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GENETIC MODIFICATION IN AGRICULTURE: THE IMPACT OF CHINA'S REGULATIONS ON FOREIGN TRADE AND INVESTMENTS

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Genetic Modification in Agriculture: The Impact of China's Regulations on Foreign Trade and Investment

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China has encouraged research in genetic modification of agricultural crops, and by some accounts its regulatory structure is more progressive than other large developing countries. But the country's legal developments in the agricultural sector to date still carry a predisposition to unnecessary trade restrictions.

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Genetic modification or genetic engineering[1] is the modification of the genetic structure of living organisms through

> "the application of a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or b. Fusion of cells beyond the taxonomic family; that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection".[2]

Genetic modification of plants has great potential for increasing crop yields, decreasing the application of chemical pesticides and reducing the encroachment of cropland into forests, pastures and nature reserves. Research institutes, private industry and various governments in many parts of the world have aggressive research development programmes in genetic modification to enhance agricultural production while mitigating some of the adverse side effects associated with modern agriculture.[3]

Critics counter that genetic modification may itself have undesirable side effects, including potential harm to human beings and other life forms, enhanced immunity to natural pests of undesired species (so-called "super-weeds"), and reduced genetic diversity. Critics therefore have demanded more stringent controls or even a moratorium on genetic modification, and in many cases mandatory labelling of products manufactured from genetically modified organisms (GMOs) so consumers can choose to avoid GMOs. A more extensive and thorough risk or safety assessment is sometimes demanded.[4] A number of governments have responded to this concern by imposing restraints on field-testing and commercialization of genetically modified crops.[5]

In comparison to most developing countries and even some advanced industrialized countries, China has made substantial investments in agricultural biotechnology, including genetic modification.[6] Senior Chinese leaders were persuaded by leading scientists of the great promise of genetic modification in agriculture. Research work in the Chinese Academy of Sciences began in the early 1980s and accelerated when biotechnology was included in the 863 Program adopted by the State Council in 1986 to promote the development of high technology.[7] The State has since expanded its support of agricultural biotechnology, including genetic modification, through increased funding of programmes conducted by various research institutes and universities under the Ministries of Science and Technology (MOST), Agriculture (MOA) and Education, and various investment preferences.[8] Premier Zhu Rongji on January 11 2001[9] as well as on several other occasions has expressed his support for research on genetic modification in agriculture, although he also reportedly has expressed caution about the potential impact on Chinese agricultural and foodstuffs exports to countries with more restrictive policies on genetic modification. China's farmers have themselves adopted new technology, including yield-increasing material, although not necessarily the highest yielding material.[10]

THE REGULATORY FOUNDATION

The development of agricultural biotechnology through genetic modification requires more than money and research facilities. It also requires a comprehensive and supportive regulatory foundation. Such foundation primarily involves two sets of issues: intellectual property and biosafety.[11] The regulatory foundation in China has also developed, but at a slower pace than government research support.[12] Nevertheless, the State's supportive posture has been reflected in the regulatory process.[13] Intellectual property rights in new plant varieties have been established. The biosafety regulatory process was led first by the former State Science and Technology Commission (SSTC), which tended to promote research and development. The State Environmental Protection Administration (SEPA) was authorized in 1998 to be national competent authority and the national focal point for biosafety.[14]

In practice, however, SEPA has not been able to assert control over biosafety that, with respect to agriculture, is dominated by the MOA and its affiliated Chinese Academy of Agricultural Sciences.[15] The MOA in particular drafts agricultural biosafety regulations in the absence of a supervening biosafety management statute or regulation to which regulations governing specific sectors would be subordinate.[16]

Protectionism has moreover been fostered in the regulatory process. State science and technology policy favours domestic research and development and the commercialization thereof over imported technology controlled by foreign interests "in several critical technology areas to catch up to international standards and reduce the gap with overseas".[17] This preference is also reflected in demanding examination and approval requirements on international technology imports, in contrast to domestic technology transfers that are not subject to such review.[18] The MOA's disfavour for foreign investment and imports with respect to staple crops (grain, cotton and oilseeds) which are deemed vital to China's security interests is reflected in regulations which prohibit majority foreign control of seed breeding enterprises.[19] The requirement for separate provincial-level approvals for the breeding and marketing of staple-crop seeds[20] has also raised capital costs and reduced the ability of foreign-invested seed breeders to serve the China market. SEPA by contrast tends to focus on safety and conservation issues without regard to the national characteristics of the source of any potential harm although, as shown below, SEPA also has not been free of protectionist impulses.

INTELLECTUAL PROPERTY RIGHTS

Intellectual property rights in genetically modified plant varieties, like varieties created through more traditional plant breeding, are established and protected in *sui generis* breeder's rights or, less commonly, patents. The establishment and enforcement of breeder's rights in plant varieties is needed to encourage and reward genetic modification. Although some countries with more advanced legal systems and strong agricultural sectors began to protect breeder's rights in the first half of the twentieth century, China moved much more slowly. Intellectual property in plant varieties was not recognized until the establishment of a breeder's rights regime in plant varieties in 1997.[21] This was some 36 years after the establishment of the International Convention for the Protection of New Varieties of Plants (UPOV), the international regime governing breeder's rights.

China subscribed to UPOV in 1998, one year after the promulgation of its regulations on breeder's rights in plant varieties.[22] Unlike most international conventions, however, UPOV maintains the effectiveness of different governing acts, allowing nations to subscribe to varying sets of obligations. China subscribed to the UPOV 1978 Act, rather than either the outmoded UPOV 1961 Act or the broader and more comprehensive UPOV 1991 Act. In particular, the UPOV 1978 Act is narrower and provides less protection for breeders than the UPOV 1991 Act: fewer plant genera and species are subject to protection, there is no right of exclusion with respect to varieties derived from protected varieties, and there is a shorter protection period.

China has complied with its obligations under the UPOV 1978 Act, encouraging agricultural research and commercialization, but only with respect to designated genera and species. This has enabled China to exclude certain key crops, especially corn (maize) and wheat, from the scope of breeder's rights protections, effectively keeping foreign agroscience companies and their advanced plant varieties out of certain markets in China. By contrast, had China subscribed to the UPOV 1991 Act, it would become obligated to protect breeder's rights in all genera and species, including crops important to food security. Some Chinese researchers as well as foreign companies have advocated more rapid expansion of the scope of genera and species eligible for protection but the MOA has maintained a policy of deliberate expansion that has pronounced protectionist effects.

BIOSAFETY REGULATION

Biosafety regulation protects against risks associated with research, testing and diffusion of genetically modified plant varieties, and may assure consumers of the safety of genetically modified crops and products manufactured therefrom. The SSTC promulgated China's first biosafety-related regulations on genetic engineering in 1993.[23] The *Measures on the Management of the Safety of Genetic Engineering* (the Genetic Engineering Measures) were intended to promote research and development in genetic modification, strengthen safety management, protect public health and the health of personnel engaged in genetic modification, prevent environmental pollution and maintain ecological balance.[24] The coupling of the promotion of research and development with safety programs indicates that the Genetic Engineering Measures were intended to promote rather than hinder the development of genetic modification.

The Genetic Engineering Measures applied to experimental research, intermediate testing, industrialized production, the release of GMOs and the utilization of products manufactured from GMOs,[25] including the import of GMOs for the conduct of genetic modification.[26] The Genetic Engineering Measures thus presumed that products manufactured from GMOs, as well as the GMOs themselves, were potentially hazardous although the level of hazard could be lower than that associated with live organisms. Responsibility for implementation of the Genetic Engineering Measures was vested in MOST's predecessor, the former State Science and Technology Commission, which formed a National Committee on Safety of Genetic Engineering (NCSGE) for this purpose.[27]

Reflecting the interest of other government departments in genetic modification and MOST's limited authority with respect to commercial production, other departments under the State Council were authorized to conduct safety management within their respective spheres of responsibility, subject to an obligation to report technical and modification standards to NCSGE for the record.[28]

The Genetic Engineering Measures reflected a generally supportive government position with respect to genetic modification. Hazards were classified into four classes: Class I (non-hazardous), Class II (low hazard), Class III (intermediate hazard) and Class IV (high hazard).[29] Each unit participating in genetic modification rated the hazard level of its own activity.[30]

Approval authority varied by hazard with NCSGE approval required only for Class IV hazards.[31] Projects were required to satisfy four approval criteria: (1) indisputable safety appraisal; (2) safety measures corresponding to the hazard classification in terms of science and technology; (3) necessary specialized knowledge and safe operations knowledge; and (4) compliance with applicable laws and regulations.[32] The first criterion demands a degree of certainty that may exceed the capabilities of a scientific risk assessment.

AGRICULTURAL BIOSAFETY MEASURES

The Genetic Engineering Measures provided little in the way of concrete guidance with respect to safety measures, particularly with respect to agricultural applications. As a partial remedy for that shortcoming, the MOA two and one-half years later promulgated the *Implementing Measures on Safety Management with Respect to Agricultural and Biological Genetic Engineering* (the Agricultural Implementing Measures).[33] The Agricultural Implementing Measures were intended to strengthen safety management, and prevent harm to people and environmental and agricultural ecology from GMOs and products manufactured therefrom.[34]

The Agricultural Implementing Measures were to be implemented by a newly-established Agricultural Biogenetic Engineering Safety Management Office in the MOA. The new Agricultural Biogenetic Engineering Safety Committee was to be responsible for the evaluation of safety with respect to intermediate testing, environmental releases and commodity production of agricultural bio-engineered organisms and products manufactured therefrom.[35]

The Agricultural Implementing Measures adopted the same hazard classification system as the Genetic Engineering Measures, while providing some additional detail on the criteria for classification.[36] Approval authority varied by activity and hazard classification. In particular, the MOA was responsible for the approval of environmental release and commodity production in Classes I, II and III, while such activities in Class IV would have to be submitted to the NCSGE for approval after review by MOA.[37]

Projects were required to satisfy four approval criteria which correspond in greater detail to those embodied in the Genetic Engineering Measures: (1) indisputable reliability of safety appraisal; (2) guarantee that the genetic modification work subject to the application conforms to safety and other standards, and safety control measures corresponding to current scientific knowledge have been adopted so there is no possibility of harm to human health or the ecological environment; (3) persons responsible for the project and workers have the necessary specialized knowledge and safe operations knowledge, and comply with the provisions of the Agricultural Implementing Measures; and (4) compliance with applicable laws and regulations.[38] The first and second criteria demand a degree of certainty and risk prevention that may exceed the capabilities of a scientific risk assessment, and the second criterion also fails to define current scientific knowledge.

Applications for the intermediate testing, environmental release or commodity production of agricultural GMOs and their products developed in other countries required submission of the approval document for the activity from the relevant country.[39] The requirement for submission of a foreign approval document would effectively bar the import of GMOs and products manufactured therefrom from foreign countries without such an approval requirement. Furthermore, the approval requirement for products manufactured from GMOs imposed a great burden on foreign producers who were not required, and may have found it impossible, to determine the extent, if any, to which their inputs were manufactured from GMOs, e.g., corn. However, the reach of the Agricultural Implementing Measures was sharply narrowed by excluding the production and business of agricultural chemicals, veterinary medicines and other biological products and agriculturally-related seeds and seedlings.[40]

AGRICULTURAL BIOSAFETY REGULATIONS

The latest and, from the perspective of foreign trade and investment, the most troubling regulations are the *Administrative Regulations on Biosafety in Agricultural Genetic Modification* (the Agricultural Biosafety Regulations),[41] which were issued by the State Council itself and therefore bear even higher authority than earlier biosafety regulations. Approved May 9 2001, the Agricultural Biosafety Regulations took effect upon their promulgation on May 23 2001. The stated purpose of the Agricultural Biosafety Regulations is to strengthen the safety of GMOs and protect human health, the safety of animals, plants and micro-organisms, and protect the environment to advance technology and research with respect to GMOs.[42] An unstated purpose is to protect China's agricultural exports from restrictions imposed by other countries with higher consumer sensitivity to GMOs. The Agricultural Biosafety Regulations thus maintain that biosafety measures are needed if GMO technology and

research is to advance, in contrast to earlier regulations in which biosafety was a secondary consideration.

The Agricultural Biosafety Regulations have broader scope than earlier regulations, bringing within their reach seeds, breeding stock and micro-organisms.[43] They establish licensing requirements for producers of genetically modified seeds, and animal and aquatic breeding stock that appear to be additions to existing licensing requirements for producers of such items.[44] Additional licences are required for marketers of such commodities.[45] Producers and processors of agricultural GMOs require the approval of the agricultural department at the national (MOA) or provincial level.[46] Advertising of GMOs also is subject to MOA approval.[47] Foreign investment enterprises engaged in the research and testing of agricultural GMOs in China also require MOA approval,[48] an additional requirement that does not apply to Chinese-invested enterprises.

The Agricultural Biosafety Regulations also impose labelling requirements on agricultural GMOs sold in China that are to be listed in the Catalogue of Agricultural GMOs, including any geographical restrictions on sales.[49] All genetically modified seeds must be so labelled.[50] The Catalogue has not yet been published, however. Although this provision does not apply to products manufactured from GMOs, it nevertheless requires packaging as well as labelling for all agricultural GMOs for sale. Such agricultural commodities as soybeans that are shipped in bulk can in principle be packaged by the importer on arrival, but this will result in additional cost for questionable benefit.

Foreign companies exporting agricultural GMOs, products manufactured therefrom or which contain components thereof to the PRC are subject to certification by MOA on the basis of: (1) prior approval of the agricultural GMO for use and prior entry of the agricultural GMO into the market in the exporting country; (2) proof by scientific testing in the exporting country that the agricultural GMO is harmless to humans, animals, plants, micro-organisms and the environment; and (3) corresponding safety and prevention measures.[51] MOA approval is discretionary, not mandatory, which compounds the difficulty presented by complex regulations. Similar requirements, plus an additional certification imposed in China, apply to the import of agricultural GMOs for processing as raw materials, but in this instance MOA approval is not discretionary.[52] Imported agricultural GMOs, but not products manufactured therefrom, cannot be admitted through customs without the requisite MOA safety certificate and other relevant but unspecified documentation.[53] MOA and the State Administration for Quality Supervision and Inspection and Quarantine shall decide whether to approve an import application within 270 days from the receipt of application,[54] which is 180 days longer than the period previously in effect and has the potential to substantially impair such trade. Such data and documentation must be generated in China,[55] essentially compelling foreign entities to conduct research in China at potentially higher cost and risk of intellectual property infringement. The first approval criterion requires that the exporting country perform certification and that the GMO already be in use in the exporting country. This requirement would effectively bar agricultural GMOs developed overseas that have no application in their country of development. The second criterion imposes higher burdens on imports than on domestically produced agricultural GMOs[56] and demands a degree of certainty that may exceed the capabilities of a scientific risk assessment.

The impact of the Agricultural Biosafety Regulations was weakened because they were promulgated and made effective, in Chinese regulatory fashion, before the promulgation of implementing measures and without prior consultation with interested foreign governments and producers, as well as some domestic stakeholders. Because MOA has yet to establish the requisite certification process, traders lack the means to satisfy regulatory requirements. Contracts concluded prior to June 6 2001 have not been subjected to such requirements. However, United States soybean growers, who had projected exports of 5.7 million tons of soybeans to China in 2001, much of it grown from genetically modified seed, found themselves and their competitors in other countries unable or unwilling to conclude sales contracts dated after June 6 2001 because of regulatory uncertainty.[57] A senior Chinese foreign trade official attempted to alleviate the problem by stating that the provisions of the Agricultural Biosafety Regulations would not be enforced until implementing regulations were promulgated.[58] Such statement of policy lacked the force of law, however, and therefore did not alleviate the impact on trade in soybeans.[59] Several months of negotiations between Chinese and US government officials ensued but without progress until the October 2001 APEC summit when US President George W. Bush personally raised the issue with President Jiang Zemin. US and Chinese negotiators agreed to further discuss the issue, but PRC commitments to accept US certifications until PRC certification procedures are in place and to reduce the PRC inspection and quarantine period have not yet become operational.[60]

China does not have an administrative procedure requiring that draft regulations be published for comment by interested parties before promulgation, and laws and regulations are typically promulgated well before implementing regulations. This creates uncertainty and confusion while depriving the government of the benefit of input from all interested parties. Where implementing regulations are necessary, the effective date of the administrative regulations should coincide with that of their implementing regulations. Furthermore, as shown below, such opacity must change as a condition of China's accession to the World Trade Organization (WTO).

NATIONAL BIOSAFETY FRAMEWORK

The National Biosafety Framework of China (Biosafety Framework), the product of an interdepartmental coordinating group formed in 1998 under the leadership of SEPA through its Department of Nature and Ecology Conservation, is intended to establish an overall policy and regulatory framework with respect to biosafety, including agriculture as well as pharmaceuticals and food. While acknowledging certain accomplishments in biosafety management, the Biosafety Framework is predicated on the need for substantial improvement in the legal system, management, supervision and capacity.[61]

Specifically, the Biosafety Framework provides that biosafety should be governed by a national statute and/or State Council regulations, below which there would be (i) departmental regulations on such specialized topics as wild animal and plant genes and agrobiology genetic engineering, (ii) management or administrative procedures on technical procedures and (iii) specialized regulations on trade, foreign investment, dispute resolution and the like.[62] Administrative authority would be centred in an interdepartmental National Biosafety Management Coordinating Committee under the State Council led by SEPA as national competent department.[63] Each relevant government department, such as MOST and MOA, would manage biosafety issues within its respective sphere of authority.[64]

Reflecting China's supportive position with respect to biotechnology including genetic modification, the Policy Framework places equal importance on research, development and commercialization on the one hand, while also placing high importance on biosafety as embodied in the precautionary approach,[65] i.e., lack of scientific certainty with respect to potential adverse impacts shall not prevent the taking of preventive action on the basis of available evidence.

In practice, the National Biosafety Framework, adopted in 2001, is not functioning as intended. SEPA has not been able to assert a leading role and there is as yet no national statute or State Council regulations of general application. Individual government departments like MOA draft regulations, such as the Agricultural Biosafety Regulations, which do not necessarily reflect broader concerns with respect to biosafety or, as we have seen, foreign trade and investment.

However, the Biosafety Framework itself reveals a disfavour with respect to imported living modified organisms (LMOs) and foreign investment that exceeds the requirements of biosafety and, as shown below, international law including China's pending World Trade Organization (WTO) obligations. The Biosafety Framework seeks to impose a four class guidance system with respect to foreign investment, ranging from encouraged to permitted, limited (restricted) and banned (prohibited).[66] Although principally based on project risk, the classification system incorporates elements characteristic of the *Foreign Investment Industrial Guidance Catalogue* that are trade rather than biosafety-oriented, and are inconsistent in part with China's pending WTO obligations. In particular, encouraged projects include not only Safety Level I (no risk) projects, but also projects for which China lacks domestic development capacity but urgently needs to develop, especially advanced technology and export promotion projects.[67] Similarly, limited (restricted) projects include not only Safety Level II (low risk) projects but also projects for which technology has already been developed or imported and for which production capacity can satisfy market demand.[68] By contrast, more hazardous Safety Levels III (intermediate risk) and IV (high risk) projects are banned strictly on biosafety grounds,[69] even though some projects are not necessarily prohibited if appropriate safety procedures are adopted.

In a serious departure from national sovereignty, the Biosafety Framework would also require foreign investors to satisfy their home country's biosafety standards with respect to research, development, commercialization and sale of LMOs and their products whenever such standards are more stringent than China's own standards.[70] Such a provision would create an unequal playing field in China to the detriment of foreign investors and impose an inconceivably complex burden on Chinese regulatory officials, who would be compelled to enforce the regulations of other countries as well as their own.

The Biosafety Framework also asserts an interest in protecting China's special genetic resources with respect to research projects funded by foreign companies or foundations.[71] While encouraging international cooperation in the development of genetic resources and joint enjoyment of the benefits thereof, the determination to pay attention to the protection of China's special genetic resources suggests an intention to go beyond biosafety concerns and assert a national interest in intellectual property rights, including breeder's rights, that derive in any way from genetic resources that originate in China. Such intention goes beyond biosafety concerns and has no foundation in UPOV.

INTERNATIONAL BIOSAFETY REGULATION

Under the Convention on Biological Diversity (CBD), to which China is among the earliest signatories, contracting parties, as far as possible and as appropriate, are required to

> "Establish or maintain means to regulate, manage or control the risks associated with the use and release of LMOs resulting from biotechnology which are likely to have adverse impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health."[72]

The Biosafety Framework was prepared for the express purpose of satisfying this element of China's

obligations under the CBD.[73] However the CBD does not itself provide detailed guidance on the nature or scope of the required regulatory means, nor does it resolve the uncertain relationship between the trading rules underlying the WTO and such multilateral environmental agreements as the CBD.[74]

Were China already a WTO member, its failure to "allow a reasonable interval between ... publication ... and its entry into force" would appear to violate the requirement that producers in exporting members have sufficient time "to adapt their products and methods of production to the requirements of the importing [m]ember".[75] Failure to provide advance notice to other countries would appear to deprive other members of the opportunity to comment on and discuss the Agricultural Biosafety Regulations before they enter into effect.[76] The imposition of stricter requirements on imports than on domestically produced agricultural GMOs would appear to contravene the WTO's national treatment principle. Specific provisions of the Agricultural Biosafety Regulations, such as the labelling and packaging requirements and the delay in issuance of implementing regulations, may also contravene the prohibitions on adoption of technical regulations that have the "effect of creating unnecessary obstacles to international trade" and are unnecessarily trade-restrictive technical regulations.[77] The Agricultural Biosafety Regulations may also be vulnerable to challenge were China a WTO member because they are not based on international standards nor does it appear that they are based on "an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations" and "taking into account the objective of minimizing negative trade effects", as required by the Agreement on the Application of Sanitary and Phytosanitary Measures.[78]

China became a signatory to the Cartagena Protocol on Biosafety to the CBD (the Cartagena Protocol) on August 8 2000. Although the Cartagena Protocol has not yet entered into effect nor has it been ratified by the National People's Congress, it is nevertheless instructive to note that the Agricultural Biosafety Regulations depart in significant respects even from the Cartagena Protocol. The Cartagena Protocol, like other multilateral environmental agreements that restrict trade, has a very uncertain relationship with WTO.[79] The Cartagena Protocol adopted the "precautionary approach", i.e., lack of scientific certainty with respect to potential adverse impacts shall not stop the taking of preventive action on the basis of available evidence,[80] to biosafety with the objective of contributing

> "to ensuring an adequate level of protection in the field of the safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements."[81]

The precautionary approach is embodied in the "advance informed agreement procedure" which requires notice to and approval by the importing country of such LMOs as seeds prior to their first intentional introduction into the environment.[82]

Parties are allowed to take action that is more protective of biological diversity than required in the Cartagena Protocol, but only if such action is consistent with the Cartagena Protocol's objective and provisions and the party's other obligations under international law.[83] Although generally in sympathy with the objective of the Cartagena Protocol, the Agricultural Biosafety Regulations go well beyond the requirements thereof. In particular, the Agricultural Biosafety Regulations apply to products of LMOs as well as LMOs, whereas the Cartagena Protocol applies only to LMOs.[84] The Agricultural Biosafety Regulations require an assurance of safety that exceeds the Cartagena Protocol's requirements, notwithstanding its adoption of the precautionary approach,[85] that risk assessments be carried out in a scientifically sound manner,[86] without presuming that imports are permissible only if the exporting country certifies that they are harmless.

CONCLUSION

As shown above, China's regulatory structure has fostered research in genetic modification with respect to agriculture, although more could be done with respect to breeder's rights and it is as yet unclear how biosafety regulations will be implemented.

China's regulations nevertheless have shown a predisposition to impose unnecessary trade restrictions with the potential to disrupt China's trade in agricultural commodities that is inconsistent with China's pending obligations under WTO and the Cartagena Protocol.

ENDNOTES

1 Genetic engineering (*jiyin gongcheng*) was the term employed in Chinese regulations until 2001 when new regulations adopted genetic modification (*zhuan jiyin*). Genetic modification is the more widely accepted term in international law.

2 This is the definition of "modern biotechnology" under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Article 3(i), which is essentially synonymous with genetic modification. This definition is adopted in China's National Biosafety Framework, which expressly excludes the following genetic operation techniques from the scope of modern biotechnology: "Traditional hybrid breeding and reproduction techniques, such as artificial selection or hybrid breeding techniques; cell combination techniques and protoplasm combination techniques; breeding of organs, tissues and cells and chromosome multiplication techniques; extra-body pollination, embryo embedding, embryo separation, nucleic transfer and multiplication techniques; chemical or physical induction." State Environmental Protection Administration of China, National Biosafety Framework of China (2001) (Biosafety Framework)

§ 3.1.1.3.

3 For a comparison of the benefits and risks of genetic modification, see Deborah Katz, "Note: The Mismatch Between the Biosafety Protocol and the Precautionary Principle," in Georgetown International Environmental Law Review 949, 2001, pp. 967-77; Sean D. Murphy, "Biotechnology and International Law," 42 Harvard International Law Journal 47, Winter 2001, pp. 55-56.

4 Brett Grosko, "Note: Genetic Engineering and International Law: Conflict or Harmony? An Analysis of the Biosafety Protocol, GATT, and the WTO Sanitary and Phytosanitary Agreement," 20 Virginia Environmental Law Journal 295, 2001, pp. 300-302; Karen Hopkin, "The Risks on the Table," Scientific American, April 2001; Barry A. Palevitz, "Assessing Risk,"15 The Scientist, No. 19 at 1, October 1 2001. With respect to genetically modified foods, see "Safety Aspects of Genetically Modified Foods of Plant Origin, Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology," May 29-June 2 2000.

5 Murphy at 57-59; Grosko at 296.

6 "The Chinese government, on one hand, adopts a series of policies and measures to encourage, support and promote the research, development and commercialization of biotechnology and is opposed to using biosafety as an excuse to limit the development of biotechnology or set a barrier to international trade ....," Biosafety Framework at § 1.1.2.1; Robert L. Paarlberg, "Governing the GM Crop Revolution: Policy Choices for Developing Countries," Food, Agriculture and the Environment Discussion Paper 33, December 2000. China's support for agriculture and science and technology have resulted in what Paarlberg has classified as a "permissive" policy on a composite four-point scale with respect to genetic modification in agriculture. China thus ranks ahead of such other leading agricultural developing countries as Brazil, India and Kenya with respect to support for genetic modification in agriculture. The four points range from "promotional" as the most supportive of genetic modification to "permissive", "precautionary" and "preventive" as the most restrictive point. Paarlberg's scale is based on several dimensions: intellectual property rights, biosafety, trade, food safety and consumer choice, and public research investment. A permissive structure protects breeder's rights but less extensively than would be the case under a patent rights regime, and includes biosafety regulations that are more extensive than the minimum yet is not biased against GMOs.

7 High Technology Research and Development Plan (the 863 Program) (Central Committee of the Communist Party and State Council 1986); Virginia Chan and Gordon Chan, "Investing in Biotechnology in the PRC," China Law & Practice, July - August 2001 at 75.

8 Paarlberg at 25; Chan and Chan at 75; "Viewing China's Genetically Modified Seeds Production Policy," *Guoji Shangbao* (International Commercial News), September 27 2001. The scope of the biotechnology component under the 863 Program includes new, superior quality, high yield and resistant animal and plant varieties.

9 "Viewing China's Genetically Modified Seeds."

10 Jikun Huang, Justin Y. Lin and Scott Rozelle, "What Will Make Chinese Agriculture More Productive?", Stanford University Center for Research on Economic Development and Policy Reform, Working Paper No. 56, August 2000, pp. 16-17.

11 With respect to biosafety, Article 8(g) of the Convention on Biodiversity, to which China is a signatory, requires that countries establish or maintain regulatory systems to regulate "the risks associated with the release of living modified organisms resulting from biotechnology"; "on the other hand [China] gives high importance to the potentiality, long-term nature and seriousness of the biosafety issues and is strongly opposed to single-minded pursuit of commercial interests and the behavior aiming at short-term and partial interests without considering the potential risks," Biosafety Framework at § 1.1.2.1.

12 With respect to biosafety, "compared with ... some developed countries, the biosafety management in China started later and there is much to be improved in the management in China," Biosafety Framework at § 2.1.2.

13 "What sets China most clearly apart from Kenya, Brazil and India so far is its decision to implement a biosafety policy toward [genetically modified] crops that focuses solely on demonstrated risks rather than on scientific uncertainties and hypothetical or undemonstrated risks," Paarlberg at 3 and 23.

14 Biosafety Framework at § 2.2.2.1.

15 Paarlberg at 24.

16 SEPA's ideal hierarchy of regulations is expressed in the Biosafety Framework at § 4.2.1.1.

17 A 15-Year Review of the State 863 Program § 1.1.

18 *Regulations on the Administration of Technology Import Contracts* (State Council, 1985); *PRC, Administration of Technology Import Contracts Regulations Implementing Rules* (former Ministry of Foreign Economic Relations and Trade, 1988). China's technology import regulations are to be revised, in part to conform with China's WTO obligations.

19 *Administration of the Examination, Approval and Registration of Foreign-invested Crop Seed Enterprises Provisions, Nongnongfa* [1997] No. 9 (Ministry of Agriculture, former State Planning Commission (SPC), Ministry of Foreign Trade and Economic Cooperation (MOFTEC) and State Administration of Industry and Commerce, 1997). This limitation was imported into the current edition of the *Foreign Investment Industrial Guidance Catalogue* (SPC and MOFTEC, 1997), Restricted Item B.I.1.

20 *PRC, Seed Law* (2000), Articles 6, 15 and 16.

21 *PRC, Protection of New Varieties of Plants Regulations* (State Council, 1997). The Regulations are separately administered for agricultural and forest varieties. For a fuller discussion, see Lester Ross and Libin Zhang, "Agricultural Development Joins the UPOV,"17 UCLA Pacific Basin Law Journal, Nos. 2-3, Fall 1999-Spring 2000, pp. 226-244. A slightly revised version is available from the authors. The judiciary over three years later formulated procedures to handle disputes concerning new plant varieties. See *Several Issues Concerning the Trial of Disputes Involving New Varieties of Plants Interpretation* (Supreme People's Court, February 5 2001).

22 The Standing Committee of the National People's Congress approved China's accession on August 29 1998 and China deposited its instrument of accession on April 23 1999.

23 *Measures on the Management of the Safety of Genetic Engineering, Guojia Kewei Ling* 17 (SSTC, December 24 1993).

24 Genetic Engineering Measures, Article 1.

25 *Ibid*, Article 3.

26 *Ibid*, Article 3.

27 *Ibid*, Articles 4 and 7.

28 *Ibid*, Article 4.

29 *Ibid*, Article 6. The Biosafety Framework at § 1.1.3.2(2) refers to such classes as safety levels.

30 Genetic Engineering Measures, Articles 8-12.

31 *Ibid*, Article 14.
32 *Ibid*, Article 18.
33 Promulgated July 10 1996 and revised December 25 1997.
34 Agricultural Implementing Measures, Article 1.
35 *Ibid*, Article 5.
36 *Ibid*, Article 7.
37 *Ibid*, Article 12.
38 *Ibid*, Article 18.
39 *Ibid*, Article 4.
40 *Ibid*, Article 5.
41 State Council *Ling* 304, May 23 2001.
42 GMO Regulations, Article 1.
43 *Ibid*, Article 3.
44 *Ibid*, Article 19.
45 *Ibid*, Article 26.
46 *Ibid*, Article 21.
47 *Ibid*, Article 30.
48 *Ibid*, Article 18.
49 *Ibid*, Articles 28-29.
50 *Administrative Measures on the Labelling of Agricultural Crop Seeds* (MOA 2001), Article 5(4).
51 GMO Regulations, Article 32.
52 *Ibid*, Article 33.
53 *Ibid*, Article 34.
54 *Ibid*, Article 35.
55 *Ibid*, Article 34.
56 A safety assessment is required for the examination and approval by the National Agricultural Crop Variety Examination and Approval Committee of a domestically-bred genetically modified staple crop variety before it can be introduced into the environment but the variety need not be harmless as is the standard for imported crop varieties. *Procedures for Examination and Approval of Agricultural Staple Crop Varieties* (MOA 2000), Article 13.
57 Statement of American Soybean Association President Bart Ruth, quoted in "ASA Pleased at China's Entry to WTO, Raises Concerns About New Biotech Import Regulations," September 19 2001, at http://www.soygrowers.com/file__depot/Ø-10000000-10000/735/folder/9533/China+entry+to+WTO$2C+Biotech+Import+Regulations-09-20-01.html.
58 Dow Jones Newswires, "China Continue to Receive Shipments of U.S. Soybeans," Asian Wall Street Journal, October 22 2001, at M14; Vice Minister of MOFTEC Long Yongtu, cited in "China Proclaims That It Will Set An Extension Period to Permit the Import of GMO Foods," *Zhong Liang Fu De Wang*(China Grain Digest), August 23 2001.
59 Peter Greenberg of Rabobank, cited in "China Prepares to Use Nontariff Barriers After Entry Into WTO," *Zhong Liang Fu De Wang* (China Grain Digest), September 20 2001.
60 Meng Yan, "Sino-US Accord Inked to Cushion GMO Rule Impact," China Daily Business Weekly, October 30 2001. "U.S. Makes Little Headway in Efforts to Remove Soybean Import Restrictions," BNA Daily Report for Executives, October 15 2001 at A16.
61 Biosafety Framework at § 2.1.2.
62 *Ibid* at § 2.1.3.
63 *Ibid* at § 4.3.2.1.
64 *Ibid* at § 4.3.4.1.
65 *Ibid* at §§ 1.1.2.1 and 1.1.2.2.
66 *Ibid* at § 1.2.3.1.
67 *Ibid* at § 1.2.3.1.
68 *Ibid* at § 1.2.3.1.
69 *Ibid* at § 1.2.3.1.
70 *Ibid* at § 1.2.3.2.
71 *Ibid* at § 1.2.3.2.
72 Convention on Biological Diversity (1992), Article 8(g).
73 Biosafety Framework at 1.
74 E.g., Grosko at 305-09. The General Agreement on Tariffs and Trade does not "prevent the adoption or enforcement by any contracting party of measures; ... necessary to protect human, animal or plant life or health;" at Article 20(b). Such measures are subject to constraints to prevent unnecessary trade restrictions, as discussed below.
75 Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement), Annex B.2.
76 E.g., SPS Agreement, Annex B.5; Agreement on Technical Barriers to Trade (TBT Agreement), Articles 2.9 and 2.10.
77 TBT Agreement, Articles 2.2 and 2.3.
78 SPS Agreement, Articles 5.1, 5.4, 5.6 and 5.7. A nation that seeks to impose sanitary or phytosanitary measures that go beyond an international standard is obligated under WTO to perform a risk assessment. "WTO Appellate Body Report on EC Measures Concerning Meat and Meat Products (Hormones)," WT/DS26/AB/R, WT/DS48/AB/R (January 16 1998), WL 1998 WTO 25520 at 176, cited in Grosko at 311.
79 E.g., Grosko at 305-309.
80 Adoption and use of the "precautionary approach" or "precautionary principle" are highly controversial. For a critical analysis of the precautionary approach or precautionary principle for failure to balance the benefits of technological innovation against its costs, see Katz at 965-967.
81 Cartagena Protocol, Article 1.
82 *Ibid*, Article 7.
83 *Ibid*, Article 2.4.
84 *Ibid*, Article 4.
85 *Ibid*, Articles 10.6 and 11.8.
86 *Ibid*, Article 15.1.