Science and Technology Research Project 2020

Genome-Editing Technology and Its Impact

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Summary

I Overview

Basics of and Applications for Genome Editing

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Genome editing that accurately modifies a targeted gene is a technology that has far-reaching applications, and there is strong competition worldwide to develop such technology. CRISPR-Cas9 is a simple yet versatile genome editing tool that was first reported in 2012. Since that time, however, disputes over patent rights have arisen worldwide, and the concern that multiple contracts may be required for commercialization has resulted in efforts to develop genome editing tools domestically in Japan. It has also been noted that the application of genome-editing technology in the fields of agriculture and fisheries will also require government policies that provide support for providing the public with a proper explanation of component analysis and safety evaluation as part of developing consumer demand. In medical fields, this is a need for a social apparatus to provide patients and their families with information on the risks, effects, and limits of this technology in deepening their understanding, which means that discussions must include not just medical specialists but also the patients and others who are to be the beneficiaries of genome editing. This technology is also expected to play a major role in improving the competitiveness of Japanese industry.

II Technology and Challenges

An Overview of Genome Editing Technology and Issues Related to Social Implementation

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The biotechnology industry is expected to undergo major changes due to social demands for a carbon-neutral and sustainable society as well as the emergence of genome editing and other breakthrough technologies, which will result in growth into even greater economic activity worthy of the name "bioeconomy." Genome editing is a technology that enables modification of genomic DNA and is now being used in drug discovery, production of microorganisms and other functional substances, and the modification of agricultural products with significant added value. This paper outlines the concepts of genome editing and describes the features of tools such as Zinc Finger Nuclease, TALE Nuclease, and CRISPR/Cas9 as part of a discussion of the economic environment for and the use of genome editing in the fields of medicine, industry, and agriculture as well as the impact of new biotechnologies such as genome editing on society.

Trends in Genome-Edited Crops and Consumer Awareness

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As the development of genome-edited crops and regulatory policies for them are announced around the world, consumer acceptance of genome-edited crops is attracting attention. While the scientific safety of genome-edited crops is an issue in the process of regulatory review, it is also necessary to compare new technologies with conventional breeding techniques if consumer understanding is to be deepened. Dispelling consumer concern regarding the long-term consequences and other uncertainties of this technology will be no easy matter, especially since these concerns go beyond the perspective of scientific safety. While it is often assumed that individual consumers benefit directly from genome-edited crops, because of their added value as food, consumers themselves do not necessarily give preference to such personal benefits, but rather set a higher value on the necessity for and the objective of crop development as well as the manner in which relevant information is provided.

Clarification of Regulatory Oversight for Products Created with Genome Editing Technology in Japan and an Overview of Related Issues

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In 2019, the Ministry of the Environment (MOE) announced policies for regulating the handling of products created with genome editing technology with regard to their impact on biodiversity, while the Ministry of Health, Labor and Welfare (MHLW) did the same from the viewpoint of food safety, thereby establishing a system that requires both a certain level of legal review as well as the provision of information, consultation, and notification before the fact. Elsewhere around the world, while other countries have instituted at least partial regulation of products created with genome editing technology, very few countries have clarified policies related to all aspects of regulation. Given the active level of research and development now going on in Japan, distribution of specific crops is expected to begin soon. Thus, increasingly complex regulations pose significant implications for trade as well as for governance and risk communication.

Against this background, this section identifies points of contention through detailed analysis of the regulation of the handling of products created with genome editing as well as to clarify the issues that a new technology would face in a legal system based on conventional technology.

Thus, the lessons learned during the process of clarifying regulatory treatment in Japan were that (1) existing regulations and legal provisions serve as the default settings from which the subsequent handling of technology will be handled in a route-dependent manner, and that (2) the management of such technology will be based on a comprehensive judgment that must include scientific and legal considerations as well as social demands. Also, future considerations will include (1) comparative research of the laws and regulations of other countries (including detailed analysis of differences in regulation as well as the necessity for thought experiments), (2) promotion of international collaboration and discussion in horizon scanning and regulatory science, and (3) promotion of policy research on the relationship of emerging technologies with society (configuration of a mechanism capable of accommodating route dependence, design of systems capable of anticipatory governance, research into the impact of regulation on domestic industries and innovation, promotion of responsible research innovation (RRI); ethical, legal, social implications (ELSI); and public engagement).

Current Issues in the Application of Genome Editing Technology to Medical Care

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Recent advances in the approval of gene therapy drugs in Japan, the United States, and Europe have once again placed gene therapy in the limelight. At the same time, advances in genome editing technology have made it possible to perform gene knockout and accurate gene repair therapies that were not possible with conventional “gene-addition” therapies. About 50 clinical trials of genome editing therapy have already been conducted in countries around the world, resulting in protocols that are not only safe but also therapeutic. There are, however, numerous difficulties yet to be overcome in the clinical application of genome editing, such as the gene transfer efficiency of conventional gene therapy and immune response to vectors and therapeutic genes, as well as challenges peculiar to genome editing technology, such as the risk of introducing DNA mutation due to off-target activity of artificial nucleases or the immune response to artificial nucleases. Further technological development is necessary to establish genome editing as a viable treatment for a wider range of diseases. In this paper, we will discuss typical preclinical and clinical trials of genome editing therapy as well as explain other recently clarified technical issues.

III Technology and Society

The Social Implementation of Emerging Technologies

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The social implementation of genome editing and other emerging technologies will require a clear understanding of the issues that are suggested by concepts such as “trans-science” and “hype cycle,” which exist in the significant gaps in understanding between technology and society. Within these gaps exist not just issues related to understanding the technology itself, but also those related to the impact of technology on safety and security as well as ethical, legal, and social issues (ELSI). Smooth social implementation will mean dealing with these issues in real time from the earliest stages of technology development. In particular, ELSI began as a systematic effort to discover and address gaps in understanding between scientists and society regarding the emerging technology of genome analysis. In the course of thirty years of ELSI research, a valuable record of suggestions related to emerging technologies from a wide variety of perspectives. The lessons learned during the social implementation of genome analysis and other emerging technologies serve as a valuable guide for future efforts and will inform the context from which the acceptance of such technologies can best be recommended.