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【内容摘要】

【关键词】

CRISPR Clustered Regularly Interspaced Short Palindromic Repeats

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1 See Alex Camacho, Allen Van Deynze, Cecilia Chi-Ham & Alan B. Bennett, Genetically Engineered Crops That Fly under the US Regulatory Radar, 32 Nature Biotechnology 1087 (2014).

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Trends in Plant Science 1204 2021 .
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134-135

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1986

CRISPR

DNA

⁶ 2015 10

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⁸ 2021

SECURE Sustainable, Ecological, Consistent,

Uniform, Responsible, Efficient Rule

SECURE

SECURE

Regulatory Status Review RSR

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SECURE

SECURE

RSR

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Directive 2001/18/EC

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2016 2 464

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DNA

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⁹ See Margaret Rosso Grossman, The SECURE Rule: New Regulations for Crop Biotechnology in the United States, 15 European Food and Feed Law Review 554 2020 .

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¹¹ See Neil E. Hoffman, Revisions to USDA Biotechnology Regulations: The SECURE Rule, 118 Agricultural Science 1 2021 .

¹² See Margaret Rosso Grossman, The SECURE Rule: New Regulations for Crop Biotechnology in the United States, 15 European Food and Feed Law Review 559 2020 .

¹³ See Clark Wolf, Public Trust and Biotech Innovation: A Theory of Trustworthy Regulation of Scary Technology, 38 Social Philosophy and Policy 29, 42-48 2021 .

DNA

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2000

Organism, LMO

2001/18/EC

GMO

Living Modified

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GMO

GMO

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22 See Martin A. Lema, Regulatory Aspects of Gene Editing in Argentina, 28 *Transgenic Research* 147 (2019) .

23 See Genetic Technology Precision Breeding Bill of UK (2023) .

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LMO

25 See Yangbin Gao & Yunde Zhao, Self-Processing of Ribozyme-Flanked RNAs into Guide RNAs in Vitro and in Vivo for CRISPR-Mediated Genome Editing, 56 *Journal of Integrative Plant Biology* 343 (2013) .

26 See Tade Spranger, Case C-528/16: Questions Raised by the ECJ' s Judgement on Gene Editing Technology, 4 *International Chemical Regulatory and Law Review* 173, 174-176 (2018) .

DNA

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RNA RNA interference RNAi

Plant-Incorporated Protection, PIP

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2019

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GMO

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28 See Steven H. Straus & Joanna K. Sax, Ending Event-Based Regulation of GMO Crops, 34 Nature Biotechnology 476 2016 .

29 See Margaret Rosso Grossman, Who Will Regulate Genetically Engineered Animals in the United States?, 16 European Food and Feed Law Review 327 2021 .

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32 See the European Commission, Study on the Status of New Genomic Techniques under Union Law and in Light of the Court of Justice Ruling in Case C-528/16, Commission Staff Working Document, SWD 2021 92 final, April 29, 2021, p. 24-28.

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34 See The EU Legislation for Plants Produced by Certain New Genomic Techniques, Ref. Ares 2021 5835503.

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1995 1 68-73

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SECURE

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SECURE

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2020 2 130

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2015 9 125

47 See Douglas A. Kysar, Preferences for Processes: The Process/Product Distinction and the Regulation of Consumer Choice, 118 Harvard Law Review 540 2004 .

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See Jennifer Kuzma & Khara Grieger, Community-Led Governance for Gene-Edited Crops, 370 Science 916 2020 .

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51	“	”	“	”	2004	6	579
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Regulatory Horizons Council

RHC

Organization for Economic Co-operation and Development OECD

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66 See Doria R. Gordon, Gregory Jaffe, Michael Doane, Aviva Glaser, Thomas M. Gremillion & Melissa D. Ho, Responsible Governance of Gene Editing in Agriculture and the Environment, 39 Nature Biotechnology 1055, 1055-1057 (2021).

67 See EU Legislation for Plants Produced by Certain New Genomic Techniques, Ref. Ares (2021) 5835503, p. 3.

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76 See EU Legislation for Plants Produced by Certain New Genomic Techniques, Ref. Ares (2021) 5835503, p. 5.

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Abstract: Gene editing technology has been successfully applied in traditional plant breeding, which quickly opens a new track of competition in the field of agricultural industry. In the world, regulating gene-edited plants mainly relies on the GMO law, such as a product-based model according to the principle of substantial equivalence, a process-based model according to the risk precautionary principle, and a separate regulatory model from process-based to product-based. However, these traditional models ignore the essential difference between gene-edited plants and GMO, and produce two extreme attitudes, that is technological optimism and technological pessimism. In order to ensure food safety and environmental safety and prevent the misuse and abuse of gene editing technology in agriculture, the regulation related to gene-edited plants should separate from the GMO law, as well as change the legislative values, the legislative principles and the specific rules.

Key Words: gene-edited plant, GMO, precautionary principle, substantial equivalence principle

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