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Legal Updates

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1. Key Takeaways from China's Pilot Plan for Segmented Production of Biological Products

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Recently, the National Medical Products Administration (the "**NMPA**") issued the "Pilot Work Plan for the Segmented Production of Biological Products" (the "**Pilot Plan**"), introducing a pilot initiative for the segmented production of biological products. This represents a breakthrough in the regulation of segmented production, a long-awaited achievement in the biopharmaceutical industry. This breakthrough suggests the possibility of cross-provincial and even cross-border production of biological products, which marks the significant progress in optimizing resource allocation, reducing production costs, and improving production efficiency, and will promote the integration of China's biopharmaceutical industry into the global market, enhancing international competitiveness. In this article, we analyze the impact of the Pilot Plan, including the types of pilot products, requirements for pilot enterprises, international/cross-border collaboration, and tightened regulatory requirements. We hope to share our insights from these perspectives to provide a reference for the industry.

Background overview

Prior to the issuance of the Pilot Plan, China had not explicitly prohibited by law the exploration of the segmented production of biological products, thereby leaving flexibility to explore future practices in this area. As the principal law governing drug regulation, the *Drug Administration Law* does not specifically prohibit the segmented production of biological products[2]. The draft amendment to the Regulations for Implementation of the *Drug Administration Law*, published in 2022, first proposed that innovative drugs or urgently needed drugs in clinical practice with special requirements could be approved for segmented production[3]. In addition, the *Provisions on Administration of Production and Distribution of Vaccines*, published in 2022, also clarified that, with the consent of the NMPA, vaccine solutions (in Chinese: 原液) and formulations (in Chinese: 制剂) can be manufactured separately through contract manufacturing[4]. In practice, since 2021, regions such as Suzhou and Shanghai have begun to implement and explore this policy[5]. These preliminary endeavors have resulted in valuable experience for the issuance of this Pilot

[1] Jingjing XU has contributions to this article.

[2] Article 32 of the *Drug Administration Law* (2019): MAHs may either manufacture drug products by themselves or entrust a drug manufacturer with production…The contract manufacturing of blood products, narcotic drugs, psychotropic substances, toxic drugs for medical use, and pharmaceutical precursor chemicals is prohibited, unless otherwise stipulated by the drug regulatory department under the State Council.

[3] Article 69 of the draft amendment to the *Regulations for Implementation of the Drug Administration Law* (2022): For innovative drugs or urgently needed drugs in clinical practice with special requirements for manufacturing process or facility, segmented production can be permitted upon approval by the State Council's drug regulatory authority.

[4] Article 12 of the *Provisions on Administration of Manufacturing and Distribution of Vaccines* (2022): The scope of contract manufacturing shall encompass the whole processes of vaccine manufacturing. If necessary, the contract manufacturing of combined or multi-component vaccines can be conducted separately for the vaccine solution manufacturing stage and the formulation manufacturing stage with the consent of the NMPA after discussion and approval.

[5] For example, the exploration of segmented production of biological products has been initiated in the Suzhou Industrial Park in 2021, and the Shanghai Medical Products Administration's 2024 initiative "Measures on Continuously Creating a

Plan, which is the first official national-level initiative to promote the segmented production of biological products.

Key takeaways from the Pilot Plan

I. Types of pilot products

The Pilot Plan covers several popular biological products available in the market, including PD-1 inhibitors, GLP-1 agonists, and antibody-drug conjugate (**ADC**) products[6]. Currently, cell and gene therapy (**CGT**) products are not explicitly covered by the Pilot Plan, and they await further clarification and guidance from regulatory authorities. The Pilot Plan also stipulates that pilot products may include other biological products as specified by the NMPA, potentially allowing CGT products to fall within the scope of the pilot products. Additionally, the Pilot Plan adopts the principle of "each product has its own policy" (in Chinese: 一品一策), i.e., distinct policies and measures will be developed for different biological products. The Pilot Plan shows that it considers the characteristics of different biological products and their specific regulatory needs, providing diverse measures for segmented production across different product types.

Notably, the recently issued *Notice on Carrying Out Pilot Programs to Expand Opening-Up in the Healthcare Sector*, foreign-invested enterprises in such pilot initiatives are also permitted to engage in the development and application of human stem cells, gene diagnostic and therapy technologies (for highlights of this notice, please refer to our article: *China Pilots Lifting Restrictions on Foreign Investment in Stem Cell, Gene Therapy, and Genetic Diagnosis Sectors in Four Free Trade Zones*). We look forward to the potential synergy between these two pilot initiatives in the future, which may facilitate segmented production of CGT products to reduce production costs and enhance R&D efficiency.

II. Requirements for pilot enterprises

The Pilot Plan imposes stringent requirements for qualified pilot enterprises. Notably, pilot enterprises must apply with their originally-developed products[7]. However, further clarification is needed regarding the definition of "originally-developed products", particularly in cases involving collaborative R&D or licensed-in projects for innovative biological products. The interpretation of this requirement will significantly impact the Pilot Plan's applicability to biological products in licensing and co-development projects, requiring close attention in future regulatory practices.

Additionally, entrusted manufacturing enterprises must implement a unified quality management system with entrusting enterprises and must have at least three years of commercial production experience in biological products. The entrusting enterprises must designate at least two qualified

first-class Business Environment in the Drug Regulatory Field" has mentioned promoting pilot work on the segmented production of biological products.

[6] The Pilot Plan states that the pilot products shall generally be innovative biological products, biological products of urgent clinical need, or other biological products specified by the NMPA, including combination and multivalent vaccines, antibody biological products, ADC products, GLP-1 products, and insulin products.

[7] Policy interpretation of the Pilot Work Plan for Segmented Production of Biological Products: The pilot products should be the originally-developed products of the pilot enterprises.

technical personnel to be stationed on-site to ensure unified standards and seamless coordination. This requirement goes beyond conventional contract manufacturing requirements, which typically only mandate that an entrusting enterprise conduct on-site audits of the entrusted manufacturing enterprises' quality management system. These more stringent requirements reflect higher standards for inter-company collaboration, operational coordination, and quality management necessary in the segmented production of biological products.

III. Cross-provincial/cross-border collaboration

The Pilot Plan supports cross-provincial segmented production of biological products. For cases where the contracting parties are located in different provinces, the Pilot Plan requires the regulatory authorities from both provinces to collaboratively develop and formulate regulatory plans. Furthermore, the Pilot Plan allows foreign applicants/holders of imported drugs to participate in the pilot program, signaling support for cross-border segmented production of biological products. This represents a significant breakthrough, particularly considering China's historical requirement that imported drugs be produced overseas. Looking ahead, more flexible manufacturing arrangements may emerge, such as producing the vaccine solutions within China while completing formulation production abroad — an arrangement that exemplifies "each product has its own policy", the regulatory approach outlined in the Pilot Plan.

IV. Tightened regulation

Under the Pilot Plan, pilot enterprises and pilot products are bound to face stricter regulation. Provincial medical products administrations will implement annual comprehensive inspections and sampling inspections on pilot products and will actively accept entrusted inspections from enterprises. Regular GMP compliance inspections and unannounced inspections are also likely to become a routine to ensure the quality of products in segmented production. Additionally, cross-provincial regulatory coordination has always been a major challenge. Differences in regulatory experience and resources among provinces may affect the effectiveness of supervision over cross-provincial segmented production. As the pilot work progresses, we anticipate that regulatory authorities will accumulate experience and establish effective cross-provincial regulatory plans.

V. Pilot regions and timeline

The pilot regions include provincial administrative areas that that have been proposed to explore new policies under the national strategy and provincial administrative areas with real project needs, industrial foundations, and strong regulatory capabilities. It is expected that these regions will include Shanghai, where the policy to promote pilot work on segmented production of biological products was proposed in March this year. We also look forward to more regions implementing the Pilot Plan in the future.

As for the timeline, enterprises must submit pilot applications by December 31, 2025, and the pilot work will conclude by December 31, 2026. We hope that the experience accumulated over two years of pilot work will lay a foundation for the subsequent official implementation of segmented production of biological products.

Conclusion

The Pilot Plan is of great significance for China's biopharmaceutical industry. The implementation of this Pilot Plan is expected to bring important opportunities to the industry, including optimizing production division, improving industrial efficiency, and strengthening regional and international cooperation. However, during the implementation of the Pilot Plan, it remains to be explored how to ensure product quality, achieve effective regulation, and coordinate cross-regional and cross-border regulatory cooperation under the segmented production model. We believe that industry participants and regulatory agencies may work together to refine the details of the Pilot Plan. Through steady advancement and experience accumulation, the regulatory authorities may overcome potential challenges, stimulate the vitality of the market participants, and promote the high-quality development of China's biopharmaceutical industry.

2. New Measures on Syndicated Loans: Policy Shifts and Insights

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The National Financial Regulatory Administration ("**NFRA**") issued the *Administrative Measures for Syndicated Loan Business* ("**Administrative Measures**") on 12 October 2024, which will take effect from 1 November 2024 and shall amend and replace the *Guidelines on Syndicated Loan Business* issued by the China Banking Regulatory Commission on 1 August 2011 (the "**Business Guidelines**"). NFRA released a draft of the Administrative Measures for public consultation on 22 March 2024. We summarized and interpreted the major amendments of the consultation draft (the "**Consultation Draft**") to the Business Guidelines (for more details, please refer to our previous article "*Optimizing the Regulation of Syndicated Loan Business — Interpretation of the Administrative Measures for Syndicated Loan Business (Consultation Draft)*"). The final version of the Administrative Measures includes several refinements and enhancements compared to the Consultation Draft, and some of these updates address the concerns we highlighted in our article in March. The key updates include: (1) refining the definition of syndication tranches and segment criteria; (2) enhancing provisions relating to distribution threshold and including distribution thresholds for cases where there is a co-lead arranger and/or sub-lead arranger involved; (3) amending provisions relating to agent banks, with an added exception allowing the borrower's related parties to serve as an agent bank; (4) clarifying requirements relating to syndicated loan charges and authorizing the industry's self-discipline organization to regulate these charges; (5) refining the right of first refusal and the scope of eligible transferees in syndicated loan transfers; and (6) removing the requirements for banks engaged in syndicated loan businesses to report to the NFRA.

The amendments, along with our analysis and suggestions, are as follows (changes from the Consultation Draft to the Administrative Measures are shown in red):

	Major amendments and suggestions	Administrative Measures in 2024	Consultation Draft	Business Guidelines in 2011/Credit Assets Transfer Notice
1	**Refining the Definition of Syndication Tranches and Segment Criteria** The Administrative Measures refine the definition of "tranching in syndicated loans" based on the Consultation Draft, clarifying that the criteria for segment are not limited to loan tenor and interest rate. At the press conference,	Paragraph 2, Article 2 Syndicated loans in these Measures refer to loans or credit facilities in RMB or foreign currency provided by two or more banks to a borrower through an agent bank, pursuant to the same loan agreement, at an agreed time and ratio.	Same as the Administrative Measures	Article 3 Syndicated loans refer to loans or credit facilities in RMB or foreign currency provided by two or more banks to a borrower through an agent bank under the same loan conditions, pursuant to the same loan agreement, at an agreed time and ratio.

	Major amendments and suggestions	Administrative Measures in 2024	Consultation Draft	Business Guidelines in 2011/Credit Assets Transfer Notice
	an NFRA official noted that the final version of the Administrative Measures includes refined definition and criteria for tranching, which is expected to facilitate the process for banks and support the establishment of syndicates. ■ Banks need to pay attention to the limitations on the number of tranches and participating banks. Compared to the Consultation Draft, the Administrative Measures moderately relax the restriction on the number of participating banks, allowing one bank to constitute a tranche; provided that, only one such tranche is permitted.	Paragraph 3, Article 2 Tranching in syndicated loans, as defined in these Measures, refers to the operational method in which loans with different conditions are provided to the customer under the same syndicated loan agreement by dividing the loans into tranches based on loan conditions such as the loan tenor and interest rate. The loan conditions must be consistent within the same tranche.	Paragraph 3, Article 2 Tranching in syndicated loans, as defined in these Measures, refers to the operational method in which syndicate members provide loans with different tenors or types under the same syndicated loan agreement by dividing the loans into tranches. The loan conditions, such as the loan tenor, interest rate, and purpose, must be consistent within the same tranche.	N/A
		Paragraph 1, Article 18 Tranching in syndicated loans generally involves no more than three tranches. In principle, each tranche shall consist of at least two banks, and there shall be no more than one single tranche with participation from a single bank.	Paragraph 1, Article 16 Tranching in syndicated loans generally involves no more than three tranches. In principle, each tranche shall consist of at least two participating banks.	N/A
2	**Enhancing Provisions Relating to Distribution Threshold and Including Distribution Thresholds for the Co-lead Arranger Structure** ■ The commitment threshold and distribution	Article 13 When a single bank acts as the lead arranger, its commitment ratio shall not be, in principle, less than 15% of the total financing amount of the syndication, and the distribution to other syndicate members shall not be, in principle, less than 30%.	Article 11 When a single bank acts as the lead arranger, its commitment ratio shall, in principle, not be less than 15% of the total financing amount of the syndication, and the distribution to other syndicate members	Article 9 When a single bank acts as the lead arranger, its commitment ratio shall, in principle, not be less than 20% of the total financing amount of the syndication, and the distribution to other syndicate

	Major amendments and suggestions	Administrative Measures in 2024	Consultation Draft	Business Guidelines in 2011/Credit Assets Transfer Notice
	threshold when a single bank acts as the lead arranger have been adjusted to 15% and 30%, respectively, consistent with the Consultation Draft. ■ The co-lead arranger structure has been updated to include a minimum commitment requirement of 10% for each lead arranger (including co-lead and sub-lead arrangers) and the maximum commitment for each syndicated participant is capped at 70%. ■ It is emphasized that, regardless of whether there is one or multiple lead arrangers, syndicated loan transfers must not exceed the corresponding limits on commitment ratio and distribution ratio.	When a sub-lead arranger or co-lead arranger is included in the syndication, the commitment ratio of each arranger shall not be, in principle, less than 10% of the total financing amount, and the commitment ratio of each bank shall not, in principle, exceed 70%. Banks conducting loan transfer transactions in accordance with these Measures shall not violate the provisions of the preceding paragraphs.	shall, in principle, not be less than 30%. Banks conducting transfer transactions in accordance with these Measures shall not violate the provisions of the preceding paragraphs.	members shall, in principle, not be less than 50%.
3	**Amending Provisions Relating to Agent Banks** ■ Both of the	Paragraph 2, Article 15 For syndicated loans with a relatively complex structure, additional agent banks such as settlement	Paragraph 2, Article 13 For syndicated loans with a relatively complex structure, additional roles such	Paragraph 2, Article 11 For syndicated loans with a relatively complex security structure, a

	Major amendments and suggestions	Administrative Measures in 2024	Consultation Draft	Business Guidelines in 2011/Credit Assets Transfer Notice
	Business Guidelines and the Consultation Draft prohibit borrower-related institutions from serving as agent banks. However, the Administrative Measures now include a new exception: provided that the relationship is disclosed in advance and all syndicate members give written consent, the borrower's related institutions are allowed to act as agent banks. This aligns with the NFRA's regulatory intention to facilitate the syndicated loan transactions. ■ Compared with the Consultation Draft, the Administrative Measures have introduced the new role of documentation agent. Syndicates can decide whether to include this role based on actual needs and the complexity of the syndicated loan	agent, security agent, or documentation agent may be included to perform specific functions and carry out the corresponding loan management work. Each agent bank shall jointly fulfill the responsibilities of the agent bank as stipulated in these Measures and the loan agreement. Only one bank may serve as the agent bank for the same function.	as a settlement agent or security agent may be included within the syndicate, based on the responsibilities of the agent bank, to carry out the corresponding loan management work as stipulated in the syndicated loan agreement. Only one bank may serve as the agent bank for the same functions.	security agent may be designated to be responsible for implementing various guarantees, as well as the registration and management of collateral or pledged assets for the syndicated loan.
		Paragraph 1, Article 15 The agent bank is designated by the lead arranger during the syndicate formation phase or determined through negotiation among syndicate members. The syndicate agent bank must represent the interests of the syndicate, and the borrower's related institutions cannot serve as the agent bank, except where the relationship is disclosed in advance and written consent is obtained from all syndicate members.	Paragraph 1, Article 13 The agent bank is designated by the lead arranger during the syndicate formation phase or determined through negotiation among syndicate members. The syndicate agent bank must represent the interests of the syndicate, and the borrower's related institutions cannot serve as the agent bank.	Paragraph 3, Article 11 The agent bank shall be determined through negotiation among syndicate members and may be held by the lead arranger or other banks. The syndicate agent bank must represent the interests of the syndicate, and the borrower's affiliated or related institutions cannot serve as the agent bank.

	Major amendments and suggestions	Administrative Measures in 2024	Consultation Draft	Business Guidelines in 2011/Credit Assets Transfer Notice
	transaction. In practice, the documentation agent typically assumes the responsibility of hiring legal counsel on behalf of the syndicate and negotiating the syndicated loan agreement with the borrower. The inclusion of a documentation agent helps improve the operational efficiency of syndicated loans and ensures that documents and records are properly managed.			
4	**Clarifying Requirements Relating to Syndicated Loan Charges** ■ Article 40 of the Consultation Draft has clarified that the fees for syndicated loans should be included in the bank's service pricing management. Article 43 of the Administrative Measures further specifies that relevant	Article 42 When banks engage in syndicated loan business, they may charge fees for services such as syndicate arrangement, underwriting, loan commitments, and management of syndication matters. Syndication charges should be under the service pricing management of commercial banks.	Article 40 When commercial banks engage in syndicated loan business, they may charge fees for services such as syndicate arrangement, underwriting, loan commitments, and management of syndication matters. Syndication charges should be under the service pricing management of commercial banks.	Paragraph 1, Article 40 Syndication charges refer to the intermediary service fees charged by syndicate members for providing services such as syndicate arrangement, underwriting, loan commitments, and management of syndication matters on behalf of the borrower. These charges are under the management of intermediary service fees by commercial

	Major amendments and suggestions	Administrative Measures in 2024	Consultation Draft	Business Guidelines in 2011/Credit Assets Transfer Notice
	regulations, such as the *Administrative Measures for Service Pricing by Commercial Banks* shall be followed. ■ The China Banking Association issued the *Self-Regulatory Convention on Fees for Syndicated Loan Intermediary Services* on 1 October 2015, which remains in effect. The China Banking Association may revise and refine the self-regulatory rules on fees based on the Administrative Measures in the future; banks need to pay attention and timely update their internal pricing mechanisms and execution standards accordingly.			banks.
		Article 43 Charges for syndicated loans shall comply with the *Administrative Measures for Service Pricing by Commercial Banks* and other relevant regulations issued by NFRA and pricing regulatory authority. They shall be determined through negotiation between syndicate members and the borrower based on the principles of "voluntary consultation, fairness and reasonableness, openness and transparency, alignment of quality and price, and separation of interest and fees" and shall be specified in the syndicated loan agreement or fee letter. Banks shall improve their pricing mechanisms, clarify internal implementation standards, establish an internal over-limit review mechanism, and fully disclose and reveal to borrowers information regarding the composition of fees, pricing standards, and billing methods. The China Banking Association shall develop detailed industry self-regulatory rules for syndication charges in	Article 41 Charges for syndicated loans shall comply with the regulations of the State Council's banking regulatory authority and the pricing regulatory authority. They shall be determined through negotiation between syndicate members and the borrower based on the principles of "voluntary consultation, fairness and reasonableness, openness and transparency, alignment of quality and price, and separation of interest and fees" and shall be specified in the syndicated loan agreement or fee letter. Banks shall improve their pricing mechanisms, clarify internal implementation standards, establish an internal over-limit review mechanism, and fully disclose and reveal to borrowers information regarding the composition of fees, pricing standards, and billing	Paragraph 2, Article 40 Charges for syndicated loans shall be determined through negotiation between syndicate members and the borrower based on the principles of "voluntary consultation, fairness and reasonableness, and alignment of quality and price" and shall be specified in the syndicated loan agreement or fee letter.

	Major amendments and suggestions	Administrative Measures in 2024	Consultation Draft	Business Guidelines in 2011/Credit Assets Transfer Notice
		accordance with these Measures and other relevant regulations.	methods.	
5	**Refining the Right of First Refusal and Scope of Eligible Transferees in Syndicated Loan Transfers** ■ Regarding the transfer of syndicated loans, the Administrative Measures have largely maintained the changes from the Consultation Draft to the Business Guidelines, permitting partial transfer of syndicated loans and specifying that syndicated loan transfers shall be carried out adhering to the regulatory requirements for the transfer of credit assets, including the prior centralized registration. ■ Compared to the Consultation Draft, the Administrative Measures further limit the scope of transferees to banks or institutions	Article 47 A syndicated loan transfer refers to a transaction where the lender under a syndicated loan, as the transferor, transfers its syndicated loan to another bank or an institution recognized by NFRA, as the transferee, with the transferee paying the transfer consideration to the transferor.	Article 45 A syndicated loan transfer refers to a transaction where the lender under a syndicated loan, as the transferor, transfers its remaining syndicated loan balance to another lender or a third party, as the transferee, with the transferee paying the transfer price to the transferor.	Paragraph 1, Article 44 A syndicated loan transfer refers to a transaction where the lender under a syndicated loan, as the transferor, transfers its share of the syndicated loan to another lender or a third party, as the transferee, with the transferee paying the transfer price to the transferor.
		Article 49 When a transferor transfers a syndicated loan, under equal conditions, it shall give priority to transferring the loan to other syndicate members. The transferee shall comply with the provisions of these Measures, enjoy the rights stipulated in the syndicated loan agreement, and perform the obligations set forth in the syndicated loan agreement.	Article 47 When a bank transfers a syndicated loan, it shall give priority to transferring the loan to other syndicate members. If none of the syndicate members wish to accept the transfer, the transferor may transfer the loan to a bank other than the syndicate members. The transferee shall comply with the provisions of these Measures, enjoy the rights stipulated in the syndicated loan agreement, and perform the obligations set forth in the syndicated loan	*Notice from the China Banking Regulatory Commission on Further Standardizing the Transfer of Credit Assets by Banking Financial Institutions* (“**Credit Assets Transfer Notice**”) Paragraph 2, Article 5 When banking financial institutions transfer syndicated loans, the transferor shall give priority to transferring the loan in its entirety to other members of the syndication. If none of the other syndicate members are willing to accept

	Major amendments and suggestions	Administrative Measures in 2024	Consultation Draft	Business Guidelines in 2011/Credit Assets Transfer Notice
	recognized by NFRA, rather than any third party. The scope of syndicated loan transferees recognized by NFRA awaits further clarification. ■ Additionally, Article 49 of the Administrative Measures clarifies that the right of first refusal for syndicate members to assume the loan is contingent upon "equal conditions", aligning with the standard nature of such right.		agreement.	the transfer and they have no objections to the transferor transferring it to a banking financial institution other than the syndicate members, the transferor may transfer the entire loan to such banking financial institution.
6	**Removing Requirements for Banks Engaged in Syndicated Loan Businesses to Report to NFRA** ■ Although the Administrative Measures removed the "Supervision and Management" chapter from the Consultation Draft, the amendments allow NFRA to take regulatory measures or impose administrative penalties on banks	N/A	Chapter VII: Supervision and Management Paragraph 1, Article 56 Banks shall submit reports, statements, documents, and materials related to syndicated loans in accordance with the regulations of the State Council's banking regulatory authority.	N/A
		Article 7 If a bank violates the provisions of these Measures, NFRA and its local offices shall take regulatory measures or impose administrative	Article 58 If a bank violates the provisions of these Measures, the banking regulatory authority shall take	N/A

	Major amendments and suggestions	Administrative Measures in 2024	Consultation Draft	Business Guidelines in 2011/Credit Assets Transfer Notice
	that violate the Measures were maintained. ■ Compared to the Business Guidelines, the Administrative Measures have eliminated the obligation for banks involved in syndicated loan activities to regularly report to the local banking association, instead allowing the China Banking Association to collect information as needed. Consequently, the China Banking Association may establish self-regulatory rules to determine the scope and types of information it collects.	penalties according to the law.	regulatory measures or impose administrative penalties according to the law.	
		Paragraph 2, Article 8 The banking association may collect information related to syndicated loans, with specific content to be determined in consultation with member institutions.	Paragraph 2, Article 56 The China Banking Association and local banking associations may collect information related to syndicated loans, with specific content to be determined in consultation with member institutions.	Article 37 Banks that engage in syndicated loan activities shall periodically report syndicated loan-related information to the local banking association. The reported content shall include the underwriting and holding volume in the primary market, the transfer volume in the secondary market, interest rates, fee levels, loan tenors, collateral conditions, borrower credit ratings, etc.
7	**Application of Syndicated Loan Regulatory Rules to Joint Leasing Business** ■ Following the release of the Consultation Draft in March, we noted that, on 14 September 2024, NFRA introduced the *Administrative*	Article 58 Non-banking financial institutions legally established in China that engage in syndicated loan business shall be governed by these Measures. *Administrative Measures for Financial Leasing Companies* Article 64 When financial leasing companies engage in joint leasing	Article 59 Non-banking financial institutions legally established in China that engage in syndicated loan business shall be governed by these Measures.	Article 49 Non-banking financial institutions legally established to conduct syndicated loan business shall comply with these Guidelines.

	Major amendments and suggestions	Administrative Measures in 2024	Consultation Draft	Business Guidelines in 2011/Credit Assets Transfer Notice
	Measures for Financial Leasing Companies (set to take effect on November 1 this year). One of the notable changes is the specification that the regulation of joint leasing business of financial leasing companies shall refer to the regulatory rules for syndicated loan business. Therefore, relevant provisions of the Administrative Measures may apply to the joint leasing business of financial leasing companies, although the detailed application of these rules awaits further clarification from NFRA.	business with institutions qualified to engage in financing leasing activities, they shall follow the principles of "information sharing, independent approval, independent decision-making, and risk assumption". They shall independently determine financing leasing activities, enjoy the proportionate share of the leased assets and other corresponding rights according to the actual capital contribution ratio or as agreed, and perform corresponding obligations. The relevant business shall be conducted with reference to the syndicated loan business regulatory rules of NFRA.		

3. Navigating New Network Data Regulation: Highlights and Actions

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Overview

On 30 September 2024, China's State Council announced the finalized *Regulation for the Administration of Network Data Security* (《网络数据安全管理条例》, "**Network Data Regulation**"), which will take effect on 1 January 2025. This regulation provides a framework for personal information (**PI**) protection, cross-border data transfers, network data security management and the responsibilities of internet platform providers.

In this article, we draw on our experience in advising foreign-funded banks on PI protection policies and cross-border data transfers, to outline the key provisions of the regulations, their implications for the operations of these banks and their clients, and to provide guidance on how to align with the new regulatory requirements.

PI protection

From the PI protection perspective, while closely aligned with the *Personal Information Protection Law* ("**PIPL**"), the Network Data Regulation has provided additional requirements for implementation of the PIPL. Please refer to below the key new requirements and implications for foreign-funded banks:

No.	New requirements under the new Network Data Regulation	Implications for foreign-funded banks
1	*Retention and disposal:* A privacy statement shall include the duration for which PI is stored (where it is difficult to specify the retention period, the method for determining the retention period shall be specified) and the procedures for PI processing after the retention period expires.	Based on our observation, most foreign-funded banks have published their privacy statements (however so named) under Article 17 of the PIPL on their official websites for processing PI. Banks will need to revisit their privacy policies, and if not already included, to include the method for determining the PI retention period if it is difficult to specify the retention period, and the procedures for PI processing after the retention period expires.
2	*User rights:* A privacy statement shall include the information on how individuals can review, copy, transfer, correct, supplement, delete, restrict processing, cancel accounts, or withdraw consent regarding their PI.	Banks should revisit their privacy policies, and if not already included, to include all these individual's rights in the bank's privacy statement.
3	*Conditions to PI transfer:* When individuals request the transfer of their PI, a data processor should facilitate access for other designated data processors	Banks should incorporate these conditions to PI transfer in the bank's privacy statement and ensure these are properly complied with in the course of

No.	New requirements under the new Network Data Regulation	Implications for foreign-funded banks
	provided that: ■ the individual's identity can be verified; ■ the information to be transferred has been collected based on the individual's consent or contract; ■ the proposed PI transfer is technically feasible; and ■ the proposed PI transfer does not infringe on the rights and interests of others. If the PI transfer request is deemed excessive, the data processor may charge a fee on cost-incurred basis.	banks' business.
4	*Deletion:* With respect to PI collected for which consent has not been obtained, a data processor must delete or anonymize it. Where the mandatory retention period for such PI has not expired, or it is technically difficult to delete or anonymize such PI, the data processor shall cease to process such PI other than storage or taking security measures.	Most foreign-funded banks may not use any automated collection technologies, thus it should be less of a concern for foreign-funded banks to collect any PI before relevant consent is obtained. That said, banks can still include this scenario where they have any chance to collect PI before obtaining consent through corporate clients (including by means of automated collection technologies if applicable in the future) in the bank's privacy statement for completeness. Banks should also ensure compliance with such requirements in the course of their business.
5	*Restrictions:* When processing is based on consent, a data processor shall not: ■ collect PI beyond what is explicitly stated and obtain consent through misleading practices, fraud or coercion; and ■ repeatedly seek consent from individuals who have previously declined.	As most foreign-funded banks do not engage in personal banking business but focus on corporate clients, this new requirement should not have material impact over foreign-funded banks. For prudent purpose, banks may revisit their compliance procedures to ensure these new restrictions are properly complied with. No action towards the privacy statement is required.
6	*Disclosure by way of lists:* When a data processor informs individuals of the purposes, methods, types of PI collected or provided to other data processors by it, as well as information about the PI recipients, it shall specify such information by way of format such	It is advisable for foreign-funded banks to prepare two lists if not already have.

No.	New requirements under the new Network Data Regulation	Implications for foreign-funded banks
	as lists. It remains to be clarified whether there will be other permitted formats, but the current prevailing understanding is that regulators prefer data processors to prepare two lists, namely the list of collected PI and the list of PI provided to other data processors.	

Important data

The Network Data Regulation (Chapter 4) integrates existing definitions and obligations (risk monitoring and assessment etc.) of important data and its processors under the *Data Security Law* (《数据安全法》, "**DSL**") and data export rules but remains generic. It's still the case that banks must wait for PBOC and NFRA's classification and catalogue of important data to be applied in the banking sector. That said, we expect most foreign-funded banks are unlikely classified and identified to handle any important data, so no action is required until the banking regulator notifies otherwise.

No.	New requirements under the new Network Data Regulation	Implications for foreign-funded banks
1	*PI threshold:* A data processor handling PI of more than 10 million individuals shall comply with some of the requirements for important data processors.	Most foreign-funded banks should not reach such threshold so no action is required.

Cross-border transfers

The Network Data Regulation (Chapter 5) integrates existing data export requirements and only provides an additional exemption and provides clarity on an existing exemption in terms of contract with individuals:

No.	New requirements under the new Network Data Regulation	Implications for foreign-funded banks
1	*Statutory duties:* where it is necessary for a data processor to provide PI overseas to perform statutory duties or obligations, it will be exempted from SCC signing and filing.	Foreign-funded banks will be able to rely on this exemption when transferring PI overseas to perform bank's statutory duties or obligations. However, the scope of such statutory duties or obligations remains further clarification by regulators.
2	*Contract with individuals:* where it is necessary for a data processor to provide PI overseas to enter into or perform a contract with individuals, it will be exempted from SCC signing and filing. Under Article 5 of the *Provisions on Promoting and Regulating Cross-border Data Flows* (《促进和规范数据跨境流动规定》), such exemption applies to eight	This would be irrelevant as long as foreign-funded banks do not enter into or perform any contract with individuals. Just in case there is any in the future, PI transferred overseas to enter into or perform any type of contracts with individuals to which the PI transferred overseas relates would be exempted from

No.	New requirements under the new Network Data Regulation	Implications for foreign-funded banks
	types of contracts specified thereunder, namely contracts for cross-border shopping, cross-border delivery, cross-border remittance, cross-border payment, cross-border account opening, air ticket and hotel reservation, visa handling and examination services, but the Network Data Regulation has removed such restriction and expanded the exemption to be applicable to any type of contract.	SCC signing or CAC filing.

Data security measures

The Network Data Regulation (Chapter 2) provides high-level data security measures as follows. We trust most of the foreign-funded banks have duly addressed most of these measures under the cross border data transfer mechanism as they conform to those having been required by the DSL and the *Guidelines for the Data Management of Banking Financial Institutions* (《银行业金融机构数据治理指引》, "**Banking Data Management Guidelines**").

No.	New requirements under the new Network Data Regulation	Implications for foreign-funded banks
1	*Protection:* A data processor shall implement comprehensive protection measures, including encryption, data backups, access controls, security authentication, and other technical safeguards to prevent data from being tampered with, destroyed, disclosed, or illegally accessed and used.	No particular action is required for most foreign-funded banks as same have been required under the DSL and the Banking Data Management Guidelines.
2	*Emergency response:* A data processor shall develop and improve emergency response plans for handling data security incidents. Where security incidents damage the rights or interests of individuals or organizations, the data processor shall notify the affected parties, providing details on the incident, the risks involved, and the corrective actions taken. The notification above can be made through various means, such as phone, text, email, or public announcements, except in cases where legal exceptions apply.	Same as above.
3	*Retention:* Records of provision or entrustment processing of PI and important data must be retained for a minimum of three (3) years.	No action is required as same has been required under the PIPL and we expect it is unlikely that most foreign-funded banks will process any important data unless otherwise notified by banking regulator.

Outlook

As foreign-funded banks operating in China navigate the evolving regulatory landscape, especially with the heightened focus on PI protection and cross-border data transfers, proactive compliance is crucial. The Network Data Regulation places significant emphasis on strict adherence, with severe penalties for non-compliance. Foreign-funded banks should revisit their privacy statements and internal procedures from time to time. We will continue to closely monitor any material developments in this regard and keep you updated.

Important Announcement

This Newsletter has been prepared for clients and professional associates of Han Kun Law Offices. Whilst every effort has been made to ensure accuracy, no responsibility can be accepted for errors and omissions, however caused. The information contained in this publication should not be relied on as legal advice and should not be regarded as a substitute for detailed advice in individual cases.

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