

# AGRO-GMO BIOSAFETY LEGISLATION IN CHINA: CURRENT SITUATION, CHALLENGES, AND SOLUTIONS

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## INTRODUCTION

Despite bringing new opportunities to agriculture worldwide, genetically modified organisms (GMOs) have negatively affected plants,<sup>1</sup> food safety,<sup>2</sup> and ecosystems.<sup>3</sup> The agricultural sector has been particularly affected by GMOs. For this reason, agricultural-GMO (agro-GMO) biosafety legislation is gaining more attention around the world, especially in developing countries with large populations and heavy agricultural dependence. China has also paid attention to GMO biosafety by enacting several key pieces of legislation and establishing an administrative body. Although China has passed regulations and rules on agro-GMO biosafety management, the country faces some challenges in this field. This paper focuses on the current situation, the challenges, and the solutions of agro-GMO biosafety management in China.

## I. THE CURRENT STATE OF CHINA'S AGRO-GMO BIOSAFETY LEGISLATION

*A. The Legal Framework*

China's legal framework of agro-GMO biosafety mainly consists of four types of laws, described below as the four pillars of agro-GMO biosafety protection. The first pillar is *The Environmental Protection Law*, which regulates the protection of specific habitats, and, to some degree, serves as the legal basis for biological safety protection. Article Seventeen of this law states that the "people's governments at various levels shall take measures to protect regions representing various types of natural ecological systems, regions with a natural distribution of rare and endangered wild animals and plants, [and] regions where major sources of water are conserved . . ."<sup>4</sup> This provision provides the legal ground for agro-GMO biosafety management at the level of basic environmental law.

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1. M.T. Holmes, E.R. Ingham, J.D. Doyle & C.W. Hendricks, *Effects of Klebsiella Planticola SDF20 on Soil Biota and Wheat Growth in Sandy Soil*, APPLIED SOIL ECOLOGY, Mar. 28, 1998, at 67-68.

2. MAE-WAN HO & LIM LI CHING, A GM-FREE SUSTAINABLE WORLD 20 (Institute of Science in Society & Third World Network 2003).

3. MORRIS LEVIN & HARLEE STRAUSS, RISK ASSESSMENT IN GENETIC ENGINEERING: ENVIRONMENTAL RELEASE OF ORGANISMS 297-318 (McGraw-Hill 1991).

4. Zhonghua Renmin Gongheguo Huanjing Baohu Fa (中华人民共和国环境保护法) [Environmental Protection Law of the People's Republic of China, art. 17] (promulgated by National People's Congress, Dec. 26, 1989, effective on date of promulgation), <http://www.china.org.cn/english/government/207462.htm>, (China).

The second pillar is comprised of legislation specifically addressing agro-GMO biosafety issues. China has established and implemented the following rules on agro-GMO biosafety: *Regulations on Agro-GMO Biosafety Management* (2001); *Management Measures on Agro-GMO Biosafety Evaluation* (issued 2002, revised 2004); *Management Measures on GMOs Labeling* (issued 2002, revised 2004); *Management Measures on Safety of Agro-GMO Import* (issued 2002, revised 2004); *Management Procedures on Agro-GMO Biosafety Evaluation*; *Management Procedures on Safety of Agricultural GMOs Import, Review, and Approval Procedures on Agricultural GMOs Labeling*; *Management Measures on Agricultural Germplasm Resources* (2003); *Approval Measures on Agro-GMO Processing* (2006); *Implementation Rules of Regulations on the Protection of New Plant Varieties* (2007); and *Licensing Measures on Livestock Genetic Materials Production* (2010). Of these regulations and rules, the *Regulations on Agro-GMO Biosafety Management* plays a leading role. All of the above laws establish basic rules pertaining to classification-based administration and evaluation,<sup>5</sup> labeling,<sup>6</sup> licensing for production,<sup>7</sup> licensing for business operations,<sup>8</sup> and examination and approval procedures.<sup>9</sup> Taken together, the above laws regulate agro-GMO research, production, and processing; business operations; import and export; supervision; and examination.

The three measures and their corresponding procedures include detailed regulations pertaining to safety evaluations, imports, and labels that are intended to make the laws more enforceable. The *Management Measures on Agricultural Germplasm Resources* touch on the management of agro-GMO safety by providing extensive guidance on the collection, evaluation, registration, conservation, reproduction, utilization, international exchange, and information management of agricultural germplasm resources. The *Approval Measures on Agro-GMO Processing* outlines the requirements for agro-GMO producers, specifically application procedures and license management. The *Implementation Rules of Regulations on the Protection of New Plant Varieties* stipulates that the name of a new plant variety and application to register a new variety must be consistent with the relevant rules regarding trans-genetic plant varieties in the *Safety Certificate of*

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5. Regulations on Safety of Agricultural Genetically Modified Organisms art. 6.

6. *Id.* art. 8.

7. *Id.* art. 19–23.

8. *Id.* art. 26.

9. *Id.* art. 39–42.

*Agro-GMOs* (production and application).<sup>10</sup> If the organism is genetically modified, the application must have either an Approval Certificate of Agro-GMOs, or a Safety Certificate of Agro-GMOs (production and application) attached.<sup>11</sup> *Licensing Measures on Livestock Genetic Material Production* regulates areas such as reporting, evaluation, review and approval, and supervision and management.

The third pillar consists of regulations addressing biosafety issues in other relevant fields. China's agro-GMO biosafety regulations consist of measures on the management of genetic engineering safety, forestry biological safety, genetically modified food safety, and the transboundary movement of biotechnological products. The *Management Measures on Biological Genetic Engineering Safety* (1993) regulates genetic engineering by requiring the laboratories to take risk management measures and operate safely. The *Approval Measures on Developing Genetically Modified Engineering Activities* (2006) governs genetic engineering pertaining to forests. The *Management Measures on Genetically Modified Food Hygiene* (2002) promotes the safety of genetically modified food through a labeling, reporting, and approval process that take into account nutritional quality. The *Management Measures on Food Labeling* (2007) mandates that genetically modified food or food containing genetically modified materials have an explanatory label on the product that is written in Chinese. The *Management Measures on Inspection and Quarantine of Imported and Exported Genetically Modified Products* (2004) requires the inspection of genetically modified products engaged in transboundary movement, including inspections during both imports and exports. The regulation requires that products failing inspection be quarantined. Other agro-GMO biosafety rules include: the *Administrative Permission Law*, the *Seed Law*, the *Law on the Entry and Exit of Animal and Plant Quarantine*, the *Regulations on Agricultural Chemical Control*, the *Management Measures of Pathogenic Microorganism Laboratory Creatures Safety*, the *Regulations on the Administration of Affairs Concerning Experimental Animals*, the *Veterinary Medicine Management Regulations*, the *Regulations on Administration of Feed and Feed Additive*, the *Approval*

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10. Zhonghua Renmin Gongheguo Zhiwu Xin Pinzhong Baohu Tiaoli Shishi Xize (Nongye Bufen) Dishiba Tiao (中华人民共和国植物新品种保护条例实施细则 (农业部分), 第十八条) [PRC Regulations on the Protection of New Plant Varieties (Agriculture Part), art. 18] (promulgated by the Ministry of Agriculture, Aug. 25, 2007, effective Jan. 1, 2008) <http://www.wipo.int/wipolex/en/details.jsp?id=6053> (China).

11. *Id.* art. 30. The Approval Certificate of Agro-GMOs or Safety Certificate of Agro-GMOs (production and application) is required by the Management Measures on Agro-GMO Biosafety Evaluation (effective 2002, amended 2004).

*Measures on Main Crop Varieties, the License Management Measures on Crop Seed Production and Business Operation, the Implementation Measures on Regulations on Agricultural Chemical Control, the Measures on Fertilizer Registration and Management.*

The fourth pillar is comprised of the technical standards for agro-GMO biosafety. From 2003 to 2006, the Ministry of Agriculture issued 26 technical standards related to agro-GMO biosafety management. These standards include technical specifications and detection standards for GMOs and products containing GMOs. Seven of these 26 standards were issued in 2003, five in 2006, and 14 in 2007. Since March 1, 2008, the Ministry of Agriculture has implemented 27 new standards.<sup>12</sup> In April 2009, the Ministry of Agriculture issued three new national standards on agro-GMO biosafety.<sup>13</sup> In addition, China established the *General Standards of Laboratory Biosafety*, which set a biosafety technical standard for laboratory activities.

### *B. Major Legal Institutions*

There are several major legal institutions in China that govern agro-GMO biosafety issues. These institutions exist pursuant to the above laws, regulations, and standards. They are discussed in the following paragraphs.

The first major legal institution is competent authorities and coordination bodies. At the national level, the Department of Agriculture under the State Council supervises and manages agro-GMO biosafety across China. It established a special commission to evaluate agro-GMO biosafety. Local governments at the county level are responsible for supervising and managing agro-GMO biosafety within their regions. Competent administrative departments of health in the local people's governments at or above the county level are responsible for supervising and managing genetically modified food safety.<sup>14</sup> Further, the State Council

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12. Dayuan Xue et al., *Genetically Modified Organisms Safety and Management*, SCI. PRESS, 224 (2009).

13. See, e.g., Test on GM Plant and Its Product Ingredients - Tomatoes Resistant to Storage D2 and Its Derived Varieties - Qualitative PCR method, Test on GM Plant and Its Product Ingredients - Rape Resistant to herbicide Topas 19/2 and Its Derived Varieties - Qualitative PCR Method and Test on GM Plant and Its Product Ingredients - Rice Resistant to Insects TT51-1 and Its Derived Varieties - Qualitative PCR Method.

14. Nongye Zhuanjiyin Shengwu Anquan Guanli Tiaoli (农业转基因生物安全管理条例) [Regulations on Safety of Agricultural Genetically Modified Organisms Safety] (promulgated by State Council, May 9, 2001, effective May 9, 2001) art. 4 (China).

established a joint inter-ministerial committee to manage and research significant issues regarding agro-GMO biosafety.<sup>15</sup>

The second legal institution consists of agencies responsible for risk evaluations. The state has created a classification-based administration and evaluation system for agro-GMO biosafety.<sup>16</sup> The evaluation covers research, experiments, production, processing, and business operations that import and export agro-GMOs.<sup>17</sup> The assessment considers the potential risks posed by agro-GMOs to human beings, animals, plants, microorganisms, and the environment.<sup>18</sup> Two bodies have overlapping jurisdiction over the evaluation process: the Agro-GMO Biosafety Commission is in charge of the evaluation of agro-GMO biosafety, while the Ministry of Agriculture's Office of Agricultural Genetically Modified Organisms also considers and manages agro-GMO biosafety.<sup>19</sup>

The third legal institution requires organizations engaged in agro-GMO research and experiments must have adequate safety measures and be equipped with appropriate safety facilities. Also, organizations must establish agro-GMO biosafety teams to ensure that experiments and research are conducted safely.<sup>20</sup> Finally, organizations and individuals that transport and store agro-GMOs must take risk control measures to ensure the safe transport and storage of agro-GMOs.<sup>21</sup>

The fourth institution is responsible for overseeing labeling. At the national level, the Ministry of Agriculture is responsible for examining, supervising, and managing the labeling of agro-GMOs in China. However, at the county level, administrative departments of agriculture supervise and manage the labeling of agro-GMOs within their regions. The General Administration of Quality Supervision, Inspection, and Quarantine of the People's Republic of China is responsible for inspecting, testing, and verifying the labeling process of agro-GMOs at ports.<sup>22</sup> Organizations and individuals must label the agro-GMOs listed in the agro-GMOs directory. If businesses or individuals remove GMOs from the original packaging for

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15. *Id.* art. 5.

16. *Id.* art. 7.

17. Management Measures on Agro-GMO Biosafety Evaluation, Article 2.

18. *Id.* art. 1.

19. Regulations on Safety of Agricultural Genetically Modified Organism Safety, art. 9.

20. *Id.* art. 11.

21. *Id.* art. 25.

22. Nongye Zhuanjiyin Shengwu Biaozhi Guanli Banfa (农业转基因生物标识管理办法)

[Management Measures on Agricultural GMOs Labeling] (promulgated by the Ministry of Agriculture, Jan. 5, 2002, effective March 20, 2002, amended July 1, 2004) MINISTRY OF AGRICULTURE, [http://www.moa.gov.cn/ztl/zjyqwgz/zcfg/201007/t20100717\\_1601302.htm](http://www.moa.gov.cn/ztl/zjyqwgz/zcfg/201007/t20100717_1601302.htm) art. 2 (China).

sale, the products must be relabeled.<sup>23</sup> For products containing multiple ingredients, the label must indicate the materials that contain GMOs. Also, if the agro-GMO regulation requires special conditions for sale, the labeling must specify those conditions.<sup>24</sup> Articles 7, 8, and 10 specify labeling methods and language.<sup>25</sup>

The fifth legal institution requires reports to various administrative agencies. China classifies the activities related to biosafety into four categories. Level III research poses medium risks to human health and ecosystems; Level IV research presents high risks. Those researching Level III and Level IV agro-GMOs must report to competent administrative departments of the State Council prior to researching.<sup>26</sup> At regular intervals, researchers must submit reports on production, processing, and safety management, and must produce trace lists for agricultural administrative departments at county-level people's governments.<sup>27</sup>

The sixth legal institution is licensing. The industry administrative departments (e.g., the Ministry of Agriculture) and environmental administrative department (i.e., the Ministry of Environmental Protection), and their corresponding departments, undertake licensing at the provincial level. The relevant types of licenses for agro-GMOs are the Certificate of Agro-GMO Biosafety,<sup>28</sup> Certificate of Non-Genetically Modified Agricultural Produce,<sup>29</sup> Temporary Certificate of Imported Agro-GMOs,<sup>30</sup> Approval Document of Importing Agro-GMOs,<sup>31</sup> Permit of Transboundary Movement of Genetically Modified Products,<sup>32</sup> Inspection and Verifying Approval Document of Agro-GMOs Labeling,<sup>33</sup> and Permit of Agro-GMOs

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23. *Id.*, art. 5.

24. *Id.* art. 6.

25. *Id.* art. 7, 8 and 10.

26. Regulations on Safety of Agricultural Genetically Modified Organisms art.12.

27. *Id.* art. 23.

28. *Id.* art. 33.

29. *Id.* art. 37. These licenses allow consumers to make informed purchases by disclosing products that contain GMO.

30. Notice on Issuing the First Batch of Temporary Import Certificates on GM Crops and Label Examine and Approval Documents, 2002.

31. Nongye Zhuanjiyin Shengwu Jinkou Anquan Guanli Banfa (农业转基因生物进口安全管理办法) [Implementation Regulations on the Safety of Import of Agricultural Genetically Modified Organisms] (promulgated by the Ministry of Agriculture, Jan. 5, 2002, effective March 20, 2002, amended July 1, 2004) art. 5 (China).

32. Regulations on Admin. of Agric. Genetically Modified Organism Safety art. 35.

33. Nongye Zhuanjiyin Shengwu Biaozi Guanli Banfa (农业转基因生物标识管理办法) [Management Measures on Agricultural GMOs Labeling] (promulgated by the Ministry of Agriculture, Jan. 5, 2002, effective March 20, 2002, amended July 1, 2004), [http://www.moa.gov.cn/ztl/zjyqwgz/zcfg/201007/t20100717\\_1601302.htm](http://www.moa.gov.cn/ztl/zjyqwgz/zcfg/201007/t20100717_1601302.htm) art. 12 (China).

Processing.<sup>34</sup> These documents cover a diverse scope, including research and experimentation, production and processing, business operation, import and export, and transboundary movement.

The seventh legal institution is comprised of administrative departments charged with supervising and inspecting agro-GMO biosafety. The departments are granted substantial authority. Administrative departments have the power to compel institutions, individuals, stakeholders, and authenticators to submit evidence and other materials related to agricultural GMOs.<sup>35</sup> Such evidence may include: certificates or other documents related to agro-GMO biosafety, accounting files, data related to research, and other documents.<sup>36</sup> Additionally, administrative departments can request related organizations and individuals to explain issues related to agro-GMO biosafety.<sup>37</sup> Administrative departments may order organizations or persons that have violated safety regulations to cease illegal activities.<sup>38</sup> Finally, in emergency situations, administrative departments may seal or seize agro-GMOs that have been illegally researched, produced, marketed, or handled.<sup>39</sup>

The eighth legal institution is requirements related to emergency response. If accidents happen during the course of production and processing of agro-GMOs, those responsible organizations and individuals must immediately take remedial measures. In the meantime, such emergencies must be reported to the agricultural administrative departments of the county-level people's governments in the county where the accident occurred.<sup>40</sup> After following this regulation, those organizations undertaking the experiment and production of agro-GMOs shall establish risk control measures and emergency methods to prevent accidents. Organizations must also keep a good record of safety supervision for later inspection.<sup>41</sup>

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34. Management Measures on Agro-GMO Biosafety Evaluation, art. 15.

35. Regulations on Safety of Agricultural Genetically Modified Organisms, art. 39.

36. *Id.*

37. *Id.*

38. *Id.*

39. *Id.*

40. *Id.* art. 24.

41. Management Measures on Agro-GMO Biosafety Evaluation, art. 35.



## II. EVALUATION OF CHINA'S LEGISLATIONS ON AGRO-GMO BIOSAFETY

China has long paid serious attention to agro-GMO biosafety management. In past decades, China has reinforced supervision and management of agro-GMO biosafety, instituted a technical support system for GMO safety, and promoted the healthy development of the agro-GMO industry. Additionally, China has taken part in international cooperation on agro-GMO biosafety, playing an increasingly important role in international affairs in this regard.<sup>42</sup> Though these are great developments, the following problems remain unresolved.

### *A. The Legal Framework Needs to be Improved*

In a civil law country, a working legal framework is critical for achieving the goal of the legislation. A functional legal framework in China is necessary to achieve effective biosafety management and supervision of agricultural GMOs. China's legal framework is currently insufficient to properly manage and supervise agro-GMO biosafety.

On the one hand, there is not a comprehensive biosafety law. The existing regulations and rules were formulated by various departments for the purpose of industry management. For example, the Ministry of Agriculture formulated the Regulations on Agro-GMO Biosafety Management, which only apply to the field of agriculture, while the General Administration of Quality Supervision wrote the Management Measures on Inspection and Quarantine of Imported and Exported Genetically Modified Products (2004) for the inspection of genetically modified products transported across borders. These regulations and rules work relatively separately in practice, and the legal mechanisms lack coordination with a higher-level comprehensive law.

On the other hand, there is a lack of specific legislation in some key fields, such as management of forestry-GMO safety, management of genetically modified microorganism safety, management of genetically modified food, management of the genetics of poultry and livestock, and management of the genetics of wildlife. It is widely accepted that although agricultural biosafety is one of the most important elements in biosafety

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42. Office of Agricultural Genetically Modification Biosafety Management of Ministry of Agriculture: *Q&A: Agro-GM Technology and Biosafety*, see *Science and Technology Daily*, Mar. 15, 2010.

management, other aspects should be given emphasis in the whole legal framework.

*B. The Administrative System Needs to be Perfected*

The complex administrative regime, with several authorities involved in agro-GMO biosafety, leads to overlaps, ambiguities, or absences of regulation. For instance, both the Ministry of Agriculture and the General Administration of Quality Supervision, Inspection, and Quarantine regulate the labeling of genetically modified products. The Ministry of Agriculture issued the *Management Measures on GMOs Labeling*, which stipulated that the agro-GMOs directory must be implemented and the listed agro-GMOs must be labeled.<sup>43</sup> Also, the General Administration of Quality Supervision, Inspection, and Quarantine issued the *Rules on Management of Food Labeling* which required labels on all genetically modified food or food containing specific genetically modified materials.<sup>44</sup> This kind of difference results in conflicts in the scope of labeling and has influenced the implementation of these regulations and rules.

*C. Imperfect Management Institutions Decrease Their Effectiveness*

Legislation empowers administrative departments to examine, approve, and supervise genetic modification in agricultural activities. However, these laws do not provide effective guidelines on information disclosure or for public participation. Administrative departments cannot effectively regulate the labeling of genetically modified ingredients contained in such products as blended edible oil, tofu, soybean milk, soybean milk powder, preserved bean curd, soy sauce, cottonseed oil, and others, because there are no stipulations on these products in the existing laws, regulations, and rules.<sup>45</sup> As to information disclosure, administrative departments of agro-GMO biosafety are obliged to disclose information, but the legislation does not clearly articulate when, where, how, and what kind of information should

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43. Nongye Zhuanjiyin Shengwu Biao zhi Guanli Banfa (农业转基因生物标识管理办法) [Management Measures on Agricultural GMOs Labeling] (promulgated by the Ministry of Agriculture, Jan. 5, 2002, effective March 20, 2002, amended July 1, 2004), [http://www.moa.gov.cn/ztl/zjyqwgz/zcfg/201007/t20100717\\_1601302.htm](http://www.moa.gov.cn/ztl/zjyqwgz/zcfg/201007/t20100717_1601302.htm) art. 2 (China).

44. Shipin Biao zhi Guanli Guiding (食品标识管理规定) [Admin. Provisions on Food Labeling] (promulgated by the State Admin. Of Quality Supervision, Inspection and Quarantine, Aug. 27, 2007, effective Sept. 1, 2008) art. 16 (China).

45. WENXUAN YU (于文轩), SHENGWU ANQUAN LIFA YANJIU (生物安全立法研究)[ON BIOSAFETY LEGISLATION] 248–249 (2009).

be disclosed. With respect to public participation and agro-GMOs, both the Constitution<sup>46</sup> and the *Environmental Protection Law* provide limited guidance.<sup>47</sup> Also, only a few general principles outline the liabilities for violation of these kinds of stipulations.<sup>48</sup> As a result, the public finds it difficult to use these principles to protect their own legitimate interests, especially the right to know information, to participate in decision-making, and to obtain remedies relevant to agro-GMO activities, which greatly impedes enforcement.

*D. Problems with Enforcement and Compliance: Taking Remedies as an Example*

While the remedies for economic loss and ecosystem and human health damages from agro-GMO activities are of great importance to consumers, farmers, producers, and society at large, neither existing legislation, nor the judicial system provide an adequate remedy. First, the numerous possible conclusions judges could reach present difficulties in adopting a methodical basis for determining appropriate damages caused by agro-GMO related activities.<sup>49</sup> Second, related legislation on agro-GMO biosafety fails to equip the public with feasible approaches for seeking relief. Thus, the public can only resort to *Contract Law*, *Law on the Protection of Consumers' Rights and Interests*, and *Torts Liability Law* to protect their legitimate interests. In the meantime, due to the restricted scope of accepting cases in administrative lawsuits,<sup>50</sup> the involved parties of agro-GMO biosafety incidents cannot lodge an administrative lawsuit on the basis of current administrative law.

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46. Xianfa [Constitution] art. 41, (2004) (China).

47. Zhonghua Renmin Gongheguo Huanjing Baohu Fa (中华人民共和国环境保护法 [Environmental Protection Law of the People's Republic of China]) (promulgated by the Nat'l People's Cong., Dec. 26, 1989) art. 6, <http://www.china.org.cn/english/environment/34356.htm> (China).

48. Bingyuan Weishengwu Shiyanshi Shengwu Anquan Guanli Tiaoli (病原微生物实验室生物安全管理条例) [Regulations on Admin. of Biosafety in Pathogenic Microorganism Laboratories] (promulgated by the State Council, Nov. 12, 2004, effective Nov. 12, 2004) art. 57 (China).

49. See Xu Kai, *Zhu Yanling Go Further Nestle GM Status of their Consumers were Questioned*, PEOPLE'S DAILY (Mar. 8, 2006, 8:53), <http://finance.people.com.cn/GB/1039/4176491.html> (noting that Yanling Zhu, a consumer in Shanghai, failed in the 2003 and 2005 litigation against Nestle on its products containing GMO ingredients, partly because of different testing results made by a Germany company and a Chinese institute).

50. Zhonghua Renmin Gongheguo Xingzheng Susong Fa (中华人民共和国行政诉讼法) [Admin. Procedure Law] (promulgated by the Nat'l People's Cong., Apr. 4, 1989, effective Oct. 1, 1990) art. 11-12 (China).

### III. RECOMMENDATIONS FOR IMPROVING CHINA'S AGRO-GMO BIOSAFETY LEGISLATION

#### *A. Legal Framework*

A new comprehensive law on GMO safety should be developed and installed as the overarching law within the legislative hierarchy. This new comprehensive law should consist of the following provisions.

First, a preamble, which includes the objectives, scope, basic policies, basic principles, basic institutions, scientific research, education and training, governmental responsibilities, rights, obligations, and incentives.

Second, a supervision and management section outlining the responsibilities of national and local authorities. This section should require authorities to coordinate, consult, and manage GMOs. The coordination, consultation, and management should include spot supervisions and inspections, qualification of risk assessment organizations, risk level assessments, GMO quality control, and provisions for dispute resolutions.

Third, a research section which includes a process for mitigating risk. This process should mandate risk assessments and detail the examination and approval process. This should incorporate stipulations on the international cooperation in research.

Fourth, a comprehensive law should include a section on release and commercialization of GMOs. This section should include a process for the approval of the release and commercialization of any GMO. It should also contain risk control measures that mandate environmental protection. Risk control measures should include filing and labeling requirements.

Fifth, the law should contain a provision on transboundary movement that regulates the imports, exports, and domestic transport of GMOs. The regulation should establish a permitting process for the transboundary movement of GMOs. Permits should be granted only after extensive examination of the risks.

Sixth, the law should contain a provision on emergency responses. The provision should include a general emergency response plan as well as a specific section on unintentional transboundary movement of GMOs.

Seventh, the law should have a section on legal liabilities. It should establish liabilities for administrative violations, illegal research and experimentation, illegal assessment, illegal environmental release and commercialization, labeling violations, illegal import, illegal export, illegal transboundary movements, violations of duty of hearing, and liabilities for other accidents. This section should also set up a forum for dispute

resolution and establish rules on burden of proof, causation, as well as malpractice.

Within the context of an overarching comprehensive law, the government should establish or improve specific legislation to fill in the gaps of the current legal framework and make it more effective. Such special and new legislation should clearly cover the management of agro-GMO safety (crop production), forestry-GMO safety and protocol, genetically modified microorganism safety, genetically modified food, the genetics of poultry and livestock, and of the genetics of wildlife. In addition, the legislation on technical activities management should touch upon the management of genetic engineering safety, risk assessment, and transboundary movement of biotechnology and its products. Further legislation would strengthen the management of biotechnology-related acts in different fields. Finally, damage compensation legislation should be issued as a special law or, at least, be included in the comprehensive law of biological safety or other similar laws.<sup>51</sup>

### *B. Administration System*

To resolve the problems in the administrative system, the government should set up three agencies to improve administrative management: a Coordinating Committee of National Biosafety, an Experts Committee for National Biosafety, and a Management Office of National Biosafety. The Coordinating Committee and the Experts Committee should be newly created, while the existing Biosafety Management Section under the Department of Natural Ecosystem Conservation of the Ministry of Environmental Protection can serve as the Management Office. The new comprehensive law on GMO safety can stipulate the functions of these three agencies as described in the following paragraphs.

The Coordinating Committee of National Biosafety would manage coordination of the different administrative bodies and consist of dispatched officials from a variety of departments under the State Council which has experience in the following areas: environmental protection, agriculture, foreign affairs, education, technology, finance, commerce, health, customs, quality inspection, forestry, food, medicine, industry, and intellectual property. It would also include other representatives from the Chinese Academy of Science Society as well as the Organization of Protecting

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51. See generally The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biodiversity, Oct. 15, 2010, 50 I.L.M. 105–13 (providing further ideas on how to better draft legislation).

Consumer Rights and Interests. The Committee would coordinate national biosafety by deliberating on plans, guidelines, policies, regulations, and standards relating to the management of national biosafety. After deliberation, the Committee would institute significant policies of national biosafety and international negotiations.

The Experts Committee for National Biosafety would provide expertise on biosafety. This Committee would consist of experts in the following fields: environmental protection, biology, agriculture, forestry, intellectual property, medication, health, food, law, economics, trade, quality inspection, commerce, industry, and protection of consumer rights. This Committee would be responsible for advising the Coordinating Committee of National Biosafety on strategic decisions regarding the guidelines, policies, laws, and standards of management of national biosafety.

The Management Office of National Biosafety would be the administrative organization serving as the secretariat of the Coordinating Committee of National Biosafety and the Experts Committee for National Biosafety. Internally speaking, the agency would remain in charge of daily management of national biosafety, while, at the international level, it would serve as the office of liaison and information exchange for national biosafety, fulfilling *The Cartagena Protocol on Biosafety*.<sup>52</sup>

### *C. Management Institutions*

It can be seen from the above that some problems exist in the management institutions in the fields of agro-GMO biosafety. A sound system of management institutions would emphasize coordination, reduce risk, and strengthen the enforcement of the law. It would include risk assessment, contained research, interim experiments, environmental release and commercialization, labeling, information disclosure and access, emergency response, and damage compensation.

First, risk assessment: organizations and individuals undertaking contained research of GMOs should first consult with a certified institution to conduct risk assessment of the donor, carrier, host, and biological characteristics of the studied GMOs. These institutions should further determine the risk level of studied GMOs. The risk assessment should be thorough. It should take into account the recipient organisms, the parental organisms, the vectors, the inserted genetic material and/or the characteristics of modification, and the living modified organism.

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52. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Sept. 11, 2003, 2226 U.N.T.S. 208.

Additionally, the risk assessment should take into account information regarding the intended use of the organism and the receiving environment, as well as consider the detection and identification of the organism in the environment.<sup>53</sup>

Second, contained research management: those research institutions with staff undertaking Level I GMO research should file records with the related administrative departments of the State Council. If there is no related administrative department, then the institutions should file records with the administrative Department of Science and Technology and Environmental Protection of the State Council. Researchers on GMOs in Levels II, III, and IV should submit applications to related administrative departments of the State Council. Research should only begin after approval. If no corresponding administrative department governs them, researchers shall submit applications to the administrative Department of Scientific Technology and the Department of Environmental Protection of the State Council. Level I research poses no risk to human health and ecosystems, while Level II research presents low risks.

Third, interim experiments management: the filing process should also apply to contained Level I laboratory research. If contained laboratory research in Levels II, III, or IV turns into an interim experiment, those activities must obtain a license in order to continue operations.

Fourth, management of environmental release and commercialization: ensuring safe release and commercialization of GMOs could be accomplished through a reporting process. Institutions conducting research of GMOs should commission a certified organization to conduct a risk assessment on their research, the findings of which should be compiled in a report completed by this organization. The report should be sent to the related administrative department and the department should complete a preliminary opinion of the examination and sign the report. The report should then be sent to the Management Office of National Biosafety, which should organize experts from the Consulting Committee of National Biosafety to deliberate on the report and suggest approval. Next, the report should be submitted to the administrative Department of Environmental Protection of the State Council for examination and approval. If the GMOs meet the requirements for environmental release and commercialization, then the administrative Department of Environmental Protection of the State Council should issue a "License of Environmental Release of GMOs" or a "License of Commercialization of GMOs."

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53. *Id.* art. 5, 6, 15, and annex 3.

Fifth, the labeling requirement for GMOs sold on the market should cover GMOs and goods containing GMOs. The scope of labeling should expand from food to animal feed. The labeling requirement should mandate that GMO distributors create and affix a label to the product that informs the reader about the genetically modified ingredients. The label should contain every single GMO ingredient, including genetically modified feedstuff and additives. Thus, the labeling requirement informs the buyer and facilitates the later tracking of the product. If the label lists no ingredients, then the distributors should explicitly state that such products originate from GMOs. The threshold of when to label should be very explicit and should be based on the quantity of GMOs in the product. Also, any products that contain less than the threshold quantity of genetically modified ingredients should be exempted from labeling requirements. As to those products with more GMOs than the threshold, labeling should be mandatory. Neither imported goods nor goods intended for export should be exempt from the labeling requirements. With regards to imports, the exporter should be required to provide detailed lists of products, including the common, scientific, and commercial names of living modified organisms (LMOs) and the code of modified acts of LMOs. The list should also include the taxonomic names, added genovariation, modified characteristics or genes, and other information on the receiver and donor. When necessary, exporters should provide special labeling documents and other documents regarding safe disposal, storage, transport, and use of LMOs.<sup>54</sup>

Sixth, information disclosure and access: producers and distributors of agro-GMO products should be obliged to disclose certain information, especially for potential risks posed by products to the ecosystem and human health. In order to ensure public access to information on GMO products, the public should have a right to know about GMOs. Rights to know includes the right to understand, collect, and use correct information. In order to ensure public access to information on GMO products, the administrative authorities should outline how the public can exercise its right to know. Administrative authorities should clarify the scope of the public's right to know, how to enforce those rights, and procedures for redress when those rights are violated. Disclosed information should include names and ingredients of GMOs and their products, names of

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54. CANFA WANG, DAYUAN XUE, WENXUAN YU: RESEARCH REPORT ON GMO BIOSAFETY LAW (DRAFT), 107-111 (Institute of Environmental and resources Law, China University of Political Science and Law, and Nanjing Institute of Environmental Science, Ministry of Environmental Protection 2007).



producers and distributors, physicochemical or biological characteristics, potential risks to ecosystem and human health, measures for inspection, and methods of waste disposal.

Seventh, emergency response: this should include response plans for accidents. The response plan should ensure adequate human, financial, and material resources for disaster amelioration. It should also organize disaster response duties and responsibilities. When an accident occurs, the party responsible should take emergency responses, inform possibly affected stakeholders, and report the emergency to the administrative Department of Environmental Protection or other related departments above the county level where the event occurred. The responsible party should neither obstruct the investigation nor offer any objection to the penalties. The departments should report any emergency to the people's government at the same level or related administrative department at the next level. The purpose of this is to inform the public, initiate the proper emergency responses, begin the investigation, and monitor the area.

Eighth, damage compensation: the party responsible for biosafety accidents should be strictly liable for the serious effects on human health, the ecosystem, and the economy. Environmental damage caused by humans is unavoidable despite the implementation of prompt and reasonable safety and mitigation measures. When those measures fail and human health or the health of the environment is compromised, compensation should come from those institutions and individuals engaged in contained research, interim experiments, environmental release and commercialization, transportation, storage, transboundary movement, and waste treatment and disposal of GMOs.

#### *D. Enforcement and Compliance*

First, China needs greater capacity to mitigate the risks posed by GMOs. This calls for better policies and legislation for the technology used for inspection and quarantine, as well as better risk assessment and tougher quarantine standards. Imported GMOs need to be better inspected, subjected to higher quarantine standards, and the imported GMOs that pass inspecting need to be better tracked. Additional legislation is needed to protect farmers' interests, promote agricultural and rural economic development, and ensure the healthy and orderly development of the national biotechnological industry.

Second, enforcement would be strengthened by better policies on the technical support system that could aid safety assessment and law enforcement. The policies and legislation should bolster the technical

support system through increased financial investment and better hardware. Additionally, the policies and legislation should improve biological resource and informational databases, as well as improve the scientific management system and other operational mechanisms. The administrative authorities should also fund more scientific research and improve the capacity of researchers.

Third, enforcement should be strengthened through better policies and legislation that promote cooperation with relevant countries and international authorities. China should actively participate in negotiations to establish international technological standards of agro-GMO biosafety. In these international negotiations, the administrative authorities should safeguard the national interest of protecting ecological and human health. Ideally, authorities should develop appropriate negotiating policies and adopt a pragmatic and flexible attitude. They must pay attention to bilateral and regional negotiations and attach great importance to the active role of environmental non-governmental organizations (NGOs) in the negotiations.

Policies and regulations to enhance the public's understanding of agro-GMO safety concerns would promote compliance. This should be accomplished through education and training, focusing especially on ecological and food safety. Different forms of training should be provided according to the varying needs of different communities or professions.<sup>55</sup> In the meantime, policies and regulations should focus on raising public awareness of agro-GMO safety. They should also use mass media to publicize any information about safety concerns regarding genetically modified agricultural products.<sup>56</sup> Promoting public understanding of GMO safety could further strengthen compliance. Public understanding could be increased if administrative authorities establish appropriate channels of public participation and guide the media to pay attention to the safety of GMOs. To do this, authorities should work to improve the media's knowledge of biosafety so it can scientifically and objectively report the information. The administrative authorities should also guide environmental NGOs in carrying out projects and activities of agro-GMO biosafety. The administrative authorities should learn from the successful experiences of other countries. Further policies and regulations should also put more emphasis on protecting the public's right to know information concerning

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55. Xinzhi Mao & Feng Zhou, *The Enlightenment on Regulations and Laws of GM Foods in the USA and EU* 39-40, *SCI. AND TECH. MGMT. RESEARCH* (2005).

56. Shuzhen Zhang, *Agricultural Genetically Modified Organism Biosafety* 28 (China Agricultural University Press, 2006).

biosafety and establish a mechanism for sound information disclosure and access to information.<sup>57</sup>

### CONCLUSION

China's legal framework of agro-GMO biosafety management mainly consists of four types of laws: the Environmental Protection Law, the legislation specifically addressing agro-GMO biosafety issues, the regulations specifically addressing agro-GMO biosafety issues in other relevant fields, and the technical standards for agro-GMO biosafety. The major legal institutions governing agro-GMO biosafety issues mainly address the arrangement of competent authorities and coordination bodies, risk evaluations, safety measures, labeling, reporting procedures, licensing, supervision and inspection, and emergency response. Although the current legal system and institutions play an active and significant role in agro-GMO biosafety management, problems in the legal framework, administrative system, management institutions, and enforcement and compliance are holding up the effectiveness of the legislation.

The proposed solutions are fourfold. First, formulate a new comprehensive legislation law on GMO safety, stipulating the arrangement of supervision, research management measures, release, commercialization, transboundary movement of GMOs, emergency responses, and legal liabilities. In the meantime, the government should establish or improve some specific legislation to make it more effective and fill in the gaps of the current legal framework. Second, improve the administrative system by setting up three agencies: a Coordinating Committee of National Biosafety, an Experts Committee for National Biosafety, and a Management Office of National Biosafety. Third, perfect such management institutions as vehicles for risk assessment, contained research management, management of environmental release and commercialization, information disclosure and access, emergency response, and damage compensation. Fourth, strengthen enforcement and compliance by improving the capacity to mitigate the risks posed by GMOs, formulating better policies on the technical support system, and promoting the public's understanding of agro-GMO safety concerns.

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57. CANFA WANG ET AL., *supra* note 54, at 122–24.