and necessary in order to attain the legitimate objectives pursued by the legislation in question, and where there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be

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61 Id. at 142.
64 Id.
disproportionate to the aims pursued... 65

B. The “Classification of Risk” System in FSL 2015 and Its Draft Implementation Rules

The Chinese approach seems to be practicing the Proportionality test separately from the Cost-Benefit Analysis. Alongside the Precautionary Principle, the revised food safety law introduced a set of methods to facilitate the Proportionality test.

Article 109 prescribes a “Classification of Risk” system for food inspectors. It requires that producers and business operators of food with high risk of food safety accidents be the priorities of food inspection and supervision. Such foods include: “(1) primary and secondary food specifically for babies and infants and other specific groups of people; (2) adding behavior in the course of health care food production and the situation of organizing production according to the requirements of registered or filed technical requirements and the situation of publicity of functions in the labels, instruction manuals, and promotional materials of health care food; (3) producers and business operators of food with high risk of food safety accidents; and (4) matters with potential food safety hazards as demonstrated by food safety risk monitoring results.”66 These types of food have manifested as high-risk areas by previous incidents. This article provides a manageable guidance for food inspectors in daily inspection from the ground up.

Following the revision of the FSL 2015, the China Food Safety Administration (CFDA) drafted the revised Implementation Rules on Food Safety Law (Draft),67 which was still open for public comment as of the date of this article. Although the State Council has not approved it, we may get a clue on the changes reflected in this rule. First, it requires that practitioners classify risks in the products on their own initiative. Article 44 requires that food business operators publish food safety information including enterprise food safety standards, risk classifications on the products, pre-market inspection information, recall information, etc.

Second, the draft rules instruct food producers and sellers to follow a layered recall system. Article 65 prescribes a three-layer recall system, depending on the seriousness and urgency of the risk. Class I recalls apply to food which might cause serious health injuries or even death. It should be initiated within 24 hours after the food business operators are aware of the risk. Class II recalls apply to food that might produce an ordinary injury to human health. Food business operators should initiate it within 48 hours after they are aware of the risk. Class III recalls apply to food products whose label

66 See fn. 20, Art. 109.
or instructions do not conform to food safety standards and such defects do not incur injuries to human health. Food business operators should initiate it within 72 hours after they are aware of the risk. They should also report these recalls to different levels of government agencies according to the classification of risks.

The “Classification of Risk” system is the first set of requirements to reflect the proportionality principle. This system puts the burden on the business operators first and sets up a “double security lock” by requiring the food agencies to inspect food safety conditions before it is put on the market and respond to food incidents after injuries are incurred.

C. Comparison

The EU and Chinese systems put forth different arrangements to make sure the risk management measures are proportionate to the desired goals. The EU approach maintains that cost-benefit analysis is implied in the proportionality test. Therefore it lays down quantitative and qualitative tests to make sure that benefit of one risk measure outweighs the cost. The cost-benefit analysis serves as a more concrete tool to make sure that a risk measure is proportionate to reduce the risks and not to cause additional harm. Furthermore, the combination of proportionality test and cost-benefit analysis avoids abuse of discretionary power by the risk managers. It adopts quantitative criteria to constrain discretion which might be affected by industrial or personal interests.

Compared to the EU approach, the Chinese approach is more conservative in the sense that it prescribes an established system to follow and allows less room for the actors to act of their own volition. The Chinese FSL 2015, for the first time, specifies an arrangement to practice the proportionality test. This system only requires actors (food business operators and food agencies) to abide by a set of established classifying rules. Unlike the EU system, there is no cost-benefit analysis required in reactions. Therefore, there is not much discretion left to the actors. They are required to analyze and categorize the situation according to the classified system. After categorization, they should act according to the requirements prescribed in certain classified levels. There is no balancing test in this process. This rigid approach might be more suitable for current China.

On the one hand, this approach reduces the risks that food business operators might bypass requirements by conducting the balancing test in an adjusted way, such as by changing the weights of different factors. On the other hand, it also prevents risk managers’ abuse of discretion in pre-market inspection as well as management of food safety incidents. Where measures for the protection of human health are concerned, the outcome of that balancing exercise will depend on account being taken of the particular circumstances of each individual case, and on the level of risk which the authority deems unacceptable for society. 68 Since balancing tests requires case-by-case analysis, food

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68 See fn. 65, paras. 160–161.
agencies, as the ones who really work in the field, are inevitably granted a high level of discretion. Such a high level discretion is very likely to be abused in China.

First, food inspectors in China are not well-trained professionals. They are recruited as public servants under a unified civil servant examination system. Due to a lack of professionalism, these food agencies might not be capable of reaching a reasonable conclusion if they conduct a balancing test. Second, corruption in the local food agencies is not an unusual phenomenon. There is a concern about power rent seeking by these food agencies. Until supervision of the local officers becomes effective, the system will be better off if not much discretion is granted to the food agencies.

VI. Problem #3: Limited Shifting of Burden of Proof

In ordinary liability cases, the victims bear the burden of proof. They should prove that there is a causal link between the accused person’s behavior and their suffering. On the contrary, the Precautionary Principle places the burden of proof on those who would cause harms rather than on those who would prevent it. This is why the government set up a series of prior review and registration rules based on standards for new activities in the public health field. Since prevention cannot be equated with unrealistic “zero-risk,” the question here is what is the standard of proof, i.e. to what extent a risk is acceptable. Alternatively, the question is to what degree of certainty new food technology providers should demonstrate between the unlikelihood of serious harm and the new technology.

A. The EU’s Conservative Attitude towards Genetically Modified Organisms (GMO)

The Precautionary Principle plays an important role in regulating GMOs. In order to protect human and animal health, food and feed consisting of, containing, or produced from GMOs should undergo a safety assessment through a Community procedure before being placed on the market within the Community. By shifting the burden of proof, it is the proponent, instead of the authority, who has the responsibility to demonstrate that the GMO in question is reasonably safe in the safety assessment. The EU, like most countries, has therefore implemented a case-by-case and step-by-step approach. The case-by-case

70 See Kriebel & Tickner, fn. 5 at 1351.
procedure entails a mandatory scientific evaluation of every notification of a GMO. The step-by-step procedure facilitates a progressive line of development of GMOs by evaluating the environmental impacts of releases in decreasing steps of physical/biological containment (from greenhouse experiments, to small-scale and large field tests, to market approval). The purpose of the case-by-case and step-by-step procedures is also to establish a learning practice that enables the authorities and the notifiers to collect information. Additionally, in the EU, proponents also have to submit a well-designed monitoring program for how environmental monitoring is to be carried out after commercialization. It has also been suggested that assigning liability or financial bonds together with conditional approval and broad-scale testing might be a means to ensure the GMO developers’ responsibility.74

Specifically, the EU prohibits placing a GMO on the market for food use or food unless it is subject to authorization.75 The application should be sent to the national competent authority of a Member State.76 The EU also requires that all food products that make direct use of GMOs at any point in their production be subject to labeling requirements, regardless of whether or not GMO content is detectable in the end product.77

B. Basic Requirements on GMOs Labeling and the License System in China

1. Requirements on GMOs. — China is about one decade behind the EU in GMO studies and regulations. Since there has been no official conclusion about whether GMOs are harmless to human health and the environment, or what kinds of GMOs are safe, the FSL 2015 adds a basic labeling requirement for GMO products. Article 69 prescribes that for production and business operation of GMOs, it should be prominently indicated according to relevant provisions. According to Article 125, violations of this requirement will lead to a penalty which amounts to five-to-ten times the product value depending on the original product value. This requirement was first set up in the Measures for the Administration of Identification Mark of the Agricultural Genetically Altered Biological Products (“the Measures”) in 2002.78 This document ranks as “ministerial rules” because its issuance body is an administrative agency, the Ministry of Agriculture. The FSL 2015 elevates this labeling requirement to the “law” level by incorporating it into a document

76 Id. Art. 5.
issued by the legislature, the National People’s Congress. This change secures execution of the labeling requirement by adding a penalizing provision. Since there are no further detailed requirements as to the standard of labeling, the Measures is still applicable. Thus, for all GMO products in China, directly and indirectly processed GMO products or products with the ingredients of GMOs are all subject to this requirement and should be labeled according to the categories they belong to.79

Basically, this labeling requirement only creates a responsibility of indication on the food producers and business operators. It leaves the decision of whether to buy GMOs to the consumers. GMOs are subject to the same requirements as ordinary (or organic) food for marketing. Article 37 requires that, where new food raw materials are used for production of food or for production of new varieties of food additives or food-related products, food providers should submit safety assessment materials to the Ministry of Health for examination of said materials within sixty days upon receipt of the application. The examination determines whether the licenses can be granted or not. Only the Ministry of Health, instead of its local branches, can conduct this examination.

Apart from the above general requirements, the law does not establish a separate procedure for admitting GMOs into the market. On the one hand, this practice indicates that the law has thoroughly considered potential harm may be caused by new technologies. On the other hand, due to the lack of scientific capability for testing GMOs’ safety, the legal system cannot provide a set of sophisticated evaluating procedures. Despite this, scholars claim that China is so far the only country in the world that requires all categories of GMO related products to be labeled, and is regarded as the strictest country for GMOs labeling.80

2. The Licensing System. — The Chinese Food Safety Law prescribes a license system for food business operators as to how food is to be marketed.81 The basic idea behind a licensing system is that the food producers bear the burden to prove that the food they plan to put into the market is safe. After they submit their evidence, the agency reviews it and decides whether to grant them market access. Without providing scientific proof or demonstrating that the food they provide poses no health hazard to consumers, food business operators cannot obtain a license to enter the food market.

China’s food licensing system has gone through three stages. In the first stage (2005−2009), the license was called the Food Hygiene License. According to the Measures for the Administration of Food Hygiene Licenses,82 food businesses that should apply for this license include: (1) food producers and food processors; (2) food business

79 Id. Art. 6.
81 See fn. 20.
82 Measures for the Administration of Food Hygiene Licenses, [2005] No. 498 (abolished).
operators; and (3) food caterers. Depending on different business types, they should abide by different sets of hygiene requirements including those regarding hygiene management system, organization and professionally-trained full-time or part-time food hygiene managerial personnel, site selection, food inspections, etc.

In the second stage (2009–2015), the FSL 2009 changed the Food Hygiene License system into a three layer system: (1) Food producers and food processors should apply for Food Production Licenses; (2) Food business operators should apply for Food Operation Licenses; and (3) Catering businesses should apply for Food Catering Licenses. The requirements are separately set forth by three ministerial rules: Measures for the Administration of Food Production Licenses (issued by General Administration of Quality Supervision in 2010 and revised by CFDA in 2015); Measures for the Administration of Food Circulation Licenses (issued by General Administration of Industry and Commerce in 2009 and abolished in 2015), and Measures for the Administration of Permits for Operating Food and Beverage Services. The purpose in dividing the licensing system by three different ministries was to make sure that different ministries supervised different phases of the food chain.

In the third stage (since FSL 2015), the FSL 2015 consolidated three licenses into one, named the Production and Business License. All food producers and processors, including online food providers, food business operators, and food catering units are subject to a long list of examinations before the license is granted, the purpose of which is to centralize power to the CFDA.

C. Comparison

Due to shift in burden of proof, food providers are required to provide scientific materials to manifest the safety of their food. Regulations of GMOs are a good example to compare the European and Chinese attitude towards novel food. The EU has established a separate set of regulations for GMOs, including a set of specifically designed approval procedures for authorization. As for labeling, the EU requires that all food products that make direct use of GMOs at any point in their production be subject to labeling requirements, regardless of whether or not GMO content is detectable in the end.

83 Arts. 12–14, Measures for the Administration of Food Hygiene Licenses.
84 See fn. 22, Art. 29.
87 Measures for the Administration of Permits for Operating Food and Beverage Services, Order No. 70 of the Ministry of Health, promulgated on Mar. 4, 2010, effective on May 1, 2010.
88 See fn. 20, Art. 62.
89 See fn. 20, Arts. 33 & 35.
China approaches this issue from a more basic perspective. The FSL 2015 does not prescribe a separate authorization procedure to GMOs from ordinary food. However, it requires that all GMO-related products, with direct or indirect use of GMOs, should provide full indications on the label. In other words, before the government is capable to test the scientific influence on human health and the environment, the food safety law adopts an indifferent approach. It neither prohibit nor promotes GMOs. It simply treats this category of food the same as ordinary food and subjects it to the same legal requirements. Then, the law leaves the final choice to the consumers.

The Chinese way is an efficient compromise to the current scientific debate about the safety of GMOs. In contrast to the EU’s huge investment in scientific evaluations and legislative efforts in regulating GMOs, China adopts a basic method. This is understandable considering the current scientific capability and resources in China. Despite this, China is trying its best to adopt the Precautionary Principle, and make the shift of burden of proof reasonable and manageable for food providers.

**CONCLUSION**

We are living in a risk society where people devised the Precautionary Principle in order to minimize the harm caused by risk ex ante. China has spent twenty years in the search for an effective way of regulating food safety. The 2015 revised FSL made a real breakthrough in the sense that it legitimated an important principle in food safety governance via the Precautionary Principle. While preventive measures were either implied or prescribed in both the FHL and FSL 2009, the FSL 2015 was the first time when the legislators drafted the entire law based on the Precautionary Principle. Apart from laying down the fundamental importance of this principle in food safety regulations, the FSL 2015 also put forth arrangements from different aspects in order to implement this principle. Therefore, the FSL 2015’s incorporation of the Precautionary Principle in a very real sense marked a transition from a demonstrative preventive food safety management regime to a more effective precautionary regime. However, one needs to bear in mind that this principle has its own limitations and defects. Incautious application of the principle may create new risks. Thus, the food safety agencies in China need to lay down a few ground rules as for when and how to apply the precautionary principle in order to avoid more risks.

This article compares the European approach in implementing the Precautionary Principle, and examines China’s legal arrangements against negative impacts brought by the Precautionary Principle. Three perspectives have been discussed: independence of scientific institutes, proportionality in risk management measures, and shift of burden of proof for market authorization. Based on these observations, this article concludes that
China is still searching for its own way to make good use of the Precautionary Principle. The legislators are mentally prepared to adopt this principle. Nevertheless, the current situation, including scientific capability and governmental structure, still impose objective limitations. In any case, China is on its way.

Neither the European nor Chinese scientific institutes are purely independent. Although the EFSA prioritizes independence as its top policy, which is supposed to shield it from governmental influence, it did not manage to ensure its independence from commercial interests in the food industry. Much worse, the CFSA suffers from a lack of independence both from the government (together with the party) and the industry. Independence of the scientific institutes is significant in the sense that it protects impartiality in scientific tests, decision-making, and efficiency of internal management of the institutes. Therefore, independence from both political influences and financial influences are problems faced by both the EFSA and CFSA. To clarify, by “independence,” the author does not mean that the CFSA has to be completely separate from the governmental structure as the EFSA is. Instead, the institute should remain unaffected by undue pressure from various powers, no matter whether it is facially independent from certain structures or not.

The Precautionary Principle requires that risk management measures should be proportionate to the desired goals. The EU and Chinese systems put forth different arrangements to ensure proportionality. The EU approach maintains that cost-benefit analysis is implied in the proportionality test. Therefore, it lays down quantitative and qualitative tests to make sure that benefit of one risk measure overweighs the cost. The cost-benefit analysis serves as a more concrete tool to make sure that a preventive measure is proportionate to the need of reducing risks and does not cause additional harm. Furthermore, a combination of the proportionality test and cost-benefit analysis avoids abuse of discretionary power by risk managers. Compared to the EU, the Chinese approach is more conservative in the sense that it prescribes an established system to follow and allows less room for actors to act on their own will. The Chinese FSL 2015, for the first time, adopts a specific arrangement to practice the proportionality test. There is no cost-benefit analysis required in reactions as in the EU system. There is no balancing test in this process. This might be a more suitable approach for China for the time being, which leaves limited discretion to the decision-makers.

The Precautionary Principle shifts the burden of proof to food providers, who should prove that the food does not cause harm to human health and the environment. Regulations of GMOs are a great example to examine this practice. China is about one decade behind the EU in GMO studies and regulations. Compared to the EU’s comprehensive regulations specifically for GMOs, the Chinese method is an efficient
compromise to the current scientific debate about GMO safety. China does not differentiate GMOs from ordinary food, except in the labeling requirement. It does not place any more burdens on GMOs providers than those on ordinary food providers. Considering the current scientific capability of China, it is understandable that it adopts such a basic method and leaves the decision of whether or not to trust GMOs to the consumers.