



Shanghai CILS® Law Firm
上海信石®律师事务所

Room 2615, Enterprise Square
No. 228 Meiyuan Road, Shanghai 200070
People's Republic of China

中国上海市梅园路 228 号
企业广场 2615 室, 邮编: 200070

Tel: +86 21 80127725
Fax: +86 21 80127724
www.cilslaw.com

法律法规简报 2022-05-31

Legal Update 2022-05-31

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一、证监会就《证券期货业网络安全管理办法》征求意见 2022.05.05

CSRC Solicits Comments on Administrative Measures for Cybersecurity in Securities and Futures Industries



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日前, 中国证券监督管理委员会起草了《证券期货业网络安全管理办法(征求意见稿)》(下称《征求意见稿》), 现向社会征求意见, 意见反馈截止于 5 月 29 日。

The China Securities Regulatory Commission ("CSRC") has recently drafted the *Administrative Measures for Cybersecurity in Securities and Futures Industries (Draft for Comment)* (the "*Draft for Comment*") to solicit public opinions by May 29, 2022.

《征求意见稿》共八章六十六条, 主要包括证券期货业网络安全监督管理体系、网络安全运行、数据安全统筹管理、网络安全应急处置、关键信息基础设施网络安全、网络安全促进与发展、监督管理与法律责任等内容。其中, 《征求意见稿》督促行业机构建立健全网络安全管理体制机制, 提升网络安全运行保障能力, 从“要求核心机构、经营机构具有完善的治理架构, 强化管理层责任, 指定牵头部门, 保障资源投入”等六个方面对网络安全运行加以规范。

The *Draft for Comment*, consisting of 66 articles in eight chapters, mainly touches upon the supervisory and administrative system for cybersecurity in securities and futures industries, cybersecurity operation, overall management of data security, cybersecurity emergency response, cybersecurity of critical information infrastructure, cybersecurity promotion and development, supervision and administration, as well as legal liability. Among others, the *Draft for Comment* urges all institutions within the industries to establish sound administrative mechanisms and systems for cybersecurity, and to enhance the capabilities to guarantee cybersecurity operation, regulating the cybersecurity operation from six perspectives, including "requiring core institutions and operating institutions to have complete governance structure, reinforce the responsibilities of the leadership, designate leading departments and guarantee resources input".

(Source: <http://www.csrc.gov.cn/csrc/c101981/c2381308/content.shtml>)

二、信安标委对个人信息跨境处理活动认证技术规范征询意见 2022.05.05



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Fax: +86 21 80127724
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NISSTC Seeks Comments on Specification on Authentication Technologies for Cross-border Personal Information Processing Activities

近日，全国信息安全标准化技术委员会秘书处发出《网络安全标准实践指南—个人信息跨境处理活动认证技术规范（征求意见稿）》（下称《征求意见稿》），现向社会征求意见，意见反馈截至 5 月 13 日。

The Secretariate of the National Information Security Standardization Technical Committee (NISSTC) has recently issued the *Practical Guide to Cybersecurity Standards - Specification on Authentication Technologies for Cross-border Personal Information Processing Activities (Draft for Comment)* (the "*Draft for Comment*") to seek public opinions by May 13, 2022.

《征求意见稿》作为认证机构对个人信息跨境处理活动进行个人信息保护认证的基本要求，适用于“跨国公司或者同一经济、事业实体内部的个人信息跨境处理活动”等两类情形。《征求意见稿》明确，跨国公司或者同一经济、事业实体内部的个人信息跨境处理活动可以由境内一方申请认证，并承担法律责任。相关基本要求涵盖法律约束、组织管理、个人信息跨境处理规则、个人信息保护影响评估等四方面。《征求意见稿》还对个人信息主体权益保障进行了规定。

The *Draft for Comment* represents the basic requirements for the authentication institutions to carry out personal information protection authentication for cross-border personal information processing activities, which shall be applicable in two circumstances, including "where the activity of cross-border personal information processing is carried out within a multination company or the same economic or business entity". In such circumstance, as specified in the *Draft for Comment*, the party within the territory of China may apply for authentication and shall assume the corresponding legal liability. The basic requirements involve four aspects, namely, legal constraints, organization and management, rules for cross-border personal information processing, and personal information protection impact assessment. The *Draft for Comment* also sets out the provisions on protection of rights and interests of the personal information subjects.



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(Source: <https://www.tc260.org.cn/front/postDetail.html?id=20220429181520>)

三、国家药监局就药品管理法实施条例修订草案征求意见 2022.05.10

NMPA Seeks Comments on Revised Draft of Implementing Regulations of the Drug Administration Law

日前, 国家药品监督管理局发布《中华人民共和国药品管理法实施条例(修订草案征求意见稿)》(下称《征求意见稿》), 现向社会征求意见, 意见反馈截止于 6 月 9 日。

The National Medical Products Administration ("NMPA") has recently issued the *Implementing Regulations of the Drug Administration Law of the People's Republic of China (Revised Draft for Comment)* (the "*Draft for Comment*") to solicit public opinions by June 9, 2022.

《征求意见稿》共十章 181 条, 与现行《条例》相比全文条目增加了 101 条, 不仅新增了药品上市许可持有人、药品供应保障专章, 其余章节也在现行《条例》相关内容的基础上进行修改、丰富。《征求意见稿》调整现行条例不相适应的内容, 细化具体管理规定, 其内容包括总则、药品研制与注册、药品上市许可持有人、药品生产、药品经营、医疗机构药事管理、药品供应保障、监督管理、法律责任和附则。

The *Draft for Comment* consists of 181 articles in ten chapters, 101 articles more than the existing regulations. There are new chapters specialized in drug marketing authorization holders and drug supply guarantee, and in the remaining chapters of the regulations, the existing contents are revised and enriched. The *Draft for Comment* adjusts some contents in the existing regulations which are no longer applicable and refines the specific administrative rules. It covers the general provisions, drug development and registration, drug marketing authorization holders, drug manufacturing, drug operation, drug management in medical institutions, drug supply guarantee, supervision and administration, legal liability, and supplementary provisions.



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其中,《征求意见稿》提出,国家鼓励罕见病药品的研制和创新,对批准上市的罕见病新药,在持有人承诺保障药品供应情况下,给予最长不超过 7 年的市场独占期。

Among others, the *Draft for Comment* notes that China will encourage the development and innovation of drugs for rare diseases and, for those new drugs for rare diseases with marketization authorization, may grant an exclusivity term for up to seven years on condition that the marketization authorization holders undertake to guarantee the supply of such drugs.

(Source: <https://www.nmpa.gov.cn/xxgk/zhqyj/zhqyjyp/20220509222233134.html>)

四、国家外汇局修订《国家外汇管理局行政处罚办法》

2022.05.20

SAFE Issues Measures of the State Administration of Foreign Exchange for Administrative Penalties

近日,国家外汇管理局公布《国家外汇管理局行政处罚办法(2022 年修订)》(下称《办法》),自 2022 年 6 月 1 日起施行。

The State Administration of Foreign Exchange ("SAFE") has recently released the *Measures of the State Administration of Foreign Exchange for Administrative Penalties (Revised in 2022)* (the "*Measures*") for implementation from June 1, 2022.

《办法》共八章 93 条,主要依据新修订的《中华人民共和国行政处罚法(2021 年修订)》,并结合外汇管理部门执法实践,修订完善外汇案件处罚实施程序,保障执法行为合法规范有序。其修订内容重点包括:一是细化规定管辖与立案标准,规范电子取证等证据收集活动,明确办案期限,增强执法透明度;二是全面落实行政执法公示制度、执法决定法制审核制度、执法全过程记录制度,强化执法监督;三是完善陈述申辩和听证程序,细化听证标准,充分保障行政相对人的合法权益。



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The *Measures*, consisting of 93 articles in eight chapters, mainly revise and improve the implementation procedures for the penalties in foreign currency-related cases, based on the newly revised *Law of the People's Republic of China on Administrative Penalties (Revised in 2021)* and the judicial practice of administrative department of foreign exchange, with a view to safeguarding legal compliance and good order. The revisions focus on: (1) refining the standards for jurisdiction and case filing, standardizing electronic evidence collection and other activities, clarifying the time limit for handling cases, and enhancing the transparency of law enforcement; (2) fully implementing the administrative law enforcement publicity system, the legal system review system for law enforcement decisions, and the whole-process law enforcement recording system, and strengthening law enforcement supervision; and (3) improving the statement, defense and hearing procedures, refining the hearing standards, and fully protecting the legitimate rights and interests of administrative counterparts.

(Source: <http://www.safe.gov.cn/safe/2022/0519/20972.html>)

本期编辑:
Author:

Chenwei Bao
Tel: 86-21-80127725
Email: wendy.bao@cilslaw.com

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Shanghai CILS® Law Firm, a partnership registered at Room 2615, Enterprise Square,
No. 228 Meiyuan Road, Shanghai, PRC.

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