



2021

生物安全法 對生物技術產業的影響

Biosecurity Law and Its Implications
For Biotech Industries

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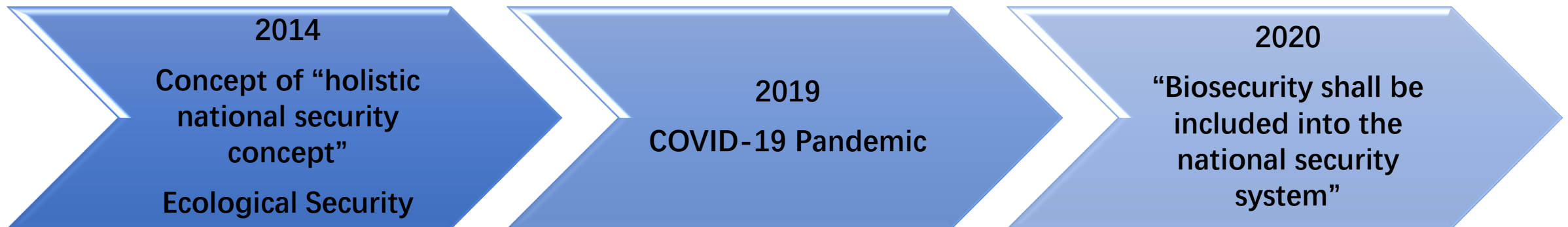
Development of Biosecurity Law System

生物安全法律體系的發展沿革

Development of the Biological Industry



Importance to the country and society



Development of Biosecurity Law System

生物安全法律體系的发展沿革



Industry Government Problem Solution & Modification Circle

Structure of Biosecurity Law

生物安全法的架構



11 fundamental systems

確立了生物安全的 11 項基本制度



8 major activities

適用於 8 類與生物安全相關的活動

Structure of Biosecurity Law

生物安全法的架構



11 fundamental systems 确立了生物安全的 11 项基本制度

Risk monitoring and early warning 風險監測預警制度	Biosecurity examination 審查制度
Risk investigation and assessment 風險調查評估制度	Biosecurity emergency response 應急制度
Information sharing 信息共享制度	investigation and source tracing for biosecurity incidents 調查溯源制度
Information release 信息發佈制度	Entry permit - for animals and plants, products of animals and plants, and high-risk biological factors that enter the country for the first time or resume entry after a suspension 國家准入
Catalog and list 名錄和清單制度	
Standardization 標準制度	Response for severe overseas biosecurity incidents 境外重大生物安全事件應對制度

Structure of Biosecurity Law

生物安全法的架構



Article 2

This Law shall apply to the following activities:

(1) Preventing and controlling a major new or sudden outbreak of an infectious disease or an epidemic in animals or plants.

(2) Research, development, and application of biotechnology.

(3) Biosecurity management of pathogenic microbe laboratories.

(4) Biosecurity management of human genetic resources and biological resources.

第二条（第二款）

从事下列活动，适用本法：

（一）防控重大新发突发传染病、动植物疫情；

（二）生物技术研究、开发与应用；

（三）病原微生物实验室生物安全管理；

（四）人类遗传资源与生物资源安全管理；

Structure of Biosecurity Law

生物安全法的架構

Article 2

This Law shall apply to the following activities:

第二条（第二款）

从事下列活动，适用本法：

(5) Preventing the invasion of alien species and protecting biodiversity.

（五）防范外来物种入侵与保护生物多样性；

(6) Responding to antimicrobial resistance.

（六）应对微生物耐药；

(7) Preventing biological terrorist attacks and defending against biological weapon threats.

（七）防范生物恐怖袭击与防御生物武器威胁；

(8) Other biosecurity-related activities.

（八）其他与生物安全相关的活动。

Implications for Biotech Industries

對生物技術產業的啟示



Biotech / Pharmaceutical Companies

生物技術 / 製藥企業

**Labs / Institutes /
Clinical Trial Centers**

病原微生物實驗室



**CRO / CMC /
Other Service Providers**

其他產業服務供應商

Chapter IV Security of Biotechnology Research,
Development, and Application

第四章 生物技术研究、开发与应用安全

Chapter V Biosecurity of Pathogenic Microbe
Laboratories

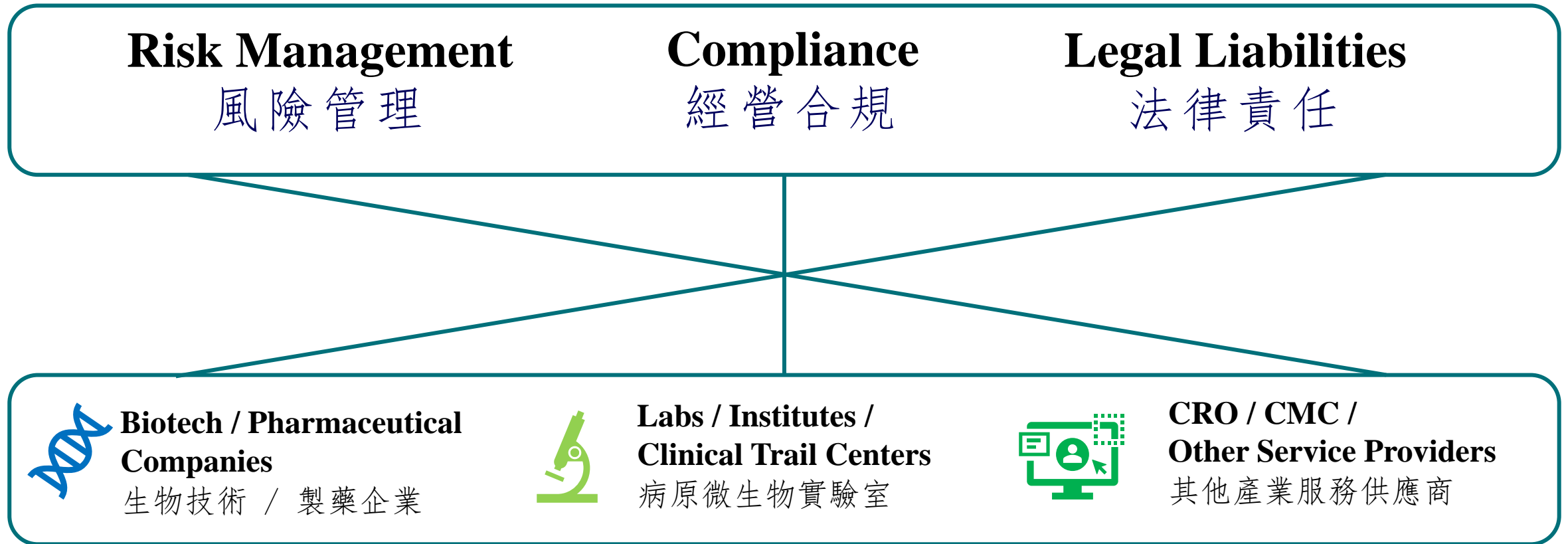
第五章 病原微生物实验室生物安全

Chapter VI Security of Human Genetic Resources
and Biological Resources

第六章 人类遗传资源与生物资源安全

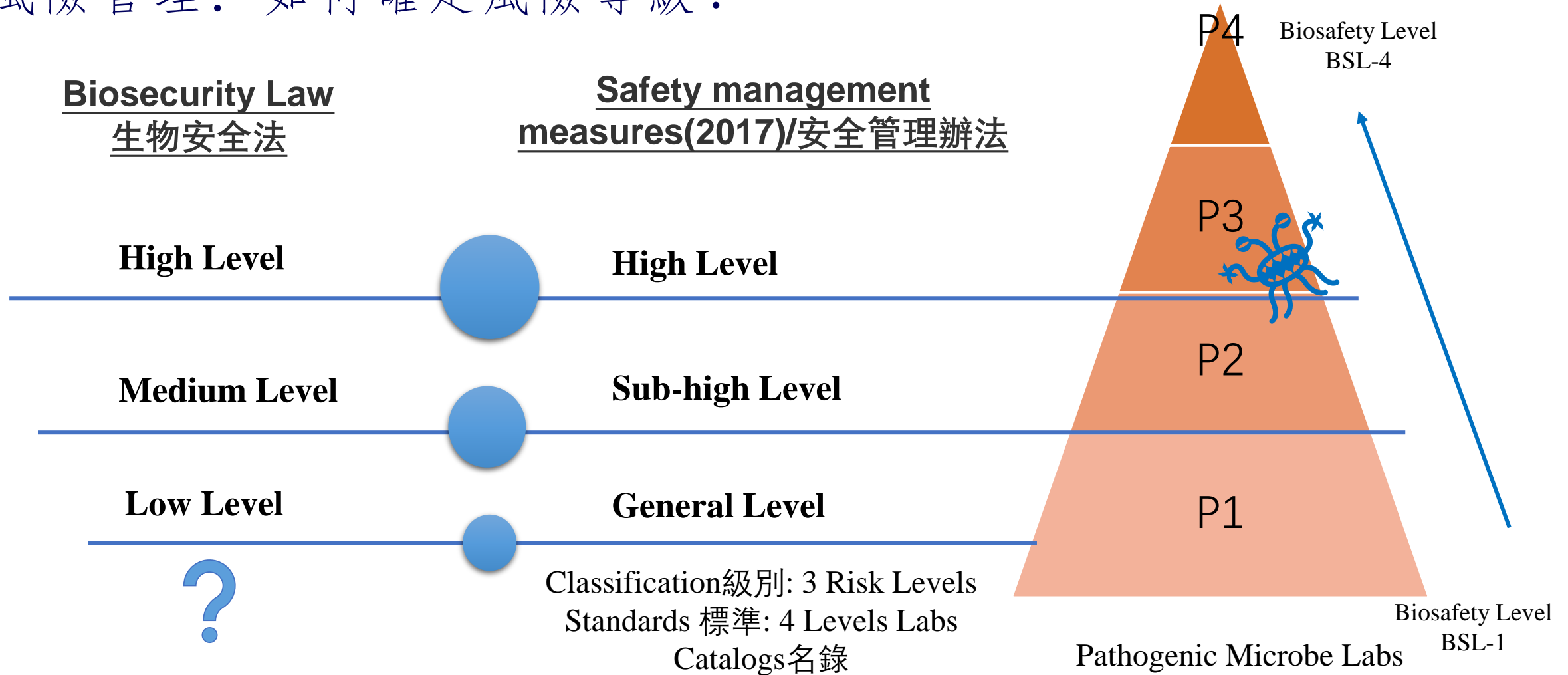
Implications for Biotech Industries

對生物技術產業的啟示



Risk Management: How to Determine?

風險管理：如何確定風險等級？

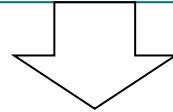


Risk Management: Who is responsible/capable?

風險管理：責任主體與合資格主體

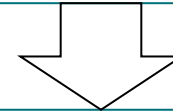
The Entities shall be responsible to the security of their activities on biological research, development & application.

從事生物技術研究、開發與應用活動的單位，應對本單位開展的活動的安全負責



High/Medium risk level biotech R&D activities shall be conducted ONLY by legal entity duly established within China.

中、高風險的生物技術研究、開發與應用活動，應當由在中國境內依法成立的法人組織進行



Legal Entity Duly Established Within China

在中國境內依法成立的法人組織

Risk Management: Who is responsible/capable?

風險管理：責任主體與合資格主體

Article 38

To conduct High/Medium Risk Level biotech R&D activities:

有關從事中、高風險的生物技术研究、开发活動的要求

Legal entity duly established within China
“在我國境內依法成立的法人組織”

① Domestic Entity / 內資

② Sino-foreign JV / 中外合資



③ WOFE / 外資

Special Administrative Measures (Negative List) for Foreign Investment Access (2020)
外商投資准入負面清單 (2020版)

Foreign investment in the research and application of human stem cells, genetic diagnosis and treatment technologies are prohibited.

禁止投資人體幹細胞、基因診斷與治療技術開發和應用。



Operating compliance :Clinical Trials

經營合規：對臨床試驗的啟示

Biosecurity Law (2021)

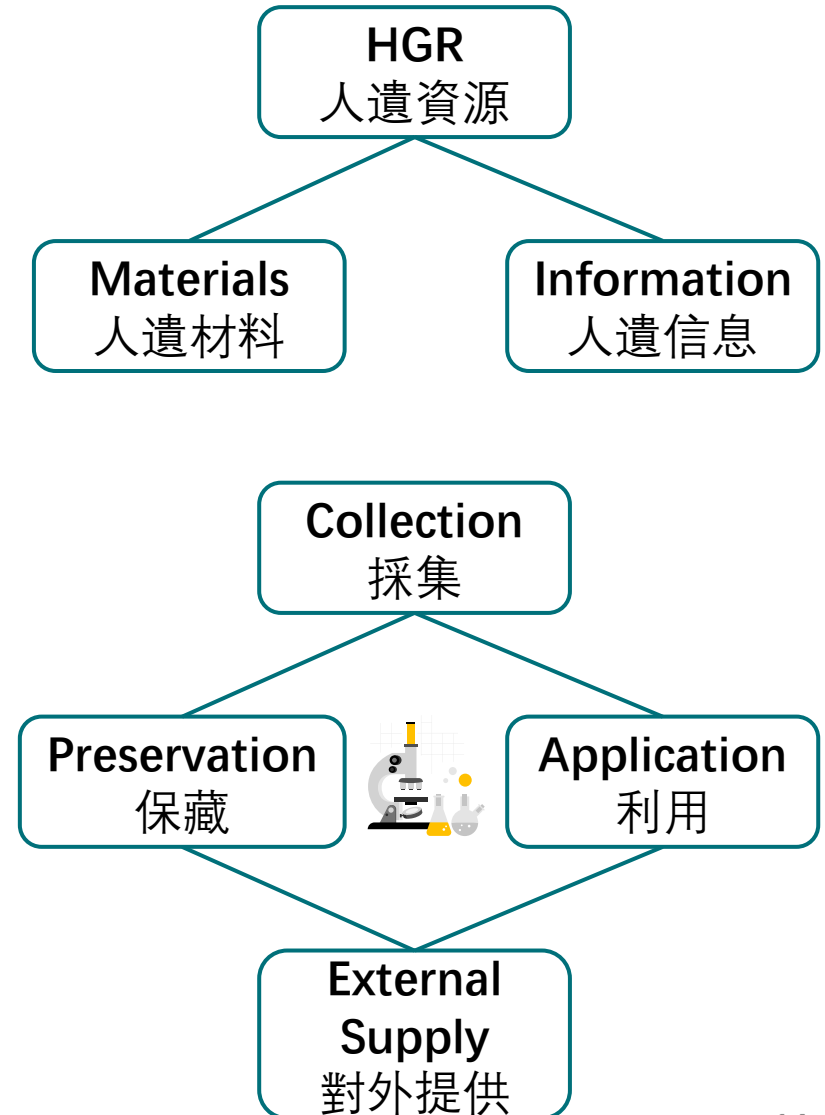
Chapter VI Security of Human Genetic Resources and Biological Resources

第六章 人类遗传资源与生物资源安全

Regulation on the Administration of Human Genetic Resources 人類遺傳資源管理條例 (2019)

Measures on Management of Human Genetic Resources 人類遺傳資源管理暫行辦法 (1998)

Guidelines issued by the Ministry of Science and Technology(MOST) 科技部發佈的有關指南



Operating compliance :Clinical Trials

經營合規：對臨床試驗的啟示

Foreign Entity/涉外主體 Biosecurity Law (2021)



Article 56 Foreign organizations, individuals and entities established or controlled by them **shall not collect** or **preserve** China's human genetic resources within the territory of China and **shall not provide** China's human genetic resources to foreign countries.

第五十六條 境外组织、个人及其设立或者实际控制的机构不得在我国境内**采集、保藏**我国人类遗传资源，**不得向境外提供**我国人类遗传资源。


Collection
採集


Preservation
保藏


Application
利用


External Supply
對外提供

Domestic Entity/中方單位 Approval/批准:

- Collection
- Preservation
- Export of the HG Materials

Advance Report/事先報告:

- External Supply 對外提供
- Open Access 開放使用

JV or International Cooperation 合資或合作

Approval/ 批准:

- International Cooperative Research
開展國際合作

EXEMPTION-Clinical Trials

Operating compliance :Clinical Trials

經營合規：對臨床試驗的啟示

International Cooperative Clinical Trial / 國際合作臨床試驗

- ✓ For purpose of obtaining relevant drug or MD registration.
為取得相關藥品和醫療器械的上市許可
- ✓ HGR shall be used by the clinical trial centers or labs engaged by such centers
在臨床機構（或經臨床機構委託的實驗室）利用人遺資源
*APPROVAL is applied if the sponsor engages other labs to test, analyze or process the leftover sample.
若由申辦人委託其他實驗室進行檢測、分析和剩餘樣本處理，適用審批。
- ✓ No export of the human genetic materials.
不涉及人遺材料出境

Advance Report to the
MOST
開展臨床試驗前,向科技部
主管部門 備案

Legal Liabilities

法律責任

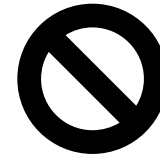
Legal Entity
法人主體



Natural Person
自然人



Administrative Liabilities
行政責任



Criminal Liabilities
刑事責任

- Biosecurity Law: Significantly raised amount of fine
生物安全法大幅提高了罰款金額
- 11th Amendment to the Criminal Law: Illegally collecting and smuggling of HGR , Fraud in drug registration application
刑法第十一修正案，就走私人類遺傳資源和提供虛假材料申請藥品註冊設立專門罪名

Legal Liabilities: Administrative

法律責任



Before the Regulation on Administration of HGR (2019) and Biosecurity Law(2021) came into force, the administrative punishment were relatively lenient to persons who violated the rules.

在2019年人遺條例及2020年的生物安全法生效之前, 對違反相關規定的處罰不算重。

- ① Warning
警告 (對實施主體)
- ② Confiscate and destroy the HGR
沒收和銷毀涉案人類遺傳資源
- ③ Revocation of 2 approvals
撤銷兩項許可
- ④ Pending all the applications of the Entity
暫停受理該主體的國際合作活動申請

Legal Liabilities: Administrative

法律責任

Biosecurity Law	Liabilities
Article 75 Failure to comply with the state regulations for the safety management of biotechnology research and development. 從事生物技術研究、開發活動未遵守國家生物技術研究開發安全管理規範的	Order of correction , warning and a fine ¥ 20,000 - ¥ 200,000 Order to cease and a fine ¥ 200,000 – 2 million
Article 79 Collecting or preserving China's HGR or using HGR to carry out international scientific research cooperation without approval 未經批准，採集、保藏我國人類遺傳資源或者利用我國人類遺傳資源開展國際科學研究合作的	The legal entity: Order to cease or a fine up to 5 million / 10 times the illegal income The liable individuals: Punishment & 5-year prohibition to the corresponding activities
Article 80 Foreign entities or individuals collecting or preserving China's HGR, or provide HGR to other foreign countries. 境外主體在我國境內採集、保藏我國人類遺傳資源，或者向境外提供我國人類遺傳資源	Order to cease Order to confiscate HGR A fine up to <u>10 million / 20 times the illicit income</u>



Legal Liabilities: Criminal

法律責任

UPDATE ON THE INVESTIGATION

Reference is made to the announcement of GenScript Biotech Corporation (the “Company”, together with its subsidiaries, the “Group”) dated 21 September 2020 (the “Announcement”). Unless the context requires otherwise, terms used in this section of the announcement shall have the same meanings as defined in the Announcement.

The Company wishes to report that in connection with the Investigation (as defined in the Announcement), on 21 November 2020, it received from the family member of Dr. Zhang a copy of a notice of arrest issued by the the Customs Anti-Smuggling Department of Zhejiang, the People’s Republic of China (“PRC”) (the “Authority”) dated 20 November 2020 in respect of Dr. Zhang (the “Notice of Arrest”). The Notice of Arrest stated that Dr. Zhang has been arrested for the suspected offence of smuggling goods prohibited by the import and export regulations under the laws of the PRC (the “Arrest”).

At the time of this announcement, two employees who had previously handled import and export activities of the Group have been arrested. (the “Relevant Employees”).

At the time of this announcement, to the best of the knowledge of the Company, no formal charge has been made against Dr. Zhang or the Relevant Employees.

As at the time of this announcement, save as disclosed above, to the Company’s knowledge, no arrest or charges have been made or filed against any entity or individual.

To the Company’s knowledge, there have been no other details released by the Authority as at the date of this announcement.

As at the date of this announcement, the Group’s business operations remain normal.

The Company has taken legal advice as appropriate. The Company will monitor this matter and will proactively assist the law enforcement authority with the Arrest, if required. The Company will make public announcement in a timely manner on any important development of the Investigation.

The 1ST Criminal Case of the Biosecurity



According to the announcement of a HK listed company on November 21, 2020, the founder, who was also the former Chief of the Board, and two employees were arrested on suspicion of smuggling.

It was allegedly reported that the relevant items were HGR.

生物安全的刑事“第一案”

根據一家香港上市公司2020年11月21日的一份公告披露，該公司創始人、前董事會主席以及兩名員工因涉嫌走私被捕。

據報道稱，涉嫌走私的物品為人類遺傳材料。

Legal Liabilities: Criminal

法律責任

Amendment(XI) to the Criminal Law / 刑法第十一修正案



Provisions	Liabilities
<p>Article 38 (article 334 of the Criminal Law) Crime of illegally collecting and smuggling human genetic resources 非法採集人類遺傳資源、走私人類遺傳資源罪</p>	<p>Severe : ≤3-year imprisonment, criminal detention or public surveillance and fine , or be fined only</p> <p>Very Severe 3-year ≤imprisonment≤7-year and fine </p>
<p>Article 7 (article 142 of the Criminal Law) (3) Providing false certificates, data, materials, samples or adopting other deceptive means in drug registration application 藥品申請註冊中提供虛假的證明、數據、資料、樣品或採取其他欺騙手段的</p>	<p>serious enough to endanger human health 足以危害人體健康 ≤3-year imprisonment, criminal detention and fine , or be fined only</p> <p>causes serious harm to human health or if there are other serious circumstances 對人體健康造成嚴重危害或有其他嚴重情節 3-year ≤imprisonment≤7-year and fine </p>

Conclusion

分享小結



- To set up robust governance structure and adjust the business model.
設立健全的管理架構
- To review the current programs and protocols especially for collection, use and cross-border transfer of HGR to full fill the stringent compliance requirements.
檢視現有的項目和操作規程，尤其是對收集，使用和對外提供人類遺傳資源的規範，以滿足更高的合規性
- Continuous attention shall be paid to the issuance of subsequent implementation regulations or guidelines.
需要持续关注后续發佈的實施細則、指引等。

Fuxion IP Team

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Thank you!