China Enacts Biosecurity Law

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Food, Drugs, and Devices

On October 17, 2020, the Standing Committee of National People's Congress ("NPCSC"), China's top legislative body, adopted a Biosecurity Law ("Law"), which will go into effect on April 15, 2021. The Law reflects a growing area of regulation of drugs and medical devices in China that is separate from the regulations to ensure safety, effectiveness, and quality of drug and device products. The Law addresses a number of different areas, from bioterrorism to the regulation of plant, animal, and human specimens, and may bring new risks for life sciences companies to consider with respect to their development plans in China. Implementing regulations, which could be issued over the next five months, should help clarify the Law's impact.

This alert summarizes the key features of the Law.

Background and Scope

China originally proposed a Biosecurity Law in 2019, which was reviewed by the NPCSC in October 2019. The COVID-19 pandemic expedited the legislative work, with the final Law formally promulgated after two more drafts in April and October 2020 respectively. The Law addresses a number of biosecurity elements, including bioterrorism, infectious disease management, biotechnology development, biodiversity protection, microbial resistance, and human and biological resource management.[1]

Coordination Mechanism for National Biosecurity

The Law treats biosecurity as an important element of national security, and contains provisions similar to those in the National Security Law (see our previous client alert on the National Security Law here). Under the Law, the national security leadership agency—that is, the National Security Commission of the Communist Party—shall be responsible for coordination of the China's biosecurity work.[2]

Due to the complexity and diversity of biosecurity matters, the Law requires: (1) the National Security Commission to establish a Coordination Mechanism for National Biosecurity ("CMNB") that consists of the competent departments of the State Council for health, agriculture and rural affairs, science and technology, and foreign affairs, as well as relevant military agencies, to analyze national biosecurity issues, and organize, coordinate, and drive national biosecurity-work;[3] and (2) the member agencies of the CMNB and other relevant departments of the State

[1] Biosecurity Law, Art. 2.
[2] *Id.* Art. 10.
[3] *Id.* Art. 11.

Council to be responsible for implementing biosecurity work in their respective areas.[4] The Law provides that the CMNB will have an office,[5] but to date, there is no public information on the establishment of such an office or operation of the CMNB, and it is not clear how the CMNB and these various member agencies will coordinate.

For example, the Law specifically establishes a biosecurity review system for major events and activities in the biological field that affect or may affect state security.[6] This is a mechanism that the Regulations on the Administration of Human Genetic Resources ("HGR") ("HGR Regulations")—probably the most prominent biosecurity area implemented to date—also establish under the Ministry of Science and Technology ("MOST") for sharing HGR with foreign parties or outside of China. It is unclear whether, in addition to MOST, the CMNB or other government bodies will also be involved in such a security review related to HGR sharing going forward.

Biosecurity Information Platform

The Law also proposes a biosecurity information sharing system, and asks the CMNB to organize and establish a unified national biosecurity information platform to which "biosecurity data and materials" should be submitted and shared. As there is no definition of biosecurity data and materials; if interpreted broadly, all HGR data submitted to MOST—i.e., all clinical trial data uploaded prior to sharing abroad and/or with certain foreign entities (an increasingly routine practice)—could become part of the biosecurity information platform, and potentially shared with the CMNB and all of its member authorities. Currently, there is no public information on the biosecurity information platform or how submitted information will be used or shared.

Biotechnology Research, Development, and Application

Based on the degree of risk to public health, industry, agriculture, and the ecological environment, the Law classifies biotechnology research and development activities[7] into three categories: high-risk, medium-risk, and low-risk. The degree of risk for different activities will be set forth in a Catalogue on the Risk Classification of Biotechnology Research and Development ("Catalogue"),[8] which has not yet been published.

For high-risk and medium-risk biotechnology activities, there are special requirements: They must be conducted by a legal person (i.e., an entity) established in China. That entity must conduct a risk assessment and propose risk prevention and emergency control plans for such activities.[9] Implementing legislation will likely be required for this system, but there is no public plan or timeline.

The aforesaid requirement does not preclude foreign companies from conducting high- or medium-risk biotechnology R&D through their subsidiaries in China, although there is still a

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[4] *Id.*
[5] *Id.*
[6] *Id.* Art. 20.
[7] Under the Law, "biotechnology research, development, and application" is broadly defined as scientific research, technological development and application, and other activities conducted by understanding, modification, synthesis, and utilization of organisms through scientific and engineering principles.
[8] Biosecurity Law, Art. 36.
[9] *Id.* Art. 38.

prohibition on foreign investment in the development and application of human stem cells, genetic diagnosis, and therapeutic technology by the Ministry of Commerce and National Development and Reform Commission.[10]

Human Genetic Resources (HGR) and Biological Resource

For the first time, the Law provides that the Chinese state has sovereignty over all HGR and biological resources in China. This pronouncement emphasizes the importance of HGR and biological resources, supporting the need for administrative requirements (introduced in the Law and elsewhere) on the collection, preservation, use and sharing of HGR and biological resources.

For HGR, the Law tracks the HGR Regulations (see our previous client alert on the HGR Regulations here), e.g., foreign entities may not collect or preserve HGR but may utilize them when collaborating with a Chinese entity under an approved or cleared research project with MOST. The Law also indicates that there must be a "prior report" before HGR-related data is transferred to foreign parties—currently, such a transfer requires a two-step record-filing or clearance process under the HGR Regulations—raising questions about whether there will be a new type of notification procedure in the future. Data transfer record-filings have placed substantial burdens on clinical trial sites and sponsors, which must be able to transfer data freely to meet safety reporting obligations around the world.

For biological resources (i.e., plants and animals), which are not covered by HGR, the Law does not provide further clarity as to the implementation of the Nagoya Protocol in China. China signed the Nagoya Protocol in 2016, and released draft implementing regulations in 2017, which it has not finalized. The Law roughly sketches a regulatory system for sharing of biological resources: it requires approval for foreign entities or individuals to obtain or utilize biological resources in China, including approvals of international collaborations on scientific research that utilizes China's biological resources.[11] The Law does not specify which agency will implement these provisions.

Pathogenic Microbe Laboratories

The Law tightens the administration of pathogenic microbe laboratories. China already regulates these laboratories in general, as well as ones that handle potentially dangerous pathogens, under regulations established by the State Council and the chief healthcare regulator, the National Health Commission. The current regulations on pathogenic microbe laboratories require a person in charge to be primarily responsible for the biosecurity of the laboratory.[12] The Law builds on this requirement, holding the legal representative of the entity (i.e., the chief corporate responsible person) responsible for establishing the pathogenic microbe laboratory, together with the person in charge, liable for regulatory compliance.[13] The

[10] Special Administrative Measures for Access of Foreign Investment (Negative List) (2020 Edition), Item 21.
[11] Biosecurity Law, Art. 58-59.
[12] Regulation on the Bio-safety Management of Pathogenic Microbe Labs, Art. 32.
[13] Biosecurity Law, Art. 48.

Law now prohibits an individual (as opposed to an entity) from establishing a pathogenic microbe laboratory or conducting any pathogenic microbe testing.[14]

Enhanced Penalties

The penalty section of the Law continues the trend seen in other recent legislation in China, increasing the degree of penalties and punishing both the entities and the responsible individuals within them. Violation of the Law may lead to various penalties including monetary fines (against the entity or an individual), orders to cease activities, confiscation of income and materials, as well as debarment sanctions for the violating individual, i.e., legal representative, person in charge, person directly responsible, and other persons directly liable.

Compared to the HGR Regulations, the Law increases the fines from 5-10 times to 10-20 times the value of illegally derived income for a foreign party's illegal use or provision abroad of HGR (both biospecimens and data) without permission if the illegal derived income is more than one million RMB.[15] In other words, the minimum fine would be ten million RMB (roughly $1.5 million USD) if the illegal derived income exceeds $150,000 USD. The maximum debarment penalty is now 10 years debarment from biotechnology research, development, and application activities.[16] Information concerning specific entities' and individuals' violations will also be included in the national credit information sharing platforms (i.e., blacklists) in accordance with applicable laws.[17]

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[14] *Id.* Art. 44.
[15] *Id.* Art. 80.
[16] *Id.* Chap. 9.
[17] *Id.* Art. 26.