Comparing Dietary Supplement Regulations in the U.S. and Abroad

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ABSTRACT

This Article analyzes the regulation of dietary supplements in the United States and around the world. The purpose of this Article is to generate a discussion on the importance of the implementation of a single, unifying international treaty that would regulate the definition, quality, dosage, and labeling of dietary supplements.

The issues examined in this Article have been presented in two main parts. The first part analyzes the U.S. regulatory framework on dietary supplements with case studies. The discussion in the second part focuses on the comparison of dietary supplements regulations in Canada, China, and the European Union (EU). This Article also raises questions about regulatory challenges in defining dietary supplements on the global scale, and it provides recommendations on establishing harmonized regulatory framework on dietary supplements.

I. INTRODUCTION

The dietary supplements market was valued at $133.1 billion in 2016.[1] It is projected to grow 9.6% from 2016 to 2024 at a compounded annual growth rate.[2] More than half of the U.S. population purchases dietary supplements on a monthly basis.[3] Thirty percent of Americans take more than four supplements a day.[4] The out-of-pocket spending on these products is a third of what people spend on prescription drugs.[5]

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[1] *Dietary Supplements Market Size, Share & Trends Analysis Report by Ingredient (Vitamins, Minerals), By Form, By Application, By End User, By Distribution Channel, By Region, and Segment Forecasts, 2020–2027*, GRAND VIEW RESEARCH, https://www.grandviewresearch.com/industry-analysis/dietary-supplements-market [https://perma.cc/M9TD-HEL9] [hereinafter GRAND VIEW RESEARCH].

[2] *Id.*

[3] *Global Nutrition Industry at $182 Billion: Supplements Top $60 Billion*, NEW HOPE NETWORK, https://www.newhope.com/global-nutrition/global-nutrition-industry-182-billion-supplements-top-60-billion [https://perma.cc/4YTN-LNQ8].

[4] R.L. Bailey, V.L. Fulgoni, D.R. Keast & J.T. Dwyer, *Examination of Vitamin Intakes Among US Adults by Dietary Supplement Use*, 112 J. ACAD. NUTRITION & DIETETICS 657, 657–63 (2012).

[5] R.L. Bailey, J.J. Gahche, C.V. Lentino, J.T. Dwyer, J.S. Engel, P.R. Thomas, J.M. Betz, C.T. Sempos & M.F. Picciano. *Dietary Supplement Use in the United States, 2003–2006*, 141 J. NUTRITION 261, 261–66 (2010).

The globalization of the manufacture and distribution of dietary supplements has made national governments take steps to ensure product quality and safety.[6] At the same time, the food safety of dietary supplements in the U.S. remains an issue.[7] Dietary supplement manufacturers are not obliged to prove the safety of their products before they enter the U.S. market.[8] There is a subsequent history of unsafe dietary supplement products that have been sold in the U.S. market and have harmed consumers.[9] A comparative analysis of dietary supplement regulations in Canada, China, and the European Union (EU) may elucidate the need for legislation in the U.S. to strengthen consumer protection regarding dietary supplements.

Canadian, Chinese, and European Union regulations of dietary supplements are more restrictive than American regulations of dietary supplements. This indicates that consumers in Canada, China, and the EU may have access to better quality products. However, the legislative framework for dietary supplements remains inconsistent across international jurisdictions.[10] In fact, there is no international treaty that provides consistent definition, quality, dosage, and labeling requirements for supplement products or drugs.[11] Instead, there is a patchwork global drug control regime.[12]

This Article analyzes dietary supplements regulations in the United States and summarizes global regulatory challenges. It also provides recommendations for the harmonization of domestic and international standards and the improvement of the dietary supplements regulatory framework.

II. DIETARY SUPPLEMENT REGULATIONS IN THE UNITED STATES

A. The Development of Dietary Supplement Regulations in the United States

In 1906, Congress passed the Pure Food and Drug Act, also known as the Wiley Act.[13] Its main feature was the implementation of a regulatory scheme intended to prevent the sale of adulterated and misbranded food, drugs, liquor, and medicine.[14] The Act regulated prohibited drugs by requiring accurate labels, monitoring of purity

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[6] *USP Global Public Policy Position: Ensuring the Quality of Dietary Supplements*, U.S. PHARMACOPEIAL CONVENTION, https://www.usp.org/sites/default/files/usp/document/about/public-policy/public-policy-dietary-supplements.pdf [https://perma.cc/AS66-RN4L] [hereinafter *USP Global Public Policy Position*].

[7] *Id.*

[8] 21 U.S.C. §§ 342(g), 343(s) (2005).

[9] J. Palamar, *How Ephedrine Escaped Regulation in the United States: A Historical Review of Misuse and Associated Policy*, 99 HEALTH POL'Y 1, 1–9 (2011).

[10] T.Y. Low, K.O. Wong, A.L. Yap, L.H. De Haan & I.M. Rietjens, *The Regulatory Framework Across International Jurisdictions for Risks Associated with Consumption of Botanical Food Supplements*, 16 COMPREHENSIVE REV.'S FOOD SCI. & FOOD SAFETY 821, 821–34 (2017).

[11] *Id.*

[12] *Id.*

[13] Daniel P. Carpenter, *Pure Food and Drug Act (1906)*, *ENCYCLOPEDIA.COM*, https://www.encyclopedia.com/history/united-states-and-canada/us-history/food-and-drug-act-1906 [https://perma.cc/X2V5-FJNJ].

[14] *Id.*

and dosage, and consumer education.[15] The Act also had several shortcomings. First, it did not specify purity standards for food manufacturing.[16] Second, it neither defined nor controlled interstate commerce of adulterated and misbranded food and drugs.[17] Finally, it proved difficult to implement. The complexity of implementation laid the groundwork for further discussions on the regulation of food and drugs in the United States.

Dietary supplements were first to the public in 1912; Casimir Funk, a Polish biochemist, discovered that protein fractions from rice polishing could prevent a beriberi-like disease in birds.[18] He chose to call those nutrient factors "vital amines," or "vitamins," and concluded that they were capable of preventing deficiency diseases.[19] Thus, Funk was perhaps the first scientist to formulate and study the concept of vitamins.[20] In following years, researchers at various institutions—including the University of Wisconsin, Yale University, Cambridge University, and some corporate laboratories—began to isolate fat-soluble A vitamins, B complex vitamins, C vitamins, D vitamins, biotin, pantothenic acid, and other nutrients.[21] Their discoveries were readily adapted into mainstream commerce.[22] Pharmaceutical companies began marketing vitamin preparations in popular magazines such as *Good Housekeeping* and *Parent's Magazine*; these advertisements focused on the importance of vitamins to bone and teeth formation in children, as well as on their ability to help children resist infections.[23]

In 1922, the United States Bureau of Chemistry began assembling basic information on the manufacturing, labeling, and advertising of vitamins.[24] In 1927, the Bureau's regulatory powers were reorganized under the new United States Department of Agriculture (USDA) and the Food, Drug, and Insecticide Administration—later renamed the Food and Drug Administration (FDA).[25] In 1932, FDA established its first laboratory dedicated to the study of vitamins.[26] In 1935, the League of Nations Health Committee formed the Conference on Vitamin Standardization; its main goal was to analyze the global impact of vitamins and minerals and promote the standardization of regulations for vitamins A, B1, C, and D.[27]

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[15] JAMES P. GRAY, WHY OUR DRUG LAWS HAVE FAILED AND WHAT WE CAN DO ABOUT IT: A JUDICIAL INDICTMENT OF THE WAR ON DRUGS 288 (2001).

[16] *See* Carpenter, *supra* note 13.

[17] *Id.*

[18] Casimir Funk, *The Etiology of the Deficiency Diseases*, 20 J. ST. MED. 341, 345–60 (1912).

[19] *Id.*

[20] GEORGE ROSEN, A HISTORY OF PUBLIC HEALTH 240 (2015).

[21] *See* John P. Swann, *The History of Efforts to Regulate Dietary Supplements in the USA* (2015), https://onlinelibrary.wiley.com/doi/pdf/10.1002/dta.1919 [https://perma.cc/X5A2-EY6M].

[22] *See id.*

[23] RIMA D. APPLE, VITAMANIA: VITAMINS IN AMERICAN CULTURE 8–32 (1996).

[24] THE PHARMACOPOEIA OF THE UNITED STATES OF AMERICA 469 (10th rev. 1925).

[25] *Milestones in U.S. Food and Drug Law History*, FDA.GOV, https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/milestones-us-food-and-drug-law-history [https://perma.cc/EFW4-5NV2].

[26] *Id.*

[27] *Id.* Food and drug research expanded to study vitamins and pharmacology.

During that time, food and drug adulteration continued to flourish because of the absence of specific authority in the law for the standards of purity and content.[28] Indeed, no formal government approval was required to market new drugs at the time.[29] Further, food and drug laws did not specifically require safety studies on new drugs.[30] Selling toxic drugs was risky and potentially damaging to a business's reputation, but it was legal.[31]

B. The Elixir Sulfanilamide Tragedy and the Federal Food, Drug, and Cosmetic Act

By the late 1930s, the Pure Food and Drug Act of 1906 was recognized as obsolete, but congressional efforts to supplement it stalled.[32] The situation changed after a national scandal in 1937, known as the Elixir Sulfanilamide Tragedy.[33] This scandal concerned the liquid form of a compound known as Elixir Sulfanilamide, which was used to treat various ailments.[34] At the time, liquid Elixir Sulfanilamide was formulated with diethylene glycol, the chemical normally used as antifreeze. [35] It was tested for flavor, appearance, and fragrance and found satisfactory.[36] S.E. Massengill Company, in Bristol, Tennessee, distributed the Elixir Sulfanilamide all over the United States without testing for toxicity. Seventy-one adults and thirty-four children died in the fall of 1937 after taking the elixir to treat a variety of ailments, from gonorrhea to a sore throat.[37]

The Elixir Sulfanilamide Tragedy created political pressure that contributed to the 1938 enactment of the Federal Food, Drug, and Cosmetic Act (FDCA).[38] The FDCA broadened FDA's oversight of consumer products and contained a variety of provisions.[39] First, the FDCA defined dietary supplements as food for special dietary use. Under the FDCA, a dietary supplement is:

> a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a

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[28] Wallace F. Janssen, *The Story of the Laws Behind the Labels* (June 1981), FOOD AND DRUG ADMIN., https://www.fda.gov/downloads/AboutFDA/History/FOrgsHistory/EvolvingPowers/UCM593437.pdf [https://perma.cc/BZ4P-UPKA].

[29] Jef Akst, *The Elixir Tragedy, 1937*, THE SCIENTIST (May 31, 2013), https://www.the-scientist.com/foundations/the-elixir-tragedy-1937-39231 [https://perma.cc/KZD8-LGDL].

[30] Carol Ballentine, *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident* (June 1981), FOOD AND DRUG ADMIN., https://www.fda.gov/files/about%20fda/published/The-Sulfanilamide-Disaster.pdf [https://perma.cc/52ZB-WLTP].

[31] *Id.*

[32] *See* Carpenter, *supra* note 13.

[33] *Id.*

[34] Elixir sulfanilamide was an improperly prepared sulfanilamide medicine that caused mass poisoning in the United States in 1937. It caused the deaths of more than 100 people. The public outcry caused by this incident and other similar disasters led to the passing of the 1938 Federal Food, Drug, and Cosmetic Act, which led to the creation of the FDA. *See* Ballentine, *supra* note 30.

[35] *Id.*

[36] *Id.*

[37] Akst, *supra* note 29.

[38] *See* Ballentine, *supra* note 30.

[39] *See* Swann, *supra* note 21.

> vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).[40]

Second, the FDCA required food manufacturers to provide consumers with a label that included information on vitamin, mineral, and other dietary properties to its value for such uses.[41] The statute defined food as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."[42]

Under the FDCA, a dietary supplement would also have been considered a food additive unless it was a substance that was "Generally Recognized as Safe."[43] The statute also prohibited the misbranding and adulteration of food, cosmetics, and medical devices.[44] Drugs had to be shown to be safe before entering the market, and food manufacturers and sellers had to abide by standards of identity.[45] Finally, the FDCA provided that food products would be considered misbranded if they:

> purport[ed] to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.[46]

Ultimately, the FDCA was a watershed moment in the regulation of foods, drugs, vitamins, and dietary supplements. Still, it did not solve nearly every serious problem.

C. The Eosinophilia-Myalgia Syndrome Outbreak and Recommended Daily Allowance Regulations

In 1941, during World War II, FDA promulgated the Recommended Daily Allowance regulations for dietary supplements.[47] The standards were used as nutritional recommendations for the armed forces, civilians, and citizens overseas.[48]

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[40] *See* 21 U.S.C. § 321(ff) (2016).

[41] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343(j) (2018) (providing that food for special dietary use would be considered misbranded unless its "label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses").

[42] 21 U.S.C. § 321(f).

[43] *See* 21 C.F.R. §§ 170.30(c),170.3(f) (2020).

[44] *See* 21 U.S.C. §§ 321(g) (defining drug), 343(j) (misbranded food), 352(f) (misbranded drug or device), 321(i) (cosmetic) (2020).

[45] *See* Peter Barton Hutt, *Government Regulation of Health Claims in Food Labeling and Advertising*, 41 FOOD DRUG COSMETIC L.J. 25, 60 (1986).

[46] 21 U.S.C. § 343(j).

[47] *See* 6 Fed. Reg. 5922–23 (Nov. 22, 1941) (describing minimum daily requirements of vitamins and minerals); *see also* Commission on Dietary Supplement Labels, REPORT OF THE COMMISSION ON DIETARY SUPPLEMENT LABELS 11 (1997), https://digital.library.unt.edu/ark:/67531/metadc1282036/ [https://perma.cc/NU4K-KGYD] [hereinafter CDSL Report].

[48] *Reference Daily Intake*, WIKIPEDIA, https://en.wikipedia.org/wiki/Reference_Daily_Intake [https://perma.cc/YRZ3-RA7W].

In 1973, the final version of the regulations classified most vitamins and minerals as drugs if they exceeded a certain level of potency and limited the sale of vitamin and mineral combination products.[49] The regulations could not, however, protect Americans from the outbreak of eosinophilia-myalgia syndrome (EMS).[50]

EMS is an incurable and sometimes fatal condition linked to the ingestion of the dietary supplement L-tryptophan.[51] The main symptoms of EMS are "cough, dyspnea, pleuritic chest pains, fever, pulmonary infiltrates, excessive eosinophils counts, and sclerodermiform skin changes."[52] At the time, dietary supplements manufacturer Showa Denko Inc. was experimenting with genetically engineered bacteria and purification process improvement; in 1989, the resulting supplement caused more than 1,500 cases of EMS and thirty-seven deaths.[53] The actions that FDA could take at that time were to limit the availability of L-tryptophan through submitting voluntary recall of tryptophan supplements and notifying consumers about its potential side effects.[54] The main reason for that limitation was the loophole in the current legislation, and FDA did not have the authority to ban herbal products (like dietary supplements) without proof that they caused deaths or serious injury.[55]

D. Current Dietary Supplement Regulations

i. The Nutrition Labeling and Education Act

Congress passed the next major law in 1990—the Nutrition Labeling and Education Act (NLEA). It created a health claim approval system for FDA with a limited separate procedure for the dietary supplement health claims.[56] The NLEA established general

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[49] *See* Definitions and Standards of Identify for Food for Special Dietary Use, 38 Fed. Reg. 20,730, 20,732 (Aug. 2, 1973); *see also* Food for Special Dietary Uses, 31 Fed. Reg. 15,730 (Dec. 14, 1966); CDSL Report, *supra* note 47, at 11, 12 (noting FDA proposed that all vitamin and mineral supplements bear the following disclaimer: "[v]itamins and minerals are supplied in abundant amounts by commonly available foods. Except for persons with special medical needs, there is no scientific basis for recommending routine use of dietary supplements."). This proposed rule was not included in the final rulemaking. In addition, the final rulemaking was subject to much FDA and court revision and was finally revoked in its entirety.

[50] *See Information Paper on L-Tryptophan and 5-Hydroxy-L-Tryptophan*, U.S. FOOD & DRUG ADMIN. (2001), http://www.nemsn.org/Articles/FDA-Info.pdf [https://perma.cc/E6JH-76X7] [hereinafter FDA Information Paper] (noting that in 1989 an epidemic outbreak of eosinophilia-myalgia syndrome (EMS), which resulted in thirty-seven known deaths, occurred in the U.S. due to the use of dietary supplements containing L-tryptophan); *see also The Ephedra Ban Is Not Enough*, N.Y. TIMES (Jan. 5, 2004), https://www.nytimes.com/2004/01/05/opinion/the-ephedra-ban-is-not-enough.html [https://perma.cc/K9FW-MCGV] (discussing the dangers of ephedra-containing weight loss products and stating "[e]phedra has generated far more reports of adverse effects than any other and has been linked to cases of heart attack, stroke and sudden death").

[51] *See* Penni Bolton et al., *A Mystery Ailment Revealed*, 9 AM. FITNESS Sept.–Oct. 1991, at 34–35; CE Lindgren et al., *L-tryptophan Induced Eosinophilia-Myalgia Syndrome*, 111 J. ROYAL SOC'Y OF HEALTH 29, 29–30 (1991).

[52] *Id.*

[53] *See Eosinophilia-Myalgia Syndrome*, NATIONAL EOSINOPHILIA-MYALGIA SYNDROME NETWORK, http://www.nemsn.org [https://perma.cc/4LYX-5B47].

[54] *See* FDA Information Paper, *supra* note 50.

[55] Gene Emery, *FDA Ban Nearly Wiped Out Deaths, Poisonings from Ephedra*, REUTERS (May 27, 2015), https://www.reuters.com/article/us-fda-ephedra/fda-ban-nearly-wiped-out-deaths-poisonings-from-ephedra-idUSKBN0OC2SR20150527 [https://perma.cc/32PZ-XE8B].

[56] Scott I. Bass & Anthony L. Young, DIETARY SUPPLEMENT HEALTH, AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 15 (1996).

principles of health claims that refer to any potential health-related condition on the labels.[57] These principles also refer to claims that characterize the relationship of food component and the disease.[58] The NLEA also had requirements for nutrient claims. [59] It required that all nutrient content claims (i.e., "high fiber," "low fat," etc.) and health claims be consistent with FDA regulations.[60] Still, the NLEA crucially did not provide FDA with recall authority in potentially fatal cases.[61]

ii. The Dietary Supplement Health and Education Act

In 1994, FDA created a new regulatory framework by separating dietary supplements into a new category in the Dietary Supplement Health and Education Act (DSHEA).[62] DSHEA defined supplements as food, and it excluded dietary supplements and dietary ingredients intended for use in dietary supplements from the definition of food additives.[63] Dietary supplements were also excluded from FDCA provisions that required specific approval from FDA for use as food additives.[64] Dietary supplements no longer had to comply with the DeLaney Clause, which excluded dietary supplements containing color additives, or with Generally Recognized as Safe regulations.[65]

At the same time, DSHEA created new standards for the evaluation of dietary supplements' safety.[66] DSHEA stated labeling and packaging provisions for dietary supplements and granted to FDA the ability to implement regulations covering good manufacturing practices.[67] DSHEA has a post-market (reactive) regulative approach with pre-market (proactive) regulative elements.[68] Generally, under a reactive approach, FDA takes an action only on unsafe dietary supplements that have been already marketed in order to increase consumer access and in response to public outcry to heightened restrictions.[69] For instance, DSHEA contains Good Manufacturing Practice (GMP) compliance provisions on post-market site audit process and

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[57] *See generally* FRONT-OF-PACKAGE NUTRITION RATING SYSTEMS AND SYMBOLS: PHASE I REPORT (Caitlin S. Boon, Alice H. Lichtenstein & Ellen A. Wartella, eds., 2010).

[58] 21 C.F.R, §§ 101.14, 101.70, and 101.71 (2020).

[59] *Nutrition Labeling and Education Act of 1990*, WORLD HEALTH ORG., https://extranet.who.int/nutrition/gina/en/node/8006 [https://perma.cc/22KB-R7Q4].

[60] *See* Mark A. Kassel, *From a History of Near Misses: The Future of Dietary Supplement Regulation*, 49 FOOD & DRUG L.J. 237, 261 (1994); Nutrition Labeling and Education Act of 1990, 104 Stat. 2353, (1990).

[61] 104 Stat. 2353.

[62] *See* Dietary Supplement Health and Education Act of 1994, 108 Stat. 4325 (1994) (codified as amended in scattered sections of 21 U.S.C.).

[63] *Id.*

[64] *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(s)(6) (2018).

[65] *Id.*

[66] *See* 21 U.S.C. § 342(f)(1).

[67] *See* 21 U.S.C. § 343(s)(2) (labeling); 21 U.S.C. § 342(g)(1) (packaging).

[68] *See* Johanna T. Dwyer et al., *Dietary Supplements: Regulatory Challenges and Research Resources*, NUTRIENTS 7 (Jan. 4, 2018).

[69] *See* Richard E. Nowak, *DSHEA's Failure: Why a Proactive Approach to Dietary Supplement Regulation is Needed to Effectively Protect Consumers*, 2010 U. ILL. L. REV. 1045, 1058 (2010).

mandatory reporting of serious adverse effects by manufacturers.[70] Dietary supplement manufacturers also must notify FDA before marketing products with the new dietary ingredients (NDI).[71] Still, dietary supplement manufacturers do not have to prove their products' safety before marketing and selling to potential consumers; further, when a dietary supplement is marketed for a new use, that new use can be marketed without proof of consumer safety.[72]

DSHEA's reactive approach proved ineffective. It prevented FDA from acting in a timely fashion to protect consumers from unsafe dietary supplements, such as ephedra, which was brought to the market in the late 1990s and used "[t]o promote weight loss or to enhance athletic performance."[73] FDA was not able to react to over 16,000 adverse event reports related to this issue and did not fully implement a ban on ephedra until 2006.[74] The delay was due primarily to the lack of FDA authority to regulate dietary supplements under DSHEA.

iii. The Dietary Supplement and Nonprescription Drug Consumer Protection Act

In response to the ephedra scandal, President Bush signed the Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNDCPA) into law.[75] It was a first step in establishing a proactive approach to dietary supplements regulation with the mandatory reporting system of serious adverse events for nonprescription drugs and dietary supplements. According to the DSNDCPA and amended Chapter VII of the FDCA:

> [T]he manufacturer, packer, or distributor whose name appears on the label of a nonprescription drug or dietary supplement marketed in the United States to: (1) submit to the secretary of health and human services (the Secretary), within fifteen business days, any report received of a serious adverse event associated with such drug or supplement when used in the United States; (2) submit, within fifteen business days, any related medical information that is received within one year of the initial report; (3) maintain records related to each report for six years from the time the report is received by the company; and (4) permit inspection of such records.[76]

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[70] *See* Dietary Supplement Health and Education Act of 1994, 108 Stat. 4325 (1994).

[71] *New Dietary Ingredients (NDI) Notification Process*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/dietarysupplements/newdietaryingredientsnotificationprocess/default.htm [https://perma.cc/FBC7-UWDB].

[72] Greg Lindquist, *Diet Starts Monday: An Analysis of Current US Dietary Supplement Regulations Through an International Comparison*, 3 ST. LOUIS U. J. HEALTH L. & POL'Y. 123, 124 (2009).

[73] *See generally* Paul G. Shekelle et al., *Efficacy and Safety of Ephedra and Ephedrine for Weight Loss and Athletic Performance: A Meta-Analysis*, 289 J. AM. MED. ASS'N 1537 (2003).

[74] The ban was first promulgated in 2004, but it was not fully implemented until 2006. 21 C.F.R. pt. 119 (2004) (promulgating that all dietary supplements containing ephedrine alkaloids are considered to be adulterated under FDCA); Larry M. Edwards, *Metabolife: Morally Corrupt or Misunderstood Victim*, SAN DIEGO MAG., Mar. 2004, at 51, 52; *see also* Nowak, *supra* note 69.

[75] Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006, Pub. L. No. 109-462, 120 Stat. 3469.

[76] *Id.*; 21 C.F.R. § 701 (2019).

The DSNDCPA improved FDA's ability to monitor and evaluate potential public health adverse events associated with the use of nonprescription drugs and dietary supplements. However, the U.S. Government Accountability Office (GAO) questioned its effectiveness.[77] According to a GAO study, FDA had too few experts that were qualified to effectively evaluate the data.[78] Another concern was that FDA might not be receiving information on all adverse events because manufacturers, distributors, and consumers were not voluntarily reporting these events to FDA.[79] It was also difficult for FDA to establish causality between a product and the health problem based on the limited information in adverse events reports.[80] GAO's suggestion was to establish a public education program, in conjunction with the MedWatch contact information on packaging, to promote voluntary reporting to FDA.[81]

iv. Current Good Manufacturing Practices

In 2007, Current Good Manufacturing Practice requirements (CGMPs) were established for dietary supplement manufacturers.[82] These standards provided manufacturers with guidelines that they must follow to ensure the safety, consistency, quality, purity, and potency of their dietary supplements; they also mandated the establishment of ingredient and finished goods specifications.[83] The purpose of CGMPs was to help Americans get accurately labeled and properly manufactured dietary supplements.[84] However, some authors described CGMPs as "[o]ne of the biggest flaws in the whole set of final rules."[85] These authors argued that CGMPs constituted "a premier example of the fox guarding the henhouse."[86]

Sidney M. Wolf, an American physician and the co-founder of Public Citizen's Health Research Group, argued that "even with these new manufacturing practices, there will be no assurance that dietary supplements work or are safe."[87] She and others specifically fear that FDA does not have enough resources to enforce CGMPs.[88] Moreover, the suppliers of raw materials to the dietary supplement manufacturing

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[77] *See* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-06-402, DRUG SAFETY: IMPROVEMENT NEEDED IN FDA'S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS (2006).

[78] DONNA V. PORTER, CONG. RESEARCH SERV., RS22480, DIETARY SUPPLEMENT AND NONPRESCRIPTION DRUG CONSUMER PROTECTION ACT (P.L.109-462) (2007).

[79] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-13-244, DIETARY SUPPLEMENTS: FDA MAY HAVE OPPORTUNITIES TO EXPAND ITS USE OF REPORTED HEALTH PROBLEMS TO OVERSEE PRODUCTS (2013).

[80] *Id.*

[81] PORTER, *supra* note 78, at 6.

[82] *See* 21 C.F.R. § 111 (2007).

[83] *Id.*

[84] *Backgrounder on the Final Rule for Current Good Manufacturing Practices (CGMPs) for Dietary Supplements*, U.S. FOOD & DRUG ADMIN. (June 22, 2007), [https://perma.cc/2QNB-GE49].

[85] *See, e.g.*, Michael D. Levin, *The New Food Current Good Manufacturing Practices and Their Effect on Dietary Supplement Quality: What You Need to Know*, 15 INTEGRATIVE MED. 22 (2016).

[86] *See, e.g., id.*

[87] Lindquist, *supra* note 72, at 148.

[88] Rick Liva, *New FDA cGMPs for Supplements: Smoke or Substance?*, 6 INTEGRATIVE MED. 28, 28 (2007).

facilities are "exempted" from the CGMPs.[89] As a result, raw materials suppliers do not have the burden of quality assurance stipulated in CGMPs.

At the same time, there are some positive developments initiated by FDA and the Agricultural Marketing Service (AMS). In 2018, FDA published a final rule that added new regulatory requirements affecting the dietary supplement industry.[90] The rule required the addition of updated nutrition information on food and dietary supplement labels; manufacturers with $10 million or more in annual sales had to make these changes by January 1, 2020, and manufacturers with less than $10 million in annual sales had to make these changes by January 1, 2021.[91] AMS also published a rule that will require food manufacturers and other entities labeling foods to disclose information about bioengineered food and food ingredient content—commonly known as genetically modified organisms (GMOs).[92]

III. GLOBAL COMPARISON OF DIETARY SUPPLEMENT REGULATIONS

There is a growing demand for dietary supplements around the world. As discussed at the outset of this Article, the global market of dietary supplements was valued at $133.1 billion in 2016, and it is projected to grow significantly between 2016 and 2024.[93] North America, Europe, and the Asia-Pacific are the regions with the largest shares of the dietary supplements market.[94] The Asia-Pacific retains the largest market share—around forty-four percent.[95] China's $20 billion market share leads the Asia-Pacific.[96]

The globalization of manufacturing and distribution of dietary supplements requires enhanced regulatory mechanisms to ensure quality and safety.[97] Canada, China, and the European Union each have different approaches to the regulation of dietary supplements, and no international treaty defines dietary supplements or standardizes requirements for their quality, dosage, and labeling.[98] As a result, a product considered to be a dietary supplement and regulated as a food in the United States may be considered a drug in another jurisdiction.[99]

Dietary supplements and ingredients are made in countries around the world; they may be faulty or mislabeled, and they could destabilize the domestic dietary supplements market.[100] An in-depth comparison of dietary supplements' regulatory

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[89] *Id.* at 28–30.

[90] 21 C.F.R. § 101 (2018).

[91] *Id.*

[92] 7 C.F.R. § 66 (2018).

[93] GRAND VIEW RESEARCH, *supra* note 1.

[94] *Id.*

[95] *Id.*

[96] *Id.*

[97] *USP Global Public Policy Position*, *supra* note 6.

[98] *Id.*

[99] *See* Dwyer et al., *supra* note 68.

[100] *USP Global Public Policy Position*, *supra* note 6.

approaches in Canada, China, and the European Union may help eliminate international product safety issues and potential public health consequences.

A. Dietary Supplement Regulations in Canada

More than three-quarters of Canadians regularly take dietary supplements, known in Canada as natural health products (NHPs).[101] Nonetheless, in 2015, Canada accounted for just 2.5% of the global production of NHPs.[102] The United States, by comparison, accounted for thirty-seven percent of the global production, and for the majority of Canadian imports.[103] The most common NHPs in Canada are vitamins and minerals, Omega-3s, fatty acids, probiotics, and antioxidants.[104]

The Canadian regulating authority for NHPs and non-prescription drugs is the Natural and Non-prescription Health Products Directorate (NNHPD).[105] NNHPD authorizes NHPs and non-prescription drugs for sale in Canada; it ensures that Canadians have ready access to a wide range of products for which safety, efficacy, and quality standards are in place.[106]

NHPs are regulated as a subset of drugs under the Food and Drugs Act and defined under the Natural Health Product Regulations (NHP Regulations); according to those regulations:

> [N]atural health product means a substance or a combination of substances in which all the medicinal ingredients are substances, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans; (b) restoring or correcting organic functions in humans; or (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.[107]

NHPs are not drugs. They are, however, allowed greater latitude than food to make claims of efficacy and therapeutic benefit for the consumers. The NHP regulations place requirements upon manufacturers, distributors, importers, packagers and labelers.[108] At the same time, the NHP regulations are less restrictive than corresponding regulations in China and the European Union.

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[101] *See, e.g.*, Hua Deng, *Selling Natural Health Products in Canada*, NATURAL PRODUCTS INSIDER, Nov. 21, 2016, https://www.naturalproductsinsider.com/regulatory/selling-natural-health-products-canada [https://perma.cc/FPH2-VNRM].

[102] Ben Chapman, *Natural Health Products: State of the Industry & NRC's NHP Program Overview*, NATIONAL RESEARCH COUNCIL CANADA, at 2, https://afdp.ualberta.ca/afdp/wp-content/uploads/sites/61/2018/05/NHP_Program_Deck_Edmonton_Workshop_November_6th_2014_v1_3.pdf [https://perma.cc/DV86-8MPK].

[103] *Id.*

[104] Deng, *supra* note 101.

[105] *Natural and Non-Prescription Health Products Directorate*, GOV'T OF CAN., https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch/natural-non-prescription-health-products-directorate.html [https://perma.cc/F2EA-WE9N].

[106] *Id.*

[107] Natural Health Products Regulations, SOR/2003-196 (Can.).

[108] *Id.*

NHPs, like dietary supplements in the United States, do not fit within the regulatory framework for pharmaceuticals.[109] The NHP Regulations require that NHP manufacturers obtain a product license through pre-market approval by the Minister of Health—the United States does not require pre-market approval for dietary supplements.[110]

Canada has adopted good manufacturing practices (GMPs) for NHP, which are similar to the cGMP standards in the United States.[111] GMPs are ongoing measures designed to ensure an effective overall approach to product quality control and risk management in Canada.[112] GMPs set standards and practices for the manufacturing, packaging, labeling, storing, and importing of NHP intended for sale in Canada.[113]

The NHP Regulations have a cost of product licensing and mandatory GMP registration for smaller companies.[114] Industry members have complained about long wait times between applying for product approval and actual approval or denial.[115] In response, Health Canada updated its rules in 2019 to reduce potential impacts on the marketplace and allow impacted stakeholders time to implement changes.[116]

B. Dietary Supplement Regulations in China

China's dietary supplement market is the largest in the Asia Pacific region.[117] The China General Association of Sport and China Marathon Association projects that the Chinese sports nutrition industry will grow from $1.7 billion in 2015 to $7 billion by 2025.

In China, dietary supplements are regulated as "health foods," together with functional foods.[118] China offers two means of market entry for dietary supplement manufacturers and distributors: "traditional trade" on mainland China or a "cross-border e-commerce" (CBEC) with the territory of Hong Kong.[119] Traditional trade requires that manufacturers secure product approval from the China Food and Drugs

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[109] Regulatory Impact Analysis Statement of the Natural Health Products Regulations, 137 C. Gaz. Part II, No. 13 at 1571 (June 18, 2003) (the Regulatory Impact Analysis Statement is not part of the Natural Health Products Regulations).

[110] *Id.* at 1579.

[111] Natural Health Products Directorate, *Good Manufacturing Practices Guidance Document*, HEALTH CANADA, http://hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/gmp-bpf-eng.pdf [https://perma.cc/977K-EJWS].

[112] *Id.*

[113] *Id.*

[114] Bill Reynolds, *Canada Prepares for New Supplement Regs*, NAT. PRODUCTS INSIDER (July 29, 2002), https://www.naturalproductsinsider.com/archive/canada-prepares-new-supplement-regs [https://perma.cc/PUP5-RJGB].

[115] *Id.*

[116] *Natural and Non-Prescription Health Products Directorate (NNHPD) June 1, 2018–December 31, 2018 Engagement and Priorities*, GOV'T OF CAN., https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-health-products/activities/activity-calendar/natural-non-prescription-health-products-directorate-nnhpd-upcoming-activities.html [https://perma.cc/EEK9-WVCZ].

[117] *Webinar for U.S. Companies: "China's Dietary Supplement Market*," HEALTH PRODUCTS ASS'N CHINA (Aug. 28, 2018), https://uschinahpa.org/tag/jeff-crowther/ [https://perma.cc/R8FW-GWTQ].

[118] *Id.*

[119] *Id.*

Administration (CFDA).[120] Manufacturers must also obtain "Blue Hat" certification for all products to be sold on mainland China.[121] CFDA approval is not required for manufacturers who wish to engage in CBEC, but such products may only be distributed in the Special Administrative Region of Hong Kong.[122]

Hong Kong has links to both mainland China and the international community; it is one of the fastest growing biotechnology and biomedical innovation hubs in the world.[123] Despite its small population, Hong Kong has a strategic interest in the dietary supplements industry.[124] The rapid growth of CBEC in Hong Kong created challenges for the Chinese government due to issues of product safety and stability of the domestic market.[125]

In 2016, the Chinese government released a set of rules, called "the April Policies," to regulate CBEC.[126] The April Policies came into effect in 2018 and attempted to regulate product safety, optimize the taxation structure of CBEC imports, and redress an imbalance between offline and CBEC import channels.[127] The Chinese government also adopted a new e-commerce law that regulates the sale of goods and the provision of services through the internet; the law went into effect on January 1, 2019.[128] The law called for the establishment of a sophisticated regulatory system that spans across customs clearance, taxation, inspection, quarantine, and payment methods.[129]

C. Dietary Supplement Regulations in the European Union

The European Union (EU) has a unique institutional legal system.[130] The EU's system of multi-level governance vertically links decisions about public policy taken

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[120] *Id.*

[121] *Id.*

[122] *Id.*

[123] PharmaBoardroom, *PharmaBoardroom Releases 'Healthcare and Life Sciences Review Hong Kong' November 2018 Pharma Report*, PR NEWSWIRE (Nov. 15, 2018, 11:54 AM), https://www.prnewswire.com/news-releases/pharmaboardroom-releases-healthcare-and-life-sciences-review-hong-kong-november-2018-pharma-report-890809357.html [https://perma.cc/7L8F-2CPF].

[124] *See id.*

[125] Jamie Rowlands & Le Rong, *Cross-Border E-commerce Operators: Be Vigilant from 2019*, LEXOLOGY (Oct. 11, 2018), https://www.lexology.com/library/detail.aspx?g=1e4d383c-2850-486a-9542-892aabf152bc [https://perma.cc/WJ7R-6TXU].

[126] *Id.*

[127] *Id.*

[128] *Id.*

[129] *See* Tingmin Koe, *Complete Regulatory System: Chinese Officials Confirm Shake-Up of Cross-Border E-commerce Rules*, NUTRA INGREDIENTS (last updated July 22, 2019, 2:27 PM), https://www.nutraingredients-asia.com/article/2018/09/04/complete-regulatory-system-chinese-officials-confirm-shake-up-of-cross-border-e-commerce-rules [https://perma.cc/J2W9-KPDM].

[130] *Institutions and Bodies*, EUROPEAN UNION, https://europa.eu/european-union/about-eu/institutions-bodies_en, [https://perma.cc/VGR6-XFAY].

Types of EU Law, EUROPEAN COMMISSION, https://ec.europa.eu/info/law/law-making-process/types-eu-law_en [https://perma.cc/AE4Y-BSAY].

in Lisbon with decisions taken by horizontal negotiations among representatives of the member states and EU officials in Brussels.[131]

EU law contains both primary law and secondary law.[132] EU primary law is based on the treaties, "[b]inding agreements between EU member countries set out EU objectives, rules for EU institutions, how decisions are made and the relationship between the EU and its members."[133] Regulations, directives, decisions, recommendations, and opinions are all forms of the EU secondary law.[134] Regulations and decisions become automatically binding throughout the EU on the date they take effect, while directives must be incorporated into national law by EU countries.[135]

Dietary supplement regulation in the European Union is grounded on three sources. The first source is Directive 2002/46/EC, the approximation of laws of the member states relating to food supplements.[136] The second source is Directive 2000/13/EC, the approximation of the laws of the member states relating to the labeling, presentation, and advertising of foodstuffs.[137] The third source is Regulation (EU) No. 1169/2011, the provision of food information to consumers.[138]

Directive 2002/46/EC defines food supplements. The definition is broad and describes food supplements as:

> foodstuffs, the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.[139]

Directive 2002/46/EC harmonizes EU regulations on food supplements to protect consumers from potential health risks and to ensure that they are not provided with

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[131] Richard Rose et al., *Vertical and Horizontal EU Policymaking*, 506 UNIV. STRATHCLYDE STUD. PUB. POL'Y at 1, 4, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2496330 [https://perma.cc/5C5U-3FQJ].

[132] *Types of EU Law*, EUROPEAN COMMISSION, https://ec.europa.eu/info/law/law-making-process/types-eu-law_en [https://perma.cc/AE4Y-BSAY].

[133] *Id.*

[134] *Id.*

[135] *Applying EU Law*, EUROPEAN COMMISSION, https://ec.europa.eu/info/law/law-making-process/applying-eu-law_en#eu-countries [https://perma.cc/9QFL-JUSP].

[136] Directive 2002/46/EC, of the European Parliament and of the Council of 10 June 2002 on the Approximation of the Laws of the Member States Relating to Food Supplements 2002 O.J. (L 183) 51, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32002L0046 [https://perma.cc/NS28-FU89].

[137] Directive 2000/13/EC, of the European Parliament and of the Council of 20 March 2000 on the Approximation of the Laws of the Member States Relating to the Labelling, Presentation and Advertising of Foodstuffs**,** 2000 O.J. (L 109) 29, http://extwprlegs1.fao.org/docs/pdf/eur34490.pdf [https://perma.cc/28XW-4ZMK].

[138] Commission Regulation 1169/2011, 2011 O.J. (L 304) 18, http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32011R1169 [https://perma.cc/5EBN-ETC3].

[139] Directive 2002/46/EC, of the European Parliament and of the Council of 10 June 2002 on the Approximation of the Laws of the Member States Relating to Food Supplements, 2002 O.J. (L 183) 51, 52, http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32002L0046 [https://perma.cc/B68L-V66L].

misleading information.[140] It also specifies which food supplements may be sold in the EU using an annex known as the "positive list."[141] It also provides recommendations on maximum and minimum levels of daily consumption of food supplements and specifies labeling requirements.[142] Labels of food supplements must contain the term "food supplement," the names of the categories of substances that characterize the product, the recommended daily portion of that supplement, a warning to not exceed the recommended daily portion, a statement that the supplement is not a substitute for a varied diet, and a warning that the product should be stored out of the reach of young children.[143]

In the EU food safety system, responsibility for risk assessment (science) and responsibility for risk management (policy) are kept separate. The European Food Safety Authority (EFSA) is responsible for risk assessment and regularly shares its scientific findings and conclusions with the public.[144] EFSA is a European agency funded by the European Union that operates independently of the European legislative and executive institutions (Commission, Council, Parliament) and the member states.[145] It was set up in 2002 after a series of food crises in the late 1990s; it is meant to be a source of scientific advice and communication on risks associated with the food chain.[146]

EFSA launched an interactive tool—the DRV Finder—in 2018.[147] It allowed making calculations using EFSA's dietary reference values for nutrients including fourteen vitamins and thirteen minerals.[148] The DRV Finder is based on thirty-two opinions of the Dietary Reference Values that EFSA has published in recent years, and it will allow corporate socially responsible companies to help consumers make healthy choices on food supplements.[149]

Despite developments in EU legislation on food supplements, the European Union has issues with the marketing and free movement of food goods and food supplements inside and between member states.[150] The European Commission has not offered any further harmonization initiatives on food supplements since the implementation of

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[140] *Ensuring Safe Food Supplements in the EU*, EUR-LEX, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:l21102 [https://perma.cc/RY6H-R45Y].

[141] *See* Council Directive 2002/46, art. 4, 2002 O.J. (L 183) 51, 53–57 (EC).

[142] *Id.* at 53.

[143] *Id.*

[144] *How We Work*, EUR. FOOD SAFETY AUTHORITY, http://www.efsa.europa.eu/en/about/howwework [https://perma.cc/59P2-3XWT].

[145] *About EFSA*, EUR. FOOD SAFETY AUTHORITY, http://www.efsa.europa.eu/en/aboutefsa [https://perma.cc/438V-CQ3Y].

[146] *Id.*

[147] *DRV Finder*, EUR. FOOD SAFETY AUTHORITY, https://www.efsa.europa.eu/en/interactive-pages/drvs [https://perma.cc/5HP3-LQNZ].

[148] *Id.*

[149] *Id.*

[150] Małgorzata Korzycka-Iwanow & Monika Zboralska, *Never-Ending Debate on Food Supplements: Harmonisation or Disharmonisation of the Law?*, 5 EUR. FOOD & FEED L. REV. 124, 124–35 (2010).

Directive 2002/46/EC.[151] Member states often have differing interpretations of which substances may be allowed as food supplements or medicine.[152]

In 2015, the European Commission launched a formal assessment of food supplement regulations as part of its Regulatory Fitness and Performance program.[153] The initiative presented a comprehensive array of additional guidance to assist practitioners in the application of the Better Regulation Guideline.[154] The initiative also:

> initiated a check to map out the current situation and the extent to which the lack of application of the Claims Regulation to plant-based products, and the lack of harmonization, have affected the objectives of the law and provided consumer protection, fair competition, free movement of goods, legal certainty and protection of innovation.[155]

The initiative started in 2015.[156] The Food Chain Evaluation Consortium (FCEC) conducted a survey that assessed the views of industry, consumers, and governments on better regulation of food supplements.[157] The conclusions of the survey were meant to inform future recommendations for the harmonization of food supplements regulations in the European Union.[158] The survey did not fully address problematic differences of opinion on food supplements classification.[159] It did, however, address the drawing of a clear border between medicinal and health effects, ensuring that both legal frameworks can co-exist and avoid overlap.[160]

D. Regulatory Challenges

The fundamental challenge in the regulation of dietary supplements is that no global consensus exists concerning how to define this category of products. Each country uses not only a different term to elucidate dietary supplements but also has a different dosage requirement for the product to be defined as a supplement or a drug. For

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[151] Patrick Coppens, *Food Supplements in the European Union: The Difficult Route to Harmonization*, REG. AFF. PROF. SOC'Y (July 10, 2018), https://www.raps.org/news-and-articles/news-articles/2018/7/food-supplements-in-the-european-union-the-diffic [https://perma.cc/R6AR-NJZV].

[152] *Id.*

[153] *REFIT – Making EU Law Simpler and Less Costly*, EUROPEAN COMMISSION, https://ec.europa.eu/info/law/law-making-process/evaluating-and-improving-existing-laws/refit-making-eu-law-simpler-and-less-costly_en [https://perma.cc/A6RH-KZ9J]; *Better Regulation "Toolbox"*, EUROPEAN COMMISSION (2015), https://ec.europa.eu/info/sites/info/files/better-regulation-toolbox-2015_0.pdf [https://perma.cc/5RJS-SPP9].

[154] *Better Regulation "Toolbox"*, *supra* note 153.

[155] Coppens, *supra* note 151.

[156] *Better Regulation "Toolbox"*, *supra* note 153.

[157] Food Chain Evaluation Consortium, *Scoping Study Delivering on EU Food Safety and Nutrition in 2050—Scenarios of Future Change and Policy Responses*, EUROPEAN COMMISSION (Dec. 20, 2013), https://ec.europa.eu/food/sites/food/files/safety/docs/final_report_scoping_study_en.pdf [https://perma.cc/GRU5-VR9D].

[158] Coppens, *supra* note 151.

[159] Arturo Anadón et al., *Evaluation and Regulation of Food Supplements*, *in* NUTRACEUTICALS, EFFICACY, SAFETY AND TOXICITY 895–923 (2016), https://www.researchgate.net/publication/303414792_Evaluation_and_Regulation_of_Food_Supplements [https://perma.cc/97Q7-C3LV].

[160] Patrick Coppens et al., *Use of Botanicals in Food Supplements*, 50 ANNALS NUTRITION & METABOLISM 538 (2006), https://www.karger.com/Article/Pdf/98146 [https://perma.cc/7Z56-P9FB].

example, Vitamin D3 5000 International Units (IU) would be defined as a drug in the European Union, while in the United States it would be considered a dietary supplement.[161] The situation is even more complicated in countries like China, which has an existing regulatory framework for traditional medicine and phytomedicine that includes crude botanicals.[162]

Another challenge arises from the fact that regulations applying to dietary supplements vary even among countries with similar legal systems and levels of economic development. Regulatory frameworks on dietary supplements in the United States, Canada, China, and the European Union are constantly changing to ensure product safety and compliance. Further, the lucrative and growing nature of the global dietary supplement industry has led to the introduction of many new manufacturers and products. Of course, there are wide-ranging and diverse opinions on what the ideal regulatory approach might be. In different jurisdictions, the same dietary supplement may be considered as a food or a drug. It is extremely important to address regulatory challenges on dietary supplements through the harmonization of national and international standards in order to improve food safety and public health.

IV. CONCLUSION

Food safety has become a top concern for American consumers, and dietary supplements pose a unique and difficult challenge for food safety regulators. Even though FDA is making efforts to ensure the safety of dietary supplements, manufacturers continue to produce dietary supplements that create health risks.

Regulations in Canada, China, and the European Union are more restrictive than those in the United States. Still, American consumers likely have the same level of access to high-quality supplements as consumers abroad. Importantly, however, Americans may have more access to low-quality and harmful supplements. There is no global consensus on how to elucidate, define, and regulate this category of products. Dietary supplements are defined and regulated differently around the globe—labeling, dosage, and safety requirements vary between jurisdictions.

The research in this Article speaks to the potential benefits of an international treaty defining dietary supplements and regulating their safety, quality, dosage, and labeling. Universal and consistent implementation of such a treaty would be critical. International standardization and coordination of dietary supplement regulations will allow countries to bridge the gaps between them and prevent harmful substances from slipping through the cracks. By coordinating their laws and cooperating with each other, countries around the world can better regulate this growing industry and better control these important and heavily used products. A single, universal international treaty would ensure that all consumers are protected from the potentially harmful effects caused by dietary supplements. Such a treaty would improve food safety and public health, both in the United States and around the world.

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[161] *DRV Finder*, *supra* note 147.

[162] *See* Dwyer et al., *supra* note 68, at 41–43.