

Legal Commentary

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Highlights on the New HGR-Related Administrative Penalty Rule

Authors: Aaron GU | Pengfei YOU | Duzhiyun ZHENG¹

Background

As the regulation system on human genetic resources (“HGR”), biosecurity and laboratory animals is experiencing continuous improvement, enforcement actions of the Ministry of Science and Technology (“the MOST”) have become more active and tight in recent years. Taking into account the actual situation in law enforcement and to meet the increasing demands for law enforcement guidance, the MOST issued the *Measures for the Implementation of Administrative Penalty of the Ministry of Science and Technology (Draft for Comments)* (“*Measures for the Implementation*”) on November 16, 2022.

In July 2021, the revised *Law of the People’s Republic of China on Administrative Penalty* (“*Administrative Penalty Law*”) was formally implemented. The central government values and sets high expectations to the effective implementation of the *Administrative Penalty Law*. In November 2021, the State Council issued the *Notice of Further Implementing the Law of the People’s Republic of China on Administrative Penalty*, requiring the departments to formulate or revise supporting policies for administrative penalties to ensure that the procedural requirements are well implemented.

In this article, we will briefly analyse the *Measures for the Implementation* and summarise the enforcement provisions and tendency of the MOST, expecting to provide some guidance to the industry for complying with compliance requirement related to the MOST.

Brief introduction of the measures

As regards of its nature, the *Measures for the Implementation* are procedural and departmental rules, which specifies the procedures for the implementation of administrative penalties rather than creating substantial compliance obligations for the industry and companies within. The *Measures for the Implementation* aims to regulate the administrative penalties and to safeguard their effective implementation.

¹ Shuwen Sun and Leyi Wang have also contributed to this article.

In line with the *Administrative Penalty Law*, which is of higher legal hierarchy, the administrative objects under the *Measures for the Implementation* are also citizens, legal persons and other organizations. In addition, the *Measures for the Implementation* restricts the scope of law enforcement to illegal acts within the territory of the People’s Republic of China, indicating that the *Measures for the Implementation* has no extraterritorial jurisdiction or force. In the *Measures for the Implementation*, *Law of the People’s Republic of China on Progress of Science and Technology*, *Law of the People’s Republic of China on Promoting the Transformation of Scientific and Technological Achievements*, *Law of the People’s Republic of China on Popularization of Science and Technology*, *Biosecurity Law of the People’s Republic of China*, *Regulations of the People’s Republic of China on the Administration of Human Genetic Resources (“HGR Regulations”)*, *Regulation on National Science and Technology Awards* and *Regulation on the Administration of Laboratory Animals* are all enumerated as the applicable penalty basis for administrative penalties. It is worth noting that, since the MOST is responsible for the administration of laboratory animals nationwide, laboratory practice involving laboratory animals shall also fall under the supervision of the MOST, and thus be subject to regulations of the *Measures for the Implementation*. Furthermore, list of penalty basis above is not exhaustive and documents related to the MOST such as the *Interim Provisions on Handling Violations of Regulations in Scientific and Technological Activities* are not listed therein.

Analyses of key provisions

I. Implementation authorities and the implementation entrustment

According to Article 5 of the *Measures for the Implementation*, the MOST shall impose administrative penalties within the scope of its functions and powers and no administrative penalties shall be imposed in the name of any internal organs of or public institutions directly under the MOST. With regard to the statutory scope of functions and powers of the MOST, taking the administration of HGR as an example, according to the *HGR Regulations*, the power of administrative penalty involving the punishment of most serious illegal utilization of HGR is conferred upon the MOST while provincial science and technology departments (commissions, bureaus) are only entitled to the authority to impose administrative penalties on relatively minor illegal acts (see the table below for more details). Moreover, according to the *Rule for Implementation of the Regulations on Administration of Human Genetic Resources (Draft for Comments)*, although science and technology departments at provincial level may be entrusted by the MOST to conduct investigation of illegal acts within their respective jurisdiction, the power to impose administrative penalties remains with the MOST. Therefore, according to laws and regulations including but not limited to *Law of the People’s Republic of China on Progress of Science and Technology*, *HGR Regulations* and *Regulation on the Administration of Laboratory Animals*, the MOST has a relatively broad authority to impose penalties, and the corresponding enforcement of administrative penalties are subject to the provisions of this *Measures for the Implementation*, the importance of which cannot be overlooked.

Scope of penalty authority of the MOST under <i>HGR Regulations</i>	Scope of penalty authority at provincial level under <i>HGR Regulations</i>
<ul style="list-style-type: none"> ■ Without Approval, to sample China’s HGR of Important Genetic Families and HGR of Specific 	<ul style="list-style-type: none"> ■ Failing to pass the ethical review, to sample, biobank, utilize or conduct

Scope of penalty authority of the MOST under <i>HGR Regulations</i>	Scope of penalty authority at provincial level under <i>HGR Regulations</i>
<p>Regions or to sample HGR meeting the threshold of types or quantities prescribed by the MOST.</p> <ul style="list-style-type: none"> ■ Without Approval, to biobank China’s HGR. ■ Without Approval, to conduct international cooperation scientific research involving China’s HGR. ■ Without Security Review, to give external provisions or open access of HGR information that are likely to affect public health, state security or public interest of China to foreign parties. ■ Fail to submit fillings before the conduct of international cooperation clinical trial. ■ To provide false materials or by any other deceptions to obtain administrative license. ■ Fail to submit annual report when biobanking China’s HGR. ■ Overseas organizations or institutions established or actually controlled by overseas organizations or foreign individuals to violate the regulation, through sampling, biobanking, utilizing or conducting external provisions of China’s HGR. ■ ... 	<p>external provision of China’s HGR.</p> <ul style="list-style-type: none"> ■ Failing to obtain prior informed consents of the providers or obtain the consents by means of concealment, misleading statement or deception, to sample China’s HGR. ■ To sample, biobank, utilize or conduct external provision of China’s HGR in violation of relevant technical norms. ■ ...

Article 6 of the *Measures for the Implementation* provides that specific cases shall be respectively administrated by the functionary departments of law enforcement of the MOST (“**Functionary Departments**”) according to their regulatory fields. In addition, the *Measures for the Implementation* particularly emphasizes that the Legislative Affairs Office and the Information Disclosure Institution of the MOST shall be responsible for legal review and information disclosure.

Article 7 and 8 of the *Measures for the Implementation* stipulate the entrustment of penalty enforcement. In a comprehensive view, the requirements of the *Measures for the Implementation* in respect of written entrustment, entrustment disclosure, content of entrustment letter, the subject name of penalty and non-delegation are consistent with the provisions of the *Administrative Penalty Law*.

As for the conditions of entrustment, the *Measures for the Implementation* requires the entrusted organization to be administrative organ or institution with the function of managing public affairs, in line with the requirements of the *Administrative Penalty Law*. In addition, according to Article 21 of the *Administrative Penalty Law*, the entrusted organization shall meet the following conditions: (a) it is formed in accordance with law and has the function of managing public affairs; (b) it is staffed with personnel who are familiar with relevant laws, administrative regulations and government rules and experienced in the work, and who have obtained qualifications for administrative law enforcement; and (c) it has the means to organize and conduct technical tests or technical appraisals where necessary.

As for the aforementioned requirements, science and technology department at provincial or municipal level both met the qualification requirements and could be entrusted by the MOST to implement administrative penalties. Based on the MOST's consideration of practical needs for penalty enforcement reflected in the *Explanations for the Drafting*, it is very likely that the MOST will actively apply the entrustment method and delegate part of its authority to science and technology departments at provincial level, so as to expand the administrative enforcement forces, invigorate the administrative enforcements activities and enhance the effectiveness of administrative management. However, according to the *Administrative Penalty Law* and the *Measures for the Implementation*, if provincial department is authorized to impose administrative penalties, it cannot further authorize other administrative organs or organizations, i.e. the authority of the MOST cannot be delegated by the provincial department to the municipal department directly. Nevertheless, since the *Measures for the Implementation* imposes no limitation on the levels of entrustment and the qualification requirements for delegated organizations are relatively lenient, the municipal science and technology departments, other administrative organs and other institutions with the function of administering public affairs may also be entrusted by the MOST to implement corresponding administrative penalties in the future.

II. Confidentiality and penalty publication

Article 4 of the *Measures for the Implementation* provides for the confidentiality and is consistent with the provisions of Article 50 of the *Administrative Penalty Law*, requiring that the confidential scope includes state secrets, trade secrets and personal privacy and the abovementioned information "shall be kept confidential" without room for discretion on this point. Meanwhile, the recognition of trade secrets is still at the discretion of administrative authorities. In determining whether the information involves trade secrets, whether such information meets the three elements - confidential, valuable and protected - provided in Article 9 of the *Anti-Unfair Competition Law of the People's Republic of China* shall be a major consideration. In addition, the *Measures for the Implementation* refines the requirements for subjects with confidentiality obligations, extending its scope from "staffs of administrative organ" as stipulated in Article 50 of the *Administrative Penalty Law* to "relevant personnel participating in the case handling", which enlarges the scope of subjects with confidentiality obligations. This will be more conducive to safeguarding the legitimate rights and interests of the administrative counterparts in respect of their trade secrets and personal privacy.

Article 14 of the *Measures for the Implementation* stipulates the publication of administrative penalty decisions, which is consistent with the provision in Article 48 of *Administrative Penalty Law*, setting "having certain social impact" as the standard for deciding whether a penalty decision shall be made public. However, it is worth noting that the determination of "having certain social impact" has always been controversial since the amendment of *Administrative Penalty Law*. It is likely that the MOST will be entitled to wide discretion in its determination and the subsequent practice is worthy of further attention. In addition, uncertainty remains in the disclosure forms of the administrative penalty decisions. Taking local practices as examples, the requirements stipulated in the *Measures for Voluntary Disclosure of Information on Administrative Penalty Cases in Shanghai* ("**Shanghai Disclosure Measures**"), the *Interim Measures for Online Disclosure of Administrative Punishment Results in Zhejiang* ("**Zhejiang Disclosure Measures**") and the *Measures for Voluntary Disclosure of*

Information on Administrative Penalty Cases in Luzhou (“**Luzhou Disclosure Measures**”) are not identical. With regard to the scope of disclosure, *Shanghai Disclosure Measures* requires the abstract of penalty decisions to be disclosed, and the full text of penalty decisions to be disclosed conditionally; the *Zhejiang Disclosure Measures* provides that the full text or the abstract of penalty decisions shall be disclosed at option and the *Luzhou Disclosure Measures* provides that the full text of the penalty decisions should be disclosed. With regard to the context of the abstract, differences exist between the *Shanghai Disclosure Measures* and the *Zhejiang Disclosure Measures*: the former requires that the abstract shall include the “cause of penalty”, while the latter only requires that such abstract shall include the “main facts of violation”. It waits for what form the MOST will adopt to disclose administrative penalty decisions and how the MOST will balance the requirements of confidentiality management and penalty disclosure.

Specific procedural requirements

I. Clue registration

The *Measures for the Implementation* stipulates that the Functionary Departments shall be responsible for the registration of clues. The registration scope includes: (a) clues discovered during supervision or administration; (b) complaints or reports received; (c) clues transferred by other departments of the MOST or other authorities. According to the requirements, the Functionary Departments shall register the clues upon receipt and proceed with preliminary verification process. It is evident that the MOST attaches great importance to reports and whistleblowing in the investigation and punishment of illegal activities, and the industry should not underestimate the intensity of future enforcement.

II. Case filing

With regard to the procedures of case filing, the *Measures for the Implementation* stipulates that the Functionary Departments shall, within 15 working days as of the date of clue registration (extended to a maximum of 30 working days), preliminarily verify the clues, provide suggestions on whether to file the case and report to the director of the MOST to make final decisions. It further clarifies the procedures and requirements for case filing on the basis of the *Administrative Penalty Law*.

III. Investigation and evidence collection

With regard to investigation and evidence collection procedures, Section 3 of the *Measures for the Implementation* proposes more detailed requirements for procedures including but not limited to evidence collection, investigation measures, sealing up and distraining, which is conducive to regulating the law enforcement activities of administrative organs and its officers.

IV. Penalty

For cases where the illegal subject and the fact of violation is clear, which fall within the jurisdiction of the MOST and in which the illegal activity is not beyond the statutory limitation, the MOST will deliver an Administrative Penalty Opinion Notification to parties concerned. The parties concerned have the right to state, defend and request a hearing in accordance with the law.

All in all, it is apparent that the *Measures for the Implementation* provides more detailed procedures for the MOST's specific administrative penalty implementation. Based on our experience, these detailed provisions will continue to be optimized and refined until its official implementation.

Legal review

Article 45 and 46 of the *Measures for the Implementation* stipulates the procedures for the legal review. The legal review system for major law enforcement decisions is one of the three systems mentioned in the *Guiding Opinions on Comprehensively Implementing the Administrative Law Enforcement Publication System, the Recording System of Law Enforcement in the Whole Process and the Legal Review System of Major Law Enforcement Decisions* ("**Guiding Opinions**") issued by the General Office of the State Council in 2018. The *Guiding Opinions* emphasizes that legal review is crucial to ensure the legitimacy and effectiveness of major law enforcement decisions and no major law enforcement decision shall be made without the legal review or passing the legal review. In this regard, Article 58 of the *Administrative Penalty Law* revised in 2021 enumerates the circumstances that shall be subject to the legal review, and the provisions of Article 45 of the *Measures for the Implementation* are consistent with this enumeration.

Connections between administrative and criminal procedures

Article 62 of the *Measures for the Implementation* stipulates the procedures for the connections between administrative and criminal procedures, requiring that the responsible persons in charge and the directly liable persons who commit such illegal acts as breach of privilege, corruption, bribery, dereliction of duty and others shall be held liable in accordance with the law and discipline and criminal liabilities shall be taken in case of a crime. From the perspective of the subject of responsibility, this article regulates the law enforcement personnel who implement the administrative punishment rather than the administrative objects.

For companies, the two-way transfer mechanism for administrative and criminal procedures provided in the *Administrative Penalty Law* is more relevant. Article 27.1 of the *Administrative Penalty Law* stipulates that where a violation of law is suspected of constituting a crime, the administrative organ handling it shall transfer the case to a judicial organ in a timely manner for investigation of criminal liability in accordance with law. Where criminal liability does not need to be investigated or it can be exempted in accordance with law, but an administrative penalty shall be imposed, the judicial organ shall transfer the case to the relevant administrative organ in a timely manner.

Impact on the industry

As mentioned before, the *Measures for the Implementation* are procedural rules that only specify the procedural requirements rather than creating substantial compliance obligations. Accordingly, the administrative penalty enforcement system strengthened by the regulations has distinguished impact on companies with different levels of compliance management:

- For companies with relatively high levels of compliance management, the *Measures for the Implementation* will have less impact on them, and under a tighter law enforcement environment, they would enjoy and show more obvious competitive advantages;
- For companies with relatively low levels of compliance management or whose compliance system is still in the process of establishment, the *Measures for the Implementation* is likely to higher their risks of being investigated or even punished. It is highly recommended that such companies chase to window before the implementation of the *Measures for the Implementation*, and make business adjustments and formulate internal compliance systems in a timely manner.

Epilogue

Similar to our previous analysis in [Highlights on the Draft HGR Regulations Implementing Rules](#), once the policy is implemented, it is very likely that the MOST may delegate part of enforcement authority to local authorities. The most immediate impact of the arrangement is the multiplication of law enforcement forces, leading to more active enforcement of administrative penalties. This will definitely bring compliance challenges to companies involved in activities within the MOST's regulatory scope, including but not limited to the utilization of HGR in China.

Changes in regulatory system present more than just challenges to corporate compliance. Since local authorities are respectively more familiar with companies within their jurisdictions, the corresponding communication will be more convenient and smoother, which will help companies to make reasonable defenses or arguments, and probably avoid rigid or mistaken law enforcement. We sincerely hope that the further development of regulatory system will provide a stable institutional environment for China's high-tech industry, promote the flourishing of science and technology, including life sciences.

Important Announcement

This Legal Commentary 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.

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

Aaron GU

Tel: +86 21 6080 0505

Email: aaron.gu@hankunlaw.com