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Adding Insult to Injury: Food Additives and U.S./ EU International Trade

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A Introduction

Food additives have played an essential role in human development for centuries.[1] From pickling with vinegar to preserving with salt, additives serve both as a safeguard for human health and a facilitator of population growth.[2] Since the latter half of the twentieth century, the number of food additives that have been introduced has exploded to nearly 4,000.[3] With the increasing adoption of processed foods, safety regulation has taken a more prominent—but questionably effective—role in the regulatory scheme.[4] For example, boric acid was widely used as a food preservative from the 1870s through the 1920s, but was banned after World War I due to numerous animal and human studies demonstrating its toxicity.[5] In the United States, this led to the adoption of the Delaney

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1 *See* The Business of Food: Encyclopedia of the Food and Drink Industries 1 (Gary Allen & Ken Albala, eds., 2007).

2 See Tori Avey, *History in a Jar: The Story of Pickles*, PBS Food (Sept. 3, 2014) http://www.pbs.org/food/the-history-kitchen/history-pickles/; Mark Kurlansky, Salt: A World History 38 (2003).

3 *See* U.S. Food and Drug Admin, Everything Added to Food in the United States (EAFUS), (Nov. 26, 2014), http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm115326.htm.

4 *See* Subcomm. on Sci. and Tech., FDA Science and Mission at Risk 5 (2007).

5 During World War II, the urgent need for cheap, available food preservatives led to boric acid being used again until the 1950s, when it was banned once more. Nonetheless, the Panel on Food Additives and Nutrient Sources added to Food (ANS) recently reauthorized the use of boric acid in the EU for use as preservatives of sturgeon eggs (caviar) in 2013. *See* Luke R. Bucci, Nutrition Applied to Injury Rehabilitation and Sports Medicine 151 (1995); 64 The Outlook (Rev. Lyman Abbott ed.) 403 (1900); *Scientific Opinion on the re-evaluation of boric acid (E 284) and sodium tetraborate (borax) (E 285) as food additives*, EFSA Journal (Oct. 24, 2013), http://www.efsa.europa.eu/en/efsajournal/pub/3407.htm.

clause, an amendment to the Federal Food, Drug, and Cosmetic Act of 1938, stating that no carcinogenic substances may be used as food additives.[6]

A merchant in the United States wishing to export goods must consider not only these types of statutory limitations, but those of the importing nation as well.[7] Because exports earn revenue and create jobs, a nation tends to encourage exports rather than limit them and domestic export controls tend to be more moderate.[8] In fact, export controls are imposed more for political or foreign policy reasons than for economic reasons.[9]

A major example of this is the Export Administration Act of 1979 (EAA).[10] This Act makes a number of congressional policy statements that suggest an intent to restrict export controls to only those necessary to achieve certain political goals.[11] That said, the Export Administration Act is of limited duration: enacted in 1979 and last amended (extended) in 1985.[12] Although the Act expired in 1994, every President since has extended the duration of the EAA by declaring a state of emergency under the International Emergency Economic Powers Act (IEEPA) in order to continue control over exports.[13]

Congress' power to regulate exports as expressed in these laws originates from the foreign commerce clause; it is the same provision establishing congressional authority to regulate imports.[14] For nations that are members of the World Trade Organization (WTO), import controls are the most identifiable violation of non-economic trade sanction modalities.[15] Export controls are mentioned in the WTO and General Agreement on Tariffs and Trade (GATT) agreements, but

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[6] *See* U.S. FOOD AND DRUG ADMIN, *Generally Recognized as Safe (GRAS)*, http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/ucm2006850.htm.

[7] *See* STEVE CARTER, GLOBAL AGRICULTURAL MARKETING MANAGEMENT (1997), *available at* http://www.fao.org/docrep/W5973E/w5973e08.html.

[8] *See* LES DLABAY ET AL., INTRO TO BUSINESS 56 (7th ed., 2008).

[9] *See* ZACHARY A. SELDEN, ECONOMIC SANCTIONS AS INSTRUMENTS OF AMERICAN FOREIGN POLICY 4 (1999).

[10] The Export Administration Act of 1979, Pub. L. No.108–458, 50 U.S.C. App. 2401, *available at* http://legcounsel.house.gov/Comps/eaa79.pdf.

[11] In a recent case, U.S. Senator Bob Corker (the ranking Republican on the Senate Committee on Foreign Relations) introduced a bill imposing against "foreign persons" the risk of exposure to severe U.S. sanctions if the President of the United States of America "determines that the foreign person knowingly makes a significant investment in a special Russian crude oil project." *See* Louis Rothberg & Margaret M. Gatti, *New Senate Bill Significantly Expands U.S. Sanctions Against Russia*, INT'L TRADE & ECON. SANCTIONS PRACTICE (Dec. 9, 2014), http://www.morganlewis.com/pubs/IT_LF_NewSenateBillExpandsSanctionsRussia_9dec14.

[12] *See* John R. Liebman, *The Export Administration Amendments Act of 1985*, 20 THE INT'L LAWYER 367 (1986).

[13] 50 U.S.C.A. §§170107 (West), *available at* http://www.treasury.gov/resource-center/sanctions/Documents/ieepa.pdf.

[14] U.S. CONST. Art. I, §8, *available at* http://www.law.cornell.edu/constitution/articlei.

[15] The World Trade Organization (WTO) is an organization that serves to supervise and liberalize international trade. The WTO deals with regulation of trade between participating countries by providing a framework for negotiating and formalizing trade agreements and a dispute resolution process aimed at enforcing participants' adherence to WTO agreements, which are signed by representatives of member governments and ratified by their parliaments. The WTO's predecessor, the General Agreement on Tariffs and Trade (GATT), was established after World War II in the wake of other new multilateral institutions dedicated to international economic cooperation. In the

as a practical matter there are no GATT or WTO obligations that significantly affect a country's use of export controls.[16] Introductory GATT language speaks of helping developing nations "share in the growth of international trade," which undoubtedly includes exports.[17]

In this note, I analyze the trade regulations of the food additive market between the United States and the European Union. In the first section, I discuss the system of export controls in the United States before turning, in the second section, to general European Union import policy and defining case law. In the third section, I examine the governing bodies of the European Union on banned additives before, lastly, considering U.S. leniency and concluding that the key to expediting trade relations lies not in loosening regulations, but rather imposing more stringent domestic standards on the use of food additives—both now and for the future.

B U.S. Export Controls

The Bureau of Industry and Security (BIS) is responsible for implementing and enforcing the Export Administration Regulations (EAR) in the United States.[18] The BIS regulates the export and re-export of most commercial items, as well as establishes the licensing requirements of certain commodities necessary to export.[19] There are different requisites for lawful export depending on the product or service being exported, and the specific restrictions vary from country to country.[20]

During the mid-1970s, the United States adopted two laws that sought to counteract the participation of U.S. citizens in other nations' economic boycotts or embargoes.[21] These "antiboycott" laws were the 1977 amendments to the

absence of an international organization for trade, the GATT rose to the level of a de facto international organization. *See* Krista N. Schefer, Social Regulation in the WTO: Trade Policy and International Legal Development 103 (2010); *see also* Peter Van Den Bossche & Werner Zdouc, The Law and Policy of the World Trade Organization 81 (2012); John H. Jackson, *Managing the Trading System: The World Trade Organization and the Post Uruguay Round GATT Agenda*, Managing the World Economy: Fifty Years after Bretton Woods (Peter B. Kenen ed.) 134 (1994).

16 *See* World Trade Org., *The GATT years: from Havana to Marrakesh*, Understanding the WTO: Basics, http://wto.org/english/thewto_e/whatis_e/tif_e/fact4_e.htm.

17 *See* World Trade Org., *Trade and development*, Millenium Development Goals, http://www.wto.org/english/thewto_e/coher_e/mdg_e/development_e.htm.

18 *See Introduction to Commerce Department Export Controls*, U.S. Dep't of Commerce Bureau of Indus. & Sec. (Aug. 2010), *available at* http://www.bis.doc.gov/index.php/forms-documents/doc_view/142-eccn-pdf.

19 For the most up-to-date database of Export Administration Regulations, *see Export Administration Regulation Downloadable Files*, U.S. Dep't of Commerce Bureau of Indus. and Sec., *available at* http://www.bis.doc.gov/index.php/regulations/export-administration-regulations-ear.

20 To learn more about country-specific regulations, *see Lists of Parties of Concern*, U.S. Dep't of Commerce Bureau of Indus. & Sec., *available at* http://www.bis.doc.gov/index.php/policy-guidance/lists-of-parties-of-concern.

21 *See* Ralph H. Folsom et al., International Trade and Economic Relations in a Nutshell 190–92 (5th ed. 2012).

Export Administration Act (EAA) and the Ribicoff Amendment to the 1976 Tax Reform Act (TRA).[22] The antiboycott laws were adopted to encourage—and, in specified cases, require—domestic firms to refuse from taking part in foreign boycotts that the United States does not sanction.[23] They have the effect of preventing U.S. firms from being used to implement foreign policies of other nations that run counter to U.S. policy.[24]

Similarly, Section 301 of the Trade Act of 1974 is one of the most politically motivated provisions of the U.S. trade laws.[25] This section applies when the rights or benefits of the United States under international trade agreements are at risk or when foreign nations engage in unjustifiable, unreasonable, or discriminatory conduct.[26] Section 301 authorizes (and in some cases mandates) unilateral U.S. retaliation if another nation is in breach of a trade agreement or engaging in said conduct.[27] Amendments contained in the Trade and Tariff Act of 1984 broadened the scope of Section 301 to include a great deal of flexibility and discretion in determining the existence of, and appropriate retaliatory responses to, these practices.[28]

That said, the United States' adherence to the WTO package of Covered Agreements, including the Dispute Settlement Understanding (DSU), has reduced the frequency with which the United States singly invokes Section 301.[29] The DSU obligates its signatories to follow streamlined dispute settlement procedures under which unilateral retaliation is restrained until the offending nation has

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[22] Export Administration Act of 1979, Pub. L. No. 96-72, 93 Stat. 503. http://www.gpo.gov/fdsys/pkg/STATUTE-93/pdf/STATUTE-93-Pg503.pdf; The Tax Reform Act of 1976, Pub. L. No. 94-455, 94 Stat. 503.; The Tax Reform Act of 1976, Pub. L. No. 94-455, 94 Stat. 503, *amended by* 26 U.S.C. §999 (1976); The Ribicoff Amendment to the 1976 Tax Reform Act may also be found online, *available at* http://www.jct.gov/s-31-76.pdf.

[23] *See Office of Antiboycott Compliance (OAC)*, U.S. DEP'T OF COMMERCE BUREAU OF INDUS. & SEC., http://www.bis.doc.gov/index.php/enforcement/oac.

[24] For example, in 1977, the United States Congress and then-President Jimmy Carter levied fines against American companies cooperating with the systematic effort by Arab League member states to economically isolate Israel. Historically, the boycott was designed to deter Jewish immigration to the region—preventing Arab states and discouraging non-Arabs from providing support to Israel. However, there were some American companies (such as McDonald's) that preferred to pay the fine than break the boycott, and thus endanger loss of business with the Arab world. Folsom, *supra* note 21, at 192–95; *see also* CHRIS E. TOFFOLO, THE ARAB LEAGUE 65 (1st ed. 2008).

[25] FOLSOM, *supra* note 21, at 198–203.

[26] *Id. See also Section 301*, U.S. DEP'T OF COMMERCE INT'L TRADE ADMIN. (Sept. 26, 2013), http://www.trade.gov/mas/ian/tradedisputes-enforcement/tg_ian_002100.asp.

[27] *See* 19 U.S.C. §2415 (1975), *available at* http://www.law.cornell.edu/uscode/text/19/2415.

[28] Under Section 301, for instance, the United States Trade Representative (USTR) is authorized to investigate trade-related complaints submitted by U.S. industries regarding unfair trading practices. One such investigation occurred in May 1991, when the USTR threatened to impose $1.5 billion in trade sanctions against China for violations of patent and copyright law. *See* PAUL R. PARADISE, TRADEMARK COUNTERFEITING, PRODUCT PIRACY, AND THE BILLION DOLLAR THREAT TO THE U.S. ECONOMY 36–37, 49 (1999); *see also* Marc A. Moyer, Comment, *Section 301 of the Omnibus Trade and Competitiveness Act of 1988: A Formidable Weapon in the War against Economic Espionage*, 15 NW. J. INT'L L. & BUS. 178 (1994).

[29] *See* THOMAS A. ZIMMERMANN, NEGOTIATING THE REVIEW OF THE WTO DISPUTE SETTLEMENT UNDERSTANDING 59–61 (2006).

failed to conform to a WTO ruling.[30] However, disputes falling outside the scope of the WTO agreements, as well as those disputes with non-WTO members, remain vulnerable to Section 301.[31]

Due to the nature of export policy and its undisputed positive economic impact, the United States pragmatically places few limitations on domestic firms—beyond, of course, those deemed politically significant. As a result, an internal reassessment of permissible additives is unlikely to arise from governmental administration, but rather a financial decision on the part of private actors as a result of external, commercial pressure. In light of that, it is valuable to examine the European Union's international trade policy.

C E.U. Import Policy

The Treaty on the Functioning of the European Union (TFEU) requires member states to coordinate and implement a common commercial policy toward non-member states.[32] Member states may adopt measures, or broad guidelines, for the purpose of coordinating economic policies within the Union—such as uniform principles regarding tariff and trade agreements, fishing rights, export policy, and other matters of external concern.[33] The TFEU attempted to achieve free movement of goods by establishment of a customs union to eliminate customs duties and all other charges having "equivalent effect" between member states.[34] No customs are levied on goods traveling within the member states, even those emanating from elsewhere in "free circulation."[35] A common customs tariff (CCT) with outside nations has also been imposed on those goods entering the Union.[36] The combined effect of the removal of internal tariffs and the creation of the CCT has been to encourage the free circulation of goods among member states and, arguably, to reduce trade with outside states.[37]

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[30] *Id. See also* Laura Carlisle & Phoebe Seers, The WTO Dispute Resolution Process (2013), *available at* http://a4id.org/sites/default/files/user/Legal%20Guide_WTO%20Dispute%20resolution.pdf.

[31] *See* Jeffrey M. Hirsch & Samuel Estreicher, Compensation, Work Hours and Benefits: Proceedings of the New York University 57th Annual Conference on Labor 9–10 (2009).

[32] Folsom, *supra* note 21, at 295–96.

[33] *Id. See also* Consolidated Version of the Treaty on the Functioning of the European Union Art. 2–6, 2008 O.J. c 115/47, *available at* http://euwiki.org/TFEU#TITLE_I_-__CATEGORIES_AND_AREAS_OF_UNION_COMPETENCE.

[34] Folsom *supra* note 21, at 275–78.

[35] *See* Consolidated Version of the Treaty on the Function of the European Union Art. 28–37, 2008 O.J. c 115/47, *available at* http://euwiki.org/TFEU#TITLE_II_-_-_FREE_MOVEMENT_OF_GOODS.

[36] *See What is the Common Customs Tariff?*, European Commission Taxation and Customs Union (Sept. 12, 2014), http://ec.europa.eu/taxation_customs/customs/customs_duties/tariff_aspects/index_en.htm.

[37] For an analysis of the empirical evidence on this point, *see Regional Integration: Observed Trade and Other Economic Effects*, Org for Econ. Co-operation and Dev. (Oct. 19 2001), *available at* http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=TD/TC/WP(2001)19/FINAL&docLanguage=En; *see also* Bart v. Vooren & Ramses A. Wessel, EU External Relations Law 281–85 (2014).

Historically, independently imposed standards operated as barriers to trade within the European Union.[38] Perhaps the most famous example is *Rewe-Zentral AG v. Bundesmonopolverwaltung für Branntwein*, also known as the "Cassis de Dijon" case.[39] A German importer, Rewe, intended to import into Germany "Cassis de Dijon," a blackcurrant liqueur originating in France.[40] At that time, the prevailing rule in Germany necessitated a minimum alcohol content of 25 percent by volume for fruit liquors, thus the German Federal Monopoly for Spirits informed the importer that the fruit liqueur—having an alcohol content between 15 and 20 percent by volume—could not be marketed in Germany.[41] In 1979, the Court of Justice of the European Communities held that, even though the German rules on alcohol levels for different categories of spirit applied to all beverages regardless of their origin, its application constituted a measure having an effect equivalent to a quantitative restriction on trade.[42]

Such restrictions are only permissible if their genuine purpose is equitable; for example, though member states may enact "reasonable" and "proportional" (i.e. no broader than necessary) regulations to ensure that the public is not harmed, they must not pursue other aims using public health as an excuse, nor may they either procedurally or substantially favor domestic manufacturers or goods over those of other member states.[43] In other words, products meeting reasonable national criteria must be freely tradable elsewhere in the region.[44] Historically, the Court has used a Rule of Reason analysis for national fiscal regulations, public health measures, laws governing the fairness of commercial transactions, and consumer protection.[45] Nevertheless, the Court of Justice has made it clear that all of the Rule of Reason justifications for national laws are purely transitory.[46]

While not intended to promote or justify non-tariff barriers (NTBs), the TFEU qualifies the free movement of goods within the Common Market.[47] National prohibitions or restrictions on imports and exports may be justified on

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[38] *See* WILLIAM A. KERR & JAMES D. GAISFORD, HANDBOOK ON INTERNATIONAL TRADE POLICY 400 (2007).

[39] *See* Rewe-Zentral AG v. Bundesmonopolverwaltung für Branntwein [1979] ECR 649 (Ger.), *available at* http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:61978CJ0120.

[40] *See* CHRIS TURNER & TONY STOREY, UNLOCKING EU LAW 357–58 (2014).

[41] Specifically, the German government argued to the Court of Justice that such a rule was justified for protection of the public and for protection of consumers against unfair competition. *See* ESA ÖSTERBERG & THOMAS KARLSSON, ALCOHOL POLICIES IN EU MEMBER STATES AND NORWAY: A COLLECTION OF COUNTRY REPORTS 52 (1998).

[42] *See* PAUL CRAIG & GRÁINNE DE BÚRCA, EU LAW: TEXT, CASES AND MATERIALS 677–79 (4th ed. 2011).

[43] *See* REINER SCHULZE ET AL., A CASEBOOK ON EUROPEAN CONSUMER LAW 43 (2002).

[44] *See* MICHAEL W. GORDON & JOHN A. SPANOGLE, JR., INTERNATIONAL BUSINESS TRANSACTIONS 191 (2009).

[45] *See* RALPH H. FOLSOM, INTERNATIONAL BUSINESS TRANSACTIONS: A PROBLEM-ORIENTED COURSEBOOK 480 (2006).

[46] *See* 2 RALPH H. FOLSOM & MICHAEL W. GORDON, INTERNATIONAL BUSINESS TRANSACTIONS 340 (1995).

[47] "Common Market" is term for a group formed by countries within a geographical area to promote duty free trade and free movement of labor and capital among its members. *See* NICOLAS DE SADELEER, ENVIRONMENTAL LAW AND THE INTERNAL MARKET 263 (2014).

grounds of public morality, public policy, or public security, including: health and safety laws, measures to safeguard national treasures, and industrial and commercial property protection laws.[48] However, such prohibitions or restrictions may not "constitute a means of arbitrary discrimination or a disguised restriction on trade between member states."[49] Although the public health escape clause has attracted headlines in some culturally symbolic litigation, the European Court had relatively little trouble in rejecting these arguments.[50]

For instance, in the case of *Commission of the European Communities v. Federal Republic of Germany*, Germany sought to invoke the public health exception to keep out beer from other member states that did not meet its purity standards.[51] The purity law originated in 1487, when Albert IV, Duke of Bavaria, declared that only three ingredients—water, malt, and hops—could be used for the brewing of beer.[52] Thirty years later, in the city of Ingolstadt in the duchy of Bavaria, two other dukes (including Duke Wilhelm IV of Bavaria) endorsed the law and added standards to the sale of beer.[53] Regulations similar to the German Beer Purity Law, *Reinheitsgebot* in German, were incorporated into various guild regulations and local laws all over Germany until 1952, when they were incorporated into the West German Beer Taxation Law, the *Biersteuergesetz*.[54] In 1988, a European Court of Justice ruling led to the *Reinheitsgebot*

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[48] Treaty on the Functioning of the European Union, *supra* note 33.

[49] *See* Regina v. Maurice Donald Henn and John Frederick Ernest Darby [1979] ECR 295 (U.K.), *available at* `http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:61979CJ0034#text`.

[50] *See* Catherine Barnard, The Substantive Law of the EU: The Four Freedoms 188 (2013).

[51] See Mimi Y. Lee, Note, *Commission v. Germany and Article 36 Protection of Human Life and Health*, 9 NW. J. Int'l L. & Bus. 444, 445–46 (1988).

[52] In the original text, the only ingredients that could be used for the production of beer were water, barley, and hops. This regulation, or *Reinheitsgebot* (literally "purity order"), was introduced in part to prevent price competition with bakers for wheat and rye. Yeast was not mentioned as a component; it was not until the 19th century that Louis Pasteur discovered the role of microorganisms in fermentation. Brewers generally took some sediment from the previous fermentation and added it to the next, the sediment generally containing the necessary organisms to perform fermentation. If none were available, brewers would rely on natural airborne yeast to inoculate the brew. The role of hops as an additive was not only to impart flavors, but also to act as a preservative. Their mention in the *Reinheitsgebot* was meant to prevent alternative methods of preserving beer that had been used before the introduction of hops. In the past, medieval brewers had used many problematic ingredients to preserve beers—such as soot and fly agaric mushrooms. According to the *Reinheitsgebot*, the penalty for making impure beer was to have the questionable barrels confiscated without compensation, *See* Ian S. Hornsey, A History of Beer and Brewing 320 (2003); 1 The SAGE Encyclopedia of Alcohol: Social, Cultural, and Historical Perspectives 301 (Scott C. Martin ed.) (2015); Robert W. Hutkins, Microbiology and Technology of Fermented Foods 315 (2008).

[53] The *Reinheitsgebot* continued to spread slowly throughout Bavaria and Germany throughout the next several centuries. Bavaria insisted on its application throughout Germany as a precondition of German unification in 1871 in order to prevent competition from beers brewed elsewhere from a wider range of ingredients. The move encountered strong resistance from brewers outside Bavaria; by restricting the allowable ingredients, many native brewing traditions and local beer specialties went extinct. *See* Patrick Love & Ralph Lattimore, International Trade: Free, Fair, and Open? 69 (2009).

[54] *See* John Wiley, Encyclopedia on Brewing 509 (2013).

being lifted, allowing ingredients beyond those listed in the *Biersteuergesetz*.[55] The Court held that the *Reinheitsgebot* constituted an unlawful restriction on trade, and could not be justified under the protection of human health exception as the prohibited additives were approved for use in other beverages.[56]

Likewise, the Italian Pasta Purity Law, which reserved the term "pasta" for only those products made wholly from hard durum wheat grown in the south of Italy, was overruled by the International Court of Justice in 1988.[57] The case arose when West German pasta producer Drei Glocken was blocked in 1985 from bringing pasta made with mixed wheat into Italy.[58] Similar to the German Beer Purity case, the Court held that Italy could only require its own pasta makers to use pure durum wheat unless there was "evidence to support the assertion that pasta products made from common wheat…necessarily contain chemical additives or colorants."[59]

A background study for the Cecchini Report characterized the law as a "technical barrier to intra-EC trade masquerading as an innocent product recipe."[60] According to the Report, its abolition would save a predicted 22 to 66 million dollars between 1987 and 1992 as a result of the creation of a genuine common market.[61] Nevertheless, Italian pasta makers insisted that the issue was not one

[55] Effectively, the lifting of the *Biergesetz* allowed any other ingredient used in other foods to also be allowed in beer. However, the lift only concerned imported beer; beer brewed in Germany must still follow the law. The revised *Vorläufiges Biergesetz* of 1993 is a slightly expanded version of the *Reinheitsgebot*, stipulating that only, water, malted barley, hops, and yeast be used for any bottom-fermented beer, while top fermented beer is subject to the same rule with the addition of malt and sugar adjuncts. Nevertheless, many German breweries continue to comply with the *Biergesetz*, and often claim compliance with the *Reinheitsgebot* even when it is patently incorrect (for example, wheat beer which was explicitly prohibited by the *Reinheitsgebot*). Today, the *Reinheitsgebot* has become a valuable marketing tool within the German community. *See* BENJAMIN MARIENFELD, THE SIGNIFICANCE OF BRANDING WITHIN THE GERMAN BEER CULTURE 3 (2009); EDUARDO PIRES & TOMÁŠ BRÁNYIK, BIOCHEMISTRY OF BEER FERMENTATION 2 (2015).

[56] Until superseded by a change in EU law, the *Reinheitsgebot* was also enforced in Greece due to a law by the first Greek king, originally a Bavarian prince, which had remained in effect for over a hundred years. *See* ANDREAS HOFMANN, STRATEGIES OF THE REPEAT PLAYER: THE EUROPEAN COMMISSION BETWEEN COURTROOM AND LEGISLATURE 4–5 (2013); *see also* DOMINIK LASOK, THE TRADE AND CUSTOMS LAW OF THE EUROPEAN UNION 79 (1998).

[57] *See* 3 Glocken GmbH and Gertraud Kritzinger v. USL Centro-Sud and Provincia autonoma di Bolzano (407/85) [1988] ECR 4233, *available at* `http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:61985CJ0407`.

[58] The case, dubbed "Pasta Wars" by the Italian press, was regarded as culturally significant as it was economically. *See Italy's Law on 'Pasta Purity' is Overturned*, L.A. TIMES (July 14, 1988), `http://articles.latimes.com/1988-07-14/news/mn-8941_1_pasta-makers`.

[59] "[I]t is the extension of the law on pasta products to imported products which is at issue, and…Community law does not require the legislature to repeal the law as far as pasta producers established on Italian territory are concerned." Glocken GmbH, *supra* note 57, at ¶¶ 13, 25.

[60] DAVID VOGEL, TRADING UP: CONSUMER AND ENVIRONMENTAL REGULATION IN A GLOBAL ECONOMY 37 (2009); The Cecchini Report is a 1988 report by a group of experts, chaired by Paolo Cecchini, examining the benefits and costs of creating a single market in Europe in accordance with provisions of the Treaty of Rome. *See* CATALIN S. RUSU, EUROPEAN MERGER CONTROL: THE CHALLENGES RAISED BY TWENTTY YEARS OF ENFORCEMENT EXPERIENCE app. 1 (2010).

[61] *Id*. *See* Richard F. Emery et al., *The Single Market: A Look at its Benefits and Recommendations for Further Progress*, 33RD ANNUAL EUROPEAN STUDIES CONFERENCE (Oct. 2–4, 2008), *available at* `http://www.unomaha.edu/esc/2008Proceedings/EmeryMarket.pdf`.

of trade barriers.[62] The spokesman for Barilla, the world's largest pasta producer, stated that imported pasta could cost up to 30 percent less than the kind made with durum wheat, but predicted that few Italians would switch brands.[63]

Another recent example of this type of inter-member cultural war is the case of *Commission of the European Communities v. Italian Republic*.[64] When Britain joined the European Union in 1973, existing EU member states defined "chocolate" as dark chocolate made with a high percentage of cocoa and cocoa butter.[65] Britain, however, specialized in producing milk chocolate sweets and often utilized vegetable fats in their manufacture process.[66] In 1999, facing substantial barriers to trade, the European Union reached a compromise: milk chocolate of about 20 percent milk and with up to five percent vegetable fat would be cleared for sale on the continent if labeled with "Family Milk Chocolate," a statement regarding the vegetable fats, or both.[67] Nevertheless, Spain and Italy continued to restrict sales of British chocolate entering their respective markets.[68] The dispute was finally resolved in 2003 when the European Court of Justice ordered Spain and Italy to lift the restrictions, holding that the characteristic element of all products bearing the name chocolate is the presence of a certain minimum cocoa and cocoa butter content, and that the addition of vegetable fats did not substantially alter the nature of those products.[69]

The overall trend within the European Union has been to facilitate the open and free transfer of goods among member states, while at the same time presenting a united—and noticeably more restrictive—barrier to outside nations. Limitations on food additives, however, encounter particular complications: nontariff barriers (NTBs), as denoted by the TFEU, are considered through a standard of proportionality when evaluating national fiscal regulations in regards to public health measures and consumer protection. Nevertheless, the Court of

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[62] *Will Italy Be Invaded by Limp Linguine?*, N.Y. Times (July 20, 1988), http://www.nytimes.com/1988/07/20/garden/will-italy-be-invaded-by-limp-linguine.html.

[63] In fact, rather than giving rise to a competitive disadvantage, the use of better quality (and thus more expensive) raw materials provided the reverse. In the case of Italian Pasta Purity Law, it was predicted that the domestic product would see an increase in demand since the lower price of imported pasta would not carry the guarantee of equal quality. *See* Alina Tryfonidou, Reverse Discrimination in EC Law 34–35 (2009).

[64] See Commission of the European Communities v. Italian Republic (14/00) [2003] ECR I-513, *available at* http://curia.europa.eu/juris/showPdf.jsf;jsessionid=9ea7d2dc30db85e20e44e74e4c9087c58f3e7035fe6e.e34KaxiLc3qMb40Rch0SaxqT

[65] The FSA Guidance on the Cocoa and Chocolate Products Regulations (revised June 2009) may be found online at http://www.food.gov.uk/sites/default/files/multimedia/pdfs/chocguidancejun2009.pdf.

[66] So-called chocolate "purists," led by Belgium and France, expressly campaigned against Britain's vegetable oil use. In response, EU law allowed each member state to decide whether or not to ban the use of vegetable fats in its own and imported chocolate. Up until the ruling, seven EU countries allowed vegetable fat and eight—Belgium, France, Italy, Spain, Luxembourg, Germany, Greece and Holland—chose not to sell the product. *See Sweet victory for UK chocolate*, BBC News (Mar. 15, 2000), http://news.bbc.co.uk/2/hi/uk_news/678141.stm.

[67] Unsurprisingly, developing African nations took special interest in the matter as several of the major exporters of cocoa butter. *See* Peggy Kahn, The European Union 30–31 (2009).

[68] *See Britain wins EU chocolate battle*, CNN World (Jan. 16, 2003), http://www.cnn.com/2003/WORLD/europe/01/16/chocolate.war/.

[69] *See* Richard Schaffer et al., International Business Law and its Environment 501–03 (2008).

Justice has yet to uphold historic or cultural arguments as reasonable grounds for NTBs to trade between members. The scientific developments surrounding the European Food Safety Authority (EFSA) Panel on Food Additives and Nutrient Sources Added to Food (ANS), on the other hand, appear to be the most likely source for successful changes in policy implementation.

D EU LAW AND BANNED ACTIVITIES

The history of food additive policy can be traced back to the creations of the Food and Agriculture Organization (FAO) in 1945 and of the World Health Organization (WHO) in 1948.[70] These two organizations collectively began a series of expert meetings on nutrition and related areas.[71] By 1950, it was evident that "food regulations in different countries are often conflicting and contradictory…New legislation not based on scientific knowledge is often introduced, and little account may be taken of nutritional principles in formulating regulations."[72] Food additives were no exception, which "must in itself occasion concern, since the existence of widely differing control measures may well form an undesirable deterrent to international trade."[73]

In 1955, the fourth report of the Joint FAO/ WHO Expert Committee on Nutrition confirmed: "The increasing, and sometimes insufficiently controlled, use of food additives has become a matter of public and administrative concern."[74] Three years later, the Treaty Establishing the European Economic Community (TEEC), also known as the Treaty of Rome, led to the founding of the European Economic Community (EEC) and the first opportunity to determine unified, enforceable standards.[75] The three most important articles of the Treaty on the subject of international trade are Articles 30, 34, and 36.[76] Articles 30 and 34 prohibit restrictions placed on the importation and exportation of goods between member states, while Article 36 allows an exception to such restrictions in the case of public morality, public order, public safety, the protection of human or animal life or health, the preservation of plant life, the protection of national treasures of artistic, historical or archaeological value, or the protection

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70 See NAOMI REES & DAVID WATSON, INTERNATIONAL STANDARDS FOR FOOD SAFETY 3 (2000).

71 *Id.* at 3–4.

72 WORLD HEALTH ORG., TECHNICAL REPORT SERIES NO. 16: JOINT FAO/ WHO EXPERT COMMITTEE ON NUTRITION, REPORT ON FIRST SESSION, at 24 (1949).

73 WORLD HEALTH ORG., TECHNICAL REPORT SERIES NO. 97: JOINT FAO/ WHO EXPERT COMMITTEE ON NUTRITION, FOURTH REPORT, at 31 (1949).

74 *Id.* at 30.

75 The Treaty of Rome proposed to create a common market of goods, workers, services and capital within the EEC's member states. *See* Giuseppe Tesauro, *Some Reflections on the Commission's White Paper on the Modernization of EC Antitrust Policy*, in 5 EUROPEAN COMPETITION LAW ANNUAL 2000: THE MODERNIZATION OF EC ANTITRUST POLICY 259 (Claus-Dieter Ehlermann & Isabela Atanasiu eds., 2001).

76 The Treaty of Rome was restyled as the Treaty on the Functioning of the European Union (TFEU) on the entry into force of the Treaty of Lisbon in 2009. As a result, Articles 30, 34, and 36 are now Articles 28, 29, and 30 respectively. *See* JOHN TILLOTSO & NIGEL FOSTER, TEXT, CASES, AND MATERIALS ON EUROPEAN UNION LAW 488–89 (4th ed. 2003).

of industrial and commercial property.[77] The application of Article 36 between member states, as demonstrated in the case law, discounts the precautionary principle in pursuance of actual economic consequences on trade.[78] Nevertheless, although the European Court has little regard for measures from individual member states, the Court of Justice has traditionally taken a more deferential role to the discretionary powers of EU regulatory institutions.[79] In *Criminal proceedings against Sandoz BV*, for example, the Court spoke of the risk as consequential and approvingly referred to EC legislation: "[T]he great prudence

[77] This last portion of Article 36 is also known as the public health "escape clause." *See* TFEU Article 30 (now 28): "Quantitative restrictions on importation and all measures with equivalent effect shall, without prejudice to the following provisions, hereby be prohibited between Member States."; TFEU Article 34 (now 29): "(1) Quantitative restrictions on exportation and any measures with equivalent effect shall hereby be prohibited as between Member States…"; *see also* TFEU Article 36 (now 30):

> The provisions of Articles 30 to 34 inclusive shall not be an obstacle to prohibitions or restrictions in respect of importation, exportation or transit which are justified on grounds of public morality, public order, public safety, the protection of human or animal life or health, the preservation of plant life, the protection of national treasures of artistic, historical or archaeological value or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute either a means of arbitrary discrimination or a disguised restriction on trade between Member States.

TFEU, *supra* note 33, at Article 36; *see id*. at Article 34 ("Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States.").

[78] The precautionary principle states that if an action or policy has a suspected risk of causing harm to the public, in the absence of scientific consensus that the action or policy is not harmful, the burden of proof falls on those taking an action. Policy makers use the principle to justify discretionary decisions in situations where there is the possibility of harm, but scientific knowledge on the matter is deficient. The principle implies that there is a social responsibility to protect the public from exposure to harm when scientific investigation has demonstrated a plausible risk. *See* Miguel A. Recuerda, *Dangerous Interpretations of the Precautionary Principle and the Foundational Values of the European Union Food Law: Risk versus Risk*, 4:1 J. Food L. & Pol'y 1 (2008). In the law of the European Union, the application of the precautionary principle has been made a statutory requirement. For example, on February 2, 2000, the European Commission issued a Communication in which it adopted a procedure for the application of this concept. *See Communication from the Commission on the Precautionary Principle*, COM (2000) 1 final (Feb. 2, 2000), *available at* `http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A52000DC0001`. As of 2006, the standard has come to inform much of EU policy, including integration into EU laws "in matters such as general product safety, the use of additives for use in animal nutrition, the incineration of waste, and the regulation of genetically modified organisms." Miguel A. Recuerda Gierla, *Risk and Reason in the European Union Law*, 5 Eur. Food & Feed L. Rev. 270, 282–83 (2006) (footnotes omitted). In the law of the European Union, the application of the precautionary principle has been made a statutory requirement. For example, on February 2, 2000, the European Commission issued a Communication in which it adopted a procedure for the application of this concept. *See Communication from the Commission on the Precautionary Principle*, COM (2000) 1 final (Feb. 2, 2000), *available at* `http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A52000DC0001`. As of 2006, the standard has come to inform much of EU policy, including integration into EU laws "in matters such as general product safety, the use of additives for use in animal nutrition, the incineration of waste, and the regulation of genetically modified organisms." Miguel A. Recuerda Gierla, *Risk and Reason in the European Union Law*, 5 Eur. Food & Feed L. Rev. 270, 282–83 (2006)(footnotes omitted).

[79] Ellen Vos, *The European Court of Justice in the Face of Scientific Uncertainty and Complexity*, in Judicial Activism at the European Court of Justice 142, 143 (Mark Dawson et al. eds., 2013).

regarding the potential harmfulness of additives, the extent of which is still uncertain in respect of each of the various substances, and leave a wide discretion to the Member States."[80] In *Ministère public v. Muller and Others*,[81] the Court referred to the EC directives on food additives—which it described as showing great prudence in regards to the potential harmfulness of such substances—as underlying the principle that the uncontrolled consumption of additives with food should be restricted as far as possible; the Court favorably characterized the directives as "a legitimate aim of health policy."[82]

However, the more recent *Ministère public v. Greenham and Léonard Abel* tempers this opinion.[83] In that case, the Court held that, inasmuch as there are uncertainties in the present state of scientific research with regard to the harmfulness of food additives, it is up to each individual member state—even without conformity—to decide what degree of "protection of the health and life of humans they intend to assure, having regard for the requirements of the free movement of goods within the Community."[84] Nevertheless, the principle of proportionality requires that the power of the member states to prohibit imports of products should be restricted to only what is necessary to attain the objectives of protection being legitimately pursued.[85] The burden of proof falls on the competent national authorities to prove that a substance is harmful and to

[80] Case C-174/82, Criminal proceedings against Sandoz BV, 1983 E.C.R. 2445, ¶ 15, *available at* http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:61982CJ0174. In this case, the Netherlands had imposed a general prohibition on the sale of food and beverages to which vitamins had been added. Unless authorization by ministerial decision had been obtained, the Dutch Government argued that it was their policy to restrict all kinds of food additives and ensure that there was no adverse effect upon public health—particularly since it was not possible to state categorically the quantity of the substance that was absorbed. *See id.*; *see also* SANDRA L. WALKER, ENVIRONMENTAL PROTECTION VERSUS TRADE LIBERALIZATION: FINDING THE BALANCE: AN EXAMINATION OF THE LEGALITY OF ENVIRONMENTAL REGULATION UNDER INTERNATIONAL TRADE LAW REGIMES 71 (1993).

[81] Case C-304/84, Ministère Public v. Muller, 1986 E.C.R. 1511.

[82] Piet Eckhout, *The EC Response*, in 4 WORLD TRADE FORUM, THE ROLE OF THE JUDGE IN INTERNATIONAL TRADE REGULATION: EXPERIENCE AND LESSONS FOR THE WTO 151, 159 (Thomas Cottier & Petros C. Mavroidis eds., 2003) (citing Muller, 1986 E.C.R. at ¶ 22).

[83] Case C-95/01, Ministère Public v. John Greenham and Lèonard Abel, 2004 E.C.R. I-01333, *available at* http://curia.europa.eu/juris/liste.jsf?language=en&num=c-95/01. Mr. Greenham and Mr. Abel, defendants in the main proceedings and joint managers of the company NSA France SARL (NSA France), were charged in 1998 with having displayed and offered for sale adulterated foodstuffs. NSA France marketed food supplements ("JUICE + mélange de légumes et de fruits") with the additive coenzyme Q10—a chemical substance not authorized in France for use in human food—as well as vitamins in amounts greater than the daily recommended intake, or in excess of the safety limits set by the Conseil supérieur d'hygiène publique de France (CSHPF). They were also charged with having misled consumers in regard to product quality by marketing meal substitutes ("JUICE + Lite, arôme chocolate et arôme vanilla"), which did not comply with either the requirements laid down in Commission Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction or the threshold set forth in the legislation for energy and certain key minerals. *See* Case c-95-01, Ministère Public v. John Greenham and Lèonard Abel (Opinion Advocate General Mischo), 2002 E.C.R. I-1335, ¶ 7, *available at* http://curia.europa.eu/juris/liste.jsf?language=en&num=c-95/01.

[84] *See* Greenham and Abel, 2004 E.C.R. at ¶ 49.

[85] This principle is widely thought to underlie the last sentence of TFEU Article 36 (now 30): TFEU, *supra* note 33, at Article 36 ("Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.").

demonstrate, on a case-by-case basis, that their legislation is necessary in order effectively to protect those interests.[86]

In so demonstrating, authorities must take account of the findings of international scientific research, and in particular of the work of the Codex Alimentarius Committee (CAC) of the Food and Agriculture Organization of the United Nations (FAO), the Community's Scientific Committee for Food, and the World Health Organization.[87] A precursor to the European Food Safety Authority, the CAC was established at the FAO Conference in 1961 with the objective of establishing international standards to facilitate food and agricultural trade.[88] During the FAO's founding during the United Nations Conference on Food and Agriculture, the organization was given a mandate to recognize food safety as an essential component to the regulatory scheme.[89] A comprehensive approach to establishing international standards for food additives began in 1989 under the framework of Dr. W. H. B. Denner, leading to the development of the Codex General Standard for the Use of Food Additives.[90]

Nevertheless, the CAC and its committees are not responsible for specific risk assessment.[91] EFSA's work on food additives is carried out by the Panel on Food Additives and Nutrient Sources Added to Food.[92] The Panel's safety evaluations involve a review of all available, relevant scientific studies and data on toxicity as well as human exposure, from which the Panel draws conclusions regarding the safety of the substance as it relates to human health.[93]

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[86] *See* Greenham and Abel (Opinion Advocate General Mischo). 2002 E.C.R. at ¶ 37. Interestingly, the Court in this case takes special issue with the marketing of the product in question as the source of the risk to public health. In so doing, however, they fail to take account of the breadth of findings of international scientific research in lieu of the consuming habits prevailing in the importing state. *Id*.

[87] Alberto Alemanno, Trade in Food: Regulatory and Judicial Approaches in the EC and the WTO 298 (2007); Greenham and Abel (Opinion Advocate General Mischo), 2002 E.C.R. at ¶ 37.

[88] Alan W. Randell, *International Food Standards: The Work of Codex*, in International Standards for Food Safety 3, 4 (Naomi Rees & David Watson Eds., 2000).

[89] *See id*.

[90] The Codex General Standard for the Use of Food Additives (FAO & WHO 1995). The Codex Alimentarius contains standards covering matters such as food labeling, food hygiene, food additives and pesticide residues, and procedures for assessing the safety of foods derived from modern biotechnology. It also contains guidelines for the management of governmental import and export inspection and certification systems for foods. There is no obligation for countries to adopt Codex standards as a member of either Codex or any other international trade organization, although the Codex is recognized by the World Trade Organization as an international reference standard for the resolution of disputes concerning food safety and consumer protection. The Codex Alimentarius may be found online at `http://www.codexalimentarius.org/about-codex/en/`; *see also* Agreement on the Application of Sanitary and Phytosanitary Measures World Trade Organization, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 69 (1999), *available at* `https://www.wto.org/english/docs_e/legal_e/15sps_01_e.htm`.

[91] *See* Foundations of EU Food Law and Policy: Ten Years of European Food Safety Authority (Simone Gabbi & Alberto Alemanno eds.) 356 (2014).

[92] *See Food Ingredients and Packaging*, Eur. Food Safety Auth., `http://www.efsa.europa.eu/en/panels/ans`.

[93] *See Food Additives*, Eur. Food Safety Auth., `http://www.efsa.europa.eu/en/topics/topic/additives.htm`.

Unlike the regulatory systems governing other chemical sectors, EFSA is required by its founding regulation to use independent scientific experts on its scientific panels.[94] These experts, however, do not serve as representatives of member state governments—instead, they are required to present science-based, independent assessments.[95] Under Regulation EU 257/2010, EFSA has the task of reviewing all additives that were authorized before 2009 in a massive reevaluation that will continue until 2020.[96]

The reevaluation has not been without controversy.[97] It has been claimed since the late 1970s that certain food colorings cause food intolerance and attention deficit hyperactivity disorder (ADHD)-like behavior in children.[98] In 2008, the Food Standards Agency of the United Kingdom called for food manufacturers to voluntarily stop using six food additive colors known as the "Southampton 6"—Tartrazine, Allura Red, Ponceau 4R, Quinoline Yellow WS, Sunset Yellow and Carmoisine—by 2009, and provided assistance in replacing the colors with safer additives.[99] Additionally, the European regulatory community required labeling and temporarily reduced the acceptable daily intake (ADI) for the food colorings, stating they "may have an adverse effect on activity and attention in children."[100] Nevertheless, in 2009 EFSA reevaluated the data at hand and determined that "the available scientific evidence does not substantiate a link between

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[94] *See* SUSAN M. BARLOW, ESSENTIAL GUIDE TO FOOD ADDITIVES 16 (Michael Saltmarsh et al. eds. 2013).

[95] *See FAQ on EFSA's Measures to Prevent Conflicts of Interest*, EUR. FOOD. SAFETY AUTH. (July 31, 2014), http://www.efsa.europa.eu/en/faqs/faqmeasurespreventconflictinterest.htm.

[96] This is significant as permitted food additives are generally not reevaluated until new data—particularly concerning consumer safety—become available. Barlow, *supra* note 94, at 18.

[97] *See* Sue Quinn, *Food Labels Deciphered: Nasty Ingredients to Look Out For*, THE TELEGRAPH (Feb. 25, 2015), http://www.telegraph.co.uk/foodanddrink/foodanddrinknews/11434202/Food-labels-deciphered-nasty-ingredients-to-look-out-for.html.

[98] For example, symptoms from tartrazine sensitivity can occur by either ingestion or cutaneous exposure to a substance containing the additive. Aspirin- and NSAID-sensitive individuals, or those who are asthmatic, are particularly susceptible. Reactions include migraine, blurred vision, itching, rhinitis and purple skin patches, and appear after exposure for periods of time ranging from minutes to hours. *See* E. Alvarez-Cuesta et al., *Pharmaceutical Preparations Which Contain Tartrazine*, 9 (1) ALLERGOL IMMUNOPATHOLOGY (MADR) 45 (1981); Joseph R. Dipalma, *Tartrazine Sensitivity*, 42 (5) AM. FAM. PHYSICIAN 1347 (1990). In regards to consumption and ADHD-like behavior in children, *see* L. D. Tomaska & S. Brooke-Taylor, Food Additives—General, 2 ENCYCLOPEDIA OF FOOD SAFETY: HAZARDS AND DISEASES (Yasmine Motarjemi et al. eds.) 449–54 (2013); J. Gordon Millichap & Michelle M. Yee, *The Diet Factor in Attention-Deficit/ Hyperactivity Disorder*, 129 (2) PEDIATRICS 1 (2012), *available at* http://pediatrics.aappublications.org/content/early/2012/01/04/peds.2011-2199.full.pdf+html.

[99] *See* Background Document for the Food Advisory Committee: Certified Color Additives in Food and Possible Association with Attention Deficit Hyperactivity Disorder in Children, FOOD ADVISORY COMM. (Mar. 30–31, 2011), *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/UCM248549.pdf.

[100] *See* Sarah Chapman, *Guidelines on Approaches to the Replacement of Tartrazine, Allura Red, Ponceau 4R, Quinoline Yellow, Sunset Yellow and Carmoisine in Food and Beverages*, FOOD STANDARDS AGENCY (Mar. 2011), *available at* http://www.food.gov.uk/sites/default/files/multimedia/pdfs/publication/guidelinessotonsixcolours.pdf.

the color additives and behavioral effects."[101] By 2014, after further review of the data, EFSA restored the prior ADI levels.[102]

A number of controversial food additives, however, have not received the same depth of consideration.[103] For example, in June 2012 the Center for Science in the Public Interest (CSPI) published results of its own study demonstrating alarming levels of carcinogens in Coca-Cola formed by ammoniated caramel coloring.[104] Nevertheless, EFSA ruled in the same year that dietary exposure was lower than the predetermined ADI level, and therefore the coloring additive was safe for consumption.[105] Sodium nitrite is responsible for the desirable red or pink color of packaged meat, but its toxicity at high doses has resulted in its application to humanely induce death in feral pigs and wild boar.[106] Propyl gallate protects the oils and fats in products from oxidation, but a 2009 study found that propyl gallate also acts as an estrogen antagonist.[107] Butylated hydroxyanisole (BHA) and butylated hydroxytoluene (BHT) have been added to edible fats and

[101] *See Scientific Opinion on the Re-evaluation of Tartrazine (E 102)*, EFSA Journal (Nov. 12, 2009), http://www.efsa.europa.eu/en/efsajournal/pub/1331.htm; *Scientific Opinion on the Re-evaluation of Allura Red (E 129) as a Food Additive*, EFSA Journal (Nov. 12, 2009), http://www.efsa.europa.eu/en/efsajournal/pub/1327.htm; *Scientific Opinion on the Re-evaluation of Ponceau 4R (E 124) as a Food Additive*, EFSA Journal (Nov. 12, 2009), http://www.efsa.europa.eu/en/efsajournal/pub/1328.htm; *Scientific Opinion on the Re-evaluation of Quinoline Yellow (E 104) as a Food Additive*, EFSA Journal (Nov. 12, 2009), http://www.efsa.europa.eu/en/efsajournal/pub/1329.htm; *Scientific Opinion on the Re-evaluation of Sunset Yellow FCF (E 110) as a Food Additive*, EFSA Journal (Nov. 12, 2009), http://www.efsa.europa.eu/en/efsajournal/pub/1330.htm; *Scientific Opinion on the Re-evaluation of Azorubine/Carmoisine (E 122) as a Food Additive*, EFSA Journal (Nov. 12, 2009), http://www.efsa.europa.eu/en/efsajournal/pub/1332.htm.

[102] *See Reconsideration of the Temporary ADI and Refined Exposure Assessment of Sunset Yellow FCF (E 110)*, EFSA Journal (July 15, 2014), http://www.efsa.europa.eu/en/efsajournal/pub/3765.htm; *see also Refined Exposure Assessment for Allura Red AC (E 129)*, EFSA Journal (Feb. 13, 2015), http://www.efsa.europa.eu/en/efsajournal/pub/4007.htm.

[103] For a current list of EU approved additives, *see Current EU approved additives and their E Numbers*, Food Standards Agency (Dec. 30, 2014), *available at* https://www.food.gov.uk/science/additives/enumberlist.

[104] *See Tests Show Carcinogen Levels in Coca-Cola Vary Worldwide*, Ctr. for the Sci. in the Pub. Interest (June 26, 2012), http://www.cspinet.org/new/201206261.html.

[105] Similarly, sodium benzoate, potassium benzoate, and calcium benzoate are approved for use as a preservative for soft drinks. However, when combined with ascorbic acid, they form benzene—a known carcinogen. *See Scientific Opinion on the Re-evaluation of Caramel Colours (E 150 a, b, c, d) as Food Additives*, EFSA Journal (Mar. 8, 2011), http://www.efsa.europa.eu/en/efsajournal/pub/2004.htm; *Scientific Opinion on the Re-evaluation of Caramel Colours (E 150 a, b, c, d) as Food Additives*, EFSA Journal (Dec. 19, 2012), http://www.efsa.europa.eu/en/efsajournal/pub/3030.htm; *see also Benzene: What is Benzene?*, Am. Cancer Soc'y (Dec. 9, 2013), http://www.cancer.org/cancer/cancercauses/othercarcinogens/intheworkplace/benzene; Bootie Cosgrove-Mather, *FDA: Too Much Benzene In Some Drinks*, CBS News (May 19, 2006), http://www.cbsnews.com/news/fda-too-much-benzene-in-some-drinks/.

[106] *See* Jeffrey Sindelar & Andrew Milkowski, *Human Safety Controversies Surrounding Nitrate and Nitrite in the Diet*, 26 (4) Nitric Oxide 259, 263 (2012), *available at* http://www.ncbi.nlm.nih.gov/pubmed/22487433; Steven Lapidge et al., *Is America Ready for a Humane Feral Pig Toxicant?*, Proceedings of the 13th Wildlife Damage Mgmt. Conference 49–59 (2009).

[107] An "estrogen antagonist" is a compound that is hostile to specific tissues, such as the breast and uterine tissues. *See* Alessio Amadasi et al., *Identification of Xenoestrogens in Food Additives by an Integrated in Silico and In Vitro Approach*, 22 (1) Chemical Research Toxicology 52 (2009), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2758355/.

fat-containing foods for their antioxidant properties; notwithstanding, the U.S. National Institutes of Health report that BHA is reasonably anticipated to be a human carcinogen based on evidence of carcinogenicity in experimental animals, and studies remain divided whether BHT raises the risk of cancer, asthma, and behavioral issues in children.[108] Carrageenan is widely used throughout the food industry for its gelling, thickening, and stabilizing properties.[109] Following several peer-reviewed animal studies that found tumor growth was promoted or initiated by carrageenan, scientists have raised concerns about whether the food-grade variety of the additive may lead to parallel health problems in humans.[110] Comparable concerns over artificial sweeteners—such as aspartame and acesulfame potassium—have been dismissed by the EU as well.[111] For example, one rodent study showed no increased incidence of tumors in response to

[108] *See* Luke K. T. Lam et al., *Synthesis and Chemical Carcinogen Inhibitory Activity of 2-tert-Butyl-4-Hydroxyanisole*, 22 (5) J. MEDICINAL CHEMISTRY 569, 569–70 (1979), *available at* http://www.ncbi.nlm.nih.gov/pubmed/458807; A. A. M. Botterweck et al., *Intake of Butylated Hydroxyanisole and Butylated Hydroxytoluene and Stomach Cancer Risk: Results from Analyses in the Netherlands Cohort Study*, 38 (7) FOOD & CHEMICAL TOXICOLOGY 599, 599 (2007); *see also* NAT'L TOXICOLOGY PROGRAM, REPORT ON CARCINOGENS (13th ed. 2014), *available at* http://ntp.niehs.nih.gov/go/roc13; *Butylated hydroxytoluene (BHT)*, 40 IARC MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISKS TO HUMANS 161–206 (1986), *available at* http://monographs.iarc.fr/ENG/Monographs/vol1-42/mono40.pdf; Thomas W. Kensler et al., *Modification of Aflatoxin B1 Binding to DNA in vivo in Rats Fed Phenolic Antioxidants, Ethoxyquin and a Dithiothione*, 6 (5) CARCINOGENESIS 759, 762 (1985), *available at* http://www.ncbi.nlm.nih.gov/pubmed/3924431; Gary M. Williams & Michael J. Iatropoulos, *Inhibition of the Hepatocarcinogenicity of Aflatoxin B1 in Rats by Low Levels of the Phenolic Antioxidants Butylated Hydroxyanisole and Butylated Hydroxytoluene*, 104 CANCER LETTERS 49, 49–51 (1996), *available at* http://www.ncbi.nlm.nih.gov/pubmed/8640745; Robert A. Franklin, *Butylated Hydroxytoluene in Sarcoma-prone Dogs*, 307 (7972) THE LANCET 1296 (1976).

[109] *See Properties, Manufacture and Application of Seaweed Saccharides—Agar, Carrageenan and Algin*, TRAINING MANUAL ON GRACILARIA CULTURE AND SEAWEED PROCESSING IN CHINA (August 1990), *available at* http://www.fao.org/docrep/field/003/AB730E/AB730E03.htm.

[110] A review of forty-five publicly funded studies concluded that "the potential role of carrageenan in the development of gastrointestinal malignancy and inflammatory bowel disease requires careful reconsideration of the advisability of its continued use as a food additive." Joanne K. Tobacman, *Review of Harmful Gastrointestinal Effects of Carrageenan in Animal Experiments*, 109 (10) ENV'T HEALTH PERSPECTIVES 983, 993 (2001), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1242073/pdf/ehp0109-000983.pdf; *see also* Kenshi Watanabe et al., *Effect of Dietary Undergraded Carrageenan on Colon Carcinogenesis in F344 Rats Treated with Azoxymethane or Methylnitrosourea*, 38 (12) CANCER RESEARCH 4427, 4427 (1978), *available at* http://cancerres.aacrjournals.org/content/38/12/4427.full.pdf; S. Taché et al., *Carrageenan Gel and Aberrant Crypt Foci in the Colon of Conventional and Human Flora-associated Rats*, 37 NUTRITION & CANCER 193 (2000), *available at* http://www.ncbi.nlm.nih.gov/pubmed/11142093; Yasuyuki Oohashi et al., *A Study on Carcinogenesis Induced by Degraded Carrageenan Arising From Squamous Metaplasia of the Rat Colorectum*, 14 (3) CANCER LETTERS 267, 267 (1981), *available at* http://www.ncbi.nlm.nih.gov/pubmed/7332904; D. E. Corpet et al., *Carrageenan Given as a Jelly, Does not Initiate, but Promotes the Growth of Aberrant Crypt Foci in the Rat Colon*, 114 (1–2) CANCER LETTERS 53, 53–55 (1997), *available at* http://www.ncbi.nlm.nih.gov/pubmed/9103253; Véronique Spichtig & Sean Austin, *Determination of the Low Molecular Weight Fraction of Food-Grade Carrageenans*, 861(1) J. CHROMATOGRAPHY B 81, 86 (2008), *available at* http://www.ncbi.nlm.nih.gov/pubmed/18055280.

[111] *See Scientific Opinion on the Re-evaluation of Aspartame (E 951) as a Food Additive*, EFSA JOURNAL (Dec. 10, 2013), http://www.efsa.europa.eu/en/efsajournal/pub/3496.htm; *Opinion: Re-evaluation of Acesulfame K with Reference to the Previous SCF Opinion of 1991*, SCIENTIFIC COMM. ON FOOD (Mar. 9, 2000), *available at* http://ec.europa.eu/food/fs/sc/scf/out52_

administration of acesulfame K, while a related study conducted showed signs of carcinogenicity in males.[112] Additionally, research suggests acesulfame K may affect prenatal development, and chronic use over time results in a moderate but limited effect on neurometabolic function.[113]

Up until this point, food additives have been subject to untenable internal import controls in favor of broader EU regulation. Multinational scientific committees like EFSA have enjoyed unchallenged influence over commercial trade, further reinforced by distinguished case law and the international courts. However, recent developments with the Transatlantic Trade and Investment Partnership (TTIP) are set to transform the heretofore established dynamic between the United States and the European Union with unpredictable consequences.

E U.S. Leniency and the TTIP

The U.S. Food and Drug Administration (FDA) is an agency of the United States Department of Health and Human Services responsible for protecting and promoting public health through the regulation of, among other goods, foods.[114] The FDA allows more than 10,000 chemicals, directly or indirectly, into human food pursuant to the United States Food Additives Amendment of 1958.[115] As of 2010, over 90% of these additives were allowed in human food under the legal categories known as "food additives" or as "generally recognized as safe" (GRAS) substances in roughly equal numbers.[116] The remaining 10% consist of color additives, pesticides, or substances sanctioned for use by the federal government before the law was enacted in 1958.[117]

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[112] See National Toxicology Program, Toxicity Studies of Acesulfame Potassium (CAS No. 55589-62-3) in FVB/N-TgN(v-Ha-ras)Led (Tg.AC) Hemizygous Mice and Carcinogenicity Studies of Acesulfame Potassium in B6.129-Trp53tm1Brd (N5) Haploinsufficient Mice (Feed Studies), Genetically Modified Model Report, 06-4460 National Institutes of Health i-113 (2005), *available at* http://ntp.niehs.nih.gov/ntp/htdocs/gmm_rpts/gmm2.pdf.

[113] *See* G. H. Zhang et al., *Effects of Mother's Dietary Exposure to Acesulfame-K in Pregnancy or Lactation on the Adult Offspring's Sweet Preference*, 36 (9) Chem. Senses, 763 (2011), *available at* http://www.ncbi.nlm.nih.gov/pubmed/21653241; Wei-na Cong et al., *Long-Term Artificial Sweetener Acesulfame Potassium Treatment Alters Neurometabolic Functions in C57BL/6J Mice*, 8 (8) Plos One (2013), http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0070257.

[114] *See About FDA: What We Do*, U.S. Food and Drug Admin. (Aug. 5, 2014), http://www.fda.gov/AboutFDA/WhatWeDo/default.htm.

[115] *See* Thomas G. Neltner et al., *Data Gaps in Toxicity Testing of Chemicals Allowed in Food in the United States*, 42 Reproductive Toxicology 85, 85 (2013), *available at* http://www.sciencedirect.com/science/article/pii/S0890623813003298.

[116] As part of Congress' grant of FDA oversight for food additives in 1958, it acknowledged that the safety of many ingredients was well established, and created the GRAS category to account for them. *Id*. *See also* Kimberly Kindy, *Industry Group to Launch Database of Food Additives Among Growing Concerns*, Wash. Post (Aug. 28, 2014), http://www.washingtonpost.com/blogs/federal-eye/wp/2014/08/28/industry-group-to-launch-database-of-food-additives-amid-growing-fda-concerns/.

[117] Neltner, *supra* note 115.

By law, food additives cannot be used in food without an affirmative determination by the FDA or the additive manufacturer that their use is safe.[118] Safety prerequisites stipulate that there is "reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."[119] Recently, a voluntary certification system has nearly replaced the previous, more formal and time-consuming, review—where the FDA, rather than the corporation, made the final determination of safety.[120]

Without the constraints of scientific investigation, many contentious additives banned in the EU are still available to U.S. consumers.[121] For example, Olestra, also known as "Olean," is a fat substitute that may cause abdominal cramping and anal leakage by inhibiting the absorption of vitamins and other nutrients.[122] Brominated vegetable oil (BVO) is used primarily to help prevent citrus-flavored soft drinks from separating.[123] Unfortunately, excessive consumption of BVO-containing products has resulted in memory loss, tremors, fatigue, loss of muscle coordination, headache, and drooping of the right eyelid.[124] Although banned for use in foods by the EU for its carcinogenic properties, potassium bromate is typically used in the United States to improve the quality of baked goods.[125] Finally, azodicarbonamide is used as a flour-bleaching agent and a dough conditioner, but can cause both asthma and skin problems and is thus banned in the United Kingdom, most European countries, Australia, and Singapore.[126]

With almost two-thirds of chemical additives lacking feeding toxicology, 78.4% of additives directly added to food lacking data to estimate a safe level of exposure, and 93% lacking reproductive or development toxicity testing, the

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[118] *See* FOOD ADDITIVES (A. L. Branen et al. eds.) 201 (2001).

[119] *See* 21 U.S.C. §321 (2010), *available at* https://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap9-subchapII-sec321.pdf; *see also* 21 U.S.C. §348 (2010), *available at* https://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap9-subchapIV-sec348.pdf.

[120] In 1997, the FDA's oversight system shifted dramatically in response to a shortage of staff members and complaints from industry that the process was too cumbersome. The agency proposed that those companies utilizing GRAS no longer had to submit their research and raw data. Instead, participants were permitted to voluntarily share a summary of their findings with the agency. *See* Kimberly Kindy, *Food Additives on the Rise as FDA Scrutiny Wanes*, WASH. POST (Aug. 17, 2014), http://www.washingtonpost.com/national/food-additives-on-the-rise-as-fda-scrutiny-wanes/2014/08/17/828e9bf8-1cb2-11e4-ab7b-696c295ddfd1_story.html.

[121] *See A Look at Food Additives that Are Legal in the U.S.*, CHI. TRIB. (Jan. 21, 2013), http://articles.chicagotribune.com/2013-01-21/news/ct-met-banned-food-additives-sidebar-20130121_1_potassium-bromate-flour-probable-carcinogen.

[122] *See* MOHAMED B. ABOU-DONIA & MOHAMED SALAMA, FOOD ADDITIVES, MAMMALIAN TOXICOLOGY 282 (Mohamed B. Abou-Donia ed.) (2015).

[123] *See* Paul Bendig et al., *Brominated Vegetable Oil in Soft Drinks—An Underrated Source of Human Organobromine Intake*, 133 (3) FOOD CHEMISTRY 678 (2012), *available at* http://www.sciencedirect.com/science/article/pii/S0308814612000921.

[124] *See* B. Z. Horowitz, *Bromism from Excessive Cola Consumption*, 35 (3) J. TOXICOLOGY: CLIN. TOXICOLOGY 315 (1997), *available at* http://www.ncbi.nlm.nih.gov/pubmed/9140329.

[125] *See* WILLIAM P. EDWARDS, THE SCIENCE OF BAKERY PRODUCTS 78, 90 (2007).

[126] In fact, serving food containing azodicarbonamide in Singapore is considered criminal offense, resulting in up to fifteen years in prison and a $500,000 fine. *See* CHARLES M. DUNCAN, EAT, DRINK, AND BE WARY: HOW UNSAFE IS OUR FOOD? 92–93 (2015).

United States cannot meet the burden of reasonable certainty that all chemical additives are safe.[127] Furthermore, once a chemical is approved, manufacturers have little incentive to add additional toxicology information because the FDA neither has a reassessment program in place nor has authority to require additional testing as opposed to EFSA's current reevaluation program.[128]

This discrepancy in regulatory bodies becomes increasingly significant with the development of the Transatlantic Trade and Investment Partnership (TTIP), a proposed free trade agreement between the European Union and the United States.[129] Proponents believe the agreement will result in multilateral economic growth, while critics are wary that such supranational deals will diminish countries' influence over such issues as environmental standards, food safety, consumer protection, and banking regulations.[130] A free trade area between the U.S. and EU would represent potentially the largest regional free-trade agreement in history, covering 46% of world gross domestic product (GDP).[131] The purpose of the TTIP would be to foster market access for goods and services by removing customs duties on goods and restrictions on services, as well as improving regulatory coherence and cooperation by dismantling unnecessary regulatory barriers.[132]

A bureaucratic duplication of effort is the very model of an unnecessary regulatory barrier, encompassing "behind-the-border" differences in national policies, standards, and approval procedures.[133] According to the *Initial EU Position on Technical Barriers to Trade*, "[t]he convergence of standards and technical regulations on the basis of the use of international standards is one of the most significant tools to facilitate trade."[134] As of July 2014, "[b]oth sides are working on the basis of a consolidated text with a view to progressively reduce divergences."[135]

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[127] "Feeding toxicology" studies are designed to estimate the amount of a chemical additive that can be eaten safely. Neltner, *supra* note 115.

[128] *See* Maricel V. Maffini et al., *Looking Back to Look Forward: A Review of FDA's Food Additives Safety Assessment and Recommendations for Modernizing its Program*, 12 Comprehensive Reviews in Food Sci. & Food Safety 439 (2013), *available at* http://onlinelibrary.wiley.com/doi/10.1111/1541-4337.12020/abstract.

[129] Information about the Transatlantic Trade and Investment Partnership may be found online at http://ec.europa.eu/trade/policy/in-focus/ttip/.

[130] *See* George Monbiot, *This Transatlantic Trade Deal is a Full-Frontal Assault on Democracy*, The Guardian, Nov. 4, 2013, http://www.theguardian.com/commentisfree/2013/nov/04/us-trade-deal-full-frontal-assault-on-democracy; Ken Clarke, *This EU-US Trade Deal is no 'Assault on Democracy'*, The Guardian, Nov. 11, 2013, http://www.theguardian.com/commentisfree/2013/nov/11/eu-us-trade-deal-transatlantic-trade-and-investment-partnership-democracy.

[131] *Countries and Regions: United States*, European Comm'n (Oct. 31, 2014), http://ec.europa.eu/trade/policy/countries-and-regions/countries/united-states/.

[132] *The Transatlantic Trade and Investment Partnership (TTIP): TTIP explained*, European Comm'n (Aug. 5, 2014), *available at* http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152462.pdf.

[133] *See* Rafael Leal-Arcas et. al., International Energy Governance: Selected Legal Issues 499 (2014).

[134] *Initial EU Position on Technical Barriers to Trade*, European Comm'n (July 16, 2013), *available at* http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc_151627.pdf.

[135] *State of Play of TTIP Negotiations Ahead of the 6th Round of Negotiations*, European

Economic relations between the U.S. and EU are often characterized as tense—frequent trade disputes between the two economies often culminate before the World Trade Organization.[136] As a result of the TTIP, the FDA is on the verge of obsolescence within both the domestic and the international systems of trade. An inefficient regulatory body, the FDA is master of its own demise—merging through absorption with an authoritative, and scientifically-based, multinational agency.

F CONCLUSION

In this note, I established that the system of export controls in the United States is minimal, but for those enforced for political motives. I then determined that European Union import policy is intolerant of alleged protectionist legislation—even in the name of public health—when levied against member states. However, this judicial exactitude extends to neither outsider nations nor the governing scientific bodies of the European Union, particularly the EFSA.

Conversely, the United States does not regulate the domestic use of additives based on a method of inquiry subject to empirical or measurable evidence. With the approval of the TTIP, the United States is likely to encounter those same benefits of EU member states for the purposes of trade—and be subject to the same restrictions. Therefore, the United States needs to utilize more stringent regulatory standards based on replicable, peer-reviewed research as opposed to outdated extrapolations of limited data. Therefore, a program is needed to effectively and efficiently fill the significant information gaps to not only to ensure that public health is protected, but also to foster a robust trade economy. The United States must either establish or adopt an authority to collect and examine the entirety of scientific findings, and EFSA's reassessment program is soon to be the most powerful player in the global economy.

COMM'N (July 11, 2013), *available at* `http://trade.ec.europa.eu/doclib/docs/2014/july/tradoc_152666.pdf`.

[136] *See* MAY T. YEUNG ET. AL., REGIONAL TRADING BLOCS IN THE GLOBAL ECONOMY 41 (1999).