THE LAUTENBERG CHEMICAL SAFETY ACT OF 2016: CANCER, INDUSTRY PRESSURE, AND A PROACTIVE APPROACH

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> The dilemma is that there have literally been thousands of new chemicals coming into the marketplace, and we have limited knowledge of their toxicity. Because many of these agents have not been screened, it is not known what health effect, if any, exposure to these chemicals will have . . . . [Do] we assume that something is safe until it causes harm, or vice versa?[1]

Introduction

In the summer of 2016, Congress amended the Toxic Substances Control Act ("TSCA"),[2] passing the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("LCSA").[3] The first major U.S. environmental law in decades,[4] LCSA was widely lauded by the American Chemistry Council ("ACC") and other industry groups[5] but less warmly received by consumer and public advocacy groups.[6] While LCSA contains policy that would move the United States toward a more health-protective federal toxics regulatory regime, especially as to new chemicals, it also calls for federal preemption of state action in some

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1. Roxanne Nelson, *President's Cancer Panel: Environmental Cancer Risk Under Estimated*, Medscape (May 13, 2010), https://perma.cc/3HD9-XJRE (quoting Dr. Jonathan Samet, Flora L. Thornton Chair of the Department of Preventive Medicine at the University of Southern California and former Co-Chair of The American Cancer Society Subcommittee on Cancer and the Environment).
2. Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified as amended at 15 U.S.C. §§ 2601–2629 (2012)).
3. Pub. L. No. 114-182, 130 Stat. 448 (2016) (to be codified at 15 U.S.C. §§ 2601–2629).
4. *See* Richard A. Denison, Envtl. Def. Fund, A Primer on the New Toxic Substances Control Act (TSCA) and What Led to it 2 (2017), https://perma.cc/AQ9W-8WB3.
5. *See, e.g.*, Press Release, ACC, ACC Lauds Passage of Senate Bill to Reform TSCA (Dec. 17, 2015), https://perma.cc/6WAM-QTJE; Puneet Kollipara, *United States Adopts Major Chemical Safety Overhaul*, Science (June 8, 2016), https://perma.cc/J3Z3-543X.
6. *See* Melanie Benesh & Scott Faber, *New TSCA Bill Falls Short of Protecting Americans from Toxic Chemicals*, Envtl. Working Group (May 24, 2016), https://perma.cc/TB9W-SWQT; Press Release, Coming Clean, When It Comes to Protecting Public Health from Toxic Chemicals, TSCA Reform Leaves Much Unfinished Business (June 23, 2016), https://perma.cc/CV6M-84P7; *see also* Ctr. for Envtl. Health, Chemical Safety Reform: Getting It Right (2015), https://perma.cc/3PEP-HCEA (discussing opposition to the bills that became LCSA).

circumstances, limits action as to existing chemicals, and, like TSCA, it remains vulnerable to agency interpretation and implementation. These concerns about implementation are relevant especially because stringent enforcement of the law seems unlikely in this political climate.[7]

Indeed, EPA's July 2017 implementation rules for review of existing chemicals and "framework" documents for new chemicals potentially vitiate many of the Act's intended protections.[8] Yet, everyday exposure to dangerous chemicals in consumer products can cause serious illness and death,[9] and LCSA and accompanying regulation are not currently adequate to properly protect human health and the environment.[10]

Part I of this Article first reviews the research suggesting that environmental exposure to toxic chemicals causes many serious illnesses, including cancers,[11] and then surveys existing and proposed mechanisms in the federal legal framework to regulate toxic substances to protect human health.[12] Despite such mechanisms in statutes like the Federal Food, Drug, and Cosmetics Act of 1938 ("FFDCA"),[13] the Food Quality Protection Act of 1996 ("FQPA"),[14] the Safe Drinking Water Act of 1974 ("SDWA"),[15] and the Clean Air Act of 1970 ("CAA"),[16] Americans are still regularly exposed to toxic substances.

Part II of this Article provides an overview of the deficiencies in the original TSCA that LCSA seeks to correct. Part III outlines the basic provisions of

7. *See, e.g.*, Coral Davenport, *Scott Pruitt, Trump's Rule-Cutting EPA Chief, Plots His Political Future*, N.Y. Times (Mar. 17, 2018), https://perma.cc/E67U-WR79 (discussing the deregulatory agenda of President Trump's first EPA Administrator, Scott Pruitt); Clyde Wayne Crews Jr., *Trump Exceeds One-In, Two-Out Goals on Cutting Regulations, but It May Be Getting Tougher*, Forbes (Oct. 23, 2018), https://perma.cc/37VY-QHVS (discussing the total number of deregulatory actions the Trump Administration took during its first two years compared to those that the Obama Administration took during its final years).

8. *See infra* Parts III.C.2–IV.A.

9. *See infra* Parts I–III.

10. *See infra* Part IV.A.

11. *See, e.g.*, *Cancer-Causing Substances in the Environment*, Nat'l Cancer Inst., https://perma.cc/6SJ8-BZXE (noting that cancer is caused when genes affect the way cells function, and that some of these changes are caused by environmental carcinogens such as asbestos or formaldehyde).

12. *See infra* Part I.B.

13. Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301–399 (2012)).

14. Pub. L. No. 104-170, 110 Stat. 1489 (1996) (codified as amended in scattered sections of 7 U.S.C. and 21 U.S.C.) (amending the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and FFDCA); *see also The Food Quality Protection Act (FQPA) Background*, EPA, https://perma.cc/8J6W-6JDT (providing background information on the functions and history of the FQPA).

15. Pub. L. No. 93-522, 88 Stat. 1660 (1974) (codified as amended at 42 U.S.C. §§ 300f–300j-27).

16. Pub. L. No. 91-604, 84 Stat. 1676 (1970) (codified as amended at 42 U.S.C. §§ 7401–7671).

LCSA, identifies its deficiencies, and critiques its initial implementation. Finally, Part IV envisions the way forward with a "proactive" stance to regulate toxic substances. Such a regulatory stance would couple TSCA, as amended, with greater information transparency and corresponding market forces to encourage industry and regulators to better protect human health and the environment from toxic chemicals[17]—a "market-assisted" approach.

This Article intends to spur a dialogue about moving TSCA's regulatory regime in this more proactive, market-assisted direction. LCSA already has the power to improve our toxics regulatory regime to better protect human health, but safety could be improved with greater information transparency. This would in turn cause consumers to demand both safer chemicals and more health-protective regulation. In Part IV, I further elaborate on how the market can make LCSA work in this more health-protective, market-assisted manner.

I. Environmental Pollution and Existing U.S. Federal Law on Toxic Substances in the Environment

A. Environmental Pollution Contributes to Serious Illnesses Including Cancer

In 2010, the President's Cancer Panel released a report that called for more precautionary measures to prevent cancers in the United States and noted that many more cancers are related to environmental risk factors than had previously been recognized.[18] When the report was released, Jeanne Rizzo, then the Chief Executive Officer of The Breast Cancer Fund, said the President's

17. *See infra* Part IV.

18. The President's Cancer Panel, Nat'l Cancer Inst., President's Cancer Panel Annual Report 2008-2009, Reducing Environmental Risk: What We Can Do Now, at vi–ix (2010). Cancer, for example, is one of the leading causes of death in the world. *See Cancer*, World Health Org. (Sept. 12, 2018), https://perma.cc/VA8H-3ZMA; *Cancer Statistics*, Nat'l Cancer Inst., https://perma.cc/3BPR-J5R3; *Cancer*, World Health Org., https://perma.cc/5XLT-2M72 (noting that cancer is the second leading cause of death globally and that it accounted for approximately 9.6 million deaths in 2018). Statistics show that at least one in three Americans will develop cancer in their lifetimes, *see Cancer Statistics*, *supra*, and that, based on past statistics, far more will die this year from the disease than from gun violence or from terrorism combined, *see* Philip Bump, *President Obama Is Right That Guns Kill More Americans Than Terrorism. So Do Lots of Other Things*, Wash. Post (Oct. 1, 2015), https://perma.cc/58NG-SJJW. The National Cancer Institute predicts that worldwide cancer incidence will increase from 14.1 million cases in 2012 to 23.6 million by 2030. *See Cancer Statistics*, *supra*. And childhood cancer rates have steadily increased by approximately 0.6% yearly since 1975. *See* Am. Cancer Soc'y, Cancer Facts & Figures 12 (2018), https://perma.cc/HD6N-CQLC. The American Cancer Society reported that medical costs for cancer care in the United States in 2015 amounted to $80.2 billion. *Id.* at 9. The World Health Organization estimated that in 2010 the economic worldwide cost of cancer was $1.16 trillion. *Cancer*, World Health Org., https://perma.cc/5XLT-2M72.

Cancer Panel "leveled a hefty critique of failed regulation [of environmental contaminants], undue industry influence, and inadequate research and funding."[19] While the American Cancer Society criticized the report, claiming that many more cancers are due to lifestyle than to environmental causes,[20] medical experts agreed that environmental factors play a significant role in disease development that has been historically underestimated by the medical community.[21]

Even prior to the 2010 President's Cancer Panel Report, leading scientists and public policy experts raised concerns about avoidable toxins in the environment and argued for a paradigm shift to make the regulatory approach more precautionary and proactive.[22] These experts urged a regulatory approach more in line with initiatives in the European Union to evaluate chemicals before they are brought to market.[23]

Nicole Bijlsma and Marc Cohen furthered the dialogue in a 2016 paper that linked the global growth of chemical sales to a global increase in the incidence of disease caused by environmental factors.[24] The article noted that global chemical sales volume had increased from $171 billion in 1970 to more than $4 trillion in 2012.[25] Bijlsma and Cohen further found that the developed world has in recent decades seen an increase in rates of chronic diseases related to environmental pollution relative to rates of infectious diseases.[26] With fifty percent of the working population now afflicted with an unexplained chronic dis-

19. Jeanne Rizzo, *It's Time for Breast Cancer Prevention Month*, Huffington Post (Oct. 12, 2010), https://perma.cc/X9NQ-4TTV.

20. *See* Kate Sheridan, *Americans Are Giving Themselves Cancer—Half of Cases Caused by Lifestyle*, Newsweek (Nov. 22, 2017), https://perma.cc/M4Q3-AEM9.

21. Marla Cone, *Doctors Underestimate Environment as Cause for Cancer*, Sci. Am. (May 6, 2010), https://perma.cc/9C2J-JMMM.

22. *See* Richard W. Clapp, Genevieve K. Howe & Molly Jacobs, *Environmental and Occupational Causes of Cancer Re-Visited*, 27 J. Pub. Health Pol'y 61, 68, 73–74 (2006).

23. *See id.* at 73. The European Union REACH Regulation, enacted in 2007, was designed to better understand chemical substances before they go to market. It requires the submission of safety data before a chemical is brought to market and is known for the phrase "no data, no market." *Environment: REACH*, Eur. Comm'n, https://perma.cc/C6Q2-MAM2.

24. *See* Nicole Bijlsma & Marc M. Cohen, *Environmental Chemical Assessment in Clinical Practice: Unveiling the Elephant in the Room*, 13 Int'l J. Envtl. Res. Pub. Health 181 (2016).

25. *Id.* at 182 (citing UNEP, Global Chemicals Outlook - Towards Sound Management of Chemicals (2013), https://perma.cc/K4YN-7BGW.

26. *See id.* at 183. The shift from communicable diseases to chronic diseases due to environmental hazards has been called the "epidemiological transition." Amalia Laborde et al., *Children's Health in Latin America: The Influence of Environmental Exposures*, 123 Envtl. Health Persp. 201, 201, 205 (2015). The Centers for Disease Control and Prevention ("CDC") estimates that five of every 1,000 boys born in the United States are born with some sort of hypospadia. *Birth Defects: Facts About Hypospadias*, CDC, https://perma.cc/HSV3-5F9R.

ease,[27] Bijlsma and Cohen posited that a long list of diseases—including diabetes, hyospadias (male reproductive disorders), infertility, Alzheimer's, autoimmune disease, obesity, and cancers—can be caused or exacerbated by environmental exposures to man-made chemicals.[28]

In the United States, chemical manufacturers produce over 80,000 synthetic chemicals, the vast majority of which are not tested for their effects on human health.[29] More so, persistent organic pollutants, such as polychlorinated biphenols ("PCBs") and other toxic chemicals regulated under TSCA, are routinely found in breast milk and in human placentas.[30] Indeed, a growing body of science suggests we are all contaminated from the womb to the grave.[31]

Many of these more than 80,000 chemicals on the market are Endocrine Disrupting Chemicals ("EDCs"), chemicals that interfere with the functioning

27. Bijlsma & Cohen, *supra* note 24, at 181 (citing Amanda Reichard et al., *Diagnosis Isn't Enough: Understanding the Connections Between High Health Care Utilization, Chronic Conditions and Disabilities Among U.S. Working Age Adults*, 8 Disability Health J. 535 (2015)).

28. *See* Bijlsma & Cohen, *supra* note 24, at 183–84; *see also* Paolo Boffetta & Fredrik Nyberg, *Contribution of Environmental Factors to Cancer Risk*, 68 Brit. Med. Bull. 71, 88 (2003) ("[D]espite the relatively small relative risks of cancer following exposure to environmental carcinogens, the number of cases that might be caused, assuming a causal relationship, is relatively large, as a result of the high prevalence of exposure. This emphasizes the need for a better understanding of the actual risk of cancer posed by environmental factors, and of the effect of measurements aimed at controlling exposure to environmental carcinogens.").

29. U.S. Gov't Accountability Office, GAO-13-249, Toxic Substances: EPA Has Increased Efforts to Assess and Control Chemicals But Could Strengthen Its Approach 10 n.12, 12–17 (2013).

30. *See* Martin van den Berg et al., *WHO/UNEP Global Surveys of PCDDs, PCDFs, PCBs and DDTs in Human Milk and Benefit-Risk Evaluation of Breastfeeding*, 91 Archives Toxicology 83 (2017); World Health Org., Fourth WHO-Coordinated Survey of Human Milk for Persistent Organic Pollutants in Cooperation with UNEP: Guidelines for Developing a National Protocol (2007).

31. *See, e.g.*, Theo Colburn, Dianne Dumanoski & John P. Myers, Our Stolen Future: Are We Threatening Our Fertility, Intelligence, and Survival? — A Scientific Detective Story 223 (1996) (noting that all persons had been subjected to some synthetic chemicals that could disrupt development); Amanda Follett, *Ignorance is Bliss? Balancing the Public's Right to Know and Industry's Claim to Confidential Business Information in TSCA Reform*, 11 Rutgers J.L. & Pub. Pol'y 590, 601 (2014) (discussing studies by the Environmental Working Group and the CDC which found, respectively, more than 200 synthetic industrial chemicals in infant subjects' blood, and measurable levels of phthalate metabolites in the general U.S. population); Nathaniel Rich, *The Lawyer Who Became DuPont's Worst Nightmare*, N.Y. Times Mag. (Jan. 6, 2016), https://perma.cc/R6NG-UK7R (noting that perfluorooctanoic acid ("PFOA"), an EDC used in Teflon, has been detected in American blood banks and that the average concentration of PFOA in the blood of an American adult by 2003 was four to five parts per billion); *ToxFAQs for Polychlorinated Biphenyls (PCBs)*, Agency for Toxic Substances & Disease Registry (July 2014), https://perma.cc/2YC2-JQ5Q ("Most people normally have low levels of PCBs in their body because nearly everyone has been environmentally exposed to PCBs.").

of the human endocrine system and often mimic hormones.[32] EDCs affect bodily regulation and have been linked at very low levels to nervous system disorders, cancers, and reproductive problems.[33] EDCs are also routinely found in everyday products regulated by LCSA and accompanying regulations, including household items, food and beverage containers, non-stick cooking surfaces, air fresheners, cleaning products, and many other chemical substances used by consumers.[34]

Concerns about EDCs escaping scrutiny of U.S. chemical regulators recall TSCA's historic indifference to PCBs. PCBs were thought to be benign chemicals when first produced in the early part of the twentieth century,[35] and they were widely used in schools and other buildings all over the United States from the 1950s to the early 1970s,[36] largely because of their ability to conduct electricity and improve the elasticity of caulking materials.[37] Congress and EPA allowed their continued production until 1979,[38] long after manufacturers had

32. Valerie J. Watnick, *Our Toxics Regulatory System and Why Risk Assessment Does Not Work: Endocrine Disrupting Chemicals as a Case in Point*, 2004 UTAH L. REV. 1305, 1308–09 (2004).

33. *See, e.g.*, Sheldon Krimsky, *Hormone Disruptors: A Clue to Understanding the Environmental Causes of Disease*, 43 ENVIRONMENT 22, 27–29 (2001); COLBURN, DUMANOWKI & MYERS, *supra* note 31, at 73–74, 80–81, 83; *infra* notes 261–265 and accompanying text.

34. Chemicals suspected of endocrine disruption include pesticides; flame retardants used in furniture and carpeting; environmental phenols, such as bisphenol A, used in personal care products and water bottles; fluorinated chemicals, like PFOA, found in non-stick cookware, furniture, and food papers; and phthalates, found in plastics, including toys and food packaging. *See* Susanna D. Mitro et al., *Consumer Product Chemicals in Indoor Dust: A Quantitative Meta-Analysis of U.S. Studies*, 50 ENVTL. SCI. & TECH. 10,661, 10,666–70 (2016); Kalyn Behnke, Comment, *Toxic Preemption: Why the Lautenberg Chemical Safety Act's Erosion of State Authority Contaminates Environmental Law*, 57 JURIMETRICS 459, 473–74 (2017); Rich, *supra* note 31; *Endocrine Disruptors*, NAT'L INST. OF ENVTL. HEALTH SCI. (Jan. 22, 2019), https://perma.cc/8DMP-4DJY.

35. *See Questions about Products of the Former Monsanto*, MONSANTO, https://perma.cc/X9JZ-MVDB (describing Monsanto's historic use of PCBs).

36. *See* Robert F. Herrick, James K. Stewart, Joseph G. Allen, *Review of PCBs in US Schools: A Brief History, Estimate of the Number of Impacted Schools, and an Approach for Evaluating Indoor Air Samples*, 23 ENVTL. SCI. POLLUTION RES. 1975, 1975–77 (2016).

37. *See, e.g.*, Valerie Watnick, *PCBs in Schools and Corporate Responsibility for Remediation: Yorktown Central School District v. Monsanto Company*, 33 ENVIRONS ENVTL. L. & POL'Y J., 231, 238 (2010); *Learn about Polychlorinated Biphenyls (PCBs)*, EPA (Mar. 31, 2019), https://perma.cc/T9L3-QJ8R; *Polychlorinated Biphenyls (PCBs)*, EPA, https://perma.cc/7MWS-52H2 (defining PCBs); *PCBs Overview*, STOCKHOLM CONVENTION ON PERSISTENT ORGANIC POLLUTANTS, https://perma.cc/K4WK-XDSV (explaining that parties to the Stockholm Convention are prohibited from producing PCBs and are obligated to stop using PCBs by 2025).

38. 15 U.S.C. § 2605(e) (2012). EPA issued a final rule to implement section 6(e) of TSCA on May 31, 1979. Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions, 44 Fed. Reg. 31,159, 31,514 (May 31, 1979) (codified as amended at 40 C.F.R. § 761 (2018)); *see also Polychlorinated Biphenyl (PCB)-Containing*

evidence that PCBs presented an unreasonable risk to human health and the environment.[39] In the years since their production has been mostly halted in this country, experts have found that PCBs do not break down easily;[40] they are still found in oceans, rivers, human blood, animal tissue,[41] and school building materials across the country.[42] And while PCBs are one of the few chemicals whose use TSCA has severely restricted since 1979 due to health and environmental concerns,[43] they are not subject to an outright ban and thus still contribute to vast environmental pollution around the globe.[44]

B. Overview of Existing Federal Statutes Regulating Toxic Substances

Congress recognized the need for a more proactive stance towards toxics regulation as early as the 1970s and originally designed TSCA to be a catch-all, proactive statute, requiring testing of the burgeoning population of chemicals brought to market after World War II.[45] But TSCA and accompanying regulation has not effectively protected humans from the deluge of chemicals brought to market by industry.[46] And, while more than twenty other laws regulate par-

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Flourescent Light Ballasts (FLBs) in School Buildings, EPA, https://perma.cc/N3LN-38KU (noting that EPA phased out the use of PCBs starting in 1979).

39. *See, e.g.*, Arthur Nelsen, *Monsanto Sold Banned Chemicals for Years Despite Known Health Risks, Archives Reveal*, GUARDIAN (Aug. 10, 2017), https://perma.cc/6EQ9-RPSN; Transwestern Pipeline Co. v. Monsanto Co., 53 Cal. Rptr. 2d 887, 890 (Cal. Ct. App. 1996) (finding that Monsanto learned that PCBs were persistent in the environment and that, in 1970, it began placing warning labels on some of its products).

40. *See* Jan Alexander et al., *Opinion of the Scientific Panel on Contaminants in the Food Chain on a Request from the Commission Related to the Presence of Non Dioxin-like Polychlorinated Biphenyls (PCB) in Feed and Food*, 284 EUR. FOOD SAFETY AUTHORITY J. 1, 89 (2005); Watnick, *supra* note 37, at 238; *PCBs Overview*, STOCKHOLM CONVENTION ON PERSISTENT ORGANIC POLLUTANTS, https://perma.cc/9TVK-LDWB.

41. *See* FRANCIS A. CAREY, Polychlorinated Biphenyl, ENCYC. BRITANNICA, https://perma.cc/DN9L-8UJW.

42. *See* Watnick, *supra* note 37, at 241.

43. *See, e.g.*, *id.* at 233; Rebecca Harrington, *The EPA Has Only Banned These 9 Chemicals — out of Thousands*, BUSINESS INSIDER (Feb. 10, 2016), https://perma.cc/5AXM-4VRQ; 40 C.F.R. § 761.20 (2018) (restricting the use, manufacture, and distribution of PCBs).

44. *See* Peter L. Lallas, *The Stockholm Convention on Persistent Organic Pollutants*, 95 AM. J. INT'L L. 692, 702 (2001).

45. COUNCIL ON ENVTL. QUALITY, ENVIRONMENTAL QUALITY: THE EIGHTH ANNUAL REPORT OF THE COUNCIL ON ENVIRONMENTAL QUALITY 5 (1977).

46. *See Preliminary Observations on Legislative Changes to Make TSCA More Effective: Hearing Before the Subcomm. on Toxic Substances, Research & Dev. of the S. Comm. on Env't & Pub. Works*, 103d Cong. (1994) (statement of Peter F. Guererro, Director, Environmental Protection Issues, Resources, Community, and Economic Development Division, United States General Accounting Office); Sheldon Krimsky, *The Unsteady State and Inertia of Chemical Regulation Under the US Toxic Substances Control Act*, PLOS BIOLOGY 1–3 (Dec. 18, 2017); *see also Chemical Regulation: Options for Enhancing the Effectiveness of the Toxic Substances*

ticular chemical substances and their uses in consumer products,[47] these laws do not generally require proactive testing and safety affirmation before a chemical goes to market.[48]

For example, in the FFDCA, the major provision regulating cosmetics prohibits both "adulterated" and "misbranded" cosmetics.[49] Misbranded cosmetics are those not properly labeled,[50] and adulterated cosmetics are those that are made under "unsanitary" conditions or contain "poisonous," "deleterious," "putrid," or "filthy" substances that may be "injurious to health."[51] The original statutory definitions of "misbranded" and "adulterated" remain in place today—despite immense advances in scientific and technological knowledge in the eighty years since the FFDCA was originally enacted.[52] Use of terms such as putrid and filthy focus on acute risks from cosmetics and evince a lack of understanding of current corporate production and concern about the long-term effects of a cosmetic product on the user.[53] By these standards, most cosmetic products are considered safe in the United States today absent some meaningful proof of long-term harm, which is not regularly available.[54]

Federal cosmetics law does not require premarket testing before sale and fails to protect the public from long term use of cosmetics that might contain

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Control Act: Hearing Before the Subcomm. on Commerce, Trade, & Consumer Prot. of the H. Comm. on Energy & Commerce, 111th Cong. (2009) (statement of John Stephenson, Director, Natural Resources & Environmental, United States Government Accountability Office).

47. ROBERT L. GLICKSMAN ET AL., ENVIRONMENTAL PROTECTION: LAW AND POLICY 780 tbl. 8-2 (5th ed. 2007) (listing the more than twenty federal laws that regulate toxic substances).

48. There are some exceptions to the fact that U.S. toxics law is not proactive in nature. For example, the FDA's review process for drugs is proactive and requires the manufacturer to prove that the drug is safe before it goes to market. *See* 21 U.S.C. §§ 355(a)–(d) (2012). Some commentators have called FIFRA proactive in that it requires manufacturers to provide basic information before marketing and also requires mandatory federal labeling. *See* John S. Applegate, *The Precautionary Preference: An American Perspective on the Precautionary Principle*, 6 HUM. & ECOLOGICAL RISK ASSESSMENT 413, 427–28 (2000). However, FIFRA does not require major safety testing before a pesticide goes to market and it is primarily a marketing and labeling statute. *See* Valerie Watnick, *Federal Preemption of Tort Claims Under FIFRA: The Erosion of a Defense,* 36 MICH. J.L. REFORM 419, 422 (2004).

49. 21 U.S.C. § 331(a).

50. *Id.* §§ 362(a)–(c).

51. *Id.* §§ 361(a)–(d).

52. Valerie J. Watnick, *The Missing Link: U.S. Regulation of Consumer Cosmetic Products to Protect Human Health and the Environment*, 31 PACE ENVTL. L. REV. 595, 602 (2014).

53. *Id.*

54. *Id.*; *see also* Mary O'Brien, *Our Current Toxics Use Framework, Our Stolen Future, and Our Options*, 11 J. ENVTL. L. & LITIG. 331, 340, 344–47 (1996) (reviewing COLBURN, DUMANOSKI & MYERS, *supra* note 31) (discussing causality between toxic EDCs and disease and noting that connection is very difficult to establish in that immune system degradation from prior chemical exposures may play a role).

toxic substances.[55] Meanwhile, many consumers in the United States incorrectly assume the chemicals in everyday consumer products, including cosmetics, are subject to rigorous testing and scrutiny.[56]

Food is, in theory, more heavily regulated in the U.S. than cosmetics. The FQPA,[57] passed in 1996 to amend FIFRA and the FFDCA, regulates the amount of pesticide residue or deleterious substances that may be found on fresh and processed food. FIFRA requires that a pesticide be registered for food use,[58] but first FFDCA requires EPA to establish either a tolerance—a legal limit on the amount of pesticide residue that can be on the food—or an exemption from a tolerance.[59] EPA sets tolerances on a single crop based on limited toxicity information, including available epidemiological studies, animal studies, and exposure information.[60] While the FQPA directs EPA to consider several factors, including the "dietary consumption patterns of consumers," available information concerning aggregate pesticide exposure levels, and "common mechanisms" of a pesticide's toxicity,[61] risk assessors often lack basic information and must rest their risk assessments on assumptions and judgments.[62]

Once EPA performs its risk assessment and sets the tolerance for a crop, actual enforcement of these "tolerable" residue levels is inconsistent and poten-

55. *See Testimony of Scott Faber Senior Vice President for Government Affairs Environmental Working Group on Exploring Current Practices in Cosmetics Development and Safety before the S. Comm. on Health, Education, Labor and Pensions* (2016); Watnick, *supra* note 52, at 601–06; Eric Lipton & Rachel Abrams, *Their Hair Fell Out. Should the F.D.A. Have the Power to Act?*, N.Y. Times (Aug. 15, 2016), https://perma.cc/DK7Z-YTGA.

56. *See* Ian Urbina, *Think Those Chemicals Have Been Tested?*, N.Y. Times (Apr. 13, 2013), https://perma.cc/R9LQ-8275; *Household Chemical Products and Their Heath Risk*, Cleveland Clinic, https://perma.cc/JCN8-6YZB; Amy Roeder, *Harmful, Untested Chemicals Rife in Personal Care Products*, Harv. T.H. Chan Sch. of Pub. Health News (Feb. 13, 2014), https://perma.cc/9WZ9-S7ND.

57. Pub. L. No. 104-170, 110 Stat. 1489 (1996) (codified as amended in scattered sections of 7 and 21 U.S.C.). FIFRA regulates the registration of pesticides for all uses, and FFDCA regulates their use on food.

58. *See* 7 U.S.C. § 136a (2012) (outlining registration requirements, procedures, and exceptions).

59. *See* 21 U.S.C. § 346a(a)(1) (defining tolerance requirements and exemptions for pesticide chemical residues).

60. *See Setting Tolerances for Pesticide Residues in Foods*, EPA, https://perma.cc/Y4L2-PXPD; Valerie Watnick, *Risk Assessment: Obfuscation of Policy Decisions in Pesticide Regulation and the EPA's Dismantling of the Food Quality Protection Act's Safeguards for Children*, 31 Ariz. St. L.J. 1315, 1318–20 (1999).

61. 21 U.S.C. § 346a(b)(2)(D) (identifying relevant factors the Administrator should consider in "establishing, modifying, leaving in effect, or revoking a tolerance").

62. *See About Risk Assessment*, EPA, https://perma.cc/6LP3-7W6Z ("[R]isk assessors often have to make estimates and use judgment when performing risk calculations, and consequently all risk estimates are uncertain to some degree"); Watnick, *supra* note 60.

tially very misleading.[63] The USDA performs periodic residue testing on a per-crop basis, reporting on pesticides found on each crop independently.[64] For example, when the USDA tested kale for pesticide residues in 2017, none of the individual pesticide residues exceeded established tolerances,[65] but a particular consumer, based on his diet, could be exposed to the same pesticide from multiple foods he eats, and thereby exceed safe exposure levels, or to a variety of pesticide residues that when combined, might be toxic. USDA testing for the period ending in 2016 showed that the majority of crops contained some pesticide residues, and many contained residues from multiple pesticides,[66] and, therefore, that the USDA cannot fully assess a consumer's likely daily exposure to all pesticides from all foods consumed.

The effect on human health of exposure to these combined and various mixtures of pesticides remains untested and unknown.[67] EPA's tolerance—based on single chemical risk assessment, with some accounting for dietary preferences, multiple pathways of exposure, and chemicals that act in similar manners[68]—does not account for real life risk.[69] The risk assessor uses "availa-

63. Department of Agriculture testing shows that some types of produce still present high risk of pesticide exposure, while others have become much safer since the FQPA was enacted. *See Eat the Peach, Not the Pesticide*, Consumer Rep. (Mar. 19, 2015), https://perma.cc/24PA-RYB8 (detailing and analyzing data on pesticide residues in food in the United States). Further, many Americans believe that there is a legal limit to how many different residues may be found on a food product, when no such legal limit exists. *See id.*; Valerie Watnick, *The Organic Foods Production Act, the Process/Product Distinction, and a Case for More End Product Regulation in the Organic Foods Market*, 32 UCLA J. Envt'l L. & Pol'y 40, 52–55, 58–60 (2014) (discussing the limitations of regulations governing residue testing and tolerance levels, as well as consumer misconceptions about organic foods).

64. *See, e.g.*, Press Release, U.S. Dep't of Agric., USDA Releases 2016 Annual Pesticide Data Program Summary (Feb. 8, 2018), https://perma.cc/5MWE-D8LR (noting that seventy-eight percent of crops tested in 2016 contained pesticide residues); Consumer Reports, *supra* note 63.

65. U.S. Dep't of Agric., Pesticide Data Program—Summary, Calendar Year 2017, at 20 (2018) (finding that three samples of kale contained seventeen different pesticide residues, all at levels below the established tolerances).

66. U.S. Dep't of Agric., Pesticide Data Program—Summary, Calendar Year 2016, at 22 (2018) (noting that, in the 2016 PDP analysis, 318 samples with 358 pesticides were reported to FDA as Presumptive Tolerance Violations); U.S. Dep't of Agric., *supra* note 64 (noting that the USDA detected pesticide residue on seventy-eight percent of crops tested in 2016).

67. *See, e.g.*, Polyxeni Nicolopoulou-Stamati et al., *Chemical Pesticides and Human Health: The Urgent Need for a New Concept in Agriculture*, 4 Frontiers Pub. Health, July 2016, Article 148, at 4; Ken Sexton, *Cumulative Risk Assessment: An Overview of Methodological Approaches for Evaluating Combined Health Effects from Exposure to Multiple Environmental Stressors*, 9 Int'l J. Envtl. Res. & Pub. Health 370, 371–72, 374–75 (2012).

68. 21 U.S.C. §§ 346a(b)(2)(D)(iv)–(v) (2012) (requiring EPA to consider aggregate exposures to a pesticide as well as consideration of chemicals that have a common mechanism of toxicity in setting tolerances).

69. Sanne H. Knudsen, *Regulating Cumulative Risk*, 101 Minn. L. Rev. 2313, 2322–27 (2017).

ble" information about aggregate risk and common mechanisms of toxicity,[70] but these factors do not account for the synergistic effects of the chemical or combined effects of multiple, daily chemical exposures to food and other chemicals in the environment (cumulative risk),[71] nor do they fully account for individual human differences and reactions to chemical exposure (intra-species risk).[72]

Similar to the FQPA, SDWA sets the permissible limits of toxic substances that may be found in public drinking water on a substance by substance basis rather than with a cumulative risk approach. The 1996 amendments to SDWA require that every five years EPA publish a list of contaminants present in public drinking water systems and not subject to national regulation and determine whether to regulate at least five of them.[73] For the contaminants that EPA decides to regulate, EPA must then set the "maximum contaminant level" within twenty-four months of the decision to regulate.[74] Similar to crop testing results, water testing has shown multiple different toxins and levels of toxins that exceed federal health limits and guidelines for individual toxic substances in drinking water. For example, a recent Environmental Working Group study found that the New York City water system—one of the largest in the country, and touted to be one of the safest—had water contaminated with toxic chemicals above federal legal limits,[75] four of which are considered carcinogens.[76] The

70. 21 U.S.C. §§ 346a(b)(2)(D)(iv)–(v).

71. *See* Adam Abelkop & John Graham, *Regulation of Chemical Risks: Lessons for Reform of the Toxic Substances Control Act from Canada and the European Union*, 32 PACE ENVTL. L. REV. 108, 120 (2015); Knudsen, *supra* note 69, at 2322–27, 2351–62 (arguing that cumulative risk assessments should play a central role in regulation, because people cannot control their daily exposures to synthetic chemicals, and because the labeling, information disclosure, and consumer choice paradigms of the existing regulatory regimes are insufficient).

72. *See* HAROLD I. ZELIGER, HUMAN TOXICOLOGY OF CHEMICAL MIXTURES (2d ed. 2011); Bijlsma & Cohen, *supra* note 24, at 4 ("Such [risk] assessments rely heavily on data extrapolated from human epidemiology, animal testing and cell culture/in vitro laboratory studies that fail to account for multiple routes of exposure, mixture effects, transgenerational epigenetic effects or individual human risk factors such as age, gender, genetics, nutrition, psychosocial determinants and comorbidities." (citing INST. OF MED., IDENTIFYING AND REDUCING ENVIRONMENTAL HEALTH RISKS OF CHEMICALS IN OUR SOCIETY: WORKSHOP SUMMARY (2014))); Philippa D. Darbre, *An Introduction to the Challenges for Risk Assessment of Endocrine Disrupting Chemicals*, *in* ENDOCRINE DISRUPTION AND HUMAN HEALTH 289 (Philippa D. Darbre ed., 2015).

73. Pub. L. No. 104-182, § 102, 110 Stat. 1618 (1996) (codified as amended at 42 U.S.C. §§ 300g-1(b)(1)(B)(I)–(II) (2012)).

74. 42 U.S.C. § 300g-1(b)(1)(E). It has been twenty years since a new contaminant has been added to the list of regulated drinking water contaminants. *See* Sarah Toy, *Contaminants in Water Are Legal but Still Pose Big Health Risks, Environmental Group Says*, USA TODAY (July 27, 2017), https://perma.cc/7CTJ-XDAU.

75. *New York City System*, ENVTL. WORKING GROUP, https://perma.cc/D58L-6SZX; *see also* Simone Wilson, *Is NYC Tap Water Safe? 6 Cancer-Causing Chemicals Found at 'Unsafe' Levels*, N.Y.C. PATCH, https://perma.cc/ZS3F-CN2M.

same study found ten contaminants above federal health limits in California and Texas water systems serving over one million people.[77] These results suggest that the pace of regulation under SDWA is too slow, too reactive, and too narrowly focused on one contaminant at a time to adequately protect human health.

Air pollution is similarly regulated under federal law by the CAA, which authorizes EPA to issue and enforce air quality standards.[78] Yet the CAA regulates only a small subset of the pollutants that firms emit—fewer than two hundred out of thousands—and firms are required only to stay within limits and use the "maximum degree of reduction" possible, taking into account the cost of such reductions.[79] Despite early successes at improving ambient air quality,[80] one recent study found the air is still so unclean that "almost 95% of Americans continue to breathe unsafe levels of hazardous air pollutants" known to cause cancer or other health effects.[81]

II. TSCA and Its Legacy: Catch-22 and Grandfathering of Existing Chemicals

In addition to the federal laws regulating human exposure to toxics in cosmetics, food, air, and drinking water, Congress designed TSCA in the 1970s as a tool to regulate toxic substances not otherwise covered by regulation.[82] However, EPA has had difficulty leveraging TSCA to require manufac-

76. *See New York City System*, *supra* note 75. Water pollution is caused by many factors, including organic compounds such as oil, plastics, detergents, chloroform, petroleum, PCBs, fertilizer, sulfur oxide, pesticide and trichloroethylene, all of which are subject to federal regulation. *See National Primary Drinking Water Regulations*, EPA, https://perma.cc/47JG-VDYP (listing organic compounds covered by SDWA).

77. *Tap Water Database*, Envtl. Working Group, https://perma.cc/W9KW-V9YQ.

78. *See* 42 U.S.C. § 7661a(a).

79. *Id.* § 7412(a), (d)(2); *see* Noah Sachs, *Rescuing the Strong Precautionary Principle from Its Critics*, 2011 Ill. L. Rev. 1286, 1327 (2011) (noting that only a small fraction of the thousands of air pollutants have been tested for their toxic properties).

80. The CAA has in fact been called one of the great success stories of environmental regulation. *See, e.g.*, Lisa Heinzerling, *The Clean Air Act and the Constitution*, 20 St. Louis U. Pub. L. Rev. 121, 121–23 (2001).

81. Michelle West, *"Once In, Always In" Now Out: How the EPA Is Reducing Regulations on Hazardous Air Pollutant Emitters*, Geo. Envtl. L. Rev. Online (Mar. 3, 2018), https://perma.cc/28HZ-6U9R; *see also Hazardous Air Pollutants*, EPA, https://perma.cc/XE4J-JPP6. The current administration is also currently rolling back air quality regulations. *See* Alexander Kaufman, *EPA to Gut the Only Major Federal Rule to Cut Climate Pollution from Vehicles*, Huffington Post (Apr. 3, 2018), https://perma.cc/6F8W-TY6C.

82. *See* H.R. Rep. No. 114-176, at 12 (2015) ("In 1971, the President's Council on Environmental Quality proposed comprehensive Federal legislation to identify and control potentially dangerous chemicals in U.S. commerce that were not adequately regulated under other Federal environmental statutes.").

turers to provide adequate safety information on new chemicals and restrict production and distribution of new or existing chemicals.[83] Federal regulation implemented under TSCA has required testing of only 200 chemicals and banned or restricted fewer than ten of these chemicals in the more than forty years since Congress enacted the law.[84]

TSCA has proven largely ineffective mainly due to a "catch-22" that prevents EPA from accessing the data it needs to effectively regulate[85] alongside the grandfathering of more than 60,000 chemicals in use at the time of its passage.[86] TSCA did not allow EPA to require testing of a chemical if it did not have adequate data, but it also did not allow EPA to request such information from industry unless it already believed the chemical presented an unreasonable risk to public health or the environment, a claim difficult to make without data.[87] EPA could only request information if it already had some data to inform it that a chemical was a danger to human health or the environment—hence, the catch-22.[88] By preventing EPA from acquiring enough information to declare a chemical unsafe, TSCA also created a disincentive for the chemical industry to do any testing, because that could create "negative" available information. Thus, not only did TSCA prevent EPA from effectively regulating, but it also created disincentives for industry to test the safety of its own products. In the years since Congress passed TSCA, industry introduced new chemicals and also continued to produce and use most of the grandfathered chemicals freely.[89]

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83. *See* U.S. Gov't Accountability Office, GAO-09-428T, Chemical Regulation: Options for Enhancing the Effectiveness of the Toxic Substances Control Act 3 (2009).

84. *See Hearing Before the H. Subcomm. on Commerce, Trade, & Consumer Prot. of the H. Comm. on Energy & Commerce*, 112th Cong. 2 (2010) (statement of Steve Owens, Assistant Administrator, Office of Chemical Safety & Pollution Prevention, EPA); Tracy Bach, *Better Living Through Chemicals (Regulation)? The Chemical Safety Improvement Act of 2013 Through an Environmental Public Health Law Lens*, 15 Vt. J. Envtl. L. 490, 491 (2014) (describing number of restricted chemicals).

85. *See* Charles Schmidt, *TSCA 2.0: A New Era in Chemical Risk Management*, 124 Envtl. Health Persp. 182, 183–84 (2016). EPA could not even ban asbestos under TSCA. *See* Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1217 (5th Cir. 1991) (holding that EPA failed to meet statutory requirement to use "least burdensome" regulation for asbestos).

86. *See* Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 4825, 4826 (Jan. 17, 2017) (discussing background on and need for recent 2016 amendments to TSCA).

87. *See* Eve Gartner, *Weak Laws and Weaker Governance Keep Toxic Chemicals on the Market*, Earthjustice (Apr. 7, 2016), https://perma.cc/DK4F-7LV4.

88. *See* David Markell, *An Overview of TSCA, Its History and Key Underlying Assumptions, and Its Place in Environmental Regulation*, 32 Wash. U. J.L. & Pol'y 333, 355–59 (2010); Schmidt, *supra* note 85, at 183–84.

89. *See* Envtl. Prot. Agency Office of Inspector Gen., Report No. 10-P-0066, EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act

In addition to creating an ineffective process for reviewing existing chemicals, TSCA also allowed manufacturers to commercialize new chemicals without adequate testing data if they had similar compound structure to existing chemicals, via a Pre-manufacture Notice ("PMN").[90] For example, in September 2016, EPA issued a Determination for PMN that polyester polyol polymer with aliphatic isocyanate and phenol was "not likely to present an unreasonable risk" under LCSA.[91] EPA estimated "the human health hazard of this chemical substance based on its estimated physical/chemical properties and by comparing it to structurally analogous chemical substances for which there is information on human health hazard," which allowed it to conclude that "there is low concern for human health hazard for the chemical substance."[92] "Between 1996 and 2008, EPA received approximately 1,500 PMNs annually, on average," and regulated, on average, less than ten percent of these applications, allowing industry to commercialize these new chemicals in the PMNs.[93]

These limitations of TSCA—avenues for new chemical approvals based on similar chemical structures without complete toxicity data, additional approvals of new chemicals absent complete safety data, the grandfathering of more than 60,000 existing chemicals, and the widely exploited catch-22 preventing EPA from seeking additional health and safety data information on substances—fostered a weak toxic substances regulatory scheme in the forty years since the law was passed. Even when EPA bypassed these barriers and tried to regulate, it had to demonstrate that the benefits of regulating outweighed the costs and that it had regulated in the least burdensome manner.[94] It also had to navigate a lengthy and often contentious rulemaking process.[95]

Responsibilities 19–20 (2010) [hereinafter Inspector Gen. Report], https://perma.cc/YJE5-K59X.

90. EPA relies on structure-activity relationships to determine if a new chemical will act like one structurally similar to it. *See* Richard Denison, *EPA's New Chemicals Program: TSCA Dealt EPA a Very Poor Hand*, Envtl. Def. Fund (Apr. 16, 2009), https://perma.cc/9ZSH-ABR4.

91. Envtl. Protection Agency, TSCA Section 5(a)(3)(C) Determination for Premanufacture Notice (PMN) P-16-0391, (Sept. 14, 2016) [hereinafter Section 5(a)(3)(C) Determination], https://perma.cc/5HML-7ME2 (Polyester polyol polymer with aliphatic isocyanate and phenol derivates); *see also* Certain New Chemicals or Significant New Uses; Statements of Findings for September 2016, 81 Fed. Reg. 65,636, 65,637 (Sept. 23, 2016) (noting availability of findings for this chemical).

92. Section 5(a)(3)(C) Determination, *supra* note 91, at 2.

93. *See* Inspector Gen. Report, *supra* note 89.

94. *See* Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1225–26 (5th Cir. 1991) (holding EPA failed to support ban with "substantial evidence" and failed use the least burdensome option to regulate under TSCA); Michael P. Wilson & Megan R. Schwarzman, *Toward a New U.S. Chemicals Policy: Rebuilding the Foundation to Advance New Science, Green Chemistry, and Environmental Health*, 117 Envtl. Health Persp. 1202, 1205 (2009) (describing analysis of benefits and costs as a barrier to regulation).

95. Markell, *supra* note 88, at 353–60 (describing testing and rulemaking process under TSCA). A Government Accountability Office report noted that a TSCA rulemaking requires signifi-

Over the last half century, EPA has largely had to assume chemicals are safe unless proven otherwise, very rarely regulating synthetic chemicals.[96]

Indeed, in the more than forty years since the enactment of TSCA, the federal government has only called for testing of 200 chemicals and restricted the use of only a handful of these.[97] Essentially, TSCA placed the burden on EPA to show that a health or safety issue existed, rather than on the producer to show that its chemical was safe.[98] For example, asbestos—known to be toxic to humans and the environment[99]—is not banned under TSCA, despite an in-

cant resources and can take two to ten years to complete. *Id.* at 354 (citing U.S. GOV'T ACCOUNTABILITY OFFICE, CHEMICAL REGULATION: OPTIONS EXIST TO IMPROVE EPA'S ABILITY TO ASSESS HEALTH RISKS AND MANAGE ITS CHEMICAL REVIEW PROGRAM, GAO-05-458, at 26 (2005) [hereinafter GAO REPORT]).

96. It is often extremely difficult to link a toxic chemical exposure to disease. For example, asbestos remains on the market today, despite its known links to mesothelioma and cigarettes remained largely unregulated for many years, despite evidence linking cigarettes to lung cancer. *See* Watnick, *supra* note 37, at 246–47.

97. *See* GAO REPORT, *supra* note 95. The lack of a proactive mechanism is common in federal regulations. For example, under the FQPA, the Administrator is to consider "available information" when establishing, modifying, leaving in effect or revoking a pesticide tolerance. 21 U.S.C. § 346a(b)(2) (2012). Thus, pesticide manufacturers are disincentivized to test for ill effects and EPA does not have the resources to conduct its own testing. While the FQPA does call for some additional protections to be built into pesticide tolerances where data is absent and to protect children, *see id.* § 346a(b)(2)(C)(ii), (calling for an additional margin of safety to take into account pre and post-natal effects and "completeness of data"), EPA has been reluctant to apply these added protections to vulnerable populations, *see* Earthjustice, Comments on EPA Proposal To Revoke Chlorpyrifos Tolerances, at 7 (Jan. 5, 2016), https://perma.cc/K9JD-KK77 (noting that EPA has eliminated one safety factor and reduced another one for the pesticide Chlorpyrifos).

98. *See* Markell, *supra* note 88, at 355 (quoting U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-428T, CHEMICAL REGULATION: OPTIONS FOR ENHANCING THE EFFECTIVENESS OF THE TOXIC SUBSTANCES CONTROL ACT 5 (2009)).

99. *See, e.g.*, *Toxic Substances Portal*, *Asbestos*, AGENCY FOR TOXIC SUBSTANCES & DISEASE, https://perma.cc/4XNX-FPJ9 (classifying asbestos as a known human carcinogen); Irving J. Selikoff et al., *Relation Between Exposure to Asbestos and Mesothelioma*, 272 NEW ENG. J. MED. 560, 560 (1965) (noting the potential relationship between asbestos exposure and cancers of the lung and gastrointestinal tract and studying the relationship of asbestos to Mesothelioma).

tense court battle.[100] Instead,[101] certain asbestos containing product uses are merely restricted[102] rather than banned outright.[103]

In addition to TSCA provisions limiting effective regulation, chronic underfunding of new research initiatives for premarket notification rulings and lack of staff have prevented EPA from effectively managing the sheer number of new chemical applications or its review of existing chemicals.[104] The EPA Office of the Inspector General noted in a 2010 report that EPA had limited oversight with regard to new and existing chemicals and that "[o]versight of regulatory actions designed to reduce known chemical risks is a low priority."[105]

TSCA has contributed to a federal toxics regulatory scheme where manufacturers produce and market most synthetic chemicals in the United States without adequate safety testing and data. In effect, the reactive and fragmented aspect of our toxics regulation subjects Americans to myriad chemical exposures in their everyday lives.[106]

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100. *See* Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1229 (5th Cir. 1991) (invalidating a final rule promulgated by EPA prohibiting future manufacture, importation, processing, and distribution of asbestos most products, in part, because TSCA requires EPA to consider the least burdensome, reasonable regulation required to protect the environment).

101. *See id.*; Charles G. Garlow, *Asbestos – The Long-Lived Mineral*, 19 NAT. RESOURCES & ENV'T 36, 36 (2005). *But see* 15 U.S.C. § 2605 (2012) (authorizing EPA to ban any substance that presents an unreasonable risk to health or the environment).

102. *U.S. Federal Bans on Asbestos, Examples of Asbestos-Containing Products Not Banned*, EPA, https://perma.cc/H82K-BQLT. Myriad products are still permitted to contain asbestos. For example, disk brake pads, roof coatings, clothing, and vinyl floor tile can contain asbestos. *Id.*

103. *Id.*; *see* 16 C.F.R. § 1145.4 (banning certain new asbestos compounds); 15 U.S.C. § 2605(a) (2012) (allowing EPA to ban any substance that presents an unreasonable risk to health or the environment).

104. Bach, *supra* note 84, at 506. Since the enactment of LCSA, EPA has been eliminating the backlog of new chemical applications quickly, approving most new chemicals for commercialization. EPA has not banned any of the new chemicals submitted for review. *See Statistics for the New Chemicals Review Program Under TSCA*, EPA, https://perma.cc/SDN9-8UAL.

105. *See* INSPECTOR GEN. REPORT, *supra* note 89 at 7.

106. *See* Valerie Watnick, *Pesticides and Children: Unwitting Participants in Experimentation*, 13 CARDOZO J.L. & GENDER 801, 803–06, 810–11 (2008) (noting that pesticide lice shampoos remain on the market for use on children despite health concerns about chemicals used in these shampoos and the special danger that pesticides pose to children); *supra* Section I.A. In some instances, states acted to fill the federal regulatory void to protect people and the environment from toxic substances. *See* Letter from Kamala D. Harris et al., Cal. Attorney Gen., to Sen. Barbara Boxer, Chairwoman, Subcomm. on Env't & Pub. Works (July 31, 2013) [hereinafter Multi-States Letter] (on file with author). California, Maryland, Massachusetts, Vermont, and Oregon all have more restrictive chemical regulations aimed at protecting consumer health. *See* CAL. HEALTH & SAFETY CODE §§ 25249.5–25249.14 (West 2019) (codifying Proposition 65 as the Safe Drinking Water and Toxic Enforcement Act of 1986); MD. CODE ANN., ENVIR. § 6-1202, 6-1303, 6-1402 (LexisNexis 2019); MASS. GEN. LAWS ch. 21I (2019) (codifying the Massachusetts Toxics Use Reduction Act); OR. REV. STAT. § 453.055 (2017); VT. STAT. ANN. tit. 18, § 1511–12 (2019); CAL. CODE REGS. tit. 22, §§ 69501–69510 (2019).

III. LCSA Legislation and Initial Implementation

A. Compromise

In the years leading up to LCSA, both public interest groups and industry pushed for reform. State coalitions sought legislation that would not preempt them from continuing to regulate to protect health.[107] Public interest groups, including environmentalist and citizens groups, did not feel that the more than forty-year-old TSCA gave EPA enough power to regulate the over 87,000 chemicals on the market.[108] These public interest groups argued that TSCA hamstrung EPA by not allowing it to ask producers for more health and safety information before new chemicals went to market and was thus ripe for change.[109]

Industry sought reform to avoid a patchwork of state laws, build jobs, and maintain innovation.[110] The chemical industry was tired of navigating a patchwork of state laws regarding chemical safety and testing and sought the certainty of a federal regulatory regime that would curtail some state action.[111] In summer 2016, a Republican-led Congress at last overhauled TSCA with the enactment of LCSA.[112] LCSA was a compromise: it made strides to better protect public health in some respects,[113] though at the same time the chemical industry hailed it as a victory that would support chemical innovation, bolster consumer confidence, reduce state regulation, and promote greater federal regulatory oversight.[114]

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107. *See* Multi-States Letter, *supra* note 106, at 1.

108. *See* Follett, *supra* note 31, at 591, 600–03 (2014) (discussing proponents of reform).

109. *See id.* at 591; Richard A. Denison, A Primer on the New Toxic Substances Control Act (TSCA) and What Led to it, Envtl. Def. Fund 3 (2017), https://perma.cc/5VRA-57L8.

110. *See* Press Release, American Chemistry Council, ACC Committed to Working on Bipartisan TSCA Reform (July 25, 2012), https://perma.cc/54TP-H9B9; Follett, *supra* note 31, at 604–05.

111. Juliet Eilperin & Darryl Fears, *Congress is Overhauling an Outdated Law That Affects Nearly Every Product You Own*, Wash. Post (May 19, 2016) https://perma.cc/HPV2-LNJC.

112. Pub. L. No. 114-182, 130 Stat. 448 (2016) (codified at 15 U.S.C. §§ 2601–2629 (2017)); *see also The Frank R. Lautenberg Chemical Safety for the 21st Century Act*, EPA, https://perma.cc/FQ96-K72H.

113. H.R. Rep. No. 114-176 (2015), ("The increased testing authority in H.R. 2576 reflects the Committee consensus that EPA should have the information necessary to fill knowledge gaps before making regulatory decisions."); *see also* David R. Sheaffer, *TSCA Reform, Preemption, and Manufacturer Influence: Does the New Law Hang States Out to Dry?* 18 (2017) (Unpublished J.D. seminar paper, Michigan State University), https://perma.cc/F3ZS-ZJ4Y.

114. *Lautenberg Chemical Safety Act (LCSA)*, Am. Chemistry Council https://perma.cc/5XH2-MP3V.

B. Statutory Reform

1. Summary

In passing LCSA, Congress envisioned a more health-protective toxics regulatory system.[115] The cornerstones of the new law were its requirement that new chemicals be reviewed for safety before being brought to market[116] and its preemption of states from regulating an EPA-designated "high priority" existing chemical substance once EPA decided to regulate that chemical.[117] In this way, public interest groups secured review of new chemicals and new chemical uses before they are brought to market, and industry secured the right to be free from evolving state regulation regarding existing EPA designated "high priority" chemicals.

LCSA attempted to correct TSCA's catch-22, eliminating the need for EPA to make a preliminary finding of risk before requiring manufacturers to submit health and safety data about new chemicals and new chemical uses.[118] LCSA gives EPA the power to issue an order or enter into a consent agreement to obtain information about a chemical, thereby avoiding a lengthy rulemaking process.[119]

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115. *See* H.R. Rep. No. 114-176, at 22 (2016) (House Report on Toxic Substances Control Act Modernization Act of 2015) (noting that "[t]he increased testing authority in H.R. 2576 reflects the Committee consensus that EPA should have the information necessary to fill knowledge gaps before making regulatory decisions" and "EPA may require the development of information by manufacturers and processors of chemicals and persons that begin to manufacture or process the chemical after the effective date of the rule, testing consent agreement, or order."); *see also id.* at 16 (statement of general performance goals and objectives, and background and objectives statement recognizing the need for greater authority for EPA to order testing).

116. 15 U.S.C.A. §§ 2604(a)(3)(A), 2604(e)–(f) (West 2019).

117. *Id.* § 2617. While states are preempted from regulating these high priority chemicals under review, they continue to have the ability to regulate with public right to know laws and to regulate in a manner designed to protect air and water consistent with the CWA and CAA. *Id.* § 2617(d)(1)(A)(i)–(iv). Additionally, California and Massachusetts state regulatory schemes remain intact after LCSA.

118. Congressional Research Service (CRS), Summary, H.R. 2576, Frank R. Lautenberg Chemical Safety for the 21st Century Act, https://perma.cc/3ZRP-3KV7. Under the old TSCA, even if EPA had concerns about a chemical's safety, it could not restrict the chemical's use without providing evidence about why such a restriction would be necessary. *See id.* The new law attempts to correct what have been called "data gaps, safety gaps and technology gaps." *See* Wilson & Schwarzman, *supra* note 94, at 1202. Data gaps refer to the inability of EPA to request data, safety gaps refer to TSCA's lack of reference to protect the public from possible health hazards, including vulnerable populations, and technology gaps refer to the inability of EPA under TSCA to adjust to new technology and do research. *See id.*; *supra* notes 85–89 and accompanying text.

119. CRS, *supra* note 118.

LCSA also requires EPA to prioritize chemical review for existing chemicals by designating chemicals as high or low priority,[120] a measure that preempts most state action when EPA acts to assess designated high priority chemicals.[121] The Act calls for EPA to administer the law in an manner that protects the health of vulnerable populations, such as children, pregnant women, and the elderly, as well as other populations, including the general public and workers.[122] Finally, LCSA improves public and agency access to confidential business information.[123] The remainder of this article will discuss the mechanisms in the Act to review and regulate new and existing chemicals.

2. Routes to Review

LCSA provides two main routes by which chemicals are reviewed.[124] As under the old TSCA framework, when a new chemical or significant new use is proposed by the industry, the industry member ("submitter") submits a PMN. EPA reviews the new chemical or use and issues a pre-manufacture determination and notice.[125] EPA has ninety days to determine whether the chemical presents an unreasonable risk to health or the environment and may request a ninety-day extension if it needs more time.[126] Under the old TSCA, many chemicals were presented to EPA with little or no toxicity data,[127] and the product in the PMN became available after the ninety-day period ended, though EPA had not conducted a thorough review of toxicity or overall health data.[128]

120. *See* H.R. REP. NO. 114-176 at 22. EPA may "require the development of information on chemicals for certain purposes, including the development of information that is necessary for reviewing new chemicals, performing safety assessments or determinations, implementing control actions on chemicals, and establishing the priority of a chemical . . . by consent agreement or [administrative] order." *Id.*

121. 15 U.S.C.A. § 2605(b)).

122. *Id.* § 2617.

123. CRS, *supra* note 118.

124. 15 U.S.C.A. § 2613.

125. In addition to creating routes of review for new and old chemicals, LCSA also requires updates to the Toxics Substances Inventory to show active and non-active uses of chemicals. *See id.* § 2607; 40 C.F.R. pt. 710 (2017). This Inventory will then be subject to prioritization for review of existing chemicals. *See* 40 C.F.R. pt. 702 (2017). New chemicals will be added to the inventory as they are commercialized. *See* 15 U.S.C.A. § 2607(b).

126. 15 U.S.C.A. §§ 2604(a)(3), (c).

127. Melanie Benesh, *Will Congress Protect Americans from Untested Chemicals?*, ENVTL. WORKING GROUP (May 2, 2016) https://perma.cc/W76S-4BH3.

128. *See* Envtl. Working Group, Comment Letter on EPA's Framework for Decision-Making on New Chemicals (Jan. 20, 2018), https://perma.cc/Y2RR-LXLW; 15 U.S.C § 2604(c) (providing for a ninety-day review period).

LCSA maintains a premarket review and notice for new chemicals and significant new uses of chemicals[129] but allows EPA to require additional testing data by order[130] or consent agreement between the parties without a showing of risk, thereby removing the old law's catch-22.[131]

Under LCSA, EPA has five potential responses to a PMN.[132] The Administrator may issue a finding that the chemical or new chemical use is likely to present an unreasonable risk.[133] EPA may alternatively issue findings of not likely to present unreasonable risk; insufficient information; insufficient information and may present unreasonable risk including to susceptible populations; or a finding that the substance will be produced in significant quantities.[134] If the Administrator determines that the information provided is insufficient; that the information is insufficient to reasonably assess the health and environmental effects and that the chemical may present an unreasonable risk of injury to health or the environment based on the submitted information under the conditions of use; or that the substance will be produced in substantial quantities, EPA is required to issue a section 5(e) order restricting manufacture, distribution, disposal, or use of the chemical.[135] LCSA, alongside the corresponding legislative history, gives EPA broad regulatory power to issue a 5(e) order restricting the chemical use or taking other action, such as requesting additional safety information.[136]

Thus, for the first time, EPA can, by order, restrict distribution of a chemical: if data are insufficient to determine if the use or chemical will present an

129. 15 U.S.C.A. § 2604(c).

130. Significant new uses of chemicals are designated by the Administrator based on volume of production, the extent to which the new use changes the form or exposure to the substance, to which it increases the magnitude and duration of exposure and the reasonably anticipated manner and methods of commercialization. *See id.* § 2604(a)(2).

131. *See id.* § 2604(a), (e).

132. *See* H.R. Rep. No. 114-176 (2015); *supra* notes 85–89 and accompanying text. While EPA now has the unilateral authority to issue orders under LCSA under section 5(e), it has been its practice to work with the submitter to develop a "consent order" signed by both sides. Such an order would have the force of an administrative order but allows input from the submitter. 15 U.S.C.A. § 2604(e); *see also* Richard Denison, *Too Little, Too Late: Why SNURs Alone Are Not a Sufficient Alternative to Consent Orders for New Chemicals*, Envtl. Def. Fund (Nov. 30, 2017), https://perma.cc/9QUN-WJ3T.

133. *See* 15 U.S.C.A. § 2604(a)(3).

134. *See id.*

135. *Id.*

136. *Id.* § 2604(e) (corresponding to section 5(e) in the Act; hence an order under the section is known as a "5(e) order"); *id.* § 2604(a)(3); CRS, *supra* note 118 ("The bill eliminates a requirement that the EPA must first make a preliminary finding about risks before the EPA can require testing by manufacturers or processors . . . . Currently, the EPA is limited to requiring the development of information through a rule. The bill allows the EPA to require the development of information through a consent agreement or an order as well.").

unreasonable risk; that the chemical will be produced in large volume;[137] or that, without regard to cost or non-risk factors, the chemical's use may present a risk of injury to health or the environment under the "conditions of use."[138] If EPA does have enough information to determine that a new chemical or use presents an unreasonable risk to human health or the environment under the "conditions of use,"[139] without consideration of cost/benefit factors, it can issue an order or a rule to restrict the use and protect the public.[140]

For existing chemicals, review is a longer process. EPA must determine if the chemical poses an "unreasonable risk of injury to health or the environment" via two steps.[141] First, chemicals are to be designated as high or low priority substances without regard to cost or benefits.[142] Once the Administrator determines that a high-priority chemical poses an unreasonable risk to health or the environment under the conditions of use, the Administrator must propose a rule within one year of the final risk evaluation and publish a final rule within two years of the risk evaluation, restricting the substance to the extent necessary so that the substance no longer presents a risk.[143] In issuing the rule, the law instructs EPA to consider the costs and benefits of the rule but states that none shall be determinative.[144]

With more than 80,000 chemicals on the market, many of which are untested for human health effects, the new law thus requires EPA to prioritize existing chemical assessment.[145] LCSA instructs EPA to designate a chemical high priority based on hazard and exposure potential;[146] the chemical's persistence and bioaccumulation; the potential exposure of susceptible sub-populations, such as chemical workers, children, and pregnant women; the chemical's

137. 15 U.S.C.A. § 2604(e); *see also* Envtl. Working Group, Comments on EPA's Framework for Decision-Making on New Chemicals, at 8 (Jan. 20, 2018), https://perma.cc/Y2RR-LXLW.

138. 15 U.S.C.A. § 2604(e)(1).

139. *Id.* § 2602(4) (defining "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.").

140. *Id.* § 2604(a)(3)(A), (f); *see also* Lisa Heinzerling, *How Not to Regulate*, 85 U. Chi. L. Rev. 2015, 2025 (2018) (reviewing Thomas A. Lambert, How to Regulate: A Guide for Policymakers (2017)) (noting that the Lautenberg Amendments limit or "soften" cost benefit analysis that previously paralyzed TSCA); Susan E. Dudley & Brian F. Mannix, *Improving Regulatory Benefit-Cost Analysis*, 34 J. L. & Pol. 1 (2018).

141. 15 U.S.C.A. § 2605(a).

142. *Id.* § 2605(b)(1)(B).

143. *Id.* § 2605(c).

144. *Id.* § 2605(c)(2); *see also Prioritizing Existing Chemicals for Risk Evaluation*, EPA, https://perma.cc/B8Z5-ETYW.

145. 15 U.S.C.A. § 2605(c)(2)(A).

146. *Id.* § 2605(b)(1)(B)(ii) (defining a low priority chemical is one that, based on sufficient information to establish, without regard to cost and benefit, the administrator does not believe is a high priority chemical).

conditions of use;[147] and the chemical's volume of production.[148] LCSA allows EPA to designate a chemical as low priority where there exists information sufficient to establish that the chemical would not meet the standard for a high-priority chemical.[149] However, EPA is required to designate only twenty chemicals high priority within three and a half years of July 2016[150] and then to continue to designate such chemicals at a pace that allows the Administrator to complete risk evaluations under the deadlines set in the Act.[151]

C. Initial Implementation

1. Proposed Rules

In January 2017, just after President Obama left office, EPA proposed rules on the procedure for chemical risk evaluation and prioritization to apply to the over 80,000 chemicals already on the market.[152] Environmental and public health groups generally responded favorably to the proposed rules.[153] Environmental and public health groups continued to argue that the new law be implemented in the most health-protective manner possible, suggesting that EPA by default designate chemicals "high priority" and that certain chemicals should always be high priority, such as those known to cause cancer or recognized as endocrine-disrupting.[154] For example, Environmental Working Group, a public interest group, urged that the considerations that inform the prioritization of high-risk chemicals ought to include aggregate exposures from sources regulated by other regimes, such as SDWA, FIFRA, or the Federal Water Power Act and regulated by the FDA.[155] It also cautioned EPA, in assessing Endo-

147. *Id.* § 2605(b)(1)(B)(i).

148. *Id.* § 2602(4).

149. *Id.* § 2605(b)(2)(B) (requiring the Administrator to designate twenty chemicals as high priority and low priority, respectively, within three and a half years of the Act's passage). EPA's website states that the deadline for such designations is December 22, 2019. *Assessing and Managing Chemicals Under TSCA: Prioritizing Existing Chemicals for Risk Evaluation*, EPA, https://perma.cc/B8Z5-ETYW.

150. 15 U.S.C.A. § 2605(b)(2).

151. The Act also required EPA to ensure that, not later than 180 days from June 22, 2016, it conduct risk evaluations on ten chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments. *Id.* § 2605(b)(2).

152. Procedures for Prioritization of Chemicals for Risk Evaluation Under the TSCA, 82 Fed. Reg. 4825, 4828 (Jan. 17, 2017) (to be codified at 40 C.F.R. pt. 702); Procedures for Chemical Risk Evaluation Under the Amended TSCA, 82 Fed. Reg. 7562, 7572 (Jan. 19, 2017) (to be codified at 40 C.F.R. pt. 702).

153. *See, e.g.*, Envtl. Working Group, Comments on Proposed Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, Docket ID: EPA-HQ-OPPT-2016-0654-0001, at 12 (Mar. 20, 2017), https://perma.cc/TUD4-5ZCZ.

154. *Id.*

155. *Id.*

crine Disrupting Chemicals ("EDCs"), not to use "sentinel exposure," a measuring process that focuses on exposures of greatest significance, rather than considering aggregate exposure to a chemical.[156] Environmental Working Group argued that focusing only on maximum exposures would be problematic because EDCs are known to have toxic effects at very low levels; that it can be difficult to identify the most exposed group; and that the approach failed to account for differences among susceptible populations, including children, pregnant women, and the elderly.[157]

The originally proposed rules also made clear that the law requires EPA to prioritize an existing chemical substance as a whole, not by single use, and indicated that EPA would consider all reasonable foreseeable uses in its risk characterizations, not just intended uses (a more limited subset of potential exposures).[158]

The ACC filed public comments opposing the interpretations in the January 2017 proposals.[159] The group sought greater clarification of the criteria for designating a chemical "high priority" and of the timeframes for EPA to complete its work and for the industry to provide information.[160] ACC also raised concerns about the implementation timeline, noting that changes to the EPA review process in the first few months of LCSA were creating backlogs of new chemicals in need of review.[161] ACC urged EPA to broaden its interpretation of "not likely to present an unreasonable risk" regarding existing chemicals to include more chemicals and to limit the statutory phrase "reasonably foreseen uses" for which a new chemical would be reviewed to only those intended by the applicant.[162] Finally, the group urged EPA to pursue alternatives to issuing a 5(e) order restricting use of a chemical, such as rulemaking.[163] ACC's com-

156. *Id.*; *see also* Envtl. Working Group, Comments on the Risk Evaluation Scoping for the First 10 Chemicals Under TSCA, at 8 (Sept. 19, 2017), https://perma.cc/X6D4-GUPH.

157. Envtl. Working Group, *supra* note 153, at 12. In the agency's public response to comments received, EPA noted that it may use sentinel exposures in its risk assessments of the first ten chemicals to be evaluated. *EPA's Responses to Public Comments Reviewed on the Scope Documents for the First Ten Chemicals for Risk Evaluation Under TSCA*, at 4–5 (May 2018), https://perma.cc/HCW3-WA6R; *see also* Watnick, *supra* note 32, at 1318–20.

158. *See* Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 7565, 7565–66 (Jan. 19, 2017); Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 4826, 4829–30 (Jan. 17, 2017).

159. *See* Am. Chemistry Council, Comments on Proposed Procedures for Prioritization of Chemicals for Risk Evaluation under the Toxic Substances Control Act as amended by the Lautenberg Chemical Safety Act (Mar. 20, 2017), https://perma.cc/3K7T-VGGU.

160. *Id.*

161. Am. Chemistry Council, Comments on the New Chemicals Review Program Under TSCA as Amended, at 2–6 (Jan. 17, 2017), https://perma.cc/2KJW-LAHZ.

162. *Id.* at 12–18.

163. *Id.* at 19–21.

ments laid the groundwork for a massive revision of the proposed rules in line with industry demands.[164]

2. Final Rules and New Chemical Framework Track Industry Concerns

As President Trump's anti-regulatory agenda took hold at EPA, the agency released new rules that largely reflected ACC's comments.[165] While the originally proposed rules provided that the default classification of an existing chemical would be "high priority,"[166] the final rule on prioritization of existing chemicals removed most references to high priority chemical designations as a default and made many more references to low-priority or safe chemicals.[167] Additionally, the initially proposed rules established a pre-prioritization information gathering period important to meet the strict LCSA periods for review,[168] which the new rules eliminated.[169]

The final rules for existing chemicals also allowed EPA to exclude consideration of uses purportedly regulated by other agencies, further limiting the overall risk evaluation of a chemical, and limited the "conditions of use" EPA must consider, allowing the agency to focus on the conditions of risk that pose the greatest risk.[170] While EPA cited efficiency concerns for the switch, the approach contradicts the statutory definition of "conditions of use."[171] Pursuant to the text of the statute defining conditions of use, and its stated legislative purpose to regulate chemical substances from manufacture to disposal, the Administrator is to consider "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[172] In fashioning rules for prioritization, EPA instead focused its interpretation of "conditions of use" for a chemical on the language "as determined by the Administrator," asserting its broad discretion to limit the

164. *See infra* Section IV.A.3.

165. *See* Press Release, Envtl. Working Group, New Chemical Safety Rules Show Industry Influence Inside EPA, (July 24, 2017), https://perma.cc/W2LJ-2TB2.

166. Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 4826, 4829–30 (Jan. 17, 2017).

167. Procedures for Prioritization of Chemical Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 33,753 (July 20, 2017) (codified at 40 C.F.R. 702.5).

168. Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 4825 (Jan. 17, 2017).

169. 15 U.S.C.A. § 2604(i) (West 2019) (stating applicable review period); 40 C.F.R. 702.5(e) (2018).

170. Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 33,729 (July 20, 2017); *see* Benesh, *supra* note 165.

171. 15 U.S.C.A. § 2602(4); Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 33,729 (July 20, 2017).

172. 15 U.S.C.A. § 2602(4).

conditions of use to be considered when prioritizing an existing chemical.[173] Therefore, EPA stated, when considering the conditions of use for an existing chemical, it would limit the overall potential risk of a chemical by not considering all exposures from manufacturer to disposal. For example, EPA might not consider potential occupational exposures regulated by OSHA, for example, when prioritizing a chemical for review.[174]

EPA has also reversed course on the approach to new chemicals. Instead of assessing a new chemical or use considering the chemical substance as a whole, EPA stated in a new "Framework Document"[175] that it would consider individually submitted conditions of use based on fact-specific applications and consider uses where the activity is "probable."[176] These changes track ACC's comments urging EPA to limit its application of the statutory language requiring EPA to consider only "intended, known or reasonably foreseen" uses.[177] EPA's stated interpretation does not incorporate all of the uses discussed in the statute, which mandates EPA consider uses over the whole life of the chemical, from manufacture to disposal, as well as its current, limited "conditions of use."[178] EPA's interpretation of the law has not been formalized beyond principles the agency first announced publicly in August 2017 and in its November 2017 Framework Document.[179]

IV. The Way Forward: The Status Quo or A Proactive Stance?

A. A Critique of the Current Agency Approach

1. Overview

As indicated earlier in this paper, a cornerstone of LCSA is that it gives EPA the ability to regulate new chemicals before they go to market and issue

173. 82 Fed. Reg. 33,729.

174. *Id.* at 33,729.

175. EPA, New Chemicals Decision-Making Framework: Working Approach to Making Determinations under Section 5 of TSCA (2017), https://perma.cc/VA5K-V2K8 [hereinafter Framework Document].

176. Press Release, EPA, EPA Eliminates New-Chemical Backlog, Announces Improvements to New Chemical Safety Reviews (Aug. 7, 2017), https://perma.cc/843J-5C3C [hereinafter EPA Press Release].

177. Am. Chemistry Council, Comments on the New Chemicals Review Program Under TSCA as Amended, at 13 (Jan. 17, 2017), https://perma.cc/A9KP-QG9E (quoting 15 U.S.C. § 2602(4)).

178. 15 U.S.C.A. § 2602(4) (West 2019); *see also* Environmental Working Group, Comments on Framework for Decision-Making on New Chemicals (Jan. 20, 2018), https://perma.cc/BM9D-FP3D.

179. EPA Press Release, *supra* note 176.

orders to restrict production, obtain safety information, and require testing.[180] EPA's latest implementation plans for the law have diverged from this fundamental goal.[181] In contravention of LCSA's mandate to issue an order regarding a new chemical use or significant new use about which it has concerns and about which it lacks sufficient information, or which will be produced in substantial quantities, EPA has stated that it will issue a Significant New Use Rule in its Framework Document.[182] In addition, since publishing the Framework Document and facing a legal challenge, EPA has again changed its position as to what regulatory actions it will take to regulate new chemicals and significant new uses of chemicals.[183]

Additionally, EPA appears to have also taken on a role as a consultant to help industry actors get new chemicals and uses on the market. According to the 2017 Framework Document, testing "is generally to reduce uncertainty associated with assessments that gave rise to a finding of 'may present unreasonable risk'" or any finding other than "not likely to present unreasonable risk."[184] In other words, testing is not done to rule out a chemical's admission to the marketplace or to fully assess its safety, but to provide just enough information so that it can be found "not likely to present an unreasonable risk" and be commercialized as soon as possible.

This approach and other deficiencies in implementing the Act as to new and existing chemicals, including failure to act proactively to protect against the risk of EDCs and to protect vulnerable populations, as well as loopholes and serious practical and resource constraints, are further detailed below.

2. The 2017 Framework Document and Proposed Use of Significant New Use Rules to Replace Orders for New Chemicals and New Chemical Uses

In its 2017 Framework Document, EPA called for replacing orders with Significant New Use Rules ("SNURs") for significant new chemicals and new chemical uses when EPA has concerns that the use presents an unreasonable risk.[185] Restricting EPA's use of orders in these circumstances limits its power

180. *See* H.R. Rep. No. 114-176, 114th Cong. (2015) (statement of general performance goals and objectives); *supra* Section III.B.

181. *See* Framework Document, *supra* note 175.

182. *Id.* at 2.

183. *See infra* Section IV.A.3.

184. Framework Document, *supra* note 175, at 3–4; *see also* EPA Press Release, *supra* note 176 ("Where the intended uses in pre-manufacture notices (PMNs) or other Section 5 notices (such as low volume exemption (LVE) requests) raise risk concerns, EPA will work with submitters . . . .").

185. EPA, New Chemicals Decision-Making Framework: Working Approach to Making Determinations under Section 5, at 3 (2017), https://perma.cc/VA5K-V2K8.

and agility. An order or consent order by agreement of the parties can require additional safety information and testing results before a chemical or new chemical use may be commercialized.[186] Additionally, an order or consent order is immediately binding on the party submitting the application and can be modified if the new use or substance is later determined to have additional uses that present unreasonable risk or if additional data is developed that indicates that the chemical or new chemical use is unreasonably dangerous.[187]

In contrast, an SNUR cannot be easily modified once released and cannot require the submitter to develop new data.[188] Further, if a manufacturer is initially allowed to produce a chemical pursuant to an SNUR without a corresponding order, the submitter might later attempt to circumvent more stringent new chemical review laws by later claiming that the chemical is now an "existing" chemical use subject to the longer bifurcated review process for existing chemicals.[189] Requiring EPA to operate via rules instead of orders would also likely slow or stall its regulatory process. For example, in 2015, EPA proposed a new rule on long-chain perfluoroalkyl carboxylate ("LCPFACs") that would require companies to notify EPA ninety days before engaging in certain designated "new" manufacture or processing activities, as part of an ongoing effort to phase out these highly toxic and persistent substances.[190] Almost four years since its proposal, this rule has not yet been finalized, implemented or published, and LCPFACs continue to be manufactured despite health concerns.

The Framework Document also fails to delineate EPA's response to findings it is required to make under LCSA regarding new chemicals and new chemical uses.[191] The Framework Document contains a flowchart with the five determinations EPA may make in the case of a new chemical application—not likely to present unreasonable risk, substantial production, insufficient information, insufficient information and may present unreasonable risk, and presents unreasonable risk—but does not specify how EPA should respond to each finding.[192] This ambiguity allows EPA to enforce via less powerful mechanisms

186. *See* Framework Document, *supra* note 175, at 3. In response to this Framework Document and EPA's announced plans to move forward with its implementation, the NRDC filed a petition for judicial intervention against EPA. *See* Brief of Petitioner, Nat. Res. Def. Council v. EPA, No. 18-25 (2d Cir. May 1, 2018).

187. *See* 15 U.S.C.A. § 2604(e) (West 2019); Denison, *supra* note 132.

188. Denison, *supra* note 132 ("Consent orders can be reopened and revised based on new information (including results of required testing). If testing shows a chemical is more toxic than initially thought, EPA can tighten conditions in the order. No such option exists with a SNUR.") (emphasis omitted).

189. *Id.*

190. *See* Long-Chain Perfluoroalkyl Carboxylate and Sulfonate Chemical Substances; Significant New Use Rule, 80 Fed. Reg. 2885 (Jan. 21, 2015) (proposed rule on long-chain perfluoroalkyl carboxylate not implemented almost three years after its proposal).

191. Framework Document, *supra* note 175.

192. *See* 15 U.S.C.A. § 2604(a)(3)(B) (West 2019); Framework Document, *supra* note 175, at 3.

than orders or consent orders between submitting parties and EPA. In these instances, EPA may issue a rule even if it lacks sufficient information to make a reasoned judgment that a new chemical or new chemical use will not present an unreasonable risk or in the face of a substantial production quantity.[193]

At least partly in response to a lawsuit by Safer Chemicals, Healthy Families, a public interest group,[194] EPA has now stated it will not use SNURs to replace orders under LCSA for new chemical uses and new chemicals.[195] However, it has not issued a new rule or framework document to supersede the 2017 Framework Document or provide guidance or information about how it will handle new chemical and significant new chemical use applications.

3. Agency as Consultant and Editor

Additionally, while LCSA requires EPA to consider PMNs based on the information submitted and to issue an order to protect public health and the environment if the information is not complete or sufficient to allow a favorable risk determination,[196] EPA has recently taken a different path,[197] instead informing the submitter of its concerns and giving the party a chance to amend its PMN.[198] This approach wastes EPA's resources, slows its review process, and makes EPA more of an industry consultant than a regulator.[199] The approach is consistent with the Framework Document, wherein EPA stated that it would issue an order for more information in such circumstances to reduce uncertainty associated with a "may *present* an unreasonable risk" determinations or remedy an "insufficient information" determination.[200] In other words, EPA seems intent to further industry goals to commercialize chemicals as soon as possible by circumventing its process and seeking more information as needed to allay its concerns.

193. Framework Document, *supra* note 175, at 5.

194. Petition for Judicial Review, Safer Chemicals Healthy Families v. EPA, No. 17-72260 (9th Cir. 2017).

195. In an undated letter released in January 2019, EPA committed to issuing and taking public comments on a revised Framework Document for new chemicals. *See* Letter from Senator Andrew Wheeler to Senator Thomas Carper, Ranking Member of the Environment and Public Works Committee at 2 (on file with author). EPA, in this recent letter, also noted that it would have its "methodology for deciding how to collect and evaluate scientific research related to a chemical's safety" developed by EPA's Office of Chemical Safety and Pollution Prevention reviewed by the National Academy of Sciences "for peer review and feedback." *Id.*

196. *See* 15 U.S.C.A. § 2604; *see also* Framework Document, *supra* note 175, at 3.

197. Envtl. Working Group, Comments on EPA's Framework for Decision-Making on New Chemicals (Jan. 20, 2018), https://perma.cc/QH4W-795D.

198. *Id.*

199. *See id.*

200. *See* Framework Document, *supra* note 175; *see also* 15 U.S.C.A. § 2604(a)(3)(B).

4. Failure to Adequately Account for Vulnerable and Exposed Subpopulations

In reviewing new and existing chemicals, EPA is also shirking its statutory obligation to account for pregnant women, workers, children, and other vulnerable subpopulations.[201] In such reviews, EPA's standard response has been to impose a default safety factor—for example, to make a determination X times safer—without accounting for subtle differences in populations. Standard scientific practice has, however, moved away from such blanket impositions of default safety factors, as they are not sufficiently comprehensive to account for life stages, such as fetal, childhood, and other developmental periods.[202] EPA would act in a more health protective manner by using up-to-date defaults that appropriately account for these vulnerable subpopulations.[203] Further, in failing to consider all conditions of use in its risk prioritizations, risk evaluations, and new chemical determinations, EPA might miss aggregate and cumulative risks to exposed and vulnerable subpopulations. Considering aggregate exposures requires EPA to consider the full life cycle of a chemical, not only fact-specific intended uses as stated by a submitter.[204]

Considering cumulative exposures is likewise important to protect vulnerable subpopulations who may have been exposed to multiple chemicals with similar negative health effects. For example, certain communities may be exposed to multiple carcinogenic solvents from different sources, such as both Tetrachloroethylene from a nearby dry-cleaning plant and 1,4 Dioxane from an industrial site.[205] Indeed, EPA has previously stated that accounting for "cumulative risk through complex exposures is one the of the Agency's high priorities."[206] Thus, EPA's current methodology fails to use up-to-date safety factors,

201. *See* 15 U.S.C.A. § 2604(a)(3) (review and determination regarding significant new uses and new chemicals shall include consideration of vulnerable populations); *id.* § 2602(12) ("[T]he term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population who, due to either greater susceptibility or greater potential exposure, are likely to be at greater risk than the general population of adverse health effects from exposure to a chemical substance."); *id.* § 2605(b)(1)(A) (stating that the process for prioritization shall include consideration of hazards to "potentially exposed or susceptible subpopulations").

202. *See* Juleen Lam et al., Comments from Academics, Scientists and Clinicians on EPA's Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (Mar. 20, 2017), https://perma.cc/B5VV-QNGH.

203. *Id.*

204. *See* Envtl. Working Group, Comments on the Risk Evaluation Scoping for the First 10 Chemicals Under TSCA, at 5–9 (Sept. 19, 2017) https://perma.cc/V9ZR-D5RW.

205. *See id.* Both 1,4 Dioxane and Tetrachlorethylene (PERC) were included in the 2014 EPA Work Plan and are subject to early risk evaluation under LCSA. *See id.*; EPA, TSCA Work Plan for Chemical Assessment 2014 Update (Oct. 2014).

206. EPA, Framework for Cumulative Risk Assessment at xi–xii (2003), https://perma.cc/KF8F-VSCE.

to adequately account for vulnerable subpopulations, and to account for cumulative risk.

5. Failure to Target EDCs

LCSA and the accompanying regulation also fail to target regulation of potential EDCs, despite the threat that widespread exposure to EDCs present to public health.[207] Specifically, EPA procedures and guidelines for assessing risk[208] are not suited to identify the risks related to EDCs, which may be even more dangerous at low levels and may have inverse bell curves for toxicity.[209] The 2017 Framework Document, for example, calls for EPA to consider both duration and magnitude of exposure in assessing the risks of new chemicals, and EPA procedures for risk evaluation call for the agency to focus first on "high-priority" existing chemicals and ignore *de minimis* exposures.[210]

Yet EDCs challenge established assumptions about linear relationships between dose and harm, complicating the development of toxicology methods and requiring new methods that do not rely on extrapolating from high-dose testing to determine human risk at lower levels.[211] Instead, these substances need to be evaluated at varying dosages and life stages, lengthening the time it will take to perform risk evaluations and further burdening and delaying agency action. According to one expert, "detection of low-dose effects in animal tests requires exquisite sophistication."[212] There exists ongoing debate in the scientific community about the best manner to both replicate and validate low-dose studies of EDCs and without scientific consensus, rulemaking will not proceed without many years of ongoing testing, which include efforts to replicate prior results so that they gain scientific support.[213] As a result, EPA's regulatory processes are not sufficiently adapted to the unique challenges presented by EDCs, nor is the agency properly focused on remedying these lapses despite the outsized risk that EDCs present to public health.

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207. *See, e.g.*, Laura N. Vandenberg et al., *Hormones and Endocrine Disrupting Chemicals: Low-Dose Effects and Non-Monotonic Dose Responses*, 33 ENDOCRINE REV. 378 (2012).

208. *See* Framework Document, *supra* note 175; Procedures for Prioritization of Chemical Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 33,753 (Jul. 20, 2017) (codified at 40 C.F.R. § 702); Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 33,726 (July 20, 2017) (codified at 40 C.F.R. § 702.5(d)).

209. *See* COLBURN, DUMANOSKI & MYERS, *supra* note 31, at 169–70; Vandenberg, et al., *supra* note 207.

210. Framework Document, *supra* note 175 at 1–2; *see also* Watnick, *supra* note 32.

211. *See* Krimsky, *supra* note 46, at 6.

212. *Id.* at 6–7.

213. *Id.*

6. Statutory Loopholes

LCSA relies on the easily exploitable premise that once an existing chemical is designated as low priority or a new chemical, or a significant new chemical use has been approved for commercialization, there will effectively be little or no further regulation.[214] While EPA has more authority to regulate certain suspect existing chemicals designated as "high priority," if EPA gives a "favorable" determination that a new chemical or use will not pose an unreasonable risk to humans or the environment based only on intended uses and the limited information provided, it may thereby allow the applicant to effectively circumvent any future restrictions. This is true even if EPA later suspects that the new chemical may present an unreasonable risk, or designates an existing chemical as low priority.[215]

While EPA is supposed to issue an order to regulate such a new substance,[216] current EPA enforcement suggests that it may allow commercialization of a new substance pending final rulemaking, rather than by order.[217] In such a circumstance, if additional information later became available, the submitter could claim that the chemical is an "existing chemical" subject to lower prioritization and protracted and backlogged review.[218]

Another anomaly of LCSA is that it allows EPA to issue a rule, order, or other requirement to protect against unreasonable risk if it *has enough information* to determine that a new chemical or significant new use presents an unreasonable risk of injury to health or the environment.[219] In such cases, EPA does not have to issue an order; the requirement to issue an order is only triggered when EPA affirmatively states that it does not have enough information to permit a reasoned evaluation of the health and environmental effect of a chemical, where the use may present unreasonable risk, or where the substance will be produced in substantial quantities, and is anticipated to enter the environment in significant quantity.[220] Section IV.B discusses a way around this potential loophole, which would make such a finding very unattractive to industry and, potentially, to EPA.

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214. *See supra* Section III.C.2.

215. 15 U.S.C.A. §§ 2604(3)(C), 2605(b)(1)(B)(2) (West 2019).

216. *Id.* § 2604(a)(3)(B) (requiring the Administrator to issue an order).

217. *See* 15 U.S.C.A. § 2604(f) (allowing EPA to engage in rulemaking where it lacks sufficient information to make a safety determination); Framework Document, *supra* note 175, at 2.

218. *See* 15 U.S.C.A. § 2605(b)(1)(B)(ii), (b)(2) (requiring EPA to ensure that risk evaluations are conducted for at least twenty high-priority existing chemicals within three years of June 22, 2016).

219. *See id.* §§ 2604(a)(3)(C), 2605(b)(1)(B)(ii), (b)(2)(B); 15 U.S.C. § 2604(f) (2012).

220. 15 U.S.C.A. § 2604(a)(3)(B) (requiring the Administrator to issue an order); *id.* § 2604(e)(1).

7. *Bureaucratic and Resource Constraints Will Prevent Effective Administration of Provisions Regarding Existing Chemicals*

While LCSA was designed to be more health-protective and, for the first time, requires EPA to review existing chemicals, the exceedingly slow process of review makes this a bureaucratic nightmare, with little potential to achieve LCSA's goals. There are over 87,000 existing chemicals potentially on the market today,[221] and over 60,000 without safety data on file. Yet LCSA calls for EPA to review just twenty existing high-priority chemicals within three and a half years of its enactment.[222]

Nor does the Act provide any requirements or mechanisms for EPA to work quickly enough through existing chemical reviews to protect human health. One report has suggested that, even considering only the ninety high-priority existing chemicals listed in the "Work Plan" established in 2014 pursuant to the old TSCA, it will take EPA twenty-eight years to complete initial risk evaluations, thirty years to finalize regulations, and thirty-five years to implement the rules.[223] Other reports are even less sanguine. Sheldon Krimsky has stated that it would take EPA 1,500 years to prioritize and evaluate 8,500 existing chemicals—just ten percent of those on the market today.[224] If the list were reduced to just 500 chemicals, with a three-year completion time to evaluate and establish rules on each chemicals, the task would take fifty years.[225]

Further, EPA likely cannot meet even these moribund deadlines without adequate resources. Given the current administration's anti-regulatory attitude and proposed budget cuts to EPA,[226] the task seems impossible. Faced with tremendous uncertainty as to the effects of chemical substances, and concerted

221. *See* Follett, *supra* note 31, at 596.

222. 15 U.S.C. § 2605(b)(2)(B) (noting that not later than three and one half years after June 22, 2016, the Administrator shall ensure that risk evaluations are being conducted on at least 20 high-priority substances); *see also* Coral Davenport & Emmarie Huetteman, *Lawmakers Reach Deal to Expand Regulation of Toxic Chemicals*, N.Y. Times (May 19, 2016), https://perma.cc/KQ6B-SUHN (noting that public health advocates had hoped to see at least 300 chemicals reviewed per year); Melanie Benesh & Scott Faber, *New TSCA Bill Falls Short of Protecting Americans From from Toxic Chemicals*, Envtl. Working Group: EWG News and Analysis (May 24, 2016), https://perma.cc/BS2J-LBTM.

223. *Assessing and Managing Chemicals Under TSCA*: *TSCA Work Plan Chemicals*, EPA, https://perma.cc/296C-GC68; Catherine Traywick & Jack Kaskey, *EPA Wins Clout to Fight Toxic Chemicals, but It May Take a While*, Bloomberg (June 8, 2016), https://perma.cc/AD4J-9DJH.

224. Krimsky, *supra* note 46, at 8.

225. *Id.*

226. *See* Glenn Thrush & Coral Davenport, *Donald Trump Budget Slashes Funds for E.P.A. and State Department*, N.Y. Times (Mar. 15, 2017), https://perma.cc/DZN2-JKHL

and well-funded industry opposition, EPA's policies will likely be politically calibrated rather than based on scientific or factual analysis.[227]

8. Failure to Account for Synergistic and Compounded Interactions Between Chemicals

Even at its best, LCSA does not properly account for interactions between the myriad chemicals to which we are exposed every day.[228] It does not even begin to tackle the problems inherent in an industrial system so dependent on so many chemicals, the continued commercialization of new substances, and the potential and likelihood for combined or even synergistic reactions between these chemicals, nor could it.[229] While EPA and Congress have begun to recognize the importance of assessing cumulative exposures, the process is daunting given the volume of untested chemicals on the market.[230] And finally, LCSA does not give due weight to our mass exposure to EDCs and the problems described in relation to such exposure.[231]

B. Resulting Implementation

Due to these lapses and omissions of LCSA, EPA will continue to approve most new chemicals for commercialization without full information about the reasonably foreseeable conditions of use subject to rulemaking, and few of the more than 60,000 grandfathered existing chemicals will be reviewed fully or quickly,[232] with most designated as "low priority" by default. The unfortunate result is the maintenance of a status quo in the toxics regulatory system in terms of assessing new chemicals and reviewing existing ones.

Indeed, in the nearly three years since Congress passed LCSA, EPA has reviewed 1,823 new chemical cases with lackluster results.[233] It has banned zero new chemicals, blocked commercialization of just six new uses or chemicals pending development of further information pursuant to a 5(e) order, allowed 194 new uses or chemicals to be commercialized without restrictions as not

227. *See* John Applegate, *Worst Things First: Risk, Information, and Regulatory Structure in Toxic Control*, 9 YALE J. ON REG. 277, 280–81, 304 (1992).

228. *See, e.g.*, Abelkop & Graham, *supra* note 71, at 120 (noting synergistic and/or combined effects of chemicals); Krimsky, *supra* note 46, at 6; Watnick, *supra* note 32, at 1327–28.

229. *See* Abelkop & Graham, *supra* note 71, at 120; Watnick, *supra* note 32, at 1321–22.

230. *See* Watnick, *supra* note 32, at 1314.

231. *See supra* notes 31–34 and accompanying text.

232. *See* 15 U.S.C.A. § 2605(b)(2)(B) (West 2019) (requiring EPA to conduct risk evaluation for just 20 "high-priority" and 20 "low-priority" chemicals in three and a half years).

233. *Statistics for the New Chemical Review Program under TSCA*, EPA, https://perma.cc/YB3W-6QBP. Based on published information, it is difficult to assess whether these approvals have been by rule or order or both, but they have all been allowed to commercialize, potentially pending a lengthy rulemaking process.

presenting an unreasonable risk, and permitted commercialization of 443 chemicals with restrictions pursuant to rule or order.[234] EPA has exempted 841 submissions from review as low volume/low release and low exposure, denying only 128 requests for such exemption.[235] The result is that, over the course of thirty months, manufacturers have filed 604 notices of "intent to commence manufacturing" new substances, and 1,528 new chemicals have been approved for use or given exemptions as low volume.[236]

The proactive approach that public interest groups anticipated when Congress mandated prescreening of new chemicals and significant new uses of chemicals with robust data has not materialized and now seems an unlikely result.[237] Such a proactive regulatory scheme would have been consistent with the precautionary principle, which provides that a lack of data and certainty as to ill effects shall not preclude a government from taking cost-effective measures to protect human health and the environment.[238] Though not without critics,[239] the principle, with varying levels of precaution and burden shifting,[240] has become widely accepted around the world as a fundamental basis for environmental regulation.[241]

A toxic chemical regulatory framework following a strong precautionary principle would acknowledge that we cannot ever know the real-life risk associated with the combination of chemicals to which we are exposed or the manner

234. *Id.* Applicants have withdrawn 222 new cases and 58 low volume exemption requests. *Id.*

235. *Id.*

236. *Id.*

237. *See supra* notes 107–114 and accompanying text.

238. *See, e.g.*, James Cameron & Juli Abouchar, *The Precautionary Principle: A Fundamental Principle of Law and Policy for the Protection of the Global Environment*, 14 B.C. INT'L & COMP. L. REV. 1, 2 (1991); Robert Percival, *Who's Afraid of the Precautionary Principle?*, 23 PACE ENVTL. L. REV. 21, 22 (2001) ("[That] uncertainty should not be used as an excuse to eschew cost-effective preventive measures . . . is fundamental to modem environmental law's quest to transcend the limits of its common law legacy.").

239. *Compare, e.g.*, Cass Sunstein, *Beyond the Precautionary Principle*, 151 U. PA. L. REV. 1003, 1008–10 (2003) (arguing that the precautionary principle is paralyzing and is appealing because of loss aversion, the myth that nature is benevolent, the availability of bad environmental results, the human tendency to neglect probability and what Sunstein calls "system neglect", or a failure to see the other side of heavy handed environmental regulation), *with* Sachs, *supra* note 79, at 1286.

240. Professor Noah Sachs advocates for what he calls the "Strong Precautionary Principle." Sachs, *supra* note 79, at 1292–1300. Sachs argues that a strong precautionary principle puts regulators in the role of "gatekeepers" and puts the burden on private actors to prove their products are safe before they go to market. *Id.* at 1295–99.

241. *See, e.g.*, The Rio Declaration on Environment and Development, U.N. Conference on Environment and Development, U.N. Doc. A/Conf. 151/5/Rev.1, princ. 15 (1992); Consolidated Version of the Treaty on the Functioning of the European Union, art. 191 (Dec. 13, 2007); Commission Regulation 1907/2006, Registration, Evaluation, Authorisation and Restriction of Chemicals, art. 1(3), 2006 O.J. (L 396) 47 (EC).

in which such exposure may affect different vulnerable and exposed populations at different life periods. Faced with this uncertainty, the strong precautionary principle would shift to private actors the burden of showing that their products are safe before they go to market.[242]

While LCSA does not specifically embody the precautionary principle, it had the opportunity to make EPA more precautionary by implementing a burden-shifting process and requiring robust screening of new chemicals.[243] While the review of existing chemicals is a time consuming and unwieldy process, one in which regulators would be unlikely to embrace the precautionary principle,[244] LCSA's critical shift was requiring the review of new chemicals with robust data to protect public health and the environment proactively from future new chemical uses.[245] Yet EPA has bowed to industry pressure and significantly weakened LCSA's protective provisions, as evident in the final rules regarding prioritization and evaluation of existing chemicals, the Framework Document, and EPA's subsequent actions regarding the new chemicals program.[246] This favorable stance toward industry is unsurprising because those in positions of power at EPA often go on to work for the very companies they regulate, and in some cases came to EPA after previously holding positions of power in industry.[247]

As originally envisioned, LCSA aimed to support innovation, build jobs, and make industry subject to less "red tape" by preempting regulation by a

242. Sachs, *supra* note 79, at 1295–99.

243. *See supra* Section III.B.2 (on the process for new chemical review and approval under LCSA); 15 U.S.C.A. § 2604 (West 2019) (procedure for EPA approval of new uses for toxic chemicals).

244. In summer 2018, EPA released its problem formulation documents for the first ten existing chemicals to be evaluated under TSCA. Problem Formulations for the Risk Evaluations To Be Conducted Under the Toxic Substances Control Act, and General Guiding Principles To Apply Systematic Review in TSCA Risk Evaluations, 83 Fed. Reg. 26,998 (June 11, 2018). Additionally, EPA sought White House approval of an information collection request to give submitters access to agency guidance that EPA hopes will speed its review of new chemicals. *Eying TSCA Backlog, EPA Seeks Expedited ICR Review*, INSIDE EPA (June 14, 2018), https://perma.cc/DLF3-PNCK.

245. *See supra* Section III.B.1.

246. *See id.*

247. *See, e.g.*, *The Ever-Revolving Door: Industry and the EPA*, BEYOND PESTICIDES (Oct. 3, 2017), https://perma.cc/HQL6-YFAD; *Trump Picks Dow Chemical Lawyer for Key Role at EPA*, ASSOCIATED PRESS (Mar. 2, 2018), https://perma.cc/LUD8-57CB. In at least one recent article, there were credible reports that industry and EPA acted together to slow down EPA action that might have hurt the manufacturer of a widely used herbicide. *See* Carey Gillam, *Collusion or Coincidence? Records Show EPA Efforts to Slow Herbicide Review Came in Coordination with Monsanto*, HUFFINGTON POST (Aug. 18, 2017), https://perma.cc/NCQ7-U4KZ.

patchwork of state laws.[248] Instead, the law leaves industry open to continuing state regulation while a protracted process of federal litigation and regulation ensues, and it also leaves industry exposed to state-initiated lawsuits where EPA engages in high priority substance review and LCSA prevents state rulemaking.[249]

LCSA initially looked like it would bring U.S. chemical regulation closer to the European Union ("EU") model contained in the Registration, Evaluation, Authorization and Restriction of Chemicals ("REACH") initiative,[250] the Canadian Environmental Protection Act ("CEPA"),[251] and California's Proposition 65 and Green Initiative.[252] Despite its limitations, LCSA still holds some promise, especially with regard to the approval of new chemicals. For the first time, the mechanisms in the law for review of new chemicals embody a forward looking, proactive stance. This stance at least signals the public's interest in a more precautionary regulatory system and could be valuable if the public coalesces around more health-protective toxics regulation.

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248. *See* 15 U.S.C.A. § 2617 (West 2019); *see also Toxic Substances Control Act Reform*, NAT'L CONFERENCE OF STATE LEGISLATURES (May 19, 2014), https://perma.cc/EKH2-5JQG (opposing preemption of states' right to regulate); *supra* Section I.A.

249. Nathan A. Cardon, Sheila A. Millar & Anushka N. Rahman, *Green Chemistry in 2017: The State of the States*, NAT'L L. REV. (May 16, 2017), https://perma.cc/KFM8-CZ3Q.

250. *See* David R. Sheaffer, *TSCA Reform, Preemption, and Manufacturer Influence: Does the New Law Hang States Out to Dry?* 4 n.12 (2017) (unpublished paper for King Scholar Program, Michigan State University College of Law), https://perma.cc/7RVY-45K9 ("The similarities between the amended TSCA and the EU REACH program are easily seen if one reviews prior scholarly work: Like [the pre-amended] TSCA, EU chemical legislation prior to REACH focused on testing of "new" chemicals (those introduced after 1981 in Europe), exempted most existing chemicals from testing, and placed the burden of proof on EU Member States to prove that chemicals were unsafe. The older European legislation led to the same informational logjams and data gaps that the United States has experienced under TSCA. Of the 30,000 existing chemicals with annual production volumes in Europe of over one ton, only 140 had been identified as priorities for testing under the prior legislation, and full risk assessments had been prepared for only about seventy of these chemicals. Chemicals introduced since 1981 had been subject to rigorous toxicity testing in Europe, but they represented less than 1 percent of all the chemicals marketed in Europe." (quoting Noah M. Sachs, *Jumping the Pond: Transnational Law and the Future of Chemical Regulation*, 62 VAND. L. REV. 1817, 1833–34 (2009))).

251. S.C. 1999, c. 33 (1999), https://perma.cc/4GRN-JS3X.

252. CAL. HEALTH & SAFETY CODE § 25249.5–25249.14 (West 2019); CAL. CODE REGS. tit. 22, §§ 69501–69510 (2019). Proposition 65 is officially known as the Safe Drinking Water and Toxic Enforcement Act of 1986. California and Massachusetts have well developed state regulatory systems that were exempted from preemption by LCSA. *See* 15 U.S.C.A. § 2617(a), (b), (d)(2) (West 2019). California and other states have been proactive about suing over environmental concerns. *See, e.g.*, Chris Mooney, *California, 17 Other States Sue Trump Administration to Defend Obama-Era Climate Rules for Vehicles*, WASH. POST (May 9, 2018), https://perma.cc/5BYU-QQBA.

C. A Proactive Approach: Premarket Review Coupled with Market Pressure

While regulatory regimes in Canada and Europe are precautionary in nature by requiring manufacturers to provide data before chemicals go to market, and LCSA attempts to move the U.S. in that direction, California has coupled this requirement with greater information transparency.[253] Information transparency has the power to drive industry to produce and sell safer products according to consumer demand. Adopting this aspect of California's regulatory scheme would make U.S. regulation more health-protective, realizing Congress' initial intent in passing LCSA.

California was the first state to enact a proactive chemical regulatory system, followed by Maine and Connecticut in 2013.[254] California's law has two parts: a proactive Green Initiative, which requires manufacturers provide safety data before the state approves a new chemical to be marketed,[255] and a comprehensive labeling statute for any product known to cause cancer, birth defects, or reproductive harm.[256]

The Green Initiative has similarities to LCSA: it provides for the prioritization of the most concerning chemicals for review and requires review of new chemical products for safety.[257] The state has released and since revised, after public comment, its priority product work plan, identifying a limited number of chemicals for consideration, in an effort to regulate high priority chemicals.[258] The priority work plan guide is easily accessible and can be downloaded for public view.[259]

Proposition 65, California's comprehensive labeling regime enacted via a ballot initiative in 1986, was officially designed to protect drinking water from chemicals known to cause cancer, birth defects, or reproductive harm.[260] The Proposition provides that before a product containing certain named substances

253. *See* CAL. HEALTH & SAFETY CODE §§ 25249.5–25249.14; CAL. CODE REGS. tit. 22, §§ 69501–69510.

254. *See* CAL. HEALTH & SAFETY CODE § 25249.8; Bach, *supra* note 84, at 511; *Chemicals Listed as Known to the State to Cause Cancer or Reproductive Toxicity*, OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT (May 1, 1997), https://perma.cc/6U93-JKW7; *Proposition 65*, OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, https://perma.cc/E2S4-TGQC.

255. *See* CAL. CODE REGS. tit. 22, §§ 69501–69510.

256. *See Chemicals Listed as Known to the State to Cause Cancer or Reproductive Toxicity*, *supra* note 254; *Proposition 65*, *supra* note 254.

257. *See* CAL. CODE REGS. tit. 22, §§ 69501–69510.

258. *See* CAL. DEP'T OF TOXIC SUBSTANCES CONTROL, SAFER CONSUMER PRODS. BRANCH, THREE YEAR PRIORITY PRODUCT WORK PLAN 2018-2020 (2018).

259. *See Priority Product Work Plan*, CAL. DEP'T OF TOXIC SUBSTANCES CONTROL, https://perma.cc/3CAC-BAJM.

260. CAL. HEALTH & SAFETY CODE § 25249.5; *see also Proposition 65 Law and Regulations*, OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, https://perma.cc/5Y5R-5UAE (describing purposes).

can go to market in California, it must bear legislatively mandated labeling stating that it contains a chemical with serious health concerns.[261] Operated under the California Environmental Protection Agency,[262] Office of Environmental Health Hazard Assessment ("OEHHA") administers the Proposition according statutory requirements to rely on outside experts and authoritative bodies, including the International Agency for Research on Cancer (the "IARC"), EPA, and the World Health Organization, to identify toxins.[263] The OEHHA lists toxic substances of concern with the reasons for causing concern (risk of cancer, birth defect, or reproductive harm) for public viewing on the agency's website.[264] Once listed, a chemical can become delisted if it meets certain statutory criteria.[265]

LCSA contains the tools for EPA to pursue a similar public list approach for new chemicals and significant new chemical uses.[266] Section 6 allows the Administrator to compile and keep current a "list" of chemical substances with "respect to which the Administrator finds that the manufacture, processing, distribution in commerce, use or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment, without consideration of cost or non-risk factors."[267] This list of "new" chemicals would include those that may be approved and subject to rules or orders to restrict their use while they are commercialized. In the interim, while they are being brought to market, these chemicals could be prominently displayed on a public "hazardous list."[268] Market pressure would incentivize manufacturers to avoid going to market with chemicals that raise such public concern. A labeling system like California's could also inspire businesses to make more health protective choices.[269]

American industries can be receptive to consumer demand and public interest.[270] For example, the organic and health food market is booming in re-

261. CAL. HEALTH & SAFETY CODE § 25249.5.

262. *Id.* In August 2018, the California Proposition 65 labeling was updated to require explicit labeling of at least one of the exact substances contained in the consumer product that is of concern. *See* CAL. HEALTH & SAFETY CODE § 25249.5–25249.14.

263. CAL. HEALTH & SAFETY CODE § 25600 *et seq.*

264. *See Proposition 65*, *supra* note 254.

265. CAL. HEALTH & SAFETY CODE §§ 25249.8(b), 25306, 25904.

266. *Id.*

267. 15 U.S.C.A. § 2604(b)(4)(A)(i) (West 2019).

268. *Id.* § 2604(b)(4). EPA already compiles a public list of all chemical substances in the TSCA Inventory of Chemical Substances. This list contains over 80,000 chemicals. *See TSCA Inventory of Chemical Substances*, CHEMSAFETYPRO, https://perma.cc/U783-9E4K. The inventory is not user friendly, however.

269. *See* Brendan Borrell, *Are Proposition 65 Warnings Healthful or Hurtful?*, L.A. TIMES (Nov. 2, 2009), https://perma.cc/D39X-QTY8.

270. *See, e.g.*, Jan Lee, *CVS Banishes Formaldehyde, Other Toxics from Cosmetics*, TRIPLE PUNDIT (Apr. 24, 2017), https://perma.cc/PZ76-22RJ (reporting that CVS will not sell consumer

sponse to consumer demand and proper labeling of organic food under federal law.[271] Public health advocates have effectively used conventional food labeling law over the past twenty years to make consumers more conscious of their food choices and drive demand for healthier foods.[272] Clearly providing information to the public has raised awareness and allowed consumers to make better food choices, driving demand for more nutritionally rich products and pushing manufacturers and retailers to respond accordingly.[273]

Consumer demand has likewise created change in the cosmetics market. When the Breast Cancer Fund charged Revlon with putting carcinogenic products in its makeup, the company initially denied the allegations,[274] but later bowed to consumer and public pressure and removed suspected toxic ingredients from some of its products.[275] At least one expert has concurred that California's labeling system, while controversial for various reasons,[276] can inspire businesses to make more health-protective choices.[277]

As seen in the nutrition and cosmetics markets, greater transparency and consumer demand can complement federal regulation in improving chemical safety. The passage of LCSA clearly signals a collective intent to more thoroughly and proactively regulate toxic substances. Americans, through their

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products containing EDCs); Bob Moritz, *America's New Healthcare Economy: Three Trends to Watch*, FOCUS INVESTMENT BANKING (Feb. 4, 2015), https://perma.cc/CG28-7TUL (discussing consumer demand effects in the healthcare industry); Press Release, Nat. Res. Def. Council, The Home Depot to Be Third Major U.S. Retailer to Ban Deadly Paint Strippers (June 19, 2018), https://perma.cc/PP6X-KG9S (announcing that Home Depot has agreed to pull all paint removal products containing toxic methylene chloride and N-methylpyrrolidone); Andy Szal, *Target Aims to Remove 'Unwanted Chemicals' from Its Products*, MANFACTURING.NET (Jan. 4, 2017), https://perma.cc/BKY4-X29T.

271. *See, e.g.*, Watnick, *supra* note 63 at 42; *Organic Market Overview*, U.S. DEP'T OF AGRIC. (Apr. 4, 2017), https://perma.cc/C359-EANJ; Michael Marlow, *Do the Benefits of California's Proposition 65 Law Outweigh Its Costs?*, Presentation at the IlSI Annual Meeting 2017, https://perma.cc/L3N5-BZGZ.

272. *See* Tobias J. Gillett, *Lessons from Nutritional Labeling on the 20th Anniversary of the NLEA: Applying the History of Food Labeling to the Future of Household Chemical Labeling*, 37 WASH. U. J.L. & POL'Y 267, 269, 335 (2011). *Id.* at 267–72.

273. *Id.*

274. *See* Letter from Lauren Goldberg, Exec. Vice President and Gen. Counsel, Revlon, to Nita Chowdhury and Shaunna Thomas, Ultraviolet (Oct. 25, 2013) (cease-and-desist letter), https://perma.cc/MNC4-MKHR. Chemicals of concern in Revlon products included parabens, DMDM Hydantoin, and Quaternium-15, which releases formaldehyde into the air and can potentially be breathed in by a person wearing a product containing the chemical, such as mascara, or by others. *Id.*; *see also* Marc Gunther, *A Toxic Situation: Walmart and Target Take on Chemical Safety*, GUARDIAN (Dec. 17, 2013), https://perma.cc/MK3C-PS6J.

275. Marc Gunther, *Under Pressure: Campaigns That Persuaded Companies to Change the World*, GUARDIAN (Feb. 9, 2015), https://perma.cc/9KY3-WCL6 (reviewing consumer impact on businesses).

276. *See* Borrell, *supra* note 269.

277. Marlow, *supra* note 271.

elected representatives, have made clear that they care about their environmental exposures to toxic chemicals.

LCSA calls for EPA to make a toxics list (the "Hazardous List")[278] of chemicals that present or may present an unreasonable risk of injury to health or the environment.[279] Such a list should be publicized and easily accessible, like that on California's Proposition 65 website,[280] to make manufacturers accountable to the consumer public. California's Proposition 65 website is easy for the public to use, full of information, and contains citations to the state code.[281]

A new chemical can be determined to have been submitted with enough information to say it is not likely to present an unreasonable risk or that it does present unreasonable risk based on enough information. If the chemical is determined to present an unreasonable risk, EPA can issue an order *or* a rule to restrict commercialization under section 5(f), but the product can still be marketed. However, manufacturers would be more likely to avoid the unreasonable risk determination if the chemical were unable to go to market while on the publicly accessible "Hazardous List."[282] To avoid the LCSA Hazardous List, manufacturers would not want to pursue the section 5(f) loophole that allows rulemaking in place of an EPA order restricting the use of the chemical under section 5(e).[283] The Hazardous List would help close the 5(f) loophole that allows commercialization of a substance by rule, even where there exists enough information to determine that the substance presents an unreasonable risk.

An easily accessible LCSA Hazardous List would inform the public about chemicals of concern, exert market pressure on industry to make their products safer, and incentivize industry to provide appropriate information for EPA to approve their application with a finding of "not likely to present unreasonable risk."[284] To further improve transparency and push industry to make safer products, EPA can and should make its new chemicals pre-market review website more user friendly and transparent by clearly identifying actions it is taking to protect the public from perceived risks in new chemicals.[285]

278. 15 U.S.C.A. § 2604(b)(4)(A)(i) (West 2019).

279. *Id.*

280. *See Proposition 65*, *supra* note 254.

281. *See id.*

282. 15 U.S.C.A. § 2604(e)–(f). When EPA finds it does not have enough information to reasonably determine whether the chemical presents unreasonable risk or will be produced in substantial quantities, EPA must issue an order, and in such cases it can restrict the commercialization of the chemical. *Id.* § 2604(e). While such a chemical might still be placed on the "Hazardous List," it would not enter the market without restrictions imposed by EPA order. *Id.*

283. *Compare id.* § 2604(e) *with* CAL. HEALTH & SAFETY CODE § 25249.6.

284. *See* 15 U.S.C.A. § 2604(a)(3)(C).

285. *Id.* § 2604(a)–(f).

V. Conclusion

The Lautenberg Chemical Safety for the 21st Century Act revised TSCA after more than forty years and is the first major environmental legislation in decades. TSCA was initially designed to regulate toxic substances found in everyday products and not regulated by other federal laws, but it proved to be largely ineffective. Over the past four decades, TSCA had rarely been used to ban or restrict toxic substances due to difficult enforcement mechanisms and the grandfathering of most existing chemicals. This ineffective toxics regulatory scheme left the public unprotected from many chemical substances that cause cancer and other diseases, and related economic and social losses.

LCSA allows EPA to move proactively to restrict new chemicals and new chemical uses on a large scale. Initial proposed interpretations called for EPA to subject new chemicals to robust review and required industry groups to submit supporting health and safety data for all reasonably expected uses of proposed new chemicals. Further, the initial interpretation of LCSA would have required EPA to categorize existing chemicals as high priority by default, which would have helped remove the "innocent until proven guilty" presumption of the existing toxic substances control regulatory regime.

Industry pushed back against these and other precautionary mechanisms in the proposed rules, and the rules finalized in July 2017 significantly weakened LCSA protections. EPA limited its review of new chemicals and new chemical uses by limiting the uses it would consider when faced with a new chemical application. Existing chemicals would mostly be designated low priority. Given the slow pace the statute sets for EPA to review the over 87,000 chemicals on the market in the United States, the current mechanism for prioritization and review of existing chemicals is unlikely to effect real and precautionary change.

Further, the legal scheme still fails to recognize that chemicals do not act individually or in isolation. The scheme does not and cannot realistically account for existing interactions between the thousands of chemicals on the market, the endocrine disrupting properties of many chemicals at varying levels, or the effects of chemical exposure on vulnerable or particularly exposed populations. When industry continues to release man-made chemicals into the market in high quantities, these chemicals find their way into our air, food, and water, combining in toxic mixtures and quantities to cause disease. When the public is exposed to multiple avenues of theoretically safe levels of pesticides and other toxic substances every day, the combination creates the potential for poisonous synergies and resulting toxicity on a large scale. Because of this daily deluge of chemical exposure, the public needs a better understanding of the risks associated with environmental exposures to the newest man-made chemicals and a more proactive approach to chemical regulation.

Going forward, regulators should act in a precautionary manner to protect vulnerable populations, consider all conditions of use for new chemicals, and actively and publicly list those existing chemicals that present or may present an unreasonable risk to human health or the environment in a transparent manner.

The public can then use market pressure to push manufacturers to produce safer chemicals and products. As written, LCSA provides new tools for EPA to proactively regulate new chemicals and new chemical uses, and for a public "Hazardous List." Most importantly, LCSA signals the public's and lawmaker's intent to seriously address chemical safety—a definite step in the right direction.