frontiers | Frontiers in Political Science

TYPE Editorial
PUBLISHED 20 September 2022
DOI 10.3389/fpos.2022.1027410

OPEN ACCESS

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SPECIALTY SECTION
This article was submitted to Politics of Technology, a section of the journal Frontiers in Political Science

RECEIVED 25 August 2022
ACCEPTED 02 September 2022
PUBLISHED 20 September 2022

CITATION
Asquer A and Morrison M (2022) Editorial: Regulation and governance of gene editing technologies (CRISPR, etc.). *Front. Polit. Sci.* 4:1027410. doi: 10.3389/fpos.2022.1027410

Editorial: Regulation and governance of gene editing technologies (CRISPR, etc.)

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KEYWORDS

gene editing, CRISPR, regulation, governance, public participation

Editorial on the Research Topic
Regulation and governance of gene editing technologies (CRISPR, etc.)

"Gene editing" describes a range of tools and techniques in molecular biology that permit scientists to make directed changes to the genetic material of any living organism. Gene editing can be understood as a "gateway technology;" these techniques offer versatile, accessible tools for use in experimental settings, and they have a wide range of potential applications in diverse sectors. Techniques for modifying DNA have been in use since the 1970s, while early gene editing techniques first emerged around 30 years ago. However, it was the identification in 2012 of CRISPR/cas9 gene editing by a research group led by Jennifer Doudna and Emmanuelle Charpentier (Jinek et al., 2012) that catalyzed the current global explosion of interest and activity in gene editing. CRISPR, which stands for Clustered Randomly Interspersed Short Palindromic Repeats, acts faster and is cheaper and easier to make and use than other genetic modification or gene editing tools. The skills and equipment needed to use CRISPR can be found in most academic and commercial life sciences laboratories, and CRISPR components were rapidly made available at low cost through existing channels for distributing biological reagents (Martin et al., 2020). The preceding 40-plus years of research and commercial activity with genetic engineering technologies also served to identify a considerable range of applications or suggest new avenues for development where CRISPR might improve on existing genetic modification practices. Accordingly, global research on gene editing, as indicated by the number of publications (Asquer and Krachkovskaya, 2021; Zhou et al., 2021) and patent filings (Bicudo et al., 2022), has demonstrated a steep increase since 2012. From being a niche research interest, gene editing must now be considered a field of international scientific, commercial, and increasingly, public interest (Martin et al., 2020).

As is now commonplace with emerging technology fields (and here we might think of artificial intelligence or nanotechnology), CRISPR/cas9 gene editing was heralded with considerable promise in both the popular and scientific press (Ledford, 2015; Maben, 2016). Gene editing can be applied in almost all organisms, from plants and

microorganisms to humans and other animals. The areas of potential application range from human health and reproduction to agriculture, industrial manufacture (for example of biofuels), control of harmful or invasive species, and other, emerging possibilities such as biocomputing (encoding data in living systems), recreating extinct species, biowarfare and bioterrorism, and do-it-yourself biology also known as bio-backing where individuals conduct experiments outside formal institutional settings (Dimond et al., 2021). However, many actual or prospective applications of gene editing have also provoked considerable concern and unease.

Most notably, and egregiously, in November 2018, He Jiankui, a scientist based in China, reported to a global audience the birth of the world's first genetically edited babies. Reproductive, or "germ line," genetic modification has been viewed as ethically unacceptable since the early days of genetic modification and is prohibited by law in many jurisdictions (Isasi et al., 2016). Unsurprisingly then, Jiankui's actions led to a considerable amount of international condemnation and commentary, and also, eventually to a custodial sentence for Jiankui himself (Rosemann et al., 2019). Nonetheless, the possibility of heritable genetic modification of humans is now a reality rather than merely a possibility and must be contended with (Martin and Turkmendag, 2021).

In the field of agricultural biotechnology, the advent of CRISPR/cas9 gene editing also gave new animus to another controversial issue from a prior era of genetic technology, genetically modified organisms (GMOs). The most pressing question for many scientists and companies was whether a new generation of gene edited crops would fall under existing legislation for the production and release of GMOs. Different jurisdictions have adopted divergent approaches: the US Department of Agriculture (USDA) opted not to subject gene editing crops to additional regulation provided the gene editing technique does not introduce "novel" DNA into the modified organism, while the EU has ruled that all gene edited plants and animals fall under its existing GMO directives (Callaway, 2018; Wolt and Wolf, 2018). The latter decision has proved particularly controversial and has provoked a range of proposals (and demands) to reform EU legislation (Ricroch and Hénard-Damave, 2016; Garland, 2021).

Another potential non-human application of gene editing is to create so-called "gene drives" that enable a genetic modification to be transmitted from one organism to another through normal sexual reproduction, potentially enabling large-scale modification of whole populations of organisms in the wild (Rabitz, 2021). The main anticipated aim is to control populations of pest organism such as invasive non-native species or "crash" populations of malaria-transmitting mosquitos. However, gene drive organisms need to be released into the wild, outside a controlled environment, which poses considerable challenges for governance, not least as modified organisms cannot be expected to stay within national jurisdictions (Oye et al., 2014; Rabitz, 2021).

Whilst not an application *per se*, the patent rights to CRISPR/cas9 have also been subject to a protracted dispute (Sherkow, 2017; Panagopoulos and Sideri, 2021), while the patenting strategy of the CRISPR patent holders has also been subject to ethical critique for its potential impacts on innovation (Feeney et al., 2018; Panagopoulos and Sideri, 2021; Bicudo et al., 2022).

This is an illustrative, rather than an exhaustive list, but it is sufficient to evoke the range of governance and regulatory challenges raised by the advent of gene editing technology, which also form the basis for this thematic collection. The title of this collection "*Regulation and Governance of Gene Editing Technologies (CRISPR, etc.)*," should not be taken to imply that it is necessarily gene editing technology *per se* that requires regulatory scrutiny (Moses, 2016). It is better read as a shorthand for a more nuanced debate, about the role of regulation in steering the (sociotechnical) systems and environments in which gene editing technology is developed into (largely commercial) products and services. Gene editing research and development is taking place in many countries, with human health and agriculture being the main commercial sectors so far. Accordingly, the papers in this collection come from authors from various nations, including the US, France, Germany, Japan, Australia, and Belgium, and the collection includes articles on governance and regulation of both human and animal gene editing.

The papers of this Research Topic can be positioned around four main themes, namely the analysis of genome editing debate, the design and assessment of regulatory tools, the role of Responsible Research and Innovation, and the integration of the regulatory and governance system for genome editing.

Two papers of this Research Topic analyse the features of the contemporary debate on gene editing. The contribution of Meyer and Vergnaud shows that governance and regulation of gene editing has been discussed across an increased number of disciplines and countries over the years. The debate gradually shifted away from reflections on the potential applications and benefits of gene editing toward calls for policy actions and regulatory interventions. The authors also notice that the public is portrayed in different ways ranging from recalcitrant subjects that must come to accept the use of gene editing to parts of the civil society that should be involved and engaged in a democratic debate on the use of gene editing. The issue of public engagement is specifically tackled by Iltis et al., who investigate the ethical roots of sources of substantive disagreement about appropriate research pathways and permissible clinical applications. They also identify five ideals that should guide the engagement of the public and stakeholders in science policy development, namely that engagement efforts should be comprehensive, transparent, inclusive, methodologically sound and accountable.

Three other papers of this Research Topic contribute advance scholarship on the design and assessment of regulatory tools in the field of gene editing, specifically dealing with patenting and marketing authorization. The study of Scheinerman and Sherkow provides a review and assessment of the various governance choices over patenting in gene editing. The authors observe that patents covering many of the most controversial applications of gene editing are regulated *via* non-democratic or anti-democratic institutions, such as private restrictions on licensing, while other patents that are more broadly related to democratic deliberation, like compulsory licenses, are poorly aimed for particular applications. The lack of democratic legitimacy is also discussed in the contribution by Feeney et al., who critically assess the advantages and disadvantages of three forms of governance of gene editing—namely, traditional regulation, ethical licensing and Parthasarathy's (2018) patenting system—before offering some amendments of Trade-Related Aspects of Intellectual Property Rights (TRIPS) and an alternative proposal of a WTO ethics advisory committee. The contribution of Nielsen et al., instead, provides an assessment of market authorization for gene edited products with respect to canons of public participation, transparency and accountability. Building on the analysis of the regulatory pathways of the US Food and Drugs Administration, the European Medicines Authority, and the Australian Therapeutic Goods Administration, the authors propose to incorporate principles of citizens participation into the regulatory process for the review of products of gene editing.

Two additional papers of this Research Topic focus on the role of Responsible Research and Innovation (RRI) in gene editing in different country contexts. The study by Kuzma and Cummings investigates attitudes toward RRI in the US in order to explore the possibility to establish coalitions on the conduct of gene editing research and applications. The authors highlight that positive attitudes toward principles and practices of RRI are associated with egalitarian cultural beliefs and higher levels of experience, and are negatively related to professional affiliation with industry or trade organizations. The work of Müller et al., instead, examines attitudes toward RRI in Germany. The authors show that agricultural stakeholders in a project that was intended to promote RRI in Bavaria expressed their skepticism toward the adoption of gene editing in Bavarian livestock agriculture. They conclude by discussing the importance of redistributing benefits among stakeholders to ease tensions between policy fields or circumvent other contextual constraints.

Finally, two papers of this Research Topic address the issue of the fragmentation of regulation and governance gene editing. The contribution by Mahalatchimy and Rial-Sebbag analyses the divisions, splits, and segmentation of the regulatory landscape for human germline editing in the EU (and France in particular), which they relate to historical and technicolegal reasons. The study of Minari et al., instead, looks at the reasons for the fragmentation of the regulatory field of gene editing in Japan and at the constraints to harmonization that arise from the tension between national and international approaches. The authors conclude by proposing a contiguous governance model that attends to both geopolitical (i.e., synchronic) and historical (i.e., diachronic) perspectives.

Taken together, the articles of this Research Topic address central concerns in the regulation and governance of gene editing, namely ensuring the participation of the public and stakeholders in identifying issues posed by gene editing technologies and approaches that should be adopted in related research and applications. Further research along these lines will help foster a democratic debate on the use of gene editing, cultivating trust toward scientists and public officers, and promoting the welfare of society at large over the exclusive pursuit of private interests.

Author contributions

Both authors listed have made a substantial, direct, and intellectual contribution to the work and approved it for publication.

Funding

The contribution of MM was supported the Leverhulme Trust under Grant No. RPG-2017-330 BioGOV; Governing biomodification in the life sciences.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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