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Han Kun Law Offices

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Legal Updates

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1. Highlights on New Draft Rules of Drug Administration

Authors: Aaron GU | Min ZHU | Ying LI | Pengfei YOU | Ruohong YAO

On May 9, 2022, National Medical Products Administration (NMPA) issued for public comments a draft revision (the "**Draft Revision**") to the *Regulations for the Implementation of the Drug Administration Law of the People's Republic of China* (the "**Regulations**"). The public comment period ends on June 6, 2022.

The Regulations were last revised and became effective in March 2019. However, the Drug Administration Law of the PRC (the "**Drug Administration Law**") was substantially revised about six months later in August 2019, officially adopting the marketing authorization holder ("**MAH**") system that had been piloted for many years in certain provinces and cities. The revised Drug Administration Law has come into effect for more than two years, and the public is eagerly looking forward to the revision of the corresponding implementing regulations. Since the implementation of the MAH system, the NMPA and other authorities have formulated and updated numerous supplementary rules in addition to the Drug Administration Law. These rules are scattered in various separate regulations, notices, announcements, and guiding principles. Per its content, the Draft Revision would add a considerable number of provisions that have not been explained or clarified in the Drug Administration Law and also integrate the scattered rules and principles found in various normative documents of different levels.

Here are our summary and commentary on the key contents of the Draft Revision.

Drug development

I. Requirements for domestic and foreign research and development activities

The Draft Revision stipulates that drug research and development activities for the purpose of marketing drugs in China, whether undertaken inside or outside China, must comply with the requirements of Chinese laws, regulations, rules, standards, and norms. This article would apply the Regulations to research and development activities undertaken overseas, which reflects an important method for the NMPA to ensure drug safety and strengthen supervision since drug development, manufacture, and distribution activities have become more and more globalized.

II. Establishment of technical specification system

China joined the International Council for Harmonization of Technology for Registration of Pharmaceuticals for Human Use (ICH) in 2017 and became a member of its management committee in 2018. China has since gradually transformed and implemented international advanced technical standards and guidelines and has actively participated in rulemaking. The Draft Revision once again specifies that China will further adapt to international rules. The NMPA will formulate relevant technical specifications and guiding principles for drug development in China and with reference to internationally accepted technical requirements.

III. Non-clinical research

In 2007, the predecessor to the NMPA promulgated the *Measures for Administration of the Certification of Quality Management Standards for Drug Nonclinical Research*, which has not since been updated. The Regulations do not currently mention this certification, but only require research institutions to comply with the corresponding quality management practices for non-clinical drug research (GLP). The Draft Revision expressly includes the GLP certification requirements for the first time and clarifies that certifications are valid for five years. The requirement on GLP certification would therefore be upgraded to be included in the Draft Revision, a State Council administrative regulation, which demonstrates that the authorities attach great importance to GLP certification and relevant supervision activities.

IV. Change of sponsor

The Draft Revision clarifies that a sponsor can change during drug clinical trials and stipulates that the change should be approved by the NMPA (if necessary, the NMPA will re-issue the drug clinical trial approval notice). The sponsor is equivalent to the status of the MAH in the clinical trial stage, and accordingly, the changed sponsor assumes the corresponding obligations and responsibilities for the drug clinical trials. This also confirms the practice of changing sponsors in the current administrative guidelines and guidelines at the level of the NMPA Center for Drug Evaluation (CDE).

Application for drug marketing authorization

I. Drug marketing authorization application (new drug application)

The Draft Revision clarifies for the first time in administrative regulations that a drug marketing authorization applicant (an "**NDA applicant**") and a drug clinical trial sponsor (an "**IND sponsor**") can be different entities. The NDA applicant assumes the obligations and responsibilities related to the marketing authorization application.

The transferability of research results and marketing rights is the core of the MAH system. In addition to determining who is responsible for the entire life cycle of drugs, another primary purpose of the MAH system is to provide liquidity for drug-related rights and interests, thereby providing flexibility for business arrangements for enterprises and enhancing the value of such rights as assets. To a certain extent, this also provides new approaches for business arrangements for companies who have established VIEs for business activities within negative list.

Notably, the Draft Revision stipulates that at the drug registration application stage, the applicant and trial drug manufacture site should both be in China or overseas. However, it does not expressly prohibit the transfer of the applicant's location and that of the drug trial manufacture from overseas to China or vice versa.

II. Encourage innovation

The Draft Revision supports clinical value-oriented drug innovation. In November 2021, CDE released the *Guidelines for Value-oriented Clinical Research and Development of Anticancer Drugs*,

which indicate that the development of new drugs should take providing patients with better treatment options as its ultimate goal (more effective, safer or more convenient). Encouraging first-in-class or best-in-class research, meanwhile, this document is seen as a powerful squeeze on the cluttered R&D "bubble". As a result, the developing prospects for numbers related companies were no longer clear and the financing and marketing plans of some were affected. Although the influences of this policy was controversial among the industry, it indicated the CDE's purpose to alleviate the homogenized competition in drug research and development and also showed CDE's determination and means. Judging from the inclusion of phrase "clinical value-oriented" in the Draft Revision, authorities may continue to, by adopting guiding principles or through other means in the future, encourage and promote higher standard innovation in the field of innovative drugs (not limited to anti-tumor drugs), emphasize avoiding the development of drugs with limited clinical value ("me worse"), and to guide companies to prudently choose R&D targets.

In addition, the Draft Revision also clearly provides that drug innovation should be supported in terms of scientific and technological project establishment, financing, credit, bidding procurement, price payment, and medical insurance. In view of the significant regulatory reforms and market fluctuations experienced by the pharmaceutical industry in recent years, there is a certain gap between the industry's expectations and the reality of the overall investment and financing environment, capital market performance, centralized procurement bidding, and national negotiations. By reaffirming this supportive position, the Draft Revision also provides a brighter perspective for the effective implementation of follow-up supporting rules to provide practical and powerful legislative and policy support for drug innovation.

III. Accelerating marketing channels

The Draft Revision references systems stipulated in the Drug Administration Law for encouraging drug R&D innovation and shortening the process of drug R&D and review, including those for breakthrough therapeutic drugs, conditional approval for marketing, priority review and approval, and special approvals. The Draft Revision does not provide for extensive details on these matters because the *Measures for Administration of Drug Registration,* promulgated in 2020, already provides sufficient rules and are accompanied by relevant implementation guidelines to support related policies concerning accelerated marketing channels.

IV. Dispute resolution mechanism

The Draft Revision proposes that the NMPA would establish a drug registration objection resolution mechanism to properly handle applicants' objections to the technical review conclusions in the registration. This is not the first reference to such a system. In August 2020, the NMPA issued the *Procedures for Resolving Objections to Drug Registration Review Conclusions (for Trial Implementation)*. Pursuant to these procedures, objection resolution refers to "where, upon completion of the comprehensive review and the conclusion is not to approve, following the CDE informing the applicant, the applicant raises an objection and the CDE organizes a comprehensive assessment or expert advisory committee demonstration to form the final technical review conclusion."

V. R&D of chemical generic drugs

The Draft Revision specifies that the NMPA is to select and publish the catalogue of generic drug reference preparations; that the R&D of chemical generic drugs refers to relevant technical guidelines to select reference preparations or reference drugs; and the NMPA is to establish a drug patent information registration platform. The drug registration applicant and the MAH would register the relevant drug patent information according to the regulations and explain the relevant drug patents involved and their ownership status.

This catalogue of generic drug reference preparation and drug patent information registration platform are combined together as a counterpart to the Orange Book in the United States. The Orange Book is not only the basis for chemical generic drug applicants to provide a patent ownership status statement, but also the patent drug MAH's reliance for its intellectual property and regulatory rights protection.

China's Orange Book is not new. The *Catalogue of Marketed Drugs in China* was formulated as early as the end of 2017. The Draft Revision merely reconfirms this system and links it with other drug regulatory laws and regulations. It is believed that if this part of the Draft Revision is adopted, the Orange Book system will continue to develop and mature in the future.

Data exclusivity / marketing exclusivity

As early as 2018, the NMPA issued the *Implementation Measures for Drug Trial Data Protection (for Interim Implementation) (Draft for Comment)*, but it has not been formally promulgated. The Draft Revision directly specifies the relevant data exclusivity rules in the absence of the draft measures. To compare, the draft measures provide data exclusivity periods for drugs approved for marketing in China: a six-year data protection period for innovative drugs, orphan drugs, and pediatric drugs; and a 12-year period for innovative therapeutic biological products.

By contrast, the Draft Revision does not distinguish between innovative chemical drugs or innovative therapeutic biological products and would uniformly grant all applicable drugs a data exclusivity period of six years from the date when an MAH obtains the drug registration certificate. Orphan drugs, pediatric drugs and first-approved generic drugs would be given marketing exclusivity periods of 7 years, 12 months, and 12 months respectively (which all differ from the draft measures).

Intellectual property protection of medicines

I. Patent linkage system

Although the Drug Administration Law (2019) does not address the drug patent linkage system, China has gradually adopted a series of related provisions firstly since the Patent Law update in 2020, such as the *Implementation Measures for Early Resolution Mechanism of Drug Patent Disputes (for Trial Implementation)*, the *Measures for Administrative Adjudication of Drug Patent Disputes under the Early Resolution Mechanism*, *Provisions of the Supreme People's Court on Several Issues concerning the Application of Law in the Trial of Civil Cases of Patent Disputes Related to Drugs Applied for*

Registration, etc. The Draft Revision also specifies patent linkage principles so that a comprehensive and holistic "China Patent Linkage System" may be established, in conjunction with the Patent Law and relevant judicial interpretations.

In practice, the first administrative and judicial decisions on the drug patent linkage system are also recently open to public-channel access. As part of the reform of innovative drug regulation, we look forward to more "drug patent linkage" practices in the industry in the future.

II. Compulsory license of drug patents

Compared to the Patent Law, the Draft Revision puts forward more specific requirements for compulsory license of drug patents. For instance, out of public health purposes or during a national emergency, the National Health Commission can purpose a compulsory patent license according to the needs of disease diagnosis and treatment. Enterprises that meet the corresponding conditions could take the initiative to apply to the China Intellectual Property Office then obtain and implement the compulsory license of the corresponding patents in accordance with the Patent Law. At the same time, the Draft Revision provides that drugs granted compulsory patent licenses will be given priority review and approval according to the regulations.

Drug marketing authorization holders (MAH)

I. All lifecycle quality assurance system

Per the MAH system established in the revised Drug Administration Law, MAHs are responsible for the safety, efficacy, and quality of their products throughout the product lifecycle, including non-clinical research, clinical trials, manufacture and distribution, and post-marketing monitoring. Correspondingly, the Draft Revision stipulates that not only MAHs (including vaccine MAHs) should establish a comprehensive quality assurance system covering all steps of drug development, clinical trials, manufacture, distribution, and use. In addition to MAHs, certain other parties involved in drug activities, including clinical trial sponsors, medical institutions, and drug manufacturers, also need to establish a quality management assurance system.

II. MAH's manufacturing license requirements

The Draft Revision again clarifies the specific qualification requirements for MAHs for drug manufacturing licenses mentioned in the *Measures for the Supervision and Administration of Drug Manufacturing*. That is, when an MAH entrusts the manufacture of drugs, it must also obtain a drug manufacturing license, but it can exempt some qualification requirements for actual contract manufacturing enterprises, such as site and facilities and equipment.

III. Appointment and change of domestic agent

The Draft Revision proposes two potential schemes for regulating overseas MAHs appointing domestic agents. Under the second scheme, overseas MAHs can appoint a domestic agent while drug marketing authorization is approved. That is, it may be possible to change the domestic agent right before marketing. This would give the MAH more flexibility in picking an onshore agent. At the same

time, such domestic agent would also need to establish a quality assurance system for all lifecycle of the products and be equipped with corresponding management department and professional and technical personnel.

IV. Post-marketing MAH obligations

The Draft Revision emphasizes that MAHs must undertake the obligations for drug traceability, pharmacovigilance, management responsibility for entrusted activities, risk management plans and post-marketing research, and management of filing and reporting matters after the drug is marketed. Each of the obligations is aimed at clarifying that MAHs are responsible for the safety, efficacy, and quality of their drugs post-marketing and continuously fulfill their responsibilities for post-marketing evaluation. According to the results of post-marketing evaluation, MAHs would be required to take measures such as revising drug inserts, improving quality standards, improving process prescriptions, suspending manufacturing and sales, recalling drugs, and canceling drug approval documents.

V. Transfer of marketing authorization for multi-specific drugs

The Draft Revision stipulates that when transferring the marketing authorization of a multi-specification drug, a change to the same variety with different specifications needs to be completed once and the manufacture site, prescription, manufacture process, and quality standards of the drug need to be changed at the same time.

Drug manufacturing

Most of the Draft Revision related to the issue of drug manufacturing has been stipulated in the *Measures for the Supervision and Administration of Drug Manufacturing*, which will not be mentioned in this article. However, the Draft Revision also answers many questions that are not clear in practice.

I. Commercial-scale batch drug sales

The Draft Revision clarifies that, after obtaining the drug registration certificate, commercial-scale batches of drugs whose quality standards and manufacture processes are consistent with the registration certificate can also be marketed if they meet the product release requirements. This kind of arrangement has not been clearly stipulated in the previous laws and regulations and can only to be permitted by negotiating with the regulatory authorities in current practice. Such clarification in the Draft Revision is a definite regulatory development, which not only effectively solves the problem of setting reasonable distinction between manufacturing release and marketing release in terms of regulatory logic, but also eliminates concerns on the unclear regulatory rules when pharmaceutical companies making specific commercial arrangements for drug manufacturing and marketing.

II. Overseas manufacturing sites

The *Measures for the Supervision and Administration of Drug Manufacturing* (2020) for the first time specified that they apply to the manufacturing, supervision and management of all drugs marketed in China. The Draft Revision would further specify that if the drug manufacturing site is overseas, its manufacturing activities must comply with the relevant requirements of Chinese laws, regulations, rules,

standards, and norms. With the upgrade of China's drug R&D level, many more drugs registered in China will extend the supply chain overseas in the future. This provision indicates that the NMPA may further strengthen the supervision and inspection of overseas manufacture activities in the future.

III. Contract vaccine manufacturing

The Draft Revision specifies circumstances regarding the contract manufacturing of vaccines. The Vaccine Administration Law stipulates that vaccine MAHs should have the vaccine manufacturing capacity and they must obtain NMPA approval if it becomes necessary to entrust third parties to manufacture the vaccines due to lack of capacity. The Draft Revision details the specific circumstances in which contract manufacturing can be approved. At the same time, it emphasizes once again that, in addition to the corresponding responsibilities of the entrusting party as the MAH, contract vaccine manufacturers must comply with relevant regulations to ensure the quality of vaccines.

IV. Staged manufacturing

For the first time, the Draft Revision stipulates the content of drug manufacturing stages, emphasizing that MAHs should establish a unified quality assurance system for the entire drug manufacturing process and all manufacture locations. The Draft Revision also clarifies that the conditions for applying staged manufacturing are limited to: innovative drugs that have special requirements for manufacturing technology, facilities and equipment, or drugs that are urgently needed in clinical practice, and need to be approved by NMPA.

Drug distribution

I. MAH network sales management

The Draft Revision stipulates that the subjects engaged in online drug sales activities include MAHs and drug distributors. Drugs to be sold online must either belong to the MAH or within the scope of drugs allowed to be distributed by the distributor. The Drug Administration Law stipulates that an MAH who engages in drug retail activities must obtain a drug distribution license. In view of hierarchy of laws and regulations, the Draft Revision cannot contravene provisions of the Drug Administration Law. Therefore, MAHs engaged in online drug retail would still need to obtain a drug distribution license and online sales activities that can be carried out without obtaining a drug distribution license are limited to drug wholesale. However, as explained above, it appears that the NMPA does not emphasize that MAHs may engage in online drug wholesale without the drug distribution license, so the NMPA needs to further explain this issue. At the same time, the Draft Revision clarifies that drug retail enterprises can sell prescription drugs through the Internet, but it is also notable that China imposes drugs under special administration or with high risk are not allowed to retail online. Corresponding catalogues will be formulated.

II. Emergency management requirements

Possibly due to actual needs against the Covid-19 pandemic, the Draft Revision contains emergency measures for drug retailers. Emergency management includes measures such as removing products from shelves and suspending sales, etc. Circumstances where emergency management is

applicable include public health emergencies and other emergencies that seriously threaten public health.

III. Prohibition on drug distribution outside manufacturing and business premises

Notably, the Draft Revision clearly prohibits MAHs and drug distributors from selling drugs in exhibitions, expositions, trade fairs, order fairs, promotion conferences, etc. outside manufacturing and business premises; this prohibition does not distinguish between prescription and over-the-counter drugs.

IV. Individuals carrying a small quantities of drugs for personal use

The Drug Administration Law removes the manufacture and import of unapproved drugs from the definition of counterfeit drugs. When importing a small quantity of drugs that have been legally marketed overseas, the regulatory authorities can impose lighter or mitigated penalties or exempt the penalties. The Draft Revision further loosens the requirements, frankly stipulating that individuals who carry or deliver a small quantity of drugs for personal use into China should declare in accordance with the Customs' administrative regulations. This article can be understood as an acknowledgement of the legality of individuals carrying a small quantities of unapproved drugs for their own use. At the same time, the Draft Revision also emphasizes that drugs must not be sold in China after entering the country (including disguised sales).

Pharmacy management in medical institutions

The Draft Revision would provide a separate chapter for the pharmaceutical management of medical institutions, indicating the NMPA intends to raise the supervision of medical institutions to a new level. The following four aspects are worth noting:

I. Pharmaceutical quality management system and requirements for medical institutions

The Draft Revision would require that medical institutions establish and improve the drug quality management system; improve the quality management system for the purchase, acceptance, storage, maintenance, and use of drugs; clarify the position responsibilities of personnel in each aspect; and set up special departments or designated personnel to be responsible for drug quality management. The standalone proposal for "Medical Institutions Drug Quality Management System and Requirements" not only to fills in the vague provision ("…shall strengthen drug management in accordance with drug management laws and regulations") in the *Regulations on Administration of Medical Institutions*, but also to addresses the widespread issue of drug quality in medical institutions. It is likely that medical institutions would be given responsibilities similar to MAHs.

II. Pharmacovigilance system of medical institutions

The Draft Revision proposes a "Pharmacovigilance System for Medical Institutions", which aims to improve and supplement the *Pharmacovigilance Quality Management Standards* because the latter only regulates MAH and IND sponsors, leaving a gap in the system. Pharmacovigilance in medical institutions has a wide range of applications and is not limited to specific activity stages. Medical institutions should report and communicate as long as they find adverse drug reactions and other

harmful drug use-related reactions in the entire drug use process. Given that medical institutions have the function of diagnosis and treatment, when they discover a cluster of adverse drug reactions, they need to take emergency measures such as actively treating patients, conducting clinical investigations, and suspending drug use.

III. Compassionate use

Compared with the revised Drug Administration Law regarding "compassionate drug use", the Draft Revision adds the principle of "voluntary request by patients". Therefore, the principle requires that "the physician believes that the benefits may outweigh the risks based on the medical analysis of the patient's condition and the patient cannot participate in the clinical trial of the drug" and "make a recommendation (the patient decides on his own)." At the same time, the requirements for physicians have also been further improved, requiring physicians to have experience or be trained in using experimental drugs, which further mitigates unnecessary risks in compassionate medication.

IV. Emergency drug use

The Draft Revision contains new provisions on the emergency drug use, which refers to where no effective treatment exists in the event of a major public health emergency or other emergency that seriously threatens public health, the National Health Commission will propose an emergency according to the needs of medical treatment. The NMPA would then organize and demonstrate, with the approval of the State Council, the drugs under clinical trials that can be used urgently within a certain scope and within a certain period of time, or the use of drugs that are not specified in the drug instructions can be used for treatment. As the most significant public health event all over the world, the Covid-19 Pandemic has also profoundly affected the development of the medical legal system. However, it can still be seen that the procedures stipulated in this article are relatively strict ("the drug regulatory department of the State Council organizes the demonstration, with the approval of the State Council"), and the scope is relatively limited ("the drugs that are undergoing clinical trials, or the use of drugs that are not specified in the drug instructions").

Supervision and management

This part of the Draft Revision mainly aims to clarify the administration responsibilities of the drug regulatory authorities at all levels for review, approval, inspection, and verification, and provides guidance for the regulatory authorities to perform their duties.

I. Extended inspection

Notably, the Draft Revision clarifies that when the drug regulatory department conducts extended inspections, the inspected units and individuals should provide true, valid, and complete relevant materials and truthfully answer inquiries. If the refusal or non-cooperation makes it impossible to complete the inspection work and cannot prove that the manufacture and distribution activities meet the statutory requirements, it will be directly deemed as non-compliance with the regulations and normative requirements. This article stipulates the cooperation obligations of relevant inspected units and individuals, and the legal consequences for failing to cooperate that result in the failure to complete

inspection activities from the perspective of allocating the burden of proof.

II. Restrictions on leaving the country

The Draft Revision adds a post-supervision measures, stipulating that, for major illegal acts and major safety hazards, the drug supervision and administration department will restrict the legal representative, main persons in charge, and persons directly responsible in charge of the relevant unit suspected of violating the law, and other directly responsible persons from exiting China.

Penalties

The Draft Revision updates the rules on administrative penalties, making itself consistent with the newly revised Law of the PRC on Administrative Penalty (2021) (the "**Administrative Penalty Law**"). Three points are worth noting:

I. Mitigation and impunity

Drug legislation has repeatedly emphasized the "four strictests" in terms of regulatory standards, but the Draft Revision has some highlights in the legal liability chapter, which also reflect the spirit of scientific supervision. For example, in response to the penalties for non-compliance with quality management standards stipulated in Article 126 of the Drug Administration Law, Article 161 of the Draft Revision specifies that the MAH or other units do not meet the general project requirements, key projects and key project requirements or basic requirements in the relevant quality management standards during the development, manufacturing and distribution activities. The provisions of Article 126 of the "Drug Administration Law" should effectively impose corresponding rules such as punishment.

In addition, Article 168 (Waiver of Penalty) stipulates that no administrative penalty will be imposed if:

- the illegal act is minor and corrected in a timely manner, and no harmful consequences are caused;
- First-time offenders whose violations cause only minor harmful consequences and are rectified in a timely manner;
- Where the parties have sufficient evidence to prove that they have fully performed their duties, that there is no subjective fault, and that no harmful consequences have been caused or that the harmful consequences are significantly minor.

The above-mentioned law enforcement provisions are in line with the conditions and principles for circumstance of non-punishment established by the Administrative Penalty Law, effective July 15, 2021, and reflects the basic "penalty proportioned with violation" principle in administrative supervision.

II. Determination of illegal gains

The current Regulations do not define or provide a method for calculating illegal gains. The Draft Revision clarifies that illegal income includes all income obtained from the illegal manufacturing, illegal sale of drugs, or the illegal provision of services, and only the taxes and social insurance funds that the parties have paid can be deducted. It is notable that the provisions on illegal gains in the Draft

Revision are different from those in the Administrative Penalty Law, which stipulates that "illegal gains refer to the gains obtained from a violation of law", and clearly increases the amount of illegal gains that can be obtained.

III. "Look-through rule"

The Draft Revision clarifies that the primary responsible person stipulated in the Drug Administration Law refers to the person who is fully responsible for the organization and operation management of the enterprise and can actually control the company. Furthermore, the Draft Revision provides for a "look-through rule". If the actual controller of an enterprise is a legal entity, the primary responsible person refers to the principal natural person in charge of the actual controller. Compared with "piercing the corporate veil", this gives the law enforcement greater discretion, and personal liability can be imposed on the principal nature person in charge of the company's actual controlling shareholder. If this provision is adopted, companies should take a more prudent attitude on the arrangement of MAH and the individual liabilities of the primary responsible persons throughout the entire drug lifecycle.

2. Specifications for Certification of Personal Information Export

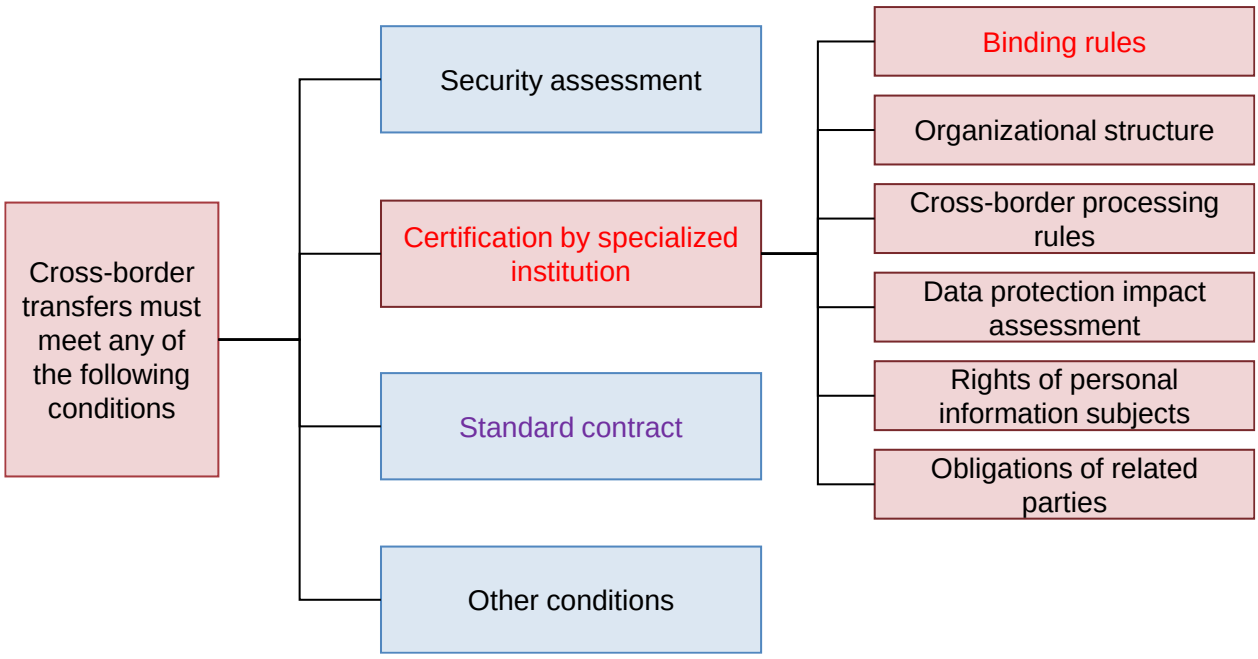
Authors: Kevin DUAN | Kemeng CAI | Minzhe HU

On April 29, 2022, the National Information Security Standardization Technical Committee issued for public comments a draft of the *Technical Specifications for the Certification of Personal Information Cross-border Processing* (the "**Draft Specifications**"). As the first official draft specifications on personal information protection certifications, the Draft Specifications are intended to refine and partially implement Article 38 of the Personal Information Protection Law (the "**PIPL**"), thus facilitating cross-border transfers of personal information ("**PI**"). In this article, we briefly analyze the key aspects of the Draft Specifications from the perspective of companies that transfer PI cross-border.

PIPL certifications: one of the mechanisms for PI cross-border transfers

Article 38 of the PIPL stipulates several alternative mechanisms for PI cross-border transfers that may be relied upon in lieu of a government security assessment. Among these alternatives is Article 38, para. 1, clause 2, which provides the guiding principle that PI handlers may obtain a "personal information protection certification" ("**PIPC**" or the "**certification**").

Notably, the PIPC cannot substitute for government security assessments that are mandatory for PI cross-border transfers by critical information infrastructure operators and PI handlers that process a specified quantity of PI which is to be determined by the Cyberspace Administration of China ("**CAC**"). Aside from these circumstances, the PIPC mechanism described in the Draft Specifications may be an option for PI cross-border transfers.



Scope of application: offshore data handlers and cross-border data transfers among multinational group companies

The Draft Specifications apply to: (1) cross-border transfers of PI in the context of cross-border data transfers to entities of an international organization or multinational group company; and (2) processing of PI of domestic natural persons by overseas handlers, if conditions are met as set out in PIPL Article 3, para. 2 (e.g., targeting of domestic natural persons).

Regarding cross-border processing of PI in multinational group companies, the Draft Specifications are similar to the Binding Corporate Rules under GDPR Article 47. The PRC entity would apply for the certification and bear legal liability. To further illustrate, the Draft Specifications would require that the overseas handler designate a person in charge and a dedicated party within China to handle affairs relating to PI protection. In practice, a company's domestic affiliate often assumes this role.

The Draft Specifications may also apply to overseas PI handlers, provided any of the conditions are met as set forth in PIPL Article 3, para. 2. Such exterritorial application raises another question—if overseas handlers directly collect PI from domestic PI subjects, do those activities constitute the "cross-border provision of PI" for purposes of PIPL Chapter III? Some professionals hold the opinion that, in light of GDPR, such direct collection does not constitute the cross-border provision of PI and that Chapter III should thus not apply. However, the Draft Specifications seemingly contradict this viewpoint.

PIPC applicants: domestic entities

According to the Draft Specifications, the following applicants are responsible for obtaining the certification:

Situation	PIPC Applicant
Cross-border transfer of PI in a group of multinational companies	Domestic affiliate
Cross-border transfer of PI of domestic natural persons by overseas handlers, which meets the conditions set in PIPL Article 3, para. 2.	Designated representative or dedicated entity established within China

According to the Draft Specifications, only PI handler's entities in China should apply for the certification, which differs from the requirements of *Regulations on Administration of Network Data Security (Draft for Comments)*, released by the CAC in November 2021. The draft regulations would require that both the domestic exporter and the overseas importer obtain a PIPC from a specialized institution in accordance with CAC rules. We await further clarification as to whether and how an overseas receiver will participate in the certification process.

Certification body: not yet specified

The PIPL stipulates only that the certification must be conducted by a specialized institution. The Draft Specifications do not specify detailed qualifications for eligible institutions. However, such certification institutions should monitor whether the relevant parties comply with their undertakings made as part of the certification.

Binding rules: binding and enforceable documents must be signed

Pursuant to the Draft Specifications, relevant parties involved in cross-border transfer of PI must sign binding and enforceable documents, in order to provide sufficient safeguards for PI subjects to exercise their rights. However, this document is not necessarily a standard contract. In fact, as prescribed in Article 38 of the PIPL, a standard contract is an alternative to PIPC. Therefore, we consider this document could also be a data processing agreement or commitment letter. The document is required to include following points:

- The relevant parties involved in cross-border processing of PI;
- The purpose of data cross-border processing and the scope and type of data transferred;
- The measures to be taken for protecting the rights of PI subjects;
- All related parties covenant to comply with unified rules of personal information processing and ensure that the level of personal data protection is be no less than that afforded by Chinese laws and regulations;
- All relevant parties covenant to accept supervision of the certification body;
- All relevant parties covenant to accept the jurisdiction of Chinese laws and regulations related to PI protection;
- The institution which bears legal liability in China;
- Other obligations prescribed in Chinese laws and regulations.

Conditions for certification: multidimensional rules

Besides binding rules, under the Draft Specifications, PI handlers must also meet other certification requirements, including organizational structure, cross-border processing rules, data protection impact assessment, and rights of PI subjects.

Requirements	Main Points
Organizational structure	Data protection officer: (1) Required to be designated by all relevant parties. (2) Has expert knowledge or practices of data protection. (3) Required to be a member of management. (4) Mainly responsible for the following work: ■ Specify main purposes, basic requirements, working missions and protective measures. ■ Provide personnel, material resources and financial support and ensure availability. ■ Provide guidance and support for relevant personnel and ensure that the goal can be achieved. ■ Report working status to the person in charge and continuously make improvements.

Requirements	Main Points
	Data protection institutions: (1) Shall be established by all related parties. (2) Perform data protection duties. (3) Prevent unauthorized access, leakage, tampering, and damage of PI. (4) Mainly responsible for following work: ■ Draw up a protection plan approved by all relevant parties. ■ Organize PI protection impact assessment. ■ Monitor compliance with the binding rules while processing PI. ■ Deal with complaints and requests from PI subjects.
Cross-border processing rules	All relevant parties processing PI must comply with unified cross-border processing rules, which at least incorporate: (1) basic information of cross-border processing, including categories, sensitivity and quantity of the data; (2) the duration of data storage overseas and the processing measures after the storage period is reached; (3) transfer country or region; (4) resources and measures dedicated to protecting rights of PI subjects; (5) rules of compensation and management in case of PI security incidents.
Data protection impact assessment	Conduct the assessment in accordance with PIPL and *Information security technology - Guidance for personal information security impact assessment (GB/T 39335-2020).*
Rights of PI subjects	■ Protect various rights of PI subjects, including the right to know, the right to decide, the right to consult and copy their PI, the right to request the handlers to correct or delete their PI, the right to reject automatic decisions, etc. ■ Immediately stop processing PI when it becomes difficult to ensure the security of PI. ■ The domestic institution promises to provide convenience for PI subjects to exercise their rights and bear liability for damages. ■ Undertake to be subject to supervision of the Chinese certification body. ■ Undertake to be subject to and comply with Chinese laws and regulations.

Conclusion

The Draft Specifications reference the BCRs and code of conduct provided for in GDPR, aiming to provide convenience for PI cross-border transfers for multinational group companies and processing of domestic PI by overseas PI handlers. The Draft Specifications only set forth the requirements used by certification bodies in their certification processes. They differ from GDPR, which requires BCRs and codes of conduct to be approved by the supervisory authority. Therefore, China's PIPC mechanism may have more flexibility in practice. The current Draft Specifications mainly provides relatively detailed substantive rules. We expect that the Draft Specifications or other subsequent normative documents can further clarify issues, including certification bodies and procedures, in order to provide more specific guidance for the implementation of the PIPC mechanism.

3. Futures Have a Future, So Do Derivatives

Authors: TieCheng YANG | Yin GE | Ting ZHENG | Eryin YING | Krystal He

Background

The PRC Futures and Derivatives Law (the "**FDL**") was adopted on 20 April 2022 and is scheduled to come into effect on 1 August 2022. This new law is another important milestone in the construction of the rule of law in China's capital market. As the "basic law" of China's futures and derivatives markets, it provides a legal basis for the high-quality development of the futures and derivatives markets, creates favorable conditions for the two-way opening up of the markets, and serves as a giant step for China toward becoming a clean close-out netting jurisdiction.

To provide more insights into the FDL and its potential implications for market participants, we analyze in this newsletter the FDL's key provisions and noteworthy points, taking into account the differences between the first and second reading drafts and the final version. Our previous newsletter on the first reading draft can be found *here*.

Key analysis

I. Applicability of the FDL

Article 2 of the FDL provides that the FDL applies to futures transactions, derivatives transactions and related activities conducted (i) within mainland China; and (ii) outside mainland China which disrupt the domestic market order or damage the lawful interests of domestic traders. In terms of scope of application, the FDL focuses on regulating the futures market while taking into account the derivatives market as well, and leaves room for future reform and innovation.

1. Definition of futures and derivatives transactions

Article 3 of the FDL provides that futures transactions refer to trading of futures contracts or standardized options contracts, while derivatives transactions refer to trading of swap contracts, forward contracts, non-standardized options contracts, and any combination of the aforementioned products, other than futures transactions.

In comparison to the second reading draft, the FDL removes the "standardized" qualifier for swap contracts and forward contracts. This seems to indicate that the trading of swap contracts and forward contracts may be categorized and regulated as derivatives transactions regardless of the standardization of those two types of contracts.

2. Distinction between futures and derivatives transactions

Article 3 of the FDL does not provide a clear means of separating futures and derivatives transactions, especially when "standardization" is not well defined. However, Article 11 of the FDL may provide a clearer standard to separate those two types of transactions, which is in line with international practice:

- futures transactions shall be conducted on futures exchanges or other trading venues as approved by the futures regulator under the State Council (i.e., the China Securities Regulatory Commission ("**CSRC**")), and shall be entered into by way of centralized bidding or other trading methods as approved by CSRC; futures transactions conducted outside of futures trading venues are prohibited; and
- derivatives transactions may be entered into by way of contract, which we understand should mean that derivatives transactions may be entered into through contractual negotiation, or other trading methods as prescribed by the State Council.

3. Cross-border OTC derivatives transactions

The FDL does not expressly provide that the law applies to cross-border OTC derivatives transactions. However, regulators have on many occasions indicated that the FDL established a basic framework in line with international practice and confirmed the close-out netting regime for OTC derivatives transactions documented by ISDA agreements.[1] This implies the FDL is applicable to cross-border OTC derivatives transactions.

4. Repos and securities financing transactions

The FDL, including the close-out netting regime under the FDL, will not apply to repos and securities financing transactions. That said, the China Banking and Insurance Regulatory Commission ("**CBIRC**") expressly confirmed that PRC commercial banks can measure the default risk exposure of counterparties and provide regulatory capital on a net basis for bond repo transactions, so long as they are trading with PRC licensed financial institutions and the repo transactions are documented by a CBIRC-recognized master agreement; see the *Notice on Issues Concerning the Measurement Rules for the Default Risk Assets of Derivatives Counterparties* and a Q&A (the "**CBIRC Circular**"), issued on 26 November 2021.

5. Extraterritorial application of the FDL

The FDL will have extraterritorial effect on offshore entities under certain circumstances, in addition to purely offshore futures and derivatives transactions and related activities which disrupt the domestic market order or damage the rightful interests of domestic traders. These offshore entity provisions mainly include:

- Article 118 of the FDL: offshore futures trading venues will need to register with CSRC and accept its supervision if they provide direct access to onshore entities or individuals to their trading system for trading services, unless otherwise provided by CSRC;
- Article 119 of the FDL: offshore futures, options or derivatives contracts listed on offshore futures trading venues that reference the price of contracts listed on onshore futures trading venues must comply with relevant CSRC rules;

[1] See releases at:
https://www.cbirc.gov.cn/cn/view/pages/ItemDetail.html?docId=1020671&itemId=915&generaltype=0
http://www.csrc.gov.cn/csrc/c100028/c2350718/content.shtml.

- Article 121 of the FDL: offshore futures trading venues will need to file with CSRC if they intend to set up a representative office in China; and
- Article 122 of the FDL: marketing, promotion and solicitation activities in China's futures market conducted by offshore entities will need to be approved by CSRC and be subject to the relevant provisions of the FDL; onshore entities will also need to obtain CSRC's approval if they intend to engage in the foresaid activities for the benefit of offshore entities. This echoes the increasingly tightened regulatory position over the marketing activities by offshore entities in China.

Notably, the final version of the FDL removes the requirement for offshore futures operation institutions to apply for registration or an exemption with CSRC and accept management and supervision to directly engage in futures trading on onshore futures exchanges on behalf of offshore entities and individuals.

II. Close-out netting

1. Confirmation of close-out netting

The FDL for the first time recognizes in law the enforceability and effectiveness of the close-out netting regime and the single agreement concept.

Article 32 of the FDL provides that where derivatives transactions are entered into by way of a master agreement, the master agreement, supplements to the master agreement, and the agreements on specific transactions (e.g., the confirmations) form a single, complete, and legally binding agreement. This may effectively eliminate concerns over the cherry-picking power of bankruptcy administrators to choose to terminate some transactions while continuing to perform others pursuant to Article 18 of the PRC Enterprise Bankruptcy Law (the "**Bankruptcy Law**").

Article 35 of the FDL further provides that derivatives transactions entered into by way of master agreement in accordance with law may be terminated pursuant to the provisions of the agreement and all profits and losses may be settled on a net basis; the netting settlement may not be stayed, invalidated or revoked due to either party's entry into bankruptcy proceedings. This may effectively eliminate concerns over the claw back right of bankruptcy administrators under Article 31 of the Bankruptcy Law and the uncertainty around the restrictions over insolvency set-offs during bankruptcy proceedings under Article 40 of the Bankruptcy Law. However, the application of Article 35 of the FDL could be uncertain in practice as discussed below.

Confirmation of the close-out netting regime may help China to be recognized as a clean close-out netting jurisdiction and bring about a number of benefits to financial institutions, e.g., financial institutions could calculate the risk exposures of Chinese counterparties on a net basis, reduce counterparty risk exposures, reduce the level of regulatory capital that it must hold in respect of its derivatives positions, and reduce the collateral required to be provided to counterparties.

2. Filing requirement for template master agreement

Article 33 of the FDL requires template master agreements to be filed pursuant to the rules of CSRC or other regulators authorized by the State Council. The following issues await further clarifications

with respect to the filing requirement:

- Filing obligor: in comparison to the first and second reading draft, the final version of the FDL removes the reference to filing obligor entirely, which leaves a question mark as to who should be responsible for the filing of relevant master agreement;
- Subject master agreement: it remains unclear what master agreements will need to be filed with competent regulators; for example, whether bespoke agreements and mini-master agreements will need to be filed;
- Duplicative filing: it remains unclear whether the relevant master agreement will need to be filed with different regulators if the master agreement is to be used for derivatives that reference different asset classes.
- According to Article 8 of the FDL, derivatives markets will be regulated by CSRC or the regulators authorized by the State Council in accordance with their respective regulatory functions. Considering China's current derivatives regulatory environment, it is possible that derivatives transactions in relation to foreign exchange/interest rate will be regulated by the People's Bank of China ("**PBoC**") and/or the State Administration of Foreign Exchange, and derivatives transactions related to commodities and securities will be regulated by CSRC. This raises the question as to whether a derivatives transaction agreement referencing different asset classes will need to be filed with each different regulator, which would inevitably add to the burden of filing obligors and be disadvantageous for the conduct of derivatives transactions in practice;
- Consequences for failure to filing: the FDL does not provide consequences for the failure to file the agreements; thus it is uncertain how the filing requirement will be enforced in practice.

3. Uncertainty around enforceability of close-out netting

Uncertainty of interpretation of "in accordance with law" under Article 35

Notably close-out netting under the FDL is no longer expressly conditioned upon filing the relevant master agreement, contrary to the first and second reading drafts. In other words, even if the relevant master agreement has not been filed with the competent regulator, it appears that the close-out netting may still be recognized regardless of the bankruptcy proceeding.

However, close-out netting remains conditioned on the pre-requisite that the derivatives transactions are conducted "in accordance with law" under Article 35. It remains unclear how to interpret "in accordance with law"; in particular, whether the requirement is satisfied when the applicable master agreement is not filed with the competent regulators.

That said, the CBIRC Circular confirmed the enforceability of close-out netting, quoting comments from the Supreme People's Court that close-out netting should not be subject to the cherry-picking right under the Bankruptcy Law and expressly referring to three qualified master agreements (i.e., NAFMII, SAC and ISDA master agreements); CBIRC made no mention of any filing requirement when the regulator was well aware of the first and second reading drafts of the FDL. This indicates that regulators do not view failure to observe the filing requirement as causing the underlying transactions

not to be conducted "in accordance with law".

Potential uncertainty from the draft PRC Financial Stability Law

On 6 April 2022, PBoC issued a consultation draft of the PRC Financial Stability Law (the "**FSL**"). The consultation period ends on 6 May 2022. Article 30 of the FSL provides that the close-out netting for qualified financial transactions could be stayed during the implementation of financial risk resolution and upon the approval of the responsible regulatory official for risk resolution. While this article does not invalidate the enforceability of close-out netting, it would pose uncertainty to the recognition of China as being a clean netting jurisdiction, as it implies that the non-defaulting party may not be able to exercise its close-out netting right for any reason during the stay period and in particular the FSL does not specify the duration of such stay period.

Temporary stay of close-out netting is necessary in the context of financial institution risk resolution, as the rush into termination of overwhelmingly large volumes of financial contracts by all counterparties solely due to a financial institution's entry into resolution would create further market instability and frustrate the implementation of the measures whose aim is to achieve continuity of the financial institution. To strike a balance between the resolution of a financial institution and normal operation of the close-out netting regime, the Financial Stability Board ("**FSB**") has provided several conditions for a temporary stay of close-out netting in the Key Attributes of Effective Resolution Regimes for Financial Institutions. The conditions include that stay should be strictly limited in time (for example, for a period not exceeding two business days); and that stay should only apply to early termination rights that arise for reasons of entry into resolution or in connection with the use of resolution powers. Further, the early termination rights of counterparties should be preserved against the financial institution in resolution in the case of any default that occurs before, during or after the period of the stay that is not related to the entry into resolution or the exercise of a resolution power (for example, a failure to make a payment or the failure to deliver or return collateral on a due date).

Notably, the drafting notes to the FSL provide that the introduction of close-out netting stays takes reference from prevailing international practices. Additionally, a similar stay clause has also been provided in Article 95 of the draft PRC Commercial Banking Law issued by PBoC on 16 October 2020, which provides that close-out netting could be stayed for up to two days during the take-over period of a commercial bank. Therefore, we believe the intention of regulators is to align international practices when exercising their resolution power; thus, stays should not affect the enforceability of close-out netting in practice. That said, we will submit comments to PBoC for the recommended revisions to the FSL to incorporate the conditions proposed by FSB and keep a close eye on the FSL's implications over the enforceability of close-out netting.

4. Title transfer-type performance assurance document

Article 34 of the FDL provides that where parties conduct derivatives transactions, they can provide performance assurance by pledge and other means in accordance with law. While this Article 34 does not expressly confirm that performance assurance could be provided by the internationally prevailing title transfer method (e.g., for satisfaction of variation margin requirement), this article has been drafted in an open-ended manner to cover all possible forms of performance assurance and

reveals a positive signal to the market, especially considering that NAFMII released in 2009 a title transfer performance assurance document, which indicates PBoC's support.

Additionally, the Supreme People's Court released the *Guiding Opinions on Providing Judicial Safeguards by People's Courts to Avoid and Mitigate Financial Risks and to Promote Financial Reform and Development* on 10 February 2012, Article 13 of which provides that in examining the legitimacy of innovative financial products, when there is no corresponding provision in laws and administrative regulations or the provision is not clear, the people's courts will follow established market practices, pay sufficient attention to the opinions of financial regulators and not simply deny the legitimacy of innovative financial products because no clear provisions exist in current laws and regulations.

Based on the above, it is likely PRC courts will honor the title transfer-type performance assurance arrangements as an established practice in the international OTC derivatives transaction markets and due to the support by PRC financial regulators.

Some market participants are concerned over the potential recharacterization of the title transfer performance assurance as security assignment or a new type of security interest that is not specifically provided under PRC law. The risk should not be high because:

- performance assurance (or similar concept of credit support in ISDA agreements) is a broader concept than security interest, and Article 34 of the FDL is not limited to security interests;
- collateral transferred outright to the collateral receiver as contemplated under the title transfer performance assurance document are not subject to any restrictions to which security collateral would typically be subject; and
- the title transfer performance assurance document will clearly specify that the outright transfer of collateral thereunder is a transaction under the master derivatives agreement, forming part of the single agreement and under the protection of the close-out netting regime; the denial of the title transfer performance assurance document would be a denial of the single agreement concept and close-out netting regime, and there is no applicable legal ground for a PRC court to invalidate such contractual arrangements.

5. Automatic early termination (AET) clauses

AET clauses are intended to ensure all transactions documented by a master agreement could be early terminated prior to the commencement of bankruptcy proceeding so that close-out netting is not be affected by the implications under the relevant bankruptcy law (e.g., the cherry-picking power as discussed above). Some market participants are curious as to whether they need to continue to use AET clauses after the effectiveness of the FDL. For now, it is advisable to take a wait-and-see approach, as the FDL is new at this stage and there exist uncertainties around the enforceability of close-out netting as discussed above.

III. Business scope of futures companies

In comparison to the first reading draft, Article 63 of the FDL takes a step back that futures companies are no longer expressly allowed to engage in derivatives business. It appears that the legislator is

taking a prudent approach on the expansion of futures companies' business scope, and most of the risk management business will still be undertaken by the risk management subsidiaries of futures companies. That said, Article 63(4) of the FDL allows futures companies to engage in "other futures business" upon approval by CSRC, which is broad enough to allow CSRC to gradually permit the expansion of business scope by futures companies when the timing is deemed appropriate.

IV. Prior approval requirement and suitability management requirement for financial institutions

The final version of the FDL added a new Article 31 in comparison to the second reading draft, which provides that all financial institutions should seek approval to engage in derivatives transactions, fulfill their trader suitability management obligations, and comply with relevant regulatory provisions. This has revealed regulator's tightened regulatory position over derivatives business generally, especially after the "Yuan You Bao (原油宝)" incident, a paper crude oil product referencing offshore oil futures contracts, that was available for trading by individual investors and caused significant losses due to a collapse in global oil prices.

Under the current rules, to engage in derivatives business, banking financial institutions need to seek approval from CBIRC, securities companies need to obtain securities proprietary license from CSRC and file with the Securities Association of China, and insurance companies need to report to CBIRC. The derivatives-related rules for different types of financial institutions may need to be updated to reflect the above requirements.

V. Cross-border data transfers

Market participants should be encouraged to see that compared with the first and second reading draft, the express prohibition on the provision of any documents and data relevant to futures activities by any entity or individual to offshore without the consent of CSRC and relevant department under the State Council has been loosened slightly; such documents and data are now prohibited from being provided without consent to offshore regulatory authorities (instead of generally offshore).

VI. Other key points

1. Trading repository

Article 36 of the FDL provides that State Council-authorized regulator or CSRC should set up a derivatives trading repository ("**TR**") to collect, store, analyze and manage information about the underlying asset, scale and counterparty of derivatives transactions and to timely disclose the relevant information to the market in accordance with provisions. Detailed rules will be formulated by the State Council-authorized regulator and CSRC. As of today, the China Futures Market Monitoring Center and the China Securities Internet System have obtained formal authorizations and recognized by FSB as TRs for commodity and equity OTC derivatives; NAFMII acts as the TR-like entity for credit OTC derivatives and CFETS acts the TR-like entity for credit, foreign exchange and interest rate OTC derivatives. However, there is currently no FSB recognized TR in China for credit, foreign exchange or interest rate OTC derivatives.

2. Settlement finality

While settlement finality for futures transactions has been provided in currently valid rules, Article 43 of the FDL confirms in law the principle of settlement finality and expressly provides that settlement and delivery in accordance with the law may not be stayed, invalidated or revoked due to the entry into bankruptcy proceedings by any party involved in the settlement. As the central counterparty is also a party involved in the settlement of futures transactions, this Article 43 confirms that the bankruptcy of the central counterparty will also not affect settlement finality.

3. Reversed burden of proof

Article 51 of the FDL provides that traders should be classified into ordinary traders and professional traders based on factors such as financial condition, trading knowledge and experience, etc. Where there is a dispute between an ordinary trader and a futures operation institution, as opposed to the principle of "he/she who claims bears the burden of proof", Article 51 of the FDL reverses the burden of proof from the ordinary trader to the futures operation institution; i.e., the futures operation institution instead bears the burden to prove that its acts are not misleading or fraudulent, among other circumstances, otherwise it will be held liable for compensations.

Outlook

The FDL provides important legal certainty as to the enforceability of the close-out netting regime under PRC law and opens a new chapter for the China's futures and derivatives markets. With the future recognition of China being a clean netting jurisdiction, it is expected that more and more foreign market participants will be willing to trade with Chinese counterparties to manage risks and Chinese market participants could also enjoy the benefit of close-out netting and save regulatory capital.

The above said, there are still a number of pending issues under the FDL awaiting clarification by the relevant regulators. We will continue to monitor for developments with respect to the FDL and share our insights in a timely manner.

Important Announcement

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If you have any questions regarding this publication, please contact:

Beijing	**Wenyu JIN**	**Attorney-at-law**
	Tel:	+86 10 8525 5557
	Email:	wenyu.jin@hankunlaw.com
Shanghai	**Yinshi CAO**	**Attorney-at-law**
	Tel:	+86 21 6080 0980
	Email:	yinshi.cao@hankunlaw.com
Shenzhen	**Jason WANG**	**Attorney-at-law**
	Tel:	+86 755 3680 6518
	Email:	jason.wang@hankunlaw.com
Haikou	**Jun ZHU**	**Attorney-at-law**
	Tel:	+86 898 3665 5000
	Email:	jun.zhu@hankunlaw.com
Hong Kong	**Dafei CHEN**	**Attorney-at-law**
	Tel:	+852 2820 5616
	Email:	dafei.chen@hankunlaw.com