COMPARISON OF U.S. GMO REGULATION AND E.U. GMO REGULATION: WHAT ARE THE POSSIBLE EFFECTS OF THE FEBRUARY 2024 E.U. VOTE TO DEREGULATE GMOS ON THE ENVIRONMENT?

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ABSTRACT

The United States and the European Union have developed drastically different approaches to regulating genetically modified organisms due to variance in public attitude and policy priorities. However, over time, the regulatory systems of the United States and the European Union with respect to genetically modified organisms have adopted similar regulatory elements and thus, have grown in alignment. This Article outlines the two regulatory systems, explains the scientific underpinnings of genetically modified organisms, and ultimately argues that the United States and European Union systems are slowly becoming more alike than previously conceptualized. Furthermore, this Article argues that the February 2024 European Union proposal to deregulate certain genetically modified organisms is another major instance of increasing alignment.

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I. INTRODUCTION

Climate change is one of the most pressing issues our world faces today.[1] As a result of human activity, Earth's average temperature rose nearly 1ºC since 1850,[2] and is projected to continue rising in temperature. Even if greenhouse gas (GHG) emissions halted today, the long-term effects of already-emitted GHGs will be felt by future generations.[3] These effects include heatwaves, droughts, floods, catastrophic weather events, sea level rise, and more—many of which are already occurring.[4] Our society needs solutions both to limit GHG emissions and adapt to the effects of climate change. Scientists propose genetically modified organisms (GMOs) as a tool to aid in the mitigation and adaptation of climate change.[5] Specifically, some scientists and public policy experts have suggested that GMOs will help support agricultural systems as conditions worsen due to climate change.[6]

The usage of GMOs as a tool to fortify agricultural systems has not been accepted universally. However, "[b]etween 1996 and 2002, the number of acres planted with [genetically engineered] crops worldwide increased over thirty-four times, from 4.25 to 146.8 million acres," showing that GMOs are widely used in our modern agricultural system.[7] The United States (U.S.) has embraced GMOs and developed a framework to regulate them, which largely allows GMO crops to be grown and consumed.[8] In fact, as of April 2025, over 90% of corn, cotton, and soy grown in the U.S. came from genetically

1. G.A. Res. 77/276, at 1(Mar. 29, 2023).
2. IPCC, GLOBAL WARMING OF 1.5 °C 36 (2018).
3. *Id*. at 8.
4. *Id*. at 13.
5. Nicholas G. Karavolias et al., *Application of Gene Editing for Climate Change in Agriculture*, 5 FRONTIERS SUSTAINABLE FOOD SYS. 685801, Sept. 2021, at 1, 2.
6. Emma Kovak et al., *Genetically Modified Crops Support Climate Change Mitigation*, 27 TRENDS IN PLANT SCI. 627, 629 (2022).
7. Maria Lee-Muramoto, *Reforming The "Uncoordinated" Framework for Regulation of Biotechnology*, 17 DRAKE J. AGRIC. L. 311, 324 (2012).
8. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302, 23302–03 (June 26, 1986).

engineered seed stock.[9] In contrast, the European Union (E.U.) regulates GMOs much more strictly and errs on the side of disallowing GMO products.[10] As of 2015, the U.S. had approved over 100 GMO crops with a single engineered trait, whereas the E.U. had approved less than 40.[11] Similarly, in 2013, where the U.S. cultivated over 70 million hectares of GMO crops, the E.U. collectively cultivated less than 0.1 million hectares.[12]

This divergence in regulatory structures is widely discussed in the literature.[13] The 2003 World Trade Organization (WTO) dispute between the U.S. and E.U. regarding the E.U.'s moratorium on approving new GMO foods highlights the separate regulatory approaches.[14] The U.S., Canada, and Argentina challenged the E.U.'s ban on procedural grounds; however, it was clear that the U.S. pushed back on the E.U. regulations based on, at least partially, the U.S.'s pro-GMO stance and desire to increase agricultural exports.[15] Ultimately, the WTO panel determined that the E.U.'s moratorium violated its trade agreements.[16] Yet, the WTO still permitted the E.U. to enforce strict policies against GMO usage, many of which continue to be in effect today.[17]

Despite historical differences, this Article argues that the U.S. and E.U. GMO regulatory systems are becoming more similar over time. For example, in 2016, the U.S. enacted a GMO labeling law,[18] a practice the E.U. has followed since 2003.[19] Moreover, in February 2024, the E.U. Parliament voted to create two categories of GMO crops and to deregulate one entire

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9. *Adoption of Genetically Engineered Crops in the United States*, U.S. DEP'T OF AGRIC.: ECON. RSCH. SERV., https://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-united-states/recent-trends-in-ge-adoption (last updated Jan. 1, 2025).

10. M.J. Peterson, *The EU-US Dispute over Regulation of Genetically Modified Organisms, Plants, Feeds, and Foods*, INT'L DIMENSIONS ETHICS EDUC. SCI. & ENG'G, June 2010, at 1, 4.

11. Jessica Lau, *Same Science, Different Policies: Regulating Genetically Modified Foods in the US and Europe*, HARV. UNIV.: SCI. IN THE NEWS (Aug. 9, 2015), https://sites.harvard.edu/sitn/2015/08/09/same-science-different-policies/.

12. *Id.*

13. *See, e.g.,* Lee Ann Jackson & Kym Anderson, *What's Behind GM Food Trade Disputes*? 4 WORLD TRADE REV. 203, 203 (2005).

14. Peterson, *supra* note 10, at 4.

15. MARK A. POLLACK & GREGORY C. SHAFFER, WHEN COOPERATION FAILS: THE INTERNATIONAL LAW AND POLITICS OF GENETICALLY MODIFIED FOODS 182–83 (2009).

16. Peterson, *supra* note 10, at 4.

17. *Id.*

18. National Bioengineered Food Disclosure Standard, Pub. L. No. 114-216, 130 Stat. 833 (2016).

19. Chantal Bruetschy, *The EU Regulatory Framework on Genetically Modified Organisms (GMOs*), 28 TRANSGENIC RES. 169, 170 (2019); Regulation 1829/2003, of the European Parliament and of the Council of 22 Sept. 2003 on Genetically Modified Food and Feed, O.J. (L 268) 1.

category.[20] If implemented, this deregulation would increase the amount of GMO crops grown and available for purchase in the E.U., and make the agricultural system more similar to that of the U.S.[21] This Article seeks to review the GMO regulatory systems of the U.S. and E.U., and analyze the possible impacts of the February 2024 E.U. vote to understand if the deregulation is an instance of convergence.

Part II provides background on scientific information of GMOs, including an explanation of the benefits and drawbacks of GMOs in the environmental realm.[22] Part III describes the emergence of the U.S. GMO regulatory framework, and explores how the framework exists today. Part IV explores how GMOs have historically been regulated in the E.U. and how the February 2024 E.U. Parliament vote would change the regulatory system. Finally, Part V analyzes the E.U. vote using the U.S. as a comparison case to understand if the deregulation would produce more similar regulatory systems.

II. SCIENTIFIC BACKGROUND ON GMOS

Humans have been altering organisms and ecosystems for tens of thousands of years prior to the invention of modern genetic engineering techniques.[23] The expansion of early *Homo sapiens* drove extinctions of ancient megafauna and caused genetic shifts in populations that were hunted and gathered, profoundly changing ecosystems.[24] With the advent of agriculture in at least 28 distinct regions of the globe,[25] 10,000–12,000 years ago, plants and animals began to change through the process of artificial selection.[26] Early farmers, despite having no knowledge of DNA or the laws of Mendelian inheritance,[27] genetically altered species via artificial selection

20. European Parliament Press Release, New Genomic Techniques: MEPs Want to Ban All Patents for NGT plants (Jan. 24, 2024).

21. *See id.*

22. This Article will focus only on the environmental impacts of GMOs; however, GMOs have many diverse impacts, including on consumer health, animal health, and farmworker rights.

23. Mercer Martin, *A New Neocolonial Threat: The Harmful Impact of European GMO Policy on African Food Security*, 26 DRAKE J. AGRIC. L. 365, 368 (2021).

24. Christopher Sandom et al., *Global Late Quaternary Megafauna Extinctions Linked to Humans, Not Climate Change*, 281 PROC. R. SOC. B., July 2014, at 1, 1.

25. Rachel Meyer et al., *Patterns and Processes in Crop Domestication: An Historical Review and Quantitative Analysis of 203 Global Food Crops*, 196 NEW PHYTOLOGIST 29, 42–43 (2012).

26. Michael B. Kantar et al., *The Genetics and Genomics of Plant Domestication*, 67 BIOSCIENCE 971, 973 (2017).

27. Mendelian inheritance describes how traits are inherited by offspring in discrete units called genes or alleles, following predictable patterns and rules, based on the observations of Gregor Mendel. Strome et al., *Clarifying Mendelian vs Non-Mendelian Inheritance,* 227 GENETICS, May 2024, at 1, 3.

by propagating organisms with desirable traits such as larger fruit or seed sizes, better flavor, and reduced toxicity.[28] In the process, they drove dramatic biological changes in these organisms such as altered chromosome counts, reproductive cycles, structural features, and specialized metabolite composition.[29] Through artificial selection, humans have produced the crops and livestock that exist today,[30] and many such as "corn, rice, potatoes, milk cows, and pigs . . . would be unrecognizable to our ancestors wGbegan and continued the artificial selection process millennia, centuries, or even decades before us."[31]

Early farmers also practiced cross-breeding and hybridization, in which they mated similar species with desirable traits. In this manner, an entirely new organism could be created with the desirable characteristics of both parent species. However, this process could take decades and was not always successful.[32] In the 1940s, scientists realized they did not need to rely upon the slow process of natural mutation that is a cornerstone of Darwinian evolution.[33] Instead, scientists began using mutagens, radiation or chemical agents that induce DNA mutation, to rapidly generate numerous new mutations, ranging from single nucleotide polymorphisms (SNPs), a change of just one G, C, A, or T DNA base pair, to large-scale rearrangements of the genome.[34] Though most of these mutations were not desirable, those that were could be cross-bred into crop lines. Over 3,400 crop varieties have been produced in this manner to date.[35] Notably, crops produced using some types of mutagens are not excluded from organic labeling in many countries, and are allowed under the United States Department of Agriculture's (USDA's) National Organic Program and are not regulated as GMOs in the EU.[36]

In the 1980s, crop geneticists began to apply their new understanding of genetics and molecular biology techniques to greatly accelerate the process of traditional breeding. They used newly developed methods to screen

28. *See* Meyer et al., *supra* note 25, at 31.

29. *See id*.

30. Martin, *supra* note 23, at 368.

31. *Id.*

32. *Id.*

33. Liqiu Ma et al., *From Classical Radiation to Modern Radiation: Past, Present, and Future of Radiation Mutation Breeding*, 9 FRONT. PUB. HEALTH, Dec. 2021 at 1,3.

34. *Id.*

35. *Mutant Variety Database*, INT'L ATOMIC ENERGY AGENCY, https://nucleus.iaea.org/sites/mvd/SitePages/Home.aspx (last visited Dec. 2, 2025).

36. Nat'l Organic Standards Bd., Formal Recommendation of Excluded Methods Determination to The National Organic Program (April 28, 2022); *see* TARJA LAANINEN, EUR. PARL. RSCH. SERV., NEW PLANT-BREEDING TECHNIQUES: APPLICABILITY OF EU GMO RULES, at 2 (2019).

organisms for desirable traits earlier in their development, reducing the workload, space requirements, and cost of traditional breeding in a process called "Marker-Assisted Breeding" (MAB).[37] This practice is now widespread in both conventional and organic agriculture around the world.[38]

While scientists created the first genetically modified organism in 1973 by moving DNA from one bacterium to another, it was not until the 1990s that increased scientific understanding and improved techniques allowed scientists to more precisely and efficiently modify the traits of organisms.[39] The 2012 development of CRISPR, a landmark gene editing technology that won the Nobel Prize in 2020, greatly enhanced the speed and accuracy of genetic modification.[40] A genetically modified organism (GMO) is any non-human organism (animal, plant, or microorganism) in which DNA has been modified by scientists or bioengineers.[41] Some of these modifications could not have occurred naturally or as a result of traditional mating techniques; for example, if scientists inserted a gene from one organism into the genome of another species when the two would not have naturally bred. However, other GMOs contain subtle modifications to the organism's genome—such as substitutions, insertions, or deletions of only one DNA base among billions—resulting in an organism that is otherwise identical to naturally occurring species. These subtle mutations frequently occur naturally as well,[42] meaning that many GMOs can be effectively impossible to distinguish from naturally occurring organisms when sequenced.[43]

Consumers, media, and regulators often discuss GMOs as if all GMOs are the same, but GMOs can vary drastically from one another in their construction methods, intended purpose, and potential impacts on environmental and human health. To better understand the benefits and adverse impacts of GMOs, it is important to first understand the different types of GMOs.

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37. Giora Ben-Ari & Uri Lavi, *Marker-Assisted Selection in Plant Breeding*, *in* PLANT BIOTECHNOLOGY AND AGRICULTURE 163, 164 (Arie Altman & Paul Michael Hasegawa eds., 2012).

38. *Id.* at 164.

39. Karavolias et al., *supra* note 5.

40. Gavin J. Knott & Jennifer A. Daudna, *CRISPR-Cas Guides the Future of Genetic Engineering*, 361 SCI. 866, 866 (2018).

41. *Genetically Modified Organisms*, NAT'L GEOGRAPHIC: EDUC. https://education.nationalgeographic.org/resource/genetically-modified-organisms/ (last visited Dec. 2, 2025).

42. René Custers et al., *Genetic Alterations That Do or Do Not Occur Naturally; Consequences for Genome Edited Organisms in the Context of Regulatory Oversight,* 6 FRONTIERS BIOENGINEERING AND BIOTECHNOLOGY, Jan. 2019, at 1, 3–5 (2019).

43. *Id*.

A. Categories of GMOs

GMOs are created for a variety of purposes and can be placed into categories based on the purpose of the modification. Some modifications address agricultural issues—where scientists edit DNA to address changing climate concerns, increase food security, or adjust crops to perform better in different landscapes. These modifications include: increasing stress tolerance; managing pests and pathogens; increasing yield; and enhancing the nutritional value of GMO crops and foods.[44] However, other modifications are made to create economic benefits or be novelty creations. Each category of GMO will be briefly described and discussed below.

In many instances, GMO crops are created to increase abiotic stress tolerance.[45] Abiotic stresses, such as drought, salinity, or flooding, pose severe threats to agriculture and are expected to increase in severity due to climate change.[46] Gene editing has proved to be an effective tool in increasing crop tolerance to abiotic stress.[47] For example, rice has been engineered to be more tolerant of drought and high temperature conditions,[48] and alfalfa has been modified to be more resistant to high salinity soils.[49]

Scientists have also created GMOs in order to boost pathogen and pest resistance among plant and animal populations.[50] For instance, cucumbers have been successfully modified to resist viral infections.[51] Similarly, CRISPR technology has been used to increase the resistance of citrus fruits to the devastating citrus canker disease.[52] GMOs can similarly be designed to be pest resistant, which may reduce pesticide use on modified crops. Most notably, nearly 40% of all GMO crops have been engineered to produce a

44. Karavolias et al., *supra* note 5, at 3–15.

45. *Id*. at 3–6.

46. *Id*.

47. *Id*.

48. *Id*. at 3; R.S. Caine et al., *Rice with Reduced Stomatal Density Conserves Water and Has Improved Drought Tolerance Under Future Climate Conditions*, 221 NEW PHYTOLOGIST 371, 371 (2019).

49. Ai-Ke Bao et al., *Overexpression of the Arabidopsis h+-PPase Enhanced Resistance to Salt and Drought Stress in Transgenic Alfalfa (Medicago sativa L.)*, 176 PLANT SCI. 232, 232 (2009).

50. Karavolias et al., *supra* note 5, at 6.

51. J. Chandrasekaran et al., *Development of Broad Virus Resistance in Non-Transgenic Cucumber Using CRISPR/Cas9 Technology*, 17 MOLECULAR. PLANT PATHOLOGY 1140, 1140 (2016).

52. Karavolias et al., *supra* note 5, at 10; Hongge Jia et al., *Modification of the PthA4 Effector Binding Elements in Type I CsLOB1 Promoter Using Cas9/sgRNA to Produce Transgenic Duncan Grapefruit Alleviating XccΔpthA4: dCsLOB1.3 Infection*, 14 PLANT BIOTECHNOLOGY J. 1291, 1292 (2016).

bacterial protein that makes them resistant to insect pests.[53]

Some GMOs have been edited to increase yields.[54] As climate change alters landscapes, many agricultural lands are projected to decrease in productivity while the global population rises.[55] To ensure food security, humankind will need to increase yield-per-acre on land already cultivated or cultivate additional lands, which will decrease biodiversity, threaten protected habitats, and harm endangered species. Scientists have edited wheat plants to increase yield without increasing land use by producing wheat plants with "significantly elevated grain weights and size."[56] On average, GMO crops have yields 21% greater than non-GMO crops.[57]

A final broad category of GMOs created to address agricultural problems is the crops and foods edited to enhance nutrition.[58] In 2019, 690 million people worldwide suffered from undernourishment or insufficient consumption of calories.[59] Thus, in addition to modifications to increase yield and increase disease resistance, scientists are also creating GMOs specifically to "increase desirable nutritional metabolites, reduce anti-nutrients, and alter macronutrients" to benefit human health.[60] For example, scientists have modified tomatoes to significantly increase the amount of lycopene which has antioxidant properties linked to various beneficial health effects,[61] and have also engineered cassava to produce 99% less toxic cyanide than unmodified varieties.[62]

Organisms have also been edited for agroeconomic purposes. For instance, Arctic Apples are genetically modified to resist browning, which enhances its marketing appeal.[63] This type of modification can also help reduce food waste as products are less likely to be thrown out for possessing

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53. Michael S. Koch et al., *The Food and Environmental Safety of Bt Crops*, 6 FRONT. PLANT SCI., Apr. 2015, at 1, 2.

54. Karavolias et al., *supra* note 5, at 12.

55. *Id.* at 11.

56. *Id*. at 12.

57. Wilhelm Klümper & Matin Qaim, *A Meta-Analysis of the Impacts of Genetically Modified Crops*, 9 PLOS ONE, Nov. 2014, at 1, 4.

58. *Id*.

59. KLAUS VON GREBMER ET AL., 2020 GLOBAL HUNGER INDEX: ONE DECADE TO ZERO HUNGER LINKING HEALTH AND SUSTAINABLE FOOD SYSTEMS 3 (2020).

60. Karavolias et al., *supra* note 5, at 14.

61. Xindi Li et al., *Lycopene is Enriched in Tomato Fruit by CRISPR/Cas9-Mediated Multiplex Genome Editing*, 9 FRONT. PLANT SCI., Apr. 2018, at 1, 10.

62. Kirsten Jørgensen et al., *Cassava Plants with a Depleted Cyanogenic Glucoside Content in Leaves and Tubers: Distribution of Cyanogenic Glucosides, Their Site of Synthesis and Transport, and Blockage of the Biosynthesis by RNA Interference Technology*, 13 PLANT PHYSIOLOGY 363, 364 (2005).

63. Nash Dunn, *What to Know About GMOs,* GENETIC ENG'G & SOC'Y CTR. (Sept. 29, 2021), https://ges.research.ncsu.edu/2021/09/what-to-know-about-gmos/.

undesirable characteristics.[64] Crop geneticists have engineered many crops to be resistant to herbicides. This modification allows farmers to more freely use herbicides to reduce weeds without harming their crops, greatly reducing costs of production.[65]

Additionally, some companies have created novelty GMOs, such as the GloFish, a "bright red fluorescent zebra fish that contains inserted genetic constructs from a sea coral, which cause the fish to glow under certain kinds of light."[66] GMOs created for novelty purposes are not typically found in agricultural products.[67]

B. Environmental Benefits of GMOs

Proponents of GMOs assert that gene editing techniques can be a tool to bolster our agricultural systems in the face of climate change.[68] Shifting weather patterns and increased global temperatures have reduced agricultural output, and one study estimates that one in six species could go extinct as the result of climate change.[69] Nearly half of the world's habitable land is used for agriculture,[70] and expanding agricultural lands are the leading cause of global deforestation.[71] Altered agricultural practices thus represent a large opportunity for addressing climate change. GMO advocates highlight the benefits of GMO usage for sustainability—such as increasing yields or losing fewer crops to disease—and the beneficial economic results associated with more consistent production of food.[72] In addition to these positive consequences, GMO crops can also have specific positive impacts on the environment.

For example, GMO crops can help prevent the conversion of additional land to agriculture by increasing yield and bolstering resistance to disease,

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64. Kate Hall, *How GMOs Help Us Reduce Food Waste & Its Environmental Impact,* FORBES (Nov. 18, 2016), https://www.forbes.com/sites/gmoanswers/2016/11/18/gmos-help-reduce-food-waste/#6e50c8676546.

65. Leonard P. Gianessi, *Economic Impacts of Glyphosate Resistant Crops*, 64 PEST MGMT. SCI. 346, 346 (2008).

66. Int'l Ctr. for Tech. Assessment v. Thompson, 421 F. Supp. 2d 1, 4 (D.D.C. 2006).

67. *See, e.g.*, *id.* at 5.

68. Karavolias et al., *supra* note 5.

69. *Id.*; Mark C. Urban, *Accelerating Extinction Risk from Climate Change*, 348 SCI. 571, 571 (2015).

70. Erle C. Ellis et al., *Anthropogenic Transformation of the Biomes, 1700-2000*, 19 GLOB. ECOLOGY AND BIOGEOGRAPHY 589, 603 (2010).

71. Philip G. Curtis et al., *Classifying Drivers of Global Forest Loss*, 361 SCI. 1108, 1109 (2018). Agriculture also accounts for 25–30% of global greenhouse gas emissions.

72. Melvin Oliver, *Why We Need GMO Crops in Agriculture*, 6 MO. MED. 492, 499 (2014).

which can help preserve natural ecosystems and prevent increasing greenhouse gas (GHG) emissions from the agricultural sector.[73] Many studies indicate that as global populations are projected to increase, we will need to correspondingly produce more food.[74] According to the U.N. Food and Agriculture Organization, we will need to produce 60% more food by 2050 to meet global demand.[75] Rather than dedicating additional land to agricultural operations, GMO advocates say current farms can be made more efficient by using GMO crops.[76] In this manner, less land needs to be converted to agricultural use, which can help protect biodiversity, preserve protected habitats, and prevent harm to endangered species. Furthermore, natural ecosystems such as forests act as large carbon sinks, and converting such ecosystems into agricultural land would result in a large release of carbon dioxide into the atmosphere.[77] The agricultural sector currently accounts for 26% of GHG emissions globally, and by increasing the land dedicated to agricultural production, we would certainly increase the GHG emissions emanating from the agricultural sector by expanding operations.[78] GMOs can also be engineered to require fewer resources. For example, scientists have engineered multiple varieties of GMO cotton that require less water than their non-GMO counterparts.[79]

Additionally, with the creation of GMO crops that exhibit pesticidal properties, less pesticides need to be used for plant cultivation.[80] Pesticides can cause wide-ranging negative impacts on ecosystems and human health, given that pesticides are designed to be "inherently toxic."[81] Pesticides can also leach into soils and waterways, causing environmental harm outside the

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73. *Id*. at 502.

74. Karavolias et al., *supra* note 5, at 11.

75. Jose Graziano Da Silva, *Feeding the World Sustainably*, 49 UN CHRON. 15, 15 (2012).

76. Joan Conrow, *New Study: GMO Crops Reduce Pesticide Use, Greenhouse Gas Emissions*, ALL. FOR SCI. (July 27, 2020), https://allianceforscience.org/blog/2020/07/new-study-gmo-crops-reduce-pesticide-use-greenhouse-gas-emissions/.

77. Marcela Angel, *Protecting and Enhancing Carbon Sinks: Natural Climate and Community Solutions*, MIT: CLIMATE PORTAL (May 4, 2021), https://climate.mit.edu/posts/protecting-and-enhancing-natural-carbon-sinks-natural-climate-and-community-solutions.

78. Hannah Ritchie, *Food Production Is Responsible for One-Quarter of the World's Greenhouse Gas Emissions*, OUR WORLD IN DATA (Nov. 6, 2019), https://ourworldindata.org/food-ghg-emissions.

79. Babar Hussain & Sultan Mahmood, *Development of Transgenic Cotton for Combating Biotic and Abiotic Stresses*, *in* COTTON PRODUCTION AND USES: AGRONOMY, CROP PROTECTION, AND POSTHARVEST TECHNOLOGIES 527, 529 (Shakeel Ahmad & Mirza Hassanuzzaman eds., 2020).

80. *See* Karavolias et al., *supra* note 5.

81. UNEP, ENVIRONMENTAL AND HEALTH IMPACTS OF PESTICIDES AND FERTILIZERS, AND WAYS TO MINIMIZE THEM, at iv (John Smith ed., 2022).

area of application.[82] Pesticidal GMOs mitigate some of these negative externalities because insecticidal compounds are within the plant itself and primarily impact insects eating plant tissue. Thus, pesticidal GMOs minimize non-target species damage compared to spray-application of conventional pesticides.[83] Overall, GMO crops need 37% less pesticide application than non-GMO varieties to successfully manage pests.[84]

C. Environmental Drawbacks of GMOs

Opponents of GMOs have noted a variety of environmental concerns with the development and proliferation of GMOs in our agricultural and food systems.[85] However, the overwhelming consensus among scientists is that GMO foods are just as safe for people and the environment as traditional crops.[86] Scientists remark that the main problem with artificial genetically modified organisms is the relative lack of information available in the public domain, which leaves the public apprehensive and skeptical about the consequences of GMOs.[87] While some of the concerns may be overblown, others present risks that scientists and policymakers need to account for and acknowledge. For example, GMOs can pose real threats to ecosystems through transgene escape, reduced genetic diversity, destruction of insect populations, and increased resistance to pesticides and herbicides.[88]

Transgene escape refers to the process by which genetically modified plant genes spread into different plants, organisms, or ecosystems.[89] For example, the genetically modified genes of a GMO could spread into wild populations, or into non-GMO agricultural areas through pollen.[90] Once modified genes have escaped, there could be ecological ramifications from altering natural plant populations—the modified organisms could displace

82. *Id.* at 18–19.

83. Steven E. Naranjo, *Impacts of Bt Crops on Non-Target Invertebrates and Insecticide Use Patterns*, 4 CAB REVS., Jan. 2009, at 1, 3.

84. Klümper & Qaim, *supra* note 57, at 1.

85. *See, e.g.*, JOHN FAGAN ET AL., GMO MYTHS AND TRUTHS 12 (2d ed. 2014).

86. THE NAT'L ACAD. OF SCIS., ENG'G & MED., GENETICALLY ENGINEERED CROPS: EXPERIENCES AND PROSPECTS 19 (2016); *see* EUR. COMM'N, A DECADE OF EU-FUNDED GMO RESEARCH (2001-2010), at 20 (2010).

87. Ram B. Singh et al., *Genetically Modified Organisms and Foods: Perspectives and Challenges*, *in* FUNCTIONAL FOODS AND NUTRACEUTICALS IN METABOLIC AND NON-COMMUNICABLE DISEASES 493, 502 (2022).

88. Aristidis M. Tsatsakis et al., *Environmental Impacts of Genetically Modified Plants: A Review*, 156 ENV'T RSCH. 818, 819–27 (2017).

89. *Id*. at 819.

90. *Id*.; Singh et al., *supra* note 83, at 494.

non-modified varieties thereby reducing overall genetic diversity.[91] Reduced genetic diversity in turn lowers an ecosystem's ability to respond and adapt to change.[92] However, transgenic crops are often not competitive with native populations outside of an agricultural setting and their transgenic elements may not confer any survival benefits, causing the escaped transgenes to become less common over time.[93] Yet, there are many notable examples of transgene escape where the transgenic elements persisted in the environment, and more robust systems are needed to detect and contain transgene escape events.[94]

Additionally, GMOs designed to resist pests can have wider-ranging ecological implications.[95] For example, by killing or starving the insects that feed on the crops, the organisms that feed on the insects will also be negatively impacted such that an entire ecosystem could be damaged and key ecosystem services may be diminished.[96] Still, the nature and extent of GMO crops on ecosystem health is highly variable and context-dependent, and thus cannot be easily generalized.[97]

Furthermore, some critics are concerned that GMOs lead to increased pesticide and herbicide use. For example, Roundup Ready Alfalfa was developed to be resistant to an herbicide, which permits an increased use of the herbicide without impacting the alfalfa crop.[98] Over time, common weeds evolve to become more resistant to the herbicides applied, and larger doses of herbicide are required to effectively manage weeds, increasing the extent of negative downstream effects of herbicide use. For instance, global glyphosate herbicide use increased 15-fold from 1996 to 2014 after the advent of Roundup Ready crops.[99] On the other hand, concerns that GMOs will increase pesticide use are largely unsupported by data, as many studies have found that GMOs require less pesticide application than non-GMO

91. Tsatsakis et al., *supra* note 84, at 823.

92. Kishan Birader, *Genetic Diversity and the Adaptation of Species to Changing Environments,* 11 J. BIODIVERSITY & ENDANGERED SPECIES, May 2023, at 1.

93. Steven E. Travers et al., *Persistence of Genetically Engineered Canola Populations in the U.S. and the Adventitious Presence of Transgenes in the Environment*, 19 PLOS ONE, May 2024, at 1, 2.

94. Gerhart U. Ryffel, *Transgene Flow: Facts, Speculations and Possible Countermeasures*, 5 GM CROPS & FOOD 249, 252–53 (2014).

95. UNEP, *supra* note 77, at 19.

96. *Id.* at 35.

97. Dennis Engist et al., *The Impact of Genetically Modified Crops on Bird Diversity*, 7 NAT. SUSTAINABILITY 1149, 1149 (2024).

98. Ctr. for Food Safety v. Vilsack, 718 F.3d 829, 831 (9th Cir. 2013).

99. Charles M. Benbrook, *Trends in Glyphosate Herbicide Use in the United States and Globally*, 28 ENV'T SCIS. EUR., Feb. 2016, at 1, 1.

crops.[100]

Ultimately, GMOs have the potential to have both positive and negative impacts on the environment, but it is crucial to consider the purpose and type of GMO when analyzing environmental impacts and avoid generalizations.

III. HOW ARE GMOS REGULATED IN THE UNITED STATES?[101]

In the United States (U.S.), the federal government is primarily responsible for monitoring and regulating biotechnology products, including genetically modified organisms (GMOs).[102] Authority to regulate GMOs is coordinated and shared among three federal agencies: the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the Environmental Protection Agency (EPA).[103] These federal agencies predominantly regulate genetically engineered foods and crops according to the characteristics of the product.[104] This Part will first trace the history of GMO regulation in the U.S., and then explain the current U.S. GMO regulatory system.

A. Historical Origins of the U.S. Regulatory System

Modern biotechnology methods arose in the 1970s with the development of the recombinant DNA (rDNA) technique which allowed scientists to modify a species' genetic material.[105] With the discovery that the genetic traits of organisms could be modified, concern grew among the public as well as among scientists engaged in GMO research.[106] In fact, scientists took the lead on developing self-imposed guidelines for rDNA research to combat growing fears regarding genetic modification.[107]

At the 1973 Gordon Conference on Nucleic Acids—after presentations

100. Klümper & Qaim, *supra* note 57, at 4.

101. This Article was conceptualized and written prior to the Trump Administration taking office. The Trump Administration has stated its commitment to decreasing environmental regulation, and changes are expected to occur in the regulatory systems of the Environmental Protection Agency, Food and Drug Administration, and Department of Agriculture. However, the exact regulatory changes remain unclear at this time.

102. Dough Farquhar & Liz Meyer, *State Authority to Regulate Biotechnology under the Federal Coordinated Framework*, 12 DRAKE J. AGRIC. L. 439, 440 (2007).

103. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302, 23303 (June 26, 1986); Christine C. Vito, *State Biotechnology Oversight: The Juncture of Technology, Law, and Public Policy*, 45 ME. L. REV. 329, 335 (2018).

104. Lee-Muramoto, *supra* note 7, at 334.

105. Farquhar & Meyer, *supra* note 102, at 441.

106. Vito, *supra* note 103, at 332.

107. Farquhar & Meyer, *supra* note 102, at 441.

revealed the discovery that DNA could be spliced and recombined—the conference participants voted to ask the National Academy of Sciences and the Institute of Medicine to form a committee to consider the risks posed by rDNA research and propose guidelines on the research.[108] In its request, the conference expressed "deep concern" about the possibility that genetically modified DNA could be hazardous to the public.[109] However, the conference participants noted that rDNA research could also help mitigate human health issues.[110] Subsequently, a small committee was convened to discuss methods for mitigating the dangers and maximizing the benefits of rDNA.[111] In 1974, this committee published four recommendations regarding rDNA research, including: (1) placing a moratorium on certain categories of experiments; (2) carefully weighing any experiments linking animal DNA to plasmid or phage DNA; (3) for the National Institute of Health (NIH) to establish an advisory committee formulating guidelines for rDNA research; and (4) holding an international meeting among leading scientists to discuss the danger of rDNA research.[112]

In 1975, the Asilomar Conference on Recombinant DNA was held in response to the fourth recommendation, which featured participation from leading international molecular biologists.[113] The Asilomar Conference highlighted the array of opinions among the scientific community,[114] but ultimately concluded with overwhelming support that research on rDNA continue with appropriate safeguards.[115] The Conference concluded that, "the standards of protection should be greater at the beginning and modified as improvements in the methodology occur and assessments of the risks change."[116] Specifically, the Asilomar Conference determined that due to the potential risks, containment should be an essential consideration in the experimental design and that the effectiveness of the containment should match the estimated risk as much as possible.[117] Additionally, the Asilomar Conference determined that certain experiments that pose serious risks

108. Donald S. Fredrickson, *Asilomar and Recombinant DNA: The End of the Beginning*, *in* BIOMEDICAL POLITICS 258, 271 (Kathi E. Hanna ed., 1991).

109. *Id.* at 271–72.

110. *Id.* at 272.

111. *Id.*

112. *Id.* at 273.

113. *Id.* at 274; Vito, *supra* note 103, at 332.

114. Fredrickson, *supra* note 108, at 282.

115. Paul Berg et al., *Asilomar Conference on DNA Recombinant Molecules*, 188 SCI. 991, 991 (1975).

116. *Id.* at 991–92.

117. *Id.* at 992.

should not be performed.[118] The NIH adopted the Asilomar conclusions to serve as interim rules for U.S. laboratories.[119]

The Asilomar conclusions have been criticized for allowing the scientific community to self-govern and produce standards that rely on those experimenting with genetic modification to simply proceed with caution, until they determine the technology is safe.[120] Despite these critiques, the guidelines agreed to were the primary standard for research and monitoring in the U.S. biotechnology industry until 1986.[121]

Meanwhile, in 1980, the Supreme Court set the stage for the prominence of the biotechnology industry by ruling that a living, human-made micro-organism could be patented.[122] Microbiologist Chakrabarty filed a patent application for his invention of a "human-made, genetically engineered bacterium [ ] capable of breaking down multiple components of crude oil."[123] However, the patent examiner rejected the claim for the bacteria because micro-organisms are "products of nature" and therefore not patentable.[124] In *Diamond v. Chakrabarty*, the Court interpreted U.S. patent laws to have a wide scope, holding that the micro-organism "plainly qualifies as patentable" because the genetically modified bacterium has "markedly different characteristics from any found in nature and one having the potential for significant utility."[125] Furthermore, the Court held that the microbiologist's discovery was "not nature's handiwork, but his own."[126] The Court's ruling provided the burgeoning biotechnology industry—a research and capital intensive enterprise—with economic security to invest in and develop GMOs.[127]

After the *Diamond* decision, and throughout the 1980s, the U.S. served as a leader in the biotechnology industry. But as genetically engineered crops became available on the market, public pressure mounted for federally imposed regulations to replace the system of self-governance under the

118. *Id.* at 993.

119. Fredrickson, *supra* note 108, at 283; Farquhar & Meyer, *supra* note 102, at 441.

120. Adam Briggle, *Asilomar Conference*, ENCYCLOPEDIA.COM, https://www.encyclopedia.com/science-and-technology/biology-and-genetics/cell-biology/asilomar-conference (last updated May 14, 2018).

121. Farquhar & Meyer, *supra* note 102, at 441.

122. Diamond v. Chakrabarty, 447 U.S. 303, 318 (1980).

123. *Id.* at 305.

124. *Id.* at 306.

125. *Id.* at 309–10.

126. *Id.* at 310.

127. Vito, *supra* note 103, at 330.

Asilomar conclusions.[128] The Reagan Administration was worried about hindering biotechnology research and development, so it opted to incorporate agricultural biotechnology and GMO regulation into existing federal laws, rather than enact new legislation.[129] Thus, in 1986, the White House Office of Science and Technology Policy established a coordinated framework for the regulation of biotechnology.[130] The Ninth Circuit indicated the purpose of this coordinated framework was to "construct a framework that would not impair the competitiveness or innovativeness of the United States' biotechnology industry."[131] This framework, which is still utilized today, is described in the next Part.

B. Current U.S. Regulatory System

In 1986, the Coordinated Framework for Biotechnology Regulation (Coordinated Framework) was created as the "comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products."[132] Pursuant to the Coordinated Framework, the FDA, USDA, and EPA work together to "ensure that GMOs are safe for human, plant, and animal health."[133] In broad terms, the FDA regulates most human and animal food, including GMO foods, and ensures that GMO products meet safety standards.[134] The USDA protects U.S. agriculture from pests and diseases by formulating regulations to ensure GMO plants do not cause harm to other plants.[135] Lastly, the EPA focuses on protecting human health and the environment through the regulation of pesticides, including pesticidal substances incorporated into GMO plants.[136] Due to the overlapping nature of the agencies' jurisdiction, determining which laws apply and which agency governs depends on the nature of the organism and the product's

128. Farquhar & Meyer, *supra* note 102, at 441.

129. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302, 23302 (June 26, 1986); Farquhar & Meyer, *supra* note 102, at 441.

130. *How GMOs Are Regulated in the United States*, U.S. FOOD & DRUG ADMIN., www.fda.gov/feedyourmind (last updated July 9, 2024).

131. Ctr. for Food Safety v. Vilsack, 718 F.3d 829, 833 (9th Cir. 2013).

132. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302 (June 26, 1986).

133. *How GMOs Are Regulated in the United States*, *supra* note 130.

134. *Id*.

135. *Id*.

136. *Id*.

intended use.[137]

Depending on the characteristics of the GMO, it may be regulated by more than one federal agency.[138] However, it is possible that one product can be subject to regulation by all three agencies:

> For example, for plant technology, the USDA will regulate a potato developed to contain a higher-solids content for field testing safety. In addition, the potato developer must complete a consultation process with the FDA. If the potato contains a known allergen, or other additive that is not [generally recognized as safe] GRAS, the FDA must approve that food additive. Additionally, if a potato has insect protection, the EPA will be involved in the regulatory process, along with the USDA and the FDA.[139]

Alternatively, depending on agency interpretation, a product could bypass the entire regulatory system.[140] For instance, the GloFish—a genetically engineered "bright red fluorescent zebra fish" created through the insertion of genetic material from sea coral—is available for purchase but is not regulated by the FDA, USDA, or EPA.[141] In 2003, the company that engineers GloFish, Yorktown Technologies, L.P., contacted the FDA to understand how the FDA would regulate the genetically modified fish.[142] In the FDA's interpretation, regulation of GloFish would be inappropriate "[b]ecause tropical aquarium fish are not used for food purposes, they pose no threat to the food supply . . . In the absence of a clear risk to the public health, the FDA finds no reason to regulate these particular fish."[143]

Following the FDA's decision not to regulate, Yorktown Technologies began selling GloFish commercially in the U.S.[144] Numerous non-profit organizations filed suit against the FDA and other governmental agencies, alleging in part that the FDA arbitrarily and capriciously denied regulatory

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137. Farquhar & Meyer, *supra* note 102, at 456–57; *see Regulation of Biotech Plants: How the Federal Government Regulates Biotech Plants*, U.S. DEP'T OF AGRIC., https://www.usda.gov/farming-and-ranching/plants-and-crops/biotechnology/regulation-biotech-plants (last visited Dec. 2, 2025).

138. *Regulation of Biotech Plants*, *supra* note 137.

139. Farquhar & Meyer, *supra* note 102, at 456–57.

140. *See* Farquhar & Meyer, *supra* note 102, at 457; *see, e.g.,* Int'l Ctr. for Tech. Assessment v. Thompson, 421 F. Supp. 2d 1, 4 (D.D.C. 2006).

141. *Thompson*, 421 F. Supp. 2d at 4.

142. *Id*.

143. *Id*. at 5.

144. *Id*.

jurisdiction over GloFish.[145] However, in a 2006 opinion, the D.C. District Court affirmed that the "FDA is simply exercising its discretion not to take enforcement actions against these particular fish."[146] The FDA's refusal leaves the genetically modified fish unregulated on the U.S. market, especially considering the EPA does not have statutory authority over the GloFish, given that the fish contains no pesticides, and the USDA does not have statutory authority because the fish is not livestock.[147] Critics argue that the GloFish creates a precedent for loose regulation of genetically modified pets, and highlights a loophole in U.S. regulation.[148]

Despite possibilities for overlapping jurisdiction or instances where no agency has authority, the Coordinated Framework maintains that the FDA, USDA, and EPA each have a distinct and primary responsibility in the U.S. biotechnology regulatory system.[149]

1. The U.S. Food and Drug Administration

The FDA is the federal agency "responsible for ensuring the safety and proper labeling of all plant-derived food and feed, including those developed through genetic engineering."[150] The FDA regulates based on the safety and nutritional characteristics of food, not on the method used to produce the food.[151] On the FDA's website, the agency supports its regulatory approach and states that, "[t]his regulatory approach is supported by more than 25 years of experience in this area demonstrating that as a class, foods from genetically engineered plant varieties don't present different or greater safety concerns than their non-genetically engineered counterparts."[152]

The FDA derives its authority to regulate GMOs from the Food, Drug, and Cosmetic Act (FDCA).[153] Under the FDCA, the FDA requires all food

145. *Id*.

146. *Id*. at 7.

147. Farquhar & Meyer, *supra* note 102, at 457.

148. *Id*.

149. *Regulation of Biotech Plants*, *supra* note 137.

150. *Id.*; *accord* Brian Sylvester, *Building the Regulatory Conversation on Cellular Agriculture*, LAW360 (Oct. 30, 2018), https://www.law360.com/articles/1096770/building-the-regulatory-conversation-on-cellular-agriculture.

151. *Food from New Plant Varieties*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/food-ingredients-packaging/food-new-plant-varieties (last updated Dec. 16, 2024); Lee-Muramoto, *supra* note 7, at 338; *New Plant Variety Regulatory Information*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/food-new-plant-varieties/new-plant-variety-regulatory-information (last updated Dec. 16, 2024).

152. *Food from New Plant Varieties, supra* note 151.

153. *Regulation of Biotech Plants*, *supra* note 137; *see* Sylvester, *supra* note 150; Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 342(a)(1), 348. Note that the FDA also derives power to regulate

and feed to pass the same safety standards, regardless of whether the crops are produced through conventional breeding techniques or are GMOs.[154] Per Section 402(a)(1),[155] the FDA has the authority to remove a food from the market if it is "adulterated," meaning it has "any poisonous or deleterious substance that may render it injurious to health."[156] Thus, if a GMO product is adulterated, the FDA can remove the product from circulation and sanction the company responsible for marketing the product.[157] Additionally, Section 409[158] regulates food additives—which must receive premarket approval—unless the substance is generally recognized as safe (GRAS).[159]

Anyone selling food in the U.S., including GMO-developers, are responsible for complying with all applicable laws. In addition, the FDA has set up two voluntary systems to work with GMO-food developers to ensure that the products are safe for human and animal consumption.[160] The first program, the Plant Biotechnology Consultation Program, was established to "help ensure that any safety or other regulatory issues associated with food from a new plant variety are resolved prior to commercial distribution."[161] In the consultation process, the FDA reviews a myriad of characteristics to ensure the GMO food is safe and nutritious, including, the use of the bioengineered food, the function of the GMO modification, and information comparing the composition or characteristics of the GMO food to that of similar non-GMO foods.[162] As of 2017, "to the best of [the] FDA's knowledge, all [genetically engineered] food crops intended for marketing have been the subject of a consultation or other relevant premarket processes

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GMOs from the Public Health Service Act. *See* EXEC. OFF. OF THE PRESIDENT, MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS: FINAL VERSION OF THE 2017 UPDATE TO THE COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY 9 [hereinafter MODERNIZING THE REGULATORY SYSTEM]; Ctr. for Food Safety v. Vilsack, 718 F.3d 829, 833 (9th Cir. 2013) (explaining that the FDA has authority under FDCA, but the FDCA "does not contain any provisions that specifically address genetically modified plants").

154. *New Plant Variety Regulatory Information*, *supra* note 151.

155. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 342(a)(1).

156. MODERNIZING THE REGULATORY SYSTEM, *supra* note 153, at 15.

157. *Id.*

158. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 348.

159. Manufacturers themselves, not the FDA, determine when a food additive is GRAS. If something is deemed GRAS, the manufacturer does not need to notify the FDA. Substances Generally Recognized as Safe, 81 Fed. Reg. 54960, 54963 (Aug. 17, 2016); MODERNIZING THE REGULATORY SYSTEM, *supra* note 153, at 16.

160. *Programs on Food from New Plant Varieties*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/food-new-plant-varieties/programs-food-new-plant-varieties (last updated Dec. 16, 2024).

161. MODERNIZING THE REGULATORY SYSTEM, *supra* note 153, at 17.

162. *Id.*

prior to marketing," despite the consultation process not being legally required.[163] If the FDA identifies a safety or regulatory issue, it works with the company to address the problem. Once all safety issues are resolved, the FDA approves the product for placement on the market.[164]

The second program, the Early Food Safety Evaluation Program (EFSEP), evaluates new non-pesticidal plant proteins intended for use in food.[165] EFSEP focuses on assessment of new GMO plants that could result in "inadvertent, intermittent, low-level presence" of new proteins in the food supply.[166] Due to this limited focus, EFSEP is not a substitute for the consultation process under the voluntary Plant Biotechnology Consultation Program, because that consultation process aims to assess the commercialization of a GMO product—not the low-level presence of a new protein in food.[167]

2. The U.S. Department of Agriculture

The USDA has broad power to regulate agricultural research and products.[168] Within the USDA, the Animal and Plant Health Inspection Service (APHIS) is "responsible for protecting agriculture from pests and diseases."[169] APHIS, which acts under the Animal Health Protection Act (AHPA) and Plant Protection Act (PPA), oversees the movement and release of GMOs that could pose a risk to plant and animal health.[170] The PPA provides APHIS with authority over GMO "plant pests."[171] The PPA defines "plant pests" to be:

> [A]ny living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any

163. *Id.*

164. *Programs on Food from New Plant Varieties*, *supra* note 160.

165. Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use, 71 Fed. Reg. 35688 (June 21, 2006).

166. *Programs on Food from New Plant Varieties*, *supra* note 160.

167. *Id.*

168. Farquhar & Meyer, *supra* note 102, at 446.

169. *Regulation of Biotech Plants*, *supra* note 137; MODERNIZING THE REGULATORY SYSTEM, *supra* note 153, at 22.

170. *Biotechnology Regulatory Services*, U.S. DEP'T OF AGRIC.: ANIMAL & PLANT HEALTH INSPECTION SERV., https://www.aphis.usda.gov/biotechnology (last updated Oct. 30, 2025); MODERNIZING THE REGULATORY SYSTEM, *supra* note 153, at 22.

171. 7 C.F.R. § 340.2 (2025); 7 C.F.R. § 360 (2025); MODERNIZING THE REGULATORY SYSTEM, *supra* note 153, at 23–24.

> plant or plant product: (A) A protozoan; (B) A nonhuman animal; (C) A parasitic plant; (D) A bacterium; (E) A fungus; (F) A virus or viroid; (G) An infectious agent or other pathogen; (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs.[172]

If a GMO is determined to be a plant pest, it becomes subject to APHIS regulations, such as the requirement to obtain a permit from APHIS for the movement of the GMO.[173] The Biotechnology Regulatory Services in APHIS implements the APHIS regulations and regulates the "introduction of certain organisms development using genetic engineering that may pose a risk to plant health."[174]

When an organism is deemed by APHIS not to be a plant pest, APHIS no longer has regulatory authority over the plant, as highlighted in *Center for Food Safety v. Vilsack*.[175] In that case, APHIS determined it did not have the authority to regulate Roundup Ready Alfalfa (RRA), a genetically modified plant engineered to be resistant to the herbicide Roundup.[176] Monsanto, the developer of both Roundup and RRA, modified RRA so that farmers could utilize the Roundup herbicide on fields without killing the alfalfa crop.[177] APHIS conducted an assessment of RRA and determined that it was not a "plant pest" under the PPA, and accordingly stopped regulating the modified crop.[178] The Ninth Circuit affirmed APHIS's deregulation, recognizing that "[o]nce the agency concluded that RRA was not a plant pest, it no longer had jurisdiction to continue regulating the plant."[179] *Center for Food Safety v. Vilsack* illustrates how APHIS does not consider concerns such as transgenic contamination (mixing of genes between modified and unmodified crops) and increased herbicide use.[180]

In 2016, Congress passed the National Bioengineered Food Disclosure Standard (NBFDS) to require the USDA to establish national, required

172. Plant Protection Act § 403(14), 7 U.S.C. § 7702.

173. 7 C.F.R. § 340.5 (2025).

174. *Biotechnology Regulations*, USDA: ANIMAL & PLANT HEALTH INSPECTION SERV., www.aphis.usda.gov/biotechnology/regulations (last updated Nov. 17, 2025).

175. Ctr. for Food Safety v. Vilsack, 718 F.3d 829, 834 (9th Cir. 2013).

176. *Id.* at 831–32.

177. *Id.* at 831.

178. *Id.* at 832.

179. *Id.*

180. *See id.* at 839.

standards for labeling genetically modified food.[181] Beginning in 2022, companies were required to label bioengineered food in accordance with the disclosure standards.[182] To keep these labeling requirements uniform, the disclosure law included a preclusion provision so no state could enact "any requirement relating to the labeling or disclosure of whether a food is bioengineered . . . that is not identical to the mandatory disclosure requirement under the [NBFDS]."[183] With this new labeling law, the U.S. now requires GMO labeling similarly to the European Union's regulatory system.

3. The U.S. Environmental Protection Agency

The EPA is tasked with protecting human health and the environment by "ensuring that a plant derived from biotechnology expressing pesticidal traits produces no unreasonable adverse effects upon man and the environment."[184] The EPA derives authority to regulate GMOs and genetically modified pesticides principally through the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[185] but also through the FDCA and the Food Quality Protection Act.[186] The EPA also regulates the use of genetically engineered microorganisms under the Toxic Substances Control Act.[187]

The predominant focus of the EPA's regulation of GMOs arises under FIFRA's mandate to control pesticides.[188] Plants can be genetically modified to include pesticidal substances; for example, the plant exhibits pest-fighting traits to become resistant to insects, weeds, or diseases.[189] The EPA regulates those pesticidal substances under FIFRA as "plant-incorporated protectants"

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181. National Bioengineered Food Disclosure Standard; List of Bioengineered Foods, 88 Fed. Reg. 83305 (Nov. 29, 2023) (to be codified at 7 C.F.R. pt. 66); 7 C.F.R. § 66.3(a)(1) (2025).

182. 7 C.F.R. § 66.13(c) (2025).

183. 7 U.S.C. § 1639b(e); Kao v. Abbott Lab'y Inc., No. 17-cv-02790-JST, 2017 WL 5257041, at *1, *4 (N.D. Cal. Nov. 13, 2017).

184. *Introduction to Biotechnology Regulation for Pesticides*, U.S. ENV'T PROT. AGENCY, https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/introduction-biotechnology-regulation-pesticides (last updated Oct. 1, 2025).

185. *Id.*; 40 C.F.R. §§ 152.1(a), 174.1 (2025).

186. *Introduction to Biotechnology Regulation for Pesticides*, *supra* note 184; 40 C.F.R. §§ 152, 174 (2025).

187. *Overview of Biotechnology Under TSCA*, U.S. ENV'T PROT. AGENCY, https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/overview-biotechnology-under-tsca (last updated Nov. 4, 2025).

188. *Regulation of Biotech Plants*, *supra* note 137.

189. *Introduction to Biotechnology Regulation for Pesticides*, *supra* note 184.

(PIPs).[190] FIFRA regulates the registration, distribution, sale, and use of pesticides in the U.S.[191] In 2001, the EPA promulgated a final rule on PIPs and stated that, "[t]he substances plants produce for protection against pests, and the genetic material necessary to produce these substances, are pesticides under [FIFRA], if humans intend to use these substances for 'preventing, repelling or mitigating any pest."[192]

Under FIFRA, a pesticide must be registered with the EPA in order to be sold or distributed in the U.S.[193] Prior to registration of a pesticide or PIP, an applicant must demonstrate that the pesticide or PIP, "will not generally cause unreasonable adverse effects on the environment," when used in accordance with the label directions.[194] In reaching a decision to register a pesticide, the EPA requires "extensive studies examining numerous factors, such as: risks to human health, nontarget organisms and the environment; potential gene flow; and the need for insect resistance management plans."[195] A PIP is only permitted to be used on human food or livestock feed crops if EPA scientists—with input from academia, industry, other federal agencies, and the public—determine that the PIP would "not pose unreasonable risk to human health and the environment during their time-limited registration."[196] The EPA can also impose conditions for the pesticide or PIP's use during the registration process.[197]

In sum, the EPA regulates bioengineered plants that are modified to include substances that act as pesticides or aid a plant's resistance to

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190. *Id.*

191. *Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Federal Facilities*, U.S. ENV'T PROT. AGENCY, https://www.epa.gov/enforcement/federal-insecticide-fungicide-and-rodenticide-act-fifra-and-federal-facilities (last updated Jan. 31, 2025).

192. Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant Pesticides), 66 Fed. Reg. 37772, 37772 (July 19, 2001) (to be codified at 40 C.F.R. pts. 152, 174); 40 C.F.R. § 174 (2002);; *see* 40 C.F.R. § 152.15 (2001).

193. *Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Federal Facilities*, *supra* note 191.

194. *Id.*; FIFRA defines "unreasonable adverse effects on the environment" as:

(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of title 21.

7 U.S.C. § 136(bb).

195. *Overview of Plant Incorporated Protectants*, U.S. ENV'T PROT. AGENCY, https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/overview-plant-incorporated-protectants (last updated Dec. 31, 2024); *see Overview of Risk Assessment in the Pesticide Program*, U.S. ENV'T PROT. AGENCY, https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program (last updated Jan. 31, 2025).

196. *Overview of Plant Incorporated Protectants*, *supra* note 195.

197. *Regulation of Biotech Plants*, *supra* note 137.

disease.[198]

4. U.S. State Laws

Although the federal government is the primary regulator regarding the health and safety of GMOs, state and local governments also have laws regulating genetically engineered crops and animals.[199] For example, Alaska, California, Maryland, Michigan, and Mississippi, each enforce laws relating to genetically modified fish.[200] State legislation on GMOs varies, with some states focusing on a consumer's right-to-know, and others adopting economic incentives for the biotechnology industry.[201] In short, states have a variety of attitudes regarding GMOs, and approach regulation differently. For instance, 33 states have a mandatory or voluntary labeling guidelines for agricultural or food products.[202] Yet, essentially all U.S. states (all, except Nevada and South Dakota), provide some state tax incentive to support bioscience companies.[203] However, states and localities are limited in their ability to enact legislation under the federal preemption doctrine. In *Atay v. County of Maui*, the Ninth Circuit held that a Maui County ordinance banning the cultivation and testing of genetically engineered plants was expressly preempted by the PPA to the extent that the banned GMOs are regulated by the USDA.[204]

IV. HOW ARE GMOS REGULATED IN THE EUROPEAN UNION?

Compared to the United States' (U.S.) regulatory system which involves voluntary consultation processes, and only mandated GMO labeling in 2016, the European Union (E.U.) regulatory system is more cautious about approving GMO usage.[205] This more cautious and regulated approach stems from the precautionary principle employed by the E.U. when assessing matters that pose environmental implications.[206]

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198. *How GMOs Are Regulated in the United States*, *supra* note 130.

199. Farquhar & Meyer, *supra* note 102, at 457.

200. *Id.* at 458.

201. *Id.* at 459.

202. Hanna Broaddus, *The Comprehensive List: Where GMOs Are Banned*, CENTRAFOODS (Aug. 2015), https://www.centrafoods.com/blog/the-comprehensive-list-where-gmos-are-banned.

203. COUNCIL OF STATE BIOSCIENCE ASS'NS, THE U.S. BIOSCIENCE INDUSTRY: A POWERFUL ENGINE FOR STATE ECONOMICS 9–10 (2025).

204. Atay v. Maui, 842 F.3d 688, 692 (9th Cir. 2016).

205. *See Programs on Food from New Plant Varieties*, *supra* note 160; *see* National Bioengineered Food Disclosure Standard; List of Bioengineered Foods, 88 Fed. Reg. 83305 (Nov. 29, 2023) (to be codified at 7 C.F.R. pt. 66); *see* Peterson, *supra* note 10, at 4.

206. Peterson, *supra* note 10, at 4.

This Part will first briefly trace the history of E.U. GMO regulations and then explore the current E.U. GMO regulatory system. Finally, this Part will explore the February 2024 E.U. Parliamentary vote to deregulate certain GMOs.

A. Historical Development of the E.U. Regulatory System

Whereas the U.S. system of GMO control emerged from scientific conferences and was designed to "not impair the combativeness or innovativeness of the United States's biotechnology industry,"[207] the E.U. system developed through a process with more input from civil society groups and prioritized minimizing risk.[208] These civil society groups advocated against the U.S.'s fragmented system of GMO regulation and called for an "overarching, specific legal framework for all types of agricultural applications of genetic technologies . . . because of the 'novelty' of GMOs."[209] The E.U. formed its regulations on GMO cultivation, production, and dissemination in accordance with the precautionary principle.[210] This general principle of law holds that measures should be taken to prevent potential or unknown risks by implementing requirements to avoid the risks.[211] The precautionary principle thus dictates that GMOs as substances with unknown impacts should be regulated strictly.[212] E.U. GMO policies "start from the proposition that [genetically modified] plants, feeds, and foods are significantly different from conventionally-bred ones and those who want to plant or sell them must prove to regulatory agencies that the product is safe."[213] With this proposition, decisionmakers pushed the burden of proof regarding the safety of the GMO onto the developers, who have to meet high safety standards. Correspondingly, Europeans tend to be skeptical

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207. Ctr. for Food Safety v. Vilsack, 718 F.3d 829, 833 (9th Cir. 2013).

208. Angelika Hilbeck et al., *GMO Regulations and Their Interpretation: How EFSA's Guidance on Risk Assessments of GMOs Is Bound to Fail*, 32 ENV'T SCI. EUR. 3 (2020).

209. *Id.*

210. Artem Anyshchenko & Jennifer Yarnold, *From 'Mad Cow' Crisis to Synthetic Biology: Challenges to EU Regulation of GMOs Beyond the European Context*, 21 INT'L ENV'T AGREEMENTS: POL., L. & ECON. 391, 392 (2021).

211. *Id.*

212. MARINE FRIANT-PERRAT, *The European Union Regulatory Regime for Genetically Modified Organisms and Its Integration into Community Food Law and Policy*, *in* THE REGULATION OF GENETICALLY MODIFIED ORGANISMS: COMPARATIVE APPROACHES 79, 84 (Luc Bodiguel & Michael Cardwell eds., 2010).

213. *The EU-US Dispute over Regulation of Genetically Modified Organisms, Plants, Feeds, and Foods,* INT'L DIMENSIONS OF ETHICS EDUC. IN SCI. & ENG'G, https://www.umass.edu/sts/ethics/online/cases/GMO/case.html (last visited Dec. 2, 2025).

about GMOs, with a majority believing that production of bioengineered food should not be supported.[214] Compared to the U.S., the E.U. system imposes stricter regulations on GMOs.[215] Additional context for the E.U.'s restrictive stance on GMOs is found in the crises of the 1980s and 1990s which prompted "many Europeans [to] lose trust in governmental food standards."[216] Specifically, the outbreak of Bovine Spongiform Encephalopathy (BSE), commonly known as mad cow disease, sparked widespread criticism and recognition that the European regulatory system failed to detect and stop the spread of the disease.[217] In fact, the BSE crisis and the associated government failure has been noted to have "significantly affected the attitude of the European public towards [genetically modified] foods,"[218] even though GMOs did not contribute to the spread of BSE.

In response, the E.U. adopted biosafety regulations in 1990 with the enactment of Directive 1990/220.[219] The 1990 Directive incorporated the precautionary principle and required GMO developers to apply to individual member countries of the E.U. to market the GMO product in that country.[220] Each member country had the ability to prohibit the developer from marketing the GMO product in their country.[221]

The 1990 Directive was replaced in 2001 with Directive 2001/18, which sought to modify the regulatory system in response to the crises of the 1990s and growing public skepticism. The new Directive aimed to "ensure a high level of protection for human, animal, and environmental health and a well-functioning EU internal market."[222] The 2001 Directive again incorporated the precautionary principle by explicitly stating, "[t]he precautionary principle has been taken into account in the drafting of this Directive and must be taken into account when implementing it."[223] Furthermore, in direct response to growing public mistrust, the 2001 Directive sought to increase transparency, requiring that "the public is consulted by either the

214. Martin, *supra* note 23, at 373.

215. Peterson, *supra* note 10, at 4–10.

216. Anyshchenko & Yarnold, *supra* note 210, at 395.

217. *Id.* at 394.

218. Cass R. Sunstein, *Precautions Against What? The Availability Heuristic and Cross-Cultural Risk Perception*, 57 ALA. L. REV. 75, 76 (2005).

219. Council Directive 90/220, 1990 O.J. (L 117) 1, 15 (EC).

220. DIAHANNA LYNCH & DAVID VOGEL, THE REGULATION OF GMOS IN EUROPE AND THE UNITED STATES: A CASE-STUDY OF CONTEMPORARY EUROPEAN REGULATORY POLITICS 7 (2001).

221. *Id.*

222. Bruetschy, *supra* note 19, at 169.; *see* Commission Declaration 2001/18, 2001 O.J. (L 106) 1, 39 (EC).

223. *Id.* at 1.

Commission or the Member States during the preparation of measures and that they are informed of the measures taken during the implementation of this Directive."[224]

The 2001 Directive strengthened the risk assessment process for GMOs by requiring analysis of impacts such as the indirect, cumulative, and long-term environmental and health risks posed by GMOs.[225] In accordance with the precautionary principle, Directive 2001/18 required that a pre-market risk assessment of GMO crops be conducted before a GMO substance could be placed on the market.[226]

The E.U. crystallized their pre-market authorization process for GMO products in Regulation (EC) 1829/2003.[227] The Regulation lays out the procedure by which GMO developers can apply for authorization to market their GMO products in the E.U.[228] First, the developer must submit an application to the individual E.U. country in which the developer wants to market the product.[229] The country informs the European Food Safety Authority (EFSA), which has six months to assess the application.[230] The EFSA is an independent scientific committee that evaluates GMO foods to assess safety risks.[231] Regulation 1829/2003 states that:

> [G]enetically modified food and feed should only be authorised [sic] for placing on the Community market after a scientific evaluation of the highest possible standard, to be undertaken under the responsibility of the [EFSA], of any risks which they present for human and animal health and, as the case may be, for the environment.[232]

A GMO can only be authorized for placement on the E.U. commercial market upon a finding that there are not "adverse effects on human health, animal health or the environment."[233] Based on the EFSA's risk assessment, the European Commission or a committee of E.U. country representatives

224. *Id.*
225. *Id.* at 19.
226. Martin, *supra* note 23, at 375; Hilbeck et al., *supra* note 208.
227. Regulation No. 1829/2003, 2003 O.J. (L 268) 1, 6–12 (EC).
228. *Id.* at 7.
229. *Id.*
230. *Id.* at 7–8.
231. Lau, *supra* note 11.
232. Regulation No. 1829/2003, 2003 O.J. (L 268) 1, 2 (EC).
233. *Id.* at 7.

determine whether the application should be granted or denied.[234] After being approved either by the European Commission or via a majority decision of E.U. member states, a GMO could be placed on the market as a food product with proper labeling.[235]

Prior to 2015, an E.U. member state could only ban the use of an approved GMO if new evidence, not examined during the original approval process, demonstrated that the GMO posed a risk to human or environmental health.[236] The European Commission requires that the member state submits the new evidence to the Commission to issue a revised approval decision regarding the GMO.[237]

This refusal and reassessment process was not always followed, as demonstrated by the 2011 case of France banning a GMO food product which the European Commission had approved.[238] The EFSA approved the genetically modified corn, but France responded that the GMO posed an environmental health risk.[239] The EFSA affirmed their initial finding, asserting that the overall environmental threat was low and that mitigation policies could be implemented to reduce the risk further.[240] However, France refused to lift its ban.[241] In 2011, the European Court of Justice declared that the French ban was unlawful, yet still France did not lift its prohibition of the genetically modified corn.[242] This case demonstrates that E.U. member states yield significant power to resist GMOs, even if the GMO is approved by the E.U. regulatory system.

In 2015, E.U. member states were provided greater flexibility to lawfully prohibit GMOs in their country through an amendment to the 2001/18/EC Directive.[243] The Directive was amended so that it may be possible for individual countries to ban or restrict GMO cultivation under certain circumstances.[244] Following this amendment, E.U. countries are able to ban or restrict the cultivation and sale of a genetically modified crop on grounds related to environmental policy, agricultural policy, socioeconomic impacts,

234. Lau, *supra* note 11.
235. *Id.*
236. *Id.*
237. *Id.*
238. *Id.*; *France Definitively Bans GM Corn*, PHYS ORG (May 5, 2014), https://phys.org/news/2014-05-france-definitively-gm-corn.html.
239. Lau, *supra* note 11.
240. *Id.*
241. *Id.*
242. *Id.*
243. Directive (EU) 2015/412, 2015 O.J. (L 68) 1, 2.
244. *Id.* at 6.

and/or land-use practices, including cultural traditions.[245] In addition to the robust centralized pre-market approval, the E.U. also enacted strict labeling and traceability requirements in Regulation (EC) 1830/2003 and transparency regulations, which were updated in 2019 by Regulation (EU) 2019/1381.[246]

B. Current E.U. Regulatory System

Today, GMOs in the E.U. are still regulated prior to their use in food and feed.[247] The E.U. regulatory system has three components to ensure robust monitoring and control. First, the E.U. requires pre-market authorization based on a risk assessment.[248] Second, the E.U. utilizes a tracing system to monitor the cultivation and use of GMOs throughout the E.U.[249] Lastly, the E.U. requires companies to label their products if the products contain GMOs.[250]

As of 2019, only 118 GMOs have been authorized for placement on the market in the E.U., and only 0.1% of worldwide GMO crops are produced in the E.U.[251] In contrast, the U.S. Department of Agriculture estimates that 170 million acres of U.S. land is currently used to produce GMO crops.[252] Some have described the strict regulations imposed by the E.U. to function as if the E.U. had completely banned GMO cultivation.[253] Under the strict policies, GMOs can only receive authorization if the EFSA conducts a risk assessment and determines that there is no risk to human health or the environment.[254] All GMOs are required to be assessed by the EFSA, and the public can submit comments on ESFA opinions and risk assessments performed by national-level authorities.[255]

Furthermore, if a GMO is not approved by the EFSA, is approved by the

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245. *Id.* at 1.

246. Council Regulation (EC) 1830/2003, 2003 O.J. (L 268) 24, 26; Council Regulation (EU) 2019/1381, 2019 O.J. (L 231) 1, 6.

247. Commission Declaration 2001/18, 2001 O.J. (L 106) 1, 2 (EC); Regulation No. 1829/2003, 2003 O.J. (L 268) 1, 1–2 (EC).

248. Bruetschy, *supra* note 19, at 169.

249. *Id*.

250. *Id*.

251. *Id.*; ISAAA, Brief 54: Global Status of Commercialized Biotech/GM Crops in 2018: Biotech Crops Continue to Help Meet the Challenges of Increased Population and Climate Change 9 (2018).

252. Gerald Berkowitz, *The Future of GMO Crops,* SCI. GMOS (Oct. 3, 2017), https://gmo.uconn.edu/topics/the-future-of-gmo-crops/.

253. Martin, *supra* note 23, at 374.

254. Regulation No. 1829/2003, 2003 O.J. (L 268) 1, 8 (EC).

255. Bruetschy, *supra* note 19.

European Commission, and is permitted to be sold in an E.U. member state, the GMO product is still subject to traceability and labeling policies which aim to "ensure that relevant information on GMOs is available for operators and consumers."[256] All GMOs need to be labeled to indicate the presence of GMO ingredients, unless the GMO "presence in conventional product[s] is not more than 0.9% per ingredient and it is unavoidable or adventitious."[257] The E.U. has a zero-tolerance policy for the presence of unauthorized GMOs.[258]

Currently, all GMOs in the E.U. are regulated using this three-part centralized system of pre-market approval, traceability, and labeling.[259] In 2018, the European Court of Justice ruled that plants created through CRISPR and similar technologies, which can make small changes to DNA that could have occurred naturally, are nonetheless subject to E.U. regulation as GMOs.[260] Following the Court's determination, some began advocating that GMOs made with these new technologies—referred to as new genomic technologies (NGTs)—should be exempt because "unlike transgenic plants created by introducing foreign genes, [crops edited with NGTs] just have tweaks to their natural genes."[261] In response to this advocacy, as well as other calls for reform based on concern that the E.U.'s "demanding regulatory framework for GMOs ha[d] contributed to very few such crops being approved in Europe for planting," the European Council requested that the European Commission study the NGTs.[262] The European Commission's Report determined the current GMO regulatory system stifled GMO and agricultural innovation.[263] Subsequently, in 2023 the European Commission submitted a proposal to the European Parliament to deregulate GMOs produced using NGTs.[264]

256. *Id.*
257. *Id.*
258. Council Directive 2001/18/EC, 2001 O.J. (L 106) 1, 2; Regulation No. 1829/2003, 2003 O.J. (L 268) 1, 7 (EC).
259. Bruetschy, *supra* note 19, at 169.
260. Erik Stokstad, *European Parliament Votes to Ease Regulations of Gene-Edited Crops*, SCI. (Feb. 7, 2024), https://www.science.org/content/article/european-parliament-votes-ease-regulation-gene-edited-crops.
261. *Id.*
262. *Id.*
263. *Id.*
264. *Id.*

C. February 2024 Vote

On February 7, 2024, the European Parliament adopted the European Commission's first-reading position "to support a simplified registration for plant varieties produced using NGTs that are deemed to be equivalent to conventional varieties, while retaining stricter controls for others that are not" with 307 votes for, 263 votes against, and 41 abstentions.[265] The proposal would create two categories.[266] Category 1 GMOs are those "considered equivalent to conventional plants,"[267] in that it "differs from the parent plant by no more than 20 genetic modifications."[268] The types of acceptable modifications are described in detail: They allow for small insertions of novel sequences, large deletions and inversions of the DNA sequence, and large insertions if the new sequence is found in the natural breeding pool of the crop.[269] Notably, modifications intended to increase herbicide resistance would not be considered for Category 1 classification.[270] Category 2 is defined simply as all other varieties of GMOs not included in Category 1.[271] Category 1 foods would not be subject to GMO labeling requirements, but their seeds would still need to be labeled as genetically modified for traceability.[272] Category 1 plants would also not be allowed on organic farms.[273] For Category 2 plants, the proposal aims to steer their intended uses toward sustainability, offering regulatory incentives such as accelerated risk assessment and enhanced pre-submission advice.[274] In essence, the proposal would "exempt NGTs from GMO legislation if the changes could have been made (albeit much more slowly) with conventional breeding."[275]

The European Parliamentary vote to deregulate some GMO crops marks a stark departure from the traditional E.U. GMO regulatory system which

265. IVANA KATSAROVA, EUR. PARLIAMENTARY RSCH. SERV., PE 754.549, PLANTS PRODUCED USING NEW GENOMIC TECHNIQUES 1 (2024).
266. *Id.* at 7.
267. *Id.*
268. *Id.*
269. *Id.*
270. *Id.*
271. *Id.*
272. *Id.* at 8.
273. *Id.*
274. *Id.* at 9.
275. Stokstad, *supra* note 260.

practically functions as a near-ban on GMO cultivation.[276] Some individuals claim that the change in Parliament's opinion can be traced to the improved reputation of biotechnology following RNA vaccines developed in response to the COVID-19 crisis.[277] Others highlight that Parliament's decision to embrace new technology GMOs comes as the impacts of climate change are threatening food production.[278] Many point out that this decision reflects trends in consumer concerns about GMO foods, which have decreased from 63% in 2005 to 27% in 2019.[279] Large agricultural companies, such as Bayer, support the Parliamentary vote and the deregulation of NGTs as a way to "boost competitiveness, sustainability, and food security across Europe."[280] Furthermore, these companies stress that "Europe's plant breeders and farmers urgently need to be enabled to harness the benefits of NGTs to successfully address the pressing agricultural challenges and deliver sustainable solutions."[281]

Meanwhile, anti-GMO groups have labeled the vote a "blow" to food and environmental safety.[282] Groups concerned about NGT-produced GMOs assert that the Parliament vote "positions the EU for even greater deregulation than in the [U.S.]" by eliminating safety checks and "failing to implement liability processes akin to those in the [U.S.]."[283]

CONCLUSION

A. Convergence Over Time

As described throughout this Article, there are many differences between the United States' (U.S.) and European Union's (E.U.) regulatory systems. For instance, while the current E.U. system is process-based,

276. Robert Hodgson, *European Governments Heading Towards GMO Deregulation*, EURONEWS (Feb. 24, 2025), https://www.euronews.com/my-europe/2025/02/24/european-governments-heading-towards-gmo-deregulation.

277. Stokstad, *supra* note 260.

278. *Id.*

279. Mihael Cristin Ichim, *The More Favorable Attitude of the Citizens Toward GMO Supports a New Regulatory Framework in the European Union*, 12 GM CROPS & FOOD 18, 18 (2020).

280. Robert Hodgson, *Parliament Reinforces Support for GMO Deregulation*, EURONEWS (Apr. 24, 2024), https://www.euronews.com/green/2024/04/24/parliament-reinforces-support-for-gmo-deregulation.

281. *Id.*

282. *EU Parliament Vote on New GMOs: a Blow to Food & Environmental Safety*, FRIENDS OF THE EARTH EUR. (Apr. 24, 2024), https://friendsoftheearth.eu/press-release/eu-parliament-vote-on-new-gmos-a-blow-to-food-environmental-safety/.

283. *Id.*

emphasizing the method of creation; the U.S. system is product-based, emphasizing demonstrated characteristics of the modified organism. Further, all genetically modified organisms (GMOs) in the E.U. are required to receive pre-market approval, whereas GMOs in the U.S. are only subject to regulation if specific characteristics exist. Additionally, pre-market authorization is required in the E.U., whereas the U.S. utilizes mandatory authorizations for some GMO characteristics while employing a voluntary consultation process for all GMO developers to receive feedback and preemptively align themselves with regulations. Individual E.U. member states can ban GMO cultivation and sale in the country, whereas U.S. states have limited authority to regulate GMOs pursuant to the preemption doctrine. The E.U. is also skeptical of granting patents to new genomic technologies (NGTs), while patentability is a cornerstone of the U.S. biotechnology sector and has shaped the structure of its regulatory system. Finally, whereas the U.S. policy on GMOs was developed with the intention of supporting and protecting the biotechnology industry, the E.U.'s policy was crafted based on the precautionary principle and amidst European skepticism about the government's regulatory capacity.

GMOs developed rapidly from the objects of laboratory research to the major force in global agricultural innovation. With an absence of legal precedent for the emerging technology, as well as poor general understanding of the complex science of genetic engineering, lawmakers across the world took drastically different approaches in their attempts to regulate the novel field. As time has passed, regulators observed and learned from the strengths and weaknesses of the regulatory frameworks of their own systems and the systems of others, and they are now adopting successful and popular elements of other systems. The U.S. and E.U. have long been regarded as having opposite approaches to GMO regulation, but proposed changes in both regulatory schemes are producing systems that share some key features.

U.S. legislation to impose labeling requirements is one example of alignment of the systems, in which the U.S. borrowed a key element of the E.U.'s approach to GMO regulation. Labeling requirements provide consumers with information regarding their agricultural system and food products, but ultimately burdens individual consumers to understand the implications of the labels in order to make an informed decision.[284] Bipartisan majorities of American consumers, almost 90% in some surveys, support

284. Andrea Freeman, *Transparency for Food Consumers: Nutrition Labeling and Food Oppression*, 41 AM. J.L. & MED. 315, 316 (2015).

labeling of GMO products, believing that people have a right to know what is in their food.[285]

Another large change is the February 2024 E.U. Parliament vote and ongoing European Council negotiations to exempt qualifying Category 1 GMOs from much of the pre-market approval process, which would result in a greater number of GMO products available in E.U. markets. This signifies a notable movement of the E.U. regulatory structure towards the U.S.'s more GMO-friendly approach. Environmental groups in the E.U. assert that the move to deregulate an entire category of GMOs goes further than the U.S. system of GMO regulation because there is no pre-market approval and no liability process.[286] GMOs in the U.S. are governed according to their characteristics rather than on the mere fact that they are genetically modified, and the deregulation of Category 1 GMOs could be interpreted as the E.U. adopting a more similar regulatory style. New GMOs in the E.U. would initially be examined to determine the amount and type of genomic change the GMO underwent, and then according to the characteristics of the GMO. Characteristics of environmental concern, like herbicide resistance, would be exempt from Category 1 classification, indicating a partial shift to product-based versus process-based regulation. The proposed shift in E.U. regulations is still more process-based than the U.S. system in that only a subset of genetic modification techniques are eligible for deregulation—marking a substantial shift from the continent's former stance. Additionally, new E.U. proposals exclude Category 1 NGTs from the "safeguard clause" that member states could use to prohibit a GMO within their borders, indicating a shift toward the U.S. system.

In totality, given the shifts in U.S. and E.U. GMO regulations, the systems seem to be converging to allow more GMO crops with labels—a deregulation-and-labeling approach. This convergence could be the result of watching and learning from each other's regulatory systems. The U.S. could have adopted labeling requirements that provide consumers with additional information after seeing how companies in the E.U. included GMO labels on their packages and consumers' positive responses. Similarly, the E.U. may have watched the U.S. biotechnology industry innovate new technologies with enhanced yields and sustainability benefits and wanted to reduce the

285. *Americans Support GMO Food Labels But Don't Know Much About Safety of GM Foods*, UNIV. OF PA.: ANNENBERG PUB. POL'Y CTR. (July 18, 2016), https://www.annenbergpublicpolicycenter.org/americans-support-gmo-food-labels-but-dont-know-much-about-safety-of-genetically-modified-foods/.

286. Katsarova, *supra* note 265, at 10.

limitations placed on its own biotechnology industries in light of climate change. However, policymakers may be hesitant to simply deregulate GMOs. Thus, partial deregulation coupled with labeling allows policymakers to strengthen food systems and boost the competitiveness of biotechnology companies while also providing more information to consumers opposed to GMOs.

B. Implications of the Deregulation-and-Labeling Approach

Ultimately, it is unclear that the arising, converged system of deregulation-and-labeling protects the environment. Even with proposed updates to the E.U. system, many regulations hinge upon process-based versus product-based reasoning, meaning that the potential environmental impact of a new crop variety is not the dominant factor considered in the level of risk assessment and regulation applied. While many GMOs do not have negative environmental impacts, and many even have positive environmental impacts, allowing GMOs into the agricultural system without thorough environmental assessments poses a significant risk. In contrast, the U.S.'s product-based approach, regulating organism characteristics, may be preferred for environmental protection because potential harm to the environment is considered equally rigorously regardless of the process used to create the product. For example, in the E.U. proposal, a plant with natural insect-resistance genes enhanced through NGTs in a manner that could have resulted through conventional breeding would not be regulated as a GMO, and may consequently have a reduced depth and scope of environmental risk assessment. Conversely, in the U.S., the same plant would be reviewed by the EPA to consider the environmental impacts of the enhanced pesticidal properties. However, current E.U. proposals indicate there will be a sliding scale of risk assessment for Category 1 NGTs, though the details and criteria have not yet been finalized. Further, they offer regulatory benefits for Category 2 NGTs with intended sustainability benefits, indicating that they intend to try and steer biotechnology companies toward sustainability-focused efforts. This is not the case in the U.S. system, in which sustainability-oriented GMOs are not similarly incentivized to guide industry efforts.

During his first term, U.S. President Donald Trump attempted to significantly deregulate GMOs, reducing the requirements for environmental

risk assessment, before being blocked by the courts.[287] Furthermore, the U.S. Department of Agriculture under the Trump Administration exempted many NGT GMOs categorically from the regulation process on the basis that they could have occurred naturally, including modifications such as targeted deletions, single base pair mutations, and insertions of DNA from the plant's gene pool.[288] Although the new framework was struck down by the courts, exemptions approved before the December 2024 court ruling remain in place.[289] Project 2025, which many believe to be the unofficial playbook for Trump's second term, describes a desire to "adopt policies to remove unnecessary barriers to approvals and the adoption of biotechnology" in agriculture and to "repeal the federal labeling mandate," indicating continued interest in GMO deregulation.[290] Future regulatory changes by the second Trump administration may seek to reinstate exemptions for certain types of NGT GMOs. This would be a large shift from the historical U.S. approach—shifting focus away from product-based thinking and toward process-based regulation—and would be a major convergence between the U.S. and developing E.U. regulatory systems. The U.S. system, already imperfect in its ability to prioritize the environment, may soon be even less well-structured to do so.

Despite their respective strengths and weaknesses, the regulatory systems of both the U.S. and E.U. fall short of encompassing the full biological complexity and diversity of the products that they regulate. The labeling requirements of both regulatory frameworks are insufficient because they do not convey meaningful information about the extent or intention of the genetic modification. For example, an NGT GMO with only a single base pair change and no altered traits is subject to the same labeling standards as an organism with dozens of genes spliced in from distantly related species. Yet the potential impacts of these two types of changes are vastly different. Further, traditional agricultural practices that create interspecies hybrids—giving rise to common foods like sweet corn and Meyer lemons—can change up to 50% of an organism's DNA. By contrast, NGT genetic modifications may alter as few as one in one billion DNA base pairs, yet only the latter

287. Nat'l Fam. Farm Coal. v. Vilsack, 758 F. Supp. 3d. 1060, 1065 (N.D. Cal. 2024).

288. Michael Ward et al., *An InSECURE Future: Court Ruling Guts USDA Regs on Genetically Engineered Plants*, MORRISON FOERSTER: LIFE SCIS. & HEALTHCARE (Dec. 19, 2024), https://lifesciences.mofo.com//topics/an-insecure-future-court-ruling-guts-usda-regs-on-genetically-engineered-plants.

289. *Id*.

290. Daren Bakst, *Department of Agriculture*, *in* MANDATE FOR LEADERSHIP: THE CONSERVATIVE PROMISE 289, 307 (Paul Dans & Steven Groves eds., 2023).

requires labeling. Thus, labeling requirements do not actually inform consumers about how much their foods differ from naturally occurring varieties. The GMO labeling requirement under both regulatory systems also do not indicate the functional implications of the genetic modification. GMOs modified to have increased herbicide-tolerance are exposed to much higher levels of herbicides than GMOs modified to enhance traits like drought resistance, yet consumers wishing to minimize herbicide exposure will be unable to differentiate the two products under current labeling requirements.

In addition, labeling requirements alone cannot produce healthy or safe food systems and are often not the main factor influencing a consumer's choice to purchase a food product. A 2023 study found that implementation of mandatory labeling requirements produced a negligible change in consumption habits.[291] Moreover, even the best-informed consumers cannot act as a substitute for government regulation to create a safe, environmentally-sound agricultural system. Thus, the current labeling requirements provide consumers with little meaningful information about what they are actually purchasing and its implications for human and environmental health.

Additionally, the U.S. and E.U.'s potential decisions to reduce regulation of NGT GMOs ignores the large impact that subtle NGT modifications, such as single base pair substitutions, can have on an organism. For example, an organism created by deleting a single gene with older technologies would be regulated as a GMO, whereas a deletion of the same gene produced by NGT would not be regulated despite the fact that the functional modification of both organisms is the same. In contrast, the U.S. system of looking only at characteristics leaves large loopholes; for example, allowing novelty GMOs to go unregulated even though these can also pose risks of transgene escape.

In conclusion, the E.U. and U.S. systems of GMO regulation have partially converged over time and share some key attributes; however, both regulatory systems have gaps in their ability to regulate GMOs in full accordance with science, and the deregulation-and-labeling approach the jurisdictions are converging towards is not optimized to maximally protect the environment or inform consumers.

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291. Aaron Adalja, *GMO and Non-GMO Labeling Effects: Evidence from a Quasi-Natural Experiment*, 42 MKTG. SCI. 233, 234 (2023).