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Uncertainty, institutions and regulatory responses to emerging technologies: the case of CRISPR Gene Editing in the US and the EU (2012-2019)

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Outline

- 1. The regulation of emerging technologies
- 2. Theories of the policy process
- 3. CRISPR gene editing technique
- 4. Regulation of CRISPR in the US
- 5. Regulation of CRISPR in the EU
- 6. Comparative analysis and discussion



1. The regulation of emerging technologies

Emerging technologies are characterized by radical novelty, relatively fast growth, coherence, prominent impact, and uncertainty (Rotolo *et al.* 2015)









1. The regulation of emerging technologies

Emerging technologies provide sources of innovation but also pose novel dangers and hazards to individuals and the environment



Uber self-driving crash 'mostly caused by human error'



'I wash all my food like crazy': scientists voice concern about nanoparticles

US foods are increasingly full of nano-scale additives, even as researchers raise alarm bells about their safety

fastFT Cryptocurrencies (+ Add to myFT

Bitpoint exchange says hackers stole \$32m in cryptocurrency

The loss follows a series of big hacking attacks on cryptocurrency exchanges

Robin Harding in Tokyo JULY 12 2019

C Share



1. The regulation of emerging technologies

How are emerging technologies regulated?

- What is it that should be regulated?
- What sort of dangers or hazards are actually posed?
- Who should be regulated?
- How should applications of emerging technologies be regulated?















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2. Theories of the policy process



- How will technology change?
- How will tech change impact regulatory activity?
- What are regulatory options and their effects?





2. Theories of the policy process





2. Theories of the policy process





CRISPR:

clustered regularly interspaced short palindromic repeats



- University of Osaka, 1987
- University of Alicante, 1993
- Danisco (DuPont), 2007
- Umeå University in Sweden, University of California, Berkeley, the Broad Institute, 2012

























Application of CRISPR/Cas9-Based Gene Editing in HIV-1/AIDS Therapy

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Perspective Published: 30 March 2020

A CRISPR way for accelerating improvement of food crops

Yi Zhang, Mathias Pribil, Michael Palmgren 🖂 & Caixia Gao 🖂

Nature Food 1, 200–205(2020) | Cite this article















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CRISPR'd babies: human germline genome editing in the 'He Jiankui affair' d

Henry T Greely 🖾 👘 Author Notes

Journal of Law and the Biosciences, Volume 6, Issue 1, October 2019, Pages 111– 183, https://doi.org/10.1093/jlb/lsz010 Published: 13 August 2019 Article history v

4. Regulation of CRISPR in the US

- **1986** Coordinated Framework for the Regulation of Biotechnology (EPA, FDA, USDA-APHIS)
- **2016** National Strategy for Modernizing the Regulatory System for Biotechnology Products, Biotechnology Working Group of the Emerging Technologies Interagency Policy Coordination Committee
- **2017** Update to the Coordinated Framework for the Regulation of Biotechnology, White House Office of Science and Technology Policy
- **2019** Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products

"... avoid arbitrary or unjustifiable distinctions across like products developed through different technologies."



5. Regulation of CRISPR in the EU

- **2001** EU Directive 2001/18 ("GMO directive")
- **2014** EU Parliament resolutions to the Commission to clarify the status of new breeding techniques and to established a separate approval process for cisgenic and transgenic plants
- **2016** Report on Technological Solutions for Sustainable Agriculture in the EU, Committee on Agriculture and Rural Development
- **2018** European Court of Justice ruled (Case C-528/16) that the new breeding techniques including CRISPR should be regulated as GMOs and therefore subjected to review, traceability, labelling and monitoring for commercial purposes

Call for review of GMO directive from the Group of Chief Scientific Advisors of the Commission



6. Comparative analysis and discussion

Similarities between cases

- Divergent values and goals among stakeholders
- Uncertainties about CRISPR applications, appropriateness of existing regulatory system, and regulatory options available

Differences between cases

- Institutional conditions (venues for policy-making)
- Anticipatory vs. reactionary policy response
- Regulatory parsimony vs. precautionary principle



6. Comparative analysis and discussion

Open issues of regulatory policy research:

- Role of CRISPR in the public debate
- Regulatory restrictions and forum shopping
- Industrial policy and global competition for talents
- Political economy of gene patents
- Ethical issues around editing human embryos



Resources on regulation of CRISPR gene editing

http://www.asquer.com/topics/regulation-of-crispr/

Regulation of CRISPR genetic editing

This page is a collection of resources around the regulation of CRISPR genetic editing. Please scroll below to find links to pieces of legislation and policies, resources, and academic papers. I will add further resources and commentary over time.



(Last update 25 May 2020)

Legislation and policies

- US 1986 Coordinated Framework
- California legislation "SB-180 Gene therapy kits: advisory notice and label
- EU 'GMO directive' <u>2001/18/EC</u> and <u>GMO legislation page</u>
- EU opinion of Advocate General Case C-528/16
- French Plan for Genomic Medicine 2025
- Oviedo Convention ETS No.164



Thank you

