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Opinion

Reasons Gene Technology Needs Legal Definition

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Gene technology, forming the core of modern biotechnology, is extensively used in the treatment of diseases and has a significant impact on the development of medical technology. Nevertheless, in addition to great benefits, a number of problems have resulted from the development of gene technology, including the risks to human health and environmental safety. It is speculated that these risks will lead to a "genetic risk society," so it is crucial that all countries actively regulate gene technology. The formulation of exclusive rules to regulate the use of gene technology must be based on a clear definition of gene technology as a legal concept. Currently, there is no standardized definition of the term "gene technology" in both international and domestic laws, and the legislative forms and definition methods adopted by the United States (US) and the European Union (EU) differ in several aspects.

The definition of "gene technology" adopted by the US can be traced to the early definition in the NIH Guidelines for Research Involving Recombinant DNA Molecules. Subsequently [1], this early definition was modified by the OSTP framework. In the third stage, the USDA, the FDA, and the EPA collaborated to follow the authorization of the Congress to formulate and implement regulations for the Act, and thereby to modify and supplement the existing gene technology regulations, although there is a lack of "gene technology" for the implementation of the law [2]. In 2016, the National Bioengineered Food Disclosure Standard defines terms such as "bioengineering" in a rather straightforward manner, indicating only the production of food that contains a substance produced through the use of a chemical or biological agent. According to the National Bioengineered Food Disclosure Standard of 2016, "bioengineered" signifies a food product containing genetic material that has been modified by in vitro recombinant DNA technology and that cannot be obtained through conventional or natural breeding [3]. Never theless, the conceptual outreach of the terms remains unclarified, as a result of which new genetic technologies such as CRISPR-Cas9 are left outside the purview of the law [4]. In general, the definition of the gene technology concept in the US has gone through industry standards, regulations, and federal legislation, revealing a trend of rising legislative level; however, the actual effect has been to deregulate the standardized use of gene technology.

There is a great difference between the direction of gene technology regulations and that of the US in general. The EU, which firmly holds that only by controlling gene technology from the source can the risks and hazards of gene technology products be controlled within the minimum scope, defines the term "gene technology" mainly through regulations and directives. It attaches great importance to the risk control of the whole process of gene technology—from research and development to the circulation of gene technology products on the market [5]. The restrictions imposed by the EU on human gene editing are equally stringent, with a preference for ethical and human rights considerations, which seem to be rooted in Europe's historically negative experiences with eugenics and human enhancement and are reflected in the regulatory framework and specific provisions at the EU level. The framework of gene technology is not only focused on the present, specific provisions, but it also considers future development [6].

The legal definitions of the concept of gene technology in the US and the EU have their respective advantages and disadvantages; however, these definitions represent the first step toward regulating gene technology. Defining gene technology scientifically and reasonably, which provides an important basis for regulating gene technology, is also a logical starting point for realizing the guidance

of science and technology and clarifying the value orientation of technology regulation. A clear understanding of the legal concept of gene technology is crucial to standardizing gene technology and forming a binding discipline. Only by clearly defining the concept can the object and scope of legal regulation be clarified, whereupon the appropriate development of gene technology with dual-use characteristics can be guided and the wrong development can be corrected to guarantee the beneficial development of gene technology.

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Conflict of Interest

None.

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