

# Negotiating Regulatory Coherence: The Costs and Consequences of Disparate Regulatory Principles in the Transatlantic Trade and Investment Partnership Agreement Between the United States and the European Union

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## Introduction

The Transatlantic Trade and Investment Partnership (TTIP), also known as the Transatlantic Free Trade Area (TAFTA), is a trade agreement currently in negotiations between the United States and the European Union. Negotiations began on July 8, 2013,<sup>1</sup> and are expected to end no

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1. OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, FACT SHEET: TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP (T-TIP) (2013) [hereinafter FACT SHEET].

earlier than 2015.<sup>2</sup> The agreement will ultimately attempt to remove barriers to trade between the United States and EU in order to facilitate greater trade and investment between the two entities. If successful, TTIP will become the largest free trade agreement in history.<sup>3</sup> The United States and EU have attempted to create a free trade agreement since the 1990s.<sup>4</sup> However, the ongoing negotiations made in the present economic climate—post-financial crisis of 2008—are the most likely to succeed, as both the United States and EU hope to achieve structural trade liberalization that will reduce trade frictions and increase investment.<sup>5</sup>

Both the United States and the European Union stand to realize great benefits from the TTIP by adding jobs supported by current transatlantic trade and by expanding upon the current total of nearly 3.7 trillion U.S. dollars that both entities have invested in each other's economies.<sup>6</sup> The EU's estimated annual benefit to be realized from the TTIP is 0.9 % of GDP, or 163 billion U.S. dollars; the United States is estimated to realize a 0.8% increase in GDP, or 132 billion U.S. dollars.<sup>7</sup> Other studies suggest much higher estimated per capita gains, from 5% for the EU to 13% for the United States.<sup>8</sup> Most of these projected gains are not from potential reductions in tariffs, as tariffs between the EU and the United States are already low at an average of around 3%.<sup>9</sup> Instead, most gains are expected to come from a reduction in non-tariff barriers to trade (NTBs).<sup>10</sup> NTBs cause trade friction that may lead to reduced trade and higher costs between parties to a trade agreement. NTBs mostly include regulatory barriers to trade access, which can result from differences in regulations and exclusionary rules.<sup>11</sup> Eliminating these regulatory differences may result in two-thirds to four-fifths of the estimated gains from a final, successful agreement.<sup>12</sup>

As a result of the potential impact of these regulatory differences, one of the main goals of TTIP is to “significantly reduce the cost of differences in regulations and standards by promoting greater compatibility, transparency, and cooperation, while maintaining our high levels of health, safety, and environmental protection.”<sup>13</sup> Initial goals of both the United

2. EUROPEAN UNIVERSITY ASSOCIATION, TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP (TTIP) UPDATE NO. 1, 1, 12 (2014) [hereinafter UPDATE].

3. Michael Beckerman, *The Future of the Global Economy Depends on the U.S.-E.U. Trade Deal*, HUFFINGTONPOST.COM (Jul. 12, 2013), [http://www.huffingtonpost.com/michael-beckerman/the-future-of-the-global-\\_b\\_3562595.html](http://www.huffingtonpost.com/michael-beckerman/the-future-of-the-global-_b_3562595.html).

4. Gabriel J. Felbermayr & Mario Larch, *The Transatlantic Trade and Investment Partnership (TTIP): Potentials, Problems, and Perspectives*, 14 CESIFO FORUM 49, 49 (2013).

5. *See id.*

6. FACT SHEET, *supra* note 1.

7. GAVIN THOMPSON, THE LIBRARY OF THE HOUSE OF COMMONS, THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP (TTIP) 1 (2013).

8. *Id.* at 2.

9. *See id.* at 1, 3.

10. *See Felbermyer & Larch, supra* note 4, at 49.

11. *See id.* at 49-50.

12. EUROPEAN COMMISSION, TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP: THE REGULATORY PART 1 (2013) [hereinafter THE REGULATORY PART].

13. FACT SHEET, *supra* note 1.

States and the EU include working toward “regulatory coherence,” a concept that looks to strike a balance between optimal regulation and maximum market freedom.<sup>14</sup> The European Commission found several key ways to achieve regulatory coherence: recognizing the similar effects of seemingly different regulations, shifting current regulations to a mutually-agreed upon middle ground, and cooperating on how to treat and enforce highly-disparate regulations.<sup>15</sup>

Despite the rhetoric of regulatory coherence, the practical implications of these negotiations will require much more political and industrial sacrifice than simple cooperation on regulatory schemes. The EU has expressly declared its refusal to compromise on some of its regulations; the European Commission has stated, “We will not negotiate existing levels of protection for the sake of an agreement. Our high level of protection here in Europe is non-negotiable . . . . There will be no compromise whatsoever on safety, consumer protection or the environment.”<sup>16</sup>

Consistent with these assertions, analysts have already identified likely areas of regulatory conflict. One of the most salient obstacles to successful negotiations arises from the disparities between U.S. and EU approaches to food and safety regulations: the EU has long blocked U.S. imports of genetically modified produce, chlorine-treated poultry, and meat from animals treated with the growth stimulant ractopamine.<sup>17</sup> These disparities are rooted in the different approaches that the United States and EU take in creating regulatory schemes. The EU blocks many imports of American food products as a precautionary measure, even if the products are regarded as safe elsewhere.<sup>18</sup> This approach is in opposition to the American regulatory principle of cost-benefit analysis.<sup>19</sup> Despite both American and European rhetoric supporting regulatory coherence, both entities remain unwilling to compromise on these specific regulatory standards. In fact, the United States has registered formal complaints with the World Trade Organization challenging the European Commission’s refusal to approve chemically treated poultry products originating from the

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14. NATIONAL CENTER FOR APEC & APEC BUSINESS ADVISORY COUNCIL, STRATEGIC FRAMEWORK FOR REGULATORY COHERENCE IN APEC: AN IMPACT ASSESSMENT OF THE DAIRY, ELECTRONICS, AND OFF-HIGHWAY VEHICLE INDUSTRIES 1 (2012), <http://www.ncapec.org/docs/Publications/Strategic%20Framework%20for%20Regulatory%20Coherence%20in%20APEC.pdf>.

15. THE REGULATORY PART, *supra* note 12, at 3.

16. European Commission Directorate-General for Trade, *Questions and Answers (TTIP)*, EUROPEAN COMMISSION: TRADE (2013), <http://ec.europa.eu/trade/policy/in-focus/ttip/questions-and-answers> [hereinafter Trade Policy].

17. Olga Khazan, *Transatlantic Trade: How Chlorine-Washed Chicken Prevents Greater U.S.-E.U. Trading*, WASHINGTON POST (Feb. 13, 2013), <http://www.washingtonpost.com/blogs/worldviews/wp/2013/02/13/the-transatlantic-trading-partnership-how-chlorine-washed-chicken-prevents-u-s-e-u-trade>.

18. *Id.*

19. Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993), [hereinafter Exec. Order].

United States.<sup>20</sup>

As a result of these conflicts, the trade negotiations between the United States and the EU will predominantly focus on reducing trade friction through the elimination of NTBs. Although commentators argue that regulatory coherence is an achievable goal based on mutual investment, similar economic development levels, and cultural proximity,<sup>21</sup> the domestic regulatory schemes and policies of both entities create formidable obstacles to successful negotiations. Even if the negotiations overcome these obstacles, any agreement that aims to achieve regulatory coherence will have significant externalities impacting domestic economics and third-party countries; however, these concerns, while important, may be overshadowed by the potential gains from an agreement. An examination of the differences in the basic regulatory principles of the United States and the EU indicates the most likely origins of any potential regulatory coherence. The disparities between the regulatory schemes of the United States and EU are a product of the fundamental differences between their respective regulatory foundations. Successful trade liberalization depends, in part, on the successful navigation of these fundamental differences in principle. Regulatory coherence in contentious industries can be best achieved either through mutual recognition of substantively similar regulatory schemes, or through reconciling cost-benefit analysis and the precautionary principle into a modified cost-benefit analysis that combines the economic considerations valued by the United States with the risk-aversion approach prioritized by the EU.

This Note will proceed in four parts. Part I explains the differences between the basic regulatory principles of the United States and the EU. Part II examines the functional outcomes of these differences in regulations and the estimated cost impact of the NTBs resulting from these divergent outcomes. Part III evaluates the externalities of a successful agreement, including effects on third-party nations, global trade, and concerns over deregulation. Lastly, Part IV submits that the two most effective methods to reach regulatory convergence without compromising existing safety standards are 1) reconciling the two regulatory principles by implementing a modified cost-benefit analysis approach, or 2) achieving mutual recognition of substantively similar regulations.

## I. The Formative Differences Between the Basic Regulatory Principles of the United States and the European Union

Regulatory principles are methodologies for structuring regulations. They provide frameworks for regulatory decision-making based on predetermined value judgments. Regulatory methodologies include cost-benefit analysis, also known as benefit-cost analysis; the precautionary principle;

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20. *European Communities - Certain Measures Affecting Poultry and Poultry Meat Products From the United States*, WORLD TRADE ORGANIZATION: DISPUTE SETTLEMENT (Feb. 24, 2010), [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds389\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds389_e.htm).

21. See Felbermayr & Larch, *supra* note 4, at 59.

multi-criteria analysis; holistic cost-benefit comparisons; and cost-effectiveness analysis.<sup>22</sup> These methodologies have overlapping considerations and applications depending on different circumstances and levels of knowledge.<sup>23</sup> Choosing a particular regulatory principle generally entails the prioritization of certain values over others. For example, cost-benefit analysis prioritizes economic efficiencies and quantifiable benefits, whereas the precautionary principle emphasizes safety and health concerns over economic costs.<sup>24</sup>

The United States formally espouses cost-benefit analysis as its foundational regulatory principle.<sup>25</sup> In Executive Order 12866, President Clinton directed that agencies base regulatory decisions on multiple factors, including “both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.”<sup>26</sup> Cost-benefit regulation focuses on efficiencies in addition to risks. As a result, this regulatory principle requires quantifiable economic gains and net benefits. The cost-benefit analysis “acts as a filter, capturing inefficient regulations while allowing efficient regulations to pass through.”<sup>27</sup>

Executive Order 12866 directs agencies to consider additional economic factors in addition to monetary costs and benefits.<sup>28</sup> The Order dictates that agencies “shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior.”<sup>29</sup> Additionally, regulatory design should also incorporate factors such as “incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity” and “tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities.”<sup>30</sup> Consequently, the American regulatory scheme primarily values economic benefits. American cost-benefit analysis assigns predetermined values to market factors and monetary costs and benefits. Although risk is an important factor to any regulatory principle, there are many other competing factors in the United States regulatory scheme.

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22. See FRANK ACKERMAN, GLOBAL DEVELOPMENT AND ENVIRONMENTAL INSTITUTE AT TUFTS UNIVERSITY, CRITIQUE OF COST-BENEFIT ANALYSIS, AND ALTERNATIVE APPROACHES TO DECISION-MAKING: A REPORT TO FRIENDS OF THE EARTH ENGLAND, WALES AND NORTHERN IRELAND 11 (2008), [http://www.ase.tufts.edu/gdae/Pubs/rp/Ack\\_UK\\_CBACritique.pdf](http://www.ase.tufts.edu/gdae/Pubs/rp/Ack_UK_CBACritique.pdf).

23. See *id.*

24. DAVID VOGEL, THE POLITICS OF PRECAUTION: REGULATING HEALTH, SAFETY, AND ENVIRONMENTAL RISKS IN EUROPE AND THE UNITED STATES 9–10 (2012).

25. Exec. Order, *supra* note 199.

26. *Id.*

27. Daniel H. Cole, *Reconciling Cost-Benefit Analysis with the Precautionary Principle*, PENN PROGRAM ON REGULATION: REG BLOG (Mar. 5, 2012), <http://www.regblog.org/2012/03/reconciling-cost-benefit-analysis-with-the-precautionary-principle.html>.

28. Exec. Order, *supra* note 9.

29. *Id.*

30. *Id.*

Criticisms of the cost-benefit principle focus on the difficulty of quantifying many variables and the misleading nature of “perceived reliability” derived from this quantitative data.<sup>31</sup> Cost-benefit analysis may filter out high-cost rules with large economic burdens, which may deter future agency rulemaking on contentious issues.<sup>32</sup> Additionally, many variables that should factor into an effective analysis are hard to quantify, such as the public-health benefits of cutting polluting emissions and the monetary value of saving thirty lives per year.<sup>33</sup> Common harms caused by pollutants and other contentiously regulated industries often do not occur contemporaneously with the actual emission or first point of contact.<sup>34</sup> The quantification of highly unquantifiable factors such as the value of human life often skews the computation of benefits and costs.<sup>35</sup> For example, many of the benefits of environmental regulation stem from the reduced risk of death.<sup>36</sup> These benefits are latent due to the delay between the actual injury and the initial cause of injury. Because these benefits are so hard to measure and quantify, a cost-benefit analysis that overlooks these factors may cause a proposed regulation to fail. As a result of these varying issues, the cost-benefit principle is a generally under-regulating methodology. Cost-benefit analysis favors risk-toleration and regulation that leads to economic positives.

The European Union, on the other hand, formally espouses the use of the precautionary principle. Unlike the cost-benefit principle, the precautionary principle applies when the EU presupposes potentially dangerous effects of a product or process, or when scientific uncertainty exists.<sup>37</sup> The EU dictates that the policy concerns underlying the precautionary principle consist of three substantive elements: 1) stepping up the drive to boost knowledge, 2) establishing scientific and technological monitoring schemes to identify new knowledge and understand its implications, and 3) staging a wide-ranging social debate on what is desirable and what is feasible.<sup>38</sup> These principles focus on the availability and quality of scientific knowledge. The precautionary principle thus applies when existing knowledge is insufficient. The EU also stresses that precaution must be distinguished from prevention. Prevention applies to measurable, quantifiable risks, and it requires some way to assess these risks. Precaution, on the other hand, entails a level of regulation beyond prevention that may be

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31. Gregory Mandel & James Thuo Gathii, *Cost-Benefit Analysis Versus the Precautionary Principle: Beyond Cass Sunstein's Laws of Fear*, 2006 U. ILL. L. REV. 1037, 1052 (2006).

32. See Cole, *supra* note 277.

33. Cass R. Sunstein, *The Stunning Triumph of Cost-Benefit Analysis*, BLOOMBERG VIEW COLUMNS (Sep. 12, 2012), <http://www.bloomberg.com/news/2012-09-12/the-stunning-triumph-of-cost-benefit-analysis.html>.

34. Richard L. Revesz, *Environmental Regulation, Cost-Benefit Analysis, and the Discounting of Human Lives*, 99 COLUM. L. REV. 941, 941 (1999).

35. *Id.*

36. *Id.* at 943.

37. 2000 O.J. (268) 9 [hereinafter O.J.].

38. *Id.* at 7.

applied when there is insufficient knowledge concerning the risk.<sup>39</sup>

The precautionary principle's concern with insufficient knowledge and lack of scientific certainty, combined with the EU's cautious approach to quantitative regulation, lead to a generally higher level of regulation and aversion to risk.<sup>40</sup> Regulatory decisions involving any uncertainties favor regulation and risk reduction. Unlike cost-benefit analysis, cost considerations are not the priority for the precautionary principle.<sup>41</sup> Because uncertainties are a primary factor in precautionary decision-making, calculations involving the precautionary principle are less quantifiable and concrete than analyses using cost-benefit analysis. The trigger of uncertainty gives regulators "ample opportunity to invoke the precautionary principle as justification for indefensible regulations" whenever there is "some scientific indication of a threat to the 'desired level' of safety."<sup>42</sup> Unlike cost-benefit analysis, the precautionary principle has a much lower threshold of proof for regulators to meet.<sup>43</sup> Any concern regarding safety or health can be sufficient to trigger precautionary regulations.

Criticisms of the precautionary principle center on the methodology's vagueness and possible over-regulatory effects. The methodology's lack of concrete factors and decision-making based on the lack of information has been described as problematic for the European Union, with suggestions that the principle can be more easily abused to block new technologies.<sup>44</sup> The Commission of the European Communities has unsuccessfully tried to provide more guidance on operational formulations of the safety principle.<sup>45</sup> Initial attempts at formulating an articulation of scientific uncertainty have resulted in the determination that "Recourse to the precautionary principle presupposes: identification of potentially negative effects resulting from a phenomenon, product or process; a scientific evaluation of the risk which because of the insufficiency of the data, their inconclusive or imprecise nature, makes it impossible to determine with sufficient certainty the risk in question."<sup>46</sup> This articulation gives greater guidance regarding the types of factors that justify the use of the precautionary principle, but the precautionary decision-making process remains more nebulous than cost-benefit analysis. Although the EU also uses cost-benefit analysis, the principle is applied much more narrowly than in the United States. The Commission dictates that while precautionary decision-making must still "include a cost benefit analysis in order to reduce the risk to a level acceptable to all concerned . . . it is not possible to quantify adverse consequences . . . in exclusively financial terms or to assess

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39. *Id.*

40. Cole, *supra* note 27.

41. See Mark Geistfeld, *Reconciling Cost-Benefit Analysis with the Principle that Safety Matters More than Money*, 76 N.Y.U. L. REV. 114, 119 (2001).

42. *Id.* at 177.

43. Cole, *supra* note 27.

44. See Maurizio Iaccarino, *A Cost/Benefit Analysis: About the Precautionary Principle*, 11 EMBO REPORTS 454, 454 (2000).

45. Geistfeld, *supra* note 41, at 174.

46. *Id.* at 178.

economic and moral impact purely on the basis of a cost-benefit analysis.”<sup>47</sup> The EU explicitly criticizes cost-benefit analysis, warning that “the value of quantitative risk analysis and cost-benefit analysis schemes must not be overrated. Nor must the figures involved be exaggerated.”<sup>48</sup>

Despite the differences between these two formative regulatory principles, some officials argue that these disparities will present fewer obstacles than previously feared. For example, U.S. Trade Representative Michael Froman acknowledged that one of the challenges facing TTIP negotiations is the “historical difference about the appropriate approach to regulation, sometimes characterized as a so-called gap between Europe’s preference for the precautionary principle and the United States’ focus on cost-benefit analysis.”<sup>49</sup> However, Froman also noted that the concern over this difference is “largely anachronistic” and that “while it might be premature to declare an end to the debate over the precautionary principle and cost-benefit analysis, that distinction is decreasingly important, at least in terms of . . . T-TIP.”<sup>50</sup> Froman notes that strict reliance on the distinction between the two principles is an oversimplification of the United States and European regulatory schemes; Froman acknowledges that the EU does not only use the precautionary principle in regulatory decision-making, and that the United States does take qualitative factors into account when regulating.<sup>51</sup>

Other commentators suggest that while the regulatory divergences cause differences in the regulation of particular products, the overall risk of both systems is similar. Twenty case studies and 3,000 observations of risk-reducing decisions seem to show that treatment of risk is approximately the same, and the perception of highly disparate regulatory effects may be caused by more heavily publicized risks.<sup>52</sup> These observations suggest that the regulatory principles may not be fundamentally irreconcilable. Instead, the ways in which they are implemented may be a major cause of regulatory divergence.

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47. O.J., *supra* note 37, at 10.

48. *Id.* at 7.

49. U.S. Trade Representative Michael Froman, Remarks on the United States, the European Union, and the Transatlantic Trade and Investment Partnership (Sept. 30, 2013) (transcript available at <http://www.ustr.gov/about-us/press-office/speeches/transcripts/2013/september/froman-us-eu-ttip>).

50. *Id.*

51. *Id.*

52. JOHN F. MORRALL III, U.S. CHAMBER OF COMMERCE, ADVANCING TRANSATLANTIC BUSINESS, DETERMINING COMPATIBLE REGULATORY REGIMES BETWEEN THE U.S. AND THE EU 22 (2011), available at [http://transatlantic.sais-jhu.edu/partnerships/Cornerstone%20Project/cornerstone\\_project\\_morrall.pdf](http://transatlantic.sais-jhu.edu/partnerships/Cornerstone%20Project/cornerstone_project_morrall.pdf).



## II. The Impacts of Regulatory Incoherence

### A. Differences in Industry and Trade Regulation between the United States and EU

The foundational regulatory principles of cost-benefit analysis and the precautionary principle can lead to very significant divergences in regulation. While the general safety and health aims and regulations of the two entities remain similar, other areas of regulation undergo different treatment. According to the Council on Foreign Relations, “In some cases, most notably drug approval, European and American standards have converged . . . . But over the last fifteen years, the EU has enacted a number of health, safety, and environmental regulations which are more restrictive than their American counterparts.”<sup>53</sup> This shift, attributed to the increasingly important role of the precautionary principle, has led to more stringent regulations in areas related to public welfare. Some of the most significant divergences between the United States and the EU can be found in regulations concerning the chemical industry, the food industry, and the environment. The United States has approved significantly more varieties of genetically modified (GM) products than the EU, while also allowing the use of hazardous chemicals.<sup>54</sup> The EU ratified the Kyoto Protocol, requiring member states to reduce greenhouse gas emissions, while the United States has only signed but has not ratified the treaty.<sup>55</sup>

#### 1. *The Chemical Industry*

The EU requires registration of all chemicals sold in Europe. The United States, on the other hand, has much more relaxed requirements for the chemical industry.<sup>56</sup> Even though the United States and EU have similar goals with respect to public safety and protection, the industry impacts of their regulations are quite disparate. Both sides have comparably high levels of protection, especially when compared with less regulated countries. Compared to the United States, the EU regulates the manufacturing of children’s products especially aggressively.<sup>57</sup> Phthalates are chemical compounds used to make plastics for a wide range of industrial applications.<sup>58</sup> Phthalates can be found in medical supplies, electrical materials,

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53. 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 RELATIONS (Apr. 5, 2001), <http://www.cfr.org/agricultural-policy/regulation-gmos-europe-united-states-case-study-contemporary-european-regulatory-politics/p8688>.

54. VOGEL, *supra* note 24, at 1.

55. *Id.*

56. Daniela Vincenti, *EU-US Trade Talks Delve into Regulatory Maze*, EURACTIV (Sept. 26, 2013), <http://www.euractiv.com/specialreport-eu-us-trade-talks/eu-us-trade-talks-delve-regulato-news-530682>.

57. *Efforts to Ban Phthalates*, PBS NOW (Mar. 21, 2008), <http://www.pbs.org/shows/412/ban-phthalates.html>.

58. Maria E. Callapez, Presentation at the Proceedings of the 2nd ICESHS: The USA and the EU: Two Perspectives on Phthalates (Cracow, Poland, Sept. 6-9, 2006) (edited transcript available at [http://www.2iceshs.cyfronet.pl/2ICESHS\\_Proceedings/Chapter\\_30/R-Varia\\_III\\_Callapez.pdf](http://www.2iceshs.cyfronet.pl/2ICESHS_Proceedings/Chapter_30/R-Varia_III_Callapez.pdf)).

clothing, toys, paints, adhesives, and even cosmetics.<sup>59</sup> Public concern over the use of phthalates in manufacturing began after findings of unacceptable levels of leaching from baby teething rings.<sup>60</sup> Since then, the EU has also banned bisphenol A (BPA), a chemical with similar industrial uses and potential health effects.<sup>61</sup> Exposure to phthalates is potentially carcinogenic, while exposure to BPA can affect young immune systems.<sup>62</sup> The Commission argued that children are particularly susceptible to adverse health effects from exposure to these compounds due to the possibility of early developmental issues and the widespread use of the chemicals in children's products.<sup>63</sup>

Although preliminary studies regarding the safety of phthalates were inconclusive, the EU issued Directive 2005/84/EC, a precautionary ban on the use of phthalates in toys and children's products.<sup>64</sup> The Council stated that "the use of certain phthalates in toys and childcare articles made of plasticized material or including parts made of plasticized material should be prohibited as the presence of certain phthalates presents or could potentially present risks related to the health of children."<sup>65</sup> The Directive stated that the precautionary principle should be applied to the use of phthalates because children are particularly vulnerable to hazardous substances and exposure should be reduced as much as possible.<sup>66</sup> However, the Directive expressly acknowledged that scientific information concerning the regulated chemicals is either "lacking or conflictual, but it cannot be excluded that they pose a potential risk."<sup>67</sup>

The EU's treatment of phthalates illustrates the application of the precautionary principle well. Despite empirically inconclusive evidence concerning the effects of phthalate exposure on human health, the EU took immediate action to limit exposure. The Directive had no discussion of economic costs and benefits. Instead, it focused only on the potential risk to children and maximum reduction of exposure to phthalates. Consistent with the Council's previous articulation of the substantive elements of the precautionary principle, the Directive required that the regulatory measures based on the principle must be subject to review under any additional or newfound scientific information.

The United States, on the other hand, had a more moderate response to the use of phthalates, and did not adopt the EU's ban on phthalates in the manufacture of children's toys. The Environmental Protection Agency (EPA) has expressed concern about phthalates and established an Action Plan in 2012 to describe its plans for possibly identifying and regulating

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59. *Id.*

60. *Id.*

61. *EU Bans Bisphenol A Chemical from Babies' Bottles*, B.B.C. NEWS: EUROPE (Nov. 25, 2010), <http://www.bbc.co.uk/news/world-europe-11843820>.

62. *Id.*

63. *See id.*

64. Council Directive 76/769, 2005 O.J. (L 344) 40 (EEC).

65. *Id.*

66. *See id.*

67. *Id.* at 41.

phthalates.<sup>68</sup> The report explicitly acknowledges the health concerns and exposure risks of phthalates, noting “the well-characterized health effects of phthalate exposure in animals in conjunction with the demonstrated widespread phthalate exposure in children.”<sup>69</sup> However, this regulatory report was released nearly seven years after the EU’s ban.<sup>70</sup> The EPA also warned that the Action Plan is not a “final Agency determination or other final Agency action.”<sup>71</sup> Instead, the Action Plan dictated an intent to “lay the groundwork to consider initiating . . . rulemaking”<sup>72</sup> rather than a definite plan to regulate. Furthermore, the EPA’s plan detailed cost considerations,<sup>73</sup> as well as possible ways in which to “encourage industry to move away from phthalates in a non-regulatory setting to expand risk management effects beyond whatever regulatory action might be taken under TSCA or could be used as input to a regulatory action.”<sup>74</sup>

The EPA’s plan provides an excellent illustration of the American regulatory scheme. Unlike the EU, the EPA has proceeded much more slowly and deliberately in considering any possible phthalate regulations. The EPA explicitly acknowledged the potential health effects of exposure to phthalates. However, the risk of adverse health effects was not sufficient to trigger regulatory action. The EPA must first conduct a cost-benefit analysis and consider the economic costs and possible alternatives before even an initial consideration of any regulation takes place, pursuant to Executive Order 12866.

## 2. *Regulation of GM products*

Similarly, the United States and EU have widely divergent schemes for regulating genetically modified (GM) products. GM products are extensively used in the United States, while a *de facto* moratorium in the EU has led to the approval of very few GM products.<sup>75</sup> The basis for U.S. regulation of GM products relies on the assumption that “GM plants, animal feeds, and human foods are essentially similar to conventionally-bred plants, feeds, and foods.”<sup>76</sup> This assumption allows U.S. regulatory agencies to treat GM products as substantially equivalent to conventionally produced products, permitting activities to proceed until any showing of significant harm.<sup>77</sup> The basis for EU regulation of GM products, on the

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68. U.S. ENVIRONMENTAL PROTECTION AGENCY, PHTHALATES ACTION PLAN (2012) [hereinafter ACTION PLAN].

69. *Id.* at 8.

70. *Id.* at 10.

71. *Id.* at 2.

72. *Id.* at 11.

73. *See id.* at 4.

74. *Id.* at 11.

75. Kym Anderson & Lee Ann Jackson, *Why Are US and EU Policies Toward GMOs So Different?*, 6 J. AGROBIOTECHNOLOGY MGMT. & ECON. 95, 95 (2003).

76. M.J. Peterson, *The EU-US Dispute over Regulation of Genetically Modified Organisms, Plants, Feeds, and Foods—Case Summary*, INTERNATIONAL DIMENSIONS OF ETHICS EDUCATION IN SCIENCE AND ENGINEERING: CASE STUDY SERIES 1, 5 (2010), <http://scholarworks.umass.edu/cgi/viewcontent.cgi?article=1007&context=edethicsinscience>.

77. *Id.*

other hand, relies on the assumption that there is a substantial difference between GM products and conventionally produced products.<sup>78</sup> As a result, producers of GM products in the EU must prove that their products are safe before they can be sold.

One of the most salient differences in treatment of GM products between the United States and the EU is the way in which food labels for GM products are regulated. In the United States, although the Food and Drug Administration (FDA) does regulate the release of genetically-modified organisms, the agency has no mandatory labeling requirement for foods containing GM products.<sup>79</sup> Instead, the FDA issued a nonbinding guidance document that provides certain labeling recommendations to producers of GM products.<sup>80</sup> Although public perception of GM products is generally negative, with over 90% of Americans favoring labeling, at least 70% of processed foods in the United States contain GM products.<sup>81</sup> However, proponents of GM products argue that “the technology boosts yields, reduces pesticide use and is a crucial tool in the struggle against global hunger. Americans have been munching GM food for two decades without ill effect, and nearly all scientists believe that GM crops are safe.”<sup>82</sup>

Like the American approach to phthalates, American regulation of GM products and foods arises out of the cost-benefit principle. Scientific evidence regarding the safety of GM products is inconclusive. The World Health Organization stated, “[I]ndividual GM foods and their safety should be assessed on a case-by-case basis and that it is not possible to make general statements on the safety of all GM foods.”<sup>83</sup> With no immediate scientific indication that GM products have any harmful effects, the cost-benefit principle has “led to regulators’ perceived certainty that GM foods do not pose significant risks, and that a narrow definition of risks connected with GM foods is acceptable.”<sup>84</sup> With economic benefits from the use of GM products and little apparent risk, the cost-benefit principle as applied to GM products favors looser regulations.

The EU’s position on labeling GM products is much stricter. In a Directive issued in 2001, the Council declared that the protection of

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78. *Id.*

79. U.S. FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: VOLUNTARY LABELING INDICATING WHETHER FOODS HAVE OR HAVE NOT BEEN DEVELOPED USING BIOENGINEERING; DRAFT GUIDANCE (2001), available at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm>.

80. *Id.*

81. *Warning Labels for Safe Stuff*, THE ECONOMIST (Nov. 2, 2013), <http://www.economist.com/news/united-states/21588898-one-way-or-another-labelling-gm-food-may-becoming-america-warning-labels-safe>.

82. *Id.*

83. *Food Safety: 20 Questions on Genetically Modified Foods*, WORLD HEALTH ORGANIZATION, <http://www.who.int/foodsafety/publications/biotech/20questions/en> (last visited May 13, 2014).

84. Celina Ramjoué, *A review of regulatory issues raised by genetically modified organisms in agriculture*, CAB REVIEWS: PERSPECTIVES IN AGRICULTURE, VETERINARY SCIENCE, NUTRITION AND NATURAL RESOURCES 6 (2008), available at <http://www.princeton.edu/morefoodlesscarbon/reading/files/Ramjoue-Review-of-Reg-Issues.pdf>.

human health and the environment required the application of the precautionary principle to the regulation of GM products.<sup>85</sup> The Directive required that GM products must be clearly labeled or documented with the words: “This product contains genetically modified organisms.”<sup>86</sup> The Directive also required the establishment of monitoring procedures and pre-release notification to a national competent authority.<sup>87</sup> A subsequent EU Directive issued in 2003 required maximum limits on trace amounts of GM products in foods before they could be labeled “GMO-free.”<sup>88</sup> This new requirement limited trace amounts of GM products to 0.9% for authorized products and 0.5% for products that have not yet been approved by the Commission.<sup>89</sup> After a three-year period, the threshold was reduced to zero for several varieties of ingredients, which caused “extreme difficulty of separating out different varieties of grain in bulk shipment and the continuing stalemate on approval of GM varieties in the EU Council.”<sup>90</sup>

The EU’s position on GM products assumes that the lack of scientific knowledge and certainty regarding the safety of GM products indicates that they are hazardous or detrimental to health. As a result, the application of the precautionary principle was appropriate given this assumption and required the EU to strictly regulate GM products. The EU’s regulatory policy towards GM products is a product of its broader definition of risks. The EU includes delayed effects on health and the environment and social and ethical issues as part of its regulatory decision-making process.<sup>91</sup> In utilizing the precautionary principle, the EU considers both normative and scientific definitions of the level of acceptable risk.<sup>92</sup> Economic concerns are mentioned only within the context of requiring industry participants to notify regulatory bodies before release of GM products.<sup>93</sup> The Council does not even appear to consider economic costs in its Directive.<sup>94</sup>

### 3. *The Environment*

Environmental regulations provide another example of a controversial difference between the United States and the EU. One of the more visible examples of the disparities between the two entities regarding environmental policy is found in their treatment of the Kyoto Protocol, which is an international agreement committing its parties to meet binding emission reduction targets.<sup>95</sup> The United States is a signatory to the Kyoto Protocol,

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85. Council Directive 90/220, 2001 O.J. (L 106) 1 (EC) [hereinafter Council Directive].

86. *Id.* at 3.

87. *Id.*

88. Peterson, *supra* note 76, at 14.

89. *Id.*

90. *Id.*

91. Ramjoué, *supra* note 84, at 6.

92. *Id.*

93. Council Directive, *supra* note 85, at 9.

94. *See id.*

95. Kyoto Protocol, U.N. FRAMEWORK CONVENTION ON CLIMATE CHANGE, [http://unfccc.int/kyoto\\_protocol/items/2830.php](http://unfccc.int/kyoto_protocol/items/2830.php) (last visited May 13, 2014).

but has refused to ratify the treaty.<sup>96</sup> President George W. Bush explained that ratifying the Kyoto Protocol would have detrimental effects on the United States economy.<sup>97</sup> The United States' reluctance to ratify the Protocol was based on cost-benefit decision-making: the short-term economic costs do not justify the benefits for the United States, despite its acknowledgment of the long-term pitfalls of climate change through signing the agreement.<sup>98</sup> The EU, on the other hand, ratified the Kyoto Protocol in 2002, which was then entered into force in 2005.<sup>99</sup> The EU has expressly declared that "preventing dangerous climate change is a strategic priority for the European Union."<sup>100</sup> The European position on climate change is consistent with the precautionary principle. The EU recognizes the cost of implementing climate change programs, but values the reduction in risk more highly than the pure economic costs.

#### B. The Estimated Cost Impact of Non-Tariff Barriers Caused by Disparate Regulations

The differences between U.S. and EU regulations cause significant barriers to trade. Some of the major benefits from the TTIP will be realized from the reduction of barriers to trade between the United States and EU. Transatlantic trade is already fairly free; there are few and low tariffs between the two economic entities.<sup>101</sup> The average tariff of transatlantic trade is under 3%.<sup>102</sup> In comparison, China's overall average applied tariff rate is 9.6%, with some categories as high as 25% on passenger vehicles and 15.6% on agricultural products.<sup>103</sup> Although eliminating these tariffs as planned will still result in considerable economic benefits, the already low average tariff rate will not provide the largest gains from the TTIP. Instead, most of the potential economic benefits will come from the elimination and reduction of non-tariff barriers to trade.<sup>104</sup>

NTBs are approximately one order of magnitude more significant than the costs of tariff duties; U.S. companies have additional costs of over 50% when exporting alcohol and tobacco to the United States, while chemical companies in the EU have additional costs of 112%.<sup>105</sup> The disparities

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96. Paul Reynolds, *Kyoto: Why Did the U.S. Pull Out?*, B.B.C. NEWS (Mar. 30, 2001), <http://news.bbc.co.uk/2/hi/americas/1248757.stm>.

97. *Id.*

98. *Id.*

99. Status of Ratification of the Kyoto Protocol, U.N. FRAMEWORK CONVENTION ON CLIMATE CHANGE, (Feb. 16, 2005), [http://unfccc.int/kyoto\\_protocol/status\\_of\\_ratification/items/2613.php](http://unfccc.int/kyoto_protocol/status_of_ratification/items/2613.php).

100. *What is the EU Doing About Climate Change?*, EUROPEAN COMMISSION: CLIMATE ACTION (Nov. 19, 2013), <http://ec.europa.eu/clima/policies/brief/eu>.

101. THOMPSON, *supra* note 7, at 1.

102. *Trade Policy: United States*, EUROPEAN COMMISSION (Nov. 19, 2013), <http://ec.europa.eu/trade/policy/countries-and-regions/countries/united-states>.

103. WAYNE M. MORRISON, CONG. RESEARCH SERV., RL 33536, CHINA-U.S. TRADE ISSUES 12 (2013).

104. See Felbermyer & Larch, *supra* note 4, at 53.

105. *Id.*

caused by NTBs are much more asymmetrical than tariffs.<sup>106</sup> Therefore, reducing NTBs will reduce many of the costs associated with transatlantic trade. Disparate regulatory schemes are one of the primary causes of NTBs. The differences between the regulations described earlier create substantial inefficiencies and excess costs. If TTIP negotiations can achieve regulatory coherence, some of the regulated areas that are expected to yield the most economic gains are the automotive industry and the chemical and pharmaceutical industries. This section will focus on the estimated cost impact of NTBs on these industries and regulated areas.

The principle method of reducing NTBs is to promote regulatory coherence by reconciling the two disparate regulatory schemes. The United States-European Union High Level Working Group on Jobs and Growth (HLWG) noted:

Both sides agree on the importance of putting processes and mechanisms in place to reduce costs associated with regulatory differences by promoting greater compatibility, including, where appropriate, harmonization of future regulations, and to resolve concerns and reduce burdens arising from existing regulations through equivalence, mutual recognition, or other agreed means, as appropriate.<sup>107</sup>

As a result, the HLWG has focused on the elimination or reduction of both conventional and non-conventional barriers to trade. The HLWG also recognizes the importance of regulatory schemes in the development of trade negotiations, stating a focus on enhancing the compatibility of regulations and standards.<sup>108</sup>

Some NTB sources that are not related to safety and public health concerns may be the best candidates for regulatory coherence that will maintain current safety standards while reducing trade costs. For example, the United States and EU use different crash test dummies for certain crash tests but not others.<sup>109</sup> The use of different testing products can lead to significant costs, especially in industries, such as the automotive industry, that are dependent upon economies of scale.<sup>110</sup> Industry practices aimed at achieving economies of scale reduce production costs and inefficiencies. However, these practices may be deterred by divergent regulatory requirements and test procedures.<sup>111</sup> Harmonizing these regulatory requirements, especially in regulations unrelated to health and public safety, can substantially increase the ability of businesses to achieve economies of scale and incur significant cost savings.

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106. *Id.*

107. EUROPEAN COMMISSION, HIGH LEVEL WORKING GROUP ON JOBS AND GROWTH 3-4 (2013), available at [http://trade.ec.europa.eu/doclib/docs/2013/february/tradoc\\_150519.pdf](http://trade.ec.europa.eu/doclib/docs/2013/february/tradoc_150519.pdf).

108. *Id.* at 1.

109. MORRALL, *supra* note 52, at 23.

110. JOSEPH FRANCOIS, CENTRE FOR ECONOMIC POLICY RESEARCH, REDUCING TRANSATLANTIC BARRIERS TO TRADE AND INVESTMENT: AN ECONOMIC ASSESSMENT 23 (2013), available at [http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc\\_150737.pdf](http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150737.pdf).

111. MORRALL, *supra* note 52, at 23.

An initial determination of cost savings can be calculated by creating an NTB index of an industry. An NTB index gives some indication of the extent of costs imposed by NTBs, as well as the relative levels of regulation among different agencies.<sup>112</sup> An NTB index ranges from 0-100, where 0 indicates no NTBs of any type, or completely free trade, and where 100 indicates prohibitively high NTBs, such that the amount of NTBs prevents trade completely by increasing costs or restricting market access.<sup>113</sup> The industries that have the largest disparities in NTB indices include the automotive, pharmaceutical, and chemical industries.<sup>114</sup> Reducing NTBs in these industries will liberalize transatlantic trade by eliminating “different approaches to the same regulatory challenges” that have “the unintended consequence of increasing costs for firms, which have to comply with two regulatory environments, dragging down productivity.”<sup>115</sup> Despite the considerable significance of tariff costs in these industries, limiting tariffs would lead to “much more limited, though positive effects.”<sup>116</sup> Instead, negotiating NTBs “provides the opportunity to pursue a mix of cross-recognition and regulatory convergence to reduce these barriers.”<sup>117</sup>

NTBs can be difficult to measure and evaluate because they rely on many different factors, including legal requirements, firm business decisions, and consumer influences. Estimates obtained from the EU’s Economic Assessment examined firm surveys to evaluate general openness of market industries, as well as gravity-based econometrics to estimate percent price impacts of variations in NTB levels.<sup>118</sup> This research reveals significant differences resulting between exports and imports, individual industries, and origins (whether EU or U.S. origin).<sup>119</sup> Transatlantic NTBs are also substantially lower in service industries as opposed to industries that produce goods.<sup>120</sup> As a result, it appears that some of the greatest gains from TTIP can be found from reducing NTBs in industries focused on goods.<sup>121</sup> However, many barriers to removing NTBs may be difficult to overcome. Some NTBs result from consumer preferences, language, geography, political considerations, and legal systems.<sup>122</sup> Some of these barriers, such as consumer preferences and geography, can be much more influential when dealing with goods-related industries.

One of the most visible NTB sources is in the automotive industry. Despite the significance of NTBs, however, tariffs still have considerable cost impact on the industry. U.S. import tariffs range from 2.5% for importing cars to the United States to 25% for importing pickup trucks

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112. Francois, *supra* note 110, at 16-17.

113. *Id.*

114. *Id.* at 18.

115. *Id.* at 2.

116. *Id.* at 2-3.

117. *Id.* at 2.

118. *Id.* at 17.

119. *Id.*

120. *Id.*

121. *Id.* at 20.

122. *Id.* at 19.



and commercial vans.<sup>123</sup> The EU, on the other hand, charges a flat rate of 10% on imported automobiles, regardless of the type of vehicle.<sup>124</sup> Sources of NTBs in the industry include differences in safety testing, emissions standards, and divergent regulations for the heights and widths of headrests.<sup>125</sup> The perceived NTB index of EU exports to the U.S. is 34.8, while the perceived NTB index of U.S. exports to the EU is 31.6.<sup>126</sup> These index estimates are relatively low compared to those present in some other industries such as food, beverage, and medical supplies, but are readily identifiable even at the consumer level.<sup>127</sup> Differences between requirements for regulatory compliance and other NTBs can have significant impacts on manufacturing costs, consumer choice, and industry performance.

The automotive industry is highly focused on consumer preferences. Jim Farley, an executive with Ford Motor Co., says, "There is no more important topic for our industry, in terms of the revenue for different companies, than [brand] loyalty."<sup>128</sup> Ensuring consumer access to the broadest possible lineup for consumers is an important goal for automakers, but disparate regulations often made this goal difficult to achieve.<sup>129</sup> Even vehicles designed for transnational appeal may be manufactured differently in order to accommodate regulatory differences. The Ford Fusion/Mondeo, for example, is supposed to represent Ford's "One Ford" philosophy; however, the global parts commonality for this model is only 80%, which is already higher than the industry standard.<sup>130</sup>

Designing cars to meet safety and environment standards in various jurisdictions is extremely costly. Cars imported into the United States must meet National Highway Traffic Safety Administration (NHTSA) guidelines, whereas cars imported into the EU must meet the European New Car Assessment Programme (NCAP).<sup>131</sup> The NHTSA guidelines and the NCAP have different protocols, methods, and priorities.<sup>132</sup> However, the general safety standards of the United States and EU are fairly similar. Safety and environmental regulations in the EU "have caught up with U.S. standards over the past 15 years. And because of new rules passed by the Obama administration, U.S. rules on fuel efficiency and emissions have nearly

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123. Justin Berkowitz, *Free-Trade Cars: Why a U.S.-Europe Free-Trade Agreement is a Good Idea*, CAR AND DRIVER (June 2013), <http://www.caranddriver.com/features/free-trade-cars-why-a-useurope-free-trade-agreement-is-a-good-idea-feature>.

124. *Id.*

125. *Id.*

126. Francois, *supra* note 110, at 18.

127. *Id.*

128. Joseph B. White, *How Auto Makers Keep You Coming Back*, WALL STREET JOURNAL (Jan. 22, 2013), <http://online.wsj.com/news/articles/SB10001424127887324624404578257703957447498>.

129. Berkowitz, *supra* note 123.

130. *Id.*

131. *Id.*

132. *Id.*

caught up with European standards.”<sup>133</sup> Despite the similarities between overall levels of safety and environmental impact, automakers must still adhere to the often duplicative requirements imposed by the United States and EU regulatory bodies. Mutual recognition of test standards will not only decrease manufacturer costs, but also may give consumers greater options in their vehicle choices by increasing the range of vehicles in the national market and making more individual vehicle options available.<sup>134</sup>

Decreased costs of production, distribution, and regulatory compliance could lead to increased manufacturing, broader product lineups for consumers, and even the resurgence of some previously unavailable brands in the United States.<sup>135</sup> Despite the relatively low NTB index for the automotive industry, the potential market access impact ranking for the industry is estimated to be the highest out of all industries evaluated.<sup>136</sup> The automotive industry will likely dominate in terms of impact as a result of high elasticities of demand and high trade barriers.<sup>137</sup> Additionally, the reduction of NTBs in the automotive industry is expected to result in a very strong expansion of the EU motor vehicle sector.<sup>138</sup> In the most ambitious forecast, total trade will increase by 43.11%.<sup>139</sup> Trade between the United States and EU in the industry should experience a substantial expansion as a result of “relatively deep changes in the integration of the transatlantic motor vehicle sector.”<sup>140</sup> Much of this integration will result from the relatively large differences in parts and components, but will also result from the expected high reductions in tariffs for the sector.<sup>141</sup>

The sector with the next-highest potential market access impact as a result of TTIP is comprised of the chemicals and pharmaceuticals industries.<sup>142</sup> The sector has regulatory issues similar to those seen in automotive trade between the EU and the United States: chemicals are regulated according to certain tests and guidelines that can be duplicative or redundant.<sup>143</sup> The chemical sector is “similar, in terms of the pattern of results, to motor vehicles.”<sup>144</sup> Regulatory guidance and reconciliation will introduce efficiencies in safety standards, development, research, and mutual recognition. As the pharmaceutical trade currently functions, the NTB

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133. Matthew Dalton, *U.S.-EU Trade Talks Aim at Barriers, not Tariffs*, WALL STREET JOURNAL (Nov. 10, 2013), <http://online.wsj.com/news/articles/SB10001424052702304868404579189731322530204>.

134. Berkowitz, *supra* note 123.

135. Francois, *supra* note 110, at 32.

136. *Id.*

137. *Id.*

138. *Id.* at 62.

139. *Id.* at 65.

140. *Id.* at 70.

141. *Id.*

142. *Id.* at 32.

143. EFPIA & PhRMA, EU-U.S. HIGH LEVEL REGULATORY COOPERATION FORUM: TTIP—AN OPPORTUNITY TO INCREASE REGULATORY COMPATIBILITY IN THE BIOPHARMACEUTICAL SECTOR 7-8 (2013), available at [http://www.uschamber.com/sites/default/files/grc/PhRMA\\_0.pdf](http://www.uschamber.com/sites/default/files/grc/PhRMA_0.pdf) [hereinafter BIOPHARMACEUTICAL SECTOR].

144. Francois, *supra* note 110, at 62.

index of EU exports to the United States is 23.8, while the NTB index of U.S. exports to the EU is 44.7; EU exports of chemicals to the United States have an index of 45.8, while U.S. exports to the EU have an index of 53.2.<sup>145</sup> Like the automotive industry, these index figures are not the highest among all industries affected by TTIP; however, many of the NTBs in the chemical industry are caused by regulatory incompatibility that could, theoretically, be harmonized for cost savings.<sup>146</sup>

An estimated 80% of the potential gains from reducing NTBs in the pharmaceutical industry are expected to come from cutting costs related to unnecessary regulatory redundancy and trade restrictions.<sup>147</sup> Some measures suggested by the International Conference on Harmonization include the acceptance of a rationalized preclinical animal study system, standardized safety updates and reporting throughout drug development, common guidelines for reporting safety and efficacy data, and consolidated reporting of new pharmaceutical candidates through common electronic documents.<sup>148</sup>

Transatlantic trade in biopharmaceuticals is currently regulated by the Food and Drug Administration (FDA) in the United States and the European Medicines Agency (EMA) in the EU.<sup>149</sup> Similar to the automotive industry, both of these regulatory agencies have established practices and inspections for acceptance of regulated goods. However, also similar to the automotive industry, these regulatory agencies are driven by similar safety objectives regarding the identification, monitoring, and minimization of risks to patient safety.<sup>150</sup> The European Commission recognized the need for creating a coherent regulatory scheme out of this common safety standard but divergent regulation, stating that “if the regulators could agree to coordinate their safety assessments of the same chemicals—assessing the same products at the same time and exchanging information—companies wouldn’t have to repeat some tests. This would save costs for both the companies and the regulators, who have to evaluate the tests.”<sup>151</sup>

The cost impacts of regulatory incoherence, and the benefits of any harmonization scheme, are considerable. The automotive, chemical, and pharmaceutical industries are two of the industries that have the most to gain from trade liberalization. 75% of the total potential gain from regulatory coherence is estimated to come from four industries alone: motor vehicles (31%), chemicals, cosmetics, and pharmaceuticals (19%), food and

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145. *Id.* at 18.

146. BIOPHARMACEUTICAL SECTOR, *supra* note 143 at 7.

147. *Id.* at 6.

148. *Id.* at 7.

149. *Id.* at 8.

150. Yvonne Lis, *A Comparison of U.S. Food and Drug Administration and European Medicines Agency Regulations for Pharmaceutical Risk Management: Report of the International Society for Pharmacoeconomic and Outcomes Research Risk Management Working Group* 10, 12 ISPOR CONNECTIONS (Sept./Oct. 2011), <http://www.ispor.org/signs/riskbenefitmanagement/A-comparison-of-US-Food-and-Drug-Administration-and-European-Medicines-Agency.pdf>.

151. THE REGULATORY PART, *supra* note 12, at 3.

beverages (14%), and electrical machinery (11%).<sup>152</sup> The potential gains from harmonizing the differing standards between the automotive industries in the EU and the United States are not surprising, as the industry is a large contributor both to the economies of the EU and the United States and to transatlantic trade between the two economies.<sup>153</sup> A successful regulatory coherence scheme for the automotive industry, even taking into account NTBs that cannot be overcome, is estimated to have a potential transatlantic welfare gain of 15 billion U.S. dollars.<sup>154</sup> Compared to the sum of 53 billion U.S. dollars of bilateral trade in this sector in 2007, this welfare gain indicates the significant cost impact of NTBs in this industry. In the pharmaceuticals and chemical industries, EU NTBs caused about 15% of pharmaceutical trade costs, whereas U.S. NTBs caused approximately 10%.<sup>155</sup> Although trade costs may only represent a relatively small amount of cost savings to society, successful harmonization of some of the regulatory NTBs in these industries can still lead to gains of 3 billion U.S. dollars.<sup>156</sup>

The considerable economic benefits of TTIP come mostly from holistic trade liberalization, rather than sole reliance on tariff elimination. TTIP should result in positive gains for both the EU and the United States even if only tariff barriers to trade were reduced.<sup>157</sup> Under a tariff-only liberalization scheme, the gains would only amount to approximately 32 billion U.S. dollars increase in GDP for the EU and 12 billion U.S. dollars increase in GDP for the United States.<sup>158</sup> On the other hand, reducing NTBs can lead to estimated GDP increases of 92 to 162 billion U.S. dollars for the EU and 68 to 129 billion U.S. dollars for the United States.<sup>159</sup> NTBs are a critical source of increased costs of transatlantic trade that are also essential talking points for a successful trade agreement.

### III. The Externalities of the TTIP and a Regulatory Coherence Scheme

The scope of TTIP and its effects on nearly all aspects of transatlantic trade will inherently create many externalities affecting third-party nations and consumers. TTIP will have considerable effects on third-party countries in addition to the costs and trade liberalization impacts on transatlantic commerce alone. Reducing or eliminating tariffs can have harmful effects on third-party nations, with particularly harmful effects for developing nations.<sup>160</sup> These harmful effects are mainly caused by intensified

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152. MORRALL, *supra* note 52, at 20.

153. *Id.* at 22-23.

154. *Id.* at 23.

155. *Id.* at 26.

156. *Id.*

157. FRANCOIS, *supra* note 110, at 95.

158. *Id.*

159. *Id.*

160. GABRIEL J. FELBERMAYR, SYBILLE LEHWALD, & BENEDIKT HEID, GLOBAL ECONOMIC DYNAMICS, BERTELSMANN FOUNDATION, TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP (TTIP): WHO BENEFITS FROM A FREE TRADE DEAL? PART 1: MACROECONOMIC EFFECTS 28

competition in the EU and U.S. markets following the reduction of tariff barriers.<sup>161</sup> Reducing NTBs will primarily help trade with some third-party countries, although developing countries may be disproportionately harmed because they are primarily supply raw resources.<sup>162</sup> Critics of TTIP argue that the agreement will diminish the value of bilateral agreements with third-party countries, as these countries would be confronted with the increased European competition on the American market.<sup>163</sup>

A second effect of TTIP on third-party countries will be on costs and income.<sup>164</sup> However, the distinction between tariffs and NTBs is important here.<sup>165</sup> Tariffs have an income redistribution function by shifting income from the consumer to the producer.<sup>166</sup> Tariffs can also harm markets by distorting consumption and production decisions.<sup>167</sup> NTBs, unlike tariffs, do not affect third-party countries by redistributing income.<sup>168</sup> Instead, NTBs generate direct economic costs by requiring producers to make products fit for a certain market and regulatory scheme.<sup>169</sup> Reducing NTBs, along with tariff barriers, has a potentially substantial and positive impact on the rest of the world—worldwide trade can experience growth of up to 99 billion euros.<sup>170</sup> Firms and third markets will likely experience reduced costs as a result of better standard establishment and recognition, reduced regulatory divergence, and reduced cost impacts of regulatory schemes on the costs of business.<sup>171</sup> NTB reduction in transatlantic trade will assist third-party nations by allowing them to minimize harmful trade diversion effects caused by previously prohibitive regulatory schemes.<sup>172</sup>

Another potential externality caused by TTIP is the “race to the bottom” feared by critics of the agreement. While working towards a unified regulatory scheme necessarily risks compromising current standards, regulatory coherence does not necessarily entail lowered standards of protection. The United States and the EU argue that TTIP negotiations will not lower standards in order to suit business interests for three reasons: first, regulators themselves will be participating in the negotiations; second, all interested parties will be briefed and consulted; and third, inherent checks and balances through the political structure of both entities will provide oversight—both the European Parliament and the United States Congress

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(2013), available at <http://www.bfna.org/sites/default/files/TTIP-GED%20study%2017June%202013.pdf> [hereinafter BENEFITS].

161. *Id.* at 28.

162. *Id.* at 27.

163. Felbermayr & Larch, *supra* note 4, at 59.

164. BENEFITS, *supra* note 160, at 26-27.

165. *See id.*

166. *Id.* at 26.

167. *Id.*

168. *Id.*

169. *Id.*

170. Francois, *supra* note 110, at 96.

171. *Id.*

172. BENEFITS, *supra* note 160, at 27.

must approve the final result.<sup>173</sup> Despite these reassurances, the harmonization of extremely divergent regulations risks compromising standards of protection or causing costly NTBs to remain. The second round of negotiations ended with a general acknowledgment of the importance of regulatory coherence in a press release issued by the Commission:

On regulatory issues, both sides agreed on the importance of horizontal rules and specific commitments in sectors. Negotiators, including regulatory experts, had a solid discussion on regulatory coherence and on possible elements for a chapter on technical barriers to trade going beyond WTO disciplines (so-called ‘TBT plus’).

Similarly, the third round of negotiations ended with renewed emphasis from participants that “neither side intended to lower its high standards of consumer, environment, health, labor or data protection, or limit its autonomy in setting regulations.”<sup>174</sup> Regulatory coherence remains one of the major goals of the negotiations. Critics of the negotiations, however, argue that these horizontal rules and sector commitments are unnecessary and risk compromising standards for health, safety, and the environment. One critic, Erich Pica, argues, “Tariffs are already low and the exchange of goods and services [between the United States and EU] is robust . . . TTIP risks being a partnership of those who seek to prevent and roll back democratically agreed safeguards such as food and chemical safety, agriculture and energy.”<sup>175</sup>

Other critics are concerned that TTIP is primarily catering to industry and its lobby groups; the Corporate Europe Observatory revealed that the commission has held 119 meetings with corporations and their lobbyists, in contrast to only eight meetings with civil society groups.<sup>176</sup> Additionally, meetings with corporate interest groups have been closed to the public and have not been disclosed online.<sup>177</sup> Critics also point to promises of economic and job growth from previous trade agreements, such as the United States–Korea Free Trade Agreement and the North American Free Trade Agreement, that have not materialized. Both of these agreements were accompanied by a loss in the number of jobs, and U.S. exports fell by 3.5 billion dollars after the United States–Korea agreement.<sup>178</sup>

As TTIP negotiations are still ongoing, third party effects and deregulatory concerns will continue to put pressure on trade talks. Erik Brattberg wrote,

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173. Trade Policy, *supra* note 16; THE REGULATORY PART, *supra* note 12, at 5.

174. US, EU Conclude Third Round of TTIP Negotiations, GLOBAL TRADE MAGAZINE, <http://globaltrademag.com/us-eu-conclude-third-round-of-ttip-negotiations> (last visited May 13, 2014).

175. Erich Pica, *Transatlantic Trade Agreement Threatens Environment and Health in U.S. and Europe*, HUFFINGTONPOST.COM (Dec. 24, 2013), [http://www.huffingtonpost.com/erich-pica/transatlantic-trade-agree\\_b\\_4468877.html](http://www.huffingtonpost.com/erich-pica/transatlantic-trade-agree_b_4468877.html).

176. George Monbiot, *The Lies Behind this Transatlantic Trade Deal*, THE GUARDIAN (Dec. 2, 2013), <http://www.theguardian.com/commentsfree/2013/dec/02/transatlantic-free-trade-deal-regulation-by-lawyers-eu-us>.

177. *Id.*

178. *Id.*

As negotiations enter into the next phase, pressure from environmental groups, labor unions and consumer advocates will also increasingly be felt. Many of these groups have recently stepped up their criticism of TTIP. While this debate is of course essential, it also puts a heavier burden on proponents of the trade deal to explain TTIP's potential benefits and debunk skeptic's criticisms.<sup>179</sup>

These issues will likely influence the extent of significant regulatory compromise from both the EU and the United States. Some of the safety and health standards can easily be reconciled through standardized procedures and mutual recognition. More divergent standards with fundamentally divergent priorities and value assessments, however, may require either regulatory compromise or avoidance in the agreement. The costs of removing some NTBs may simply be too high, whether due to insufficient economic benefits (such as the Kyoto Protocol situation), or due to political sensitivities.<sup>180</sup> Consequently, some of the more contentious divergences between the United States and the EU regulatory schemes will likely see either the most or the least amount of retooling in order to finalize the trade agreement.<sup>181</sup>

#### IV. Reconciliation of the Cost-benefit and Precautionary Principles

The significant differences between the regulatory principles of the EU and the United States lead to substantial cost impacts upon transatlantic trade. While these costs are results of fundamentally different regulatory schemes, cost-benefit analysis and the precautionary principle are not necessary rivals or substitute methods for making regulatory and deregulatory decisions.<sup>182</sup> In fact, cost-benefit analysis and the precautionary principle can be reconciled by assigning greater weights to societal health and safety concerns within a cost-benefit analysis framework. Incorporating quantitative values for societal health and safety into cost-benefit analysis allows the use of both schemes to create coherent regulations.<sup>183</sup>

A modified cost-benefit analysis that incorporates safety interests satisfies both economic and social welfare concerns. The economic desire for scientific rigor and cost impacts is satisfied by using social welfare concerns along with traditional risk, cost, and gain variables. The precautionary desire for maintaining social welfare standards is satisfied by prioritizing strong safety and health standards over other variables. The cost-benefit analysis can specify a high level of risk-aversion within cost-benefit analysis using an adjusted Ramsey equation, which combines valuations of the social discount rate, pure rate of time preference, base-case coefficient of relative risk-aversion, and expected rate of growth in per capi-

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179. Erik Brattberg, *Is 2014 the Transatlantic Trade Deal's 'Make-or-Break' Year?*, HUFFPOST WORLD (Jan. 10, 2014), [http://www.huffingtonpost.com/erik-brattberg/is-2014-the-transatlantic\\_b\\_4577270.html](http://www.huffingtonpost.com/erik-brattberg/is-2014-the-transatlantic_b_4577270.html).

180. Francois, *supra* note 110, at 19.

181. *Id.*

182. Cole, *supra* note 27.

183. *Id.*

tal consumption.<sup>184</sup> Daniel Cole argues that this calculation can mimic the precautionary principle by reflecting relatively high risk-aversion rather than risk-neutrality.<sup>185</sup> This regulatory approach allows legal decision-makers to “employ cost-benefit methodology to formulate health and safety regulations while still respecting the principle that safety matters more than money.”<sup>186</sup>

Not only can incorporating the risk-aversion of the precautionary principle achieve the fundamental goals of both regulatory principles, the calculations can also be modified according to different policies. Regulatory policies designed to tolerate routine risk can have a more risk-neutral, economically traditional cost-benefit analysis.<sup>187</sup> Policies that may implicate substantially greater or intolerable risks, such as existential threats and irreversible impacts upon unique goods, can build in higher levels of risk-aversion to the cost-benefit analysis.<sup>188</sup> This sliding-scale approach to tolerating risk within cost-benefit analysis is consistent with the fundamental goals behind the cost-benefit and precautionary principles, as well as the EU’s approach to applying these principles: tolerable risks can be addressed using cost-benefit analysis, while more intolerable or unknown risks should be addressed with greater risk-aversion under the precautionary principle.<sup>189</sup>

Mark Geistfeld agreed with the general incorporation of risk factors into cost-benefit analysis while also noting the distributive implications of modified cost-benefit analysis. He wrote, “[Cost-benefit analysis] modified in this manner is more beneficial to potential victims, and consequently more distributively fair, than conventional cost-benefit outcomes. Moreover, modified [cost-benefit analysis] is not unfair to potential injurers.”<sup>190</sup> Modified cost-benefit analysis, then, is more beneficial to the parties helped by regulation than pure cost-benefit analysis. The modified principle is also potentially less unfair to the parties being regulated, as opposed to the sweeping regulations under the precautionary principle.

Additionally, a reworked cost-benefit analysis incorporating precautionary factors is not necessarily required for some aspects of the trade negotiations. Regulatory convergence can also be achieved through mutual recognition of existing, substantively compatible regulations. Many existing regulations can actually be reconciled with procedural means, rather than resorting to a reformulation of substantive safety standards. The best examples of these potential sources of regulatory coherence come from the automotive and pharmaceutical industries. The United States and EU have similar general safety goals in regulating both industries, but thus far have regulated these industries using different methods to achieve these

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184. *Id.*

185. *Id.*

186. Geistfeld, *supra* note 41, at 187.

187. Cole, *supra* note 27.

188. *Id.*

189. O.J., *supra* note 37, at 9.

190. Geistfeld, *supra* note 41, at 183.



goals. Recognizing convergent regulations will prevent the need to create new regulations that could be counterproductive or less rigorous.

In the automotive industry, the actual substantive safety standards of U.S. and European regulations are “generally functionally equivalent and produce similar levels of safety.”<sup>191</sup> Automakers generally try to build vehicles that will satisfy requirements for both jurisdictions, but must still engineer vehicles to market specifications.<sup>192</sup> Designing cars to meet specific regulations can be inefficient and costly, especially when the regulations have the same substantive safety standards but divergent procedures. European crash tests require compliance with pedestrian impact, whiplash, and infant protection standards.<sup>193</sup> NHTSA requires these tests as well, but performance in the tests themselves is not scored.<sup>194</sup> Reductions of these types of redundancies account for 31% of the total benefits estimated from reducing NTBs in the automotive trade.<sup>195</sup> Additional procedural divergences include the EU’s *ex ante* gatekeeper type approval of automobiles, whereas the United States uses *ex post* enforcement and self-certification.<sup>196</sup> Based on these procedural differences, mutual recognition of the substantive similarities and high levels of overall safety standards between these regulatory regimes will encourage reduction of NTBs, decrease costs, and liberalize automotive trade.

Similarly, the pharmaceutical and chemical industry standards of the United States and EU are substantively comparable.<sup>197</sup> The process for approving new drugs is similar in both jurisdictions, although the EU does have two added steps to evaluate cost-effectiveness and member state pricing.<sup>198</sup> A study by the International Society for Pharmacoeconomic and Outcomes Research Risk Management Working Group found that the FDA and EMA have similar data needs, objectives for identification, monitoring, and minimization of risk, and evaluation components.<sup>199</sup> One of the most important and divergent regulatory issues for U.S. exports is not a safety regulation: the EU regulates pricing policies, while the United States does not.<sup>200</sup> Mutual recognition of the many overlapping regulatory measures of the United States and EU could decrease or eliminate NTBs without compromising regulatory goals and safety standards.

For the divergent regulatory practices responsible for large amounts of NTBs, the United States and EU could either employ a modified cost-benefit analysis or mutually recognize substantively comparable, existing stan-

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191. MORRALL, *supra* note 52, at 23.

192. Berkowitz, *supra* note 123.

193. Clifford Atiyeh, *Automakers Seek Common Ground in Europe, U.S. on Safety Regulations*, CAR AND DRIVER (Dec. 23, 2013), <http://blog.caranddriver.com/automakers-seek-common-ground-in-europe-u-s-on-safety-regulations>.

194. *Id.*

195. MORRALL, *supra* note 52, at 22.

196. *Id.*

197. *Id.* at 26.

198. *Id.*

199. Lis, *supra* note 150, at 12.

200. *Id.*

dards. Cost-benefit analysis and the precautionary principle are not necessarily incompatible regulatory principles. While their practical application by the United States and EU can often result in disparate regulatory schemes, the differences between the schemes are often matters of procedure and methodology. Many of the divergences in regulation can be reconciled through mutual recognition without compromising the safety standards and regulatory goals that critics of TTIP want to uphold. Similarly, even vastly disparate schemes can achieve coherence through a modified cost-benefit analysis that incorporates the economic considerations of pure cost-benefit analysis and the risk-aversion of the precautionary principle. The modified cost-benefit analysis approach to regulatory coherence retains the decision-making employed by both the United States and the EU on policies with tolerable risks, while adding a layer of risk-averse safety for less tolerable risks. Applying modified-cost benefit analysis to regulatory divergence can decrease NTBs and increase trade gains by reconciling the two principles of cost-benefit analysis and the precautionary principle.

## Conclusion

Achieving regulatory coherence, one of the primary goals of the TTIP, requires an understanding of the foundational regulatory principles of the United States and the EU. These foundational principles account for some of the disparities between the respective regulatory schemes of the United States and the EU, as well as the costs of any trade relationship that must navigate these regulatory schemes. These disparities are responsible for significant costs and barriers to transatlantic trade, and also influence trade with third-party nations. Regulatory disparities impacting trade, known as NTBs, are one of the most important sources of cost savings and potential gains from TTIP. Reducing NTBs, along with tariff barriers to trade, will decrease costs for industries and lead to significant GDP gains for both the United States and the EU.

Successful regulatory coherence and reduction of NTBs must involve reconciliation of regulatory schemes. The United States and the EU regulate based on cost-benefit analysis and the precautionary principle, respectively. These principles are often applied with disparate results. The EU has very strict regulations on many products and industries, including chemicals, environmental standards, and food products. The United States, on the other hand, bases regulatory decisions on economic and scientific factors. While the United States regulatory scheme can be described as under-regulating, the European regulatory scheme is often described as over-regulating.

Despite these fundamental and practical differences, the United States and European regulatory schemes can be reconciled. Although the cost-benefit principle and the precautionary principle seem highly divergent in methodology and outcome, the two principles can be incorporated into a modified cost-benefit analysis to create regulatory coherence. Modified

cost-benefit analysis retains the traditional aspects of pure cost-benefit analysis for more tolerable, routine risks. However, when more intolerable, unknown, or especially dangerous risks are possible, modified cost-benefit analysis builds risk-aversion into the analysis. Risk-aversion calculations can approximate the behavior of the precautionary principle, allowing regulators to use the economically preferred cost-benefit principle while also valuing safety at a higher level. Modified cost-benefit analysis will retain the United States focus on economic considerations for more risk-neutral policies and provide further precautionary protections with more risk-averse regulatory policies.

Even though modified cost-benefit analysis is a workable way to create regulatory coherence, using this principle is not necessary in all aspects of the trade negotiations between the United States and the EU. Some existing regulations, especially in the automotive and pharmaceutical industries, are already compatible substantively. The regulatory schemes can diverge on procedural and methodological grounds, which can create costly redundancies that restrict trade. Identifying and reducing the NTBs caused by substantively similar regulations can lead to trade gains and other benefits without compromising on any safety standards or regulatory goals.

The biggest obstacle facing TTIP negotiators is the reduction of NTBs in transatlantic trade without compromising safety standards. While eliminating or reducing tariff barriers to trade will also create gains, the benefits from reducing NTBs are far greater than those incurred from reducing the already low tariffs between the United States and the EU. These NTBs, which mostly consist of regulatory divergences between the United States and the EU, have large cost impacts that can lead to billions of U.S. dollars of potential gains upon elimination or reduction of the NTBs. Reducing NTBs requires U.S. and EU trade negotiators to acknowledge regulatory divergence and redundancy while simultaneously working towards regulatory coherence. In order for TTIP to have the maximum possible gains and benefits, the United States and EU must apply mutual recognition to substantively similar regulations or reconcile existing regulations to work towards regulatory coherence. If regulations cannot be mutually recognized for substantive compatibility, then the best way to achieve regulatory coherence in TTIP negotiations is to apply a modified cost-benefit analysis that reconciles pure cost-benefit analysis with the precautionary principle.

