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Review of Administrative Regulations on Human Genetic Resources

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Review of the Administrative Regulations on Human Genetic Resources——With a Clause by Clause Comparison between Former Regulations and New Regulations

On May 28, 2019, the State Council promulgated the Administrative Regulations on Human Genetic Resources of the People's Republic of China (State Council Order No. 717, hereinafter referred to as the "Regulations"), which shall come into effect on July 1, 2019.

I. Legislative Background of the Regulations

At present, China's regulations on the administration of human genetic resources mainly include:

1. In June 1998, the General Office of the State Council forwarded the Interim Measures for the Administration of Human Genetic Resources which were jointly formulated by the Ministry of Science and Technology

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("MOST") and the Ministry of Health ("MOH") (Guo Ban Fa [1998] No. 36, hereinafter referred to as the "Interim Measures"). It is the first normative document in China that comprehensively regulates the administration of human genetic resources, stipulates the administrative system of human genetic resources in China, the use of China's human genetic resources for international scientific and technological cooperation, and the approval procedures for the export of China's human genetic resources. It provides important reference for the administration of human genetic resources in China.

2. In August 2015, the General Office of the MOST issued the Notice of the General Office of the MOST on Implementing the Administrative License for Collection, Sale, Export and Exit of Human Genetic Resources (Guo Ke Ban She [2015] No. 46). It supplements and improves the regulation and administration of the collection, sale, export, and exit of human genetic resources in China.

Since the promulgation of the former regulations, some new situations and new problems came up in the administration of human genetic resources in China:

1. With the rapid development of life science and biotechnology, the international competition centering around the intellectual property rights of functional genes and their products and the development of biotechnology industry has become increasingly fierce. Human genetic resources are the most precious strategic resources for the development of biotechnology industry. It is helpful for China to grasp human genetic resources, with a view to take the upper hand in the competition of biotechnology industry development.

2. In recent years, illegal collection and seizure of human genetic resources by foreign institutions have occurred frequently in China, and their modes of activities have become increasingly covert and diversified. For example, the collection mode has expanded from self-collection to cooperation with domestic institutions or experts, and then domestic institutions or experts will do the collection and export; the export mode has changed from carrying genetic samples abroad to transferring genetic data through the Internet. These modes bring serious challenges to the supervision of human genetic resources in China.

3. The Interim Measures, with many room for improvement, are no longer suitable for the current situation of human genetic resources administration in China. For example, the Interim Measures lack administrative rules on the collection, preservation, and utilization of human genetic resources in China; the relevant system of international cooperation in scientific research by utilization of China's human genetic resources is inadequate; the legal liabilities are not clear and the punishment is not severe enough; and the regulatory measures need to be further improved.

Therefore, in order to solve the outstanding problems in practice, improve the existing legal and administration system, and promote the effective protection and rational utilization of human genetic resources in China, the Regulations come into being.

II. Main Contents of the Regulations

The Regulations consists of 6 chapters and 47 articles, which are divided into general provisions, collection and preservation, utilization and external provision, service and supervision, legal liability, and supplementary provisions. On the basis of the basic principles laid down in the Interim Measures, the main amendments and additions of the Regulations are as follows.

1. Improving Administration System of Human Genetic Resources

The Regulations apply to the collection, preservation, utilization and external provision of human genetic resources in China. With regard to the collection and preservation of human genetic resources for the purposes of clinical diagnosis and treatment, blood collection and supply services, investigation of crimes, doping testing and funeral burials, relevant regulations have already set forth relevant rules. Therefore, the Regulations have excluded these activities from the scope of application of the Regulations (Article 3).

According to the Interim Measures, human genetic resources were originally administrated jointly by the MOST and the MOH. The Human Genetic Resources Administration of China (hereinafter referred to as "HGRAC"), established jointly by the MOST and the MOH, is specifically responsible for daily oversight. According to the Regulations, in the future, human genetic resources will no longer be administrated by the MOH, but only by the MOST (Article 4).

2. Strengthening Administration of Human Genetic Resources Activities

2.1 Basic Principles

The Regulations stipulate four basic principles for the collection, preservation, utilization and external provision of human genetic resources:

(1) It shall not endanger the public health, national security and public interests of China (Article 8);

(2) It shall conform to ethical principles and shall be subject to ethical reviews in accordance with relevant national regulations (paragraph 1, Article 9);

(3) The privacy rights of human genetic resource providers should be respected, their prior informed consent obtained and their legitimate rights and interests protected (paragraph 2, Article 9);

(4) Technical specifications formulated by the MOH shall be observed (paragraph 3, Article 9).

2.2 Pre-approval Matters

The following activities on human genetic resources shall be subject to the conditions set out in the Regulations and shall be implemented only after approval by the MOST:

(1) Collection: collecting of human genetic resources of important genetic families or in specific regions in China, or collecting of the human genetic resources of which the types and quantities are prescribed by the MOST (Article 11);

(2) Preservation: preserving of human genetic resources in China and providing of a basic platform for scientific research (Article 14);

(3) Utilization: international cooperation in scientific research by utilization of China's human genetic resources (however, in order to obtain the market license for related pharmaceuticals and medical devices in China, the use of China's human genetic resources in clinical institutions for international cooperation clinical trials, which does not involve the export of human genetic resources, does not require approval) (Article 22);

(4) External provision: international cooperation in scientific research by utilization of China's human genetic resources, or transportation, mailing and carrying of China's human genetic resources materials abroad due to other special circumstances (Article 27).

2.3 Specific Administrative Measures

With regard to the collection of human genetic resources, the Regulations emphasize the protection of personal rights such as the right to know and privacy of human genetic resource providers, including the need to obtain written consent from human genetic resources providers to guarantee the right of providers to participate voluntarily and to withdraw unconditionally at any time (Article 12).

With regard to the preservation of human genetic resources, the Regulations emphasize the obligations of human genetic resources preservation entities, including taking measures to ensure the safety of preservation, keeping complete records of preservation, and submitting annual reports on preservation to the MOST (Article 15). The Regulations also point out that China will strengthen the construction of the basic platform for the preservation of human genetic resources and the big data of human genetic resources. The basic platform and database will be open to relevant scientific research institutions, institutions of higher education, medical institutions and enterprises (Articles 13 and 16).

With regard to the utilization of human genetic resources, the Regulations retain the principles of

"equality and mutual benefit, good faith, joint participation and sharing of achievements" in the Interim Measures for international cooperation research projects. On this basis, the Regulations further clarify the interests of China in international cooperative scientific research: foreign entities must cooperate with Chinese entities to carry out scientific research activities by utilization of China's human genetic resources (Article 21); and Chinese entities and their researchers shall participate "substantively in the whole process" of research during the cooperation period. All records and data information in the course of the research shall be made available to Chinese entities, with backups provided to Chinese entities (Article 24).

With regard to the external provision of human genetic resources, the Regulations retain and refine the requirements of the Interim Measures for the approval of the export of "materials" of human genetic resources. In addition, the Regulations add new administration to the external provision of "information" of human genetic resources, including: when information on human genetic resources is made available to foreign entities or individuals, it shall be file for record with the MOST, with a backup of information submitted; if the provision of human genetic resources to foreign entities or individuals may affect public health, national security and social public interests, it should pass the security review organized by the MOST (Article 28).

In addition, the Regulations also prohibits the sale of human genetic resources (Article 10).

3. Strengthening Supervision and Inspection of Human Genetic Resources Activities

The Regulations strengthen the supervision and inspection of all aspects of human genetic resources activities, stipulate that the MOST at the national and provincial levels shall supervise and inspect human genetic resources activities (Article 33), and specify specific supervision and inspection measures, including on-site inspection, inquiry of relevant personnel, consulting and duplicating relevant materials, sealing up or seizing relevant human genetic resources (Article 34).

At the same time, the Regulations require the preservation entities to submit annual reports on the preservation of human genetic resources to the MOST (Article 15), and require both parties of international cooperation in scientific research by utilizing China's human genetic resources to jointly submit a report on cooperative research to the MOST within six months after the completion of the cooperation (Article 26).

4. Improving Legal Liability System of Violations

The Interim Measures contain more than 20 obligatory provisions, but only stipulate 3 corresponding legal liabilities. Because of many obligatory provisions without illegal consequences, the implementation effect of the Interim Measures was to some extent affected. At the same time, the prescribed penalties are not severe enough to cause the disciplinary effect that they should have.

In order to strengthen the effective implementation of the Regulations and enhance the authority and enforcement powers of the human genetic resources administration system, the Regulations improve the legal liability system for violations, and stipulate different administrative legal liabilities for different violations respectively, including confiscation of human genetic resources, confiscation of illegal income, imposition of fines of up to 10 million yuan or 10 times of illegal income.

It is worth mentioning that the Regulations add administrative penalties that law enforcement agencies can impose. For example, for some violations, the Regulations stipulate that law enforcement agencies may impose a prohibition (permanent prohibition utmost) on entities that violate the Regulations from engaging in the collection, preservation, utilization and external provision of human genetic resources (Article 43). For some violations, the Regulations require law enforcement agencies to impose penalties on the legal representatives, principal responsible persons, directly responsible persons and other responsible persons of the entities that violate the Regulations, including confiscation of illegal income, imposition of fines, and prohibition of engaging in human genetic resources activities in China (Article 43). In addition, entities and individuals that violate the Regulations will be recorded in their credit records and be disclosed to the public (Article 43).

III. Transitional Arrangements for the Interim Measures and the Regulations

The Regulations will come into effect on July 1, 2019, and the Interim Measures will be abolished at the same time. In order to maintain the continuity of administrative approval work, the HGRAC issued a notice on June 17, 2019 on the work arrangements in the transition period before the implementation of the Regulations: as to paper applications for administrative approval received by 17:00 on June 28, 2019, the applications will still be accepted and processed in accordance with the Interim Measures and corresponding working procedures; as to applications received after 17:00 on June 28, 2019, the applications will be accepted and processed in accordance with the Regulations and the corresponding working procedures.

Appendix: Clause by Clause Comparison between Former Regulations and New Regulations

	Interim Measures for the Administration of Human Genetic Resources	**Administrative Regulations on Human Genetic Resources of the People's Republic of China**
Chapter One General Provisions		
Legislative purposes	**Article 1** The Measures are formulated for the purpose of efficiently protecting and rationally	**Article 1** The Regulations are formulated for the purposes of effectively protecting and reasonably utilizing China's human genetic resources as well as **safeguarding public**

	utilizing human genetic resources of China, strengthening the research and development of human genes and promoting international cooperation and exchange on the basis of equality and mutual benefits.	**health, national security and public interest**.
Definition of human genetic resources	**Article 2** For the purpose of the Measures, the term "human genetic resources" refers to the genetic materials such as human organs, tissues, cells, blood specimens, preparations of any types or recombinant DNA constructs, which contain human genome, genes or gene products as well as the information relating to such genetic materials.	**Article 2** The term "human genetic resources" as mentioned in the Regulations shall include both human genetic resource **materials** and human genetic resource **information**. Human genetic resource **materials** refer to genetic materials such as organs, tissues and cells that contain hereditary substances such as human genomes and genes. Human genetic resource **information** refers to information materials such as data generated from human genetic resource materials.
Application scope	**Article 3** Whoever engages in such activities in China as **collecting, researching, developing, trading or exporting** human genetic resources or taking such resources outside the territory of the People's Republic of China shall abide by the Measures.	**Article 3 Collecting, preservation, utilization and external provision** of China's human genetic resources shall comply with the Regulations. **Collecting and preserving** human substances such as organs, tissues and cells and carrying out related activities for the purposes of clinical diagnosis and treatment, blood collecting and supplying services, crime investigation, doping detection and funeral and interment shall comply with the provisions of relevant laws and administrative regulations.
Administrative authority	**Article 6 The State carries out administration of human genetic resources at**	**Article 4 The administrative department of science and technology under the State Council is responsible for the management of human genetic resources nationwide; and**

	different levels and implements unified approval system. **Article 7 The competent <u>administrative department of science and technology</u> as well as the competent <u>administrative department of health</u> under the State Council shall be jointly responsible for the administration of human genetic resources all over China and shall jointly establish the Human Genetic Resources Administration of China (hereinafter referred to as the "HGRAC" in short) to carry out routine duties.** **Article 10** The competent administrative department of science and technology as well as the competent administrative department of health in all provinces, autonomous regions or centrally-administered municipalities (hereinafter referred to as the "local administrative departments" in short), shall be responsible for the administration of human genetic resources in their	**other relevant departments of the State Council are responsible for the management of human genetic resources within the scope of their respective functions and responsibilities.** **The administrative departments of science and technology of the people's governments of the provinces, autonomous regions and centrally-administered municipalities are responsible for the management of human genetic resources in their respective administrative areas; and other relevant departments of the people's governments of the provinces, autonomous regions and centrally-administered municipalities are responsible for the management of human genetic resources in their respective administrative areas within the scope of their respective functions and responsibilities.**

	own respective regions. The relevant department under the State Council shall be responsible for the administration of human genetic resources within their respective administrative domains.	

* Due to space constraints, only part of the Appendix is excerpted here for readers. If you need a full text of the *Appendix: Clause by Clause Comparison between Former Regulations and New Regulations*, please contact the author.

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