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【内容摘要】

【关键词】

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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).

2 CRISPR

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Trends in Plant Science 1204 2021 .  
4 2005 10 115-116  
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134-135

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1986

CRISPR

DNA

<sup>6</sup> 2015 10

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Uniform, Responsible, Efficient Rule  
SECURE

<sup>8</sup> 2021  
SECURE Sustainable, Ecological, Consistent,

SECURE

Regulatory Status Review RSR

<sup>9</sup> SECURE

SECURE  
SECURE

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Directive 2001/18/EC

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2016 2 464

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<sup>9</sup> 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 .

<sup>10</sup> 552-553

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

<sup>12</sup> 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 .

<sup>13</sup> 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 .

Genetically Modified Organisms<sup>14</sup> 2016

2001/18/EC

GMO

GMO<sup>15</sup> 2018

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14 See Ludivine Petetin, The Precautionary Principle and Non-Scientific Factors in the Regulation of Biotech Foods, 8 *European Journal of Risk Regulation* 106, 107-109 (2017).

15 See Thorben Sprink, Janina Metje, Joachim Schiemann & Frank Hartung, Plant Genome Editing in the European Union — to Be Or Not to Be — a GMO, 10 *Plant Biotechnology Reports* 349 (2016).

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17 See Fyodor D. Uronov, Pamela C. Ronald & Dana Carroll, A Call for Science-Based Review of the European Court’s Decision on Gene-Edited Crops, 36 *Nature Biotechnology* 801 (2018).

18 See Giovanni Tagliabue, The EU Legislation on “GMOs” Between Nonsense and Protectionism: An Ongoing Schumpeterian Chain of Public Choices, 8 *GM Crops & Food* 67 (2017).

19 See Martin A. Lema, Regulatory Aspects of Gene Editing in Argentina, 28 *Transgenic Research* 148 (2019).

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

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Organism, LMO

2001/18/EC

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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

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DNA

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RNA RNA interference RNAi

Plant-Incorporated Protection, PIP

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GMO

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Regulatory Horizons Council

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Organization for Economic Co-operation and Development OECD

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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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