

# GENETICALLY MODIFIED ORGANISMS: HOW THE UNITED STATES' AND THE EUROPEAN UNION'S REGULATIONS AFFECT THE ECONOMY

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## INTRODUCTION

Genetically engineered (GE) foods have been commercialized for nearly two decades and continue to be produced globally with no sign of slowing down. The use of biotechnology to genetically engineer or modify plants—by inserting or deleting specific genetic information—has become an integral part of our society. Unsurprisingly, the United

States (U.S.) is the world's largest producer of GE crops.<sup>1</sup> In contrast, many nations, especially within the European Union (EU), such as Switzerland, France, Austria, and Italy, have banned cultivation of genetically modified crops within their borders.<sup>2</sup> In recent years, debates around the world have arisen regarding the risks of cultivating and consuming genetically modified foods.<sup>3</sup> These disagreements among nations have led to disparate regulatory and legislative frameworks and rules.<sup>4</sup> When countries have different regulations regarding testing and approval procedures for GE foods or incompatible regulations concerning labeling and identification requirements, trade problems arise globally. Most notably, these disparities have created friction between the U.S. and the EU, which generally have an expansive trade relationship.<sup>5</sup> The objective of this Article is to examine the potential economic impact of regulations concerning GE foods in the EU and the U.S. and analyze whether changes to these regulations would be beneficial to either entity. This Article is comprised of five sections: first, a general overview of GE foods; second, a background of U.S. and EU past and current regulations regarding genetically modified organisms (GMOs); third, an overview of international guidelines and agreement

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1. *Genetically modified plants: Global cultivation on 174 million hectares*, GMO-COMPASS (Apr. 9, 2014), [http://www.gmo-compass.org/eng/agri\\_biotechnology/gmo\\_planting/257.global\\_gm\\_planting\\_2013.html](http://www.gmo-compass.org/eng/agri_biotechnology/gmo_planting/257.global_gm_planting_2013.html).

2. *GMO cultivation bans in Europe*, GMO-FREE EUROPE, <http://www.gmo-free-regions.org/gmo-free-regions/bans.html> (last updated Aug. 2014).

3. See M. Buiatti et al., *The application of GMOs in agriculture and in food production for a better nutrition: two different scientific points of view*, 8 GENES & NUTRITION 255 (2013), available at [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3639326/pdf/12263\\_2012\\_Article\\_316.pdf](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3639326/pdf/12263_2012_Article_316.pdf).

4. See, e.g., *id.* at 256 (“As a consequence of the different American and European public attitudes towards this technology and the foods produced, the regulatory approaches in Europe and North America are essentially different.”).

5. Ilona M. Demenina, *Genetically Modified Foods in the International Arena: Trade Conflicts, Labeling Controversy, and the Importance of Informed Consumer Choice*, 2 BYU INT’L L. & MGMT. REV. 311, 312–13 (2006) (noting the United States’ and EU’s “wide-ranging trade relationship”).

concerning GMOs and how they relate to the U.S. and EU; fourth, an explanation of how these differences in regulations impact national and global economies; and last, an analysis of whether the EU or the U.S. should change its regulations on GE foods.

The first section will explain GMOs, their commercial use, and the upsides and downsides to their cultivation and consumption. The second section will describe the early histories of U.S. and EU GMO regulations and their current regulations. The third section will explain the important international guidelines and agreements that set the stage for international standards on GMO trade and cultivation. It will also specify how these international guidelines and agreements affect the U.S. and EU. The fourth section will detail and assess potential impacts EU and U.S. GMO regulations have on the respective economies. Finally, the fifth section will explain why changes to the EU's regulations would not substantially benefit the EU's economy, but why nominal changes in U.S. regulations may benefit the U.S. economy.

## I. OVERVIEW OF GENETICALLY MODIFIED FOODS

According to the World Health Organization (WHO), “genetically modified (GM) foods are foods derived from organisms whose genetic material (DNA) has been modified in a way that does not occur naturally.”<sup>6</sup> The technology used to create these foods is often called “gene technology,” “genetic engineering,” or “recombinant DNA technology.”<sup>7</sup> The purpose of genetically modifying organisms is to introduce new genetic traits to improve the usefulness and value of that organism.<sup>8</sup> It is important to note that “genetically modified organisms” and “genetically engineered foods” are interchangeable terms in conversation, such that the European Commission uses the term

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6. *Food, Genetically Modified*, WHO, [http://www.who.int/topics/food\\_genetically\\_modified/en/](http://www.who.int/topics/food_genetically_modified/en/) (last visited Oct. 25, 2014).

7. *Frequently Asked Questions on Genetically Modified Foods*, WHO, [http://www.who.int/foodsafety/areas\\_work/food-technology/faq-genetically-modified-food/en/](http://www.who.int/foodsafety/areas_work/food-technology/faq-genetically-modified-food/en/) (last visited Nov. 5, 2014).

8. See Theresa Phillips, *Genetically modified organisms (GMOs): Transgenic crops and recombinant DNA technology*, 1 NATURE EDUCATION 21 (2008).

“genetically modified,” and the U.S. uses the term “genetically engineered.”<sup>9</sup> The most common GMOs found on the market today are GE crops.<sup>10</sup> One of the main reasons for the development of genetically modified crops is “to improve yield, through the introduction of resistance to plant diseases or of increased tolerance to herbicides.”<sup>11</sup>

GE crops were first commercialized in 1996, and the hectareage of these crops has grown exponentially since.<sup>12</sup> The hectares of GE crops increased “from 1.7 million in 1996, to over 175 million hectares in 2013.”<sup>13</sup> Along with the increase in GE crop hectareage, the number of countries growing these crops increased to twenty-seven in 2013.<sup>14</sup> Of all the countries planting GE crops in 2013, the top five were: the U.S., Brazil, Argentina, India, and Canada.<sup>15</sup> Additionally, soy, maize, and cotton are the three most produced biotech crops worldwide.<sup>16</sup>

Even though the commercialization of GE crops has grown exponentially, controversies exist on whether these GMOs are completely safe and whether they should continue to be grown. On one hand, GE crops contribute to food security, sustainability, and environmental change. For example, between 1996 and 2012, the production and use of GE crops over conventional crops saved 497 million kg a.i.<sup>17</sup> of pesticides, reduced CO<sub>2</sub> emissions by 26.7 billion kg

9. James H. Maryanski, *Genetically Engineered Foods*, FDA, <http://www.fda.gov/newsevents/testimony/ucml15032.htm> (last updated Aug. 8, 2009).

10. See *GMO Facts*, NON-GMO PROJECT, <http://www.nongmoproject.org/learn-more/> (last visited Mar. 31, 2016) (“Over 80% of all GMOs grown worldwide are engineered for herbicide tolerance.”); see also Deborah B. Whitman, *Genetically Modified Foods: Harmful or Helpful?*, in *CSA DISCOVERY GUIDES* 1, 4 (Apr. 2000), available at <http://biomed.brown.edu/arise/resources/docs/GM%20foods%20review.pdf>.

11. *Food, Genetically Modified*, *supra* note 6.

12. *ISAAA Brief 46-2013: Top Ten Facts*, ISAAA, <http://www.isaaa.org/resources/publications/briefs/46/topfacts/default.asp> (last visited Nov. 15, 2014).

13. *Id.*

14. *Id.*

15. *Id.*

16. *Genetically modified plants*, *supra* note 1.

17. A.i. stands for “active ingredient.” S.K. Pal & S.K. Das Gupta, *Pest Control, INT’L CROPS RESEARCH INST. FOR THE SEMI-ARID TROPICS* 1 (1994), available at <http://oar.icrisat.org/2424/1/Pest-Control.pdf>.

in 2012 alone, and helped alleviate poverty for approximately 16.5 million small farmers.<sup>18</sup> On the other hand, with every new technology, there is potential for risk. The WHO outlined three main issues of concern that GE foods pose to human health: (1) the potential of unintentionally introducing allergens into foods, among other anti-nutrition factors; (2) the danger of gene transfer, specifically with using antibiotic resistance genes; and (3) the issue of outcrossing, which is the “migration of genes from GM plants into conventional crops or related species in the wild.”<sup>19</sup> An obvious risk of cultivating and consuming GE crops is the possibility that pests develop a resistance to the toxins that are produced by GE crops.<sup>20</sup> These risks and rewards are essentially what divide countries on the use of GE foods and how they should be handled.

## II. PAST & CURRENT REGULATIONS ON GENETICALLY MODIFIED FOODS IN THE U.S. AND E.U.

Despite using identical technologies, GE food regulations in the U.S. and EU vary widely. These divergent approaches to regulation create barriers to free trade.<sup>21</sup> Both the U.S. and the EU have seen changes in regulation policies regarding risks to health, safety, and the environment.<sup>22</sup> The regulation of crops produced through biotechnology started off similarly in both the U.S. and Europe.<sup>23</sup> However, it did not take long for the two to take opposing paths. Between the 1960s and 1980s regulations were considered more strict in the U.S. than in

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18. *ISAAA Brief 46-2013: Top Ten Facts*, *supra* note 12.

19. *Frequently Asked Questions on Genetically Modified Foods*, *supra* note 7.

20. *Pocket K No. 1: Q and A About Genetically Modified Crops*, ISAAA, <http://www.isaaa.org/resources/publications/pocketk/1/> (last visited Nov. 4, 2014).

21. Laurence Peter, *TTIP Talks: Food Fights Block EU-US Trade Deal*, BBC NEWS (June 10, 2015), <http://www.bbc.com/news/world-europe-33055665>.

22. See generally Ragnar E. Löfstedt & David Vogel, *The Changing Character of Regulation: A Comparison of Europe and the United States*, 21 RISK ANALYSIS 399 (2001).

23. Diahanna Lynch & David Vogel, *The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics*, COUNCIL ON FOREIGN REL. (Apr. 5, 2013), <http://www.cfr.org/agricultural-policy/regulation-gmos-europe-united-states-case-study-contemporary-european-regulatory-politics/p8688>.

Europe,<sup>24</sup> but in the mid-1980s, Europe's regulations on health, safety, and environmental risks became, and are still, more restrictive than the U.S.<sup>25</sup> The U.S. moved from a highly politicized regulatory system encompassing public mistrust in the government and skepticism in new scientific technology<sup>26</sup> to a more "sector-specific, product-oriented" regulatory system, more supportive of technological and scientific innovation.<sup>27</sup> Comparably, Europe moved from a cooperative and concealed style of a regulatory system<sup>28</sup> to a "more horizontal, process-oriented" style of regulatory legislation, involving more public criticisms and reviews.<sup>29</sup>

### A. United States Regulations

The first stepping-stone to genetically modified food regulations started in 1976. That year, the National Institute of Health (NIH) initiated regulations for federally funded experiments on rDNA, which is the foundation of genetic engineering.<sup>30</sup> In 1980, the first GMO patent was issued.<sup>31</sup> That year, in *Diamond v. Chakrabarty*, the Supreme Court held that genetically altered life forms could be patented.<sup>32</sup> Shortly after this, in 1982, the U.S. Food and Drug Administration (FDA) approved the first GE drug.<sup>33</sup> It was a biosynthetic human insulin, a form of insulin

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24. *Id.*

25. *Id.*

26. *Id.*

27. Joachim Scholderer, *The GM Foods Debate in Europe: History, Regulatory Solutions, and Consumer Response Research*, 5 J. PUB. AFF. 263, 264 (2005).

28. Lynch & Vogel, *supra* note 23.

29. Scholderer, *supra* note 27, at 264.

30. Lynch & Vogel, *supra* note 23.

31. GL Woolsey, *GMO Timeline: A History of Genetically Modified Foods*, ROSEBUD, <http://www.rosebudmag.com/truth-squad/gmo-timeline-a-history-of-genetically-modified-foods> (last updated Dec. 3, 2013).

32. *Diamond v. Chakrabarty*, 447 U.S. 303, 303 (1980).

33. Suzanne White Junod, *Celebrating a Milestone: FDA's Approval of First Genetically-Engineered Product*, FDA, <http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SelectionsFromFDLIUpdateSeriesonFDAHistory/ucm081964.htm> (last updated Apr.10, 2009).

produced by bacteria, created through rDNA technology.<sup>34</sup> In 1986, the federal government created a formal policy entitled the *Coordinated Framework for Regulation of Biotechnology*.<sup>35</sup> This framework established the FDA, the U.S. Environmental Protection Agency (EPA), and the U.S. Department of Agriculture (USDA) as the primary regulatory agencies responsible for overseeing the products of agricultural modern biotechnology.<sup>36</sup> In 1989, the National Research Council (NRC) published an influential report regarding the safety of GMOs.<sup>37</sup> This report concluded first that “the *product* of genetic modification and selection should be the primary focus for making decisions . . . not the *process* by which the products were obtained.”<sup>38</sup> Second, it concluded that although information concerning “the process used to produce a genetically modified organism is important in understanding the characteristics of the product . . . the nature of the process is not a useful criterion for determining whether the product requires less or more oversight.”<sup>39</sup> Finally, the report concluded that “[t]he same physical and biological laws govern the response of organisms modified by modern molecular and cellular methods and those produced by classical methods.”<sup>40</sup> The NRC Report was a large step towards the acceptance of GMOs.

From there, the FDA published a statement of policy in 1992, clarifying its interpretation of the Federal Food, Drug, and Cosmetic Act

34. *Id.*

35. *How the Federal Government Regulates Biotech Plants*, USDA, [http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology/sa\\_regulations/ct\\_agency\\_framework\\_roles!/ut/p/a0/04\\_Sj9CPykssy0xPLMnMz0vMAfGjzOK9\\_D2MDJ0MjDzd3V2dDDz93HwCzL29jAyMTPULsh0VAU1Vels/](http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology/sa_regulations/ct_agency_framework_roles!/ut/p/a0/04_Sj9CPykssy0xPLMnMz0vMAfGjzOK9_D2MDJ0MjDzd3V2dDDz93HwCzL29jAyMTPULsh0VAU1Vels/) (last updated Jan. 20, 2015); *Coordinated Framework for Regulation of Biotechnology*, 51 Fed. Reg. 23, 302 (June 26, 1986).

36. *See How the Federal Government Regulates Biotech Plants*, *supra* note 35; *Coordinated Framework for Regulation of Biotechnology*, *supra* note 35.

37. *See NATIONAL RESEARCH COUNCIL, FIELD TESTING GENETICALLY MODIFIED ORGANISMS: FRAMEWORK FOR DECISIONS* (1989), *available at* <http://www.nap.edu/catalog/1431/field-testing-genetically-modified-organisms-framework-for-decisions>.

38. *Id.* at 14.

39. *Id.* at 14–15.

40. *Id.* at 15.

(FDCA) with respect to the use of biotechnology.<sup>41</sup> The FDA contended that GE foods should not be subject to special regulations solely because the food is genetically modified.<sup>42</sup> Additionally, the FDA announced that special labeling is not required for GE foods unless there is a “material” change from its conventional counterpart.<sup>43</sup> Two years later, the first GE product was commercialized, known as the FLAVR SAVR tomato, which the FDA approved in May 1994.<sup>44</sup> This GE tomato delayed ripening, generating a longer shelf life than regular tomatoes.<sup>45</sup> It was at this point in time when the production of GE foods began to increase exponentially.<sup>46</sup> Due to this increase, “[i]n 1997, the USDA . . . simplified the notification procedure for importing” and exporting GMOs across state lines.<sup>47</sup> The USDA Animal and Plant Health Inspection Service (APHIS) also permitted petitions to remove GE plants from its oversight that posed no risk to the environment.<sup>48</sup>

The FDA, USDA, and EPA are the three federal agencies responsible for regulating and evaluating GE crops.<sup>49</sup> They are responsible for food and feed safety, the agricultural and environmental safety, and food and environmental safety concerns, respectively, when new pesticides are introduced.<sup>50</sup> Not every GMO has to go through all three agencies, but, to date, the USDA has evaluated every GE crop in the U.S.<sup>51</sup>

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41. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984-01 (May 29, 1992).

42. Neil A. Belson, *US Regulation of Agricultural Biotechnology: An Overview*, 3 *AGBIOFORUM* 268, 275 (2000).

43. Statement of Policy: Foods Derived From New Plant Varieties, *supra* note 41.

44. G. Bruening & J.M. Lyons, *The Case of the FLAVR SAVR Tomato*, 54 *CAL. AGRIC.* 6, 7 (2000).

45. *Id.* at 6.

46. Debra M. Strauss, *Genetically Modified Organisms in Food: a Model of Labeling and Monitoring with Positive Implications for International Trade*, 40 *INT'L LAW.* 95, 95 (2006).

47. Lynch & Vogel, *supra* note 23.

48. *Id.*

49. Alan McHughen, *Plant Genetic Engineering and Regulation in the United States*, 8178 *ANR PUBL'N* 1, 2 (2006).

50. *Id.*

51. *Id.*

The FDA is the governmental body that has legal authority over GE foods.<sup>52</sup> Under the FDCA, GE foods and food ingredients “must adhere to the same standards . . . that apply to their conventional counterparts.”<sup>53</sup> The FDA’s broad authority allows it to take action if a product fails to meet one of the safety standards set out in the FDCA.<sup>54</sup> One of two sections of the FDCA that the FDA primarily relies on to ensure food safety is the adulteration provision of section 402(a)(1).<sup>55</sup> This provision is a post-market authority that gives the FDA the power to remove foods from the market if they find the food to be a risk to public health.<sup>56</sup> The FDA also relies on the food additive provision in section 409.<sup>57</sup> Under this provision, a substance considered to be a food additive requires premarket approval.<sup>58</sup> This provision defines a food additive as any substance that is purposely added to a food unless it is “generally recognized as safe” or otherwise excluded.<sup>59</sup> Thus, under this provision, many GE crops do not require pre-market approval because GE crops are “generally recognized as safe.”<sup>60</sup>

Since the FDA’s policy statement of 1992, there have been no changes to the labeling requirements for GE foods.<sup>61</sup> The labeling of GE foods is governed by sections 403(a) and 201(n) of the FDCA.<sup>62</sup> In 2001, the FDA issued the *Draft Guidance for Industry: Voluntary Labeling*

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52. Maryanski, *supra* note 9.

53. *Id.*

54. *Id.*

55. 21 U.S.C. § 342(a)(1) (2006).

56. Michael M. Landa, *FDA’s Regulatory Program for Genetically Engineered (GE) Food*, FDA (Dec. 10, 2014), <http://www.fda.gov/NewsEvents/Testimony/ucm426541.htm>.

57. 21 U.S.C. § 348 (2006).

58. Landa, *supra* note 56.

59. *Id.*

60. THE LIBRARY OF CONGRESS, RESTRICTIONS ON GENETICALLY MODIFIED ORGANISMS 1, 214 (2014), available at <https://www.loc.gov/law/help/restrictions-on-gmos/restrictions-on-gmos.pdf>.

61. Landa, *supra* note 56.

62. 21 U.S.C. §§ 343, 321(n) (2006).

*Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering.*<sup>63</sup> The FDA stated that,

The agency is still not aware of any data or other information that would form a basis for concluding that the fact that a food or its ingredients was produced using bioengineering is a material fact that must be disclosed under sections 403(a) and 201(n) of the act. FDA is therefore reaffirming its decision to not require special labeling of all bioengineered foods.<sup>64</sup>

In November 2015, the FDA finalized the *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants*, reaffirming that no special labeling is required for “food derived from genetically engineered plants.”<sup>65</sup> Thus, at this point in time, labeling products with GMO labels or non-GMO labels is voluntary and up to the manufacturer.

APHIS is the principal USDA agency primarily responsible for biotechnology regulation, namely “for protecting agriculture from pests and diseases.”<sup>66</sup> Its regulatory authority over biotechnology products that may pose a risk to plant health comes from the Plant Protection Act.<sup>67</sup> “[O]rganisms and products altered or produced through genetic engineering that are plant pests or are believed to be plant pests,”<sup>68</sup> are called “regulated articles.”<sup>69</sup> Most GE plants are considered “regulated articles” under 7 C.F.R. § 340 regulations.<sup>70</sup> The USDA-APHIS

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63. FOOD AND DRUG ADMINISTRATION ET AL., VOLUNTARY LABELING INDICATING WHETHER FOODS HAVE OR HAVE NOT BEEN DEVELOPED USING BIOENGINEERING; DRAFT GUIDANCE (2001), available at <http://www.fda.gov/OHRMS/DOCKETS/98fr/001598gd.pdf>.

64. *Id.*

65. *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants*, FDA, <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm059098.htm> (last visited Apr. 3, 2016).

66. *How the Federal Government Regulates Biotech Plants*, *supra* note 35.

67. *Id.*

68. 7 C.F.R. § 340.0(a)(2) n.1 (2014).

69. *How the Federal Government Regulates Biotech Plants*, *supra* note 35.

70. Belson, *supra* note 42, at 269–70.

essentially regulates not only the handling, but the import, movement, and environmental release of the GE plants considered to be regulated articles.<sup>71</sup> This includes GMOs undergoing field tests or experimental use.<sup>72</sup>

Aside from these regulatory bodies, there have been recent steps towards change regarding GMOs from both state and federal legislative bodies, including introduced bills that attempt to implement mandatory labeling for GE crops.<sup>73</sup> In February 2015, three Democratic Senators reintroduced legislation that would require the labeling of GE foods.<sup>74</sup> The Genetically Engineered Food Right-to-Know Act would amend the FDCA to “require that genetically engineered food and foods that contain genetically engineered ingredients be labeled accordingly.”<sup>75</sup> There are currently fifty-two co-sponsors of the bill, and, although this bill was recently introduced and has many obstacles to surpass before becoming law, there is large support for this change.<sup>76</sup> To date, the *Just Label It* campaign has collected 1.4 million signatures on its petition to the FDA seeking mandatory labeling of GE foods.<sup>77</sup> At the state level, approximately half of all states have bills in progress requiring labeling of GE foods.<sup>78</sup> In 2013, Connecticut became the first state to sign a GE food-labeling bill into law.<sup>79</sup> Following Connecticut, Maine and Vermont also passed GE labeling laws.<sup>80</sup> At this point in time, there seems to be

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71. *How the Federal Government Regulates Biotech Plants*, *supra* note 35.

72. *Id.*

73. *See State Labeling Initiatives*, CENTER FOR FOOD SAFETY, <http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/state-labeling-initiatives#> (last visited Apr.3, 2016).

74. Genetically Engineered Food Right-to-Know Act, H.R. 913, 114th Cong. (1st Sess. 2015).

75. *Id.*

76. *Id.*

77. *About Just Label It*, JUST LABEL IT, <http://www.justlabelit.org/about-just-label-it/> (last visited Mar. 16, 2015).

78. *Why Food Labels Should Have GMO Information*, CONSUMER REPORTS (Apr. 3, 2014), <http://www.consumerreports.org/cro/news/2014/04/why-we-need-to-label-gmo-foods/index.htm>.

79. *Id.*

80. *GMOs and food: Do you know what you're eating?*, CONSUMER REPORTS (Oct. 17, 2014, 4:15 PM), <http://www.consumerreports.org/cro/news/2014/10/gmos-and->

no new movement on the part of the FDA or USDA to alter or modify any of its regulations concerning GMOs.

## B. European Union Regulations

Prior to the 1990s, the EU lacked policies concerning biotechnology.<sup>81</sup> The first piece of EU legislation focusing on GMOs was the European Council Directive 90/220/EEC.<sup>82</sup> The *Deliberate Release of Genetically Modified Organisms Directive* was founded on the “precautionary principle.”<sup>83</sup> This essentially means to take protective action before there is complete scientific proof of a risk.<sup>84</sup> It is important to note that in practice many EU regulations read the precautionary principle as *any* scientific proof of risk.<sup>85</sup> The directive set established multiple hurdles to overcome before a GMO could be marketed. This directive also allowed Member States some discretion in limiting or banning GMOs within its borders. It explained that,

Where a Member State has justifiable reasons to consider that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory.<sup>86</sup>

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food-do-you-know-what-you-are-eating/index.htm (It is important to note that in order for Connecticut and Maine’s laws to go into effect, neighboring states must pass similar laws).

81. Ian M. Sheldon, *Regulation of Biotechnology: Will We Ever ‘Freely’ Trade GMOs?*, 29 EUROPEAN REV. AGRIC. ECON. 155, 158 (2002).

82. *Id.*

83. Lynch & Vogel, *supra* note 23.

84. *Communication from the Commission on the Precautionary Principle*, at 15, COM (2000) 1 final (Feb. 2, 2000), available at <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52000DC0001>.

85. John N. Hathcock, *The Precautionary Principle—An Impossible Burden Of Proof For New Products*, 3 AGBIOFORUM, 255, 256 (2000).

86. Council Directive 90/220, art. 16 1990 O.J. (L 117) 1, 15 (EC).

Following this provision, some countries, such as Luxembourg and Austria, banned the import of a type of Bt corn.<sup>87</sup>

The next major step in GMO regulations was the Novel Foods Regulation No. 258/97, which was adopted in 1997.<sup>88</sup> This regulation established an approval procedure to ensure that genetically modified foods were not dangerous, misleading, or “nutritionally disadvantageous for the consumer.”<sup>89</sup> Essentially, this regulation focused on the pre-market safety assessment of novel foods.<sup>90</sup> In addition, this regulation set out specific labeling requirements for genetically modified foods.<sup>91</sup>

During the period of 2000 to 2003, the EU overhauled its GMO legislation. As of 2003, the EU created “a whole updated EU legal framework on GMOs.”<sup>92</sup> The precautionary principle that now governs the EU’s approach to GMOs was enshrined in Articles 130(2) and 174 of the EC Treaty.<sup>93</sup> The EU’s legislation concerning genetically modified foods was, and still is today, “among the strictest in the world, and provides for a high level of scientific assessment, while at the same time safeguarding the consumer’s right to choose.”<sup>94</sup> The European Commission outlined two main objectives of the EU’s legislation on GMOs: (1) to protect the environment and general health of individuals;

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87. Sheldon, *supra* note 81, at 158. Bt stands for “*Bacillus thuringiensis*,” which is a naturally occurring soil bacterium that produces a protein known to paralyze the larvae of certain harmful insects. Bt corn is thus corn that has been genetically engineered to include this protein. *Pocket K No. 6: Bt Insect Resistant Technology*, ISAAA, <http://www.isaaa.org/resources/publications/pocketk/6/> (last updated July, 2014).

88. Commission Regulation 258/97, art. 3, 1997 O.J. (L 43) 1.

89. *Id.*

90. Demenina, *supra* note 5, at 321–22.

91. *Id.* at 322.

92. DAMIEN PLAN & GUY VAN DEN EEDE, THE EU LEGISLATION ON GMOs: AN OVERVIEW, JRC SCIENTIFIC & TECHNICAL REPORTS 1, 3 (2010), available at <http://gmo.kormany.hu/download/e/55/40000/EU%20Legislation%20Overview%20JRC%20Report.pdf>.

93. *Summaries of EU Legislation: Environment*, EUR-Lex, <http://eur-lex.europa.eu/legal-content/EN/TEXT/?qid=1421439424904&uri=URISERV:a15000> (last visited Feb. 5, 2015).

94. *EU Confirms Quality of European GMO Legislative Framework*, EUROPEAN COMM’N, [http://ec.europa.eu/dgs/health\\_consumer/dyna/consumerveice/create\\_cv.cfm?cv\\_id=72](http://ec.europa.eu/dgs/health_consumer/dyna/consumerveice/create_cv.cfm?cv_id=72) (last updated Feb. 8, 2012).

and (2) “to ensure the free movement of safe and healthy genetically modified products in the European Union.”<sup>95</sup> The two major legal instruments on GMO legislation in the EU currently are Directive 2001/18 on the Deliberate Release into the Environment of Genetically Modified Organisms, and Regulation (EC) No. 1829/2003 on Genetically Modified Food and Feed.<sup>96</sup>

Directive 90/220 was repealed by Directive 2001/18.<sup>97</sup> This new directive clarified and improved the old directive, detailing standards on the commercial marketing of GMOs and products containing GMOs.<sup>98</sup> The notification procedure required “an environmental risk assessment, a plan for monitoring, a proposal for labeling and a proposal for packaging,” among other things.<sup>99</sup> The member state has 90 days to respond to the notification, and if all requirements are met, it may consent to placing the GMO on the market.<sup>100</sup> The main intention of Directive 2001/18 is “to protect human health and the environment” when GMOs are released into the natural world.<sup>101</sup> It covers two categories of GMO activities: (1) the experimental release of GMOs into the environment, which is regulated by Part B of the directive;<sup>102</sup> and (2) the placing of GMOs on the market, which is regulated by Part C of the directive.<sup>103</sup> Part C defines a GMO as “an organism . . . in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.”<sup>104</sup>

Commission Regulation 1829/2003, on the other hand, regulates the food and feed “containing, consisting of, or produced from GMOs” being

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95. PLAN & VAN DEN EEDE, *supra* note 92.

96. *Id.* at 3–4.

97. Council Directive 2001/18, 2001 O.J. (L 106) (EEC).

98. Compare Council Directive 90/220, 1990 O.J. (L 117) (EEC), with Council Directive 2001/18, 2001 O.J. (L 106) (EEC).

99. Sheldon, *supra* note 81, at 159.

100. Council Directive 2001/18, *supra* note 97, art. 6.

101. *Id.* art. 1.

102. See *id.* arts. 5–9.

103. *Id.* arts. 12–24.

104. *Id.* art. 2.

placed on the EU market.<sup>105</sup> The regulation sets out three key objectives, which are to:

- (a) provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market; (b) lay down Community procedures for the authorisation and supervision of genetically modified food and feed; (c) lay down provisions for the labelling of genetically modified food and feed.<sup>106</sup>

Under this regulation, approval of genetically modified foods and feeds are limited to a maximum of ten years, but may be renewed.<sup>107</sup> This regulation also sets out the standards for labeling GMOs in the market place.<sup>108</sup> Prior to 2003, genetically modified food-labeling requirements “were based on the detection of DNA or protein resulting from the genetic modification.”<sup>109</sup> Commission Regulation 1829/2003 now requires mandatory labeling for all genetically modified food or feeds, “irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product.”<sup>110</sup>

On the whole, scientists at the European Food Safety Authority (EFSA) are responsible for GMO safety assessments in line with the directive and regulation mentioned above (among others).<sup>111</sup> They “assess all applications to sell GMO products in the EU,” and the “EU governments then consider their findings before deciding whether to approve the application.”<sup>112</sup> Moreover, in January 2016, the European Parliament passed a new rule that allows individual member states “to ban the cultivation of genetically-modified organisms (GMOs) on their

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105. PLAN & VAN DEN EEDE, *supra* note 92, at 8.

106. Commission Regulation 1829/2003, art. 1, 2003 O.J. (L 268) 1 (EC).

107. PLAN & VAN DEN EEDE, *supra* note 92, at 8.

108. See Commission Regulation 1829/2003, *supra* note 106, arts. 12–14.

109. PLAN & VAN DEN EEDE, *supra* note 92, at 8.

110. *Id.*

111. *About TTIP – basics, benefits, concerns*, EUR. COMMISSION, [http://ec.europa.eu/trade/policy/in-focus/ttip/about-ttip/questions-and-answers/index\\_en.htm](http://ec.europa.eu/trade/policy/in-focus/ttip/about-ttip/questions-and-answers/index_en.htm) (last updated Mar. 19, 2015) [hereinafter EUR. COMM’N].

112. *Id.*

own territory, even if such a crop has been approved at EU level.”<sup>113</sup> This allows European nations more freedom to format their respective laws regarding GMOs.

### III. INTERNATIONAL GUIDELINES AND AGREEMENTS ON GENETICALLY MODIFIED FOODS

The four main sources governing the regulation of genetically modified foods are: (1) the UN Codex Alimentarius, (2) the World Trade Organization (WTO), (3) the Cartagena Protocol to the Convention on Biological Diversity, and (4) the Organisation for Economic Co-operation and Development (OECD) Task Force for the Safety of Novel Foods and Feeds.<sup>114</sup> These institutions influence and help shape GMO regulations in multiple countries. They set the foundation on how GMOs should be dealt with on a national and international scale. These institutions also play a role in how the EU and U.S. deal with the commercialization of GE crops. Additionally, the Transatlantic Trade and Investment Partnership (TTIP), once negotiated, may have a sizable impact on the pre-market approval procedures for genetically modified crops.

#### A. FAO/WHO Codex Principles for the Risk Analysis of GM Foods & Guideline for the Conduct of Food Safety Assessment of GM Foods

In 1963, the Food and Agriculture Organization of the United Nations (FAO) and the WHO established the Codex Alimentarius Commission (CODEX).<sup>115</sup> This Commission “develops harmonised international food standards, which protect consumer health and promote fair practices in

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113. *New Law Gives EU Member States Right to Authorize or Ban GMO*, EURANET PLUS (Jan. 14, 2015), <http://euranetplus-inside.eu/new-law-gives-eu-member-states-right-to-authorize-or-ban-gmo/>.

114. Michele M. Compton, *Applying World Trade Organization Rules to the Labeling of Genetically Modified Foods*, 15 PACE INT’L L. REV. 359, 366 (2003).

115. CODEX ALIMENTARIUS, <http://www.codexalimentarius.org/> (last updated Feb. 8, 2016).

food trade.”<sup>116</sup> Although CODEX texts are non-binding, the WTO uses these texts as reference standards in trade disputes concerning food safety and consumer protection.<sup>117</sup> Essentially, implementing legislation and regulations consistent with CODEX decreases the risk of being brought before a WTO Disputes Panel.<sup>118</sup> In 2003, CODEX published two reports pertaining to GE foods, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* (CAC/GL 44-2003), and *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003).<sup>119</sup> These standards and guidelines provide an insight on how GE foods should be assessed before being allowed on the global market.

The principles for risk analysis include risk assessment, risk management, and risk communication.<sup>120</sup> The risk assessment process of GE foods includes a safety assessment to identify whether any safety concerns are present, and if so, “to gather information on its nature and severity.”<sup>121</sup> This safety assessment is an assessment of the whole “food or a component thereof relative to the appropriate conventional counterpart[] [that] tak[es] into account intended and unintended effects[,] . . . new or altered hazards[,] [and] . . . changes, relevant to human health, in key nutrients.”<sup>122</sup> Notably, a proper risk assessment uses all available scientific information and data drawn from a number of testing procedures.<sup>123</sup> After the risk assessment is completed, the risk management measures of these GE foods should be taken “proportional to the risk,” and account for uncertainties described in the risk

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116. *Id.*

117. *FAQs – General questions*, CODEX ALIMENTARIUS, <http://www.codexalimentarius.org/faqs/general-questions/en/> (last updated Feb. 1, 2016).

118. *Id.*

119. *List of Standards*, CODEX ALIMENTARIUS, <http://www.codexalimentarius.org/standards/list-of-standards/> (last updated Feb. 1, 2016).

120. *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, CODEX ALIMENTARIUS, [ftp://ftp.fao.org/es/esn/food/princ\\_gmfoods\\_en.pdf](ftp://ftp.fao.org/es/esn/food/princ_gmfoods_en.pdf) (last visited Feb. 2, 2015).

121. *Id.* para. 10.

122. *Id.* para. 11.

123. *Id.* para. 15.

assessment.<sup>124</sup> Risk communication is essential throughout the entire risk analysis process.<sup>125</sup> Effectively, transparency, and full disclosure of all stages are necessary, and “should include responsive consultation processes.”<sup>126</sup>

CAC/GL 45-2003 sets out guidelines for the conduct of food safety assessment for GE plants.<sup>127</sup> The food safety assessment is a step-by-step process that addresses a number of relevant factors.<sup>128</sup> These steps include:

- A. description of the recombinant-DNA plant;
- B. description of the host plant and its use as food;
- C. description of the donor organisms(s);
- D. description of the genetic modification(s);
- E. characterization of the genetic modification(s);
- F. safety assessment:
  - a) expressed substances (non-nucleic acid substances);
  - b) compositional analyses of key components;
  - c) evaluation of metabolites;
  - d) food processing;
  - e) nutritional modification; and
- G. other considerations.<sup>129</sup>

The goal of this safety assessment is to provide assurance that the GE food is harmless when prepared, used, or eaten properly.<sup>130</sup> The safety assessment will conclude whether the GE food is “as safe as the conventional counterpart.”<sup>131</sup> This conclusion also takes into account

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124. *Id.* para. 16.

125. *Id.* para. 22.

126. *Id.* paras. 23–24.

127. *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*, CODEX ALIMENTARIUS, [ftp://ftp.fao.org/codex/publications/Booklets/Biotech/Biotech\\_2009e.pdf](ftp://ftp.fao.org/codex/publications/Booklets/Biotech/Biotech_2009e.pdf) (last visited Feb. 2, 2015).

128. *Id.* para. 18.

129. *Id.*

130. *Id.* para. 21.

131. *Id.*

“changes in nutritional value or content.”<sup>132</sup> The assessment also establishes the guidelines for handling GMOs.<sup>133</sup>

Both the U.S. and the EU are members of the Codex Alimentarius Commission.<sup>134</sup> Be that as it may, the EU and the U.S. apply CODEX standards and guidelines differently. The U.S. generally complies with CODEX texts, yet, at times, maneuvers around these standards. The U.S. is the most dominant and influential country in CODEX, playing a large role in formulating its standards and guidelines.<sup>135</sup> The U.S., along with Canada, Mexico, and Argentina, has been able to use its position of power to block mandatory GE labeling for almost two decades.<sup>136</sup> Eventually, in 2011, the U.S. ultimately agreed to, and CODEX finally adopted, guidelines that permit voluntary GE food labeling.<sup>137</sup> In certain instances, CODEX guideline definitions depend on a country’s standard, which allows countries such as the U.S. to divert from the average definition and standard without risking being brought before a WTO Disputes Panel.<sup>138</sup> For example, the definition of “low-level contamination” depends on the respective government’s standards.<sup>139</sup> The U.S.’s standard allows up to ten percent GMO contamination for organic foods, the highest of all CODEX members.<sup>140</sup> Comparably, the EU’s standard definition for “low-level contamination” is 0.9 percent.<sup>141</sup>

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132. *See id.*

133. *See id.*

134. *See List of Codex Members*, CODEX ALIMENTARIUS, [http://www.codexalimentarius.org/members-observers/members/en/?no\\_cache=1](http://www.codexalimentarius.org/members-observers/members/en/?no_cache=1) (last updated Feb. 1, 2016).

135. *See* Gregory Damato, *Combating the Codex Alimentarius*, 15 NEXUS MAG. 15, 15 (2008), available at [https://www.nexusmagazine.com/articles/doc\\_view/97-combatting-the-codex-alimentarius](https://www.nexusmagazine.com/articles/doc_view/97-combatting-the-codex-alimentarius).

136. *See* Henry J. Chang, *The Codex Alimentarius Commission Adopts Guidelines for the Labelling of Genetically Modified Foods*, BLANEY MCMURTY BARRISTERS & SOLICITORS LLP, [http://www.blaney.com/sites/default/files/The-Codex\\_HJC.pdf](http://www.blaney.com/sites/default/files/The-Codex_HJC.pdf) (last visited Feb.18, 2015).

137. *See id.*

138. Damato, *supra* note 135, at 18.

139. *Id.*

140. *Id.* at 18–19.

141. *Id.*

While the U.S. by and large complies with CODEX texts or sets slightly lower standards, the EU has on multiple occasions gone above guidelines set out by CODEX. When a government implements a higher level of protection than CODEX standards, and a trade dispute arises, that government “may be required to justify the sanitary measure corresponding to its chosen level of protection on scientific, health, or other legitimate grounds.”<sup>142</sup> This is exactly what happened to the EU in the 1990s with its ban on hormone-treated meat.<sup>143</sup> In 1989, the EU finalized its ban on the production and importation of beef derived from cattle treated with “growth-promoting hormones,”<sup>144</sup> which caused import restrictions for the U.S. and started a series of disputes between the EU and U.S.<sup>145</sup> The EU’s decision to ban hormone-treated meat was a deviation from CODEX standards, and the WTO found that “the ban violated several provisions of the [Sanitary and Phytosanitary Standards (SPS)] Agreement.”<sup>146</sup> Likewise, the EU tends to take higher levels of precaution with GMOs than the CODEX guidelines—instead of voluntary GMO labeling, the EU adopted mandatory GE food and feed labeling requirements.<sup>147</sup> This illustrates how different food safety perceptions affect the application of international food safety guidelines and standards. The EU tends to implement higher standards of protections than CODEX, whereas the U.S. tries to limit the amount of protection possible while complying with CODEX guidelines.

#### B. The Cartagena Protocol on Biosafety to the Convention on Biological Diversity

The Cartagena Protocol on Biosafety was adopted on January 29, 2000, and entered into force on September 11, 2003.<sup>148</sup> To date, this

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142. *FAQs – General questions*, *supra* note 117.

143. See RENÉE JOHNSON, CONG. RESEARCH SERV. R40449, THE U.S.-EU BEEF HORMONE DISPUTE 1 (2015), available at <http://fas.org/sgp/crs/row/R40449.pdf>.

144. *Id.* at 2.

145. *See id.* at 1.

146. *Id.* at 5. Despite this ruling, the European Union continues to ban imports of hormone-treated meat.

147. PLAN & VAN DEN EEDE, *supra* note 92, at 8.

148. *Treaty Collection*, UNITED NATIONS,

international agreement has 103 signatories and 170 parties.<sup>149</sup> This agreement provides the rules for the international trade of living modified organisms (LMOs).<sup>150</sup> A LMO is “any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.”<sup>151</sup> Essentially, LMOs are “GMOs that have not been processed, and could live if introduced into the environment, such as seeds.”<sup>152</sup> The primary objective of the Cartagena Protocol is to ensure a sufficient “level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.”<sup>153</sup>

Under this agreement, a country that wants to export LMOs for “intentional introduction into the environment,” such as seeds for planting, must seek consent from the importing country prior to the first shipment.<sup>154</sup> This is called an “advanced informed agreement.”<sup>155</sup> Furthermore, this agreement mandates that bulk shipments of LMOs, like soybeans and corn, “intended to be used as food, feed or for processing” must have documents that state the shipments “may contain” LMOs and

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[https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg\\_no=XXVII-8-a&chapter=27&lang=en#1](https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXVII-8-a&chapter=27&lang=en#1) (last visited Mar. 2, 2015).

149. *Id.*

150. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 39 I.L.M. 1027 (2000).

151. *Id.* art. 3(g).

152. FAO, *Low Levels of Genetically Modified Crops in International Food and Feed Trade: FAO International Survey and Economic Analysis*, TC-LLP 1, 8 (2014), available at [http://www.fao.org/fileadmin/user\\_upload/agns/topics/LLP/AGD803\\_3\\_Final\\_En.pdf](http://www.fao.org/fileadmin/user_upload/agns/topics/LLP/AGD803_3_Final_En.pdf).

153. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, *supra* note 150, at art. 1.

154. *Pocket K No. 8: Cartagena Protocol on Biosafety*, ISAAA, <http://www.isaaa.org/resources/publications/pocketk/8/default.asp> (last updated July 2004) (quoting Cartagena Protocol on Biosafety to the Convention on Biological Diversity, *supra* note 150, art. 18(2)(a)).

155. *Id.*

are “not intended for intentional introduction into the environment.”<sup>156</sup> Notably, the Cartagena Protocol fails to address food safety concerns, and also “does not require consumer product labeling.”<sup>157</sup> The Cartagena Protocol, although an important agreement concerning GMO regulations, does not have a strong impact on EU and U.S. GMO regulations.

### C. OECD Task Force for the Safety of Novel Foods and Feeds

The OECD’s Task Force for the Safety of Novel Foods and Feeds (Task Force) was instituted in 1999 with the primary goal of “promot[ing] international harmonisation in biotechnology among member countries.”<sup>158</sup> The Task Force consists of thirty delegates from OECD member countries and the European Commission, as well as other observers and invited experts.<sup>159</sup> Its main focus is to ensure that the information used in risk and safety assessments of GMOs, as well as the methods of collecting this information, are as analogous as possible between countries.<sup>160</sup> This is mainly done through the creation of consensus documents.<sup>161</sup> These documents contain information and considerations of new “transgenic organisms,” creating food and feed safety and risk assessments.<sup>162</sup> They also provide information on key nutrients, anti-nutrients, toxicants, and allergens.<sup>163</sup> The creation of consensus documents is a multi-step process.<sup>164</sup> First, a delegation makes

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156. *Id.*

157. *Id.*

158. Organisation for Economic Co-operation and Development, *An Introduction to the Food/Feed Safety Consensus Documents of the Task Force*, INT’L SERV. FOR THE ACQUISITION OF AGRICULTURE BIOTECH APPLICATIONS (Apr. 20, 2006), available at <http://www.oecd.org/science/biotrack/46815266.pdf> [hereinafter OECD].

159. *Id.* at 7.

160. *Contribution of OECD’s Task Force for the Safety of Novel Foods and Feeds*, BIOSAFETY GMO PORTAL, <http://www.gmo.hr/eng/Legal-Frameworks-on-GMOs/Other-Int.-Conventions-Treaties-and-Organizations/OECD/Contribution-of-OECD-s-Task-Force-for-the-Safety-of-Novel-Foods-and-Feeds> (last visited Feb. 19, 2015).

161. *Id.*

162. OECD, *supra* note 158, at 5.

163. *Id.* at 7.

164. *Id.* at 9.

a proposal in writing to draft a document concerning a new GE food in a formal meeting of the Task Force.<sup>165</sup> If agreed to by the Task Force, a first draft is prepared.<sup>166</sup> A single country, or multiple countries working together (that have expertise in the crop at issue), prepares the first draft.<sup>167</sup> The draft undergoes review by the Task Force, which leads to a second draft.<sup>168</sup> After this, the Task Force “may be asked to recommend that the document be declassified.”<sup>169</sup> If the Task Force agrees, “it is forwarded to the supervisory Committee, the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology (Chemicals Committee), which is invited to declassify the document.”<sup>170</sup> Following this, the consensus document is published.<sup>171</sup>

The OECD has published several consensus documents concerning GE foods and feeds, including cotton, bread wheat, soybean, maize, sunflower, and potato products.<sup>172</sup> Generally, with regards to its research, “[t]he OECD applies a science and rules-based approach.”<sup>173</sup> Moreover, the concept of “substantial equivalence” is the standard for food safety assessments.<sup>174</sup> The Task Force also indicated that there is a “need for greater post-market surveillance of GMF to assess potential human health issues,” and is putting in efforts to tackle this issue.<sup>175</sup> Aside from publishing consensus documents, the Task Force is also working jointly with the Working Group on Harmonisation of Regulatory Oversight in Biotechnology on a project concerning the Molecular Characterization

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165. *Id.*

166. *Id.*

167. *Id.*

168. *Id.* at 9–10.

169. *Id.* at 10.

170. *Id.*

171. *Id.*

172. Peter Kearns, *Harmonisation in the field of GMO food/feed risk/ safety assessment*, OECD (May 27, 2013), <http://www.selamat.net/web/file?uuid=8029a355-f05f-4d90-8bedc73c924ef843&owner=a902d91f-8a9b-4b43-95b3-9be9cdf53978>.

173. Compton, *supra* note 114, at 371.

174. *Contribution of OECD’s Task Force for the Safety of Novel Foods and Feeds*, *supra* note 160.

175. Compton, *supra* note 114, at 371.

for Transgenic Plants.<sup>176</sup> As a whole, the OECD plays a substantial role in the standardization and harmonization of GMO risk and safety assessments.

#### D. Transatlantic Trade and Investment Partnership

The Transatlantic Trade and Investment Partnership (TTIP) is a free trade agreement being negotiated between the U.S. and the EU.<sup>177</sup> If the agreement is finalized and put into effect, trade regulations between the EU and the U.S. will change significantly. The objective of the agreement is to remove trade barriers in order “to create growth and jobs on both sides of the Atlantic.”<sup>178</sup> The TTIP “could have its biggest effect on growth in the area of standards and regulations,” however, neither side of the Atlantic wants to dilute or weaken their levels of protection.<sup>179</sup> Through this agreement, the EU hopes to achieve “a single approval process for [food] exports from all EU countries, just like there is a single approval process for US exports to the EU,” among other things.<sup>180</sup> One of the goals of the U.S. is to remove barriers that have hindered agricultural exports to the EU.<sup>181</sup> This raises the issue of GMO regulations and food safety regulations in general. Throughout TTIP negotiations, American business groups have pressured a number of EU member states “to allow GM products and other foods into EU markets that would violate the EU’s current standards, in the name of free

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176. *Contribution of OECD’s Task Force for the Safety of Novel Foods and Feeds*, *supra* note 160.

177. *The Transatlantic Trade and Investment Partnership Explained*, EUROPEAN COMM’N (Mar. 19, 2015), [http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc\\_152462.pdf](http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152462.pdf).

178. *Id.*

179. *Id.*

180. *Food safety and Animal and Plant Health in TTIP*, EUROPEAN COMM’N, [http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc\\_153004.3%20Food%20safety,%20a+p%20health%20\(SPS\).pdf](http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153004.3%20Food%20safety,%20a+p%20health%20(SPS).pdf) (last visited Mar. 27, 2016).

181. *Why Trade Promotion Authority is Essential for U.S. Agriculture and the Transatlantic Trade and Investment Partnership*, USDA (Apr. 2014), <http://www.fas.usda.gov/sites/default/files/2014-04/tpa-ttip.pdf> [hereinafter *USDA on TIPP*].

trade.”<sup>182</sup> However, the EU has a strict stance on regulations concerning GMOs.<sup>183</sup> The European Commission stated on a number of occasions that “[t]he EU basic law on GMOs—including the European Food Safety Authority’s (EFSA) safety assessment and the risk management procedure—is not up for negotiation. It will not change as a result of TTIP.”<sup>184</sup> It further stated that the EU and the U.S. have already exchanged information regarding GMO “policy, regulations and technical issues.”<sup>185</sup> The only effect TTIP will have on GMO regulations according to the European Commission is more efficient information sharing, which “would help limit the effect on trade of [the] different systems for approving GMOs.”<sup>186</sup> In reality, only time will tell how the TTIP will effect GMO regulations between the U.S. and the EU.

#### IV. ECONOMIC IMPACTS DUE TO GMO REGULATIONS

Biotechnology, especially the creation of GMOs, is a large, potentially profitable field. Regulations on GMOs not only affect a country’s economy, but other countries as well, and also help shape trade relationships. The legal, cultural, and political differences between the U.S. and the EU created a stark difference in the regulation of GMOs. The liberal regulations in the U.S. on GE foods can be explained by the cultural account of government and business relations in international exports.<sup>187</sup> Lobbying plays a large part in creating regulations, and effective lobbying is seen in the regulations of GE foods as companies and organizations spend millions of dollars a year to lobby against restrictive GE food regulations. For example, in 2014, companies and organizations opposed to GE food labeling requirements disclosed \$63.6

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182. Fiona Harvey, *EU Under Pressure to Allow GM Food Imports From US and Canada*, GUARDIAN (Sept. 5, 2014), <http://www.theguardian.com/environment/2014/sep/05/eu-gm-food-imports-us-canada>.

183. Lynch & Vogel, *supra* note 23.

184. *About TTIP – basics, benefits, concerns*, *supra* note 111.

185. *Id.*

186. *Id.*

187. Demenina, *supra* note 5, at 333.

million in lobbying expenditures that made reference to GMO labeling.<sup>188</sup> On the other side of the Atlantic, the EU's restrictive regulations on GMOs can be largely attributed to public opposition to genetically modified foods.<sup>189</sup> In Europe, there is no demand for genetically modified products because European consumers prefer food that is "natural" over possessed or genetically modified.<sup>190</sup> One possible reason for this opposition is that over the years, Europe has undergone a number of health scares such as mad cow disease, E-Coli, Salmonella, and Dioxin-tainted products.<sup>191</sup> These kinds of epidemics can make consumers concerned and apprehensive about novel foods.<sup>192</sup>

These differences in regulations create obstacles to free trade between the U.S. and the EU. The import/export problems are a product of incompatible risk assessment procedures and different labeling requirements. Moreover, the U.S. lobbyists play a large role in influencing governmental departments by promoting profit-making industries such as the genetic engineering industry, whereas the EU's belief in the precautionary principle and consumer influence plays a large role in its regulation of GMOs. Despite the reasons for having different GMO regulations, the regulations of the U.S. and EU not only affect their own economies but also each other's. Additionally, since both the U.S. and EU are dominant forces in the global market, their choices in structuring their GMO regulations influence other countries' regulations.

When looking at the efficiency, costs, and profits of GE crops, there are several things that should be taken into consideration. The use of GE seeds does not actually increase the yield potential of crops.<sup>193</sup> Instead,

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188. Libbey Foley, *Corporate Spending to Fight GMO Labeling Skyrockets* (April 23, 2015), <http://www.ewg.org/research/anti-label-lobby>.

189. Demenina, *supra* note 5, at 333.

190. See JORGE FERNANDEZ-CORNEJO ET AL., USDA, REPORT NO. 162, GENETICALLY ENGINEERED CROPS IN THE UNITED STATES 34 (2014) (Surveys "found that when consumers in five EU countries plus New Zealand were surveyed, they selected organic over conventional or GE fruit.").

191. Tim Knowles et al., *European Food Scares and Their Impact on EU Food Policy*, 109 BRIT. FOOD J. 43, 44 (2007).

192. Demenina, *supra* note 5, at 335.

193. FERNANDEZ-CORNEJO ET AL., *supra* note 190, at 12. Potential yield is "the yield of an adapted cultivar when grown with the best management and without natural

GE seeds help prevent crop yield losses due to pests, thus allowing the crop to reach its yield potential.<sup>194</sup> Therefore, farmers likely purchase GE seeds not to increase the potential yield of crops but to minimize the losses of crops in a season. The profitability of these seeds largely depend “on the value of the yield losses mitigated and the associated pesticide and seed costs.”<sup>195</sup> GE seed prices are influenced by a number of factors, such as “the costs associated with seed development, production, marketing, and distribution,” as well as “the competitiveness of the particular seed market, and the pricing behavior of those firms that hold large shares of the market.”<sup>196</sup> Between 2001 and 2010, GE corn and soybean seed prices rose approximately fifty percent when adjusted for inflation.<sup>197</sup> Multiple factors can be attributed to this increase in price, including an increase in price premiums over conventional seeds, the increase in traits genetically engineered in a seed, and the improvement in seed genetics.<sup>198</sup>

#### A. Economic Impact on the European Union

The EU’s strict regulations of GMOs affect its trade relationship with the U.S.; however, the affect it has on the EU’s economy is difficult to measure. The EU is unique in the sense that it has the world’s largest market backed by vigorous regulatory institutions.<sup>199</sup> The EU has the largest economy in the world with a Gross Domestic Product (GDP) of approximately \$18.5 trillion.<sup>200</sup> Because of this, the EU’s rules and

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hazards such as hail, frost, or lodging, and without water, nutrient, or biotic stress limitations (water stress being eliminated by full irrigation or ample rainfall).” R.A. Fischer & Gregory O. Edmeades, *Breeding and Cereal Yield Progress*, 50 CROP SCI., (Mar.–Apr. 2010 Supp.), at S-85, S-86.

194. FERNANDEZ-CORNEJO ET AL., *supra* note 190, at 12.

195. *Id.* at 14.

196. *Id.* at 17.

197. *Id.* at 19–20 (noting that genetically engineered cotton seed prices grew more rapidly).

198. *Id.* at 20.

199. Anu Bradford, *The Brussels Effect*, 107 NW. U. L. REV. 1, 5 (2012).

200. *European Union Data*, WORLD BANK, <http://data.worldbank.org/region/EUU> (last visited Apr. 3, 2016).

regulations “have penetrated many aspects of economic life within and outside of Europe through the process of ‘unilateral regulatory globalization.’”<sup>201</sup> Many countries and companies choose to adapt to the EU’s regulatory standards to gain access to its market making it a major force in the global economy.<sup>202</sup> For this reason, the EU benefits economically from strict regulations in the global market.

With the U.S. having the second largest economy in the world with a GDP of approximately \$17.4 trillion,<sup>203</sup> it is not surprising that the U.S. and the EU are significant trading partners. Nonetheless, when looking at the EU’s agricultural products market, the U.S. market share has “fallen from 15 percent in 2000 to 9 percent in 2013.”<sup>204</sup> In 2013, the EU imported close to \$135 billion in agricultural products from across the globe, which is an increase of more than 150 percent from 2000.<sup>205</sup> However, U.S. exports of agricultural products to the EU, only grew by 82 percent, while its “exports to the world grew by 181 percent.”<sup>206</sup> This demonstrates that U.S. agricultural exports are failing to keep pace with both EU market growth and overall U.S. export growth. This can be partially attributed to the stark differences in GMO regulations across the Atlantic. Because the EU’s stringent GMO regulations create agricultural trade barriers for the U.S., the EU turned elsewhere for agricultural products.<sup>207</sup> The EU successfully managed to pursue “bilateral preferential trade agreements with other countries,”<sup>208</sup> specifically with

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201. Bradford, *supra* note 199, at 3. “Unilateral regulatory globalization occurs when a single state is able to externalize its laws and regulations outside its borders through market mechanisms, resulting in the globalization of standards.” *Id.* Anu Bradford uses the term “Brussels Effect” to refer to the EU’s unilateral regulatory globalization. *Id.*

202. *Id.* at 5–6.

203. *United States Data*, WORLD BANK, <http://data.worldbank.org/region/EUU> (last visited Feb. 21, 2015) (this number reflects the 2014 GDP measurements).

204. *USDA on TIPP*, *supra* note 181.

205. *Id.*

206. *Id.*

207. *Id.*

208. *Id.*

countries in South America, such as Chile.<sup>209</sup> By doing this, the EU effectively “averted supply deficiencies in agricultural products.”<sup>210</sup>

When it comes to agricultural products, the EU is not especially reliant on the U.S. Interestingly, in 2013, the EU exported more agricultural products to the U.S. than the U.S. exported to the EU.<sup>211</sup> Accordingly, the largest importer of agricultural products to the EU was Brazil.<sup>212</sup> Generally speaking, there is no indication of any immediate concern or necessity for the EU to consider increasing agricultural product imports. If there was a larger demand for agricultural products in the EU, the strict GMO regulations in place may have negatively impacted the EU’s economy. However, the EU’s imports of agricultural products such as maize, are modest, and should continue to be for the foreseeable future.<sup>213</sup> Although the EU’s restrictive GMO regulations seemingly do not harm its economy, it is not clear whether these stringent regulations have fiscally benefited European agricultural producers.<sup>214</sup> Even if the EU were to loosen its GMO regulations, it can be argued that there would not be a great deal of competition to produce these products. Because the EU is self-sufficient in maize, EU producers do not need import protection.<sup>215</sup> Similarly, “US soybeans are largely non-competing imports.”<sup>216</sup> Essentially, it does not appear that the trade barriers associated with genetically modified seeds financially benefit European farmers,<sup>217</sup> nor does it seem to harm them.

It is also important to note that consumer acceptance of GE foods largely affects the success or failure of marketing these products.<sup>218</sup> For a

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209. Tim Josling et al., *Latin American Agriculture in a World of Trade Agreements*, AMER. J. AGR. ECON. 1, 17 (2015).

210. In addition, EU’s self-sufficiency in the production of maize aids in preventing its stringent GMO regulation negatively impacting its economy in the global market. See Lynch & Vogel, *supra* note 23.

211. *EU28 Agricultural Trade with: United States*, EUR. COMM’N (June 30, 2014), [http://ec.europa.eu/agriculture/trade-analysis/statistics/outside-eu/us\\_en.pdf](http://ec.europa.eu/agriculture/trade-analysis/statistics/outside-eu/us_en.pdf).

212. *Id.*

213. See Lynch & Vogel, *supra* note 23.

214. See *id.*

215. *Id.*

216. *Id.*

217. *Id.*

218. FERNANDEZ-CORNEJO ET AL., *supra* note 190, at 34.

product to be successful, there must be a demand for it. However, there is a public consumer opposition to GE foods, and even stronger opinions about the necessity of GMO labels.<sup>219</sup> The general consensus in Europe is that genetically modified foods are inferior to their conventional or organic counterparts.<sup>220</sup> This lack of consumer demand further demonstrates that stringent GMO regulations in the EU fail to have any substantial negative impact on its economy. Essentially, because of the EU's unique position as a major force in the global economy, it can retain its "cultural importance on small-scale farming"<sup>221</sup> and tend to consumer wants without negatively impacting its economy.

### B. Economic Impact on the United States

Biotechnology in the U.S. is a large profit-making industry. Since the commercialization of GE foods, the U.S. has seen major developments in GE crops.<sup>222</sup> The USDA reported that biotech firms are rapidly developing GE seed varieties and farmers continue to adopt these GE seeds at rapid rates.<sup>223</sup> Many companies profit off of patenting GE seeds and selling them to farmers. Monsanto for example, the world's largest seed company, controls more than a quarter of the global commercial seed market.<sup>224</sup> It also holds a large number of patents on a variety of GE corn, soybean, cotton, canola, alfalfa, and sugar beet seeds.<sup>225</sup> Companies like Monsanto make a large profit by selling GE seeds not only nationally, but also globally.<sup>226</sup> However, these GE seed manufacturers

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219. See generally *id.*; *infra* note 280.

220. GianCarlo Moschini et al., *On the Segregation of Genetically Modified, Conventional and Organic Products in European Agriculture: A Multi-market Equilibrium Analysis*, 56 J. AGRIC. ECON. 347, 348 (2005).

221. Bradford, *supra* note 199, at 32.

222. See Strauss, *supra* note 46.

223. See FERNANDEZ-CORNEJO ET AL., *supra* note 190, at 17.

224. *Just 3 Companies Control More Than Half (53%) of the Global Commercial Market for Seed*, ETC GROUP (June 26, 2012) <http://www.etcgroup.org/content/just-3-companies-control-more-half-53-global-commercial-market-seed>.

225. See *Agricultural Seeds*, MONSANTO, <http://www.monsanto.com/products/pages/monsanto-agricultural-seeds.aspx> (last visited Apr. 3, 2016).

226. ETC GROUP, WHO OWNS NATURE? CORPORATE POWER AND THE FINAL FRONTIER IN THE COMMODIFICATION OF LIFE 12 (2008) available at,

strongly oppose strict regulations of GMOs. The stricter the regulations the more money needs to be spent producing the product. Moreover, mandatory labeling of GMO products in the U.S. could potentially stigmatize GMO products, decreasing overall sales and profits. On the other hand, lax regulations regarding GMOs may actually hinder the U.S. economy in the global market.

U.S. agricultural producers depend on the U.S. internal market as well as the global market for income. The global market plays a substantial role for U.S. farmers, where agricultural product exports comprise “approximately 20% of . . . [a] farm[‘s] income.”<sup>227</sup> Accordingly, “foreign market expansion is critical to [American farmers’] continued success.”<sup>228</sup> The U.S. is the world’s leading GMO producer and sees biotechnology and GE foods as a means for maintaining competitiveness in export markets, whereas the EU is the opposite.<sup>229</sup> Although the EU is a large trading partner with the U.S., the largest receivers of U.S. agricultural exports are China, Canada, and Mexico.<sup>230</sup> As mentioned earlier, “U.S. agricultural exports to the EU are not keeping pace with either EU market growth or with overall U.S. export growth.”<sup>231</sup> Over the years, there has been an increase in international competition in the EU, which had made it more difficult for the U.S. to export agricultural goods.<sup>232</sup> One main reason for this exporting shortfall is that there are extensive delays in reviews of GE products.<sup>233</sup> Additionally, to date, the EU has only authorized fifty-eight GMOs for import to the EU,<sup>234</sup> including a number of variations of GE cotton, flowers, maize,

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[http://www.etcgroup.org/sites/www.etcgroup.org/files/publication/707/01/etc\\_won\\_report\\_final\\_color.pdf](http://www.etcgroup.org/sites/www.etcgroup.org/files/publication/707/01/etc_won_report_final_color.pdf).

227. *USDA on TIPP*, *supra* note 181.

228. *Id.*

229. See Aseem Prakash & Kelly L. Kollman, *Biopolitics in the EU and the U.S.: A Race to the Bottom or Convergence to the Top?*, 47 INT’L STUD. Q. 617, 627 (2003).

230. *Facts on U.S. agriculture*, STATISTICA, <http://www.statista.com/topics/1126/us-agriculture/> (last visited Mar. 3, 2015).

231. *USDA on TIPP*, *supra* note 181.

232. *Id.*

233. *Id.*

234. EUR. COMM’N, *supra* note 111.

rapeseeds, soybeans, and sugar beets.<sup>235</sup> This substantially limits what the U.S. can import to the EU. The use of biotechnology and GE crops has increased dramatically over the years, reducing the amount of conventional crops being cultivated.<sup>236</sup> Therefore, the U.S. has an undersized amount of agricultural products that can be easily and readily imported into the EU.

Essentially, the relaxed regulations of the U.S. on GE foods create trading obstacles, ultimately leading to a negative impact on the economy. Having said that, this impact is insignificant. Even though agricultural exports to the EU are low, U.S. world exports continue to grow,<sup>237</sup> and the U.S. continues to have the second largest economy in the world.<sup>238</sup> The issue arises when other nations choose to adopt the same regulations as the EU. The more countries that adopt the same or substantially similar GMO regulations, the fewer destinations the U.S. will have to export its agricultural goods. This problem has already arisen. Many countries have followed in the EU's footsteps and adopted mandatory GMO labeling schemes,<sup>239</sup> including Australia, Brazil, Japan,<sup>240</sup> and China (the largest food importer to the U.S.).<sup>241</sup> China's implementation of its ban against certain varieties of GE corn led to large shipment rejections of GE corn from the U.S. due to the presence of one variety in particular, MIR 162.<sup>242</sup> These rejected shipments "resulted in losses of at least \$1 billion on the economy."<sup>243</sup> On the whole, U.S. corn

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235. *GMO Database*, GMO COMPASS, <http://www.gmo-compass.org/eng/gmo/db/> (last visited Mar. 17, 2015).

236. *See, e.g., USA 2013: No Reversal of Trend – Farmers Stick to Their Varieties of GM Crops*, GMO COMPASS (May 21, 2014), [http://www.gmo-compass.org/eng/agri\\_biotechnology/gmo\\_planting/506.usa\\_cultivation\\_gm\\_plants\\_2013.html](http://www.gmo-compass.org/eng/agri_biotechnology/gmo_planting/506.usa_cultivation_gm_plants_2013.html).

237. *USDA on TIPP*, *supra* note 181.

238. *See supra* text accompanying note 203.

239. Bradford, *supra* note 199, at 33.

240. *Id.*

241. *China*, USDA, <http://www.fas.usda.gov/regions/china> (last visited Apr. 3, 2016).

242. Tom Polansek, *China's Rejection Of GMO Corn Has Cost U.S. Up To \$2.9 Billion*, HUFFINGTON POST (June 17, 2014), [http://www.huffingtonpost.com/2014/04/17/gmo-corn-china\\_n\\_5162921.html](http://www.huffingtonpost.com/2014/04/17/gmo-corn-china_n_5162921.html).

243. *Id.*

exports have dropped by roughly eighty-five percent from early 2013 to early 2014.<sup>244</sup>

In 2014, China announced it would be lifting its ban on GE corn, however, U.S. corn exporters will likely see little impact from the lift of this ban.<sup>245</sup> China has created a strong domestic corn market with “no obvious need for excess supplies over the near term.”<sup>246</sup> This situation exemplifies how the EU’s stringent GMO regulations can impact the U.S.’s international agricultural trade market. Of course agricultural products only account for a small portion of the U.S. economy, but decreasing agricultural exports to the world’s largest economies may adversely affect U.S. farmers. To make up for these losses, the U.S. must export more agricultural goods to developing countries, where consumers in certain countries, such as India, “are willing to pay a slight premium for GE foods.”<sup>247</sup> According to the USDA, “developing countries . . . [are] the main source of projected growth in global food demand and trade.”<sup>248</sup> Despite trade obstacles for GMO exports with two of the top three largest economies in the world, the U.S. has been able to retain one of the strongest agricultural export markets.<sup>249</sup> “Farm exports in fiscal year 2014 reached a record \$152.5 billion and supported 1 million jobs in the United States.”<sup>250</sup> These figures show that although U.S. non-stringent and GMO-friendly regulations hinder its trade with the EU, these regulations sustain the U.S. economy on the whole.

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244. Jacob Brunge, *U.S. Corn Exports to China Dry Up Over GMO Concerns*, WALL ST. J. (Apr. 11, 2014), <http://www.wsj.com/articles/SB10001424052702303873604579493790405023808>.

245. Gavin Maguire, *Corn Bulls Shouldn't Get Too Excited About China's GMO Corn Nod*, REUTERS (Dec. 18, 2014, 6:38 AM), <http://www.reuters.com/article/2014/12/18/us-maguire-grains-idUSKBN0JW17F20141218>.

246. *Id.*

247. FERNANDEZ-CORNEJO ET AL., *supra* note 190, at 37.

248. Birgit Meade et al., *Income Growth in Developing Countries Can Increase U.S. Agricultural Exports*, USDA (Mar. 14, 2011), <http://www.ers.usda.gov/amber-waves/2011-march/income-growth-in-developing-countries.aspx#.VQvmzWTF84Q>

249. *See USDA Helps Open and Expand Export Markets for U.S. Agriculture*, USDA (Nov. 19, 2014), <http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=2014/11/0255.xml>.

250. *Id.*

V. SHOULD THE EU ADOPT GMO REGULATIONS SIMILAR TO THE U.S.  
OR VICE VERSA?

It is evident that the differences between the EU and the U.S. in regulating GE foods create trade barriers between the two trade partners. Due to the fact that roughly ninety percent of agricultural crops produced in the U.S. are genetically modified,<sup>251</sup> U.S. agricultural exports to the EU are impeded.<sup>252</sup> The harmonization of, or steps toward the harmonization of, GMO regulations would categorically improve trade procedures for food and animal feed between the U.S. and the EU. For this to occur, either the U.S., the EU, or both entities need to adopt regulatory changes for GE products. The issue here is whether the harmonization of GMO regulations would have a substantial enough impact on the EU and/or U.S. economy to be desirable, and to what extent regulatory changes should be made. Two important factors to consider when deciding if GMO regulatory changes should be made are: (1) how changes would affect trade across the Atlantic and globally and (2) how these changes would affect consumers. Deciding to what extent changes should be made is a difficult question to answer. It is important to take into consideration international guidelines on GMOs along with other nations' regulations.

A. From a Trade Standpoint

The existence of non-tariff barriers considerably increases trade obstacles between the U.S. and the EU.<sup>253</sup> The transatlantic differences in GMO regulations negatively impact the U.S. more than the EU. As mentioned previously, the EU exported more agricultural goods to the U.S. than it imported from them in 2013.<sup>254</sup> Because the EU's regulations satisfy U.S. import requirements, it follows that the EU has no regulatory

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251. See *GMOs in Food*, INST. FOR RESPONSIBLE TECH., <http://www.responsibletechnology.org/gmo-basics/gmos-in-food> (last visited Feb. 28, 2015).

252. *USDA on TIPP*, *supra* note 181.

253. *Id.*

254. See *supra* text accompanying note 211.

difficulties exporting to the U.S. Thus, if the EU harmonized its GMO regulations with the U.S., there is no evidence that their imports to the U.S. would substantially grow. The main reason for this is that the U.S. is a mass producer of agricultural products and, as a result, is self-sufficient in the production of crops.<sup>255</sup> While it is often difficult and costly to trade with multiple countries when you have to comply with multiple sets of sometimes conflicting regulations, the EU consistently complies with other countries regulations with ease due to its elevated standards. Additionally, because of the EU's wealth, it has been able to import the agricultural products it needs despite other countries' difficulty in complying with the EU's GMO regulations for imports.<sup>256</sup>

The transatlantic trade difficulties concerning agricultural products and GMO regulations are relatively similar to the trade complications associated with the EU's hormone-treated beef ban instituted over two decades ago. The EU's ban on hormone-treated meat severely reduced U.S. beef exports to the EU, thus harming American beef producers.<sup>257</sup> This ban had a strong enough impact on the U.S. to bring the dispute to a WTO dispute panel.<sup>258</sup> Despite the harmful effects on the U.S., "the hormone ban did not reduce imports of beef to the EU; it merely shifted their source," from the U.S. to Argentina, Brazil, and Australia.<sup>259</sup> Notwithstanding the WTO finding the EU in violation of the SPS Agreement and the U.S. imposing punitive tariffs on the EU, the EU still continues to uphold the ban.<sup>260</sup> All things considered, while the hormone ban did not appear to financially benefit European beef producers or the economy, it "certainly injured American producers."<sup>261</sup> Likewise, the

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255. See *USDA Helps Open and Expand Export Markets for U.S. Agriculture*, *supra* note 249.

256. See *Common Agricultural Policy*, USDA (last updated Jan. 25, 2016), <http://www.ers.usda.gov/topics/international-markets-trade/countries-regions/european-union/common-agricultural-policy.aspx> ("In preferential trade agreements, such as those with former colonies and neighboring countries, the EU satisfies domestic consumer demand . . ."); see e.g., EUR. COMM'N, *supra* note 211.

257. Lynch & Vogel, *supra* note 23.

258. *Id.*

259. *Id.*

260. *Id.*

261. *Id.*

EU's restrictive GMO regulations do not appear to financially benefit or injure its economy, whereas EU GMO regulations do harm the U.S. by restricting agricultural trade.<sup>262</sup>

Here, the EU does not seem to have a substantial financial incentive to change its GMO regulations to be more harmonious with the U.S. On the other hand, if the U.S. were to alter its GMO regulations to comply with the EU's, the U.S. *would* benefit from increased agricultural exports to the EU. Because several countries are starting to adopt more stringent GE food regulations, such as mandatory labeling,<sup>263</sup> the U.S. should not have significant issues with other countries attempting to import GMO goods into the U.S. if it requires mandatory labeling. Furthermore, modifying U.S. GE food-labeling regulations to mirror that of the EU could increase agricultural exports over time as more and more GE crops and seeds pass the EU's assessments.<sup>264</sup> A counter argument is that, because multiple EU member states have nation-wide bans on GMOs,<sup>265</sup> restrictions would still apply to U.S. agricultural exports regardless of the existence of mandatory labeling requirements. However, although gradual, consumer opinions of GMOs may be shifting to a more tolerable ideal. For example, in the 1990s, although the United Kingdom was a large player in the anti-GE movement, British public opinions shifted by 2011 as "only 27% thought GM food was risky, while 34% thought the benefits were far greater."<sup>266</sup> Even if public opinion does not change in Europe, a U.S. mandate requiring GMO labels would reduce the "[I]ong

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262. *Id.*; Bradford, *supra* note 199 at 33.

263. Bradford, *supra* note 199, at 33; Andrea Rock, *Where GMOs Hide in Your Food*, CONSUMER REPORTS (Oct. 2014), <http://www.consumerreports.org/cro/2014/10/where-gmos-hide-in-your-food/index.htm> (noting that over sixty countries have mandatory labeling requirements for foods that contain genetically modified ingredients).

264. Thus far, the European Union has authorized fifty-eight GMOs for import to the EU. EUR. COMM'N, *supra* note 111.

265. *GMO cultivation bans in Europe*, *supra* note 2.

266. *Frankenfine*, THE ECONOMIST (Nov. 29, 2014), <http://www.economist.com/news/britain/21635033-attitudes-genetically-modified-food-seem-be-changing-frankenfine>.

delays in reviews of biotech products[,] [which] create barriers to U.S. exports of grain and oilseed products.”<sup>267</sup>

Although mandatory labeling requirements in the U.S. would increase U.S. agricultural exports to the EU, their potential economic impact is debated.<sup>268</sup> On the one hand, opponents of mandatory GMO labeling, such as large GE manufacturers and producers, argue that mandatory labels “would be very costly and that their costs would be paid by all consumers, including those who do not wish to avoid GE.”<sup>269</sup> On the other hand, proponents of labeling requirements, such as consumers, argue that the implied cost of implementation would be minimal.<sup>270</sup> A number of studies looking at the “potential costs of [implementing] mandatory labeling,” in states like California and Washington varied “from more than \$1 billion per year to a few thousands of dollars.”<sup>271</sup> At this point in time, it is difficult to have a clear representation of the cost of implementing such labeling requirements in the U.S.; however, most recent studies tend to show the cost to consumers will not be high.<sup>272</sup> In sum, from a trade perspective, the U.S. would benefit from altering its GMO regulations to become more compatible with the EU because it would remove the trade barriers currently hindering U.S. agricultural exports.

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267. *USDA on TIPP*, *supra* note 181.

268. See generally Alison Van Eenennaam et al., *The Potential Impacts of Mandatory Labeling for Genetically Engineered Food in the United States*, COUNCIL FOR AGRIC. SCI. & TECH., Apr. 2014, available at [http://www.cast-science.org/file.cfm/media/products/digitalproducts/CAST\\_Issue\\_Paper\\_54\\_web\\_optimized\\_29B2AB16AD687.pdf](http://www.cast-science.org/file.cfm/media/products/digitalproducts/CAST_Issue_Paper_54_web_optimized_29B2AB16AD687.pdf).

269. *Id.*

270. *Id.*

271. *Id.*

272. See Andrew Dyke & Robert Whelan, *GE Foods Labeling Cost Study Findings*, ECONORTHWEST (Sept. 12, 2014), [https://consumersunion.org/wp-content/uploads/2014/09/GMO\\_labeling\\_cost\\_findings\\_Exe\\_Summ.pdf](https://consumersunion.org/wp-content/uploads/2014/09/GMO_labeling_cost_findings_Exe_Summ.pdf).

## B. From a Consumer Standpoint

Consumer acceptance of genetically modified foods largely affects the success or failure of marketing these products.<sup>273</sup> Simple supply and demand dictates that for GE foods to be profitable in Europe there must be a demand for them. However, many consumers in the EU “have indicated a reluctance to consume GE products,”<sup>274</sup> and are “willing to pay more for non-GE foods than consumers in other regions.”<sup>275</sup> As mentioned previously, this can be attributed to the high value Europeans put on food safety.<sup>276</sup> Accordingly, when asked to assess a variety of risks, “European consumers rank environment and food safety higher than crime and terrorism,”<sup>277</sup> which ultimately leads to “high levels of consumer and environmental protection.”<sup>278</sup> If the EU was to soften its GMO regulations, chances are there would be significant backlash from consumers. European consumers’ disapproval of relaxing GMO regulations in the EU was illustrated in January 2016 when approximately 50,000 people marched through Berlin “to denounce the proposed TTIP treaty” and the importation of American farming practices, such as commercializing GE crops.<sup>279</sup> If the EU decided to harmonize its GMO regulations with the U.S., GE foods would not be successful (at least initially) within the European market. Strong consumer opposition of genetically modified foods creates a market with a lack of demand, and if Europe’s GMO regulations were relaxed, it could easily lead to an over-supply of GE foods and a larger demand for GE-free products. For changes in GMO regulations to be successful, the changes must occur slowly to coincide with consumer demands. Therefore, at this point in time, it would not be advisable for the EU to ease its regulations concerning GMOs.

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273. FERNANDEZ-CORNEJO ET AL., *supra* note at 190, at 34.

274. *Id.*

275. *Id.* at 39.

276. *See supra* Sec. II(B).

277. Bradford, *supra* note 199, at 15.

278. *Id.*

279. ‘We are Fed Up!’: Thousands March Against TTIP & GMOs in Berlin, RT (Jan. 17, 2015, 8:08 PM), <http://on.rt.com/d1iiv3>.

On the other side of the Atlantic, the U.S. is also dealing with unfavorable consumer opinions about GE foods. The International Food Information Council (FIC) polls appear to indicate that the percentage of consumer opinions approving GE foods has decreased since 2003.<sup>280</sup> Furthermore, the National Research Center conducted a survey regarding consumer opinions on GE food mandatory labeling.<sup>281</sup> According to that survey, “[s]ome 92 percent of respondents stated that it should be legally required to label genetically engineered food accordingly.”<sup>282</sup> Over the years it has become apparent that consumers want to know what is in their food, so much so that over half of the states in the U.S. have introduced bills for mandatory labeling of GE food.<sup>283</sup> Implementing mandatory labeling of GE foods would be more efficiently accomplished if done by the FDA instead of having each state implement their own requirements. Having a national labeling standard would not only coincide with public opinion, but it would also help facilitate trade with the many countries that require mandatory GMO labeling. Ignoring public opinion on this issue could become troublesome down the road, which is why the U.S. should seriously consider altering its regulations on GMOs to accommodate its citizens.

## CONCLUSION

In a number of important respects, the transatlantic disparities concerning GMO regulations shed light on trade issues and effects on the respective economies. In the last few decades, GMOs have been commercially adopted by North America, but have yet to be adopted by Europe and many Asian countries. The EU’s restrictive procedures for

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280. FERNANDEZ-CORNEJO ET AL., *supra* note at 190, at 40; *see also* Rock, *supra* note 263 (“More than 70 percent of Americans say they don’t want genetically modified organisms in their food, according to a recent Consumer Reports National Research Center survey of 1,000 adults.”).

281. National Research Center, Survey, *Consumer Preferences for Labeling of Genetically Engineered Food in the United States in 2014*, STATISTA, <http://www.statista.com/statistics/306320/consumer-preferences-for-labeling-of-genetically-engineered-food-in-the-us/> (last visited Feb. 11, 2016).

282. *Id.*

283. *See supra* text accompanying notes 77-80.

pre-market approval of GE foods has hurt U.S. agricultural exports to the EU, while allowing other nations that have adopted a similar stance to that of the EU to benefit economically by exporting their agricultural products to EU countries. Many importing countries have followed in the EU's footsteps and have adopted more stringent regulations such as "requir[ing] mandatory labelling of such foods."<sup>284</sup> Essentially, this trend causes the U.S. to focus on exporting its agricultural product to developing countries to compensate for the lack of agricultural exportations to places such as EU members countries.

Currently, the EU's system of regulations helps it remain a major force in the global market while effectively responding to public opinion about relevant issues. However, the U.S. is facing increased competition in the EU while non-tariff barriers have hampered its agricultural exports to the EU.<sup>285</sup> Nevertheless, through the possible TTIP agreement, the U.S. hopes to remove these trade barriers.<sup>286</sup> Essentially, lenient U.S. GMO regulations negatively impact its economy by restricting its possible export destinations. Moreover, the current U.S. system is failing its citizens in the sense that "it excludes the public from the decision-making process," and thus, is "insufficient to protect [its] consumers."<sup>287</sup> If done correctly, the negative impacts the U.S. is facing with regard to GE foods can be improved by altering some of its GMO regulations. While altering its regulations to be completely harmonized with the EU may not be the answer, some form of mandatory labeling of GE foods is likely the best solution. "With labeling, informed consumers can maximize their utility, relative prices will reflect their choices, and the gains from trade will be maximized."<sup>288</sup> Essentially, certain trade obstacles between the U.S. and EU will be removed, improving the economy, while reflecting the needs and wants of the consumers.

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284. Sheldon, *supra* note 81, at 173.

285. *USDA on TIPP*, *supra* note 181.

286. *Id.*

287. Demenina, *supra* note 5, at 343.

288. Sheldon, *supra* note 81, at 174.