

The article "Ukraine as a Regulatory Bridge: Harmonizing GMO Laws Across the EU, US, and UK Approaches" was published on the website of Anwaltskanzlei "SePavlov & Professionals" ([www.marsser.com](http://www.marsser.com)). It is publicly accessible and protected by copyright. The views expressed in the article represent the author's personal opinion.



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## **UKRAINE AS A REGULATORY BRIDGE: HARMONIZING GMO LAWS ACROSS THE EU, US, AND UK APPROACHES**

### *Abstract:*

Ukraine has been a Party to the Cartagena Protocol on Biosafety since 2002. The adoption of Law No. 1103 in 2007 established the legal framework for the regulation of genetically modified organisms (GMOs) and biotechnology in the country. However, the emergence of an illegal GMO market has revealed significant deficiencies in the existing legislative system.

Following a protracted legislative process, on 23 August 2023, Ukraine enacted Law No. 3339, which repealed the 2007 Law No. 1103 and introduced a new regulatory regime governing the circulation of GMOs and GMO-related products.

This article examines the sixteen-year legislative trajectory that culminated in the adoption of Law No. 3339 and proposes an explanation for the prolonged duration of the lawmaking process.

**Keywords:** Ukrainian bioengineering, genetically modified organisms (GMO), regulation of genetically modified organisms (GMOs)

### ***I. Introduction.***

On September 12, 2002, Ukraine joined the Cartagena Protocol on Biosafety under the Convention on Biological Diversity (hereinafter referred to as the Cartagena Protocol).<sup>1</sup> This means that Ukraine, like other countries participating in the Cartagena Protocol, has joined in order to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling, and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health and specifically focusing on transboundary movements.

In order to implement its international obligations, Ukraine has developed a legislative framework for regulating biodiversity and biotechnology, the creation and transportation of genetically modified organisms, and biological and food safety. Ukrainian biotechnology legislation is based on the Law of Ukraine "On the State System of Biological Safety in the Creation, Testing, Transportation and Use of Genetically Modified Organisms" No. 1103 of May 31, 2007 (hereinafter referred to as Law 1103).<sup>2</sup>

Law No. 1103 served as a framework and system-forming act for the entire field of GMO regulation in Ukraine. On 23 August 2023, Ukraine adopted a new framework law entitled "*On State Regulation of Genetic Engineering Activities and State Control over the Placement on the Market of*

<sup>1</sup> Law of Ukraine "On the accession of Ukraine to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity" Verkhovna Rada of Ukraine, No. 152-IV dated January 29, 2000., <https://zakon.rada.gov.ua/laws/show/152-15#Text>

<sup>2</sup> Law of Ukraine "On the State System of Biosafety at the Time of Creating, Testing, Transporting, and Using Genetically Modified Organisms" Verkhovna Rada of Ukraine, No. 1103 dated May 31, 2007., <https://zakon.rada.gov.ua/laws/show/1103-16#Text>

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*Genetically Modified Organisms and Products,* " No. 3339 (hereinafter referred to as the "New Law" or "Law No. 3339"), intended to replace Law No. 1103.

The repeal of Law No. 1103 and the full entry into force of Law No. 3339 are to occur gradually over a three-year transitional period.

It is well established that, in any national legal system, a framework law plays a fundamental role. It sets out the general principles and objectives of regulation for an entire sector of social relations, establishes the legal foundation for subsequent legislative and regulatory acts, defines institutional mechanisms, and codifies the rights and obligations of stakeholders.

What necessitated the adoption of the new framework Law No. 3339, and why was it enacted sixteen years after the entry into force of Law No. 1103?

To answer this question, it is useful to examine publicly available sources concerning the practical implementation of Law No. 1103. It is important not only to understand the historical background of this legislative shift, but also to assess what may be expected from the newly adopted Law No. 3339.

## ***II. Public Assessment of Law No. 1103***

On December 12, 2008, columnist Ksenia Nesterenko in a publication titled "Do Ukrainians eat tomatoes with the flounder gene and scorpion bread?" writes, "... the shelves of Ukrainian supermarkets are filled with food products containing GMOs, and the main issue is that Ukrainians, unlike Europeans, do not know about it. ... Recently, Ukraine was visited by well-known Canadian farmer and winner of the Alternative Nobel Prize Percy Schmeiser, recognized globally for his resistance to the spread of genetically modified organisms. Percy Schmeiser spoke about the consequences of the uncontrolled spread of GMOs in Canada and urged Ukrainians to be cautious about such products. Despite the fact that Canada and the US are the world's largest lobbyists for GMOs, not all residents of these countries support such policies..."<sup>3</sup>

On January 21, 2010, columnist Evgenia Ustinova in her publication "Ukraine GMOs in the Law" quotes Ruslan Golubets, chairman of the Molecular Genetic Laboratory of "Ukrmetrteststandard",<sup>4</sup> "... there are already 13 accredited laboratories in the Gospotrestandart system, equipped with both the necessary equipment and personnel ..."<sup>5</sup>. However, Ustinova expresses doubt, "... Experts are confident that the law will work, and that all the issues are temporary, but why is there such confidence that the law will work properly? Where are the mechanisms for enforcing labeling requirements for GMO-containing products? We don't even have enough laboratories...".<sup>6</sup>

Nine years after the adoption of Law 1103, on November 22, 2016, columnist Inna Strebkova in her publication "GMOs in Ukraine: Prohibition cannot be used" writes, "... In recent years, Ukraine has taken the lead in Europe for the cultivation of genetically modified soybeans. Today, the annual volume of its production exceeds the total amount of GM legumes harvested by farmers in European countries. According to various estimates, the percentage of genetically modified soybeans in domestic fields ranges from 30% to 94%. Experts cannot give a more precise figure, as none of the GM varieties are officially registered in our country. Moreover, the material and technical base of Ukrainian laboratories does not always allow for the identification of genetically modified products. After reviewing the documents, one may get the impression that Ukrainian farmers do not cultivate GMOs at all. However, officials from the Ministry of Agrarian Policy, grain traders, and farmers themselves are well aware of the widespread planting of genetically modified crops resistant to

<sup>3</sup> Ksenia Nesterenko., Do Ukrainians eat tomatoes with the flounder gene and scorpion bread? Ukrainian Independent Information Agency. 2008. <https://www.unian.net/society/171268-ukraintsyi-edyat-pomidoryi-s-genom-kambalyi-i-hleb-iz-skorpionov.html>

<sup>4</sup> Literal translation of the names of Ukrainian state-owned companies

<sup>5</sup> Literal translation of the names of Ukrainian state-owned companies

<sup>6</sup> Evgenia Ustinova., Ukraine. GMOs are legal. Vlasti.Net., 2010. <https://vlasti.net/ru/news/74350/feed>

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glyphosate in the southern regions of the country. At the same time, part of the harvest remains in Ukraine, while about 50% is exported to foreign markets. However, the issue is not so simple...".<sup>7</sup>

On February 4, 2020, columnist Anastasia Kiriyenko, citing Yuriy Symonenko, a researcher at the Institute of Cell Biology and Genetic Engineering of the National Academy of Sciences of Ukraine, writes in her publication "GMOs in Ukraine: Is it Necessary and How Best to Check Raw Materials", "... According to a large-scale study conducted in 2018 by the association Donau Soja and Agent Green, about 48% of soybeans grown in Ukrainian fields are genetically modified. This raises the question: how is nearly 50% of GM soybeans produced in a country where GMOs are not officially registered? 'It's all about the imperfect Ukrainian legislation, which limits but does not prescribe a clear regulatory mechanism. This creates conditions in which businesses intentionally seek ways to sell GMO-containing products,' notes Yuriy Symonenko...".<sup>8</sup>

Numerous publications and scientific studies have addressed the challenges of legally regulating bioengineering activities in Ukraine. For example, in 2009, with the support of the Federal Ministry for Consumer Protection, Food and Agriculture of the Federal Republic of Germany, a book titled "Ukraine's Policy in the Field of Agriculture, Bioenergy and Food Industry: Research, Conclusions and Recommendations" was published, edited by Heinz Strubenhoff and others.<sup>9</sup>

In 2013, also with the support of the same German ministry, the book GMOs: Current Challenges and Legal Experience in Regulation" was released under the editorship of Bohdan Balasynovych and others.<sup>10</sup>

### **III. Legislative Attempts to Repeal Framework Law No. 1103**

On October 6, 2017, the Parliament of Ukraine registered the first draft law titled "On State Control over Genetically Modified Products in Agriculture and the Food Industry", under registration number 7186. The draft was submitted by Members of Parliament M. Lyushnyak, A. Kot, O. Kulinich, I. Rybak, V. Luchenko, and others.<sup>11</sup>

On October 19, 2017, the Parliament of Ukraine registered a second draft law titled "On Amendments to Certain Laws of Ukraine Regarding the Tracking and Labelling of Genetically Modified Organisms and the Handling, Tracking, and Labelling of Food Products, Feed and/or Feed Additives, and Veterinary Drugs Obtained Using Genetically Modified Organisms", under registration number 7210. This second draft law was submitted by the Cabinet of Ministers of Ukraine.<sup>12</sup>

Despite receiving positive assessments from several parliamentary committees, Draft Law No. 7210 was ultimately rejected. On November 20, 2018, the Verkhovna Rada Committee on Agrarian Policy and Land Relations recommended that the Parliament of Ukraine reject Draft Law No. 7210,

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<sup>7</sup> Inna Strebkova., GMOs in Ukraine: ban cannot be used. 2016., <https://latifundist.com/spetsproekt/206-gmo-v-ukraine-zapretit-nelzya-ispolzovat>

<sup>8</sup> Anastasia Kirienko., GMOs in Ukraine is it necessary and how best to check raw materials. 2020.,

<https://agroportal.ua/ru/publishing/lichnyi-vzglyad/gmo-v-ukraine-nuzhno-li-i-kak-luchshe-proverit-syre>

<sup>9</sup> Ukraine's policy in the field of agriculture, bioenergy and food industry research, conclusions and recommendations. Edited by Heinz Strubenhoff, Veronika Movchan and Igor Burakovsky. Institute for Economic Research and Policy Consulting. Publishing house "ADEF-Ukraine". 2009. 383 p.

<sup>10</sup> Ukraine's policy in the field of agriculture, bioenergy and food industry research, conclusions and recommendations. Edited by Heinz Strubenhoff, Veronika Movchan and Igor Burakovsky. Institute for Economic Research and Policy Consulting. Publishing house "ADEF-Ukraine". 2009. 383 p.

<sup>10</sup> GMO: current challenges and legal experience regulation. Edited by Bohdan Balasynovych, Yustyna Yaroshevska. Institute for Economic Research and Policy Consulting. – Kyiv – 2013., p. 84.

<sup>11</sup> Draft Law "On State Control over Genetically Modified Products in Agriculture and Food Industry", Verkhovna Rada of Ukraine., No. 7186 dated October 06, 2017., [http://w1.c1.rada.gov.ua/pls/zweb2/webproc4\\_1?pf3511=62693](http://w1.c1.rada.gov.ua/pls/zweb2/webproc4_1?pf3511=62693)

<sup>12</sup> Draft Law "On Amendments to Certain Laws of Ukraine Regarding the Tracking and Labeling of Genetically Modified Organisms and the Handling, Tracking and Labeling of Food Products, Feed and/or Feed Additives, Veterinary Drugs

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suggesting that its constructive provisions should instead be incorporated into the revision of Draft Law No. 7186.<sup>13</sup>

On the same day, November 20, 2018, the same committee recommended that Draft Law No. 7186 be adopted as a basis for further legislative work.<sup>14</sup> Nevertheless, on August 29, 2019, for reasons that remain unclear, Draft Law No. 7186 was withdrawn from parliamentary consideration.

It is difficult to assert definitively - absent concrete evidence - that this three-year legislative process from 2017 to 2019 was deliberately prolonged to delay the adoption of critical GMO legislation. However, such a conclusion is suggested by the fact that, unlike Draft Law No. 7186, the government-initiated Draft Law No. 7210 had received broadly positive feedback and, under normal legislative procedure, could not have been withdrawn without a formal decision of the Cabinet of Ministers of Ukraine - especially at such a late stage in the process.

In 2021, fourteen years after the adoption of Law 1103, the Ministry of Economy of Ukraine officially acknowledged the existence of an illegal GMO market in the country. A fragment of the Ministry's statement, published on its official website, reads:

“According to current de jure regulations, genetically modified plant varieties are not registered, which means that GMOs are neither produced nor grown in Ukraine. De facto, however, in recent years, agricultural producers have actively cultivated genetically modified crops resistant to herbicides (soybeans, rapeseed, corn). According to various estimates, approximately 80% of soybeans, 30% of rapeseed, and 10% of corn grown in Ukraine originate from genetically modified seeds.

This shadow market for genetically modified products harms Ukraine's reputation in international trade and requires a proper regulatory response. At the same time, consumers lack confidence that the products they purchase are free from GMOs.”

Therefore, it can be argued that the legal regulation of the treatment of GMOs is ineffective and makes it impossible to exercise effective state control over the use of genetically modified products in agriculture, and also creates prerequisites for the illegal use of unregistered GM products in Ukraine.

The legislation of Ukraine, unfortunately, is not only outdated and does not contain effective regulatory mechanisms in this area, but also does not comply with Ukraine's obligations under the Association Agreement. ...”<sup>15</sup>

As a result, on April 15, 2021, the Ministry of Economy of Ukraine published a draft of a new law on its official website, intended to replace the current foundational Law No. 1103. Subsequently, on August 5, 2021,<sup>16</sup> the Cabinet of Ministers of Ukraine (hereinafter referred to as the Government of Ukraine) submitted this draft - Law No. 5839 - to the Parliament of Ukraine.

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<sup>13</sup> Conclusion of the Verkhovna Rada Committee on Agrarian Policy and Land Relations of November 20, 2018, [http://w1.c1.rada.gov.ua/pls/zweb2/webproc4\\_1?pf3511=62750](http://w1.c1.rada.gov.ua/pls/zweb2/webproc4_1?pf3511=62750)

<sup>14</sup> Conclusion of the Verkhovna Rada Committee on Agrarian Policy and Land Relations of November 20, 2018. [http://w1.c1.rada.gov.ua/pls/zweb2/webproc4\\_1?pf3511=62693](http://w1.c1.rada.gov.ua/pls/zweb2/webproc4_1?pf3511=62693)

<sup>15</sup> Analysis of regulatory impact to the draft Law of Ukraine “On state regulation of genetic engineering activities and state control over the circulation of genetically modified organisms and genetically modified products to ensure food safety” Ministry of Economy of Ukraine, 15.04.2021. <https://me.gov.ua/Documents/Detail?lang=uk-UA&id=798bbc2-d239-4bf0-8352-a41403a45938&title=ProktZakonuUkrainiproDerzhavneReguluvanniaGenetichnoinzhenernoiDzialnostiTaDerzhavniKontrolZaObigomGenetichnoModifikovanikhOrganizmivIGenetichnoModifikovanojProduktsiiDliaZabezpechenniaProdovolchoiBezpeki>

<sup>16</sup> Draft Law of Ukraine “On state regulation of genetic engineering activities and state control over the circulation of genetically modified organisms and genetically modified products to ensure food safety” <https://me.gov.ua/Documents/Detail?lang=uk-UA&id=798bbc2-d239-4bf0-8352-a41403a45938&title=ProktZakonuUkrainiproDerzhavneReguluvanniaGenetichnoinzhenernoiDzialnostiTaDerzhavniKontrolZaObigomGenetichnoModifikovanikhOrganizmivIGenetichnoModifikovanojProduktsiiDliaZabezpechenniaProdovolchoiBezpeki>

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The title of the draft law is: "*On State Regulation of Genetic Engineering Activities and State Control over the Circulation of Genetically Modified Organisms and Genetically Modified Products to Ensure Food Safety.*"

On November 16, 2022, the Parliament of Ukraine adopted Draft Law No. 5839 in the first reading. Later, on April 12, 2023, it passed the second reading in the legislative process.

After a prolonged hiatus, a new bill, No. 5839, was registered on July 5, 2021.<sup>17</sup> The aim of this bill was to systematically review the current legislation regarding GMOs and to implement the European Union regulations into Ukrainian law. This bill proposed the establishment of a unified legal framework for regulating the circulation of GMOs, including mechanisms for state registration, labelling, control, and accountability for violations. In particular, Bill No. 5839 suggested harmonizing Ukrainian legislation with European norms, specifically with Directive 2001/18/EC.

However, despite its ambitious goals, the bill was not supported by the parliament. Although the specific official reasons for the rejection of Bill No. 5839 were not publicly disclosed in detail.

#### ***IV. Conclusion.***

##### ***Adaptation of Law No. 3339 and harmonization international law***

Given the need for rapid adaptation of legislation to European standards, on August 23, 2023, the Verkhovna Rada of Ukraine adopted Law No. 3339 "On State Regulation of Genetic Engineering Activities and State Control over the Placement of Genetically Modified Organisms and Products on the Market." This bill was initiated by the Cabinet of Ministers of Ukraine and registered in the Verkhovna Rada as a government-sponsored bill.

Law No. 3339-IX represents a significant step toward harmonizing Ukrainian legislation with World standards in the regulation of GMOs. Law No. 3339 is aimed at improving regulation in the field of GMOs, ensuring control, and establishing clear procedures for the registration and labelling of products containing GMOs. Specifically, it provides for the creation of a unified registry of GMO sources, strengthening state control at all stages of GMO circulation, and establishing accountability for violations of legislation in this area.<sup>18</sup>

During the night of April 30 to May 1, 2025, Ukraine and the United States signed an agreement establishing the American-Ukrainian Reconstruction Investment Fund with equal participation of both parties. On May 8, 2025, the Verkhovna Rada of Ukraine ratified the aforementioned agreement. The document outlines the procedures for the use of Ukraine's subsoil, infrastructure, and natural resources.<sup>19</sup>

On January 16, 2025, President of Ukraine Volodymyr Zelenskyy and Prime Minister of the United Kingdom Keir Starmer signed the Agreement on a Century-long Partnership between Ukraine and the United Kingdom of Great Britain and Northern Ireland.<sup>20</sup> This agreement contains a number of provisions aimed at strengthening economic and trade cooperation, as well as enhancing collaboration in the fields of energy, climate, and the transition to clean energy.

It is well known that Ukraine has been striving for over thirty years to attain full membership in the European Union. While the bilateral agreements signed with the United States and the United Kingdom do not directly pertain to the field of GMOs, it is reasonable to consider the indirect legal, economic, and biological implications arising from the coexistence of legally distinct GMO markets.

<sup>17</sup> Draft Law of Ukraine "On state regulation of genetic engineering activities and state control over the circulation of genetically modified organisms and genetically modified products to ensure food safety"

<https://me.gov.ua/Documents/Detail?lang=uk-UA&id=798bbbc2-d239-4bf0-8352->

a41403a45938&title=ProktZakonuUkrainiproDerzhavneReguluvanniaGenetichnoinzhenernoiDzialnostiTaDerzhavniKontrolZaObigomGenetichnoModifikovanikhOrganizmivIGenetichnoModifikovanoiProduktsiiDliaZabezpechenniaProdovolchoiBezpeki

<sup>18</sup> Law No. 3339 [https://leap.unep.org/en/countries/ua/national-legislation/law-no-3339-ix-state-regulation-genetic-engineering-activities?utm\\_source=chatgpt.com](https://leap.unep.org/en/countries/ua/national-legislation/law-no-3339-ix-state-regulation-genetic-engineering-activities?utm_source=chatgpt.com)

<sup>19</sup> The Rada ratified the agreement with the US on subsoil. <https://www.rbc.ua/rus/news/rada-ratifikovala-ugodu-z-ssha-nadra-1746635236.html>

<sup>20</sup> One Hundred Year Partnership Agreement between the United Kingdom of Great Britain and Northern Ireland and Ukraine. <https://www.president.gov.ua/news/ugoda-pro-storichne-partnerstvo-mizh-ukrayinoyu-ta-spoluchen-95461>

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In this regard, it is essential to note that the European Union (EU), the United States, and the United Kingdom have substantially different approaches to the regulation of genetically modified organisms (GMOs), which creates significant challenges for countries attempting to integrate their markets simultaneously.

The European Union maintains some of the strictest GMO legislation in the world. Its regulatory framework is based on the precautionary principle and the imperative to ensure the highest level of safety for human health and the environment. The main legal foundations include Directive 2001/18/EC, which governs the release of GMOs into the market, and Regulation (EC) No. 1829/2003 concerning genetically modified food and feed.

The United States adopts a significantly more liberal approach to GMO regulation compared to the EU. In the United States, GMO products such as corn, soybeans, and cotton are widely used and marketed with few restrictions.

Following its exit from the European Union, the United Kingdom substantially altered its approach to GMO regulation, particularly through the adoption of the Genetic Technology (Precision Breeding) Act 2023.<sup>21</sup> The 2023 Act introduces the term "precision breeding," which encompasses methods enabling targeted changes to the DNA of plants and animals without introducing genes from other species.<sup>22</sup> The legislation on precision breeding applies solely in England. Scotland, Wales, and Northern Ireland retain stricter rules, similar to those previously in force under EU regulations.

From the foregoing, a legitimate question arises: in drafting and adopting Law No. 3339 on August 23, 2023, did Ukraine anticipate that in 2025 it would embark on such large-scale and non-diversified economic cooperation with the world's leading economies?

The answer is self-evident -Ukraine clearly did anticipate this. This is evidenced by the following arguments.

First, the legislative mechanisms underpinning Law No. 3339 of August 23, 2023, correspond to the Western legal tradition, are legally universal, and offer international partners the world's best practices in GMO legal regulation.

As an example, let us consider several arguments.

Law No. 3339 provides for a three-year transitional period before it fully enters into legal force. The signing of the aforementioned international agreements occurred within this transitional period, which allows for a smooth shift toward comprehensive legal regulation of genetic engineering activities by 2026.

Law No. 3339 introduces a conceptually and categorically flexible legal framework.

The concepts of "biosafety" and "genetic safety." In the European Union, the term *biosafety* is actively used in the context of EU directives (e.g., Directive 2001/18/EC<sup>23</sup>), although greater emphasis is placed on *risk assessment* and *environmental release control*. The United States and the United Kingdom use the terms *biosafety* and *biosecurity*; however, in the context of GMO regulation, the term *risk assessment* is more frequently applied. Law No. 3339 reflects these approaches and, in its definitions, to some extent normatively consolidates the regulatory perspectives of the EU, the US, and the UK.

The concepts of "genetically modified organism," "genetically modified product," and "genetically modified source." In the EU, these concepts are defined in accordance with Directive 2001/18/EC<sup>24</sup> and Regulation (EC) No. 1829/2003<sup>25</sup>. The Ukrainian definitions are fully aligned with EU standards. The United Kingdom uses terms with meanings similar to those applied in the EU. In the United States, there is no unified legal definition of a GMO; however, the term *bioengineered*

<sup>21</sup> Genetic Technology (Precision Breeding) Act 2023.

[https://www.legislation.gov.uk/ukpga/2023/6/pdfs/ukpga\\_20230006\\_en.pdf](https://www.legislation.gov.uk/ukpga/2023/6/pdfs/ukpga_20230006_en.pdf)

<sup>22</sup> Genetic Technology (Precision Breeding) Bill 2022-23. <https://commonslibrary.parliament.uk/research-briefings/cbp-9557/>

<sup>23</sup> 2001/18/EC. <https://eur-lex.europa.eu/eli/dir/2001/18/oj/eng>

<sup>24</sup> 2001/18/EC. <https://eur-lex.europa.eu/eli/dir/2001/18/oj/eng>

<sup>25</sup> Regulation (EC) 1829/2003. <https://eur-lex.europa.eu/eli/reg/2003/1829/oj/eng>

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food is introduced by the National Bioengineered Food Disclosure Standard (2016)<sup>26</sup>, which corresponds to the Ukrainian concept of *genetically modified product* (ГМ-продукція).

Scope of application of Law No. 3339. The law applies to: genetic engineering activities in contained systems; research and testing in open environments; state registration; market placement; labelling; and state control.

In the European Union, we observe a similar regulatory structure. Contained use is governed by Directive 2009/41/EC.<sup>27</sup> Deliberate release into the environment and field trials are regulated by Directive 2001/18/EC.<sup>28</sup> Registration, risk assessment, market placement, monitoring, and labelling are governed by Regulations (EC) No. 1829/2003<sup>29</sup> and No. 1830/2003.<sup>30</sup>

In the United States, the handling of genetically modified organisms (GMOs) is regulated by three federal agencies, each acting within its jurisdiction and under applicable legislation:

- The USDA (United States Department of Agriculture) under the Plant Protection Act (7 U.S.C. §§ 7701<sup>31</sup> et seq.);
- The EPA (Environmental Protection Agency) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 U.S.C. §§ 136<sup>32</sup> et seq.) and the Toxic Substances Control Act (TSCA, 15 U.S.C. §§ 2601<sup>33</sup> et seq.);
- The FDA (Food and Drug Administration) under the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. §§ 301<sup>34</sup> et seq.).

Following Brexit, the United Kingdom retained the core structure of GMO regulation inherited from EU law. Regulation of contained use and environmental release (e.g., laboratory research and field trials) continues to follow the adapted provisions of former EU directives, in particular Directives 2001/18/EC<sup>35</sup> and 2009/41/EC.<sup>36</sup> National registers, licensing procedures, and control mechanisms are administered by UK authorities, primarily Defra (Department for Environment, Food & Rural Affairs) and ACRE (Advisory Committee on Releases to the Environment).

As of 2023, the UK has begun liberalizing the regulation of site-directed mutations, including technologies such as CRISPR. The Genetic Technology (Precision Breeding) Act 2023<sup>37</sup> exempts certain organisms from the stricter regulatory framework traditionally applied to GMOs, provided they contain targeted DNA changes without the insertion of foreign genetic material. This approach currently differs, at least in part, from Ukrainian regulation, where all organisms created using genetic engineering techniques are still classified as GMOs and subject to uniform legal treatment.

Second, the aforementioned international instruments are not legally contradictory, indicating coherent economic, infrastructural, and institutional processes among the partner countries.

Third, Ukraine's awareness of the impending consolidation of global economies around itself is evidenced by the fifteen-year legislative process described in this article, aimed at creating the world's most effective GMO regulatory framework. Notably, no other country in the world has undertaken such a prolonged legislative process to develop legal mechanisms for GMO regulation.

<sup>26</sup> National Bioengineered Food Disclosure Standard. <https://www.congress.gov/crs-product/R46183>

<sup>27</sup> 2009/41/EC. <https://eur-lex.europa.eu/eli/dir/2009/41/oj/eng>

<sup>28</sup> 2001/18/EC. <https://eur-lex.europa.eu/eli/dir/2001/18/oj/eng>

<sup>29</sup> 1829/2003. <https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=celex%3A32003R1829>

<sup>30</sup> 1830/2003. <https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=CELEX%3A32003R1830>

<sup>31</sup> Plant Protection Act. <https://faolex.fao.org/docs/pdf/us190799.pdf>

<sup>32</sup> FIFRA. <https://www.epa.gov/enforcement/federal-insecticide-fungicide-and-rodenticide-act-fifra-and-federal-facilities>

<sup>33</sup> Toxic Substances Control Act. <https://uscode.house.gov/view.xhtml?path=/prelim@title15/chapter53&edition=prelim>

<sup>34</sup> Federal Food, Drug, and Cosmetic Act. <https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act>

<sup>35</sup> 2001/18/EC. <https://eur-lex.europa.eu/eli/dir/2001/18/oj/eng>

<sup>36</sup> 2009/41/EC. <https://eur-lex.europa.eu/eli/dir/2009/41/oj/eng>

<sup>37</sup> Genetic Technology (Precision Breeding) Act. <https://bills.parliament.uk/bills/3167>

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These arguments indicate that Ukraine's long-term legislative process in the field of GMOs was aimed at establishing the best legal foundation in global practice, enabling Ukraine to serve as a bridge between the three different regulatory approaches to GMOs. Law No. 3339 of Ukraine enters into force on September 16, 2026, which logically aligns with global investment processes. The consistency of the legal processes described herein is also explained by Ukraine's unique geographical location, which holds critical intercontinental significance for planetary health and ecology.

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