

China Biosecurity Law and its implications for businesses

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Introduction

China's Biosecurity Law was passed by China's top law-making body on 17 October 2020 and will take effect on 15 April 2021.

Key stipulations

The Biosecurity Law provides that biosecurity is a key component of China's national security and the Government will strengthen the regulation and supervision over handling of major pandemics, quarantines for animals and plants, R&D and application of biological technology, establishment and security of pathological microorganism labs, and collection, preservation, use and provision of China's human genetic resources (HGR) and biological resources.

The provisions in relation to the Biosecurity Law contains some provisions specifically addressing cross-border handling of HGR. It is provided under the Law that any foreign organisation, individual or foreign-controlled entity is not allowed to collect or preserve China's HGR, unless approved by Chinese regulators. Any international collaboration in the use of China's HGR or the transfer of China's HGR abroad is subject to approval by China's Ministry of Science and Technology (MOST). There are a few permissible exemptions such as for the purpose of clinical diagnosis, blood supply, cracking down on crimes, and stimulants testing.

The PRC Government started the law-making process for the Biosecurity Law since 2018 and there had been several rounds of public consultation before the Law was finally released. Compared with the previous version, the following major developments reflected from the final version are worth noting:

- Biosecurity assessment will be established as a fundamental regime for regulating biosecurity. It is provided in the Biosecurity Law that any major biological event or activity which affects or may affect the national security is subject to biosecurity assessment conducted by relevant regulators. This has hugely expanded the application scope of biosecurity assessment, compared with the previous consultation draft which provides that biosecurity assessment only applies to the establishment of pathological microorganism labs by foreign parties or the provision of China's human genetic resources outside China.
- The Biosecurity Law introduces some extraterritorial effect by stipulating that Chinese regulators are empowered to take actions against foreign entities or individuals that jeopardise China's biosecurity by shipping, mailing or bringing dangerous biological items to China.
- The Biosecurity Law follows the same legal principle as provided in the Human Genetic Resources Regulations that MOST approval is required for international collaborations in the use of China's HGR, but the scope of exemptions from MOST approval is further narrowed down. For example, training is not a permissible exemption anymore.
- Legal liabilities for non-compliance have been hugely increased. Violators are now subject to an administrative fine up to 20 times illegal gains, plus civil compensation. In addition, the authorities have power to take other actions such as suspension of the relevant biotech R&D activities and revocation of operation permits or licences. The legal representative or persons-in-charge can also be subject to personal liability.

Implications

The issuance and implementation of the Biosecurity Law will have significant implications for international and Chinese companies in a wide range of industries such as pharma, healthcare, biotech, cosmetics, food, agriculture, forestry, animal husbandry and fishery. Businesses in relevant sectors will need to assess the implications of the Biosecurity Law for their business operations in China and abroad, and take proper compliance and risk management actions, including without limitation, setting up a robust governance structure for biosecurity, reviewing the current program and operation for collection, use and cross-border transfer of human genetic resources and biological resources, reviewing and revising the relevant contracts, and training the team.

With drafts available for public consultation for a couple of years now, many international labs have generally known the intent and direction of the Government with this new law. Within the last year, the current pandemic has heightened awareness around the world, and in China, of the importance of biosecurity to sovereigns and public health. Further broadening the scope allows for unforeseen incidents to be handled and yet the law is also more specific in terms of inclusions and exclusions.

With China R&D / innovation rapidly advancing on the global stage, as we can see with the progress on the Covid-19 vaccines and other biotech innovation, global and regional R&D labs will need to factor into their programs these new laws in how they can both embrace new administration which promotes getting innovative products to the population faster, by including China population in clinical studies, but also complying with these new laws for the sake of security.

Let's talk

For a deeper discussion of how this impacts your business, please contact:

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